A CASE-CONTROL STUDY OF MENSTRUAL DYSFUNCTION OCCURRING IN WOMEN ATTENDING A GENERAL PRACTICE AFTER TUBAL LIGATION.

RESEARCHER

Breslau Kruger

This thesis was submitted as part II of the requirements for the degree of Master of Family Medicine and Primary Care, University of Cape Town.

JUNE 1998

DECLARATION

I, Breslau Kruger, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise), and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the University of Cape Town to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature Signed by candidate

3/6/1998

Date

ACKNOWLEDGEMENTS

My heartfelt thanks and appreciation to the following for making this thesis possible:

- Dave Whittaker, for supervising this thesis,
- V P de Villiers, for co-supervising,
- Miranda, my wife, for her motivation, patience and typing this thesis,
- Natasha and Nicklaus, my understanding children,
- Nicolette and Shireen, for collecting information, and
- God Almighty, who carried me through the difficult times.

This thesis is dedicated to the memory of Gareth Brendan Kruger.

SUMMARY

Tubal sterilization is the world's most popular contraceptive method. The possibility of subsequent menstrual dysfunction has been a cause for concern. This study was conducted to examine whether post-sterilisation menstrual dysfunction was measurable in a group of women attending a general practice, by means of a case-control study. Biopsychosocial factors, such as health status, social support, psychological and medical history, and reasons for sterilisation were investigated to see whether any of these factors could be predictive of post-sterilisation menstrual problems.

Sterilised women attending a general practice over an eight-month period were invited to participate in the study. 143 out of 144 patients completed a highly structured interview (questionnaire) administered by two interviewers. Forty-nine cases were identified and compared to ninety-four controls.

The results showed that women with menstrual dysfunction differed from a comparison group in that; those with menstrual dysfunction were generally less satisfied with their quality of life, had significantly more fears about sterilisation, felt that the quality of their social support was inferior, and suffered from depression and tension headaches more often than controls. Menstrual dysfunction was also more common during the first two years after tubal ligation.

These results could point to factors other than biological factors involved in menstrual dysfunction following tubal ligation.

CONTENTS

TABLES

CHAPTER ONE.

1.1 INTRODUCTION

More than 10 million women in the USA alone have undergone tubal sterilisation. All over the world the trend is for more and more women to have themselves sterilised. In South Africa sterilisation has never reached the same percentage as compared to the USA. In the USA this figure amounts to thirty percent of all women. Women in Paarl have free access to sterilisation as a form of birth control. From 1971 to 1995 more than 15000 women have been sterilised in this area. Because of the fact that tubal ligation is generally an irreversible procedure, it is important to identify any complication that could be related to the procedure.

Do patients experience menstrual problems after sterilisation? In the researcher's experience in general practice, some patients present with symptoms of menstrual dysfunction which they relate to their tubal ligations. The purpose of this case-control study was to assess patients' responses to sterilisation and to determine whether women who experience symptoms of menstrual dysfunction differed from women who do not with respect to (1) health status, (2) social support, (3) psychological and medical history, (4) quality of life, (5) reasons for sterilisation, and (6) feelings about sterilisation.

In this study a questionnaire was used to determine patient reactions. A control group of sterilised women who did not experience symptoms of menstrual dysfunction following sterilisation was used. The intention was to include all sterilised patients attending the practice from October 1996 until May 1997. Analysis of patient responses would indicate how they perceive the results of tubal ligation, and whether certain factors may have played a role in the development of menstrual dysfunction, compared with the control group.

1.2 LITERATURE REVIEW

More than 10 million women in the USA alone have undergone sterilisation, and by 1990 more women had undergone tubal ligation than were using any other method of contraception. [1-3] All over the world the trend is for more and more women to have themselves sterilised. The procedure is generally irreversible and it is therefore important to be aware of any possible complications of the operation which could affect these patients.

1.2.1 POST-STERILISATION SYNDROME

Is there an entity such as a post-sterilisation syndrome? This issue has been debated over a number of years. The medical literature on the subject of post-tubal sterilisation syndrome is still controversial. [4-19] Some studies suggest that this does not exist, and other studies claim that the entity is real. Table 1.1 reviews selected studies for the existence of the post-sterilisation syndrome.

The table illustrates the following points:

(1) Most of the studies reported after 1980 were prospective in design.

(2) Large patient populations were studied.

(3) A slight majority of the studies concluded that the post-sterilisation syndrome does not exist.

(4) In the only study where blood loss was measured objectively (Kasonde / Bonnar), it was found that there was no significant difference in blood loss before and after sterilisation.

TABLE 1.1 POST-STERILISATION SYNDROME --- Selected studies reported from USA, UK and Korea since 1975.

COUNTRY	YEAR REPORTED	AUTHORS (REF. NO.)	STUDY TYPE	SAMPLE SIZE	OUTCOME MEASURED	EXISTENCE OF SYNDROME
UK	1975	Neil et al. (6)	Retrospective	545	Menstrual loss and dysmenorrhoea	Yes
UK	1976	Kasonde / Bonnar (7)	Prospective	25	Objective menstrual blood loss	No
UK	1979	Whitelaw (8)	Retrospective	547	Gynaecological symptoms	No
KOREA	1980	Kwak et al. (9)	Prospective	2501	Menstrual parameters	No
USA	1981	Hargrove / Abraham (10)	Case-control	29	Endocrine profile midluteal phase	Yes
USA	1983	Fortney et al. (11)	Prospective	1555	Menstrual parameters	No
USA	1983	Bhiwandiwala et al. (12)	Prospective	10004	Menstrual parameters	No
UK	1983	Vessey et al. (13)	Prospective	17032	Gynaecological and psychiatric disorders	No
USA	1985	Rulin et al. (14)	Prospective	389	Menstrual parameters and gynae symptoms	No
USA	1985	DeStefano et al. (15)	Prospective	719	Menstrual parameters	Yes
USA	1989	Rulin et al. (16)	Prospective	1213	Dysmenorrhoea	Yes
USA	1992	Shy et al. (17)	Cohort	7253	Hospitalisation for menstrual disorders	Yes
USA	1993	Rulin et al. (18)	Prospective	500	Menstrual indices and pelvic pain	No
USA	1993	Martinez-Schnell et al. (19)	Prospective	10685	Menstrual dysfunction	Yes

Menstrual Parameters = abnormal cycles, adverse bleeding and menstrual cramps.

1.2.2 PROCEDURES FOR TUBAL OCCLUSION:

Different procedures for tubal occlusion are used. Three common methods are: [20] [21]

Surgical Techniques: This usually involves simple single or double ligation. The original Pomeroy procedure consisted of ligation of the base of the loop of the isthmic portion of the fallopian tube with an absorbable ligature, preferably plain catgut, followed by excision of the knuckle of the loop.

Electrocautery: At first the tubes were cauterised using unipolar, high-frequency electro-coagulation. Because of complications like bowel burns, bipolar coagulation, with less danger of sparking, were introduced.

Clips and rings: Spring-loaded clips were developed as a safe alternative to electrocautery, while offering the hypothetical advantage of high potential reversibility, for example, Filshie clip. As an alternative to occlusion with clips, silastic bands or rings were developed to offer less injury to the tube, creating a better situation should reversal be needed. [20] [21]

1.2.3 EFFECTS OF DIFFERENT PROCEDURES ON REPRODUCTIVE SYSTEM:

Some studies were done to try and establish what the effects of different procedures for tubal ligation would be on the reproductive system. [22-24] Stock [22] found that patients who had tubal ligation with coagulation techniques were more likely to have pelvic pain and subsequent hysterectomy when compared to ring methods.

Donnez et al. investigated the relation between different methods of sterilisation and the incidence of alterations of the tubal mucosa and endometriosis. [23] They concluded that dilatation of the proximal tubal lumen, flattening of the folds, polyps and increase in mitotic activity of the epithelium occurred in all forms of tubal ligation. Endometriosis was found only after Pomeroy ligation and tubal coagulation.

Riedel et al. investigated the effect of two tubal sterilisation procedures (high-frequency and endocoagulation techniques) in relation to late complications. [24] High-frequency coagulation causes more tissue destruction than endocoagulation. Endocoagulation, in contrast to that of all other pelviscopic sterilisation methods, caused the least damage to the vessels and nerves of the mesosalpinx. Contraceptive method up to the time of sterilisation (oral contraceptives or intrauterine contraceptive device) was considered. Those patients with the same menstrual irregularities before and after sterilisation were not included in this study. They found that the high-frequency coagulation group had a higher incidence of menstrual disorders, curettages and hysterectomies.

Rock et al. analysed the previously ligated fallopian tubes of 79 sterilised patients. [25] They found that laparoscopic cautery methods were responsible for a higher percentage of fistula formation and endometriosis.

1.2.4 REASONS FOR STERILISATION:

Between 1955 and 1970 the percentage of women sterilised for contraceptive reasons in the USA remained fairly constant at about 4 to 5 percent. [21] By 1976 the use of voluntary female sterilisation for contraception had doubled, reaching 9.5 percent. [21]

It is interesting to note how the indications for sterilisation have changed over time. Muldoon [26] in 1972 gave, in decreasing order of frequency, the following reasons for sterilisation in a study of 374 patients:

(1) Multiparity (5 or more children).
(2) Socio-economic factors (fewer than 5 children).
(3) At caesarian section.
(4) Bad obstetric history.
(5) Medical disease (mainly cardiovascular).
(6) Termination of pregnancy (hysterectomy).
(7) Miscellaneous.

In 1986 Allyn et al. mentioned the following major reasons for sterilisation in a survey of 457 patients, in decreasing order of frequency. [27]

(1) Had achieved desired family size.
(2) Health.
(3) Preferred never to have children.
(4) Other (age, financial, personal or marital problems).

Since sterilisation is an elective procedure it should be done when the patient is in optimal physical and mental condition. [28] Patients should be counselled adequately so that an informed decision is made as to sterilisation.

1.2.5 CONTRACEPTION:

The effect of oral contraception on sterilisation was examined by Rulin et al. [14] They examined contraceptive usage in three categories: oral contraception, intrauterine devices, or neither. The authors postulated that contraceptives and intrauterine contraceptive devices may strongly influence menstrual parameters, and that discontinuing these practices after sterilisation may exert an effect independent of the sterilisation process per se. They

found that previous oral contraceptive users exhibited an immediate increase in menstrual flow and dysmenorrhea after tubal ligation, which declined with time. The study concluded that increases in menstrual parameters were probably a return to what the baseline menstrual parameters would have been if these women had not taken the pill.

Another study by Rulin et al. studied changes in menstrual parameters in two groups of women: those women who planned to be sterilised soon, and those who did not want more children but were not planning sterilisation as controls. [16] Among sterilised women there was a significant net increase in the degree of dysmenorrhoea, independent of contraceptive usage.

Bhiwandiwala et al. [12] studied a large group of sterilised women (10,004 cases). Controlling for prior contraceptive use, the menstrual patterns in these women sterilised by four different techniques were compared with respect to cycle regularity, cycle length, menstrual flow duration, amount of flow, dysmenorrhoea, and intermenstrual bleeding. The majority of women reported no menstrual changes subsequent to sterilisation. Among the former users of oral contraceptives who experienced a change, more became irregular and experienced an increased cycle length, flow duration and amount of flow than the converse. Discontinuation of the intrauterine contraceptive device resulted in more women becoming regular and experienced a decrease in flow duration, amount of flow, dysmenorrhoea and intermenstrual bleeding.

1.2.6 HOSPITALISATION AND OPERATIONS AFTER STERILISATION:

The study by Shy et al. [17] investigated tubal sterilisation and subsequent hospitalisation for menstrual disorders. The object was to clarify the

relationship between tubal sterilisation and first hospitalisation for a menstrual disorder, using a large population-based cohort study. Comparisons were made with an age-matched cohort of non-sterilised women and a non-matched cohort of spouses of men with vasectomies. Hospitalisations during the first year after sterilisation were excluded because routine pre-operative and post-operative evaluation would have resulted in increased opportunity for diagnosis and treatment of menstrual disorders among sterilised women soon after the procedure. This form of detection bias would have increased estimates of the risk for menstrual disorders soon after sterilisation.

Results showed that sterilised women had higher rates of hospitalisation for menstrual disorders than did the general population women. [17] Among women of the age group 20 to 29 years, the risk of hospitalisation for menstrual disorders was more than five times greater among sterilised women compared with non-sterilised women. The authors also analysed sterilisation procedures individually, but there were no statistically significant differences between sterilisation procedures and risk of hospitalisation for menstrual disorders.

Sterilised women also had higher rates of hospitalisation for menstrual disorders than did vasectomy spouses. [17] The authors put forward three possible explanations for this phenomenon:

(1) Tubal destruction interferes with the utero-ovarian blood flow and results in altered ovarian hormone production leading to menstrual irregularity.

(2) Women who elect tubal sterilisation for contraception are inherently greater users of other elective gynaecologic surgeries (eg. curettage, hysterectomy).

(3) After reproduction is no longer possible, doctors and their patients are more inclined to choose hysterectomy as management for menstrual disorders.

Under the first hypothesis, unipolar fulgaration, which disrupts more of the mesosalpinx than other sterilisation techniques, would be expected to have a greater risk of menstrual disturbance than other sterilisation methods. The results indicated the opposite, because risk of menstrual disturbance was lowest among women with unipolar sterilisation. The authors concluded that patients' and physicians' views regarding the reduced need to preserve reproductive potential may have contributed to the increase in hospitalisation for menstrual disorders after tubal ligation, and that factors other than a biological effect may be responsible.

Hillis et al. estimated the long-term probability of hysterectomy after sterilisation according to demographic and clinical characteristics before the procedure. [29] The study was a large, prospective, multicentre cohort study of women undergoing tubal ligation to examine the cumulative probability of hysterectomy up to 14 years after sterilisation. The cumulative probability of undergoing hysterectomy 14 years after sterilisation was 17%. The highest probabilities of hysterectomy occurred among women who, at the time of sterilisation, reported a history of endometriosis (35%) or were older than 30 years and reported prolonged bleeding during menses (46%). An increased risk of hysterectomy was also detected among women who, at the time of tubal sterilisation, reported a history of heavy menstrual flow, severe menstrual pain, bleeding of more than 7 days during menstrual cycles, pelvic inflammatory disease, endometriosis, or uterine leiomyomata. They found that although women with gynaecologic disorders before tubal sterilisation were at greater risk of hysterectomy during the 14 years after sterilisation

than were women without these disorders, the majority of sterilised women in both categories did not undergo subsequent hysterectomy. The authors concluded that any differences in the risks of hysterectomy between sterilised and non-sterilised women most likely reflect non-biologic factors, rather than a biologic effect of tubal sterilisation. [29]

1.2.7 SEX LIFE AFTER TUBAL LIGATION:

Sterilisation has no adverse effect on sexual function in women and men. [28] Women may experience improvement in sexual function due to relief of anxiety about an unwanted pregnancy and or discontinuation of oral or injectable contraceptives that cause loss of libido.

Dueholm et al. determined the frequency of late sequelae after laparoscopic sterilisation in the pregnant and non-pregnant woman. [30] This study compared data on women who underwent induced first-trimester abortion and concurrent laparoscopic sterilisation, with women who had sterilisation performed at least 3 months after induced abortion. The authors found that 42,8% reported an improvement and 4,3% a deterioration in their sexual life.

Whitelaw studied patients' views on their sterilisation, evaluating how they felt about their sex lives. [31] About 36,3% reported an improvement in their sex lives, compared to 10% who reported a deterioration, and 53,8% who reported no change. Of those who believed that that the quality of their sex lives had improved, almost all spontaneously attributed the improvement to the fact that sterilisation, by removing the fear of pregnancy, had enhanced the pleasure derived from sexual intercourse. Of the 10% who complained about their sex lives, the majority (25 out of 48) believed that the deterioration was not caused by sterilisation.

1.2.8 PSYCHOLOGICAL ILLNESS:

A study conducted under the auspices of the WHO, aimed to investigate the effects of tubal ligation on the mental and physical health, and psychosexual and menstrual functioning, of women choosing to undergo the procedure for contraceptive purposes only. [5] Two groups of healthy multiparous women having either interval sterilisation (at least 6 months since an obstetric event) or postpartum sterilisation (within 72 hours of delivery) were recruited. Two control groups were recruited from women using or planning to use non-permanent methods of contraception. The women were interviewed pre-operatively and six months later. Results showed that sterilised women did not differ from the control samples in mental state, or in subjectively assessed mental health.

Campanella and Wolff mentions the possibility of menstrual changes that could be related to hypothalamic impulses affecting hormonal secretion. [32] This therefore suggesting a psychosomatic origin as the cause of menstrual dysfunction. They concluded that younger patients are more apt to have postoperative psychologic problems. Increased complaints, menstrual problems, and poorer sexual relations tended to correlate with the following parameters present prior to surgery: [32]

(1) Poor knowledge of the procedure, especially irreversibility, seemed to be directly correlated with increased problems.

(2) Guilt feelings, both conscious and unconscious, may produce anxiety which is resolved with other psychosomatic symptoms.

(3) Females who placed overemphasis on minor somatic complaints in past pregnancies and who had tried several contraceptives showed more

problems. Their overreaction and indecisiveness in the past suggest that problems may arise in this group.

Whitelaw studied patients' views on their sterilisation in 485 patients. [31] As far as mental health is concerned, 6,4% of women reported a deterioration in mental health. Attributed causes included: alcoholic husbands, diseases of the spine, financial troubles, family troubles, death of an only son, severe menopausal symptoms, recurrent depression, and physical symptoms - stress incontinence and dysmenorrhoea.

1.2.9 REGRET AND STERILISATION:

Regret after sterilisation occurs in about 3-5% of women and tends to be associated with sterilisation after delivery, abortion or caesarian section, marital breakdown and divorce, desire to bear children with a new partner, and sterilisation for medical reasons. [28]

Wilcox et al did an analysis of the pre-sterilisation characteristics most consistently associated with post-sterilisation regret from the Collaborative Review of Sterilisation Study. [33] If women who are at increased risk for post-sterilisation regret could be identified before the procedure, appropriate counselling of these women might reduce the likelihood of such regret. These women were interviewed before undergoing tubal ligation and received annual post-sterilisation interviews for 5 years after the procedure. The results indicated that the risk of regret in this study was higher for younger women than for older women: younger women had up to 2,9 times the risk of regret as women 30 to 34 years old, who in turn had twice the risk of women more than 34 years old. Women sterilised after caesarian delivery had a significantly higher regret rate than women undergoing interval procedures. Although the timing of sterilisation after abortion was not significant, women

with a history of abortion were more likely to report sterilisation regret than women with no history of abortion. Women who used public funds to pay for their sterilisation had a higher regret rate than women using private insurance or other methods of payment. Race, pre-sterilisation marital status, education, work status and number of living children did not have a statistically significant association with regret.

Chi and Jones (1994) in a review of the literature, examined the reported incidence of, and risk factors for post tubal-sterilisation regret and requests for sterilisation reversal in both developed countries and less-developed countries. [34] The reported incidence of regret varied considerably among studies. Selected studies from Europe since 1980 showed an incidence varying from 3.7% to 7.1%. The time elapsed after sterilisation ranged from 4 to 11 years. In summary this review has demonstrated that:

(1) The problem of post-sterilisation regret exists in a small group of women regardless of their cultural backgrounds or the development stage of the country in which they reside.
(2) Young age at sterilisation is a universally strong risk factor for regret.
(3) Infant or child death is an important risk factor for regret and desire for reversal in less-developed countries.
(4) Postpartum sterilisation or tubal ligation with caesarian section are risk factors for regret.
(5) Marital disharmony may lead to regret.

1.2.10 CARE BY PARTNER:

The study by Bordahl followed up 216 sterilised women for 6 years. The majority reported an improvement in sexual life and marriage after the sterilisation. [35] This study did not have a control group.

Whitelaw [31] reported an improvement in stability of marriage in 24,3% of women following sterilisation, with deterioration in 7,6% of the sterilised women. Many of the women who reported an improvement in the caring attitude of their partners attributed this to the sterilisation.

1.2.11 RISK OF PREGNANCY AND OTHER RARE EVENTS:

Peterson et al undertook a study to determine risk of pregnancy after tubal sterilisation for common methods of tubal occlusion. [2] They followed up 10,685 women after tubal ligation for 8 to 14 years. A pregnancy identified after sterilisation was classified as either a true sterilisation failure, a luteal phase pregnancy (pregnancy conceived before sterilisation but identified after sterilisation), a pregnancy resulting from tubal anastamosis or in vitro fertilisation, or a pregnancy of unknown status (because of insufficient information). One hundred and forty-three women pregnancies classified as true sterilisation failures. The most effective methods were postpartum partial salpingectomy and laparoscopic unipolar coagulation (7,5 pregnancies per 1000 procedures). Laparoscopic spring clip application had the highest probability of failure (36,5 pregnancies per 1000 procedures). The cumulative risk of pregnancy after tubal ligation varied depending on age. The younger a woman was at the time of sterilisation, the more likely she was to have a sterilisation failure. This study also found that black women were more likely than white women to experience sterilisation failure. [2]

A study on the risk of ectopic pregnancy after tubal sterilisation was done on data obtained from the U.S. Collaborative Review of Sterilisation. [1] Women sterilised by bipolar tubal coagulation before the age of 30 years had

a probability of ectopic pregnancy that was 27 times as high as that among women of similar age who underwent postpartum partial salpingectomy (31,9 versus 1,2 ectopic pregnancies per 1000 procedures). Therefore, a history of tubal sterilisation does not rule out the possibility of ectopic pregnancy, even many years after the procedure.

Chi et al. [36] reviewed rare events related to tubal sterilisation. These included luteal phase pregnancy , intra-operative complications, deaths, early re-admission following laparoscopic sterilisation, hysterectomy after laporoscopic sterilisation, and pregnancy (intra-uterine and ectopic) conceived after tubal sterilisation. The authors made a concerted effort to delineate the risk factors associated with the events by case-control analysis. Two risk factors in patients characteristics, age and lactation status, and two risk factors in provides variables, tubal occlusive technique and center's experience, were independently associated with incidences of post-sterilisation pregnancies. The younger the woman at the time of sterilisation, the greater the risk of pregnancy. Lactating women after sterilisation have increased protection during that period. One important clinical finding was that the ectopic versus intra-uterine pregnancies ratio was 1:14.2 at 1 year after sterilisation, and 1:2,0 at more than two years after sterilisation.

1.2.12 MENSTRUAL CHANGES OVER TIME:

Rulin et al. [18] in their prospective study of 500 sterilised women, found an increase in severe dysmenorrhoea 6 - 10 months after sterilisation. These symptoms did not progress over the next 4.5 years. Therefore they concluded that tubal sterilisation has no long-term effect on menstrual indices.

De Stefano et al. [15] who compared sterilised women with vasectomy spouses, found that at the 6 to 24 month interval, the tubal sterilisation group

had a significantly increased prevalence of moderate to severe cramps among women who had no or mild cramps before sterilisation. The tubal sterilisation group also had moderately increased risk of adverse bleeding at all follow-up intervals, but in no instance was the increase significant.

Bhiwandiwala et al. [12] found that the proportion of women who reported menstrual changes, after controlling for occlusion technique and prior contraceptive use, was essentially the same where the time periods 0 to 6 months, 0 to 12 months and 0 to 24 months were compared. This finding suggests either that the women experienced most changes in the first 6 months after sterilisation and then experience no further changes during later periods, or that the women experienced changes periodically and then reverted to their former status before the completion of one time period or another,

The small study by Campanella and Wolff [32] involved 94 patients who were followed up over a two year period. There was no control group. They found that none of their patients sought gynaecological care because of menstrual symptoms, but menstrual differences were noted. As time progressed, more of the younger patients noted menstrual irregularities: 40% at 6 months, 60% at 1 year and 65% at 2 years. The authors postulated that a possible psychosomatic origin was possible in terms of the relation of hypothalamic impulses to hormonal secretion. Because no controls were available, this response as related directly to sterilisation may be debatable.

1.2.13 SOCIAL SUPPORT AND STERILISATION:

Haynes and Wolfe followed up sterilised patients in a medically indigent population. [35] The most common indications for sterilisation were multiparity, previous caesarian section and socio-medical circumstances.

They argued that the psychological adjustment to the operation (tubal ligation) is often determined by the circumstances constituting the indication for sterilisation. They reasoned that emotional responses are dependent on the presence or absence of a good doctor-patient relationship, on the educational level of the patient, and the availability of suitable counselling services.

The study by Whitelaw reported deterioration in social relationships in 1,7% of a study involving 485 sterilised women. [31] Of the eight women who believed that their social relationships had deteriorated since sterilisation, 5 had psychiatric histories and said their social relationship had always been poor but they appeared to have deteriorated still further since sterilisation. One patient had lost her only son and believed that she had become more withdrawn. One patient stated that her marriage had been unhappy for years and that her ability to enjoy the company of other people had consequently suffered. The eight patients could not explain the deterioration but did not believe that it had anything to do with her sterilisation.

Shain et al considered factors associated with married women's selection of tubal sterilisation and vasectomy. [37] They found that tubal ligation women discussed sterilisation with their husbands on average 6,7 times, compared with 8,5 times for vasectomy wives ($p = 0,000$). This probably meant that social support is a more important factor for men than for women in their decision to undergo sterilisation.

1.2.14 THE HYPOTHALAMIC-LIMBIC SYSTEM:

The hypothalamus is phylo-genetically a very ancient part of the brain. [38] It evolved as part of the limbic system, which is concerned with survival of

the individual and of the species. It provides the interface between the nervous and endocrine systems. Most of its functions are expressed through the pituitary gland and through both divisions of the autonomic nervous system. It has major functions in homeostasis and survival. Its survival functions include regulation of food and water intake, the sleep-wake cycle, sexual behaviour patterns, and defence mechanisms against attack. [38]

One of the discoveries in the field of behaviour was the so-called "pleasure and pain" areas in the brain, involving the hypothalamic-limbic system. [39] This part of the brain plays the greatest role in controlling emotions and other patterns of behaviour. The hypothalamus, under the influence of the cerebral cortex and emotional stimuli, initiates the hormonal cycle by secreting releasing factors that affect the pituitary gland and results in raised levels of follicle-stimulating hormone and luteinizing hormone. [40]

Thus, after reviewing the literature, many questions about the post-sterilisation syndrome or menstrual dysfunction following sterilisation remain unanswered. It is clear from the literature that, while many studies were done, each with its own limitations, few were done from the general practice perspective. This thesis aims to address some of the limitations of previous studies by conducting personal interviews, making provision for confounding variables, and restricting the study to a case-control study in a general practice setting.

1.3 MOTIVATION

Some patients in general practice present with symptoms, mostly gynaecological, which they relate to sterilisation. This, in the opinion of the researcher, required further investigation. The purpose of this study was to

analyse patients' reported responses to sterilisation, and to determine whether women who experience symptoms of menstrual dysfunction differ from women who do not with respect to (1) health status, (2) social support system, (3) psychological and medical history, (4) quality of life, (5) reasons for sterilisation, and (6) feelings about sterilisation. The results of this study would indicate which of these biopsychosocial factors would put patients at risk to develop these symptoms after tubal ligation. This would make health personnel aware of these problems when they have to counsel patients before tubal ligation.

1.4 AIMS

This study was conducted to examine whether post-sterilisation menstrual dysfunction was measurable in a group of women attending a suburban general practice in the Western Cape, by means of a case-control study. Certain biopsychosocial factors, such as health status, social support, psychological and medical history, reasons for sterilisation were investigated to see whether any of these factors could be predictive or associated with post-sterilisation menstrual problems.

1.5 OBJECTIVES

1. To determine patients' reported experience of menstrual indices before and after tubal ligation.
2. To determine how people perceive their health status and quality of life after sterilisation.
3. To evaluate the psychological and medical history, and reason for sterilisation from respondents.

4. To describe any difference in group characteristics of patients who experienced menstrual dysfunction after sterilisation, compared with a control group.

5. To determine patients' feelings about tubal ligation, in terms of fears and regret.

6. To analyse and discuss patient responses in terms of current knowledge and research, and identify possible risk factors.

CHAPTER TWO

METHODS

2 . METHODS

2 .1 DEFINITION OF TERMS:

2.1.1Menstrual dysfunction:

For the purpose of this study, menstrual dysfunction was defined as a significant change in a menstrual function perceived as negative by the patient, after sterilisation. Because of the retrospective nature of the study, and the fact that subjects had to recall from memory, the following menstrual parameters were considered: pain, bleeding, length of flow, lowered work performance, and avoidance of social activities during menstruation.

All sterilised women attending the practice from October 1996 until May 1997 were invited to participate. Patients refusing to take part in the study were excluded, and reasons for refusal were obtained from those patients.

2.1.2 Definition of cases:

The definition of a "case" is critical to the case-control study. [41] [42] It involves two distinct specifications:

(1) establishment of objective criteria for the selection of individuals for study; and

(2) a statement of eligibility criteria for the selection of individuals for study.

Eligibility criteria are established to restrict the study to persons who were potentially at risk of exposure. Such criteria should be applied equally to potential cases and controls. Eligibility criteria can be applied either in the selection phase or in the analysis of the study, whichever is operationally more convenient. In this study a "case" of menstrual dysfunction was defined as a patient with a change in menstrual function in any of the five

menstrual parameters as described above, worse than before, following sterilisation. The study design took into account the menstrual pattern before tubal ligation. Patients who suffered from menstrual dysfunction before tubal ligation, and whose symptoms deteriorated after the operation, were also included as cases.

2.1.3 Definition of controls:

A control group is used to compare the history of exposure in the cases with that in individuals who are free of the study disease. [41] Individuals selected as controls should not only be free of the study disease, but should also be similar to the cases in regard to past potential for exposure during the time period of risk under consideration. The control group in this study consisted of sterilised females who did not experience a change in menstrual dysfunction after sterilisation.

2.2 DESCRIPTIVE ASPECTS:

One of the major objectives of this study was to examine different variables, which could assist in identifying risk factors that would lead to menstrual dysfunction after tubal ligation. The cases and controls were confined to a general practice in Paarl in the Western Cape Province. The patients were all of the middle and lower income group of the Coloured section of the population.

2.3 CASE-CONTROL ASPECTS:

An important objective of this study was to examine the relationship between risk of menstrual dysfunction and exposure to different variables as described under descriptive aspects.

2.4 STUDY DESIGN:

This study was designed as an observational case-control study. The test instrument was in the form of a questionnaire. In a number of clinical conditions standard questionnaires, already tested for validity and reliability, can be used. [44] In many general practice projects, the information being sought is more diffuse and subjective, where more discriminating analyses of graduations of the attitudes or opinions held by the responders are required. For the purposes of this kind of research, attitudes and rating scales are particularly helpful. [43] [44]

The three common methods of obtaining information through questionnaires are (a) by sending a questionnaire through the mail for the study subject to fill out and return; (b) by having an interviewer administer a questionnaire on the telephone; and (c) by having an interviewer administer a questionnaire in person. This structured interview was administered by the two receptionists of the practice, following a well-defined structure to prevent their own interpretation of the questions. Questions were all asked in the same way, with the same probes and clarifications, while recording was also uniform. The answers were coded for use in a statistics computer programme. (Epi Info 6)

2.5 STUDY POPULATION AND SAMPLING:

This general practice consisted of roughly 2000 families representing approximately 6000 patients in suburban Paarl. Ethnically they all belonged to the Coloured population middle and low-income group. All these patients were private patients. Eighty percent of the patients were covered by medical aid of some form and twenty percent of patients paid privately for medical

service. Patients were sterilised at the local Paarl hospital, and by some general practitioners and gynaecologists in private practice.

All sterilised female patients seeking help or attending the practice from October 1996 until May 1997, were identified by the interviewers and invited to participate in this study. Those who reported a significant change in menstrual dysfunction following sterilisation were regarded as cases and those with no changes in menstrual function as controls. Response rate was more than eighty percent of those invited. Reasons for non-responders were established.

Study size:

It can be very difficult to decide on the size of a study. Statistical advice is usually helpful. There are different ways of recruiting the necessary size of patient population or sample. Either many doctors can be asked to contribute a few patients over a short time, or fewer doctors (or one doctor) can study more patients over a longer time. [44]

Each policy has its pros and cons. The more doctors who are involved, the greater the difficulty of ensuring standard criteria of recording and the greater the likelihood of losing co-operation over the duration of the study. The duration is itself an important consideration; the longer a study lasts, the more likely it is that time itself will become a variable which will influence the results produced.

The size of this particular study was based on simple pragmatism; it was limited to the number of sterilised females attending the practice over an eight months period.

2.6 MEASUREMENT

The test instrument was in the form of a questionnaire (highly structured interview), constructed mainly from existing, standardised questionnaires. This instrument had been constructed to assess each patient's functioning with regard to general health, gynaecological parameters, social support and perception of quality of life.

Repeatability:

A percentage of questionnaires were repeated by the practice nurses to determine the reliability of responses (ten percent). This was done by random sampling of the cases and controls respectively, and repeating the interview with these selected patients.

Confounding:

The term confounding refers to the effect of an extraneous variable that wholly or partially accounts for the apparent effect of the study exposure or that masks an underlying true association. [41]

A confounding variable is an extraneous variable that satisfies both of two conditions:

(1) it is a risk factor for the study disease;

(2) it is associated with the study exposure but it is not a consequence of exposure.

From the literature it seemed that possible confounding factors for this study included contraceptive use, menstrual pattern before sterilisation, and uterine or ovarian pathology. [4] [11] [12]

There is no generally agreed upon procedure for determining whether adjustment should be made for any given variable suspected of being a confounder. [41]

Quality of data collected:

A valid method is one that measures what it sets out to measure; a reliable method is one that produces repeatable results. It is essential that data are reliable, valid and complete. [44] [45] The environment in which data collection takes place can at times influence the data. For the purpose of this study, all the respondents were interviewed in a private room in the surgery, in a relaxed atmosphere.

The following sources may cause error in measurement:

(1) The instrument

(2) The observer

(3) The subject

(4) The environment.

Variation between measurements can be decreased by addressing the source of variation.

(1) The instrument variation can be reduced by improving the quality of the questionnaire.

(2) Observer variation can be reduced by standardisation of the interview, intensive training periods for interviewers, by supervision and periodic checks on their work, and by selection of observers along similar criteria with reference to age, sex, educational level and social class.

(3) Subject variations, in this study, may be due to inconsistencies of memory.

Instrument (questionnaire), observer and subject variations can be evaluated by asking related questions, which, if in disagreement, show inconsistencies.

Validity:

Validity refers to the extent to which the questionnaire actually measures what it is meant to measure. [44] [45] Questionnaires are particularly vulnerable to measurement bias. Because a number of patients in this practice were illiterate, self-administered questionnaires would not have given valid results.

Bias in case-control studies:

The following is a list of possible sources of bias and error in case-control studies: [45]

(1) information on the potential risk factor may not be available either from the records or the study subjects' memories;

(2) information on potentially important confounding variables may not be available either from records or the study subjects' memories;

(3) cases may search for a cause for their disease and thereby be more likely to report an exposure than controls (a form of recall bias);

(4) the investigator may be unable to determine with certainty whether the suspected agent caused the disease or whether the occurrence of the disease caused the person to be exposed to the agent;

(5) identifying and assembling a case group representative of all cases may be unduly difficult;

(6) identifying and assembling an appropriate control group may be unduly difficult.

Most of the questions in this study were obtained from existing, standardised questionnaires, where extensive validity studies confirmed reliability and validity

2.6.1 QUESTIONNAIRE (SEE APPENDIX)

The test instrument was divided into different sections:

Demographic information

The patient's age, parity, occupation, and whether she was a smoker, were recorded. Occupation would be classified in classes from I to V, representing from professional to unskilled respectively. A sixth category represented housewives.

Sterilisation

The reason for sterilisation, the duration since the operation, as well as the timing of the operation would be considered as factors which could influence subsequent menstrual dysfunction. Previous studies indicated that contraception is a confounding factor in post-sterilisation menstrual dysfunction; therefore this was also recorded.

General health

The affect balance scale was described by Bradburn as an indicator of happiness or of general psychological well-being; these terms denote an individual's ability to cope with the stresses of everyday living. [43] Overall well-being is expressed as the balance between positive and negative affect. An individual will be high in psychological well-being in the degree to which he has an excess of positive over negative affect and will be low in well-

being in the degree to which negative affect predominates over positive. The affect balance score is calculated as the positive score minus the negative. Bradburn reported test-retest reliability results over three days for 174 respondents. The resulting test-retest associations (Yule's Q) exceeded 0.9 for nine of the items, while the question "excited or interested" had a reliability of 0.86. As far as validity is concerned, positive affect was shown to be related to social participation, satisfaction with social life and engaging in novel activities. The strength of the Bradburn scale is that it has been widely used in many large surveys, so that it is possible to compare findings across studies.

Chronic illness and other operations were also considered under general health.

Gynaecological symptoms.

Because of the retrospective nature of the study, and to minimise recall bias, the following symptoms were considered: pain, bleeding, length of flow, lowered work performance, avoidance of social activities, weight gain and sexual performance before and after sterilisation. The short-form McGill Pain Questionnaire was used to rate menstrual pain, (0) representing no pain and (3) representing the worst possible pain. [46]

The questions on lowered work performance and avoidance of social activities were extracted from the Menstruation Distress Questionnaire of Moos (1969). [47]

Social support

The Social Relationship Scale of McFarlane covers the quantity of social contacts and their supportive qualities. This scale was developed to measure

the extent of an individual's network of social relationships and its perceived helpfulness in cushioning the effects of life stresses on health. [43] [46] The conceptual basis of this is that social bonds are considered necessary for the individual to cope with adverse events. The scale was designed to summarise the qualitative and quantitative aspects of a person's network of relationships that help him to deal with stresses. Test-retest reliability assessment provided correlations for the number of individuals in the person's network ranging from 0.62 to 0.91, and for the helpfulness score correlations were lower, ranging from 0.54 to 0.94.

An abbreviated version of this scale was used in this study. This could have affected the validity of the data obtained in this section.

Psychological history

This part of the questionnaire enquired about psychological illness and whether patients had any regrets after tubal ligation.

Quality of life.

Andrews (1976) described four single indicators of well-being. This is to assess satisfaction with life in general, or with something more specific such as health, economic status or housing. [43] [46] The faces scale is a seven-point scale consisting of stylised faces. Each face consists of a circle with eyes that do not change and a mouth that varies from a smile of almost a half-circle to a similar half-circle upside down, representing gloom. The estimated average test-retest reliability for each scale is about 0.70. This scale may provide a more direct representation of the feelings involved in quality of life than would a verbal translation of the response in a conventional question.

2.7 PILOT STUDIES

The questionnaire was piloted to ensure that the questionnaire :

(1) was easily understood by the patient,

(2) was easy to complete,

(3) captured the required data or responses from the patient,

(4) helped to identify defects in the study design.

2.8 LOGISTICS

The time taken to complete the questionnaire, was recorded. This information was used to make it more convenient to schedule interviews with participants.

In-person interviewing:

In-person interviewing, with properly trained and motivated interviewers, is still the most frequently used method of obtaining data in epidemiologic studies. [45]

Two receptionists of the practice were the interviewers. Training of these two was done on a regular basis by the researcher. This was in the form of a half-hour session, discussing the questionnaire, once a month before and during the duration of the study. The emphasis was on eliciting honest and reliable responses from participants without influencing them. The two interviewers were not informed as to whom would be regarded as cases or controls.

2.9 DATA MANAGEMENT AND ANALYSIS

The Epi Info 6 statistical programme was used to assist in analysing the results. Two by two tables were be used to determine a crude disease-

exposure association by estimating the odds ratio. Adjustment was made for potential confounding variables, and it was assessed whether the magnitude of the odds ratio was increased or diminished by adjustment. The power of the study was determined to help in assessing significance of results. Odds ratios (OR) were applied to measure the strength of the association between risk factors and disease outcome. Ninety-five percent confidence intervals (95% CI) were also calculated.

Study power:

The probability of detecting a difference when one actually exists is known as the power of the test. [44] The power of a study can always be increased by increasing the sample size.

Statistical methods are available for assessing at the planning stage whether the proposed study will achieve sufficient precision to be informative. [41] [45] In practice the size of a study is often restricted by financial resources, the number of available cases, or a time limitation.

Dummy tables were drawn up, describing sample characteristics, as well as associations between variables. Once the data had been collected, these tables were used as a starting point for analysis.

Characteristic	Cases	Controls
Present	a	b
Absent	c	d

Odds ratio = a x d / b x c

Measures of relative risk: comparison of odds ratios:

Traditionally, the basic case-control comparison is expressed in terms of the proportion of cases versus the proportion of controls who show a particular characteristic. If the characteristic is a quantitative rather than a qualitative attribute, then its distribution in the cases and controls can be compared, including the mean, standard deviation, and median. [42] If the cases show a higher proportion with an attribute than do the controls (i.e., relative risk greater than 1), or if the distributions or mean levels of an attribute differ, then there is an observed association between the attribute and the disease.

Interpretation:

The concept of an association refers to a dependence, which may or may not be causal, between two or more variables. Interpreting whether this association implies a cause-and-effect relationship is another matter, involving a number of considerations. [41] [42] [44] Statistical association may be measured in terms of odds ratio, relative risk or correlation coefficient. The correlation coefficient indicates the degree to which a set of observations fits a linear relationship.

2.10 RESOURCES

This study was conducted in the general practice of the researcher. All the stationery used was generated from the office computer equipment. The Epi Info 6 programme was used to do the various calculations. No outside financial assistance was required.

2.11 ETHICAL AND LEGAL CONSIDERATIONS

Informed consent and confidentiality:

The medical questionnaire or interview must frequently probe the deeper levels of a person's private experience. [41] Often sensitive facts such as educational level attained, age or even sexual habits are included. Such intrusion raises issues concerning the right to privacy and to protection from exploitation of delicate material. Although case-control investigations do not involve administering or withholding therapies, they do obtain personal information and consequently involve ethical issues relating to "informed consent" and confidentiality.

In granting consent, the individual should understand the general nature and purpose of the study, the possible risks and benefits, and his or her right to withdraw from the study at anytime without prejudicing present or future treatment. [41] [42] The patients in this study were informed about the research and asked whether they would like to participate. They were also informed about their right to refuse to participate. It was also made clear to them that confidentiality would be guaranteed. Verbal consent was required for the purpose of this study.

Numerous techniques can be used to help guarantee that the information collected from each individual is held in confidence. In this study, no names were recorded on questionnaires. Each respondent was assigned a number, and the corresponding name and number entered into a separate file, known only to the principal investigator and the interviewers. They were also instructed to refrain from discussing any personal aspects of the data collected. Permission to go ahead with this study was obtained from the UCT ethics committee.

2.12 REPORTING OF THE DATA AND IMPLEMENTATION OF RESULTS

A summary of results and findings would be available upon request to interest groups such as family planning clinics, gynaecologists, counsellors and general practitioners. It was also intended to submit a report of this study to a medical journal for possible publication.

CHAPTER THREE
RESULTS

3.1 The cases of menstrual dysfunction:

3.1.1 Case ascertainment

3.1.2 Case characteristics

3.2 The controls: numbers and characteristics

3.3 Comparison of characteristics of cases and controls

3.4 Comparison of odds ratios for different exposures or variables

Table 3.1

Table 3.2

Table 3.3

Table 3.4

RESULTS

One hundred and forty-four women were invited to participate in this project, and only one patient refused to participate. This means that the response rate was 99,3%. The reason given by the patient who refused to be interviewed, was that she did not want to be questioned about her sterilisation, because this was too personal a matter for her to discuss it with someone else.

3.1 THE CASES OF MENSTRUAL DYSFUCTION AFTER TUBAL LIGATION

3.1.1 Case ascertainment:

Out of 143 respondents interviewed, 49 were classified as suffering from menstrual dysfunction after the interview. Five criteria were used; pain, bleeding, length of flow, lowered work performance and avoidance of social activities as a result of menstruation. Respondents had to be worse off after sterilisation than before to be included in the "cases" category. This meant that those patients who had menstrual problems before and after tubal ligation, but with no change in the degree of the symptoms, were not regarded as cases. The interviewers were "blind" as to who would be regarded as cases or controls.

3.1.2 Case characteristics:

Case characteristics are represented in Table 3.1. The 49 respondents classified as cases had a mean age of 39,61 years (standard deviation 7,94). The mean duration (in years) since the operation was done was 7,92 years

and the mean parity was 3,38. The majority of cases were housewives (32,7%) and skilled workers (26,5%). Only 10,2% were professional people.

3.2 THE CHARACTERISTICS OF THE CONTROLS:

There were 94 respondents who were identified as controls. They were also classified according to their responses, where there was no deterioration of symptoms after tubal ligation. Out of the 94 controls there were 39 respondents who actually reported an improvement in their symptoms after the tubal ligation. The controls had a mean age of 41,4 years. Mean duration since the operation was 8,47 years. These results are presented in Table 3.1. The mean parity was 3,55. The majority of the controls were housewives (37,4%), skilled workers (23,4%) and only 9,9% were professional people.

TABLE 3.1

COMPARISON OF CASE AND CONTROL CHARACTERISTICS:

	Cases n = 49		Controls n = 94			
Variable	Mean	S.D.	Mean	S.D.	t-value	p-value
Age	39,61	7,94	41,40	8,32	1,241	0,214
Duration	7,92	6,72	8,47	6,56	0,471	0,644
Parity	3,38	1,40	3,55	1,62	0,606	0,552
Weight gain kg	9,16	5,02	8,93	6,32	0,175	0,855
Qual. life score	2,61	1,96	1,63	1,02	8,122	0,004*

* = significant at 95% confidence limits.

S.D. = Standard Deviation of the Mean.

3.3 COMPARISON OF CHARACTERISTICS OF CASES AND CONTROLS:

These results are represented in Table 3.1. Of note here are the differences between quality of life score, with p-value of 0,004. Patients in the control group were more satisfied with the quality of their lives when compared to cases.

In the open-ended question section, patients were asked about their fears after tubal ligation. The results are tabulated in Table 3.2. Fifteen out of forty-nine (30,6%) cases and nine out of ninety-four (9,6%) controls reported certain fears.pertaining to sterilisation. Six out of forty-nine cases (10,2%) and three out of ninety-four (3,2%) had the specific fear of another pregnancy after tubal ligation.

TABLE 3.2 FEARS EXPRESSED BY PATIENTS AFTER TUBAL LIGATION:

	CASES n = 49		CONTROLS n=94	
	FREQUENCY	(%)	FREQUENCY	(%)
Pregnancy	6	12,2	3	3,2
Decreased libido	3	6,1	1	1,1
Cancer	2	4,1	1	1,1
Heavy menstruation	2	4,1	0	0
Abdominal cramps	1	2,0	0	0
Headaches	1	2,0	0	0
Loss of pelvic organs	0	0	1	1,1
Too young at sterilisation	0	0	2	2,1
Weight gain	0	0	1	1,1

Three cases as compared to one control expressed the fear of decreased libido as a complication of tubal ligation. The fear that a person may be too young when sterilised, was expressed by two controls.

3.4 COMPARISON OF ODDS RATIOS:

Tables 3.3 and 3.4 compare various factors related to cases and controls. The power of this study was generally less than 80 percent. The results have been adjusted for confounding factors such as contraception.

TABLE 3.3 COMPARISON OF ODDS RATIOS BETWEEN CASES AND CONTROLS.

	CASES n = 49		CONTROLS n = 94				
HEALTH FACTOR	Frequency	Percentage	Frequency	Percentage	Odds Ratio	95% CI	P-value
Sterilisation health reasons	13	26,5	15	16,0	1,9	0,76 to 4,80	0,130
Smoking	24	49,0	30	31,9	2,0	0,90 to 4,23	0,063
General contraception	17	34,7	38	40,4	0,8	0,37 to 1,76	0,562
Hormonal contraception	9	18,4	25	26,6	0,6	0,25 to 1,61	0,301
Chronic illness	17	34,7	23	24,5	1,6	0,71 to 3,67	0,209
Operations in general	20	40,8	39	41,5	1,0	0,45 to 2,08	0,938
Operations reproductive system	11	55	14	36	2,2	0,64 to 7,58	0,159
Weight gain	34	69,4	59	62,8	1,3	0,61 to 3,01	0,431
Sex life worse	15	30,6	19	20,2	1,8	0,76 to 4,26	0,146
Psychological illness	25	51,0	41	43,6	1,3	0,62 to 2,80	0,431
Headaches + depression	12	24,5	8	8,5	3,5	1,19 to 10,19	0,001*

CI = Confidence interval
* = Significant at 95% confidence interval

TABLE 3.4 COMPARISON OF ODDS RATIOS BETWEEN CASES AND CONTROLS.

	CASES n = 49		CONTROLS n = 94				
HEALTH FACTOR	Frequency	Percentage	Frequency	Percentage	Odds Ratio	95% CI	P-value
Regret	8	16,3	7	7,4	2,4	0,73 to 8,08	0,100
Partner less caring	5	10,2	4	4,3	2,6	0,57 to 12,3	0,155
Timing postpartum	26	53,1	46	49,0	1,4	0,64 to 3,12	0,352
Fears after tubal ligation	15	30,6	9	9,6	4,2	1,53 to 11,53	0,001*
Age 30 or less	5	10,2	7	7,4	1,4	0,36 to 5,34	0,573
Time elapsed < 2 years	17	34,7	18	19,1	2,3	0,96 to 5,48	0,039*
Parity 2 or less	13	26,5	27	28,7	0,9	0,41 to 2,26	0,925
Health status score < 0	15	30,6	26	27,7	1,2	0,50 to 2,63	0,712
Helpfulness score	25	51,0	32	34,0	2,1	0,93 to 4,51	0,050*
Social support score 1 or less	31	63,3	73	77,6	0,6	0,24 to 1,30	0,138

CI = Confidence interval
* = Significant at 95% confidence interval

CHAPTER FOUR:

DISCUSSION

4.1 LIMITATIONS:

4.1.1 Limitation of descriptive aspects

4.1.2 Limitation of case-control aspects

4.2 MEASURES OF RELATIVE RISK (odds ratios):

4.2.1 Reason for sterilisation

4.2.2 Smoking

4.2.3 General contraception

4.2.4 Hormonal contraception

4.2.5 Chronic illness

4.2.6 General surgical operations

4.2.7 Reproductive system operations

4.2.8 Weight gain

4.2.9 Sex life

4.2.10 Psychological illness

4.2.11 Regret after tubal ligation

4.2.12 Caring attitude of partner

4.2.13 Timing of tubal ligation

4.2.14 Reported fears after tubal ligation

4.2.15 Age

4,2,16 Time elapsed since operation

4.2.17 Parity

4.2.18 Health status

4.2.19 Helpfulness of discussion

4.2.20 Social support

4.3 SIGNIFICANT FINDINGS:

4.3.1 Quality of life

4.3.2 Fears after tubal ligation

4.3.3 Time elapsed since operation

4.3.4 Helpfulness score

4.3.5 Depression and headache

4.1 LIMITATIONS

4.1.1 LIMITATIONS OF DESCRIPTIVE ASPECTS:

Case ascertainment:

To achieve a study power of eighty percent, more than 900 sterilised women had to be interviewed. This was not possible for several reasons:

(1) The study was conducted from a single general practice

(2) The time frame did not allow for such a big study

(3) The practice population was not large enough to obtain such a large number of cases and controls.

The classification of cases was based on information obtained from respondents, and not on a strictly patho-physiological diagnosis. Therefore definition of cases depended on recall from patients' memories, which could have led to bias in classifying cases and controls.

Representativeness of cases:

One of the aims of this study was to identify all patients with menstrual dysfunction after tubal ligation who attended a general practice over a period of eight months. These patients were then compared with patients who did not have menstrual dysfunction following tubal ligation. One of the problems of case-control studies is the representativeness of cases.

These cases represent patients of a particular general practice in Paarl. This may not be representative of other general practices in other areas. The study sample may also not be a truly representative sample of sterilised women in Paarl, because a large percentage of sterilised women attend the local hospital for treatment. The exact number of women who had undergone tubal ligation in the area is not known.

Measurement:

There are limitations in measuring menstrual parameters using a questionnaire. Quantifying factors such as degree of menstrual pain and bleeding, length of flow in days, lowered work performance and avoidance of social activities in retrospect is open to recall bias. However, repeat questionnaires administered to a random sample of the population of women interviewed initially, resulted in one hundred percent correct reclassification of cases and controls. Therefore, although the patients' responses determined how they were classified, they were at least consistent in their responses.

4.1.2 LIMITATIONS OF CASE-CONTROL ASPECTS:

The size of the study was small and study power was generally less than eighty percent. The study was limited to a single general practice, so that it lacked generalisability.

Confounding:

Confounding variables considered included contraception prior to tubal ligation, and menstrual pattern prior to sterilisation. These possible confounders were all considered in the design of the study. Because of this, these potential confounding factors were considered a minor source of bias in this study.

Representativeness of controls:

Controls were taken from the same general practice population as the cases, and they all had tubal ligations. Jick and Vessey (1978) and Cole (1979) have stressed that past emphasis (Feinstein 1973) on the acquisition of a "representative" sample of cases and controls has been misplaced, since it

has been urged not for reasons of generalisability, but rather for validity. A valid study may be carried out in a highly restricted group of individuals. [41]

Misclassification:

Misclassification due to incorrect reporting of menstrual indices as a result of recall bias should be considered. A number of strategies were adopted to control for this bias in this study:

(1) Interviewers were not informed prior to the study who would be regarded as cases or controls.

(2) The questionnaire was rigidly structured.

(3) Training of interviewers emphasised the requirement of a standardised approach to the interview

Repetition of a ten percent sample of cases and controls resulted in one hundred percent reclassification as before.

Analysis deviation:

Where statistics represented a skewed distribution, nonparametric measures of statistics were used. The Fischer's exact test were used where expected cell frequencies were less than five. For most odds ratios the corrected values were obtained using the Mantel-Haenszel formula. When it was regarded as necessary, odds ratios were adjusted for possible effects of confounding. In summary, in this study it was attempted to minimise substantial bias for this type of study.

4.2 MEASURES OF RELATIVE RISK:

4.2.1 REASON FOR STERILISATION:

The majority of studies have shown that tubal ligation was performed more often for reasons of having achieved the desired family size than for medical reasons. [8] [27] [35] Campanella and Wolff found no statistical difference between patients who were sterilised for medical reasons versus personal choice. [32]

Dueholm et al. compared women who underwent induced first trimester abortion and concurrent laparoscopic sterilisation with women who had sterilisation performed at least three months after induced abortion. [30] They found that there was no statistical difference between the two groups with respect to lower abdominal pain or change in bleeding pattern after tubal ligation.

The results of this researcher's study have shown that a bigger percentage (26.5% versus 16.0%) of cases were sterilised for health reasons, compared to controls. Statistically the difference was not significant (odds ratio 1,9, p-value 0,130).

4.2.2 SMOKING:

The percentage of smokers was much higher in the cases (49%) than in the controls (31,9%). Odd ratio = 2,0 p= 0,063. This result falls just outside the limit of statistical significance, but the odds ratio was unaffected by adjusting for a confounder such as contraception. The small study size makes it difficult to interpret this result and this should be looked into detail by another study. The questionnaire did not make provision for ascertaining the number of cigarettes smoked or for how many years the respondent were

smoking. This requires further investigation before a meaningful conclusion can be drawn.

The study by DeStefano et al. compared the menstrual characteristics of women who had tubal ligations with women whose partners had undergone vasectomy. [15] The tubal ligation group included a slightly higher percentage of cigarette smokers (34,6% versus 30,7%). The results indicated that at follow-up intervals longer than two years, the tubal ligation group had significantly increased risks of abnormal menstrual cycles. However, it is not clear from their study whether there is a significant association between cigarette smoking and menstrual dysfunction.

4.2.3 + 4.2.4 GENERAL AND HORMONAL CONTRACEPTION:

In a number of studies the researchers have recognised the important confounding effect of previous contraceptive use on menstrual function. [12] [14] [17] [18] Rulin et al. found that previous oral contraceptive users exhibited an immediate increase in menstrual flow and dysmenorrhoea following tubal ligation, which declined slightly with time. [14] While using oral contraceptives, women have shorter, more regular periods. [21] While using intra-uterine contraceptive devices, they have longer, less regular periods. Bhiwandiwala et al. found that former users of oral contraceptives who experienced a change after sterilisation, experienced increased cycle length, flow duration and amount of flow, and irregular cycles. [12] After discontinuation of intra-uterine contraceptive devices, more women became regular and experienced a decrease in flow duration, amount of flow, dysmenorrhoea and intermenstrual bleeding.

In this study contraception did not appear to have a significant effect when comparing cases and controls (odds rates 0,8 p-value 0,562).

As far as hormonal contraception is concerned, a smaller percentage of cases (18,4 %) used hormonal contraceptives compared to 26,6% controls (odds ratio 0,6 p-value 0,301) prior to tubal ligation.

Although the size of the authors' study was small, from the results it appears that contraception did not have a significant statistical effect when comparing cases and controls.

4.2.5 CHRONIC ILLNESS:

A higher percentage of cases (34,7%) compared to 24,5% of controls suffered from chronic illness. This difference did not appear to be statistically significant. The three most common chronic illnesses mentioned by respondents were hypertension, diabetes and polyarthritis.

From the literature certain chronic illnesses, such as hypertension and diabetes were mentioned as reasons for sterilisation. [26] [35]

4.2.6 + 4.2.7 GENERAL OPERATIONS AND OPERATIONS OF THE REPRODUCTIVE SYSTEM:

There was no difference between cases and controls when comparing the history of general surgical operations. Considering the operations involving the reproductive system (breast, uterus, ovaries) there was a difference in percentage of 55% in cases and 36% in controls. Odds ratio 2.2 p-value 0,159. The numbers involved were small and this could account for the fact that it did not appear to be statistically significant. The exact type of procedure used for sterilising these patients were also not known.

Shy et al. found higher rates of hospitalisation for menstrual disorders in sterilised women when compared to women in the general population. [17] Hillis et al. found an increased risk of subsequent hysterectomy in sterilised women compared to non-sterilised women. [29] Both authors concluded that factors other than a biological effect could have been responsible for these findings. Riedel et al. found that a higher percentage of women sterilised with the high frequency procedure, subsequently underwent hysterectomy when compared to women sterilised with the endocoagulation technique. [24]

4.2.8 WEIGHT GAIN:

The majority of cases (69,4%) and controls (62,8%) gained weight following tubal ligation. The difference in weight gain did not appear to be statistically significant.

4.2.9 SEX LIFE:

The studies by Dueholm et al. and Whitelaw showed that the majority of sterilised women is satisfied or experienced an improvement in their sex life after the operation. [30] [31] Bordahl reported that a very high percentage of sterilised women indicated an improvement in their sex life. [48] Whitelaw reported that 36,3% of the sterilised women in his study experienced an improvement in the quality of their sex life. [31]

The results of this researcher's study indicated that 30,6% of cases regarded their sex life as worse after tubal ligation, compared to 20,2% of controls. There was therefore a tendency for females with menstrual dysfunction to report that their sex lives were affected negatively. (Odds ratio 1,8, $p = 0,146$). This was not statistically significant.

The power of this researcher's study was less than 80% so that a bigger sample is required to determine whether this result is statistically significant. However, the results still indicate that the majority of sterilised women are satisfied with their sex lives after tubal ligation.

4.2.10 PSYCHOLOGICAL ILLNESS INCLUDING SPECIFIC ILLNESS:

In the study conducted by Whitelaw a small percentage of sterilised women mentioned recurrent depression as a cause of deterioration in mental health. [31] Vessey et al. analysed data concerning hospital referrals for psychiatric disorders between two groups of women. [13] The one group had undergone tubal ligation and the other group had husbands who had undergone vasectomy. As far as psychiatric illness is concerned, there was no important difference between the two groups.

In this researcher's study a slightly higher percentage of cases (51%) compared to controls (43,6%), had a history of psychological illness. This difference was not statistically significant. On examining a subgroup of specific illnesses , then there was a marked difference between cases and controls where depression and tension headaches were grouped together. (24,5% versus 8,6%, odds ratio 3,5, p = 0,001).

The interview with respondents in this study of menstrual dysfunction did not specify whether psychological illness followed tubal ligation or not, so that it is not possible to say whether depression and tension headaches preceded or occurred after sterilisation. It is also theoretically possible that external factors such as marital problems, work related problems or, domestic or personality problems, could account for this finding. This could be the objective of another study to test this hypothesis.

4.2.11 REGRET AFTER TUBAL LIGATION:

The most common cause for regret following tubal ligation is a wish for more children. [27] [48] The ethnic background of women and their number of children at the time of surgery were not factors for regret.

Young age at sterilisation, remarriage, and infant or child death frequently are associated with regret. [34] Satisfaction with pre-sterilisation counselling is important to prevent later dissatisfaction with the operation. [27] [34] [48]

The above-mentioned variables were not explored further in the researcher's study. There was a difference of 8.8% between cases (16.3%) and controls (7.4%) who reported feelings of regret about their tubal ligation (odds ratio 2.4 p = 0.100). Although this was not statistically significant, there was a tendency for regret to be a significant factor when comparing cases and controls.

Because tubal sterilisation is the world's most commonly used contraceptive method, even a small proportion who regret their tubal ligation would translate into a large number of sufferers.

4.2.12 CARE BY PARTNER:

A slightly higher percentage of cases felt that their partners cared less for them after the tubal ligation when compared to controls (10.2% versus 4.3%). This difference was not statistically significant.

Bordahl and Whitelaw reported an improvement in marital relations following sterilisation. [31] [35] Many of the women attributed this improvement to the sterilisation. [31]

4.2.13 TIMING OF TUBAL LIGATION:

Rulin et al. observed no differences in menstrual sequelae when comparing post-partum sterilisation and interval sterilisation. [18] The study by Dueholm et al. supported these findings. [30]

The results of the author's study indicated that there was no statistically significant difference between cases and controls who had their sterilisation postpartum.

4.2.14 FEARS REPORTED AFTER TUBAL LIGATION:

A much higher percentage of cases (30.5%) reported fears after tubal ligation, compared to controls (9.7%) (odds ratio 4,2 p= 0.001). This was statistically significant. These fears are listed in Table 3.2. The majority listed fears of pregnancy, decreased libido, cancer and heavy menstruation. These fears are not without foundation when the literature is considered.

Peterson et al. found that the probability of failure for all sterilisation methods was 18,5 per thousand procedures. [2] Laparoscopic spring application had the highest probability of failure (36,5 pregnancies per thousand procedures). The younger the woman at the time of the sterilisation, the more likely she was to have a sterilisation failure.

Another study reported by Peterson et al. found that the cumulative probability of ectopic pregnancy was 7,3 per thousand procedures. [1] Women of younger age at the time of tubal ligation were also at increased risk. Ectopic pregnancies may occur many years after the procedure.

Various studies have shown that there was an improvement in libido following sterilisation. [30] [31] [48] The question of heavy menstruation following sterilisation is still controversial. A number of studies found significant menstrual changes after sterilisation. [6] [10] [15-17] [19]

4.2.15 AGE:

Comparing the younger age group (30 years or less) of cases with controls, no significant statistical differences were found (10,2 versus 7,4, odds ratio 1.4 p= 0,573). Because of the small size of the study sample, and the small number of cases and controls in this age group, it is difficult to tell whether there is a tendency for the younger age group (age at sterilisation) to suffer from menstrual dysfunction.

Bhiwandiwala et al. found that age was not a confounding factor when they analysed menstrual pattern changes after laparoscopic sterilisation. [12]

4.2.16 TIME ELAPSED SINCE TUBAL LIGATION:

The study reported by Bhiwandiwala et al. found that the proportion of women who reported menstrual changes after sterilisation was essentially the same over various time periods. [12] These time periods included 0 to 6 months, 0 to 12 months, and 0 to 24 months. Their findings suggested either that the women experienced most changes in the first six months after sterilisation and then experience no further changes during later periods, or that the women experienced changes periodically and then reverted to their former status before the completion of one time period or another.

When cases and controls in the researcher's study were compared with respect to the time elapsed since tubal ligation; there was a significant difference between cases and controls at 2 years or less after sterilisation. (Odds ratio 2,3 p = 0,039). This difference remained statistically significant after adjusting for possible confounding (contraception). When the time elapsed since tubal ligation was extended to 10 years, then the difference between cases and controls became insignificant. The data suggest that over

a long period of time, menstrual patterns tend to stabilise, or that women are more comfortable with menstrual patterns in the long term. The data also suggest that surgical sterilisation does not cause changes in menstrual pattern over the long term. This finding is supported in studies by Bhiwandiwala et al. and Vessey et al. [12] [13]

4.2.17 PARITY:

No significant differences were detected between cases and controls when those with 2 children or less were compared. Odds ratio 0,96 p-value 0.925.

4.2.18 HEALTH STATUS:

There was a slight difference in perceived negative health status between cases (30,6%) and controls (27,7%). This difference was not statistically significant (odds ratio 1.2, p-value 0,712). One would have expected more cases, because of the menstrual dysfunction, to feel negative about their health, but this was not the finding in this study. It could also be that menstrual dysfunction was not regarded as a significant determinant of health by the women in the study.

Whitelaw found that the large majority of sterilised patients reported that their mental health was either the same or improved after tubal ligation. [31] Campanella and Wolff reported that the majority of patients (94%) were positive about their health after sterilisation. [32]

4.2.19 HELPFULNESS OF DISCUSSING PERSONAL HEALTH EVENTS:

Shain et al. analysed the factors associated with married women's selection of tubal sterilisation and vasectomy. [37] They found that younger

women with fewer children were more likely to perceive social pressure against sterilisation. Tubal ligation women discussed sterilisation with their husbands an average of 6,7 times, compared with 8,5 times for vasectomy wives. They also found that tubal ligation women discussed sterilisation with an average of 2,1 individuals, compared with 3,2 individuals for vasectomy wives, before the actual decision was made.

In the researcher's study there was a notable difference when comparing how cases and controls viewed helpfulness of discussing personal health events with significant others. A score of three or less was found in 51,0% of cases, compared to 34,0% of controls. Odds ratio 2,1 p-value 0,050. This suggests that the quality of the social relationships was generally regarded as inferior in the case group.

4.2.20 SOCIAL SUPPORT SCORE:

When the number of people (one or less) supporting women after tubal ligation were compared, there was a slight difference between cases (65,9%) and controls (77,6%). This difference was not statistically significant. (Odds ratio 0,6 p-value 0,138).

Shain et al. found that women who had tubal ligations needed less social support than wives whose husbands had undergone vasectomy. [37]

4.3 SIGNIFICANT FINDINGS:

The following five points were regarded as important findings by the researcher, resulting from this case-control study:

4.3.1 QUALITY OF LIFE:

There was a significant difference between cases of menstrual dysfunction and controls, with cases being less satisfied with their quality of life than the controls. Of note however, is the fact that the tendency was still for the majority of cases to be satisfied with their quality of life, rather than dissatisfied. This would suggest that patients in general, are comfortable with the idea of sterilisation and the effects of sterilisation.

4.3.2 FEARS AFTER TUBAL LIGATION:

It was quite clear from this study that cases of menstrual dysfunction had a higher percentage of fears expressed as compared to controls. Some of these fears have been validated in numerous studies and therefore need to be taken seriously.

The fears expressed by this study sample included fear of pregnancy, decreased libido, cancer, heavy menstruation, abdominal cramps, headaches, potential loss of pelvic organs, too young age at sterilisation and weight gain.

4.3.3 TIME ELAPSED SINCE TUBAL LIGATION

It appeared that cases of menstrual dysfunction were more prevalent during the first 2 years after sterilisation, but with time menstrual patterns became stabilised so that the difference became insignificant after 10 years. This could also mean that over a longer time period menstrual parameters returned to baseline parameters before sterilisation.

4.3.4 HELPFULNESS OF DISCUSSION SCORE:

It was found that the quality of the social relationships of cases and controls are more important than the quantity of people involved in social relationships with regard to health problems. Cases generally had a lower score, suggesting that the quality of social support received was not on the same level as those in controls.

4.3.5 DEPRESSION AND HEADACHES:

There appeared to be an association between cases of menstrual dysfunction and depression and headaches. This study sample was small and did not go into detail as to the nature or relationship of this association. It is quite possible that a larger study with the major objective of studying this relationship may provide more light on this matter.

CHAPTER FIVE

SUMMARY OF CONCLUSION AND RECOMMENDATIONS

5.1 Evaluating the statistically significant findings

5.2 Conclusion

5.3 Recommendations

5.4 This research in the context of general practice

5.1 EVALUATION OF SIGNIFICANT FINDINGS

The above group of five apparent associations were evaluated in terms of:

(1) whether this was a chance observation;

(2) whether this was due to bias;

(3) whether this was due to confounders;

(4) who did this apply to;

(5) whether this represented a cause- and effect- relationship. [42]

THE ROLE OF CHANCE

The size of the sample and therefore the power of the study was small and there was therefore always the possibility that the study could not detect an association, when in fact such an association existed. However, the significance tests in the group of five associations showed that the probability of the association being a chance finding was small.

THE ROLE OF BIAS:

The two main types of bias that had to be considered were selection bias and information bias. Selection bias did not seem to be a problem, because a ten- percent random sample of repeat questionnaires by the same interviewers resulted in a 100% correct re-classification of cases and controls.

Information bias or recall bias was more of a problem, although the majority of repeat responses coincided as before. This is one of the problems of case-control studies, where information was gathered retrospectively. The overall impression was that bias probably did not play such a big role in this study.

THE ROLE OF CONFOUNDING:

The design of the study was such that the two big possible confounders, contraception and menstrual pattern before tubal ligation, was taken care off in terms of prevention. Specification eg. age was also used to control for confounding. Adjustment was used to eliminate confounding by the stratified variable when estimating odds ratios. The method used was the Mantel-Haenszel test, which is commonly used to determine whether the summary relative risk differs to a statistically significant degree from the no-association relative risk of 1.0. [42]

APPLICABILITY OF ASSOCIATION:

This study was conducted in a general practice population which generally differs from the average hospital population. There are many similarities between general practice and hospital practice of primary care level, but generally the social class of patients is different. Therefore, this study has internal validity, but these findings are probably not generalisable to other patient populations or other general practice populations with different patient profiles.

CAUSE-AND-EFFECT RELATIONSHIPS:

Usually, the stronger the association, the more likely it represents a cause-and - effect relationship. [42] Weak associations often turn out to be spurious and explainable by some known, or as yet unknown, confounding variable. In order for an association to be spurious, the underlying factor that explains it must have a stronger relationship to the disease than does the suspected causal factor. Strength of association in case-control studies is measured by the odds ratio. The odds ratio was highest when comparing

fears after tubal ligation in the menstrual dysfunction group. (Odds ratio 4,2).

In a causal relationship the characteristic or event associated with the disease must precede the disease. [42] This relationship could not be clearly established in this study, because the fears regarding tubal ligation were not established before the operation took place. This association cannot be explained in terms of a known biological mechanism, but possibly on a psychological basis. It is probable that menstrual dysfunction could cause anxiety in these patients, which may result in certain fears about tubal ligation.

5.2 CONCLUSION

The purpose of this study was to identify women who developed a significant change in menstrual dysfunction after sterilisation, and to compare various characteristics with a control group in order to identify possible risk factors. The result of this case-control study showed that:

(1) Patients with menstrual dysfunction generally were less satisfied with their quality of life compared to controls.

(2) There was a significant difference between the case and control group regarding fears about tubal ligation, the group with menstrual dysfunction having legitimate fears.

(3) Menstrual dysfunction was more common during the first two years following tubal ligation.

(4) The quality of social relationships was more important than the number of people in relationships.

(5) Depression and tension headaches appeared to be more common among women with menstrual dysfunction after tubal ligation.

The author would like to put forward a possible explanation for some of these findings, as various studies done previously have failed to prove consistency of results in studies to account for reasonably reliable explanations. Two factors should be considered :

(i) the hypothalamic-hormonal control system.

(ii) the doctor-patient relationship.

(i) THE HYPOTHALAMIC-HORMONAL SYSTEM:

Sterilisation is an intensely personal matter, which affects the core of being a woman. Curtailing the reproductive capacity of a woman may evoke deep emotions, which will differ from patient to patient. The hypothalamus, influenced by the cerebral cortex and by various emotional stimuli, initiates the hormonal cycle by secreting releasing factors that enter the circulation and cause the pituitary gland to secrete two gonadotropins, follicle-stimulating hormone and luteinizing hormone. [40] It is therefore quite possible that psycho-social factors may affect women who were sterilised, in terms of menstrual parameters and experiences about tubal ligation. This could explain the wide variety of responses in sterilised women, as compared to a consistent biological effect.

(ii) THE DOCTOR-PATIENT RELATIONSHIP:

Michael Balint described the importance of the doctor-patient relationship. [49] Certain people, for some reason or other, find it difficult to cope with the problems of their lives and resort to becoming ill. If the doctor has the opportunity of seeing them in the first phases of their becoming ill, i.e. before

they settle down to a definite "organised" illness, the doctor may observe that these patients propose various illnesses, and that they have to go on offering new illnesses until between doctor and patient an agreement is reached, resulting in the acceptance by both of them of one of the illnesses as justified. The variety of illnesses available to any one individual is limited by his constitution, upbringing, social position, his conscious or unconscious fears and fantasies about illness. One of the important effects of the drug "doctor" is his response to the patient's offers. [49] [50] This would suggest that if a good doctor-patient relationship exists between doctor and patient, and the patient is followed up by the same doctor before and after tubal ligation, there should be a minimal amount of problems after sterilisation.

5.3 RECOMMENDATIONS:

From the results of this study, it is clear that two important aspects of sterilisation should be considered:

(i) Patient selection

(ii) Patient counselling

Penney et al. expressed the opinion that, despite the frequency of sterilisation and the concerns regarding litigation and patient regret, there were no agreed guidelines within Scotland covering selection of patients, pre-sterilisation counselling or appropriate techniques for tubal occlusion. [51] They reviewed contemporary medical literature relating to laparoscopic sterilisation, providing the basis for a list of criteria, regarded as summarising essential elements of good practice. The criteria covered four broad aspects of patient management: patient selection, information and counselling, techniques for tubal occlusion and timing of sterilisation. A questionnaire was then designed to assess level of agreement with each criterion. The

results showed that these criteria for good quality care in relation to sterilisation was validated by agreement among Scottish gynaecologists.

(i) PATIENT SELECTION:

In most cases sterilisation should be refused to women under the age of 25 and reversible methods of contraception advised. This recommendation is based on evidence that younger women have a higher incidence of post-sterilisation regret and request reversal. [34] [51]

Prior to sterilisation it should be verified, by gynaecological history taking and examination, that a more radical operation is not indicated. [51] There is evidence that there is a higher risk of undergoing hysterectomy after tubal ligation. [29] Patients should be psychologically sound at the time of sterilisation, because this could lead to later psychological problems, regret or possibly menstrual dysfunction.

(ii) PATIENT COUNSELLING:

Prior to female sterilisation, it should be ascertained that the option of vasectomy has been fully discussed with married or cohabiting couples. Counselling should include discussion of failure rate (including risk of ectopic pregnancy) and complications and should emphasise that the procedure is intended to be permanent. [27] [34] [48] [51]

The counselling should include enquiry into any disharmony within the current relationship. The likelihood of a less acceptable menstrual pattern following sterilisation should be discussed with current users of the contraceptive pill. Women should be advised to continue with their current method of contraception (including the contraceptive pill) until their admission for sterilisation.

Women should also be informed about the possibility of external factors that may affect their menstrual parameters and feelings about sterilisation.

5.4 THIS RESEARCH IN THE CONTEXT OF GENERAL PRACTICE

McWhinney [50] described the biopsychosocial model which provides the theory for the three stage diagnosis used in family practice. This clinical method involves a clinical diagnosis, exploring the patient's experience of the illness (individual diagnosis), and the illness in context. Considering the three-stage diagnosis, the typical woman in the researcher's practice, who is likely to suffer from menstrual dysfunction following tubal ligation may be profiled as follows:

PROFILE OF THE WOMAN WITH MENSTRUAL DYSFUNCTION:

CLINICAL:

Sterilised for health reasons, postpartum or post-abortion.

Sterilised at young age < 30 years.

Psychological illness, such as depression, tension headaches.

Prone to operations of the reproductive system.

INDIVIDUAL:

Fears: pregnancy, decreased libido, cancer, heavy menstruation, abdominal cramps, headaches.

Feelings: possibility of regret, feeling less cared for.

CONTEXTUAL:

Poor quality of social relationships.

Deteriorating sex life.

These characteristics are not generalisable to the total population of sterilised women. This study only has internal validity and refers to a specific general practice population.

By being aware of this problem and profile of the woman with menstrual dysfunction following sterilisation, the general practitioner or family physician could play an important role in the prevention and treatment of patients who develop problems after sterilisation.

CHAPTER SIX : REFERENCES

1. Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LS, Trussell J. The risk of ectopic pregnancy after tubal sterilization. The New Eng J of Med 1997 Mar; 336 (11): 762-767.

2. Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: Findings from the US Collaborative Review of Sterilization. Am J Obstet Gynecol 1996; 174 (4) : 1161-1170.

3. Peterson LS. Contraception in the United States: 1982-1990 Hyattsville, Maryland: National Centre for Health Statistics, 1995; advance data from vital and health statistics of the Centers for Disease Control and Prevention / National Center for Health Statistics no. 260.

4. Strickler RC. Tubal ligation syndrome. Does it exist? Postgraduate Med 1984 Jan;75(1):233-237.

5. World Health Organisation. Mental health and female sterilization: report of a WHO collaborative study. J Biosoc Sci 1984;16: 1-21.

6. Neil JR, Hammond GT, Noble AD, Rushton L, Letchworth AT. Late complications of sterilisation by laparoscopy and tubal ligation – A controlled study. The Lancet Oct 1975; 699-700.

7. Kasonde JM, Bonnar J. Effect of sterilisation on menstrual blood loss. Br J Obstet Gynaecol 1976;83:572-575.

8. Whitelaw RG. 10-year survey of 485 sterilisations Part I: sterilisation or hysterectomy? BMJ Jan 1979; 1:32-33.

9. Kwak H M, Chi I, Gardner SD, Laufe LE. Menstrual changes in laparoscopic sterilization patients whose last pregnancy was terminated by therapeutic abortion. J Reprod Med Aug 1980; 25(2):67-71.

10. Hargrove JT, Abraham GE. Endocrine profile of patients with post-tubal-ligation syndrome. J Reprod Med 1981; 26(7):359-362.

11. Fortney JA, Cole LP, Kennedy KI. A new approach to measuring menstrual pattern change after sterilization. Am J Obstet Gynecol 1983 Dec;147(7):830-6.

12. Bhiwandiwala PP, Mumford SD, Feldblum PJ. Menstrual pattern changes following laparascopic sterilization with different occlusion techniques: A review of 10,004 cases. Am J Obstet Gynecol 1983 Mar;115(6):684-93.

13. Vessey M, Huggins G, Lawless M, McPherson K, Yeates D. Tubal sterilisation: findings in a large prospective study. Br J Obstet Gynaecol March 1983;90:203-209.

14. Rulin MC, Turner JH, Dunworth R, Thompson DS. Post-tubal sterilization syndrome - A misnomer. Am J Obstet Gynecol 1985 Jan;151(1):13-19.

15. DeStefano F, Perlman JA, Peterson HB, Diamond EL. Long-term risk of menstrual disturbances after tubal sterilization. Am J Obstet Gynecol 1985 Aug;152(7):835-41.

16. Rulin MC, Davidson AR, Philliber SG, Graves WL, Cushman SG. Changes in menstrual symptoms among sterilized and comparison women: a prospective study. Obstetrics and Gynaecology 1989 Aug; 74(2):149-153.

17. Shy KK, Stergachis, Grothaus LG, Wagner EH, Hecht J, Anderson G. Tubal sterilization and risk of subsequent hospital admission for menstrual disorders. Am J Obstet Gynecol 1992 Jun;166(6):1698-706.

18. Rulin MC, Davidson AR, Philliber SG, Graves WL, Cushman LF. Long-term effect of sterilization on menstrual indices and pelvic pain. Obstetrics & Gynecology 1993 Jul;82(1):118-21.

19. Martinez-Schnell B, Wilcox LS, Peterson HB, Jamison PM, Hughes JM. Evaluating the effects of tubal sterilization on menstrual functions: selected issues in data analysis. Statistics in Medicine. 1993 Feb ; 12(3-4):355-63.

20. Wilson EW. Sterilization. Bailiere's Clinical Obstetrics and Gynaecology. April 1996; 10(1):103 -117.

21. Liskin L, Rinehart W. Minilaparotomy and laparoscopy: safe,effective, and widely used. Series C (9). May 1985; 8(2):125-167.

22. Stock RJ. Evaluation of sequelae of tubal ligation. Fertil and Steril Feb 1978; 29(2): 169-174.

23. Donnez J, Casanas-Roux F, Ferin J, Thomas K. Tubal polyps, epithelial inclusions, and endometriosis after tubal sterilization. Fertil and Steril April 1984; 41(4):564-567.

24. Riedel HH, Ahrens H, Semm K. Late complications of sterilization according to method. J Reprod Med July 1981; 26(7):353-358.

25. Rock JA, Parmley TH, King TM, Laufe LE, Su BC. Endometriosis and the development of tubo-peritoneal fistulas after tubal ligation. Fertil and Steril Jan 1981; 35(1): 16-20.

26. Muldoon MJ. Gynaecological illness after sterilization. BMJ 8 Jan 1972: 84-85.

27. Allyn DP, Leton DA, Westcott NA, Hale RW. Presterilization counseling and women's regret about having been sterilized. J Reprod Med Nov 1986; 31(11):1027-1032.

28. Sapire KE. Contraception and sexuality in health and disease. McGraw-Hill Book Company (UK) Limited 1990: 16-32.

29. Hillis SD, Marchbanks PA, Tylor LS, Peterson HB. Tubal sterilization and long-term risk of hysterectomy: findings from the United States Collaborative Review of sterilization. Obstetrics & Gynecology April 1997; 89(4): 609-614.

30. Dueholm S, Zingenberg HJ, Sandgren G. Late sequelae after laparascopic sterilization in the pregnant and non-pregnant woman. Acta Obstet Gynecol Scand 1987; 66: 227-231.

31. Whitelaw RG. 10-year survey of 485 sterilisations Part II : patients' views on their sterilisation. BMJ Jan 1979; 1:34-35.

32. Campanella R, Wolff JR. Emotional reaction to sterilization. Obstet Gynecol 1975;45:331-334.

33. Wilcox LS, Chu SY, Eaker ED, Zeyer SL, Peterson HB. Risk factors for regret after tubal sterilization: 5 years of follow-up in a prospective study. Fertil and Steril May 1991; 55 (5):927-933.

34. Chi IC, Jones DB. Incidence, risk factors, and prevention of poststerilization regret in women: An updated international review from an epidemiological perspective. Obstetrical and Gynecological Survey 1994; 49 (10): 722-731.

35. Haynes DM, Wolfe W. Tubal sterilization in an indigent population. Am J Obstet Gyn 1970;106(7): 1044-1053.

36. Chi I, Potts M, Wilkens L. Rare events associated with tubal sterilization: An international experience. Obstetrical and Gynaecological Survey 1986; 41 (1): 7-19.

37. Shain RN, Miller WB, Holden AE. Factors associated with married women's selection of tubal sterilization and vasectomy. Fert and Steril Feb 1985; 43(2): 234-244.

38. Fitzgerald MJT. Neuroanatomy - Basic and clinical. Second Edition. Bailliere Tindall. London 1992.

39. Guyton AC. Physiology of the human body. Sixth Edition. Saunders College Publishing. New York 1984.

40. Rakel RE, Conn HF. Family practice. WB Saunders company. Second Edition. 1978.

41. Schlesselman JJ. Case-control studies. Design, conduct, analysis. Oxford University Press. New York 1982.

42. Friedman GD. Primer of epidemiology. 3 rd Edition. Mcgraw-Hill Book Company USA 1987.

43. McDowell I, Newell C. Measuring health: a guide to rating scales and questionnaires. Oxford University Press 1987: 120-124.

44. Howie JGR. Research in general practice. 2nd Edition. Chapman and Hall. London 1989.

45. Kelsey JL, Thompson WD, Evans AS. Methods in observational epidemiology. Oxford University Press. New York 1986.

46. Wilkin D, Hallam L, Dogget M. Measures of need and outcome for primary health care. 1st Edition. Oxford University Press 1992: 267-273.

47. Moos RH. Typology of menstrual symptoms. Am. J. Obst. & Gynec. 1969 Feb; 390-402.

48. Bordahl PE. The social and gynecological long-term consequences of tubal sterilization. Acta Obstet Gynecol Scand 1984;63: 487-495.

49. Balint M. The doctor, his patient and the illness. Second Edition. Churchill Livingstone, Edinburgh 1986.

50. McWhinney IR. A textbook of family medicine. Oxford University Press. New York 1989.

51. Penney GC, Souter V, Glasier A, Templeton AA. Laparoscopic sterilisation: opinion and practice among gynaecologists in Scotland. Br J Obstet and Gynae Jan 1997; 104:71-77.

CHAPTER SEVEN : APPENDIX

Questionnaire (three page document)

QUESTIONNAIRE

A CASE-CONTROL STUDY OF FACTORS INVOLVED IN POST-STERILIZATION MENSTRUAL DYSFUNCTION IN FEMALES IN GENERAL PRACTICE

GROUP: CASES = 1 CONTROLS = 2

1 DEMOGRAPHY Number .....

Age .....

Parity ..... Smoker..... Yes | No

Occupation .....

2. STERILIZATION Duration since operation (in years) .....

Reason .....

Timing postpartum = 1 elective = 2 postabortion = 3 [ ]

Contraception in 6 months prior to sterilization ..... yes | no

If yes, what form? pill = 1 IUCD = 2 other = 3 [ ]

3 GENERAL HEALTH The Affect Balance Scale (Bradburn)

During the past few weeks, did you ever feel	(Yes / No)
A Particularly excited or interested in something?	
B Did you ever feel so restless that you couldn't sit long in a chair?	
C Proud because someone complimented you on something you had done?	
D Very lonely or remote from other people?	
E Pleased at having accomplished something?	
F Bored?	
G On top of the world?	
H Depressed or very unhappy?	
I That things were going your way?	
J Upset because someone criticized you?	

Do you suffer from chronic illness ? ..... Yes | No

If yes , please specify .....hypertension = 1 diabetes = 2 arthritis = 3 other = 4 ..... [ ]

Any other operation? .....

4. GYNAECOLOGICAL Please describe your periods as you experienced before and after sterilization. Please rate on scale from no problem to partially disabling.

		(1)NONE	(2)MILD	(3)MODERATE	(4)SEVERE	
1. PAIN	Before	1	2	3	4	☐
	After	1	2	3	4	☐
2. BLEEDING	Before	1	2	3	4	☐
	After	1	2	3	4	☐

3. LENGTH OF FLOW in days Before ..... After .....

4. LOWERED WORK PERFORMANCE Please rate on scale from no problem to partially disabling (1-6)

Before 1.....2.....3.....4.....5.....6 ☐

After 1.....2.....3.....4.....5.....6 ☐

5. AVOID SOCIAL ACTIVITIES Before 1.....2.....3.....4.....5.....6 ☐

After 1.....2.....3.....4.....5.....6 ☐

6. Have you gained weight since the operation? YES NO ..... If yes, how much in kg? .....

7. How would you describe your sex life after the tubal ligation?

1. WORSE 2. SAME 3. IMPROVED ☐

5. SOCIAL Social Relationship Scale (McFarlane)

Please list the people with whom you generally discuss personal health events, using initials only. After each set of initials fill in a one- or two-word description of the relation each person has to you. Then go on to check the box which indicates the degree of helpfulness or unhelpfulness of your discussions with each person, and lastly, check of yes or no if you feel this person would come to you to discuss personal health events.

I discuss personal health events with:		Helpfulness of discussion				Would this person come to you to discuss personal events?	
Initials	Relation	makes things 1 a lot worse	makes things 2 a bit worse	helps things 3 a bit	helps things 4 a lot	yes	no
____	_____	1	2	3	4	☐	☐
____	_____	1	2	3	4	☐	☐
____	_____	1	2	3	4	☐	☐
____	_____	1	2	3	4	☐	☐

6. PSYCHOLOGICAL

Were you ever treated for tension or mental disorder? | Yes | No | Specify if Yes .....

.....

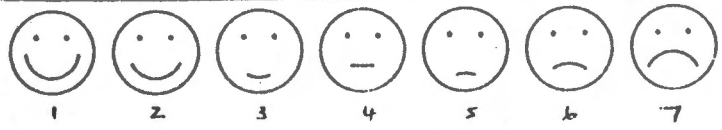
Do you regret having had the sterilization? | Yes | No |

Would you say that your husband / partner care for you less, the same or more after sterilization? ..... ☐

LESS = 1 SAME = 2 MORE = 3

7. QUALITY OF LIFE

Which of the following faces best describe how sterilization affected your life? ☐



8. PATIENT FEELINGS

Is there anything that you fear about sterilization?

.....

.....

.....

How do you feel about sterilzation for females? Eg is it good or bad?

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....