Hygroscopic dilator (Dilapan-S™) and misoprostol combination for the early first-trimester termination of pregnancy: a pilot study

Mannampallil I Samuel, John H Parsons

Abstract

Background and methodology Uptake of the mifepristone/ misoprostol combination to induce early medical abortion in England and Wales has been slow. Women's concern that early medical abortion is painful may be a contributory factor. This pilot study evaluated the pain experienced by women when Dilapan-S™, a synthetic hygroscopic dilator (polyacrylonitrile) is used instead of mifepristone as cervical preparation prior to administration of a misoprostol.

Results Of 25 patients completing the trial, 17 aborted in a median of 6 hours with an interquartile range of 4.5–11.5 hours. Of these, 15 patients recorded mild discomfort only, 14 considered the procedure excellent and three good.

Discussion and conclusions This study suggests that the Dilapan-S/misoprostol combination reduces the pain associated with early medical abortion. Further investigation of the protocol is merited.

Keywords Dilapan-S™, early medical abortion, mifepristone, misoprostol, pain in abortion

Introduction

Medical termination of pregnancy (TOP) using a combination of anti-progesterone (mifepristone) and a prostaglandin has been slow to gain popularity in England and Wales, though recently there has been an increase in uptake. The experience in Scotland where uptake has been better suggests that increasing provision and promotion of the method has a positive impact. A significant number of women experience pain during medical TOP,1,2 which may deter some women from opting for this procedure.

Mifepristone is an anti-progestogenic steroid that sensitises the myometrium to prostaglandin-induced contractions and ripens the cervix. Dilapan-S™ (Figure 1), a hygroscopic mechanical dilator (Gel-Med International, spol. s.r.o., Karlovarska 20, Kamenne Zehrovice, CZ 273 01, Czech Republic/PO Box 65, St Albans, Herts AL3 8EQ, UK) may be used to prepare the cervix before TOP. This device is used routinely prior to second-trimester dilatation and evacuation at King’s College Hospital, London, UK. Inserted 4–24 hours prior to TOP, it absorbs fluid and painlessly dilates the cervix. The hypothesis was that prior cervical preparation with Dilapan-S followed by misoprostol would be more effective and therefore less painful than the mifepristone/misoprostol combination. There are no reported studies comparing the effect of mifepristone and Dilapan-S on the cervix. As a first step the pain experienced by women during abortion using the Dilapan-S/misoprostol combination was assessed. There are no reports in the literature of this combination being used to cause medical abortion in pregnancies of less than 9 weeks.

This communication reports a pilot study that could be taken forward to a randomised study to compare the use of Dilapan-S/misoprostol with mifepristone/misoprostol in the induction of abortion.

Methods

Provided there were no medical contraindications (i.e. cerebrovascular disease, coronary artery disease, peripheral vascular disease, known allergy to prostaglandins, a median of 6 hours with an interquartile range of 4.5–11.5 hours. Of these, 15 patients recorded mild discomfort only, 14 considered the procedure excellent and three good.

Discussion and conclusions This study suggests that the Dilapan-S/misoprostol combination reduces the pain associated with early medical abortion. Further investigation of the protocol is merited.

Keywords Dilapan-S™, early medical abortion, mifepristone, misoprostol, pain in abortion


Key message points

- Reduction of pain in medical abortion may further improve the acceptability and uptake of early medical abortion.
- This pilot study suggests that a Dilapan-S™/misoprostol combination reduces the pain associated with early medical abortion.
- A full randomised trial of the Dilapan-S/misoprostol combination is therefore merited.

Department of Sexual Health, King’s College Hospital NHS Trust, London, UK
Mannampallil I Samuel, MRCOG, MFSRH, Associate Specialist

Department of Obstetrics and Gynaecology, King’s College Hospital NHS Trust, London, UK
John H Parsons, FRCPG, Consultant

Correspondence to: Dr Mannampallil Samuel, Department of Sexual Health, King’s College Hospital, 100 Denmark Hill, London SE5 9RS, UK. E-mail: ittsamuel@hotmail.co.uk

Figure 1 Dilapan-S™, a synthetic hygroscopic mechanical dilator, before and after cervical insertion

©FSRH J Fam Plann Reprod Health Care 2009: 35(1)
untreated pelvic infection or a patient aged under 16 years) suitable patients referred to the King’s College Hospital termination counselling clinic were offered the procedure if they were less than 64 days’ pregnant (crown–rump length <22 mm) as an alternative to suction TOP under general anaesthesia or medical TOP with mifepristone/misoprostol. All patients were given an information sheet describing the purpose of the pilot study and the procedure was explained by a nurse counsellor. Those opting to be included in the study were then seen by a doctor to confirm that they understood the information they had been given. It was made clear that if the procedure did not result in a complete abortion by 2.00 pm on the day of the termination then the patient would be placed on a routine operating list for a surgical TOP under general anaesthesia that day. The patient then signed a consent form.

On the afternoon before the planned abortion a 4 mm hygroscopic dilator was inserted into the endocervical canal through the internal cervical os. This was done by first passing a Cusco speculum to expose the cervix. The dilator was grasped using sponge-holding forceps by the threaded end and gently pushed through the endocervical canal until the operator felt that it had passed through the internal os.

The first five patients placed 800 mg misoprostol intravaginally at 6.00 am on the day of the abortion. The subsequent 21 patients placed 400 mg misoprostol intravaginally at 8.00 pm on the day the Dilapan-S was inserted and 400 mg at 6.00 am the following morning.

The women were admitted to the ward at 8.00 am. To control pain analgesics were given depending on the pain score. Patients who had no discomfort were given no analgesia. Those who had mild discomfort were offered paracetamol 1 g orally. Those with moderate discomfort were offered dihydrocodeine 30–60 mg or co-dydramol (paracetamol 500 mg + dihydrocodeine tartrate 10 mg) two tablets 4-hourly orally. Those who had severe unbearable pain were given pethidine 50–100 mg intramuscularly. To control nausea/vomiting patients were given prochlorperazine 12.5 mg intramuscularly 4-hourly as required.

The time from first administration of misoprostol to a successful abortion was recorded. Pain was scored by the patient on a scale of 0 to 10. The scores were defined as follows: 0 to 5 – nil to slight pain, 6 to 8 – moderate pain, 9 to 10 – severe pain. Patient satisfaction, side effects and the place of abortion were recorded.

Where the doctor was in doubt regarding the completeness of the termination procedure a vaginal scan was undertaken. All patients were followed up 2 weeks later and assessed prior to discharge from care.

Ethical approval
The study was approved by the King’s College Hospital Ethics Committee.

Results
A total of 26 patients were recruited to the study. One patient withdrew after the insertion of the Dilapan-S and requested a surgical TOP. Of the remaining 25 patients, 17 aborted completely within 2–17 hours (median time 6 hours, interquartile range 4.5–11.5 hours) of the first dose of misoprostol. Dilapan-S was expelled in all of those that miscarried. Two women aborted incompletely and six did not abort before the 3.00 pm deadline (i.e. 18 hours after the administration of misoprostol).

Of the 17 patients aborting completely, 15 recorded mild discomfort. One patient complained of moderate pain and one severe pain, both of whom were given co-dydramol as analgesia in hospital. Pain was reported to be highest at the time of expulsion of the products of conception.

Of the 17 cases who aborted, 14 considered the procedure to be excellent and would recommend it to others. The remaining three patients (including the two reporting more than mild discomfort) considered the procedure to be good but did not commit themselves as to whether they would recommend it to others.

Of the 25 patients taking part in the study, eight reported diarrhoea, one vomiting, three nausea and two headache.

Discussion
The earlier a TOP is performed the safer it is for the woman, therefore ways of making early medical abortion more appealing are of interest. The incidence of significant pain is difficult to assess from the published literature on early medical abortion. Spitz et al. studied 2121 women in 17 centres in the USA. Nearly all complained of abdominal pain and approximately half complained of severe pain. Westhoff et al. studied the predictors of analgesia use in the same group of women and concluded that the most important determinant was the clinic that provided the care during the abortion. Of the women they studied, 27% received narcotic analgesia (co-dydramol).

Ashok et al. reported the analgesic requirements of 3146 women; 58.6% required oral analgesia (co-dydramol) and 4.7% required parenteral opiates for pain.

This pilot study was performed to investigate the hypothesis that a Dilapan-S/misoprostol combination was effective and less painful than mifepristone followed by misoprostol. A single dose of misoprostol 36–48 hours after mifepristone leads to a complete abortion in approximately 95.0–97.5% of cases. Misoprostol alone has been used for early medical abortion, and with repeated doses over 1 to 3 days successful termination may occur in over 90% cases.

This protocol only allowed 18 hours between insertion of the first dose of misoprostol and a decision to send the patient for surgical TOP if abortion was not complete. This was because the investigators did not wish to put pressure on the already stretched availability of operating space for emergency evacuation of retained products of conception and to ensure that volunteers to the study did not have to wait unduly for their abortion to be complete. Had a longer period been available before surgical TOP was performed and further doses of misoprostol been given then the proportion of successful abortions is likely to have been higher. In retrospect, the women who had not aborted could have been offered suction TOP or manual vacuum aspiration with or without local anaesthesia as their cervixes would not have required dilatation.

The majority (15/17) of the women who aborted complained of mild discomfort, one complained of moderate and the other severe pain. The numbers in the study were small but the authors feel the data are encouraging. There were no complaints following the slight pain on insertion of the Dilapan-S.

Dilapan-S (4 mm) costs approximately £6.00 and needs a nurse or doctor for insertion whilst mifepristone 200 mg costs £13.94 and is taken orally. Taking into consideration the labour costs associated with the use of Dilapan-S, the Dilapan-S/misoprostol combination is more expensive but the labour costs associated with the use of Dilapan-S, the Dilapan-S/misoprostol combination is more expensive but if the women attracted to this technique were to have had suction TOP there would be a cost saving. Some women opting for early medical abortion may do so because they wish to avoid medical interference and, when offered the option to have pain reduced by Dilapan-S preparation of
Conclusions
This pilot study suggests that the Dilapan-S/misoprostol combination reduces the pain associated with medical TOP. Future studies should address the efficacy and cost-effectiveness of this combination in comparison to mifepristone/misoprostol and surgical TOP.

Statements on funding and competing interests
Funding None identified.
Competing interests None identified.

References