SECOND TRIMESTER TERMINATION OF PREGNANCY AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

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A Dissertation that is being submitted for an MMed in Obstetrics and Gynaecology in partial fulfilment of the FCOG (SA) Part II

07 April 2015

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I. Abstract

Objectives: The main objective of this study was to characterise women who presented at Chris Hani Baragwanath Academic Hospital (CHBAH) between 12 and 20 weeks for termination of pregnancy (TOP). Secondary objectives were to determine time to abortion, compare sonar gestational age to gestational age by dates and reasons for late presentation.

Method: This was a prospective cohort study of women over the age of 18 who were referred to CHBAH for second trimester TOP between August 2012 and May 2013. The exclusion criteria were pregnancies more advanced than 20 weeks gestation. Data was collected from the medical file and by interview. Demographics and reasons to terminate were extracted from the files. Outcome variables included bleeding, pain, and time to abortion.

Results: One hundred and ninety one women (91.39%) aborted. The median age of women was 25.00 (IQR=21.00-31.00), range (18-43). Women older than 25 years were 33% less likely to abort than women less than 25 years of age. Ninety nine women (47.14%) bled severely. One woman had a uterine perforation following evacuation of the uterus. The median gestational age by sonar was14.71 (IQR=13.86-16.14), range (13.00-20.00). The median gestational age by dates was13.57 (IQR=12.29-15.00), range (4.14-26.28). One hundred and thirty five women (63.98%) had an MVA for RPOC using analgesia following medical induction. Two women (0.95%) needed hysterotomy following failed TOP. The median time to abortion was 11.50(IQR=8.67-17.92), range (3.50-69.33) and incidence rate of 0.5 per hour or 1 per 2hours.

Conclusion: The majority of women (91%) aborted within 72 hours following medical induction with less complication rate and short induction to abortion time. This affirm misoprostol efficacy as the suitable drug for conducting second trimester medical TOP.

II. Declaration

I, Dr Stephen Baloyi declare that this research is my personal work that I have extensively researched and compiled. It has never been submitted before to any institution for any degree. It is being submitted to the University of the Witwatersrand for an MMed (Obstetrics & Gynaecology). This is in partial fulfilment of the requirements for the fellowship of Obstetrics and Gynaecology of South Africa- FCOG (SA).

Part of this research had been presented at the Priorities Conference as an oral presentation on the 11th March 2014 and title of presentation was "Comparison of gestational age calculated using last normal menstrual period vs ultrasound in women requesting second trimester abortion at CHBAH".

Dr Baloyi Stephen

Signature....

Date.....07 /April /2015.

III. Acknowledgement

I would like to pass my sincere gratitude to my supervisor Dr Yasmin Adam for persistent support and guidance from topic conception and protocol formulation through to the final presentation of the research.

Special thanks to Professor Buchmann for constant enquiries about the progress of the study and for reminding me time and again of how important my study is. My heartfelt appreciation goes to Dr Frank for the basic teachings on scientific report writing.

I would also like to thank Professor Guidozzi for the encouragement he offered during our yearly individual academic assessments in the last two years. To my brother Patrick, your genuine support especially assistance with editing, you remain my source of inspiration. I am truly indebted to CHBAH staff, especially doctors and nursing personnel for helping me with making sure the medical notes were complete and also grateful to the Chief executive officer (CEO) of CHBAH for allowing me to conduct my research.

IV. Dedications

I dedicate this work to my wife Belinda for genuine support and sacrifice she showed during the course of my training.

To my daughters: Vuthlari, Vutivhi and Vukona for acknowledging a hero in me and giving me every reason to carry on when the going gets tough.

To Tata Madiba who recently passed on, for the love and sacrifice he showed us as a nation

Finally to the all mighty God for protecting and channelling my life into the person I am today.

V. List of tables

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VIII. Acronyms and abbreviations

ART- Anti-retroviral therapy

CDC- Centre for Disease Control and Prevention

CD4- Cluster of differentiation 4

CFR- Case fatality rate

COC - Combined oral contraceptive

CTOP - Choice of termination of pregnancy

CEO - Chief Executive Officer

CHBAH- Chris Hani Baragwanath Academic Hospital

CMJAH-Charlotte Maxeke Johannesburg Academic Hospital

D&C- Dilation and curettage

D&E- Dilation and evacuation

ID&E- Intact dilation and extraction

FCOG - Fellowship of College of Obstetrics and Gynaecology

FE- Fisher's exact

HB - Haemoglobin

HIV- Human Immunodeficiency Virus

HREC - Human Research Ethics Committee

IMI - Intramuscular injection

IQR- Interquartile range

IV - Intravenous

IVI – Intravenous infusion

MI - Maternal index

MMR - Maternal mortality rate

MVA - Manual vacuum aspiration

µg - Microgram

NVD - Normal vaginal delivery

PG - Prostaglandins

RCOG - Royal College of obstetricians and gynaecologists

RCT- Randomized control trial

Rh - Rhesus blood group

ROC - Receiver operator characteristics

RPOC - Retained products of conception

SD - Standard deviation

SA - South Africa

TOP- Termination of pregnancy

USA- United States of America

VAS - Visual assessment score

WHO - World Health Organization

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CHAPTER 1: INTRODUCTION

This chapter gives an overview on abortion and its prevalence in various regions of the world and is followed by the problem statement and justification of the study.

1.1. Introduction

Abortion of an unwanted pregnancy is one of the most common gynaecological procedures performed annually. Globally, it is estimated that 29 Termination of Pregnancy's (TOP) are performed per 1000 women aged 15- 44 years every year. Legal TOP's are usually safe in well-resourced countries (1). For every 100 000 procedures performed, the combined rate of mortality is 10 women (2). Countries which are poorly resourced and with stringent abortion laws have an unsafe abortion rate estimated at 98%(3) and approximately 130 women die from complications related to unsafe abortions daily (4).

Maternal death due to termination of unwanted pregnancy increases with a more advanced gestational age. The Centres for Disease Control and Prevention (CDC) indicated that maternal death associated with termination of unwanted pregnancy ranges from 0.5/100 000 gestation less than 9 weeks to 2.9 at gestation between 13 and 15 weeks , 9.3 at gestation between 16 and 20 weeks, and 12.0 at more than 20 weeks gestation(5).

"Worldwide, approximately 10% of abortions take place in the second trimester", but developing or low resource countries like South Africa (SA) and India have high figures of up to 25% to 30 % (6). In SA, with the passing of the Choice of Termination of Pregnancy Act no.92 of 1996 (CTOP), safe pregnancy terminations are available for the majority of women (7, 8). About 1600 abortions per year were reported in 1996 before the passing of the Act. This number went up to 26 519 in 1997 and jumped to nearly 90 000 in 2004. The

reason for the significant difference in the numbers before and after the Act may be because most abortions were performed illegally before the Act was passed and therefore not reported (9).

Abortion in SA is still associated with a number of problems; the number of facilities that perform them have reduced (10), women present late for abortions, contraceptive services are lacking, repeat abortions are common, women do not access safe TOP because of stigma and there are no services in some parts of the country. Second trimester abortions are associated with more complications and a greater cost (11).

At CHBAH 1224 second trimester abortions were performed in 2010 and 807 were performed in 2011 (12). The main objective of this study is therefore to explore factors associated with late presentation, reasons for late presentation and complications associated with second trimester TOP.

1.2. Problem statement

Abortion in the second trimester makes up 10-15% of the overall abortions worldwide and the majority (more than half) are considered unsafe (13). Generally, TOP is safe in developed countries with more abortion resources but mid - trimester abortion still accounts for higher mortality than TOP performed in the first trimester irrespective of the level of country's development. The dangers of mortality rise with increase in gestational age (14).

CHBAH is designated to conduct second trimester abortions and deal with complications associated with abortion such as haemorrhage, uterine rupture, sepsis, cervical laceration, uterine atony, perforation, retained tissue, and coagulopathy (15).

A local retrospective study which was not published conducted by Gamedze et al looking at second trimester abortions at CHBAH showed that the number of failed TOPs and the need for surgical intervention is high. This is a concern and there is a need to investigate why women present late for pregnancy terminations.

1.3. Justification

Ideally women who are not planning pregnancy should be using contraception. If contraception fails they must seek termination of pregnancy as early as possible. Knowing the reasons why women present late for abortions may aid in tailoring services for safe abortions and may also assist with informing education programs for women.

By investigating why women present late, we may be able to provide information to women and health care workers on how to reduce late presentation for TOP. Reducing second trimester abortions may help reduce complications such as haemorrhages, infection, uterine rupture, perforation and maternal death. Knowing the time to abortion may assist with logistical aspects of TOP services.

CHAPTER 2: LITERATURE REVIEW

This chapter defines abortion and describes why safe abortion is an imperative for public health. Reasons for abortion and in particular second trimester abortion will be explored. Methods of procuring abortion and complications associated with abortion will then be described and will be followed by the aim and objectives of the study.

2.1. Definition and background

Abortion occurs when an unwanted pregnancy is terminated by use of any method before viability is reached by the foetus. Gestational age of 23-24 weeks is currently the cut off for viability (16). "Second trimester or mid-trimester is a period ranging from 13 to 28 weeks of gestation which again is subdivided into an early period between 13 and 20 weeks and a late period between 20 and 28weeks"(17).

TOP is associated with minimal complications when it is done in a medical centre with required resources or equipment and in countries with no restrictive laws. "Of the 210 million pregnancies that occur each year, over 46 million (22%) end in induced abortions, mostly during the first trimester (18)". Mid-trimester abortions represent between 10% and 15% of all induced abortions but result in two-thirds of all serious complications (19).

One of the main challenges with managing mid-trimester TOP is the development of safe and effective procedures or techniques. Recently, the management of mid-trimester abortion is mostly by medical induction; operative management is also effective and should be used but can result in serious complications (20). Unsafe abortions are responsible for up to 13% of maternal deaths globally, estimated at 47 000 mortalities per year (21). United States of America (USA) has 0.7 maternal mortalities per 100 000 procedures (22). Developing

countries with few resources have case fatality rate's (CFR) as high as 218 per 100 000 unsafe abortions (23). It will be difficult for many developing or low income countries to meet the millennium development goal number five, that is to reduce maternal death by 2015 by 75% if they fail to address avoidable factors leading to maternal mortality from unsafe abortions (24).

The CTOP Act No. 92 of 1996 regulates abortion in SA. The passing of the CTOP Act in SA resulted in a significant decline in maternal mortality and the incidence of women presenting with incomplete abortions. Despite a significant decline in the CFR, mortality index (MI) and maternal mortality rate (MMR), the presentation of critically ill women has not changed. The MMR per 100 000 births from abortion was 63.6 in 1997 to1998 and dropped to 5.54 per 100 000 births in 2003 to 2005 (25).

The Act allows abortion on demand up to 12 weeks and may be performed by a doctor or an appropriately trained nurse or midwife. Because of possible complications of second trimester abortion, the law is more stringent for pregnancies above 12 weeks (13 to 20 weeks) and states that "from the 13th up to and including the 20th week of the gestation period, if a medical practitioner, after consultation with the pregnant woman is of the opinion that

- The continued pregnancy would pose a risk to the woman's physical or mental health
- There exist a substantial risk that the fetus would suffer from a severe physical or mental abnormality; or
- The pregnancy resulted from rape or incest; or

- The continued pregnancy would significantly affect the social or economic circumstances of the woman"

And for pregnancies more than 20 weeks gestation "After 20th week of gestation period if a medical practitioner, after consultation with another medical practitioner or a registered midwife is of the opinion that the continued pregnancy

- Would endanger the woman's life
- Would results in a severe malformation of the foetus; or
- Would pose a risk of injury to the foetus"

A second trimester abortion can only be performed by a doctor (26). The Choice on Termination of Pregnancy Amendment ACT no. 38 of 2004 made an addition of a registered nurse in the termination of pregnancy on request during the first 12 weeks of pregnancy (27).

2.2. Indications and reasons for second trimester abortion

Medical and social factors may contribute to decision making regarding termination and may lead to a delay in seeking TOP. Other factors that may lead to delays are late pregnancy testing and diagnosis, financial barriers and delay within the referral system (28).

Abortion because of fetal anomalies also contributes to the increase in second trimester abortion as anomaly scans are best done in the second trimester. Late detection of genetic anomalies results in a delay in TOP in 47%-48% of women. (29).

Other reasons for mid-trimester TOP include foetal death, pre-eclampsia and prelabour preterm rupture of membrane (30).

2.3. Methods of procuring an abortion

There are several methods of performing an abortion; surgical, medical and mixed methods. Surgical abortion techniques in the form of D&E are widely used in many regions around the world especially in the United States of America where more than 98% of second trimester TOP were performed by using D&E (31). .

2.4. Cervical priming

Cervical pre-operative preparation is important in order to achieve dilation and softening prior to a surgical procedure resulting in minimal uterine and cervical trauma. It is recommended for most second trimester TOPs except when a hysterotomy is indicated. The cervix needs to be primed to permit instruments and retained products of conception (RPOC) without inflicting injury to the cervix. The cervical dilation needed for D&E rises with gestational age. Late TOPs require additional force to effectively dilate the cervix and this has the potential risk of damaging the cervix and causing other complications (32). Below are the common cervical priming and induction agents:

2.4.1. Laminaria

Laminaria is made from *laminaria japonica* and *laminaria digitata* seaweed stems, which are harvested, dried and made into cervical tents. Tents are from 2 -10mm in diameter and 60 - 85mm in length. When placed, they swell or bulge up to 4 times their original diameter following fluid absorption from the cervix, for example, a 3mm laminaria tent will achieve up to 1cm dilatation in situ overnight (33). The majority of cervical ripening usually happens in

the initial 6 hours. The cervical dilation puts pressure on the cervical canal which leads to prostaglandin (PG) production and this will allow manual dilation to be easy (34).

2.4.2. Lamicel

Lamicel is a synthetic osmotic dilator that was first reported in 1982. It is a dehydrated polyvinyl alcohol sponge embedded with 450mg of magnesium sulphate. It works faster than laminaria with cervical ripening effects occurring within 2 hours to 6 hours (35). It is usually 67mm in length and can bulge to 3 - 4mm its original state. It basically does not produce radial force in view of the fact that it is compressible (36). It may work by stimulating PG production or breaking down collagen tissues within the cervix. The exact mechanism is unclear (37).

2.4.3. Dilapan S

Dilapan S is made up of aquacryl which is the polyacrylate associated proprietary hydrogel and is a synthetic osmotic dilator. When dry, it exists in length of 55 and 65mm with the diameters of 3 - 4mm. In situ, Dilapan S swells 3 - 4times in diameter. When using a 4mm dilator, major effects are seen within 2 hours and it produces 7.8 - 10mm of cervical dilation. Dilapan S needs longer tents for cervical dilation and shortens by 18% as it bulges. It archives sufficient cervical dilation in the shortest time frame (38).

2.4.4. Misoprostol

Misoprostol is a synthetic PGE1 analogue (15-deoxy-16hydroxy-16methyl PGE1). It was developed for the management of peptic ulcer and it was later used off-label as an abortifacient. “It is cheap, stable at room temperature and can be stored for a long time.

Misoprostol in the required dose has few minor side effects and it is easily accessible in many centres" (39).

Misoprostol is efficient when taken orally and is metabolised by the liver. It has a half-life of up to 40 minutes following a plasma concentration peak at 30 minutes after oral administration (40).

Studies have looked at Misoprostol as an alternative cervical priming agent to natural osmotic dilators like Dilapan S, Laminaria and Lamicel. Like Lamicel, Misoprostol makes the cervix soft rather than expanding it (41).

2.5. Second trimester abortion procedures

2.5.1. Medical abortion

I. Intra amniotic instillation

Intra-amniotic solution is given via amniocentesis, using concentrated saline or urea. This technique was most frequently used in the 1970s and 1980s. It has been substituted by newer methods because of safety concerns, increased duration from induction to attaining abortion and incidences of retained placenta or RPOC which necessitate curettage following fetal expulsion (42).

II. Intra-amniotic PG

Intra-amniotic PG has complications like major blood loss that requires blood transfusion. Despite all these, intra-amniotic PG administration remains a successful method of mid-trimester TOP. In a Czech study performed between January 1991 and June 1997 that included 179 women, pregnancies were terminated using intra-amniotic PG. Of the 179

women, 72% of them aborted within 24 hours. Intra-amniotic administration was repeated twice in 26% of women and three times in 2% of women. The mean induction period was 22.6 hours (43). The World Health Organisation (WHO) PG task force organized a study where both the PGF2α and hypertonic saline were found to be more efficient in mid-trimester TOP. PGF2α was more efficacious with significantly higher rates in the initial 48 hours (44).

III. Oxytocin

This is a potent uterotonic hormone synthesized physiologically by the posterior section of the pituitary gland. Synthetic Oxytocin is mainly used in second trimester TOP as an add-on to either other induction drug agents or mechanical dilators. If intravenous (IV) Oxytocin is used in isolation as an induction agent, much higher dosages are needed than in full-term induction of labour, not forgetting that in early gestation, there is failure to respond by myometrial oxytocin receptors of the uterus. IV Oxytocin increases the frequency of contraction, amplitude and uterine basal tone. A common high dose side effect is fluid overload, which can be prevented by giving intermittent dosages.

The use of oxytocin at a higher dosage together with mechanical techniques is not a preferable method of abortion and is rarely a method of choice due to lack of response of the uterus to Oxytocin at this level of gestation. (45).

IV. Oxytocin and PG preparation

A randomised control trial (RCT) compared the efficiency of a high vaginally administered Misoprostol regimen to concentrated intravenous infusion (IVI) of Oxytocin in combination with low dose vaginally administered Misoprostol for second trimester labour induction. The two modalities were compared in terms of induction to delivery time and adverse effects. It

was noted that high dose Misoprostol greatly shortened mid-trimester induction to abortion time and the success rate of induction is shortened to within 12hours. Using high dose Oxytocin in combination with low dose vaginal Misoprostol failed to produce expected combined benefit (46).

V. Prostaglandins

The introduction of PGs and their analogues has been shown to be a more efficient and a safer method of medical TOP in the mid-trimester. RCT have reported shorter duration of time from induction of labour to aborting the fetus when Misoprostol is used (47).

VI. The use of Misoprostol alone for second trimester abortion

Studies show that Misoprostol used alone for mid- trimester TOP is effective. The only disadvantage is its longer time from induction to abortion, side effects are more common and high doses are needed compared to Misoprostol plus Mifepristone regimen. Mifepristone is a more expensive induction agent and is not readily available in many centres, even in some regions in the USA. Misoprostol on its own should be used in regions that do not have or cannot afford Mifepristone (48).

Many studies have documented the success rate, regimens and routes of administrating Misoprostol on its own in the mid- trimester TOP. Dosages from as low as 200microgram (µg) to 800µg at intervals of between 3 and 12 hours have been used by researchers. Higher doses of 600µg and 800 µg have produced successful abortion rates, but have higher incidences of complications like vomiting, diarrhoea, nausea and fever. The 6 hour dose interval is less effective than the 3 hour dose interval (48).

Meckstroth et al compared Misoprostol administered buccaly, rectally and vaginally. Vaginal Misoprostol was also compared when it was administered dried and when it was moistened and found that Misoprostol administered buccaly has lower serum drug levels compared to vaginal Misoprostol even though uterine contractility and tone were increased when all routes were compared. The rectal route of Misoprostol administration had both serum levels and uterine tone at the lowest level. Misoprostol administered vaginally has been shown to be the most efficacious method to carry out TOP effectively in the mid-trimester abortion with minimal adverse effects (49). The safety and efficiency of both oral and vaginal Misoprostol were compared and similarities were confirmed between the two routes (50).

VII. Induction with Mifepristone and Misoprostol regimens

The use of PGE1 analogues and Mifepristone to terminate pregnancy in the mid- trimester has been approved and recommended by international organizations like the Royal College of Obstetricians and Gynaecologists (RCOG) and WHO. The use of Mifepristone before Misoprostol as a combination results in safer and quicker abortion, especially in the mid-trimester **(**51).

Misoprostol and Mifepristone are more efficient when the initial Mifepristone dose is given and followed by Misoprostol 36-38hours later. A RCT of Misoprostol (vaginally) given together with Mifepristone versus after 36 - 38hours found that 91.5% aborted in the simultaneous group vs 100% in the misoprostol 36-38 hours later at 24hours period. There was a lower mean induction to abortion time of 4.9 hours in 36 - 38 hours compared to 10 hours in the immediate group (52).

Mifepristone use produces a 5-fold rise in sensitivity to PG 24 -48 hours following its administration (53). The synergy between Mifepristone and PG allows good success rate of

PG at lower dosages, with lower adverse effects. Mifepristone followed by PG for induction in the mid-trimester require approximately half the time as inductions using PG alone and approximately 95% women abort within 24hours(54).

The RCOG recommendation for TOP in the second trimester using Misoprostol in combination with Mifepristone is to give Mifepristone 200mg followed by Misoprostol 800µg vaginally36 - 48 hours later. Misoprostol (400 µg) is repeated 3 hours later and every 3 hours until abortion occur for a total of 4 doses (55).

2.5.2. Surgical abortion

The surgical technique for mid- trimester abortion has evolved remarkably in the USA since the legalization of abortion in 1973. D&E was found to be safer and therefore more popular than labour induction during the early 1980s (56). At the moment, several surgical techniques for second trimester abortion are available and "these procedures are suction dilation and curettage (D&C), D&E, intact dilation and extraction(ID&E) and hysterotomy" (57).

I. Suction D&E

This surgical procedure is only used during the early mid- trimester and should be avoided after 16 -18 weeks of gestation because fetal bones are already calcified which will make the task of fitting the products of conception through the suction tubing or cannula difficult. The average size of the tubing is mostly 12mm and the largest is 16mm in diameter. Cervical preparation includes using or putting osmotic dilators or using Misoprostol to dilate the cervix. (57).

II. Dilation and evacuation

The efficacy and safety of D&E was documented through a series of studies (58). D&E is currently conducted as a two stage procedure involving cervical dilation by using one or more sets of hygroscopic dilators or with Misoprostol alone for the cervical preparation. The second stage involves aspiration of amniotic fluid and trans-cervical evacuation using forceps 6 – 24 hours following the first stage. (59). Fourteen to nineteen millimetres is the baseline dilation needed to allow the majority of the instruments used to carry out D&E, however, wider dilations are often required in advanced gestations to remove products of conception (60).

Todd et al reported sufficient dilation following cervical preparation using 600µg of buccal Misoprostol in 32 women at 14 -16 weeks 2 - 4 hours prior D&E. "The procedure time was comparable with women at 16-18 weeks of gestation who had cervical ripening with Laminaria" (61).

Edelman et al conducted a study in order to ascertain if adjuvant Misoprostol given buccaly improves cervical ripening with Laminaria. The trial compared pre-operative cervical priming with Laminaria tent inserted overnight and either placebo or Misoprostol buccaly 90 minutes prior mid-trimester D&E at 16-20 weeks gestation. "The study found no objective differences in cervical dilation measured by passage of rigid dilators, and there was no need for additional dilation or duration of procedure at less than 19 weeks". Some surgeons subjectively documented easier dilation after pre-treatment with Misoprostol. Of note was that women who received buccal Misoprostol experienced more side effects. Researchers concluded that Misoprostol causes dilation of the cervix when used as a replacement to Laminaria in gestation beyond 19weeks (62).

Disadvantages of D&E are that clinicians are fully involved during the whole procedure and must cope with the site of removing the remains of the mid-trimester foetus in an intimate, direct and a more physical way which is a psychologically and emotionally traumatic experience (63). The advantage for both the provider and the patient is that the procedure can be scheduled on an outpatient basis and operation times are shorter compared to medical abortion which requires hospitalisation (64).

III. Intact dilation and extraction

ID&E is almost the same as D&E and entails more than one placement of hygroscopic dilators over a 2-3days period to ensure more dilation of the cervix .This will lead to the removal of intact foetus except that the calvarium is decompressed **(**65).The RCOG description of the procedure includes all 4 elements as follows:

- "Deliberate dilation of the cervix, usually over a sequence of days,
- Instrumental conversion of the foetus to footling breech.
- Breech extraction of the body.
- Partial evacuation of the intracranial contents of the living foetus to effect vaginal delivery of a dead but otherwise intact foetus" (66).

Intact dilation and extraction is vital in circumstances where anatomical preservation and conservation of the foetus is crucial (66). There are no good comparative studies to compare the efficiency and safety of D&E or ID&E but both are important useful procedures for offering safe second trimester abortion care (67).

IV. Hysterotomy

Hysterotomy was a most used procedure before the widespread use of D&E but is now seldom used. It is made up of laparotomy followed by the extraction of RPOC through hysterotomy incision and the procedure is completed when the uterus and abdomen are repaired. The procedure is the same as performing the caesarean section delivery on a pre-term uterus .This procedure is performed in circumstances where the cervix is blocked by either uterine pathologies like fibroid or where the uterine cavity is so thin that manipulation of the instrument is impossible (68).

In a retrospective study conducted at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), which looked at ways to actively manage mid-trimester TOP following failed medical induction, the incidence of hysterotomy was 0.5% among women who had failed a medical induction. The need for hysterotomy was influenced by presentation at advanced gestation (close to 20 weeks) and the presence of more than one caesarean deliveries or request by the woman for tubal ligation (69). There were no hysterotomies in women undergoing TOP who had had more than one previous caesarean delivery undergoing abortion in a study in the same institution by Daponte, Nzewanga and Guidozzi (70).

2.6. Complications

The prevalence of abortion related mortality rises with each week of gestation. The mortality rate was estimated at 0.1 for every 100 000 procedures at 8 weeks gestation or less and 8.9 for every 100 000 procedures at 21 weeks or greater (71). Complications include disseminated intravascular coagulation (DIC), RPOC, embolism, tear of the cervix, infections, rupture of the uterus, haemorrhage, failed induction and Asherman’s syndrome (72). Complications can be grouped into immediate, delayed and late complications.

2.6.1. Immediate complications

I. Post abortion haemorrhage

Post abortion haemorrhage was defined by the Family Planning society as haemorrhage that warrants blood transfusion, requires admission or has a blood loss of 500mls. (73). D&E procedures require blood transfusion following haemorrhage in 0.1-0.6% of cases compared to 0.7% of abortions perfomed medically (74). Causes include RPOC, cervical laceration, abnormal placentation, DIC, uterine atony, uterine perforation and rupture. In one study of post abortion embolisation of the uterine artery for bleeding, the causes of bleeding were noted to be; uterine atony (52%), abnormal placentation (17%), cervical laceration (12%), uterine perforation (7%), lower uterine segment bleeding without atony (5%) and DIC (5%) (75).

II. Retained products of conception

RPOC or incomplete TOP has been higher with medical abortions (8%) than with D&E (<1%) (76). In some studies, incomplete TOP were more common following TOP with Misoprostol induction in the mid- trimester as compared to D&E (77).

III. Uterine atony

Uterine atony is a failure of uterus to contract and results in excessive bleeding .In a review of up to 3000 D&E cases, atony occurred in about 2.6% of women. Predictors of uterine atony were increased maternal age and gestational age (78).

IV. Cervical laceration

Cervical laceration has been noted following medical TOP and D&E and made up 3.3% of mid-trimester TOP cases (79).

V. Uterine perforation

The prevalence of perforation of the uterus in mid-trimester operative TOP is low, at 0.2 - 0.5%. It usually occurs in combination with increased gestational age, lack of experience by the person conducting TOP and higher parity. They seldom occur in situations where the cervix is sufficiently prepared (80).

VI. Uterine rupture

Despite reported rupture of the uterus associated with medical abortions among women with previous caesarean scars and women without, the dangers of uterine rupture remain unknown. The danger of rupture of the uterus was 0.28% in women in women with previous caesarean delivery whereas it was 0.04% in women without a scar in studies reviewing mid-trimester TOP using Misoprostol (81).

VII. Disseminated intravascular coagulation

DIC arises as result of severe haemorrhage which may result in coagulopathy. The demise of the foetus in the mid-trimester put’s a woman at risk of developing DIC (82).

2.6.2. Delayed complications

I. Infection

The occurrence or incidence of post abortion infection in mid-trimester has not been clearly defined but figures ranging between 0.1- 4% have been reported (83). Symptoms and signs usually occur a few days following TOP and such women should be evaluated for RPOC. Ascending genital tract infections are caused by multiple micro-organisms and broad-spectrum antibiotics are indicated in the management of such infections (84).

II. Embolism

The prevalence of fatal and non-fatal pulmonary thrombo embolism is 10 - 20 per 100 000 abortions (85). The occurrence of amniotic fluid embolism is usually between 1 in 10 000 and 1 in 80 000 pregnancies and when it occurs after mid-trimester abortion, it has the mortality rate up to 80% (86).

2.6.3. Late complications

I. Rhesus (RH) isoimmunisation

RH isoimmunisation is a common late complication which can be detected in a subsequent pregnancy. The risk increases with an increase in gestational age and is low in association with abortion. One study found that 3.1% of RHD negative women were sensitized following suction abortion in the first trimester where Anti D immunoglobulin was not given to the women. In SA, the recommendation is that 50µg of Anti D be given IVI to all women who lose their pregnancies at less than 20 weeks (87). The RCOG recommended that all women who are pregnant should receive anti D after any potential sensitizing event, and this was

reviewed in studies looking at mid-trimester TOP using Misoprostol. Their recommendation after 20 weeks is to give 500 units followed by Kleinhauer test to quantify or estimate a foetal maternal haemorrhage so that additional Anti D can be given if required (88).

2.8 Aims and objectives

The main objective of this study was to characterise women who presented to CHBAH between 12 and 20 weeks for termination of pregnancy between August 2012 and May 2013. The specific objectives were:

- To describe women presenting to CHBAH for second trimester abortions, their demographics, social factors and co-morbidities
- To determine the time to abortion and describe factors associated with an increased time from induction to delivery.
- To compare sonar gestational age to gestational age by last normal menstrual period.
- To describe the complications - amount of bleeding (including the need for transfusions), infection, pain, uterine rupture and perforation.
- To describe final procedures - manual vacuum aspiration (MVA) under local anaesthesia, evacuation in theatre, dilation and evacuation (D & E) and hysterotomy.
- To describe reasons for late presentation.

CHAPTER 3: MATERIALS AND METHODS

This section presents the study setting and protocol of management of second trimester TOPs at CHBAH. The study population, sampling, study design and statistical methods are described. Ethical consideration and funding are outlined at the end of the chapter.

3.1. Study setting

The study was conducted at CHBAH, a tertiary institution that sees women mainly from Soweto. The population is predominantly Black but also comprises other population groups - Coloured, White, and Asian. The population size of women is 640 588 which makes 50.38% of the adult population in Soweto (89).

Women requesting a TOP in the second trimester and those with medical or surgical complications are referred from Community Health Centres to the Gynaecology Department at CHBAH.

The unit performs between 16 and 20 second trimesters abortions per week. The protocol for the management of second trimester abortion is as follows:

Day 1:

- Women are admitted. A complete examination and an ultrasound examination (for gestational age) is performed.
- Blood tests including haemoglobin (HB), urea and electrolytes, Rhesus blood group, Human Immunodeficiency Virus (HIV) testing and other tests that are clinically necessary are done.

- The woman is given 600 µg of Misoprostol to be administered vaginally at about 22H00, 6 hourly for 3 doses. Or until she has pain or bleeding.
- If there is pain and bleeding, an Oxytocin IVI of 20 milliunits /min is started. If she fails to abort, she proceeds to the next day's regimen.

Day 2:

- The doctor inserts 800 µg Misoprostol into the posterior fornix at 08H00.
- This is followed 3 hours later by 20 units of IV Oxytocin in 1 litre normal saline to run at 125ml per hour.
- If she fails to abort, she proceeds to day 3 regimens.

Day 3:

- PG E2 (prepidil gel) 0.5mg is administered intracervically
- OR two doses of Misoprostol at 400 µg are given vaginally 6 hourly followed by Oxytocin IVI 20 units in 1 litre of normal saline 3 hours later.
- OR an extra amniotic infusion of PG F2ὰ 5mg in 200ml normal saline over 5 hours. If she fails to abort, this constitutes a failed medical termination which necessitates other methods of abortion on day 4.

Day 4:

- The procedure to be done is dependent on the surgeon and this could be a hysterotomy, D&E or suction curettage.

In those women where there is an incomplete abortion, an MVA under analgesia or under anaesthesia or an evacuation in theatre is performed. The choice of procedure is dependent on the surgeon and individualised on the clinical findings. Patients are generally discharged 2- 6 hours after a procedure. Contraceptive choices are discussed. Discharge after a hysterotomy occurs 48 - 72 hours in uncomplicated cases.

3.2. Study design, study population and sampling

A prospective cohort study of women who presented at CHBAH for second trimester termination of pregnancy between August 2012 and May 2013 was performed. The study sample was a convenience sample where women were recruited 3 days a week. All women aged 18 and above and of between 13 and 20 weeks of gestation were included in the study. The exclusion criterion was as follows:

- Pregnancy more advanced than 20 weeks gestation.
- Threatened miscarriage at any gestation.
- Women requiring TOP due to severe pre eclampsia, eclampsia or other medical disease.
- Women unwilling or unable to give consent.
- Women whose TOPs were started outside the institution.

3.3. Data collection

The data was collected from medical files and by interviewing women on day 1 and again on discharge (Data sheet and questionnaire – Appendix A). The researcher returned every afternoon and morning to assess the progress of women who had been recruited, but only recruited 3 days a week.

Baseline and explanatory variables recorded from patients file and by interview include:

- Demographics: highest level of education achieved, home language, marital status, monthly income, age, HIV status, smoking, alcohol, drug use and contraception use.
- Date and time of admission, date and time of Misoprostol insertion.
- Gestational age, Bishops score, HB done on admission, previous obstetrics history.
- Reasons to terminate the pregnancy and for not having the TOP in the first trimester of pregnancy.

Outcome variables included the following:

- Date and time of abortion
- Bleeding,
- The need for blood transfusion,
- Pain,
- Infection and
- Other complications and surgical procedures.

Blood loss was quantified by using a 10 point scale where women were asked to grade bleeding they sustained during the course of TOP from 0-10. Bleeding from 6 and above was considered severe. Using the visual assessment score (VAS) scale bleeding of more than 6 was considered severe.

Pain was also quantified by using a 10 point scale where women were asked to grade the pain they sustained during the course of the TOP. Pain was graded from 0-10 with the score of 6 and above considered a severe pain.

3.4. Data processing and analysis

All data collected was captured into a Microsoft Excel spreadsheet 2007 and exported to STATA 10 statistical software (Stata Corp, Texas, and USA) for analysis. The data was explored and all outliers were re-checked with the source data (Medical files). All categorical variables were described using frequencies and percentages and continuous variables were described using means with standard deviations and medians. Ranges were also presented. Those women who did not abort the foetus were coded as "0" and those who aborted the foetus were coded as "1", even if the abortion was incomplete. Those who did not abort were excluded from the time to abort analysis.

All the explanatory variables were compared in those individuals who aborted and in those who did not abort. The cross tabulation tables were performed with every explanatory variable and the outcome. For the numeric (continuous) variables – the Wilcoxon rank sum test was used to test the equality of the median values where the variables were not normally distributed. Normality was assessed both graphically (using box and whisker plots and histogram plots) and statistically (using the Shapiro-Wilk test). For normally distributed numeric variables the t-test was used. All categorical variables were compared using the Chi2 test or the Fisher exact test for those that had fewer than 5 observations in a cell.

A new variable: "Time to abortion" was made which was the outcome of interest. The Kaplan - Meier curve was drawn to show incidence of abortion in those who had aborted.

3.5. Ethics

The study was approved by the Human Research Ethics Committee (HREC) of the University of the Witwatersrand. The approval letter with clearance number: M120653 is

attached below as Appendix C. Hospital permission to conduct the study was granted by the CHBAH Medical Advisory Committee on behalf of the CEO as noted in Appendix D. All participants provided written informed consents (Appendix B). Confidentiality and anonymity were ensured by not using women's names and addresses or birth dates on the data sheet and questionnaire.

Study procedures were carried out in accordance with the revised version of the Helsinki Declaration and with the standards of good clinical practice. The women were all given an information sheet and the details and procedures were then fully explained to them. Time was given to ask questions. The consent form, Appendix B, was signed by those willing to participate in the study prior to commencing with data collection. A separate list of recruited women was kept with names and hospital numbers because women had to be followed up until discharge and for record purposes.

3.6. Funding

Funds were only needed for stationery, files and printing. Photocopying and funding was borne by a researcher.

CHAPTER 4: RESULTS

4.1. Introduction

In this chapter, results are presented by first describing the study population. Outcomes, complications, reasons why women requested an abortion and reasons for the request in the second trimester are then described.

4.2. Women eligible for interview

The total number of women who were included in the study was 211 as described in figure 1 below. There were 338 women between 12 weeks and 20weeks pregnant that were admitted between 14 August 2012 and 13 May 2013 and 21 were under 12 weeks pregnant.

382 women admitted for TOP

382 ↓→ 21 women had first trimester TOP

361 ↓ → 23 Women were less than 18 years of age

338 ↓ →127 women were not interviewed

211 Women were included in the study

Fig 1: A schematic representation showing the number of women eligible for interview.

Women were ethnically diverse. The largest proportion of women were Zulu speaking 65 (30.80%) and only 2 (0.95%) spoke Ndebele. Their ethnicity, highest education attained and marital status and are summarised in table 1 below.

Table 1: A list of women's Ethnicity, education and marital status

		N (%)
Ethnicity		
	Zulu	65 30.80%)
	Southern Sotho	43 (20.38%)
	Xhosa	31 (14.69%)
	Tswana	19 (9.00%)
	Pedi	11 (5.21%)
	Tsonga	10 (4.74%)
	Zimbabwean languages	7 (3.32%)
	Venda	4 (1.89%)
	Ndebele	2 (0.95%)
	Other	19 (9.00%)
Education		
	No education	5 (2.37%)
	Primary education	155 (73.46%)
	Secondary education	50 (23.70%)
	Tertiary education	1 (0.47%)
Marital status		
	Not living with partner	95 (45.02%)
	Living with partner	26 (12.32%)
	Married	12 (5.69%)
	Single (no partner)	74 (35.07%)
	Widowed	3 (1.42%)
	Divorced	1 (0.47%)

Most women had an income of less than R3000. 00 per month as shown in the figure 2 below.

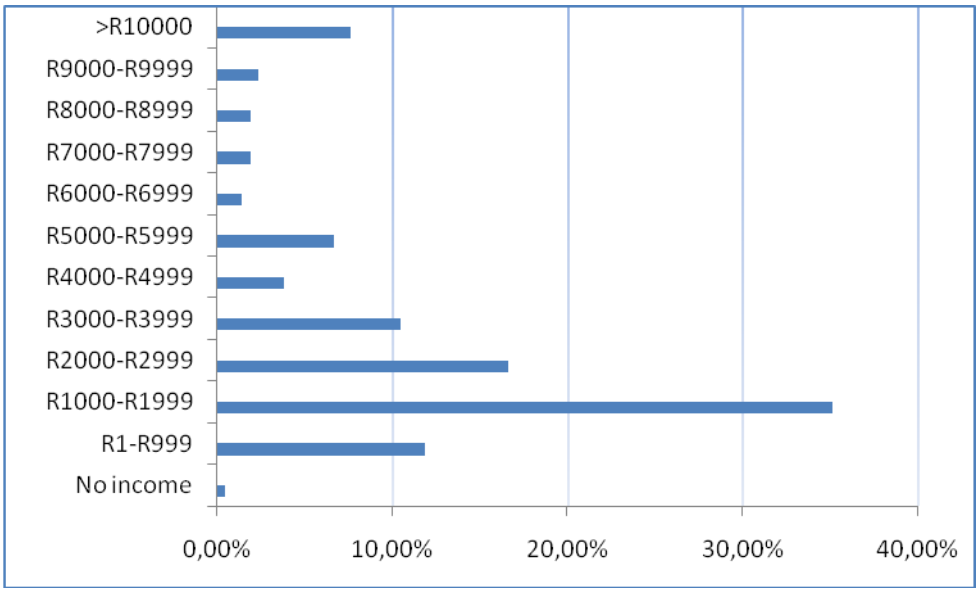


Fig 2: A description of the income per month.

The mean age of women was 26.52 (SD± 6.38), the median age was 25 (IQR- 21-31) and the range was 18 - 43. Thirty (14.22%) women smoked cigarettes, 60 (28.44%) used alcohol and none of them admitted to using recreational drugs. The mean parity of the women was 1.63 (SD± 1.34). The median was 1 with the IQR 1-2 and a range of 0 - 6. The previous obstetrics history was that most women had had a normal vaginal delivery (NVD), n=146 (69.19%), 35 (16.67%) had a caesarean section and 4 (1.89%) had had a previous TOP.

One hundred and three women (48.81%) were using contraception at the time of conception. Ten (4.74%) - of these said that the method had been used correctly. Condom failures were reported as the highest.

Ninety three women gave possible reasons for contraception failure and explained the failures as follows; 34 (38.64%) had condom accidents; 31 (35.23%) had missed their pill; 4(4.54%) used combined oral contraception (COC) with antibiotics; 21 (23.86%) missed their injection and 3 (1.42%) had a delay in the time that they had to take injection.

Fifty one (24.17%) women were found to be HIV positive and the HIV status of 14 (6.64%) women was unknown. The mean CD4 cell count was 468.54 (SD±200.31).The median was 500 (IQR=350-560). The range was 45 - 913. Twenty three women (48.94%) of those who were HIV positive used antiretroviral therapy (ART).

4.3. Complications

Ninety- nine women (46.92%) bled severely. The mean blood loss using the VAS was 5.86 (SD±1.45). The median was 6.00 with the IQR = 5-7 and the range were 2 - 9.

There were 187 women (88.62%) whose Hb was known on admission, of those the mean Hb was 12.12 (SD ± 1.32). The median was 12.3 with the IQR of 11.4 -13. The range was 6.9-15.5. The Hb was only repeated if it was clinically indicated. Sixteen women (7.58%) needed their HB measured after the procedure and 7 (43.75%) of the 16 needed blood transfusions. The mean Hb (n=16) was 8.82 (SD± 2.20) and the median of 8.55 with the IQR 7.00-10.90. The range was 5.60-12.60.

Almost all 210 women (99.52%) felt pain during the course of TOP process. One hundred and twenty two women (57.82%) needed analgesia for pain and 89 (42.18%) received and used it. The mean pain according to the VAS was 6.14 (SD±1.74). The median was 6 with the IQR=5-7 and the range was 2-10.

Antibiotics were prescribed for 192 women (91.43%) during the TOP procedure. There were 28 women (13.27%) who had temperature spikes above 37.5 degree Celsius. One woman (0.47%) sustained uterine perforation after evacuation of the uterus in theatre and another woman (0.47%) had persistent hyperkaleamia post MVA.

4.4. Reasons for TOP

Table 2 shows that the main reason for requesting TOP was financial problems, followed by education and relationship problems. Women with relationship problems included those whose partners were cheating and abusive, while other women wanted to further their studies. Those with “family influence” were where parents influenced their decision.

Table 2: A list of the reasons for requesting TOP

Reasons for requesting a TOP	Number of women n=211(%)
Financial problems	61 (28.91%)
Education	35 (16.58%)
Relationship problems	34 (16.11%)
Baby still young	17 (8.06%)
Family completeness	16 (7.58%)
Not ready to be a mother	13 (6.16%)
HIV status	9 (4.26%)
No reason given	9 (4.26%)
Raped	6 (2.84%)
Family influence	4 (1.89%)
Medical reasons	4 (1.89%)
Incarceration in jail	1 (0.47%)

4.5. Reasons for coming late for TOP

Table 3 shows reasons for not having the TOP in the first trimester. Thirty one women (14.69%) experienced logistic and staff related problems at the clinic with their first consultation. Some women, 6 (2.84%) lacked information about where and how to seek TOP while 3 women (1.42%) had relationship problems like partner not supportive of pregnancy and partner vanishing.

Table 3: A list of the reasons for coming late for TOP

Reasons	**Number of women n=211(%)**
Pregnancy diagnosed late	92 (43.60%)
The decision was taken late	39 (18.48%)
Clinic related problems	31 (14.69%)
Underestimated gestational age	15 (7.11%)
Was scared and confused	9 (4.26%)
Information on how to get abortion	7 (2.37%)
Work related constraints	6 (2.84%)
Financial constraints	4 (1.89%)
Relationship problems	4 (1.89%)
Exam/education	2 (0.95%)
Others	2(0.95%)

4.6. Gestational age

There was a poor correlation between dates calculated using the woman's dates and those calculated using ultrasound dating with a Spearman's rho of 0.38(p=0.00). The table below gives the values and the graph shows the differences with using the two methods of gestational age calculation.

Table 4: A comparison of gestational age calculated using dates (LNMP) and Ultrasound.

Modality used to calculate gestational age	Gestational age in weeks		
	Mean (SD)	**Median (IQR)**	**Range**
Sonar	15.18 (±1.67)	14.71 (13.86- 16.14)	13.00-20.00
Dates	13.77 (±2.69)	13.57 (12.28-15.00)	4.14-26.28

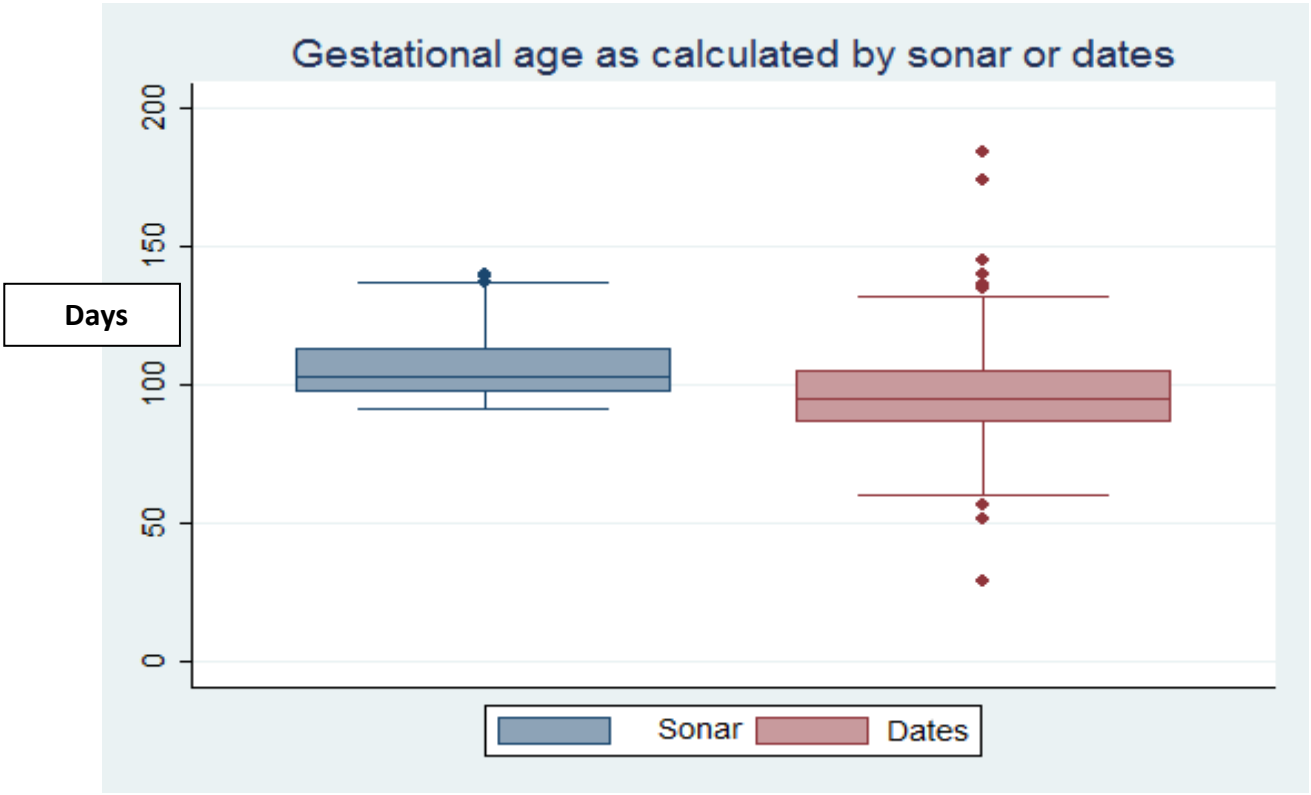


Figure 3: A box and whisker plot comparing sonar gestational age to gestational age by dates. The correlation between dates and sonar is median of 1 week.

4.7. Final procedures

One hundred and thirty five women (63.98%) had an MVA using analgesia. The number of women who had an evacuation in theatre was 39 (18.48%) and 14 women (6.63%) needed suction curettage in theatre under general anaesthesia. Two women (0.95%) needed a hysterotomy, another 2 women (0.95%) required D&E in theatre. Nineteen women (9.00%) aborted both foetus and placenta completely and did not need any further intervention.

Table 5: Comparison between women who aborted and those that did not after 72 hours.

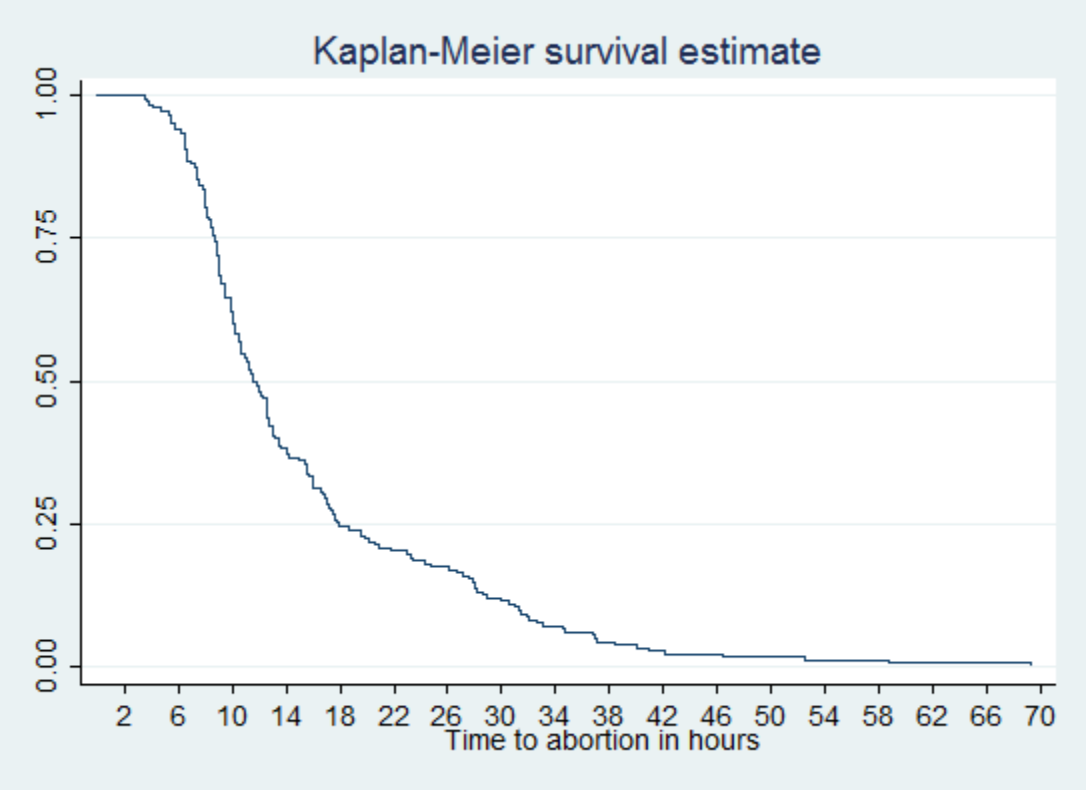
	Aborted n= 191 (91.39%)	**Failed to abort after 72 hours- 18(8.61%)**	**P value**
Age	26.03 (SD±6.25)	31.67(SD±5.81)	0.00 (Chi2)
Less than and equal to 25years	102 (53.40%)	3 (16.67%)	0.00 (FE)
Greater than 25years	89 (46.60%)	15 (83.33%)	
Parity	1.59(SD±1.34)	2.00(SD±1.46)	0.27t-test
Type of delivery if the patient had had a prior delivery			
C/S n=35	31 (20.13%)	4 (25.00%)	0.74 (FE)
NVD n=135	123 (79.87%)	12 (75.00%)	
Gestational age			
Gestational age-mean(weeks)	13.77(2.76)	13.52 (1.81)	0.60 (t-test)
Gestational age on sonar>14 weeks	140(73.30%)	8(44.44%)	0.01 Chi2
HIV			
HIV positive	44 (24.86%)	7 (38.89%)	0.20 (Chi2)
HIV negative	133 (75.14%)	11 (61.11%)	
Social factors			
Alcohol use	54 (28.27%)	5 (27.78%)	P=1.00(FE)
Smoking	25 (13.09%)	4 (22.22%)	P=0.29
Haemoglobin			
Hb less than 10.5	18 (9.42%)	3 (16.67%)	0.33

Women who were older than 25 years were 33% less likely to abort than women less than 25 years.

4.8. Time to abortion

The mean time to abortion was 15.61 hours (SD±18.80). Median was 11.50 hours with IQR=8.67-17.92 and the range was 3.50 - 69.33.The incidence rate was 0.5 per hour or 1 per 2hours. This time was calculated from the time the first Misoprostol was inserted to the time of the abortion of the foetus.

Figure 4: Kaplan- Meier survival curve showing the incidence of abortion



CHAPTER 5: DISCUSSION

The study is the first in recent years at CHBAH to prospectively characterise women coming for TOP in the second trimester.

One of the major finding was that 191women (91.39%) aborted following a medical induction using Misoprostol only. MVA and evacuation were done to complete a medical induction after assessment by clinicians. There were few women who aborted completely following medical induction. The assessment of whether an abortion was complete or not was made between 1 and 8 hours after the abortion. It may be that many of these women would have had a complete abortion if the time for the assessment was longer. South Africa also has had a recent history of having had stringent abortion laws making the association between septic incomplete abortion and maternal morbidity and mortality a major concern, this may also contribute to the larger number of women who had to have an MVA.

The study's main outcome underlines the efficacy of Misoprostol as the first line drug for second trimester TOP in this setting. The failure rate of the drug was 9.48% and is comparable with other local studies. Gamedze reported 5% while Basu reported 8 %(67).

In terms of the demographics and characteristics of the sampled population, the majority of women 45% were Nguni (Zulu and Xhosa speaking) with little education, poor financial background and a poor marital support system which appeared to have played a bigger role in the decision to terminate the pregnancy.

Their mean age was 26.52 ±6.38 (18 - 43) which is comparable to local and international studies. Internationally, Ngoc et al (90) reported a mean age of 25±6.8 (15-49) in a study to estimate the clinical benefit of pre - treatment with Mifepristone followed by Misoprostol

compared with Misoprostol alone for second trimester TOP. Locally, studies by Gamedze and Basu et al (69) showed similar mean ages of 25.90 (SD) and 25.00 (SD). It is of concern that there were 103 women who were using contraception and that these methods failed. It is important that when educating women on contraception, possibilities of methods failure be discussed in combination with advice on emergency contraception.

Sixteen women (7.58%) needed their HB re - measured after the procedure and 7(43.75%) of 16 needed blood transfusion. The mean HB was 8.82±2.20, higher than in other studies on second trimester abortion and is higher than other studies both local and international studies which reported mean HB as low as 1±0.6 in a study by Shaw et al (94) n=158.

In this study antibiotics were used liberally prescribed and were used for 192 women (91.43%). Twenty eight women (13.27%) had temperature spikes above 37.5 degrees Celcius warranting an extended period on IVI antibiotics.

There was however no serious morbidity requiring intensive care unit i.e. DIC and no death occurred during the study period.

One uterine perforation was reported during evacuation using sharp curettage. Most of the procedures were done using suction rather than sharp curettage and that may have also contributed to the low rate of perforation. This may also be that the majority of health care providers are well trained to carry out the evacuation of the uterus. Shaw et al (94), reported 2 perforations (1.26%), n=158 sample was small.

The majority of women 92(43.60%) reported not being aware of pregnancy as their main reason for presenting late for pregnancy termination. Some women 31(14.69%) reported poor referral system as main reason for a delay.

There was poor correlation between assessment of gestational age by dates and by sonar. The mean gestational age by ultrasound was 15.8±1.67 (13.00-20.00) and mean gestational age by date was 13.77±2.69 (4.14-26.28) .However, the median of 1 week was found and clinically this is in fact a very good correlation. Ultrasound and dates are not expected to agree completely in value. Reason for this difference could be due to women's failure to remember their last normal menstrual period. This population of women may be different from women who are planning a pregnancy and who would therefore easily remember their menstrual dates.

Two women (0.95%) needed hysterotomy to complete TOP. This finding was comparable with other local studies. Basu et al (69) reported (0.53%). Two women (0.95%) needed dilation and evacuation to complete TOP. Fourteen women (6.63%) needed suction curettage in theatre to complete TOP under general anaesthesia which is incomparable to other local studies.

In comparing characteristics of women who aborted and failed to abort after 72 hours it was noted that women less than and equal to 25 years aborted quicker than women greater than 25 years despite their higher parity.

The history of having had a caesarean section was not significantly different in this study. Thirty one women (88.57%) with prior caesarean section aborted while 4 (11%) failed to abort which is comparable with other local studies. Basu (69) reported 42(89%) for the abortion group and 5(11%) for the failure group, n=47.This outcome is however not important for our study.

The mean time to abortion was 15.61hours±18.80 (3.50-69.33) hours. This time was calculated from the time of the first Misoprostol insertion to the time of abortion. This is

similar to local studies which reported 16.7 hours (69). The findings were not comparable with an international study by Ngoc et al (90) which reported 10.6hours±2.5 (6.5-15.5) hours. This may be because they were using the Misoprostol dosage of 400µg 3 hourly which maintains high concentration of Misoprostol and facilitates a quicker abortion compared to the protocol of vaginal Misoprostol 600µg 6 hourly. The RCOG recommends 400µg of vaginal Misoprostol 3 hourly for up to 5 dosages in termination of pregnancy between 13 and 22 gestational weeks (91). More frequent doses decrease the abortion time interval. Two meta-analyses reported significantly shorter induction to abortion time with 3 hourly vaginal administration of 400µg of Misoprostol than 6 hourly dosages without a significant rise in side effects (92). In the current study, giving a higher dose of 600µg 6 hourly achieved higher success rate and this worked better for the unit in view of the shortage of mid wives required to manage these abortions.

6 Strengths

The study was conducted at CHBAH located in Soweto, serving a greater part of southern Gauteng. These women are similar to women who attend public health facilities in other parts of the country and therefore these findings may be generalizing. The researcher speaks 8 languages and carried out all the interviews.

7 Limitations

There was no uniformity in the recording of history and examination findings in the patient's files. Variables like time of admission, bishop score and times of discharge were often not complete. This was a convenience sample and rare outcomes or complication might have been missed but we also may have overestimated some complications. Lack of follow up of

patients after discharge may lead to patients presenting elsewhere and this may lead to inability to capture delayed complications.

Measurement of some outcomes like blood loss and pain will be difficult since individual women may understand grading differently and grade them differently.

8 Conclusion and Recommendations

The findings show that most women, n= 191 (91.39%) aborted the foetus with the use of Misoprostol only. While the number of women who abort in the first 24 hours is acceptable, there is still some percentage of women who will remain in the hospital for a longer period. Eighteen (8.61%) women who did not abort in 72 hours required a surgical TOP. The number of women requiring an MVA was high, but this may be because repeat Misoprostol would mean a longer hospital stay.

Even though the WHO and other abortion bodies worldwide still favour D&E for second trimester TOP, in this hospital Misoprostol and evacuation of RPOC have shown that reasonable success. It may be that clinicians in this service are not trained to perform D&E. Studies perfomed have shown that clinicians are not comfortable conducting D&E because of lack of training and experience and the fact that it is psychologically traumatic (93).

Proper contraception services and sexual education will help prevent unwanted pregnancies amongst the young and old. Pregnancy tests should be available at primary health care services. Education regarding early signs and symptoms of pregnancy and adequate first trimester abortion will help reduce incidences of second trimester abortions.

Our protocols need to consider adding Mifepristone to decrease the time to abortion and using ultrasound post abortion to assess the completeness of the medical procedure. Future research is necessary to look at the high MVA rate after abortion of the foetus and whether repeat Misoprostol in such situations could reduce the risk of RPOC.

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Appendix A: Questionnaire and data sheet

Questionnaire / Data sheet 1: Day of admission

Patient number:_____
Date and time of admission_____
How old are you? _____

What level of schooling have you achieved? (Just tick)

No school	
Primary school	
High School	
Tertiary	

What is your mothers tongue? or which is your home language? Or which is your main language?

English		Pedi (Northern Sotho)	
Tsonga		Xhosa	
Venda		Afrikaans	
Zulu		Ndebele	
Tswana		Southern Sotho	
Zimbabwean		Other	

*If other specify:*_____

How much income does your house hold receive in a month?

None		R2000-R2999		R6000-R6999		>R10000	
Unknown		R3000-R3999		R7000-R7999		Other	
≤R999		R4000-R4999		R8000-R8999			
R1000-R1999		R5000-R5999		R9000-R9999			

Social factors:-

Marital status
(answer yes or no)

Living with partner	
Married	
Divorced	
Widowed	
Not living with partner	

1

Single (no partner)	

If other specify: _____

Just circle;

Smoking :Yes/ No	*If yes, how much? Give a daily amount*
Alcohol: Yes / No	*If yes, How much?* Daily_____ Weekly_____ weekends_____ Socially _____ More often_____
Other Recreational drugs: Yes / no	

When was the first day of your last normal period- (get as much detail as possible)_____

Did you have a normal period for 3 months before that? _____ yes or no.

Parity: *tell me about your pregnancies- how many have you had? did you have any miscarriages?,*

any previous termination of pregnancy(TOP)?

year	GA	Outcome

Contraception?

Were you using any contraception at the time that you fell pregnant?.yes or no

If yes, *which one? Choose below and circle yes or no*

Injectable....*did you miss the injection?. yes or no*

Condoms- *were you using it consistently? yes or no*

Combined oral contraceptives (COC), *Did you miss any?, yes or no*

Progesterone only pills (POP), *did you miss any? Yes or no*

Intrauterine contraceptive device (IUCD), *what happened?*_____

_____

Co-Morbidities:

HIV Pos /neg/ unknown (*just circle)*

2

If positive when was the diagnosis made (mo/yr) or just year_____
If positive- *CD4 count* _____ Date (month/year) or even just year)_____

Use of ARV's?, *How long*
Other.

I would like to ask you what was the reason that made you want to terminate this pregnancy...in other words, why did you decide to do TOP.-

_____
_____

*Women who present after 3 months of pregnancy have complications which are different from women who present before 3 months...I would therefore like to ask you what was the reason that made you seek to stop this pregnancy at this time...in other words why did you not come sooner*_____

_____

Sonar done
Date of sonar_____
Gestational age_____
Clinical examination of the cervix- as written by a medical officer

Dilation	
Effacement	
Length	
Position	
Consistency	

Date and Time of first misoprostol insertion_____

Questionnaire / Data sheet 2: Day or time of discharge

Patient number_____
Date and time of abortion (from patients file)_____

Complications

1) Bleeding

Hb on admission	
Any Hb performed later in the ward	
Requirements for blood transfusion How many units?	

Questionnaire: *In the whole time since the medication was used, would you say it was a lot of bleeding or not so much ..... (Circle) a lot/ not a lot*

Subjective assessment: (Show patient numbered line (picture) and write down the number she indicates)
Can you show me on this scale how much you bled? With 0 being a little and 5 being like a period and 10 being a lot.

No bleeding like a period severe bleeding

2) Pain

Did you need medication for pain (yes/ no)	
Analgesia prescribed and taken (from the file)	

Subjective assessment
Questionnaire: When was the pain worst?_____
How would you rate it....from a scale of 0 to 10, (show the patient a picture) When the pain was most intense' (write the number)

Mild pain Moderate pain severe pain

3) Infection

Temperature chart at discharge	
Number of temperature spikes above 37.5degree Celsius (taken from the bed letter)	
The use of prophylactic antibiotics	
The use of therapeutic antibiotics	
Relatedness of antibiotics(was it used for non	

4

gynecological infection)- taken from the bed letter)	

Detailed descriptions of the following complications from bed letter

Hysterectomy	
Perforation	
Laparotomy	
Rupture	
Other	

Descriptions of the final procedures from the bed letter

Manual vacuum aspiration(MVA) under local anesthesia	
Dilation and evacuation in theatre	
Evacuation in theatre	
Hysterotomy	
Suction curettage in theatre	

Date and time of discharge_____

5

Appendix B: Patient consent form

Consent form.

To be completed by participant.

I voluntarily agree to participate in the research study described above. I have had some chance of asking some questions about the research.

(Print name)	(Date)	(Signature)

To be completed by a researcher

I have discussed the proposed research with this participant, and in my opinion, this participant understands the risks, benefits and is capable of freely consenting to participate in this research.

(Print name of researcher Obtaining consent)	(Date)	(Signature)

3

Appendix C: Ethics Certificate

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

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Stephen Baloyi

CLEARANCE CERTIFICATE	M120653
PROJECT	Second Trimester Termination of Pregnancy at Chris Hani baragwanath Academic Hospital
INVESTIGATORS	Dr Stephen Baloyi.
DEPARTMENT	Department of Obstetrics & Gynaecology
DATE CONSIDERED	29/06/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

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

DATE 29/06/2012 CHAIRPERSON .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Yasmin Adam

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 D: CEO Permission to conduct the research

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 26 July 2012

TITLE OF PROJECT: Second trimester termination of pregnancy at Chris Hani Baragwanath Academic Hospital

UNIVERSITY: Witwatersrand

Principal Investigator: Dr S Baloyi

Department: Obstetrics and Gynaecology

Supervisor (If relevant): Dr Y Adams

Permission Head Department (where research conducted): Yes

Date of start of proposed study: July 2012
Date of completion of data collection: December 2012

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.

.....
Recommended
(On behalf of the MAC)
Date: 26 July 2012

.....
Approved/Not Approved
Hospital Management
Date: 01/08/12