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The incidence of hysterotomy in second trimester termination of pregnancy

Gamedze, Audrey Gugu

2014-04-25
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THE INCIDENCE OF HYSTEROTOMY IN SECOND TRIMESTER TERMINATION OF PREGNANCY

STUDENT: DR AUDREY GUGU GAMEDZE

STUDENT NUMBER: 360784

SUPERVISORS: DR KA FRANK AND

PROF EJ BUCHMANN

A research report submitted to the faculty of Health Sciences, University of Witwatersrand, in partial fulfilment for the degree of Master Of Medicine in Obstetrics and Gynaecology

Johannesburg 2013

ABSTRACT

OBJECTIVES: To determine the incidence of hysterotomy in second trimester termination of pregnancy, including differences in women that abort following medical induction and those that fail to abort requiring surgical abortion, and the factors that influence choice of surgical operation.

METHOD: Records of all women (n=1080) who presented for elective second termination of pregnancy (14-20weeks) in the years 2008 until 2010 were reviewed retrospectively. Theatre records were also used to verify the operation. The women were divided into two groups according to the method of abortion they finally responded to: a medical group that aborted following medical induction (n=1715), and a surgical group that failed to abort following medical induction (n=88). Apart from demographics, the surgical group was studied further in detail of previous uterine operation, surgical operation done for current abortion, complication profile and seniority of operating surgeon.

RESULTS: Failed medical induction accounted for 5% of all second trimester abortions. The incidence of hysterotomy was 52% in the surgical group and 2.5% of all the second trimester abortions. Hysterotomy was more common in higher gestations ($p=0.005$). Suction curettage was frequent as a surgical abortion method in gestations below 16 weeks. Nulliparous women were more likely to fail to abort than multiparous women ($p=0.002$) and those with twin pregnancy more likely to abort on medical induction ($p<0.001$). Surgical evacuation was done mostly by registrars and consultants (senior members of staff). The two common complication profiles were haemorrhage and incomplete evacuation of the uterus. No cases of uterine perforation were identified, and there were no intensive care unit admissions and no deaths.

CONCLUSION: Hysterotomy is still a common surgical procedure for management of failed second trimester abortions in our institution, and is practiced by senior members of staff, despite worldwide recommendations that dilatation and evacuation should be the method of choice for surgical abortion between 16 and 20 weeks of gestation.

DECLARATION

I, Audrey Gugu Gamedze, declare that this research is my own work. It is being submitted for the degree MMed in the university of the Witwatersrand, Johannesburg. It has never been submitted before for any degree or examination at this or any other university..

Signed.....at ….Johannesburg….the..03. dayof..September..2013



ACKNOWLEDGEMENT

Special gratitude to my supervisors Dr KA Frank and Prof EJ Buchmann for tireless critique and unfading patient guidance from the conception of the topic, organising, analysing and the final presentation of the research.

I would also like to thank Chris Hani Baragwanath Academic Hospital staff in the records department, gynaecology theatre and CTOP ward for assistance with record retrieval.

DEDICATION

I dedicate this work to my daughter Scelisiwe, who has always acknowledged the hero in me, giving me endless reasons to hang on.

To my husband for exposing the strong "I AM" in me.

To the Almighty God for keeping me in one piece.

LIST OF TABLES

Table 1. Procedures used for second-trimester termination of pregnancy……..**12**

Table 2. Risk stratification for placenta praevia and placenta accrete, according to the number of previous caesarean sections…….**24.**

Table 3. Parity distribution of women who presented for elective TOP……**34**.

Table 4. Comparison of obstetric parity between successful and failed abortion groups…**35**

Table 5. Gestational age distribution and comparison between successful and failed abortion groups……**36**

Table 6. Comparison of occurrence of multiple pregnancy in successful and failed abortion groups……**36**

Table 7. Surgical procedure chosen after failed abortion, grouped by gestational age……**38**

Table 8. Post procedure complications (haemorrhage and incomplete evacuation) following interventions for failed abortion on medical induction regimen……**38**.

Table 9. Seniority of surgeons performing the different procedures following failed abortion on medical induction (n=88)……**39**

LIST OF APPENDICES

Appendix A. Data collection sheet…….**51-52**

Appendix B. Ethics certificate……..**53**

Appendix C. Hospital permission…….**54**

Appendix D. Prototype of recommended CTOP discharge summary……..55

TABLE OF CONTENTS

ABSTRACT……1-2

DECLARATION……...3

ACKNOWLEDGEMENT……4

DEDICATION……5

LIST OF TABLES……6

LIST OF APPENDICES……6

TABLE OF CONTENTS……7-8

LITERATURE REVIEW..……9-10

SECOND TRIMESTER TERMINATIONS……10

TECHNIQUE FOR PERFORMING SECOND TRIMESTER ABORTIONS.…….11

Cervical priming agents and induction a*g*ents……13

***MISOPROSTOL*...…….13**

***OTHER PROSTAGLANDINS*……...…….13**

***MIFEPRISTONE*…….14**

***MECHANICAL DILATORS*…...…….14**

***OXYTOCIN*…..……15**

Medical abortion……..15

Surgical methods……16

***SUCTION CURETTAGE*…….....16**

***HYSTEROTOMY*……17-20**

***DILATATION AND EVACUATION*……..20-22**

COMPLICATIONS OF SECOND TRIMESTER LEGAL ABORTIONS…….22

Immediate complications……..22-25

Delayed complications.……...…25

Late complications.…….26

Other complications.……..26

PROBLEM STATEMENT……..27

STUDY OBJECTIVES……27

METHODS AND MATERIALS……28-30

Study design population and sampling..……30-31

Data collection……...31-32

Data processing and analysis……32

Ethics……...33

RESULTS……..34-39

DISCUSSION…….....40-43

LIMITATION……...43-44

CONCLUSION AND RECOMMENDATION……...45

REFERENCES……..…46-51

APPENDIX A……52-53

APPENDIX B……..54

APPENDIX C…….55

APPENDIX D…….56

LITERATURE REVEIW

INTRODUCTION

The implementation of the legalisation of termination of pregnancy (TOP) in developing African countries is met with several challenges. Those countries in which it is legal have penal codes or very restrictive laws e.g. Ghana[1]. Ethiopia is another country where the penal code was lifted only in 2005[2]. Consequently there have been large numbers of unsafe abortions which are disastrous to women, and not infrequently fatal. Grimes compared such effects to be like a crash of 168 jumbo flights (per year) each carrying 400 women, all below the age of 45, however no proportional global response is effected by such losses[3]. According to the World Health Organisation, unsafe abortion is defined as 'a procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills, or in an environment lacking the minimal medical standards or both'.[4]

In South Africa, the legalisation of the Choice on Termination of Pregnancy (CTOP) Act of 1996 [5] has improved the prospects for the health of women in the reproductive age group, who find themselves with unwanted pregnancies. Maternal mortality and morbidity from unsafe abortion has been significantly reduced as the number of legal abortions has increased.[6] In 2004, Jewkes published work on the prevalence of morbidity associated with TOP before and after the implementation of the CTOP legalisation and found that morbidity rates had fallen from 17% in 1994 to 10% in 2000.[6] The South African CTOP Act has no age restriction for request for TOP, however it stipulates the cut-off gestational age for elective TOP to be 20weeks. TOP above 20 weeks is indicated for maternal safety or on condition

where there is a serious threat to the well-being of the fetus if it is born alive. Such a procedure has to be recommended by at least two health practitioners.[5]

SECOND-TRIMESTER TERMINATIONS

Second trimester abortions, from 13 to 24 weeks of gestation, account for 10-15% of the total abortions performed worldwide.[7,8] Late presentation for termination of pregnancy or abortion is a significant problem in developing countries. A large proportion of women present in the early second trimester (13 to 20 weeks), compared to high-income countries, where 90% of women present in the first trimester [9]. In some cases where women have presented early (first trimester), they are failed by the referral system or lengthy waiting lists, and this results in second-trimester abortions.[10] In South Africa, in 2003, the legal abortion rate was 6 per 1000 women[11]. Dickson, in the same year documented that access was still found to be limited and inequitable, with many hospital-based providers being openly hostile towards women seeking abortion.[12]

Finer et al in 2006 conducted a study in the United States of America (USA) of the timing between steps and reasons for delay in obtaining TOP. A total of 1209 women with second-trimester abortions were recruited and 38 had in-depth interviews. It transpired that 58% of women would have preferred earlier or first-trimester abortion, and 59% admitted that they had taken excessively long to procure an abortion, and 36% had only realised relatively late that they were pregnant. The average time from the last normal menstrual period to abortion was prolonged in both the women who presented in second trimester and in teenagers, as signs of pregnancy were either unknown or ignored.[13]

TECHNIQUES FOR PERFORMING SECOND-TRIMESTER ABORTION

There has been a remarkable evolution in the management options for second-trimester abortion, regardless of the gestational age at presentation. Bygdeman and Gemzell-Danielson[14] did a historical overview of second-trimester methods of abortion (Table 1). With the exception of hysterotomy, the outdated methods listed will not be discussed further in this review. Hysterotomy is still used frequently in South Africa. [15]

The definitive method of management varies from one institution to the other depending on available resources, and within the same institution it may vary from one clinician to the next, depending on experience and moral beliefs. Most clinicians prefer induction of abortion and delivery (as this tends to mimic the natural delivery process), followed by evacuation of retained products of conception.[16] Failed medical abortion is a major concern[17] as there is a prolonged induction to abortion interval which is financially draining on already limited health resources, [18,19] and carries the risk of additional clinical complications such as infection and haemorrhage.

From as early as the 1970s, there was a documented concern about failed second trimester abortions. A spectrum of definitions was developed. Any of the following scenarios would constitute a failed abortion:[20]

- Development of fever above 38.0^0 C during the induction of abortion, not of extra-uterine origin
- If the primary/initial method in combination with an oxytocic agent does not result in imminent abortion
- Development of excessive uterine bleeding before expulsion of the conceptus which is not controlled with oxytocic agents

- Exceeding an arbitrary time limit from induction to abortion. This may vary from one agent to the other and among protocols from different institutions.

The term 'failed labour induction' may be used interchangeably with failed abortion and is defined as the failure to expel a fetus within a specific time frame, necessitating an additional procedure[20]. 'Labour' in current obstetric terminology generally refers to the expulsion process after fetal viability (about 24 weeks). 'Successful abortion' is described as expulsion of the fetus by the intended method regardless of whether complete or whether placental tissue is retained.

Table 1. Procedures used for second-trimester termination of pregnancy, divided into those not frequently used, and those used in modern practice (reproduced from Bygdemann and Gemzell-Danielson [14])

	Time of introduction
No longer recommended methods	
Medical methods	
Intra-amniotic	
Saline	1960
Urea	1960s
$PGF_{2\alpha}$	1972
Carboprost	1975
Extra-amniotic	
Rivanol (ethacridine lactate) + oxytocin	1970
$PGF_{2\alpha}$	1972
Intra-muscular	
Carboprost	1975
Sulprostone	1980
Vaginal	
PGE_2	1980
Gemeprost	1985
Surgical method	
Hysterotomy	early 20th century
Currently recommended methods	
Mifepristone + misoprostol	1990s
Misoprostol alone	1990s
Dilatation & evacuation (D&E)	late 19th century

Cervical priming agents and induction agents

All the methods of abortion mentioned above, except for hysterotomy, require a favourable uterine cervix that can allow safe evacuation of the uterus regardless of the gestational age. A substantial number of studies have been carried out to determine the drugs and combinations that are suitable for induction of abortion, or at minimum give adequate cervical priming to facilitate emptying of the gravid uterus in the second trimester.[9,18,21,22]

Misoprostol

Misoprostol, a prostaglandin E_1 analogue, is the drug of choice regardless of previous uterine scarring.[23] The advantages of cost, easy storage conditions, ease of administration (oral, sublingual or vaginal) and tolerable side-effect profile makes misoprostol acceptable even in under-resourced areas.[9,24,25] Misoprostol may be used alone or in combination with either mechanical dilators or with oxytocic drugs. There has been concern about uterine rupture, especially after previous caesarean section. In 2009, Goyal published a systematic review which included 63 articles, and reached the conclusion that the risk of uterine rupture after caesarean delivery during a second trimester misoprostol-induced abortion was less than 0.3%.[26]

Other prostaglandins

Prostaglandin E_2 analogues, such as gels and tablets (Prepidil and Prandin) are expensive and require refrigeration. This makes them inappropriate for use in under-resourced areas where the cold chain may be broken. Both products have a uterotonic effect on the myometrium.[27]

Prepidil gel is an intracervical gel that is indicated for ripening of the cervix at term or near term in pregnant women with an indication for induction of labour. Prandin gel, on the other hand, is a vaginal preparation indicated for termination of pregnancy in the second trimester.

Mifepristone

Mifepristone is an antiprogesterone drug, previously known as RU486, which is believed to reverse the quiescent effect of progesterone on the uterus thus making the uterus more sensitive to the effects of uterotonic agents such as misoprostol. It has been proven to markedly reduce the induction-to-abortion time and failure rate of termination of pregnancy. It is usually administered 24 to 48 hours before misoprostol.[28] The main disadvantages of the drug are high price and unavailability.[29] In South Africa, it is currently unavailable for general use at government health institutions.

Mechanical and osmotic dilators

Lamicel is a polyvinyl alcohol sponge impregnated with magnesium sulphate and packed in a sterile pack. It has a greater chemical than mechanical effect on the cervix. Its onset of action is about 30 minutes and the maximum effect is achieved in a few hours. Optimum results are obtained in gestations below 20 weeks.[30]

The more classic laminaria tent is a dried compressed seaweed stem that absorbs fluid and expands gradually, thus giving two end results: mechanical dilatation and endogenous prostaglandin release. Effective dilatation is achieved after 3 hours and it has a full dilatation potential after 12 to 24 hours.[31]

Dilapan is a hygroscopic dilator rod made from hydrophilic polymers. It exerts its effect by outward expansion and prostaglandin release resulting in degradation of collagen and cervical softening. A revised version called Dilapan-S was released in 2002. The maximum effect is achieved within after 4 to 6 hours.[32]

In state practice lamicel and laminaria tent were commonly used but now they are not available

Oxytocin

Oxytocin is a potent uterotonic hormone produced physiologically by the posterior pituitary gland. Synthetic oxytocin is predominantly used in second-trimester TOP as an adjuvant to either other uterotonics drugs or mechanical dilators. If used in isolation as an induction agent, much higher doses are needed than in those needed for a term induction of labour, bearing in mind that in early gestation, there is a relative paucity of oxytocin receptors in the myometrium. Oxytocin exerts its effect by increasing contraction frequency, amplitude and uterine basal tone. A known side-effect of high-dose administration is fluid overload, which can be minimised by administration of intermittent doses.[33]

Medical abortion

Induction with or without curettage

Rorbey et al, in 2004 investigated medical versus surgical abortion in terms of efficacy, complication profile, and leave of absence from work, in a partially randomised study. They suggested that medical abortion has become an alternative to surgical TOP and that it has improved the safety and accessibility of legal abortions in underdeveloped health care systems with limited resources. The authors also highlighted that medical abortion is more acceptable to women. Importantly, the results showed that the success rate after medical

induction decreased with increasing gestational age. There was shorter leave of absence from work in the medical abortion group. [34]

In a review of 1002 consecutive cases of medical induction in the second trimester (13 weeks -21 weeks) using mifepristone and misoprostol, Ashok et al found that nulliparous women and those with advanced gestation (17-21 weeks) required a higher number of prostaglandin doses than parous women and thus had an increased induction to delivery interval. Failure of the medical abortion method was less likely in parous women.[35]

As alluded to by the studies above, the two common agents used for medical abortions include misoprostol and mifepristone. Misoprostol is a prostaglandin analogue which has been used off-label for abortion induction. Side-effects include fever and gastrointestinal symptoms such as diarrhoea, nausea and vomiting. Depending on the dosage, the induction-to-abortion interval may be prolonged. The antiprogesterone agent mifepristone may act to reduce the induction-to-abortion interval.[27,29] Of note is that there is currently no consensus on the dosage of misoprostol but IPAS (a worldwide non-government organisation focusing on women health and specific abortion needs) has provided some guidelines in the 2007 edition of Clinician's Guide for Second Trimester Abortion.[36]

Surgical methods

Suction curettage

This procedure entails the use of electric suction using a cannula of about 16 mm diameter. The patient is positioned in dorsal lithotomy and the prior primed cervix is dilated to fit the cannula. Suction is used to aspirate the uterine contents. This method can be used for

gestations less than 16 weeks before which point the fetal bones can be forced through the cannula and tubing.[37]

Hysterotomy

In the mid-twentieth century, hysterotomy was the method of choice for second-trimester terminations.[20] The procedure has however fallen out of favour among clinicians who perform second trimester abortions, and is no longer recommended by the professional bodies that regulate these procedures.[3] Hysterotomy is defined as a surgical operation where abdominal access into the gravid uterus is attained with an aim of evacuating the conceptus before viability.[37] In the western world, during the 1970s, hysterotomy was either a primary (driven either by patient or doctor preference) or secondary (due to failed medical induction) abortion procedure. [38]

In 1975, Nottage et al reviewed a total of 700 hysterotomies done in Aberdeen between 1968 and 1972. The frequency of hysterotomy in the study was 24.2% of all terminations. The authors acknowledged that hysterotomy was, at the time, already an out-dated method of abortion due to its increased risks of mortality and morbidity. In Britain in the 1970s, hysterotomy declined as an abortion method, with the emergence of medical induction, and dilatation and evacuation. In the same paper there was acknowledgement on how little scientific literature there was on hysterotomy[40]. This scarcity has remained, and hysterotomy is considered by many to be a "museum" procedure, of historical interest only. [41] Despite this, hysterotomies are still done in many countries, but the worldwide frequency is difficult to estimate.

Hysterotomy has its own intraoperative technical challenges, as there is no lower segment on the uterus to ease uterine incision, compared to advanced gestations. Traditionally, the uterus was cut in the midline longitudinally, with the fundus being included in the incision. This had complications with haemostasis and overall weakening of the uterus for subsequent pregnancies. The technique was then modified by suggesting a transverse incision on peritoneum to reflect the bladder inferiorly so that a longitudinal incision could be made lower on the uterus and be covered with the transverse fold of peritoneum and bladder. The complications of this method were:

1. extension of the incision further down to injure the cervical internal os resulting in cervical stenosis or incompetence;
2. injury to the bladder base and haemorrhage during downward reflection of the bladder; and
3. overstretching of the bladder to a higher anatomical position during covering of incision, which increased the risk of injury at subsequent operations.

In 1973, Mukerjee[39], an Indian gynaecologist, published a recommendation of the surgical procedure at hysterotomy and the description can be summarised as follows:

The uterus is accessed from the anterior abdominal wall through a midline or transverse lower abdominal incision. On opening the peritoneal cavity, bowel must be packed away with the assistant surgeon straightening the uterus by applying gentle traction the fundus. An incision on the loose peritoneum anteriorly is made transversely with the convexity downwards. The bladder should not be pushed down; rather the opened peritoneum should be slightly reflected. On that exposed area, a small transverse incision is made through the myometrium in the midline of the uterus, just big enough to introduce the surgeon's index and middle fingers. Further extension is made with scissors under the guidance of the two

fingers to follow the curve of the previous peritoneal incision, upwards and laterally. The end result should be the corners of the incision pointing towards the direction of the round ligament insertions. Following evacuation of the uterus, retrograde dilatation of the cervix may be done, and the uterine incision sutured in two layers.[39]

Locally at Charlotte Maxeke Johannesburg Academic Hospital in a study published in 2009 by Basu and Basu, the incidence of hysterotomy was 0.5% among women who had failed medical induction[15]. The need for hysterotomy was influenced by presentation at advanced gestations (close to 20 weeks, just under the legal cut-off according to the CTOP legislation), the presence of more than one previous caesarean section, or a request by the woman for tubal ligation. In a study published two years prior to the one above, in 2007, in the same institution by Daponte, Nzewanga and Guidozzi, the incidence was 0% among women (n=12) who had more than one previous caesarean delivery undergoing TOP.[23] Published data or studies from other South African academic institutions were not found. Literature from other African countries does not include hysterotomy as a surgical procedure for abortions.[1,2]

Other indications for hysterotomy apart from the ones mentioned above include suspicion of a thin myometrium where danger of perforation is likely if blind manipulation with instruments is done. Anomalies of the cervix and uterus have also been identified in some cases resulting in technical difficulty in accessing the conceptus vaginally. Strong religious, moral and emotional objections by health facility staff against dilatation and evacuation in underdeveloped areas such as South Africa have pushed hysterotomy up the priority list of surgical abortion in second trimester [42].

At Chris Hani Baragwanath Academic Hospital, in Soweto, Johannesburg, hysterotomy is indicated for failed medical induction of abortion in second trimester termination of pregnancy. However, South African guidelines for second trimester abortions published by IPAS in 2007 recommend dilatation and evacuation for failed medical induction of abortion[36].

Hysterotomy is historically associated with morbidity and mortality.[43] This includes the risks associated with both surgery and hospitalisation, for example primary and secondary haemorrhage, sepsis and deep vein thrombosis [20]. In 1981, the complication rate for hysterotomy in the USA was 17% and this was not influenced by age, parity or history of previous pregnancy. Later statistics show a mortality rate of 51.6/100 000 when combining both hysterotomy and hysterectomy as second trimester TOP methods.[42]

Dilatation and evacuation

In most high-income countries, hysterotomy has largely been replaced by dilatation and evacuation (D&E). [3,18,37] D& E is associated with a lower mortality rate of 4.9/100 000 terminations, but after 20 weeks of gestation the rate increases to 8.9-11.9/100 000.[42] D&E is currently the surgical method of choice recommended by the World Health Organisation,[4] and can be considered as the gold standard method for second-trimester TOPs. In the USA it accounts for 96% of second-trimester abortions above 12weeks of gestational. It is defined as a procedure where the cervix is primed (with misoprostol or with osmotic dilators like a laminaria tent), then dilated manually with Hegar dilators. The uterine contents are evacuated using forceps followed by sharp curettage or suction curettage.[16,44] D&E has the advantage of being a same-day procedure with the woman discharged early. This is especially true for developing countries where resources including hospital beds are restricted [3]. It is generally considered to be the safest and most cost effective surgical technique.[14] Grimes, in a paper

published in 2008, advocates for the procedure and further puts forward an ethical challenge to gynaecologists who do not provide D&E as part of second trimester abortion service procedure. He gives four reasons why D&E should be the method of choice for second-trimester abortion:

1. Women prefer it (which contradicts Rorbey's findings that women preferred medical induction);
2. it does not 'confuse' the uterus which was designed to expel early or late in pregnancy not in the mid-trimester;
3. it is safe; and
4. it embraces the principles of beneficence, autonomy and justice, hence gynaecologists who do not provide D&E present a barrier to better care for women.[41]

The main disadvantage of D&E is that it requires special experience and skill. [15] D&E may be time-consuming and several different instruments may be required during one case.[16] Associated complications are failure to dilate the cervix, cervical lacerations, retained fetal head and or placental tissue, haemorrhage and uterine perforation. Emotional trauma to the clinical staff cannot be underestimated as the fetus is rarely retrieved in its entirety and is extracted piecemeal .[16,45]

The National Abortion Federation, a body that has members in North America and Australia, conducted a study in 2008 reviewing at practices in second trimester abortions amongst institutions which are members of the Federation.[46] The general findings were that second trimester abortions are conducted safely. The level of qualification ranged from specialists (obstetrician/gynaecologist) to doctors who had more than 20 years of experience in performing abortions. The common methods employed were medical induction plus an evacuation after the abortion, and dilatation and evacuation. Older clinicians were more

comfortable with dilatation and evacuation. In the study, hysterotomy did not feature as a second-trimester surgical abortion procedure.[46]

To further augment the safety of D&E, clinicians in the USA and Canada are now trained on abortions at residency level, and 51% of institutions have adopted the procedure as part of their curricula. The use of intraoperative ultrasonography is consistently employed in these training institutions to minimise avoidable complications like uterine perforation and incomplete evacuation of products of conception .[47]

COMPLICATIONS OF SECOND TRIMESTER LEGAL ABORTIONS

The complications of second trimester abortion rise disproportionately with each week of gestation when compared to below 8weeks gestation. In the USA a 38% increase in complication rate is estimated per week of advance in gestation. [48] The common complications can be grouped into immediate, delayed and late complications.

Immediate complications

Failed Abortion

This is a situation where there is no expulsion of the contents of the uterus with the intended method. It is a common complication with medical induction and with suction curettage. High success rates of 92-95% are reported before 7 weeks, and after 9 weeks the failure rate is about 10%. Surgical interventions like D&E are usually the gold standard in managing such complications.[17] Failure of a surgical method is considered to be a complication. This may happen where there are structural abnormalities e.g. obstructive fibroids and Müllerian

abnormalities like bicornuate uteri.[34] In a few isolated cases, women who have failed abortions opt to continue with the pregnancy and this may pose challenges to the clinician in charge, for the safety of the woman and her baby.

Haemorrhage

Haemorrhage is defined as loss of 250-500ml of blood or a blood loss requiring transfusion of blood. [42] Haemorrhage is mainly due to uterine atony, cervical lacerations, abnormal placentation (common in previous uterine surgery) and retained products of conception. These complications, if anticipated, can be prevented and if not preventable, at least managed before onset of hypoovolaemic shock. Ultrasonography in assessment of gestational age can assist to plan the degree of cervical dilatation to avoid cervical lacerations, and can be used intraoperative to detect any retained products after emptying uterus. Cervical priming has also been shown to reduce trauma during cervical dilatation. [49]

The IPAS Clinicians' Guidelines for Second Trimester Abortion[36] highlights the common causes of haemorrhage within the first 24 hours after abortion and the management thereof. These are:

- Uterine atony - this is a situation where the uterus fails to contract and stop bleeding. Atony is treated with bimanual uterine massage where the one hand holds the fundus of the uterus and the other is passed into the vagina to give counter pressure while massaging the fundus. Drug are also administered during the massage, including misoprostol 800 micrograms rectally, intramuscular or intravenous oxytocin, and oral methylergonovine 0.2 mg orally 4-8 hourly for a day or two (bearing in mind contraindications to the drug). The latter is not available in South Africa , syntometrine, a combination of oxytocin and ergot, is used,
- Retained products - these need re-evacuation by suction curettage.

- Cervical lacerations - if superficial and numerous, pressure alone may suffice. If the cervix is not friable, a ring forceps can be used to apply pressure on the bleeding part. If a laceration is deep, it must be sutured. Silver nitrite can also be applied on the bleeding vessel.
- Uterine rupture - This demand prompt identification and urgent laparotomy to stop bleeding and repair the defect.

Abnormal placentation with morbid adherence, such as placenta accreta, is another possible cause of bleeding during the removal of the placenta. This may be detected by ultrasound Doppler studies if suspected, for example, in a woman with previous caesarean section and a low-lying placenta. Such patients can be transferred to facilities which are well-equipped and have personnel with experience who can perform the terminations. Abnormal placentation is the most important complication that increases the risks of hysterotomy or emergency secondary hysterectomy. Table 2 illustrates the risk stratification for placenta praevia and placenta accrete, according to the number of previous caesarean sections.[50]

Table 2. Risk stratification for placenta praevia and placenta accrete, according to the number of previous caesarean sections.[50]

Number of previous caesarean sections	% risk of placenta praevia	% risk of placenta accreta
1	0.7	11
2	Not mentioned	39
3	3.0	6*
4 or more	10	Not mentioned

*Percentage risk for 3 or more previous caesarean sections

Acute haematometra or postabortal syndrome is associated with suction curettage, and is characterised by cramps and vaginal bleeding. Repeating the suctioning curettage, and administration of uterotonics usually resolves the problem.[7,42]

Uterine perforation

Perforation of the uterus is more common in advanced gestation where fetal bones have ossified. Other factors strongly associated with uterine perforation are multiparty, where the myometrium is likely to be thin, and clinician inexperience, for example inappropriate sounding of uterus. The insertion of a laminaria tent for cervical dilatation has also been reported to increase the risk of perforation by fivefold. The management of the perforation depends on the extent and site on the uterus. Laparotomy or conservative management can be employed. [41] Perforation with a sound or dilator is unlikely to cause visceral damage as compared to suction curette or forceps which may avulse, lacerate or perforate the intestine. Also, perforation on the lateral cervico-isthmic area is likely to cause vascular injuries and significant haemorrhage.

Delayed complications

Retained products of conception commonly present as secondary haemorrhage, often complicated by sepsis or septic shock. In institutions where routine intraoperative or post-abortion ultrasound is mandatory, this risk is minimised. The risk can be further reduced in instances where there is scheduled post procedure follow up.[36]

Late complications

Rhesus isoimmunisation

Rhesus sensitisation is a common late complication which can be detected in a subsequent pregnancy. The risk of isoimmunisation increases with advancing gestational age, but is

relatively low in association with abortion. In one study, it was found that 3.1% of Rhesus-negative women were sensitised following suction abortion in first trimester where anti-D immunoglobulin was not given. In South Africa, the recommendation is that 50 micrograms (250 unit) of anti-D be given intramuscularly for all pregnancy losses less than 20 weeks gestation.[51] The Royal College of Obstetricians and Gynaecologists recommends that anti-D be given to all pregnant women after a potentially sensitising event. According to their recommendations, after 20weeks, 500 units should be given followed by Kleihauer testing for the amount of feto-maternal haemorrhage so that additional anti-D can be given if needed.[52]

Asherman's syndrome

This is a condition where the inner wall of the uterus is denuded of endometrium, resulting in obliteration of the cavity by scarring (synechiae). The patients affected normally present with amenorrhea following evacuation of the uterus, or secondary infertility. Synechiae are treated by specialist gynaecologists, by hysteroscopy and resection.[36,42,49]

Other complications

Other complications example cervical incompetence and ectopic pregnancy have not been adequately correlated with second-trimester abortion. It has however been well proven that there is a strong association between previous abortion and a small for gestational age baby in subsequent pregnancies.[36,42,49]

PROBLEM STATEMENT

Hysterotomy is no longer recommended as primary surgical method of second-trimester abortion. It is however still recommended at Chris Hani Baragwanath Hospital as a primary

method of managing failed medical induction of abortion. D&E is also performed, but generally only by experienced consultants. The extent or frequency of use of hysterotomy, needs to be determined at this hospital, and, if possible, the factors that influence this choice by the clinicians need to be established.

OBJECTIVES OF THE STUDY

The study aims to achieve three main objectives:

1. To determine the frequency of hysterotomy in second trimester termination of pregnancy at Chris Hani Baragwanath Academic Hospital
2. To compare the differences between women who abort successfully following misoprostol induction regimen and the group that fails to abort and requires surgery at Chris Hani Baragwanath Academic Hospital.
3. To determine factors that influence the decision to perform hysterotomy versus dilatation and evacuation vs. suction curettage in women who fail to abort after medical induction.

METHODS AND MATERIALS

Study setting and background

The study was conducted at Chris Hani Baragwanath Academic Hospital; a community based tertiary institution in Soweto, south west of Johannesburg in South Africa. The hospital is the only state institution in the area that offers second trimester elective TOP services. The service is cost free to the patient, excluding transport. Most first-trimester abortions are done at Soweto and other local clinics. Only those expected to cause complications, such as those in women with medical disorders or previous uterine surgery, are referred to Chris Hani Baragwanath. However, all second-trimester requests are referred for the procedure to be done at Chris Hani Baragwanath.

The total daily intake of women requesting TOP is 50, and this number includes both first and second-trimester requests. All women must have been referred from a local clinic or a family physician. Due to limited resources for abortion services due to staff and space constraints, a total of 30 women are accepted each day, of which a quota of only 4 to 6 are admitted for second trimester terminations. The system operates on first come, first served principle.

The local protocol for second-trimester abortions

A medical officer is designated to determine gestational age by ultrasound on all women presenting with a request for abortion. Women less than 14 weeks pregnant are treated on an outpatient basis. Those from 14 to 20 weeks are admitted for medical induction to the TOP ward, in accordance with the second-trimester protocol. The day one regimen is always self-administered by the patient and on day two till day four, TOP treatments are administered to by the doctor. There are trained nursing staff and a doctor (usually a registrar) to oversee the ward at night. On average two ward rounds are done at night. The nursing staff offer support,

analgesia, and alert the duty doctor of any complications. The regimen, as reproduced from the Chris Hani Baragwanath Academic Hospital gynaecology protocol is described below.

- Day 1 is the admission day. The dosage of 600 micrograms of misoprostol is given to the woman to self-administer at 16:00, with another dose of 600 micrograms at 22:00 in the evening. If there is pain or bleeding, 10 units of oxytocin is added into 1 litre of normal saline or Ringer-lactate solution and administered intravenously at a rate of 125 mL per hour. If the woman aborts, she undergoes routine evacuation of uterus the following day in theatre . If she fails, she goes on to the next day's regimen.
- **Day 2:** 800 micrograms misoprostol is inserted into the posterior fornix at 08:00 followed 3 hours later by 20 units of oxytocin in 1 litre of normal saline run at 125 mL per hour. If the woman aborts, she has a routine evacuation of the uterus. If she fails, she proceeds to the day 3 regimen.
- **Day 3**: Prostaglandin E_2 (Prepidil gel) 0.5 mg is administered by a doctor intracervically. Alternatively, misoprostol at 400 micrograms is given vaginally 6 hourly for two doses followed by oxytocin infusion 20 units in 1 litre of normal saline 3 hours later. (The alternative is an extra-amniotic infusion of prostaglandin $F_2\alpha$, 5 mg in 200 mL normal saline over 5 hours.). If abortion occurs, an evacuation of the uterus is scheduled; failure to abort at this stage constitutes failed termination, which demands other methods of abortion (day 4).
- **Day 4**: the protocol explicitly states that women who have failed to abort after 3 days must be booked for hysterotomy. This is however operator-dependant. The actual procedure done varies between suction curettage, dilation and evacuation, and hysterotomy, and may depend on the clinician in charge, the gestational age, or the woman's wishes.

With experience and increasing comfort in performing manual vacuum aspiration (MVA) and the limiting factor of available theatre time, most clinicians opt for MVA if the placenta has been expelled or if on clinical examination it is detached and can be removed by minimal traction. Most women who abort at less than 16 weeks of gestation undergo MVA after expulsion of the fetus and placenta.

After recovery from anaesthesia, the women are observed in the ward for immediate postoperative complications. Those who have had suction curettage, and dilatation and evacuation, spend about 4 to 6 hours in the ward and are then discharged home with contraceptives (influenced by patients choice and medical status), analgesia (paracetamol and ibuprofen), haematinics if necessary, and antibiotics (usually a full course of doxycycline, or amoxicillin and metronidazole). If a hysterotomy is done, the woman is transferred to the main gynaecological ward and managed as a major surgical postoperative patient until discharge, usually 3 days postoperatively.

It should be noted that intraoperative or postoperative ultrasound assessment is not routine at Chris Hani Baragwanath, nor is the measurement of postoperative haemoglobin level. Such investigations are done according to clinical indications.

Study design, population and sampling

This was a cross-sectional study in which records of all elective second trimester (14 to 20 weeks) TOP were retrospectively reviewed. A period sample was used of all records of women who presented for elective TOP in the year 2008, from 1 January 2008 to 31 December 2010. In addition, all hospital files of women who failed to abort following four or more days of admission to the TOP ward were retrieved and analysed as is described below. Women were excluded from the study if they had medically indicated TOP (for example

maternal hypertensive disease or cardiac disease), TOP indicated for fetal abnormalities, missed abortions, and molar pregnancies.

Data collection

A data sheet was designed to include all the categories of variables of interest. The termination of pregnancy register and admission book was used to retrospectively identify all women who had second-trimester procedures. The operating theatre register was used to identify women who required surgical procedures for failed abortions. The hospital numbers of these women were used to retrieve their files from the hospital records department. Clinical and operation notes in the files were analysed to check if the operation described in the theatre register matched that of the supposed termination procedure. In cases where there was poor description of the operative procedure, the description or name assigned by the surgeon was used. For the women who aborted on the induction regimen, the files were not retrieved, and only the first three baseline variables in the list below were entered. For those who failed to abort and went onto the day 4 regimen, the full case-notes were available, and all variables were analysed.

Baseline and explanatory variables of interest were:

- Age and parity
- Ultrasound-based gestational age in weeks
- Number of fetuses
- Blood results: Rhesus group, rapid plasma regain (syphilis) serology, HIV status
- Previous termination of pregnancy
- Previous uterine surgery, for example myomectomy, caesarean section

- Seniority of the surgeon performing the surgery (consultant: four years of specialist training in obstetrics and gynaecology, registrar: in training, medical officer: no formal specialist training).

Outcome variables included were:

1. Type of surgical intervention used to abort current pregnancy
2. Immediate postoperative complications found included:

   a) Failure to abort - ongoing pregnancy in a woman who has received four days of misoprostol (and other prostaglandins) and oxytocics as medical induction of abortion.

   b) Haemorrhage - loss of blood rendering a woman symptomatic to necessitate blood transfusion.

The study data sheet is attached as Appendix A.

Data processing and analysis

All data was captured onto a Microsoft Excel spreadsheet and exported to Stata 11 statistical software for analysis. Standard descriptive data analysis was done, including means with standard deviations, and frequencies with percentages. The Chi-square test and Fischer exact tests were used to assess association between categorical variables, and Mann Whitney and Students-T test for comparison of frequency distributions. The level of significance used to indicate statistical significance was is a probability (P) value less than 0.05.

Ethics

Ethics approval to conduct the study was obtained from the Human Research Ethics Committee of the University of Witwatersrand, and the approval letter with clearance number M110226 is attached as Appendix B. Confidentiality in the data was assured by not using women's names, hospital numbers, birthdates or addresses on the data sheets.

Hospital permission to conduct the study was granted by the Chris Hani Baragwanath Academic Hospital Medical Advisory Committee, on behalf of the Chief Executive Officer (Appendix C).

RESULTS

The total number of 1803 women were eligible for inclusion in the study and whose case notes were found..

A data gap of about 6 months was found among the women who aborted following medical induction. This is because the hospital disposed of files to create physical space in the archives.

The 1803 were grouped into:

1) Medical induction group (success) = 1715 who aborted following medical induction
2) Surgical group (failure) = 88 who had a surgical intervention after failed induction

The mean age of the women was 25 with a standard deviation of 6.4years. The ages ranged from 13 to 49, with four aged 13. Table 3 shows the distribution of parity among the women, with 453 (24.8%) being nulliparous.

Table 3. Parity distribution of women who presented for elective TOP (n=1803).

Parity	Frequency	Percentage
0	453	24.8
1	691	38.3
2	412	22.9
3	177	9.8
4	33	1.8
5	14	0.8
6	8	0.4
7	1	0.1
Unknown	14	0.7

For all the women, the mean gestational age based on ultrasound scan at the time of abortion was 16.0 with a standard deviation of 1.7 weeks. The median was 16 weeks, with a range of 14 to 20.

Women with successful abortions were compared with women whose abortions failed and required surgical intervention. The mean ages were not different (25. 4 vs. 25.5 years; P=0.97). There was a greater proportion of nulliparous women among failed abortions (43% vs. 25% in the successful abortion group). This is shown in Table 4, which compares overall parity between the two groups (Wilcoxon Rank Sum test; P=0.02). Comparison of the successful abortion with the failed abortion group in terms of gestational age is shown in Table 5. There was no statistically significant difference in mean gestational age between the successful and failed groups (16.0 v. 15.8 weeks; P=0.20). Multiple pregnancy was associated with a decreased likelihood of failed abortion (Table 6), with0.3% of failed abortions being multiple pregnancies, compared to 3.5% of successful abortions (Fisher's exact test, P=0.005).

Table 4. Comparison of obstetric parity between successful and failed abortion groups (data incomplete for parity, hence reduced totals)

Parity	Successful abortion group (n=1715) (%)	Failed abortion group (n=75) (%)
0	421 (25)	32 (43)
1	672 (39)	19 (25)
2	396 (23)	16 (21)
3	171 (10)	6 (8)
4	33 (2)	0 (0)
≥5	22 (1)	2 (3)
P-value (Wilcoxon ranksum test)	0.02	

Table 5. Gestational age distribution and comparison between successful and failed abortion groups

Ultrasound-based gestational age (weeks)	Successful abortion group (n=1715)	Failed abortion group (n=88)	Total (%)
14	408	32	440 (24)
15	379	15	394 (22)
16	285	11	296 (16)
17	271	10	281 (16)
18	227	15	242 (13)
19	122	2	124 (7)
20	23	3	26 (<1)
Mean ± SD	16.0 ± 1.6	15.8 ± 1.8	
P-value (Student's t-test)	0.20		

Table 6. Comparison of occurrence of multiple pregnancy in successful and failed abortion groups.

	Successful abortion group (n=1715)	Failed abortion group (n=88)
Singleton	1710	85
Multiple (%)	5 (3.5%)	3 (0.3%)
P-value (Fisher's exact test	0.005	

Further results are confined to the failed abortion group of women whose full case-files were retrieved (n=88). Of the 31 women in whom the HIV result was available, 15 (48%) had seropositive results. Out of 64 women tested for Rhesus blood group, all except one were Rhesus- positive. There was no data on anti-D administration in the Rhesus-negative woman. Previous uterine surgery was recorded in 17 of the 88 women (19%) whose abortions failed.

This included 11 with previous caesarean sections and 6 with previous evacuation procedures including manual vacuum aspiration.

The surgical methods used in the failed abortions were hysterotomy (n=46; 52%), dilatation and evacuation (n=14; 16%), and suction curettage (n=28; 31%). Suction curettage was confined mostly to lower gestational ages, with 27 procedures done at 16 weeks or less. No D&Es were done at more than 18 weeks of gestation. The trend to hysterotomy being used at greater gestation was statistically significant (Fisher's exact test, $P<0.001$). The distribution of these procedures grouped by gestational age is shown in Table 7.

Complications were confined to 8 cases of haemorrhage, 2 of incomplete evacuation (Table 8). No women were admitted to the intensive care unit, none required abdominal hysterectomy, and there were no maternal deaths.

The level of experience of doctors performing the procedures is shown in Table 9. The more senior grades (senior registrars and consultants) tended to perform the D&E and hysterotomy procedures.

Table 7. Surgical procedure chosen after failed abortion, grouped by gestational age.

Gestational age (weeks)	Hysterotomy (n=46)	D&E (n=14)	Suction curettage (n=28)	Total
14	4	6	22	32
15	8	4	3	15
16	7	2	2	11
17	9	1	0	10
18	13	1	1	15
19	2	0	0	2
20	3	0	0	3

Table 8. Post procedure complications (haemorrhage and incomplete evacuation) following interventions for failed abortion on medical induction regimen

Procedure	Haemorrhage	Incomplete evacuation
Hysterotomy	3	0
Dilatation and evacuation	3	0
Suction curettage	2	2
TOTAL	8	2

Table 9. Seniority of surgeons performing the different procedures following failed abortion on medical induction (n=88)

	Hysterotomy(n=46)	D&E(n=14)	Suction curettage(n=28)	Total(%)
Medical Officer	4	0	0	4 (5)
Registrar year 1 and 2	5	2	3	10 (11)
Registrar year 3 and 4	27	5	20	52 (59)
Consultant	10	7	5	22 (25)

DISCUSSION

In this study a majority of women requesting second-trimester TOP aborted following medical induction, as expected. The failure rate was found to be about 5%, which is comparable to a study done at Charlotte Maxeke Johannesburg Academic Hospital where the failure rate was 8% after medical induction,[38] and women had to undergo a second cycle of misoprostol. In our study, those who failed had to undergo the various surgical procedure.ie suction curettage, D&E or hysterotomy.

In terms of the women's demographics, the age range varied from 13 to 49 with age of 25 which is comparable with other local studies[1,2,4,14]. It is however interesting to note that the four women who were 13 years old may have just started menses or had not even experienced menstrual flow. Although there is a fine line between confidentiality for minors and protection of their interests (children's rights), such cases should, by law, be reported to the South African Police Service via social workers to exclude sexual abuse. Women above 45 are expected to be approaching the climacteric, hence the use of contraception declines.

The ultrasound gestational age ranged from14 to 20weeks with the mean gestational age being 16 weeks. A total of 440 women presented for TOP at about 14weeks. There is an inverse relationship in the number of women per gestational age from 14 weeks to 20weeks. This may indicate that a good proportion of women present in the first trimester or early second trimester and are delayed in the referral system. The few who presented late (approaching 20 weeks) were usually women who are younger who may not be aware of signs and symptoms of pregnancy resulting in delay in deciding to abort. The determination of various reasons for abortion and different gestational ages and maternal age groups were beyond the objectives of this study.

Singleton pregnancies accounted for 99.6%. Out of the 8 sets of twins, 5 were aborted following medical induction, with a disproportionately high number of failures (n=3). This might suggest that size of uterus or some other characteristic of multiple pregnancy impacts on success of medical induction. Nulliparous women had low success rate with medical abortion.

Rhesus blood grouping was not consistently tested. In the surgical group, 26% of women had unknown status at discharge, with some potential opportunities missed to give Anti-D. For some of those whose results were known, most were retrieved at the time of data collection for the purposes of this study and all but one was fortunately found to be positive for rhesus antigen. For future pregnancies, our patients may be likely to present with Rhesus sensitisation and its complications. Since there is still stigma attached to TOP, the history may not be revealed in future assessments.

Regarding the main outcome of interest, the frequency of hysterotomy was 52% in the failed abortion group (n=88) and 2.6% as a proportion of all second trimester abortions (n=1803). The frequency only comparable to studies from the 1970s with no comparable recent studies found. Basu and Basu reported a frequency of 0.5% but the sample size was smaller (n=567). Daponte et al reported no hysterotomies in a small sample of women with two or more caesarean sections requesting second-trimester TOP.

It is likely that the reason for the high frequency of hysterotomy for second-trimester abortion is the fact that hysterotomy is the prescribed method of choice for failed abortions at Chris Hani Baragwanath Hospital, and that junior doctors are trained to do, and are comfortable with, hysterotomy. Experience of the attitudes of doctors at this hospital suggests that most prefer delivery of a whole fetus than the piecemeal delivery which is associated with D&E,

which is considered traumatic for the surgical team, including also the anaesthetist and operating theatre nursing staff.

Although dilatation and evacuation is recommended for second-trimester abortions by bodies like the World Health Organization (WHO) and Ipas, in our institution most doctors still consider it a destructive procedure, and it made up only 16% of surgical operations for failed abortion. Few surgeons perform it and it is rarely documented as a D&E in both theatre register and on surgeons' operative notes. It is only if one reads the descriptive notes of the operation that it transpires to be a D&E.

Suction curettage was a frequently used procedure, accounting for 31% of second-trimester operations for failed abortion, and is mainly done at a gestation of 14 weeks. In our study only one case of suction curettage was done at 18 weeks. This seems technically impossible to execute at such advanced gestation, and it is the one isolated case done by a senior registrar where there was no description of the procedure on the surgical notes, yet in the theatre records it was a suction curettage. This case is likely to have been a D&E. The common finding was a case assigned as a suction curettage yet described as a D&E.

Only two categories of complications were observed in our surgical study group, i.e. haemorrhage and incomplete evacuation of uterus. Only 10 women complicated and 8 of these were cases of haemorrhage. Two cases of women with previous caesarean section had haemorrhage, but there was no documentation of possible abnormal placentation being the cause. One has to mention that it was an unexpected finding for a teaching hospital to have no cases of uterine perforation.

Seniority of surgeons who perform surgical operations was within the expected confines. Registrars run the CTOP ward and are expected to carry out the operative procedures as part of their training. In the cases done by consultants, from our experience the main reasons

would have been religious beliefs or moral ethics of the responsible registrar who felt unable to do the procedures, or the unavailability of the registrar because of other more urgent duties.

Interestingly, four cases of hysterotomy were done by medical officers, and in all four a consultant was assisting (teaching). This further illuminates that in our institution, hysterotomy is still being taught by senior staff, rather than D&E. Again, surgical abortion is left to skilled and experienced staff. D&E was done by only a few registrars. It is known that the registrars who are confident and skilled in D&E learned their skills while in general practice before specialising.

Limitations

This was a retrospective review of patient documentation, hence poor record keeping was a major problem. It was not realistic or feasible to search for all 1803 records of second-trimester TOPs. Some records were missing both from the group that aborted following medical induction and from those failed medical induction of abortion and needed surgical intervention. The data gap resulting from disposal of files by the record department further makes it impossible to report the total number of second-trimester TOPs done during the study period.

Poor history taking by the doctors initially interviewing the women on admission deprived the researcher of important information about previous pregnancies, making the data somewhat unreliable in that respect. In some files the variables studied were not recorded at all, although they are a standard part of gynaecological history-taking.

A further difficulty was poor intra-operative descriptive notes by the surgeon, compounded by occasional failure of theatre staff to correctly and accurately document the operation done e.g. hysterectomy instead of hysterotomy. This falsely impacts on our operating theatre statistics for major surgery.

CONCLUSION AND RECOMMENDATIONS

Second trimester abortions still account for the sole reason for admission among women presenting for CTOP done at Chris Hani Baragwanath Hospital. The frequency of hysterotomy is still as high as in the 1970s in the USA. This may predispose women to complications of major surgery and indirectly increase the caesarean section rate in the hospital by presenting women with scarred uteri in subsequent pregnancies.

To accommodate the patient load and high demand for the CTOP facility, the abortion protocol may need to be adjusted. Literature has shown that the rest of the world has moved forward to D&E, this being a safer alternative and a same-day procedure. Our doctors need to be trained on D&E and support should be offered to those who still view it as a traumatic procedure. This will however come at a cost of training the doctors on performing D&E safely and effectively. The unit can benefit in the long term, in savings on bed costs, and theatre time, as in accordance with the current protocol, patients spend up to 4 days in hospital before surgical intervention takes place, and theatre space may not be available for a day or two thus prolonging hospital stay. Another option may be adopting the protocol of our sister hospital Charlotte Maxeke Johannesburg Academic Hospital, where the women are discharged and readmitted for a second cycle of medical induction. The benefit will be savings on theatre time, but perhaps not on hospital stay.

Record keeping for abortions is inadequate as this is usually a once of procedure and the files are disposed of after 2 to 3 years. This hampers further studies on the subject of CTOP. We therefore recommend a structured discharge summary which will include all important details on one sheet for separate and easily accessible filing. A prototype of such a summary is attached as Appendix D.

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APPENDIX A

DATA SHEET

STUDY NUMBER: (8=2008),(9=2009), (10=2010)……

AGE: ……....

PARITY: …….GRAVIDITY……..

ULTRASOUND GESTATIONAL AGE(weeks)…….

NUMBER OF FOETUSES……..

BLOOD RESULTS:

Rhesus; 1.***NEGATIVE*** ***2.POSITIVE*** ***99 UNKNOWN***

RPR; 1. ***NEGATIVE*** ***2.POSITIVE*** ***99 UNKNOWN***

HIV Status; 1. ***NEGATIVE*** ***2. POSITIVE*** ***99 UNKNOWN***

PREVIOUS TERMINATION OF PREGNANCY 1. *YES* *2. NO* *99 UNKNOWN*

PREVIOUS UTERINE SURGERY

1. None
2. myomectomy
3. hysterotomy
4. caesarean section; 5.C/S ×1 6.C/S ×2 7. C/S ×3 and more

8.evacuation of uterus or MVA

NUMBER OF DAYS ADMITTED TO TOP WARD: 1 2 3 4 5 6 7

SURGICAL EVACUATION PROCEDURE DONE:

1. Hysterotomy
2. Dilation and evacuation
3. Suction curettage

COMPLICATIONS:

1. Haemorrhage

2. Sepsis

3. Incomplete evacuation

4. Nil

SURGEON CATEGORY:

1. Medical officer(COMMUNITY SERVICE AND BEYOND BUT NOT A REGISTRAR)
2. Junior registrar(YEAR 1 &2)
3. Senior registrar(YEAR 3 &4)
4. consultant

APPENDIX B

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Audrey Gugu Gamedze

CLEARANCE CERTIFICATE	M110226
PROJECT	The incidence of hysterotomy in the late trimester termination of pregnacy.
INVESTIGATORS	Dr Audrey Gugu Gamedze.
DEPARTMENT	Department of Obstetric and Gynaecology
DATE CONSIDERED	25/02/2011
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 25/02/2011 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr KA Frank

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX C

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 11 February 2011

TITLE OF PROJECT:

The incidence of hysterectomy in second trimester termination of pregnancy

UNIVERSITY: Witwatersrand

Principal Investigator Dr A G Gamedze

Department: O & G

Supervisor (If relevant):. Dr K Frank

Permission Head Department (where research conducted) Yes

Date of start of proposed study: March 2011

Date of completion of data collection Dec 2011

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

PROF JOHN PETTIFOR
.....
CHIEF PAEDIATRICIAN
Recommended

(On behalf of the MAC)

Date: 11 February 2011

.....

Approved/~~Not Approved~~

Hospital Management

Date: 15 Feb 2011

Dr. P. Lingham
M B B Ch (Rand) DCH(S A) DOH(Rand)
Deputy CEO
Chris Hani Baragwanath Hospital
Mobile 082 419 1048
linghamp-dr@mweb.co.za

APPENDIX D

PROTOTYPE OF DISCHARGE SUMMARY FOR CTOP

NAME……..

HOSPITAL NUMBER……

AGE……PARITY……GRAVIDITY……..

LMNP……GA (dates) ……GA(u/s)……(singleton/twins)

BLOOD RESULTS

Rh POS NEG

RPR POS NEG

HIV POS CD_4 COUNT NEG DECLINED

REASON FOR TOP(as per consent) ……
……
……
……
……

SIGNIFICANT OBS ANG GYNAE HISTORY

CONTRACEPTION(SPECIFY)

PREVIOUS TOP

UTERINE/CERVICAL SURGERY(SPECIFY)

TYPE OF SECOND TRIMESTER TOP

MEDICAL day1 day2 day3 day4

SURGICAL

Surgeon: consultant/registrar/medical officer/intern

Operation: hysterotomy / D&E / Suction curettage / other(specify)

COMPLICATIONS

Nil/haemorrhage/perforation/incomplete abortion/sepsis

DISCHARGE/FOLLOW-UP (specify)

antibiotics/analgesia/contraception