A systematic review evaluating the effects of bilateral tubal ligation on menorrhagia and dysmenorrhoea (post-tubal ligation syndrome).

By

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A mini-thesis submitted in partial fulfillment of the requirements for the degree of Magister Curations in Advance Midwifery and Neonatology in the Department of Nursing of the Faculty of Community and Health Sciences, University of the Western Cape, Bellville, South Africa.

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KEY WORDS

Post-tubal ligation

Tubal sterilization,

Systematic review,

Dysmenorrhoea,

Menorrahagia,

Laparotomy,

Tubal ligation,

Menstruation,

Long-term risks,

Laparoscopy.

Declaration

I declare that, "A systematic review evaluating the effects of bilateral tubal ligation on menorrhagia and dysmenorrhoea (post-tubal ligation syndrome)" is my own work, and that it has not been submitted before for any examination in any other university, and that all sources I have used or quoted have been indicated and acknowledged by complete reference.

Veronica L. Muntanga November 2004

Signed.....

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I want to thank God, the Father of our Lord Jesus for the opportunity to be in school again and to fulfill the dream of my life, and for His strength, grace and mercy that are indeed new every morning; my strength did not fail, neither my health because He watched over me and supplied my every need.

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Abstract

Title of thesis

A systematic review evaluating the effects of bilateral tubal ligation on menorrhagia and dysmenorrhoea (post-tubal ligation syndrome).

Background

The complaints about the tubal sterilization surgery leading to post-tubal ligation syndrome first surfaced in the 1950s. With the introduction in the 1970s of laparoscopy, which was less invasive than previous surgery, more women than ever before chose tubal ligation, and reports of post-operative symptoms increased. Alteration in menstrual flow, dysmenorrhoea, menorrhagia and change in cycle length after tubal sterilization have been reported in several studies since 1970. The term "poststerilization syndrome" has been used to refer to these changes. Often studies have failed to account for factors other than tubal sterilization that can affect menstrual cycles.

Objective

The primary objective of this research project is to evaluate the long-term risks associated with female tubal ligation by executing a systematic review.

Search strategy

An electronic search of available search engines was used to draw literature relevant to bilateral tubal ligation.

Selection criteria

Types of studies

All randomized controlled, quasi-randomized or clinical controlled trials that mention an experimental and comparison group (own controls are allowed), reporting on long-term risks associated with changes in the menstrual cycle after female sterilization have been included in the review.

Types of participants

Women in their reproductive years who had a tubal ligation compared to women who did not have a tubal ligation.

Types of intervention

Tubal sterilization (by macro- or micro-surgery, laparotomy, minilaparotomy or laparoscopy).

Types of outcome measures

Outcome measures relevant to post-tubal sterilization long-term risks concentrating on: Dysmenorrhoea, menorrhagia and duration of menstruation period.

Data Analysis

The reviewer extracted the data unto a data collection sheet. Thereafter it was captured onto a computer. Review Manager software program was used to do the analyses.

Results

The studies in this review were of poor methodological quality. Women who have a tubal ligation have an increased risk to experience dysmenorrhoea and menorrhagia after the procedure. They may also be at risk to experience an increase in the duration of their menstruation period.

Key Words

post-tubal ligation, tubal sterilization, systematic review, dysmenorrhoea, menorrahagia, laparotomy, tubal ligation, menstruation, long-term risks, laparoscopy.

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Chapter one: Proposal

1.1 Introduction

Bilateral tubal ligation (BTL) is one of the most common methods of fertility regulation in the world (Limpaphayom, 1991: 501). Many researchers have looked at short-term complications such as pain, hospital stay, infection, blood loss and women's satisfaction. Few researchers have looked into the long-term effects of tubal ligation.

Currently there is no systematic review available that reviews all the trials concerning the long-term effects of female tubal ligation. The aim of this study would be to do a systematic review on the literature to establish the severity of post-tubal ligation syndrome so that women can be aware of the long-term complications of female sterilzation. Chapter one gives an overview of the proposed review.

1.2 Background literature

Complaints about tubal sterilization surgery leading to post-tubal ligation syndrome first surfaced in the 1950s. Gentile, Kaufman and Helbig (1998:179) stated that, the term "post-tubal ligation syndrome" was coined to describe a variety of symptoms that have been reported to occur after female sterilization.

Earlier studies show a strong relationship between sterilization and menstrual disorders, but these studies have been challenged because of methodological weaknesses. Corson, Levinson, Batzer, and Otis (1981:363) study showed no significant difference in the hormone levels between women who had been sterilized and those who were not, indicating that the ovaries were not damaged by the surgery. Rulin, Davidson, Phillliber, Graves, and Cushman (1989: 149) on the other hand reported that the incidence of dysmenorrhea is significantly more in patients who underwent sterilization. Previous method of contraception may also contribute to changes in the menstrual cycle post sterilization (Lieberman, Belsey, Gorndon, Wright, Letchworth, Noble, & Niven, 1978: 376). Six months

after the tubal ligation, women who had previously used oral contraceptives reported a significant increase in days of menstruation, more dysmenorrhea, and an increase in excessive bleeding.

It is evident from the literature that post-tubal ligation syndrome does exist. The current problem is the contradictonary information that is in the literature. A systematic review is one answer to bring all the literature together and to do a meta-analysis of the results to decide to what extent does tubal ligation influence the menstrual cycle.

1.3 Research Problem

The current literature is contradictive when reporting on post-tubal sterilization syndrome. Due to the inconclusive literature as to whether tubal ligation causes menorrhagia and dysmenorrhea, the researcher decided to undertake a systemic review on the long-term effects after bilateral tubal ligation.

1.4 Research objectives

The primary objective of this research project is to evaluate the long-term risks associated with female tubal ligation by executing a systematic review.

1.5 Research question

The research question that arises is: Does bilateral tubal ligation cause long-term risks associated with the menstrual cycle?

1.6 Research statement

An extensive literature search could not identify a systematic review on the effects of bilateral tubal ligation on the menstrual cycle. The current available evidence is ambiguous. A systematic review with a meta-analysis of the results may provide readers with a better understanding of the possible long-term risks associated with female sterilization.

1.7 Definitions

1.7.1 Tubal sterilization

Tubal sterilization is pressumed to be a permanent surgical method of family planning where the fallopian tubes are occluded to prevent the ovum from being fertilized.

1.7.2 Menorrhagia

Menorrhagia is defined as a condition of excessive blood loss either in flow or duration, during menstruation, that is, a total blood loss exceeding 80 ml per cycle or menses lasting longer than seven days. In research, it is usually defined as an objectively measured blood loss of 80 ml or more per period, and in practice it is defined by the woman's subjective assessment of blood loss (Effective Health Care Bulletin, 1995:8).

1.7.3 Dysmenorrhoea

Dysmenorrhoea is often described as cyclical lower abdominal or pelvic pain, which may also radiate to the back and thighs, occurring before or during menstruation, or both. Dysmenorrhoea comes from the Greek word meaning "difficult monthly flow", but is taken to mean painful menstruation (Shaw et al., 1992:196).

1.7.4 Post-tubal ligation syndrome

Post-tubal ligation syndrome is a term used to describe a group of symptoms reported to occur after female sterilization, these symptoms include; an increase in menstrual flow, dysmenorrhea, amenorrhoea, an increase in the duration of the menstruation period, changes in sexual behaviour and emotional health (Pati, Carignan & Pollack 1998).

1.7.5 Systematic reviews

Systematic reviews refer to the systematic collection of relevant primary papers that deal with a focused question and include a summary of the evidence from the primary sources (Jadad & McQuay, 1996: 235).

1.7.6 Allocation concealment

Allocation concealment is when the trial is so planned that neither the doctor nor the participant is aware of the group allocation and the treatment received.

1.7.7 The Review Manager (RevMan) 4.2

Review Manager 4.2 (RevMan) is a software program designed to assist reviewers to prepare and maintain Cochrane Systematic reviews within the Cochrane Collaboration's programme. RevMan allows the user to enter text such as: background, objectives, references and criteria for included and excluded studies characteristics of studies in the database. It further allows the reviewer to enter data in comparison tables for analyses. The program allows for meta-analysis of the data entered and is able to present the results graphically.

1.7.8 Relative risk

Relative risk is the ratio between the rate of intervention in the population exposed to a particular factor (for this study it is women who had a female sterilization) and the rate in those not exposed (in this study it is women who are in the control group).

1.7.9 Heterogenity

Heterogenity is when the studies do not share the same common treatment effect and so the studies are said to be heterogynous.

1.7.10 Homogeneity

Homogeneity is when the studies share the same common treatment effect.

1.8 Research design and methodology

1.8.1 Types of studies

All randomized controlled, quasi-randomized or clinical controlled trials that used a comparative group or own controls, and that reported on long-term risks associated with changes in the menstrual cycle after female sterilization were evaluated for inclusion in the review.

1.8.2 Types of participants

Women in their reproductive years who requested bilateral tubal ligation as a form of birth control, irrespective of the surgical procedure or the sterilization method. Control groups may consist of women who had partners who were sterilized.

1.8.3 Types of intervention

Post-tubal sterilization using any method of surgery (macro- or micro-surgery, laparotomy, minilaparotomy, laparoscopy or culdoscopy) and any method of tubal occlusion (coagulation, rings, clips, sutures and excision).

1.8.4 Types of outcome measures

Studies considered for inclusion in this review were appropriately designed to evaluate the objective outcome measures relevant to post-tubal sterilization long-term risks of:

- Dysmenorrhea (pain or cramps).
- Menorrhagia (excessive bleeding or heavy menses).
- Increase in duration of menstruation period.

1.8.5 Search strategy for identification of studies

Using a specific search strategy with appropriate key words was to ensure that appropriate trials were identified for inclusion. Electronic searches of the main electronic databases were done to identify appropriate literature for inclusion in the review. The Cochrane Collaboration in specific the Cochrane Menstrual Disorders and Subfertility Review Group were contacted to request a printout of trials on the specific topic.

1.8.6 Methods of the review – Validity and reliability

The selection of trials for inclusion in the review were done by the candidate and supervised for inclusion by the supervisor and co-supervisor. The data was entered twice to ensure correctness. Further information was sought from the authors where papers contained insufficient information, where authors were

contactable. A record was made available of studies that were not included in the review and the reasons why they are not included.

1.8.7 Data analysis

Statistical analysis was performed in accordance with the guidelines developed by the Menstrual Disorders and Subfertility Group using Review Manager software.

1.9 Relevance of the study

The results of the systemic review will help to define the long-term risks associated with tubal sterilization.

1.10 Ethical statement

The proposal was submitted to the University of the Western Cape (UWC), Faculty of Community and Health Sciences Higher Degree Committee and Senate for ethical clearance. This is a systematic review of literature and patient consent is irrelevant. The review will also be sent to the Cochrane Menstrual Disorders and Subfertility Review group for peer review and possible publication in the Cochrane Library.

1.11 Chapter outline

Chapter one gives a summary outline in the form of a proposal. Current literature is discussed in chapter two concerning the clinical practice of female sterilization and the effects on the menstrual cycle. Chapter three describes the methodology of the review. Results are given in chapter four. Chapter five contains the discussions of the results with conclusions and possible implications for further research.

1.12 Time line

Writing of Proposal	April 2004 – July
Submission of proposal to Higher Degree	August 2004
Approval of proposal	September 2004
Sorting out of articles	April - September 2004
Entering of data in tables	September - October 2004
Analysis of data	September - October 2004
Formatting conclusions	September - October 2004
Complete writing of thesis	September - October 2004
Presentation of data at a conference	December 2004
Submission of thesis	November 2004

1.13 Budget

Various ways were explored to support the financial implication of this study.

Activity	Cost
Attending RevMan workshop	R5000
Photocopying	R800
Stationary	R2500
Consumables	R1750
Purchase of a computer for search	R8000
Ordering of Articles	R300

1.14 Summary

Chapter one consists of a short introduction and synopsis of the research methodology that were followed to execute this systematic review. The aim of the review is to gain information as to whether bilateral tubal sterilization has long-term risks associate with the procedure.

Chapter two: Literature Review

2.1 Introduction

This chapter provides a literature review on female sterilization. It discusses the history, methods and current literature concerning the clinical practice of female sterilization as well as the long-term effects such as "post tubal ligation syndrome".

2.2 History of the female sterilization

Female sterilization in the United States was generally performed only for medical indications before the 1960s. A specific formula was endorsed by the American College of Obstetricians and Gynecologists, until 1969 that was used for the indication of sterilization. The formula consisted of the following parameters: the age multiplied by parity had to be greater than or equal to one hundred and twenty, before elective sterilization could be considered. The view on sterilization changed later when the procedure became a safe and minimally invasive procedure.

At present, approximately 700,000 bilateral tubal sterilizations are performed annually in the United States (US), of which half are performed postpartum and half are ambulatory interval procedures. Eleven million US women aged 15 - 44 years rely on bilateral tubal ligation (BTL) for contraception, and more than 190 million couples worldwide use surgical sterilization as a reliable method of permanent contraception (Peterson, Pollack & Warshaw, 1997:529).

2.2.1 History of the female sterilization procedure

Table1: History of the female sterilization procedure

Gynaecologist	Year	Female Sterilization Procedure
Blundell	1823	He was the first person to suggest tubal ligation for sterilization before the Medical Society of London.
Lungren	1880	He was the first to ligate a woman's tubes.
Porro	1876	He performed a cesarean hysterectomy with the secondary intention of sterilization.
Thomas	1885	Suggested tubal ligation as opposed to Porro's operation for sterilization.
Dührssen	1895	Used a double ligature and was the first to perform tubal ligation via colpotomy.
Kehrer and Buettner	1897	They divided the tubes between the sutures.
Ruhl	1898	He cut the tube 5 cm from the uterus and sutured the ends.
Rose	1898	She removed the tubes at the cornua.
Madlener	1919	He crushed and ligated the tubes with non absorbable suture.
Irving	1924	Published his method in which the proximal portion of the severed tube is buried in a small myometrial tunnel on the anterior uterine surface.
Colleagues (Pomeroy)	1930	Posthumously published the Pomeroy technique in the *New York State Journal of Medicine.*
Uchida	1940s	He developed a technique, which can be performed as an interval or puerperal procedure.
Bosch	1936	He performed the first laparoscopic tubal occlusion as a method for sterilization.

(Ricci, 1945:539; Bishop & Nelms, 1930:214).

The era of laparoscopy began during the 1960s, which led to the development of unipolar electrocoagulation tubal sterilization, the Hulka spring clip, the Yoon plastic Falope ring and bipolar cautery. Currently, bipolar laparoscopy using Falope rings or Filshie clips is the most popular method of female sterilization in non-pregnant women. While Pomeroy and Parkland technique (peri-umbilical minilaparotomy) are the most common in the immediate postpartum period (Uchida, 1975:154).

2.3 The incidence and prevalence of female sterilization

The incidence of female sterilization is usually expressed as the rate at which people in a given population begin to use sterilization, over a specified period of time (usually one year), relative to the number of women aged 15 – 49 who are married or in union during that time period. In practical terms, it reflects the number of sterilization procedures performed annually among people of reproductive age (Ross, Hong & Huber, 1985:10).

Reliance on both male and female sterilization has grown substantially. Bilateral tubal ligation is one of the most common methods of fertility regulation in the world and it is estimated that more than100 million women have chosen this method of birth control (Limpaphayom et al., 1991:501). Increase prevalence was noticed since the 1980's when it was estimated that about 99 million couples used female sterilization as a method of contraception. This number had multiplied by 1995 to about 223 million couples, 180 million women using female sterilization and 43 million men using vasectomy. The use of female sterilization services has even increased in regions where it had been low before, particularly in Sub-Saharan Africa. In nations such as Botswana, Cape Verde, Kenya, Mauritius, Namibia, South Africa, and Swaziland, sterilization prevalence rates are now 5% or higher. The introduction of minilaparotomy services into family planning programs in Sub-Saharan Africa may account for some of this increase in use (Ross et al., 1985:12).

The incidence of female sterilization is the highest in Latin America and the Caribbean and is the lowest in Eastern Europe, North Africa, and the Middle East. The prevalence of female sterilization is also the highest in Latin America and the Caribbean and in Asia. In contrast, the prevalence of male sterilization is the highest in parts of Western Europe, in North America, and in Asia. Most sterilization users live in Asia, with China and India accounting for 75% of the world's total number of sterilization users (Ross et al., 1985:13).

Sterilization is the most widely used method of contraception in the United States. Approximately 700,000 female sterilizations occur yearly in the USA. According to the National Survey of Family Growth, in 1990 26% of all USA women relied on sterilization (18% female and 8% male) for contraception. The largest numbers of women depending on sterilization were between 35 - 44 years of age. Thirty three percent of these women used either female or male sterilization for birth control. Among women using contraception, the percentage relying on female sterilization increased consistently with increasing age: 33% of the ages were between 30 – 34 years, 45% between 35 – 39 years and 51% of between 40 – 44 years (Peterson, 1995:1).

2.4 Indication for tubal ligation

Tubal sterilization is indicated for women who want a safe, permanent method of contraception. Tubal sterilization is also indicated for women in whom a pregnancy could represent a significant clinical and medical risk (Shaw, Soutter & Stanton 1992:193).

2.5 Relevant anatomy for female sterilization

The fallopian (uterine) tubes (oviducts) lie on each side of the uterus in the upper margin (mesosalpinx) of the broad ligament. Each tube is divided into four parts. From lateral to medial, the parts are as follows: The fimbriated end (infundibulum) is a bugle-shaped extremity with a fimbriated mouth that overlies the ovary, to which one long fimbria (the fimbria ovarica) adheres. The ampulla

is wide, thin-walled, and somewhat tortuous and is the largest portion of the tube. The isthmus is a narrow, straight, thin-walled portion of the tube immediately adjacent to the uterus. In the intrauterine or intramural portion, the lumen narrows to approximately one mm or less as it pierces the uterine wall. The isthmic portion of the fallopian tube is the proper site for all sterilization procedures that depend on tubal occlusion rather than on removal of a tubal segment (Shaw et al., 1992:193).

2.6 Normal menstrual cycle

The majority of menstrual cycles are between 24 - 32 days and a normal cycle is considered to be 28 days. Menstrual cycle during reproductive age is most regular between the ages of 20 - 40 years. It tends to be longer just after the onset of menarche and shorter as menopause approaches. The mean menstrual blood per menstruation in healthy women ranges between 37 and 43ml. Seventy percent of the loss occurs in the first 48 hours. Loss between consecutive menses in the same woman does not vary to a great extent. Only 9 - 14% of women lose more than 80ml / period and 60% of these women are usually anaemic. The upper limit of normal menstruation is thus taken as 80ml / menses. However, actual fluid loss (mucus, tissue) may be considerably more than the blood loss alone and amounts vary considerably (Shaw et al., 1992:193).

2.7 Dysmenorrhoea

Dysmenorrhoea comes from the Greek word meaning "difficult monthly flow", but is taken to mean painful menstruation (Shaw et al., 1992:196). It is a complex symptom which can present as cramping or lower abdominal pain radiating to the back and legs. It may often be accompanied by gastrointestinal and neurological symptoms as well as general malaise. It may be associated with pathology or may be idiopathic in origin (Shaw et al., 1992:196). Dysmenorrhoea is often described as cyclical lower abdominal or pelvic pain, which may also radiate to the back and thighs, occurring before or during menstruation, or both. Primary

dysmenorrhoea occurs in the absence of any obvious underlying disease. Pathogenic causes are uncertain but uterine hyperactivit, prostaglandins, leukotrienes, and vasopressin have all been implicated. Secondary dysmenorrhoea is due to an underlying disease, most commonly endometriosis. Other causes include possible adhesions after pelvic inflammatory disease or previous surgery (Smith, 1993:759).

2.8 Menorrhagia

Menorrhagia is one of the most common gynecologic complaints in women. Current gynecological surveys report that 30% of all premenopausal women perceive their menses to be excessive. The World Health Organization recently reported that 18 million women aged 30 - 55 years perceive their menstrual bleeding to be exorbitant. Reports show that only 10% of these women experience blood loss severe enough to be defined clinically as menorrhagia (Kadir, Economides & Sabin, 1998:488). Menorrhagia is defined as a condition of excessive blood loss either in flow or duration, during menstruation. Thus the total blood loss exceeds 80 ml per cycle or menses lasting longer than seven days. In research, it is usually defined as an objectively measured blood loss of 80 ml or more per period, and in practice it is defined by the woman's subjective assessment of blood loss (Effective Health Care Bulletin, 1995:8).

Perceived severity of menstrual blood loss correlates poorly with objective measurements. Many women who seek help for heavy periods do not have greater than average losses. In one study, 26% of those with losses below 60 ml considered their periods heavy, while 40% of those with losses greater than 80 ml considered their periods to be light or moderate. Possible causes of menorrhagia include local pathology such as fibroids, carcinoma, infection, systemic disease like hypothyroidism, haematological disorders, and iatrogenic causes like intra-uterine devices and sterilization (Effective Health Care Bulletin, 1995:10-14).

2.9 Methods of bilateral tubal ligation

Surgical approaches for female sterilization include laparoscopy, microlaparoscopy laparotomy (concurrent with cesarean delivery), minilaparotomy, and vaginal approaches. The standard approaches are laparoscopy, minilaparotomy, and laparotomy at the time of cesarean delivery. Although minilaparotomy is the most common approach worldwide, laparoscopy is used most commonly for interval procedures in the United States. The subumbilical minilaparotomy is the most common procedure used during the postpartum period. Vaginal colpotomy is rarely used because it is associated with a higher incidence of infection (Peterson, Pollack & Warshaw, 1997:762). Local anesthesia is used for more than 75% of sterilizations worldwide (Borgatta, Gruss & Barad, 1991:12).

Post partum tubal ligation usually occurs at the time of a caesarean or within 72 hours post delivery. It is convenient because the women are in hospital and cost effective especially when it is done at the time of the caesarian section. The World Health Organization (WHO) recommends that postpartum sterilization be ideally performed within the first forty-eight hours, when the enlarged uterus is easily accessible through the subumbilical incision. Complications do occur and some of the reported complications are: bleeding, infection, and thromboembolism when sterilizations are performed between 49 hours to five days post partum (Chi, Gates & Bunce, 1991:33).

Postpartum bilateral tubal ligation is technically simple because the uterine fundus is at the level of the umbilicus, making the fallopian tubes readily accessible through a small periumbilical abdominal incision. Chi et al. (1989:257) found that sterilization concurrent with caesarean section does not increase post partum maternal morbidity. If the procedure is delayed for several days or if the patient has a significantly involuted uterus, then delaying to an interval procedure is usually wise (Patis & Cullins, 2000:861).

Minilaparotomy is defined as a laparotomy with an incision size smaller than five cm. The operation can be performed through a suprapubic incision in the interval after pregnancy and through a subumbilical incision within the first 48 hours after delivery. A two to five-cm peri-umbilical semilunar incision is made with the skin tented up with clamps. Dissection is carried down to the fascia, which is grasped with clamps and opened transversely, exposing the peritoneum, which can then be gently entered. With manipulation and retraction, the tubes can be visualized and grasped. Often, the oviducts can be palpated laterally, near the fundus, and then flipped anteriorly. A major cause of bilateral tubal ligation failure is mistakenly ligating the round ligament, falsely identified as the tube (ACOG, 1996:282). The risks of blind abdominal penetration are not present with minilaparotomy; therefore, the risks of life-threatening vessel and bowel injuries are decreased (WHO, 1982:645).

The studies of Bhiwandiwala, Mumford & Feldblum (1983:684) and Letchworthy, Kane & Noble (1980:119) reported that the major complications such as death and technical failures are low for minilaparotomy and laparoscopic sterilization. In both procedures, most major complications are related to general anaesthesia and abdominal entry. Letchworthy et al. (1980:119) reported that about two percent of women experience complications due to sterilization. Some of the complications are: unintended laparotomy due to organ and vascular injury. Nevertheless, the complications from laparoscopy are more serious, for example; bowel injuries, and vessel laceration while minilaparotomy had manageable injuries to the bladder.

Conventional laparoscopy is performed through punctures of five mm and greater; however, with the advent of microlaparoscopy, smaller puncture sites are being used. Advantages include small incisions, rapid access to the oviducts, rapid recovery, and the ability to inspect intraperitoneal organs. Disadvantages include the maintenance of fragile and expensive equipment and the risks of vessel / viscera injury with needle insufflation / trocar entry. Entry injury accounts for 30-50% of all laparoscopic sterilization complications. The patient should

always have an examination under anesthesia, and the bladder should be catheterized. A uterine manipulator and the use of the Trendelenburg position enhance exposure (Cunanan, Courey & Lippes, 1980:504).
WHO (1982:645) reported comparable overall complication rates of unintended laparotomy, transfusion, hospitalization and organ injury, of laparoscopy and minilaparotomy of less than two percent. Complications from laparoscopy are more often serious for example bowel injuries and vessel lacerations when compared with complications from minilaparotomy.

Microlaparoscopy involves the use of microendoscopes and suprapubic ports for bipolar coagulation or mechanical occlusive devices. This surgery is possible because of improved technology in light transmission and fiberoptic bundles. The theoretical advantages of less pain, less cost, and faster patient recovery have not been assessed through randomized controlled trials, although several studies have been reported in an office setting (Peterson et al., 1997:530).

The Pomeroy technique is the simplest and most commonly performed puerperal tubal sterilization. The mid portion of the oviduct is grasped with a clamp, creating a loop, which is tied with a suture, and each limb of the tubal knuckle is cut separately. Specimens are usually submitted to pathology. The endosalpinx at the cut ends may be cauterized (optional). Many modifications of the Pomeroy technique have been described; the most common involves doubly ligating each loop. Failure rates are reported to be one case in 300-500 patients (Gabbe, Niebyl & Simpson, 1996:184). Patis & Cullins (2000:873) reports excellent result in using the Pomeroy method through microlaparoscopes.

The Parkland technique is a midsegmental resection similar to the Pomeroy technique, except each leg of the loop is tied separately. The Parkland technique was designed to avoid the intimate approximation of the tubal cut ends, as occurs with the Pomeroy technique, thereby eliminating the risk of secondary adherence and subsequent recanalization. An avascular area in the mesosalpinx directly under the tube is perforated with a hemostat, and the jaw is

opened to spread the mesosalpinx, thereby freeing approximately 2.5 cm of tube. Alternatively, a Bovie tip can be used to cauterize small vessels in the mesosalpinx before perforating it with the hemostat. The freed tube is then ligated proximally and distally with a suture, and a one to two cm tubal segment is excised and submitted for pathologic confirmation. Failure rates are reported to be one case in 400 patients (Peterson et al., 1997:529).

During the Uchida technique the mid portion of the oviduct is raised with clamps. The tubal serosa is raised from the muscularis by subserosal injection of a dilute (1:100,000) saline solution of epinephrine or isotonic sodium chloride solution. A linear incision is made in the ballooning serosa on the antimesosalpingeal aspect of the tube with a small sharp scalpel. The serosal peritoneum is grasped on both sides of the tubal incision with hemostats, and a third hemostat is used to bluntly dissect and reflect the serosa and the surrounding areolar tissue from the tubal muscularis. With the tubal muscularis exposed, a relatively long (five cm) segment of tubal muscularis is ligated proximally and distally with a suture and resected. The raw serosal edges are then reapproximated, burying the proximal cut tubal end within the leaves of the broad ligament and exteriorizing the distal end from the broad ligament (Gabbe et al., 1996:639).

The Irving technique is usually used in conjunction with caesarean delivery. A mesosalpingeal window is created beneath the tube approximately four cm from the uterotubal junction. The tube is doubly ligated with absorbable suture and severed, with the sutures on the proximal end left long. The proximal tubal stump may require mobilization by dissecting it free from the mesosalpinx. A small cut is made into the serosa on the posterior (or anterior) uterine wall near the uterotubal junction. A hemostat is used to deepen the incision, creating a pocket in the myometrium approximately one to two cm deep. The two free ends of the proximal stump ligature are then individually threaded onto a curved needle and brought deep into the myometrium tunnel and out through the uterine serosa. Traction on the sutures draws the proximal tubal stump deep into the myometrial tunnel, and the sutures are tied. The serosal opening of the tunnel is

then closed around the tube with fine absorbable suture. An additional option is to bury the distal end of the tube between the leaves of the broad ligament as originally described by Irving. Failure rates are less than one case in 1000 patients (Gabbe et al., 1996:630).

The electrocoagulation technique is preferable when the fallopian tube is edematous, thickened, or cannot be mobilized easily for mechanical device placement. This technique should always be readily available during laparoscopic bilateral tubal ligation both as a backup method of sterilization and for control of unexpected bleeding. Electrocoagulation causes greater tubal damage, making tubal reversal more difficult if the patient regrets her decision (Peterson et al., 1997:765).

Bipolar current is inherently safer than unipolar current because tissue destruction is essentially confined to the area between and immediately adjacent to the bipolar paddles. The oviduct is identified and grasped at the mid isthmus region laterally from the uterotubal junction, with the bipolar forceps. The tube is tented up to ensure the forceps are not in contact with any other structure (for example; bowel, sidewall), and 25 Watts of non-modulated cutting current (cutting, not coagulation waveform) is applied using an ampere meter to document cessation of flow and, hence, complete coagulation.

Formation of uteroperitoneal fistula, with a subsequent risk of pregnancy (including ectopic pregnancy) or possible pelvic inflammatory disease (PID), is minimized by maintaining the most proximal burn no closer than two cm to the uterine cornua. Leaving a two to three cm stump allows enough space for absorption of intrauterine fluid under pressure, such as during menstruation, and minimizes the risk of fistula formation (Sonderstrom, Levy and Engel, 1989:396).

The initial popularity of unipolar current occurred during the early years of laparoscopic sterilization and diminished following bowel injuries (that is, burns, although these can be trocar-related). Unipolar current has largely been replaced with bipolar electrode method. Renewed interest in this technique has

occurred as a result of findings from the US Collaborative Review of Sterilization (CREST) study that suggests unipolar coagulation is the most effective method of laparoscopic sterilization. A large grounding plate is placed on the patient, then the unipolar current is applied to the oviduct and it flows through the patient's body and out through the plate. The use of a metal trocar sleeve avoids the formation of a capacitor between the forceps and the sleeve, and any electrical current flowing to the trocar is dispersed through the patient's abdominal wall. An electroco-agulating grasping forceps is placed completely around the isthmic portion of the tube, approximately four cm from the uterine cornua. The oviduct is mobilized away from any viscera and the sidewall. A low-voltage generator with a maximum peak of 600 V and maximum power of 100 W is used to apply current for approximately five seconds, until blanching and swelling of the tube is visible. The highest success rates are achieved when at least three cm of tube is destroyed. Thermal injury to the bowel may occur either from direct current flow via the tube being coagulated or from unsuspected contact between the forceps or trocar sleeve and bowel. Areas of thermal injury should be widely dissected as soon as they are recognized. Patients with unsuspected injuries tend to present four to five days after the procedure with peritoneal signs mimicking acute appendicitis (Sonderstrom et al., 1989:397).

The Falope (Yoon) ring is a non-reactive silicone rubber band measuring 3.6 mm in outer diameter and five percent of barium sulfate is incorporated for radiographic identification if needed. The applicator consists of inner grasping prongs and an outer double-barreled sheath. The Falope ring is stretched around the base of the narrow sheath, and after the prongs grasp the narrow isthmic portion of the tube (at least three cm from the uterine cornu, the tube is pulled into the barrel. The larger-diameter outer barrel then pushes the dilated Falope ring over the knuckle of tube, and the ring constricts back to its undilated state, with an inner diameter of one mm. The loop of the tube should clearly contain two complete lumens. Slowly, advancing the entire applicator toward the tube, while gradually retracting the tongs and tube into the applicator and avoiding excessive traction on the tube are important. Failure to do this can

result in mesosalpingeal hemorrhage and tubal laceration, which occurs in approximately one to five percent of cases. This can be treated with bipolar coagulation, or a Falope ring may be placed on each transected end. Falope ring application has traditionally been considered more painful postoperatively secondary to ischemia; however, this has not been established in a randomized controlled trial. The failure rate of the Falope ring is reported to be 3.3 cases per 1000 patients (Lipscomb, Stovall, Ramanathan and Ling, 1992:647).

The Hulka-Clemens clip is applied at a right angle to the isthmic portion of the tube 2.5 to three cm from the uterotubal junction. When properly applied, only four mm of the tube and virtually none of the blood supply is destroyed. The clip consists of two toothed jaws of Lexan plastic joined by a stainless steel hinge pin. The lower jaw has a distal hook. A gold-plated spring maintains the clip in an open position. When completely advanced, the spring closes and locks the jaw. Once the oviducts have laparoscopically been identified and deemed suitable for clip sterilization, the Hulka clip applicator is introduced with the clip in the closed position, and the clip is opened after the applicator is in intra-abdominal in position. The hook of the lower jaw is placed against the posterior mesosalpinx, the tube is tented slightly upwards, and the clip is applied. The clip may be opened and repositioned repeatedly until the correct position is achieved, at which time the center piston is advanced to permanently lock the clip and unseat it from the applicator. If the clip has not been applied satisfactorily, a second clip is placed immediately along side the first. The applicator is withdrawn from the abdomen and reloaded, and the contralateral tube is treated in the same fashion. Failure of the Hulka clip should not exceed two -three cases per 1000 patients (Lipscomb et al., 1992:648).

The Filshie clip technique is widely used in Canada, the United Kingdom, and Australia and was approved for use in the United States in 1997. This technique involves a 12.7-mm long clip of titanium with a silicone rubber lining. The clip is applied laparoscopically with an applicator, much like the Hulka spring clip, at right angles to the isthmus approximately two to 2.5 cm from the uterotubal

junction. Initially, the clip occludes the tubal lumen by pressure. As tubal necrosis occurs, the rubber expands to maintain blockage of the lumen. The tube eventually divides, and the stumps heal and close. The Filshie clip usually remains attached and is eventually covered by peritoneum.

Theoretically, because the silicone rubber of the Filshie clip is able to expand and provide continuous pressure even when the tube becomes ischemic, any residual tubal patency, which may occur with the spring clip, is prevented (Tulandi, 1997:796). Rare reports of migration of the Filshie clip into the bladder, vagina, peritoneal cavity, and appendix have been published, as have reports of expulsion of Filshie clips from the vagina, urethra, and rectum (occurring at a similar rate as expulsion of the Hulka clip). Migrations and expulsions are usually asymptomatic and of little clinical significance. In all cases, the clips were found closed, the tubes were fully occluded, and no long-term adverse sequelae occurred (Siew, 1991:695). Cumulative data of 11 trials at 24 months of follow-up report a failure rate of seven cases per 1000 patients (Tulandi, 1997:796).

2.10 Complications of tubal ligation

2.10.1 Death

The risk of death from tubal sterilization is one to two cases per 100,000 procedures. Most of these are complications of general anesthesia. The most common cause of death during laparoscopic bilateral tubal ligation appears to be hypoventilation related to anesthesia. Cardiopulmonary arrest and hypoventilation are reported as the leading cause of death in most cases. Sepsis as a cause of death from laparoscopic sterilization is directly related to bowel perforations or electrical bowel burns. The mortality rate is low when compared with the risk of death from hysterectomy (Jamieson, Hillis & Duerr, 2000:998).

2.10.2 Unintended laparotomy

Unintended laparotomy occurs with one – two percent of laparoscopic procedures. Most of these conversions are attributable to technical inability to

complete the laparoscopic procedure rather than to complications of the procedure (Patis & Cullins, 2000:875).

2.10.3 Bowel injury

Bowel injury can occur during insertion of the insufflation needle or trocar or during electrocoagulation. Small injuries from the needle or trocar with no bleeding or leakage of enteric contents can usually be managed expectantly; otherwise, prompt laparotomy is indicated (Grimes & Wallach 1997:185).

2.10.4 Vascular injury

Vascular injury can occur during insufflation needle or trocar insertion. Injury to a large vessel is a life-threatening emergency. An immediate laparotomy needs to be done. Direct pressure over the injury to control bleeding until repair (usually by a vascular surgeon) can be performed as an intermediate emergency procedure (Grimes & Wallach, 1997:185).

2.10.5 Bilateral tubal ligation failure

Although sterilization is highly effective and considered the definitive form of pregnancy prevention, it has a failure rate during the first year of 0.1-0.8%. At least one third of these are ectopic pregnancies. Recent findings suggest that pregnancy is somewhat more common than previously estimated, that the risk of pregnancy persists for many years after sterilization, and that the risk varies by method and patient age at sterilization (Peterson et al., 1997:763).

2.11 Post–tubal ligation syndrome

It appears from the literature that complaints about tubal sterilization surgery leading to post-tubal ligation syndrome first surfaced in 1950s (Williams, Jones & Merrill, 1951:423). These authors described an outcome that was observed in women who had been sterilized. They found that a higher number of women complained about increased menstrual flow and intermenstrual spotting after sterilization (Williams et al., 1951:423).

Female sterilization increased extensively since 1970, this occurred with the use of laporoscopy (the so-called "belly button surgery") to perform the procedure. As the incidence of female sterilization increased so did the debate around post-tubal sterilization syndrome increase, as more and more women started to complain about abnormal menstrual patterns after sterilization (Corson, Levinson, Batzer & Otis, 1981:363).

An increase in menstrual flow, dysmenorrhea, and an increase in the duration of the menstruation period after tubal sterilization has been reported in several studies. The term "post-tubal ligation syndrome" has been used to refer to these changes (Pati, Carignan & Pollack 1998). Gentile, Kaufman & Helbig (1998:180) stated that, the term "post-tubal ligation syndrome" was coined to describe a variety of symptoms that have been reported to occur after female sterilization. For some investigators, this describes only abnormal bleeding and pain. For others, it may include changes in sexual behaviour and emotional health, exacerbation of premenstrual symptoms and menstrual disturbances significant enough to lead to further gynaecological surgery, including hysterectomy or tubal reanastomosis. Proposed in 1951, this syndrome is a controversial constellation of symptoms, including pelvic discomfort (dysmenorrhoea), ovarian cystic changes, and menorrhagia, which are suggested to occur as a result of disruption of the uteroovarian blood supply, which result in disturbances of ovulatory function after tubal ligation. Often, these patients have a history of these problems before tubal ligation or have been taking birth control pills, which masked their symptoms (Gentle et al., 1998:180).

Gentle et al. (1998:180) found increased premenstrual distress, heavier and more prolonged menstrual bleeding, and increased dysmenorrhea in the study. However, the study results were criticized because of failure to control for age, parity, obesity, previous contraceptive use, interval since sterilization, or type of sterilization that may have affected the study results. Other comments of criticism against post-tubal ligation syndrome is that the studies reported on these effects did not control for prior contraceptive use (William et al.,1951:423; Neil, Hammond & Noble,1975:699; Poma, 1980:272; Alder, Cook, Gray, Tyrer,

Warner & Bancrof, 1980:45 and Shy, Stergachis, Grothaus, Wagner, Hecht & Anderson, 1992:1698).

The etiology and pathophysiology of the post-sterilization syndrome is unclear. There are suggested etiologic factors, which include impaired ovarian blood supply (Radwanska et al., 1979: 376) and disturbed innervations of the tube and ovary (Koninckx et al. 1980: 85). In Donnez et al. (1981: 65) study it was noted that women sterilized by other methods of tubal ligation had a lower mi-luteal plasma progesterone level than women sterilized by Hulka clip. Hargrove & Abraham (1981: 359) also reported that patients with the post-tubal ligation syndrome had high serum estradiol and low serum progesterone levels as compared with normal controls. The authors suggest that abnormal luteal function may be responsible for the symptoms observed in post tubal ligation syndrome. Several other authors agree that post-tubal syndrome do exist and is possibly due to injury to the uterine artery. Doppler studies showed that there was an increased resistance index of the uterine artery blood flow in the women who had tubal ligations compared to women who have not been sterilized (El-Minawi, 1999; Lu & Chun, 1967: 875; Douglas, 1974:168 and Faber et al., 1981:96).

Wilcox, Martinez-Schnell, Peterson, Ware & Hughes (1992:1368) controlled for prior contraceptive use, and reported an increase in menstrual pain and bleeding after sterilization. DeStefano Huezo & Peterson (1983:673) reported a decrease in cycle length and days of menstrual bleeding and an increase in pain only when tubal ligation was done by unipolar cautery. While Reidel, Ahrens & Semm (1981:353) reported significantly fewer menstrual complaints when endocoagulation rather than unipolar cautery was used for the sterilization procedure. Shain, Miller, Mitchell, Holden & Rosenthal (1989:192) reported significant menstrual changes and more pain when bipolar cautery or Pomeroy procedure was used, but not when Falope ring procedure was used.

Rulin et al. (1998:149) noted that the relationship between tubal sterilization and the subsequent development of menstrual disorders has been debated both in

the lay press and the medical literature. Earlier studies show a strong relationship between sterilization and menstrual disorders, but these studies have been challenged because of methodological weaknesses. The critique was principally related to reliance on patient recall of menstrual patterns over several years. Rulin et al. (1998:149) reported on a large multicenter, prospective controlled study, which showed that dysmenorrhea increased significantly in patients who underwent sterilization compared to the control group.

Hefnawi, Kandil, Tayi & Zak (1979:37) reported on the sequelae of abdominal tubal sterilization. They studied 30 women and observed for changes in menstrual patterns, endometrial histology, and plasma levels of estradiol 17-beta and progesterone. The women ranged between 32 - 40 years of age. The post sterilization menstrual pattern was regular and normal in 12 of 30 cases. The other 18 cases showed various alterations in menstrual pattern, mostly in the form of polymenorrhagia; no cases of oligohypomenorrhea were recorded. Endometrial biopsies revealed normal findings in all cases. Estradiol 17-beta levels were lower in those women who experienced irregular menstruation cycles.

Destefano, Perlman, Peterson & Diamond (1985:835) followed participants up for a few years. The tubal sterilization group had slightly increased risks of moderate to severe menstrual cramps and adverse menstrual bleeding. At follow-up intervals longer than two years, the tubal sterilization group had significantly increased risks of abnormal menstrual cycles and combinations of two or more adverse menstrual outcomes. They state that tubal sterilization was not associated with an increased risk of premenstrual symptoms, but that the type of tubal sterilization procedures may carry some increased risk of menstrual disturbances, particularly abnormal cycles.

Rulin, Turner, Dunworth & Thompson (1985:13) looked at changes in menstrual patterns after surgical tubal occlusion and how they attributed to damage in the uterine and ovarian blood vessels leading to reduced blood supply and ultimately

to abnormal maturation of ovarian follicles and hormonal changes. Their results showed that psychogenic factors may play a role and that the surgical intervention and the materials used for suturing may be possible sources of local or regional inflammation that could have repercussions in blood perfusion and nervous function, leading to menstrual disturbances.

Wilcox et al. (1992:1368) found an increase in menstrual function changes, like menstrual pain, heavy menstrual flow and sporting between periods compared to the presterilized menstrual function after a five year follow up of bilateral tubal ligation of 5,070 women. They attribute the menstrual function changes to the aging of the cohort and other study limitations, but suggests that the findings on menstrual function changes may take sometime to develop. Previous method of contraception may also contribute to changes in the menstrual cycle post sterilization. Six months after the tubal ligation, women who had previously used oral contraceptives reported a significant increase in days of menstruation, more dysmenorrhea, and an increase in excessive bleeding (Lieberman et al., 1978:376).

Patis & Cullins (2000:859) deny the claim that changes in the menstrual cycle after two years could still be ascribed to the actual tubal ligation. However, Audebert & Emperaire (1983:35) stated that experimental studies on the topic are limited and the findings in the literature are contradictory, so that no formal conclusion is as yet possible regarding the influence of tubal ligation on ovarian function. Corson et al. (1981:363) led a study that compared hormone levels in women who had tubal ligation versus those women who did not. Their study showed no significant difference in the hormone levels of the two groups, indicating that the ovaries were not damaged by the surgery.

The debate on the existence of post-tubal ligation sydrome continues as professionals differ on the existence of such a syndrome. Gentle et al. (1998:179) concludes that, "tubal sterilization is not associated with an increased risk of menstrual dysfunction, dysmenorrhea, or increased premenstrual distress

in women who undergo the procedure after age 30 years. There may be some increased risk for younger women, although they do not appear to undergo significant hormonal changes". Stephen L. Corson, MD, professor at the department of obstetrics and gynaecology at Thomas Jefferson University and Women's Institute in Philadelphia refer to it as: "A medical myth" (Bloom, 2004). The number of women who claim to have post-tubal ligation syndrome is not known in the medical literature. However the syndrome has been a popular topic in Internet chat rooms and support groups.and women worldwide struggle to find answers to their menstrual disturbances after tubal ligation as medical experts refuse to accept that post-tubal ligation syndrome does exist (Bloom, 2004). A final analysis of the United States, Collaborative Review on Sterilization has found no menstrual changes attributable to sterilization at one - two years after the procedure. The study did find some changes at five years after sterilization that may have been attributable to ageing. The study found no differences in menstrual changes between those methods causing the most tissue destruction and those causing the least (Peterson et al., 2000:1685).

2.12 Summary

The current problem is the contradictory information that is in the literature on post-tubal ligation syndrome. A systematic review is needed to bring all the literature together and to do a meta-analysis of the results. A further problem in executing such a review is that the only consistency in the articles reviewed about pot-tubal ligation syndrome is their inconsistency (Peterson et al., 2000:1685). The conclusion of the current systematic review may give understanding on the debate on whether the syndrome exists or not.

Chapter three: Research Methodology

3.1 Introduction

Research is essential to the successful promotion and protection of health, well-being and to modern and effective health care. In research it is important to identify, develop and use appropriate research methods so that health and social care can be built on the best possible evidence base. The systematic review approach acknowledges the large body of existing research and seeks to synthesize the findings from relevant, good quality, studies. Meta-synthesis is the science of summing up, and a building block of evidence-based practice. The meta-analysis value lies in the recognition that busy practitioners find it almost impossible to make decisions based upon the massive and increasing volume of research evidence. Health care decision makers need to access research evidence to make informed decisions on diagnosis, treatment and health care management, both for individual patients and whole populations. Systematic reviews are recognized as one of the most useful and reliable tools to assist this practice of evidence-based health care (Sleep & Clark, 1999: 306; Lemmer, Grellier & Steven, 1999: 315).

This chapter will discuss the research methodology of the current systematic review. An overview of the analyses program, Review Manager (RevMan) software, a general discussion on systematic reviews, the criteria for selection of studies for this review, the search strategy for identification of the studies, review of the methodological quality of the review and the description of included and excluded studies will be discussed.

3.2 The Review Manager (RevMan) 4.2

Review Manager 4.2 (RevMan) is a software program designed to assist reviewers to prepare and maintain Cochrane Systematic reviews within the Cochrane Collaboration's programme. RevMan allows the user to enter text such as: background, objectives, references and criteria for included and

excluded studies characteristics of studies in the database. It further allows the reviewer to enter data in comparison tables for analyses. The program allows for meta-analysis of the data entered and is able to present the results graphically. Meta-analysis is the most preferred statistical method when writing systematic reviews as it summarizes the results from two or more separate studies. A variety of statistical procedures can be used to perform the meta-analyses. Some focus on pair wise comparisons of interventions, such as an experimental intervention versus a control intervention, or the comparison of two experimental interventions. When combining the outcomes from different studies, one may use a fixed or random effects model to do the analyses. A fixed effects model assumes that all the studies share the same common treatment, thus there is degree of homogeneity between the studies, while a random effects model assumes that they do not share the same common treatment effect and that the studies are significantly heterogynous. If significant heterogeneity is present, the random effects model will yield wider confidence intervals. Recent research suggests that the random effects model is preferable to the fixed effects model when there is heterogeneity between the studies (Hunter & Schmidt, 2000:288).

The strength of the treatment effect can be measured by the relative risk. If the relative risk is equal to one, then there is no evidence of an effect of the treatment between the treatment group and control group, which means that the incidence rate in the treatment group is the same as in the control group. If the relative risk is less than one then the treatment is beneficial (decreases the risk of disease) and if relative risk is greater than one, then treatment is associated with an increased risk of disease (Hunter & Schmidt, 2000: 288).

3.3 Systematic reviews

Systematic reviews refer to the systematic collection of relevant primary papers that deal with a focused question and include a summary of the evidence from the primary sources (Jadad & McQuay, 1996: 235). In general, there are two types of systematic reviews, quantitative (meta-analysis) and qualitative. Both

types of reviews follow the same rigorous steps, except that a qualitative review does not combine the endpoints for statistical analysis, because it is not appropriate to combine them into any type of common metric (Detsky, Naylor, O'Rourke, Mc Geer & L'Abbe, 1992: 225).

The four basic steps for conducting a meta-analysis systematic review include the literature search, the establishment of criteria for what studies will be included in the meta-analysis, the recording of data from the included studies, and the statistical analysis of the data (Alderson, Green, & Higgins, 2004: section 2). For the current study, the focus will be on the meta-analysis of summary data.

3.4 Rationale for systematic reviews

The execution of a systematic review is a scientific activity, the rationale for which is well established (Mulrow, 1994:597). With over two million articles published every year in over 20,000 biomedical journals it is impossible for any individual to stay up to date with primary research, even within a very specialized area. Increasingly, therefore, it is necessary to rely on reviews of research findings. The role of systematic reviews is now well established in clinical settings, but they are also of great value to researchers. Reviews can be used to identify, justify and refine hypotheses, and they can help to identify and avoid pitfalls of previous work, estimate sample sizes and delineate adverse effects. Although a review may be time consuming, it is likely to be quicker and less costly than doing a new study, and most importantly, it may provide a conclusion that can guide practice. Equally important, the review may actually demonstrate that another trial is unnecessary. Reviews can also speed the implementation of effective interventions and the withdrawal of ineffective or harmful interventions (Antman, Lau, Kupelnik , Mosteller & Chalmers, 1992: 242).

The generalizability and consistency of research findings can be established and explored within systematic reviews. When reviews include a synthesis of data from individual studies (meta-analyses) then power and precision will both be

increased. The rationale for systematic reviews can be summarized as follows: Health care decision makers need to access research evidence to make informed decisions on diagnosis, treatment and health care management, both for individual patients and whole populations. There is too much information around for decision makers to keep up to date; therefore, decision makers need scientific systematic reviews of existing information. Traditional reviews can be unscientific and biased in the way they collect, appraise and summarize information but systematic reviews attempt to minimize these biases to provide a reliable basis for making decisions (Lemmer et al., 1999: 315; Mulrow, 1994: 559).

3.5 Systematic reviews as scientific research

Systematic reviews are science and not new, and have been used for some time in the natural sciences, such as physics. Science is cumulative, with new ideas being based on previous knowledge and observation, and new advances in science should help make sense of what is already known and have been observed. Systematic reviews further guide the researcher on what implications there are for new studies in the same field (Mulrow, 1994: 560).

3.6 Difference between traditional and systematic reviews

Systematic reviews are not simply bigger than ordinary reviews, but they are quantitatively different. The aim is not to be simply comprehensive but to answer specific questions, to reduce bias in the selection and inclusion of studies, to appraise the methodological quality of studies and to objectively summarize the results. Traditional narrative reviews, while valuable, are usually subjective in nature and do not follow the criteria as listed above. A quantitative systematic review follows all four of the above criteria while a qualitative systematic review is limited to the first three criteria because the investigators feel that it is inappropriate to apply any type of statistical analysis to the data (Petticrew, 2001: 99).

Cochrane Systematic reviews concentrate mainly on the inclusion of randomized controlled trials. Systematic reviews of other study designs other than randomized controlled trials can be carried out, when no randomized trials are available. Systematic reviews of non-randomized clinical trials are common when randomization is not possible, but good comparative control groups are selected (Petticrew, Song, Wilson & Wright, 1999: 673).

3.7 Systematic reviews in a health setting

The common legend holds that systematic reviews adopt a biomedical model that is of relevance to medicine and that they should not be applied to other domains. Systematic reviews are a good measure for hypotheses testing, for summarizing the results for existing studies, and for assessing consistency among previous studies; these are not unique to medicine (Petticrew, 2001:100). Systematic reviews have been portrayed as being obsessed solely with disease outcomes and randomized controlled clinical trials carried out within health care systems. However, they have also been widely used to examine an array of modern and often-contentious "real world" issues such as prevention of vandalism, crime deterrence, domestic violence, child abuse and other social issues (Petticrew, 2001:100).

3.8 Main objectives of systematic reviews

The main objectives of systematic reviews are to find treatment effects that cannot be obtained from a single study. If considered separately, any single study may be either too small to detect moderate treatment effects or too limited in scope to provide clear, or generalizable conclusions that allow application to other patient populations. Combining results across studies can often strengthen the evidence about treatment efficacy (Johnson, 1993: 328). Systematic reviews in which results of individual studies are combined statistically are valuable instruments to resolve conflicts when reports of primary studies disagree. It further increases the likelihood of detecting small but clinically important effects

and generate new hypothesis and avoid unnecessary research. Traditional reviews can be misused easily to produce inaccurate, biased and / or misleading effectiveness of medical interventions (Jadad & McQuay, 1996: 238). Systematic reviews can be used to answer particular research questions. A further use is when a review identifies the need for further primary research; the results of the review could be used for planning further primary clinical trials. Reviews can be used to change practice where the conclusion of the specific intervention has shown that it is effective (Detsky et al., 1992; 256). In systematic reviews the study and not the patient becomes the unit of analysis. The characteristics of included studies selected can shed light on controversies. By doing a meta-analysis, the results from multiple studies in a single figure, can reveal trends that are not evident by individualized components of a single study. A primary benefit of the meta-analysis is that the data set develops adequate statistical power from a group of studies having a sample size too small for detecting clinical significant effect (Jadad & McQuay, 1996: 240).

3.9 Advantages of systematic reviews

Systematic reviews can help to discover present and future research needs and help to clarify contradictions in the literature. Systematic reviews provide a gain in statistical power by a meta-analysis of data from a number of smaller clinical trials, which is an attractive economic alternative. Systematic reviews give scientific findings that are consistent and can be generalized across populations, settings, and treatment variations. Exceptional advantages of quantitative systematic reviews or meta-analyses are the increased power and precision in estimating effects and risks. Both qualitative and quantitative systematic reviews, with their overt methods, limits bias and improve the reliability and accuracy of recommendations (Mulrow, 1994: 599).

Systematic reviews aim to reduce uncertainty by strengthening the evidence. They also contribute to resolve uncertainty when original research, reviews and editorials disagree. Systematic reviews can be conducted in an effort to resolve

conflicting evidence, to answer questions where the answer is uncertain or to explain variations in practice. Systematic reviews are needed to inform policy and decision-making about the organization and delivery of health and social care. They are particularly useful when there is uncertainty regarding the potential benefits or harm of an intervention (Petticrew et al., 1999: 672).

3.10 Limitations of the systemic reviews

The problem is that some reviews go to extreme lengths to seek out the best evidence, only to conclude, "Good evidence is currently lacking." Although this may be an accurate representation of the state of the evidence, it is not useful for guiding practice or policy, and users and funders will not see value in reviews that consistently and predictably conclude that no good evidence exists. Systematic reviews also risk being perceived, quite incorrectly, as simply a means of criticizing existing research rather than informing decision-making. Worse, their positive messages may be overlooked (Petticrew, 2003: 757).

The strength of systematic reviews lies in selecting methodologically sound studies and not incorporating data from poorly conducted studies. This gives a challenge in identifying relevant research as there are varying qualities of studies and the concern about combining certain study results of poor quality, results in publication bias. Identification of relevant research does not guarantee that data from studies can be combined. Another problem is that there can be a bias due to editors who have a specific publication bias and many findings never get in the journals (Dickersin & Berlin, 1992: 174). Problems can occur when combining results from individual experiments that may differ considerably from each other. Poor quality studies that are inadequately blinded, generates a biased estimate effect and if combined with high quality studies will materially affect the results of the systematic review and can reduce precision and added variability (Detsky et al., 1992: 258).

3.11 Ensuring quality of the systematic reviews

The quality of a systematic review lies in the inclusion of published and non-published randomized controlled trials. Electronic searches must be supplemented by hand searches of key journals and querying experts. In analysis of the systematic review, the use of a data driven method that weights the individual effect and aggregates the effect size rather than arbitrary scores is used (Detsky et al., 1992: 259).

3.12 Criteria for selection of studies for this review

The decision on studies to include in this systematic review was based on a focused research question of this systematic review, being - Does bilateral tubal ligation cause long-term risks associated with the menstrual cycle? The issues considered in this systematic review were:

- Types of study designs. Randomized trials and non-randomized trials were included (prospective or retrospective). As it is very difficult to randomized women to have a bilateral tubal ligation, the reviewer decided to include controlled, comparative studies.
- Types of participants. Women in the reproductive age between 21-51 years.
- Types of publications. Due to time constrain only English published journal articles were used in this review. One author has been contacted for further information, but no information has been received to date.
- Type of interventions. Women who had a female sterilization. The comparative group existed of women whose husbands had vasectomies, or women who used a non-permanent method of contraception. Own controls, before and after the sterilization were also used as a control group. No discrimination was made in the analyses between prior or current contraceptive. No discrimination was made between the method of female sterilization or vasectomy. The time frame for the included studies was 1951 to June 2003.

- Types of outcomes. Studies that looked at dysmenorrhoea, menorrhagia and duration of the menstruation period were included. Only studies that had data in an appropriate format for inclusion in the review were included.

3.13 Types of studies

Thirteen studies met the inclusion criteria as specified above. None of the trials used random allocation to allocate women specifically to have a bilateral tubal ligation. One study randomized the surgical intervention and then compared the intervention to each other and to a comparative group. In the thirteen studies, some sub-studies were also identified when the results were given in more than one comparison. For example if the study reported on the outcomes comparing two groups as well as in the form of a before and after study. With these sub-analyses, the included studies then resulted in eighteen "studies" that were used during the analyses. Six of the thirteen studies were prospective trials and seven were retrospective analyses. Five of the eighteen sub studies compared women who had a tubal ligation with women whose partners were sterilized. Seven of the eighteen sub studies compared women who had a tubal ligation with women who used any method of non-permanent contraception. A total of fifteen studies could be combined under the comparison of comparing women who had a tubal ligation to women using any other method of contraception. Three studies provide data in a before and after context.

3.14 Types of participants

All the studies included women in their reproductive age who requested or who had a bilateral tubal ligation, irrespective of the surgical procedure or the sterilization method. The comparative groups differ between the studies. Some women used no method of contraception as their husbands had a vasectomy, other women used a non-permanent method of contraception and in one study the method of contraception in the control group was not specified. The

contraception method used before the sterilization was similar in most of the studies.

3.15 Types of intervention

Bilateral tubal ligation using any method of surgery such as macro- or micro-surgery, laparotomy, minilaparotomy, laparoscopy or culdoscopy and any method of tubal occlusion such as coagulation, rings, clips, sutures and excision were included. The reviewer decided to categorize the control groups in four comparisons: women whose partners had a vasectomy, women who used any method of non-permanent contraception, and women who used any other method of contraception (this includes the above two comparisons) and lastly women who act as their own controls in a before and after study.

3.16 Types of outcome measures

Studies were considered for inclusion in this review if they were appropriately designed to evaluate the objective outcome measures relevant to post-tubal sterilization long-term risks: dysmenorrhea (pain or cramps), menorrhagia (excessive menstrual bleeding or heavy menses) and duration of menstrual bleeding (meaning the number of days or number of subjects with increased days of menstrual bleeding).

3.17 Search strategy for identification of studies

A comprehensive electronic literature search was carried out to minimize bias and to ensure that all relevant literature was reviewed for inclusion in the review. Electronic data bases such as EMBASE, PubMed, Medline and the Cochrane Controlled Trials Register was used for the initial search. Hand searching of the reference lists of studies, reviews and relevant textbooks was done to ensure that all relevant studies are included in the systematic review. Some of the key words for the electronic searches included words such as: "female sterilization, post tubal ligation syndrome, tubal ligation, post tubal sterilization menstrual

changes, long-term risks of tubal ligation". Initially, the reviewer evaluated all identified citations on the basis of titles and / or abstracts against the eligibility criteria. The full articles were ordered through the University of the Western Cape Interlibrary Loan locally and abroad for those abstracts that discussed the menstrual changes after sterilization. The reviewer undertook the study selection independently and erred on the side of over-inclusion after employing the search strategy outlined above. The reviewer assessed whether the studies meet the inclusion criteria. Thirteen articles were found to meet the inclusion criteria. Those deemed to be irrelevant were excluded and reasons for exclusion noted. A list of excluded reports and the reasons for exclusion are available (see appendix A). Thirteen studies were entered into tables of study characteristics of included studies: the study is identified by the author and the year it was carried out; and further describes each study under the following sub-headings: type of study; methodology; type of participants; intervention; outcomes and special notes. All the studies were assessed independently by the reviewer, and further reassessed by the supervisor. Discrepancies were resolved by discussion. Thirteen out of the thirty-five articles qualified to be assessed for inclusion in the current systematic review.

3.18 Methodological quality, validity and reliability

The validity of a study in the context of a systematic review may be measured according to the way in which the study was designed and conducted. The reviewer and her supervisor critically appraised thirty-five articles for inclusion and exclusion in the systematic review. The articles, which did not meet the inclusion criteria, were excluded. Disagreement whether a study should be included or not was resolved by discussion between the reviewer and her supervisor. It is well known that the lack of adequate allocation concealment is associated with bias. The nature of the intervention, bilateral tubal ligation, does not allow for adequate concealment between the intervention and a control group. Control for confounders such as matching instead of allocation concealment was used as a criterion to assess validity for inclusion to this

review. The reviewer included studies that made use of well-described comparative control groups or studies that used the participants as their own control. Performance bias was based on the measure of exposure to the intervention in the control group. Attrition bias, which is the difference between the comparison groups in the loss of participants from the study, was used and noted, but not used as a validity criterion (Schulz, Chalmers, Hayes, & Altman, 1995: 408). Detection bias was based on the case definitions. This was a problem in these articles as the primary outcomes for this review were often not the initial outcome assessment of the intervention allocation and was analyzed as secondary outcomes.

The reliability of a systematic review refers to the degree to which different reviewers review the study. Two reviewers assessed all the studies and consensus was achieved by discussion.

Further reliability and validity was ensured by double entry. The reviewer, without masking of authors' names, study site, intervention, or trial results, extracted the data from each publication independently, and the results were double-checked by the supervisor. The data was entered twice in Revman to ensure correctness. Further information was sought from the author in the study of Parsanezhad (2003), but no correspondence has been received to date.

It is very important to note that the overall validity of the included studies in this review has a high risk of bias. This means that the poor quality of the studies could weaken the confidence of the results, but scrutiny was applied to ensure that the best criterion for these comparative studies was used to assess for bias before the studies were included.

3.19 Data Collection

Data was extracted independently from each publication, without masking of authors' names, study site, intervention, or trial results. Data were entered on a

special data collection sheet (see appendix A), one sheet for each included study, indicating the categorical outcome measures of the sterilized group versus the control group. Only the systematic review variables of dysmenorrhoea, menorrhagia and the duration of menstrual bleeding were extracted from the studies. Although some articles used the words like pain or cramps before and during menstruation, the current review used the term dysmenorrhoea as defined by Shaw et al. (1992:196). While at the same time excessive bleeding or heavy menstrual loss meant menorrhagia.

3.20 Data analysis

Data was extracted from each individual study and entered into the data collection sheet, there after it was entered onto the Review Manager Software (RevMan) computer program for analysis. Revman is specifically designed to calculate statistics used in meta-analyses. The program display results in tabular and graphical form. The tabular summary display list the comparisons and the associate outcomes included in the systematic review. The summary displays the results in five columns. The comparisons and the outcomes are in the first column. The number of studies that contributed to the analysis for the specific outcome is in the second column. The third column shows the total number of participants for the studies that contributed to the analysis of the outcome. The statistical method used to do the analyses is displayed in the fourth column. This review draws on the random effects relative risk (RR) model and the 95% confidence interval (CI) as the statistical method of analysis. The last column displays the effect size as the effect estimate and the CI that resulted from the meta-analyses.

The Review Manager software also uses a standard graphic chart in the format of a forest plot to display the results. The first column displays the study identifier. The incidence of the event (n) and the sample size (N) of the intervention group are displayed in the second column. This is followed by the n / N of the control group.

The graphical section of a forest graph displays effects estimates in relative risks and 95% confidence intervals for both individual studies and the meta-analyses. A blobbogram for each study. The horizontal line depicts the confidence interval. The square block in the blobbogram represents the point estimate. The size of the square block corresponds to the weight of the specific study in the meta-analyses. A bigger block represents a larger weight, thus the study confidence intervals is narrow. Studies with a lesser CI carry more weight to the meta-analyses. The diamond represents the confidence intervals for the totals of the meta-analyses. The percentage weight that each study contributed is then given in column five followed by the numeric values of RR and CI. The bottom of the forest plot displays the total events that occurred in each group. This is followed by the test of heterogeneity (Chi^2 statistic with its degrees of freedom (df) and P-value and the I^2 statistic, measures the extent of inconsistency among the results). The random relative effects model was used as most (9 / 12) of the comparisons showed heterogeneity among the results. This is followed by the test for overall effect, Z statistic with the P-value.

The interpretation of the results in the forest plot is based on the position of the relative risk (RR) and confidence interval (CI). For this review a confidence interval of 95% and a random relative risk was used. Relative risk is the ratio between the rate of intervention in the population exposed to a particular factor (i.e. women who had a female sterilization) and the rate in those not exposed (i.e. women who are in the control group). The relative risk value can yield three different interpretations:

- If the RR = one, or the confidence interval (CI) includes one, then there is no significant difference between the sterilized group and control group.
- If the RR> one and the CI does not include one, events are significantly more likely in the sterilized group than the control group.
- If the RR< one and CI does not include one, events are significantly less likely in the sterilized group than the control group (Guyatt et al., 1995: 497; Fahey, Griffiths & Peters, 1995: 1056).

3.21 Characteristics of included studies

The author, the year it was carried out, and the title of the article identifies the research study. Where the study used more than one comparison group it was further divided into sub-studies, where the control group consisted of women whose husbands had a vasectomy (v), in the case where there was a control group other than a vasectomy control group (c) and (o) where own controls, before and after sterilization.

Study Identifier: Alder (1981). The effects of sterilization: a comparison of sterilized women with the wives of vasectomized men.

Methods: A retrospective comparative study, comparing women who had an interval tubal ligation or diathermy during 1976 with women whose husbands had had a vasectomy during 1976. The study also compared dysmenorrhoea in the sterilization group before and after the procedure.

Participants: A sample of 50 sterilized women was selected and asked to agree to an interview, two moved and three refused to participate, 45 were successfully interviewed. There were also 45 women in the comparison group, 57 were originally contacted, but 12 refused to participate. The sterilization sample group (s) was randomly selected from hospital records of women who were sterilized in the Eastern General Hospital, Edinburgh. The comparison group (c) of women was selected from the patients register in the Family Planning Centre, Stockbridge and Edinburgh. The comparison group was matched for age, parity and social class with the sterilized women. The mean age of the groups was 33.4 (s) years and 32.5 (c) years and the mean parity 2.7 (s) and 2.5 (c). None of the women had gynaecological problems or a baby within the year preceding the sterilization or the vasectomy. The principle method of contraception used before the sterilization or vasectomy was similar, 27/45 (s) and 28/45 (c) used the oral contraceptive pill. Outcome data was available on 43 patients in the sterilized group and 42 patients in the vasectomy group.

Interventions: Women who had an interval tubal ligation or diathermy were compared with women whose husband had vasectomies. Women were interviewed two years after the sterilization or vasectomy. All women were interviewed using a semi-structured questionnaire.

Outcomes: This study looked at menorrhagia (more clots or increased blood loss) and dysmenorrhoea (pain in the week before their period). Other outcomes measured but not reported on in this review are: understanding of the operation, satisfaction with the operation, marriage and sexual relationship, premenstrual symptoms and general health.

Allocation concealment: Not used, as it was not a randomized controlled study, it was a retrospective, comparison study.

Notes: The women were interviewed two years after sterilization.

Study Identifier: Bledin (1985). The effects on menstruation of elective tubal sterilization: a prospective controlled study.

Methods: This report is on a retrospective sub analysis of a prospective comparative study conducted by the World Health Organization (WHO) to investigate the psychological and psychosomatic effects of elective contraceptive tubal sterilization. The sub analyses compared women who had tubal ligation to women who used non-permanent contraceptive methods. Women were also requested to comment on their own experience regarding menorrhagia and duration of menstruation period before and after the sterilization.

Participants: Four groups of women were used in the study. Two groups of sterilized women were selected; the first group (69) had an interval tubal ligation six months or more since an obstetric event and the second group was women who were sterilized in the post partum period (69). The comparison groups were women who planned to use non-permanent contraceptive methods. The first

comparison group was women from the local family planning clinics (interval group, 66) and the second group was selected from the post partum wards (69). The selection criteria were not mentioned in this article, but were specified in the original WHO report. The attrition rate at six and twelve months was 19% and 17% for the sterilization group and 14% and 31% for the controls. The reason for attrition was not mentioned in this article. The sterilization interval group (si) was selected from four gynecological wards of two Nottingham hospitals and the sterilization post partum group (sp) from four maternity wards of the same hospitals within 72 hours of a normal delivery. Comparable, interval control groups (ci) were selected from four local family planning clinics and the comparable, post partum control control group (cp) group from the same maternity wards as the sterilized group. The women in the comparison groups chose to use non-permanent contraception. All the participants were healthy, multiparous women in stable relationships. The mean age in years was 25.3 (si), 25.3 (sp), 24.2 (ci) and 25.3 (cp). Seventy percent (97/138) of women in the sterilization group used oral contraception (84/138) or the IUCD (13/138) within three months before the sterilization or pregnancy. The proportion of women who used oral contraception or the IUCD in the comparison groups was not reported in this article.

Interventions: The method used for female tubal ligation is not mentioned in this article. Women who had a tubal ligation were compared to women who chose a non-permanent form of contraception. The first group had an interval tubal ligation six months or more since an obstetric event and the second group were sterilized within 72 hours post partum. The first comparison group was women from the local family planning clinics (interval group) and the second group was selected from the post partum wards. All women were interviewed using an interview schedule that included questions on menstrual functioning and contraceptive history. Women were interviewed at six months and at 12 months after enrolment.

Outcomes: This study looked at menorrhagia (very heavy blood loss) and dysmenorrhoea (pain with menstruation) and duration of menstruation period. Other outcomes measured but not reported in this review is interference with daily life.

Allocation concealment: Not used, as it was not a randomized controlled study.

Notes: The data extracted and used for analysis was from the one year follow-up.

Study Identifier: DeStefano (1985). Long-term risk of menstrual disturbance after tubal sterilization.

Methods: This report is a retrospective sub analyses of a long-term prospective comparative study. The original study viz the "Contraceptive study" was designed to evaluate the non-contraceptive effects of oral contraceptives and was conducted over the period of December 1968 till February 1972. This sub analyses compared women who had a tubal ligation to women whose partners had vasectomies.

Participants: Women who underwent a tubal sterilization (n719) procedure were compared to a group of women whose partners were assumed to have undergone a vasectomy (n1083). The method of selection was not described in this article. The analyses were restricted to white women who had at least one follow up visit after the sterilization. Outcome data was available on 425 women in the sterilization group and 683 women in the control group. The participants were all members of the Kaiser-Permanente Family Health Plan of Walnut Creek, California. The analyses adjusted the groups for pre-sterilization age, contraception, history of gynecologic disorders, gravidity, body mass index, cigarette smoking, education and religion. There were no statistical differences between the groups for above variables. The majority of women was between

the ages of 30-39 (41.9s vs 47.5% c), had a gravidity of 1-2 (45.8% s vs 47.9% c) and used oral contraceptives before the procedures (35.2% s vs 45.3% c).

Interventions: The method used for the tubal ligation in the sterilized group is not mentioned in this article. The selection of the comparison group was based on the assumption that the woman's partner has had a vasectomy if the woman recorded that she started to use a surgical method of contraception and there were no mention of a female sterilization, hysterectomy, or bilateral oophorectomy in her notes. Information was gathered at a pre-sterilization visit, which was the taken as the visit closest to the sterilization. The mean interval for this visit was 16 months for the female sterilization group and 15 months for the vasectomy group. A self-administered questionnaire, which contained questions regarding the woman's menstrual cycle, was completed at 6-24, 25-48 and 49-87 months.

Outcomes: This study looked at menorrhagia (moderate or severe large clots, ≥ 12 full pads or tampons) and dysmenorrhoea (moderate to severe menstrual cramps). Other outcomes measured but not reported in this review was abnormal cycles and spotting.

Allocation concealment: Allocation concealment was not used in this study.

Note: The study had follow-up interviews at 6-24 months; 25-48 months and 49-87 months. The data from the 6-24 months follow-up was used for the current systematic review.

Study Identifier: Foulkes (1985). Effects of sterilization on menstruation.

Methods: Retrospective analyses of a comparative study to investigate the effects on the menstrual cycle. Women who had a tubal ligation were compared to women whose husbands had vasectomies.

Participants: The selection of participants is not mentioned. A total of 650 questionnaires were sent out and 551 were returned. A total of 350 women had tubal ligation via laparoscopy and 101 women via a laparatomy. The comparison group consisted of 135 women whose spouses had a vasectomy. Falope rings or Hulka clips were used for the female sterilization procedure. All the procedures were done after an interval period, thus no women were recently pregnant. The recruitment took place at two hospitals in England, the Plymouth General Hospital and The Chelsea Hospital for Women in London. There were no differences between the mean ages and parity between the groups. No other selection criteria were mentioned. The majority of woman used oral contraceptives before the surgical procedure 328/551, 71/551 used an IUCD and 152/551 used other contraceptive measures.

Interventions: Laparascopic and laparotomy interval tubal ligation using Falope ring or Hulka clip. The comparison group was women whose husbands had vasectomies. All women were surveyed by questionnaire one and two years after the female sterilization and vasectomy.

Outcomes: The study looked at menorrhagia (days of heavy bleeding, more days of blood loss). Duration of days of bleeding was reported in a categorical way (fewer, no change or more). The study also looked at the number of days of cycle but that is not reported in this review.

Allocation concealment: Allocation concealment was not used in this study.

Study Identifier: Harlow (2002). Does tubal sterilization influence the subsequent risk of menorrhagia or dysmenorrhea?

Methods: A retrospective, cross-sectional, sub analysis of the Harvard Study of Moods and Cycles. This sub analyses was done to evaluate the relation between tubal ligation and changes in the menstrual cycle including the early follicular phase hormones. The changes in the menstrual cycles from the first

five years of menarche were compared with the current characteristics. Comparisons were made between women who had no history of a tubal ligation, to those who had a tubal ligation.

Participants: Three groups were compared. Comparisons were made between women with any history of tubal ligation (97) versus no tubal ligation and between women with a tubal ligation greater than five years before the study enrolment (57). The contraception method in the women who did not have a tubal ligation is not clear. Participants were selected from an address list from seven Boston metropolitan area communities. The main inclusion criteria were that the participants had to be between the ages of 36 – 44 at the time of the study enrolment. Slightly fewer women in the tubal ligation group (14.4% vs 23.6%) never used oral contraceptives before.

Interventions: The method used for bilateral tubal sterilization is not mentioned in the article. The method of contraception in the non-sterilized group is also not clear. A postal questionnaire was mailed to all participants requesting participation. In-person interviews were conducted with all the study participants. Participants were asked if they ever had a tubal ligation, and if so at what age. They were also asked to report on the characteristics of their current menstrual cycle. In addition they were asked to recall the characteristics of their menstrual cycle during the first five years after menarche.

Outcomes: The study reported on dysmenorrhoea, menorrhagia, duration of menstruation period as well as hormonal levels.

Allocation concealment: Allocation concealment was not used in this study.

Study Identifier: Neil (1975). Late complications of sterilization by laparoscopy and tubal ligation.

Methods: A retrospective controlled study comparing the frequency of late complications of sterilized women to women whose husbands had vasectomies

Participants: The selection criteria for enrolment were not mentioned. Three groups of women were requested to participate. A total number of 652 questionnaires were sent out. Of these 327 questionnaires were sent to women who had laparoscopic interval sterilization in the 18-month period between January 1972 and June 1973 at the Royal Hampshire County Hospital and the Andover War Memorial Hospital. One hundred and twenty seven questionnaires were sent to women at the same hospitals who had abdominal tubal ligation (laparotomy) either as an interval or post-partum procedure during the same 18 months period. It is not clear where the control group participants were selected from but 143 questionnaires were sent to women whose husbands had vasectomies. A total of 493 completed questionnaires were received, laparoscopic 257, laparotomy 93 and vasectomy 143. There were no difference between the mean ages of the groups, 34, 33.6 and 33.7 years. The average number of children was 2.9, 2.7 and 2.6 for the three groups. The use of previous contraception was not noted in this study.

Interventions: Women who had laparoscopic (interval only) and laparotomy tubal ligation (interval and post-partum) were compared to women whose husbands had a vasectomy. Questionnaires were completed by all participants who had a tubal ligation and were followed up for 10 – 28 months after the procedure.

Outcomes: Questions were asked about menstrual loss, and dysmenorrhoea. Additional outcomes were: pain with intercourse, libido and satisfaction or dissatisfaction with the procedure.

Allocation concealment: Allocation concealment was not used in this study.

Study Identifier: Parsanezhad (2003). Menstrual abnormalities and pain after five tubal sterilization methods: A randomised controlled trial.

Methods: A prospective trial. The sterilized group of women was randomized to receive different interval methods for the tubal ligation procedure (laparoscopic unipolar electrocauterization (unipolar), laparoscopic bipolar electrocautirization (bipolar), laparoscopic by Falope ring, laparoscopic by Filshi clips, and minilaparotomy Pomeroy technique), to evaluate the effect on the menstrual cycle. The group of sterilized women was then compared to women who were not sterilized and who did not use any hormonal contraception.

Participants: A total of 1358 women who were referred to Shiraz University Medical Sciences were randomised to one of the five female sterilization groups. The data of 1119 female sterilized women were analysed; clips (191) bipolar (202), unipolar (212), ring 252 and pomeroy (262). The data excluded were due to loss to follow up, incomplete data or excluded for other reasons. A total of 312 of the original 815 participants assigned to the control group were analysed. Exclusions were due to loss to follow up or excluded, as they did not met the inclusion criteria. Outcome data was available on 1115 women in the sterilization group and 293 in the control group.

The mean ages between the groups were similar: clips (32.2), bipolar (33.2), unipolar (31.6) ring (31.5), Pomeroy (31.7) and the control group 33.6 years. There was also no statistical significant difference between the parities: clips (3.1), bipolar (3), unipolar (2.8), ring (2.8) Pomeroy (2.9) and the control group 2.8. None of the women in any of the groups including the control group were on any hormonal contraceptives or IUCD's or suffered any endocrine abnormality at the time of enrolment.

Interventions: Women who had an interval tubal ligation using one of five methods (laparoscopic unipolar electrocauterization (unipolar), laparoscopic bipolar electrocautirization (bipolar), laparoscopic by Falope ring, Filshi clips, and

minilaparotomy Pomeroy) were compared to women who did not had a female sterilization and who did not use any hormonal contraception or IUCD.
The women in the study group were interviewed before the sterilization. All the participants were followed up every six months for three years.

Outcomes: The study was designed to look at changes in the menstrual pattern. Menorrhagia was one of the outcomes. Other outcomes were, cycle length, intermenstrual bleeding, duration of bleeding and pain after the sterilization.

Allocation concealment: Although this was a randomized controlled trial, it was the sterilized group of women who were randomized to receive different interval methods for the tubal ligation procedure. While the control group no allocation concealment was used.

Study Identifier: Rulin (1985). Post-tubal sterilization syndrome – A misnomer.

Methods: This is a prospective, longitudinal study, comparing the menstrual patterns of women who underwent an interval tubal ligation to women whose husbands were undergoing a vasectomy. The authors unfortunately decided not to analyses the data according to "intention to treat" as the baseline demographic data differ between the two groups. A sub analysis of menstrual patterns in women who had a tubal ligation was then compared between presterilization status and post sterilization status at six months and at one year.

Participants: A total number of 389 women had a tubal ligation. There were 40 women in the group whose husbands had a vasectomy. But results in this group are not available. There is no reference from where the population sample was drawn, but the authors are from Pittsburgh and Magee- Women's Hospital. Tubal ligation was performed via laparoscopic procedure using the Falope band technique.

Interventions: Women who had a bilateral tubal ligation via a laparoscpy using the Falope band technique was analyzed in the context of a before and after study design. The comparison with women whose husbands had vasectomies was not reported on.

Outcomes: Menstrual characteristics and dysmenorrhoea.

Notes: The 389 sterilized women served as their own control and the 40 females whose partners had had a vasectomy as independent cohort because of difference and the disparity in sample size.

Allocation concealment: Allocation concealment was not used.

Study Identifier: Rulin (1989). Changes in menstrual symptoms among sterilized and comparison women: A prospective study.

Methods: A prospective, longitudinal study comparing three groups of women. The first group had a tubal ligation, the second group stated they want no more children but refuse sterilization and the third group did not want permanent contraception. The results of the sterilized vs the non-permanent contraception women were used for this review.

Participants: Ethnically diverse, poor women from Magee-Womens Hospital, Pittsburgh, Pennsylvania, Grady Memorial Hospital, Atlanta, Georgia and the Presbyterian Hospital, New York who requested tubal sterilization were recruited to participate in the study. The tubal ligation technique was modified Pomeroy for the post-partum sterilizations and the interval sterilizations was done by Falope rings or bipolar electrocautery. The comparison group was women with the similar backgrounds, age and parity, but who were not sterilized. A total of 1107 women stated at the initial interview that they request female sterilization but only 657 of these women had tubal ligation. A total of 600 women were identified as controls but data was only available on 508 women. The mean age

(28s vs 28.3c) and parity (2.85s vs 2.55 c) was similar between the groups. More than 50% of the women in the sterilized group used oral contraceptives or IUCD's before the procedure.

Interventions: Women who had an interval or post-partum sterilization compared to women who used non-permanent methods of contraception. All women were interviewed at an initial visit and between eight and 11 months later.

Outcomes: The study reported on dysmenorrheoa as well as changes in the menstrual cycles, bleeding between periods and duration of heavy flow.

Allocation concealment: allocation concealment was not used.

Study Identifier: Rulin (1993). Long – term effect of tubal sterilization on menstrual indices and pelvic pain.

Methods: This was a prospective and longitudinal study to evaluate the long-term effects of sterilization on menstrual indices. Women who had a female sterilization were compared to women to women who used non-permanent contraceptives.

Participants: Ethnically diverse, poor women from Magee-Womens Hospital, Pittsburgh, Pennsylvania, Grady Memorial Hospital, Atlanta, Georgia and the Columbia Hospital, New York participated in the study. A total of 500 of women who had been sterilized for at least three years were compared to 466 women who were not sterilized. A sub analyses were also done comparing the sterilized women against a comparative group of women who used non-permanent contraception excluding oral contraception (319). The median age was similar between the groups 28s, 27c and 29 years in the sub analyses control group. There were also no statistical difference in parity, 2.87s, 2.45c and 2.56subc.

Interventions: Female sterilized women were compared with a control group of women who used a non-permanent method of contraception. Women in both groups were requested to participate in a pre-sterilization or pre- enrolment interview and were then again interviewed between eight –11 months later and a third interview was conducted 3-4.5 years later. The third interview was done telephonically.

Outcomes: Menstruation indices compared were menorrhagia (heavy bleeding), dysmenorrhoea (pain and cramps) and other outcomes such as: bleeding between periods and abnormal cycles.

Allocation concealment: Allocation concealment was not used.

Study Identifier: Shain (1989). Menstrual pattern change 1 year after sterilization: Results of a controlled, prospective study.

Methods: A prospective controlled study. Participants were enrolled from 1980 to1982 from approximately 50 obstetric and gynecology and urology offices and clinics in San Antonio. The participants were white women aged between 19 and 49 years. The initial sample consisted of 728 women; the refusal rate was 10.9%. Attrition between the initial and first follow-up year was 6.5%, yielding a total sample of 681 women. Most women in the initial group were excluded by the first follow-up year from the analysis because of inadequate information on their procedure. Four groups of women were further excluded: (1) sterilization by fimbriectomy or vaginal route, because of a small sample size; (2) users of IUDs within 3 months of the initial interview; (3) all those who used hormonal or IUDs contraception during and after the initial interview and (4) those women who failed to menstruate or return to normal cycle after at first-year follow-up. After all exclusions, 227 tubal sterilization women, 132 vasectomy wives and 87 women who did not plan to be sterilized remained. Out of the 227 sterilizations, 91 were postpartum procedures; 29 were conducted during caesarean section, 57 were performed within 90 days of birth and the remaining 136 were interval procedures. Follow-up was for 5 years. Analyses were presented in three ways,

sterilized group vs vasectomy group, sterilized group vs another non-permanent contraceptive group and vs own controls.

Participants: A total of 227 women who had tubal ligation and a comparison group of 132 women whose husbands had vasectomy and 87 women who were not planning sterilization as a second control group. The cohort was aged 19-49 yrs. Gravidity was between two to three. Previous contraception use was noted.

Interventions: Bilateral Tubal ligation (88 by Pomeroy ligations; 53 Bipolar cauterizations, via laparoscopy; and 86 Falope rings via laparoscopy) and the comparison had had husbands with vasectomy for the control group. Follow-up was 5yrs of yearly interval after sterilization.

Outcomes: Dysmenorrhoea, menorrhagia and duration of menstruation period were reported on. Other outcomes not reported on in this review are menstrual characteristics of abnormal cycles and adverse bleeding.

Notes: Three women in the control group had gynaecology problem were excluded in the analysis. The data used in the current review was for the first follow-up year.

Allocation concealment: Allocation concealment was not used.

Study Identifier: Visvanathan (2000). Tubal ligation, menstrual changes and menopausal symptoms.

Methods: A retrospective controlled study. The study was primarily a detailed baseline study of the health status in 1981 of 5398 college alumnae, half were college athletes and the other half were non athletic classmates, a follow-up of health history of 3940 of the original respondents with a second questionnaire in 1996 was conducted, 80.5% (3170) had had at least one pregnancy. The tubal

ligation women were 14.8% (583). This study emphasis on women between 40-44 years in premenopausal period, to test the hypotheses that sterilization affects the menstrual and menopausal changes that result in hormonal imbalances. Out of the 3940 respondents 10.85% were aged between 40-44 years. A marched group in age (40-44 years) and parity of 516 of the 3940 were compared between the sterilized women (56) and non-sterilized (460) women.

Participants: A total of 56 sterilized women and a matched number of 460 as a control group were enrolled in the study. The control group women did not have their husbands sterilized. The women were aged between 40-44 yrs with a history of at least one pregnancy. There were no significant differences in age, athletics status, body mass index and smoking history, characteristics that could be associated with accelerated onset of menopause.

Interventions: Bilateral tubal sterilizations, types of sterilization methods are not mentioned in the study.

Outcomes: Dysmenorrhoea, menorrhagia and menopausal symptoms were reported on this study.

Notes: The control group comprising of non-sterilized women, had no specification of the contraception method.

Allocation concealment: Allocation concealment was not used.

Study Identifier: Weil (1979). Long-term effects of Interval Laparoscopic Sterilization by Bipolar Electrocoagulation on Menstrualtion.

Methods: A prospective controlled study. The research studied public patients who had a laparoscopic sterilization by the Department of Social and Preventive Medicine. The sterilization was conducted at the Department of Obstetrics and Gynaecology of Bassle Medical Centre between July 1, 1974, and December 31,

1976. A total of 288 questionnaires were sent out to participants before sterilization in 1977, 258 responded to the questionnaires giving a response rate of 90%. The duration of follow-up varied from 12-42 months. A control group of non-sterilized women from the outpatients who sought a routine gynaecological

examination and had no history of hormonal contraception or IUDs usage, or pregnancy in the preceding 6 months. The control group was matched for age and parity. The mean age was 34 years; 2.3%(6) were ≤ 25; 20.1% (52) were 26-30 years; 38.8% (100) were 31-35; 29.5%(76) were 36-40 years; 7.8% (20) were 41-45 years and 1.5% (4) were ≥ 46 years.

Participants: A total of 258 sterilized women and a matched non-sterilized control group for age and parity of 258 women. The control group women were not on any hormonal contraception and IUDs.

Interventions: Bilateral tubal sterilization with laparoscopic sterilization by bipolar diathermy, which were interval sterilizations.

Outcomes: Dysmenorrhoea, irregular cycles, metrorrhagia, menorrhagia, hypermenorrhea, hypomenorrhea, polymenorrhea and amenorrhea.

Allocation concealment: Allocation concealment not used.

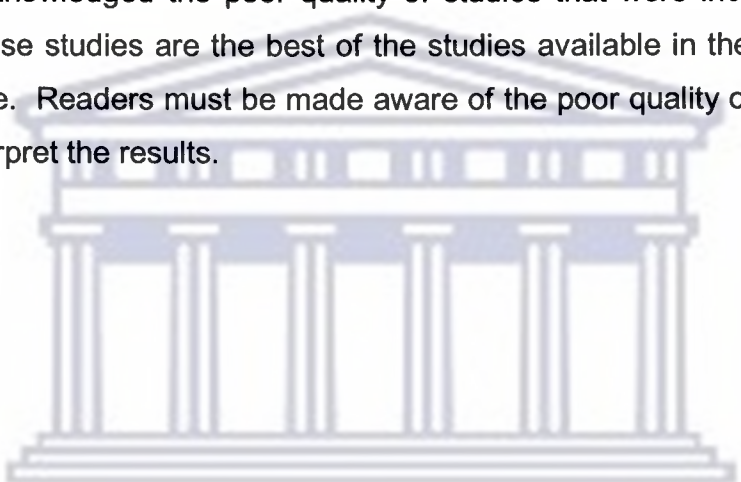
3.22 Excluded studies

These are studies that also almost met the inclusion criteria and seemed to answer the research question but looked at different outcomes (see Appendix B for excluded studies).

3.23 Summary

The systematic review builds on several principles, two of which are to minimize bias and to ensure relevance. Pre-specifying the inclusion and exclusion selection criteria during the protocol stage of this review ensured relevance. The

topic of this review does not lead itself to randomization, as women can not be asked to be randomized to have a bilateral tubal ligation or not. The issue of different control groups in the different studies further challenged the reviewer. Another problem was that seven of the thirteen studies were retrospective analyses or even sub analyses of other studies. The primary researchers also did not use clear inclusion and exclusion criteria when they established the comparative groups. The researcher used the pre-specified selection criteria. These criteria opened the inclusion for weak methodological studies. The researcher acknowledged the poor quality of studies that were included in this review, but these studies are the best of the studies available in the field at this moment in time. Readers must be made aware of the poor quality of the studies when they interpret the results.



Chapter four: Results

4.1 Introduction

Chapter four reflects the results of the meta-analysis of the thirteen research articles that met the inclusion criteria for this systematic review. The analysis was done using the Review Manager software. Outcomes such as: dysmenorrhoea, menorrahgia and percentage of women who reported an increase in menstrual bleeding were analyzed as dichotomous outcomes, using relative risks and 95% confidence interval.

A total of thirteen studies met the inclusion criteria and were used in this review:

- Alder (1981)
- Bledin (1985)
- DeStefano (1985)
- Foulkes (1985)
- Harlow (2002)
- Neil (1975)
- Parsanezhad (2003)
- Rulin (1985)
- Rulin (1989)
- Rulin (1993)
- Shain (1989)
- Visvanathan (2000)
- Weil (1979).

Some of the studies gave the results in more than one comparison. Thus for instance some studies use a control (c) as well as an own (o) control group. The studies that had a group whose husbands had vasectomies are labeled as (v). These outcomes were analyzed as separate studies. Thus a total of eighteen "sub studies" have been reviewed.

- Alder (o) (1981) Alder (v) (1981)
- Bledin (c) (1985) Bledin (o) (1985)
- Shain (c) (1989) Shain (o) (1989) Shain (v) (1989)
- Weil (c) (1979) Weil (o) (1979)

The analysis was done within four main comparison groups:

Comparison: 01 Sterilized women versus (vs) women whose partners had vasectomies.

Comparison: 02 Sterilized women vs women who used any method of non-permanent contraception.

Comparison: 03 Sterilized women vs any other group (own control, vasectomized husbands or non-permanent contraception.

Comparison: 04 Sterilized women after and before the sterilization (own control).

The results in this chapter are displayed in a summary table (Table 4.1 – 4.3), as well as forest graft for individual outcomes (Figures 4.1 – 4.12). The explanation of the characteristics of the graphs has been discussed in chapter three.

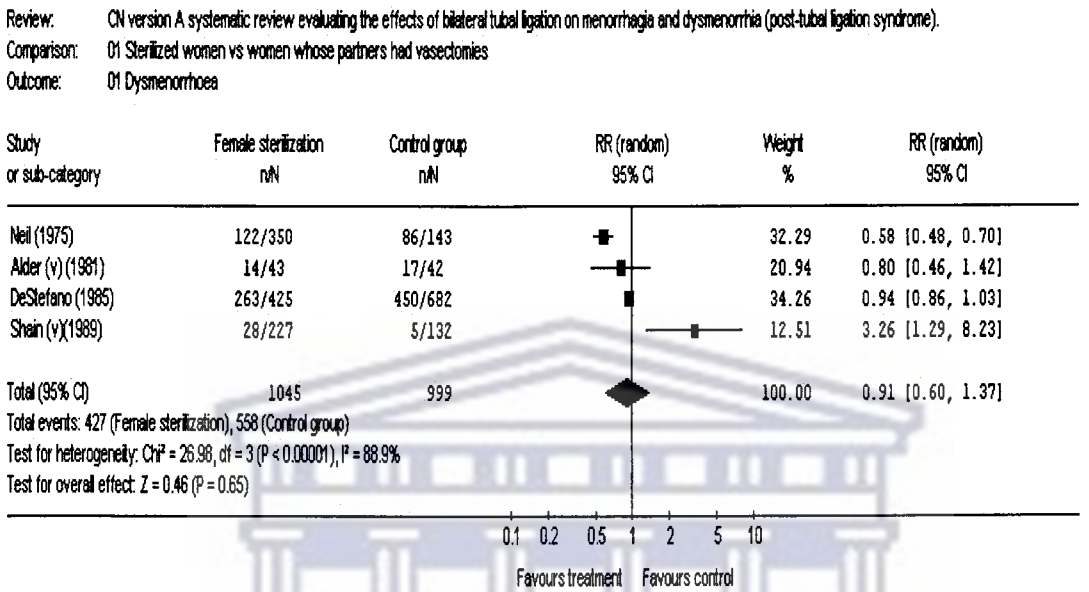
Three of the outcomes, all in the fourth comparison, sterilized women after and before the sterilization showed homogeneity among the results, the results of all the other outcomes (9) in the other three comparisons were significantly heterogeneous.

4.2 Dysmenorrhoea

Fourteen "sub studies" were identified that reported on dysmenorrhoea: Alder (o) (1981), Alder (v) (1981), Bledin (c) (1985), DeStefano (1985), Harlow (2002), Neil (1975), Rulin (1985), Rulin (1989), Rulin (1993), Shain (c) (1989), Shain (o) (1989), Shain (v) (1989), Visvanathan (2000) and Weil (c) (1979).

Fewer women who had been sterilized (40.9%, 427 / 1045) reported to experience dysmenorrhoea, compared to those women whose husbands had vasectomies (55.9%, 558 / 999). This difference was not statistically significant (RR 0.91 CI 0.80 – 1.37, P = 0.65) in Figure 4.1.

Figure 4.1 Dysmenorrhoea: Sterilized women vs women whose partners had vasectomies



In contrast to the above results, significantly more women who had a bilateral tubal ligation experienced dysmenrrhoea compare to women:

- who use any method of non-permanent contraception (Figure 4.2).
  21.6% (396 / 1829) vs 16.4% (288 / 1760) RR 1.79 CI 1.24 – 2.58, P = 0.002).

- any other group (own control, vasectomized husbands or non-permanent contraception (Figure 4.3).
  27.5% (890 / 3241) vs 27.3% (1068 / 3908) RR 1.38 CI 1.04 – 1.77, P = 0.02)

- after and before the sterilization (own control) (Figure 4.4).
  37.8% (249 / 659) vs 30.2% (199 / 659) RR 1.25 CI 1.08 – 1.43, P = 0.002)

Figure 4.2 Dysmenorrhoea: Sterilized women vs women who use any method of non-permanent contraception.

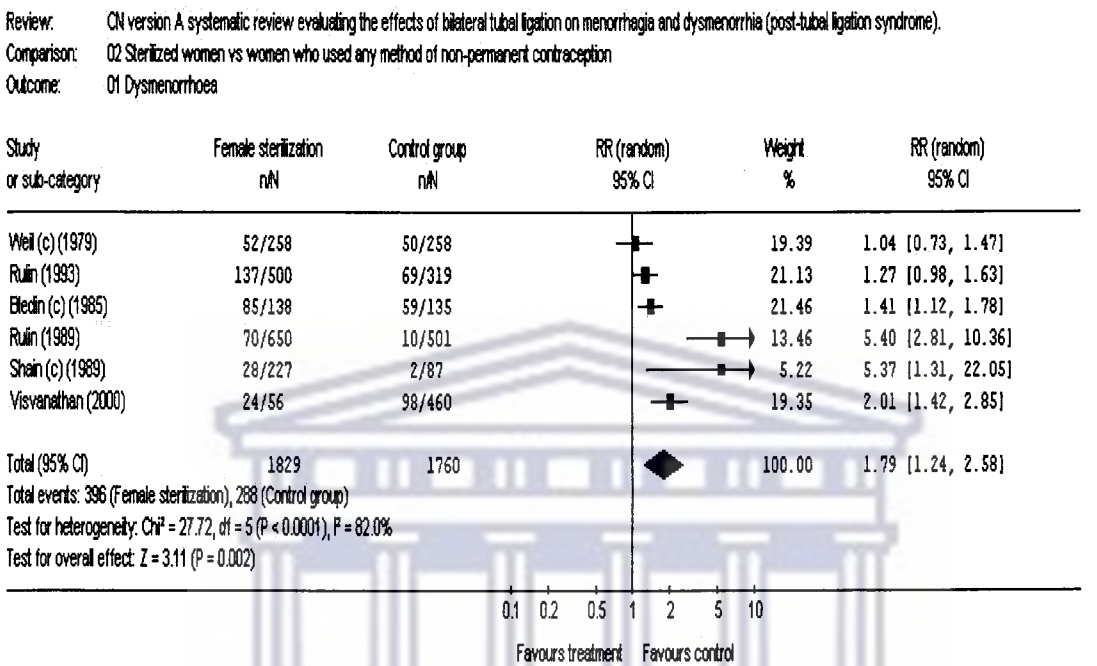


Figure 4.3 Dysmenorrhoea: Sterilized women vs any other group (own control, vasectomized husbands or non-permanent contraception.

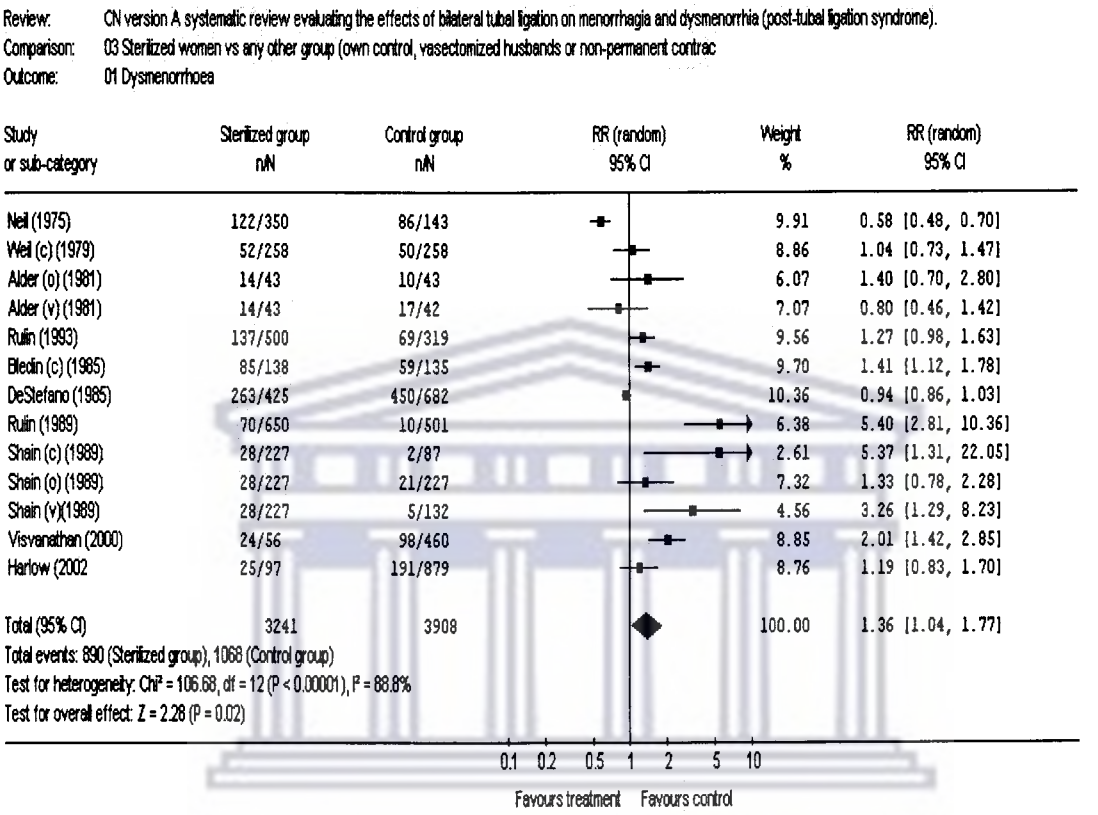
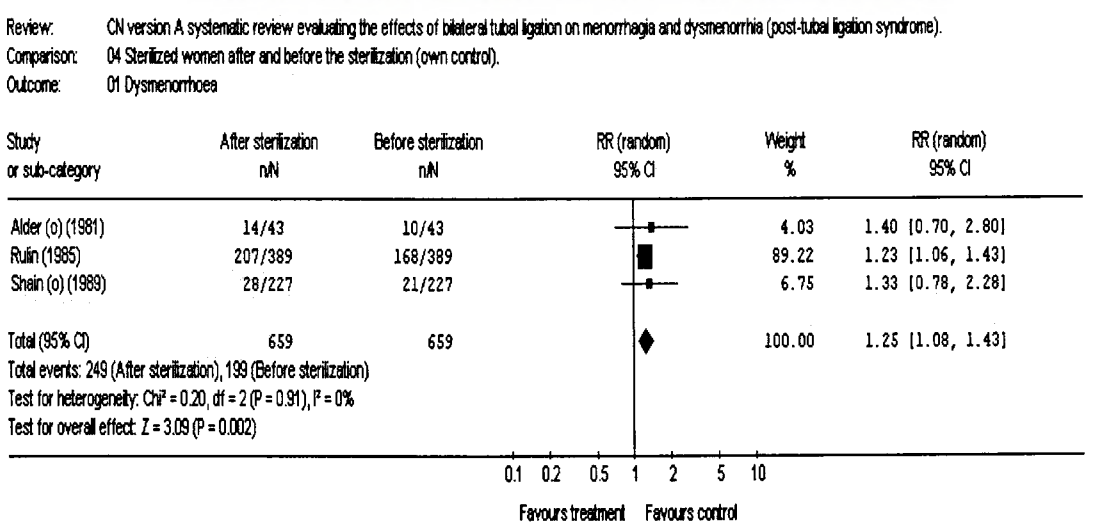


Figure 4.4 Dysmenorrhoea: Sterilized women after and before the sterilization (own control).



4.3 Menorrhagia

Sixteen "sub studies" were identified that reported on menorrhagia: Alder (v) (1981), Bledin (c) (1985), Bledin (o) (1985), DeStefano (1985), Foulkes (1985), Harlow (2002), Neil (1975), Parasanezhad (2003), Rulin (1985), Rulin (1993), Shain (c) (1989), Shain (o) (1989), Shain (v) (1989), Visvanathan (2000), Weil (c) (1979) and Weil (o) (1979).

All four comparisons showed that women who have been sterilized have an increase risk to experience menorrhagia after tubal ligation. In three of the comparisons the risk showed a statically significant difference between the women who had a sterilization compare to the control groups. Although more women (25.4% vs 18.3%) who had a tubal ligation reported an increase in menorrhagia, compare to women who used any method of non-permanent contraception, the difference was not statistically significant (NS).

- Sterilized women versus (vs) women whose partners had vasectomies (Figure 4.5). 59.9% (876 / 1463) vs 44.8% (509 / 1135) RR 2.07 CI 1.12 – 3.83, P = 0.02

- who use any method of non-permanent contraception (Figure 4.6).
  25.4% (697 / 2745) vs 18.3% (312 / 1706) RR 1.47 CI 0.85 – 2.52, P = 0.17 NS

- any other group (own control, vasectomized husbands or non-permanent contraception (Figure 4.7).
  37.9% (1699 / 4477) vs 28.3% (1190 / 4208) RR 1.65 CI 1.30 – 2.11, P <0.0001

- after and before the sterilization (own control) (Figure 4.8).
  40.9% (255 / 623) vs 33.1% (206 / 623) RR 1.24 CI 1.10 – 1.39, P= 0.0005

Figure 4.5 Menorrhagia: Sterilized women versus (vs) women whose partners had vasectomies.

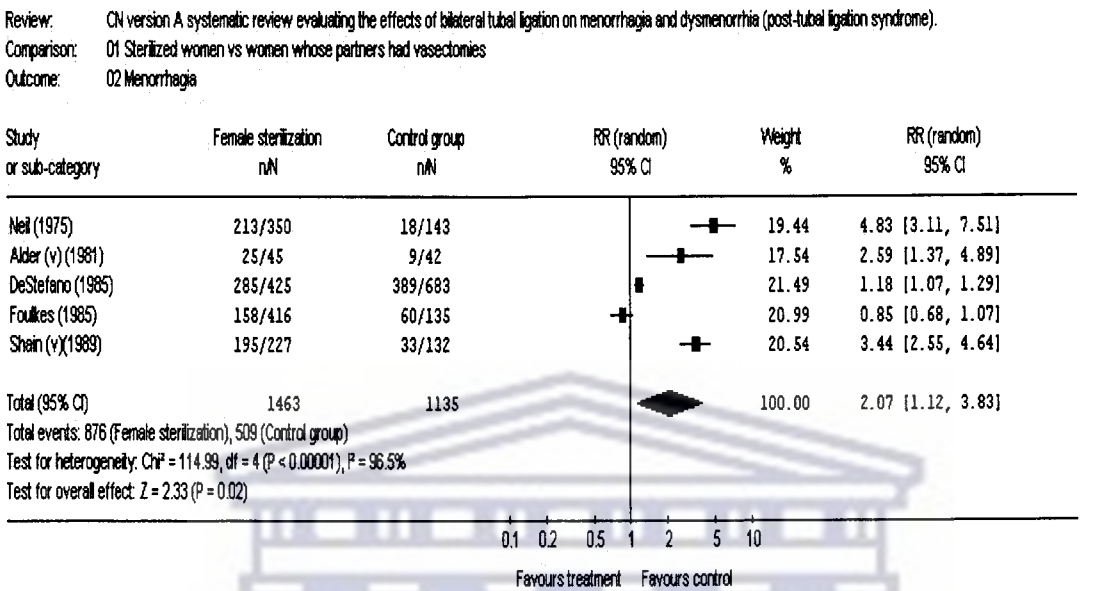


Figure 4.6 Menorrhagia: Sterilized women vs women who use any method of non-permanent contraception.

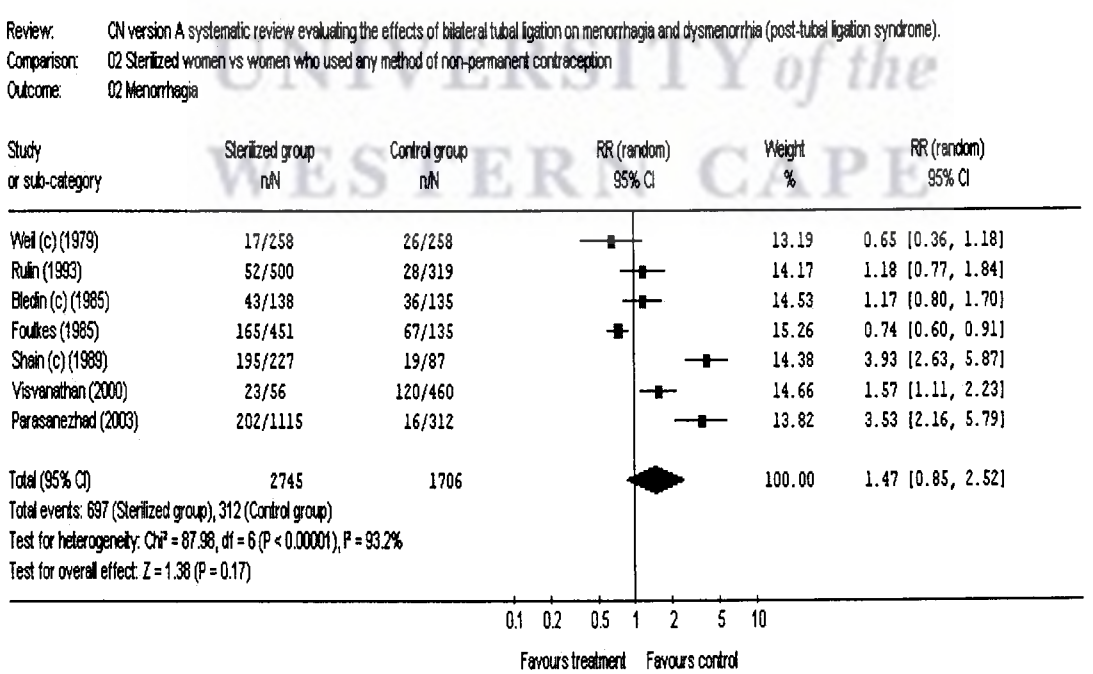


Figure 4.7 Menorrhagia: Sterilized women vs any other group (own control, vasectomized husbands or non-permanent contraception.

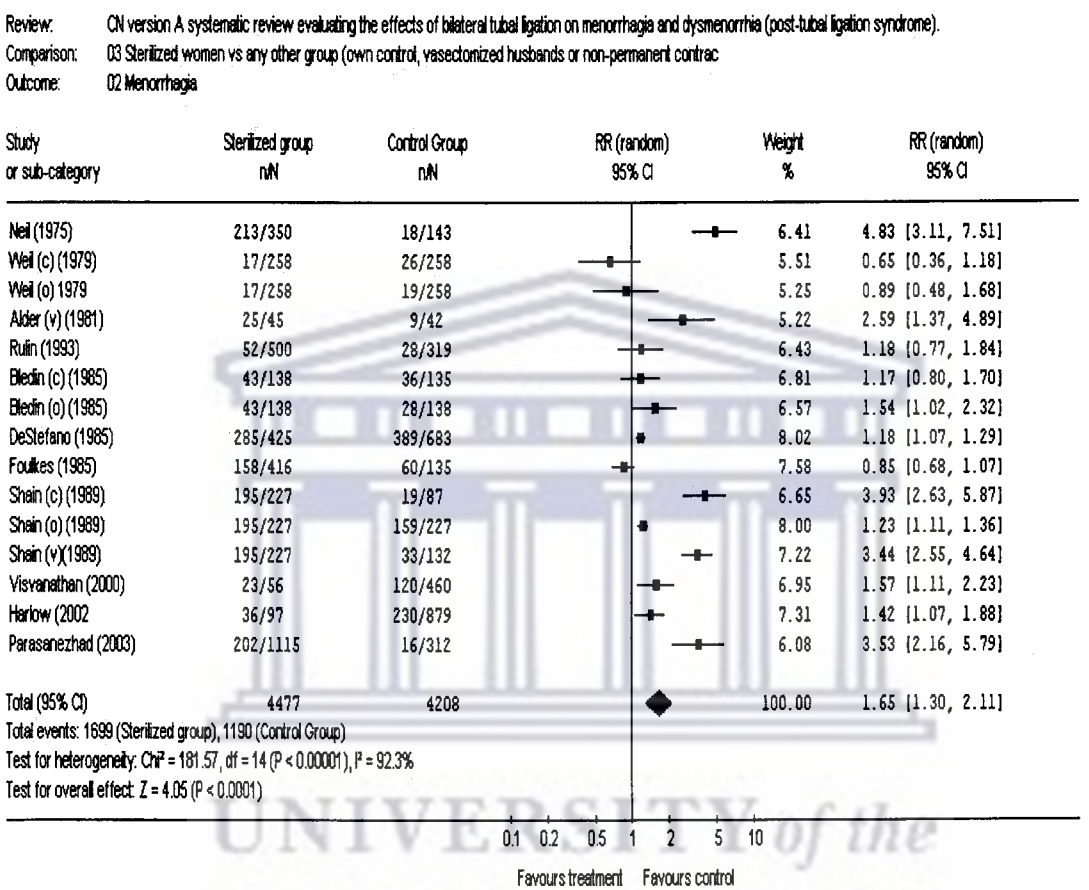
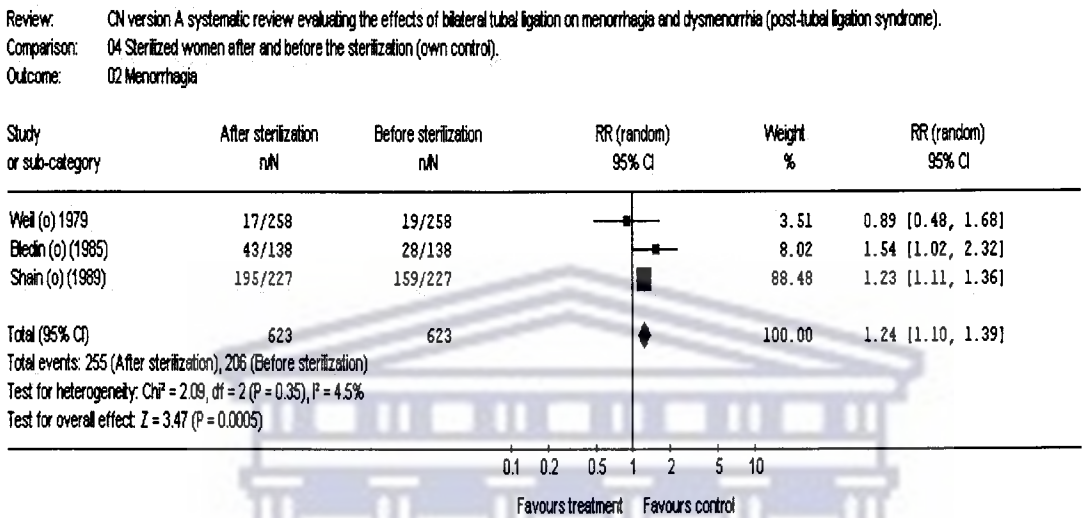


Figure 4.8 Menorrhagia: Sterilized women after and before the sterilization (own control).



4.4 Increase duration

Eight "sub studies" studies were identified that reported on women who experience an increase in the duration of menstruation period: Foulkes (1985), Harlow (2002), Parasanezhad (2003), Rulin (1993), Rulin (1989) Shain (c) (1989), Shain (o) (1989), Shain (v) (1989).

All four of the comparisons showed a slight increase in the percentage of women who reported that they experienced an increase in the duration of their menstruation period, but none of the results showed a statistical significance.

- Sterilized women versus (vs) women whose partners had vasectomies (Figure 4.9). 30.9% (199 / 643) vs 27.7% (74 / 267) RR 1.42 CI 0.39 – 5.22, P = 0.59

- who use any method of non-permanent contraception (Figure 4.10).
  6% (147 / 2491) vs 4% (48 – 1197) RR 1.71 CI 0.84 – 3.48, P = 0.14

- any other group (own control, vasectomized husbands or non-permanent contraception (Figure 4.11).
  11.4% (393 / 3458) vs 9.4% (241 / 2570) RR 1.42 CI 0.95 – 2.10, P = 0.08

- after and before the sterilization (own control) (Figure 4.12).
  15% (34 / 227) vs 13.2% (30 / 227) RR 1.13 CI 0.72 – 1.79, P = 0.59

Figure 4.9 Increase duration: Sterilized women versus (vs) women whose partners had vasectomies.

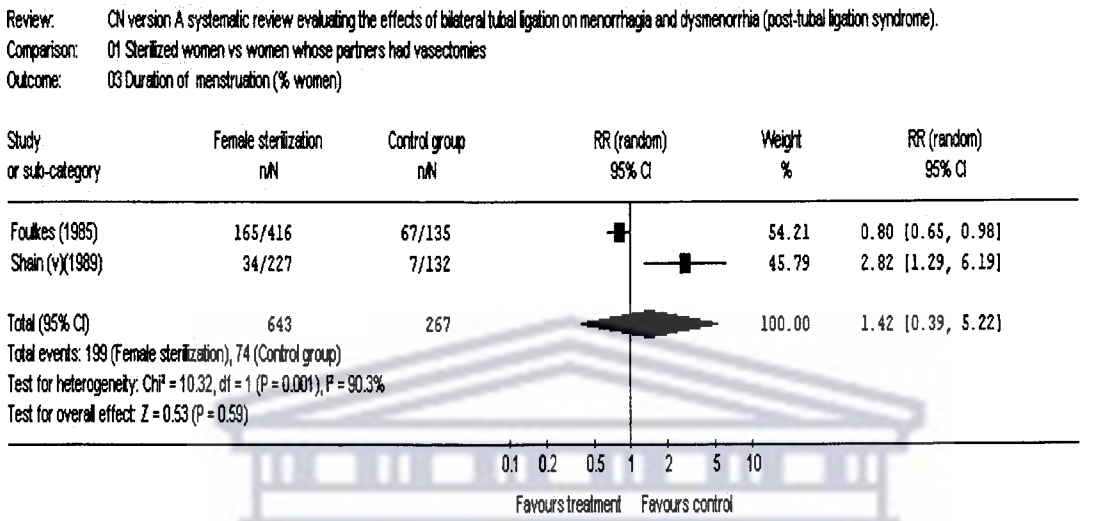


Figure 4.10 Increase duration: Sterilized women vs women who use any method of non-permanent contraception.

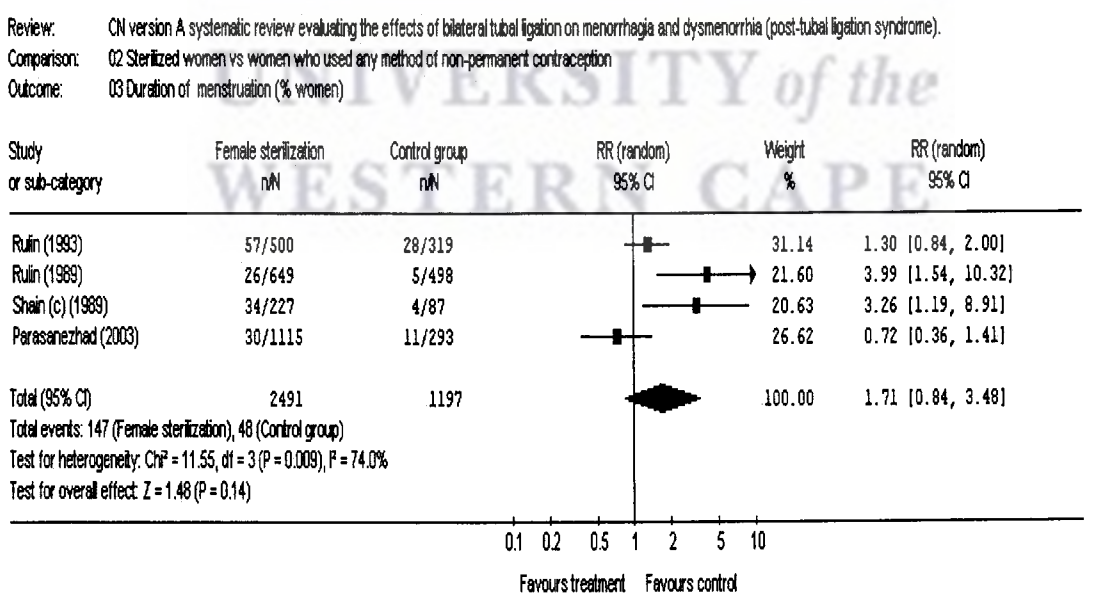


Figure 4.11 Increase duration: Sterilized women vs any other group (own control, vasectomized husbands or non-permanent contraception.

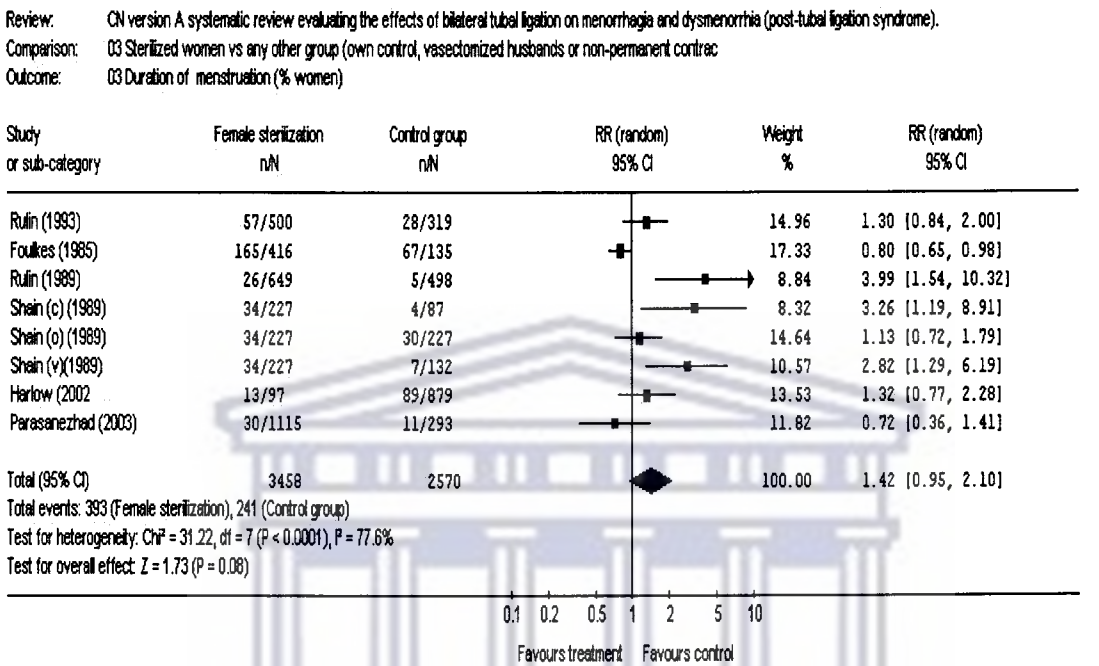
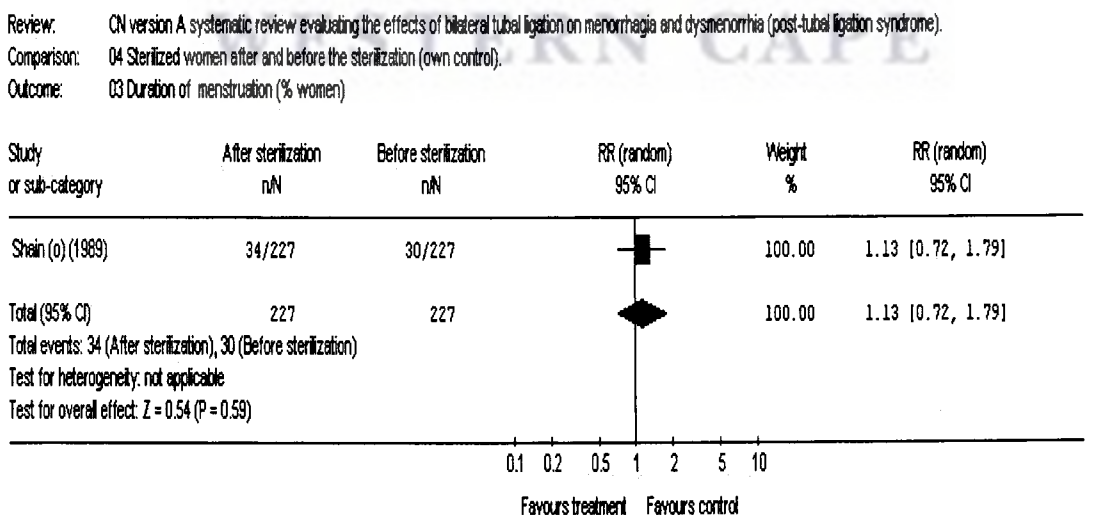


Figure 4.12 Increase duration: Sterilized women after and before the sterilization (own control).



4.2 Summary results

The results of this systematic review show that women who had a tubal ligation have an increased risk to experience dysmenorrhoea and menorrhagia after a female sterilization procedure compared to women who are not sterilized. These women may also experience an increase in the duration of their menstruation period as the results showed a slight increase in the percentage of the women who had a tubal ligation, but this result was not statistically significant (Table 4.1 - 4.3).

Chapter five: Discussion

5.1 Introduction

Systematic reviews recapitulate large amounts of information and are more likely than individual trials to explain the true clinical effect of an intervention. Evidence from clinical research is becoming more and more important in medical-practice decisions as more and better evidence is published. Individual studies that involve only small numbers of patients may have results that are indistinct and may thus lead to less than optimal decisions. The research process of a systematic review is able to identify, critically appraise, and review all the relevant studies on a clinical question and is more likely to give a valid answer. The systematic review uses rigor methods and quality standards to reduce bias. The systematic review results are the closest to reaching the truth given the current state of knowledge when treatments are involved (McQuay & Moore, 1997:712).

A systematic review can be used to answer the question on how effective an intervention is. In the current systematic review the effects of the intervention vz tubal ligation in women were evaluated. To narrow the research on the many long-term complications of tubal sterilization, the review focused on the long-term outcomes of dysmenorrhoea, menorrhagia and duration of menstrual bleeding after sterilization. This chapter is a discussion of findings of the current review, the reviewer's conclusion and the suggested implication for future research.

5.2 Discussion

The current systematic review findings were compared with the findings of other scientific publications. The results of the current systematic review were consistent throughout, indicating that symptoms of "post- tubal ligation syndrome" do exist. Meta-analyses have shown that women who had a bilateral tubal ligation experienced a significant increase in dysmenorrhoea and menorrhagia compared to women who have not been sterilized. They may also be at risk to

experience an increase in the duration of their menstrual period. Shy et al., (1992:1698) reported on a study where they compared women who had been sterilized to women whose husbands had vasectomies. They found that 97% of the women who were sterilized and admitted to hospital due to gynaecological reasons complained about menorrhagia and seven percent complained of dysmenorrhoea. Poma (1980:272) also reported an increase in hospitalization of women for abnormal menstrual bleeding after female sterilizations. Punnonen & Erkkola (1984:149) and Buytaert & Viane (1980:119) supported this and noted an increase in menorrhagia after the women had a tubal ligation. Wilcox et al. (1992:927) noted an increase in menstrual pain in women five years after they had a tubal ligation. Studies done by Reidel, Ahrens & Semm (1981:353) compared different sterilization methods and concluded that sterilization done by endocoagulation results in fewer women complaining of menorrhagia than the group who had a sterilization via unipolar technique. Chamberlain & Foulkes (1976:1475) also did a study on different techniques used for sterilization and agree that different sterilization methods yield an increase in both groups regarding menorrhagia and may increase the duration of bleeding period.

In contrast, other authors such as DeStefano et al. (1983:673); Fortney, Cole, Kennedy (1983:831) and Rubinstein et al. (1979:631) reported that they do not support an increase in dysmenorrhoea and menorrhagia after sterilization as they observed no differences in the women in their studies. Bhiwandiwala et al. (1983:685) did a study comparing different techniques of sterilization and they also reported that they found no changes in these characteristics in women before and after the sterilizations. Kasonde and Bonnar (1976:575) and Kwak et al. (1980:67) compared women's menstrual cycles before and after sterilizations and reported that they did not find any difference in the menstrual cycle regarding dysmenorrhoea or menorrhagia.

A review of the literature on post-tubal ligation problems by Hargrove and Abraham (1978: 359) revealed an incidence of long-term complications in as many as 22 to 37% of sterilized women. The recent publications, on the other

hand, give clearly lower percentages (Rubinstein et al., 1976: 631 and Stock, 1978: 173) because the results were adjusted for use of oral contraceptives and pre-existing gynaecological complaints, the incidence has decreased between 5.4 to 6.0%. In the study done by Buytaert and Viaene (1980: 119) in 322 participants a figure of 7.1% of menorrhagia and six percent for dysmenorrhoea was found in sterilized women.

Chamberlain and Foulkes (1976:1475) were the first to report the effect of prior contraceptive use on menstrual symptoms after tubal sterilization. Chamberlain and Foulkes (1976:1544) found a significant increase in both pain and bleeding after sterilization in the 74 women who had been using Intrauterine devices (IUDs), Sterilization led to a significant reduction in the length and heaviness of the menstrual period. Grimes (1993:4) wrote that, "The literature suggests that if tubal sterilization syndrome occurs at all, it affects a very small minority of women." The question still remains what is the small minority in a given small population.

5.3 Implications for practice

The reviewer acknowledged that the conclusions of this review are drawn from poor quality studies with a heterogenous background. Yet, it is recognized that the included studies were the best evidence currently available on the issue of post-tubal ligation syndrome. Strict rigor was applied when the included studies were selected, which give some support for the findings of the review. It is evident from the review that health care givers need to inform their clients about the possible increase in dysmenorrhoea and menorrhagia after a tubal ligation. Some women may also experience a slight increase in the duration of their menstruation period. In the light of no other evidence should we at this stage make women aware about possible long-term effects, but the results should not be emphasized and women should not be lead to belief that they should not opt for a tubal ligation. The important lesson is not that women should avoid tubal sterilization because of the probability of increased menstrual problems, rather

that they should be aware of all the risks before tubal ligation, as well as to consider the benefits of tubal ligation as a contraceptive method. Any change can be upsetting, but if a woman is prepared for the likelihood of change, it becomes easier to adjust to and accept the change.

The reviewer recommends that:

- Adequate counseling before a tubal sterilization is a must. It is important that the women make an informed choice.
- The immediate risks and the probable long-term risks should be made known to the women before the sterilization procedure.
- A complete investigation for any gynaecological problems must be done before the sterilization surgery. This is to ascertain any conditions that can cause menstrual disturbances post tubal sterilization. A hysterectomy may also be advisable if medical conditions exist, that may put the women at a high risk.
- Previous users of hormonal contraceptives and intrauterine devices should be made aware of the withdrawal effects of the method of contraceptive before the sterilization procedure.

5.4 Implication for future research

The aim of this review was to establish the long-term effects of tubal ligation on the specific parameters of the menstruation pattern vs post-tubal ligation syndrome. It is highly evident that there is a lot of literature on this topic. The problem is that not one study was found that included a well-controlled comparative group of women. Most of the studies were sub-analysis of other primary trials. There were huge differences in the sample sizes of the comparative groups. A large number of the studies were retrospective trials, which recall on memory for the information that was included in the data analyses.

As stated before, this intervention does not lead to the possibility of a randomized controlled trial, but it does not exclude primary research using well-controlled comparative groups. The researcher recommends that health care workers should embark on prospective trials that include well-controlled comparative groups. The inclusion criteria could be well described to ensure that the groups are similar before the intervention. For example a good study would use women whose husbands requests vasectomies. The groups could then be match for many variables before inclusion in the trial. Inclusion criteria could be: age, education, parity, race, similar previous contraceptives, both groups will not use any contraception before the interventions etc. The interventions could then be executed during the similar time periods. The outcome data can then be prospectively collected after the interventions have occurred.

5.5 Conclusion

It is evident from this review that bilateral tubal ligation may have long-term effects that may influence the menstrual cycle. Clinicians must no longer decline the existence of "post-tubal ligation syndrome", but should rather acknowledge the possible changes that may occur in the menstrual cycle after sterilization. Women should be made aware that they might experience an increase in dysmenrrhoea, menorrhagia and an increase in the duration of the menstruation period after a bilateral tubal ligation. Primary researchers should be encouraged to embark only on well-controlled comparative studies to enhance the quality of the outcome.

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APPENDICES

Appendix A

Data collection sheet

DATA COLLECTION SHEET:

Study Identifier:

Comparison groups:

	Categorical outcome measures	Experimetal Group Tubal Sterilized women group		Control Group Women of husbands had vasectomy	
		Events (n)	**Total (N)**	**Events (n)**	**Total (N)**
1	Dysmenorrhoea				
2	Menorrhagia				
3	Duration of menstraution				
4					
5					
6					
7					
8					

Appendix B

Excluded studies

These are studies that also almost met the inclusion criteria and seemed to answer the research question but looked at different outcomes.

Study Identifier: Corson (1981). Hormonal levels following Sterilization and hysterectomy.

Reasons for exclusion: Looking at hormonal changes after sterilization.

Study Identifier: Vesey (1983). Tubal sterilization: findings in a large prospective study.

Reasons for exclusion: All menstrual outcomes categorized as gynaecological problems.

Appendix C

Table 2 Dysmenorrhoea

Comparison: 01 Sterilized women vs women who's partners had vasectomies

Study or sub-category	Female sterilization n/N	Control group n/N	Weight %	RR (random) 95% CI
Alder (v) (1981)	14/43	17/42	20.94	0.80 [0.46, 1.42]
DeStefano (1985)	263/425	450/682	34.26	0.94 [0.86, 1.03]
Neil (1975)	122/350	86/143	32.29	0.58 [0.48, 0.70]
Shain (v)(1989)	28/227	5/132	12.51	3.26 [1.29, 8.23]
Total (95% CI)	427/1045	558/999	100.00	0.91 [0.60, 1.37]
Test for heterogeneity: $Chi^2 = 26.98$, df = 3 ($P < 0.00001$), $I^2 = 88.9\%$				
Test for overall effect: Z = 0.46 (P = 0.65)				

Comparison: 02 Sterilized women vs women who use any method of non permanent contraception

Study or sub-category	Female sterilization n/N	Control group n/N	Weight %	RR (random) 95% CI
Bledin (c) (1985)	85/138	59/135	21.46	1.41 [1.12, 1.78]
Rulin (1989)	70/650	10/501	13.46	5.40 [2.81, 10.36]
Rulin (1993)	137/500	69/319	21.13	1.27 [0.98, 1.63]
Shain (c) (1989)	28/227	2/87	5.22	5.37 [1.31, 22.05]
Visvanathan (2000)	24/56	98/460	19.35	2.01 [1.42, 2.85]
Weil (c) (1979)	52/258	50/258	19.39	1.04 [0.73, 1.47]
Total (95% CI)	396/1829	288/1760	100.00	1.79 [1.24, 2.58]
Test for heterogeneity: $Chi^2 = 27.72$, df = 5 ($P < 0.0001$), $I^2 = 82.0\%$				
Test for overall effect: Z = 3.11 (P = 0.002)				

Comparison: 03 Sterilized women vs any other group (own control, vasectomized husbands or non permanent contraception

Study or sub-category	Sterilized group n/N	Control group n/N	Weight %	RR (random) 95% CI
Alder (o) (1981)	14/43	10/43	6.07	1.40 [0.70, 2.80]
Alder (v) (1981)	14/43	17/42	7.07	0.80 [0.46, 1.42]
Bledin (c) (1985)	85/138	59/135	9.70	1.41 [1.12, 1.78]
DeStefano (1985)	263/425	450/682	10.36	0.94 [0.86, 1.03]
Harlow (2002	25/97	191/879	8.76	1.19 [0.83, 1.70]
Neil (1975)	122/350	86/143	9.91	0.58 [0.48, 0.70]
Rulin (1989)	70/650	10/501	6.38	5.40 [2.81, 10.36]
Rulin (1993)	137/500	69/319	9.56	1.27 [0.98, 1.63]
Shain (c) (1989)	28/227	2/87	2.61	5.37 [1.31, 22.05]
Shain (o) (1989)	28/227	21/227	7.32	1.33 [0.78, 2.28]
Shain (v)(1989)	28/227	5/132	4.56	3.26 [1.29, 8.23]
Visvanathan (2000)	24/56	98/460	8.85	2.01 [1.42, 2.85]
Weil (c) (1979)	52/258	50/258	8.86	1.04 [0.73, 1.47]
Total (95% CI)	890/3241	1068/3908	100.00	1.36 [1.04, 1.77]
Test for heterogeneity: $Chi^2 = 106.68$, df = 12 ($P < 0.00001$), $I^2 = 88.8\%$				
Test for overall effect: Z = 2.28 (P = 0.02)				

Table 3 Menorrhagia

Comparison: 01 Sterilized women vs women who's partners had vasectomies

Study or sub-category	Female sterilization n/N	Control group n/N	Weight %	RR (random) 95% CI
Alder (v) (1981)	25/45	9/42	17.54	2.59 [1.37, 4.89]
DeStefano (1985)	285/425	389/683	21.49	1.18 [1.07, 1.29]
Foulkes (1985)	158/416	60/135	20.99	0.85 [0.68, 1.07]
Neil (1975)	213/350	18/143	19.44	4.83 [3.11, 7.51]
Shain (v)(1989)	195/227	33/132	20.54	3.44 [2.55, 4.64]
Total (95% CI)	876/1463	509/1135	100.00	2.07 [1.12, 3.83]
Test for heterogeneity: $Chi^2 = 114.99$, df = 4 ($P < 0.00001$), $I^2 = 96.5\%$				
Test for overall effect: Z = 2.33 (P = 0.02)				

Comparison: 02 Sterilized women vs women who use any method of non permanent contraception

Study or sub-category	Sterilized group n/N	Control group n/N	Weight %	RR (random) 95% CI
Bledin (c) (1985)	43/138	36/135	14.53	1.17 [0.80, 1.70]
Foulkes (1985)	165/451	67/135	15.26	0.74 [0.60, 0.91]
Parasanezhad (2003)	202/1115	16/312	13.82	3.53 [2.16, 5.79]
Rulin (1993)	52/500	28/319	14.17	1.18 [0.77, 1.84]
Shain (c) (1989)	195/227	19/87	14.38	3.93 [2.63, 5.87]
Visvanathan (2000)	23/56	120/460	14.66	1.57 [1.11, 2.23]
Weil (c) (1979)	17/258	26/258	13.19	0.65 [0.36, 1.18]
Total (95% CI)	697/2745	312/1706	100.00	1.47 [0.85, 2.52]
Test for heterogeneity: $Chi^2 = 87.98$, df = 6 ($P < 0.00001$), $I^2 = 93.2\%$				
Test for overall effect: Z = 1.38 (P = 0.17)				

Comparison: 03 Sterilized women vs any other group (own control, vasectomized husbands or non permanent contraception

Study or sub-category	Sterilized group n/N	Control Group n/N	Weight %	RR (random) 95% CI
Alder (v) (1981)	25/45	9/42	5.22	2.59 [1.37, 4.89]
Bledin (c) (1985)	43/138	36/135	6.81	1.17 [0.80, 1.70]
Bledin (o) (1985)	43/138	28/138	6.57	1.54 [1.02, 2.32]
DeStefano (1985)	285/425	389/683	8.02	1.18 [1.07, 1.29]
Foulkes (1985)	158/416	60/135	7.58	0.85 [0.68, 1.07]
Harlow (2002	36/97	230/879	7.31	1.42 [1.07, 1.88]
Neil (1975)	213/350	18/143	6.41	4.83 [3.11, 7.51]
Parasanezhad (2003)	202/1115	16/312	6.08	3.53 [2.16, 5.79]
Rulin (1993)	52/500	28/319	6.43	1.18 [0.77, 1.84]
Shain (c) (1989)	195/227	19/87	6.65	3.93 [2.63, 5.87]
Shain (o) (1989)	195/227	159/227	8.00	1.23 [1.11, 1.36]
Shain (v)(1989)	195/227	33/132	7.22	3.44 [2.55, 4.64]
Visvanathan (2000)	23/56	120/460	6.95	1.57 [1.11, 2.23]
Weil (c) (1979)	17/258	26/258	5.51	0.65 [0.36, 1.18]
Weil (o) 1979	17/258	19/258	5.25	0.89 [0.48, 1.68]
Total (95% CI)	1699/4477	1190/4208	100.00	1.65 [1.30, 2.11]
Test for heterogeneity: $Chi^2 = 181.57$, df = 14 ($P < 0.00001$), $I^2 = 92.3\%$				
Test for overall effect: $Z = 4.05$ ($P < 0.0001$)				

Table 4 Percentage of women with increased duration of menstruation

Comparison: 01 Sterilized women vs women who's partners had vasectomies

Study or sub-category	Female sterilization n/N	Control group n/N	Weight %	RR (random) 95% CI
Foulkes (1985)	165/416	67/135	54.21	0.80 [0.65, 0.98]
Shain (v)(1989)	34/227	7/132	45.79	2.82 [1.29, 6.19]
Total (95% CI)	199/643	74/267	100.00	1.42 [0.39, 5.22]
Test for heterogeneity: $Chi^2 = 10.32$, df = 1 ($P = 0.001$), $I^2 = 90.3\%$				
Test for overall effect: $Z = 0.53$ ($P = 0.59$)				

Comparison: 02 Sterilized women vs women who use any method of non permanent contraception

Study or sub-category	Female sterilization n/N	Control group n/N	Weight %	RR (random) 95% CI
Parasanezhad (2003)	30/1115	11/293	26.62	0.72 [0.36, 1.41]
Rulin (1989)	26/649	5/498	21.60	3.99 [1.54, 10.32]
Rulin (1993)	57/500	28/319	31.14	1.30 [0.84, 2.00]
Shain (c) (1989)	34/227	4/87	20.63	3.26 [1.19, 8.91]
Total (95% CI)	147/2491	48/1197	100.00	1.71 [0.84, 3.48]
Test for heterogeneity: $Chi^2 = 11.55$, df = 3 ($P = 0.009$), $I^2 = 74.0\%$				
Test for overall effect: $Z = 1.48$ ($P = 0.14$)				

Comparison: 03 Sterilized women vs any other group (own control, vasectomized husbands or non permanent contraception

Study or sub-category	Female sterilization n/N	Control group n/N	Weight %	RR (random) 95% CI
Foulkes (1985)	165/416	67/135	17.33	0.80 [0.65, 0.98]
Harlow (2002	13/97	89/879	13.53	1.32 [0.77, 2.28]
Parasanezhad (2003)	30/1115	11/293	11.82	0.72 [0.36, 1.41]
Rulin (1989)	26/649	5/498	8.84	3.99 [1.54, 10.32]
Rulin (1993)	57/500	28/319	14.96	1.30 [0.84, 2.00]
Shain (c) (1989)	34/227	4/87	8.32	3.26 [1.19, 8.91]
Shain (o) (1989)	34/227	30/227	14.64	1.13 [0.72, 1.79]
Shain (v)(1989)	34/227	7/132	10.57	2.82 [1.29, 6.19]
Total (95% CI)	393/3458	241/2570	100.00	1.42 [0.95, 2.10]
Test for heterogeneity: $Chi^2 = 31.22$, df = 7 ($P < 0.0001$), $I^2 = 77.6\%$				
Test for overall effect: Z = 1.73 (P = 0.08)				