Preparation of the cervix for surgical termination of pregnancy in the first trimester

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Worldwide, surgical vacuum aspiration is the method of choice of terminating first trimester unwanted pregnancy. Cervical priming prior to surgical evacuation reduces the risks of cervical injury by making the cervix softer and easier to dilate. Over the years, a number of effective methods of cervical priming have become available: osmotic dilators; antiprogestosterone and prostaglandins. Of these, prostaglandins remain the most widely used method of cervical preparation. However many of the natural and synthetic analogues of prostaglandins are either expensive or associated with troublesome side-effects. More recently, misoprostol, a synthetic 15-deoxy-16 hydroxy 16-methyl analogue of naturally occurring prostaglandin E, used in the management of peptic ulcers, has established a lead for cervical priming in terms of availability, ease of administration, cost and effectiveness. In fact it appears that both oral and vaginal misoprostol given at dosages of 400 µg are effective for cervical priming when administered 3 h prior to surgical vacuum aspiration. Now that the use of misoprostol for cervical priming has been validated, its widespread use in gynaecological practice is expected.

Key words: misoprostol/pre-abortion cervical priming/pregnancy termination

TABLE OF CONTENTS
Introduction
Literature search methodology
Efficacy of misoprostol
Route of administration
Efficacy of vaginal misoprostol
Optimal dose of vaginal misoprostol
Minimum evacuation time interval
Role of acidic media
Conclusion
References

Introduction
Induced first trimester abortion is one of the most commonly performed gynaecological procedures in the world. In fact, in most parts of the world where cost, time and ease of application are important considerations, surgical vacuum aspiration is still the method of choice for terminating first trimester unwanted pregnancies. Cervical dilatation prior to suction evacuation is probably the most critical step in vacuum aspiration. However, surgical and forceful cervical dilatation causes a significant complication rate that is largely dependent upon operator experience and the force applied (Hulkan et al., 1974). Microscopic cervical tears invariably appear as the cervix is dilated to >9 mm and it has been suggested that this may represent actual tearing of the internal os rather than true dilatation (Hulkan et al., 1974). Once 12 mm is exceeded, the fibrous matrix of the cervix risks irreversible damage resulting in long-term consequences such as cervical incompetence, mid-trimester abortion and increased incidence of preterm delivery in future pregnancies (Johnstone et al., 1976; Harlap et al., 1979; Lumley, 1986). Technically difficult dilatations are also associated with increased frequency of haemorrhage, incomplete evacuation of uterine contents (predisposing to infection and the need for repeated curettage) and uterine perforation (Moberg, 1976). Mechanical cervical dilatation is, therefore, an important cause of complications during first trimester pregnancy termination and any means of facilitating this dilatation will reduce the morbidity associated with surgical vacuum aspiration.

Cervical priming prior to surgical termination reduces the risks of cervical injury and uterine perforation (Schulz et al., 1983; Grimes et al., 1984) by making the cervix softer and easier to dilate. Although pre-operative cervical priming does not reduce the total axial force required to disrupt the fibrous structure of the cervix, it shifts the force/dilatation curve to the right allowing a greater dilatation to be achieved before damage occurs (Gupta and Johnson, 1992). The value of pre-operative cervical priming is indisputable and it can reduce the operative morbidity 27-fold (Schulz et al., 1983). Current guidelines by the Royal College of Obstetricians and Gynaecologists (RCOG, 1997) recommend that cervical preparation should be routine where the woman is aged <18 years of age or the gestation is >10 weeks. A number of effective methods of cervical priming are available.

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Table 1. Trials evaluating misoprostol versus placebo for pre-abortal cervical priming

| Author and year | Randomization method | Allocation No of Allocation Route of Dose (µg) Interval Efficacy |
|-----------------|----------------------|--------------------|--------------------|-----------------------|-----------------------------|
| Bugallo et al. (1994) | Random number tables. Allocation concealment not stated. Consent pre-randomization. | 2    | 100 | Vaginal | 200 | 6 h | Criteria: cervical dilatation > Hagar 8 |
|                  |                      |                    |                   | Misoprostol (74%) versus placebo (10%)
|                  |                      |                    |                   | Odds ratio 25.6 (95% CI 9.6,68.3) |
| El-Refaey et al. (1994) | Computer generated random tables. Allocation concealment not stated. Consent pre-randomization. | 3    | 90  | Vaginal | 600 | 2–4 h | Criteria: baseline cervical dilatation (mm)
|                  |                      |                    |                   | Misoprostol versus placebo: 8.0 versus 7.0 (P < 0.006) |
| Ngai et al. (1995b) | Random number tables. Allocation concealment not stated. Consent pre-randomization. | 2    | 75  | Oral    | 400 | 12 hrs | Criteria: baseline cervical dilatation (mm)
|                  |                      |                    |                   | Misoprostol versus placebo: Nullip: 7.4 ± 2.0 versus 6.1 ± 1.7 (P < 0.0001)
|                  |                      |                    |                   | Multip: 9.2 ± 1.7 versus 6.5 ± 1.5 (P < 0.0001) |
| Ficicioglu et al. (1996) | Randomization not specified. Consent pre-randomization. | 2    | 60  | Vaginal | 200 | 5 h | Criteria: cervical dilatation > Hagar 8 |
|                  |                      |                    |                   | Misoprostol (72.5%) versus placebo (10%) P < 0.001 |
| Wiebe and Rawling (1998) | Random number tables. Numbered opaque envelopes. Consent pre-randomization. | 2    | 93  | Vaginal | 750 | 2 h | Criteria: Pratt dilator(mm) first meeting resistance |
|                  |                      |                    |                   | Misoprostol 21.4 versus placebo 19.6 (P = 0.67) |
| Ngai et al. (1999) | Random number tables. Allocation concealment not stated. Consent pre-randomization. | 5    | 204 | Vaginal/oral | 200/400 | 3 h | Criteria: baseline cervical dilatation (mm)
|                  |                      |                    |                   | Placebo 5.5 ± 1.4 versus: Oral 200 µg 6.6 ± 0.9 (P < 0.01)
|                  |                      |                    |                   | Oral 400 µg 7.2 ± 1.0 (P < 0.01) |
|                  |                      |                    |                   | Vaginal 200 µg 6.8 ± 1.2 (P < 0.01) |
|                  |                      |                    |                   | Vaginal 400 µg 6.8 ± 1.3 (P < 0.01) |

**Osmotic dilators – laminaria and hygroscopic tents**

Hydrophilic dilators inserted into the cervix swell gradually and prepare the cervix prior to surgical termination (Bokstrom and Wiqvist, 1993; Munstick and Fineberg, 1996). Laminaria tents and other osmotic dilators (Lamicil, Dilapan) are inexpensive but they require trained personnel for insertion. This may be difficult especially if the cervical os is very tight. A false passage may be created or bleeding may be induced. Despite accurate placement, the dilator may fall out or be displaced inside the uterus and perforation of uterus may occur (Johnson, 1989; Hern, 1994). Moreover a long latent period (8–10 h) is often needed for maximal dilatation and the tent itself has been associated with infection.

**Antiprogestrone – mifepristone**

Recently, the antiprogestrone mifepristone (RU486) has been reported to be an effective cervical priming agent. It compares favourably with prostaglandins (World Health Organization, 1990, 1994; Henshaw and Templeton, 1991; Carbone et al., 1995). Although the incidence of side-effects is low, a long latent period of 24–36 h is required for the drug to be effective (World Health Organization, 1990). Vaginal bleeding and incomplete abortion have also been reported following mifepristone administration in the late first trimester (Durlot et al., 1988).

**Prostaglandins**

Prostaglandins remain the most widely used method of cervical preparation prior to vacuum aspiration. Pre-operative treatment with prostaglandins has been shown to be effective in facilitating cervical softening and dilatation. However the naturally occurring prostaglandins are associated with frequent side-effects which limit their acceptability (Karim and Filshie, 1970; Moscary and Caspo, 1975). A variety of synthetic analogues are now available...
of which gemeprost (16, 16 dimethyl-trans-D2-PGE1 methyl ester) is currently the main preparation used but this has not eliminated troublesome side-effects (Bygdeman and Green, 1979).

Misoprostol, a synthetic 15-deoxy-16-hydroxy 16-methyl analogue of naturally occurring prostaglandin E1 has been used for several years for the prevention and treatment of peptic ulcers by its cytoprotective effect. The use of misoprostol for cervical priming prior to surgical vacuum aspiration has been proven to be effective using both the oral (Ngai et al., 1995a,b) and vaginal (El-Refaey et al., 1994; Lawrie et al., 1996) routes.

This systematic review assesses the efficacy and safety of misoprostol used for cervical priming before surgical termination of pregnancy in the first trimester and provides an update on the current state of knowledge on pre-abortion cervical priming.

**Literature search methodology**

We used several sources to identify all published clinical trials that have evaluated the use of misoprostol for pre-abortion cervical priming. Searches were conducted for the years 1990–2000 using the following electronic computerized databases: MEDLINE (National Library of Medicine, Bethesda, MD, USA) and OVID (Ovid Technologies Inc., USA). Medical subject heading keywords included pre-abortion cervical priming, prostaglandins and misoprostol. In addition we manually screened references of studies and review articles for relevant studies. Abstracts and review articles were not analysed. Only published randomized controlled trials in the English language comparing the use of misoprostol for cervical priming before surgical termination with the use of other prostaglandins, antiprogesterone, hygroscopic agents or placebo were included in the analysis.

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**Table II. Trials evaluating misoprostol versus other agents for pre-abortion cervical priming**

<table>
<thead>
<tr>
<th>Author and year</th>
<th>Randomization method</th>
<th>Allocation groups</th>
<th>No of patients</th>
<th>Cervical priming agent used, dosage, route and interval</th>
<th>Dose, route and interval of misoprostol</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>El-Refaey et al. (1994)</td>
<td>Computer generated random tables. Allocation concealment not stated. Consent pre-randomization.</td>
<td>3</td>
<td>90</td>
<td>Gemeprost 1 mg Vaginal, 2–4 h</td>
<td>600 µg vaginal 2–4 h</td>
<td>Criteria used: baseline cervical dilatation (mm) Misoprostol versus gemeprost: 8.0 versus 8.0 (NS)</td>
</tr>
<tr>
<td>Ngai et al. (1995a)</td>
<td>Random number tables. Allocation concealment not stated. Consent pre-randomization.</td>
<td>2</td>
<td>64</td>
<td>Gemeprost 1 mg Vaginal, 3 h</td>
<td>400 µg oral 12 h</td>
<td>Criteria used: baseline cervical dilatation (mm) Misoprostol versus gemeprost: 8.1 ± 1.7 versus 7.0 ± 1.7 (P&lt;0.02)</td>
</tr>
<tr>
<td>Platz-Christensen (1995)</td>
<td>Randomization not specified</td>
<td>2</td>
<td>88</td>
<td>Gemeprost 1 mg Vaginal, 3–5 h</td>
<td>600 µg oral 17–19 h</td>
<td>Criteria used: baseline cervical dilatation (mm) Misoprostol versus gemeprost: 7.5 versus 6.6 (NS)</td>
</tr>
<tr>
<td>Ngai et al. (1996)</td>
<td>Random number tables. Allocation concealment not stated. Consent pre-randomization.</td>
<td>2</td>
<td>93</td>
<td>Mifepristone 200 mg orally, 36 h</td>
<td>400 µg oral 12 h</td>
<td>Criteria used: baseline cervical dilatation (mm) Misoprostol versus mifepristone: 8.0 ± 1.6 vs 7.7 ± 1.2 (P=0.4)</td>
</tr>
<tr>
<td>Sparrow et al. (1998)</td>
<td>Randomization not specified</td>
<td>2</td>
<td>313</td>
<td>Dinoprostone 3 mg vaginally, 12 h</td>
<td>400 µg oral 1 h, plus 200 µg oral 30 min in 36.3% of patients</td>
<td>Criteria used: easy dilatation Misoprostol versus dinoprostone: 134 (83.8%) versus 124 (81.0%) (P = 0.004)</td>
</tr>
<tr>
<td>MacIassac et al. (1999)</td>
<td>Computer generated assignment (ratio = 1:3:3). Numbered sealed opaque envelopes. Consent pre-randomization.</td>
<td>3</td>
<td>106</td>
<td>Laminaria tent intracervical, 4 h</td>
<td>400 µg oral, 4 hrs 400 µg vaginal, 4 hrs</td>
<td>Criteria used: baseline cervical dilatation (Pratt dilator) Laminaria tent 25.9 ± 5.8 versus: Oral misoprostol 24.2 ± 4.8 (NS) Vaginal misoprostol 28.0 ± 7.3 (NS)</td>
</tr>
<tr>
<td>Henry and Haukkamaa (1999)</td>
<td>Random number tables. Numbered sealed envelopes. Consent pre-randomization.</td>
<td>2</td>
<td>188</td>
<td>Gemeprost 1 mg Vaginal, 3 h</td>
<td>200 µg vaginal 4 h</td>
<td>Criteria used: baseline cervical dilatation (mm) Misoprostol versus gemeprost: 7.1 ± 2.1 versus 6.7 ± 1.8 (NS)</td>
</tr>
</tbody>
</table>
Table III. Comparison of oral versus vaginal misoprostol for pre-abortion cervical priming

<table>
<thead>
<tr>
<th>Author and year</th>
<th>Randomization method</th>
<th>Allocation groups</th>
<th>No of patients</th>
<th>Oral dosage and interval</th>
<th>Vaginal dosage and interval</th>
<th>Efficacy</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lawrie et al. (1996)</td>
<td>Random number tables. Sequentially numbered, sealed opaque envelopes. Consent pre-randomization.</td>
<td>2</td>
<td>60</td>
<td>400µg 12 h 800µg 2–4 h</td>
<td>Criteria used: baseline cervical dilatation (mm) Oral versus vaginal: 6.91 versus 6.99 (NS)</td>
<td>More pain and vaginal bleeding in oral group</td>
<td></td>
</tr>
<tr>
<td>MacIssac et al. (1999)</td>
<td>Computer generated assignment (ratio = 1:3:3). Numbered sealed opaque envelopes. Consent pre-randomization.</td>
<td>3</td>
<td>106</td>
<td>400µg 4 h 400µg 4 h</td>
<td>Criteria used: baseline cervical dilatation (pratt dilator, mm) Oral versus vaginal misoprostol: 24.2 ± 4.8 versus 28.0 ± 7.3 (P&lt;0.05)</td>
<td>Vaginal more effective for pregnancies &gt;12 weeks (P&lt;0.05)</td>
<td></td>
</tr>
<tr>
<td>Ngai et al. (1999)</td>
<td>Random number tables. Allocation concealment not stated. Consent pre-randomization.</td>
<td>5</td>
<td>204</td>
<td>200 or 400µg, 3 h</td>
<td>200 or 400µg 3 h</td>
<td>Criteria: baseline cervical dilatation (mm) Oral 400µg 7.2 ± 1.0 versus: Vaginal 200µg 6.8 ± 1.2 (NS)</td>
<td>Similar incidence of side-effects in 4 groups</td>
</tr>
</tbody>
</table>

NS = not significant.

All data were extracted by the second author and were then checked by the first author. When data were not available in the published papers, the principal investigators were contacted for additional information. The following data were extracted from the studies: randomization method, allocated groups in study, number of patients randomized, cervical priming agent used, dosage, route of administration, evacuation time interval and efficacy of treatment. The final decision about whether a trial should be included was made collaboratively by the two authors.

**Efficacy of misoprostol**

We initially reviewed the effectiveness of misoprostol for pre-abortion cervical priming. In six of these studies, the efficacy of misoprostol was evaluated against a placebo and in all six studies, misoprostol was shown to significantly improve the baseline cervical dilatation (Table I). Table II shows the comparison of misoprostol versus other agents used for pre-abortion cervical priming. In the only study where laminaria tents were used, misoprostol used vaginally had a greater cervical mean dilatation than the laminaria tent group, although this difference did not reach significance. However the women who received laminaria tents reported significantly more pain at the time of placement compared with women who received misoprostol by the oral and vaginal routes (MacIssac et al., 1999).

When misoprostol was compared with mifepristone or other prostaglandin analogues, it was found to be as efficacious or better (Table II). However the high cost of mifepristone and its lack of availability in many parts of the world make it impractical for use as cervical priming agent. Similarly, gemeprost, currently the main prostaglandin analogue used, is expensive (Singapore $51 for a 1 mg vaginal pessary), relatively unstable and requires refrigeration for storage. On the other hand, misoprostol is safe, easy to administer and is inexpensive. The cost for a 200µg tablet is only Singapore $0.85.

**Route of administration**

In three studies, oral versus vaginal misoprostol was evaluated with regards to efficacy for cervical priming prior to vacuum aspiration (Table III). In two studies, both the oral and vaginal routes were demonstrated to be as effective for cervical priming (Lawrie et al., 1996; Ngai et al., 1999).

However, oral misoprostol tends to be unpredictable in its onset and intensity of action when given 12 h prior to vacuum aspiration, resulting in spontaneous abortion before the scheduled timing and a higher incidence of abdominal pain and pre-abortion vaginal bleeding (Lawrie et al., 1996). More recently, it was shown that with a shorter evacuation time interval of 3 h, there is no difference in the incidence of side-effects between misoprostol given orally or vaginally (Ngai et al., 1999).

Vaginal misoprostol was found to be more effective than oral misoprostol. This was especially so for pregnancies of 12–14 weeks (MacIssac et al., 1999). The side-effects were also less with the use of vaginal misoprostol. As a result the vaginal route tends to be preferred.
### Table IV. Optimal dose and evacuation interval of vaginal misoprostol for pre-abortion cervical priming

<table>
<thead>
<tr>
<th>Author and year</th>
<th>Randomization method</th>
<th>Allocation groups</th>
<th>No of patients</th>
<th>Dosage and interval</th>
<th>Efficacy</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fong et al. (1998)</td>
<td>Random number tables. Sequentially numbered, sealed opaque envelopes. Consent pre-randomization.</td>
<td>2</td>
<td>60</td>
<td>200 versus 400 µg, 3–4 h</td>
<td>Criteria used: baseline cervical dilatation (mm) 400 versus 200 µg: 8.2 ± 0.8 versus 6.4 ± 1.3 (P &lt; 0.001)</td>
<td>400 µg dose is significantly more efficacious</td>
</tr>
<tr>
<td>Singh et al. (1998)</td>
<td>Random number tables. Sequentially numbered, sealed opaque envelopes. Consent pre-randomization.</td>
<td>4</td>
<td>120</td>
<td>200, 400, 600, 800 µg, 3–4 h</td>
<td>Criteria used: cervical dilatation &gt;Hegar 8 200 µg: 7/30 (23.3%) 400 µg: 29/30 (96.7%) 600 µg: 30/30 (100%) 800 µg: 30/30 (100%)</td>
<td>No significant difference between 400, 600 and 800 µg for dilatation &gt;Hegar 8. More side-effects for 600 and 800 µg</td>
</tr>
<tr>
<td>Singh et al. (1999a)</td>
<td>Random number tables. Sequentially numbered, sealed opaque envelopes. Consent pre-randomization.</td>
<td>2</td>
<td>60</td>
<td>400 µg, 3 h 600 µg, 2 h</td>
<td>Criteria used: baseline cervical dilatation (mm) 400 µg, 3 h versus 600 µg, 2 h 8.1 ± 0.1 versus 6.6 ± 0.2 (P &lt; 0.001)</td>
<td>More side-effects with larger dose. Less efficacy if interval shortened to 2 h</td>
</tr>
<tr>
<td>Singh et al. (1999b)</td>
<td>Random number tables. Sequentially numbered, sealed opaque envelopes. Consent pre-randomization.</td>
<td>3</td>
<td>180</td>
<td>400 µg, 3 h 600 µg, 2 h 800 µg, 2 h</td>
<td>Criteria used: baseline cervical dilatation (mm) 400 µg, 3 h: 8.1 ± 0.1 versus 600 µg, 2 h: 6.7 ± 0.1 (P &lt; 0.001) 800 µg, 2 h: 6.8 ± 0.1 (P &lt; 0.001)</td>
<td>More side-effects with larger dose.</td>
</tr>
</tbody>
</table>

### Efficacy of vaginal misoprostol

With the vaginal route, several treatment regimes have been used with varying degrees of success. Initial trials using a dose of 200 µg of vaginal misoprostol with an evacuation time interval of 5–6 h were only able to achieve a success rate of <74% for a cervical dilatation of Hegar 8 or more (Bugallo et al., 1994; Ficioglu et al., 1996). Since termination of pregnancy is often on an outpatient basis, an evacuation time interval of ~3–4 h would be more suitable for cervical priming before vacuum aspiration. However, when the evacuation time was shortened, it has been shown that a 200 µg dose of vaginal misoprostol is unsuitable for use in pre-abortion cervical priming: in a randomized trial no patient achieved a successful dilatation of ≥8 mm at 3 h and only 46.7% achieved a similar dilatation at 4 h (Fong et al., 1998). On the other hand, a dose of 400 µg of vaginal misoprostol was able to attain a successful cervical dilatation of ≥8 mm at 4 h in all patients, with 93.3% achieving a similar dilatation at 3 h in this trial (Fong et al., 1998).

### Optimal dose of vaginal misoprostol

The Royal College of Obstetricians and Gynaecologists (1997) has recommended 800 µg of misoprostol vaginally, 3 to 4 h before surgery for cervical priming. A randomized study comparing four different dosage groups (200, 400, 600 and 800 µg) showed that the efficacy of misoprostol is dose-dependent at a fixed evacuation time interval of 3–4 h (Singh et al., 1998). Among the four dosages used in this study, the 400 µg dose was associated with at least 96% successful dilatation and minimal side-effects. Increasing the dosage to >400 µg, with a constant evacuation interval of 3–4 h, did not confer any additional advantage on the rate of successful cervical dilatation (Singh et al., 1999a) but instead was associated with more side-effects, e.g. pre-operative vaginal bleeding, abdominal pain, products of conception at the cervical os and fever over 38.0°C. Thus, doses of 600 and 800 µg of vaginal misoprostol 3–4 h before surgery for cervical priming cannot be recommended (Table IV).

### Minimum evacuation time interval

Having shown the optimal dose of vaginal misoprostol to be 400 µg at an evacuation interval of 3–4 h, the question of whether the evacuation time interval could be lowered with a higher dosage of misoprostol was next explored. This hypothesis was tested and a randomized study showed that higher doses of misoprostol (600 and 800 µg) at a shorter evacuation interval of
2 h failed to achieve the desired successful cervical dilatation of \( \geq 8 \) mm compared with 400 \( \mu \)g of misoprostol at an interval of 3 h (Singh et al., 1999a,b). Despite the shorter interval, the higher doses were associated with significantly more abdominal pain and fever of over 38.0\(^\circ\)C compared with 400 \( \mu \)g at an evacuation interval of 3 h. A similar result was reported in a Canadian trial where there was no statistical significance between placebo and 750 \( \mu \)g misoprostol used at 2 h (Wiebe and Rawling, 1998). Absorption pharmacokinetics of misoprostol were studied (Ziemen et al., 1997) and it was found that with intravaginal misoprostol, peak plasma values were reached 60–120 min after administering the dose. Plasma concentrations were sustained to up to 240 min and systemic bioavailability of vaginal misoprostol was three times higher than oral misoprostol, which probably indicates that there is a relationship between plasma concentrations of misoprostol and its therapeutic effect. Thus in keeping with the absorption kinetics of misoprostol administered vaginally, this confirms that the efficacy of vaginal misoprostol for cervical priming is both dose and time dependent and this minimal evacuation time appears to be 3 h (Singh et al., 1999b).

**Role of acidic media**

Misoprostol is said to liquefy better in an acidic medium (American Hospital Formulary Drug Information, 1998). Ficicioglu et al. (1996), using 200 \( \mu \)g of vaginal misoprostol, with one tablet of gynoflor to create an acidic medium to enhance misoprostol absorption, showed that after 5 h, 72.5% of women achieved a successful cervical dilatation of 8 mm. However a recent comparative study between the use of acetic acid and water as a liquefying media for vaginal misoprostol did not find any enhanced efficacy when acetic acid was used for a 200 \( \mu \)g dose of vaginal misoprostol at an evacuation time interval of 3–4 h (Singh et al., 1999c). It thus appears that a 400 \( \mu \)g dose is still required to achieve optimal cervical priming (Fong et al., 1998).

**Conclusion**

The advantages of preparing the cervix before surgical termination of pregnancy in the first trimester are well recognized. Among the available options available for this purpose, it appears that misoprostol has established a lead in terms of availability, ease of administration, cost and effectiveness. Now that the use of misoprostol for this purpose has been validated, its widespread use in gynaecological practice is expected.

**References**


Royal College of Obstetricians & Gynaecologists (1997) *Induced Abortion*. 

**Preparation of cervix for pre-abortion cervical priming** 447


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