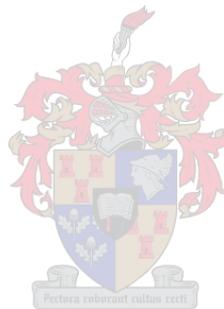


**A retrospective audit on the introduction of Post Placental  
Copper-T 380A intra uterine contraceptive device insertion at  
Tygerberg Hospital  
By Michelle Bryan-Mc Innes**



Dissertation presented for the Degree of Master of Medicine:  
Obstetrics & Gynaecology in the Faculty of Health Sciences,  
at Stellenbosch University

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December 2017

## DECLARATION

By submitting this dissertation electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the sole author thereof (save to the extent explicitly otherwise stated), that reproduction and publication thereof by Stellenbosch University will not infringe any third party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

December 2017

## DEDICATION

I would like to dedicate this thesis to my family that have supported me throughout this process. I need to especially thank my husband and my daughter for their patience and understanding. I could not have done this without them.

## **AKNOWLEDGEMENTS**

Dr Judy Kluge for her guidance, understanding and patience

Dr Alistair Mc Intyre Mc Innes for his statistical analysis

Dr Marsel Coetzer for her statistical expertise and guidance

Sister Cupido and Sister Naude at Family Planning for assisting with record keeping and retrieval

Ms RK Bryan for assisting with data capturing and support

Dr H Le Riche and Sr D Bryan for their Translation skills

## **ABSTRACT**

### **INTRODUCTION**

The Copper-T 380A intrauterine contraceptive device (Cu-IUCD) is a safe and effective long-acting reversible form of contraception (LARC) that is used by over 100 million women worldwide it is therefore of great concern that in South Africa the use of IUCD is < 2 %.

### **AIM & METHOD**

In 2012 progestogen-only injectables and IUCDs were the only LARCs available in South Africa. A new protocol for post-placental insertion of the Cu-IUCD (PPIUD) was introduced at Tygerberg hospital, Cape Town to encourage the uptake of this method. The purpose of this study was to audit the implementation of this protocol and outcomes, which included the rate of return and complications. Only pregnancies that were >24 weeks of gestation or >500 g were included.

### **RESULTS**

According to the IUCD register, 523 women had the IUCD inserted between June 2013 and February 2014. Forty-two records were excluded from the analysis due to insufficient information giving a total of 481 women of which only 437 had an IUCD inserted.

Antenatally only 108 women opted for the Cu-IUCD and most (301) women only made the decision to have the IUCD inserted around the time of delivery. The majority were inserted at emergency caesarean section (312) compared to elective caesarean section (66) and vaginal deliveries (57).

There were 39 (8.6%) cases identified with puerperal sepsis of which five were diagnosed with endometritis (1.1%). The PPH rate was 1.8% with and increased risk of expulsion during this period.

Only 118 (24.5%) returned for follow-up at Tygerberg with three expulsions (2.5%) and five partial expulsions (4.2%), 22 devices (18%) were removed for various reasons and there were no identified perforations.

## **CONCLUSION:**

Post placental insertion of the IUCD copper T380A is a safe, effective and affordable form of contraception that is ideal for women in a low-middle income country. There was significant risk of infection, bleeding and associated with insertion although one should be aware of exclusion criteria and should select the appropriate patients for the procedure. Although there is an increased risk of expulsion in immediate post placental insertion the risk of loss to follow up with consequent resulting pregnancies is higher.

## **ABSTRAK**

### **BEKENDSTELLING**

Die Koper T (Copper T380A) intra-uteriene toestelling (IUT) is 'n veilige langewerkende omkeerbare voorbehoedmiddel (LARC) wat deur meer as 'n 100 miljoen vrouens wêreldwyd gebruik word. Dit is dus kommerwekend dat in Suid Afrika die gebruik van die IUT minder as 2% is.

### **DOEL & METODE**

In 2012 was progestogeen inspuitings en IUT die enigste LARC beskikbaar in Suid Afrika. 'n Nuwe protokol vir post partum inplasing van die koper IUT was bekend gestel in Tygerberg Hospital in 2012 om die implimentasie van die metode te bevorder. Die doel van die navorsing was om die implementasie van die protokol en die gevolge te oudit. Dit sal aantal en tipe komplikasies, sowel as die terugkeer van pasiente insluit.

### **RESULTATE**

Volgens die IUT register het 523 vrouens die IUT laat inplaas tussen Junie 2013 en Februarie 2014. Twee en veertig notas was onvolledig wat beteken het dat 481 vrouens se mediese rekords ge-analiseer was waarvan net 437 'n IUT laat inplaas het.

Voorgeboortheid het slegs 108 vrouens die IUT gekies en die meeste vrouens (301) het die besluit eers geneem rondom die tyd van geboorte.

Meeste toestelle (312) was ingesit by nood Keisersnitte vergeleke met (66) elektiewe Keisersnitte en (57) Vaginale verlossings.

Daar was 39 gevalle (8.6%) geïdentifiseer met puerperale sepsis waarvan vyf (1.1%) pasiente gediagnoseer was met endometritis. Slegs 118 (24.5%) van die pasiente het vir hul opvolg na Tygerberg gekom. Daar was 3 (2.5%) uitwerpings en 5 (4.2%) gedeeltelike uitwerpings is noteer, 22 Apparate (18%) is verwyder vir verskeie redes en geen perforasies is geïdentifiseer nie.

### **GEVOLGTREKKING**

Post plasentale inplasing van IUT Copper T380A is 'n effektiewe en bekostigbare vorm van kontrasepsie wat ideaal is vir vrouens in 'n ontwikkelende land. Daar is geen beduidende risiko vir infeksie of bloeding wat geassosieer word met inplasing van die apparaat nie alhoewel mens bewus moet wees van die uitsluitel kriteria en die korrekte aanvaarbare pasiente kies vir die prosedure. Alhoewel daar n verhoogte risiko vir uittwerping is met die onmiddellike post partum inplasing, is die kans van 'n volgende swangeskap voor 'n interval inplasing inplasing 'n groter problem.

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**LIST OF ABBREVIATIONS**

<b>AMA</b>	Advanced maternal age
<b>BMI</b>	Body mass Index (kg/m <sup>2</sup> )
<b>bpm</b>	beats per minute
<b>CD4</b>	cluster of differentiation 4
<b>CS</b>	Caesarean Section
<b>°C</b>	degree Celsius
<b>Cu- IUCD</b>	copper Intrauterine contraceptive device
<b>d</b>	Days
<b>ECM</b>	Electronic Content Management
<b>ELCS</b>	Elective caesarean section
<b>EPP</b>	Early post placental
<b>g</b>	grams
<b>HAART</b>	Highly active anti-retroviral therapy
<b>HIV</b>	Human Immunodeficiency Virus
<b>II</b>	Interval post placental Insertion
<b>IPP</b>	Immediate post placental insertion
<b>IUCD</b>	Intra uterine contraceptive device
<b>kg</b>	kilogram
<b>LARC</b>	Long acting Reversible contraception
<b>LNG IUS</b>	Levonorgesterel intrauterine system
<b>LMIC</b>	Low- and middle income countries
<b>NVD</b>	Normal vaginal delivery
<b>PE</b>	Pre-eclampsia
<b>PPIUD</b>	Post Placenta intrauterine contraceptive device
<b>PPH</b>	Post partum haemorrhage
<b>PPROM</b>	Premature Prelabour rupture of membranes
<b>ROM</b>	Rupture of membranes
<b>T</b>	Temperature
<b>TBH</b>	Tygerberg Hospital
<b>WHO</b>	World Health Organization
<b>WHO MEC</b>	World Health Organization medical eligibility Criteria

## DEFINITIONS

- EPP** Early post placental insertion from 10 minutes after delivery of the placenta up to 72 hours.
- II** Interval post placental Insertion is from 4-6 weeks post delivery
- IPP** Immediate post placental insertion after delivery of the placenta but before 10minutes
- LARC** Long acting Reversible contraception a form of contraception that is used that only needs to be administered once in a menstrual cycle
- WHO MEC** World Health Organization medical eligibility Criteria, It is a guide developed by the WHO that provides recommendations for the use of contraception based on systematic reviews of available clinical and epidemiological research
- WHO MEC category 1** there is no restrictions for the use of this form of contraception

## 1. INTRODUCTION

In 2012 Els et al<sup>1</sup> implemented a new protocol at Tygerberg hospital with the introduction of the insertion of an intrauterine copper 380A device (Cu-IUCD) post placenta. The Cu-IUCD was introduced into the department and training was done before the service was implemented. The purpose of this study is to audit the implementation of that new protocol and the outcomes there of.

The protocol was aimed at counselling, technique of insertion and follow up of patients that had a cu- IUCD inserted immediately after delivery of the placenta (IPP). The counselling and assessment of patients looked at general health, education, individual counselling, methods used and follow up counselling. They were to be seen and counselled antenatally, during early labour, at any antenatal admission, prior to caesarean section and post insertion counselling as well as at the follow up visit.

An initial assessment was to be made of the patient antenatally to see if they were suitable for a Cu-IUCD.

The protocol advised on immediate insertion of the Cu-IUCD after delivery of the placenta but before 10 mins had elapsed. Two methods were described and used including the manual insertion technique and the ringed forceps technique. Cu-IUCDs could be inserted post normal vaginal delivery and at caesarean section.

Following insertion each patient was counselled on warning signs of potential complications, checking for strings, and were reassured that it did not affect breastfeeding. For all cases a record was kept of the insertion on a record sheet. Patients were assessed for heavy vaginal bleeding, severe lower abdominal discomfort, fever, unusual vaginal discharge, suspected expulsion and any other problems that could have been identified. Each patient was given a counselling sheet and a date to return for review.

## 2. LITERATURE REVIEW

The World Health Organization (WHO) recommends that the use of IUCDs is a safe and effective form of contraception. According to the WHO MEC (Medical Eligibility criteria) post-placental insertion up to 48 hours post-partum is a category 1 form of contraception (ie there are no restrictions for the use of this form of contraception).<sup>2</sup>

The intrauterine copper T 380A (CuT380A) is an effective, safe, affordable and reversible form of contraception<sup>3-6</sup> and can work for up to 12 years. It is used by >100 million women and is the most widely used form of long-acting reversible contraception (LARC) since 1967. It is therefore of great concern that in Sub-Saharan Africa the use of IUCDs is at less than 2%.<sup>7</sup> In the 1980s it was questioned as a feasible option when the WHO published a multicentre report stating its concern about the 'unacceptably high pregnancy and expulsion rate'.<sup>8</sup> Subsequent to this report there have been multiple studies that have reviewed and disputed this finding and will be explored further in this literature review.

Els et al<sup>1</sup> did a study on the introduction of the post-placental intra-uterine device (PPIUD). They investigated the "effect of skill training on knowledge and attitudes of use of the PPIUD". They introduced a new protocol and offered training to staff at the hospital. They concluded that in-service training resulted in an improvement in self-reported competency, counselling and insertion and advised on repeated training.

In South Africa Cu-IUCD is a freely available form of contraception that is not being utilised effectively. According to the South African Department of Health guidelines "IUCDs should be available to clients on request at a clinic, otherwise should be referred to a trained service provider."<sup>9</sup> It is alarming to find that the use of IUCDs has gone from 1% in 1998 to 0.6% in 2003.<sup>10,11</sup> It is 99.2% - 99.4% effective and has a pregnancy rate of 0.6/100 per first year of use if used correctly and with a typical use pregnancy rate per year of 0.8/100. This is comparable to permanent sterilization at 0.5/100 and

implants at 0.05/100. It has a continuation rate of 78 % at one year.<sup>9</sup> which is comparable to Implanon Nxt® and LNG-IUS(Mirena) with far better continuation rates than the commonly used Depo-Provera®, the 3 month injectable contraception(57%) and the combined hormonal contraceptives(68%)<sup>9</sup>

The post partum period is an important opportunity to introduce and establish a form of contraception in women. Women are highly motivated and keen to use contraception after birth and it is an ideal opportunity for them as well as for the health provider. In low middle income countries(LMIC) accessibility to health centres may be a limiting factor for many women.<sup>6</sup> It provides a good opportunity to reduce the number of unwanted pregnancies and potential abortions.<sup>12</sup> Pregnancies that occur within two years of the previous pregnancy carry a higher risk for the mother and the pregnancy. Complications include preterm labour and delivery, low birth weight babies, fetal losses as well as post partum haemorrhage and maternal death.<sup>13</sup>

Some of the advantages of post placental IUCD (PPIUD) insertion cited by various authors include:- <sup>6,8,14</sup>

immediate contraception

non-interfere with lactation

loss to follow up is not a barrier to insertion

relatively painless when compared to interval insertion where the cervix may need to be dilated

reassurance that the patient is not pregnant.

does not cause any weight changes, mood changes

does not interact with anti retrovirals.<sup>4</sup>

## **2.1 COMPLICATIONS**

As mentioned before, there are many concerns regarding this form of contraception but there have been numerous studies conducted in order to look at the different elements and complications related to IUCDs.

Some of the proposed complications include: - expulsion rates, pregnancy rates, bleeding, pain, sepsis including PID and perforation.

### **2.1.1 EXPULSION**

In the 1980s the WHO published a multicentre report which questioned the 'unacceptably high pregnancy and expulsion rate' of PPIUD.<sup>8</sup> Since then there have been many studies to look at the different elements and reasons for expulsion. Different elements that influence the rate of expulsions include time of insertion, type of device used, method of insertion, type of delivery and the skill of the health care provider.

#### **2.1.1.1 TIME OF INSERTION**

Studies have been done looking at the influence of timing of insertion on the rate of expulsion. Although there have been differences in timing, most studies looked at immediate post placental insertion (IPP) (after delivery of the placenta but before 10 minutes), Early post placental insertion (EPP) (from 10 minutes after delivery of the placenta up to 72 hours) and Interval Insertion (II) (from 4-6 weeks post delivery).

A systemic review done by Kapp et al<sup>15</sup> compared 6 studies that looked at the safety and effectiveness of immediate post placental insertion versus late post partum IUD insertions.<sup>6,16-20</sup>

The rate of expulsion in the IPP group ranges from 1% to 14.3% with a partial expulsion rate of 22.6% whereas the EPP shows a higher rate of complete expulsion ranging from 2.5% to 18.6% and a partial expulsion of 51.2%. When these figures are compared to the II group the expulsion rate was only explored in one study and was 3.8%. This clearly demonstrates that IPP insertion is better than EPP for the risk of expulsion but the delayed II has the lowest rate of expulsion by far. Interestingly, the cumulative pregnancy rate

was similar in all three groups. There were no perforations in the IPP or EPP group but there was an increased risk of perforation in the II group.

In a Study done in Turkey it was found that 95% of post partum women were agreeable to IUCD placement but only 70% left with any form of contraception.<sup>6</sup> The follow up of patients are often difficult in a LMIC countries as patients do not always have a lot of support from family and child care may be a problem for them as well as financial constraints. It is again emphasized that the immediate post partum period is the ideal opportunity to assist these patients prior to discharge. <sup>6</sup>

Fox et al<sup>12</sup> compared immediate insertion(IPP) of IUCDs to interval insertion(II). Although the expulsion rate was higher in the IPP group of greater concern was their return rate. Only 23 % of patients returned for insertion of IUCD in the interval group and 77% did not have them inserted at all. Up to 58% of patients were lost to follow up completely. Of the patients that did follow up and did not have the IUCD inserted, 19/28 (68%) were pregnant again within a year.

The rate of expulsion may be higher but in a situation where the risk of an unwanted pregnancy is very high and the loss to follow up is a known problem the risk of not inserting a device is higher than the risk of expulsion. <sup>21</sup>

A small study done in New Mexico <sup>22</sup> looked at some of the barriers to IUCD insertion. Some of the barriers included 11.6 % of all eligible patients requesting insertion but only 8% being inserted. Some women chose a different form of contraception without giving specific reasons for their choices. There were 16% of the women that came back pregnant before a device was inserted.

### **2.1.1.2 CAESER VERSUS NORMAL VAGINAL DELIVERY METHOD OF INSERTION**

There was one study that compared the mode of delivery and insertion of the IUCD. It seems that insertion at Caeser has a lower incidence of expulsion than with normal vaginal delivery.<sup>15</sup>

The proposed reason is that during a Caeser the IUCD is placed at the fundus under vision and is easier to reach compared to the insertion at normal vaginal delivery.

### **2.1.1.3 SKILL OF THE HEALTH CARE PROVIDER**

Thiery et al<sup>8</sup> found that the rate of expulsion was also influenced by the operator skills. A lack of operator skills affected the outcome of placement. The pregnancy and expulsion rates were significantly lower for experienced inserters and improved with time.

### **2.1.1.4 DEVICES USED**

In this study we only looked at the copper IUCD (Cu380A) as this was the device used at Tygerberg hospital. There is a large amount of literature that has looked at different devices and it has been shown the shape of the IUCD device influence the outcome and that the T shape has a better outcome and decreased rate of expulsion.

### **2.1.2 INFECTION**

One of the biggest concerns and fears surrounding IUCDs is the risk of infections namely PID, STI and HIV. Although there have been some incidences of infection post insertion of the IUCD, there has been no significant increase in infection.<sup>8,12,13,15,23</sup> In South Africa a study done at a tertiary hospital in Pretoria showed that the rate of sepsis in women with severe organ dysfunction was 0.07/100.<sup>24</sup>

Most studies had certain exclusion criteria for post placental insertion which included<sup>5,8,13,25</sup>:-

Rupture of membranes ranging from 6 hours to 12 hours

Prolonged labour

Fever, infections or features of Chorioamnionitis

Some studies even included a previous history of PID or ectopic<sup>5</sup>

This would then decrease the chance of infection secondary to existing infections. Infections associated with insertion of IUCDs are often related to pre existing infections and some institutions recommend testing for Chlamydia and Gonorrhoea before interval insertion. Prophylactic antibiotics are not advised<sup>12</sup>

### **2.1.3 BLEEDING**

A known complication of IUCDs is an increase in monthly menstrual flow and discomfort. It is therefore suggested that women should be screened prior to insertion and if they are known to have heavy menses and dysmenorrhoea an alternative form of contraception should be considered including the LNG-IUS. Studies have shown that number of days of bleeding post partum may be increased but the amount of pads used during this period was not increased.<sup>26</sup> In a study done by Welkovic et al<sup>27</sup> they concluded that there was no difference in basal haemoglobin concentration when comparing patients with PPIUD with those that did not accept and IUCD. It is however important to note that patients were excluded from insertion of the IUCD if they had a Haemoglobin of less than 8g/dl.

Exclusion Criteria used in the Tygerberg protocol is also important when considering insertion in order to identify patients at risk of complications

unexplained vaginal bleeding

post partum haemorrhage

Hb less than 8g/dl

patients with uterine abnormalities

patients with cavity distorting fibroids

Although there is no proven increase in bleeding with post placental insertion it is still one of the main reasons for elective removal of the device<sup>3,6,15</sup>

#### **2.1.4 PERFORATION**

Perforation is also a concern but numerous studies have shown that there is no increased risk of perforation in PPIUD. Interval insertion of the IUCD has a slightly higher risk of perforation however it is not statistically significant.<sup>6</sup>

#### **SUMMARY**

In summary, post placental insertion of the IUCD copper T380A is a safe, effective and affordable form of contraception that is ideal for women in a developing country. There are misconceptions about the risk of infection and bleeding associated with insertion. One should be aware of exclusion criteria and should select the appropriate patients for the procedure. Even though there is an increased risk of expulsion in immediate post placental insertion the risk of loss to follow up with consequent resulting pregnancies is higher.

### **3. AIM AND OBJECTIVES**

#### **AIMS**

To evaluate the implementation of the new protocol of post placental insertion of IUCD 380A introduced at Tygerberg Hospital 2012 and to assess the success and complications of IUCD insertion.

#### **OBJECTIVES**

To assess the counselling that was provided

To evaluate whether the protocol was followed

To determine the rate of complications of post placental Cu-IUCD including PPH and Sepsis

To assess follow up rate and complications such as expulsion

To make recommendations for future research and intervention.

## **4. METHODOLOGY**

### **4.1 DESCRIPTION OF STUDY DESIGN:**

This was retrospective audit of all patients that had a Cu-IUCD inserted at Tygerberg Hospital over an eight month period between June 2013 and February 2014.

### **4.2 SETTING AND STUDY POPULATION**

Tygerberg hospital is a public sector, academic hospital in Cape Town, South Africa. The department is a level 2 and 3 unit which serves as a referral unit for midwife obstetric units as well as district / level 1 hospitals and patients are generally at increased risk of obstetric and / or medical complications. The population seen in this unit is predominantly from a low- income community.

### **4.3 INCLUSION CRITERIA:**

All patients that had a device inserted that were >24 weeks gestation or >500g were included in the study. All methods of delivery were included ie Normal vaginal delivery and caesarean section

### **4.4 EXCLUSION CRITERIA AS PER PROTOCOL**

Patient that were <24 weeks gestation or <500g at delivery.

#### **4.4.1 COUNSELLING**

##### **4.4.1.1. ANTENATAL COUNSELLING**

During counselling patients were assessed on general health education, individual counselling, selection and exclusions criteria as well as follow up counselling. The protocol advised on using the following opportunities for counselling during the antenatal period, during early labour, at any antenatal admission, prior to caesarean section and post insertion counselling as well as at the follow up visits.

An Initial assessment was to be made of the patient to see if they were suitable for a Cu-IUCD antenatally and the exclusion criteria included:

Cavity distorting lesions

Suspected Gonorrhoea or Chlamydia

AIDS if the patient was clinically unwell or not on ARVS

Suspected Cancer or pelvic tuberculosis

Malignant or trophoblastic disease

#### **4.4.1.2 INTRAPARTUM**

Patient could be counselled during latent labour but the decision to counsel a patient during active labour was not advised.

Another assessment was made of the patient prior to insertion in order to assess suitability of insertion of the device exclusion criteria included:-

chorioamnionitis :- defined as having a maternal pulse >110bpm

Foetal tachycardia >160bpm

Offensive vaginal discharge

Lower abdominal pain

Fever T > 37.8°C

Prolonged rupture of membranes > 24 hours

Unresolved post partum haemorrhage

Extensive genital trauma.

#### **4.4.1.3 POST PARTUM**

Post insertion each patient was to be counselled on warning signs, checking for strings, reassured that it did not affect breastfeeding and record the insertions on a record sheet.

They were assessed for:-

Post partum endometritis or puerperal sepsis

Heavy vaginal bleeding

Severe lower abdominal discomfort

Fever Temp >37.8°C

Unusual vaginal discharge

Suspected expulsion

Any other problems that may be identified.

They were to be given a counselling sheet and a date to return for review at the family planning unit.

#### **4.4.1.4 INSERTION**

The protocol advised on immediate insertion of the IUCD after delivery of the placenta but before 10mins had passed. Two methods were described and used including the manual insertion technique and the ringed forceps technique. IUCDs could be inserted post normal vaginal delivery and during caesarean section.

#### **4.5 FOLLOW UP**

The family planning Cu-IUCD register and notes were audited looking at any complications and rate of return.

Post partum patients were routinely asked to return for a follow up date after 6 weeks to the family planning clinic to assess placement of the device looking at strings, expulsions, placement, pain, bleeding and any other complications

#### **4.6 SAMPLE SIZE AND SAMPLING METHOD:**

Participants were identified by using registers that were kept in the labour ward of the devices that were used during the study period between June 2013 and February 2014. At Tygerberg Hospital patient records are stored on the open text Electronic Content management (ECM) system as well as in records kept at the family planning clinic and register. The total population of women that met the inclusion criteria and had the device inserted were audited. The hospital registration electronic system (Clinicom) was then used as well as the attendance register at the family planning clinic to find the patients that followed up at the hospital post partum.

Records were reviewed and data captured in 7 main categories:

General / Demographic (age / body mass index etc.)

Counselling (antenatal counselling, peripartum counselling and post partum)

Medical (Underlying medical conditions, HIV status etc.)

Protocol Violations( exclusion criteria as per protocol)

Obstetric (Gravidity / Parity / Time from rupture of membranes / Previous CS etc.)

Complications (Puerperal sepsis, PPH,)

Follow up (expulsion, partial expulsion, outcomes etc.)

Pregnancy at 1 year was assessed by using the hospital registration computer system Clinicom. This was used to see if patients had returned to any facility in one year especially for antenatal care. This system only keeps record of patient at level one hospitals as well as some of the day hospitals but does not include midwife obstetric units (MOU).

## **5. DATA MANAGEMENT AND STATISTICS**

Data was collected and captured electronically and was kept strictly anonymous. Patients were assigned a number which was kept separately in a secure code protected file which could be used for future auditing purposes. Research codes and captured data were stored on a password protected computer.

Data were collected in Microsoft Excel® and data represented in two ways. Continuous data is presented using means and standard deviations with 95% confidence intervals for the population, if data is normally distributed. In the case where the data was non-normally distributed, medians and interquartile ranges were used. Data is presented graphically using pie charts and bar graphs.

The primary aim of the study was to assess the outcomes of the device related to complications including bleeding, sepsis, return for follow up and expulsion rates. Thus this objective is descriptive in nature and was analysed using the aforementioned methodology.

## 6. ETHICAL CONSIDERATIONS

Ethical approval was granted by the Health Research Ethics Committee, University of Stellenbosch Ethics Reference #: S15/08/177 approval was also granted to waiver informed consent for the purpose of this study.

## 7. RESULTS

### 7.1 DEMOGRAPHICS

According to the IUCD register, 523 women had the IUCD inserted between June 2013 and February 2014, 481 women's records were analyzed as 35 had notes missing and 7 were excluded as they did not meet our inclusion criteria of a gestational age >24 weeks or 500g. Of these 481 women, 437 had an IUCD inserted and for various reasons, 44 women did not have the device inserted. Sixteen patients did not have a documented reason for not having the device inserted, 7 patients changed their minds at the time of insertion and were put on an alternative method of contraception, 1 was a failed insertion, 7 were not inserted because of PPH, 3 because for sepsis risk as per protocol, 1 because of genital trauma and 1 because there was an uterine rupture at caeser. Seven were related to human error, either forgotten at time of delivery or delayed time for insertion. (The protocol advised on only inserting the device immediately after delivery of the place up to 10minutes)

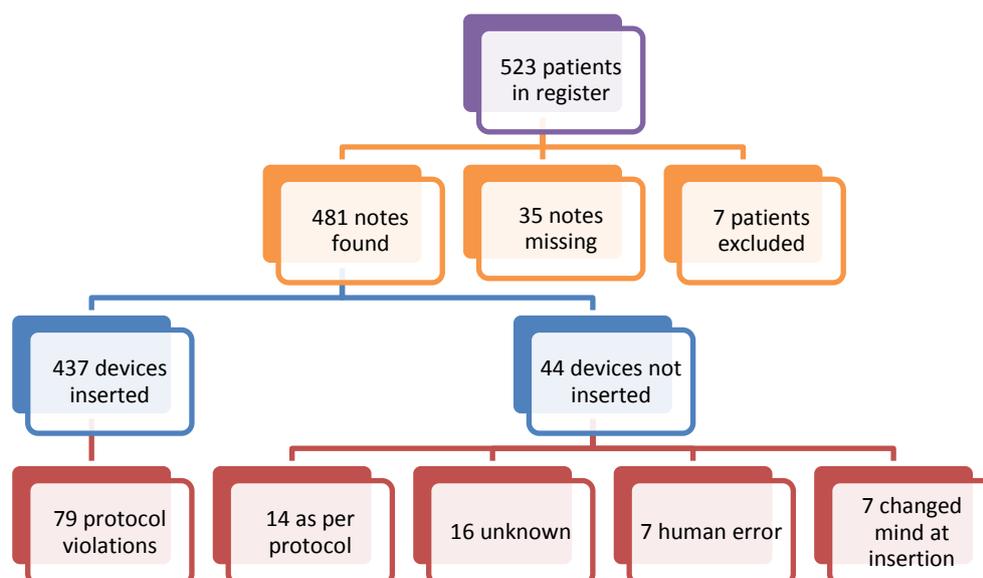


Figure 7.1.1 Data profile and protocol violations

## 7.2 PROTOCOL VIOLATIONS

Prior to insertion there were 33 patients that had prolonged rupture of membranes (>24 hours) yet 29 of these women had the IUCD inserted. There were 66 patients that had features suggestive of chorio-amnionitis and 55 devices were inserted in these patients. There were 8 with foetal tachycardia, 20 with maternal tachycardia, 12 with LAP (lower abdominal pain), 15 with a combination of factors. There were 76 patients that were counselled during active phase of labour for the first time and the protocol advised on not counselling patients during the active phase of labour. There were 4 patients that had multifibroid uteruses and 1 with a bicornuate uterus

## 7.3 PATIENT CHARACTERISTICS

Patient demographics are listed in the tables below with most of the patients being between the ages of 21-37 (78%) with a mean gestational age of 36 weeks 2 days.

	N Patients (%)	mean (SD)median(P10-90)
Total	481 (100)	
Age		26.2 (±6.3)
<20 years old	81(16.8)	
21-37	378(78)	
>37	22(4)	
Gravidity		2.3(±1.3)
Parity		1.1(±1.1)
Nulliparity	133 (27.6)	
Multiparity	340 (70.6)	
Grandmultips	8 (1.6)	
Body mass index (kg/m <sup>2</sup> )		31.5 (±9.5)
<30	183	
>30-35	75	
>35	109	
Booked	460	
Unbooked	21	
Gestation		36w2(±26days)

Table 7.2.1 Patient demographics

REASON FOR REFERRAL TO TBH	N of Patients
advanced maternal age	4
anteartum haemorrhage	13
Diabetic	28
BMI	65
foetal complications	13
Hypertension	195
medical problem	7
Other	85
preterm+ PPRM	29
previous bad outcome	31
previous caeser	25
psychiatric illness	5
twin pregnancy	35
Unknown	11

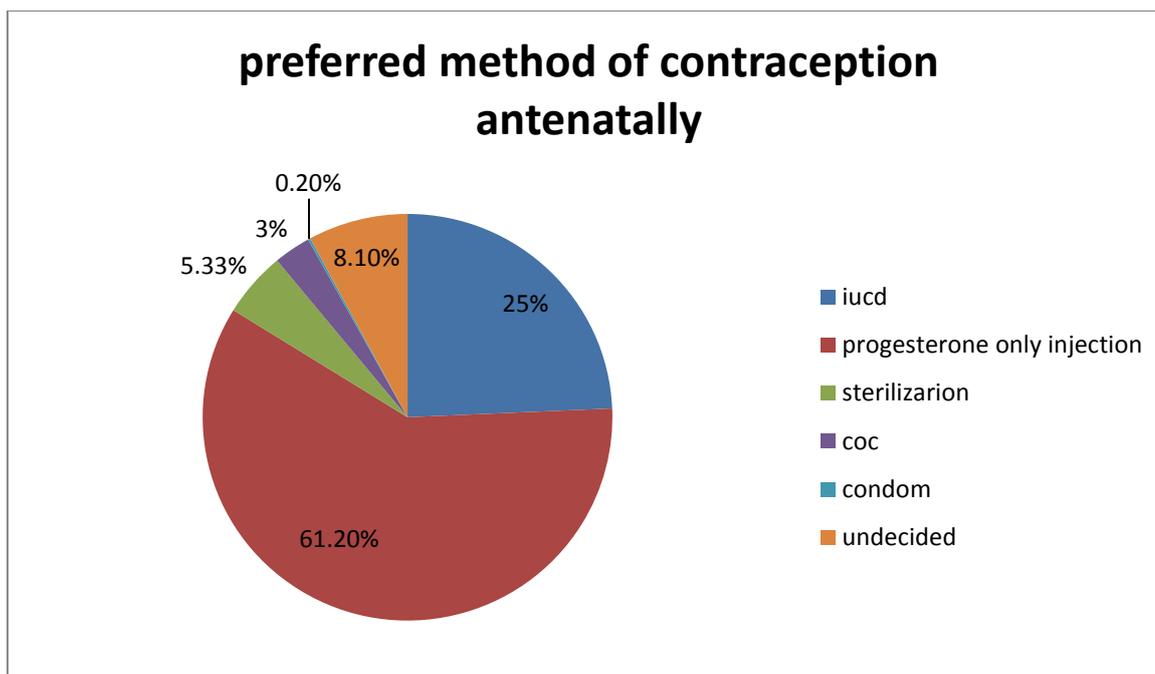
**Table 7.2.2 Indications for referral to Tygerberg hospital**

Data for Chlamydia and Gonorrhoea could not be accurately assessed as it was not well documented or investigated, 3 patients were suspected and 2 were treated during pregnancy, there were no identified cases of gestational trophoblastic disease.

There were 89 patients that were HIV positive patients and 81(18.5%) had devices inserted, 5 patients had cd4 under 200 but they were all on antiretroviral treatment for at least a month prior to insertion.

#### **7.4.1 ANTENATAL COUNSELLING**

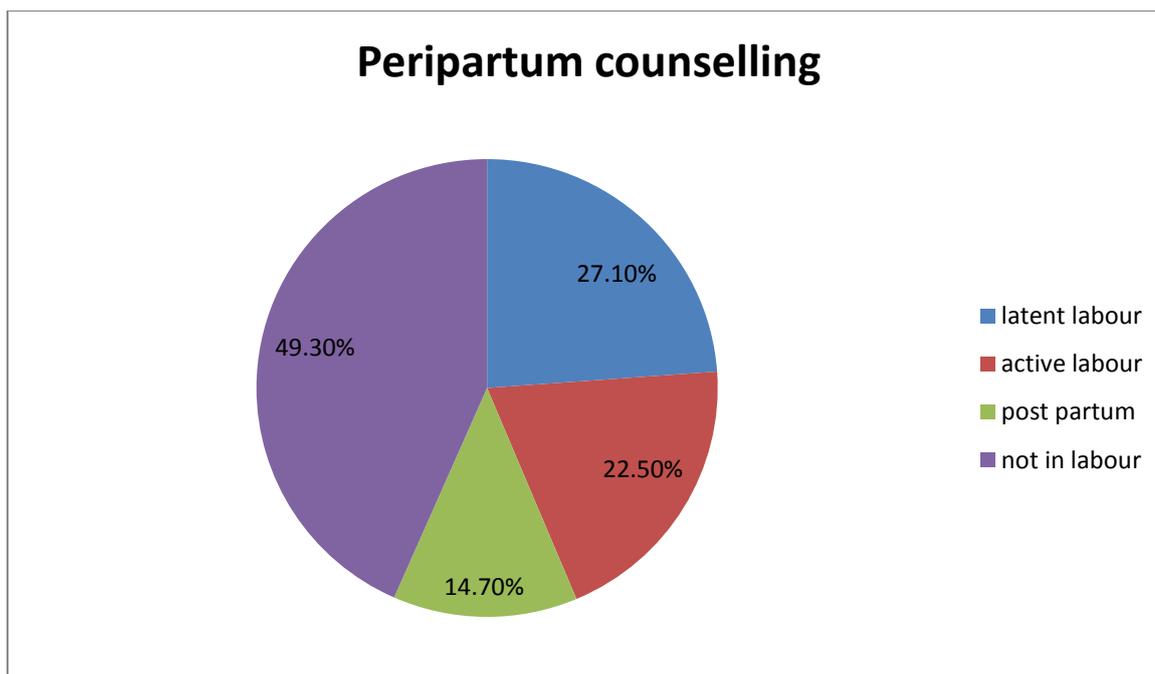
The maternal antenatal records were assessed and on the initial clerking sheet patients indicated what they preferred as their choice of contraception post partum. Of the 481 patients, 431 patients (89.6%) had antenatal counselling and contraceptive choice at initial consult that was documented and 50 (10.4%) patients had no documentation. IUCD was the preferred method of contraception in 108 (25%) women whereas 264 (61.2%) women had chosen progesterone only injectables and 23 (5.33%) had opted on sterilization, 13(3%) on combined oral contraception, 1 chose to use condoms only and 35(8.1%) were undecided on which method they preferred.



**Figure 7.4.1.1 Antenatal contraceptive choices**

#### **7.4.2 PERIPARTUM COUNSELLING AND ASSESSMENT**

There were 332 (68.9%) patients had peripartum counselling for insertion of the Cu-IUCD and of those patients 301 were inserted. These included patients that had documented counselling around the time of the delivery. There were 164 (49.3%) patients that were not in labour with 90 (27.1%) in latent labour, 78 (22.5%) were in active labour and 49 (14.7%) were counselled post partum.



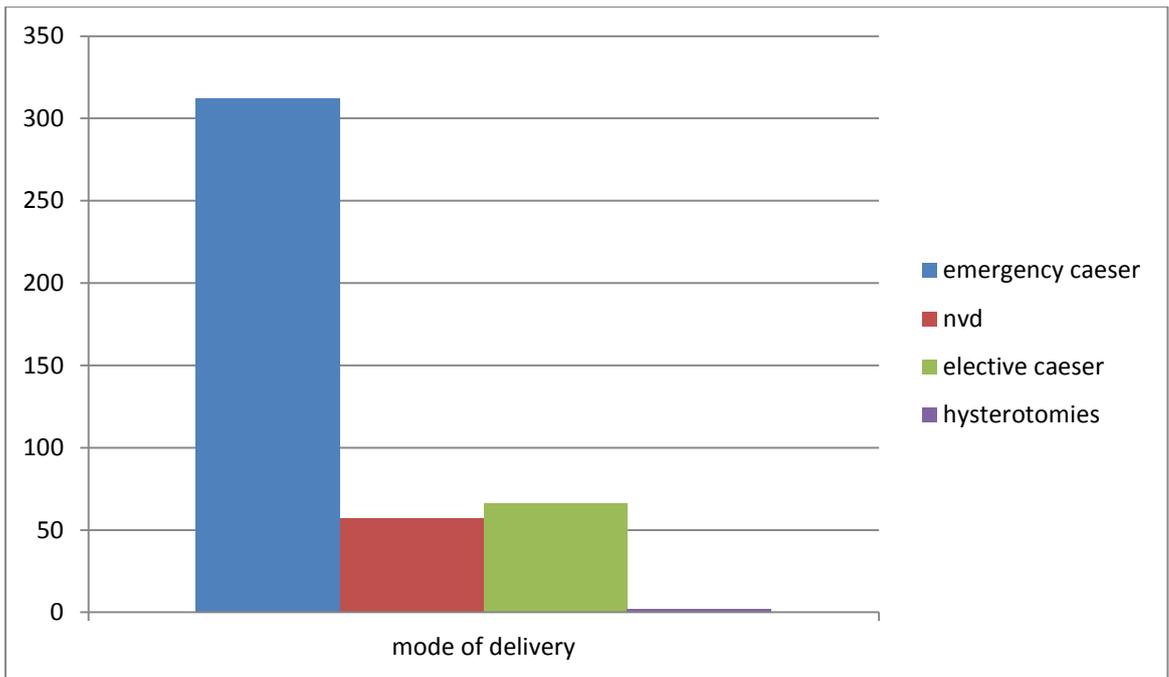
**Table 7.4.2.1 Peripartum counselling**

Post-Partum 266 (60.8%) patients received an information pamphlet with advice on complications and follow up procedures. In 82 (18.7%) patients it was documented that the sheets were out of stock and 89 (20.3%) patients did not receive a counselling sheet according to the records. There were 68 of the 266 counselling sheets that were left behind in the folder.

There were 188 (39%) patients that were given a date to return on their discharge letter to return to the family planning clinic, 189 (39%) patients were simply documented to come back in 6 weeks with 104 (21.6%) patients that did not receive a follow up date at all.

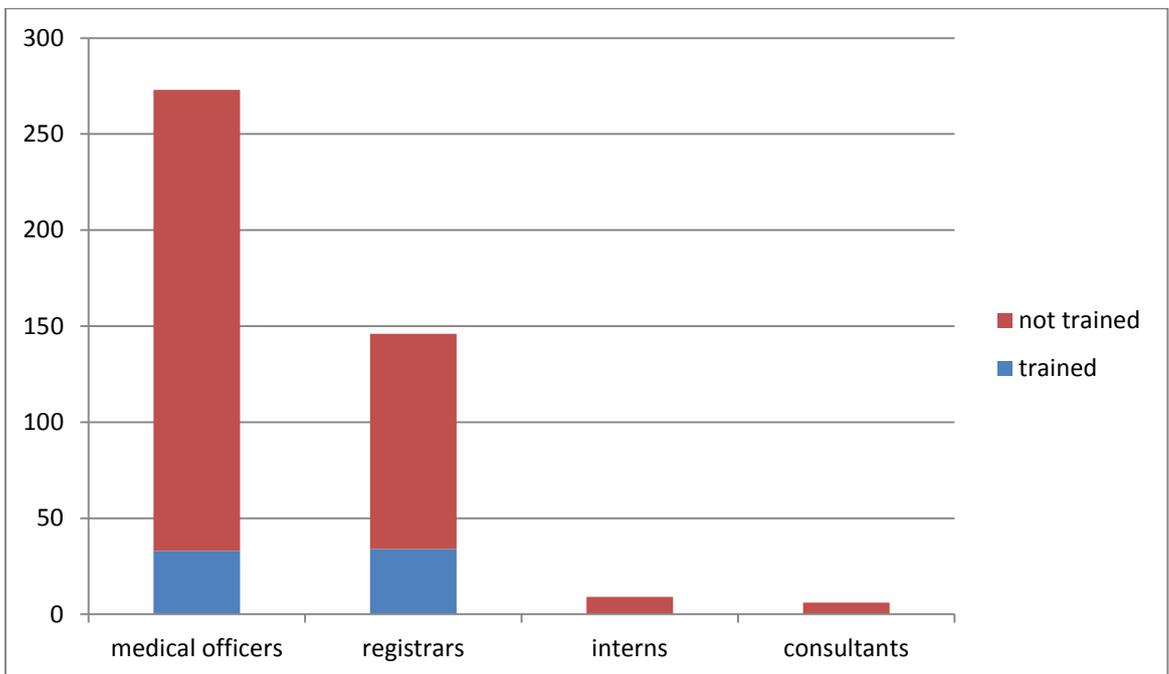
### **7.5 MODE OF DELIVERY:**

Most of the devices were inserted as caeserean section. Of the 437 that were inserted 312 (71.3%) were at emergency caeser, 66 (15.1%) were elective caesers, 2 (0.4%)hysterotomies and 57 (13%) post normal vaginal deliveries



**Figure 7.5.1 mode of delivery**

Most of the devices were inserted by medical officers, 273 (63%), followed by registrars 146 (33.4%). Only 67 (15.2%) of the devices that were inserted were inserted by people that had attended the training in 2012



**Figure 7.5.2 Number of devices inserted by trained personal**

## 7.6 TIME OF INSERTION

There were only 20 sets of notes that recorded timing of insertion of the device, in effect this could not be analysed accurately. Of the 20 recorded insertion times there were 19 inserted within 10 minutes and one was inserted before 20 minutes. All Cu-IUCD inserted at caesarean section were inserted after delivery of the placenta and prior to closure of the uterine incision. All devices inserted post NVD were inserted on the same day after delivery prior to leaving the labour room.

## 7.7 COMPLICATIONS

### 7.7.1 PUERPERAL INFECTION

	N/N of patients (%)
TOTAL	39
devices inserted	34
devices not inserted	5
endometritis	5(1.1%)
wound sepsis	10(2.2%)
other medical conditions	19(4.3%)

**Table 7.7.1.1 Puerperal Sepsis**

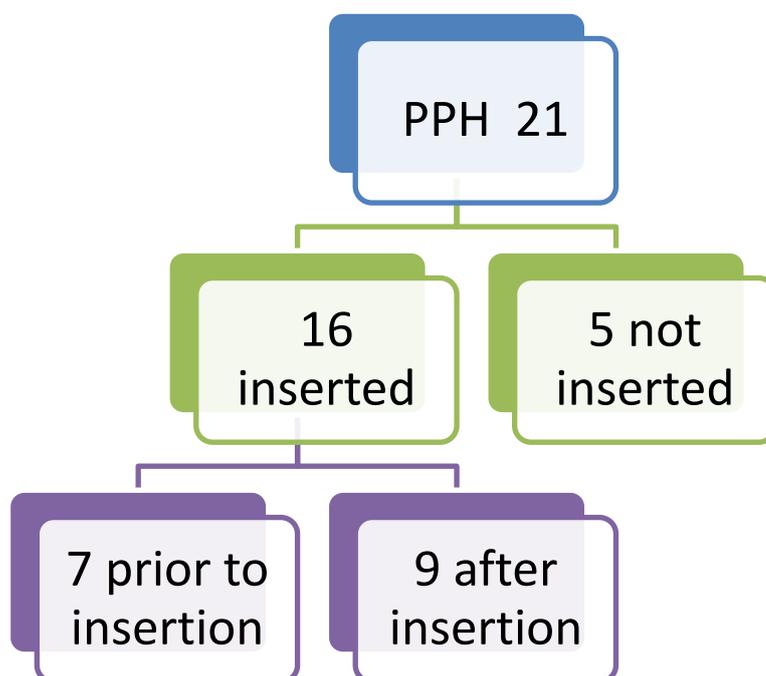
Of the 5 that were diagnosed with suspected endometritis, 2 had prolonged rupture of membranes and should not have had an IUCD inserted according to the protocol. All of the devices were inserted at caesarean delivery, 4 emergency and 1 elective. Two of the emergency caesars were for failed induction of labour and two were for foetal distress. These confounding factors are risk factors for puerperal sepsis themselves. All of the devices were removed and all of them were placed on antibiotics. Four of the 5 made a complete recovery and one complicated and required a hysterectomy, however she had surgical complications during caeser and cultured many different organisms and had many possible sources of infection, endometritis and the Cu-IUCD was not suspected to be the main source of the puerperal sepsis. All five patients were HIV negative.

Risk factor	with sepsis	without sepsis	RR	CI	P value
BMI >35	6	105	0.2973	0.0680-1.3002	0.1071
BMI <35	22	203	4.5	02.8-73.0455	0.2815
HIV Positive	4	77	0.3951	0.05-3.1228	0.3786
HIV Negative	29	356	0.6591	0.2458-1.7675	0.4075
Cs	30	282	0.4597	0.1805-1.1707	0.1032
Elcs	3	63	0.4179	0.0258-6.7784	0.5394
Nvd	0	55	0.1367	0.0058-302387	0.218

**Table 7.7.1.2 Cofounder factors for puerperal sepsis**

The relative risk for co founder factors were demonstrated in the above table but none of them were found to be statistically significant as the P value was > 0.05.

### 7.7.2 BLEEDING



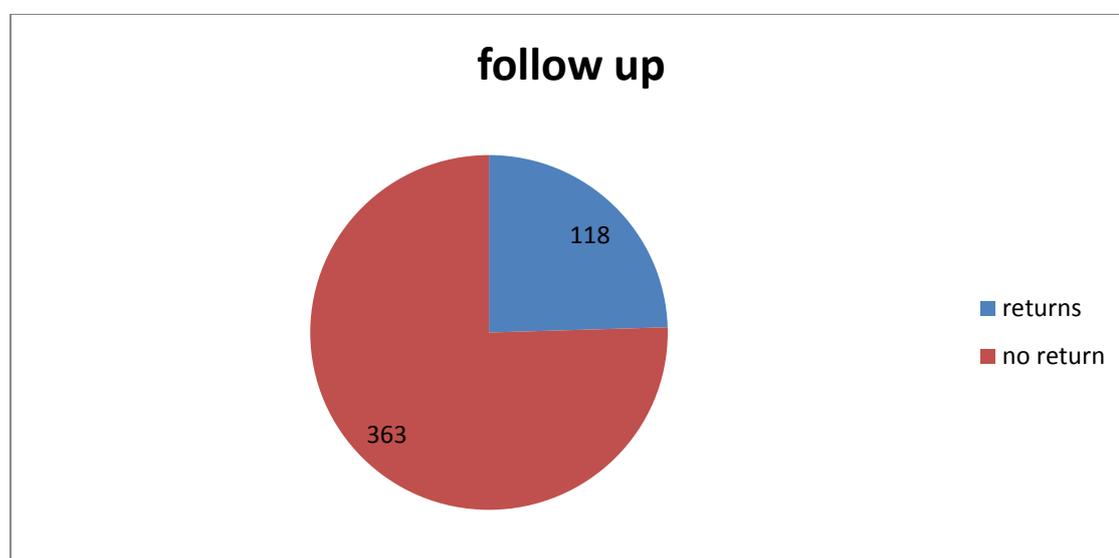
**Figure 7.7.2.1 Post Partum Haemorrhage**

There were 392 (89.7%) patients that had the device inserted with an Hb greater than 8 g/dl, 10 (2.2%) with an Hb less than 8g/dl and 46 (10.5%) were unknown.

There were 21 (4.3%) cases of post partum haemorrhage (PPH) and 5 (1%) devices that were not inserted because of the PPH. Of the 16 (3.3%) that were inserted 7 (1.4%) had PPH prior to insertion which resolved. Of the 9 (1.8%) devices that were inserted with PPH after insertion. One patient required a relook laparotomy and was found to be bleeding from the lower segment. They all had an Hb of more than 9g/dl prior to insertion. Seven of them were delivered by emergency caesarean section and 2 NVD. Four of them had induction of labour and 2 with prolonged rupture of membranes. One patient was HIV positive and the rest were HIV negative. One of the 9 patients was known with a multifibroid uterus. They were all booked patients and there were 4 patients with BMI of more than 40. One patient had an abruption and had a disseminated coagulopathy which resolved with delivery and blood products. All 9 patients were managed with oxytocin, 3 (0.6%) devices were expelled spontaneously during the PPH and the rest resolved with time with no further surgical intervention.

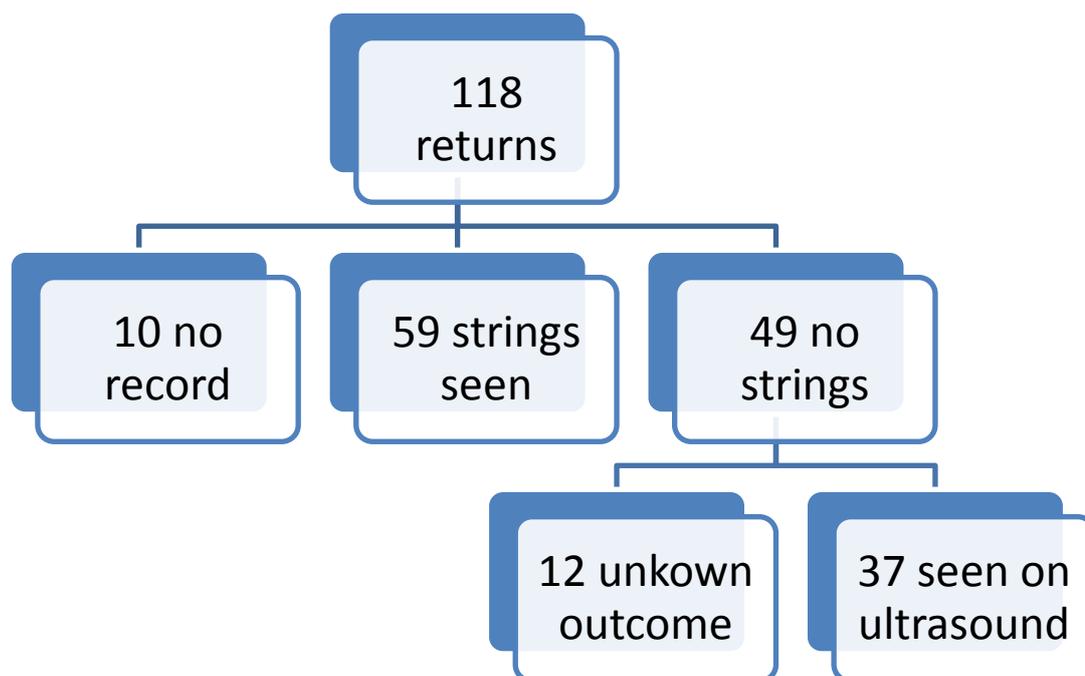
## 7.8 FOLLOW UP AND EXPULSION RATE

### Returns



**Figure 7.8.1 Follow up**

There were 118 (24.5%) patients that returned for follow up at Tygerberg hospital and 363 (75.5%) that did not return to Tygerberg for follow up.



**Figure 7.8.2 outcomes of IUCD at Follow up**

Of the patients that returned 10 sets of notes could not be found regarding their follow up visit. Strings were seen in 59 (54.6%) of the 108, 43 (40.1%) did not see strings and 6 (5.6%) had no comment or ultrasound done to ascertain if the device was still in situ. There were 3 expulsions (2.6%) which were all shortly after insertion and they were all identified early and 5 partial expulsions (4.6%), all 5 partial expulsions had the devices removed and none were replaced.

Three of them were inserted at caeser and 2 NVD and all 5 had a BMI less than 35. Sixteen of 107 (14.9%) patients wanted to have their devices removed 4(for malposition and 3 were replaced) 2 were for pain and bleeding, 1 for long strings and one for pv discharge, 1 complained of amenorrhoea, 8 were by patient request with no explanation documented.

## 7.9 PREGNANCY AT 1 YEAR

It was attempted to find if patients were pregnant at one year by using the Clinicom data base and ECM to see if patients had been to Tygerberg or to another health facility for antenatal care. Only 1of the patients was found to be pregnant by 1 year but she did not return for follow up post insertion and details of her pregnancy could not be obtained.

This data may also not be fully representative as not all facilities especially the MOUs use the Clinicom system to record visits so this figure is not fully representative.

## **8. DISCUSSION**

### **8.1 COUNSELLING**

In the index study the majority of women (61.2%) chose Progesterone injectables as their preferred method of contraception during the antenatal period, as indicated on the maternal record. This is compared to 25% that chose the Cu- IUCD and 8.1% of patients who were undecided on their method of contraception. The sexual demographic survey in SA in 2004 showed that injectable use in South Africa was as high as 33%. Most of the patients who had a PPIUD inserted were counselled and chose this method during the peripartum period (68.9%). This demonstrates the importance of counselling of patients during their pregnancy as most patients in the index study changed their mind during the peripartum period.

Counselling is considered an integral part of insertion of a cu- IUCD. A large proportion of the protocol at Tygerberg was focused on adequate counselling and selecting the appropriate patient for the device. The protocol advised on antenatal counselling with informed consent as well as post partum counselling. Counselling during the active phase of labour was not advised.

Almost half of the patients (49.3%) were not in labour with 27.1% in latent labour. One in 4 (22.5%) women was counselled during the active phase of labour which was not advised in the Tygerberg protocol. The women's ability to give informed consent may be questionable while they are in pain

A small study done in New Mexico<sup>22</sup> looked at some of the barriers to IUCD insertion and found that of the 11.6 % of all eligible patients requesting insertion only 60% had the device inserted. Some women chose a different form of contraception without giving specific reasons for their choices. There were 16% of the women that came back pregnant before a device was

inserted. Teal <sup>28</sup> suggested that the success of LARC contraception would depend on counselling and proposed that the third trimester of pregnancy is an ideal time to counsel a patients and to assist her in making a decision with regards to her choice of contraception and interval between pregnancies.

The index study reveals that improvements at counselling in the third trimester need to be made to increase uptake of LARCs including PPIUD.

## **8.2 COMPLICATIONS**

### **8.2.1 PUERPERAL INFECTION**

Despite protocol violations in the index study the sepsis rate related to the device was still low at 1.1%. Coetzer et al (unpublished data, personal communication) found a post CS sepsis rate of 4.69% at Tygerberg hospital in the year 2014 which overlapped with the index study period and those patients were followed up at level 1 hospitals in the drainage area. In the index study most of the patients were delivered by emergency caesarean section (69.8%) and elective caesarean section (15.1%). The index study's low sepsis rate could be biased as patients were only identified if they had presented back to Tygerberg hospital with sepsis therefore the sepsis rate may be higher. It is interesting to note that patients with endometritis were all HIV negative. At Tygerberg Hospital HIV positive patients who have emergency caesars all receive 3 days of empiric antibiotics, ampicillin and metronidazole, as per sepsis prevention protocol.

Although infection occurring after PPIUD has been reported, studies have shown that there is no statistically significant increase in infection. <sup>8,12,13,15,23</sup>

The most important aspect of puerperal sepsis prevention is the identification of patients at risk of developing sepsis. Careful examination and assessment is essential prior to insertion. Most studies relating to this matter had certain exclusion criteria for post placental insertion, <sup>5,8,13,25</sup> which includes prolonged

rupture of membranes ranging from 6 hours to 12 hours, prolonged labour, fever, infections or features of chorioamnionitis. The protocol at Tygerberg had clear guidelines on examining patients and criteria to identify patients at risk. Some studies even included a previous history of PID or ectopic<sup>5</sup> These confounding factors are risk factors for puerperal sepsis themselves and are used to identify patients at risk of puerperal sepsis. Some studies were more cautious than the TBH exclusion criteria with respect to ROM.

### **8.2.2 BLEEDING**

In the index study there were 21(4.3%) cases of PPH. These included cases of PPH prior to insertion who then later received the PPIUD after resolution of PPH. Cases who were meant to receive a PPIUD but did not as per protocol and those who experienced a PPH after insertion [n=9(1.8%)]. Three women expelled the device subsequent to PPH. Interestingly, all of the cases of PPH resolved with Oxytocin except one that was related to a bleeding uterine incision and required a relook laparotomy. Although there is no proven increase in bleeding with post placental insertion it is still one of the main reasons for elective removal of the device.<sup>3,6,15</sup> It is however important to identify patients at risk of bleeding prior to insertion of the device. Studies have shown that number of days of bleeding post partum may be increased but the amount of pads used was not increased.<sup>26</sup>

In a study done by Welkovic et al<sup>27</sup> there was no difference in basal haemoglobin concentration when comparing patients with post placental insertion with those that did not accept a PPIUD

Patient assessment prior to insertion is essential as PPH is a serious complication and every attempt should be made to identify women at risk of PPH prior to insertion. PPIUD insertion should not compromise or delay the management of PPH. The patients who experience a PPH after PPIUD insertion are at higher risk of expulsion and both health care providers and patients should ensure that expulsion has not occurred.

### 8.3 FOLLOW UP AND EXPULSION RATE

This study had a return rate of 24.5% with an expulsion rate of 2.6% and partial expulsion of 4.6%, all 5 partial expulsions had the devices removed and none were replaced. Two were placed after NVD and 3 at Caesarean section.

Fox et al <sup>12</sup> had a comparable return rate of 23% and found that their immediate insertion expulsion rate(3%) was higher than interval insertion(0%) and up to 58% of patients were lost to follow up completely and 19/28 (68%) patients that did not have the device inserted at all were pregnant at 1 year.

The high risk of post placental expulsion should therefore be weighed up against the high rate of loss to follow up and increased risk of pregnancy when not providing a PPIUD. One can argue that the risk of not returning for contraception at a later stage and the resultant unplanned pregnancies is outweighed by the risk of PPIUD expulsion and their unplanned pregnancies

The follow up of patients are often difficult in a low to middle income countries. Women do not always have adequate support from family, limited child care and financial constraints. The immediate post partum period is ideal as this might be the only opportunity to provide contraception.

Kapp et al <sup>15</sup> found rate of expulsion in the IPP group ranges from 1% to 14.3% with a partial expulsion rate of 22.6% where as the EPP shows a higher rate of complete expulsion ranging from 2.5 % to 18.6% and a partial expulsion of 51.2%. Immediate post placental insertion is better than early placental insertion for the risk of expulsion but the delayed interval insertion has the lowest rate of expulsion by far. Interestingly, the cumulative pregnancy rate was similar in all three groups.

There were no identified perforation in the index study which is similar to finding of Kapp et al<sup>15</sup> with no perforations in the IPP or EPP group but there was an increased risk of perforation in the II group.

The rate of expulsion may be higher but in a situation where the risk of an unwanted pregnancy is very high and the loss to follow up is a known problem the risk of not inserting a device is higher than the risk of expulsion.<sup>21</sup>

In the Index study just over half (54.6%) had strings visible at follow up. This is expected as the majority of PPIUDs were inserted at caesarean section. Almost 1 in 10 patients wanted to have their device removed at the follow up visit for various reasons but no obvious complication.

#### **8.4 SKILL OF THE HEALTH CARE PROVIDER**

Most of the devices that were inserted in the index study was done by medical officers (63%) and only 67(15.2%) of the devices that were inserted were inserted by people that had attended the training in 2012. Despite this finding the rate of complications was still found to be low. Thiery et al<sup>8</sup> found that the rate of expulsion was also influenced by the operator skills. A lack of operator skills affected the outcome of placement. The pregnancy and expulsion rates were significantly lower for experienced inserters and improved with time.

It is advisable to provide ongoing education and training to improve skills and for inserters to familiarise themselves with the protocols.

#### **8.5 PREGNANCY AT 1 YEAR**

In the index study only one patient was identified as being pregnant within the first year however this number may not be accurate as not all patients could be followed up and identified accurately and this figure may not be underestimated

## **9. CONCLUSION**

Post placental intrauterine devices are a safe and effective method of contraception and should be offered to all medically eligible women. Complications such as PPH and puerperal sepsis are often associated with confounding pre existing conditions and patients should be carefully screened prior to insertion to decrease the complication rate. The risk of expulsion is outweighed by the risk of a patient not returning for family planning post partum. Patients should be counselled frequently and offered contraceptive advice at every opportunity. In a setting where there is high turnover of staff there should be ongoing education and re enforcement of protocols to ensure better outcomes.

## **10. LIMITATIONS**

This was a Retrospective study that looked at patient records which were often poorly documented

The study only looked at follow up at Tygerberg hospital returns and complications and did not extend the complications to the level one hospitals and clinics. This may influence the complication rates and pregnancies following PPIUD.

Follow up rates looked specifically at return rates to the study site and did not look at follow up at other health facilities.

There was a limited number of NVD in this study and most devices were inserted at caesarean section.

## **11. FUTURE AREAS OF RESEARCH**

Ongoing education and training have been shown to improve outcomes and decrease complications. A prospective study should be done on the outcomes of PPIUD after NVD in order to properly assess the complications and expulsion rates.

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