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Intracervical foley catheter versus vaginal prostaglandins for induction of labor in women with previous one cesarean section-a pilot study

Abstract

Objective: To compare the efficacy, safety and acceptability of Intracervical foley catheter, dinoprostone and misoprostol, for induction of labor in women with previous one cesarean section at term. **Study design:** A prospective quasi-randomised clinical trial included 90 term pregnant women who were randomly assigned to receive intracervical foley catheter, dinoprostone 3 mg tablets or misoprostol 25 µg tablets vaginally. Induction to delivery interval, outcomes of labor, maternal adverse effects and acceptability were assessed. **Results:** Successful vaginal delivery was comparable in the three groups; mean induction to delivery interval (h) was greater for dinoprostone group (20.10±2.62) than catheter (19.93±2.92) and misoprostol (18.76±2.47) groups (P>0.05). Oxytocin was more needed in the catheter group (23.3%) than in the dinoprostone (20%) and misoprostol (13.3%) groups (P>0.05). The cesarean rate was not significantly different among the three groups, but the main indications were different: failure to progress (44.5%) in the catheter group versus (50%) in dinoprostone group and non-reassuring FHR pattern (42.8%) in the misoprostol group with no major maternal complications reported. **Conclusion:** Intracervical Foley catheter is safe, effective and acceptable method for induction of labor in women with previous one cesarean section with unripe cervix at term.

Keywords: intracervical foley catheter, dinoprostone; misoprostol, vaginal prostaglandins, induction of labor

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Introduction

It is well documented that the risks of cesarean section for women increase with increasing numbers of cesarean deliveries. These include potentially life-threatening complications including hemorrhage, surgical complications and placenta accreta.[1,2] Promoting vaginal birth after previous cesarean (VBAC) may help to avoid these complications in future pregnancy, but attempting VBAC may result in a significantly greater risk of a serious morbidity for infants.[3] With the induction of labor in a previous cesarean section, the uterine rupture can be a serious event that can threaten the life and the neurological status of the baby. So, a cautious attempt should be taken in inducing labor in the women with a previous one cesarean section.[4–6]

Current medical evidence indicates that 60-80% of women can achieve vaginal delivery after a previous lower uterine segment cesarean delivery. The incidence of uterine rupture with trial of labor (TOL) in a mother who has had a low transverse incision is approximately 0.2%-0.5%.[7,8] Several studies were conducted in the past to induce labor in women with previous cesarean section with prostaglandin gel with no conclusive evidence that labor induction creates a risk in trial of labour (TOL) in a mother who has had a low transverse incision.[9–12]

The aim of this study was to compare the efficacy, safety and acceptability of Intracervical Foley catheter, intravaginal dinoprostone tablets and misoprostol tablets in the induction of labor in women with a previous one cesarean section with an unfavorable cervix at term.

Materials and methods

This was a single center quasi-randomized parallel group study carried out at the Department of Obstetrics and Gynaecology, Menoufia University Hospital, Egypt in the period between April 2012 and January 2014. The institutional review board approved the study protocol and an informed consent was obtained from all participants prior to commencing the study. Based on the rate of achieving successful vaginal delivery of 76% in women with previous cesarean section from the literature. We assumed that there will be a difference of 3 hours between misoprostol group and other two groups concerning the induction to delivery interval. Accordingly, power was set at 80% and alpha level at 0.05, a total sample size of 90 participants (30 participants in each group) was required after adding a percentage of 10% for possible drop out cases during the study.

The study was conducted on 90 healthy pregnant women with previous one lower segment cesarean section at 37 weeks and beyond, with a Bishop's score of ≤6, intact membranes, reactive non-stress test, normal umbilical arterial Doppler indices, absence of labor and willingness of women to participate in the study. The indications for the induction of labor were pregnancy induced hypertension and controlled diabetes mellitus.

A detailed history including age, parity, and period of gestation were noted and details of clinical examination were also recorded. Ultrasonography (Acuson 128 XP 10, computed sonography system, Mountain View, California, USA) was done to confirm gestational age, presentation, estimated fetal weight, placental localization and umbilical arterial Doppler indices. Patients with intrauterine foetal death, twin's pregnancy, polyhydramnios, placenta previa, severe anemia, severe hypertension, uncontrolled diabetes, coagulopathy and any contraindication for the labor induction were excluded from the study.

Enrolled women were equally allocated into three groups via restricted shuffled approach, through apportioning a number of 30 prepared cards for each treatment group according to the allocation ratio 1:1:1. The cards were inserted into opaque envelopes then were shuffled to produce a form of random assignment according to the final arrangement of the envelopes. It was not possible to blind the study participants from knowledge of which intervention a participant received because methods were clearly different.

Group 1 (catheter group)

30 pregnant women in whom intracervical Foley catheter inserted, inflated, and placed on traction. Under aseptic conditions, with the patients lying in the lithotomy position, the cervix was assessed and Foley catheter No. 14-16 Fr Ch was inserted into the endocervical canal, beyond the internal os and the balloon was inflated with 50-60ml of normal saline. The catheter was strapped to the thigh with gentle traction. The catheter was checked for its position and the traction at 3-6 hours intervals. The catheter was either removed at 12 hours or it was expelled spontaneously and it was checked whether a spontaneous rupture of the membranes had occurred or not.

Group 2 (dinoprostone group)

30 pregnant women were received moistened one tablet of Dinoprostone 3mg (Dinoglandin, Egypharma, Egypt) inserted vaginally twice with 6 hours apart.

Group 3 (misoprostol group)

30 pregnant women were received moistened one tablet of Misoprostol 25µg (Vagiprost, Adwia Pharmaceuticals, Egypt) inserted vaginally twice with 6 hours apart.

The above dosage for vaginal prostaglandin tablets in accordance with NICE guidelines.[13] Subjects were examined regularly at 3, 6, 9, 12, and 24 hours after starting the method of induction to evaluate the change in Bishop score. Vital signs were monitored every 30 minutes. Artificial rupture of membranes (AROM) was performed for all women when their cervical dilatation reached 3-4cm. Intravenous oxytocin infusion was started if there is no efficient uterine contraction. An oxytocin infusion was started at 2mU/min and increased in increments of 1-2 mU/min at 15-30 minutes intervals as needed to achieve adequate uterine contraction pattern (≥200 MVU). Opiate and epidural analgesia was given on the patient's request and at the discretion of the obstetrician. Continuous cardiotocography (CTG) was done during delivery and the modified WHO partograph was followed up for the labor management.

Outcome measures

Primary outcome measures included successful vaginal delivery, the induction to delivery interval and the mode of delivery. Maternal major adverse effects (which include uterine rupture, postpartum hemorrhage, puerperal pyrexia and venous thromboembolism), maternal acceptability assessed after delivery via face-to face interview (included emotional discomfort, likelihood of recommending the induction method to other women and the overall satisfaction rate) and neonatal outcome (Apgar score at 5 minutes, neonatal weight and admission to neonatal intensive care unit) were recorded as secondary outcomes.

Statistical analysis

Data entry and analysis was carried out using SPSS version 16 (2006, SPSS Inc., Chicago, IL, USA).

Descriptive statistics: Quantitative data are expressed to measure the central tendency of data and diversion around the mean, mean (x) and standard deviation (SD). Qualitative data expressed in number and percentage.

Analytic statistics: T test was used for comparison of two groups of normally distributed variables Mann Whitney test was used for comparison of two groups of non normally distributed variables.

All these tests were used as tests of significance at:

1. P value>0.05 was considered statistically non significant.
2. P value≤0.05 was considered statistically significant.

P value≤0.001 was considered statistically highly significant.

Results

Table 1 displays the maternal characteristics. There were no significant difference between the three groups regarding maternal age, parity and gestational age. Outcomes of induction and labor dynamics are shown in Table 2. Successful induction was comparable in the three groups with the mean induction to delivery interval (h) was greater for dinoprostone group (20.10±2.62) than catheter (19.93±2.92) and misoprostol (18.76±2.47) groups (P>0.05). Oxytocin was needed more in the catheter group (7/30, 23.3%) than in the dinoprostone (6/30, 20%) and misoprostol (4/30, 13.3%) groups (P>0.05).

Table 3 shows the mode of delivery. The caesarean delivery rate was not significantly different among the study groups, but the major indications were different: failure to progress (4/9, 44.5%) in the catheter group versus (4/8, 50%) in dinoprostone group and non-reassuring FHR pattern (3/7, 42.8%) in the misoprostol group.

Table 4 displays the major maternal complications and neonatal outcome which was not significantly different among the study groups. Table 5 displays the maternal acceptability which was not significantly different among the study groups.

Table 1 Maternal characteristics

	Group 1(N=30)	Group 2 (N=30)	Group 3 (N=30)	t-test	P value	Difference 95% CI
Maternal Age (years)	27.56±4.07	27.53±3.89	27.63±4.19	0.005	0.94	-4.26
Parity	2.5±0.77	2.4±0.62	2.06±0.73	3.015	0.58	-0.72
Gestational Age (weeks)	39.8±1.03	39.5±0.77	39.8±1.03	0.99	0.21	-0.94
Body Mass Index	23.9±2.1	24.4±1.8	24.2±1.7	1.31	0.19	-1.52

95%CI=95% Confidence interval

Table 2 Outcomes of induction and labor dynamics

	Group I (N=30)	Group 2 (N=30)	Group 3 (N=30)	Chi- square	P value
Augmentation					
AROM	23	24	26	1.015	0.25
AROM & Oxytocin	7	6	4		
Induction to Delivery Interval (hrs)	19.93±2.92	20.10±2.62	18.76±2.47	*2.208	0.81
Failed Induction	9	8	7	0.341	0.39
Mode of Delivery					
VD	21	22	23		
CS	9	8	7	0.29	0.38

*Student t- test, VD, vaginal delivery; CS, cesarean section

Table 3 Indications of cesarean section

	Group I N=9	Group N=8	Group 3 N=7	P value
Failed Induction	3 (33.3%)	3 (37.5%)	2 (28.6%)	
Failure to Progress	4 (44.5%)	4 (50%)	2 (28.6%)	0.49
Non reassuring FHR tracing	2 (22.2%)	1 (12.5%)	3 (42.8%)	

Table 4 Maternal complications and neonatal outcome

	Group I (N=30)	Group 2 (N=30)	Group 3 (N=30)	Student t-test	P value	Difference 95% CI
Uterine Rupture	0	0	0	-	-	-
PPH	5	4	6	0.480*	0.49	-45.6
Puerperal Pyrexia	4	3	4	0.207*	0.48	-39
VTE	0	0	0	-	-	-
APGAR score at 5 Minutes	7.3±1.51	7.3±1.52	7.4±1.27	0.134	0.78	-1.44
Neonatal Weight	3.05±0.309	3.14±0.19	3.10±0.24	0.959	0.48	-0.28
Admission to NICU	5	4	6	0.480*	0.49	-45.6

*Chi-square

95%CI, 95% confidence interval; PPH, postpartum hemorrhage; VTE, venous thromboembolism; NICU, neonatal intensive care unit

Table 5 The acceptability of methods of termination of pregnancy

	Group I N= 30	Group 2 N= 30	Group 3 N= 30	Chi square	P-value
Overall discomfort with induction					
Moderate/High/Extreme	12	11	9		
None or slight	18	19	21	0.68	0.29
Overall satisfaction with induction					
Very or somewhat satisfied	25	27	28		
Neutral or somewhat not satisfied	5	3	2	1.68	0.35
Would recommend the induction method to other women					
Highly or Somewhat Agree	19	22	24		
Neutral or Somewhat Disagree	11	8	6	2.11	0.12

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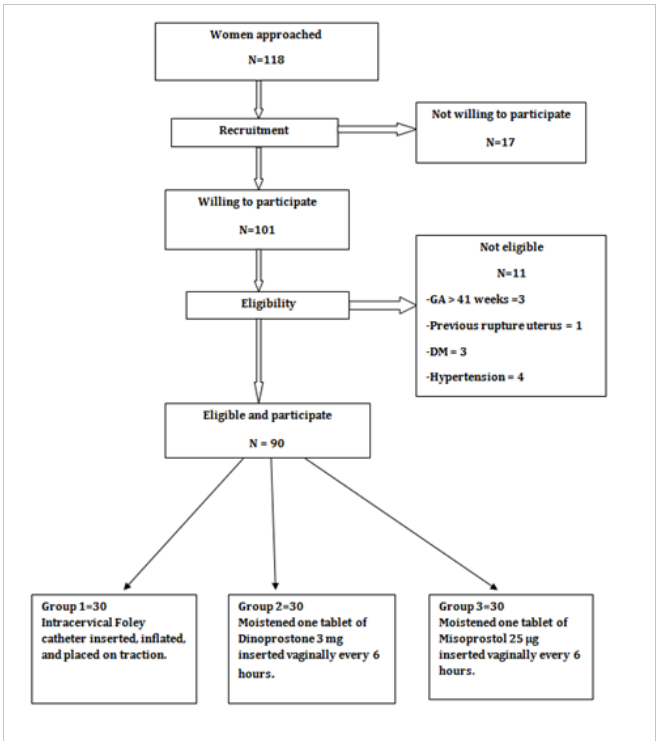

Figure 1 The flow diagram.

GA, gestational age; DM, diabetes mellitus

Discussion

Cervical ripening is an active process resembling an inflammatory reaction, which involves a complex cascade of degradative enzymes accompanied by degradation and disorganization of collagen framework, increased water content, and rearrangement of extracellular matrix proteins and glycoproteins.[14,15] Among factors regulating cervical ripening (i.e, mechanical factors, estrogens, cytokines, neuropeptides, and other inflammatory agents), prostaglandins are regarded to have a crucial role.[16]

Retrospective analysis of 2119 trials of labor, of which 575 (27%) were induced. The overall rate of uterine rupture was 0.71% (15/2119). Uterine rupture rates associated with different methods of induction were compared with the rate seen with spontaneous labor and were as follows: prostaglandin E(2) gel, 2.9% (5/172; P=0.004); intracervical Foley catheter, 0.76% (1/129; P=0.47); and labor induction not requiring cervical ripening, 0.74% (2/274; P=0.63).[17]

The intracervical placement of the Foley catheter induces the cervical ripening without inducing any uterine contractions, while the prostaglandins affect the cervical ripening and the uterine contractions simultaneously.[4,17] But, Foley catheter has been linked with a possibility of introducing infections in some studies. Thus, its insertion should be carried out under a septic technique to avoid possible maternal & neonatal infections.[18]

In our study, intracervical foley catheter and vaginal prostaglandins tablets produced similar effects in the induction of labor in women with a previous one lower segment cesarean section. A previous study which was conducted on the VBAC showed that the Foley catheter induction was associated with a lowest rupture rate in the induced TOL group and that it was comparable to the results in the spontaneous TOL group. The PGE2 exposure during the TOL was associated with more than a 6 fold increase in the uterine ruptures as compared to that in the spontaneous labor.[17] In our trial, symptomatic uterine rupture was not reported.

Intravaginal misoprostol and intracervical Foley catheter were comparable for preinduction cervical ripening in previous randomized trials but, uterine contractile abnormalities and meconium passage were more common with misoprostol.[19,20] In our trial, the major indication for cesarean section was non reassuring FHR tracing with more neonates required NICU admission in the misoprostol group but, this difference was not significant.

Vaginally administered misoprostol was more effective than the dinoprostone vaginal insert for cervical ripening and labor induction. The safety profiles of both drugs were similar.[21,22] In our trial, misoprostol achieved successful vaginal delivery more rapid than dinoprostone.

In an analysis of nationally collected data from Scotland, prostaglandin induction compared with non-prostaglandin induction in women with previous one cesarean section was associated with a statistically significant higher uterine rupture risk and a higher risk of perinatal death from uterine rupture.[23] However, a recent Cochrane review about the methods of term labor induction for women with a previous cesarean section [24] did not make any recommendations due to shortage of randomized controlled clinical trials. It is obvious that trial of scar after previous cesarean delivery is safe for patients who are managed in tertiary care hospitals where intensive surveillance, expertise and facilities for emergency cesarean section and exploratory laparotomies are available.

Inability to design a double blind trial, to include a control group with spontaneous onset of labor and the small number of our participants were the main limitations of this study. According to the results obtained in this clinical trial, intracervical foley catheter could be mentioned as safe, effective and acceptable method for labor induction in term pregnant women with previous one cesarean section. However, further larger studies should be carried out to obtain more definite results and to address the best agent for induction.

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None.

Conflicts of interest

The authors declare there is no conflict of interests.

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