

Termination of second and early third trimester pregnancy: comparison of 3 methods

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إنهاء الحمل في الأثلوث الثاني أو بداية الثالث: مقارنة ثلاث طرق

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الخلاصة: قام الباحثون بتقييم كفاءة ومأمونية ثلاث طرق قانونية مستخدمة في إنهاء الحمل بوصفه ضرورة علاجية في الأثلوث trimester الثاني أو بداية الأثلوث الثالث، لدى 258 من الحوامل الأردنيات اللاتي تم توزيعهن بشكل عشوائي لتطبيق قنطار فولي مع أو بدون سحب أو إعطاء أقراص مهبلية من البروستاغلاندين E2. وقد كان معدل فشل إنهاء الحمل والمدة الإجمالية بين إدخال القنطار وبين إنهاء الحمل أعلى لدى استخدام قنطار فولي دون سحب (فقد زاد معدل الفشل بنسبة 16.5% والمدة بنسبة 16.5 ساعة عما لو استخدم قنطار فولي مع السحب (حيث بلغ معدل الفشل 10% والمدة 14.2 ساعة) كما كان أعلى أيضاً مما لو استخدمت الأقراص البروستاغلاندين E2 المهبلية (حيث بلغ معدل الفشل 8% والمدة 11.5 ساعة). ومع ذلك، تُعدُّ قنطرة فولي طريقة مأمونة وزهيدة التكاليف لإنهاء الحمل في الأثلوث الثاني أو بداية الأثلوث الثالث منه، ويمكن تعزيز فعاليتها باستخدام السحب لإعطاء نتائج تشابه ما تُسفر عنه الأقراص المهبلية للبروستاغلاندين E2.

ABSTRACT The efficacy and safety of 3 methods used in legal termination of pregnancy in the second and early third trimester was assessed in 258 women in Jordan randomly assigned to receive Foley catheter (with and without traction) or prostaglandin E2 vaginal tablets. The failure rate of termination and the total insertion-to-termination time was higher with Foley catheter without traction (16.5%, 16.5 hours) than with traction (10.0%, 14.2 hours) or prostaglandin (8.0%, 11.5 hours). However, Foley catheter as a method of termination of pregnancy in second and early third trimester is safe and inexpensive, and its efficacy can be enhanced with the use of traction to give similar results to prostaglandin E2.

Interruption de grossesse au deuxième trimestre et au début du troisième trimestre : comparaison de 3 méthodes

RÉSUMÉ L'efficacité et l'innocuité de trois méthodes utilisées pour l'interruption légale de grossesse au deuxième trimestre et au début du troisième trimestre ont été évaluées chez 258 femmes en Jordanie qui ont été randomisées pour recevoir une sonde de Foley (avec ou sans traction) ou des ovules vaginaux de prostaglandine E2. Le taux d'échec pour l'interruption de grossesse et le temps total entre l'insertion et l'interruption de la grossesse étaient supérieurs avec la sonde de Foley sans traction (16,5 %, 16,5 heures) qu'avec traction (10,0 %, 14,2 heures) ou qu'avec la prostaglandine (8,0 %, 11,5 heures). Toutefois, la sonde de Foley, en tant que méthode d'interruption de grossesse au deuxième trimestre et au début du troisième trimestre, est sûre et peu coûteuse, et son efficacité peut être renforcée par le recours à la traction pour donner des résultats similaires à ceux de la prostaglandine E2.

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Introduction

Despite recent advances in prenatal diagnosis during the first trimester, termination of pregnancy in the second and early third trimester of pregnancy due to fetal abnormalities or intrauterine fetal death still accounts for 10% of abortions in the USA [1]. Achieving termination after the first trimester of pregnancy is one of the great challenges facing obstetricians today. Unfortunately, not all women who need termination have a favourable cervix for induction. As first described by Bishop [2], cervical ripening is an important process preceding effacement and dilatation of the cervix. A variety of techniques for termination of mid-trimester pregnancy can be used, but there is no consensus about which is the best [3].

Use of the Foley catheter for termination of pregnancy was first described by Krause in 1833 [4]. In 1967 Embrey and Mollison [5] reported a 94% successful induction rate after using the Foley catheter for cervical ripening in 100 women. The Foley catheter appears to affect cervical ripening by direct mechanical dilatation and also through release of endogenous prostaglandin [6] and this effect can be enhanced when traction is applied.

The vaginal or intracervical application of prostaglandin E2 (PGE2) has been widely used for mid-trimester termination because of its effect on both cervical ripening and uterine contraction [7]. In most studies PGE2 has been applied locally in gel form and the high dosages frequently cause severe side-effects, including vomiting, diarrhoea and fever [7-10]. In this study, we used tablets of PGE2 to replace the gel formulation, to diminish the side-effects.

The aim of this study was to compare the efficacy and safety of 3 methods of termination of pregnancy in the second and early

third trimester: PGE2 vaginal tablets, Foley catheter without traction and Foley catheter with traction.

Methods

The study was conducted from July 1998 to February 2000 at the Department of Obstetrics and Gynaecology in Prince Hashem Ben Al-Hussein and Prince Rashed Ben Al-Hassan Military Hospitals in Jordan. The study sample comprised healthy women who were 15-30 weeks pregnant and admitted for legal termination of pregnancy due to intrauterine fetal death or gross congenital abnormality. Patients with known placenta praevia or unexplained vaginal bleeding and rupture of membranes were excluded from the study. The study was approved by the scientific committee in the Department of Obstetrics and Gynaecology of the King Hussein Medical Centre. Verbal consent was obtained from each woman after explaining the aims and design of the study. A total of 261 patients were entered into the study; 3 women were discharged after randomization but before the start of termination and were lost to follow-up.

During the study period the women were randomly assigned to 1 of 3 treatments until the time when the study was terminated: Foley catheter without traction ($n = 91$), Foley catheter with traction ($n = 79$), or PGE2 vaginal tablets ($n = 88$). Intravenous oxytocin drip was used for augmentation of termination in all 3 groups when cervical ripening was achieved. All patients were admitted to hospital and managed by the attending physician. The following were recorded: complete blood count and cross-match, vital signs and signs of uterine hyperstimulation from oxytocin.

The group randomly assigned to receive PGE2 had tablets (3 mg) (Pharmacia &

Upjohn, Belgium) placed into the endocervical canal or posterior vaginal fornix by sterile speculum examination. The dose was repeated every 6 hours as long as the Bishop score was still ≤ 5 , to a maximum of 4 doses. Intravenous oxytocin was started when Bishop score reached > 5 (cervical effacement $> 50\%$).

Those in the Foley groups had a no.14 Foley catheter with 40 mL balloon inserted into the endocervical canal under direct visualization by sterile speculum examination. Once it passed the internal os, 40 mL water was instilled in the balloon, then the catheter was placed inside the patient's thighs and firmly attached. In the group of patients randomized to receive traction, a continuous traction by 500 mL normal saline was achieved by taping the end of the Foley catheter to the long side of the patient's thigh, so that gentle, steady traction was applied. The catheter was checked for Foley bulb extrusion every 4 hours by vaginal examination, and the traction was adjusted so that gentle traction continued.

Because the aim of the trial was to evaluate the success of cervical ripening, the outcome measures for the 3 methods were: total time from insertion to expulsion of uterine contents, side-effects, patients' comfort (assessed by asking the women if they were comfortable with the procedure or if they were feeling any discomfort) and success/failure of termination.

Analysis of variance was used to investigate whether there was a difference between the 3 methods used. Student–Newman–Keuls post-hoc test was used to test the difference between the 3 methods. A probability of $P < 0.05$ was considered statistically significant.

Results

The mean age of the 258 women was 27.1 years and parity ranged from 0 to 7; 39.2% were nulliparous. The mean gestation age was 19 weeks. There was no statistically significant difference between the 3 groups with respect to maternal age, gestational age or parity. The main indication for termination was intrauterine fetal death for different reasons (84.6% of women), while gross congenital abnormality of the fetus, mainly due to anencephaly, was the indication for 15.4% of women.

In the prostaglandin E2 group, most of the patients required 3 applications of PGE2 tablets (mean 2.3 applications). No Foley catheter needed to be replaced after the initial application.

The overall failure rate of termination for all 3 methods was 11.6% (Table 1). The failure rate was higher when the Foley catheter was used without traction (16.5%) compared with Foley catheter with traction (10.0%), although the lowest failure rate in termination was with PGE2 tablets (8.0%) ($P < 0.001$). The average insertion-to-termination time was longer with Foley catheter without traction compared with Foley with traction (16.5 hours versus 14.2 hours), while it was shorter (11.5 hours) with PGE2 tablets ($P < 0.002$).

There were few maternal side-effects in all groups. The most common side-effect was discomfort at insertion of the Foley catheter (only 37 reported minimal to mild discomfort), while 4 of the patients in the PGE2 group reported nausea and vomiting. Uterine hyperstimulation, defined as 6 contractions per 10 minute period, occurred in only 2 patients. Despite reports of discom-

Table 1 Outcome of pregnancy termination in second and early third trimesters using Foley catheter with and without traction or prostaglandin (PGE2) tablets

| Method | Total | | Successful termination | | Failed termination | | Insertion to termination time (hours) ^a | |
|---------------------------------------|-------|-----|------------------------|------|--------------------|------|--|------|
| | No. | No. | No. | % | No. | % | Mean | SD |
| Foley plus oxytocin, without traction | 91 | 76 | 76 | 83.5 | 15 | 16.5 | 16.5 | 0.93 |
| Foley plus oxytocin, with traction | 79 | 71 | 71 | 89.9 | 8 | 10.1 | 14.2 | 1.24 |
| Prostaglandin vaginal tablets | 88 | 81 | 81 | 92.0 | 7 | 8.0 | 11.5 | 0.67 |
| Total | 258 | 228 | 228 | 88.4 | 30 | 11.6 | | |
| P-value | | | | | P < 0.001 | | P < 0.002 | |

^aTime between insertion of Foley catheter or PGE2 tablets until expulsion of uterine contents.

SD = standard deviation

fort at the time of Foley catheter insertion there were few complaints of discomfort with any of the methods.

Discussion

Mid-trimester labour induction is necessary in a variety of circumstances; the indications may be maternal or fetal, but it is usually accompanied by an unfavourable cervix. To solve this problem, different methods of artificial cervical ripening have been developed. Mechanical devices such as the cervical balloon [5,11,12] and laminaria [13,14] have been used safely. In addition, preparations of prostaglandin have been used, in a variety of concentrations and application methods, to pharmacologically mature the cervix [10].

In this study we compared the use of a pharmacological method for cervical ripening, PGE2 tablets, with a mechanical method, the insertion of a Foley catheter with or without traction to enhance its effect. Early studies comparing the Foley catheter with PGE2 tablets found no difference in the time of cervical ripening or termination time [8,9]. Both Thomas et al. [8] and St Ong and Connors [9] com-

pared the Foley catheter with PGE2 tablets and found both to be effective in changing the Bishop score, but neither found Foley catheter to be more effective than PGE2 tablets. It has been suggested that PGE2 tablets are cost-effective in termination of pregnancy [15]. In our study, the alternative was Foley catheter, which is relatively inexpensive and safe and has almost similar results in achieving success in termination of pregnancy and insertion-to-termination interval. With traction applied, it enhances the mechanical effect of Foley catheter to ripen the cervix, and this makes the method of traction competitive for PGE2 tablets and avoid the pharmacological side-effects such as nausea and vomiting.

To evaluate the efficacy of any method of termination for patients with unfavourable cervix, nulliparity should be one of the main considerations, as the cervix is more prone to faster ripening. In our study around 40% of women were nulliparas.

We can conclude that in locations where there is no experience with the use of PGE2, or when it is unavailable, the Foley catheter appears to be a safe, effective and relatively inexpensive method for termination of pregnancy, particularly when gentle traction is applied.

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