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Sonographic Association of Endometrial Thickness at Proliferative Phase in Infertile Females

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Abstract
Objectives: To determine the sonographic association of endometrial thickness at the proliferative phase in infertile females. Study Design: This Cross-sectional observational. Place and duration: Government Nawaz Sharif Hospital yakki gate Lahore 10st March 2017 to 10th September 2018. Methodology: This Cross-sectional observational study was conducted at Government Nawaz Sharif Hospital yakki gate Lahore 10st March 2017 to 10th September 2018. Ultrasound (Mindray (Dc-3)) with the convex transducer, frequency ranging 3-6 Mhz was used. All 103 participants were scanned trans abdominally in the supine position with full urinary bladder. Result: By using independent sample test with the help of SPSS 25 that evaluates Levine's Test for Equality of Variances and t-test for Equality of Means. The t-test for Equality of Means shows there was a statistically significant association between endometrial thickness and infertility. Conclusion: Thick endometrium is more favorable for implantation as compared to thin endometrium. By comparing the mean of endometrial thickness, it was observed that the mean endometrial thickness in fertile females was greater than infertile females.

Keywords: Infertility, Endometrial Thickness, Endometrial Blood Flow, Ultrasound

INTRODUCTION

Infertility is one of the most common Social, economic, Psychological and medical problems in the female of childbearing age[1,2]. Infertile women and men have reported experiencing depression, helplessness, and marital strain. Major depression related to infertility is 2–3 times as common in women as in men[3,4]. The clinical definition for infertility proposed by WHO and International Committee for Monitoring Assisted Reproductive Technologies, as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse"[5]. In under-developed countries, the 12-month prevalence rate ranges from 6.9 to 9.3%. Substantial geographic differences in the prevalence are noted, and these differences are largely explained by different environmental, cultural and socioeconomic influences[6,7]. The overall reported prevalence of infertility was 12.5% among women and 10.1% among men[8]. Although the population of Pakistan is rapidly increasing its population growth rate is around 2%, its rate of infertility is

21.9% (primary and secondary 3.5%, and 18.4% respectively)[9]. There are numerous of infertility but the most common causes include problems with ovulation (Hormone imbalance, Tumor or cyst, use of various medicine, Thyroid gland pathologies, obesity, Stress), Intense exercise that causes a significant loss of body fat, Extremely brief menstrual cycles, damage to fallopian tubes or uterus (Pelvic inflammatory disease, A previous infection, Polyps in the uterus, Endometriosis or fibroids, Scar tissue or adhesions, Chronic medical illness, Previous ectopic (tubal) pregnancy, Birth defect), or problems with the cervix. Age, Abnormal cervical mucus, and deficient endometrial preparation contribute to infertility[10,11].

Endometrial preparation for the implantation of the zygote is one of the key features of fertility and is called decidua reaction[12]. Decasualization succeeds when pregnancy occurs and subjected to further development[13]. The endometrium is the inner lining of the uterus. it is a mucosal lining and changes in thickness throughout the menstrual cycle[14]. Endometrium thickness changes throughout the menstrual cycles[15]. The menstrual cycle has three phases; menstrual phase, proliferative phase, and secretory phase[16]. The menstrual changes in the endometrium are essentially degenerative. The coiled arteries undergo vasoconstriction a few hours before the onset of menstrual bleeding. The Proliferative phase, define the regeneration of endometrium and lasts until the 14th day of a 28 day of the cycle. Secretory phase is referred to the further hypertrophy of endometrium so that immediately before menstruation its average thickness is about 8 to 10mm[16,17]. Deficient decasualization can lead to poor implantation and ultimately early loss of pregnancy and infertility[17]. Following ovulation, the luteal phase of a natural cycle is characterized by the formation of corpus luteum, which secretes steroid hormones estrogen and mainly progesterone[18]. Progesterone is essential for secretory transformation of the endometrium that permits implantation as well as maintenance of early pregnancy[19]. Luteal phase insufficiency is one of the reasons for implantation failure, which has been responsible for the failure of many cases of pregnancies and assisted reproduction[20,21]. The endometrial preparation (decasualization) could be assessed by various imaging methods, but Ultrasound is one of the best and safe method to measure the thickness of endometrium for as determinant of decasualization[22]. A few of the most common anomalies are discussed[33].

Sonographic appearance of the endometrium is very reliable and accurate imaging method to measure it during entire cycle[15]. The reliability of transvaginal as well as trans abdominal sonographic is within clinically acceptable limits[23]. With the developments of the machines and introduction of the high-resolution transducer in state of the art modalities, improved the accuracy of ultrasound in the measurement of endometrium[24].

The purpose of this study was to assess the association of infertility with endometrial thickness. There are many causes of infertility, but it is postulated that deficient endometrial thickness is one of them. As it is obvious from the discussion in the context of previous studies that endometrial thickness plays a crucial role in the implantation of the zygote and deficient decasualization can lead to infertility. The researcher, therefore, intended to compare the endometrial thickness with infertility so that the alarming situation may be highlighted.

METHODOLOGY

Sampling technique is convenient sampling, and the sample size is 103 including for both genders which are calculated from the prevalence of infertility (7%) with the following sample power formula, $n=z^2(pq)/d^2$. This Cross-sectional analytical study was conducted at Government Nawaz Sharif Hospital yakki gate Lahore 10st March 2017 to 10th September 2018. Ultrasound (Mindray (Dc-3)) with the convex transducer, frequency ranging 3-6 Mhz was used. All 103 participants were scanned trans abdominally in the supine position with full urinary bladder. All the females with primary and secondary infertility at fertile age group and all the fertile females from the same population are included. All infertile females with uterine anomalies and females with an ill-defined, undifferentiated uterus are excluded.

RESULTS

All the 103 patients calculated with sample power equation were scanned, having to mean age 31.42 ± 5.304 (19 to 43). Mean age at the time of marriage of all females was 23.06 ± 2.95 (18 to 33) and the mean endometrial thickness was 6.24 ± 2.11 (3 to 12) mm. Frequency distribution of the participants among fertile females, Primary infertility, and secondary infertility was 57 (55.3%), 32 (31.1%), and 14 (13.6%). All the participants

were divided into a different class with a class width of 5, their frequency and percentage are summarized in Table 1. The thickness of the endometrium was classified in three classes with class width of 3mm, the frequency, and percentage of ≤ 6 mm 61 (59.2%), 7-9 mm 34 (33%), and 10+ mm 8 (7.8%). Independent t-test was used to compare the mean of the endometrial thickness in fertile and infertile females. The mean endometrial thickness in 57 (55.33%) fertile females was 7.28±2.024mm, while in 46 (44.775) infertile females were 4.96±1.398mm. Distribution of fertile, primary infertility and secondary infertility in classes of age (years) is shown in Figure 1. Distribution of fertile, primary infertility and secondary infertility in classes of endometrial thickness (mm) is shown in Figure 2. A significant association of endometrial thickness was estimated with fertility, primary infertility and secondary infertility cases, while using Analysis of variance (ANOVA. Calculated p-value was 0.000, which reflect a significant association. Multiple Comparison Test was used to compare the mean of endometrial thickness in 32 (31.06%) Primary infertility, 14 (13.59%) Secondary infertility, and 57 (55.33%) fertile women was 4.88mm, 5.14mm, and 7.28mm respectively. No significant difference between the endometrial thickness of primary and secondary infertility was noted with multiple comparison Test reveals (p-value 0.89) (Figure 3), while endometrial thickness infertile women and primary/secondary infertility was significant with p-value 0.000 each.

Table I: Frequency and percentage of Age groups of the participants.

Groups of Age (year)	Frequency	Percent
≤ 25	16	15.5
26 - 30	30	29.1
31 - 35	31	30.1
36 - 40	25	24.3
41+	1	1
Total	103	100

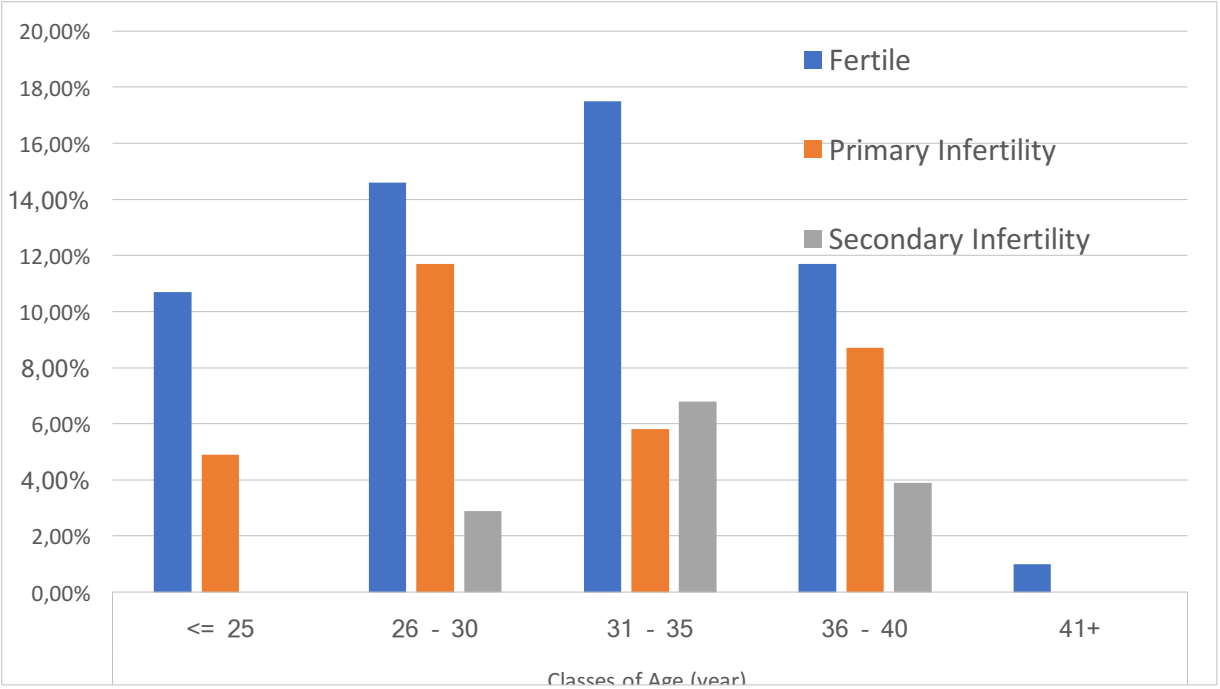

Figure I: Classes of age in years versus fertility/ infertility cross-tabulation

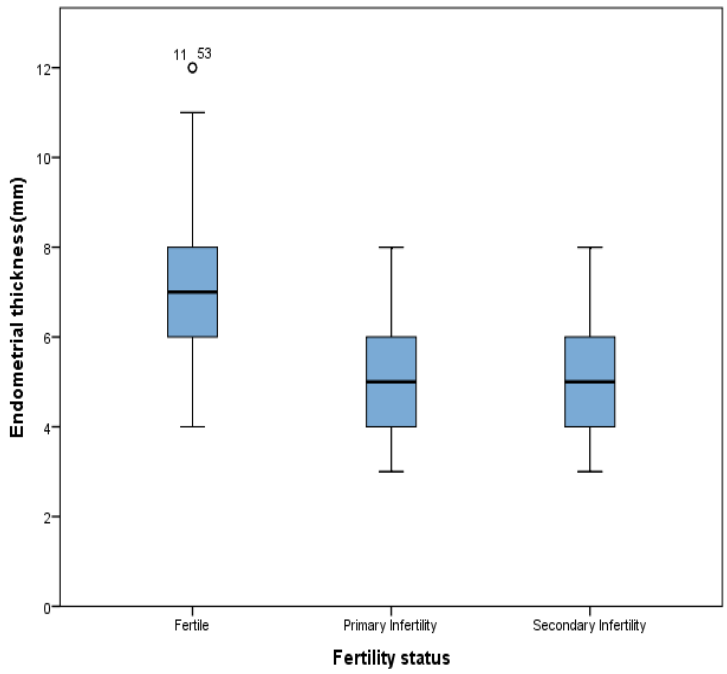

Figure II: comparison of the mean of endometrial thickness in Primary infertility, Secondary infertility, and fertile women.

DISCUSSION

Decasualization is the preparation of endometrium for the implantation fertilized ovum. Capability Endometrial preparation has an effect on receptivity to some or great extent. Very well prepared thick, fully nourished, and vascularized endometrium have more chances to conceive than unprepared, thin, avascular endometrium. Endometrial thickness was greater in cycles resulting in pregnancy than in cycles not resulting in pregnancy. The results of the study show that pregnancy rate was gradually increased from 53% females having an endometrial lining of <9 mm, to 77% of females with an endometrial lining of ≥16 mm.[27]. It was therefore concluded that the

rate of favorable pregnancy outcomes increases significantly with an increase in endometrial thickness, independent of the effects of patient age and embryo quality. Increased endometrial thickness predicts the likelihood of normal intrauterine pregnancies[28]. Shireen J Sathar et al. studded to explore the impact of industrialization, promotion of education, female employment, urbanization, and migration on proportions never married Pakistani population[29]. By studding data for the various era in time, the mean age for female marriage was calculated in 1961as 18.1 years, in 1972 as 19.8 years, and in 1981 as 20.7 years. According to this data, the expected mean age for marriage in 2021 will be 24.3 years. Schemes of marriage behavior were expected to vary in Punjab, Sind, NWFP, and Baluchistan, due to cultural variations, different levels of development, and variations in urbanization. Punjab had the highest proportions of never married females both in urban and in rural areas. The much more unmarried individual was calculated in 15-19 years' age group, in Punjab, which is considered the most developed province. Never married proportion in the different provinces was significant especially for females than for males. The mean age at the time of marriage was calculated as 23.06±2.95 years, which was proportionally increased with industrialization. In the current study, the mean age of females at the time of marriage was similar to the estimated age proposed by previous studies.

To investigate the role of sonography in the assessment of endometrial receptivity, 135 individuals were transvaginal studied. Association between implantation rate and spiral artery blood flow and between implantation rate and endometrial thickness was calculated. Mean endometrial thickness was 11.4 6 2.8 mm (4.9 to 21.1) [30]. To examine the association between medicated frozen-thawed embryo replacement (FER) outcomes and endometrial thickness, a retrospective observational study was conducted. The endometrial thickness 7 mm and heights than 14mm were associated with the lowest pregnancy rates. In those cycles in which endometrial thickness was 9 to14 mm, significantly higher implantation rates were achieved as compared to 7 to 8 mm endometrial thickness[31]. In the current study, fertile and infertile female were included; therefore the overall mean endometrial thickness is less than the previous studies. Endometrial thickness was greater for fertile age group but lesser for infertile. In the current study, all the participants were divided into three groups; fertile group, primary and secondary infertility. The mean endometrial thickness was almost similar in primary and secondary infertility, moreover, there was less variation in the endometrial thickness of these groups as how in boxplot (Figure 3).

Boivin et al. conducted a study in 2007, for the estimation of infertility prevalence and proportion of couples seeking treatment[7]. The 12-month prevalence prevalence of infertility was estimated as 9%, in more developed countries 3.5% to 16.7% range, while in less-developed nations the range was 7.0% to 9.3%. In developed countries about 56.1% of couples seeking treatment amongst the total infertile couples. But in underdeveloped countries, about 51.2% of the couples seeking treatment. Based on the current world population survey and these estimates, currently about 72.4 million women are infertile; amongst them, about 40.5 million are currently seeking for infertility treatment. The Prevalence of primary and secondary infertility was estimated in the tertiary center in eastern Saudi Arabia by Haifa A.Al-Turki, through a retrospective study in in 2015[32]. In this study, 2414 patients were randomly selected from the multiple clinics of obstetrics and gynecology department of the hospital. It was estimated that 18.93% of the total female population was infertile. Among these infertile females, 78.99% were primary infertility, and 21.01% were secondary infertility. It was concluded that that the prevalence of primary infertility was more common as compared to secondary infertility. The current study agrees with the international data, and we also observed that the prevalence of primary infertility (74.4%) was more than that of secondary infertility (25.6%) as shown in Table 2, Figure 2.

Kevin S. Richter studded 1294 infertile patients were in 2016, to evaluate the relationship between endometrial thickness and fetal outcomes of "In Vitro Fertilization. The thickness of the endometrium was greater in cycles resulting in pregnancy than in cycles wherein the is no pregnancy. According to the study pregnancy rates gradually increased from 53% in patients with an endometrial thickness of less than 9 mm, to 77% in patients with an endometrial thickness more than 16 mm. Significant effects of age, embryo quality, and endometrial thickness on both pregnancy rates and live-birth were calculated through multiple logistic regression analysis. There was a weak association between decreasing rates of spontaneous abortion with increasing endometrial thickness. It was concluded that the chances of live birth increase significantly with an increase in endometrial thickness[27]. A significant association between endometrial thickness and fertility was found in the current study.

CONCLUSION

Thick endometrium is more favorable for implantation as compared to thin endometrium. By comparing the mean of endometrial thickness, it was observed that the mean endometrial thickness in fertile females was greater than infertile females.

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Can the Improvements Reported by Individuals with Chronic Fatigue Syndrome Following Multi-Convergent Therapy Be Sustained in the Longer-Term: A Three-Year Follow-Up Study

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Abstract
Results from a small study into the efficacy of a Multi-Convergent Therapy intervention for patients with Chronic Fatigue Syndrome (CFS) had proved encouraging at the post-therapy and six-month follow-up time points. It was, however, important to re-evaluate these findings over a longer period. Eleven patients who had completed the original therapy trial responded to a follow-up call (91.7% response rate). Subjective data was returned by between 9 and 11 of the participants and 7 completed the objective measures. Participants in the current study completed a similar set of outcome measures as those used to assess treatment success previously. These data suggested that patients attending the therapy continued to show improvements in functioning, had lower levels of fatigue and disability, improved sleep quality and levels of activity and lower symptom scores at a three-year follow-up. The long-term efficacy for this treatment is suggested by these results. Multi-convergent therapy is indicated as a promising approach to the rehabilitation of CFS patients.

Keywords: Chronic Fatigue Syndrome (CFS), Multi-convergent therapy (MCT), Long-term efficacy, Myalgic Encephalomyelitis (ME).

1. Introduction

1.1 Background

Fatiguing illnesses are difficult to accurately assess and diagnose due to the symptom being largely subjective in nature. Fatigue means different things to different people, and the term itself describes conditions ranging from moderate tiredness to clinical exhaustion (Thomas, 2018).

The fatigue experienced in Chronic Fatigue Syndrome (CFS) is not only of sufficient severity to cause substantial functional impairment but it is also accompanied by four or more co-existing symptoms including those of a cognitive or neuropsychiatric nature (Fukuda et al., 1994). The illness must be of at least six months

duration with the potential for it to become debilitating and persistent (Andersen, Permin & Albrecht, 2004). CFS has no known aetiology or distinctive biological diagnostic markers and appears to be more prevalent in middle-aged women who experience measurable cognitive impairment (Thomas & Smith, 2009) and high levels of somatic symptoms, anxiety, and depression (Thomas & Smith, 2006). Together with decreased personal, occupational and social activities which impact negatively on their quality of life, individuals with CFS are more likely to be unemployed than their peers (Smith, Thomas & Sadlier, 2009). Although the incidence of the syndrome is relatively low (Afari & Buchwald, 2003) this does not detract from the severe effect the illness has on the individual. Decreased personal, occupational and social activities accompany the illness and combine to instil a sense of frustration and hopelessness within the patient. In addition, financial concerns have been raised regarding the increased uptake of unemployment benefits, and the drain on healthcare resources brought about by the illness (Reyes et al., 1999; Reynolds, Vernon, Bouchery & Reeves, 2004). For these reasons, the search to find a suitable treatment for this, often, debilitating illness became paramount.

In a report by the Royal Colleges, practitioners were encouraged to provide a service for patients and take steps to manage patients in their care (Royal Colleges of Physicians, Psychiatrists & General Practitioners, 1996). Cognitive Behaviour Therapy (CBT) and graded exercise were recommended as the most successful methods for managing symptoms of the illness (CFS/ME Working Group, 2002). In their 2007 guidance, the National Institute for Health and Care Excellence (NICE) also regarded GET and activity management programmes and recommended that individualised, patient-centred programmes should also address sleep hygiene together with physical, emotional and cognitive symptoms (NICE, 2018).

It was in response to the call for efficacy studies to manage the symptoms associated with CFS that we conducted a small randomised controlled trial of behaviour and graded exercise-based intervention in a multi-convergent therapy (MCT) approach. MCT was developed by a registered NHS Physiotherapist who had recognised qualifications in all aspects of the therapy. The intervention was set up to provide a service for patients with a range of medically unexplained symptoms – such as irritable bowel syndrome and tinnitus – which did not respond to first-line medical intervention and where no solution was readily available (Sadlier & Stephens, 1995; Shaw et al., 1991).

The commonality between these medically unexplained symptoms and CFS implied that MCT might be of value to patients with the syndrome. Indeed, data collected retrospectively on the twenty-four patients completing a pilot study provided preliminary evidence as to the efficacy of the treatment for CFS (Sadlier, Evans, Phillips & Broad, 2000).

MCT incorporates CBT and GET with other appropriate strategies in a holistic approach. The CBT phase aimed to identify factors that can influence, precipitate or prolong the illness and improve sleep quality. Dysfunctional beliefs and thought patterns were explored and positive beliefs, thoughts, and behaviours re-enforced. During the graded exercise phase, the therapist introduced a programme of planned activity and rest (referred to as ‘pacing’) and explored the relationship between fatigue and cognition. The rationale for this aspect of the therapy was based upon a model suggested by Noakes and colleagues where gentle walking was introduced every second day at a level appropriate for each individual case to prevent post-exertional malaise (Noakes, St Clair Gibson & Lambert, 2005). The distance and time walked were increased as the patient's confidence in the belief that this would not cause a relapse of their symptoms grew, and increases were controlled by the patient in discussion with the therapist.

Mindfulness (or insight) meditation techniques were also blended with the CBT and graded exercise phases and patients were encouraged to fix their thoughts on the present without being distracted by the associations attached to those thoughts or sensations, such as fatigue or pain (Mason & Hargreaves, 2001; Carlson, Speca, Patel & Goodey, 2004; Grossman, Niemann, Schmidt & Walach, 2004; Kabat-Zinn, Lipworth & Burney, 1985). The therapy adopted a multi-dimensional approach which used aspects of behaviour modification, breathing and relaxation techniques, connective tissue massage and psychodynamic counselling. An in-depth description of our randomised controlled trial (RCT) is presented elsewhere (Thomas, Sadlier & Smith, 2006; Thomas, Sadlier & Smith, 2008). However, a brief overview of the trial is outlined below.

1.2 Previous Research

In the original RCT (Thomas, Sadlier & Smith, 2006; Thomas, Sadlier & Smith, 2008), patients were recruited from a CFS Outpatient clinic by a single consulting physician. Inclusion criteria for the trial were: (a) patients fitting the CDC criteria for CFS (Fukuda et al., 1994), (b) scores below 70% on the Karnofsky performance scale (Karnofsky, Abelmann, Craver & Burchenal, 1948) indicating significant functional impairment and (c) were willing to attend all therapy and assessment sessions. Patients were excluded from the study if their fatigue was of known aetiology.

Twelve patients were randomly allocated to the MCT group, 14 were allocated to a relaxation therapy group, and 9 were allocated to a non-intervention control group. Due to the small numbers in the study, patients recruited into the trial were assigned to a treatment group individually. Referral letters for the MCT clinic, the relaxation therapist together with a letter indicating usual medical care were prepared for each patient who agreed to participate. These were placed into a large blank envelope and one letter selected and posted by a colleague blind to the study's protocol. The remaining letters were shredded. The patient was contacted by the appropriate therapist, and subsequent assessment appointments were made through a third party.

The relaxation therapy used in the trial was based on the Rapid Relaxation Technique of Lars-Goran Ost (Ost, 1987). This technique has been successfully used to alleviate a range of problems – such as tinnitus and pain – as well as CFS. Rapid Relaxation offered the patient a way of coping with their symptoms and managing them. The therapist would guide the patient through the relaxation technique over a period of weeks, concentrating on different major muscle group each week. We used this therapy as a comparison to MCT as relaxation therapy had been one of the approaches favoured by various centres and patient groups (Action for ME, for example) throughout England, Scotland and Wales and had been used as a comparison by other research groups (Deale, Chalder, Marks & Wessely, 1997).

Individuals attended ten, 1-hour MCT or relaxation sessions per week for 10 weeks on a one-to-one basis. The time spent on each component within MCT was decided during discussions between the therapist and the patient.

Outcome measures for the trial included those assessing mood, performance and health-related measures that were developed previously (Thomas & Smith, 2009; Thomas & Smith, 2006). In order to align our findings to other intervention studies, functional performance and global measures of health were also administered (Deale, Chalder, Marks & Wessely, 1997). Data collection points included: (a) baseline (before randomisation), (b) immediately post-therapy and (c) 6-months post-therapy. Control group data were collected to simulate a ten-week therapy programme. To provide context to the current study, a brief overview of the RCT is presented here.

At the post-therapy point, the MCT group reported significant improvements in alertness together with improved sleep quality and levels of activity than the relaxation and control groups. They also reported significantly lower levels of anxiety and improvements in cognitive performance (e.g., motor speed and vigilance) than the control group. A health-related measure of the number of physical and mental symptoms indicated that the MCT group reported significantly lower total symptom scores than the relaxation and control groups. The global assessment of function measures suggested that the MCT group reported significantly greater improvements in their overall condition, lower levels of fatigue and a reduction in disability than the relaxation and control groups.

Our findings also indicated that these improvements were maintained over a six-month period. The MCT group continued to report significantly improved motor speed than the relaxation. This group also continued to report: (a) higher levels of alertness, (b) lower levels of anxiety, (c) greater vigilance and (d) improved episodic memory than the control group. Improvements in global measures of health were also reported at this time point including an overall improvement in their condition, lower fatigue levels and feeling far less impaired by their illness. Regarding the primary outcome measure of the trial, attainment of a Karnofsky performance score of 80% or more, the MCT group were significantly more likely to meet the desired outcome.

Although (as indicated above) the sample size for the study was small, a previous retrospective study suggested a recovery rate of 72% among those receiving MCT (Thomas, Sadlier & Smith, 2006) compared with 6% for untreated controls (Thomas & Smith, 2006). These findings indicated that a sample of 8 MCT recipients and 8 controls would have an 80% chance of detecting a treatment effect at the 5% level of statistical significance. Ethical approval for the therapy trial was granted by the Local Health Authority Ethics Committee and covered all aspects of the study up to the six-month follow-up data collection point.

Findings from this small study suggested that MCT had the potential to effectively addressed a wide range of problems associated with CFS and improved patient outcomes which were sustained over a six-month period. However, whilst the success of our trial was of note, patients with CFS understand the illness is plagued with bouts of apparent recovery. In these instances, the person can feel as if they have returned to normal health only to be struck down again with the illness weeks or even months later. In terms of the longer-term efficacy of interventions for CFS, most trials report findings at 6-month follow-up (Nijhof, Bleijenberg, Uiterwaal, Kimpen & van de Putte, 2012) with a study by White et al (2013) conducting a follow-up assessment 1-year post-therapy (White, Goldsmith, Johnson, Chalder & Sharpe, 2013). We judged it important to assess the efficacy of MCT over a longer period, that is 3-years after the final trial assessment, to see whether the intervention prevented relapses in the condition.

2. Methods

Ethical approval for the 3-year follow-up study was granted by the host institution's departmental Research Ethics Committee.

2.1 Participants

The 12 CFS patients who completed the MCT arm of the original study were contacted by post and asked if they would attend a follow-up evaluation session. The relaxation and control groups were not contacted as, although they had been offered MCT following the outcome of the original study, they had not agreed to be contacted regarding further follow-up sessions.

2.2 Procedure

The MCT group were sent an information sheet describing the nature of the study along with a letter inviting them to participate in the follow-up study. Data collection took place at the Research Unit, and the group completed the same outcome measures that were administered during the original trial. Those who were not able to travel to the Unit completed the measures at home and returned them in a prepaid envelope.

2.3 Primary Outcome Measure

The main indicator for continued treatment success was the Karnofsky Performance Scale which categorises the patient according to their functional performance on a scale of 0 to 100% (Karnofsky et al., 1948). The scale was modified, however, by removing the more catastrophic lower elements. In this way, we were able to assess the ability of the patient to examine improvements in functioning subjectively.

2.4 Secondary Outcome Measures

2.4.1 Mood and performance (Thomas et al., 2006)

The mood and performance test data were collected using a laptop computer which was connected to a simple 3-button response box. The testing session lasted approximately fifteen minutes and recorded data regarding mood, memory, motor speed and vigilance.

Mood: The task presented 18 visual analogue mood scales. Each scale composed of a pair of adjectives (e.g.) drowsy/alert or happy/sad. Using the keys marked left or right on the response box, individuals asked to move the cursor on the screen towards the word they felt most represented their mood at that time. The 18 scales were presented successively and scores between 1 and 51 recorded. Using a factor analysis, three scores were derived from the 18 scales; alertness, hedonic tone, and anxiety.

Free Recall task objectively assessed episodic memory. Individuals were shown a list of 20 words on the computer screen – each word was presented for two seconds. Once all twenty words had been presented, the individual was asked to write down the words that they remembered – in any order. They were given two minutes to complete this task. The number of words remembered, the number of words correctly recalled, and the number of words incorrectly remembered were recorded.

Variable Fore-Period Simple Reaction Time Task is an objective measure of motor speed. During this task, an empty box was displayed in the centre of the screen. At varying intervals (up to 18 seconds) a target square would appear inside the bigger box. Individuals were asked to press a specified response key, using their dominant as soon as the saw the target square appear on the screen. The task lasted for 3 minutes and data recorded included the reaction time for each presentation, the mean reaction time for each minute of the task and the number of trials completed per minute. These data also provided a measure of overall mean reaction time and the total number of trials completed over the duration of the task.

Repeated Digits Detection Task is a visual cognitive vigilance task which measures an individual's ability to detect targets at irregular intervals. The task successively presents 3-digit numbers in the centre of the screen at the rate of 100 per minute. Usually, each 3-digit number differs from the one immediately preceding it (e.g., 463, 563, 562). Eight times per minute, however, the same 3-digit number is repeated on successive trials (e.g., 463, 563, 563). Individuals were asked to respond to the repeated numbers as quickly as possible by pressing the nominated key on the keyboard using the forefinger of their dominant hand. The task lasted for 3 minutes and data recorded included the reaction time for each repeated digit recorded, the mean reaction time for each minute of the task. The number of targets correctly identified, the number of false alarms and the number of missed targets were recorded per minute. These data also provided a measure of overall mean reaction time and the total number of trials completed over the duration of the task.

2.4.2 Global Measures of health (Deale et al., 1997)

Ratings of overall improvement in illness condition and changes in the level of fatigue and disability were recorded on Likert-type scales. Each scale ran from extreme negative through 'no change' to extreme positive responses. Patients were asked to rate their responses in relation to their six-month follow-up scores.

Quality of sleep and levels of activity were measured on Likert-type scales ranging from 'much worse' through 'unchanged' to 'much better' (in the case of sleep quality) and 'significantly decreased' through 'unchanged' to 'significantly increased' (for levels of activity). A symptoms checklist with 28 physical (e.g., *legs feeling heavy*) and psychological ailments (e.g., *anxiety/panic feelings*) from which they could select the individual symptoms they were currently experiencing was also administered. The number of positive responses was summed to provide total symptom score data (Thomas et al., 2006).

2.5 Data Analysis

Data for the current study included those variables which provided significant improvements previously (Thomas et al., 2006; 2008) continue in the longer-term. Frequency data were used to compare the proportion of patients who continued to report normal function (70% and above and 80% or above) on the Karnofsky scale, activity levels and quality of sleep at 6-months and 3-years. For the secondary outcome measures, negative scores were summed into a single variable as were the positive ones with the third variable being 'no change.' Descriptive data were used to compare the performance data for the group at 6-months and 3-years. Only those who competed for measures at both time points were included in the analysis.

3. Results

Of the twelve patients who have completed the original MCT trial, eleven completed at least part of the three-year follow-up study (range=9-11) and seven completed the mood and performance measures.

3.2 Primary Outcome Measure

Nine of the MCT group provided Karnofsky Performance score data group at the 3-year follow-up point. Seven respondents (77.8%) continued to report function scores of over 70%, indicating normal functioning, with 5 recording scores of more than 80%.

3.3 Secondary Outcome Measures

3.3.1 Mood and performance

Seven of the original MCT group completed the mood and performance tests. Table 1 compares data from the 6-month follow-up data from the original trial and the 3-year data.

Table 1. Subjective ratings of mood and objective performance data for the MCT group at six months and three years. Scores are means and s.d.

	MCT patients (n=7)	
Measure	Six-months post-therapy	Three-years post-therapy
Mood:		
Alertness	205.00 (59.45)	183.85 (33.56)
Anxiety	76.00 (20.02)	71.43 (6.68)
Episodic Memory:		
No. of words recalled	10.00 (1.63)	9.00 (1.82)
Simple Reaction Time:		
Mean reaction time (msecs)	394.25 (91.65)	376.86 (109.70)
Vigilance:		
Mean reaction time (msecs)	777.44 (90.31)	751.80 (106.33)
No. of targets correct	15.57 (7.09)	16.28 (4.11)

We can see in Table 1 that, although the small sample size precludes statistical analysis, the MCT patients appear to be maintaining the improvements in mood and performance recorded 6-months post-therapy 3-years later.

3.3.2 Global measures of health

Nine of the original MCT group completed the sleep measure, 10 completed the activity, fatigue, overall improvement in condition and disability measures and 11 completed the 28-item symptom checklist. Table 2 compares data from the 6-month follow-up data from the original trial and the 3-year data.

Table 2. Three-year follow-up secondary health-related outcome measures for MCT patient group when compared to their six-month post-therapy scores. Percentage scores indicate ‘better/much better' or ‘unchanged' from post-therapy or 6-month scores. Scores are a percentage or mean and s.d.

	MCT patient group	
Measure	Six-months post-therapy	Three-years post-therapy
Improvement in condition (%)	100	90
Fatigue (%)	67	90
Lower levels of disability (%)	83	90
Improved sleep (%)	83	90
Improved activity (%)	100	91
Total symptoms (mean)	11.58 (3.87)	11.54 (7.06)

Only one person reported feeling worse at 3-year follow-up than they had at 6-month follow-up for each of the secondary outcome measures of their overall condition, fatigue, disability, sleep, and activity. There was no difference between the mean total symptom scores at 6-months post-therapy and three-year follow-up.

4. Discussion

Chronic Fatigue Syndrome (CFS) is a condition which comes under the umbrella group of medically unexplained symptoms (MUS). The severity of the fatigue experienced in the condition causes substantial

functional impairment, and it is also accompanied by four or more co-existing symptoms including cognitive deficits (Fukuda et al., 1994). Individuals with CFS experience significant impairments in daily living and in social and occupational settings and spontaneous recovery rates from the illness are low (Thomas & Smith, 2006).

It was the increasing problem that MUS were presenting to both primary and secondary care that prompted the development of an outpatient clinic to provide a service for patients with these types of illnesses. The subsequent intervention, multi-convergent therapy (MCT), had already shown to be of benefit to patients with irritable bowel syndrome and tinnitus as well as Chronic Fatigue Syndrome (Sadlier & Stephens, 1995; Shaw et al., 1991; Sadlier et al., 2000).

MCT is a holistic, individualised programme which aims to address several symptoms associated with CFS including sleep, activity, and fatigue. Poor sleep and reduced activity levels had been identified as confounding factors in perpetuating the illness. The therapy combines aspects of Cognitive Behaviour Therapy (CBT) and Graded Exercise Therapy (GET) which previous studies had identified as the most consistently successful treatments for CFS (Deale et al., 1997; Sharpe et al., 1996; Fulcher & White, 1997). In addition to these components, MCT included aspects of mindfulness meditation (Kabat-Zinn et al., 1985), relaxation techniques and psychodynamic counselling. Heart rate monitors were also used to supervise the progress of exercise therapy.

A small randomised controlled trial of the intervention was conducted where MCT was compared to relaxation therapy and a control group who received general medical care. Overall the trial data provided evidence for the efficacy of the intervention across a range of impairments associated with CFS. This included improved mood, fatigue, symptomology, sleep and activity levels following the 10-week therapy sessions. We were also the first researchers to report objective evidence that intervention for CFS could improve cognitive performance (Thomas et al., 2006; 2008). Whilst our findings were encouraging, and they only indicated the intervention's efficacy over a relatively short period of time – that is 6-months post-therapy. Further assessment of the therapy over an extended period was warranted to assess the endurance of these positive outcomes as it was well established that periods of remission regularly occur in this condition (Reyes et al., 1999). Previous behaviour therapy trials for CFS had, at most, collected follow-up data 12-months post-therapy (White et al., 2013).

The stand-alone study described here reports data collected 3 years after the final assessment of the original trial. Eleven of the twelve CFS patients who attended MCT sessions in the original trial answered our three-year follow-up call (92% response rate). Of these respondents, 78% reported that they were able to conduct the normal day-to-day activity with only a few signs or symptoms of the illness present on the Karnofsky scale (Karnofsky et al., 1948). This scale was used in the original trial as both an inclusion/exclusion criterion and a primary outcome measure. In terms of the secondary measures, the majority of those who had received MCT sessions reported that their overall condition maintained the improvement reported at the 6-month post-therapy level and that they continued to report lower levels of disability. The significantly lower levels of fatigue and total symptom scores reported at 6-months post-therapy were also maintained at 3-year follow-up. This is judged an important finding as fatigue, and the number of associated mental and physical symptoms are good indicators of recovery (submitted manuscript).

We acknowledge that the sample size precluded any meaningful statistical analysis of the 3-year data. However, our aim was to provide follow-up information on this group over an extended period. In a much larger multi-centre trial of CBT, GET, adaptive pacing therapy (APT) and specialised medical care (SMC). White et al. also used several standardised measures of fatigue and physical functioning (Chalder et al., 1993; Bowling, Bond, Jenkinson & Lamping, 1999) to define recovery (White et al., 2013). In their study, recovery was interpreted as those patients who fell within the normal ranges for both scales. Their study found that at the 52-week follow-up point: (a) 30% of those receiving CBT, (b) 28% of those receiving GET, (c) 16% of those receiving APT and (d) 15% of those receiving SMC met the study criteria for recovery. The authors concluded that although CBT or GET was more likely to facilitate recovery, only a small proportion of the patients did recover. They attributed their findings to the heterogeneous nature of CFS and suggested that current therapies needed to be enhanced (White et al., 2013). It is judged that a holistic multi-convergent approach which addresses the

individual needs of the patient and that is patient centred offers the best way forward for sustainable improvement for patients with CFS.

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Probiotics for Cardiovascular Diseases, Hypertension, Hypercholesterolemia, and Cancer Condition: A Summary of the Evidence

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Abstract

For a few decades, bacteria called probiotics have been added to some foods because of their salutary effects for human health. Although only various clinical studies have been conducted, that probiotic could be feasible in obstructing and treating some leading diseases such as cardiovascular disease, hypertension, hypercholesterolemia, cancer & other potential diseases. Probiotics have been suggested to reduce cholesterol via various mechanisms without any deleterious effect on human health. Among their various effects, anti-cancer properties have been highlighted in recent years. Such effect includes suppression of the growth of microbiota implicated in the production of mutagens and carcinogens, alteration in carcinogen metabolism and protection of DNA from oxidative damage as well as regulation of the immune system. Outcomes from animals and human studies suggest a tolerable cholesterol-lowering action of dairy products fermented with adequate strain(s) of LAB (lactic acid bacteria) and bifidobacteria. Mechanistically, probiotic bacteria ferment food-derived indigestible carbohydrates to produce short-chain fatty acids in the gastrointestinal tract, which can then cause a reduction in the systemic levels of blood lipids by suppressing hepatic cholesterol synthesis and/or redistributing cholesterol from plasma to the liver. Besides, some bacteria may intervene with cholesterol absorption from the gut by deconjugating bile salts and therefore affecting the metabolism of cholesterol, or by directly embodying cholesterol which is then helpful for reducing coronary heart disease, including hypertension and hypercholesterolemia. In this review, we will focus mainly on reviewing existing studies concerning the effects of probiotic food in ameliorating health and treating diseases particularly cardiovascular diseases, hypertension, hypercholesterolemia & cancer.

Keywords: Cholesterol, Functional Foods, Bifidobacteria, Cancer, Hypertention

Introduction

Probiotics (i.e., subsisting microbial food supplements) considered as a functional food, have obtained much attention and they target the gastrointestinal microbiota (Ziemer and Gibson, 1998; Saarela et Al., 2002). It is exactly documented that the large intestine is one of the most deeply populated ecosystems in nature comprising of over 500-1,000 different species of bacteria (Xu and Gordon, 2003; Meyer and Stasse-Wolthuis, 2009) of which bifidobacteria are usually predicted to be health improving and favorable (Kimura et al., 1997). Impacts of probiotics can be affected by the hereditary attributes of intestinal microbiota in every person, natural factors, diet, and use of antibiotics. Additionally, different impacts of probiotics in various ages of consumers are expected (Salminen and Isolauri, 2006; Eckburg et al., 2005).

A. Probiotics

The name probiotic comes from the Greek 'pro bios' which implies 'for life' (Gismondo et al., 1999). The term "probiotics" was 1st introduced in 1953 by Werner Kollath. In 1989, Roy Fuller recommended a definition of probiotics that has been wide used: "A live microorganism feed supplement that beneficially affects the host animal by raising its intestinal microbial balance". Parker in 1974, proposed that “probiotics are organisms and substances that contribute to intestinal microorganism balance” (Parker, 1974). Salminen et al. (1998) outlined probiotics as the 'food that contains live microorganisms useful to health', whereas Marteau et al. (2001) outlined them as 'microbial cell preparations or parts of microorganism cells that have a useful impact on the health and well-being. Some fashionable definitions embrace a lot of exactly a preventive or therapeutic action of probiotics. Charteris et al. (1997) For instance, outlined probiotics as 'microorganisms that, when ingested, could have a positive impact within the interference and treatment of a particular pathologic condition. The presently used accord definition of probiotics was advised by the Planet Health Organization and by the Food and Agriculture Organization of the U.S. in 2001. They outlined probiotics as “live microorganisms that when administered in adequate amounts confer a health benefit on the host” (Shah, 2007).

Probiotics are microorganisms, molds, yeast. Among them, the carboxylic acid manufacturing microorganism is more common. A number of the species are (Srionnual et al., 2007) -

1. Lactic acid manufacturing microorganism (LAB): *Lactobacillus*, *Bifidobacterium*, *Streptococci*.
2. Non lactic acid manufacturing microorganism species: *Bacilli*, *Propionibacterium*.
3. Non-pathogenic yeasts: *Saccharomyces*.
4. Non reproductive structure forming and non-flagellated rod or coccobacilli.

The *lactobacillus* species facilitate in production of enzymes to digest and metabolize proteins and carbohydrates. Necessary probiotic microorganism species helpful in the oral cavity are *L. Acidophilus*, *L. Case*, *L. Rhamnosus Gc*, *L. Sporogens*, *L. Bulgaricus*, *L. Johnson*, *L. Termophilus*, *L. Bifidum*, *L. Reuteri*, *L. Salivaricus*, *L. Paracasei*, *S. Thermophilus*, *S. Salivarius*, *W. Siberia* and *Bifidobacterium*. They aid in the synthesis of vitamin B, fat-soluble vitamin and facilitates breakdown of digestive juice salts. They’re sometimes distributed in gel, paste, powder and liquid forms. Commonest vehicles for probiotics in oral health embrace lozenges, tablets, yoghurt, cheese, milk and mouth rinse (Kamal et al., 2013).

Fuller in 1989 listed the subsequent as the options of a good probiotic (Narang et al., 2011) -

1. It ought to be a strain, that is capable of exerting a useful impact on the host animal, e.g. magnified growth or resistance to sickness.
2. It ought to be non-pathogenic and non-toxic.
3. It ought to be present as viable cells, ideally in massive numbers.
4. It ought to be capable of living and metabolizing within the gut surroundings.
5. It ought to be stable and capable of remaining viable for periods under storage and field conditions.

Methods

We searched for articles in the PubMed (1974–2013), from which we also found some additional relevant references. The keywords were ‘beneficial bacteria’, ‘probiotics’, ‘*lactobacilli*’, ‘lactic acid bacteria’ and ‘bifidobacteria’. We focused on microbiological studies and clinical trials. Specifically, we found relevant information from original articles and reviews regarding the role of probiotics in human health and nutrition, probiotics and health effect, probiotic and cancer, etc. These have been overviewed to find out the overall

function of probiotic on the human body and also find out how probiotic food preventing and treating some major diseases such as cardiovascular disease, hypertension, hypercholesterolemia, cancer & other potential diseases.

Result:

Kim et al. (2011) reported that consumption of Kimchi (Korean Fermented Vegetables) as a probiotic food leads to a reduction in body weight, BMI, and percent body fat in overweight and obese subjects, which might reduce the risk for CVD and metabolic syndrome related to the metabolic parameters. Probiotic bacteria, which take part in the bile salt metabolism, can be useful in patients with CVD (Jones et al., 2013).

Yamamoto et al. (1994) suggested that the peptides liberated from casein by the proteinase in the culture medium showed antihypertensive effect in Spontaneously Hypertensive (*SHR*) *rat.* Therefore, this soymilk could potentially be used as a dietary therapy to reduce the risks of hypertension.

The use of bioactive foods has been recommended for the cure and prevention of human diseases like hypercholesterolemia (Rao, 2003). Bile acids are essential for absorption of cholesterol molecules from the intestinal lumen since cholesterol is hardly soluble in water. The so-called cholesterol micelle formation and thus cholesterol absorption is also impaired via deconjugation of bile salts. This information is used for production of probiotic strains to treat hypercholesterolemia. The activity of BSH (a non-allosteric, oxygen non-sensitive enzyme that is found inside the cell and its activity is dependent on an optimum pH (5 ~ 6) and an adequate biomass density (Begley et al., 2006 and Li, 2012) and other bile salt modifiers may lower cholesterol level (Martin et al., 2007 and Jones et al., 2008).

Bacterial fermentation has been reported to produce some specific end products, such as Short-chain fatty acids, that allegedly reduce the risk of cancer (Cho et al., 2010).

A placebo-controlled trial showed that oral administration of *Lb. salivarius* UCC118 in IL-10 KO mice decreased the prevalence of colon cancer (O'mahony et al., 2001). Regular consumption of beverages containing *Lb. casei* Shirota and soy isoflavones was inversely associated with the incidence of breast cancer in Japanese women (Toi et al., 2013).

Table 1: Impact of probiotics on the treatment of cardiovascular diseases

Reference	Study name	Findings
Gilliland et al., 1985 & Rašić et al., 1992	Assimilation of cholesterol by *Lactobacillus acidophilus*. Assimilation of cholesterol by some cultures of lactic acid bacteria and bifidobacteria.	There is also some in vitro evidence to support the hypothesis that certain bacteria can assimilate (take up) cholesterol. It was reported that *Lactobacillus acidophilus* and *Bifidobacterium bifidum* had the ability to assimilate cholesterol in vitro studies, but only in the presence of bile and under anaerobic condition.
Hylemon, 1985	Metabolism of bile acids in intestinal microflora.	Probiotics' mechanism of action on cholesterol reduction include physiological actions of the end products of fermentation short chain fatty acids (SCFAs), cholesterol assimilation, cholesterol binding to bacterial cell walls, and deconjugation of bile acids which is catalyzed by conjugated bile acid hydrolase enzyme produced exclusively by bacteria. It has been well documented that microbial bile acid metabolism is an irregular probiotic effect involved in the therapeutic role of some bacteria. Deconjugation ability is widely found in many intestinal bacteria including genera *Enterococcus, Peptostreptococcus, Bifidobacterium, Fusobacterium*, *Clostridium, Bacteroides,* and *Lactobacillus*.
Klaver and Van Der Meer, 1993	The assumed assimilation of cholesterol by *Lactobacilli* and *Bifidobacterium bifidum* is due to their bile salt-deconjugating activity.	They concluded that the removal of cholesterol from the growth medium in which *L. acidophilus* and *Bifidobacterium spp*. were growing was not due to assimilation but due to bacterial bile salt deconjugase activity.
Mann and Spoerry, 1974	Studies of a surfactant and cholesteremia.	As a result of low consumer compliance of low-fat diets, attempts have been made to identify other dietary components that can reduce blood cholesterol levels. These have included investigations into the possible hypocholesterolaemic properties of milk products, especially in a fermented form. An 18% fall in plasma cholesterol occurred after feeding 4-5 L of fermented milk per day for three weeks.
Usman and Hosono, 1999	Binding of cholesterol with lactic acid bacterial cells.	Cholesterol binding to cell surfaces is the mechanism by which *L. gasseri* could remove cholesterol from the medium. Since there was a significant variation in the cholesterol binding ability in 28 different strains of *L. gasseri*, it has been suggested that cholesterol-binding property is growth- and strain-specific, a difference that originates from differing chemical and structural characteristics of bacterial cell wall peptidoglycans.

Table 2: Impact of probiotics on the treatment of hypertension

Reference	Study name	Findings
Aihara et al., 2005	Effect of powdered fermented milk with *Lactobacillus helveticus* on subjects with high-normal blood pressure of mild hypertension.	In this study were able to reduce blood pressure in patients with high-normal blood pressure or mild hypertension by daily feeding of tablets containing powdered milk fermented with *L. helveticus* CM4 for four weeks.
Appel et al., 1997	A clinical trial of the effects of dietary patterns on blood pressure.	In this clinical trial, dietary approaches to stop hypertension with almost 459 normotensive or mildly hypertensive subjects, which showed that a diet rich in fruits, vegetables, and low-fat dairy products (the so-called combination diet) was found to reduce blood pressure significantly.
Nakamura et al., 1995	Antihypertensive effect of sour milk and peptides isolated from it that are inhibitors of angiotensin I-converting enzyme.	In animal studies, the authors demonstrated that oral administration of Calpis sour milk or the peptides to spontaneously hypertensive rats was able to lower systolic blood pressure in these animals.
Seppo et al., 2003	A fermented milk high in bioactive peptides has a blood pressure-lowering effect in hypertensive subjects.	Studies in humans also have shown promise for the use of probiotic bacteria in the reduction of hypertension. In this study hypertensive subjects were fed milk fermented with *L. helveticus* LBK-16H containing bioactive peptides. At the end of 21 weeks, test subjects showed a significant lowering of their blood pressure.

Table 3: Impact of probiotics on the treatment of hypercholesterolemia

Reference	Study name	Findings
Ataie-Jafari et al., 2009	Cholesterol-lowering effect of probiotic yogurt in comparison with ordinary yogurt in mildly to moderately hypercholesterolemic subjects.	In humans, a study demonstrated that hypercholesterolemic patients fed probiotic yogurt containing *Lactobacillus acidophilus* and *Bifidobacterium lactis* were able to reduce their cholesterol levels compared to cohorts who consumed ordinary yogurt.
Bhathena et al., 2009	Orally delivered microencapsulated live probiotic formulation lowers serum lipids in hypercholesterolemic hamsters.	Several studies have reported lowering of cholesterol levels by probiotic bacteria. For example, hypercholesterolemic hamsters consuming microencapsulated live *L. fermentum* 11976 led to significant reductions in their serum total cholesterol and triglyceride levels as well as low density lipoprotein cholesterol levels.
Danielson et al., 1989 & Gilliland et al., 1985	Assimilation of cholesterol by *Lactobacillus acidophilus*. Anticholesterolemic property of *Lactobacillus acidophilus* yoghurt fed to mature boars.	Probiotic bacteria have demonstrated abilities to reduce blood cholesterol and are thought to work by several mechanisms including assimilation of cholesterol, binding cholesterol and bile acids to the cell surface thus inhibiting absorption from the small intestine.
Wang et al., 2009	Effects of *Lactobacillus plantarum* MA2 isolated from Tibet kefir on lipid metabolism and intestinal microflora of rats fed on high-cholesterol diet.	Similar results were seen in rats fed a high cholesterol diet supplemented with lyophilized *L. plantarum* MA2 to significant reductions in their serum total cholesterol and triglyceride levels as well as low density lipoprotein cholesterol levels.

Table 4: Impact of probiotics on different types of cancer

Reference	Probiotic strain	Subjects	Dose and duration of study	Efects (P<0.05)
El-Nezami et al., 2006	*Lactobacillus rhamnosus* LC705 and *Propionibacterium freudenreichii subsp. shermanii strains*	(i) Afatoxin-induced liver cancer (ii) 90 male students with high afatoxin level in urine	5 weeks , (1:1, wt: wt) at a dose of $2–5\times10^{10}$ colony-forming units/day	61.5% reduction of a liver cancer biomarker which leads to reduced urinary excretion of afatoxin B1-N7guanine (AFB-N7-guanine)
Liu et al., 2013	*Lactobacillus plantarum* CGMCC, *Lactobacillus acidophilus*-11 and *Bifdobacterium longum*-88	(i) Colorectal cancer patients (ii) 150 patients (1;1 ratio of probiotic and placebo group)	(i) *Lactobacillus plantarum* CGMCC no.1258;10^{11}(CFU)/g (ii) *Lactobacillus acidophilus*;10^{11}CFU/g, (iii) *Bifidobacterium longum*-8810^{10} (CFU/g) (iv) The patients administrated with probiotic 6 days preoperatively and 10 days postoperative.	Probiotics decreased the serum zonulin concentration, duration of postoperative pyrexia, duration of antibiotic therapy, and rate of postoperative infectious complications as well as inhibited the p38 mitogen-activated protein kinase signalling pathway.
Ma et al., 2010	*Lactobacillus casei Shirota* (LcS)	(i) Cervical cancer (ii) 54 women with an HPV-positive intra epithelial lesion	Daily administration of (Yakult) containing LcS for 6 months.	60 % reduction in human papilloma virus (HPV) associated infection and cervical cancer precursors.
Ohashi et al., 2002	*Lactobacillus acidophilus* L1	(i) Bladder cancer (ii) A total of 180 cases (mean age: 67 years, SD 10) and 445 population-based controls	200 g of yoghurt containing *L. acidophilus* L1 for 10 weeks	Habitual intake of lactic acid bacteria reduces the risk of bladder cancer.
Toi et al., 2013	*Lactobacillus casei* Shirota (LcS)	(i) Breast cancer (ii) 968 breast cancer patients (306 probiotic group; 662 control) aged 40 to 55.	Frequent consumption of Yakult containing *Lactobacillus casei Shirota* and isofavones from soy product for 2 years	Regular consumption of LcS and isofavones since adolescence was inversely associated with the incidence of breast cancer in Japanese women.

Discussion

An expanding number of clinical trials supporting the probiotic-dependent weakening of hypertension and hypercholesterolemia could give colossal help for the application of such cultures to improve cardiovascular health. Subsequently, dietary mediation to correct gut microbiota could be an imaginative nutritional therapeutic technique for hypertension. The knowledge gained on probiotic potential against cardiovascular diseases is still at the earliest stage and current discoveries propose that hypotensive impacts of probiotics are exceptionally encouraging and worth investigating to promote cardiovascular health. Probiotics have obtained expanding medicinal significance in view of their helpful impacts upon the host wellbeing. Oral administration of probiotics has various impacts, such as standardization of the intestinal microflora, improvement of the gastrointestinal obstruction, and hindrance of potential pathogens or carcinogenesis in the gut. Together with the enhancement of systemic immune or/and anti-inflammatory activities, probiotics may have an impact on the concealment of tumor development and development. While research center based investigations have exhibited encouraging outcomes that probiotics have antitumor impacts, the advantages ought not to be overstated before we get more outcomes from human subjects. In any case, more examinations are required for a superior comprehension of gut microbiota-host cross talk and biochemical networks underlying the control of hypertension. Randomized double-blind, placebo-controlled clinical trials ought to be done to pick up the acceptance of the broader medical community and to investigate the capability of probiotics as an alternative therapy for cancer control.

Future Challenges

Owing to their perceived health advantages, probiotics are currently widely added to yogurts and fermented milks (Özer et al., 2005; Menrad, 2003 and Stanton et al., 2001). However, the production of probiotics at industrial scale faces many challenges, as well as (i) the affordable production of probiotics; (ii) the advance of probiotic viability after storage, during the manufacturing method of the functional food and during transit through the abdomen.

A. Affordable production of probiotics

Low-cost production of concentrated cultures of probiotics are a key challenge to satisfy the increasing demand for probiotics in the market (Mattila-Sandholm et al., 2002). Probiotic micro-organisms are normally difficult to grow as they lack the biosynthetic capacity of most vitamins and amino acids, so culture media for probiotic production must be supplemented with both amino acids and vitamins (Altermann et al., 2005 & Remacle et al., 2004). The reduction of production costs at an industrial scale might start with the use of some agro-industrial residual effluents as cultivation media for probiotics. In this regard, effluents from fruit and vegetable processing usually contain high amounts of proteins, carbohydrates, lipids and vitamins.

B. Improving viability of probiotics

The quality of probiotic micro-organisms depend greatly on their viability that may be a basic fulfillment to reach and colonize the intestine (Lahtinen et al., 2005 & Tuomola et al., 2001). Probiotics must retain their viability during three important stages: (i) storage; (ii) manufacturing method of the functional food; (iii) transit through the stomach and small intestine. Therefore the viability of probiotics is an issue of vital importance from both associate economic and a technological viewpoint.

Conclusions

This review confirms the potential effectiveness of probiotics in disease interference and/or management by many mechanisms, for example, stimulating and decreasing the incidence of duration and complaints of rotavirus-induced or antibiotic-associated diarrhea as well as alleviation of complaints because of lactose intolerance, the concentration of cancer-promoting enzymes and/or putrefacient (bacterial) metabolites within the gut, general and irregular complaints of the gastrointestinal tracts in healthy people, allergies and atopic diseases in infants, Respiratory tract infections (common cold, influenza) and different infectious diseases as well as treatment of urogenital infections, etc. Probiotics food has beneficial effects on microbial aberrancies, inflammation and other complaints in connection with inflammatory diseases of the

GIT, *Helicobacter pylori* infection or bacterial overgrowth. It is also normalization of passing stool and stool consistency in subjects suffering from constipation or an irritable colon. The presence of bacteria in the gut is critical and barriers and containments in the gut are crucial for preventing bacterial infection in other areas of the body. Microorganisms in the gut interact with the host in many ways, including functions as diverse as the uptake of nutrients and preventing and/or modifying toxic substances from reaching critical organs in a toxic form. Due to its essential function, these are preventing & alleviating different types of diseases and improves human health. While the mechanisms of their effects on gut bacteria are slowly being unraveled, their effects on health are much more difficult to demonstrate.

Conflict of interests

The authors declare that they have no competing interests.

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Author's Contribution

Mohammad Asadul Habib carried out the studies, participated in the sequence alignment, performed in the analysis of the findings and drafted the manuscript. Mohammad Hasan Chowdhury participated in the design of the study, sequence alignment & drafted the manuscript. Farzana Afroz Tumpa, Jannatul Nayeem participated in the design of the study and drafted the manuscript. Md. Abdullah Al Mamun, Md. Ruhul Kabir; Assistant Professor, Noakhali Science & Technology University conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

Abbreviations

DNA – Deoxyribonucleic Acid
LAB – Lactic Acid Bacteria
CVD – Cardiovascular Disease
BMI – Body Mass Index
BSH – Bile Salt Hydrolase
GIT – Gastrointestinal Tract

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Correlation of Glasgow Coma Scale (GCS) with Computed Tomography (CT) in Patients of Intra-Cranial Injuries

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Abstract

Objective: To determine the correlation of Glasgow coma scale with Computed Tomography (CT) in patients of intra-cranial injuries. Material and methods: This study is a cross-sectional analytical study with a sample size of 138 patients. Sampling techniques were non-probability convenient sampling. The study was performed in the Department of Radiology in Lahore General Hospital. The study was finished in 3 months after approval of synopsis. Ultrasound was performed with a convex transducer of 3.5 - 5MHz frequency. Outcome variables are Prostate volume and post-micturition residual (PMR). The data collection sheet was used to record observed data, and individual patient personal data will not be published. Sections were taken parallel to the canthomeatal. CT machine: Toshiba Scanner Aquilion 16 SLICE, model no: TSX-101A, model no: CGGT-018A, slice thickness: 5-7mm, gap b/w slices: 5mm, window width: 1600, window length: +350, kV: 120, mA: 200, pitch: 5. Result: Total 138 patients were enrolled in the study, in which 54 (39.1%) were females, and 84(69.9%) were males with a mean age of 37 years with a range of 4-85 ± 16.28 years. The present study was conducted for a period of two years in the Department of radiology with association from Department of Emergency medicine and included 138 patients with a history of intra-cranial injuries. The cases were referred from the Emergency unit after clinical and neurological systemic examination and calculating the GCS score. The score was blinded for the radiologist examining the case for avoiding bias in reporting. Conclusion: To conclude from our study, patients with low GCS score were considered as a severity risk factor in association with more intra-cranial injuries CT findings. Patients with low GCS score are affected by severe morbidity and devastating effects as observed from other studies.

Introduction

Traumatic brain injury (TBI) is a non-degenerative, non-congenital insult to the brain from an external mechanical force, possibly leading to permanent or temporary impairment of cognitive, physical, and psychosocial functions, with an associated diminished or altered state of consciousness[1]. Intracranial bleeding (IB) is a common and serious consequence of traumatic brain injury (TBI). Intracranial bleeding can be classified according to the location into: epidural hemorrhage (EDH) subdural hemorrhage (SDH) intra-cerebral hemorrhage (ICH) and subarachnoid hemorrhage (SAH)[2].

According to the Centers for Disease Control and Preventions (CDC), the leading causes of TBI include falls, road traffic accidents, being struck by or colliding with an object. Other causes include domestic violence and work-related and industrial accidents. The global incidence of TBI per 100,000 people was greatest in North America (1299 cases, 95% CI 650-1947) and Europe (1012 cases, 95% CI 911-1113) and least in Africa (801 cases, 95% CI 732-871) and the Eastern Mediterranean (897 cases, 95% CI 771-1023). Sixty-nine million (95% CI 64-74 million) individuals are estimated to suffer TBI from all causes each year, with the Southeast Asian and Western Pacific regions experiencing the greatest overall burden of disease. Head injury following road traffic collision is more common in low and middle-income countries (LMICs), and the proportion of TBIs secondary to road traffic collision is likewise greatest in this countries[3].

Pakistan is a low-income country with over 180 million populations, with a high rate of TBIs. A large road traffic injury surveillance study (n>100,000) in Pakistan showed that nearly a third of patients had a TBI, and of them, about 10% percent had moderate to severe TBI[4]. The management of patients with head trauma is clinically based on the Glasgow Coma Scale (GCS) that can present a comprehensive framework for assessing the three clinical aspects of verbal, visual, and motor responsiveness leading proper stratifying neural impairment and head injury severity[5,6].

It is essential to determine the cause of the trauma, the intensity, presence of neurological symptoms, convulsion, and particularly document any report on the loss of consciousness[7]. The GCS has been the most valuable and frequently used scoring system for assessing the severity of neurologic injury after head trauma. According to the GCS, traumatic brain injuries are classified as mild (GCS score 13–15), moderate (GCS score 9–12) or severe (GCS score equal to or <8) and is currently the most widely used parameter for assessment of consciousness level[8]. It comprises a set of very simple and easy-to-perform physical examinations, high inter-observer reliability and generally good prognostic capabilities. Radiography was the main imaging method recommended in emergency evaluations. The protocols were then modified to include CT, GCS and the presence of cranial fracture a risk factor. Currently, the imaging method of choice for the diagnosis and prognosis of Traumatic Brain Injury (TBI) is Computed Tomography (CT). Besides the clinical management of head trauma patients, intracranial lesions in patients can be detected by imaging methods even before clinical manifestations[9].

CT is indicated in all patients with moderate and severe head injury (GCS ≤12). Low threshold for taking CT is advisable in elderly and alcohol-intoxicated patients. In mild head injury, CT has indicated if any one of the following risk factors is present: loss of consciousness (LOC >5 min), history of vomiting, history of seizures, history of ear bleed, and history of nosebleed[10].

With the advent of computed tomography (CT), the diagnostic radiology has revolutionized[11]. The aim of this study is to find an association between CT findings and GCS categorization and to test the possibility of predicting intracranial lesions by determining GCS score on admission. If a good correlation between the CT scan appearance and GCS scoring can be found, then the use of follow-up CT scans would only be recommended in patients with clinical deterioration unexplained by intracranial pressure changes alone. Thus, substantially, lowering the radiation dose and also reducing the cost by preventing unwanted CT scans[12].
At present, there is no updated study regarding the correlation of the Glasgow Coma Scale (GCS) and intracranial injuries. Different hospitals follow different protocols. By this study, if we find a good correlation, the patient can be saved from the irrelevant CT radiation exposure. The accurate assessment of the GCS scoring can prove to be very helpful for the differential diagnosis of intracranial injury.

METHODOLOGY

Study Design is Cross-sectional analytical study. This study was conducted in the Department of Radiology in Lahore General Hospital. Three months study Duration after the approval of synopsis. Sampling Technique was non-probability convenient sampling and sample size 138.

The patient is given the consent to read and to sign after he/she agrees for the procedure. The patient is placed on the CT table in a supine position. Head first into the gantry also placed within the head holder. Centre the table height such that the external auditory meatus is at the center of the gantry. Sections were taken parallel to the canthomeatal. CT machine: Toshiba Scanner Aquilion 16 SLICE, model no: TSX-101A, model no: CGGT-018A, slice thickness: 5-7mm, gap b/w slices: 5mm, window width: 1600, window length: +350, kV: 120, mA: 200, pitch: 5.

Results

Total 138 patients were enrolled in the study, in which 54 (39.1%) were females, and 84(69.9%) were males with a mean age of 37 years with a range of 4-85 ± 16.28 years. The present study was conducted for a period of two years in the Department of radiology with association from Department of Emergency medicine and included 138 patients with a history of intra-cranial injuries. The cases were referred from the Emergency unit after clinical and neurological systemic examination and calculating the GCS score. The score was blinded for the radiologist examining the case for avoiding bias in reporting.

Total 138 patients were enrolled in the study, in which 54 (39.1%) were females, and 84 (60.9%) were males (table # I). This table is showing different blood pressure level frequencies table # II. Types of injuries on CT frequency epidural hemorrhage was 49 (35.5), Intra-cerebral hemorrhage 1 (.7), Intra-ventricular hemorrhage 10 (7.2), Subarachnoid hemorrhage 2 (1.4) and Subdural hemorrhage 25 (18.1) table # IV. The mean age of the patients was 37 years with a range of 4-85 ± 16.28 years (table # V). Glasgow coma scale, types of injury on CT cross-tabulation table # VI.

Table-I: Frequency of gender

	Frequency	Percentage
Female	54	39.1
Male	84	60.9
Total	138	100.0

Graph-I: Frequency of gender

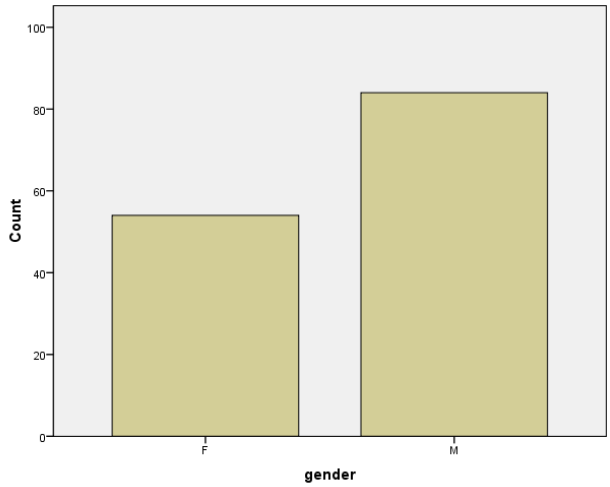

Table-II: Frequency of blood pressure

	Frequency	Percentage
100/70	2	1.4
100/80	1	.7
110/70	10	7.2
110/80	7	5.1
110/90	6	4.3
120/10	1	.7
120/11	1	.7
120/70	1	.7
120/80	9	6.5
120/90	5	3.6
130/10	5	3.6
130/80	14	10.1
130/90	16	11.6
140/10	1	.7
140/80	3	2.2
140/90	14	10.1
150/10	1	.7
150/11	2	1.4
150/90	2	1.4
160/10	6	4.3
160/11	4	2.9
160/90	4	2.9
170/10	9	6.5
170/11	2	1.4
170/80	2	1.4
170/90	3	2.2
180/10	4	2.9
180/11	1	.7
200/11	1	.7
200/14	1	.7
Total	138	100.0

Graph-II: Frequency of blood pressure

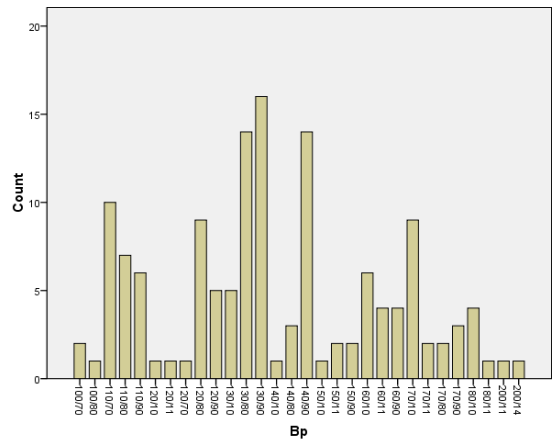

Table-III: Frequency of Glasgow coma scale.

	Frequency	Percentage
10/15	20	14.5
11/15	23	16.7
12/15	13	9.4
13/15	13	9.4
14/15	10	7.2
15/15	28	20.3
3/15	2	1.4
4/15	3	2.2
6/15	5	3.6
7/15	3	2.2
8/15	6	4.3
9/15	12	8.7
Total	138	100.0

Graph-III: Frequency of Glasgow coma scale.

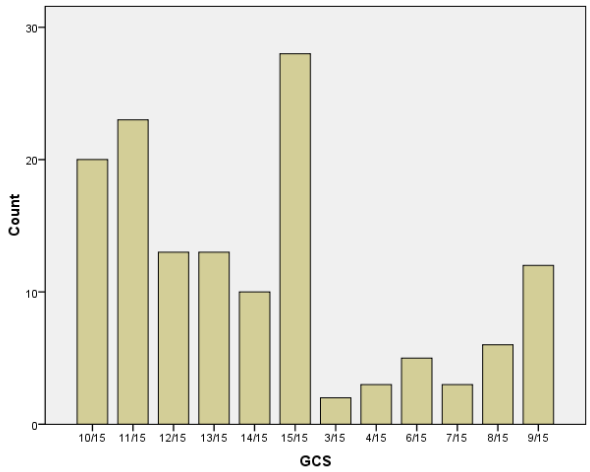

Table-IV: Types of injury on CT

	Frequency	Percentage
EDH	49	35.5
ICH	1	.7
IVH	10	7.2
SAH	2	1.4
SDH	25	18.1
Total	138	100.0

Graph-IV: Types of injury on CT

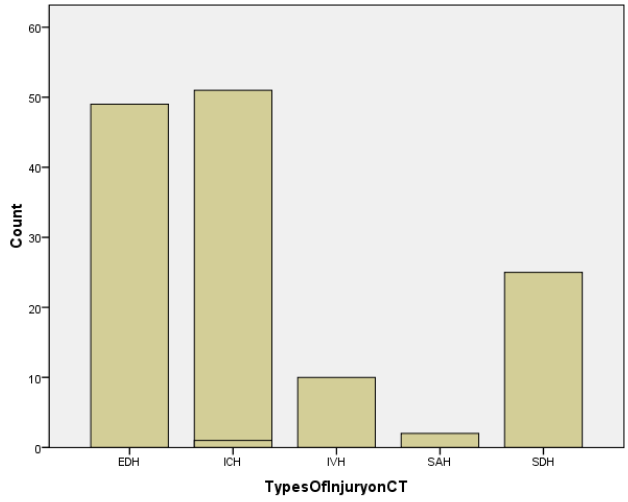

Table-V: Descriptive statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Age	138	4.00	85.00	37.3696	17.63088
Valid N (list wise)	138				

Graph-V: Descriptive statistics

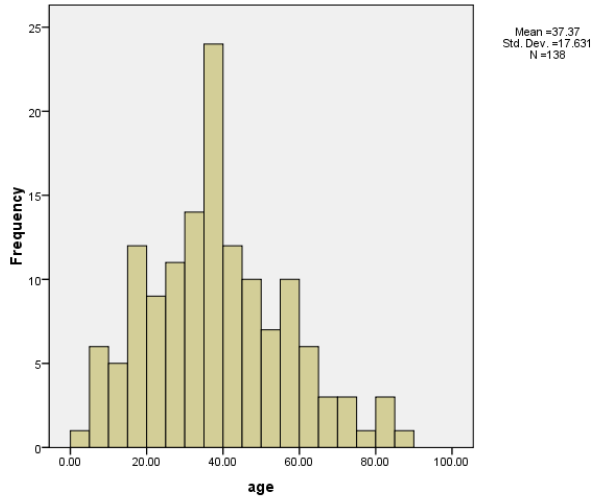

Table-VI: Glasgow coma scale, types of injury on CT cross-tabulation

		Types Of Injury on CT					
		EDH	ICH	IVH	SAH	SDH	Total
GCS	10/15	6	0	2	1	6	20
	11/15	5	0	5	0	0	23
	12/15	4	0	1	0	2	13
	13/15	4	0	0	0	4	13
	14/15	6	0	0	0	2	10

	15/15	20	0	1	0	4	28
	3/15	0	0	0	0	1	2
	4/15	1	1	0	0	0	3
	6/15	0	0	0	0	2	5
	7/15	1	0	0	0	0	3
	8/15	1	0	0	0	2	6
	9/15	1	0	1	1	2	12
Total		49	1	10	2	25	138

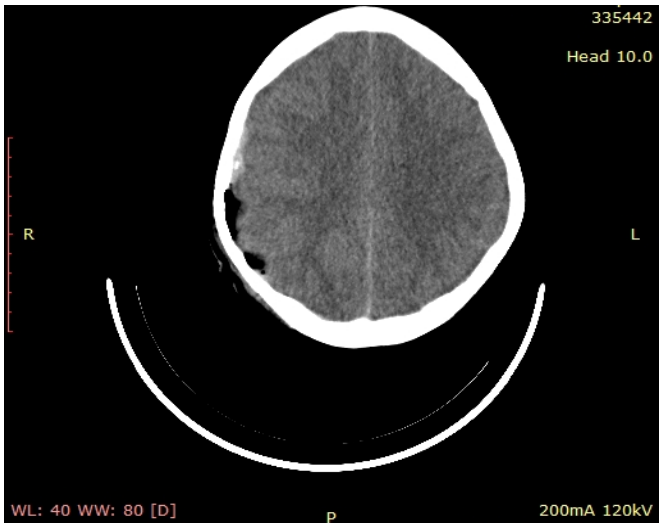

Figure-1: Subdural hemorrhage

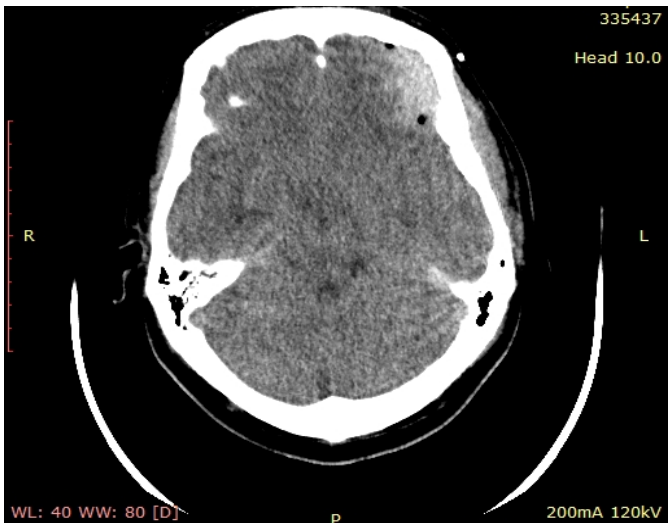

Figure-2: Intra-cerebral hemorrhage

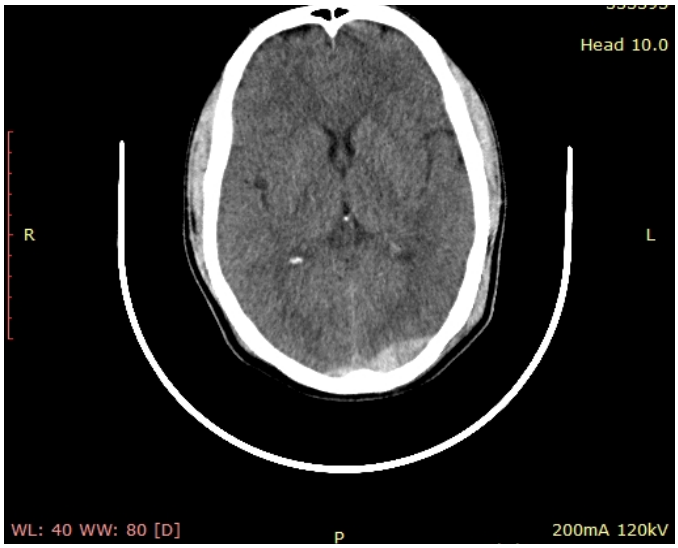

Figure-3: Epidural hemorrhage

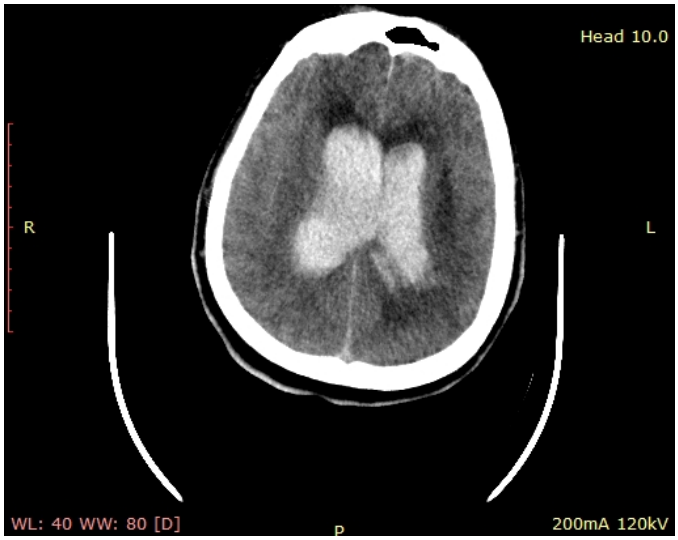

Figure-4: Intra-ventricular hemorrhage

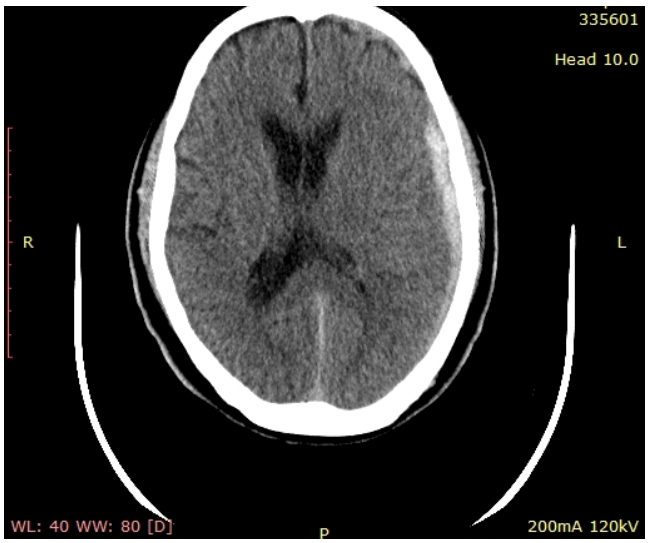

Figure-5: Subdural hemorrhage

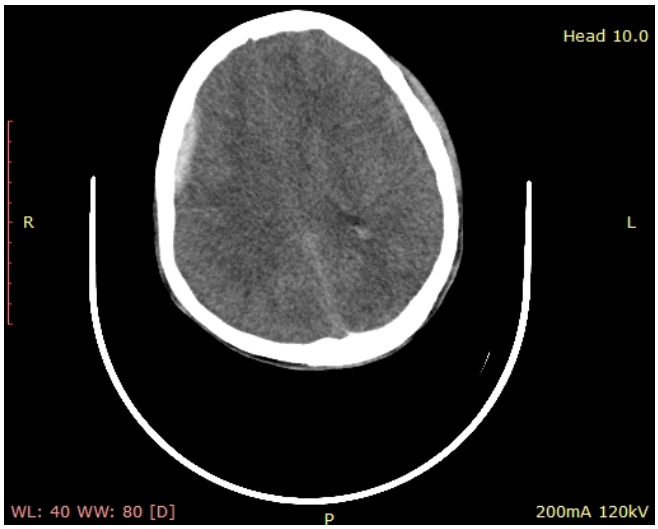

Figure-6: Epidural hemorrhage

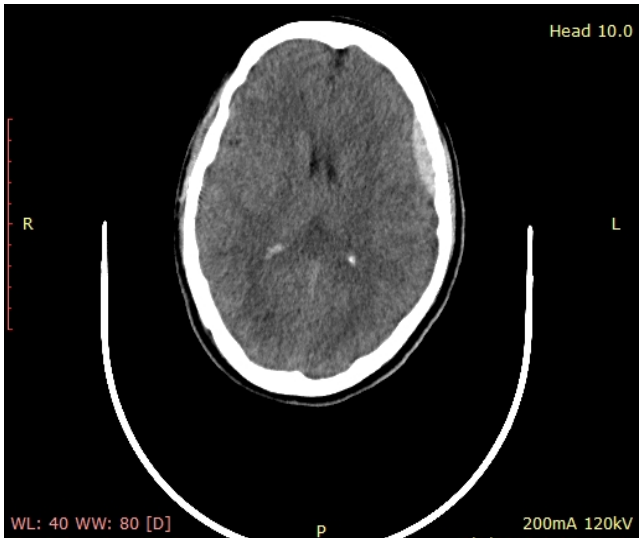

Figure-7: Epidural hemorrhage

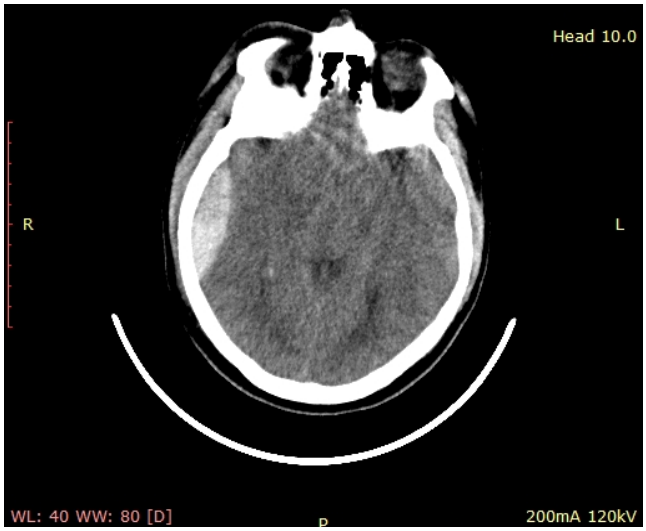

Figure-8: Epidural hemorrhage

Discussion

In the present study, 138 patients were enrolled in the study, in which 54 (39.1%) were females, and 84(69.9%) were males with a mean age of 37 years with a range of 4-85 ± 16.28 years. The present study was conducted for a period of two years in the Department of radiology with association from Department of Emergency medicine and included 138 patients with a history of intra-cranial injuries. The cases were referred from the Emergency unit after clinical and neurological systemic examination and calculating the GCS score. The score was blinded for the radiologist examining the case for avoiding bias in reporting.

Association between the severity of brain lesion assessed by the level of consciousness on GCS scoring system and the presence or absence of brain lesions in CT scan is now considered as a new subject to minimize unnecessary CT following in patients with intra-cranial injuries. This subject can be very important in children, as well as in those with complete or partial contraindications of CT scanning. Our study attempted to determine the association between CT findings and GCS categorization to test the possibility of predicting brain lesions by determining GCS score on admission. In our observation and among those with positive CT findings on brain abnormality, 77.1 patients had a mild brain injury, 11.0% had a moderate brain injury, and 11.9% had a severe brain injury. On the other hand, a notable number of patients with abnormal CT findings may have only mild injuries leading to mild consciousness impairment while about one-fourth of patients with CT findings may have moderate to severe consciousness impairment. In fact, the presence of CT finding may not be an indicator for the level of consciousness impairment assessed by GCS score. A few recent studies assessed the correlation between GCS score and CT scan to assess brain lesions.

In a study by Lee *et al*., the change in CT scans was compared with the GCS the day of the scan showed a positive correlation between the two modalities. In this regard, in patients with unchanged or improved GCS, 73.1% had improved or the same CT appearance, while in those with a worse GCS, the CT was worse in 77.9%. Finally, the authors concluded that due to good correlation between the CT scan appearance and the clinical status, the use of follow-up CT scans was recommended only in patients with clinical deterioration unexplained by intracranial pressure changes alone[13].

Farshchian *et al*.[14] Showed that only three lesions of extra-axial hematoma, subarachnoid hemorrhage, and hemorrhagic contusion might be associated with low GCS scores. In a study by Joseph *et al*.,[15] a mild GCS score (GCS 13–15) in patients with an intracranial injury does not preclude progression on repeat head CT and the need for neurosurgical intervention. Melo *et al*.[16] also indicated that of patients with mild brain injury, neurosurgery was performed in 6.7% and 9.2% had neurological disabilities. In fact, mild brain injury based on GCS score may be associated with significant abnormalities in CT scan, require neurosurgical procedure and Intensive Care Unit admission. Moreover, Chieregato *et al.* [17]showed that the GCS scoring system was not enough for assessing brain injury, and, therefore, it should be combined with other systems such as traumatic brain injury classification.

Leonidas Grigorakos conducted a study in 2016 on the topic of Predictors of Outcome in Patients with Severe Traumatic Brain Injury. The study was performed Neurosurgery Department, Tzaneio General Hospital of Pireus, Greece. This article has been published in the Journal of Neuroscience & Clinical Research. A retrospective study was carried on patients (n=621) with a severe head injury, defined as Glasgow Coma Scale (GCS) ≤ 8 who were admitted to the general ICU over a 15-year period (1999-2013). Most important variables that could be correlated with outcome (demographics, cause of injury, GCS, clinical variables and computed tomography–CT scan) were analyzed. The conclusion they gave for this study was that severe TBI has high mortality and morbidity in Greek society as it has a high negative impact on young people, especially men. The age of the patient, GCS at admission and the CT scanning are significant predictors of outcome[18].

Conclusion

In summary, because of disagreement between intra-cranial injuries assessed by GCS score and findings brain abnormalities in CT scan, the use of GCS score for assessing the level of injury may not be sufficient and thus considering CT findings as the gold standard, the combination of this scoring system and other applicable

scoring systems such as intra-cranial injuries classification and also considering clinical signs like depressed fracture may be more applicable to stratify brain injury level.

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Assessment of Factors Influencing Outsourcing Strategy in Teaching Hospitals in South-Western Nigeria

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Abstract
This study investigated factors influencing outsourcing strategy in South-Western Nigerian teaching hospitals. The study utilised primary data which were collected through questionnaire and key informant interviews. The data collected were analysed using descriptive and inferential statistical techniques. The paper found that cost reduction, greater flexibility, reduced manager's burden, improved services, efficient use of resources, reduced staff workload and innovation and creativity, are the most factors influencing outsourcing strategy in Nigerian teaching hospitals. The study, however, revealed that technical convenience and efficiency, increased productivity/performance, the need to focus on core activities, Improvement of service delivery and quality, as well as to meet changing customers' needs is the major rationale for outsourcing in Nigerian teaching hospitals. In addition, the study concluded that reduced manager's burdens, reduction staff workload, are the major benefits of outsourcing in the Nigerian teaching hospitals. The study, however, concluded that outsourcing is an emerging process in Nigeria. Therefore, the Nigerian health sector needs to pass through a learning phase before outsourcing is recognized as an efficient management and regulatory tool.

Keywords: Outsourcing Benefits, Strategic Management, Nigerian Teaching Hospital

1.0 Introduction

The need for outsourcing has grown over the last two decades due to some factors which include among others, global competition, downsizing, the move to flatter organization, the need to reduce cost, improved quality services and delivery, increased flexibility which facilitate change and the emphasis on core competencies (Dyer and Ouchi, 1993; Huber, 1993; Fan, 2000). Hospitals and healthcare subsystems in Nigeria have been criticized as inefficient owing to factors of underfunding, use of obsolete equipment, low-quality patient care, poor leadership capabilities and inappropriate management (ref). In view of the observed phenomenon, hospital management has evolved a new management strategy termed "outsourcing" with the hope that better service delivery will be guaranteed.

There are three major categories of motivations for outsourcing: cost, strategy, and politics. The first two commonly drive outsourcing by private industry. Political agenda often drive outsourcing by the public organization (Kakabadse and Kakabadse, 2000a). While there may be three categories, outsourcing activities are likely to be initiated for more than one reason and in fact, may be driven by elements from all the three

categories. For example, the outsourcing of taxing and health services for the British government was driven by elements from both cost and political categories (Willcocks and Currie, 1997a).

Since 2006, outsourcing had become a key thrust of government policy in Nigeria, provided for under the "Generic guidelines for the reform of parastatals" as directed by the Bureau of Public Service Reforms (BPSR, 2006). Although the strategy of outsourcing has long been used in the private sector this policy shift by the government has made it compulsory for the public sector to outsource. This practice is not new in the Nigerian private sector as was pointed out by Adeleye (2004) that outsourcing is becoming a prominent strategy in service-related businesses in Nigeria (Adeleye, 2004).

While a sizeable number of studies have investigated the management practices associated with the outsourcing of services in sectors like banking, oil, and gas, less attention is paid to the healthcare sector. There is, therefore, a need to investigate the factors influencing the outsourcing strategy adopted by the teaching hospital in Nigeria, most especially those teaching hospitals that enjoy some level of independence and autonomy in their management and service delivery policy, as a critical step towards enhanced performance; hence this paper explores the factors determining outsourcing practices in the tertiary health sector in Nigeria with the specific of identifying the services outsourced in selected teaching hospitals in South-western Nigeria and then examining the factors influencing outsourcing of services in the hospitals. The study is restricted to the health sector in South – Western Nigeria. A large concentration of teaching hospitals is present in South-Western Zone and whatever is happening in the zone is a reflection of what is likely to happen in the tertiary health sector in other zones in Nigeria all things being equal.

The paper is divided into five sections. Apart from this introduction, section 2, review the salient concept and empirical studies on outsourcing and lay the background for the empirical methodology in section3. Section 4 presents the empirical results and finding while the paper concludes with policy implications in section 5

2.0 Literature Review

There is much debate in management literature defining outsourcing (Gilley and Rasheed, 2000). Outsourcing is defined by Espino-Rodriquez et al; (2006) as a "strategic decision that entails the external contracting of determined non-strategic activities or business processes necessary for the manufacture of goods or the provision of services by means of agreements or contracts with higher capability firms to undertake those activities or business processes with the aim of improving competitive advantage". It is the transfer of one or more internal activities of an organization to an external vendor. Sharpe (1997) defines outsourcing as turning over to supplier those activities outside the organization's core competencies. Generally, outsourcing can be defined as the "transfer of previously in-house activities to a third party (Lonsdale, 1999). Wasner (1999) defines outsourcing as "…turning over to an external vendor the control of an in-house activity or activity for which an immediate ability exists of performing it internally." Wasner (1999) states that outsourcing is composed of a make or buy decision with the transfer. Gilley and Rasheed (2000) claim that "...outsourcing represents the fundamental decision to reject the internationalization of an activity…"

Nonetheless, despite an abundance of literature which looks into outsourcing, there appears to be a lack of a common definition of the term outsourcing (Deavers, 1997; Wasner, 1999). Domberger 1998 defines outsourcing "… as the process whereby activities traditionally carried out internally are contracted out to external providers…" Gilley and Rasheed (2000) provide clarification for the definitional confusion position and therefore defines outsourcing as procuring something that was either originally sourced internally (i.e., vertical disintegration) or could have been sourced internally notwithstanding the decision to go outside (i.e., make or buy). This includes arrangement and concepts which have been termed – internal vs external sourcing strategic make or outsource decisions contracting out (Gustafsson, 1995), contractorization (Hood, 1997), sub-contracting, purchasing, privatization (Seidenstat, 1996) compulsory competitive tendering, market testing liberalization (Beaumont 1991) and make or buy and focus. (Knight and Harland).

Wasner (1999) and Gilley and Rasheed (2000) emphasize that defining outsourcing in terms of procurement limits the definition – "defining outsourcing simply in terms of procurement of activities does not capture the

true strategic nature of the issue … outsourcing is not simply a purchasing decision". (Gilley and Rasheed, 2000). To better capture the conceptual basis of outsourcing it has been argued that the definition will be more meaningful if it incorporates the notion of transfer of activities that previously have been governed internally to external source (Greaver, 1999; Wasner, 1999; Gilley and Rasheed, 2000; Ellram and Billington, 2001; Heywood, 2001). Ellram and Billington (2001) define outsourcing as "…. the transfer of the production of goods or services that had been performed internally to an external party".

Along a similar line, Heywood (2001) defines outsourcing as "… the transferring of an internal business function or functions plus any associated assets to an external supplier or service provider who offers a defined service for a specified period of time at an agreed but the probably qualified price". Similarly, Gilley and Rasheed (2000) claim that outsourcing "… represents the fundamental decision to reject the internalization of an activity…" Outsourcing is an important aspect of health sector reform programmes in many countries, because it provides the government with a management and regulatory tool that creates incentives for improved performance and accountability (WHO, 2006). Therefore, outsourcing in the context of this study is defined as the process whereby activities traditionally carried out internally are contracted out to external body or bodies. It is, therefore, the transfer of activity from the internal governing body to the external governing body.

Young (2003) also observes that in outsourcing the major elements are first, the third party should be outside the normal employment conditions that govern traditional employees of the organization, and second, the functions should have been previously conducted in-house. Mylott (1995), Pearlson (2001), and Butler et al.; (2001) distinguished two forms of outsourcing namely full outsourcing and selective outsourcing. In full outsourcing, all the services are outsourced to the vendor. This according to Pearlson (2001) happens when the organization does not see outsourcing of their services as a "strategic advantage" that should be developed internally. Arguments for full outsourcing usually involve the allocation of organizational resources to areas that can add value to the organization value chain or reduce cost per transaction due to economies of scale. In selective outsourcing, only a range of services is selectively outsourced or contracted out to a third party. It often results in greater flexibility and better services (Pearlson, 2001). Thus outsourcing in the context of this study is more related to transfer than procurement and is the transfer of activity from internal governance to external control.

According to Quinn and Hilmer (1994), maintaining a competitive edge means focusing on intellectual skills and management systems, not products or functions which can easily be duplicated or replaced. Therefore, in determining which activities should be outsourced, it is widely suggested that core activities should be in-sourced and none-core activities outsourced. None-core activities are peripheral to a company's competitive advantage (Quinn and Hilmer, 1994). Flexibility can also be achieved as outsourcing enables access to rapidly developing new technologies or complex systems (Kakabadse and Kakabadse, 2000b). Thus, outsourcing allows for the possibility to fully exploit competencies and technologies of the outside sources which would be difficult and costly to develop internally (Quinn and Hilmer, 1994; Gilley and Rasheed, 2000). By this outsourcing can contribute to enhancing the quality of products/service (Canez et al.; 2000).

In an era of rapid technological change and short product life cycles, companies were trying to reduce cost and maintain quality at the same time which implied that companies would need to specialize in what they did best and de-emphasize management attention from business processes that did not directly impact the business. Outsourcing is a means by which the organizations improve their businesses by enabling them to handle specific business processes – better, faster and at a lower operating cost (Krishna, 2001). It was defined as the transferring one or more internal functions of an organization to external service providers. Outsourcing has become an alternative, which all major corporations must consider in order to remain competitive. Outsourcing helps to increase efficiency, improve service quality, accountability, values, decreased headcounts and cash infusion and gain access to world-class capability and sharing risk (Outsourcing Institute, 2006).

3.0 Methodology

The study was conducted in two selected teaching hospitals, namely: Obafemi Awolowo University Teaching Hospital Complex (OAUTHC), Ile-Ife and University College Hospital (UCH), Ibadan.

Study Design

Both primary and secondary data were used. The primary data employed included a closed-ended questionnaire. The questionnaires were sent to senior staff members of UCH and OAUTHC respectively. Prior to the hospitals surveyed, the questionnaire was discussed independently with some staff of OAUTHC Ile-Ife for validation. Based on their comments the questionnaire was modified and finalized.Interviews were also conducted with some of the top management staff of the hospital, including the Chief Medical Director (CMD), the Director of Administration (DA) and the Deputy Director of Finance (DDF) of each hospital to enhance the richness of the study. Questionnaires were used to elicit information for OAUTHC and UCH. Secondary data were also collected through records from the hospitals. Thus, the study adopted the usage of a questionnaire as a way of collecting information.

Study Population

The study population for this study consisted of senior staff of the two hospitals, i.e., OAUTHC and UCH.

Sample Size Determination

A total of 700 questionnaires were distributed equally in OAUTHC and UCH. The questionnaire has 12 items divided into four sections. Section one relates to the background information while section two covers issues on awareness and types of service outsourced. Section three deals with perceived benefits and risks of outsourcing and section four ask questions on the outsourcing management practices.

Out of 350 questionnaires distributed in OAUTHC, 330 (94%) of the questionnaires were returned duly filled with 20 questionnaires (6%) that were not returned. In the case of UCH Ibadan, 323 (92%) of the questionnaires were returned as filled while 27 (8%) were not returned. In all 93% (653) of the questionnaires out of the 700 were finally analyzed.

Sampling Technique

The samples of 700 respondents were selected through non-probability technique. Primarily, purposive sampling technique was used because the specific information required could only be provided by a well-defined set of people. Therefore, random or stratified sampling or any other probability sampling would not have been effective. The questionnaire was designed to elicit information on outsourcing management practices in hospitals. Each construct was represented by a set of indicators, which form the questions in the survey. The opinions of the respondent were captured on a positive to negative five-point Likert Scale while information relating to the personal attribute of respondents was captured using gender, age, level of education and position on the organizations.

Questions on the level of outsourcing of services were captured by the extent of outsourcing, i.e. totally outsourced/partially /not outsourced. Questions on perceived risks and benefits gave a statement and asked for the level of agreement on the following scale: Strongly Agree (SA), Agree (A), Undecided (U), Disagree (D) and Strongly Disagree (SD). Data collected were processed using the SPSS (Statistical Package for Social Science). Data were analysed using descriptive statistics with the application of inferential statistics.

4.0 Empirical Results

Social Demographic Characteristics of the Respondents

Table 1 depicts the demographic characteristics of the respondents. Basically, three key variables of the respondents were presented: Gender, Age and Religion.

Gender

Out of the 330 respondents from OAUTHC, only 130 (39.4%) were male while the remaining 200(60.6%) were female. The similar distribution pattern was observed in UCH, where 151(46.2%) were male, and 172(53.8%) were female. In all 281(42.8%) were male while 372(57.2%) were female. This implies that there were more female respondents than male. Generally, one would have expected the male to be dominating especially in a country like Nigeria where almost all professions were traditionally male-dominated. Nursing Cadres was responsible for this distribution pattern because the nursing profession was mainly dominated by female and

their entry point was senior staff. Also, statistics showed that they formed one-third of the total population of senior staff in each hospital. This pattern notwithstanding, the representation of the gender still seems balanced and sufficiently representative of the gender composition of the respondents.

Age

The age composition of the respondents in table 1 shows that the bulk 104(31.4%) and 162 (50.2%) of the respondents were between the age of 30 years and 39 years in OAUTHC and UCH respectively. Eight-nine (26.8%) and one hundred and twenty-one (37.3%) of the respondents were between the age of 40 and 49 years while 74 (22.7%) and 32 (9.9%) are above 50 years respectively in the two teaching hospitals. Only a small proportion of 63 (19.1%) and 8 (2.6%) of the staff surveyed aged below 30 years respectively in the two teaching hospitals. However, the pattern was similar, but the proportions were different across the age bracket in the two teaching hospitals. The respondents were more evenly distributed in OAUTHC than in UCH. For instance, while more than half (50.2%) of the respondents in UCH were between 30 and 39 years, only 31% in OAUTHC were within this age bracket. There seems to be younger and elderly staff in OAUTHC than UCH. Of all the respondents, 19% in OAUTHC as against 3% in UCH aged below 30 while about 23% of respondents from OAUTHC as against 10% from UCH aged above 50 years. There were more middle-aged workers in UCH than OAUTHC. About 88% of the respondents from UCH were between the age of 30 and 49 years while only 58% in OAUTHC are in this age bracket.

Overall, only 11% of the respondents were below age 30, 41% are between ages 30-39, 32% are between ages 40-49years while 16% aged above 50% years. The preliminary survey of the civil service of the federation in 2002 revealed an aging service of 60% of officers within the age bracket of 40 years and above. Therefore, part of the reform of 2006 is that the civil service is expected to have an organization that is competently staffed and well managed. Thus, the survey revealed that the problem of ageing service is gradually being solved, because 50.5% of the respondents in OAUTHC and 52.8% of the respondents in UCH are between ages 1-39 years while 49.6% of the respondents in UCH aged above 40 years. Overall, 51.6% of the respondents are between ages 1-39years while 48.4% of the respondents are above 40 years in age.

Religion

As shown in Table 1 most (508) of the respondents who responded to the issue of religion claimed either Christianity or Islam. The survey revealed that among those who responded to the question of religion, the dominance of Christianity is noticeable and apparent. Two hundred and seven (80.8%) and two hundred and seventy-three (74.6%) of the respondents from OAUTHC and UCH respectively were Christian while only 30 (9.2%) and 50 (15.4%) were Muslims respectively. In total 508 (87.7%) of the respondents are Christians while 80 (12%) are Muslims. Thirty-three (10%) and thirty-two (10%) failed to pick either Christianity or Islam.

In all 65 (10%) failed to respond to this question; 34(10%) and 32(10%) in OAUTHC and UCH respectively. Two reasons may be apparent. They might be reluctant to disclose their religion since they might believe that it was too personal and may not want to give too much of their personal information on the official response to the questionnaire. Two, they might be wondering what additional value their religions would add to the quality and authenticity of their perceptions and responses they provide to the issues raised in the questionnaires. They rather believed that if the interviewer cannot trust them without stating their religion, then they are not fit to respond; that religion has no bearing on the issues raised in the questionnaires and hence is immaterial to their perception of the outsourcing. This argument notwithstanding, it is interesting to note, however, that none of the respondents claimed to be a traditionalist or other religions.

Table 1: Socio-Demographic characteristics of the respondents (%)

		OAUTHC (obs=330)	UCH (Obs=323)	Total (Obs=653)
Gender	Male	130(39.4%)	151(46.2%)	281(42.8)
	Female	200(60.6%)	172(53.8%)	372(57.2)
Age	less than 30	63(19.1%)	8(2.6%)	71(10.85%)
	30-39	104(31.4%)	162(50.2%)	266(40.8%)

	40-49	89(26.9%)	121(37.4%)	210(32.2%)
	50+	74(22.7%)	32(9.9%)	106(16.3%)
Religion	Christianity	267(80.8)	241(74.6)	508(77.7)
	Islam	30(9.2)	50(15.4)	80(12.3)
	No Response	33(10.0)	32(10.0)	65(10.0)

Source: Author Field Survey 2018

Employment Profile of the Respondents

Table 2 present the distribution of the responses according to the employment profile of the respondents. Four categories of employment traits were identified, Educational level attained, employment status in the hospital, Job status and years of experience as a staff.

Educational Qualification

Among the 330 and 323 of the OAUTHC and UCH staff who responded to the question on the level of education, about 20 (6.2%) and none (0%), of staff from OAUTHC and UCH were primary school certificate holders. Eighteen (5.5%) and 27 (8.4%) were the holders of WASC or Vocational Certificate holders in the two hospitals respectively. Forty-seven (14.2%) and seventy-two (22.3%) are OND/HND holders. The University (first) Degree holder accounted for about 197 (59.7%) and 159 (49.1%) in OAUTHC and UCH respectively while about 48 (14.5%), and 65 (20.1%) were postgraduate (second Degree) holders. Overall 20 (3.1%) and 46 (7%) were primary and Secondary school certificate holders respectively. Approximately 119 (18%) of the staffs are holder Polytechnic certificate while the 355 (54.4%) and 113 (17.3 %) were university first degree and second-degree holders respectively. The distribution patterns show that the bulk of the workers were graduates and indeed more than half of the respondents held at least a university degree. This implied that the respondents were well educated, with 71.7% holding at least a university degree while the remaining 28.3% were junior staff who rose to become senior staff.

The problem identified in the reform of 2007 that the civil service consists of junior staff largely unskilled and constitute about 70% of the workforce was also solved because more than half of the respondents are university degree holders. This implies that most of the staff in the two teaching hospitals are senior staff, are well educated and are professionals in the various field of endeavour.

Job Status

The issue of outsourcing has a direct implication on the job duties of the staff. Once the services in the teaching hospital are outsourced, there would always be a change in staff duties and responsibilities. Some of the staff may even lose their jobs, redeployed and change jobs completely. So the views of these vulnerable staff are very crucial in the appraisal of the outsourcing activities in a teaching hospital. Seven types of Job categories in the teaching hospitals were identified in the survey: Management, Administration, Medical Doctor, Pharmacist, Nurses/Midwives, Laboratories Scientists, and General Staff. The distribution patterns of these job categories as presented in Table 4.2 show that 12 (3.6%) and 16 (5.1 %), constitute the management staff, 42 (12.8%) and 104 (32.2%) are in the administration staff, 70 (21.3%) and 68 (21.2%) are Medical doctors and 164 (49.5%) and 73 (22.7%) are Nurses/Midwives, while the Pharmacists accounted for 17 (5.2%) and 5 (1.5%) of the respondents from OAUTHC and UCH respectively, The distribution pattern also shows that the laboratory scientists constituted about 17 (5.2%) and 23 (7%) while General staff 8 (2.4%) and 34 (10.3%). In both Teaching hospitals, the Nurses/Midwives account for the largest proportion 237 (36.1%) of the respondents, followed by administration 146 (22.5%) and Medical doctors 138 (21.3%). The least represented is Pharmacist 22 (3.4%) followed by Management 38 (4.4%) and Laboratory scientists 40 (6.1%).

Length of Service

The years of experience of the staff in the hospitals is another factor considered important in gauging their perception about the desirability and relevance of outsourcing in the healthcare sector. As shown in table 4.2, 144 (43.7%) and 99(30.6%) of OAUTHC and UCH staff had spent less than 5 years on the job. 35(10.6%) and 81(25.2%) of the respondents from the OAUTHC and UCH claimed to have spent between 6 and 10 years while

72 (21.8%) and 80(24.7%) had between 11 and 20 years of experience. Seventy-nine (23.9%) and sixty-three (19.5%) of the respondents had more than 20 years of working experience as the staff of the teaching hospitals respectively. This pattern of distribution shows that most of the staff (37.2%) has spent less than years in the hospital which implies that a sizeable proportion of the respondents are less experienced and matured staff in the system. Interestingly, it was within these five years that outsourcing begun in the two hospitals. This increasing proportion of the staff with less than 5 years might be as a result of outsourcing that might have led to an upsurge in the number of staff engaged in the hospitals. However, a remarkable proportion of the workers in both hospitals between 11 and 20 years, showing that a sizable proportion (23.3%) of the health care workers are experienced and matured.

Table 2: Employment Profile of the Respondents (%)

		OAUTHC	UCH	Total
Level of education	Primary	20(6.2%)	0(0%)	20(3.1%)
	secondary/Vocational	18(5.5%)	27(8.4%)	46(7.0%)
	Polytechnic	47(14.2%)	73(22.3%)	119(18.3%)
	University First Degree	197(59.7%)	159(49.1%)	355(54.4%)
	Postgraduate	48(14.5%)	65(20.1%)	113(17.3%)
Job Status	Management	12(3.6%)	16(5.1%)	28(4.4%)
	Administration	42(12.8%)	104(32.2%)	146(22.5%)
	Medical Doctor	70(21.3%)	68(21.2%)	138(21.3%)
	Pharmacist	17(5.2%)	5(1.5%)	22(3.4%)
	Nurses/Midwives	164(49.5%)	73(22.7%)	237(36.1%)
	Laboratory scientists	17(5.2%)	23(7%)	40(6.1%)
	General Staff	8(2.4%)	34(10.3%)	42(6.4%)
length of services	Less than 5	144(43.7%)	99(30.6%)	243(37.2%)
	between 06 and 10 yrs	35(10.6%)	81(25.2%)	116(17.9%)
	between 11 and 20 years	72(21.8%)	80(24.7%)	152(23.3%)
	above 20 years	79(23.9%)	63(19.5%)	142(21.7%)

Source: Author Field Survey 2018

4.1 Identification of Services Outsourced in the Teaching Hospitals

In this section, the level of awareness of the respondents about the services being outsourced in their hospitals was inquired about. The types of services being outsourced and the numbers of years outsourcing activities have taken place in those services.

As depicted in Table 3 most of the respondents 578 (89%) were aware of the introduction of outsourcing in their teaching hospitals. Compositional distribution of these people, who claimed to be aware of outsourcing, shows further that more people in UCH 293 (90.8%) are more conversant with outsourcing than OAUTHC 287 (87%). The possible reason for this might be the fact that outsourcing had been implemented in UCH much longer than in OAUTHC.

How long the respondents have been aware of outsourcing is considered a crucial factor in determining their ability to appreciate the benefits and challenges of outsourcing. Among those that reported being aware of outsourcing, only 146(22.3%) of the respondents got to know about outsourcing within the last one year. 463 (70.9%) became aware of outsourcing in the last 5 years. A small proportion of 43 (6.7%) had heard about outsourcing for more than five years. Between OAUTHC and UCH, the pattern is similar, except in the case of those who knew about outsourcing in less than a year, UCH respondents are relatively larger in the proportion that OAUTHC. The reason is that UCH started outsourcing before OAUTHC. The concentration of the respondents in the 1-5 years bracket is due to the fact that outsourcing really started in these teaching hospitals

just five years ago. Obviously, most of them would have got to know about outsourcing after it started in their hospitals

Outsourcing is being implemented with caution in the teaching hospitals surveyed. Not all services have been outsourced. As shown in Table 4.3 and Figure 4.3, Administration remained the most outsourced department in the two teaching hospitals with 10 units in the department being outsourced while 4 units in account/treasury and 5 units in clinical services having been outsourced.

In terms of compositional distribution of the units outsourced among the two hospitals, Table 3 showed that more units were outsourced in UCH than in OAUTHC. Specifically, 8 units in contrast to 2 units (in OAUTHC) of administration department were being outsourced in UCH. A similar pattern is observed in account/treasury and clinical. This, therefore, implies that outsourcing is just emerging in OAUTHC while it is more established in UCH.

Table 3: Awareness and Types of Activities Outsourced

Items	Responses	OAUTHC	UCH	Total
Awareness of outsourcing	Yes	287(87%)	293(90.8%)	580(88.9%)
	No	43(13%)	30(9.2)	73(11.1%)
Years of awareness	under 1 yr	86(26%)	60(18.6%)	146(22.3%)
	1 to 5years	225(68.2%)	238(73.6%)	463(70.9%)
	5 to 10 years	18(5.4%)	25(7.9%)	43(6.7%)
	10 to 15 years	1(0.4%)	0(0%)	1(0.2)%
No. of Services Outsourced	Administration	2	8	10
	account/treasury	1	3	4
	clinical services	1	4	5

Source: Author Field Survey 2018

4.2 Degree of Outsourcing

Outsourcing could be full or partial. Outsourcing is said to be full of all the activities/services are outsourced to the vendor, and it is partial or selective if only a range of services is selectively outsourced or contracted out to a third party. The study also examined the degree of outsourcing in these departments. All the 4 units being outsourced in OAUTHC were fully outsourced. In the case of UCH, out of the 15 units being outsourced, 7 were fully outsourced while 8 are partially outsourced. (See table 4).

In administration, a total of 10 services were outsourced in the two teaching hospitals. In OAUTHC, only 2 units: Environmental Health and Security units were fully outsourced. As shown in table 4 all the 10 units identified in administration are being outsourced either partially or fully in UCH. Of these 8 services outsourced in UCH, five (5) (i.e., security, laundry, kitchen, cafeteria environmental health) services are fully outsourced. The remaining 3 units are partially outsourced. Both OAUTHC and UCH fully outsourced environmental health and security.

Generally, in teaching hospitals, general administration work consists of basic non-clinical activities/services. Most of the activities that are fully outsourced by the teaching hospital have been identified in the literature (See Kakabadse and Kakabadse 2001) as the most frequently outsourced functions in both private and public institutions. In effect, outsourcing in public healthcare delivery/teaching hospitals tends to concentrate on the basic non-clinical services such as management of canteen, record keeping, general maintenance work, laundry, car parking, computing and general practices that have no direct bearing on the overall mandate of efficient and effective healthcare delivery. Also, environmental health which comprises of the gardeners, labourers and cleaners and security are non-core services and hence are easily outsourced by the hospital management in order to concentrate on the core administrative work.

In the account and treasury, four basic units were identified. Out of these four units, OAUTHC outsourced only one (cash point) unit partially while UCH partially outsourced two (expenditure control, recurrent) unit and fully outsourced cash point unit. Treasury and account section of any organization is very sensitive and highly prone to abuse and unethical practices. It is the life of the business, and any awkward practice can jeopardise the efficient and smooth running of the organisation. Therefore, most organisations when outsourcing is careful and even reluctant to allow such sensitive unit to be in the hand of an organisation that is not directly under the scrutiny and control of the organisation. However, in spite of this fact and concern, some of the activities in the treasury and account section of the two teaching hospitals are being outsourced. Especially the cash point where the staff gets in contact with raw cash. This shows that there is a possibility of other overriding benefits for outsourcing that override the fear with the risk involved. Or that there might be some mechanisms put in place to prevent the possible unwholesome activities by the subcontractors in charge of this sensitive unit in the hospitals. Therefore Reconciliation/Auditing Unit is intact, i.e. not outsourced. This may be because of the critical role the internal audit unit plays in the organization. It is interesting to note that even some of the core clinical services are also being partially outsourced in both hospitals. As shown in fig 4.4 and 4.5; of the 18 activities identified in the clinical services only one (Nursing Assistant) is being outsourced fully by OAUTHC, while UCH outsourced fully nursing assistants and partially the management of pharmacy, radiology, and dialysis.

Overall, the analysis of this section revealed that cleaning and security are the most outsourced services in the two hospitals. However, the finding also revealed that UCH went further by outsourcing laundry, kitchen/cafeteria fully, while Electrical, Mechanical, Civil and Maintenance were partially outsourced. Also, radiology and pharmacy were partially outsourced.

Table 4: Services Being Outsourced

Department	Services	OAUTHC	UCH
Administration	Establishment	N	N
	Servicom	N	N
	Public Relation Department	N	N
	Medical records	N	N
	biomedical Department	N	N
	Electrical and Mechanical	N	P
	Civil and maintenance	N	P
	Store and Supply	N	P
	Laundry	N	F
	Kitchen	N	F
	Cafeteria	N	F
	Pension	N	N
	Environmental health	F	F
	Security	F	F
Accounting/ Treasuring	Expenditure	N	P
	Cash point	F	F
	Recurrent	N	P
	Internal/Audit	N	N
Clinical	Paediatrics	N	N
	Medicine	N	P
	Surgery	N	N
	Mental Health	N	N
	Morbid Anatomy	N	N
	Chemical Pathology	N	N
	Pharmacy	N	P
	Nursing Services	N	N
	Physiotherapy	N	N
	X-ray Clinic	N	P
	Dental Surgery	N	N
	Nursing Assistants	F	F
	Schools	N	N
	Orthopaedic	N	N

	General Outpatient	N	N
	Consultant	N	N
	Adult casualty	N	N

Source: Author Field Survey 2018. Note: F=Fully, P= Partially and N = Not Outsourced

Factors Influencing Outsourcing of Activities in the Teaching Hospitals

Outsourcing the services in any organization is a policy issue that is usually taken at the highest level of management. To some, it is a political decision but with economic motive. Therefore, the decision to undertake to outsource is based on the benefits that outsourcing will bring to the organization. In this study, we equate the potential and actual benefits as the driving forces behind outsourcing. Yet, there could be political, social and expedient factors behind outsourcing. Such factors are recognized, but economic factors remain the main driving force behind outsourcing. The challenge facing most organizations is usually how to reduce cost, increase efficient and effective service delivery as well as expand the knowledge frontiers. These are issues raised as factors that may be behind outsourcing in the teaching hospitals. However, possible drawbacks of outsourcing are also considered to balance the view.

4.3 Benefits of Outsourcing as factors influencing Outsourcing

As noted in the literature, outsourcing is a concept that is evolving. It evolvement must result in a paradigm shift from the orthodox public sector perspective to a corporate governance strategic perspective which views the outsourcing as a way for an organization to be focused and be more productive (Velma 2001). In corporate governance where outsourcing has become more relevant, managers view their organisation operations as a value chain designed to provide value to the clients. The managers determine what service to be eliminated, outsourced, or joint ventured so that the organisation can become efficient and more relevant to meeting the social challenges it is established to address. The activities that remain in the organisation are the core competencies that are activities that are critical to the delivery of services to the client. These core activities become the focus of strategic attention, and they are not considered for outsourcing. Teaching hospitals as a risk-sensitive sector, most of their activities are core and as such only a few none-core activities are outsourced. In view of the above, there is a need to gauge the extent the outsourcing of this none-core activity has impacted on the overall performance, efficiency, and productivity of the teaching hospital staff. Also, it is equally important to gauge the perceptions of the staff both management and none-management, on the benefits from the outsourcing of some of the hitherto internally provided services.

The results of the questionnaire analysis of the responses to the perceived benefits of outsourcing are shown in Table 5. A remarkably significant proportion of the respondents generally agreed with the notion that outsourcing brings many benefits to the teaching hospitals. The health care workers were almost unanimous in agreement with the benefits identified in the questionnaire. None of the 10 listed benefits received less than 50% of the proportional distribution of the respondents. For instance, 79% and 85% of the respondents from OAUTHC and UCH respectively considered cost reduction as one of the major benefits of outsourcing. One of the major challenges of public institutions in Nigeria is the overhead cost; such as staff emoluments, office maintenance, general administration expenses. These costs are usually unrelated to the level of activities carried out by the organisations. Whether the workers work fully or not, their full salary will be paid, and the office must be maintained whether work activities take place or not. With outsourcing, all these staffs may have to be engaged on the basis of needs. The use of discretion and political consideration in staff employment and keeping over-bloated size will drastically change, and the size of the workforce will be as moderate as required. The overall effect of this is a drastic reduction in the cost of running the hospital and possibly greater efficiency and effectiveness of the workers.

A lower but significant proportion of 54% and 62% of the respondents cited greater flexibility as potential benefits of outsourcing. This lower response only reflects the fact that the activities outsourced are basic none-core activities, and these may not have a direct bearing on the greater core services that are still be done using the in house staff. The proportion of respondents, 80% and 75% for OAUTHC and UCH respectively that cited reduction in staff workload was also high and remarkable. This reduction in workload will also bring about increased productivity, the concentration of more attention to patients needs and indeed boost staff and patients

morale to the activities of the teaching hospitals. It will also lead to efficient utilisation of the resources as waste that usually result as a result of lack of concentration and fatigue will indeed reduce, the issue of fatal error usually made by doctors and another health professional when working under severe pressure will also be mitigated.

Increased focus also received a relatively high percentage of responses 61% and 63% from OAUTHC and UCH respectively. It shows that the staffs are also becoming conscious of the advantages of outsourcing as it made them leave trivial and unimportant distractive activities for the core activities. It allows them to concentrate and remain the focus. Focused brings greater efficiency, effectiveness and high productivity. It prevents frustration and disappointment. As the staff now concentrates on their best core strength and competences, this will give them greater accomplishment and fulfilment that will propel them to do more. Increased focus will not only lead to greater efficiency but also may result in new discovery and invention. It may also lead to the development of an alternative strategy for handling critical cases as the staff will now have time to think on a narrow and more specific area that they have competences.

A higher proportion of 81% and 80% of the respondents from OAUTHC and UCH respectively cited access to new technology as the major benefits of outsourcing. This high proportion is a reflection of the perception of the hospital staff to the improvement in equipment and hospital machines that were noticed since the introduction of outsourcing. In these teaching hospitals, some of the equipment being used is obsolete and none-functional. The introduction of outsourcing resulted in the subcontractors bringing in new and modern technology as they have the required technical know-how. The existing workers of the teaching hospitals were trained in the act of using this equipment and thus increasing their proficiency. The service delivery improved with the new technology, and they become more efficient. This has significantly affected the staff perception of outsourcing and indeed could have helped in disabusing their possible wrong impression about outsourcing.

Also, a high proportion of 81% and 80% of the OAUTHC and UCH staff, are of the view that outsourcing leads to more efficient utilization of resources. Similar proportion 86% in both OAUTHC and UCH cited improved services while 86% and 87% respectively from OAUTHC and UCH also cited a reduction in management burden as the major benefits of outsourcing. This implies that with outsourcing the worries of the hospital management about none core activities will be taken care of and this gives them the opportunity to worry only on the core activities. With this leeway, they will avoid wasting unnecessary time on issues that have no direct bearing of the core activities of the hospital and thereby increasing the management efficiency and concentration.

As expected, the reduction in industrial unrest received the least proportion. 52% and 64% of the respondents were of the opinion that a reduction in industrial unrest is a benefit of outsourcing in these hospitals. The events in the public services in recent times made this point more glaring. The negative effects of civil servant reactions to the introduction of monetisation and consolidation of salary and pension schemes all at the time of introducing outsourcing exacerbated the industrial unrest in public institutions including the health care sector. Many of the unions in the health care industry had to embark on industrial action to resolve their grievances over the implementation of the public sector reform agenda; especially on the issues of monetisation and consolidation of salary. It is on record that none of the industrial strikes was as a result of the introduction of outsourcing; therefore the relatively low responses to the potential benefits of outsourcing in terms of reduction in industrial unrest may be due to the difficulty of the respondents to disentangle outsourcing from other reforms in the hospital. So outsourcing possibly might have even reduced unrest because management would have been able to concentrate more on the welfare of the staff as they now have more focus and less distraction which affect them overall operation before.

Innovation and creativity were also considered as a major benefit of outsourcing. Seventy-two per cent and 695 of respondents from OAUTHC and UCH cited creativity and innovation as benefits from outsourcing. This is not surprising as the staff is now focused and with new technology and reduction in workload, they can develop and adopt new strategies that will result in greater efficiency and effectiveness. Indeed, the impact of outsourcing on creativity and innovativeness of staff may just be evolving. This is because outsourcing is a long term strategy, which the short term is just a tip of the iceberg.

Table 5: Perceived Benefits of Outsourcing

	U	SD	D	A	SA
PANEL A	**OAUTHC**				
Cost Reduction	42(13%)	13 (4%)	17(5%)	148(45%)	109(34%)
Greater Flexibility	36(11%)	66(20%)	50(15%)	105(32%)	73(22%)
Reduction of staff workload	23(7%)	20(6%)	23(7%)	172(52%)	92(28%)
Increase Focus	39(12%)	42(13%)	49(15%)	138(42%)	62(19%)
Access to new technology	30(9%)	33(10%)	30(9%)	138(42%)	99(30%)
Efficient use of resources	30(9%)	20(6%)	17(5%)	188(57%)	75(23)
Improved Services	30(9%)	10(3%)	07(2%)	184(56%)	99(30%)
Reduced Manager's burdens	20(6%)	10(3%)	17(5%)	172(52%)	111(34%)
Reduces industrial unrest	46(14%)	56(17%)	56(17%)	109(33%)	63(19%)
innovation and creativity	46(14%)	26(8%)	20(6%)	119(36%)	119(36%)
PANEL B	**UCH**				
Cost Reduction	42(13%)	38(12%)	32(10%)	128(40%)	83(25%)
Greater Flexibility	36(11%)	67(21%)	22(7%)	121(38%)	77(24%)
Reduction of staff workload	25(8%)	42(13%)	14(4%)	135(42%)	107(33%)
Increase Focus	48(15%)	62(19%)	10(3%)	122(38%)	81(25%)
Access to new technology	28(9%)	19(6%)	16(5%)	183(57%)	77(24%)
Efficient use of resources	32(10%)	28(9%)	03(1%)	153(47%)	107(33%)
Improved Services	19(6%)	10(3%)	16(5%)	168(52%)	110(34%)
Reduced Manager's burdens	16(5%)	16(5%)	10(3%)	162(52%)	119(37%)
Reduces industrial unrest	35(11%)	71(22%)	13(4%)	125(39%)	80(25%)
innovation and creativity	35(11%)	52(16%)	13(4%)	152(47%)	71(22%)

Source: Author Field Survey 2018

5.0 Conclusion and Policy Implication

The broad objectives of the study examine the factors influencing outsourcing practices in two main teaching hospitals in southwest Nigeria. Specifically, the study identified the types and nature of outsourcing practices in the selected teaching hospitals and examined the factors influencing outsourcing of services in these hospitals. This is in a view to establish whether outsourcing policy has been effective in improving the healthcare delivery services in the selected teaching hospitals in south west Nigeria. As part of the background to the study and in fulfillment of the objective of the study, the demographic and socioeconomic characteristics of the respondents were analyzed and examined. It is established that most of the respondents were matured and experienced staff of the teaching hospitals and they had required qualification to be an employee of the hospitals. The following are the highlights of the findings from the data analysis: The two teaching hospitals are at different stages of outsourcing. While UCH started in 2004, OAUTHC started in 2007. Empirical evidence from the study also indicates that the three main driving forces; cost, strategy, and politics; for outsourcing identified in the literature were also found to the motivating factors for the introduction of outsourcing in the two teaching hospitals (OAUTHC and UCH).

Outsourcing is an emerging process in the Nigerian health sector. Therefore, the Nigerian health sector needs to pass through a learning phase before outsourcing is recognized as efficient management and regulatory tool. Thus the health sector needs time before the capacities of managers and providers are adequately developed and streamlined. Outsourcing is complex and cannot be the solutions for all problems of healthcare services not

everything can or should be outsourced. When outsourcing is applied judiciously, it could contribute to the improvement of the health system performance. It is also vital for the continued success of the hospital and its services to regularly review and update its outsourcing process. The management team should be actively involved in the supplier selection and management of the suppliers.

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Measurements of Recovery and Predictors of Outcome in an Untreated Chronic Fatigue Syndrome Sample

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Abstract
The current study examined a large cohort of untreated Chronic Fatigue Syndrome patients at initial assessment and at specific time points over a three-year period. Methods used in previous studies to assess patient health, were validated and used to assess recovery and improvement. Possible predictors of outcome would then be identified by assessing improvements in health status at specific follow-up points. The illness was also assessed in terms of recovery and improvement by using health related and psychosocial measures together with the aetiology of the illness. These were further used to investigate possible mechanisms influencing or predicting recovery or improvement. Two-hundred and twenty-six patients completed wide ranging questionnaires at initial assessment and again six and eighteen months and three years later. A current state of health score was used to measure recovery over time and analyses conducted to investigate the relationship between this and other health related measures. Regression analyses were conducted to assess predictors of improvement and recovery. Spontaneous recovery rates in the untreated patient at three-year follow-up were low (6%). The data suggested, however, that illness length, symptom severity and health status have an important role in recovery. Although there was no evidence to suggest an association between illness onset type and subsequent recovery or psychopathology scores at initial assessment and recovery, regression analyses did indicate that levels of anxiety, cognitive difficulties and social support at initial assessment predict a positive outcome. The state of health measure was validated as a method of accurately assessed the health status of patients and was used as an indicator of improvement and recovery within this group. Spontaneous recovery in the patient group was associated with several factors measured at initial assessment. However, further studies are necessary to more fully identify the factors which affect recovery or improvement and to investigate the exact nature of the mechanisms involved. The present study shows that spontaneous recovery of CFS patients is rare. Treatment or management is essential, and the efficacy of different approaches must be assessed.

Keywords: Chronic Fatigue Syndrome, Improvement, Predictors of outcome, Recovery

1. Introduction

The fatigue experienced in Chronic Fatigue Syndrome (CFS) is not only of sufficient severity to cause substantial functional impairment but is accompanied by four or more co-existing symptoms including those of a cognitive or neuropsychiatric nature (Centre for Disease Control (CDC) criteria; Fukuda et al., 1994). The illness (by definition) must be of at least six months duration and can become very debilitating and persistent (Andersen, Permin & Albrecht, 2004).

In order to provide insight into the prevalence of CFS, Afari and Buchwald conducted an in-depth appraisal of the literature (Afari & Buchwald, 2003). Evidence from epidemiological studies suggested that, in large scale surveys, up to half the general population would report suffering fatigue-like symptoms (Chen, 1986; Pawlikowska et al., 1994) and 20% of this group would subsequently seek medical care (Bates et al., 1993; Cathebras, Robbins, Kirmayer & Hayton, 1992; David et al., 1990; Kroenke et al., 1988; McDonald, David, Pelosi & Mann, 1993). However, in the majority of these cases, the fatigue experienced could be explained by other mitigating circumstances. Therefore, the incidence of CFS in the general population, the review concluded, is relatively low. Similarly, Price et al. (1992) reported findings from a community-based survey suggesting that 7.4 per 100,000 of the population (0.0074%) fulfilled the CDC criteria for CFS. More recently, Ranjith's review of the literature also agreed that, although the symptom of fatigue is common, cases of medically unexplained fatigue that fulfil the CDC criteria are somewhat rare (Ranjith, 2005). The relatively low incidence of CFS should not, however, detract from the severe effect the illness has on the individual sufferer's quality of life. Decreased personal, occupational and social activities combine to instil a sense of frustration and hopelessness within the patient. In addition, financial concerns have been raised regarding the increased uptake of unemployment benefits and the drain on healthcare resources caused by the illness. Data collected as part of the CDC's surveillance study (Reyes et al., 1999) estimated that the cost in terms of lost productivity, per annum, for each CFS patient in the United States was $20,000. In the light of this, continued research into the causes of and potential therapies for CFS are vital to alleviate this financial burden (Reynolds, Vernon, Bouchery & Reeves, 2004).

Before coherent treatment protocols were in place, research mainly concentrated on investigations into the long-term prognosis of CFS. These longitudinal studies also attempted to calculate recovery rates and identify possible predictors of positive outcome. However, when reviewing the literature, it became apparent that several different criteria had been used to define recovery in the patient group. For example, a patient in recovery (or remission) was described in one study as; (a) no longer suffering from fatigue, (b) experiencing less than four CFS related symptoms and, (c) a person whose health no longer interfered with normal activities (Reyes et al., 1999). When these criteria were applied, spontaneous recovery was calculated at 31.4% during the first five years of the illness (Reyes et al., 1999). Similarly, an assessment of 98 consecutive referrals to a specialised CFS clinic produced data suggesting that 41% of the sample were moderately to completely recovered two to three years post-baseline. Furthermore, 2.6% of these patients rated themselves as 'fully recovered' and 29.5% had returned to work (Russo et al., 1998). The issue of CFS and recovery was raised in a discussion by Cairns and Hotopf (2005) which highlighted inconsistencies in the literature. The review concluded that although improvement in patients at follow-up ranged from 8 to 63%, full recovery from the illness was actually quite rare.

CFS patients themselves are well aware that short periods of remission are common and can occur at any time during the illness. However, several studies have indicated that bouts of recovery are more likely in patients with short illness duration (Reyes et al., 1999; Nisenbaum, Jones, Jones & Reeves, 2000). Furthermore, there is evidence to suggest that several other factors may also influence recovery, including younger age (at onset), fewer physical symptoms, higher mental and general health scores and low levels of emotional distress at baseline (Russo et al., 1998). In addition, low levels of fatigue (at baseline), a sense of control over the symptoms associated with the illness and, the attribution of non-physical cause have also been linked with more favourable outcomes (Cairns & Hotopf, 2005).

Overall, when reviewing previous studies assessing recovery within this patient group it appeared that there were several crucial points that needed to be addressed. Firstly, the method used to define recovery should be as clear cut as possible. Each patient's perception of recovery will differ, that is, one patient's idea of recovery may not correspond to that of another. It might be more appropriate in illnesses such as CFS, therefore, to measure improvements within an individual sufferer's health rather than using a 'one size fits all' approach. This, in turn, would affect the choice of parameter(s) used to measure it. In the particular case of CFS these problems are further confounded by reports from sufferers of periods of remission throughout the illness. Ideally, therefore, several independent measures should be used to assess the validity of the recovery measure. In addition, the evaluation process must be capable of differentiating between true recovery and bouts of remission. The final point to consider is intervention. Longitudinal studies are, by definition, conducted over several years.

Although the studies reviewed were not part of any specific treatment protocols, it can not be assumed that the patients questioned did not attend some form of therapy during the intervening time period. Therefore, these data might not represent the true nature of the illness and this may be being reflected in high recovery rates.

Previous research had already highlighted several aspects of the disorder, such as psychopathology, ratings of well-being, psychosocial and demographic factors, which may affect outcome (Smith, Behan, Bell, Millar & Bakheit, 1993). CFS patients had been studied using a wide range of questionnaires and these data had indicated that there were possible confounding variables that affect the severity of CFS including psychosocial factors, support mechanisms, health measures and psychopathology (Smith, Pollock, Thomas, Llewelyn & Borysiewicz, 1996; Smith, Borysiewicz, Pollock, Thomas & Llewelyn, 1999). The severity of the illness was assessed by means of physical symptoms (Cohen & Hoberman, 1983; Smith et al., 1996), fatigue related symptoms (Ray, Weir, Stewart, Millar & Hyde, 1993), cognitive failures (Broadbent, Cooper, Fitzgerald & Parkes, 1982) and a 5-item health status measure (Smith et al., 1996). Psychosocial aspects of the disorder such as stress (Cohen, Kamarack & Mermelstein, 1983), social support (Henderson, Bryne & Duncan-Jones, 1981), self-esteem (Fleming & Watts, 1980) and the impact of inter-current life events (Cohen & Hoberman, 1983) were also assessed using several measuring instruments. Furthermore, measures of psychopathology (Beck, Ward, Mendelson, Mock & Erbough, 1961; Radloff, 1997; Spielberger, Gorsuch & Lushene, 1971), health related behaviours and illness history (Smith et al., 1996) were included in the study in an attempt to provide a more comprehensive picture of this complicated and debilitating illness.

With these measuring instruments in place, the aim of the current study was, in the first instance, to describe the characteristics of a large cohort of CFS sufferers at initial assessment and validate a measure for accurately measuring the health status of the individual patient. When validated, this measure was used to define and assess recovery and investigate possible predictors of outcome by comparing the health and psychosocial measures (at initial assessment) of patients who recovered over a three-year period to those who did not recover. These data also allowed us to monitor the natural progression of the untreated illness over time.

2. Method

2.1 Design

The study was longitudinal in nature, with assessments occurring at initial assessment (baseline), six and eighteen months and three years later.

2.2 Participants

Ethical approval for the study was granted by the relevant local Health Authority. Potential volunteers were informed that the research was being conducted as part of a long-term project investigating CFS and, that they would be asked to complete similar test batteries over a period of time as part of a research panel. Participation in the study was voluntary and all participants gave written, informed consent. Patient data were coded to ensure anonymity.

The research panel comprised consecutive GP referrals over a 7 year period to a specialised CFS outpatient clinic meeting the CDC criteria for Chronic Fatigue Syndrome. Patient volunteers were assessed at initial clinic visit (baseline), at six and eighteen months and again three years later. As there was no formal treatment available to these patients at that time, the data represents the untreated illness. However, a small number of participants were taking antidepressant therapy at baseline. Data from these patients were not included in the final analyses.

2.3 Materials and Method

The CFS volunteers completed wide ranging questionnaires developed to measure global ratings of well-being, sleep and psychopathology and established indicators of quality of life (Smith et al., 1996; Smith et al., 1999). Demographic data relating to the sample were collected, along with an illness history questionnaire and a 28-item symptom check-list. The resulting data were then used to examine associations between these measures and recovery or improvement.

2.3.1 Measurement of Recovery

Health status and severity were measured by a 'current state of health measure' (Smith et al., 1996). This 5-item scale categorised the patient's health as follows: (1) worse than at any stage of the illness; (2) bad; (3) bad with some recovery; (4) recovering with occasional relapses and (5) almost completely recovered. In order to test the validity of this measure to accurately describe health status at any given time, patients were categorised into two groups at baseline: those who were in poor health (scoring 'worse than any stage', 'bad' and 'bad with some recovery') and those who thought they were recovering (scoring 'recovering with occasional relapse' and 'almost completely recovered'). These baseline data were then compared to measures known to be associated with the illness, including: (a) positive and negative mood (Zevon & Tellegen, 1982); (b) depression (Beck et al., 1961; Radloff, 1997); (c) anxiety (Spielberger et al., 1971); (d) fatigue related symptoms (Ray et al., 1993); (e) physical symptoms (Cohen & Hoberman, 1983; Smith et al., 1996); (f) cognitive failures (Broadbent et al., 1982) and, (g) stress (Cohen et al., 1983).

Once validated, if measurable recovery was indicated at follow-up, we would then be able to identify factors at baseline that appear to be linked with recovery and, therefore, predict recovery later on. Improvement was also measured with the 5-item current state of health score by examining differences between the follow-up and baseline scores.

Recovery and improvement were then used as outcome measures. By comparing these data to other health related outcomes known to be associated with exacerbating and prolonging the illness we investigated possible predictors of outcome.

2.4 Procedures

The various measuring instruments were administered in the form of two questionnaire booklets. The first booklet concentrated on measures of a general nature, such as demographic and illness history data (Smith et al., 1996), cognitive failures, perceived stress and social support which could be completed by the patients at home in their own time. The second booklet required responses to subjective measures such as, anxiety, depression and fatigue related symptoms, which referred to the previous week.

Patients also responded verbally to a range of questions relating to illness beliefs, including type of onset (acute or gradual) and events which were thought to have preceded the illness. These data were recorded by research registrars at initial clinic visit.

2.5 Data Analysis

Continuous data were run through analysis of variance and categoric data from the study were run through Chi-Squared cross-tabulation analyses to describe the nature of the sample at initial assessment (baseline). Two-way contingency table analyses (Chi-Square) were carried out to investigate the relationship between: (a) the current state of health variable and other health measures and (b) the current state of health variable and psychosocial factors. Recovery and improvement were used as grouping variables in independent sample t-test analyses. Logistic regression analyses were conducted to assess predictors of improvement and/or recovery using the health and psychosocial measures. A further model was created which complied with findings discussed by Cairns and Hotopf (2005). That is to say, age, illness length, illness onset type, physical cause, total symptoms, fatigue, health status and emotional distress have all been previously indicated as predictors of outcome.

3. Results

In all, 307 CFS patients were recruited to the research panel. Patients taking antidepressant medication at baseline and for those whom antidepressant medication status was unknown (n=81) were excluded from the final analyses. 130 patients completed the baseline, six and eighteen months and three years later.

3.1 Patient Sample and Illness Characteristics

Table 1 describes the basic demographic data for the 226 patients at baseline which follows the profile one would expect in CFS. The majority of the patients fell into the 'bad with some recovery' category of the current

state of health variable (43%) and the mean total symptom score (calculated from the 28-item check list) was 15.84 (s.e.m=0.36). The mean illness length was approximately 5 years.

Table 1: Baseline Demographic and Illness History data for the original cohort of CFS patients and the final cohort who completed the study.

Baseline Measures		Original Cohort (n=226)	Final Cohort (n=130)
Gender:	Male	31%	34%
	Female	69%	66%
Mean Age:		41.7 (0.80)	45.05 (1.15)
Marital Status:	Single	21%	10%
	Married	65%	75%
	Divorced/ Separated	10%	9%
	Widowed	3%	5%
Educational	No Formal Schooling	0	0
Status:	Primary Education only	0	0
	Secondary Education	29%	30%
	O Levels	33%	31%
	A Levels	9%	9%
	At least 1yr at University	7%	8%
	BSc or BA	16%	17%
	MSc or MA	2%	2%
	PhD, MD, etc	3%	2%
Illness Duration (months):		62.13 (3.84)	65.49 (5.83)
Current State of	Worse than at any stage	8%	6%
Health:	Bad	20%	15%
	Bad with some recovery	43%	43%
	Recovering with relapses	38%	36%
	Almost completely recovered	0.9%	0
Total Symptom Score (maximum = 28):		15.84 (0.36)	16.32 (0.59)

In addition, the majority of patients (68%) had their condition diagnosed by their GP and 34% of the sample was in employment at the time of initial assessment. 49% were unemployed and 16% were on sick leave. These groups represented 76% of the total sample (the rest of the sample being either retired or home-makers). Of the patients who were working, 21% believed that their job security was threatened by the illness. Respondents who reported trying alternative therapies to alleviate their symptoms spent on average £235 doing so. Less than half of these patients believed that they had received value for money by taking the alternative therapy route.

3.2 Health Measures

Re-examining the sample in terms of type of illness onset (that is, acute or gradual onset) provided no significant differences with regard the demographic nature, illness history or total symptom scores of the sample.

The majority of patients (84%) believed that a specific event had proceeded, and therefore, may be attributed to their illness. The majority of these (42%) suggested that influenza was the causal agent. We found no evidence to suggest that there might be a link between type of onset (acute or gradual) and the patient's belief that a virus had caused the illness. Table 2 goes on to describe the 28-item symptom check-list for the group at baseline in detail.

Table 2: The Symptom Checklist Scores for the patient group at baseline. Scores are ranked most to least prevalent.

Symptom	%	Symptom	%
Lack of concentration	91	Sensitivity to light	53
Muscle pain	89	Sore throat	52
(back, arms or legs)		Wind	49
Excessive fatigue	87	Insomnia	47
Physical weakness	81	Nausea	46

Legs feeling heavy	80	Shivering	45
Fever	77	Glands swollen	45
Loss of memory	76	Racing heart	44
Headache	70	Chest pain	44
Aching joints	69	Indigestion	41
Sensitivity to noise	59	Panic attacks	40
Bloated stomach	55	Depression	37
Sweating	54	Allergies	35
Sore eyes	53	Earache	33

These data indicate that muscle pain, lack of concentration and excessive fatigue were the highest rated symptoms in the patient group.

3.3 Comparability of the Follow-up Sample

Chi-squared cross-tabulation and analysis of variance were used to compare the baseline demographic and illness history data from members of the original CFS cohort assessed at baseline (n=226) to those completing all follow-up sessions (n=130). Table 1 indicates that the original cohort assessed at baseline have comparable data at baseline, in terms of gender, age, marital and educational status to those completing all assessment session. In addition, there were no significant differences between the two samples in respect to length of illness, health status and total symptom scores at initial assessment (baseline).

3.4 Validation of the Health Status Measure

The following table presents data in relation to the patient's current state of health at baseline. Patients in the 'recovering' group had fewer symptoms at baseline than those in the 'not recovering' group. Table 3 indicates further associations between the current state of health measure and physical and mental health variables.

Table 3: The relationship between Current State of Health at baseline and Health Outcomes. 'Recovering with occasional relapses' and 'Almost completely recovered' represent the 'Recovering' group, the remaining values represent the 'not recovering' group. Values are the group means with s.e.m in parenthesis.

		Baseline Current State of Health		
		Not Recovering	Recovering	P value
Baseline Measures:				
Positive Mood		25.02 (0.74)	29.44 (1.19)	0.002
Negative Mood		24.66 (0.92)	20.28 (1.21)	0.009
CES_depression		42.21 (0.82)	37.78 (1.25)	0.004
State Anxiety		41.20 (0.83)	37.25 (1.14)	0.009
PFRS	*Emotional Distress*	49.04 (1.73)	42.36 (2.50)	0.036
	Fatigue	67.22 (1.05)	53.95 (2.07)	0.000
	Cognitive Difficulties	49.33 (1.21)	41.47 (1.95)	0.001
	Somatic Symptoms	57.56 (1.56)	44.97 (2.17)	0.000
BDI		16.20 (0.66)	12.28 (0.82)	0.001
Cohen-Hoberman Inventory of Physical Symptoms		27.02 (0.60)	20.36 (0.92)	0.000
Six Month Follow-up Measures:				
PFRS	*Fatigue*	62.42 (1.59)	54.39 (2.55)	0.007
	Somatic Symptoms	55.39 (2.17)	45.82 (2.60)	0.011
Inventory of Physical Symptoms		25.18 (0.82)	20.21 (1.23)	0.001
Three Year Follow-up Measures:				
PFRS	*Fatigue*	61.43 (2.02)	52.54 (2.92)	0.012
Inventory of Physical Symptoms		23.92 (1.13)	20.02 (1.34)	0.031

The data here provides clear-cut differences between the 'recovering' and 'not recovering' groups in terms of both emotional and health related scores at baseline. As these health-related measures are often associated with the severity of the illness (Russo et al., 1998; Smith et al., 1993) the 'current state of health' variable also appears to accurately assess the true severity of the illness for each patient.

3.5 Health Measures and Recovery

The topic of recovery over time was examined using the current state of health variable. People responding 'almost completely recovered' to this scale represented recovery. The results suggest that very few patients will completely recover over time without treatment. Levels of spontaneous recovery were only 2% at 6 months and rose to 6% at 18 months and 3 years.

As the number of patients who completely recover over time was low, recovery was redefined as patients who were 'recovering with occasional relapses' and those who had 'almost completely recovered'.

When considering illness onset type, there was no evidence to suggest that an association existed with recovery either in terms of state of health measures or total symptom scores. Similarly, there was no indication from the data that an association between the belief that physical or non-physical event caused the illness and recovery exists. When considering illness length at baseline, there were no significant differences associated with current state of health (recovering/not recovering) or total symptom scores except with respect to recovery at three year follow-up. To investigate this further, illness length was further split into quartiles and cross-tabulated with the recovering/not recovering variable. Although there was no association between illness length and recovery at baseline, 6 and 18 months, there was an association between the lowest quartile history length group and the likelihood of recovery at three-year follow-up ($df=3$, $p<0.032$).

3.6 Employment Status and Recovery

Table 4 describes the employment status of the patient sample at baseline. When comparing the three employment status groups there was an association between recovery and employment status at baseline, eighteen month and three-year follow-up. Patients in the employed group were significantly more likely to recover over time than those that were unemployed or on sick leave at baseline.

Table 4: The relationship between employment status at baseline and recovery at baseline, 18-months and 3 year follow-up. 'Recovering with occasional relapses' and 'Almost completely recovered' represent the 'Recovering' group, the remaining values represent the 'not recovering' group.

	EMPLOYMENT STATUS AT BASELINE			
	Employed	Unemployed	On sick leave	P value
Baseline:				
Not Recovering	31	43	17	n/s
Recovering	52	43	14	
Six Month Follow-up:				
Not Recovering	27	35	17	n/s
Recovering	56	47	18	
Eighteen Month Follow-up:				
Not Recovering	19	54	21	0.000
Recovering	60	36	10	
Three Year Follow-up:				
Not Recovering	20	46	13	0.035
Recovering	67	40	14	

3.7 Symptoms and Recovery

The association between recovery at initial assessment (baseline) and two other health related measures namely, total symptom and fatigue scores were then examined at baseline, six month, eighteen month and three year follow-up. Patients in the 'recovering' group at baseline reported significantly lower total symptom scores at baseline (recovering=13.71 (sem=0.69), not recovering=16.71 (sem=0.41), $p<0.000$), 6 months (recovering=12.89 (sem=0.93), not recovering=15.82 (sem=0.56), $p<0.006$) and 18 months (recovering=12.72 (sem=0.86), not recovering=15.54 (sem=0.54), $p<0.006$).

Fatigue in this cohort of patients was assessed using the Profile of Fatigue Related Syndromes questionnaire (PFRS). When splitting these scores into quartile ranges, there was an association between fatigue levels at baseline and rates of recovery. Patients who recorded low levels of fatigue at baseline were significantly more

likely to be in the 'recovering' group than those with high fatigue scores. This association occurred at baseline (recovering=55%, p<0.000), 6 months (recovering=67%, p<0.000), 18 months (recovering=56%, p<0.001).

3.8 Psychopathology and Recovery

In terms of psychopathology, there was an association between low depression scores at baseline (BDI) and recovery at baseline (recovering=67.2%; not recovering=47.5%, df=1, p<0.006). This trend was repeated at six-month follow-up (recovering=70.7%; not recovering=44.6%, df=1, p<0.001). This suggests that patients with lower depression scores at baseline were more likely to be in the recovering group. The trend, however, did not continue at the three-year follow-up point. There was no association between anxiety scores at baseline and subsequent recovery.

3.9 Psychosocial Measures and Recovery

The psychosocial measures administered in the current study included those assessing illness coping strategies, levels of perceived stress and daily hassles and levels of social support. Previous studies had already highlighted the differences between the psychosocial data from the CFS population when compared to a group of healthy controls [Thomas & Smith, submitted].

There were, however, no associations between baseline psychosocial measures and recovery at baseline, six months, eighteen months and three-year follow-up.

3.10 Health Measures and Improvement

Improvement was again calculated using the current state of health score. Patient responses at baseline were subtracted from subsequent follow-up measures to calculate whether their health status was 'improving' or 'not improving' at that time point. It is clear that when measuring recovery in terms of improvement, the percentages become much greater. Improvement is rated at 25% at 6 month follow-up rising to 29% at 18 months and 3 years.

This measure was then run through a similar analysis process to the 'recovering'/ 'not recovering' variables. However, these data did not show the clear-cut differences between observed when using the recovery variable.

3.11 Psychosocial Measures and Improvement

There no associations between improvement and these baseline scores. One exception being positive life events at baseline: patients in the highest quartile of positive life events were significantly less likely to be in the improved group at 3 year follow-up (improved=9%; not improved=29%, df=2, p<0.029). This implies that patients with the higher positive life events at baseline are least likely to improve three years later. As we can offer no explanation as to why this should be the case, it is considered that this finding represents chance effect.

3.12 Illness Characteristics and Health Measures as Predictors of Outcome

Logistic regression analyses were used to examine the relationship between baseline questionnaire data and improvement at three-year follow-up. Improvement was chosen as the dependant variable due to the low numbers of patients in the study who could be classified as recovered at the follow-up point (that is, only 6% of the sample). Two models were created, the baseline predictor variables being; (a) the aetiology of the illness (illness onset type, length of illness, viral cause and health status at onset) and, (b) health measures (fatigue, emotional distress, somatic symptoms, cognitive difficulties, cognitive failures, total symptoms, physical symptoms, anxiety and depression). There was no evidence to suggest that any of the health measures recorded at initial assessment were predictors of outcome. However, in terms of the aetiology of CFS, the current state of health measure was indicated as a predictor of outcome. Patients who reported better health status at initial assessment were significantly more likely to show improvement at the three-year follow-up point (OR=4.924, df=1, CI=1.453 – 16.688). 91 cases were used in the analysis and 70% of the sample was correctly classified by the prediction variables. Illness onset type, illness length and viral cause were not indicted as predictors of outcome.

3.13 Psychosocial Measures as Predictors of Outcome

There was no indication that any of the psychosocial factors measures at baseline could be described as predictors of improvement at three-year follow-up.

3.14 Further Regression Analyses

Further logistical regression analyses were conducted to test whether certain factors discussed in the literature namely, age, illness length, illness onset type, viral cause, total symptom scores, fatigue scores, emotional distress scores and health status scores are predictors of outcome in CFS. Again, only the current state of health of the patient at initial assessment (baseline) was indicated as a predictor of outcome at three-year follow-up (OR=9.618, df=1, CI=2.094 – 44.175). 89 cases were used in the analysis 75% of the sample were correctly classified by the prediction variables.

4. Discussion

The aims of the current study included the description of the demographic and illness characteristics of a large group of Chronic Fatigue Syndrome (CFS) patients at initial assessment, the validation of a measure (developed in previous studies) which could accurately evaluate health status and, therefore, recovery in the condition, and to identify factors which influence and predict positive outcome.

The patients recruited onto the volunteer panel were consecutive GP referrals to a dedicated research clinic and were categorised by the Centre for Disease Control case definition for CFS (Fukuda et al., 1994). The demographic data of the sample follows a similar profile to patients described by others Fukuda et al., 1997) and, therefore, the group comprises predominantly married females in their forties. There has, in the past, been some debate as to whether an association between social classification and increased cases of Chronic Fatigue Syndrome exists (Fukuda et al., 1997; Dowsett, Ramsay, McCartney & Bell, 1990; Hinds & McClusky, 1993; Ho-Yen & McNamara, 1991). Data from the current research indicates that the majority of the sufferers recruited to the study were grouped in the professional or semi-professional social categories confirming that patients with this illness are more likely to be members of a specific social grouping.

The persistent and debilitating nature of the illness, demonstrated by a mean history length of five years and the number of symptoms present (16 of a possible 28), is apparent. For example, in the case of total symptoms, one would expect scores of 3 from a group of healthy controls (Thomas & Smith, 2009). The findings reported in the current study, therefore, indicate the wide range of symptoms associated with this illness. Furthermore, symptoms such as lack of concentration, muscle pain, excessive fatigue, physical weakness and legs feeling heavy were reported in over 80% of the cases. The length and severity of the illness is also reflected in the high numbers of patients who were either unemployed or on sick leave at initial assessment (baseline).

The health status of the patient group was assessed by the 5-item current state of health variable (Smith et al., 1996). Applying this measure at initial assessment (baseline) revealed data indicating that the health status for the cohort was poor; the majority of the group (41%) rating their health as ‘bad with some recovery’. Further analyses also suggests that the health status variable correlates negatively with other measures such as total symptoms scores, that is, lower scores on the current state of health measure are accompanied by increased total symptom scores.

Considering that the patients described in the current study represented different stages of the illness in terms of severity and illness length, one might presuppose a link between the current state of health variable and the length of illness measure. That is to say, either patients with longer illness length could be categorised as having greater illness severity or conversely, after a certain length of time, the patient begins to recover. This, however, does not appear to be the case. Cross-tabulation analyses reveals data indicating that illness length (represented by quartile ranges) is equally spread over the 5-items of the health status measure.

The current state of health measure was also used to assess recovery. Spontaneous recovery rates for the group are low at only 2% at six-month follow-up. Furthermore, these rates did not improve a great deal eighteen months or three years later (6%). The recovery rates reported here are much lower than those seen in previous studies (Reyes et al., 1999) but are in-keeping with results from a recent review by Cairns & Hotopf (2005) and a patient survey conducted by Thomas & Smith (2005), which indicate that the occurrence of spontaneous recovery from CFS is, in fact, relatively rare. When changes (or improvement) in health status rather than

recovery were measured, 25% of the sample reported an improvement at six months follow-up. These levels of improvement rose to 29% at eighteen months and remained constant at three years. As both recovery and improvement are calculated from the same 5-item scale, the problems one might encounter when interpreting subjective data are highlighted. Data from the improving/ not improving grouping did not provide the associations between state of health and improvement in other health-related measures that one sees in the recovery/ not recovering grouping. However, these data do indicate that both recovery and improvement peak at the 18 month follow-up point in the untreated patient.

Data linking state of health at baseline (recovering or not recovering) with other health-related measures at baseline, such as fatigue and depression, suggests that this measure can be used to accurately assess an individual patients' health at any given point. In addition, these data also demonstrate that illness status at baseline affects outcome i.e. better health status at baseline is associated with positive outcome at follow-up.

There is also evidence to suggest that total symptom scores and shorter illness lengths, again at baseline, are associated with more favourable outcomes. Overall, these data re-enforce the well held belief that diagnosing CFS effectively and setting coping and/or management strategies in place swiftly are vital to prevent the entrenchment of negative illness perceptions in patients and help facilitate positive outcome.

There is no suggestion from these data that physical cause attribution is associated with outcome. Similarly, there is no evidence to suggest that type of illness onset (acute or gradual) affects prognosis (although the type and frequency of symptoms reported by patients with acute or gradual illness onset do differ). Furthermore, there is no evidence from these data to suggest that co-morbid anxiety or depression at baseline is associated with recovery in the longer term. Physical cause, illness onset type and co-existing psychopathology have all been cited as possible factors affecting recovery in this patient group (Cairns & Hotopf, 2005; Russo et al., 1998). The data from the current study indicates that these associations may not exist.

Of interest, however, is evidence linking employment status at baseline and subsequent recovery. The suggestion being that patients in employment at baseline are more likely to be in the recovered group at baseline, eighteen months and three years later. These data can be interpreted in two ways, (a) employment brings with it a sense of belonging and maintains levels of social support which prevents feelings of isolation which may in turn exacerbate the illness, or (b) patients in employment may be able to continue working because they have better health scores and these data may simply be reflecting illness severity.

Logistical regression analyses were used to highlight possible mechanisms for predicting positive outcome in terms of improvement. It had already been suggested that a wide range of psychosocial, psychopathological and health related factors are associated with prolonging CFS (Surawy, Hackman, Hawton & Sharpe, 1995). We aimed to examine the role of these factors by means of improvement in the condition. These data suggests that, despite the findings reported in previous research, only one measure, namely the current state of health variable could accurately predict positive outcome. When the analyses were re-run using the factors indicated to be predictors of outcome in previous research, again only the current state of health variable is indicated as a predictor of outcome. These data should be regarded with caution due to the large confidence intervals involved; however, the heterogeneity of CFS may explain the large differences observed. Although these data are interesting, the health status of the patient at initial assessment only exerts (at most) an 18% effect over improvement. There are, therefore, other factors, which we have not yet considered, exerting a greater effect on recovery.

5. Conclusion

Overall, the current longitudinal study has provided data indicating that prognosis for the untreated CFS patient is poor. Associations between the state of health measure and other physical and mental health variables have been verified using a large group of patients. The validation of a simple 5-item measure by other standardised measures leads us to believe that this score can be used to accurately rate patient illness severity. We have also shown that this measure can predict and assess recovery. Positive outcome measures are indicated in cases where illness length is short and when the number and severity of symptoms are low. We have confirmed the

widely held belief among healthcare professionals that offering care to this patient group before the illness is allowed to become entrenched is of major importance if therapy is to be successful. The measures described here can now be used to evaluate the efficacy of treatments in future studies. Further research is necessary, however, to identify the, as yet, unidentified factors which can accurately predict positive outcome in this illness.

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Using an IVF Population to Examine Gestational Age Patterns in Early Miscarriage

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Abstract
The lengths of gestation of 68 confirmed miscarriages from an in vitro fertilization (IVF) program were compared to expected gestational ages from the literature in order to elucidate patterns of early, undiagnosed miscarriages. The peak frequency of miscarriages in the IVF group was earlier than expected, suggesting that the rate of early miscarriage in the general population might be underestimated.

Keywords: Gestation, IVF, Miscarriage, Spontaneous Abortion

INTRODUCTION

The incidence of spontaneous abortion has commonly been quoted as anything from 9-10% of all pregnancies (Tietze, 1953; Tong et al, 2008) to 20% (Merck Manual, 2019) and above (García-Enguídanos et al, 2002), though the probability of an event seems to decline with advancing gestational age (Tong et al, 2008). There are differences in etiology between early miscarriages, defined as those occurring before the 12th week of pregnancy, and late miscarriages (Kallen, 1988). It seems that the majority of early miscarriages display gross chromosomal anomalies, perhaps explained as a maternal immunologic response in a natural selection paradigm (Warburton et al, 1980). Late miscarriages, on the other hand, have a host of causes, from disease to injury (Regan & Rai, 2000).

It is possible that oft cited statistics, while including induced or surgical abortions, do not include many early unrecognized abortions, since these often go unreported or indeed unrealized, more commonly experienced and dismissed as heavy periods. To this way of thinking, common statistics would underestimate the incidence of early miscarriage in the general population. In seeming support of this hypothesis, after examining the morphology of embryos recovered after hysterectomies, Hertig et al (Hertig et al, 1944) suggested a rate of 28.6% for early miscarriages, thus pushing the overall rate of spontaneous abortion to over 50% of all pregnancies. This high estimate is shared by others, who suggest that half of all zygotes spontaneously fail (Cunningham et al, 2013).

Infertility programs provide a valuable opportunity to observe pregnancies from the point of conception to their eventual outcomes, thus providing a window into a stage of fetal development that is typically unrecognized or unmonitored in the naturally conceiving population (Shoham &Zosmer, 1991). Among pregnancies achieved after difficulties in conceiving, the reported miscarriage rate is typically higher, in part because such pregnancies are more closely monitored. For instance, Wang et al (2004) computed a relative risk of 1.20 (1.03, 1.46) in the assisted reproduction population, relative to the naturally conceiving population. Shoham et al (1991) point out

that such figures lead to the impression that infertility patients have an actual higher incidence of spontaneous abortion than the so-called "spontaneously conceiving" population, when the disparity may in fact be a data artefact caused by the lack of a suitable control group that is as closely monitored.

Some types of infertility treatment might actually counter tendencies toward miscarriage. Balasch et al (1996) investigated the use of IVF (in vitro fertilization) as a treatment for women who have experienced unexplained recurrent miscarriages. In their pilot study, their interpretation was that the IVF process somehow avoided or negated the physiological process that was causing spontaneous abortions in those women. Since immunological aberrations have been proposed as the commonest cause of unexplained fetal losses (Hill, 1992), Balasch et al (1996) suggested that their findings were explained by the implantation of several embryos, as is the typical IVF methodology, thus encouraging the maternal immune system to actively support the pregnancy by favouring the recognition of fetal antigens.

To add further empirical data to the discussion of the true incidence of early miscarriage, the present study was undertaken. We examined the experiences of a closely monitored IVF population to observe the timing of spontaneous abortion in a small clinical set.

METHODS

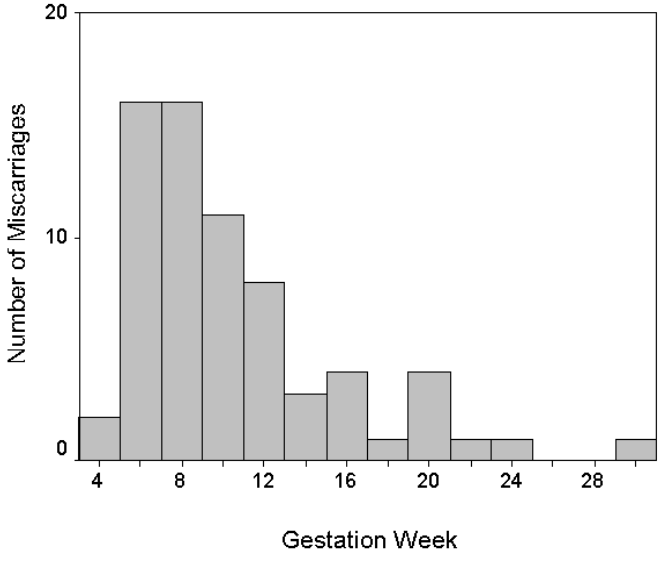
As part of a larger, unrelated study (Deonandan et al, 2000), 191 random patient files from between 1992 and 1997 were examined at a Canadian IVF clinic. Incidences and details of confirmed miscarriage were noted, with their lengths of gestation analysed descriptively and graphically.

RESULTS

Of the 191 patient files examined, 68 were found to have experienced spontaneous abortion. Karyotypic data were available on 10 of the 68 subjects; chromosomal anomalies were present in 5 of these. Thus, the prevalence of chromosomal anomalies in cases of early miscarriage is difficult to assess in these data, but is apparently not high. Indeed, the clinical procedure for selecting appropriate gametes for combination is typically one that tries to maximize eventual zygote robustness.

The frequency distribution of gestational ages for these 68 miscarriages is presented in Figure 1. The steepest attrition rate occurs from the gestational age of 4 weeks to 12 weeks; the majority of losses were reported in that age range.

Figure 1- Pregnancy Week Distribution in 68 IVF Miscarriages



DISCUSSION

In these data, the peak frequency of miscarriages was greatest at 8 weeks gestational age. This is earlier than the peak of 9-13 weeks reported by Kallen (1988) based on the distribution of gestational ages for 610 presumably non-IVF related miscarriages in a given hospital. It is also an earlier peak than that reported by Mukherjee et al (2013), who found a rate of 2-4% in the general population for pregnancies at 8-13 weeks.

The Kallen and Mukherjee data described general populations, whereas the present data arise from IVF clinical patients. Thus, the samples may not be comparable in terms of miscarriage risk. However, it is most likely that the major difference between the clinical and general population samples is in the extent of pregnancy detection. For the general population, only outcomes of detected pregnancies are known. It has been suspected that very early miscarriage is under-detected and under-reported (Kallen, 1988) and our data would support that suggestion. In addition to skewing the gestational age distribution of miscarriages, such under-detection would also result in under-estimation of miscarriage rates. The value of an IVF population in this exploration is that each attempt at pregnancy is closely monitored, so undetected pregnancies (and hence undetected miscarriages) are unlikely.

Epidemiological miscarriage data are flawed by a lack of consistency in reporting gestational age (Santee & Henshaw, 1992). For example, pregnancy can be measured from the beginning of last menstruation or from fertilization, which is 14 days after the 1st day of the last menstrual period (Santee & Henshaw, 1992). Hence, there is significant data quality value in closely monitoring a particular clinical population whose reproductive enterprise is transparent. The challenge is finding such a group that is representative of the general population, and not of an etiology suggestive of impaired reproduction, as is our IVF population.

One approach is to consider a larger sample size of IVF (or otherwise closely monitored) pregnancies, to more convincingly compare to the spontaneously conceiving population. Concerns for the supposed fragility of IVF embryo implantations may be alleviated by consulting a population of less severe fertility impairment, such as fecund women utilizing donor sperm in unstimulated non-IVF cycles for cases of male-factor infertility. Such a group would more closely resemble the reproductive profile of the general population.

CONCLUSION

Miscarriage may occur more commonly than generally reported and there may be a higher proportion of miscarriages occurring before 8-12 weeks gestational age.

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A Giant Epidermoid Splenic Cyst in a Teenage: A Case Report

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Abstract
Introduction: Splenic cysts are rare and are either primary or secondary. Epidermoid splenic cysts are an example of primary congenital cysts. Most often, they are asymptomatic discovered incidentally, but they may present with abdominal discomfort predominantly at young female age. Case presentation: We have reported a case of 14 -years- old girl presented with intermittent abdominal pain. The physical examination revealed a palpable mass in the left hypochondriac region. Ultrasonography and computed tomography of the abdomen showed a giant unulocular splenic cyst without a clean wall. Operative treatment was necessary, and at laparotomy, a huge cyst was found. A partial splenectomy was performed. The diagnosis of a splenic epidermoid cyst was confirmed with histological examination. Conclusion: Splenic cysts are not frequent especially in children and adolescents. Imaging is useful for diagnosis. The confirmation of the diagnosis is histological. Different treatment modalities are discussed. However, partial or total splenectomy remains a relatively safe procedure, associated with few complications and avoiding any future problems.

Keywords: Conservative Treatment, Surgery, Splenic Cyst, Teenage

1. Introduction

Splenic epidermoid cysts are a congenital benign mass of the spleen (Pastore, Bartoli 2014; Da Costa, Gaujoux, Gouya, Dousset, Legmann 2015). They belong to the non-parasitic primary cysts that constitute approximately 10%-25% (Kiran, Balachandran, Mohan 2017; M. Zganjer, V. Zganjer and Irenej Cigit 2010). Splenic epidermoid tumors are well histologically described entity. These cysts are often asymptomatic, sporadic and discovered incidentally in childhood or adolescence.

The traditional treatment of splenic cysts had been total splenectomy led to short and long-term complications especially in children. Currently, it is recommended to practice a conservative surgical treatment (Rana, Kaur, Singh, Malhotra, Kuka 2014). However during the last two decades, new interventional radiological approaches are starting to be tried (López et al. 2017; Accinni, Bertocchini, Madafferi, Natali, Inserra 2016)).
We reported a rare case of large splenic epidermoid cyst in a 14-year-old girl with conservative surgical treatment.

2. Case presentation

A 14-year-old girl, with a history of abdominal trauma, presented intermittent left hypochondriac pain. She was admitted in our department for exacerbation of the pain. Physical examination revealed a firm and painful mass in the left hypochondriac region.

Ultrasonography (US) of the abdomen revealed a huge intra splenic cyst that measured 142*113 mm. Computer Tomography (CT) scan of abdomen confirmed the presence of a large well defined cystic mass which was 145*143*118 mm in size. The lesion was not raised after injection of contrast medium. The wall of the lesion was imperceptible (fig 1).

The inflammatory biological test was negative. The hydatid serology was negative. Elective laparotomy was performed. On exploration, we found a large splenic cyst which was located at the posterior face of the spleen. The cyst doesn't have a regular wall (fig2). Reduction in size of cyst was done by intraoperative aspiration of about 1 liter of turbid colored fluid (fig 3). A conservative surgical treatment was performed, and we practiced a partial cystectomy with inserting a suction drain (fig 4). The postoperative clinical course of the patient was satisfactory and uneventful. The diagnosis of a splenic epidermoid cyst was confirmed with histological examination.

3. Discussion

Splenic cysts are rare and not often encountered in surgical practice especially in the pediatric age (Czauderna et al. 2006). They are classified as true or primary cysts and false post-traumatic cysts (Martin 1958)). Primary cysts have an epithelial lining and can be non-parasitic or parasitic. In fact, Echinococcus infection is the most common cause of a primary splenic cyst especially in endemic countries (Kiran et al. 2017; ETsakayannis, Harry, WKozakewich, CShamberger 1995). Non-parasitic cysts are neoplastic or congenital which are classified as epidermoid, dermoid and endodermoid depending on the type of lining.

Splenic epidermoid cysts are a benign tumors that histologically characterized by the presence of a stratified columnar, cuboidal or squamous epithelial lining (Schlittler; Dallagasperina 2010). Usually, they are solitary, unilocular, and contain a serous fluid which is often blood-stained (Thomas and Taiwo 1994, Sarvaiya, Raniga, Vohra, Sharma, Bhrtyan 2006).

Epidermoid cysts are the most common among all congenital cysts which occur in the spleen (Tassopoulos, Wein, Segura. 2017). Their etiopathogeny still unknown and several hypotheses have been proposed (Schlittler; Dallagasperina 2010, Sarvaiya et al. 2006). The most of epidermoid splenic tomors are asymptomatic and discovered incidentally in childhood or adolescence with a female predilection. But may become sometimes symptomatic who testify for complication by compression, infection, trauma or haemorrhage (Da Costa et al. 2015, Accinni et al. 2016). In these cases, we find an acute abdomen with or without a palpable mass.

In our case, the patient presented dull pain in the left costal margin for the last years with a history of trauma. Imaging often poses the diagnosis which is confirmed by the anatomopathological analysis. In fact, US and CT scan are the most useful examination to find the correct diagnosis. Also, the interventional radiology finds its place in the treatment and oversight of these cysts. In our case, the US of the abdomen and CT scan have oriented the diagnosis.

According to the literature, for asymptomatic and smaller splenic cysts (<5cm diameter) a simple clinical and radiological oversight can be a safe approach. Whereas for symptomatic or larger cysts (>5 cm in diameter), surgical intervention has been suggested (Czauderna et al. 2006, Sinha, Agrawal. 2011). The conventional treatment of these symptomatic splenic cysts was a total splenectomy. But today, the splenic surgery treatment is more conservative with preservation of the spleen if possible especially in children and adolescent in order to avoid serious postoperative infections (Accinni et al. 2016, Czauderna et al. 2006). The various splenic surgery procedures described in the literature are total or partial splenectomy and total or partial cystectomy whether with laparoscopy or laparotomy.

Sinah (Sinha, Agrawal. 2011) presented a systematic study on 157 non-parasitic splenic cysts treated with various surgical procedures. This review found that the recurrence rate with the laparoscopic partial and total cystectomy was unacceptably high. However, total cystectomy with open approach did not show high recurrence and hence proved to be an acceptable option. Also, they indicated a total splenectomy if the cyst was giant or miltifocal. Evenly Czauderna (Czauderna et al. 2006) presented a multicentric study about 50 non-parasitic splenic cysts treated with different surgical procedures. This study noted recurrence only with the laparoscopic partial cystectomy. In fact, several authors recommended a partial splenectomy or cystectomy as soon as possible. But total splenectomy is the treatment of choice in case of larger cysts, as it prevents serious complications like rupture, haemorrhage, infection and recurrence (Rana et al. 2014; Schlittler, Dallagasperina. 2010). In our case, we opted for conservative surgical treatment, and we practiced a partial cystectomy.

Recently, a more conservative approach is developed <Splenic scleroterapy> which is a potentially less invasive treatment for splenic cysts than surgery (Rifai et al. 2013). Several studies (López et al. 2017, Czauderna et al. 2006, Tassopoulos et al. 2017) have concluded that this technique is an effective initially alternative therapy predominately for the pediatric population and does not exclude surgery if this conservative treatment fails.

4. Conclusion

Splenic epidermoid cysts are benign tumors that their treatment must be as conservative as possible. Radiological examinations have a diagnostic and therapeutic interest. However, the confirmation of the diagnosis is histological. The total splenectomy was the gold standard, and recently several conservative approaches are developed.

FIGURES

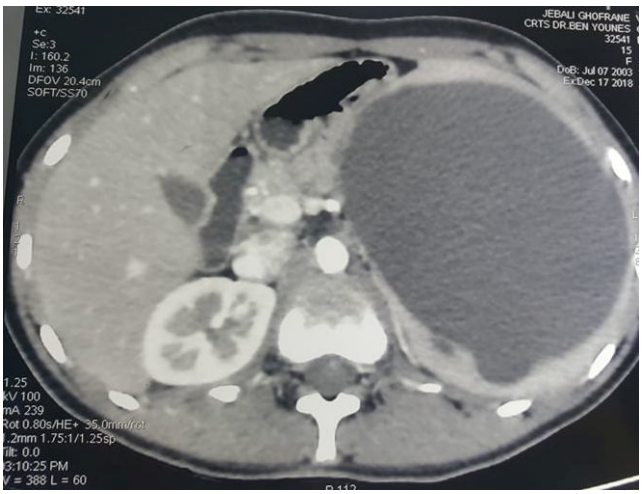

Figure 1: Dimensions of the splenic cyst on the CT scan

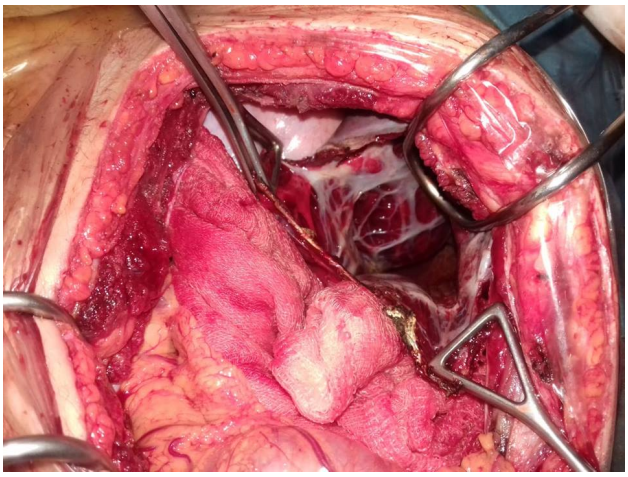

Figure 2: Intraoperative view of the cyst cavity

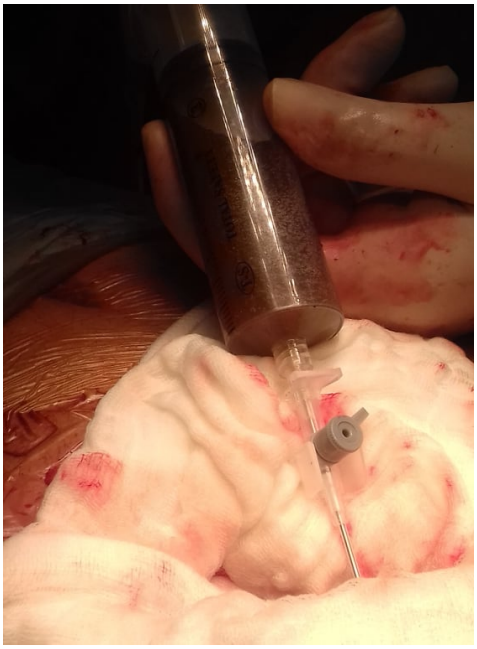

Figure 3: Ponction of the cyst

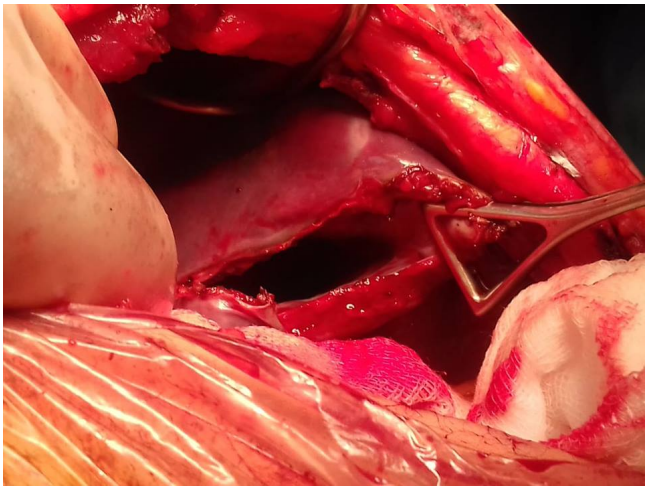

Figure 4: Partial cystectomy

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Training Intervention on TB Knowledge Among Lesotho Village Health Workers

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Abstract
The role of Village Health Workers (VHW) is to educate communities about tuberculosis (TB) and its causes, conduct TB screening, and directly observe the treatment of TB. The knowledge of TB among VHWs is crucial because it impacts not only their work at the community level but also the overall outcome of TB treatment. The study is aimed at assessing the training intervention on TB knowledge among Lesotho VHWs. This aim is achieved by comparing VHWs' TB knowledge before and after the training. The study used mixed methods design with a quantitative approach. Three study populations were interviewed, two at the household level and one at the clinic level. The third study population was made up of VHWs, serving in the selected clinics. Open Development Kit (ODK) was used to administer a structured questionnaire. Statistical Package for Social Sciences (SPSS) was used for data analysis. Ethical approval was granted by the National Ethics and Review Board of the Ministry of Health (MOH). The mean scores of overall knowledge of TB in all the 9 measures used to assess VHWs' TB knowledge increased from 44.63% at baseline to 61.84% post-intervention. This result implies a positive impact of the intervention strategy, although adequate knowledge, indicated by an overall post-intervention score of 31.50 (75%) was not achieved. It was concluded that household members have inadequate knowledge about TB causes that is seen to be a direct cause from VHWs who lacked such knowledge.

Keywords: Tuberculosis (TB) Knowledge, Village Health Workers. Evaluation training

Background

Worldwide, VHWs are expected to promote good health practices in the community, through health education on topics of concern in the country (Bedelu et al. 2007:176; MOHSW, 2003: 33; Rigodon *et al*., 2012: 138;

Mwai et al. 2013:7). The most important matters of concern in Lesotho currently are a failure to meet Millennium Developmental Goals (MDGs) targets for HIV/AIDS, TB, and maternal/child mortality, of which a VHW can play a vital role as part of the community where he/she lives (Perry & Zullinger 2012:26,27; MOHSW, 2011:4, 6; Rachlis *et al*., 2014:3). For VHWs to provide meaningful education to the community, he/she must have adequate information and knowledge about how to improve health outcomes related to TB (MOHSW, 2003: 33; MOHSW, 2011:4; Rigodon *et al*., 2012: 138), hence the need to establish a level of knowledge and curriculum for VHWs. It is equally important to determine if VHWs have access to refresher courses to revive their TB knowledge periodically. Formerly, Lesotho had 17 health service areas. Each one had a hospital and several clinics. Each clinic had a certain number of VHWs that served under it, and each had a certain number of villages that they served. Presently, VHWs are part of a key referral system for MOH. This has been recognized by MOH as a service for which they are remunerated.

The criteria used for selection of VHWs are stipulated in MOH and Social Welfare (MOHSW) training manual and is in line with practices in other countries (MOHSW 2011:8; Crigler *et al*. 2011). According to the criteria, a person must be a full-time resident of the village with no other responsibilities. He/she must be elected by the village itself and be literate. He/she should have gone through a 6-week VHW training programme from the MOH and must attend refresher courses as provided (Crigler *et al.* 2011; Rachlis et al. 2014:3). He/she must be in good health and be an adult between the ages of 25-70 years. VHWs must have the following attributes: be a dedicated, trainable, and respected member of the community. He/she must be a person who maintains confidentiality and can work on a voluntary basis (MOHSW 2011:8; Rachlis et al. 2014:3). In Lesotho, VHWs are seen as members of the primary health care team, and they are trained and supervised by a nurse from the nearby clinic or health centre (Crigler *et al*. 2011; Kumar. *et al.* 2014:10). He/she serves as a link between the community and primary health care facility (MOHSW 2011:14).

According to MOHSW (2011: 9), VHWs operate through home visits, small group discussions, and community gatherings. He/she assists the village in developing and maintaining safe water supply and sanitation (Kumar. *et al.* 2014:10). He/she must identify village health needs and facilitates the use of village health resources to meet these needs (WHO, 2010:45). He/she must assist the health centre team in controlling disease outbreaks and assist the chief with vital statistics (births and deaths registration). He/she must promote good nutrition and must recognize, manage, and organize follow-up for under-nourished children (Kumar. *et al.* 2014:10). He/she is expected to promote maternal and child health care, including antenatal care, PMTCT, skilled deliveries, postnatal care, child care, family planning, and follow-up of clients and defaulters (PIH, 2011:5). He/she identifies and provides initial treatment of diseases such as diarrhoea and vomiting (Kumar. *et al.* 2014:11). He/she recognizes, refers, and organizes follow-up of HIV/AIDS, TB, and leprosy patients (Khabo et al. 2013: 13). He/she provides first aid and home-based care. He/she must participate in health centre meetings. He/she keeps patient records and reports monthly activities to the health centre nurse. He/she cooperates with the development of extension workers (Kumar. *et al.* 2014:11; Rachlis et al. 2014:3).

An in-depth analysis of community health workers (CHWs) by Perry & Zullinger (2012: 1) found that CHWs work under varied conditions and have a wide range of work environments and expectations. There are disparities in the time taken to train CHWs, where some have only a few days of training, while others have six months or more of training. Training of VHWs in Lesotho is stipulated in the VHWs training manual by MOH. For someone to qualify as a VHW, he/she must have completed a six-week training using the MOH training manual (MOH 2011; Rachlis et al. 2014:3). Competency of VHW has to be measured and improved through refresher courses on services they are expected to provide (PIH, 2011; Rachlis et al. 2014:3; WHO 2010: 45). Education for CHWs should include training on the more logistical aspects of their jobs, such as household entry, community sensitization, data collection and recording, and relevant ethical issues, mainly on how to maintain confidentiality (Rachlis et al. 2014:9).

In 2003, Lesotho developed an essential service package which specifies the role of VHWs, while in 2011, revitalization of the health services strategy was established. These two strategies clearly specify the role of VHWs. Accordingly, health centre nurses have to provide supportive supervision to VHWs and ensure that records are kept and available for inspection (MOHSW, 2011; Kumar. *et al.* 2014: 13). Partners In Health (PIH) (2011) stipulates the organogram for VHWs, which includes VHW supervisor, VHW coordinator, and Nurse as part of the supervisory structure for VHWs in Lesotho in areas run by PIH. Rachis *et al*. (2014:3) shows that

there is a Community Health Extension Worker (CHEW) whose role is to supervise a group of CHWs. This allows the nurse to focus more on the clinical role and receive reports from the CHW coordinator who is based at the clinic, and whose duties include collating information received from the CHW supervisors and submitting it to the nurse and clinic administrator (PIH, 2014:21). Performance management should be carried out based on a standardized set of skills that correspond with community needs (WHO 2010: 45). The programs should have regular and continuous supervision, and monitoring systems in place and supervision should be taught to be undertaken in a participatory manner that ensures a two-way flow of information (WHO 2010: 45).

Lesotho Demographic and Health Survey (LDHS, 2014) shows that in Lesotho, there is lack of comprehensive knowledge about HIV/AIDS among men and women in the general public, although women have slightly more knowledge than men (39 and 31% respectively). There is a widespread presence of VHWs in all villages in Lesotho. If these VHWs have comprehensive knowledge about HIV/AIDS, they will educate the communities where they live (PIH 2011:10). VHWs should be knowledgeable about HIV/AIDS as diseases, ARVs as a treatment for HIV, side effects, adherence issues, disclosure, stigma, and discrimination (Mwai et al. 2013:7, 8). When communities have comprehensive knowledge about HIV, they will be more likely to cooperate with efforts made to respond to the HIV/AIDS pandemic, such as the "test and treat" strategy (Rachlis et al. 2014:9).

Records submitted by VHWs should have a standardized format, with one copy at the health centre and the other copy remaining with the VHW. WHO (2010) and Rachlis et al. (2014:4) stated that VHWs should be trained in data collection skills. Data collected by VHWs should be transformed into meaningful, interpretable, and comprehensible information that can be shared among the communities (Rachlis et al. 2014:9). This information can also be used for planning purposes by the MOH. However, Kumar et al. (2014:13) states that since there is no Monitoring and Evaluation (M&E) system in place, data collection is often paper-based and not reliable. There should be clear two-way/bidirectional communication across all the systems from VHWs to health centre nurses to district hospitals to the central level, yet Kumar *et al.* (2014:14) iterates that information from VHWs is not monitored by supervisors and is not used to bring necessary impact. The role of District Health Management (DHMT) in information management systems has to be identified as an institution that plays a supervisory role in the health centres. Therefore, for a VHW program to be effective, it needs to be structured with clear supervisory roles and attached to an M&E system for fair remuneration as Lesotho compensates VHWs (MOHSW 2011).

Goal and Objectives

This evaluation study is part of a National Baseline Assessment of the TB and HIV/AIDS Knowledge Among Lesotho Village Health Works and the Communities They Serve. It was commissioned by the Lesotho Ministry of Health, and its main goal is to assess the effectiveness of a training intervention on TB knowledge amongst VHWs in Lesotho. The objectives were addressed by comparing TB knowledge before and after the intervention and the utilization of VHWs' services for TB treatment.

Methods and procedures

A representative sample of 19 clinics, covering all districts, was selected using multistage sampling. A TB knowledge assessment tool was administered to all VHWs of the selected clinics. The baseline report on the assessment of TB knowledge among Lesotho VHWs provides details of the sampling procedure for those interested in the details. Data collection took place between September and October 2016 for the baseline phase and in 2017 for the evaluation phase. An estimate of the number of households to be covered in the study was established using statistical methods. Households were used as sampling units for soliciting information about the utilization of VHWs' services. The estimated number of households was distributed proportionally to the ten districts of the country. The allocation for the district was further distributed among the selected sample clinics.

To measure knowledge, summary variables were computed based on the collected information. To assess knowledge, the respondent was asked to list all known modes of TB transmission and methods of prevention. The research assistant made a tick against those mentioned by the VHW from the master list. When the respondent mentioned all known responses, unknown responses would be left without a tick. For data capturing

purposes, the ticks were given a code of 1 while those without a tick were given a code of 0. By adding together all responses from one question (ex: modes of TB transmission), a summary measure was computed. For the mode of TB transmission, the value of the summary measure would range from 0 indicating no known modes of TB transmission to 6 where all 6 modes of TB transmission were known by the VHW. Master lists of the modes of TB transmission, methods of TB prevention, and signs that someone might be suffering from TB were taken from the listing in the VHW training manual.

To assess the adequacy of knowledge, Nachega, Lehman, Hlatshwayo et al. (2005)'s definition of adequate knowledge was used. According to this definition, at least 75% of listed modes should be known for a VHW to be considered as possessing adequate knowledge. Ethical clearance was secured from the Lesotho Ministry of Health.

The intervention was implemented in 2018 in all of the 19 clinics. It was done through training of the VHWs, specifically on TB for a period of five days. It was designed to align with national health priorities and the needs of the VHWs, which were explored in the first phase of the study. The curriculum encompassed the following TB topics: signs that someone has TB, predisposing factors for TB infection, and measures that can be taken to prevent the spread of TB and MDR-TB. This curriculum was developed by updating the existing Lesotho VHWs training manual of 2011 to include new relevant topics, such as the Code of Ethics for VHWs, how to contact public gatherings, and talking points at the end of every chapter for VHWs use for public gatherings. In this way, we seek to ensure that the curriculum covered material necessary to understand each topic and would help VHWs meet the needs of their communities and improve their TB knowledge.

The results and discussion

Characteristics of Household Members

In total, 2040 households were visited during the 2016 baseline survey with a population of 8295 individuals. During the evaluation, a total of 3654 households and a household population of 13,385 were covered. Regarding the profile of household members, more than a third (37% and 34.6% for 2016 and 2018 respectively) of household members were children while grandchildren constituted 17% in 2016 and 16% in 2018. More than half (52% for 2016 and 53% for 2018) were females. Forty-two percent (42%) of the household members were aged less than 20 years, while 13% were aged 60 years and above (Table 1.1). Comparable figures for 2018 were 38% for age less than 20 and 13% for 60 years and above. About a fifth (17%) of the members were absent from the household in 2016 while 82% were present. A similar situation prevailed in 2018, with 18.9% absent and 79.7% present. More than half (54% for 2016 and 50.1% for 2018) of household members had completed the primary level of education. A quarter (25%) had completed secondary education or more in 2016 compared to a third (30.9%) in 2018. Less than forty percent (38%) of household members were never married compared to 47% and 16% of currently married and previously married respectively for 2016. Comparative figures for 2018 were 33.2%, 50.1%, and 16.6% respectively, for never married, currently married, and previously married (Table 1.1).

Table 1.1: Characteristics of the Household Population

Characteristic	**Category**	**2016**		**2018**	
		Percent	**N**	**Percent**	**N**
Relationship to Head	Head	23.7	1970	27.3	3656
	Spouse	12.4	1031	12.9	1720
	Child	37.0	3068	34.6	4618
	Son/Daughter in law	1.9	156	2.1	274
	Grandchild/great grandchild	16.8	1391	16.1	2145
	Other relative	6.4	535	6.2	826
	Other person not related	1.6	132	0.9	126
	No response	0.1	12	0.0	2

Sex	Male	47.8	3963	47.3	6337
	Female	52.2	4326	52.7	7052
	No response	0.1	6	0.0	0
Age	00-10	18.8	1559	17.1	2281
	10-19	22.9	1902	21.3	5846
	20-29	16.1	1338	16.3	2181
	30-59	24.7	2046	26.8	3574
	60+	13.2	1095	12.5	1675
	Age not stated	4.3	355	6.0	799
Residential Status	Present	81.8	6786	79.7	10669
	Visitor	0.6	49	0.4	52
	Member elsewhere in Lesotho	9.2	761	11.7	1570
	Member outside Lesotho	8.2	681	8.0	1069
	Do not know	0.1	6	0.1	8
	No response	0.1	12	0.1	8
Marital Status	Never married	37.8	2162	33.2	3164
	Currently married	46.7	2669	50.1	4787
	Previously married	15.5	884	16.6	1588
Level of Education	Pre-school	3.3	273	3.2	434
	Primary	54.1	4489	50.7	6773
	Secondary and above	25.0	2077	30.9	440
	Other	0.2	14	0.0	0
	Do not know	0.5	44	0.6	81
	Aged less than 5/no response	16.9	1398	14.5	1936

Characteristics of Village Health Workers

Seven hundred and twenty-three (723) VHWs responded to the VHW questionnaire in 2016 compared to 718 in 2018. The age distribution of VHWs is bell-shaped for both 2016 and 2018. For 2016 figures, it increased from a low of 18% for those aged less than 40 years and reached a peak of 28% for those aged between 50 and 59 years (Table1.2). Comparative figures for 2018 are 17.0% and 32.3% respective for age less than 40 and age 50-59. According to 2016 figures, almost all VHWs were females (93%); while the majority (64%) are currently married and a third (33%) were previously married. Corresponding figures for 2018 are similar with 95.1% of VHWs being female, 65.1% currently married, and 34% previously married. For both 2016 and 2018, more than two thirds (77% for 2016 and 74.7% for 2018) of the VHWs had completed primary education, and a fifth had completed secondary education or higher (21.2% for 2016 and 24.0% for 2018) (Table.1.2).

Table 1.2: Profile of Village Health Workers

Characteristic	**Category**	**2016**		**2018**	
		Percent	**N**	**Percent**	**N**
Sex	Male	6.6	48	4.9	35
	Female	93.2	676	95.1	683
	No response	0.1	1	0.0	0
Age	<40	18.0	130	17.4	125
	40-49	25.4	184	22.6	162
	50-59	28.1	203	32.3	232

	60-69	22.8	165	24.9	179
	70+	5.2	38	2.8	20
	No response	0.4	3	0.0	0
Marital Status	Never married	2.2	16	0.8	6
	Currently married	64.4	466	65.2	436
	Previously married	33.2	240	34.0	244
	No response	0.1	1	0.0	0
Education	No education	1.2	9	1.4	10
	Primary	77.5	560	74.7	536
	Secondary or higher	21.2	153	24.0	172
	No response	0.1	1	0.0	0

Comparison of VHWs TB Knowledge before and after training

The mean scores of overall knowledge of TB in all the 9 measures used to assess VHWs' TB knowledge increased from 16.96 (44.63%) at baseline to 23.36 (61.84%) post-intervention (Table 1.3). This result implies a positive impact of the intervention strategy, although adequate knowledge, indicated by an overall post-intervention score of 31.50 (75%) was not achieved. However, there were disparities across the indicators. "Signs that someone has TB" was the only indicator that reached adequate knowledge post-intervention, with a score of 4.07 (81.40%). This was an improvement of 15.8 percentage points. The indicators "Importance of TB treatment" (71.00%), "What may be observed after completion of TB treatment" (70.25%), and "Role of VHW in the Prevention of the Spread of TB" (71.33%) were all less than 5% short of achieving adequate knowledge. These indicators showed an improvement of 9.33-18.00 percentage points. However, indicators such as "Predisposing factors for TB infection" (52.67%), "Side effects of MDR-TB drugs" (50.62%), and "Role of the VHW in the treatment of TB" (50.71%) were all over 20% away from achieving adequate knowledge in the post-intervention phase (Table1.3). Although, these indicators did show a 12.71-22.24 percentage-point improvement. It is assuring that the indicator with both the lowest baseline and post-intervention scores, "Side effects of MDR-TB drugs," also had the greatest improvement in score, a 22.24 percentage-point difference (baseline 28.28%, post-intervention 50.62%). Furthermore, all indicators reached statistically significant improvement from baseline to post-intervention scores. Generally, these summaries suggest that the intervention has had a significant effect on overall knowledge of TB amongst the VHWs in Lesotho.

Table 1.3: Summary Knowledge for TB among VHWs

Knowledge Summary Measure of:	**Mean (%)**			
	2016	**2018**	**Sig level**	**Adequate Score (75%)**
Signs that someone has TB	3.28 (65.60)	4.07 (81.40)	p<0.001	3.75
Predisposing factors for TB infection	2.30 (38.33)	3.16 (52.67)	p<0.001	4.50
Measures that prevent spread of TB infection	2.22 (55.50)	2.72 (68.00)	p<0.001	3.00
Side effects of TB drugs	2.78 (34.75)	4.53 (56.63)	p<0.001	6.00
Side effects of MDR-TB drugs	2.27 (28.38)	4.05 (50.62)	p<0.001	6.00
Importance of TB treatment	1.71 (57.00)	2.13 (71.00)	p<0.001	2.25
What may be observed after completion of TB treatment	2.41 (60.25)	2.81 (70.25)	p<0.001	3.00
Overall TB Knowledge	**16.96 (44.63)**	**23.36 (61.84)**	**p<0.001**	**28.50**

Role of VHW in the Prevention of the Spread of TB	1.86 (62.00)	2.14 (71.33)	p<0.001	2.25
Role of the VHW in the treatment of TB	2.66 (38.00)	3.55 (50.71)	p<0.001	5.25
Overall knowledge of the role of VHWs in TB treatment	**4.52 (45.20)**	**5.69 (56.90)**	**p<0.001**	**7.50**

Notes: N denotes number of responses used to compute the summary measure. Expected mean is based on Nachega, Lehman, Hlatshwayo et al. (2005)'s definition of adequate knowledge.

Utilization of VHWs' Services for TB Treatment

When asked who assisted household members with TB treatment initiation, the household head reported that a third (34.9%) of those diagnosed with TB were helped by the VHW (Figure 1.1). Among household members aged 15 years and above (self-reported), more than a third (36.9%) reported that they were advised by the VHW to go for TB screening (Figure 1.2). Both reports (household head reporting on treatment initiation assistance and self-reporting on screening assistance) were similar in terms of the utilization of VHW services, which is estimated at around 33%. According to VHWs during validation workshops, members of the community continue to be secretive about the disease, while other members of the community believe TB is caused by witchcraft. This might explain a high percentage of villagers not seeking help from the VHW.

Figure 1.1: Percentage that Received Help from VHW for TB Treatment

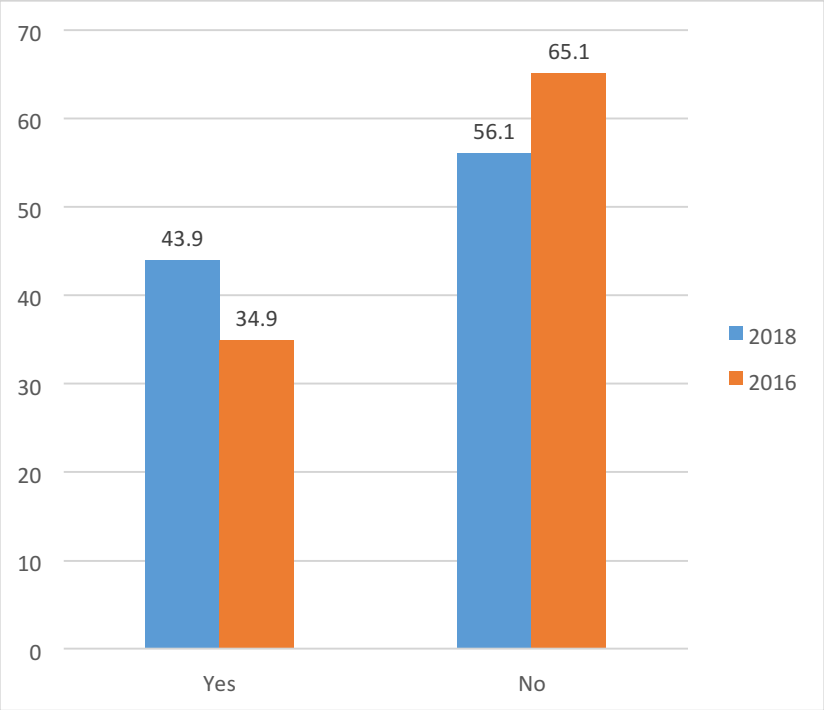
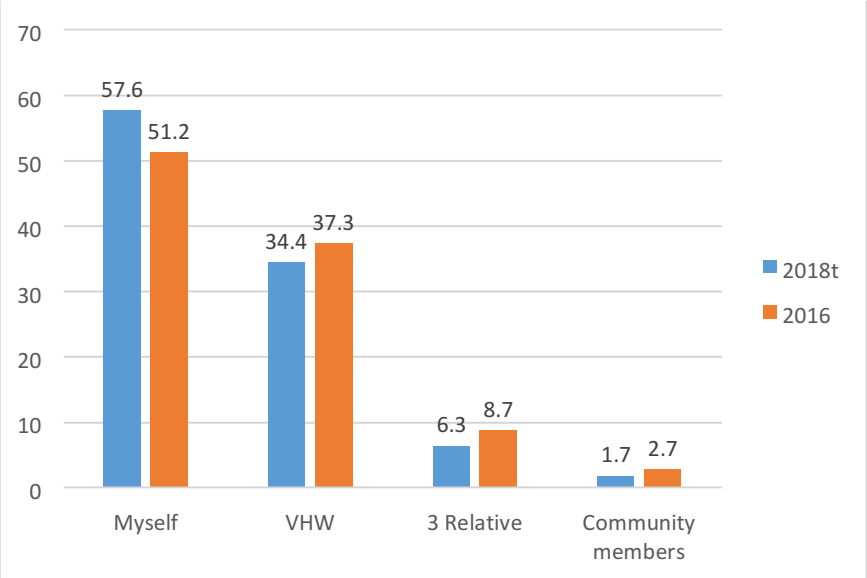


Figure 1.2: Percentage that Received Help from VHW for TB Screening



Conclusion and recommendations

VHWs attained a mean score that was lower than the expected mean in all of the indicators for them to qualify as having adequate knowledge. It was only with respect to the signs that someone has TB where they achieved adequate knowledge, with a post-intervention score of 81.40%. Similar findings were noticed about TB and its treatment. VHWs with knowledge about TB and who knew their role in TB passed knowledge to the household members. This was demonstrated by a large number of household members reporting that they were referred by VHW for TB screening and a high percentage on TB treatment as a result of the VHW. In one clinic, household heads acknowledged that they were advised by the VHW to get TB treatment. In the same clinic, 8 in 10 household members reported that they were helped by the VHW to go for TB screening. Generally, these summaries suggest that the intervention had a significant effect on overall knowledge of TB amongst the VHWs, as improvements in knowledge scores were seen across all the measures used to assess VHWs' TB knowledge. All of these changes in knowledge were statistically significant ($p<0.001$). Therefore, the training intervention was effective in increasing TB knowledge among Lesotho VHW and the communities they serve.

VHWs can clearly contribute to the treatment of TB service delivery and strengthening human resource capacity in Lesotho at the village level. For their contribution to be sustained, VHWs need to be trained regularly, specifically on their roles in the community, TB symptoms, transmission, prevention, and treatment. Since VHWs work with councillors and chiefs, it is also critical for these individuals to be trained on the role of the VHW in TB treatment.

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Evaluation of Mast Cell and Eosinophil Count in Duodenal Mucosa- A Study on 69 Functional Dyspepsia Cases from Bangladesh

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Abstract

The exact cause of functional dyspepsia is not known. This study was designed to investigate the association between duodenal infiltration of immune-mediating cells, namely eosinophils and mast cells with functional dyspepsia. Total of 69 patients presenting with symptoms of functional dyspepsia and matched healthy 42controls were included in this cross-sectional study. Tissue from duodenum was taken from both patients and controls, and the number of eosinophils and mast cells per five high power fields were counted. ‘t' test and chi square tests were done to find out the association of immune-mediating cells with functional dyspepsia. p value <0.05 was taken as significant. Duodenal eosinophil count ranges from 1-92 with mean 21.59 in cases and from 3-51 with mean 14.90 in controls. Eosinophil count was abnormally high among 29 (42.02%) and 08 (19.02%) among cases and controls, respectively, and the difference was significant (P=0.013).Mast cell density was seen among 56 cases and 23 controls from the same sample. Mast cell per 5 high power fields varied from 1-139 (mean 20.0536) and 3-57 (mean 20.86) were found in cases and controls groups, respectively (P=0.627).This study showed that functional dyspepsia is associated with a significant increase of eosinophils count in duodenum, but no significant association could be identified between of mast cell count in duodenum and functional dyspepsia.

Keywords: Functional Dyspepsia, Duodenum, Eosinophil, Mast Cell

Introduction

Functional dyspepsia (FD) is defined as unexplained pain or discomfort centered in the upper abdomen affecting 10% of the world’s population (El-Serag & Talley,2004; Zagari et al.,2010). Many who suffer with dyspepsia take medication, and up to 23% visit the general practitioner in a year (Penston & Pounder ,1996). Although FD

is generally non-life threatening, this disorder places a substantial burden on affected individuals because of a decreased quality of life compared with healthy subject and incurs high direct and indirect health care costs (Nyrop et al., 2007). Current diagnostic criteria use a symptom-based classification, the Rome III criteria and patients are defined by symptoms (epigastric pain or burning, postprandial fullness, or early satiation) but no pathology (Tack et al., 2006).

Currently, various mechanisms, including visceral hypersensitivity, Helicobacter pylori (H. pylori) infection, altered gut microbiome, and psychosocial dysfunction, have been proposed (Futagami et al., 2011). However, the pathogenesis of FD still remains poorly understood. Recent evidence implicates the duodenum in altering gastric accommodation and emptying (Lee & Tack, 2010). Researchers recently noticed close relation of FD with duodenal immune activation (Friesen, Schurman, Colombo, & Abdel-Rahman, 2013).Studies from Sweden (Talley et al., 2007), and UK (Walker et al., 2010) found significant duodenal eosinophilia in subjects with FD compared with controls. Similarly, in post infectious FD in Japan (Futagami et al., 2010) and in children with FD in USA (Friesen, Sandridge, Andre, Roberts, & Abdel-Rahman , 2006; Friesen, Garola, Hodge, & Roberts, 2002), duodenal eosinophilia has been observed, indicating that these observations are highly likely to be clinically relevant.

Furthermore, mast cells (MCs) are known to be involved in and essential for eosinophilic inflammation. There is a crosstalk between MCs and eosinophils, apparently because the 2 types of cells interact with each other (Walker & Talley, 2008). Recent studies have demonstrated that MCs can initially induce eosinophils into the gastric mucosa and these eosinophils, in turn, promote MC survival, proliferations, maturation and degranulation by secretion of various growth factors((Friesen et al., 2013; Walker & Talley, 2008). Thus, eosinophils and MCs are co-dependent in the development of visceral hypersensitivity, and their interaction may be a leading cause of symptoms of functional gastrointestinal disease (Powell et al., 2010).

With this background, this study was designed to see the duodenal eosinophil count and mast cell count in patients with functional dyspepsia, especially patients with postprandial fullness, early satiation and to compare those with healthy individuals.

Material and methods

Selective patients presenting with postprandial fullness, early satiation, bloating, and distress syndrome having no lesion at endoscopy of upper GIT were included in the study. Patients having GIT surgery, pancreatico-biliary disease, pregnant lady, age below 18 years and unwilling to take part in the study were excluded from the study. Patients with overt or medical conditions known to increase peripheral and tissue eosinophils like inflammatory bowel disease, coeliac disease, vasculitis, connective tissue disease, active infection, and allergy were also excluded. Consecutive (age-matched) 42 patients undergoing upper GIT endoscopy with indications other than above-mentioned symptoms were taken as controls. Two grasps of tissue using biopsy forceps were taken from the second part of duodenum for histological examinations from cases and controls. Tissue samples were examined for eosinophil counts and mast cells using Hematoxylin and Eosin stain (H-E) (Figure 1) and Giemsa stains, respectively. Eosinophil counts < 22 / 5 HPF were taken as normal[9].

Statistcal analysis

Both eosinophil counts and mast cell counts per 5 high power fields were analyzed using SPSS version 20. "t" test, and chi square tests were done to find out the differences between cases and controls. P value <0.05 was taken as significant.

Result

Total 69 patients (male 50, female 19) of functional dyspepsia (symptoms – postprandial fullness, bloating, and early satiety with normal upper GIT at endoscopy) were enrolled as cases. Age of them varied from 18 to 85 (mean 34.73 and SD 13.61). Forty-two controls undergoing upper GI endoscopy for symptoms other than dyspepsia age varying from 18 to 51 (mean 29.18 and SD 9.16) were taken as controls (Table 1). Duodenal eosinophil counts per 5 high power fields varied from 1-92 with mean 21.59 and SD 18.812 were found in cases. Eosinophil counts in duodenal mucosa in controls varied from 3-51 with mean 14.9048 and SD 10.74, and the difference was statistically significant (P=0.009. Eosinophil count was abnormally high among 29 (42.02%) and 08 (19.02%) among cases and controls respectively, and the difference was also significant (P=0.013).

On the other hand, mast cell density was seen among 56 cases and 23 controls from the same sample. Mast cell per 5 high power fields varied from 1-139 (mean 20.0536 and SD 24.28) and 3-57 (mean 20.86 and SD 16.44) were found in cases and controls groups respectively (Table 2) which was almost similar (P=0.627). Neither the cases nor the controls had the feature of celiac disease or parasite infestation in duodenal tissue.

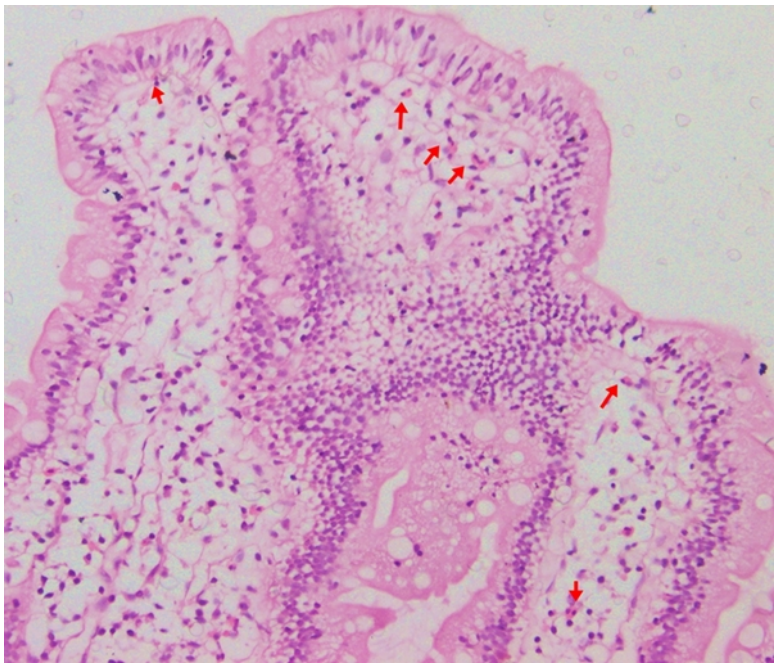

Figure 1: Hematoxylin and eosin staining for eosinophil (Eosinophils are indicated by red arrows, Magnification, x 40).

Table 1: Eosinophil count in duodenum

	Number	Eosinophil cell range	Mean	SD	P value	Count in normal range	Count higher	P value
Case*	69	1-92	21.59	18.81	0.009	40	29	0.013
Control	42	3-51	14.9	10.74		34	8	

*Functional dyspepsia patients

Table 2: Mast cell count in duodenum

	Number	Mast cell range	Mean	SD	P value
Case*	69	0-139	20.05	24.86	0.627
Control	23	3-57	20.86	16.44	

* Functional dyspepsia patients

Discussion

The etiology and pathophysiology of FD are not completely established, and no single physiologic abnormality can be implicated as the cause of symptoms in every patient. Inflammation of the upper gastrointestinal tract has been implicated in the development of functional gastrointestinal disorders (Friesen et al., 2013; Collins, 1996). Among the inflammatory cells, mast cells and eosinophils are especially important t(Friesen et al., 2013; Walker et al.,2011; Theoharides & Cochrane, 2004).

In this study, counts of eosinophil in the second part of duodenum in 69 patients and 42 controls and eosinophil counts were found significantly higher among cases.Recruitment and activation of eosinophils are usually accompanied by an inflammatory response that is initiated by a number of internal and external triggers(Thumshirn,2002). The internal triggers, such as anxiety and stress, act via brain-gut axis and external triggers, such as microbes, allergens, stimulate inflammation (Tack et al., 2004). During inflammatory response, degranulation of eosinophils leads to neural stimulation and smooth muscle contraction, which consequently elicits gastrointestinal symptoms, including flatulence, cramps, and abdominal discomfort (Powell, 2010; Rothenberg, 2001).

Previous clinical studies have reported that children and adults with FD had eosinophilia in duodenum (Friesen et al., 2002; Walker et al., 2008). In our study, we found significantly high eosinophil count in the second part of duodenum, which is also consistent with the findings by Walker et al. (2011).

Our study does not show an increase in mast cell infiltration in duodenum which is consistent with the report by Walker et al. (2013) But Schurman et al. (2010) found increased mast cell count in duodenum in pediatric patients with FD. It is to mention that the number of control in case of mast count in our study was very small.

Conclusion

Functional dyspepsia is associated with a significant increase of eosinophil infiltration in duodenum. But the association of mast cell infiltration in the duodenum in FD could not be established in our study.

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Correlation of Sonographic Appearance of Chronic Liver Disease with Serological Findings of Hepatitis B and C in Multan City

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Abstract
Liver cirrhosis is the irrecoverable disease of the liver, finally it causes necrosis of liver cells, as a result, change normal cells into an abnormal knot as well as structural abnormalities occur. It caused by many of reason, but here we discussed only by the hepatitis b virus and hepatitis b virus. The hazard of liver cirrhosis increased day by day. Recently liver cirrhosis prevalence of Pakistan was 13.5%. Sonography can easily diagnose the liver cirrhosis caused by hepatitis b and c virus. Objective: The object of this study to examine the analyses of ultra-sonographic diagnosis of liver cirrhosis in patients with chronic viral hepatitis B and C. Method: the cross-sectional study was conducted at Fatima ultrasound center. All age group patients with hepatitis B and C virus liver cirrhosis was included. Scanner GE Logic 5 and 7 Pro, DP-20 used for this study to examine the collaboration of liver cirrhosis. The liver cirrhosis associated hepatitis B virus and hepatitis C virus were analyzed on trans-abdominal by concave prob 2.5- 5MHz. Result: Total 376 patients determine to have hepatitis B and C virus cause liver cirrhosis were incorporate all age patients which a large portion of them was male the absolute level of liver cirrhosis was 46%. Conclusion: We observe that liver cirrhosis associated with hepatitis B and C virus more common in male than female. Rural areas are more effective by liver cirrhosis associated with hepatitis B and C virus.

Keywords: Chronic Liver Disease, Hepatitis

Introduction

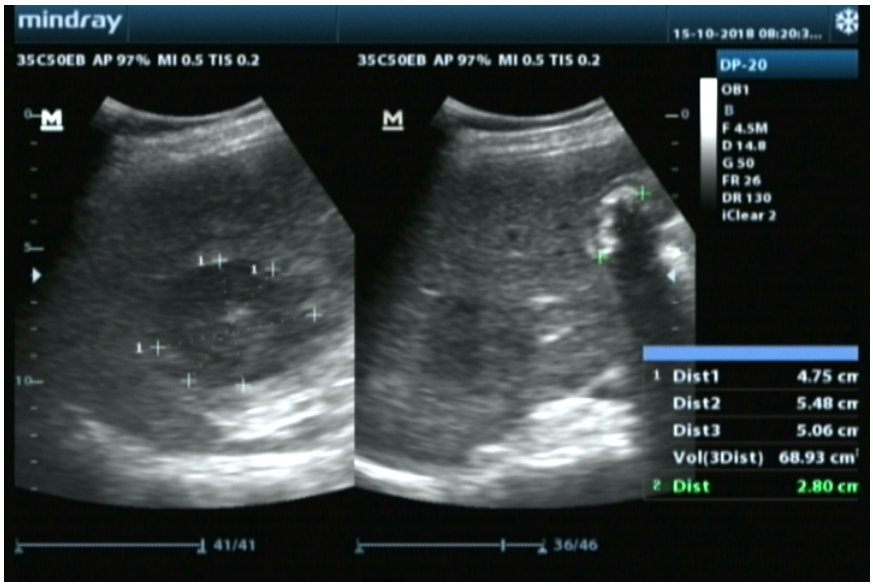
Cirrhosis is a genuine degenerative infection that happens when solid cells in the liver are harmed and supplanted by scar tissue, for the most part, because of incessant hepatitis B and C. As liver cells offer an approach to extreme scar tissue, the organ loses its capacity to work appropriately. Extreme harm can prompt liver disappointment and potential demise. Consistently, (around 31,000 individuals in the U.S.?) pass on from cirrhosis, ceaseless hepatitis B and C. The malady can't be turned around or restored aside from, now and again, through a liver transplant. In any case, it can regularly be impeded or ended, particularly if the sickness is identified in the beginning periods. Despite the fact that capacity can never be reestablished to the pieces of liver that have swung to scar tissue, can carry on with a sound existence with the rest of the segment if the illness is gotten in time. In any case, there is a point of no arrival with cirrhosis. As more cells are supplanted by scar tissue, less solid cells are left to deal with the liver's numerous errands. This is the reason it's vital to recognize the hidden causes at the earliest opportunity and start finding a way to dispose of them. Hepatitis B or C infection intense contamination can prompt recuperation, intense liver disappointment, or perpetual disease. Chronicity of hepatitis B virus and hepatitis C virus disease relies upon the age, sex, and safe ability at the season of contamination. In most immuno-skillful grown-ups, 5% to 10% create perpetual hepatitis B virus disease, while 75% to 85% create interminable hepatitis C virus contamination. Ceaseless contamination may result in a 'solid bearer' state, liver cirrhosis and additionally hepatocellular carcinoma of person who creates intense liver disappointment 80 percent bite the dust within days and weeks after disease.

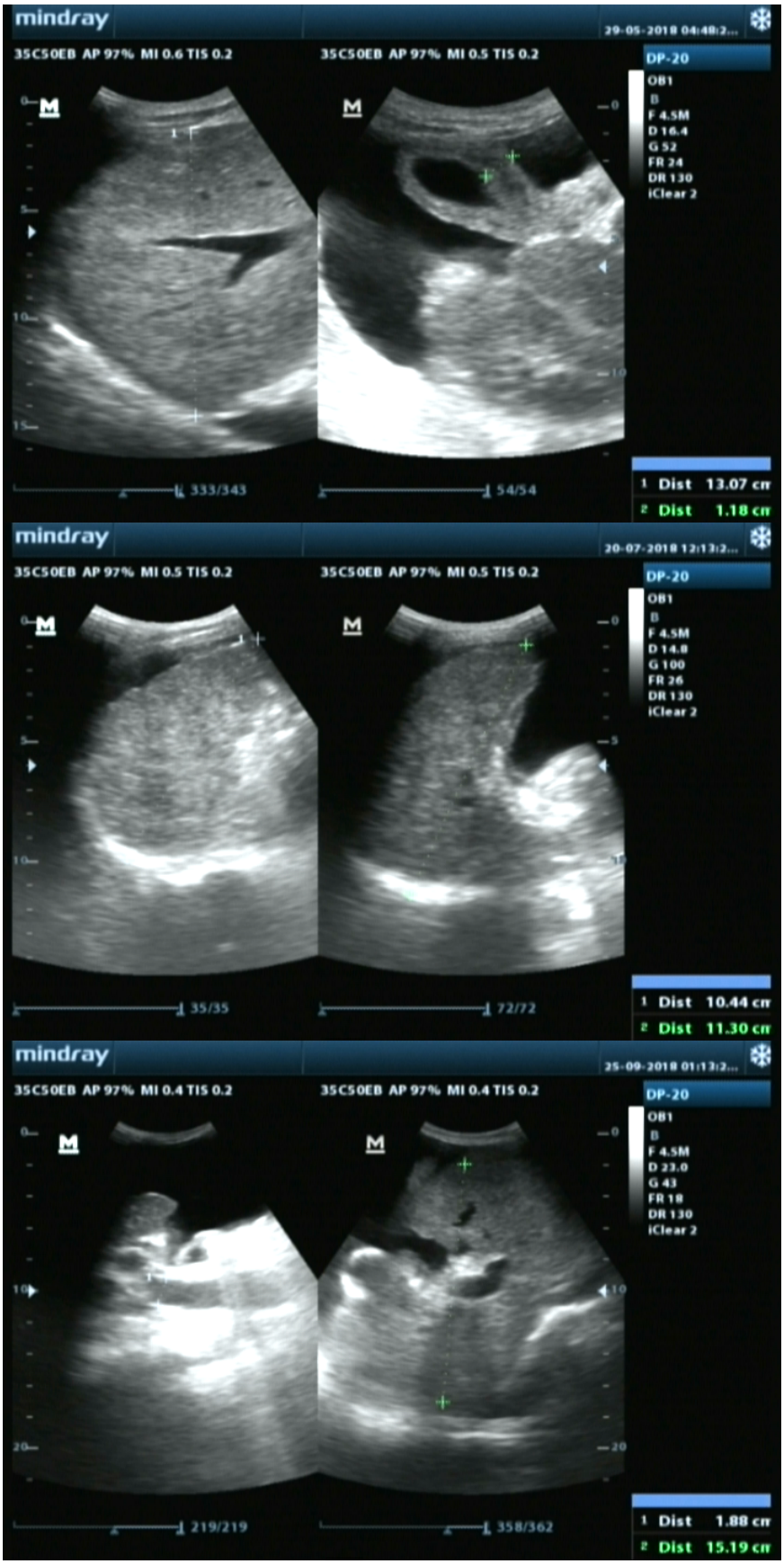
The sonography conclusion shows Chronic hepatitis fundamentally uncovered diminished splendor and number of entryway vein radicle dividers and overall expanded liver echogenicity. Furthermore, the neurotic seriousness intently paralleled these ultrasound designs.

Method

The cross-sectional study was conducted at Fatima ultrasound center. All age group patients with hepatitis B and C virus liver cirrhosis was included. Our sample size was 376 patients. 376 patients were included after the approval of synopsis from an institutional review board (IRB).

All age patients diagnose liver cirrhosis associated with hepatitis B virus, and hepatitis C virus were included, Scanner used for diagnosis GE logic 5 and 7 pro, DP-20. The liver cirrhosis associated with hepatitis B virus and hepatitis C virus were analyzed on trans-abdominal by concave prob 2.5- 5MHz.

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2 Dist 11.30 cm
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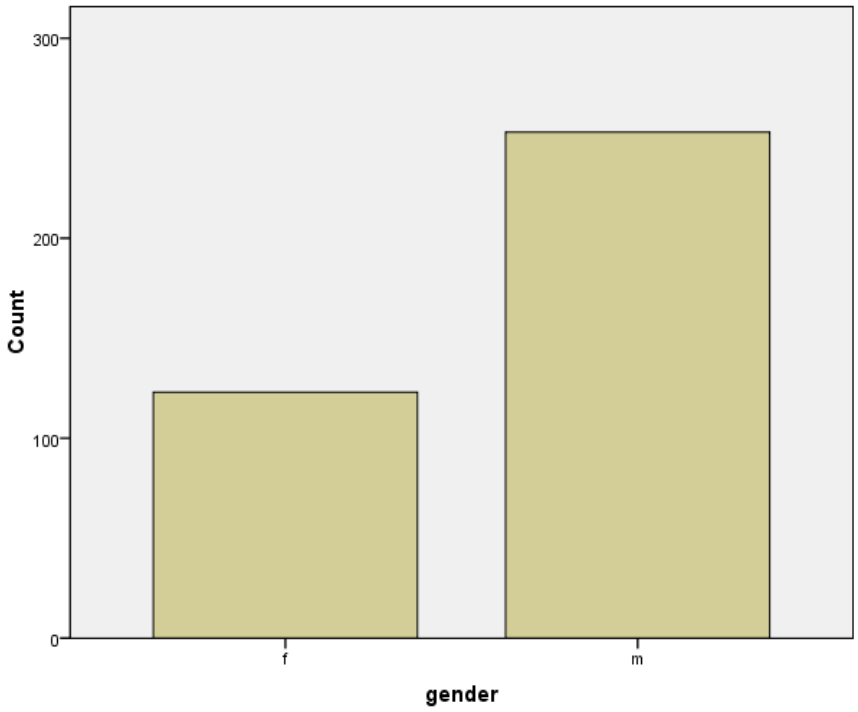
F 4.5M
D 23.0
G 43
FR 18
DR 130
iClear 2
219/219
358/362
1 Dist 1.88 cm
2 Dist 15.19 cm

Results

Total patients of 376 included this study. Most of the patients were belong in rural areas. Major patients were 30-70 years old. In this study, both gender were included 123 female (32%) and 253 male (67.3%). Frequencies obtain abdominal ascites (62%), liver cirrhosis (38.3%), liver margin irregular (38.6%), mild irregular (39.4%).

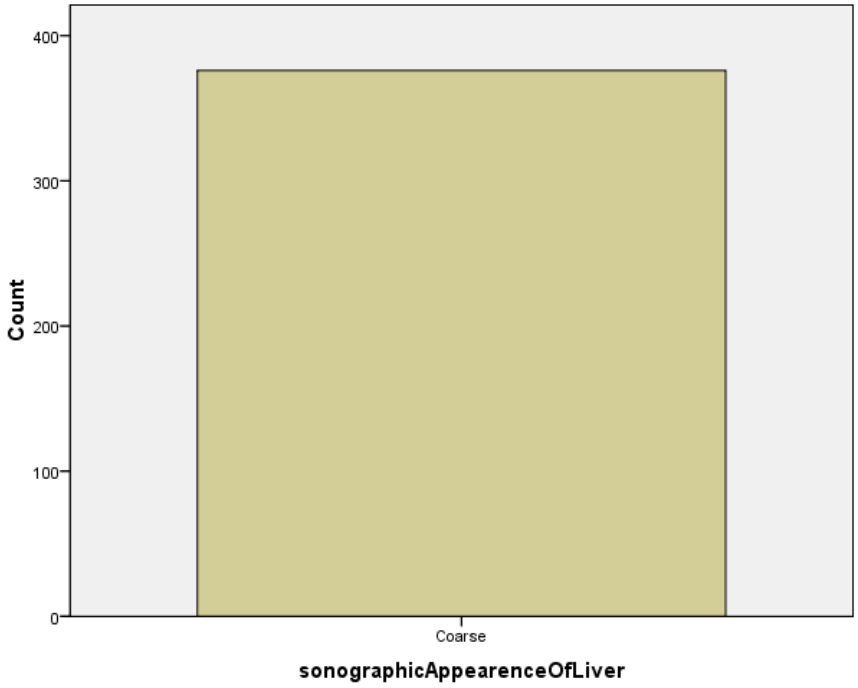
Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	f	123	32.7	32.7	32.7
	m	253	67.3	67.3	100.0
	Total	376	100.0	100.0	



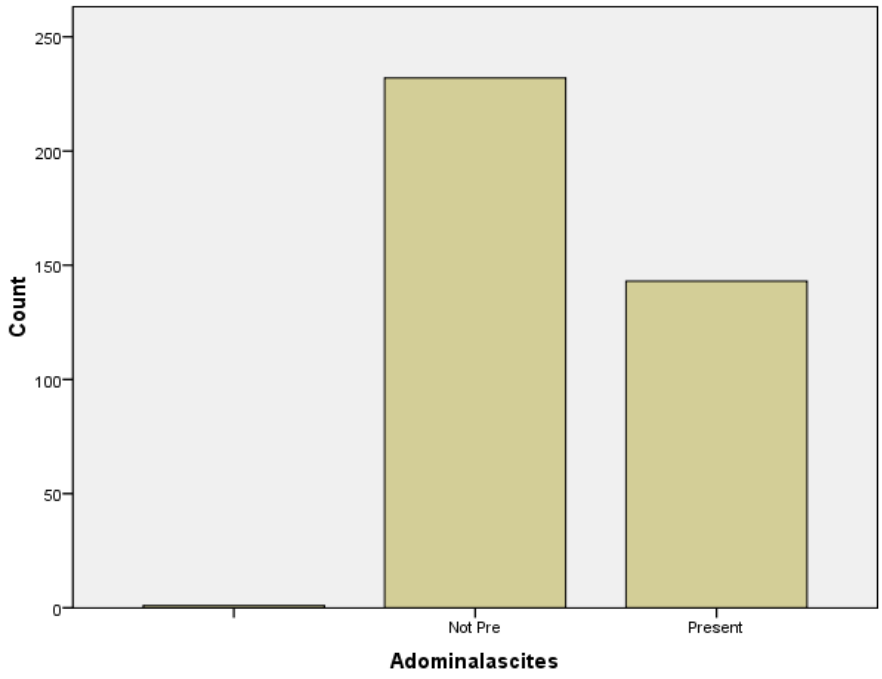
Sonographic Appearance of Liver

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Coarse	376	100.0	100.0	100.0



Abdominal ascites

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Pre	232	61.7	61.7	62.0
	Present	143	38.0	38.0	100.0
	Total	376	100.0	100.0	



Liver cirrhosis

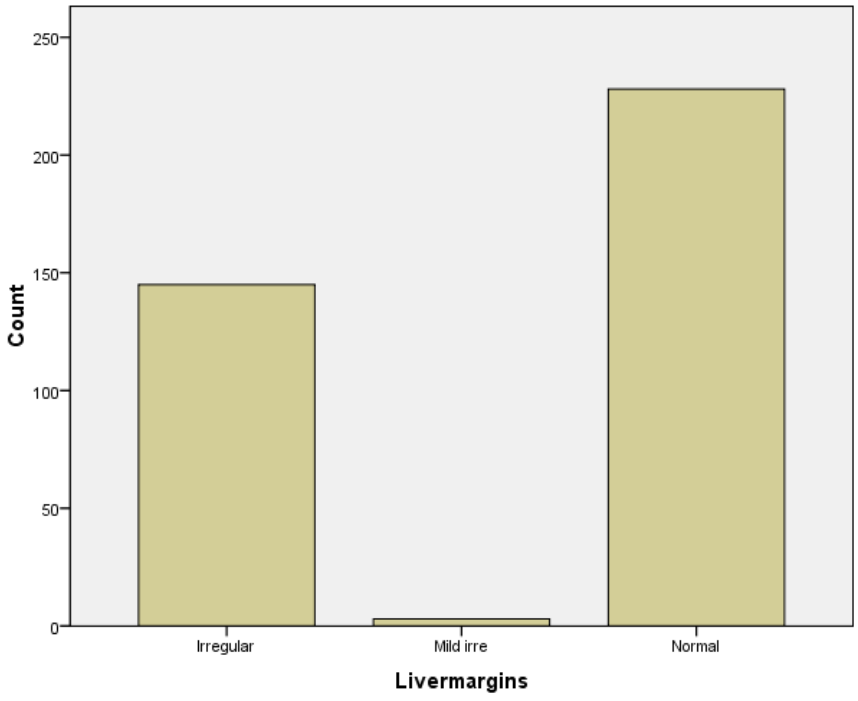
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Cirrhosis	144	38.3	38.3	38.3
	Not present	232	61.7	61.7	100.0
	Total	376	100.0	100.0	

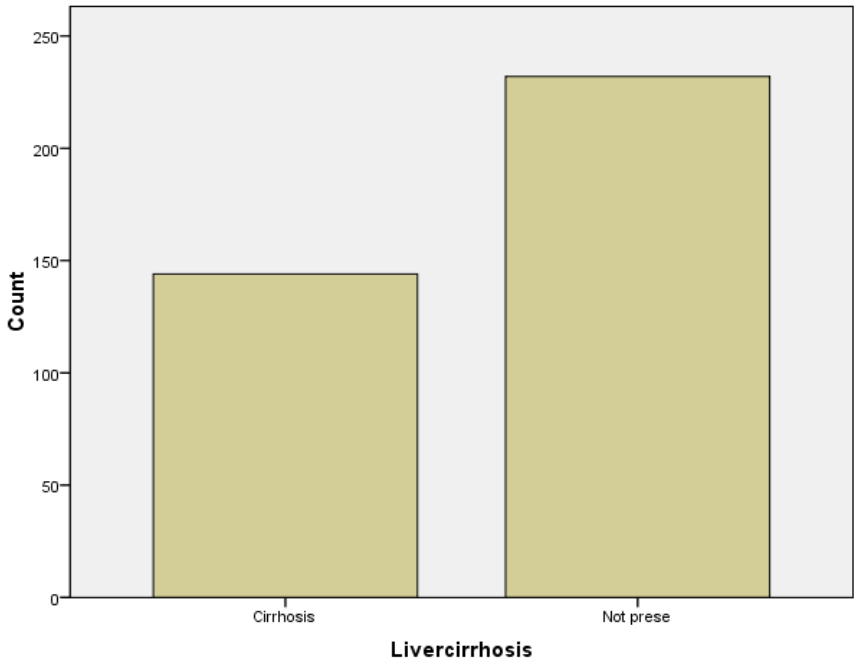
Abdominal ascites

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not Pre	232	61.7	61.7	62.0
	Present	143	38.0	38.0	100.0
	Total	376	100.0	100.0	

Liver margins

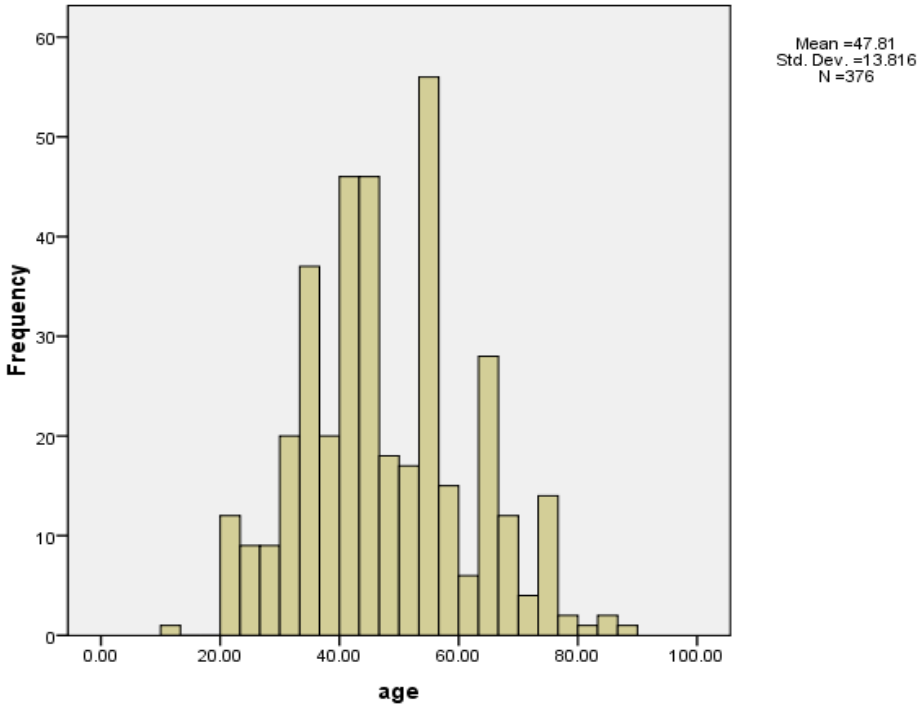
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Irregular	145	38.6	38.6	38.6
	Mild irregular	3	.8	.8	39.4
	Normal	228	60.6	60.6	100.0
	Total	376	100.0	100.0	





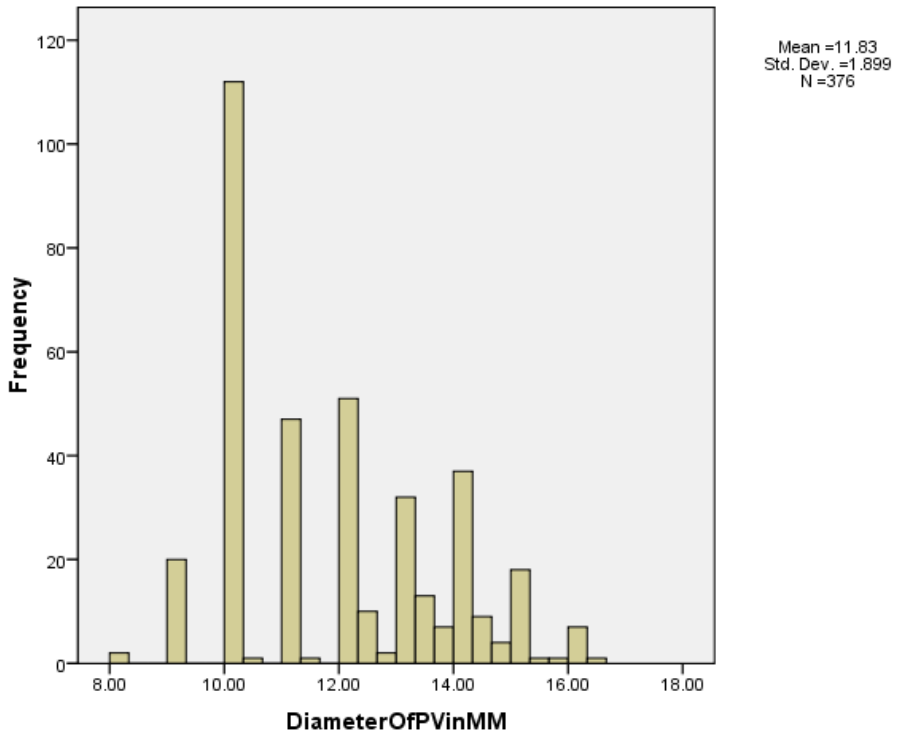
Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Age	376	12.00	87.00	47.8138	13.81603
Valid N (listwise)	376				



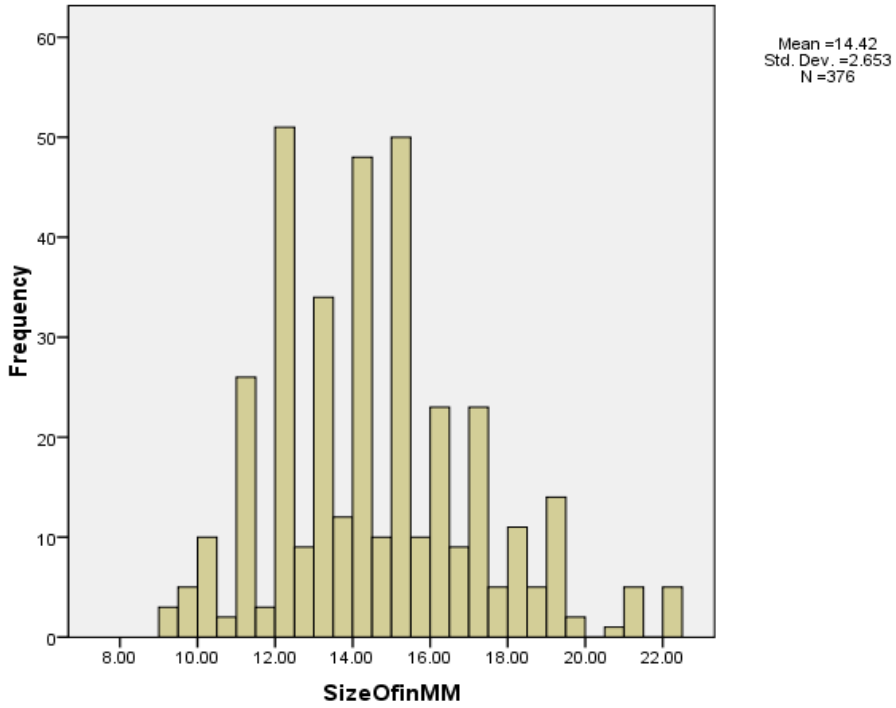
Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
DiameterOfPVinMM	376	8.00	16.50	11.8258	1.89866
Valid N (listwise)	376				



Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
SizeOfinMM	376	9.00	22.10	14.4191	2.65308
Valid N (listwise)	376				



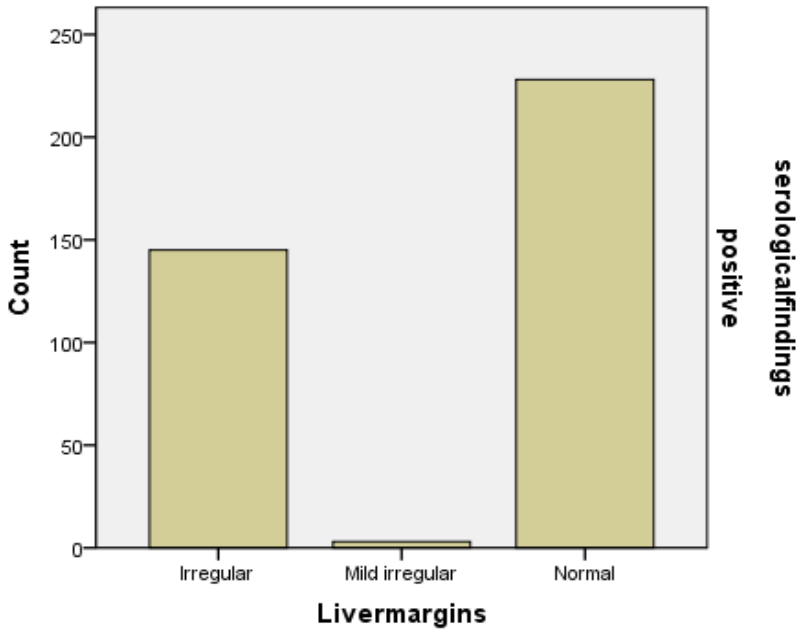
Liver cirrhosis * serological findings Cross tabulation
Count

		Serologicalfindings	Total
		Positive	
Livercirrhosis	Cirrhosis	143	143
	Not present	233	233
Total		376	376

Liver margins * serological findings Cross tabulation

Count

		Serologicalfindings	Total
		Positive	
Livermargins	Irregular	145	145
	Mild irregular	3	3
	Normal	228	228
Total		376	376



Discussion

Alexandra von herbay MD and Julia westendorff MD performed the study in 2009, examine the 209 patients surfing malignant focal lesions, 107 patients were included hepatocellular carcinoma,70 patients were metastases, 26 patients were cholangiocellular carcinoma and six others types of malignancy. 108 patients surfing focal lesion, 30 patients were regenerative nodules, 30 patients were hemangiomas, 13 patients had focal nodular hyperplasia, 12 abscesses, 8 necrosis, 7 steatosis areas, and 8 other benign lesions. In the last stage, 91% hypoenhancement as a result malignant lesion, 37% of a benign lesion. In the last stage, 20% hyperenhancement benign lesion, not a malignant lesion. Sonography value of diagnosis in sensitivity 90% ,specificity 99%, and accuracy 89% malignant lesion .

Another study was introduced by Y-F zhang MD, in 2012. He observed hypervascularity was 94.8%, macroregenerative nodules, and 60.0%, high- grade dysplastic nodules during arterial phase on ultrasound. Location rates of normal vascular example (i.e., hypervascularity amid blood vessel stage and ensuring washout) in HCCs with a distance across of <2.0 cm, 2.1-3.0 cm, and 3.1-5.0 cm were 69.2%, 97.1%, and 100.0% individually. Ultrasound altogether improved the affectability [88.8% (103/116)versus 37.1% (43/116),p<0.001] in separating HHCs from non-neoplastic injuries when contrasted and pattern ultrasound. Notwithstanding, the affectability and precision of ultrasound for HHCs <2.0 cm in measurement were altogether lower than those for HHCs of 2.1- 3.0 cm and 3.1-5.0 cm in the distance across.

Another study was introduced by IoanSporea, Alina Martie, Simona Bota in 2014. He detects from 1329 patients, and ultrasound was convincing for a particular pathology in 1102 cases (82.9%). For the separation of

benign/ malignant injury. Ultrasound achieved a definitive analysis in 1196 (90%) cases. The percentage of convincing ultrasound examination was altogether higher in patients without ceaseless liver infection as contrasted and those with unending hepatopathies 87.3% versus 74.4%($p<0.0001$).

Another study was introduced by ShahidSarwar, and Anwaar A. Khan in 2017. In this study, 216 patients included, liver cirrhosis was available in 112 (51.9%) patients, and 69(31.9%) were treatment experienced. Liver sickness was decompensated in 37 (17.1%) patients. 206 patients who finished examination convention, 173 (83.1%) accomplished SVR12, 89.2% (25/28) with triple treatment, and 82.2% (148/180) with sofobuvir/ ribavirin treatment. Treatment reaction was comparative between treatment innocent 86.2% (119/138) and treatment experience 79.4%(54/68) patients (p value 0.9) SVR12 was mediocre in cirrhosis patients 75.4% (80/106) when contrasted with those with no cirrhosis 93%(93/100) (p value <0.000). It was considerably lesser in those with decompensated liver ailment 68.8% (24/35).
In my study, total patients 376 included this study. Most of the patients were belong in rural areas. Major patients were 30-70 years old. In this study, both gender were included 123 female (32%) and 253 male (67.3%). Frequencies obtain abdominal ascites (62%), liver cirrhosis (38.3%), liver margin irregular (38.6%), mild irregular (39.4%).

Conclusion:

We observe that liver cirrhosis associated with hepatitis B and C virus more common in male than female. Rural areas are more effective by liver cirrhosis associated with hepatitis B and C virus.

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The Use of Pelvic Binders in Prehospital Management: Risk vs Reward

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Abstract
Pelvic binding devices are used in prehospital management of cases of severe physical trauma, such as falls and motor vehicle accidents. From briefly reviewing the published evidence of the procedure's risks and effectiveness, we conclude that binding represents an inexpensive and easily applied emergency strategy that offers pelvic stability while only minimally raising the risk of bleeding and other undesirable outcomes.

Keywords: Pelvic Binding, Prehospital Management, Emergency Medicine

Introduction

Severe blunt trauma, such as motor vehicle collisions and falls from a height, usually result in a constellation of injuries with multiple system involvement. The ideal management of such patients is constantly evolving. (1) An important consideration in these patients is the potential for pelvic fracture. In patients with multiple blunt trauma injuries, 5-16% receive pelvic ring injuries leading to a 11-54% mortality rate that primarily attributed to hemorrhagic shock. In cases where hemorrhage isn't controlled, the patient rapidly approaches the lethal triad of hypothermia, coagulopathy, and acidosis secondary to hypotension and hypoperfusion. (1) These outcomes can be prevented by pelvic binding, which is the act of compressing the pelvis, usually through the use of a pelvic binding device. Below, we present a brief overview insights gleaned from the academic literature into the value of pelvic binding in general prehospital care.

The Value of Binding

Binding reduces the diastasis in the fractured pubic symphysis, which is strongly associated with pelvic volume. A diastasis of 5 cm results in 20% increased pelvic volume, while a diastasis of 10 cm results in 35-40% increased pelvic volume. (2,3) Decreasing pelvic volume via binding produces a tamponade effect on soft tissues as well as vessels commonly involved in hemorrhage, such as the presacral venous plexus and iliac vessels. Resultant diminished bleeding and decreased clotting time is crucial for good patient outcomes. (1,4) The proposed mechanism of tamponade is supported by a cadaver study measuring pelvic pressure. Pelvic binding

with the T-POD (trauma pelvic orthotic device) increased the mean pelvic pressure to 24cm water compared to a 8cm water baseline representative of average central venous pressure. (5)

Recently, the value of early pelvic stabilization was recognized by Hsu et al at a level 1 trauma center in Taipei, Taiwan. (1) In a comparison between a historical group of suspected pelvic fracture patients where stabilization was applied after radiological confirmation of fracture and the study group of early stabilization, it was found that early stabilization resulted in lower average blood transfusion requirements in the first 24 hours, as well as overall lower mortality. A similar study 2017 comparing treatment outcomes of pelvic fractures in 2002 and 2013 by Fitzgerald et al recorded a decrease in mortality from 20% to 7.7% with updated protocols emphasizing early stabilization. (6) The importance of early stabilization is further corroborated by Schweigkofler et al, who found that early binding led to decreased risk of hemorrhage. (7)

While the benefits of early pelvic stabilization have been established, they require correct use of the preferred device. The correct placement of the pelvic binder at the level of the greater trochanters as opposed to superior placement contributes to a greater reduction of the pelvic ring and results in a better outcome for patient with pelvic fractures. It was found that high placement was associated with a larger (2.8X) symphyseal diastasis, in a 2017 study by Naseem et al. (8)

Of course, it is also important that the benefits of pelvic binding outweigh the technique's potential negative outcomes. The most commonly observed drawback with these devices is the development of pressure sores after prolonged use. Research suggests that prolonged skin pressures of 9.3 kPa or more result in the occlusion of capillaries resulting in hypoxia and necrosis, and sores are more likely to develop at bony prominences and in patients with lean fat content; such patients include the elderly and poorly nourished. (9) Skin pressure was also measured to be higher while patients were on a spinal board. (10)

Choice of Device

There are several pelvic binding devices available on the market. Most prominent are the T-POD (Trauma Pelvic Orthotic Device), the pelvic sling from SAM Medical Inc., and of course the simple bed sheet. In 2013, Pizanis et al found that the use of true pelvic binding devices was associated with the lowest rate of lethal bleeding compared to other devices. (11) This study compared the use of true pelvic binders to C-clamps and sheet wrapping, and found that the latter had an incidence of 23% lethal hemorrhage compared to 8% for c-clamps and 4% for pelvic binders. While this study supports the use of pelvic binders, it should be noted that the patients treated with pelvic binders in this sample were significantly younger than the other groups. The mean age was 26 for pelvic binder users, 47 for sheet users, and 42 for C-clamp users. (11) It is unclear whether these age differences negate the study's otherwise compelling findings.

Furthermore, in a cadaver study comparing the sheet wrapping and T-POD's ability to reduce pelvic ring fractures, only the T-POD showed statistically significant improvement in injury measurement. Symphyseal diastasis was reduced from 39.3 mm to 17.4 mm with the sheet, and 39.3 mm to 7.1 mm in the T-POD. The T-POD reduced symphysis to normal measurements of <10 mm in 75% of cases vs 17% of cases with the sheet wrap. (12) This study did not assess the SAM sling. A study in living patients measured hemodynamic stability and diastasis distance in patients with untreated pelvic fractures and hypovolemic shock. Measured before T-POD application and two minutes after application, heart rate and mean arterial pressure showed statistically significant improvements of 107 to 94 bpm and 65.3 to 81.2 mmHg respectively. (13)

While much of the literature purports that pelvic binders (usually referring to the T-POD) have benefits over sheet wrapping, there are several studies that compare the T-POD and the SAM sling. In a skin pressure study between the three devices, it was found that the SAM sling had the smallest mean contact area, and the highest skin pressure, although this pressure difference was not statistically significant. (14) A second study performed on cadavers measured the force required for complete reduction of the pubic symphysis as well as displacement of fracture fragments during reduction. Both the SAM sling and T-POD achieved closure with no adverse displacement. The SAM sling required 112+/- 10N for closure and the T-POD required 60+/- 9N. (10)

Lastly, Schweigkofler et al. (2017) recommends that patients with suspected pelvic fractures not be cleared without pelvic imaging, in order to rule out any suspected fractures. (7) This is because the application of a pelvic binder leads to the anatomical closure of the pelvic ring, which could underestimate the injury.

Conclusion

Pelvic injuries can range from benign to life-threatening with a high mortality rate. These injuries can occur not only in patients who sustain a high-energy impact mechanism from injuries, such as motor vehicle collisions and high falls, but also from minor mechanisms such as ground-level falls in the case of the elderly patients. When comparing the risk of missing a rapid uncontrolled occult pelvic hemorrhage into the retroperitoneal space to the risk of pelvic binding complications associated with pelvic bleeding, we conclude that the balance of evidence indicates a recommendation for the consideration of pelvic binders in prehospital managements in all patients with a suspected pelvic trauma. Pelvic binders are not only inexpensive and easy to apply in a prehospital sitting, but also offer pelvic stability while representing a low potential for associated complications.

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Patient Satisfaction with Care as Managed by the Physician Associate or the Doctor as Part of a Pilot Project in Ireland

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Abstract
Objective: The objective of this study was to examine if patients, visiting a hospital outpatient's clinic, were satisfied about the care delivered when a PA instead of a doctor is the provider. Methods: The study methodology was a descriptive quantitative approach using an eight-item survey and an option to include free text comments. Results: There was no difference in satisfaction levels between consultations with doctors or PAs, as part of a pilot project introducing the PA role. Conclusions: In Ireland, patients are just as satisfied with the care they received from PAs and doctors. Findings are consistent with findings in other countries where the PA role is embedded. In meeting the patient's needs, an important aspect of care given by both doctor and PA seems to be keeping the patient informed and behaving in a professional manner.

Keywords: Ireland, Out-Patients, Patient Satisfaction, Physician Associate

1. Introduction

Healthcare in Ireland has a two-tiered system of public and private services. The government-funded public hospitals are owned and run by the Health Service Executive (HSE) or are voluntary public hospitals, which may be privately operated but funded by the government. The public system, although providing similar quality care to private hospitals, is overbooked and waiting lists can be long, even for operations that demand some urgency. In fact, Ireland, together with the UK and Sweden, had the worst patient feedback on accessibility/waiting time problems among the 35 countries ranked by the EHCI, Ireland coming in at 21st place (Health Consumer Powerhouse (2016). The fact that Ireland has the highest percentage of the population (> 40 %) purchasing duplicate healthcare insurance could be regarded as an extreme case of dissatisfaction with the public system.

During the Irish recession, it is suggested that resources were not well deployed and cost savings were, in fact, 'false economies' (Williams & Thomas, 2017). According to these authors, the claimed financial savings was offset substantially by overtime payments, and the need to rely on more expensive agency workers. While a key focus in many countries during the time of austerity was to move away from a reliance on doctors in primary care, Williams & Thomas (2017) suggest that this was not a policy focus for Ireland. It seems that staff nursing

numbers fell during the period monitored (2008 -2014), but there was an increase in nurse specialists and therapists. In summary, a more efficient use could have been made of the resources, in particular, those deployed on agency staff and retirement packages offered. The opportunity of considering a Physician Associate/Assistant (PA) role to address the shortfalls in staffing is opportune. The challenges to meet health targets, shortage of doctors, over-reliance on secondary care without investment in primary care, have been political issues tackled by several Irish governments. The focus on healthcare can be seen to change, depending on which political party is in power. In 2016 the opportunity to form a committee across the political spectrum was provided. This committee developed consensus on a long-term policy direction for Ireland's healthcare system, to ensure that, in future, everyone has access to an affordable, universal, single-tier healthcare system, in which patients are treated promptly on the basis of need, rather than ability to pay (Houses of the Oireachtas, 2017).

Alongside these challenges and developments, a pilot project was set up with the Department of Health, in Ireland, to introduce the role of the PA in 4 surgical services in one large urban teaching hospital in Dublin. As part of an evaluation of a two-year pilot project (Joyce et al., 2019), the team undertook a study on patient willingness to be seen by a PA with surrogate patients who were not yet familiar with the role in Ireland (Joyce et al., 2018). The findings of the latter study suggest that patients are willing to see a PA, if they can be seen quicker than any other clinician. In other words, expediency is a primary motivator. The study presented here formed part of the overall evaluation of the pilot project and followed the focus of a study in the US (Hooker et al., 1997) comparing clinicians. Patient satisfaction was measured in two of the surgical services in a hospital where the PA role was being piloted. While the project commenced with 4 PAs (recruited from North America) across four services, there were two PAs in two services, in the second year of the project, when this data was collected. The other PAs returned to their country of origin. The aim of this study was to examine whether patients, visiting a hospital outpatient's clinic, were satisfied with the care delivered when a PA instead of a doctor was the provider. Embedded in this study is whether there is a correlation between the patient satisfaction and socio-demographic factors.

2. Methods

The study methodology is a comparative quantitative approach. There was an option to include free text comments at the end of the survey. During the four weeks of the study, there were 285 patients booked to attend the out-patients' clinics, sampled. Using convenience sampling, all were invited to participate in the study.

2.1 Data Collection

Data was collected via survey, with eight items, examining the effectiveness of communication of doctors and PAs with patients. A Likert-type scale was used, measuring agreement with statements from strongly disagree to strongly agree (on 5 levels). Using an instrument already tested (Counselman et al., 2000), communication and interpersonal skills were viewed as core attributes contributing to patient satisfaction. Patients were invited to complete the survey after their consultation with the PA or the doctor. The sample site is a training hospital with the supervising physician and trainee doctors attending to patients in the clinics. Some patients did not complete the survey. In some cases, this may have been due to the outcome of their consultation, for example, in the breast clinic, patients have an initial consultation with the doctor or PA. A follow-up mammogram is sometimes ordered, which necessitates the patient going to the radiology department and returning later to the clinic. Some of these patients may not complete the survey if they receive bad news, or they are stressed after the consultation. When it was noted by the researcher that patients seemed upset or stressed, they were not reminded about the survey on checking out.

3. Results

Data was analysed by descriptive statistics, and free text comments were analysed using content analysis.

During the four week period of data collection, 260 patients attended the outpatients' clinics across the two services sampled (15 patients in total did not attend their appointment as scheduled). Seventy-four completed surveys were returned (28% response rate), out of which 22 (30%) were seen by the PA and 52 (70%) by the doctor (supervising physician and/or trainee). Where patients saw both supervising physician and doctor/PA, they completed the survey for the first clinician encountered. Table 1 shows the characteristics of the survey respondents.

Table 1 Characteristics of Sample

Age (years)	**Seen By Supervising Physician**	**Seen by Doctor in training**	**Seen By PA**
	N=19	*N=33*	*N=22*
18-30 years	0%	4%	2.7%
31-40 years	10.8%	8.1%	12.1%
41-50 years	4%	17.5%	5.4%
51-60 years	2.7%	5.4%	2.7%
61-64 years	0%	2.7%	0%
65+ years	8.1%	6.7%	6.7%
Gender	*N= 14*	*N= 24*	*N= 20*
Female	18.9%	32.4%	27%
Male	6.7%	12.1%	2.7%
Education	*N= 19*	*N= 33*	*N= 22*
Primary School	6.7%	4%	1.3%
Secondary School	8.1%	20.2%	12.1%
Third Level	10.8%	20.2%	16.2%

As the clinics surveyed included a breast clinic, it is not surprising that the majority of the patients were female (77%) with 58% of the age group between the ages of 31-50 years. Both groups of patients were compared on age and education in addition to gender.

3.1 Differences in patient satisfaction

Overall there was no difference in the satisfaction rating with doctors and PAs (Table 2).

Table 2 Patient Satisfaction with Doctors and Physician Associates

Statement	**Strongly Disagree/ Disagree**	**Neutral**	**Agree/ Strongly Agree**
The clinician was courteous and respectful	1.3%	1.3%	97.3%
The clinician demonstrated understanding of my problem	1.3%	0%	98.6%
The clinician explained to me what he or she was doing and why	1.3%	1%	97.2%
The clinician used words that were easy for me to understand	1.3%	0%	97.2%
The clinician listened to my concerns and questions	1.3%	2.7%	95.9%
The clinician spent enough time with me	1.3%	2.7%	95.9%
I have confidence in the clinician's ability or competence	1.3%	2.7%	95.9%
Overall, I am satisfied the service that I received from the clinician	1.3%	1.3%	97.3%

Twelve out of the fourteen free text comments support these satisfaction levels.

Examples from consultations with the doctor include:

> *My doctor X was excellent today, very patient and kind, and answered all my questions. One of the best consultations I have ever had! (P02)*
>
> *Very approachable and a pleasure to deal with Y. Spoke in a manner that was very understandable. Also very pleasant (could see funny side). (P28)*
>
> *Very professional and courteous. (P63)*
>
> *I am happy with my treatment today. All staff were polite and friendly. (P56)*

Consultations with the PA were equally positive as indicated with this sample of comments:

> *A well-planned clinic. Very satisfied with service. (P10)*
>
> *I was very nervous. All the staff were friendly and put me at ease. Thank you. (P70)*
>
> *Out of all the appointments, this one has been the most informative and put me at ease. (P33)*
>
> *Z was very nice and helpful. (P44)*

Where improvements were indicated, the following comments were volunteered by two patients:

> *With respect to organising the appointment, it was a little unclear that I should have come in earlier to get the blood tests done. (P15)*
>
> *Extremely slow. Waited 2 hours for appointment. People with later appointment taken before me. (P41)*

While both patients (P15 and P41) were seen by a doctor, these comments relate to administration issues in organising the clinic and have been communicated to the appropriate staff. It is interesting to note that another patient had a very positive experience around wait time in the clinic:

> *So efficient, thank you. (P69)*

There were no significant differences found between satisfaction levels and age, gender, or education.

4. Discussion

Numerous studies (Hooker et al, 1997; Counselman et al, 2000; Hooker, 2001; Freeborn et al, 2002; Roblin et al, 2004; Hooker et al, 2005; Cipher et al, 2006; Budzi et al, 2010; Berg et al, 2012; Dill et al, 2013; Johnson, 2016; Kurtzman & Barnow, 2017; Meijer & Kuilman, 2017) have found that care given by the PA is at the level of that given by doctors with high levels of satisfaction. Patient satisfaction is believed to be an important component of healthcare because satisfied patients are more likely to seek medical advice, follow through with treatment recommendations, keep their follow up appointments, and maintain a good patient-doctor relationship (Levesque et al., 2000). This study found similarities with previous studies in that, once patients' needs are met and in particular, that they are communicated with, and informed of their health status, they are satisfied. For Ireland, this is the first study on patient satisfaction with a PA and a doctor because this is the first project piloting the PA role. Being a small exploratory study, it draws on previous studies and an instrument already tested. One study in the US compared the level of patient satisfaction with the PA and NP in people aged 65 years and older (Cipher et al., 2006) while an earlier study (Hooker et al., 1997) added certified nurse midwives and physicians as providers. There was no difference in patient satisfaction levels regardless of provider. Conclusions reached

for both studies are that patients do not generally distinguish preferences for types of providers once communication and interpersonal care needs are met. However, one study (Budzi et al., 2010) suggests that patients prefer to see NPs as compared with PAs and physicians because they focus on health promotion, disease prevention, health education, and counselling.

The PA development drive emerged from a scarcity of doctors, and the process for filling the void varies among countries (Ballweg & Hooker, 2017). The PA profession has emerged as a reasonable strategy for augmenting a stretched doctor cadre. According to a recent Irish report (Walsh & Brugha, 2017), there are three main medical workforce stressors that continue to undermine Ireland's ability to achieve medical workforce sustainability and compliance with the WHO (2012) Global Code on recruiting international health personnel. These include high rates of emigration among Irish medical school graduates, the need to comply with European Work Time Directive (restricted work hours for doctors), and increasing demand (Walsh & Brugha, 2017). The resulting dilemma is that the increased domestic supply of doctors is not sufficient to keep Irish hospitals staffed (Pflipsen et al., 2019). These findings support the consideration of a PA role to meet some of the current challenges to a sustainable medical workforce.

The small sample size is the main limitation of this study. The restriction to two services was due to there being a PA in each of these services, as part of a pilot project. The data collection timeframe coincided with the first national patient experience survey in Ireland (HIQA/HSE/Department of Health, 2017). Some of the patients had already received an invite to take part in the national survey if they had been inpatients in the hospital during the month of May. This confusion may have reduced the response rate. Where the patient was seen by a trainee doctor/PA and supervising physician, they may have evaluated their overall satisfaction with the consultation. Furthermore, unless the PA introduced themselves, the patients were not aware of been seen by a different provider. The researcher noted that some patients marked ‘doctor' on the survey even though they had their consultation with the PA. Lessons learned from the study included the importance of having a researcher (who is not a clinician) on-site in the clinics to check the surveys following its completion, and to remind the patients, on checking out, to return the survey if they were willing to complete it. Further research is needed with a larger sample of patients over a longer timeframe. Data was collected the month prior to doctors in training rotating to different services. Clinical rotations occur in these services three and six monthly.

This study suggests that patients, in Ireland, are just as satisfied with care they received from PAs and doctors. Findings are consistent with those in other countries where the PA role is embedded. In meeting the patient's needs, an important aspect of care given by both doctor and PA seems to be keeping the patient informed and behaving in a professional manner. Although the findings are based on a small pilot study, where patients are unfamiliar with the PA role, it is encouraging for the introduction of the role in Ireland. It seems that the provider of care is less important than meeting the interpersonal needs of patients. The qualitative data (via free text) supports the importance of professionalism and good communication skills with patients, including putting patients at ease and communicating in a method that is understandable to them. Although the pilot project focused on specific areas of surgery, feedback is positive from colleagues in medicine and primary care where Irish PA graduates have now secured a role, as per the global trend. The opportunity to expand the PA role across the broader health system in Ireland is being considered, and the future is hopeful for further expansion of the role.

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Idiopathic Acute Pancreatitis (IAP): The Value of Endoscopic Ultrasound

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Abstract
Introduction: Acute pancreatitis with unknown etiology comprises about 10-30% of all cases of acute pancreatitis. Endoscopic ultrasound is an important tool for revealing etiologies of the unknown causes of acute pancreatitis. The aim of this study was to evaluate the role of endoscopic ultrasound in sorting out the cause of idiopathic acute pancreatitis. Materials & Methods: It was a cross-sectional study which was carried out in the department of gastroenterology of Sir Salimullah medical college & Mitford hospital from January 2013 to December 2017. A total of 109 patients suffering from acute idiopathic pancreatitis were enrolled in this study. Underlying etiologies could not be detected after thorough history, physical examinations, blood tests, ultrasonography, CT, and/or MRI. These patients underwent endoscopic ultrasound under proper sedation after taking informed consent. Results: Among the 109 patients, 67 were male and 42 were female (P=0.03). Number of patients below 40yrs of age were 67 and above 40 years of age were 42 (P=0.01). Moreover, 81 patients had their gall bladder in situ and 28 had previous history of cholecystectomy (P=0.001). Microlithiasis 20 (24.6%), common bile duct stone or sludge 20 (24.6%), ampullary neoplasm 20 (24.67%), early stage of chronic pancreatitis 12 (14.8%), biliary ascariasis 08 (9.8%), small pancreatic head tumor 02 (2.5%) and pancreatic divisum 02 (2.5%) were found out as the underlying etiologies of idiopathic acute pancreatitis patients who had intact gall bladder. In patients who underwent cholecystectomy; endoscopic ultrasound revealed chronic pancreatitis 04 (14.3%), common bile duct stone or sludge 20 (24.6%), biliary ascariasis 06 (21.4%) and ampullary neoplasm 01 (3.5%) as the hidden causes of idiopathic acute pancreatitis. Conclusion: Gastroenterologists face difficulties to diagnose the actual etiology of idiopathic acute pancreatitis. As endoscopic ultrasound shows high efficacy and accuracy to detect etiologies in such cases; it can be included as a first line investigation in idiopathic acute pancreatitis.

Keywords: Endoscopic Ultrasound, Idiopathic Acute Pancreatitis, Microlithiasis, Common Bile Duct Stone, Gall Bladder Stone.

Introduction

Inflammation of pancreas without any previous morphological changes on imaging studies is termed as acute pancreatitis (Bradley, 1993). Biliary stones, alcohol, hypercalcemia, hypertriglyceridemia, drugs and trauma are the common causes of acute pancreatitis (Al Haddad & Wallace, 2008). The etiology of acute pancreatitis remains idiopathic in about 10-30% of patients even after thorough history, examination and noninvasive imaging studies (Villa, 2010). So, idiopathic acute pancreatitis is a diagnostic and therapeutic challenge for gastroenterologists (Al Haddad & Wallace, 2008). It is more prone to develop recurrence and also related to disease-specific morbidity and mortality (Saleem et al, 2015) .In this context, endoscopic ultrasound may help to identify the exact underlying etiology (Villa et al, 2010; Frossard et al, 2000; Tandon & Topazian, 2001; Coyle et al, 2002; Liu et al, 2000; Yousoff, Raymond & Sahai, 2004). It is a minimally invasive test which can provide high-resolution visualization of the pancreas (Sivak & Kaufmann, 1986; Hisanga et al, 1980).

It is found that microlithiasis is a major cause of idiopathic acute pancreatitis with gall bladder in situ. On the other hand, chronic pancreatitis is the common cause in patients' previously undergone cholecystectomy (Ros et al, 1991). Previously, microscopic examination of bile (Ros et al, 1991;Neoptolemos et al, 1988), endoscopic retrograde cholangiopancreatography (ERCP) (Neoptolemos et al, 1988;Gregor, Ponich & Detsky, 1996)and magnetic resonance cholangiopancreatography (MRCP) (Testoni et al, 2008) have been used to find out the actual etiology of idiopathic cases. But ERCP has more complications than endoscopic ultrasound (Petrov & Savides, 2009). In case of MRCP, it has lower diagnostic yield than endoscopic ultrasound in idiopathic pancreatitis patients (Ortega et al, 2011). Moreover, EUS has several other advantages such as detection of small stones (<5mm), small tumors (Al Haddad & Wallace, 2008) and chronic pancreatitis (Irisawa et al, 2007). But data regarding the value of endoscopic ultrasound for diagnosing idiopathic acute pancreatitis is limited. The aim of our study was to evaluate the role of EUS in detecting etiologies in idiopathic acute pancreatitis.

Materials & Methods

It was a cross-sectional study with study period of 3 years lasting from January 2014 to December 2017.Total of 109 patients who were referred to the department of gastroenterology of Sir Salimullah Medical College as diagnosed case of acute pancreatitis of unknown etiology after thorough history, examination, investigations especially imaging studies like USG, CT/MRI; were enrolled in this study. Alcoholics, patient suffering from recent infections, history of recent abdominal trauma or surgery and persons taking drugs which may cause pancreatitis were excluded from the study.

All the 109 patients gave informed consent. Their age, sex and demographic features were noted down with interest. Routine blood examination, liver function tests, ultrasonography reports and CT/MRI reports of these patients were collected. Afterwards, all patients underwent endoscopic ultrasound examination in an interventional suite. Endoscopic ultrasound was done under sedation. It was carried out by Fujinon echoendoscope (Model EG-530 UR_2 for radial array and E-530 UT_2 for linear array). The findings of endoscopic ultrasound were written and compared with their respective trans abdominal ultrasound and CT/MRI reports.

The statistical analysis was done by SPSS 20.0 software (SPSS, Inc. USA). Statistical significance was calculated by Pearson Chi square test. Differences in age of the patients were compared by Students't test. Statistical significances of the study was set at <0.05.

Results

Total of 109 patients took part in the study. Of them, 69 were male and 40 were female with good statistical significance (P=0.03).Total 67 patients were below 40 years of age while 42 patients were above 40 years of age (P=0.01). Among the patients, 81 patients had gall bladder in situ and 28 patients had history of cholecystectomy. Table below shows the results of the study.

Fig 1: Distribution of sex in idiopathic acute pancreatitis

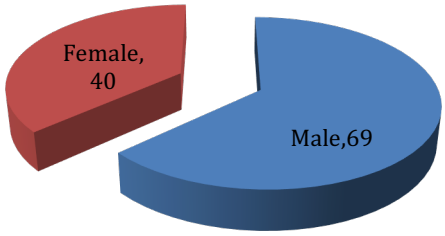
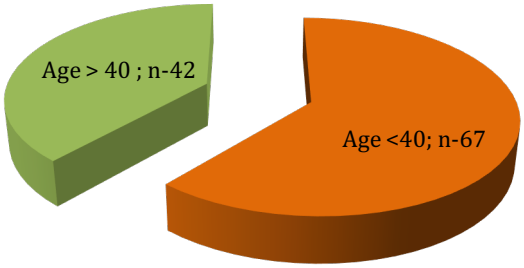


Fig 2: Distribution of age in idiopathic acute pancreatitis



Among the patients, 81 patients had gall bladder in situ and 28 patients had history of cholecystectomy. Table below shows the results of the study.

Parameter	Intact gall bladder group	Cholecystectomy group	Total	P Value
Number of patients	81 (74.3%)	28(25.7%)	109(100%)	**0.001**
Microlithiasis or GB sludge	20 (24.6%)			
Chronic Pancreatitis	12 (14.8%)	04 (14.3%)	16(14.67%)	0.853
CBD stone or sludge	20 (24.6%)	20 (24.6%)	40(36.7%)	**0.001**
Biliary ascariasis	08 (9.8%)	06 (21.4%)	14(12.84%)	**0.028**
Ampullary neoplasm	20 (24.6%)	01 (3.5%)	21(19.27%)	**0.001**
Small pancreatic head tumor	02 (2.5%)			
Pancreatic divisum	02 (2.5%)			

Table 1: Comparison between two groups of patients with intact gall bladder and removed gall bladder with endoscopic ultrasound diagnosis (GB- gall bladder, CBD- common bile duct).

Endoscopic ultrasound revealed etiologies in 46 (56.79%) patients previously diagnosed as idiopathic acute pancreatitis having gall bladder in situ. Of the 28 patients suffering from idiopathic acute pancreatitis with cholecystectomy, endoscopic ultrasound revealed etiologies in 13 patients.

Discussion

When the etiology could not be identified on initial evaluation of patients suffering from acute pancreatitis or recurrent acute pancreatitis, it can be defined as idiopathic acute pancreatitis (Levy & Geenen, 2001; Somani & Navaneethan, 2016; Lee, Nicholls & Park, 1992). Indication of endoscopic ultrasound in these patients is to find out the etiology to prevent further attacks. The common causes of idiopathic recurrent acute pancreatitis are bile duct stones, gall bladder sludge, microlithiasis, pancreatic cancer and early chronic pancreatitis. Endoscopic ultrasound plays pivotal role to diagnose these conditions (Ortega et al, 2011; Prat et al, 1996; Sahai et al, 1998; Catalano et al, 1998; Dill et al, 1995; Dahan et al, 1996; Baillie, 2001)

Total of 109 patients of acute pancreatitis with unknown etiology were enrolled in the study. Of them 69 were male and 40 were female (P= **0.03**) showing higher prevalence in male which is consistent with previous studies conducted in Bangladesh (Ahmed et al, 2016; Ahad, 2016) and Frossard et al in Europe (Frossard, Steer & Pastor, 2008). Moreover, 67 patients were below 40 years of age while 42 patients were above 40 years of age with good significance (P=**0.01**). It shows idiopathic acute pancreatitis is more common in young age which is consistent with previous studies (Elzouki et al, 2019).In foregone studies, among the patients of idiopathic acute pancreatitis about 20-50% presented with microlithiasis (Liu et al, 2000;Ros et al, 1991;Dill & Dill, 2002;Lee & Nicholls, 1986;Levy, 2002) , 15% with chronic pancreatitis(Wilcox & Kilgore, 2009), 25% with common bile duct stone (Choudhary et al, 2016) and about 3.2% with pancreatic cancer (Tandon & Topazian, 2001). Our study almost resembled those previously found data. In fact, patients having their gall bladder in situ with idiopathic acute pancreatitis showed microlithiasis (24.6%), chronic pancreatitis (14.8%), common bile duct stone (24.6%) and small pancreatic tumor (2.5%) as the main causes. Patients with operated gall bladder showed common bile duct stone (24.6%) and biliary ascariasis (21.4%) as the leading causes in our study. But Choudhary NS et al showed early chronic pancreatitis (38.6%) as the main cause of idiopathic acute pancreatitis

in patients who underwent cholecystectomy (Choudhary et al, 2016). Khuroo MS and associates showed that biliary ascariasis is found in 23% of acute pancreatitis patients in South East Asia which is 21.4% in our study (Khuroo et al, 2016).

There were some limitations in our study especially the findings of endoscopic ultrasound were not compared with ERCP or MRCP findings in all cases. Still this study goes a long way to make the physicians aware of the causes and value of endoscopic ultrasound in diagnosing idiopathic acute pancreatitis.

Conclusion

About one-third patients of acute pancreatitis are idiopathic. Diagnosis of exact etiology of these patients, are a challenge for clinicians. Endoscopic ultrasound is a useful means which has a high accuracy to diagnose such cases. So, it should be considered as the first line investigation for the diagnosis and management of patients of acute pancreatitis with uncertain etiology.

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Weight Changes and Cognitive Functions in Patients with Stroke: Case Report

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Abstract
Objective of the study: Cognition is an important factor for determining the rate of recovery of stoke so finding the factors that might affect cognition is important to improve it and so to improve recovery rate in patients with stroke. Methodology: Fifteen chronic stroke male patients were recruited to this study. The patients age ranged from55 to 65. All patients were assessed for body mass index (BMI) and also for cognitive functions by Montreal Cognitive Assessment (MOCA) scale and rehacom. Results: the study found a Negative strong correlation between MOCA and BMI (R= -.95),Negative moderate correlation between BMI and Attention(R=-.66) ,Weak negative correlation between BMI and memory (R=-.38),Weak positive correlation between MOCA and memory (R=.38),Moderate positive correlation between MOCA and attention (R=.61) and Strong positive correlation between memory and solutions (R=.77).Conclusion: There is a negative correlation between BMI and cognition, so it should consider body weight management in the rehabilitation of stroke patients to improve cognitive functions.

Keywords: Stroke, Cognition, Attention, Memory, BMI, Rehacom, MOCA

Introduction

The brain has to interpret, organize, and store the information. This is the way to do daily activities. A stroke can affect any part of this process, from picking up the information to planning how to respond (Isabel et al.,2019).

Stroke is one of the primary causes of death and disability worldwide. Cognitive impairment frequently occurs after a stroke. This impairment is a significant factor in delayed functional recovery. Post-stroke cognitive impairment is common in the acute stage. Cognition is a predictor factor of long-term recovery.There is the development of new-onset cognitive impairment or a worsening of cognition in up to 50% of those who have survived a stroke in the chronic stage also (Obaid et al.,2018; Mellon et al.,2015). The recovery of cognition depends on the stroke lesion's size and location(Rosaria et al.,2018; Nys et al.,2005). There are also other factors that might affect cognition as age of patients, drugs, psychological state, level of physical impairment, gender, nature of nutrition and weight of patients might also affect cognition (Pushpendra et al.,2015).

Cognition involves many domains as memory, attention, perception, planning (apraxia), making decisions, and social cognition. Studies exploring relationships between obesity and cognitive impairment in the elderly(Ira et

al.,2011).Identifying the risk factor of cognition for stroke patients is important because if the doctors could minimize or control it, the recovery of patients with stroke could improve, and the level of impairment could decrease.From this concept, the purpose of this study was to identify if there is a relation between cognition and weight or body mass index(BMI) as no study was done to assess relationships between obesity and cognitive impairment in patients with stroke.

Methodology

Fifteen male patients diagnosed as ischemic chronic stroke were recruited from the Outpatient Clinic of faculty of physical therapy, Cairo University. A written informed consent was signed by the patient before starting the study. The study was conducted from March 2017 to March 2018. All the patients had a primary level of education only. Age of patients ranged from 55 to 65 years old, and All the patients were assessed for weight and length to calculate body mass index (BMI) through the equation :

Formula: weight (kg) / [height (m)]^2

The formula for BMI is weight in kilograms divided by height in meters squared. If height has been measured in centimeters, divide by 100 to convert this to meters.

Or through Formula: 703 x weight (lbs) / [height (in)]^2

When using English measurements, pounds should be divided by inches squared. This should then be multiplied by 703 to convert from lbs/inches2 to kg/m2.

Also, all the patients were assessed for the level of cognition by using MOCA scale and rehacom;

Montreal Cognitive Assessment scale MoCA-A is a 30 points scale that assesses cognitive functions in adults. It is a screening test as it is sensitive to minor impairment in cognitive domains (Zixu et al. ,2018).

Alternating trial making, visuoconstructional skills, naming, memory, attention, serial 7s, sentence repetition, verbal fluency, abstraction, delayed recall, and orientation are sections of MoCA scale. The Arabic version of MOCA-A test was used in this study, and it was validated in Egyptians (Rahman & El Gaafary., 2009).

This scale has two parts: part written by the patient about solving alternating trial making, visuoconstructional skills, and the serial of seven. The remaining sections of the scale were asked orally by the researcher to the patient. Illustration of each section was given to the patient before solving. Each section was scored, then the total score was calculated (Zixu et al. ,2018).

Patients were assessed also using a computer-based software Rehacom. The Rehacom software contains 32 tasks for assessment of Attention & concentration and vigilance, Memory and learning ability, Visuo- motor co-ordination, Reaction time and precision, Visuo- constructive ability and problems Solving and developing strategies. The Rehacom composes regular PC, 1G RAM, DVD drive, 100 GB hard drive with Windows XP SP3, 128 MB RAM direct 3D graghic card, screen at least 19, regular PC Keyboard or Rehacom panel and printer. The software version is (patient enpult (1990-1997)EN/ISO-13485-certified) (Mattioli et al., 2010).

The available modules in Egypt are attention & concentration, figural memory, logical reasoning, and acoustic reactivity. The logical reasoning and acoustic reactivity module were difficult for the education level of our patients, so we used attention &concentration and figural memory modules in this study.

For each module, every task was illustrated for all patients before starting the assessment to be familiar with the procedure of assessment. Patients received no help during the assessment procedure. Time was set at twenty continuous minutes, and if the patient suffered from fatigue (complaint of the patient or repeated errors after correction) at any time during the assessment, the pause was set. An obligatory five minutes rest was obtained between the two parts of the assessment.

For attention and concentration measurement; Level one was selected, then the patient was asked to select a specific picture from a matrix of pictures on the screen. Levels had many tasks if the patient made a wrong answer, another trial was allowed. This increased the time of the levels. Depending on the right answer of the patient and reaction time, the duration of every level was increased or decreased. Values were calculated as the average values of all tasks during the assessment session.

The figural memory module of Rehacom is composed of two phases: acquisition phase and solution phase. Factor words were set at 7 with normal speed. The acquis. Picture- repro. Picture training mode was selected. Pictures were selected as words were available only in the English language, and all patients did not have knowledge of the English language.

During the acquisition phase, a picture or group of pictures was shown to the patient, and the patient was asked to press ok after memorizing them immediately. The duration of this phase was increased or decreased depending on the speed of memorization of figures. The number of pictures depends on the level of difficulty.

During the solution phase, the patient was asked to remember pictures of the previously shown pictures. In this section, a screen of pictures was passing in front of the patient. The screen was passing from right to left. All patients were asked to select only the pictures which were selected in the acquisition phase when passing inside the area marked by 3 red arrows. Data obtained from the figural memory module were acquisition time and solution time.

Data collection and statistical analysis

All variables of BMI and MOCA scores and rehacom variables of attention, acquisition, solution, and memory were collected and correlated together to find which variables of cognition measurement correlated with BMI.

The correlation was done through SPSS package of statistical analysis by Pearson's Correlation Coefficient. Pearson's correlation coefficient (r) is a measure of the strength of the association between the two variables. Pearson's correlation coefficient (r) for continuous (interval level) data ranges from -1 to +1. “0” means there is no relationship between the variables at all, while -1 or 1 means that there is a perfect negative or positive correlation. Values between 0 and 0.3 (0 and −0.3) indicate a weak positive (negative) linear relationship through a shaky linear rule. Values between 0.3 and 0.7 (0.3 and −0.7) indicate a moderate positive (negative) linear relationship through a fuzzy-firm linear rule. Values between 0.7 and 1.0 (−0.7 and −1.0) indicate a strong positive (negative) linear relationship through a firm, linear rule.
Results:

Mean values of age 60.87 ±1.03, mean values of MOCA scores 21.33±.82, mean values of BMI 25.67±1.12, mean values of attention4.13±.52, mean values of memory 3.07±.35, mean values of acquisition 6.2±.55 and mean values of solutions 44.27±2.1.

From the data representing in (table 1); there is a moderate negative correlation between BMI and attention (-.65) (fig.1)and weak negative correlation between BMI and memory (-.37) (fig.2). There is also a strong negative correlation between MOCA scores and BMI (-.95) (fig.3).

There is a moderate positive correlation between MOCA scores and attention (.61) (fig.4) and between MOCA scores and memory (.38) (fig.5) while there is a positive, strong correlation between solution time and acquisition (.76) (fig.6).

Table 1: correlation between BMI and different variables of cognition

	age	*MOCA*	*BMI*	*attention*	*memory*	Acquisition	Solution
age	1						
MOCA	-0.02437	1					
BMI	-0.1181	**-0.95031**	1				
Attention	-0.09612	**0.61219**	**-0.65486**	1			
Memory	0.06873	**0.381835**	**-0.37846**	0.211029	1		
Acquisition	0.147262	-0.0213	0.062409	-0.17635	-0.05578	1	
Solution	-0.1438	0.118862	-0.03324	0.071378	**0.769478**	0.045882	1

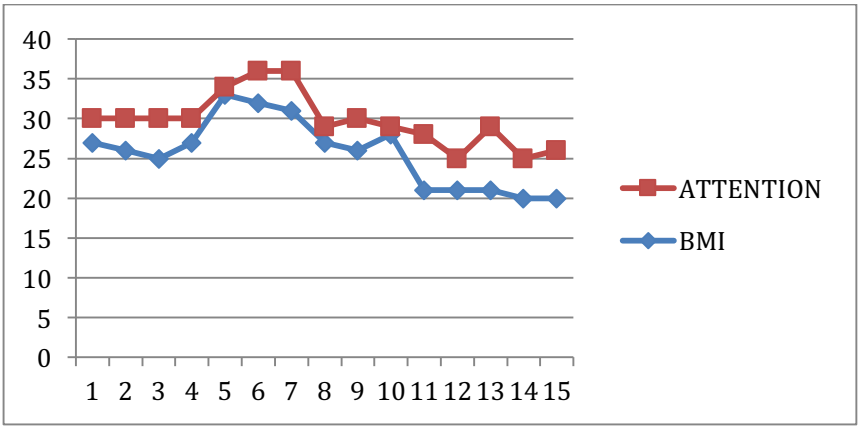

Fig 1: Negative moderate correlation between BMI and Attention.

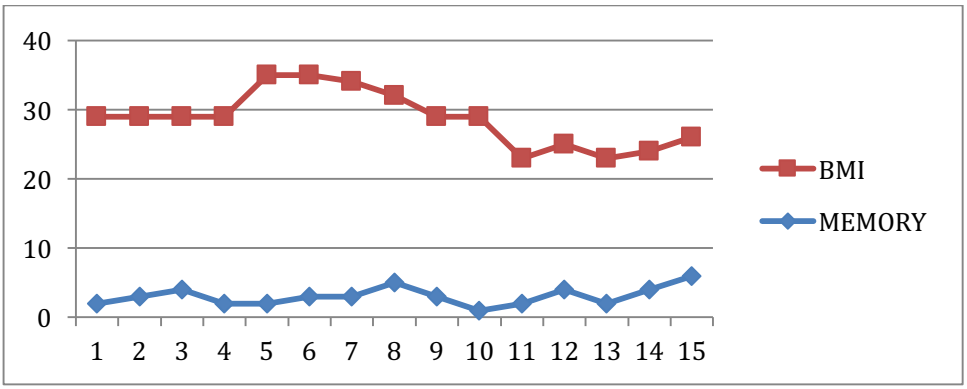

Fig 2: Weak negative correlation between BMI and memory.

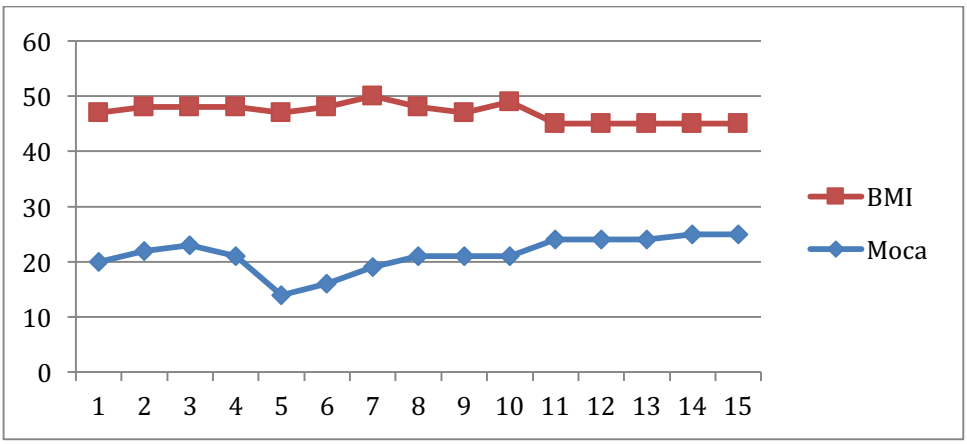

Fig 3: Negative strong correlation between MOCA and BMI.

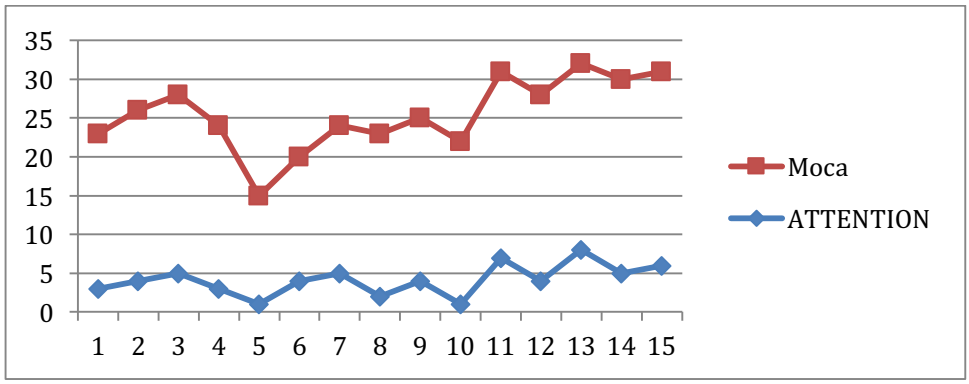

Fig.4: Moderate positive correlation between MOCA and attention.

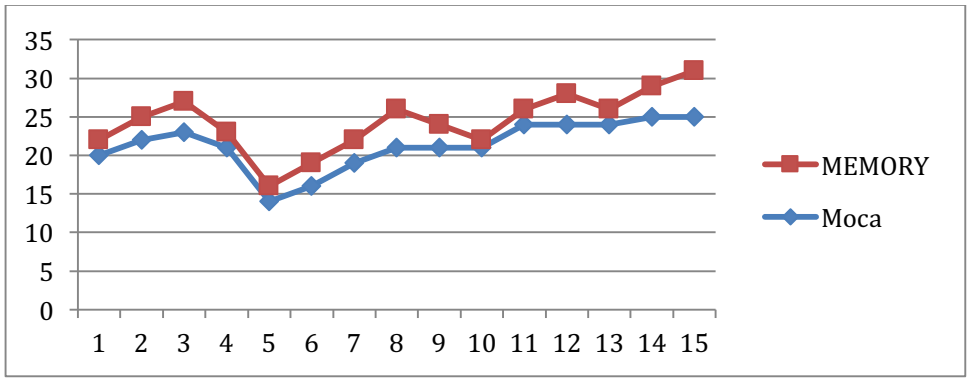

Fig.5: Weak positive correlation between MOCA and memory.

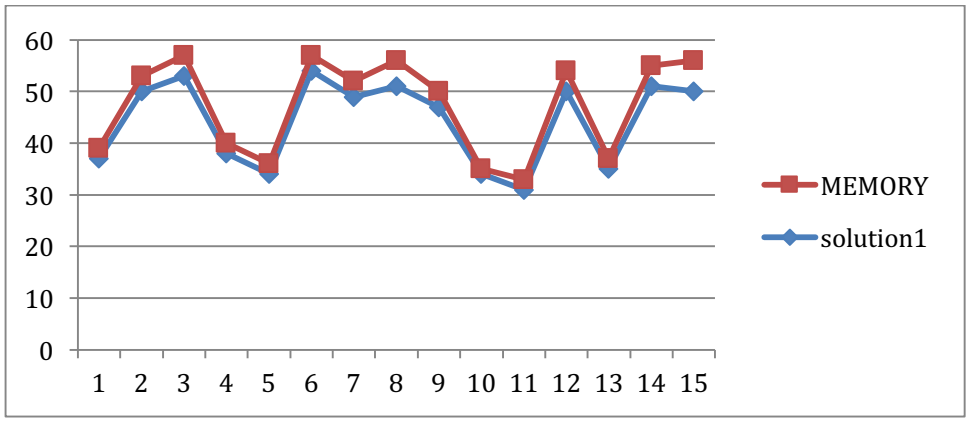

Fig 6: Strong positive correlation between memory and solutions.

Discussion

From the results of our study, there was a negative correlation between BMI and cognition as there was a negative correlation between BMI and MOCA scores and also between it and attention measurement and also between it and memory but for the correlation of memory it was a weak one.

The negative correlation between BMI and cognition might be attributed to overweight and obesity are abnormal or excessive fat accumulation that might impair health. In order to classify overweight or obesity, the body mass index (BMI) is used as an index of weight-for-height in kilograms per square meter (kg/m2). A BMI higher than 25 indicates overweight, whereas a BMI equal to or higher than 30 indicates obesity (Volkow et al.,2009).

There is growing evidence that higher BMI is related to both structural and functional brain differences. BMI was found to relate linearly to reduced prefrontal metabolism in healthy adults with a BMI between 19 and 38 kg/m2.Brain and total gray matter volume are reduced as well as white matter tract integrity (Stanek et al.,2011).

High BMI is associated with chronic low-grade inflammation and with augmented production of pro-inflammatory cytokines.Cytokines released at the periphery of the body are known to enhance the production of brain-produced cytokines. Interestingly, there seems to be a solid there is a link between the effects of inflammation in the brain and the release of dopamine (DA). Overweight and obesity are associated with less responsive DA functioning, less striatal DA-D2/D3 receptor density, and diminished phasic striatal DA signaling. Reductions in baseline prefrontal metabolism were related to decreased memory- and executive performance, often thought to rely on fronto-striatal structures (Frank et al.,2012; Felger et al.,2015).

Memory affection was significantly more common in chronic stroke .an overall prevalence of mild cognitive impairment (MCI) detected based on neuropsychological testing was 14.89% (95% CI: 12.19 to 17.95). Prevalence of the amnestic type was 6.04% (95% CI: 4.40 to 8.1), and that of the multiple domain types was 8.85% (95% CI: 6.81 to 11.32). Adjusted for age, education, and gender, the amnestic type was more common among men and the multiple domain types among women with the advancement of age. Rates differed considerably with educational attainment. Hypertension and diabetes mellitus were the major risk factors for both types of MCI (Pushpendra et al.,2015). And both risk factors are related to obesity so our study confirms that BMI or obesity is correlated to cognition as attention and memory .the higher the BMI the lower the cognitive function of stroke patients so on treatment of stroke patients body weight should be considered as to improve body performance and cognition as cognition not depend only on lesion but also on body weight.

Our study found a correlation between MOCA scores and memory and attention, which were measured by rehacome, which is considered an objective tool to assess cognition functions. The correlation was weak for meamory but moderate for attention, that means that MOCA could be an objective tool to assess attention than a memory.

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Sexuality in Marriage: A Case Study of 1 Corintians 7:1-9

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Abstract
The Apostle Paul writes to the Corinthian congregation one of the churches he established about A.D 55. The Corinthian church had some challenges, one of which had to do with the morality of sexuality to both the unmarried and married. To the unmarried, whether men or women the counsel he gave them was not to have sexual contact with anyone since sexual intercourse is allowed only in a marriage setting. The unmarried should control their sexual passions, but if they cannot continue to control themselves, then it is better for them to get married. The married husbands and wives are allowed to have sexual intercourse with their spouses. They should, by all means, try to avail themselves to their partners sexually because are obligated to satisfy each other. If for some reason would like to refrain themselves from sex, it should be something agreed between the two of them for whatever reason are advancing, but it should be for a short time. It could be for day or so, and thereafter they resume having sex together because for not having sex would be an abnormal practice. Unfortunately, some married couples do not have free access sexually to their partners, and as a result, these unhealthy relationships lead to immoral practices. If married couples would take Paul's counsel seriously, they would prevent many immoral sexual practices happening in our society today. Sometimes, husbands and wives though do not feel interested to have sexual intercourse with their partners when they are not sick, they should oblige for their spouses' sake to have sexual intercourse with them so that there is no room to encourage their husbands or wives to consider having sex with other men or women who are not their married couples.

Keywords: Sexuality, Marriage

BACKGROUND TO THE TEXT

The immediate context of 1 Corinthians 7:1-9 is 1 Corinthians 5 & 6 and its fourfold. The first context is the practices of sexual immorality in the Corinthian congregation, which the Apostle Paul found taking place. There was a member who outrightly transgressed God's law which forbids having sex with a woman married to his father. The law is found in Leviticus 20:11 which states: "And the man that lies with his father's wife has uncovered his father's nakedness: both of them shall surely be put to death; their blood shall be on them." Paul condemned the church because it never disciplined the sexually immoral church member. As a result of this behavior by the church, he condemned the whole church as involved in sexual immorality. The second context has to do with the counsel the Apostle Paul gave to the Corinthian church prohibiting them from taking each other to court like the unbelievers used to do at the time to resolve issues. Apparently, this counsel was given for the purposes of preventing the wrong practices that were happening in Corinth of rushing to the court of law over cases or disagreement that used to happen between and among believers. The believers were supposed to be wiser because their behaviors were guided and shaped by the word of God. John, the author of the book of

Revelation, discusses the high level the righteous will be involved of judging the unrighteous that will be dead at the time the righteous will be spending one thousand years in heaven. Seventh-day Adventists Believe (1988) elucidates: "John saw that during the millennium the saints would be involved in judgment; he 'thrones and they sat on them, and judgment was committed to them' (Rev. 20:4). This is the time of the judgment of Satan and his angels that Scripture notes (2 Peter 2:4; Jude 6). It's the time when Paul's declaration that the saints would judge the world and even the angels (1 Cor. 6:2, 3) will come to pass." What is the purpose of the righteous' involvement in judgment? Ibid (1988) explains: "The judgment in which the righteous participate serves the purpose of answering any questions the righteous may have as to why the wicked are lost. God wants those to whom He has given eternal life to have full confidence in His leadership, so He will reveal to them the operation of His mercy and justice" P. 367. Thirdly, Paul reveals the context to them the evil practices of the unbelievers and what God will do to them at the time of judgment. The evil practices he outlines are fornication, idolatry, adultery, homosexuality, sodomites, thieves, covetous, drunkards, revelry; extortion will not inherit the kingdom of God."

Fourthly, Paul unfolds the context in which he warns the church members to flee from sexual immorality because this is the only sin not done outside the body, but inside the body, which unites the culprits regardless of whether they like it or not when they are in a sexual relationship. It is the same reason that sexually transmitted diseases such as gonorrhea, syphilis, HIV AIDS are passed on from one sexual partner to the other. This is why it is important that sexual intercourse must always take place in the context of marriage because sex unites a man and a woman as "one flesh" according to how God has commanded at the time he originated marriage in Genesis 1, 2 & 3.

I. "Do not touch a woman."

Having rebuked the Corinthian Christians about sexual immoral practices that were happening in the church and how they condoned them, Paul clearly gives them some moral guidelines on how sex could be experienced. He wanted them to know that sex was originated by God and was given to humans to practice only in marriage setting. Sex outside marriage is wrong and should be avoided at all cost because doing so is transgressing the law of God which states: "You shall not commit adultery" (Exodus 20: 14, NKJV), "But the cowardly, unbelieving, abominable, murderers, sexually immoral, sorcerers, idolaters, and all liars shall have their part in the lake which burns with fire and brimstone, which is the second death" (Revelation 21:8, NKJV).

In 1 Corinthians 7:1, Paul wrote as follows: "Now concerning the things of which you wrote to me: It is good for a man not to touch a woman." In this verse, he articulated clearly that it is morally right for a man who is not married not to have any sexual intercourse with any woman. The woman, too, who is not married is morally right not to have sexual intercourse with any man. It is not sin for man or woman who is not married to live without sexual intercourse. The sexual immoral are those men and women who engage into sexual intercourse outside the married setting.

Spence & Excell (1962) explains verse 1 the last part as follows: "The word used is not agathon, good, but kalon, fair; "an excellent thing" (p. 223). What are they saying? They are saying that the Greek word used is not agathon, which is translated well. But the Greek word used is kalon, which means fair. Fair means an excellent thing. In other words, it is an excellent thing for a man, not touch a woman. What kind of touch was Paul talking about? Paul was not refuting or condemning mere touch or normal touch of a man to a woman without sexual intentions. He was condemning a man's touch of a woman such as greeting, hugging, etc. with intent to advance towards sexual involvement.

Heading, J (1995) explains what Paul meant in 1 Corinthians 7:1 as follows: "It is good for a man not to touch a woman," similar to Matthew 19:10. He continues: "They could not discern the proper course for a Christian in a scene of abounding evil, so they confused complete abstention with a form of spirituality. Let us not confuse spirituality with abstention from legitimate things today" (p.102). In other words, a husband and wife are allowed by God to engage into sexual intercourse because are upholding the guidelines set by Him. Married couples should not feel that they are committing sin whenever they are engaged into sexual intercourse.

Jesus also in Matthew 19:1-10 explained why God created human beings comprised of males and females. The purpose was to unite them into marriage whereby they became one flesh signifying that they were not to be ashamed to one another naked. He condemned divorce, which the Pharisees were advancing using the example of Moses when he permitted divorce in his time. Jesus' answered unhesitatingly to this query by informing that it was due to the hardness of heart of the people in Moses time. Their hardness of heart made them to disregard the counsels God had held from the time of creation to his time and beyond.

Is it true that sin has perverted the beauty of sex which God created at the very beginning of human beings in Genesis 1-3? He did not create man alone; he made a woman for him by the name of Eve. He told both of them "be fruitful and multiply" (Genesis 1:28). These words were commands to allow Adam and Eve to have sexual intercourse. The Bible goes on to tell us that Adam knew his wife Eve (Genesis 4:1) and she conceived and bore him Cain. Therefore, again he knew his wife (Genesis 4:2) and she conceived Abel. God is the one who originated sex. It should not be regarded as evil. Sexual intercourse was not created as a result of sin. It was given to Adam and Eve before sin entered the world.

In 1 Corinthians 7:1, Paul was solving the problem of those who advocated that it was wrong to have sexual intercourse with couples in a married setting. It was wrong to practice abstinence from sexual intercourse in marriage. He made it clear that sexual intercourse to married couples was allowed and is allowed even today. God originated marriage and sex so that human being would increase in this world. Human beings, whether they like it or not, are the products of sexual intercourse. Those who are married should not feel that they are committing sin whenever they are having sex with their rightful spouses. Sexual intercourse is sinful or immoral outside the marriage context only.

II. Sexual Immorality

What is sexual immorality? Before, this question is answered, in 1 Corinthians 7:2, Paul writes as follows: "Nevertheless, because of sexual immorality, let each man have his own wife, and let each woman have her own husband" (NKJV). According to this context, sexual immorality is sexual intercourse between a man and woman who are not married. They are transgression the law of God that states: "You shall not commit adultery" (Exodus 20:14, NKJV). How can they avoid sexual immorality? They can avoid sexual immorality first by recognizing that a man and a woman have sexual feelings and desires that can only be fulfilled in sexual relationship with each other. Secondly, they should get married. As soon as they are married, declared husband and wife, are allowed to have sexual intercourse any time they want, without them feeling guilty that they are committing sin. Biologically, a man and woman are not the same, and this makes sexual union-compatible. This is why it is not right for man to marry a fellow man and a woman to marry a fellow woman. It should always be a man with a woman and a woman with a man.

Heading J (1995) explains the sin of immorality in detail as follows: "The sin of fornication was one of the prevalent sins of nature. This term is used for immorality in general and would embrace, among other things, the common trend today of pre-marital relationships. It is wider than the term adultery, which is usually restricted to the breaking of the marriage bond" (p. 102). In other words, sexual immorality encompasses sexual sins that take place before and after marriage. For example, the young men and women are deceived even during dating experiences that they turn to sexual intercourse before marriage. Those also who are married, leave their spouses, and engage in sexual intercourse with spouses who are not their own. Jesus in the New Testament expanded the sin of sexual immorality to even lusting. He taught that men who look at women lustfully are already committing sexual intercourse in their hearts with them (Matthew 5:28).

Sexual immorality is prevalent everywhere among men and women. How can it be solved? Heading J (1995) echoes Paul's solutions as follows: "Paul's argument is that, because of these, it is not best to abstain from marriage particularly if the grounds for abstention are that it is more spiritual. Some would say that this is a very low philosophical view of marriage, treating it as a mere safeguard against sin. But Paul is not dealing with a positive spiritual philosophy here, that may be found elsewhere, Eph. 5:22-33. He is only dealing with certain practical implications." In other words, each man should have his own wife, and each woman should have her own husband. This is a personal to holder relationship that cannot be shared. They should display faithfulness

to each other, especially sexually. Paul writing to the Hebrews wrote as follows: "Marriage is honorable among all, and the bed undefiled; but fornicators and adulterers God will judge" (Hebrews 13:4 NKJV).

III. Husband and Wife renderings.

In defending sexuality in the context of marriage, the apostle Paul admonishes the Corinthian Christian husbands and wives as follows: “Let the husband render to his wife the affection due to her, and likewise also the wife to her husband” (1 Corinthians 7:3, NKJV). The affection is needed by the wife from the husband and husband needs the same from the wife. None should think that it is immoral for husbands and wives to engage into sexual intercourse in marriage.

Heading (1995) points out a unique connection between rendering affection to husband and wife found in Paul's writings 1 Corinthians 7:3 and to the phrase revealed in Ephesians 5:29 that states "nourishing and cherishing." The context in Ephesians 5 is an analogue Paul gives between Christ the bridegroom's love for the church, which is the bride and the love of a husband to the wife. Christ loves the church so much that he nourishes and cherishes her like his own body. The husband and wife must love each other like they nourish and cherish their bodies. He says that no one hurts his/her body because everyone nourishes and cherishes his/her body. In the same way, the husband must nourish and cherish the wife's body and vice versa like they do to their bodies (Ephesians 5:33). Therefore, unselfishly, the husband must meet the needs of affection to his wife, and the wife must meet the affection for her husbands. Need for affection is important for each person and is met to be fulfilled in a marriage relationship between husband and wife. The husband must render the services of affection to his wise unselfishly, and the wife should do the same to the husband. It is God who gives affection to human beings and must use it according to the manner He stipulated in the scriptures. It is a command God gave to the husband and wife to share affection to each other and must be neglected.

The other connection Heading (Ibid, 1995) gives of rendering for affection between husband and wife is found in 1 Corinthians 7:1-11and in 1 Peter 3: 7 which has to do with husband and wife "being heirs together of the grace of life …" What is heading's (Ibid, 1995)'s point? His point is that "it embraces the mutual care that one partner should have for the other" since both of them are "heirs together of the grace of life." Husbands and wives must provide affection to each other because doing so is a sign that both of them care for each mutually. It is not good for husbands and wives to act selfishly when it comes to meeting each other's affection. Just like a husband needs affection, he should remember that the wife also needs the same affection she should receive from the husband. It means that even during sexual intercourse, the husband should not release his sperms quickly so that he gives his wife time to reach orgasm. Unfortunately, many women hurt sex because they rarely reach orgasm. Most times, men are selfish and should avoid this state of affairs of denying wives mutual love and affection.

No Authority over their Bodies

What did the apostle Paul mean with these words in this verse 4: "The wife does not have authority over her own body, but the husband does. And likewise, the husband does not have authority over his own body, but the wife does" (1 Corinthians 7:4, NKJV). Obviously, Paul is dealing with sexual relationship in a marriage setting, which he believed and taught that God sanctions it. In terms of sexuality and in avoiding sexual tension and difficulties to married couples, the counsel given by him applied can solve many challenges they face today. Paul is saying that a married woman ceases to have authority over her own body at the time she gets married. She should avail her body to the husband so that he can enjoy it sexually. A husband should not struggle to access his wife sexually at the time of marriage because her body has been handed over to the husband. She ceases to have authority over her body, and as a result, the husband has free access to her. The man also at the time of marriage ceases authority over his body because he hands it over to his wife. His wife is the one who has authority over his body. She should have free access to his body even to enjoy it sexually. Barker and Kohlenberger III (1994) add: "So that no abnormal situations in the Christian marital status might develop, leading to sexual immorality." It is not good for husband and wife to suffer for lack of sexual intimacy when they are married. They should strive to satisfy each other sexually even when at times they face sexual challenges. Sexual challenges will always be there due to the sinful world human beings have found themselves. God knowing that human beings would face challenges including sexual gave this counsel: "Ask, and it will be

given you; seek, and you will find, and it will be opened to you. For everyone who asks receives, and he who seeks finds, and to him who knocks it will be opened" (Matthew 7:7&8, NKJV). The Bible in Luke 1:37 says: "For with God nothing will be impossible."

Barker & Kohlenberger III (1994) continue to explain verse 4 as follows: “Christians should have normal sexual relations, and Paul strengthens his argument by stating that the bodies of the marriage partners belong to each other” (p. 625). The meaning is that married couples should have normal sexual relationship that is satisfying so that temptations to have sexual relations with other people who are not their spouses can be avoided completely. It important to point out that this guideline Paul gives to husbands and wives that at marriage, they hand over their authority to their spouses, strengths the idea of writing wills. A will is a written document by any person still alive so that when he or she dies, the property will be shared according to the stipulation written. A husband must write a will indicating that whatever they own together in case of death belongs to the wife, children, or relatives. He can write a will that his wife is the owner of everything they have and give her authority in that will to share with their children or others. The wife also should write a will in case she dies earlier than the husband that property remains in the charge of the husband and the children. It is difficult for African husbands to write a will because they fear that death can come sooner than normal. They should not be afraid because, at the time of death, their relatives minus will grab the property. His relatives, when grabbing property, will not remember the wife and children. The wife and children will become homeless as a result of not writing a will during the time he was alive.

1. Do not deprive each other.

The complete thought of verse 5 renders like this: "Do not deprive one another except with consent for a time that you may give your selves to fasting and prayer, and come together again so that Satan does not tempt you because of your lack of self-control" (NKJV). This verse is within the same context of principles of marriage. Paul is teaching the Corinthian church. The first idea is, "do not deprive each other." What is he talking about? He is talking about the married couple that they should not deprive each other sexual intercourse. Sexual intercourse cannot be done by the husband and wife alone. It always takes place in the context of husband and wife. It does not matter who initiates, and as soon as that happens, the other should respond and give the body to the other so that they engage into sexual intercourse. Sometimes the other may not be interested but forsake of the other person they should both agree and enjoy the sexual intercourse. Spence & Excell (1962) add to this line of thought as follows: "St. Paul purposely leaves the expression general. Primarily he is thinking of ‘the due' or ‘the power' which each has over the other, as is shown by verse 6; but he does not confine the expression to this" (p. 224).

After Paul commanding them "not to deprive each other," he points out an exception. The exception states: "except with consent for a time." The consent is not an individual matter; it has to be agreed by both the wife and the husband. It does not matter who brings the idea of refraining from sexual intercourse. The idea should be discussed and then agreed by both the husband and wife, thereafter, it can be implemented. The implementation means that the husband and wife will not be having sexual intercourse for a period of time. The time also is not indefinite; it could be for three or five days. It should not be for a long time like two weeks or one month. The time for refraining from sexual intercourse is not for many days, weeks, or months, but a shorter time. Spence & Excell (Ibid) expressed it this way: "The exception he regards as something possible but not normal" (p. 224). The decision to refrain from sexual intercourse is possible. The couple can discuss this possibility and refrain from sexual intercourse. However, this way of refraining from having sexual intercourse is not a normal practice. It is done for special purpose like fasting and praying, which Paul mentions further in the verse.

It is interesting that the idea of a couple to refrain from sexual intercourse was practiced in the Old Testament for special purposes or occasion. Spence & Excell (Ibid) do point out as follows: "Temporary separation for special reasons had been recognized from the earliest times (Exod. xix.15; 1 Sam. xxi.4)" (p. 224). The first example they are giving is found in Exodus 19: 15. The context had to do with the children of Israel, led by Moses. They had been travelling for the last three months since they left Egypt. This time they had arrived at Mount Sinai, and a special consecration service had to be done by God to his people. Moses was given instructions by God to

his people whom he was to communicate to them. Among other things, God instructed married couples were to consecrate themselves to the Lord. Exodus 19: 15 reveals as follows: "And he said to the people, 'be ready for the third day; do not come near your wives" (NKJV). What did he mean? He meant that married men during the consecration period, which was the third day only were advised not have sexual intercourse. The periods of refraining were not for a long time, but just for the third day of the event, God had prepared the people, which was the preparation for the people to receive the moral law. The day was so special that men were advised not to have sex on the third day. God would come down to give them the law. This service did not mean that the law was holier than marriage, but that it meant total consecration and devotion to God on the third day He revealed himself to them since they had left Egypt.

The second Bible passage related to temporal refraining from sexual intercourse by married couples is found in 1 Samuel 21:4, that states: "And the priest answered David and said, 'There is no common bread on hand; but there is holy bread, if the young men have at least kept themselves from women'" (NKJV). The context here is that David approached the priest Ahimelech and asked from him bread, which he was carrying in his hands. The priest answered David and told him that there was no common bread in his hands except holy bread, which was kept in the temple. The holy bread could not be given to men who had recently engaged into sexual intercourse with their wives. What did this mean in those days? Barker & Kohlenberger III (1994) elucidate as follows: "No 'ordinary' bread is available, but 'there is' some 'consecrated' (lit., 'holy') bread that David and his men may eat. There was a condition, however: The men must not recently have had sexual relations with women, which would have rendered them ceremonially unclean (Ex 19:14-15; Lev 15:18) and therefore temporarily unfit to partake of the holy food. David assured Ahimelech that women had indeed been "kept" from himself and his men, and they are thus clean" (p. 417).

David's actual words are recorded in 1Samuel 21:5 as follows: "Truly, women have been kept from us about three days since I came out. And the vessels of the young men are holy, and the bread is in effect common, even though it was consecrated in the vessel this day." After what David said, what did the priest do? 1 Samuel 21: 6 tells us what the priest did as follows: "So the priest gave him holy bread; for there was no bread there but showbread which had been taken from before the LORD, in order to put hot bread in its place on the day when it was taken away." Is sexual intercourse in a marriage setting sinful? It sounds evil in the above Bible passage we have dealt with. It is not evil, but according to the Jewish custom, a man who had sexual intercourse recently could not partake of such services as sacrificial offerings. Those men who had sexual intercourse with their wives recently (a day or two), would be regarded as ceremonially unclean according to the Jewish ceremony. This type of teaching was not in harmony with the scriptures because, in Genesis 1, 2 &3, God is the one who inverted sex. He created Adam and Eve and therefore after he united them into holy marriage and commanded them to be "fruitful," which can only be arrived through sexual intercourse between them.

2. Fasting and prayer.

Paul, in 1 Corinthians 7:5 gives the reason why a married couple can once a while refrain from sexual intercourse for the purposes of "fasting and prayer." The reason for genuine refraining from sexual intercourse between a husband and wife is important in their Christian lives. Omartian & Hayford (2003) define fasting: "as an instrument that cripples the power of spiritual and evil forces in the realm of the darkness so they cannot sustain their grip on human life, minds, and circumstances" (p. 60). If fasting has the capacity to cripple the power of evil forces, all couples are urged once a while whenever it is convenient to stay away from food and sexual intercourse to experience higher spiritual growth in their lives. Sometimes couples experience challenges that cannot be solved by human intelligence. They can just fast and pray for a day or so by not having sexual intercourse for a meaningful spiritual experience.

(Ibid) wrote an interesting statement about fasting, "Fasting is a way of saying, 'I'm a spirit being before 'I'm a physical being. 'I'm physical, so I need to eat, but 'I'm spiritual too, so 'I'll sometimes assert the supremacy of spiritual allegiance beyond and before my allegiance to my body and its cry." It is important to fast because according to Omartian & Hayford, it helps those fasting to "assert the supremacy of spiritual allegiance." In other words, fasting can enable the participants bring their bodies to where there will show allegiance to God. Obedience to God and his commandments is not easy because the evil powers are also pulling from the opposite

directions. The devil and his angels are working hard to ensure that human beings do not obey God. When Christians fast, they place themselves where God can use and transform them to obedience to him.

Towns (1996) wrote two important statements about fasting: “If every Christian fasted, the results could shake our society like a windstorm bending a sapling. Christians would demonstrate that they live differently, that their faith is imperative, that the Almighty works in their daily lives”(p. 15). The second one is: “If all our churches fasted, they would move forward in evangelism and reach out in feeding and helping others. God would then pour His presence upon His people” (Ibid).

3. Come together Again

Having given the reason why married couples should refrain from sexual intercourse for a time, Paul informed them the next thing they were supposed to do as follows: "and come together again so that Satan does not tempt you because of your lack of self-control." What did he mean in this phrase? Spence & Excell (1962) explain: "The true reading is, ‘be together again,'" not "come together" (p. 224). There is a difference between be together again and come together. To come together again means that you did not separate; you are simply resuming the usual activities or practices you do. However, to "come together" means that you were never together, therefore this phrase does not refer to people who had separated, but who did not know each other. Therefore it is wrong to use the phrase come together. The correct is "to be together again," you continue the usual practices you are always doing. Spence &Excell adds: "For your incontinency; rather, because of. Their past lives and their present temptations were a warning that they could not lay on themselves burdens which God did not require. They should not strive ‘…to wind themselves too high for sinful man beneath the sky'" (Ibid). In other words, God is encouraging couples to refrain from sexual intercourse during spiritual disciplines such as fasting and prayer. It is not an immoral issue. Couples can either refrain or not refrain from sexual intercourse during spiritual discipline; they are not sinning either way. No Biblical command prohibits them to have sex during spiritual discipline, but it them to decide to do what they want.

Fasting and prayer is something good for the couple to practice. Heading (1995) supports this line of thought as follows: "In verses 3 and 4, we have the truth of togetherness, but in verse 5, we find legitimate untogetherness" (p. 103). In other words, the reason advanced for a husband and wife to refrain from sexual intercourse is legitimate one. The reason is to fast at times, which could include refraining from sexual intercourse by the couples. Sexual intercourse is not the only thing they can refrain from; there other things like refraining from meals, talking, and so on for specified time chosen by the participants. After fasting, they come to begin together again to engage into sexual intercourse.

Why is Paul telling the couple to begin again living and experiencing normal marriage life? The last part of verse 5 gives the reason, and it says: "so that Satan does not tempt you because of your lack of self-control." Satan is there, and he looks for areas of weakness among Christians so that he can tempt them. In this context, if married couples are refraining from sexual intercourse for a long time because of religious purposes, he will step in and deceive them. They will start rationalizing using the excuse that they have not been having sexual intercourse for long time, therefore they can fall into sin. This is why Paul does not want couples to refrain from sexual intercourse for religious purposes for a long time. In line with this counsel, Paul is admonishing the couple to watch out because, in the process of fasting unusually from sexual intercourse, they can lose self-control. Self- control is strengthened when the couple is living a normal married life including experiencing sexual intercourse. On the other hand, if couples are refraining from sexual intercourse for a long time, they can lose self-control even when they seem to be strong. Paul does not want to create a situation whereby the devil can find space to tempt the couple to have other sexual experiences other than the ones in normal marriage experience.

4. Concession versus commandment.

What did Paul mean in 1 Corinthians 7:6 that states: “But I say this as a concession, not as a commandment”? There are two keys words in this sentence. The first one is concession. What does it mean? Merriam dictionary defines concession as: “Something done or agreed to usually grudgingly in order to reach an agreement or improve a situation.” Therefore Paul is not establishing a rule for married couples but each couple in their own volition they can decide to refrain from sexual intercourse for whatever reason being advanced. It is neither evil nor bad to refrain; the decision rests on the purpose for fasting. The second key word is “commandment?” What does it mean? Merriam dictionary defines: “an important rule given by God that tells people how to behave.” A commandment does not change because it was originated by God. Once God utters it, it remains binding and never to change forever. This is why the apostle Paul does not make a rule on couples when and how long they can refrain from sexual intercourse, but that it is a concession between the two of them. Seventh-day Adventist commentary (1957) adds to this line of thought as follows: “In Gr. Suggnome- ‘agreement’ mutual opinion or judgment,’ ‘concession.’ He does not intend to give the impression that married persons are under obligation to abstain from sexual intercourse during spiritual discipline. He simply explains that if they so desire, they are perfectly free to enter into such an arrangement; they are not commanded to do so” (p. 707).

Another view of interpreting 1Corinthians 7:6 is given by Keener (2014) as follows: "Jewish law permitted concessions for human weakness; here Paul permits but does not require periods of abstinence, implying that it is those who wish to abstain (rather than those who do not) who are weak. Abstinence within marriage is their idea (7:1), not his" (p. 474). In other words, Jewish laws allowed couples to decide themselves when to abstain from sexual intercourse for the purpose of devoting time for God. On the other hand, those couples who decided to abstain from sexual intercourse should do so on their own and not for long periods of time; otherwise, they would open floodgates for sexual temptations. Paul makes it very clear that the decision is theirs; it is not imposed by anyone. Since the decision is the couples', they should not be condemned but encouraged.

Heading (1995) adds: "but I speak this by permission and not of commandment'. In the previous four verses, there is no commandment either for or against marriage, either for or against special service. Paul is writing by way of ‘permission,' namely making ‘allowance for circumstances,' the only time this word appears in the New Testament. There is no legislation in Christian liberty. There must be a harmonious working of one's own exercise with the call of God to service" (p. 104). In other words, 1 Corinthians 7, which Paul wrote does not give commandment for or against marriage. A man or a woman is free to either get married or not to get marriage. Marrying and not marrying is not morally wrong. And those who are married, can have sexual intercourse daily or can skip some does, it is up to them what they decide to do. They are free to have sexual intercourse any time as long as they do not break God's commandment of engaging into sexual intercourse outside the marriage setting.

Another thought by Barker & Kohlenberger III (1994) state: "In Paul's comment that ‘this' comes not by direct command (i.e., from the Lord) but by permission or concession, it is not clear what the ‘this' refers to. Perhaps it is best to understand it as referring to v.2, indicating that though marriage is desirable and is according to God's creation, it is not mandatory" (p.626). In other words, God does not force or require any man or woman to get married. What God does not like is a man or a woman who experiences sexual intercourse outside the marriage covenant. Those men and women who get married are allowed to have sexual intercourse within the marriage setting. Those who not have the urge to marry should remain unmarried, and this means that they should not have any sexual relationship with anyone because it would be committing adultery or fornication.

5. Gift from God

What does the phrase "gift from God" mean in 1 Corinthians 7:7? This verse reads: "For I wish that all men were even as I myself. But each one has his own gift from God, one in this manner and another in that" (NKJV). In the context of the passage Paul is talking about his gift from God, which he received, which does not allow him to get married. He does not have urge for sexual feeling towards women, thus why he did not get married. He seems to have a gift of celibacy which hinders him from getting married. He wished that everyone was gifted with the gift of celibacy; then there would no struggle for men to get married. He does agree that other men are different, they do have the gift of celibacy; therefore, and they have the urge to marry. Getting married is not sin, and not getting married is not sin as well.

Barker & Kehlenberger III (Ibid) express this idea of verse 7 as follows: "That this is Paul's meaning is evident from v.7, where he says he really wishes everyone was single like him" (p. 626). The gift he is talking about is the one of not getting married. He was single meaning that he was not married. He had a gift of single life, therefore, sexual temptation was not an issue with him. He did not have a weakness in sexual temptation. This is why he wished everybody else to have the gift of celibacy, and as a result, issues of sexual immorality would not be prevalent in his time. Those who do not have the gift of single life should not remain single but should get married. If they are single and indulge in sexual intercourse out marriage setting, then they are committing sin against God. Hence Paul's admonition that those who do not have a gift of celibacy should not continue being single but should get married to avoid sexual immorality.

Heading (Ibid) broadens Paul's idea of wishing Christians of his day to be like him. He writes: "This is the secret of Paul's whole argument; his desire was that others should be as he was. That is to say, not just to be saved, not just to be called, not just to be unmarried, but that these blessings and positions should be used in special devoted service—a service that could not be accomplished effectively if there were legitimate home and family ties" (p.104). In other words, Paul's gift of celibacy was not just for his own pleasure or for showing off that he did not like women, it was for providing service to God. This gift of single life was better placed in him so that he could devote more time and increase effectiveness in the Lord's work without inferences of family matters. There is one married couple that I came across who did not bear any children by choice so that they could serve the Lord as missionaries in different places of the world without interferences of children. They used wholly their time and money to serve the Lord.

Keener (Ibid) elucidates: "Paul recognizes that not all are called to singleness and equipped for it" (p. 475). There are some Christians today who have the gift of celibacy like the one Paul had. It is clear in this verse that some do have while some do not have the gift of celibacy. He does not condemn them for not having the gift of celibacy. It should also be pointed out that it is God who decides which gift a Christian should have, according to Ephesians 4. It is not right to be envies of gifts of other Christians. Each Christian should accept his or her gift and use it for the benefit of the Lord's work. These gifts, too, can be increased or sharpened by learning more about them and also by using them.

6. The unmarried and widows.

In 1 Corinthians 7:8, the apostle Pau focuses on those Corinthian Christians who were not married and ladies whose husbands had died and as a result became widows. What counsel is he giving them? He declares this in verse 8: "But I say to the unmarried and to the widows: It is good for them if they remain even as I am" (NKJV). He could be referring to himself on the issue that he is not married. Since he is not married and he knows the benefits it renders him in working for the Lord, he wishes that the unmarried and the widows can decide not to marry so that they can devote their time and gifts to the spreading of the word of God to those who have not yet been reached. He wishes the unmarried and widows to be involved in planting churches in cities and villages close to where they reside. They can begin in those areas near to where they stay before they travel or drive to long distant places. Paul's gift of celibacy is not for his own pleasure, but it is for enhancing the preaching of the gospel in his generation. Paul did his part when he was alive, he worked hard planting churches and nurturing those he had planted. As age caught upon him, he used the methods of writing letters to his churches so that they could read them and put into practice the counsels and principles he communicated to them. He had an advantage of doing what he did because he did not have a family to take care of, thus why he wishes the unmarried and widows to do the same.

Barker & Kohlenberger III (Ibid) explain Paul's idea in these words: "Paul now gives advice to those who are single, who he classifies as the unmarried and the widows. It is good or advisable for them to remain in their single state for the reasons spelled out in vv. 26, 32-35" (p. 626). One of the reasons for encouraging the unmarried or widows to remain single is in 1 Corinthians 7:26, it reads: "I suppose therefore that this is good because of the present distress—that it is good for a man to remain as he is:" (NKJV). Here the reason he is advancing for single life is distress which existence at the time of writing the first letter to the Corinthians. It was good to stay single because of the present distress that was going on at the time. The problem is not spelled

out, but whatever it was, it was better for the single to remain single than to inflict pain on other people who came together as a result of marriage.

The next reason is in verse 32, reads: "But I want you to be without care. He who is unmarried cares for the things of the Lord—how he may please the Lord and verse 33 says: "But he who is married cares about the things of the world—how he may please his wife" (NKJV). Paul is pointing out the major focus of the unmarried person versus the one who is married. The one who is unmarried cares for the things of the Lord. He is determined to please God, especially in rendering service to the Lord. For example, he can run evangelistic efforts in different places and times without being bothered about shelter, food, health, etc., of the family that he does not have. He can devote more time and can be more effective in carrying out the work of God. However, the married one is faced with a number of distractions to do with supplying needs such as shelter, food, health for the family. He cannot live in a one bedroomed house because it will not be enough for his family. He needs to buy more food for his family; otherwise, the wife especially will not understand what he is doing. He needs to balance his time between the family and the Lord's work. If he does not do that he will end up failing as a family man and also as a worker for the Lord.

7. Self-Control and Marriage.

The last verse of the study is 1 Corinthians 7:9, reads: "But if they cannot exercise self-control, let them marry. For it is better to marry than to burn with passion" (NKJV). Paul is clear in his discourses because he builds from one counsel to another progressively. He encourages the unmarried and the widow not to marry, and he gives advantages for this type of life, especially in enhancing the Lord's work. However, if they cannot control themselves against sexual pressure or desire, Paul says they should get married. It is better to marry than to keep burning with sexual passions. The reason is because it is moral to experience sex in the context of marriage. On the other hand, if sex is done outside marriage setting, it is immoral and must not be condoned at all cost.

Keener (Ibid) gives both the historical context and the meaning of the term "burn" as follows: "'Burn' (NIV, NRSV, and GNT interpret correctly by adding ‘with passion') was used throughout ancient romances and other sources to describe the arousal of passion, often (metaphorically) through Cupid's fiery darts. Whereas Greco-Roman literature, in general, saw nothing wrong with sexual passion, Paul knew that sexual passion was solely permitted in marriage, and he advocates two alternatives, either self-control or marriage" (p. 474). It is true that there are two alternatives Paul provides in this issue of single life and married life. Those who are not married should stay on exercising self-control to avoid sexual intercourse with anyone and any time. However, if they fail to exercise self-control, then they can use the second alternative of getting married because, in marriage, they are allowed to have sexual intercourse.

Barker & Kohlenberger III (Ibid) explain also the two alternatives in this way as follows: "If the situation is such that these persons cannot control their sexual desires, they should marry. It is, after all, better to get married than be inflamed with sexual desire, which is hard to control outside of marriage" (p. 626). The emphasis here is to get married than for one to keep burning or inflamed with sexual desires unattended to. Sometimes in marriage, the husband and wife forget their obligation of providing sexual pleasure to each other. There should not be difficult in matters of availing themselves to their spouses for sexual intimacy. However, if they do, they will create problems that in long run very difficult to solve. Sometimes couples use the justification that because their spouses are not responding to their sexual needs, thus why they go to other people for sexual fulfillment. Doing so is breaking God's commandment, which says, "You shall not commit adultery" (Exodus 20:14).

Richards (1995) adds his understanding of the meaning of the word "burn" as follows: "But, and this is an important ‘but,' if a church member realizes that sexual desire is a controlling factor in his life, he should marry. Marriage is obviously better than burning with passion (vs. 9)—which could lead to the very immorality Paul is opposing" (p. 127). In other words, if the sexual desire in a man is so tense, then it is better for him to get married than to keep burning with unfulfilled sexual passions. If he does not marry the likely thing to happen is commit Sexual immorality, which the apostle Paul is opposing. He is admonishing that before sexual desire is out of hand, a man or woman must quickly get married. Getting married is not sin; therefore, Paul is encouraging those without self-control to get married.

SUMMARY AND CONCLUSION

The journal of research 1 Corinthians 7:1-9 has been long and rewarding. In brief, this passage means that sexual intercourse in marriage was invented by God, and as such, it should be treated that way throughout human existence. There are some like the apostle Paul himself who has the gift of celibacy. Those with the gift of celibacy should stay unmarried as long as they can control themselves from sexual temptation. However, if they fail to control themselves, they should get married because sexual intercourse is allowed only in the context of marriage. Paul also points out that those who can practice self-control over sexual temptation will provide more effective service for the Lord than one who is married. According to Paul, the gift of celibacy is not to use for selfish purposes but for enhancing the spread of the gospel to masses that have been reached. Therefore Christians, in general, should not mock those who have the gift of celibacy because their aim to hasten the coming of Jesus through giving themselves more to the Lord doing effective service for him.

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