A comparison of Lamicel tents and gemeprost (Cervagem) pessaries prior to first trimester abortion

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Summary. In an open, randomized study 108 women were treated with either a Lamicel tent or a 1 mg gemeprost pessary (Cervagem) 4 h before first trimester abortion. Both treatments were effective in producing cervical dilatation, however further dilatation was significantly easier after Cervagem. Preoperative abdominal pain and gastrointestinal side-effects were significantly more frequent in the Cervagem group. The incidence of postoperative pain and blood loss were similar in the two groups. Advantages and disadvantages of the two treatments are mentioned.

Key words: First trimester abortion – Cervagem – Lamicel – Cervical dilatation

Introduction

Vacuum aspiration is the most common method used for termination of first trimester pregnancy. Mechanical dilatation of the cervix can be associated with adverse short-term effects including cervical laceration, uterine perforation and incomplete uterine evacuation. In addition, there can be long-term effects including mid-trimester abortions and premature deliveries in subsequent pregnancies.

Prostaglandins have been shown to lower the resistance of the cervix when using mechanical dilatation (Welch and Elder 1982, Christensen et al. 1983). The use of natural prostaglandins has been limited due to a high incidence of gastrointestinal side-effects and slow action. Gemeprost pessaries (Cervagem®), a prostaglandin analogue, have been shown to produce cervical dilatation in a shorter time and with fewer side-effects (Kajanoja et al. 1984, Christensen and Bygdeman 1984).

Another preoperative treatment to dilate the cervix is the introduction of a cervical dilatator (Nicolaides et al. 1983, Norstrøm et al. 1988). Lamicel® is a
synthetic hydrophilic polymer impregnated with magnesium sulfate and compressed to a cylindrical tent.

In an open study Welch et al. (1984) found no significant difference in cervical dilatation between Lamicel and Cervagem. Helm et al. (1988) reported in a single-blind trial with the same treatments that dilatation was significantly easier after Cervagem.

This study was set up to evaluate the effectiveness of the Lamicel tent compared with the gemeprost pessary in an open, randomized study.

Patients and methods

One hundred and eight nulliparous patients, admitted to pregnancy termination, were enrolled into the study after having given informed, legal consent. All were between 7 and 12 weeks pregnant as determined by period of amenorrhea and by clinical assessment of uterine size. If there was a discrepancy an ultrasonic measurement was performed.

Patients were excluded from the study if they had asthma, cardiovascular insufficiency, elevated intraocular pressure, allergy to prostaglandins or had any surgery involving the cervix.

The patients were randomly allocated to receive either a 1 mg gemeprost pessary (Cervagem, May & Baker Ltd., Dagenham, Essex, UK) or a Lamicel tent (Cabot Medical Corp., Langhorne, Pennsylvania, USA). Approximately 4 h before surgery either a gemeprost pessary or a Lamicel tent were inserted. The gemeprost pessary was inserted into the posterior fornix of the vagina.

Pre- and postoperative side-effects and uterine cramps were recorded, as was the need of mild or strong analgetic medication.

All patients received standard premedication and a general anaesthesia for the surgical procedure. The degree of cervical dilatation was measured by the size of the largest Hegar dilator which could be inserted through the cervical canal without resistance. If further dilatation was necessary, this was assessed “easy”, “moderate” or “difficult”, and the diameter of the largest Hegar dilator used was recorded. Preoperative the patients received 0.2 mg Methergin intravenous, and no further uterine contracting agents were given. Operative bleeding was measured after sieving the product of conceptus.

Any complications at the time of surgery and during the immediate postoperative period were documented, as was any readmission to the gynaecological unit during the first month.

In the statistical analysis the following non-parametric methods were used: Mann-Whitney’s rank sum test and Fisher’s exact test. Two-tailed tests were performed, and a significance level of 5% was chosen.

Results

One hundred and eight patients entered the study, 57 in the Cervagem group and 51 in the Lamicel group. A 3-mm Lamicel was inserted in 48 cases, a 5-mm tent in the last three. There were problems with the insertion on two occasions, and a third patient was excluded as the insertion was impossible. Three tents fell out before start of the operation.

There were no significant differences between the two treatment groups in median age, gestational age, cervical dilatation at the time of operation or size of final mechanical dilatation of the cervix (Table 1).

The assessment of ease of cervical dilatation was recorded as “none required”, “easy”, “moderately difficult” and “difficult”. The number of patients in whom dilatation was difficult or moderately difficult was significantly reduced in the Cervagem group (33% vs 57% in the Lamicel group) (Table 2).