An Experience with Misoprostol for the Induction of First Trimester Abortions in a Secondary Hospital in South Africa

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Abstract

Background: Misoprostol is a prostaglandin analogue with uterotonic properties. Administered orally or vaginally, it is an effective agent for induction of first trimester abortions.

Aim: To establish the effectiveness and complications arising within the first week following the administration of Misoprostol for termination of pregnancy (TOP) in the first trimester of pregnancy.

Setting: A regional hospital in the Helderberg basin of the greater Cape Town area, serving both as district and secondary hospital.

Methods: Prospective descriptive study of patients using Misoprostol as induction agent in the first trimester of pregnancy. Success rate, side effects and complications were monitored over three visits, up until one week after termination

Results: 105 patients were enrolled into the study. Following the intake of Misoprostol, 70% reported a successful induction within 48 hours. The evacuation of the uterus was found to be uncomplicated in 64% of these patients. 9% received a repeat dose of Misoprostol, 3% required a third medical induction. In 1 patient with an unsuccessful induction, an ectopic pregnancy was diagnosed. In 4 women the uterus had been surgically perforated, without need for further surgery.

Conclusion: The use of Misoprostol for the induction of termination of pregnancy in the first trimester proved to be effective and acceptably safe.

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Introduction

In most developing countries abortion constitutes an important public health problem. Illegally induced abortions under unsafe conditions are important contributors to maternal morbidity and mortality, particularly in developing countries, which do not have the resources to manage abortion-related complications.[1,2]

In countries where early abortions are legal and available on demand and safe, maternal morbidity and mortality have decreased significantly. In the United Kingdom, the 1985-1987 report on Confidential Enquiries into Maternal Deaths recorded, that for the first time abortions no longer contributed to maternal mortality.[3]

During 1997, South Africa introduced new legislation legalising termination of pregnancy on demand (Choice on Termination of Pregnancy Act, Act No.92 of 1996) .[4] (see Table I, *over page*)

First trimester abortions are supposed to be handled at the district hospital level in South Africa. This responsibility, though, was shifted to some secondary hospitals due to widespread staff resistance. Only limited numbers of terminations of pregnancies (TOP) are presently carried out outside the tertiary hospitals of the Western Cape.[5]

Table I: Choice on Termination of Pregnancy Act (Act No.92 of 1996).

• Section2.(1): A pregnancy may be terminated--- (a) Upon request of a woman during the first twelve weeks of the gestation period of her pregnancy.
Counselling • 4.The State shall promote the provision of non-mandatory and non- directive counselling, before and after the termination of a pregnancy.
Consent • 5.(1) Subject to the provision of sub sections (4) and (5), the termination may only take place with the informed consent of the pregnant woman. • (2)Notwith standing any other law or the common law, but subject to the provisions of subsections (4) and (5), no consent other than that of the pregnant woman shall be required for the termination of a pregnancy. • (3): in the case of a pregnant minor, a medical practitioner or a registered midwife, as the case may be , shall advise such minor to consult with her parents, guardian, family members or friends before the pregnancy is terminated. Provided that the termination of pregnancy shall not be denied because such minor chooses not to consult them.

By using Misoprostol the medical induction of termination of pregnancy can be initiated by the patient herself at home, followed by an easier surgical evacuation (after the patients aborts) in the day theatre. In the South African context this is cheaper and more practical. The alternative would be a surgical termination requiring admission, a formal anaesthetic and surgical dilatation and curettage, which is more traumatic for the patient and the medical staff involved.

Misoprostol, (methyl 11, 16-dihydroxy-16-methyl-9-oxoprost-13E-en-1-oate) is a prostaglandin E1 analogue, that has been used for several years for the prevention of non-steroidal anti-inflammatory drug-induced gastric ulcers.[6,7] Reported adverse effects have been mainly observed in the gastrointestinal tract, dose related ranging from mild abdominal cramps to diarrhoea, less frequently constipation, nausea and vomiting. It is contraindicated in pregnancy, because its intake causes uterine contractions and may cause uterine bleeding and miscarriage.[8] Other advantages of Misoprostol include: (a) No need for refrigerating; (b) Low cost (1 Rand per tablet); and (c) Easy to administer (orally or vaginally)

Literature about the effect of Misoprostol used on its own to induce abortion in the first or second trimesters is limited.[9] Local experience from secondary level hospitals in South Africa is lacking, but international experience from other developing countries is promising.[10,11]

At the time of the study, Misoprostol was not yet registered in South Africa for the use of termination of pregnancy (TOP), but clinical trials were allowed with special permission. This study was performed as an extension of an approved clinical trial of the use of Misoprostol at Tygerberg Hospital, to evaluate the effectiveness and safety of Misoprostol in termination of pregnancy in first trimester TOPs

The study setting was Hottentots Holland Hospital (HHH), situated at Somerset West in the Western Cape Province of South Africa. It serves as a district hospital for a community of about 140 000 people and also functions as a secondary level centre for the Helderberg and Overberg region.

Methods

The design was a prospective, descriptive study, carried out between 1 December 1997 and 31 December 1998. The principal researcher carried out the screening process, pre-procedural counselling, the actual procedure and the follow up.

All women who requested termination of pregnancy in the hospital during the study period were referred to the researcher. They were evaluated clinically and by ultrasound for gestational age and for their general medical and psychological condition. Only women with a first trimester pregnancy of less than 12 completed weeks qualified for this study.

At the first visit, blood was taken for Haemoglobin and VDRL. A pre-procedural counselling session was part of this first visit. Once admitted to the study, the patient

received 4 tablets of Misoprostol (200mcg per tablet) with the instruction to take 2 tablets (400mcg) orally the same day. The other 2 tablets had to be inserted vaginally 24 hours later, if no bleeding had occurred.

The patient was instructed to report back to the hospital 48 hours after the first visit. following an overnight fast for the surgical procedure (vacuum aspiration). If the patient did not report any bleeding or the passing of products during this period, the whole procedure was repeated. If this medical induction with Misoprostol failed three times, the patient had a surgical termination by dilatation and curettage 48 to 72 hours after the failed last attempt.

Before the surgical evacuation, patients were asked about the possible side effects of the medication, vaginal bleeding and the passing of products of conception. If the patient had bled or had passed products of conception, a suction curettage (vabra) under anaesthetic (either general or neuroleptic with Ketamine 1 mg per kg, Fentanyl 100ug and Droperidol 10mg) was performed.

Following the procedure, the patient was asked to report back for a final follow-up visit one week later. This final visit was used to examine the uterus with ultrasound, and to control for any intra-operative or post-operative complications.

Ethical aspects:
All patients gave their written consent to participate in the study after the initial counselling. The ethics committee at Tygerberg Hospital and the Research Committee of the University of Stellenbosch approved the study.

Results

1. Patients: 105 patients requesting TOP qualified for the study. Only two patients requested a repeat TOP.

Ethnicity:
Most women (61%) were of mixed ethnic origin ("Coloured"), 21% were Black and 18% White.

Education:
Seventy percent (70%) had a scholastic level of Grade of 10 (St. 8) or higher.

Age:
The youngest woman requesting TOP was 13 year old, the oldest 40 years old, whilst the majority were between 16 and 25 years old (50%). (See Figure 1)

Reason for request of termination:
40 women (38%) had a combination of financial and psychological problems, followed by 36 (34%) with only psychological, and 28 (27%) with financial reasons only. Only one request was based on an existing medical risk factor for the mother - she developed kidney failure in her previous pregnancy.

Employment and marital status:
Only 26 (25%) women were unemployed at the time of the request, whilst 85 (81%) were not married.

Parity: Almost half of the women were Primagravida (46%), whilst 18% were Parity 1 (See Figure II, *overleaf*)

Contraception: 64 (61%) women did not use any kind of contraception prior to conception. Of those women who had used contraception before conception more than 60% (25) were on the pill, but admitted to skipping tablets.

2. Effectiveness and complications:
Of the 105 patients, 100 returned for the evacuation procedure 48 hours after administration of Misoprostol. Of the five 5 that did not return, one decided to continue with the pregnancy, a second changed her mind after taking Misoprostol due to the pressure from her boyfriend and

Figure 1: Age profile of women requesting TOP

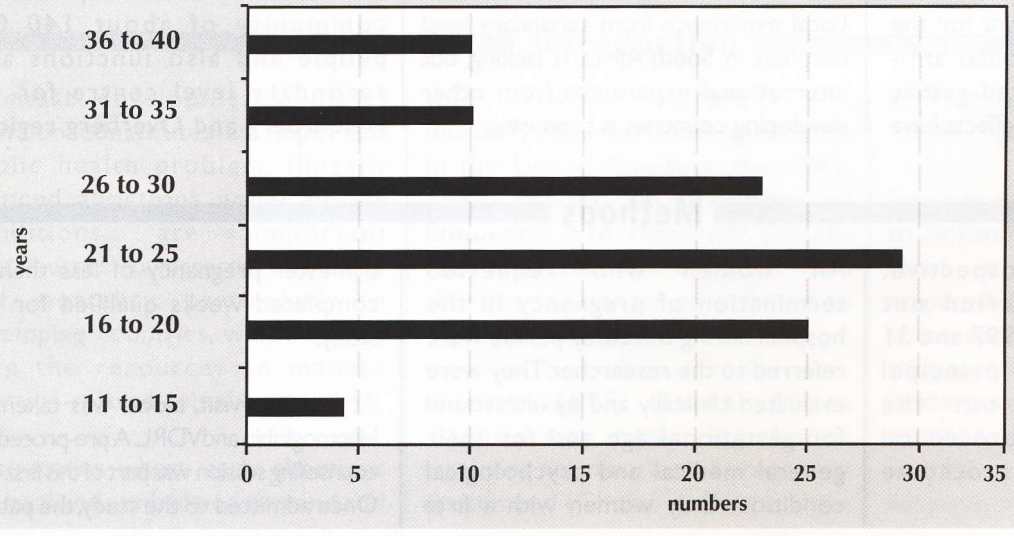
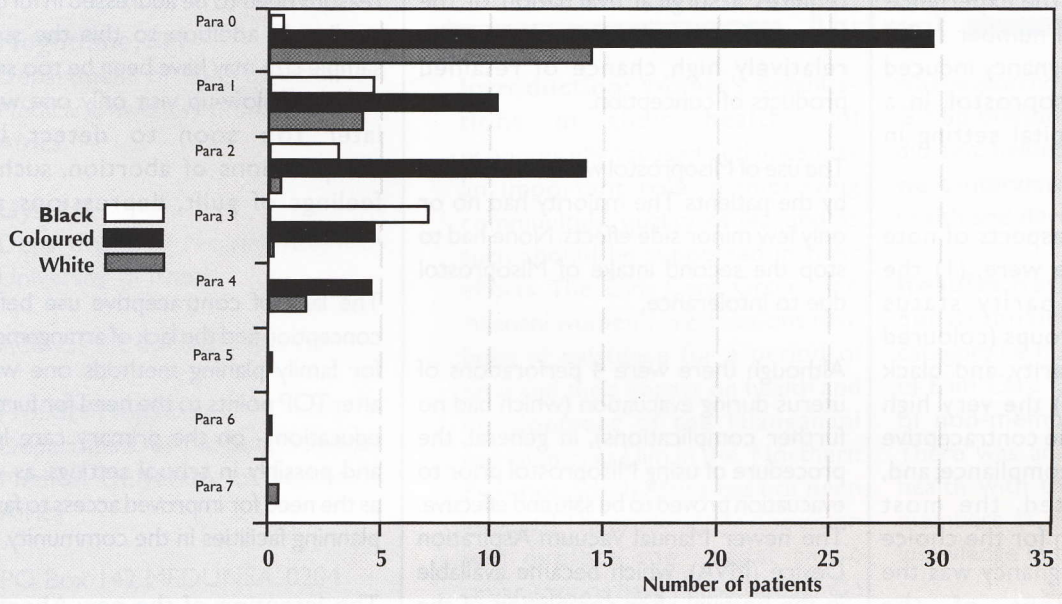


Figure 11: *Parity in different ethnic groups of women requesting TOP*



in spite of the risk involved. No information could be obtained of the remaining three.

The 100 women who continued with the protocol reported the following possible side effects of Misoprostol:

- 30 experienced cramping abdominal pains. 44% (20) of Primagravidas and 18% (10) of Multigravidas experienced cramping abdominal pains (P<0.01)
- 24 felt some nausea
- 11 experienced a combination of cramping abdominal pains and nausea
- 8 had vomited
- 7 developed diarrhoea

Outcome:

- 87 of the 100 women had the TOP performed at the return visit 48 hours after taking Misoprostol. Of them 83 (95%) reported a successful medical induction with Misoprostol manifested by vaginal bleeding and passing of products. 17 (20%) took only 2 Misoprostol tablets.
- 12 of the 100 women had to take a second dose of Misoprostol with the procedure following 48 hours later. In 7 the second induction was successful. Three of the latter group had a third medical induction with Misoprostol, with the procedure done 72 hours later. In 2 of them the induction was successful.
- The one patient initially changed her mind and did not continue with the evacuation, but did so 6 weeks later.46 (45%) TOP's were performed under general anaesthetic. 56 (55%) patients received a neuroleptic anaesthetic.15 (15%) patients asked for sterilisation at the first visit, 13 of which were done at the same time and 2 were given a separate appointment. The average hospital stay after the procedure was 4 hours.

Complications

In one patient with an unsuccessful induction, an ectopic pregnancy was diagnosed.

In 4 (4%) women, the uterus was perforated during the surgical evacuation without further complications. One of the 4 women was admitted for observation overnight and discharged in a good condition the next morning. None of the 100 women required blood transfusion. No complications regarding retained products, infection or need for repeated curettage were observed.

Intake of Misoprostol tablets

- Multigravidas used an average of4.5 tablets,and Primagravidas4.0.tablets (P>0.01)
- Primagravidas took an average of 2.36 tablets orally and 1.68 tablets vaginally, whilst Multigravidas took an average of 2.35 tablets orally and 2.17 tablets vaginally.(P =0.024)
- The maximum number of tablets used by one patient was 12, whilst the minimum number of tablets used by one patient was 2.

The last visit one week later

Only 43 (42%) patients came for a follow-up visit one-week after the surgical procedure. Of these women 26 (60%) experienced a small post-operative bleeding and 13 (30%) had moderate to heavy bleeding. 11 (26%) were still bleeding at the time of the visit.

15 (35%) had already started with a contraceptive after the TOP, of whom 9 (21%) had Depo-Provera and 6 women (14%) went on oral contraception. 28 (65%) still had **to** arrange an appointment at the family planning clinic.

Discussion

This study reports on the experience with a relatively small number (100) of terminations of pregnancy induced by the intake of Misoprostol, in a district/regional hospital setting in South Africa.

The most important aspects of note in the patient sample were: (1) the differences in the parity status between the ethnic groups (coloured and white - lower parity, and black more multiparity); (2) the very high failure rate (24%) of the contraceptive pill as result of poor compliance; and, as could be expected, the most common reason given for the choice of termination of pregnancy was the financial implications of the pregnancy.

Misoprostol produced a successful medical induction of abortion in 95% of cases with a maximum dose of 4 tablets, and was almost 100% effective after a second dose. This is extremely cost-effective, because the surgical evacuation could be done as a day theatre procedure, suitable for a busy secondary hospital, a district hospital or a community health centre with surgical facilities. It must be remembered that this study focused on first trimester abortions, which always requires a surgical evacuation of the uterus after an abortion, due to the relatively high chance of retained products of conception.

The use of Misoprostol was well accepted by the patients. The majority had no or only few minor side effects. None had to stop the second intake of Misoprostol due to intolerance.

Although there were 4 perforations of uterus during evacuation (which had no further complications), in general, the procedure of using Misoprostol prior to evacuation proved to be safe and effective. The newer Manual Vacuum Aspiration Device (MVA), which became available in the hospital after completion of the study, is softer than the older Vabra device used in this study and reports about decreased uterus perforations are promising.

If an induction has not been successful with Misoprostol, an early ultrasound investigation is warranted and possibility of an ectopic pregnancy should be kept in mind.

The poor compliance with the follow-up visits in spite of the initial counselling is a reason for concern and the underlying reasons need to be addressed in further studies. In addition to this the study sample size may have been be too small and the follow-up visit only one week later too soon to detect late complications of abortion, such as feelings of guilt, depressions and infertility.

The lack of contraceptive use before conception and the lack of arrangements for family planing methods one week after TOP points to the need for further education - on the primary care level and possibly in school settings, as well as the need for improved access to family planning facilities in the community.

The intention of the new Abortion law was to address the problem of unsafe and illegally performed backstreet abortion of unwanted pregnancies, associated with high incidence of mortality and morbidity for the women. To offer terminations of pregnancy free on demand in facilities designated by the Health Department may reduce the mortality and morbidity. With the use of Misoprostol the terminations were effective, safe and easy to perform, promoting its use more freely in future in South Africa.

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