

**ONE-STEP USE
of
MISoPROSTOL ONLY
in
EARLY PREGNANCY
TERMINATION**

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ABSTRACT AND INTRODUCTION

- **Medical methods of abortion have been proved to be safe, effective and offer a new range of choices for patients and providers (Grimes D.A 1997, Trussell & Ellertson 1999). Medical abortion with a combined regimen of mifepristone, an antiprogestogen, and a prostaglandin analogue was first approved in France in 1988 and there were subsequent approvals in the UK and Sweden and China, where the method has been in use since 1992.**
- **The mechanism of action is based on the ability of mifepristone to bind progesterone receptors, inhibiting the action of progesterone and thereby interfering with the continuation of pregnancy. Usual treatment regimens entail an initial dose of mifepristone followed a day or two later by the administration of a synthetic prostaglandin analogue which induces uterine contractions leading to the expulsion of the products of conception.**

- **The prostaglandin analogue most commonly used today is misoprostol, a prostaglandin E₁ analogue widely used for the prevention of gastric ulcer in patients taking non-steroidal anti-inflammatory drugs. Maternal mortality rates in the developing world, most especially in sub-Saharan Africa is alarmingly high and a sizeable proportion of this high mortality is as a result of unsafe abortions. The citizens of these same countries are further encumbered by grinding poverty compounded by ignorance, and very restrictive abortion laws. So, even though medical methods of abortion would be very ideal for these countries, the high cost of mifepristone would ensure that even if the drug becomes available, it would be beyond the reach of those most in need of it.**

- **The advent of misoprostol into the medical abortion arena constitutes a remarkable milestone. It is extremely cheap and generally available in most countries, albeit for other indications. A misoprostol-alone regimen could greatly improve the access of safe medical abortion services by women in poor developing countries. Several studies have been conducted to examine the potential of misoprostol alone for early termination of pregnancy (Norman et al 1991, Bugalho et al 1996, Jain et al 1998). The designs, population sampling methods and regimens varied from study to study. But the common factors in all these studies were: that the patient had to visit the hospital more than once and the success rates were considerably lower than with the combined regimen.**
- **The objective of this study is to explore the possibility and effectiveness of a one-stage misoprostol-alone regimen that would provide affordable and safe medical abortion to women in resource-poor countries without compromising their innate desire for secrecy and anonymity, which is very vital in such environments.**

METHOD

- **Several in-house trials were conducted before the regimen for this study was formulated. It involves the placement of 400mcg (2 tablets) of misoprostol sublingually or in the buccal cavity and the insertion of another 400mcg (2 tablets) into the posterior fornix of the vagina. Prior to the insertion, with the patient in the supine position, and knees abducted, the vaginal cavity is thoroughly cleansed with a sterile swab soaked in tepid water. The vaginal tablets are dipped into warm water before insertion. Results from our previous unpublished studies have shown that warm-water immersion considerably enhances dispersibility and shortens the induction-abortion interval. The patient, after the vaginal insertion, is allowed to rest in a side room for about 15 minutes before being allowed home with a supply of paracetamol and diclofenac. The severity of pain determines which medication to use.**

- Each prospective patient was duly counseled about this new method of termination, about the possibility of severe menstrual-type pains, about the possibility of heavy bleeding and about side effects like nausea, vomiting,
- dizziness and fever. Each patient was also given the option of a surgical evacuation. As almost all the patients had cell phones (or easy access to one), they were instructed to document all the events and phone the next day to file a report which was entered into a pro-forma. Those who failed to phone were contacted by me. Patients were further instructed to return to the hospital promptly in the event of any untoward occurrence like excessive bleeding, severe pain, extreme dizziness or rigors.
- The limit of gestational age for this study was 8 weeks (56 days from the 1st day of the last menstrual period). Altogether 80 patients have been involved in this study so far, and it is still on going. The age range is from 15-47 years, parity 0-9, and about 30 patients are married; and 4 with previous caesarean section scars.
- Family planning counseling was offered to all the patients before the procedure and they were all asked to report back for review after the first menstrual period.

RESULTS

- **Abortion was achieved in all patients. 79 (98.8%) expelled completely and only one person returned 10 days later still complaining of heavy bleeding with clots and severe low abdominal pain. On vaginal examination products were felt protruding through the cervical os. Surgical evacuation was carried out and remnants of the placenta removed.**
- **The mean onset of cramp-like low abdominal pain from the time of misprostol insertion was 95 minutes and the mean abortion time, defined as the passage of the faetal sac large clot and the immediate cessation/reduction of cramp-like pain) was 5 hours 45 minutes. The average duration of bleeding post-abortion was 8½ days.**

- **30 patients used an analgesic; while the rest considered the pain was bearable. 25 patients had nausea, 10 had vomiting, 12 experienced a low grade fever. 2 patients were brought back to the hospital with severe and prolonged rigors and required intravenous medication. But each was allowed home within 2 hours. One patient was admitted with dizziness and hypotension just over an hour after the misoprostol insertion. She was commenced on an infusion of normal saline, and stabilized quickly. She expelled the products of conception about an hour after admission and was allowed home 2 hours later in a satisfactory condition.**

DISCUSSION

- **The study explored the feasibility, efficacy and safety of a combined sublingual/vaginal, one-step misoprostol use for early pregnancy termination. Any new regimen is assessed by its safety, efficacy, ease of availability, general acceptance and cost when compared with existing methods. A randomized study on this subject would be very difficult in this environment for very obvious reasons, so this is more of a comparative study. Our results are comparable to that of the combined mifepristone/misoprostol regimen, and much better than other published results on misoprostol-only use (Bugalho et al, 2000). The induction-abortion interval was considerably shorter and the rate of gastro-intestinal side effects was significantly lower. The experienced side effects were very mild and very few required treatment.**

- **After the pre-treatment counseling, 30% of the patients still preferred the surgical method more like a case of the devil you know. But the uptake of the medical method was higher amongst the middle class and educated patients (95%) and they were all happy with the outcome as it simulated a normal menstruation and caused no disruption whatsoever to their daily routine. All the patients who used the method would elect to use it again if the need arises.**

CONCLUSION

- **Medical abortion regimens have become accepted as safe, effective and easily-accessed methods of termination and have widened the range of options for both patients and providers alike. The onus on those practicing in poor resource settings, bedeviled by poverty, ignorance, low contraception uptake and high maternal mortality rates, to which the fallouts of unsafe abortions contribute substantially, is to continue to work to adapt existing methods to fashion out protocols that would find wide acceptability in our respective country-environments without compromising safety and quality of care.**
- **The positive results from this study, and if confirmed by other studies, would point a way to addressing several problems peculiar to abortion-seekers in a third-world setting with restrictive abortion laws, namely: secrecy, anonymity, safety and affordability, and assist in the struggle to reduce the unacceptably high maternal mortality rates.**