



Reproductive health in women following sterilisation in Durban,

South Africa

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I, Dr Gaysheen Kistan, submitted this dissertation in fulfilment of the requirements for the degree of Masters in Medicine in the Department of Obstetrics and Gynaecology, Faculty of Health Sciences, University of KwaZulu-Natal.

The study described in this dissertation was approved by the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (BE 139/13).

DECLARATION

I declare that the work on which this dissertation is based is original and is my own unaided work carried out by me, under the supervision of Dr M. Panday and Professor J.S Bagratee.

Neither the whole work, or any part of it, has been submitted to any other university or Examination Body.

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ACKNOWLEDGEMENTS

I wish to express my gratitude to the following people whose help and support has made it possible for me to undertake and complete this study:

To my parents, who have encouraged me to overcome the obstacles of my life. Thank you for your encouragement, support and tolerance always.

To Dr M Panday and Professor J.S Bagratee, my mentors and supervisors, whose continual guidance and support has made this study possible. Thank you for your expert guidance and support in undertaking this study.

I wish to extend my gratitude and much appreciation to Ms Jesca Batidzirai, statistician at the University of KwaZulu-Natal for her assistance with the statistical analysis of the data and assistance with the collation of results.

To the management and staff of King Dinuzulu Hospital, thank you for permitting me to carry out this study at their institution.

To the women from King Dinuzulu Hospital who participated in this study.

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LIST OF ACRONYMS AND ABBREVIATIONS

ART	Antiretroviral treatment
ASCUS	Atypical squamous cells of undetermined significance
BMI	Body mass index
CREST	U.S Collaborative Review of Sterilization
COC	Combined oral contraception
FDC	Fixed drug combination pill
FSD	Female sexual dysfunction
HAART	Highly active antiretroviral treatment
HIV	Human immunodeficiency virus
HSIL	High grade squamous intraepithelial lesion
IUD	Intra-uterine device
LARC	Long acting reversible contraception
LLETZ	Large loop excision of the transformation zone
LSIL	Low grade squamous intraepithelial lesion
OR	Odds ratio
RR	Relative risk
SD	Standard deviation
STIs	Sexually transmitted infections
TL	Tubal ligation

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PREFACE

Female sterilisation remains an important method of family planning. Globally voluntary tubal sterilisation accounts for one third of contraceptive use (Rowlands & Hannaford, 2003). In South Africa, according to the South African Demographic Health Survey (SADHS) of 2003, 23% of all women age 45-49 years and 18% of women aged 40-44 years had been sterilised.

King Dinuzulu Hospital Complex (formerly King George V Hospital) is the primary referral center for elective interval laparoscopic sterilisations for women in Durban. Following the day procedure at King Dinuzulu Hospital Complex, women are followed up at their nearest clinics or hospitals. All women are subsequently seen at King Dinuzulu Hospital Complex approximately one year later to assess their reproductive health and satisfaction post procedure.

Internationally, studies have been conducted to address both personal and health outcomes post sterilisation. However, to our knowledge, no local studies have been conducted in Durban, South Africa addressing women's reproductive health and satisfaction post sterilisation.

This has encouraged the concept of a study of this nature to be conducted. This study aimed to assess the reproductive health and satisfaction prospectively in a cohort of women following interval sterilisation in Durban. Such information would allow local health care providers to counsel women better who choose sterilisation as their method of contraception. This study would also serve as an audit of current practice and allow for improvements in service

delivery. This research study has identified issues in reproductive health of women undergoing sterilisation and has attempted to recommend strategies to improve women's reproductive health and satisfaction post sterilisation. These recommendations can thus be extended to women undergoing sterilisation both locally and nationally.

ABSTRACT

AIM

A prospective study was conducted to determine reproductive health, women's use of the health services and overall satisfaction following interval laparoscopic sterilisation at King Dinuzulu Hospital, South Africa.

METHODS

The study population included women who underwent interval tubal ligation from 1 August 2012 to 30 April 2013 with follow up one year after the procedure. Data were captured and analysed using SPSS version 19.0.

RESULTS

The study cohort consisted of 225 women who returned for follow up one year post sterilisation. Of the cohort, 97% of women (n=220) were satisfied with the procedure. Complications were minimal with 1 procedure (0.4%) requiring conversion to laparotomy due to haemorrhage and 3 procedures (1.3%) complicated by uterine/cervical perforations during laparoscopy. The rate of regret was low (0.8%) and mainly due to change in partners. There were no failures at one year follow up.

Following sterilisation, sexually transmitted infections were increased only in women with a past history of infection pre-sterilisation (OR 6.7; 95% CI (2.2–20.9); p=0.002). There was no significant risk of HIV acquisition post sterilisation.

In women who had not used hormonal contraception or used barrier methods pre-sterilisation, no change in frequency, volume of menstrual bleeding or dysmenorrhoea post sterilisation was found. There was an increase in duration and amount of menstrual bleeding and dysmenorrhoea post sterilisation among previous combined oral contraceptive users. Among women on injectable contraception who were amenorrhoeic pre-sterilisation, 73.8% reported return to regular menses and 26.2% reported abnormal uterine bleeding post sterilisation. Among injectable contraceptive users with regular menses or spotting pre-sterilisation, 71.4% reported no change in menses post sterilisation and 28.6% reported abnormal uterine bleeding post sterilisation.

CONCLUSION

Interval tubal sterilisation is a safe and effective procedure. The procedure is associated with high patient satisfaction, low incidence of regret and minimal complications.

In women undergoing interval tubal sterilisation, the risk of sexually transmitted infections is only increased in those women with a prior history. Menstrual abnormalities post sterilisation are more likely in women who had utilised hormonal contraception prior to sterilisation.

CHAPTER 1: ORIENTATION AND LITERATURE REVIEW

1.1 INTRODUCTION AND BACKGROUND TO THE STUDY

This chapter provides the background detail to the research study. It commences by focusing on the introductory background to the problem investigated by reviewing both international and local literature and related research conducted followed by the legislative frameworks on health practices in South Africa.

Tubal sterilisation is a safe, permanent and effective contraceptive method used worldwide (Rowlands & Hannaford, 2003). Approaches for tubal sterilisation include laparotomy, mini-laparotomy, laparoscopic and hysteroscopic techniques (e.g. Essure micro insert). Techniques of sterilisation include partial salpingectomy, unipolar or bipolar coagulation, silicone rubber band or clip application. Sterilisation may be performed in relation to pregnancy (after abortion, caesarean section or normal vaginal delivery) or remote from pregnancy (interval sterilisation) (Peterson et al., 2008).

The surgical methods for tubal ligation include partial salpingectomy (via the Pomeroy technique or “Modified” Pomeroy technique, Parkland method or Irving method). Laparoscopic mechanical methods include the Yoon ring (composed of silicone or rubber) and repetition clips (such as the Filshie and Hulka clips) (Lawrie et al., 2011).

A Cochrane review by Lawrie et al (2011) included randomized controlled trials and compared the different techniques of tubal sterilisation. This review compared morbidity, technical difficulties and failure rates associated with the various techniques. The overall findings of the meta-analyses were that electrocoagulation is associated with less morbidity and pain than Pomeroy and ring methods. Minor morbidity was higher in the ring versus the clip groups. Less technical difficulties were found in the clip group compared to the ring group with no difference in failure rates between these two groups. The Pomeroy technique was associated with higher major morbidity and postoperative pain when compared to electrocoagulation technique. The tubal ring group was associated with greater postoperative pain than the electrocautery group. No pregnancies were reported in either group. One pregnancy was reported after 1 year with the Pomeroy technique and no pregnancies found with the Filshie clip. Comparing the Hulka to the Filshie clip, no differences were found between these two devices.

Tubal sterilisation is a highly effective contraceptive with a Pearl index of 0.18 (Von Mering et al., 2003). At King Dinuzulu Hospital Complex (formerly King George V Hospital), interval sterilisation is performed via laparoscopic Filshie clip application.

1.2 PROFILE OF WOMEN REQUESTING STERILISATION AND TRENDS IN STERILISATION

1.2.1 Internationally

Globally statistics show that the age of sterilisation is inversely related to the prevalence of sterilisation in the area. In high sterilisation prevalence settings such as Brazil, Dominican Republic and El Salvador the mean age of sterilisation is <29 years with overall prevalence of sterilisation being near 25%. The mean age of sterilisation in low prevalence (prevalence <10%) countries such as Egypt, Ghana, Indonesia and Peru is 32 years. The number of living children of women presenting for sterilisation varies between countries. In the United States and China the majority of sterilisation users have 0-2 living children while in North Africa and Sub-Saharan Africa the majority of users have 5 or more living children (Henderson & Escandon, 2002).

Gender differences regarding sterilisation have been studied in both developed and developing countries. Rowlands and Hannaford (2003) found no significant differences in incidence between men and women having sterilisation in the United Kingdom over an eight year period (1992-1999). They further demonstrated a 30% decline in female sterilisation during their study period in the United Kingdom. In contrast in a third world setting, Gupta et al (1996) demonstrated that female sterilisation had grown in popularity in India with an increase in the number of interval laparoscopic sterilisations performed.

1.2. 2 Durban, KwaZulu-Natal, South Africa

The most common contraception method in South Africa presently is progestogen injectable contraception being utilised by up to 56% of sexually active women according to the South African Demographic and Health Survey (SADHS) of 2003. Female sterilisation accounts for 14% of contraceptive use among sexually active women. In 2003, 23% of all women aged 45-49 and 18% of all women aged 40-44 years had been sterilised. Compared to previous data in 1998, there is an increase in the age of timing of sterilisation implying women are choosing to be sterilised later in their reproductive lives. In 1998, 64% of women who had been sterilised had undergone the procedure by the age of 34 years compared to 61% in the 2003 survey. The median age of sterilisation of just over 32 years has not changed between surveys.

A retrospective study of tubal sterilisation at King Dinuzulu Hospital (formerly King George V Hospital) from the period 1989–1991 examined the demographic characteristics of women undergoing tubal sterilisation at the health facility. The population in this study was 67.57% African women and 32.44% Asian women as evidence of the population representative in Durban. The mean age of women was 31.30 years and 34.5 years among Asian and African women respectively. Ninety two percent of Asian and 41.2% of African women were married. The mean parity among groups was 2.96 among Asian women and 5 for African women (Green-Thompson et al., 1993).

1.3 National Contraception Clinical Guidelines and Consent, South Africa

In South Africa, there has been an increase in the availability and free supply in the public sector of long acting reversible contraception. The National Contraception Clinical Guidelines encourage health professionals to counsel women adequately on all available contraceptive methods to ensure autonomy of women in the decision making process. Furthermore, avoiding coercion to accept sterilisation in pre-sterilisation counselling has been enforced heavily by the Department of Health, South Africa. Recommendations include adequate counselling of women on long acting contraceptive methods with similar efficacy (subdermal implants, copper intrauterine devices and levonorgestrel intrauterine devices) as well as male sterilisation before recommending female sterilisation (National Contraception Clinical Guidelines, 2012).

In South Africa, the Sterilisation Act 44 of 1998 (Section 2) prohibits the “*sterilisation of women without their informed consent*”. The Act stipulates that “*all women must fully understand the sterilisation procedure, risks, and the consequences thereof, before they are able to give informed consent*” (National Contraception Clinical Guidelines, 2012). The Sterilisation Amendment Act (Act No 3 of 2005) makes provision for women not considered competent to make an informed decision and consent to surgery. Informed consent as set out by the bill is a process, and a signature on a consent form is not sufficient. “*A person giving consent to sterilisation needs to be in a physical and psychological state to understand the information, and make the decision without feeling pressured*” (National Contraception Clinical Guidelines, 2012).

The National Contraception Clinical Guidelines emphasises that human immunodeficiency virus (HIV) status should not be a reason to recommend sterilisation and that both HIV positive women and HIV negative women should be afforded the same legal protection and rights. The national guidelines also emphasises that women must be counselled that sterilisation offers no protection from HIV and sexually transmitted infections (STIs). All women must be counselled on condom use post sterilisation (National Contraception Clinical Guidelines, 2012).

These guidelines in South Africa help to empower women to make an informed decision regarding sterilisation. The guidelines are set in place to relieve women's concerns regarding the sterilisation procedure and to prevent complications after the procedure such as post sterilisation regret (National Contraception Clinical Guidelines, 2012).

1.4 IMMEDIATE COMPLICATIONS

In the United States of America deaths post sterilisation are rare. Assessment of sterilisations performed in hospitals from 1979-1980 revealed a case fatality of 1-2 per 100,000 procedures. Complications of general anaesthesia were the leading cause followed by sepsis and haemorrhage (Peterson et al., 2008).

Morbidity following sterilisation is largely dependent on the surgical approach and method of tubal ligation employed. Data from the United States of America showed infection (1% of cases), minor or major bleeding (up to 1% of cases) and anaesthetic events (up to 2% of cases) have been reported (Bartz & Greenburg, 2008). Complications of mini-laparotomy typically

include minor wound infection, longer operating time, longer postoperative convalescence time and greater postoperative pain. Laparoscopic complications include thermal bowel injury, viscus perforations and life-threatening haemorrhage (Peterson et al., 2008).

At King Dinuzulu Hospital (formerly King George V Hospital), a retrospective analysis revealed low immediate complication rates. 5360 procedures were performed during a 3 year period (1989–1991) with no deaths or serious injuries noted. Of these procedures, two laparotomies were performed for haemorrhage (0.37 per 1000 laparoscopies) and no organ or bowel injury was reported (Green-Thompson et al., 1993).

1.5 DELAYED COMPLICATIONS AND REPRODUCTIVE HEALTH

1.5.1 Pregnancy

Pregnancies secondary to sterilisation failures have been reported in the literature with cases occurring years after the sterilisation procedure. In the first year following sterilisation, pregnancy rates among women are documented as up to 0.5% and this rate is similar and comparable to pregnancy rates for women using LARC (long-acting hormonal contraception) such as the intrauterine device or subdermal implant. Sterilisation failure may be due to the result of conception occurring prior to the sterilisation procedure, incomplete tubal occlusion or from the formation of fistulas (Lawrie et al., 2011).

Tubal sterilisation is an effective contraceptive method. The efficacy rates vary dependant on the method of sterilisation employed as well as the women's age, race and ethnicity. Data from the U.S Collaborative Review of Sterilization (CREST) study revealed a 10-year probability of pregnancy following tubal ligation being 18.5 pregnancies per 1000 procedures performed (Peterson et al., 1996).

Pregnancy rates were highest among women sterilised via laparoscopic clip insertion (36.5 pregnancies per 1000 procedures) with lowest rates following laparoscopic unipolar coagulation and postpartum partial salpingectomy (7.5 pregnancies per 1000 procedures). Sterilisation failure rates are generally higher in women sterilised at younger ages due to increased fertility in these women (Peterson et al., 1996).

Luteal phase pregnancy rates range from 2-3 per 1,000 sterilisation procedures. This complication can be prevented by performing sterilisation in the follicular phase of the menstrual cycle. The likelihood of ectopic pregnancy is higher when pregnancy does occur following sterilisation. However, the overall risk of ectopic pregnancy in women post sterilisation is lower than women using no contraception and similar in women using barrier or oral contraceptives. The CREST study revealed a 10 year probability of an ectopic pregnancy of 7.3 ectopic pregnancies per 1000 sterilisation procedures and ectopic pregnancy accounted for one third of all post sterilisation pregnancies (Peterson et al., 2008).

1.5.2 Menstrual changes

It has been hypothesised since 1951 that sterilisation might increase a woman's risk of abnormal uterine bleeding (post tubal ligation syndrome—risk of heavy bleeding and intermenstrual bleeding). This was thought to be due to sterilisation adversely affecting ovarian function (by disrupting ovarian blood flow). However, laboratory findings found no consistent abnormalities in ovarian function post sterilisation (Peterson et al., 2008). Wilcox et al (1992) found an increased risk of menstrual abnormalities up to 5 years post sterilisation, while Peterson et al (2000) found women to report decreases in number of days and amount of bleeding, dysmenorrhoea and increase in cycle irregularity. Controlled for previous contraceptive use, further studies have found no direct influence of sterilisation on menstrual patterns (Harlow et al., 2002; Westhoff, 2000; Rulin et al., 1993).

Wilcox et al (1992) found that sterilisation at a younger age leads to more menstrual abnormalities than sterilisation at older ages. Initial data from the U.S Collaborative Review of Sterilization Study revealed menstrual abnormalities were more likely during the fifth year than the second year post sterilisation. Five years after sterilisation, 35% of participants reported higher levels of menstrual pain, 49% reported very heavy flow and 10% reported spotting between periods. In women interviewed one year after sterilisation, no menstrual function changes were noted. This initial data, however, had no comparisons and did not account for ageing.

In 2000, Peterson and colleagues studied menstrual function before and after sterilisation among women who underwent tubal sterilisation and compared them to women whose

partners underwent vasectomy. The study used data from the U.S Collaborative Review of Sterilization Study. The study consisted of 9514 women who had undergone sterilisation and 573 women whose partners underwent vasectomy. These women were followed up for 5 years telephonically and asked about menstrual changes. The results revealed that women who underwent sterilisation were no more likely than those who had not undergone sterilisation to report persistent changes in their menstrual bleeding or length of their menstrual cycle. Women who underwent sterilisation were more likely to have decreases in the number of days of bleeding, volume of menstrual bleeding and dysmenorrhoea and were more likely to have an increase in cycle irregularity (Peterson et al., 2000).

1.5.3 Hysterectomy

It is a common belief that sterilisation increases the risk of women having a hysterectomy. The CREST study found a 5 year cumulative probability of hysterectomy of 8.4% compared with 1.8% in non-sterilised women (Hillis et al., 1998). It has, however been demonstrated that women who are sterilised are at no increased risk of needing a hysterectomy but rather a hysterectomy is more readily offered to women for gynaecological complaints (i.e. menstrual disorders) (Bartz & Greenburg, 2008).

The term post tubal sterilisation syndrome has been used to include abnormal menstrual bleeding, dysmenorrhoea, premenstrual distress and menopausal symptoms experienced by women post sterilisation. The syndrome is hypothesised to be caused by altered blood circulation in and around the fallopian tubes and ovaries, pressure on associated nerves and intrapelvic adhesions (Moradan et al., 2012).

Moradan et al (2012) compared the incidence of hysterectomy for bleeding disorders among sterilised women with the incidence of hysterectomy for bleeding disorders among non-sterilised women. Statistical analyses showed that there were no significant differences between two groups ($RR=0.85$; $p=0.418$). The results of this study showed that previous tubal sterilisation is not a risk factor for undergoing hysterectomy because of abnormal uterine bleeding.

Mackenzie et al (2010) demonstrated that 6% of women following tubal sterilisation undergo hysterectomy or endometrial ablation because of abnormal uterine bleeding. Analysis, however, showed that tubal sterilisation is not an independent risk factor for hysterectomy due to abnormal uterine bleeding. Ozerkan et al (2010) reported that some kind of menstrual pattern changes happened in 7.6% of cases after tubal sterilisation, however, these changes were mild. Thus consistently, these studies have found that there is no increased risk of requiring a hysterectomy for abnormal uterine bleeding post sterilisation.

With regard to menopause and menopausal age, Nichols et al (2013) found that women who had a tubal ligation were more likely to report hot flashes and other symptoms of menopause (poor sleep, night sweats, irritability and depression) compared to women who did not previously have a tubal ligation. However, no association was observed between tubal ligation and actual menopausal age. A study of 3650 postmenopausal women in the United Kingdom reported a 38% increase in the odds of menopause before the age of 49 years among women who had a tubal ligation (Pokoradi et al., 2011). However, other studies have not confirmed this association (Nichols et al., 2013).

1.5.4 Sexual function post sterilisation

Women often report little or no change in sexual interest and pleasure following tubal sterilisation. In those women who do report change, the majority report favorable effects of sterilisation on sexual interest and pleasure (Costello et al., 2002; Cooper et al., 1982; Bean et al., 1980; Richards et al., 1991; Smith et al., 1994).

Costello et al (2002), as part of the working group for the U.S Collaborative Review of Sterilization Study (which represents the largest United States cohort of women undergoing tubal sterilisation), undertook a cohort study to assess sexual function post sterilisation. The study population comprised 4 576 women who were followed up two years post procedure to assess sexual function post tubal sterilisation. Of the cohort, 80% of women reported no change in their sexual interest or pleasure after interval tubal sterilisation. In those women with change in sexual function, positive change was reported up to 15 times more often than negative change. Women who experienced post sterilisation regret were identified as those at risk for decreased sexual interest and pleasure post sterilisation.

In contrast, Gulum et al (2010) in a smaller series, found higher rates of female sexual dysfunction among women who had previously had tubal sterilisation and this finding was more common among women of lower socio-economic status.

1.5.5. Regret

Regret following sterilisation can be prevented by careful patient selection and patient counselling pre-procedure. Data from the U.S Collaborative Review of Sterilization Study revealed the cumulative probability of expressing regret following sterilisation was 12.7% (Hillis et al., 1999).

Young age (<30) at the time of sterilisation is one of the most important predictors of regret. Another important predictor of regret is the timing of sterilisation with regret rates higher with sterilisation done during a caesarean section or immediately postpartum rather than interval sterilisation. The greater the interval from an obstetric event, the lower the incidence of regret reported by patients (Rosenfeld et al., 1998).

Regret following sterilisation may also be related to changes in the patient's situations or attitudes and dissatisfaction resulting from adverse side effects from the procedure.

1.5.6. Health benefits

Tubal sterilisation has been documented in the literature as being protective against the development of ovarian cancer. The Nurse's Health Study found a 67% risk reduction of epithelial cancer development in sterilised versus non-sterilised women. Women who have BRCA 1 gene mutation have an up to 60% reduction in risk of ovarian cancer following sterilisation (Hankinson et al., 1993).

A significant additional health benefit of sterilisation is the reduction of pelvic inflammatory disease following sterilisation. Sterilisation does not protect against sexually transmitted disease, however, appears to protect against pelvic ascent of such infection (Bartz & Greenburg, 2008).

1.5.7. HIV and sterilisation

Up to 80% of the world's 15.5 million HIV-infected women reside in Sub-Saharan Africa. Each year, these women experience over 1.4 million pregnancies of which 50-84% are unintended (Kaida et al., 2010).

The history of ART (antiretroviral treatment) in South Africa began in 2004 with the introduction of ART into the public sector. In 2009, President Jacob Zuma announced new key interventions to improve ART access to special groups (all HIV positive infants, pregnant women, those with TB and HIV co-infection and those patients with CD4 counts less than or equal to 350 cells/ μ l). This intervention was implemented to decrease the disease burden.

Furthermore, the implementation was made to reduce maternal and child mortality as well as to improve life expectancy. This resulted in a widespread increase in the uptake of use of these drugs (Kaida et al., 2010). In 2013, the fixed-dose combination pill (FDC) was introduced to improve both adherence and retention. In July 2014, coverage of ART was expanded to include those individuals with a CD4 count ≤ 500 cells/ μ l and the Prevention of mother to child transmission (PMTCT) programme was expanded to adopt the B+ approach, which entitles every pregnant and breastfeeding women to lifelong ART regardless of CD4 count or clinical staging. This policy was brought into effect in January 2015 (Department of Health, South Africa, 2014).

The widespread availability and uptake of ART may reflect contraceptive knowledge as well as the utilisation of contraception among HIV positive women. In the pre ART era, contraceptive choices, particularly long acting and permanent methods, remained poorly understood by HIV positive women. In a study comparing contraceptive choices among HIV positive and HIV negative women in Cape Town, South Africa, it was found that the majority of pregnancies were unplanned (61.6% HIV positive and 63.2% HIV negative). Amongst both groups of women short term contraceptives were most commonly used with only 6.44% of all women using long acting and permanent methods. Poor knowledge of long acting and permanent methods of contraception was the most common factor in both groups of women contributing to the poor uptake of these methods (Crede et al., 1995).

Post ART availability, data regarding contraception knowledge as well as usage appears to be more promising. In a cross sectional survey in Soweto, South Africa 2010, 78% of women reported using contraception, with significant variation by HIV status. Contraceptive use was

86% among ART users, 82% among HIV positive women not on ART, and 69% among HIV-negative women ($p=0.0001$). HIV positive women receiving ART were more likely to use contraception than HIV negative women ($OR=2.40$). Among HIV positive women, ART users were non-significantly more likely to use contraception compared with non-ART users ($OR=1.55$). Similar patterns were observed for barrier (primarily male condoms), permanent, and dual protection contraceptive methods. Among HIV positive patients, only 39% reported consistent condom use (with or without another contraceptive method). This prevalence is comparable to condom use rates reported in South Africa overall. Overall, 7% of women used permanent methods (hysterectomy and/or female sterilisation) with non-significant, small differences by HIV status and HAART use (Kaida et al., 2010).

Internationally, it has been demonstrated that HIV positive women are more likely than HIV negative women to undergo tubal sterilisation as a method of contraception (Lindsay et al., 1995). Postoperative complications would depend on the patient profile and immune status. Devito and Robinson (1995) had demonstrated asymptomatic HIV has minimal effect on the outcome of elective gynaecological surgery with complications among HIV infected and non-infected individuals being similar.

1.5.8. Sexually transmitted infections and sterilisation

The prevalence of sexually transmitted infections (STIs) in Durban, South Africa remains extremely high with a disproportionate burden amongst women. STIs occur in up to 13% of women with an incidence rate of up to 20 per 100 women years. The sequelae include facilitated HIV transmission and acquisition, pelvic inflammatory disease and chronic pelvic pain (Naidoo et al., 2014).

Literature regarding the influence of sterilisation on the risk of STIs suggests that high risk women (multiple partners and HIV positive) are at an increased risk of STIs due to low rates of condom use post sterilisation (Pruitt et al., 2010). Contrary to this finding, Sangi-Haghpeykar et al (1998), reported women at high risk of contracting STIs (past history or multiple partners) are significantly more likely to plan condom use post sterilisation with insignificant risk of exposure to disease post procedure.

1.5.9. Reproductive health and sterilisation

Reproductive health, as outlined by the World Health Organisation (WHO), addresses the *“reproductive processes, system and functions at all stages of life”*. This involves the *“right of both men and women to be informed of and to have access to safe, effective, affordable and acceptable methods of fertility regulation of their choice and the right of access to appropriate health care services”* (WHO, 2015).

Internationally, studies have been conducted to address reproductive health after sterilisation as outlined above, however, there remains a lack of local evidence to guide current practice and identify issues in reproductive health of women undergoing sterilisation. This has encouraged the concept and undertaking of this study.

CHAPTER 2

THE RATIONALE AND SIGNIFICANCE OF THE STUDY

2.1 Introduction

This chapter outlines the significance of the study. In other words, the foundation of the study is laid out clearly. It highlights the purpose of the study, the research questions, the methodology and the statistical analysis.

2.2 Purpose of the Study

A prospective study was conducted to determine reproductive health, women's use of the health services and overall satisfaction following interval laparoscopic sterilisation at King Dinuzulu Hospital Complex (formerly known as King George V Hospital), in the Province of KwaZulu-Natal, South Africa.

2.3 Objectives

The following specific objectives were pursued:

1. To determine the demographic profile of women having interval sterilization at King Dinuzulu Hospital.
2. To determine reasons women choose sterilisation as a contraceptive method.
3. To assess overall satisfaction one year post the sterilisation procedure.

4. To determine the prevalence of and reasons for regret post sterilisation.
5. To determine whether sterilisation influences the prevalence of gynaecological disorders in women e.g. menstrual abnormalities, sexually transmitted infections and pelvic inflammatory disease.
6. To assess if women are at a greater risk of HIV acquisition post tubal ligation.

2.4 Research context and methodology

This was a prospective cohort study of women who underwent sterilisation with regard to their reproductive health and overall satisfaction with the procedure one year post sterilisation. King Dinuzulu Hospital Complex (formerly King George V Hospital) remains the primary referral centre in Durban, KwaZulu-Natal, South Africa for elective interval laparoscopic sterilisation. King Dinuzulu Hospital Complex (formerly King George V Hospital) is situated in Springfield in Ward 25 of the eThekweni health district. This public hospital complex offers the following specialised services:

- Multi-drug resistant (MDR) and complicated TB
- Orthopaedic spinal surgery, psychiatric, family planning (sterilisation)

Women who are referred to King Dinuzulu Hospital Complex (formerly King George V Hospital) for sterilisation routinely are offered a gynaecological consultation, HIV test, RPR test and Pap smear (if indicated as per national screening program). These women are then routinely followed up one year post sterilisation with a gynaecological consultation, HIV test, RPR and Pap smear (if symptomatic or as per national screening program).

The proposed study would have included all women who presented for sterilisation from 1 June 2012 to 28 February 2013. Their follow up at one year post sterilisation i.e. 1 June 2013 to 28 February 2014 would have been included in the study. However, ethical approval had not been granted by this time, hence commencement of the study was subsequently delayed.

Full ethical approval of the study was granted on the 25 July 2013, hence the study period and population group were changed with the approval of the University of KwaZulu-Natal Ethical Board.

The study population included all women who presented to King Dinuzulu Hospital Complex from the 1 August 2012 to 30 April 2013. These women were routinely offered a gynaecological consultation, HIV test, RPR test and Pap smear (as per national screening program). The information of this consultation was subsequently recorded in women's records as per routine pre-sterilisation data sheet (**Appendix 1**).

These women subsequently underwent the tubal ligation procedure. This procedure is an outpatient procedure at King Dinuzulu Hospital Complex. The procedures were performed under local anaesthetic and conscious sedation. These procedures were performed by a registrar under the supervision of the consultant in charge of the unit (the supervisor of the study). Women were positioned and draped in theatre following the administration of 1-2 milligram (mg) of midazolam hydrochloride and 1-2 mg/kg of fentanyl citrate. The procedures were performed via a two port laparoscopic technique (sub-umbilical and suprapubic ports) using Filshie clips applied to both fallopian tubes. Women were reviewed and discharged post operatively the same day. All significant intra-operative findings were recorded in women's

charts. All women received a 25 mg diclofenac suppository per rectum during the procedure (provided there were no contra-indications) and a 3 day nocte course of the suppository and 1 week paracetamol course (1 gram 6 hourly) for analgesia. On discharge all women were given a one year follow up appointment and reminder form.

Women were then followed up one year post sterilisation i.e. 1 August 2013–30 April 2014 on an outpatient basis. They were offered a gynaecological consultation, HIV test, RPR test and Pap smear (as per national screening program). These data were recorded in post sterilisation sheets with consent from the women to utilise this information for study purposes (**Appendix 2**).

Women who failed to return for follow up consultation were contacted telephonically to return for their follow up 12-18 months post procedure. These women were subsequently followed up till ethical approval expired i.e. 25 July 2014. Women who returned for follow up one year post sterilisation for review and who consented to utilise their information for the study were included in the study cohort.

Data were collected according to the attached data sheet (**Appendix 1: Data sheet: Pre-sterilisation, Appendix 2: Data sheet: Post sterilisation**). These data were collected from interview and charts review. Registrars in family planning were trained on the use of the data sheet and the conduct of the interview. These interviews were conducted by registrars and the consultant in charge of the unit (the supervisor of the study). All questionnaires were completed as per standard layout from interview and examination of women. Confidentiality was ensured in that these interviews and examinations of women were conducted in a private

room. Following the interviews, patient names were blocked off the data sheet with a black pen and a data number allocated to the data sheet by the supervisor of the study. These data were then placed in a lock-in cupboard for only the research team to access. The data were kept confidentially and strictly for the purpose of the study at hand.

Both quantitative and qualitative research designs were used in gathering data. Within the qualitative approach; the use of document analysis, observations and semi-structured interviews were utilised with the intention of obtaining in-depth qualitative information. The quantitative approach was utilised by the administration of questionnaires. This strategy was used to gather numerical data from the study population.

2.5 Statistical analysis

Results were summarised by frequencies and percentages (categorical variables) and means, medians, standard deviation or percentiles (numerical variables) as appropriate. Normal distributed data were analysed using a paired samples Students t-test when comparing two groups. The Wilcoxon sign rank test was used for comparison of the pre and post sterilisation differences on certain variables like menstrual abnormalities. Pearson's chi-square or Fischer's Exact test were utilised to identify trends between categorical data variables as appropriate. Data were captured and analysed using the Statistical Package for Social Sciences (SPSS) version 19.0 (SPSS Inc. Chicago, Illinois). A p value <0.05 was considered as statistically significant.

2.6 Limitations

Selection bias was encountered in that only women who were willing and able to present themselves one year post sterilisation were included in the study. A further limitation was that information regarding menstrual patterns, STIs and sexual behaviours were obtained from the women's history and from subjective observations with no objective methods of measurement. The study follow up was over a one year time period while longer follow up may have been more beneficial to add value to the results.

Both pre and post sterilisation data sheets categorised Marital Status as either "single", "married", "divorced" and "widowed". A limitation to this categorisation is that women may have claimed to be "married" when either in a casual relationship with a partner or in a legally or formally recognised union. A further limitation to our study was that we did not ask women about the nature of their marital relationship (i.e. if they suspected their partner to be unfaithful or if they were unfaithful themselves).

CHAPTER 3

DATA ANALYSIS AND INTERPRETATION

3.1 Introduction

Chapter 3 provides a detailed analysis of data collected through various instruments such as questionnaires and documents. Both quantitative and qualitative research methods were employed in the study. Both figures and tables are designed to illustrate the research findings based on the data collected. The detailed interpretation and analysis are directly linked to the research questions and purpose of the study as encapsulated in chapter two.

3.2 Sample size and sampling techniques

A total of 337 women underwent tubal sterilisation at King Dinuzulu Hospital Complex from 1 August 2012 to 30 April 2013. Of these 337 women, 127 returned for their one year follow up appointment. The remaining women were telephonically contacted to remind them to return for their appointments. Their reasons for not attending their follow up included: forgotten appointment, no reason to return as had no medical complaints, financial constraints as well as relocation. Of the remaining 210 women who were contacted to return for follow up, 98 returned for their follow up with the remaining women being unreachable telephonically (voicemail, incorrect number) or being unable to return due to work constraints, financial difficulties, relocation or family commitments. The total number of women who did return was 225 with a return rate of 66.7% and these women were included in the study cohort.

3.3 Data gathering and techniques

Data were collected by means of questionnaires (**Appendix 1: Data sheet: Pre-sterilisation**) and (**Appendix 2: Data sheet: Post sterilisation**). These questionnaires were administered by registrars training in family planning and the consultant in charge of the unit (the supervisor of the study). Registrars were supervised by the above mentioned consultant on the administration of the questionnaires and entry of data into data sheets based on responses from women and examination findings. Quantitative data were collected directly from the responses on the questionnaires. Qualitative data were collected from the open ended questions in the data sheets. These included: (**Appendix 1: Data sheet: Pre-sterilisation**) “current medications”, “previous operations”, “gynaecological problems pre-sterilisation” and “treatment sought”. In **Appendix 2: Data sheet: Post sterilisation**, open ended questions included: “gynaecological complaints post sterilisation”, “hospitalisation and treatment sought” and “reasons for regret” as expressed by women. These responses were further categorised by similarity and analysed accordingly. Before administering the questionnaires, informed consent was obtained from women with the assurance of confidentiality written in both English and in Zulu (**Appendix 3 and Appendix 4**). In addition to consent from women, a further letter was written to women outlining the purpose and significance of the research study [**Appendix 5 (English) and Appendix 6 (Zulu)**]. Data were collected and computed into Excel and SPSS spreadsheets by myself. This data was then crosschecked and analysed by the statistician.

As with all research, permission had to be granted by the institution (King Dinuzulu Hospital Complex), to conduct this research study at their premises and have access to the women’s

files. This consent was granted by the Medical Manager (**Appendix 7**). The study needed to be registered at the Postgraduate Office, Department of Obstetrics and Gynaecology, School of Clinical Medicine at the University of KwaZulu-Natal, Durban. This was duly done (**Appendix 8**). Finally, ethical clearance was obtained from the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (**Appendix 9**).

3.4 Analysis and interpretation of data collected

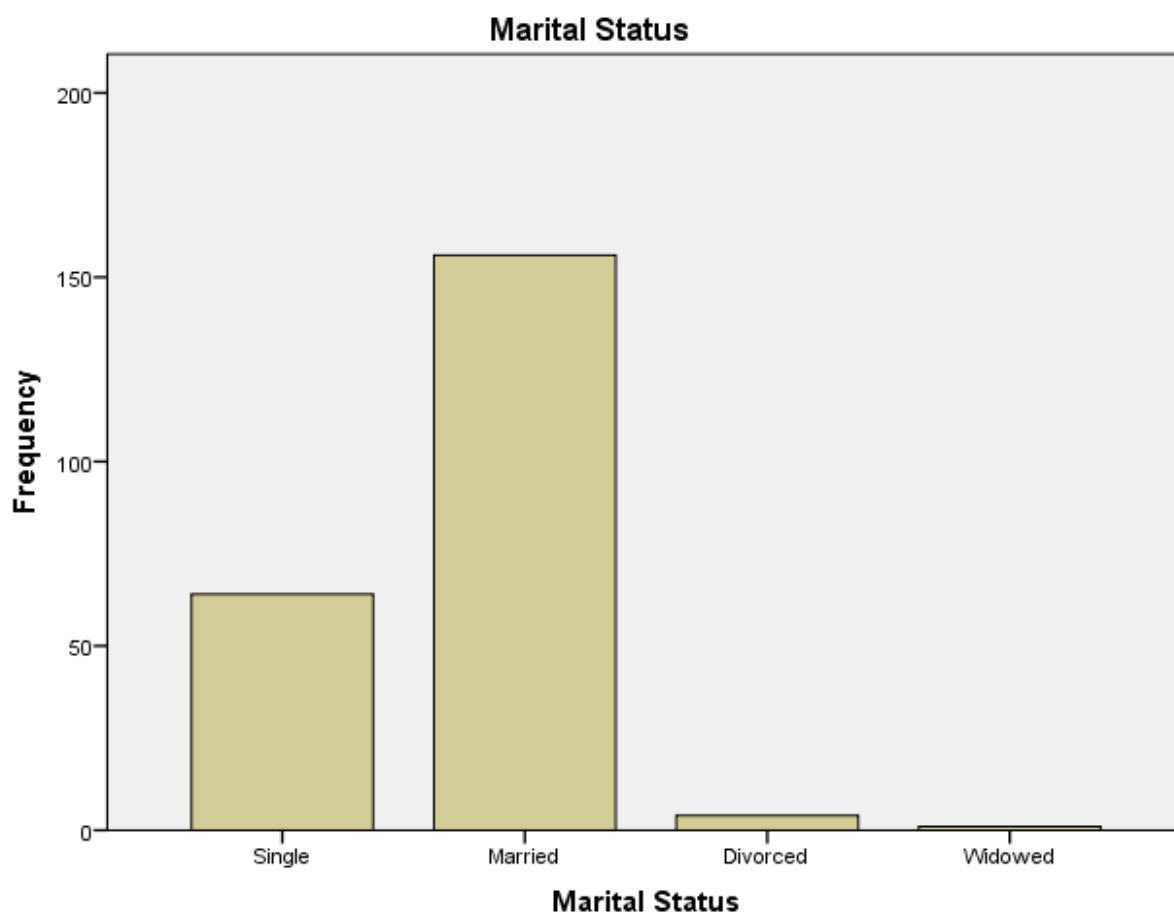
3.4.1 Demographic data

Of the 225 women who returned for follow up, 156 women (69.3%) were married, 64 (28.4%) were single, 4 divorced (1.8%) and 1 widowed (0.4%) (**Figure 1**). The mean age of women was 35 years with a range of 26 years and maximum age of 42 years (SD 4.26) (**Table 1**). Of those women who were married (or in a monogamous relationship), the mean husband's age was 39 years with a range of 27–56 years (SD 5.55).

Table 1: Demographic characteristics of study cohort (mean \pm SD)

Age	35 \pm 4.26
Partner's age	39 \pm 5.55
Parity	3 \pm 1
Haemoglobin	12.4 \pm 6.19
Body mass index	33.3 \pm 7.42

Figure 1: Marital status of women



All women were parous. The majority of women had at least 2 or more children (99.6%) (Table 2). The mean parity was 3 children.

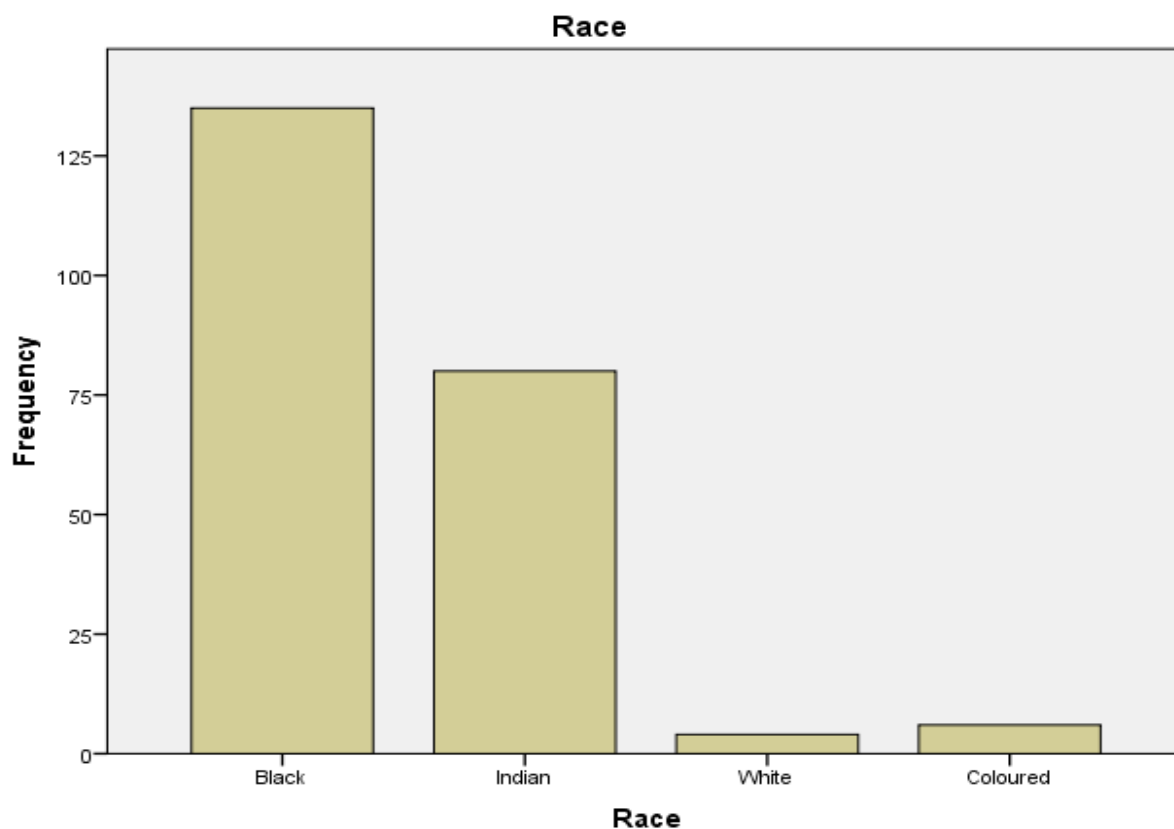
Table 2: Parity of women

Parity	Frequency	% of Cohort
1.00	1	0.4
2.00	70	31.1
3.00	82	36.4
4.00	49	21.8
5.00	20	8.9
6.00	2	0.9
8.00	1	0.4
Total	225	100.0

The number of living children women had were: 1 (n=6; 2.7%), 2 (n=66; 29.3%), 3 (n=86; 38.2%), 4 (n=49; 21%), 5 (n=15; 6.7%), 6 (n=2; 0.9%) and 8 (n=1; 0.4%) respectively. The mean age of the youngest child was 3.6 years (SD 4.21) with a range of 6 weeks to 21 years. Of the 225 women, 8 (3.6%) had previous miscarriages. Of these women, 6 women (2.7%) had 1 previous miscarriage and 2 women (0.9%) had 2 previous miscarriages.

The majority of women were Black (n=135; 60%) with the remaining study population being Indian (n=80; 35.6%), White (n=4; 1.8%) and Coloured (n=6; 2.7%) (**Figure 2**).

Figure 2: Race of study population



The mean BMI of women was 33.3 kg/m² with a range of 17–55 (SD 7.42). The mean ward haemoglobin of women was 12.4 g/dl with a range of 7-16 (SD 6.19).

The majority of women had received secondary school education 163 (72.4%) with 16 women (7.1%) receiving only primary school education, 45 women (20%) receiving post-secondary school education and 1 women (0.4%) receiving no formal school education. Of the total 225 women, 105 (46.7%) were employed and 120 (53.3%) were unemployed. The majority of women had a family income of <R5000 a month (48.9%), with 30.7% of women having a

family income of between R5000-R10000 and 20.4% of women having a family income of >R10000 a month as illustrated in **Table 3**.

Table 3: Family income per month

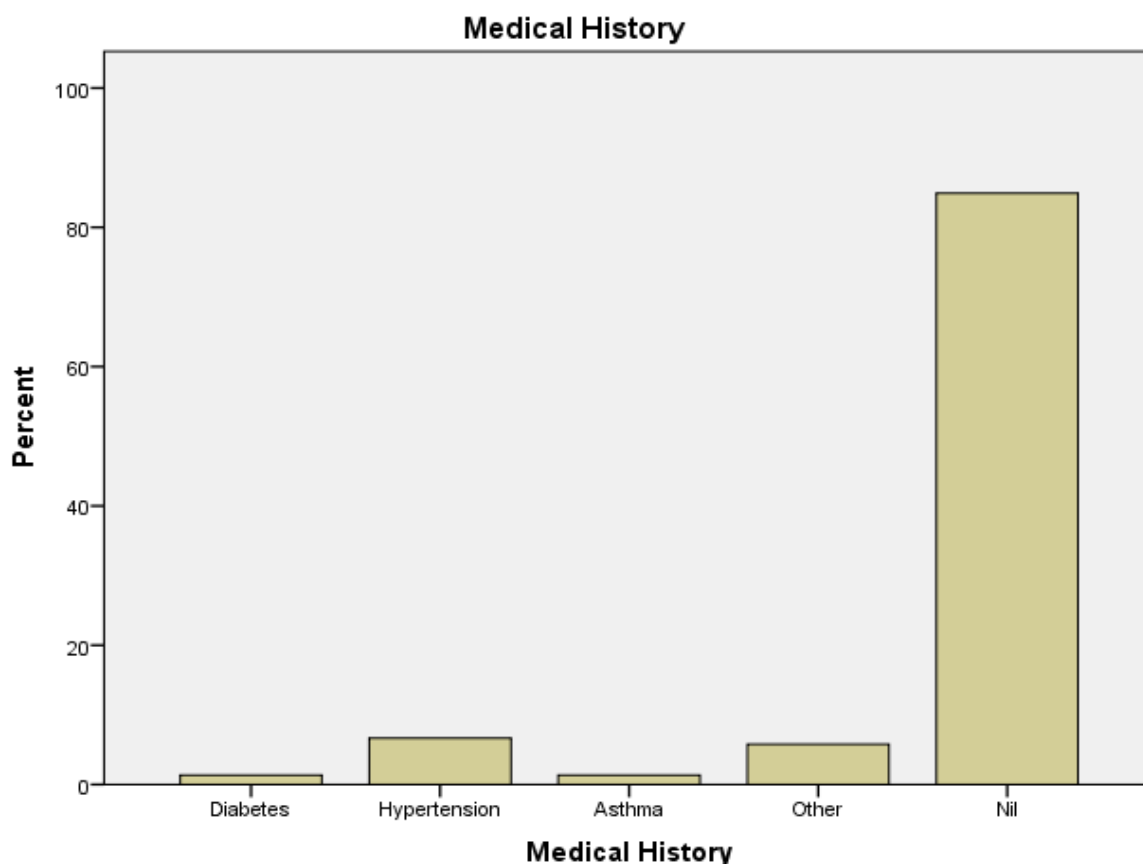
Family Income	Frequency	% of Cohort
Rands <5 000	110	48.9
=5 000-10 000	69	30.7
>10 000	46	20.4
Total	225	100.0

3.5 General health

Of the 225 women, 169 were HIV negative (75%). Of the 56 women (25%) who were HIV positive, 38 (67.9%) were on ART and 18 (32.1%) were not on treatment due to CD4 counts >350 cells/ μ l.

All 225 women tested RPR negative pre-sterilisation. The majority of women were previously well with no co-morbidities: 191 women (84.9%). The co-morbidities of the remaining women included diabetes mellitus (n=3; 1.3%), hypertension (n=15; 6.7%), asthma (n=3; 1.3%) and other co-morbidities including epilepsy, hypothyroidism, depression, tuberculosis, autoimmune disease (scleroderma), sinusitis, peptic ulcer disease (n=13; 5.8%) as illustrated in **Figure 3**.

Figure 3: Medical history and co-morbidities



A total of 47 women (20.9%) had previous abdominal surgical procedures. These procedures included one previous caesarian section (n=25; 11.1%), two previous caesarian sections (n=12; 5.3%), three previous caesarian sections (n=1; 0.4 %), previous laparotomy for ectopic pregnancy (n=3; 1.3%), previous ovarian cystectomy (n=2; 0.9%), previous unsuccessful tubal ligation done in 2005 (n=1; 0.4%) and previous surgical laparotomy (n=3; 1.3%).

3.6 Reproductive health pre-sterilisation

Of the cohort of 225 women, 206 women (91.6%) had normal Pap smears pre-sterilisation with 2 women (0.9%) with LSIL, 4 with HSIL on Pap smear (1.8%) and 1 woman (0.4%) with ASCUS on Pap smear. Twelve women (5.3%) had no recorded Pap smear pre-sterilisation. The women with normal Pap smears were advised about repeat smears as per national screening program. Those women with LSIL and ASCUS were counselled on repeat smears in 6 months. Of the 4 women with HSIL on Pap smear, 3 were HIV positive and 1 woman HIV negative. Two women had colposcopy and LLETZ procedures performed and 2 women were referred to their base hospitals for colposcopy and LLETZ procedures.

The majority of women were on injectable contraception [norethisterone enanthate (NET-EN) or depot medroxyprogesterone acetate (DMPA)] [n=149; (66.2%)], with the remaining participants utilising combined oral contraception (COC) [n=52; (23.1 %)], barrier methods [n=11; (4.9%)] or no contraception [n=13; (5.8 %)]. Of the cohort, 15.5% (n=35) of women used dual contraception. Of 212 current contraceptive users, 119 women (56.1%) had used their current method for less than 2 years, 64 women (36.2%) used their method for 2-5 years and 29 (13.7%) used their method for more than 5 years. Ninety two of the contraceptive users (43.4%) had used their method continuously and 120 women (56.6%) had used their current method interruptedly. One hundred and thirty seven women (60.9%) were not currently using condoms while 43 (19.1%) used condoms occasionally and 45 (20%) always used condoms during sexual intercourse.

Before sterilisation, most women had 1 sexual partner (n=209; 92.9%), with 9 women (4%) having 1-3 partners and 6 women (2.7%) with no partner. Women were asked about sexual partners before sterilisation and whether these were current or ever sexual partners was not obtained.

Of the 225 women, 191 (84.9%) had no previous history of sexually transmitted infections. Thirty four patients (15.1%) reported a past history of vaginal discharge, vaginal ulcers, pelvic inflammatory disease or genital warts. Other past gynaecological problems reported by women were endometriosis (n=1; 0.4%) and polycystic ovary syndrome (n=1; 0.4%).

Of the 225 women, 107 (47.6%) were amenorrhoeic due to injectable contraception, 80 women (35.6 %) reported days of menses less than 4 days, 36 women (16%) reported days of menses between 4-8 days and 2 women (0.9%) reported menses greater than 8 days. Fifty three women (23.6%) reported light flow, 57 women (25.3%) reported average flow, 8 women (3.6%) reported heavy flow and 107 women were amenorrhoeic. Three women (1.3%) reported pain with menses not requiring medication.

3.7 Reasons for sterilisation and intra-operative findings

The primary reason that women in the study gave as the reason for requesting tubal ligation was that their families were complete. All procedures were successful.

One laparoscopic procedure (0.4%) was converted to laparotomy due to difficulty of the procedure and suspected broad ligament bleed. This bleed resolved spontaneously and no

sutures were applied. This woman was morbidly obese with a BMI 42 with no prior surgical history. Intra-operative complications included cervical perforation with the Hulka manipulator (n=1; 0.4%) and uterine perforation with the Hulka manipulator (n=2; 0.8%). In one woman the cervix was torn with a uterine manipulator and was repaired. The two cases of uterine perforation were successfully managed conservatively.

Other intraoperative findings included:

- Adhesions from previous operations (n=9; 4%) – nil failures or complications noted from the tubal ligation procedure
- Ovarian cysts – (n=5; 2.2%) – All women were referred to their base hospitals for further management
- Unilateral hydrosalpinx – (n=2; 0.8%)
- Incidental fibroids – (n=2; 0.8%)

3.8 General health post sterilisation

Of the 225 women, 169 women had tested HIV negative pre-sterilisation. Of these, 168 women remained HIV negative. One woman who had tested HIV negative pre-sterilisation had tested positive post sterilisation. She had complaints of recurrent vaginal discharge which made her seek attention at her clinic before her follow up date. Of note she had one sexual partner before sterilisation and two partners post sterilisation. Whether these sexual partners were two new partners or two simultaneous partners was not obtained. She had also noted an increase in sexual activity post sterilisation (once a week) as opposed to pre-sterilisation (once a week to once a month). Her repeat Pap smear was normal and repeat HIV test positive. She was aware of her status at follow up consultation. Among the study cohort, there was no

increase in new HIV infections post sterilisation (RR 0.006; 95 % CI (0.001-0.042); p=1). When stratified by race, the majority of HIV positive women were Black (n= 57; 98%) with the remaining woman being Coloured (n=1; 2%). The risk of HIV acquisition among Black women did not reach statistical significant (p=1).

Of the 56 women (25%) who were HIV positive, 38 (67.9%) were on anti-retroviral drugs (ARVs) and 18 (32.1%) were not on treatment due to CD4 counts >350. Of the 18 women who did not qualify for ARVs on the basis of high CD4 counts of >350 cells/ μ l pre-procedure, one patient had a drop in CD4 count post procedure (600 cells/ μ l to 341 cells/ μ l) requiring referral for ARVs. In women who were HIV positive, the mean CD4 count pre-procedure was 425.5 cells/ μ l and 600.9 cells/ μ l post procedure. There was a significant rise in CD4 (p=0.02) with 67.9% of women being on anti-retroviral drug treatment.

Table 4: HIV status pre and post sterilisation

	HIV negative	HIV positive		Mean CD4 (HIV +)	Standard deviation	Standard error of the mean
		Not on HAART (CD4 >350)	On HAART			
Pre-sterilisation	169	18 (32.1%)	38 (67.9%)	425.5	276	66.8
Post sterilisation	168	17 (29.8%)	40 (70.2%)	600.9	297	69.9

Of the 225 women who tested RPR negative pre-sterilisation, 224 women tested negative post procedure with one woman testing positive post procedure. She was previously noted to be HIV negative and was asymptomatic for syphilis. Her formal titres and confirmatory Treponema pallidum haemagglutination assay (TPHA) were negative and she required no treatment. There was no statistical difference in RPR results pre and post procedure.

3.9 Reproductive health post sterilisation

Pap smears post sterilisation were performed on women who had not had a recent Pap smear (as per national screening program), women who had gynaecological symptoms and women who had abnormal or inadequate Pap smears pre-sterilisation.

Of the 206 women with normal Pap smears pre-procedure, 26 (12.6%) repeat smears were normal. One hundred and seventy five (84.9%) women had no indication for a repeat smear and 4 women (1.9%) had LSIL on repeat Pap smears. Of these 4 women, 3 were HIV positive (75%) and 1 woman HIV negative (25%). Among women with LSIL on pre-sterilisation smears, 1 woman had HSIL on repeat smear and the other patient persistent LSIL. Both women were HIV positive and referred for colposcopy. Of the 12 women with no pre-sterilisation Pap smear, 9 had repeat Pap smears which were normal (75%) and 3 had HSIL on repeat Pap smears (25%). All 3 of these women were HIV positive. The 1 woman with ASCUS on pre-sterilisation Pap smear had LSIL on repeat smear and was subsequently referred for colposcopy. She was HIV negative. Statistically, there was no change in Pap smear abnormalities over time $p=0.214$.

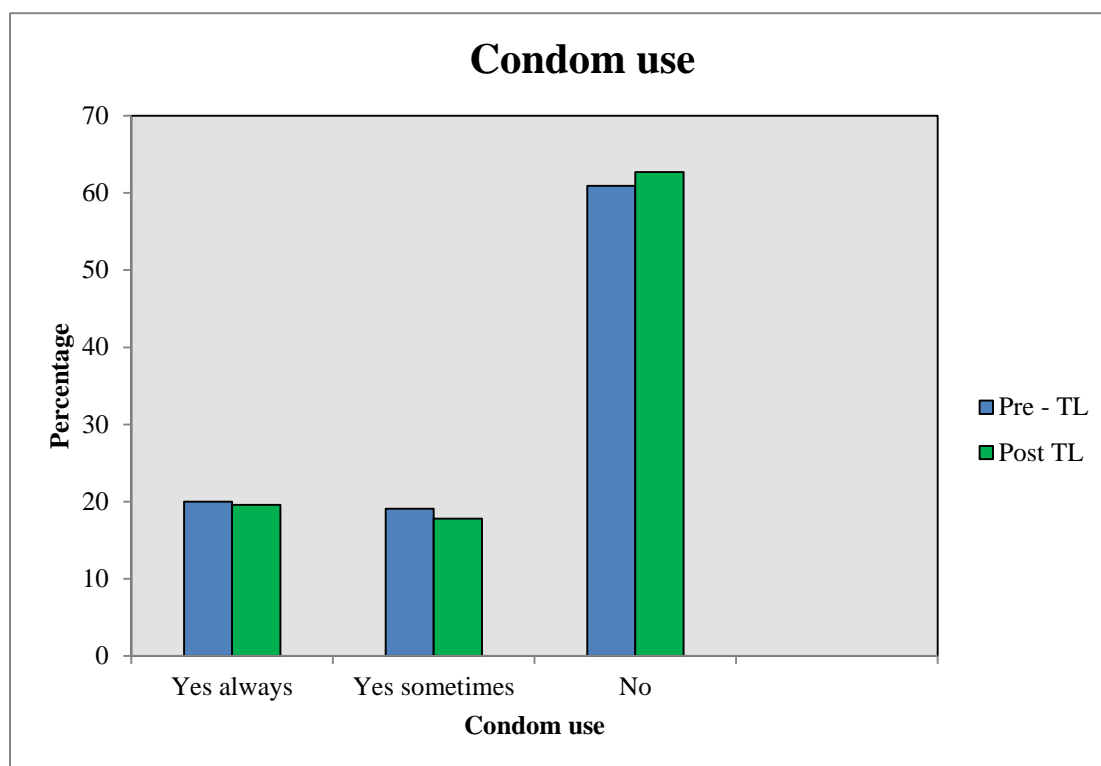
Table 5 : Pap smear pre and post sterilisation - Cross-tabulation

		Pap smear post sterilisation					Total
		Not Done	Normal	LSIL	HSIL	Not Required	
Pap smear	Not Done	5	4	0	3	0	12
pre-	Normal	23	26	4	0	153	206
sterilisation	LSIL	0	0	1	1	0	2
	HSIL	3	0	0	1	0	4
	ASCUS	0	0	1	0	0	1
Total		31	30	6	5	153	225

Of the 45 women who always used condoms pre-sterilisation, 42 (93.3%) continued to always use condoms, 1 woman (2.2%) used condoms occasionally and 2 (4.4%) stopped using condoms post procedure. Of those women who occasionally used condoms, 2 of the 43 women reported stopping condom use post sterilisation (4.7%) with 39 women still occasionally using condoms (90.7%) and 2 always using condoms (4.7%).

Of the total cohort of women, 62.7% did not use condoms post procedure (from 60.9% pre-procedure), with only 37.3% of women using condoms either occasionally or always (**Figure 4**). This increase in non-use of condoms did not reach statistical significance ($p=0.228$).

Figure 4: Condom use pre and post procedure



Seven women reported no sexual partner pre-sterilisation. Five of these women reported 1 partner post sterilisation and 2 reported no partners post sterilisation. Of women with 1 partner pre-sterilisation, 199 of the 209 reported still 1 partner with 4 reporting 1-3 partners post sterilisation and 6 women reporting no partner post sterilisation. The 9 women with 1-3 partners pre-sterilisation all reported just 1 partner post sterilisation. There was no statistically significant change in sexual partners post sterilisation ($p=0.313$).

Post sterilisation, 11 of the 225 women (4.9%) reported STIs. Ten women sought medical attention for vaginal discharges and 1 for genital warts. None of these women reported a history of PID post sterilisation. Of the 11 women with STIs post sterilisation, 6 women had previously sought medical attention for STIs pre-sterilisation (17.6%) and 5 women (2.6%) had no history of a prior STI. There was a statistically significant increase in STIs post sterilisation in those women who had previous STIs (OR 6.7; 95% CI (2.2–20.9); $p=0.002$) compared to women who had no history of STIs pre-sterilisation. In women with no prior history of a STI, there was no significant risk of STIs post sterilisation (OR 0.8; 95% CI (0.7–0.9); $p=0.001$) (Table 6, 7, 8).

Table 6: STIs pre and post sterilisation

	Pre-sterilisation: n (%)	Post sterilisation: n (%)
STIs	34 (15.1)	11 (4.9)
Vaginal Discharge	30 (13.3)	10 (4.4)
Genital Warts	2 (0.9)	1 (0.4)
PID	2 (0.9)	0 (0)

Table 7: STIs post sterilisation

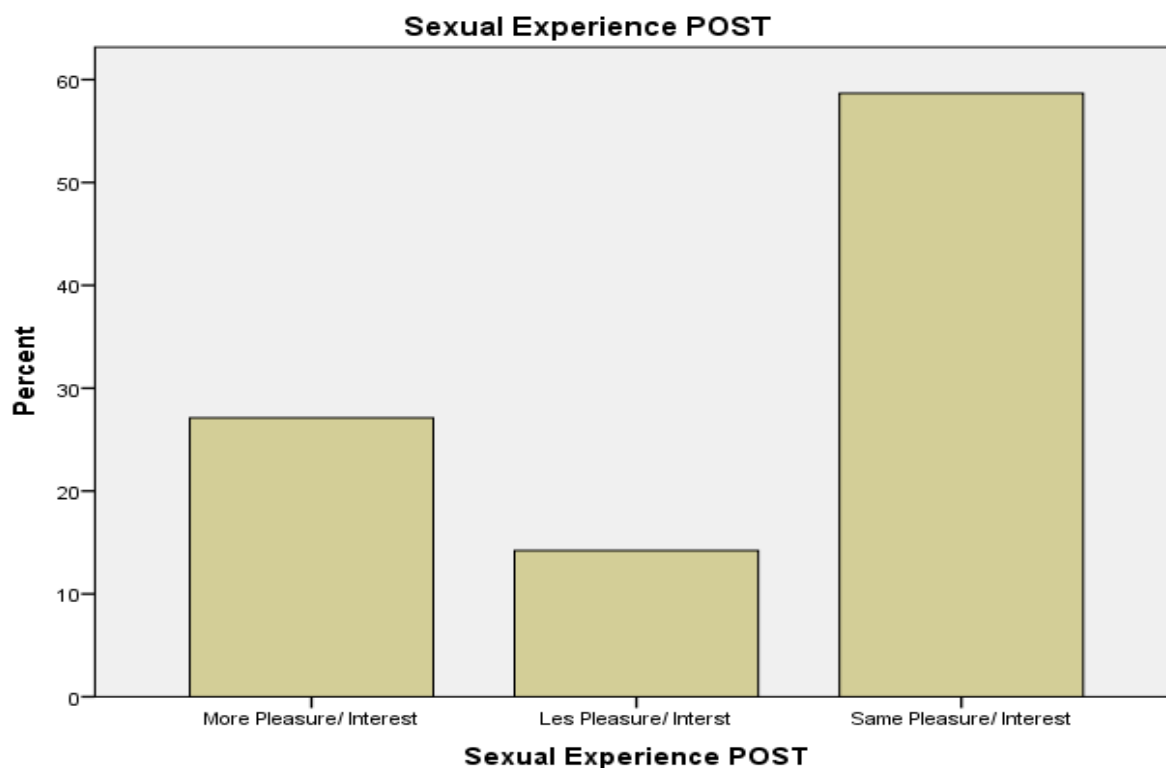
			Post sterilisation		Total
			Yes	No	
Previous STIs	Yes	Count	6	28	34
		%	17.6%	82.4%	100.0%
Pre-sterilisation	No	Count	5	186	191
		%	2.6%	97.4%	100.0%
Total		Count	11	214	225
		%	4.9%	95.1%	100.0%

Table 8: Risk estimate for STIs post sterilisation

	OR for previous STI	95% Confidence Interval	
For cohort post = yes	6.741	2.179	20.855
For cohort post = no	0.846	0.723	0.990
N of Valid Cases	225		

When questioned on sexual activity post sterilisation, the majority of women (n=120; 53.3%) reported more than 1x weekly sexual intercourse with 94 women (41.8%) reporting sexual activity between 1x weekly to 1x month and 11 women (4.9%) reported not being sexually activity post procedure. When asked about sexual pleasure and interest post procedure, 58.7% reported same interest and pleasure compared to pre-procedure, 27.1% more interest and pleasure and 14.2% less interest and pleasure (**Figure 5**).

Figure 5: Sexual experience post sterilisation



Among women with STIs post sterilisation, 6 (54.5%) women had a previous history of STIs pre-sterilisation. Of these 6 women, 4 (66.7%) were HIV negative and 2 (33.3%) were HIV positive. Among the HIV positive women, 1 woman (50%) reported an increase in partners post procedure. Both women reported condom use occasionally during sexual intercourse and not consistently. Both women reported an increase in sexual activity post sterilisation with the same sexual interest and pleasure as pre-sterilisation. The remaining 4 women who were HIV negative all reported no condom use post sterilisation. Two of these 4 women (50%) reported an increase in sexual partners post sterilisation. Three of the four women (75%) reported

increased sexual activity and pleasure post sterilisation and 1 woman (25%) reported the same sexual interest and pleasure.

Of the 5 women (45.5%) who had no prior history of STIs pre-sterilisation, all were HIV negative. Four women (80%) reported 1 partner pre and post sterilisation and 1 (20%) reported 1 partner pre-sterilisation and 2 partners post sterilisation. None of these women reported condom use pre and post sterilisation. Four of these women reported more frequent sexual intercourse with the same interest and pleasure. One woman reported same frequency and sexual interest and pleasure as pre-sterilisation.

Table 9 outlines menstrual patterns pre and post sterilisation controlling for previous contraceptive use. Women on barrier methods and those not on any contraceptive pre-sterilisation had no statistically significant change in their days of menstrual bleeding or dysmenorrhoea ($p=1$ and $p=0.89$ respectively).

Among the 107 women with amenorrhoea on injectable contraception pre-sterilisation, 73.8% ($n=79$) reported return to regular menses and 26.2% ($n=28$) reported abnormal uterine bleeding post sterilisation (prolonged menstrual bleeding, heavy menstrual bleeding and cycle irregularity). Among the 42 injectable contraceptive users with regular menses or spotting pre-sterilisation, 71.4% ($n=30$) reported no change in menses post sterilisation and 28.6% ($n=12$) reported abnormal uterine bleeding post sterilisation (prolonged menstrual bleeding and heavy menstrual bleeding).

Among previous injectable users, there was a statistically significant increase in days of bleeding ($p=0.03$), amount of menstrual bleeding ($p=0.01$) and dysmenorrhoea post sterilisation ($p=0.005$). Fourteen women (9.4%) sought medical attention post sterilisation for heavy menses ($n=4$; 28.6%) and cycle irregularity ($n=10$; 71.4%). These women were assessed clinically for abnormalities and 1 woman (7.1%) was found to have leiomyomas and referred to her base hospital for further treatment. The remaining women in whom no abnormalities were found were successfully treated medically.

Among previous COC users, 37 women (71.2%) reported heavy or prolonged menses post sterilisation. Cycle irregularity was reported by 5 women (9.6%) and dysmenorrhoea by 33 women (63.5%). There was a statistically significant increase in duration of menses ($p=0.02$), flow of menses ($p=0.01$) and dysmenorrhoea ($p=0.001$) post sterilisation. Five women (9.6%) sought medical attention post sterilisation for heavy menses and cycle irregularity. Clinically no organic cause was found and these women were successfully treated medically.

Table 9: Menstrual patterns pre and post tubal ligation controlling for contraceptive use

Parameter	Contraceptive use pre-tubal ligation (TL)							
	Injectable contraception n (%) = 149 (66.2)		COC n (%) = 52 (23.1)		Barrier n (%) = 11 (4.9)		Nil n (%) = 13 (5.8)	
	Pre – TL	Post – TL	Pre – TL	Post–TL	Pre – TL	Post –TL	Pre – TL	Post- TL
Days of menses n (%)								
Amenorrhoea	107 (71.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
< 4 days	27 (18.1)	79 (53.0)	38 (73.1)	4 (7.7)	7 (63.6)	7 (63.6)	8 (61.5)	69 (46.2)
4 - 8 days	14 (9.4)	65 (43.6)	14 (26.9)	44 (84.6)	3 (27.3)	3 (27.3)	5 (38.5)	7 (53.8)
> 8 days	1 (0.7)	5 (3.4)	0 (0)	4 (7.7)	1 (9.1)	1 (9.1)	0 (0)	0 (0)
Flow of menses n (%)								
Amenorrhoea	107 (71.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Light	21 (14.1)	46 (30.9)	24 (46.2)	2 (3.9)	4 (36.4)	4 (36.4)	4 (30.8)	3 (23.1)
Average	18 (12.1)	76 (51.0)	28 (53.9)	27 (51.9)	5 (45.5)	4 (36.4)	6 (46.1)	7 (53.9)
Heavy	3 (2.0)	27 (18.1)	0 (0)	23 (44.2)	2 (18.2)	3 (27.3)	3 (23.1)	3 (23.1)
Cycle regularity n (%)								
Amenorrhoea	107 (71.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Regular	32 (21.5)	130 (87.3)	52 (100)	47 (90.4)	10 (90.9)	10 (90.9)	13 (100)	13 (100)
Irregular	10 (6.7)	19 (12.8)	0 (0)	5 (9.6)	1 (9.1)	1 (9.1)	0 (0)	0 (0)
Pain with menses n (%)								
Nil	149 (100)	104 (69.8)	52 (100)	19 (36.5)	11 (100)	11 (100)	10 (76.9)	9 (9.2)
Yes, not requiring meds	0 (0)	39 (26.2)	0 (0)	28 (53.9)	0 (0)	0 (0)	3 (23.1)	3 (23.1)
Yes, requiring meds	0 (0)	6 (4.0)	0 (0)	5 (9.6)	0 (0)	0 (0)	0 (0)	1 (7.7)

3.10 Complications post sterilisation

No pregnancy or pregnancy related events were noted in the study population during the given time period.

One woman (0.4%) was readmitted a day post procedure for urinary retention. Investigations revealed a urinary tract infection which was successfully treated with a course of antibiotics.

One woman (0.4%) reported port site hernia post procedure which required surgical treatment at her base hospital. Of note this patient was morbidly obese with a BMI of 40.2 kg/m².

One woman (0.4%) sought medical attention for wound sepsis post procedure. This was successfully treated with dressings and antibiotics.

Abnormal uterine bleeding was a common complaint expressed by women post procedure. Nineteen patients (8.4%) sought medical attention from their local clinics, general practitioners or regional hospitals for this complaint. None of the women required admission and 17 women were treated with a course of tranexamic acid with or without haematinics and 2 women were treated with the combined oral contraceptive pill.

Eleven women (4.9%) sought medical attention for a vaginal discharge post procedure. No women were admitted to hospital. Ten received syndromic treatment for a sexually transmitted infection and 1 patient received treatment for vaginal candidiasis.

Other complaints experienced post operatively by women included:

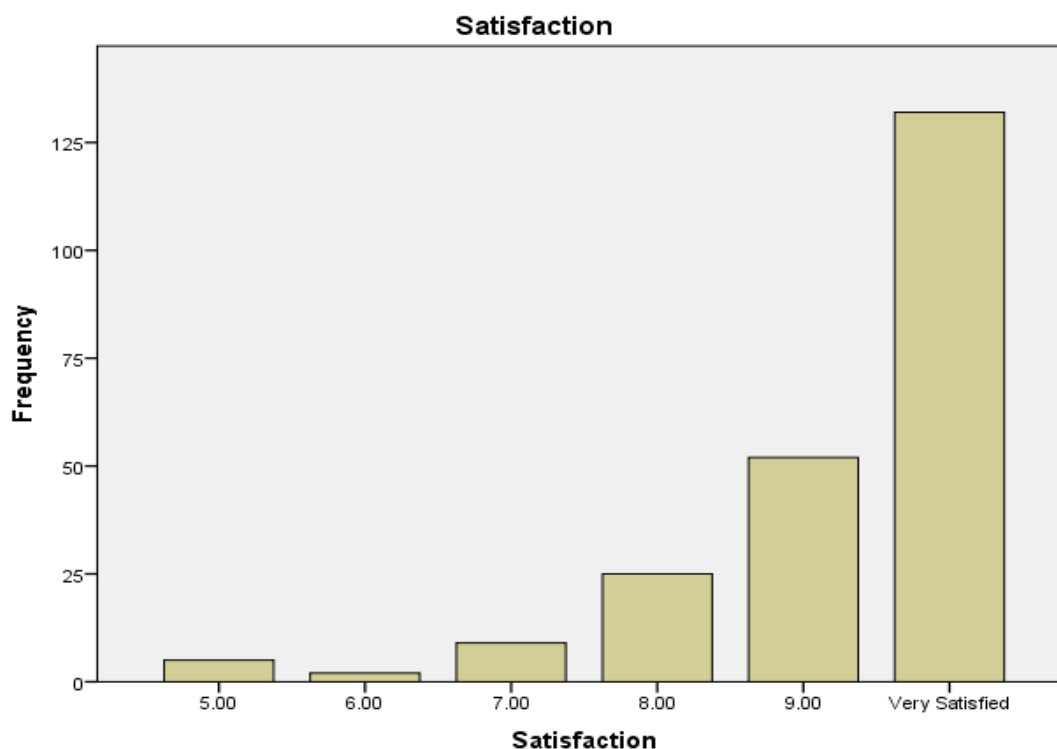
- Four women (1.8%) reported pain over the port site relieved by simple analgesia (Paracetamol +/- Non Steroid Anti-inflammatory Drugs).
- Pelvic pain (n=2; 0.9%). 1 woman was successfully treated with Non-Steroid Anti-inflammatory Drugs (NSAIDs) and the other woman was being worked up for an organic cause.
- One woman (0.4%) reported an offensive vaginal discharge and irregular menses post procedure. Examination revealed a cervical polyp which histology confirmed as benign.
- One woman (0.4%) reported persistent lower backache post procedure. Examination revealed no organic cause for the complaint and she was successfully treated with simple analgesia.
- Three women (1.3%) reported feelings of bloatedness post procedure
- Two women (0.9%) reported ovarian cysts (1 diagnosed intra-operatively) and 1 woman diagnosed post operatively due to abdominal distension. Both women were assessed their base hospitals for cystectomy.
- Two women (0.9%) reported at least 5 kg weight gain post procedure.

Regret was expressed by 2 women in the study population (0.8%). The first woman was 35 year olds. She was married with 4 living children at the time of sterilisation. She subsequently divorced and remarried and regretted the procedure. She and her new husband wanted a child together. The second woman was 33 years old with 2 children. She had divorced her husband post procedure. She had found a new partner and wished she could have a child with her new partner.

Women were requested to rate their overall satisfaction of the procedure presented on a visual analogue scale. The rating of 1 being dissatisfied and 10 being very satisfied was used. The majority of women (n=132; 58.7%) were very satisfied with the procedure with women scoring the procedure 9 (n=52; 23.1%), 8 (n=25; 11.1%), 7 (n=9; 4%), 6 (n=2; 0.9%), 5 (n=5; 2.2%). Of the women who were least satisfied with the procedure (those giving scores of 5 and 6), the cited reasons were:

- Heavy or prolonged menstrual bleeding post procedure (n=4)
- Regret from the procedure due to remarriage (n=1)
- Weight gain and bloatedness (n=1)
- Laparotomy scar (n=1)

Figure 6: Women's satisfaction with the sterilisation procedure



3.11 Comparisons

In women who were HIV positive, the mean CD4 count pre-procedure was 425.5 cells/ μ l with the mean CD4 post procedure being 600.9 cells/ μ l. There was a significant rise in CD4 counts with 67.9% of women being on anti-retroviral drug treatment. When using the t-test the statistical significance was $p=0.02$.

Eleven women (4.9%) reported sexually transmitted infections post sterilisation. STIs were found in 3 of the single women (27.3%) and in 8 of the married women (72.7%). As most

women in the study population were married (n=156), the incidence of STI in this population was 5 in 100 and in single women 4 in 100. There was a non-significant increased risk of STIs among married women versus single women (RR 1.2; 95% CI (0.3–4.3); p=0.8029).

The association between condom use and marital status further adds value to the above mentioned. Thirty nine of 156 (25%) married women used condoms during sexual intercourse while 42 of 64 (65.6%) single women used condoms during sexual intercourse. This association did not however reach statistical significance. The likelihood of single women using condoms during sexual intercourse was significantly higher than married women (likelihood ratio 35.6; p=0.228).

Further analysis of condom use post sterilisation revealed that the majority of HIV positive patients used condoms always during coitus post sterilisation (66.7%). The remaining 21.1% of HIV positive patients used condoms occasionally and 12.3% did not use condoms post sterilisation. Of these HIV positive patients, 33% were married.

CHAPTER 4

DISCUSSION AND INTERPRETATION OF THE FINDINGS

4.1 Introduction

In this chapter, we address the six objectives and the purpose of the study as outlined in chapter two. The analysis of the data from the previous chapter is discussed and interpreted with reference to the literature review and similar research conducted locally and internationally. The discussion focuses on the reproductive health, women's use of the health services and overall satisfaction following interval laparoscopic sterilisation of women at King Dinuzulu Hospital Complex in Durban, South Africa.

Unintended pregnancy jeopardizes the lives and health of women and their families globally. The availability and accessibility of contraceptive services are key tools in the prevention of unintended pregnancy. Tubal ligation is an effective, safe and accessible contraceptive method and serves as an invaluable tool in trying to solve this global problem.

In South Africa, female sterilisation accounts for up to 14% of contraceptive use among sexually active women (South African Demographic Health Survey, 2003). This procedure is offered free of charge to all women in the public health system. In Durban, South Africa, King Dinuzulu Hospital (formerly King George V Hospital) remains the primary referral center for interval laparoscopic sterilisation.

This study aimed to assess the reproductive health and patient satisfaction following interval sterilisation in Durban. The information gathered from this research will not only assist local health care providers to counsel their patients who choose sterilisation as their method of contraception better but also serves as an audit of current practice and allows for improvements in service delivery. The study has identified issues in reproductive health of women undergoing sterilisation and has attempted to recommend strategies to improve women's reproductive health and satisfaction post sterilisation. In this research study, we have also compared our study findings with previous studies and publications and acknowledge that the findings of our study will contribute to current literature and promote further research in this field.

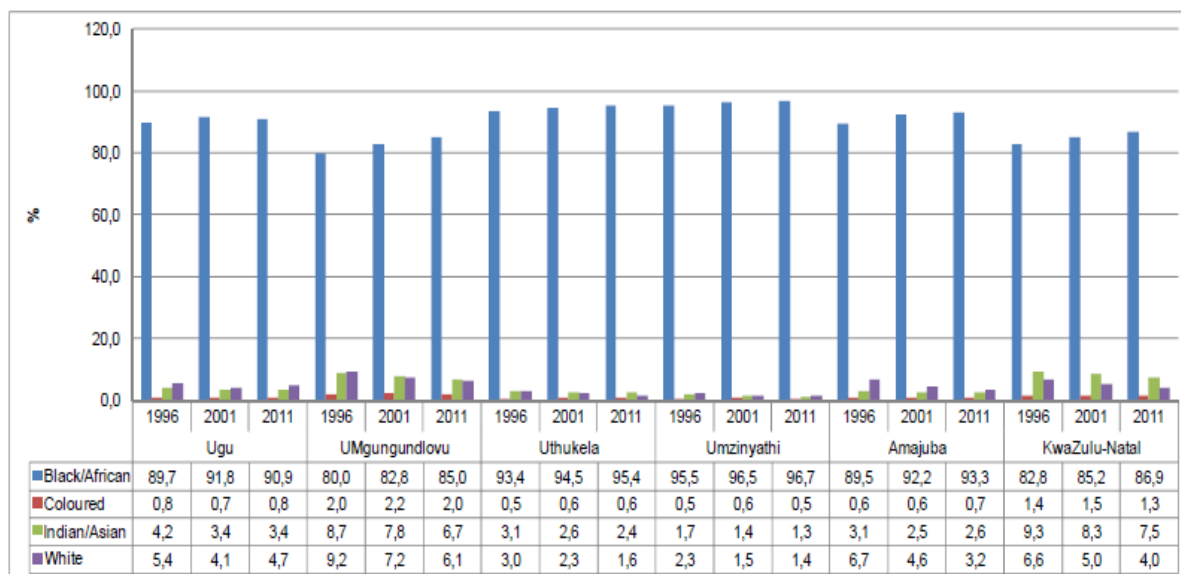
4.2 Discussion and interpretation of the findings

Objective 1: To determine the demographic profile of women having interval sterilisation at King Dinuzulu Hospital Complex.

The majority of the study population consisted of Black women (60%) with the remaining women being Indian (35.6%), White (8%) and Coloured (2.7%). This profile is similar to a previous retrospective study in the same setting with the study population of African women being greater than Asian women (67.56% compared to 32.44%) (Green-Thompson et al., 1993). The racial demographic profile of KwaZulu-Natal, as by the Census 2011 Municipal report KwaZulu-Natal, illustrated that the population of KwaZulu-Natal is predominately African/Black (86.9%) with the remaining groups representing the minority (Coloured: 1.3%, Indian: 7.5% and White: 4%) (**Figure 7**).

Our study population illustrates that the majority of our cohort was African/Black women however the figures illustrate an under-representation of this population group in comparison to population statistics in the province.

Figure 7: Distribution of population by population group and district municipality - 1996, 2001 and 2011. KwaZulu-Natal



(Census 2011 Municipal report KwaZulu-Natal)

This South African demographic profile differs from data from the United States of America with the population group in the CREST study being predominately white (65.8%) and just 28.5 % of patients being of Black race (Costello et al., 2002).

The mean age of women was 35 years. These results are similar to previous data in our setting with a mean age of 34.5 years in African women (Green-Thompson et al., 1993). This age is

moderately higher than the national median age of sterilisation which is 32 years of age in South Africa (South African Demographic Health Survey, 2003). This mean age of sterilisation appears higher compared to the CREST study which showed that 75% of women were 35 years or younger (Costello et al., 2002). Our study thus demonstrates that women are choosing sterilisation at an older age. Probable reasons would include career and delayed child bearing, accessibility to other contraceptive methods and adequate counselling of women pre-procedure to avoid regret in the future. Age less than 30 years at sterilisation is a single most important predictor of regret. Overall, the literature suggests that younger women are more likely to regret their decision and to request information about sterilisation reversal. Up to 20.3% of women aged 30 years or younger at the time of sterilisation regret their decision versus 5.9% of women older than 30 years (Curtis et al., 2006). In our study, 0.8 % of the study population expressed regret following sterilisation. The mean age of these women was 34 years and reason for regret being a change in partners.

The majority of women were married 69.3% versus 30.7% unmarried patients. The mean husband's age was 39 years. All women were parous with the majority of women having at least 2 or more children (99.6%). The mean age of the youngest child was 3 years. Green-Thompson et al (1993) found the mean parity of 2.96 and 5 (Asian and African women respectively) in this setting. Similarly, populations from the CREST study revealed the majority of women being married (63.9%) and having children (93.1%) (Costello et al., 2002). This illustrates that women who are in stable relationships with children may choose sterilisation as their contraceptive method.

The mean BMI of women was 33.3 kg/m² (obese). Obesity has been previously recognised as a risk factor for laparoscopy but there were no failed or unsuccessful procedures in this study group. One woman (0.4%) in the population group was morbidly obese and the laparoscopic procedure was converted to laparotomy due to difficulty of procedure and suspected broad ligament bleed. This study was based in a training hospital, with registrars performing the procedure under supervision. Although overall laparoscopy complications rates were low, data from our training facility may differ from international studies where laparoscopy is performed by consultant specialists. Literature suggests no differences in complications rates during laparoscopic tubal ligation among obese versus non obese women. Singh et al (1996) performed a retrospective analysis of interval laparoscopic tubal sterilisation in 147 obese women and compared their findings to 101 non-obese women. Their results revealed no overall differences in operating times or estimated blood loss, and no woman in either group had a complication. They showed that laparoscopic tubal sterilisation was safe in obese women.

The majority of this study population received secondary and post-secondary education, however, only 46.7% were employed and 53.3% were unemployed. Most women were of low socio-economic status earning < R5000 a month (48.9%). This illustrates our population group having received formal education but not being employed with low socio-economic status.

The majority of the study population was well with no significant co-morbidities (84.9%). Of the total population, 20.9% had previous abdominal surgical procedures. Among these women, no procedures were unsuccessful or required conversion to laparotomy.

Objective 2: To determine reasons women choose sterilisation as a contraceptive method

A total of 337 women underwent tubal sterilisation at King Dinuzulu Hospital (formerly King George V Hospital) over a nine month period. This is a substantial decrease in procedures conducted in the same setting from a case series between 1989 to 1991 (over 5360 procedures performed over this 3 year period) (Green-Thompson et al., 1993). This illustrates that women are choosing interval sterilisation less frequently than in the past with a 70% decline in its use from the previous case series. This may be the result of less contraceptive use by women in this setting, more availability and usage of other contraceptive methods or lack of referral of women for interval sterilisation.

The majority of our cohort, 66.2% of the study population, was previously using injectable contraception at the time of sterilisation. This illustrates the popular use of injectable contraceptives in the country as evidenced by South African statistics of this method being used by up to 56% of sexually active women (South African Demographic Health Survey, 2003).

Of this study cohort, only 15.5% of women used dual contraception [barrier + oral contraception (2.2%) and barrier + injectable contraception (13.3%)] pre-sterilisation. Of particular importance is that 60.9% of women did not use condoms pre-procedure and 62.7% post procedure. This low rate of condom use is disappointing. As encouraged in the National Contraception Clinical Guidelines 2012 of South Africa, condom use post sterilisation should be emphasised by health professionals to women and they should be made aware that sterilisation offers no protection from HIV and STIs.

The principal reason for tubal ligation expressed by the women was that their families were complete.

Objective 3: To assess overall satisfaction one year post sterilisation procedure

The majority of women were highly satisfied with the sterilisation procedure (97%). The remaining women stated their dissatisfaction due to bleeding abnormalities, regret following the procedure, weight gain and surgical scar.

This investigation clearly shows that the risk of complications following interval sterilisation is low. The results are similar to complication rates reported in the literature, these being less than 1% with interval timing (Bartz & Greenburg, 2008). Huber et al (2007) reported major complications in women undergoing laparoscopic sterilisation being up to 1.7%. All procedures in this study were successful with few minor complications noted. No anaesthetic related complications or direct injuries to surrounding structures were reported in this series.

Only 0.4% (1 woman) required conversion to laparotomy due to bleeding. Similarly, Green-Thompson et al (1993) showed low immediate complications rates in their study in the same setting. They noted a rate of conversion to laparotomy for haemorrhage of 0.37 per 1000 laparoscopies and the incidence of haemorrhage being 1.12 per 1000 laparoscopies. No organ or bowel injury was reported in this series. As our case series was much smaller than this series and over a narrower time frame, the rate of 4 in 1000 procedures is higher than the previously noted (0.37 per 1000 procedures). Our data are, however, comparable with case

series from the United States of America as minor or major bleeding accounts for 0.6–1% of their cases (Bartz & Greenburg, 2008).

The procedure which required conversion to laparotomy was performed on a morbidly obese woman. The procedure was converted to laparotomy due to difficulty of the procedure and suspected broad ligament bleed. Chi et al (1985) showed that the incidence of surgical difficulties, technical failure rates and surgical time is higher for obese women than for non-obese women. However, none of their surgical difficulties or technical failures led to serious consequences. Literature has shown no overall differences in complication rates among obese versus non obese patients following laparoscopic sterilisation. This has been reported by Singh et al (1996). No differences in complications were noted between obese and non-obese women.

In this research study, 3 women (1.3%) had uterine/cervical perforations during laparoscopy. In a previous case study at King Dinuzulu Hospital (formerly King George V Hospital), the rate of uterine perforation was at 0.37 per 1000 procedures, however, this case series included more women over a 3 year period (Green-Thompson et al., 1993). Mehta et al (1981) reported accidental uterine perforation of 1.96% during laparoscopic sterilisation of which all cases were managed conservatively. The incidence of uterine perforations during gynaecological surgery is estimated at 1.6% with higher incidences reported during surgical termination of pregnancies and hysteroscopic procedures (Shakir & Diab, 2013). Perforations are uterine and cervical and may be surgical and surgeon dependent. As in this case series, perforations were as a result of a uterine manipulator (5mm in diameter) with no active bleeding noted.

Conservative management with antibiotics, observation and explanation was successfully used to treat these women.

Other postoperative complaints included urinary tract infection, port site hernia and wound sepsis (incidence 0.4% each). This is comparable to reported incidence of infection of 1.12 per 1000 laparoscopies (Green-Thompson et al., 1993). This confirms laparoscopic sterilisation to be safe with a low procedure related morbidity and mortality. Huber et al (2007) found an incidence of urinary tract infections of 0.04% and wound dehiscence of 0.01% following interval sterilisation with a total minor complication rate of 0.26%.

A proportion of women also reported non-specific lower abdominal pain (1.8%) and weight gain post procedure (0.9%) Both somatic and psychosocial problems post sterilisation have been observed in previous studies (Hendrix et al., 1999; Lutala et al., 2011). While women may report some peace of mind post procedure due to the removal of fear of pregnancy, reports have confirmed other women experience a range of complications stemming from their perceived body image, psyche, surroundings, and their relationship with healthcare providers (Lutala et al., 2011).

Consistent with previous studies (Costello et al., 2002; Cooper et al., 1982; Bean et al., 1980; Richards et al., 1991; Smith et al., 1994), the majority of the women reported no change in sexual interest and pleasure after interval tubal sterilisation (58%). Of those women who did report change, most women reported more sexual interest and pleasure than less sexual interest and pleasure (27.1% versus 14.2%; almost 2x likely). This is similar to findings of previous studies which support that women report positive change substantially more than negative

change post sterilisation (Costello et al., 2002; Cooper et al., 1982). This is contrary to findings of a Turkish study by Gulum et al (2010) and a Danish study by Kjer et al (1990), who demonstrated negative effects of sterilisation on sexual function. Our study cohort also reported regular sexual activity with the majority of women (53.3%) being frequently sexually active (> 1x week). This positive effect of sterilisation on sexual activity, interest and pleasure may be attributed to the removal of fear of pregnancy as well as removal of adverse side effects from previously used contraceptives.

Objective 4: To determine the prevalence of and reasons for regret post sterilisation

Regret rates following sterilisation vary from 0.1–50%. (Curtis et al., 2006; de Melo et al., 2005; Bartz & Greenburg, 2008). This variation occurs from different geographic population groups, different countries, age categories and life circumstances of women as well as time periods between delivery and tubal ligation. Although women after tubal sterilisation may experience regret and feelings of sorrow, pain, affliction, hurt, dissatisfaction, and anxiety, some authors have considered “true regret” when women desire and request reversal of tubal sterilisation (de Melo et al., 2005).

Literature has shown an association between regret after tubal sterilisation and the death of children, a new partner or marriage, changes in socioeconomic status or life circumstance, age at the time of sterilisation, lack of information on sterilisation, and the time sterilisation is performed in relation to delivery (Curtis et al., 2006; de Melo et al., 2005; Bartz & Greenburg, 2008).

Regret was expressed by 2 women in this study population (0.8%). The first woman was 35 years old. She was married with 4 living children at the time of sterilisation. She subsequently divorced and remarried and regretted the procedure as she and her new husband wanted a child together. The second woman was 33 years old with 2 children. She had divorced her husband post procedure. She had found a new partner post procedure and wished she could have a child with her new partner. Both women had new partners post sterilisation and desired children with their new partner. Neither of these women, however, requested sterilisation reversal.

Over a narrow time frame, this rate of regret is lower than found in the literature which reports regret rates of up to 12.7% (Bartz & Greenburg, 2008). None of the women were less than 30 years of age. This factor appears to be the strongest predictor of regret with regret being expressed by up to 20.3% of these women (Curtis et al., 2006). The research finding is supported by further literature which has shown that women who changed partners after tubal sterilisation experience regret by up to 40 times more compared to those who had not changed partners (Hardy et al., 1996; de Melo et al., 2005).

This has implications for this study population as selection and counselling of women on the risk of regret is essential. Women in unstable relationships, divorced or single must be aware of the high risk of regret if they do find new partners and should be counselled extensively pre-procedure.

Objective 5. To determine whether sterilisation influences the prevalence of gynaecological disorders in women e.g. menstrual abnormalities, sexually transmitted infections and pelvic inflammatory disease

The South African National Cervical Screening Programme states that every woman should be offered 3 Pap smears in her lifetime starting at age 30 years. These Pap smears are performed at 10 year intervals if normal and repeated if the smear is inadequate. However, women with any gynaecological complaint must have a Pap smear performed as part of their gynaecological examination irrespective of their screening history. This 10 year interval screening results in a reduction of 64-70% of cervical cancer. More frequent screening has been shown to have greater reductions in cervical cancer incidence with reduction of up to 84% with 5-year intervals and 94% with 2-year interval screening. A major concern with cytology is a high false-negative rate of 15-30%. International screening programmes involve more frequent screening as a result of this dilemma. The United Kingdom policy offers screening every 3-5 years if normal and United States screening is 3 yearly if smears are normal (Adam et al., 2013).

Concern exists with Pap smears and HIV positive women. It has been shown that abnormal smears are increased 10 fold in HIV positive women (Maiman, 1998). Progression and regression of Pap smear abnormalities have also been associated with the level of immune suppression and plasma viremia, as reflected by the CD4 count and HIV viral load (Massad et al., 2001; Schuman et al., 2003). It is recommended that women with HIV infection have more frequent screening with cervical cytology. This involves screening twice in the first year after

diagnosis of HIV and, if normal, annually thereafter (Centres for Disease Control and Prevention (CDC), 2009).

In this study population, the majority of women had normal Pap smears pre-sterilisation procedure (91.6%). Among the remaining 8.4% of women; 0.9% had LSIL, 1.8% HSIL and 0.4% ASCUS on Pap smear. Of the women with HSIL on Pap smear, 75% were HIV positive and 25% were HIV negative.

Post procedure, of those women with normal Pap smears pre-procedure; 12.6% had normal repeat smears and 1.9% LSIL and 84.9% had no indication for a repeat smear at their one year follow up. This finding is comparably lower than demonstrated by Adam et al (2013) who showed the incidence of cytological abnormalities was 6.48% yearly in women with a previously normal Pap smear and 11.71% yearly in women with an inadequate smear result. They further showed that the incidence of HSILs was low (<0.5%) in the first 2 years after a normal or inadequate Pap smear, even in a setting with a high prevalence of cytological abnormalities. Of our cohort of women with LSIL, 75% were HIV positive and 25% HIV negative. Among women with LSIL on pre-sterilisation smears, 50% had HSIL on repeat smear and 50% persistent LSIL. Both groups of women were HIV positive and referred for colposcopy. Denny et al (2010) demonstrated that 27.3 % of women referred for colposcopy had LSIL, and most of these women were HIV positive. They also demonstrated that 35% of women had LSIL on Pap smear at entry and 4% of them progressed to HSIL over a 36-month follow-up period. In our study, 50% of women with LSIL on pre-sterilisation smears had HSIL on repeat smear and were referred for colposcopy.

Of the women with no pre-sterilisation Pap smear, 75% had normal Pap smears and 25% HSIL (all were HIV positive). The one woman with ASCUS on pre-sterilisation Pap smear had LSIL on repeat smear and was subsequently referred for colposcopy. She was HIV negative.

Overall the majority of the women with cytological abnormalities requiring colposcopy were HIV positive (75%). This is comparable to the study by Denny et al (2010) who found that up to 70.2% of women referred to colposcopy for HSIL were HIV positive.

It can then be concluded from our research study that cervical cancer screening efforts must be scaled up for all HIV infected women with proper referral criteria for colposcopy as required. We also noted cervical abnormalities in HIV negative women. There was, however, no significant progression of these lesions during the time period. Hence screening and appropriate referral in both HIV positive and negative women is mandatory.

Sexually transmitted infections (STIs) are infections spread by vaginal, oral or anal intercourse. Most STIs are asymptomatic but carry a risk of transmission. Symptoms and signs include vaginal discharge, genital warts and pelvic pain. The causative agents include bacteria, viruses or parasites. Bacterial infections include chlamydia, gonorrhoea, and syphilis. Viral STIs include genital herpes, HIV and genital warts. Parasitic STIs include trichomonas vaginalis. STI diagnostic tests are easily available in the developed world, but in developing countries are often not available due to the lack of resources and funding (Morrison et al., 2009). In this study population, STIs were categorised by symptoms experienced by women including a vaginal discharge, genital ulcers, warts or pelvic

inflammatory disease. Due to the lack of diagnostic tests available, women in this investigation study cohort were treated syndromically according to their symptoms.

An estimated 340 million new STIs occur annually worldwide. This STI burden falls disproportionately on developing countries. Therefore, a priority in developing countries is to reduce this burden and treat infection in order to reduce the long term sequelae of untreated infection. These sequelae include pelvic inflammatory disease, chronic pelvic pain, ectopic pregnancy and increased risk of HIV transmission and acquisition. The use of barrier contraception is paramount to prevent both STI and HIV risk (Morrison et al., 2009).

In this study, it was found that the risk of STIs is not directly affected by interval tubal sterilisation but is rather a reflection of sexual behaviour prior to sterilisation. A history of a prior STI in women undergoing tubal sterilisation conferred a 6 times risk of a repeat STI after sterilisation compared to women with no history of infection. In this subset of women, condom nonuse post sterilisation, increase in sexual partners and sexual activity, interest and pleasure was found. There was no statistically significant risk of HIV acquisition post sterilisation however an increase in STIs and HIV risk behaviour was found in women with a past history of STIs. Similarly, low rates of condom use and increased risk of STIs in high risk groups post sterilisation is supported by previous literature (Pruitt et al., 2010; Armstrong et al., 1992). Similar to Pruitt et al (2010), women in our study cohort were unlikely to use condoms if they were HIV negative or reported being married or having only one sexual partner post sterilisation. Previous literature found that women with a past history of STIs are more likely to plan condom use post sterilisation (Sangi-Haghpeykar et al., 1998) which differs from our study findings. In women with a past history of STIs, interventions to increase

condom use post sterilisation are needed to reduce both the risk of subsequent infections and HIV. Education of both women and partners and offering ample free supplies may alleviate this problem. Sweat et al (2012), found condom social marketing (condom branding, media-based marketing campaign and targeted population based campaigns) may double the odds of condom use. This may be an effective strategy in high risk populations to advocate condom use and increase its usage.

Reassuring findings from our study was that the majority of HIV positive women used condoms post sterilisation (66.7%) which may reflect women's use of the health system and counselling at HIV clinics which needs to be emphasised more and extended to all health facilities for both HIV positive and negative women.

In women with no prior history of STIs, we found no risk of infection post sterilisation. This was due to older age of women, monogamous faithful relationships, no change in partners post sterilisation and no change in condom use post sterilisation. Furthermore, consistent with previous studies (Costello et al., 2002), the majority of women reported no change in sexual interest and pleasure after interval tubal sterilisation (58%).

In our study cohort, we found an increased risk of STIs post sterilisation in women who had previously sought medical attention for a STI pre-sterilisation and amongst married women. The association between condom use and marital status further adds value to the above statement. Thirty nine of 156 (25%) married women used condoms during sexual intercourse while 42 of 64 (65.6%) single women used condoms during sexual intercourse. The likelihood of single women using condoms during sexual intercourse was higher than married women

(likelihood ratio 35.56; $p=0.228$). The majority of HIV positive women always used condoms during coitus post sterilisation (66.7%). The remaining 21.1% of HIV positive women used condoms occasionally and 12.3% did not use condoms post sterilisation. Of these HIV positive women, 33% were married.

Studies in developed settings have found low levels of understanding among patients on the symptoms and consequences of sexually transmitted infections. Condom use remains low within marriages (or between regular sex partners) in both developed and developing countries. This is despite the substantial STI /HIV risk within many primary relationships (Morrison et al., 2009).

Data on the relationship between STIs, HIV and marital status appears to differ as Rehle et al (2007) demonstrated HIV positive patients were more likely to be single or widowed than being married. While Bogaerts et al (2001) demonstrated a high prevalence of STI and herpes simplex virus in up to 23% of married women in a community in India.

In women not on hormonal contraception pre-sterilisation, we found no change in menstrual patterns post sterilisation. This is supported by Wilcox et al (1992), who found that menstrual abnormalities (dysmenorrhoea, heavy bleeding) are more common 5 years post sterilisation than within the first 2 years post procedure. Menstrual abnormalities in our study cohort were significant in women previously using hormonal contraception. There was an increase in duration and amount of menstrual bleeding and dysmenorrhoea post sterilisation among previous COC users. Among previous injectable contraceptive users, abnormal uterine bleeding and dysmenorrhoea was found in our study cohort. Our study findings suggest that menstrual changes post sterilisation are due to recent discontinuation of hormonal contraception rather than the sterilisation procedure itself. Literature further supports that sterilisation has no direct influence on menstrual patterns (Harlow et al., 2002; Westhoff, 2000; Rulin et al., 1993). Accounting for prior contraceptive use, changes in menses post sterilisation have been shown to result in the return of pre-contraceptive use characteristics including dysmenorrhoea, heavy menstrual flow and cycle irregularity (Westhoff, 2000).

Previously, it has been shown that women utilising injectable contraception have re-establishment of menstrual cycles up to 6-8 months following the last injection (Westhoff, 2000). In our study group, women subjectively reported changes in menses due to prolonged amenorrhoea (women on injectable contraception) and due to previous COC use.

Abnormal uterine bleeding was a common complaint expressed by women post procedure. Among our cohort, 8.4% sought medical attention from their local clinics, general practitioners or regional hospitals for this complaint. None of these women required admission

and all women were treated medically (tranexamic acid with or without haematinics or the combined oral contraceptive pill).

Objective 6: To assess if women are at greater risk of HIV acquisition post tubal ligation

To our knowledge, no study has previously observed if sterilisation influences the risk of HIV transmission and the impact on CD4 counts. This study demonstrated no significant risk of HIV acquisition post sterilisation. The relative risk of HIV acquisition post sterilisation was 0.006 ($p=1$). Although HIV acquisition was not affected by sterilisation in this short term follow up, risk behaviour was increased post sterilisation among women with a past history of STIs. Armstrong et al (1992) compared HIV risk behaviours of sterilised and non-sterilised women. They found that sterilised women were more sexually active and tended not to use condoms. In their study, only 12% of participants used condoms after sterilisation. They showed no statistical differences of HIV risk related to multiple sex partners or to prostitution. There was an improvement in condom use among sterilised women with their follow up and attendance of family clinics and gynaecological services. The increase in HIV risk behaviour in women with a past history of STIs in our study can be improved by identifying and screening these women for HIV and STIs post procedure and offering continued family service counselling and condom usage post sterilisation.

The South African National HIV management guidelines of 2014 states that all adults should be offered HIV counselling and testing whenever an opportunity arises, and this should be repeated annually, depending on the risk of HIV.

The role of CD4 counts in managing patients who test HIV positive is:

- At initial diagnosis and annually thereafter
- To identify eligibility for Cotrimoxazole (CD4 <200 cells/ μ l)
- To identify eligibility for Cryptococcal antigen test screening (CD4 <100 cells/ μ l)

(Department of Health, South Africa, 2014)

CD4 counts are used for the monitoring of therapeutic response to ART. For most women on therapy, an adequate response is defined as an increase in CD4 count in the range of 50-150 cells/ μ l during the first year of ART. Within the first 3 months of treatment, there is an accelerated rise in CD4 count with subsequent increases approximately 50 to 100 cells/ μ l per year (Kaufmann et al., 2003). In our study population, in women who were HIV positive, there was a statistically significant increase in CD4 count post procedure (pre-procedure mean of 425.5 cells/ μ l to post procedure mean of 600.9 cells/ μ l; $p=0.02$). This reflects both the effectiveness of anti-retroviral drugs and possibly indirectly reflects the compliance of our study population to their treatment regimens and their follow up appointments at health facilities.

CHAPTER 5

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Summary

A prospective study was conducted to determine reproductive health, women's use of the health services and overall satisfaction following interval laparoscopic sterilisation at King Dinuzulu Hospital Complex (formerly known as King George V Hospital), in the Province of KwaZulu-Natal, South Africa. The research questions/objectives provided direction to the investigation under study. The research study covered five logical chapters which systematically and methodologically presented the research design and its findings. The following summary of the chapters gives the reader an in-depth insight into the study:

Chapter 1: Orientation and Literature Review

The first chapter provides a background to the research study. It commences by focusing on the introductory background to the problem investigated by reviewing both international and local literature and related research conducted followed by the legislative frameworks on health practices in South Africa.

Chapter 2: Research Design and Methodology

This chapter outlines the significance of the study. In other words the foundation of the study is laid out clearly. It highlights the purpose of the study, the research questions, the methodology and the statistical analysis.

Chapter 3: Analysis of the data collected and the findings

Chapter 3 provides a detailed analysis of data collected through various instruments such as questionnaires and documents. Both quantitative and qualitative research methods were employed in the study. Both figures and tables are designed to illustrate the research findings based on the data collected. The detailed interpretation and analysis are directly linked to the research questions and purpose of the study as encapsulated in chapter two.

Chapter 4: Discussion and Interpretation of the findings

In this chapter, the six objectives and the purpose of the study as outlined in chapter two are answered. In this chapter, the analysis of the data in the previous chapter are discussed and interpreted with reference to the literature review and the similar research conducted internationally. The discussion also focuses on the reproductive health, women's use of the health services and overall satisfaction following interval laparoscopic sterilisation of women at King Dinuzulu Hospital Complex in Durban, South Africa.

Chapter 5: Summary, Conclusion and Recommendations

This final chapter highlights the important contribution of this study to the reproductive health of the women undergoing interval laparoscopic sterilisation. The chapter further outlines how the underpinning research questions, purpose and objectives of the study were addressed.

Secondly the chapter makes concluding remarks on the findings and their importance to the overall health services and welfare of women. The chapter concludes by making some recommendations which are intended to improve the quality of health services of women who have opted to undergo sterilisation.

5.2 Conclusion

Interval tubal sterilisation is a safe and effective procedure in Durban, South Africa. This study not only serves as an audit of current practise but will assist local health care providers to better counsel women who choose sterilisation as their method of contraception. This would allow improvements of service delivery.

This study found a low rate of complications from interval laparoscopic sterilisation. This finding is relevant in counselling women who fear the operative procedure due to surgical risks. This would also serve as a key aspect in alleviating women's concerns pre-procedure. The study also found that complications rates are similar in both obese and non-obese women. This serves as an important aspect of counselling women who are obese who may fear the procedure due to misconceptions of an increase in failure or complications from the procedure.

The risk of STIs in women undergoing tubal ligation was increased only in those women with a past history of infection. These findings have highlighted the importance of identification of women with a past history of sexually transmitted infections to be counselled and screened for infection post procedure. These women need to be counselled on correct and consistent use of condoms post sterilisation. Education of both women and partner in condom use and the non-

protection of sterilisation in acquisition of HIV and STIs is crucial. Social marketing may be an effective strategy in South Africa to advocate condom use and increase its usage. The increase in HIV risk behaviour in women with a past history of STIs may further be improved by offering continued family service counselling and increasing more frequent follow up for these women post sterilisation procedure.

In women previously using hormonal contraception, menstrual abnormalities are more likely post sterilisation. These symptoms were successfully treated conservatively or medically with no serious consequences. This is important in counselling women pre-procedure, particularly those women on hormonal contraceptive methods. They should be made aware that menstrual changes will occur (similar to their pre-contraceptive patterns). They should also be reassured that symptoms are minor and often require minimal or no treatment at all.

The rate of regret was low post sterilisation. Regret was only expressed by women who had a change of partners. Women in unstable relationships, divorced or single must be aware of the high risk of regret if they do find new partners and counselled extensively pre-procedure.

5.3. Recommendations

A substantial decline was noted in sterilisation procedures from a previous report in this setting. Our study recommends health practitioners to offer extensive counselling to all women who present to contraceptive services about sterilisation as a contraceptive method. Furthermore, women should be empowered with the knowledge that sterilisation is not only a simple, accessible procedure but also carries a low risk of both morbidity and mortality and has minimal effect on general and reproductive health.

Our study found an increased risk of STIs post sterilisation in those women with a previous history of STIs pre-sterilisation. These findings have highlighted the importance of identification of women with a past history of STIs to be counselled and screened for infection post procedure.

A significant rate of Pap smear abnormalities in this study population was noted. Thus, we recommend that cervical cancer screening efforts must be scaled up for all HIV infected women with proper referral for colposcopy as required. This research study also found cervical abnormalities in HIV negative women however there was no significant progression of these lesions during the time period. Hence screening and appropriate referral for both HIV positive and negative women is mandatory.

Further research recommendations

Further research on factors responsible for the decline in use of sterilisation in South Africa is needed. Further research on the effect of HIV on sterilisation and risk behaviour is needed. Large trials examining risk behaviours in HIV positive and negative women post sterilisation is recommended.

REFERENCES

Adam Y, McIntyre JA, de Bruyn G. Incidence of cytological abnormalities within 24 months of a normal cervical smear in Soweto, South Africa. *S Afr Med J*. 2013; 103(1):34-39.

Armstrong KA, Samost L, Tavis DR. HIV-risk behaviours of sterilized and non-sterilized women in drug-treatment programmes -- Philadelphia, 1989-1991. *Morbidity and Mortality weekly report*. 1992; 41(9):149-52.

Bartz D, Greenburg J. Sterilisation in the United States. *Rev Obstet Gynecol*. 2008; 1:23-32

Bean FD, Clark MP, South S, Swicegood G, Williams D. Changes in sexual desire after voluntary sterilisation. *Soc Biol*. 1980; 27:186–93.

Bogaerts J, Ahmed J, Akhter N, et al. Sexually transmitted infections among married women in Dhaka, Bangladesh: unexpected high prevalence of herpes simplex type 2 infection. *Sex Transm Inf*. 2001; **77**:114–119.

Census 2011 Municipal report KwaZulu-Natal. Statistics South Africa.

http://www.statssa.gov.za/census/census_2011/census_products/KZN_Municipal_Report.pdf.

[Accessed 1 February 2015].

Centres for Disease Control and Prevention (CDC). Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. 2009; 58:1-207.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5804a1.htm>. [Accessed 19 April 2015].

Chi I, Potts M, Wilkens L. Interval tubal sterilisation in obese women: an assessment of risks. *Am J Obstet Gynecol*. 1985; 152(3):292-7.

Cooper P, Gath D, Rose N, Fieldsend R. Psychological sequelae to elective sterilisation: A prospective study. *Br Med J*. 1982; 284:461-4.

Costello C, Hillis S, Marchbanks P, Jamieson D, and Peterson H. The Effect of Interval Tubal Sterilisation on Sexual Interest and Pleasure. *Obstetrics and Gynaecology*. 2002; 100(3):511-517.

Crede S, Hoke T, Constant D, Green MS, Moodley J, Harries J. Factors impacting knowledge and use of long acting and permanent contraceptive methods by postpartum HIV positive and negative women in Cape Town, South Africa: a cross-sectional study. *Obstet Gynecol*. 1995; 85:675-9.

Abstracts of publications from the Collaborative Review of Sterilization (CREST).

<https://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/crest.pdf>. [Accessed 19 April 2015].

Curtis KM, Mohllajee A, Peterson HB. Regret following female sterilisation at a young age: a systematic review. *Contraception*. 2006; 73:205–210.

deMelo Machado K, Ludermit AB, da Costa AM. Changes in family structure and regret following tubal sterilisation. *Saúde Pública, Rio de Janeiro*. 2005; 21(6):1768-1777.

Denny L, Batra P, Kuhn L. Utilisation and outcomes of cervical cancer prevention services among HIV-infected women in Cape Town. *South African Medical Journal*. 2010; 100(1).

Department of Health, Republic of South Africa (DOH SA). National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults. 24 December 2014.
www.kznhealth.gov.za/family/HIV-Guidelines-Jan2015.pdf. [Accessed 12 September 2015].

Devito JR, Robinson WR. Gynecological surgical outcomes among asymptomatic human immunodeficiency virus-infected women and uninfected control subjects. *J La State Med Soc*. 1995; 147(3):109-12.

Green-Thompson RW, Popis M, Cairncross NWA. Outpatient Laparoscopic Tubal Sterilisation under Local Anaesthesia. *O+G Forum*. 1993:4-13.

Gulum M, Yeni E, Sahin MA, Savas M, Ciftci H. Sexual functions and quality of life in women with tubal sterilisation. *International Journal of Impotence Research*. 2010; 22:267-271.

Gupta U, Kumar P, Bansal A, Sood M. Changing trends in the demographic profile and attitudes of female sterilisation acceptors. *The Journal of Family Welfare*. 1996; 42(3):27-31.

Hankinson SE, Hunter DJ, Colditz GA, et al. Tubal ligation, hysterectomy, and risk of ovarian cancer: a prospective study. *JAMA*. 1993; 270:2813-2818.

Hardy E, Bahamondes L, Osis MT, Costa RG, Fatindes A. Risk Factors for Tubal Sterilisation Regret, Detectable Before Surgery. *Contraception*. 1996; 54:159-162.

Harlow B, Missmer SA, Cramer DW, Barbieri RL. Does tubal sterilization influence the subsequent risk of menorrhagia or dysmenorrhea? *Fertility and Sterility*. 2002; 77(4):754-760.

Hendrix NW, Chauhan SP, Morrison JC. Sterilisation and its consequences. *Obstet Gynecol Surv*. 1999; 54:766-777.

Henderson L, Escandon I. Characteristics of Female Sterilisation users. In *Contraceptive sterilisation: Global Issues and trends*. Engender Health. 2002: Chapter 3: 65-85.

https://www.engenderhealth.org/files/pubs/family-planning/factbook_contents.pdf. [Accessed 12 December 2014].

Hillis SD, Marchbanks PA, Taylor LR, Peterson HB. Higher hysterectomy risk for sterilized than nonsterilized women: findings from the U.S. Collaborative Review of Sterilisation. *Obstet Gynecol*. 1998; 91:241-246.

Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Post sterilisation regret: findings from the United States Collaborative Review of Sterilization. *Obstet Gynecol.* 1999; 93:889-895.

Huber A, Mueller D, Ghezzi F, Cromi A, Dreher E, Raio L. Tubal sterilisation: Complications of laparoscopy and minilaparotomy. *European Journal of Obstetrics & Gynecology and Reproductive Biology.* 2007; 134:105–109.

Kaida A, Laher F, Strathdee SA, et al. Contraceptive Use and Method Preference among Women in Soweto, South Africa: The Influence of Expanding Access to HIV Care and Treatment Services. *Plos One*; 5(11). <http://dx.doi.org/10.1371/journal.pone.0013868>. [Accessed 2 December 2014].

Kaufmann GR, Perrin L, Pantaleo G, et al. CD4 T-lymphocyte recovery in individuals with advanced HIV-1 infection receiving potent antiretroviral therapy for 4 years: the Swiss HIV Cohort Study. *Arch Intern Med.* 2003; 163(18):2187-2195.

Kjer JJ. Sexual adjustment to tubal sterilisation. *Eur J Obstet Gynecol Reprod Biol.* 1990; 35:211–4.

Lawrie TA, Nardin JM, Kulier R, Bouvain M. Techniques for the interruption of tubal patency for female sterilisation. *The Cochrane Library.* 2011; 2. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003034.pub2/full>. [Accessed 2 November 2014].

Lindsay MK, Grant J, Peterson HB, Willis S, Nelson P, Klein L. The impact of knowledge of human immunodeficiency virus serostatus on contraceptive choice and repeat pregnancy. *Obstetrics and Gynaecology*. 1995; 85:675-679.

Lutala PM, Hugo JF, Luhiriri LB. Psychosocial implications of tubal ligation in rural health district. *Reproductive Health*. 2011; 8:38.

MacKenzie IZ, Thompson W, Roseman F, Turner E, Guillebaud J. A prospective cohort study of menstrual symptoms and morbidity over 15 years following laparoscopic Filshie clip sterilisation. *Maturitas*. 2010; 65(4):372-377.

Maiman M. Management of cervical neoplasia in human immunodeficiency virus infected women. *J Natl Cancer Inst Monogr*. 1998; 23:43–49.

Massad L, Ahdieh L, Benning L, et al. Evolution of cervical abnormalities among women with HIV-1: evidence from surveillance cytology in the women's interagency HIV study. *J Acquir Immune Defic Syndr*. 2001; 27(5):432-42.

Mehta PV. Laparoscopic experience with Falope Ring: Experience with 10,100 women in rural camps. *Obstetrics and Gynaecology*. 1981; 57(3):345-350.

Moradan S, Gorbani R. Is Previous Tubal Ligation a Risk Factor for Hysterectomy because of Abnormal Uterine Bleeding? *Oman Medical Journal*. 2012; 27(4):326-328.

Morrison CS, Turner AN, Jones LB. Highly effective contraception and acquisition of HIV and other sexually transmitted infections. *Best Practice & Research Clinical Obstetrics and Gynaecology*. 2009; 23:263–284.

Naidoo S, Wand H, Abbai S, Ramjee G. High prevalence and incidence of sexually transmitted infections among women living in Kwazulu-Natal, South Africa. *AIDS Research and Therapy*. 2014; 11(31):2–7.

National Contraception Clinical Guidelines. Department of Health, Republic of South Africa 2012.http://www.gov.za/sites/www.gov.za/files/Contraception_Clinical_Guidelines_28jan2013-2.pdf. [Accessed 1 January 2015].

Nichols HB, Baird D, DeRoo LA, Kissling GA, Sandler DP. Tubal ligation in relation to menopausal symptoms and breast cancer risk. *British Journal of Cancer*. 2013; 109:1291–1295.

Ozerkan K, Aydin G, Koc I, Uncu Y, Uncu G. Menstrual pattern following tubal sterilisation. *Med Sci Monit*. 2010; 16(4):197-201.

Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilisation: findings from the U.S. Collaborative Review of Sterilisation. *Am J Obstet Gynecol*. 1996; 174:1161-1170.

Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilisation. *N Engl J Med*. 1997; 336:762-767.

Peterson HB, Jeng G, Folger SG, Hillis SA, Marchbanks PA, Wilcox LS. The risk of menstrual abnormalities after tubal sterilisation. *N Engl J Med*. 2000; 343(23):1681–1687.

Peterson HB, Pollack AE, Warshaw S. Tubal Sterilization. Chapter 23. In: Rock JA, Jones HW, Te Linde RW. *Te Linde's Operative Gynaecology*. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins. 2008: 609–629.

Pokoradi AJ, Iversen L, Hannaford PC. Factors associated with age of onset and type of menopause in a cohort of UK women. *Am J Obstet Gynecol*. 2011; 205(1):1–13.

Pruitt SL, von Sternberg K, Velasquez MM, Mullen PD. Condom Use among Sterilized and Non-sterilized Women in County Jail and Residential Treatment Centers. *Womens Health Issues*. 2010; 20(6):386–393.

Rehle T, Shisana O, Pillay V, Zuma K, Puren A, Parker W. National HIV incidence measures – new insights into the South African epidemic. *South African Medical Journal*. 2007; 97(3):194-199.

Richards JM Jr, Kohler CL, Ryan WG, Jackson JR, Goldenberg RL. Contraceptive female sterilisation in Alabama: A replication of the WHO study. *Contraception*. 1991; 43:325–33.

Rosenfeld BL, Taskin O, Kafkashli A, Rosenfeld ML, Chuong CJ. Sequelae of postpartum sterilisation. In Archives of Gynecology and Obstetrics. 1998; 261(4):183-187.

Rowlands S, Hannaford P. The incidence of sterilisation in the UK. BJOG: an International Journal of Obstetrics and Gynaecology. 2003; 110(9):819–824.

Rulin MC, Davidson AR, Philliber SG, Graves WL, Cushman LF. Long-term effect of tubal sterilisation on menstrual indices and pelvic pain. Obstet Gynecol. 1993; 82(1):118-21.

Sangi-Haghpeykar H, Poindexter A. Planned Condom Use Among Women Undergoing Tubal Sterilisation. Sexually Transmitted Diseases. 1998; 25(7):335–341.

Schuman P, Ohmit SE, Klein RS, et al. Longitudinal study of cervical squamous intraepithelial lesions in human immunodeficiency virus (HIV)-seropositive and at risk HIV-seronegative women. J Infect Dis. 2003; 188(1):128–136.

Shakir F, Diab Y. The perforated uterus. The Obstetrician & Gynaecologist. 2013; 15:256–61.

Singh KB, Huddleston HT, Nandy I. Laparoscopic tubal sterilisation in obese women: experience from a teaching institution. Southern Medical Journal. 1996; 89(1):56–59.

Smith EM, Friedrich E, Pribor EF. Psychosocial consequences of sterilization: A review of the literature and preliminary findings. Comp Psych. 1994; 35(2):157–63.

South African Demographic and Health Survey (SADHS). 2003.

<http://www.gov.za/documents/south-african-demographic-and-health-survey-sadhs>. [Accessed 3 March 2015].

Sweat MD, Denison J, Kennedy C, Tedriwc V, O'Reilly K. Effects of condom social marketing on condom use in developing countries: a systematic review and meta-analysis, 1990–2010. *Bull World Health Organ.* 2012; 90:613–622.

Von Mering R, Merki GS, Keller PJ. Is there a place for tubal ligation in modern contraception. *Gynakol Geburtshifliche Rundsch.* 2003; 43(1):25-30.
<http://www.ncbi.nlm.nih.gov/pubmed/12499754>. [Accessed 2 March 2015].

Westhoff C. Tubal sterilisation—safe and effective. *N Engl J Med.* 2000; 343:1724–6.

Wilcox LS, Martinez – Schnell B, Peterson HB, Ware JH, Hughes JM. Menstrual function after tubal sterilisation. *Am J Epidemiol.* 1992; 135(12):1368-81.

World Health Organisation. http://www.who.int/topics/reproductive_health. [Accessed 12 December 2015].

APPENDIX 1: DATA SHEET: PRE-STERILISATION

Study no:

Demographics

Age Parity Abortions No of living children

Race (1= Black, 2= Indian, 3= White, 4= Coloured)

BMI Haemoglobin (g/dl)

Marital Status (1=Single, 2= Married, 3= Divorced, 4=Widowed)

Education

(1=None, 2=Primary, 3=Secondary, 4=Postsecondary)

Occupation (1= Employed, 2= Unemployed)

Family income per month

(1=<R5000, 2=R5-R10000, 3=>R10000)

HIV Status (1= Negative, 2= Positive, 3= Unknown)

If HIV positive CD 4 Count

If HIV positive (1= On HAART, 2= Not on HAART)

RPR (1=Positive, 2=Negative, 3=Unknown)

If RPR positive (1=Treated, 2=Incompletely treated, 3=Untreated)

Medical History

(1=Diabetes, 2= Hypertension, 3= IHD, 4=Asthma, 5=other and state)

Current medications

Previous operations

Reproductive Health

Last Pap Smear

Date of last pap smear

(1=Not done, 2=Normal, 3= LSIL, 4=HSIL, 5=pending)

Current Contraception:

(1=Oral contraception, 2=Injectable contraception, 3=Intrauterine device, 4=Barrier method, 5=Dual contraception: Barrier+Oral contraception, 6=Dual Contraception: Barrier + Injectable contraception)

Duration of current contraception: ☐
 (1= <2years, 2= 2-5years, 3= >5years)

Use of contraceptive methods ☐
 (1=Continuous, 2=Interrupted use)

No of partners (1=0, 2=1, 3=1-3, 4=>3) ☐

Use of condoms (1= Yes always, 2= Yes sometimes, 3=No) ☐

Previous STIs (1=Yes, 2=No) ☐

Type of STI ☐
 (1=Vaginal discharge, 2=PID, 3=Genital warts, 4=Genital ulcers)

Menstrual Pattern before sterilisation: ☐

Days of bleeding (1=<4, 2= 4-8, 3= >8)

Amount of bleeding ☐
 (1= Light, 2=Average, 3=Heavy, 4=Very heavy)

Pain with menses ☐
 (1=None, 2=Pain not requiring medication, 3=Pain requiring medication)

Cycles (1=Regular, 2= Irregular) ☐

Intermenstrual bleeding (1=No, 2=Yes) ☐

Known Gynaecological Problem before sterilisation and treatment sought:
 E.g. MFU, PID, Infertility etc.

Any Gynaecological condition diagnosed at sterilisation and treatment received:

Reason for Sterilisation ☐
 (1=Family complete, 2=Socio-economic, 3=Advice from health personal, 4=Advice from spouse/family, 5=Advise from fellow patient)

APPENDIX 2: DATA SHEET: POST STERILISATIONStudy no:

HIV status post sterilisation (1=Negative, 2=Positive)

RPR (1=Positive, 2=Negative, 3=Unknown)

If RPR positive (1=Treated, 2=Incompletely treated, 3=Untreated)

Pap smear result post sterilisation

(1= Normal, 2=LSIL, 3=HSIL)

Use of condoms post sterilisation

(1=Yes always, 2=Yes sometimes, 3=No)

No of partners (1=0, 2=1, 3=1-3, 4=>3)

Sexual activity post sterilisation

(1=>1x weekly, 2=1x week-1x month, 3=No)

Sexual experience post sterilisation

(1=More pleasure/interest, 2=Less pleasure/interest, 3=Same pleasure/interest)

Menstrual Pattern after sterilisation:

Days of bleeding (1=<4, 2= 4-8, 3= >8)

Amount of bleeding

(1= Light, 2=Average, 3=Heavy, 4=Very heavy)

Pain with menses

(1=None, 2=Pain not requiring medication, 3=Pain requiring medication)

Cycles (1=Regular, 2= Irregular)

Intermenstrual bleeding (1=No, 2=Yes)

Changes after sterilisation

Menses

(1=Increase in amount or flow of bleeding, 2= Decrease in amount or flow of bleeding, 3=Cycle irregularity, 4= Intermenstrual bleeding)

Pain with menses

(1= Increase in pain with menses, 2= Decrease in pain with menses, 3= No change)

Patient presentation to doctor or clinic for any gynaecological complaints after sterilisation

(1= Abnormal uterine bleeding, 2= Vaginal discharge, 3= Pregnancy/pregnancy related complaints, 4= Other and state)

Patient hospitalisation for any gynaecological complaints after sterilisation ☐

(1=Abnormal uterine bleeding, 2= Vaginal discharge, 3= Pelvic inflammatory disease, 4= Pregnancy/pregnancy related complaints, 4= Other and state)

Treatment received at hospital ☐

(1=Antibiotics, 2=Hormonal treatment, 3= Hysterectomy, 4=Other and state)

Patient's wish for more children after sterilisation (1=Yes, 2=No) ☐

Expression of regret post sterilisation (1=Yes, 2=No) ☐

If yes, state reason:

Overall satisfaction with TL procedure:

(1=dissatisfied, 10=very satisfied)

1	2	3	4	5	6	7	8	9	10
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APPENDIX 3: INFORMED CONSENT TO WOMEN

Good morning/Sawubona

We are conducting research on reproductive health following sterilisation in Durban. Research is just the process to learn the answer to a question. In this study we want to learn how patients feel about the sterilisation procedure and if they have any gynaecological or personal problems one year after the procedure. We ask you to participate in the study in allowing us to use some of the information you have given us today to be used in the study. Your name will not be included in the study at any time and your information shared today will only entered by response not by your name. We hope that the information you will give us will allow us to better understand patients' experiences post sterilisation so that if many problems arise, measures can be put in place to improve them. Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop at any time.

You may contact Dr Gaysheen Kistan at 0832934845 any time if you have questions about the research or if you are injured as a result of the research. You may contact the **Biomedical Research Ethics Office** on **031-260 4769 or 260 1074** or Email BREC@ukzn.ac.za if you have questions about your rights as a research participant.

The research study, including the above information, has been described to me orally. I understand what my involvement in the study means and I voluntarily agree to participate. I have been given an opportunity to ask any questions that I might have about participation in the study.

Signature of Participant

Date

Signature of Witness

Date

APPENDIX 4: INFORMED CONSENT TO PARTICIPANTS – ZULU

IMININGWANE YAKHO YOKUBA INGXEYI YOCWANINGO

Sawubona

Senza ucwaningo mayelana nokuzalanisa kulandela ukuthenwa kwamagciwane amandla eThekwini. Lolu cwaningo indlela yokuthola izimpendulo kumibuzo ekhona. Kulesi sifundo sifuna ukuthola ukuthi iziguli zithini (umbono wazo) mayelana nezindlela zokuthenwa amagciwane amandla nokuthi zibakhona yini izinkinga zezifo zabesizane emva konyaka. Siyakucela ukuba ube yingxenyi yalesi sifundo usivumele sisebenzise ulwazi osinike lona namuhla kulesi sifundo (cwaningo). Igama lakho ngeke lidalulwe nanoma yinini kanti nolwazi osinike lona luzofakwa ngaphandle kwegama lakho. Sethemba ukuthi ulwazi ozosinika lona luzosenza sazi kangcono ukuthini iziguli zibhekana nani emva kokuthenwa kwamagciwane amandla, khona uma kwenzeka inkanga, kukhona izinyathelo ezingathathwa zokulungisa. Awuphoqiwe ukuthi ube yingxenyi yalolu cwaningo, futhi ngeke wajeziwa noma uphucwe okungokwakho uma ngabe unquma ukuyeka nanoma ngasiphi isikhathi. Ungaxhumana no Dr Gaysheen Kistan kulenombolo 0832934845 nanoma ingasiphi isikhathi uma unemibuzo mayelana noma ulimele ngesikhathi socwaningo. Ungaxhumana nehhovisi le **Biomedical Research Ethics** kule nombolo 031 260 4769 noma 260 1074 noma nge email BREC@ukzn.ac.za uma ngabe unemibuzo mayelana nalolu cwaningo. Lesi sifundo socwaningo sinemininingwane yocwaningo engichazelwe yona. Ngikwazi kahle okumele ngikwenze kulolu ncwaningo futhi ngizinikele ngokuthanda. Nginikiwe ithuba lokubuza nanoma yimuphi umbuzo mayelana nalolu cwaningo.

Signature of Participant

Date

Signature of Witness

Date

APPENDIX 5: INFORMATION SHEET

To all participants

Our study aims to assess who chooses sterilisation as a contraceptive and the reasons women choose sterilisation as a contraceptive. We are following up women after sterilisation to assess how they feel about the procedure and if they have any problems with the sterilisation procedure. We wish to also assess if women have any regret following the procedure as well as if they have gynaecological problems after the sterilisation procedure. We hope that with the information given to us, we can address problems with the procedure and better improve the sterilisation process.

We thank you for your participation in the study.

APPENDIX 6: INFORMATION SHEET (ZULU)

ULWAZI LWESIGULI

Kubo bonke abayingxenywe yalolu cwaningo

Isifundo sethu sihlolise ukuhlola ukuthi obani abakhetha ukusebenzisa ukuthenwa

kwamagciwane amandla njengedlala yokuvimbela ukukhulelwa nokuthi yiziphi izizathu

abesifazane abanazo lokukhetha lendlala yokuyimbela ukukhulelwa. Siyabalandelela

abesifazane abesifazane abasebenzisa lendlala yokuvimbela ukukhulelwa. Siyafisa futhi

ukuhlola ukuthi ingabe abesifazane bayazisola ngokusebenzisa lendlala nokuthi babanazo yini

izinkinga zezifo eziphathelene nabesifazane ngemuva kokusebenzisa lendlala.

Siyathemba ukuthi ngolwazi osinike lona, singakwazi futhi sithuthukise indlela yokuthena
amagciwane amandla.

Siyabonga ngokuba yingxenywe yalesi sifundo.

APPENDIX 7: PERMISSION TO KING DINUZULU HOSPITAL COMPLEX (KING GEORGE V HOSPITAL)

PERMISSION TO CONDUCT A RESEARCH STUDY/TRIAL

To: Hospital Manager

Permission is required to utilise patient records and patient files for the above study at hand (protocol attached). The research involves the use of patient files and records as well as their follow up interview to assess their reproductive health and satisfaction following sterilization at King George V Hospital.

Permission is requested to conduct the above research study at the hospital/s indicated below:

Site 1 address:

King George V Hospital
75 R.D Naidu Rd
Sydenham Durban
4015

Investigator/s:

Principal: Dr Gaysheen Kistan
Supervisor: Dr Mala Panday

Signature of Hospital Manager:



Date: 10/10/2012

DR S. B. MAHARAJ
MEDICAL MANAGER
KING GEORGE V HOSPITAL

APPENDIX 8: POSTGRADUATE PERMISSION



28 March 2013

Dr M Panday
Department of Obstetrics and Gynaecology
School of Clinical Medicine

Dear Dr Panday

PROTOCOL: "Productive health in women following sterilization in Durban, South Africa" G
Kistan student number 212561142

The School of Clinical Medicine has ratified the approval of the abovementioned study on 24 March 2013.

Please note:

- The School of Clinical Medicine must review any changes made to this study.
- The study may not begin without the approval of the Biomedical Research Ethics Committee.

May I take this opportunity to wish the student every success with the study.

Yours sincerely

A handwritten signature in black ink, appearing to read "Dr V Singaram".

Dr V Singaram
Academic Leader: School Research

CC. Dr G Kistan

Biomedical Research Ethics Committee
Westville Campus

Postgraduate Education Administration Medical School Campus

Postal Address: Private Bag 7, Congella, 4013, South Africa

Telephone: +27(0)31 260 4495

Facsimile: +27(0)31 260 4723

Email: mbokazi@ukzn.ac.za

Website: www.ukzn.ac.za

Founding Campuses:

■ Edgewood

■ Howard College

■ Medical School

■ Pietermaritzburg

■ Westville

APPENDIX 9: ETHICS COMMITTEE APPROVAL



**UNIVERSITY OF
KWAZULU-NATAL**
INYUVESI
YAKWAZULU-NATALI

25 July 2013

Dr. Gaysheen Kistan
Department of Obstetrics and Gynaecology
Nelson R Mandela School of Medicine
University of KwaZulu-Natal

PROTOCOL: Reproductive health in women following sterilization in Durban, South Africa. REF: BE139/13.

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 02 April 2012.

The study was provisionally approved pending appropriate responses to queries raised. Your responses received on 16 July 2013 to queries raised on 20 May 2013 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 25 July 2013.

This approval is valid for one year from **25 July 2013**. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its next meeting taking place on **13 August 2013**.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely



Professor D.R. Wassenaar
Chair: Biomedical Research Ethics Committee

Professor D Wassenaar (Chair)
Biomedical Research Ethics Committee
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban, 4000, South Africa
Telephone: +27 (0)31 260 2364 Facsimile: +27 (0)31 260 4609 Email: brec@ukzn.ac.za
Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>

Funding Campuses:  Edgewood  Howland College  Medical School  Pietermaritzburg  Westville

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