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

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%.4,7 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.8,12

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 the 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 appointing 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, Advvia Pharmaceuticals, Egypt) inserted vaginally twice with 6 hours apart.

The above dosage for vaginal prostaglandin tablets in accordance with NICE guidelines. 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 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 2 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.

**Results**

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 non 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.

**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 | 27.3±3.89 | 27.63±4.19 | 0.005 | 0.94 | -4.26 |
| Parity | 2.5±0.77 | 2.5±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

---

Citation: Masood A. Intracervical Foley catheter versus vaginal prostaglandins for induction of labor in women with previous one cesarean section—a pilot study. Obstet Gynecol Int J. 2015;2(5):160–164. DOI: 10.15406/jocr.2015.02.00054
Intracervical foley catheter versus vaginal prostaglandins for induction of labor in women with previous one cesarean section— a pilot study

**Table 2** Outcomes of induction and labor dynamics

|                        | Group 1 (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 1 N=9 | Group 2 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 1 (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 1 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    |

Citation: Masood A. Intracervical foley catheter versus vaginal prostaglandins for induction of labor in women with previous one cesarean section—a pilot study. Obstet Gynecol Int J. 2015;2(5):160–164. DOI: 10.15406/jccr.2015.02.00054
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. Among factors regulating cervical ripening (i.e., mechanical factors, estrogens, cytokines, neuro-peptides, and other inflammatory agents), prostaglandins are regarded to have a crucial role.

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).

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. But, Foley catheter has been linked 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.

Acknowledgments
None.

Conflicts of interest
The authors declare there is no conflict of interests.

References
1. Knight M, Kurinczuk JJ, Spark P, et al. Cesarean delivery and peripartum hysterectomy. Obstet Gynecol. 2008;111(1):97–105.
2. Silver RM, Landon MB, Rouse DJ, et al. Maternal morbidity associated with multiple repeat cesarean deliveries. Obstet Gynecol. 2006;107(6):1226–1232.
3. Crowther CA, Dodd JM, Hiller JE, et al. Planned Vaginal Birth or Elective Repeat Caesarean: Patient Preference Restricted Cohort with Nested Randomised Trial. PLoS medicine. 2012;9(3):e1001192.
4. Farah Z, Seema H, Sridevi B. Transcervical Foley Catheter Versus the Vaginal Prostaglandin E2 Gel in the Induction of Labour in a Previous One Caesarean Section-A Clinical Study. J Clin Diag Res. 2013;7(1):140–143.
5. Smith GC, White JR, Pell JP, et al. Predicting cesarean section and uterine rupture among women attempting vaginal birth after prior cesarean section. PLoS Medicine. 2005;2(9):e252.

6. Guise JM, Dennman MA, Emeis C, et al. Vaginal birth after cesarean: new insights on maternal and neonatal outcomes. Obstet Gynecol. 2010;115(6):1267–1278.

7. Rageth JC, Juzi C, Grossenbacher H. Delivery after previous cesarean: a risk evaluation. Obstet Gynecol. 1999;93(3):332–337.

8. Lydon-Rochelle M, Holt VL, Easterling TR. Risk of uterine rupture during labor among women with a prior cesarean delivery. N Engl J Med. 2001;345(1):3–8.

9. Stone JL, Lockwood CJ, Berkowitz G, et al. Use of prostaglandin E2 gel in patients with previous caesarean section. Am J Perinatol. 1994;11(4):309–312.

10. Del Valle GO, Adair CD, Sanchez-Ramos L, et al. Cervical ripening in women with previous cesarean deliveries. International J Gynecol Obstet. 1994;47(1):17–21.

11. Norman M, Ekman G. Preinductive cervical ripening with prostaglandin E2 in women with one previous cesarean section scar. Acta Obstet Gynecol Scand. 1992;71(5):351–355.

12. Blanco JD, Collins M, Willis D, et al. Prostaglandin E2 gel induction of patients with a prior low transverse cesarean section. Am J Perinatol. 9(2):80–83.

13. National Institute for Health and Clinical Excellence (NICE) clinical guideline 70: Induction of labour.

14. Leppert PC. Proliferation and apoptosis of fibroblasts and smooth muscle cells in rat uterine cervix throughout gestation and the effect of the antiprogestosterone onapristone. Am J Obstet Gynecol. 1998;178(4):713–722.

15. Maul H, Longo M, Saade GR, et al. Nitric oxide and its role during pregnancy: from ovulation to delivery. Curr Pharm Des. 2003;9(5):359–380.

16. Kelly RW. Inflammatory mediators and cervical ripening. J Reprod Immunol. 2002;57(1–2):217–224.

17. Ravasiax D, Wood S, Pollard J. Uterine rupture during induced trials of labour in women with a previous cesarean delivery. Am J Obstet Gynaecol. 2000;183(5):1176–1179.

18. Salva S, Nadeem FZ, Alafia Z, et al. Increased risk of cervical canal infections with intracervical Foley catheter. J Coll Physicians Surg Pak. 2003;13(3):146–149.

19. Sciscione AC, Nguyen L, Manley J, et al. A randomized comparison of transcervical Foley catheter to intravaginal misoprostol for preinduction cervical ripening. Obstet Gynecol. 2001;97(4):603–607.

20. Chang JH, Huang WH, Runney PJ, et al. A prospective randomized controlled trial that compared misoprostol, Foley catheter, and combination misoprostol-Foley catheter for labor induction. Am J Obstet Gynecol. 2003;189(4):1031–1035.

21. Ozkan S, Caliçkan E, Doğer E, et al. Comparative efficacy and safety of vaginal misoprostol versus dinoprostone vaginal insert in labor induction at term: a randomized trial. Arch Gynecol Obstet. 2009;280(1):19–24.

22. Austin SC, Sanchez-Ramos L, Adair CD. Labor induction with intravaginal misoprostol compared with the dinoprostone vaginal insert: a systematic review and metaanalysis. Am J Obstet Gynecol. 2010;202(6):e1–624, e9.

23. Smith GC, Pell JP, Pasupathy D, et al. Factors predisposing to perinatal death related to uterine rupture during attempted vaginal birth after caesarean section: retrospective cohort study. BMJ. 2004;329(7462):375.

24. Jozwiak M, Dodd JM. Methods of term labour induction for women with a previous caesarean section. Cochrane Database Syst Rev. 2013;3:CD009792.