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Research Article

Combined Use of Intracervical Foley Catheter and Vaginal Isosorbide Mononitrate for Induction of Labour in Women with One Previous Caesarean Section

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Abstract

Objective: To evaluate the combined use of Foley catheter and vaginal isosorbide mononitrate tablets to induce labour in women with one previous cesarean section.

Methods: A prospective study including 200 term pregnant women with one previous caesarean section, in whom 100 women (group A) were induced by intracervical Foley catheter and 100 women (group B) were induced by intracervical Foley catheter and one moistened tablet of isosorbide mononitrate (IMN) 40 mg vaginally.

Results: There was a significant difference between the two groups regarding the duration of the active phase and the second stage of labour with shorter duration in (group B). The induction to delivery interval in (group A) was 22.20 ± 4.96 hours while in (group B), it was 20.75 ± 3.17. There was a significant difference in the occurrence of headache in group B (18, 18%) in comparison to group A (6, 6%). There was no difference between both groups regarding other maternal complications and neonatal outcome.

Conclusion: The combined use of Foley catheter and vaginal IMN tablets seems safe and effective novel method for induction of labour in women with one previous cesarean section.

Keywords: *Intracervical Foley Catheter; Isosorbide Mononitrate; Labour; Caesarean*

Introduction

It is well documented that the risks of cesarean section for women increase with increasing numbers of caesarean deliveries. These include placenta accreta; injury to bladder, bowel or ureter; ileus; the need for postoperative ventilation; intensive care unit admission; hysterectomy; blood transfusion requiring four or more units and the duration of operative time and hospital stay [1-3].

In an analysis of nationally collected data from Scotland, prostaglandin induction compared with non-prostaglandin induction in women with one previous caesarean section was associated with a statistically significant higher uterine rupture risk and a higher risk of perinatal death from uterine rupture [4].

A recent Cochrane review about the methods of term labour induction for women with a previous caesarean section [5] did not make any recommendations due to shortage of randomized trials.

An agent that ripens the cervix without stimulating uterine activity would be ideal for induction. Nitric oxide (NO) is a free radical with a short half-life for cervical ripening, its main effect is rearrangement of collagen, thereby allowing NO to soften the cervix without causing uterine contractions [6,7].

Induction of labour with a mechanical method as Foley catheter seems to be effective as induction with intravaginal prostaglandin E2 gel in women with previous caesarean section at term, with fewer maternal and neonatal side-effects [8].

The aim of this study was to test the efficacy and safety of combined use of intracervical Foley catheter and vaginal NO donor; isosorbide mononitrate (IMN) compared to intracervical Foley catheter alone for induction of labour in women with one previous caesarean section at term.

Subjects and Methods

This was a prospective randomized clinical study carried out at the Department of Obstetrics and Gynecology, Menoufia University Hospital between June 2013 and May 2015.

The ethical review board of Menoufia faculty of Medicine approved the study protocol and an informed written consent was obtained from all participants prior to commencing the study.

Based on the rate of failure of induction of labour with unfavourable cervix at term of 15% from the literature, power was set at 0.8, alpha level at 0.05, and the confidence interval (CI) at 95%. A total sample size 150 subjects was needed for this trial (75 subjects in each group). We enrolled 100 subjects in each group to compensate for possible drop out of cases.

The study was conducted on 200 healthy pregnant women with previous one lower segment caesarean section at 37 weeks and beyond with intact membranes, reactive non-stress test and normal umbilical arterial Doppler indices.

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 labour dystocia as an indication of the previous caesarean section, intrauterine foetal death, multiple pregnancy, fetal macrosomia, polyhydramnios, placenta previa, severe anemia, severe hypertension, uncontrolled diabetes mellitus, coagulopathy and any contraindication for the vaginal delivery were excluded from the study. Patients accepting to participate the study were randomly divided into two groups:

Group A: 100 pregnant women with one previous caesarean section, not in labour and willingness of women to participate in the study. Intracervical Foley catheter was 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.16 Fr Ch. was inserted into the endocervical canal, beyond the internal os and the balloon was inflated with 50ml of normal saline. The catheter was strapped to the thigh. The catheter was checked for its position and the traction at 3-6 hours intervals. The catheter was either removed at 24 hours (and considered failure if no active labour) or it was expelled spontaneously and the woman was checked for cervical dilatation and/or occurrence spontaneous rupture of the membranes.

Group B: 100 pregnant women with one previous caesarean section, not in labour and willingness of women to participate in the study.

Intracervical Foley catheter was inserted, inflated, and placed on traction, as prescribed above in group A and one moistened tablet of isosorbide mononitrate 40 mg (Monomak, October pharma, Egypt) was inserted vaginally once.

The catheter was checked for its position and the traction at 3 - 6 hours intervals. The catheter was either removed at 24 hours (and considered failure if no active labour) or it was expelled spontaneously and the woman was checked for cervical dilatation and/or occurrence spontaneous rupture of the membranes.

The indications for the induction of labour were pregnancy induced hypertension and controlled diabetes mellitus, small for gestational age, cholestasis of pregnancy, decreased fetal movements and postdates.

Labour was diagnosed when cervical dilatation was 3 - 4 cm with regular uterine contractions of 3-4 contractions per 10 minutes.

Subjects were examined every 3 hours then regularly after admission to evaluate the degree of cervical dilatation and progress of labour. Vital signs were monitored every 30 minutes. Artificial rupture of membranes (AROM) was performed for all women when their

cervical dilatation reached 5 cm and intravenous oxytocin infusion was started if there is no efficient uterine contractions. An oxytocin infusion was started at 1.2 mU/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) and not exceeding 4.8 mU/min as a maximum dose. Opiate analgesia was given on the patient's request and at the discretion of the obstetrician. Continuous CTG was used during delivery and the modified WHO partogram was followed up for the labour management.

Outcomes

Successful vaginal delivery, the induction to delivery interval and the length of the second and third stages of labour were the primary outcome measures. Maternal complications (major as uterine rupture, postpartum hemorrhage requiring blood transfusion and venous thromboembolism, or minor as maternal pyrexia, hypotension, nausea, vomiting and headache) and fetal outcome (abnormal fetal heart rate tracing, meconium stained amniotic fluid, Apgar score at 5 minutes, neonatal weight and admission to neonatal intensive care unit) were recorded as secondary outcome measures.

Statistical Analysis

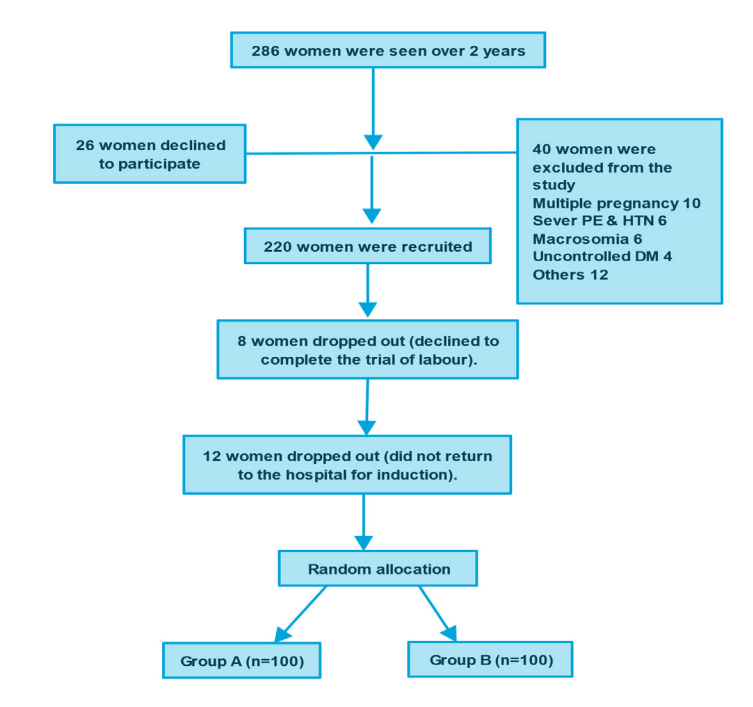
Data entry and analysis was carried out using SPSS version 16 (2006, SPSS Inc., Chicago, IL, USA).

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:

- P value > 0.05 was considered statistically non significant.
- P value ≤ 0.05 was considered statistically significant.
- P value ≤ 0.001 was considered statistically highly significant.

Results

Table 1 reveals maternal characteristics of both groups, there was no significant difference between the group A and group B regarding the age, parity, gestational age and body mass index.

	Group A (n=100)	Group B (n=100)	t-test	P-value
Maternal Age (years)	28.50 ± 3.45	28.49 ± 3.72	0.03	> 0.05
Parity	2.60 ± 0.66	2.57 ± 0.71	0.307	> 0.05
Gestational age (weeks)	Range 39 - 41 Mean ± SD 40.78 ± 0.77	Range 37 - 41 Mean ± SD 39.84 ± 1.00	1.261	> 0.05
Body mass index	Range 19 - 23 Mean ± SD 21.02 ± 1.45	Range 18 - 25 Mean ± SD 21.28 ± 1.77	1.134	> 0.05

Table 1: *Maternal Characteristics.*

Table 2 displays the labour dynamics, there was no significant difference between group A and group B regarding the use of artificial rupture of membranes (AROM), oxytocin administration, mode of delivery, use of analgesia and the duration of the third stage of labour. There was a significant difference between group A and group B regarding the induction to delivery interval, the duration of the active phase and the second stage of labour with shorter duration in group B. The induction to delivery interval was significantly different, in group A, it was 22.20 ± 4.96 hours, while in group B it was 20.75 ± 3.17 hours.

	Group A (n=100)	Group B (n = 100)	Chi-square test	P-value
Augmentation 1-AROM 2-AROM and Oxytocin	 71 29	 79 21	1.707	> 0.05
Mode of delivery 1-Successful VBAC 2-Caesarean section -Non reassuring FHR tracing. - Failure to progress	 64 36 24 12	 72 28 18 10	1.47	> 0.05
Induction to delivery interval (hours)	22.20 ± 4.96	20.75±3.17	2.18*	< 0.05
Duration of the active phase (hours)	8.05 ± 1.58	7.46±1.18	2.98*	< 0.05
Duration of the second stage (minutes)	37.10 ± 13.44	33.33±10.29	2.23*	< 0.05
Duration of the third stage (minutes)	11.36 ± 3.79	10.90±2.92	0.96*	> 0.05
Use of analgesia	29	21	1.707	> 0.05

Table 2: *Labour dynamics.*

**t-test*

AROM: Artificial Rupture of Membranes

VBAC: Vaginal Birth after Caesarean Section

FHR: Fetal Heart Rate

Table 3 reveals the mode of delivery in relation to prior vaginal delivery, in group A, 16 women (34.8%) with no prior vaginal delivery and 48 women (88.8%) with prior vaginal delivery achieved successful VBAC while in group B, 20 women (46.5%) with no prior vaginal delivery and 52 women (91.2%) with prior vaginal delivery achieved successful VBAC.

	Group A (n = 100)	Group B (n = 100)	Chi-square test	P-value
Successful VBAC -No prior vaginal delivery -Prior vaginal delivery	16 48	20 52	0.244	> 0.05
Caesarean section -No prior vaginal delivery -Prior vaginal delivery	30 6	23 5	0.41	> 0.05

Table 3: *Mode of delivery in relation to prior vaginal delivery.*

Table 4 displays the maternal complications in both groups, no cases with rupture uterus or venous thromboembolism were encountered in both groups. Also there was no significant difference between both groups regarding postpartum hemorrhage, puerperal pyrexia, hypotension, palpitation, nausea and vomiting. There was a significant difference between the two groups regarding headache with more women suffering from headache in group B.

	Group A (n = 100)	Group B (n = 100)	Chi-square test	P-value
PPH*	6	4	0.42	> 0.05
Puerperal pyrexia	13	7	2.00	> 0.05
Headache	6	18	6.81	< 0.05
Palpitation	6	3	1.05	> 0.05
Nausea & vomiting	3	8	2.41	> 0.05
Hypotension	5	9	1.229	> 0.05
Uterine rupture	0	0	-	-
Venous Thromboembolism	0	0	-	-

Table 4: *Maternal complications.*

****PPH**= Postpartum hemorrhage*

Table 5 reveals the fetal-neonatal outcome, there was no significant difference between group A and group B regarding abnormal fetal heart rate tracing, meconium stained amniotic fluid, APGAR score at 5 minutes, neonatal weight and admission to neonatal intensive care unit.

	Group A (n = 100)	Group B (n = 100)	Chi-square test	P-value
Abnormal fetal heart rate tracing	6	4	0.42	> 0.05
Meconium stained amniotic fluid	10	8	0.244	> 0.05
APGAR score at 5 minutes	7.40 ± 1.63	7.37 ± 1.72	1.24*	> 0.05
Neonatal weight (Kg)	3.06 ± 0.29	3.03 ± 0.25	0.77*	> 0.05
Admission to neonatal intensive care unit	5	9	1.23	> 0.05

Table 5: *Fetal-neonatal outcome.*

**t-test*

Discussion

There are particular concerns about induction of labour in women with a previous caesarean section, with previous studies highlighting the risk of uterine rupture, a catastrophic event for both mother and infant [9].

The policy of vaginal birth after caesarean (VBAC) is a contribution towards bringing down the caesarean section rate and reducing the maternal morbidity and mortality in subsequent deliveries [8].

In our study, the rate of successful vaginal birth after caesarean (VBAC) was 64% in group A and 72% in group B. These results are in accordance with previous studies in which the rates of caesarean section in women undergoing planned VBAC were 33%, 26% and 19% for induced, augmented and spontaneous labour groups, respectively [10,11]. The success rates of 72 – 76% concurs with pooled rates derived by systematic reviews and meta-analysis [12,13].

In our study, 16 women (34.8%) with no prior vaginal delivery and 48 women (88.8%) with prior vaginal delivery in group A achieved successful VBAC while in group B, 20 women (46.5%) with no prior vaginal delivery and 52 women (91.2%) with prior vaginal delivery achieved successful VBAC.

In McNally's series, only 36% of women with an unfavorable cervix and no previous vaginal delivery were delivered vaginally, while in women with a previous vaginal delivery, the rate of a repeat caesarean section was only 4% with 96% of women delivered vaginally [14]. In another series by Kayani, in which the majority of women were induced with prostaglandins, the vaginal delivery rate was 44% in women with no previous vaginal delivery and 83% in women who had delivered vaginally [15].

Most of our patients were non-obese (with body mass index between 18 - 25). It is well known that maternal obesity is associated with dysfunctional labour [16], decreased chance of successful VBAC [17] and increased maternal and fetal adverse outcome when attempting VBAC [18].

The overall risk for symptomatic uterine rupture at term is 74/10,000 in planned VBAC [10]. In our study, there were no cases with symptomatic uterine rupture.

Ravasia., *et al*. conducted a study including a total of 2119 trials of labour, of which 575 (27%) were induced, to compare the rates of uterine rupture during induced trials of labor after previous caesarean delivery with the rates during a spontaneous trial of labor which showed that the Foley catheter induction was associated with the lowest rupture rate in the induced trial of labor (TOL) group and that it was comparable to the results in the spontaneous TOL group. The relative risk of uterine rupture with prostaglandin E2 use was six times higher than spontaneous trial of labor [19].

The main advantages of the cervical ripening with the Foley catheter over the prostaglandin E2 gel are the low costs, reversibility and a lower risk of serious side effects like uterine hyperstimulation and rupture, as well as it induces a significant ripening and dilatation of the cervix and it produces a shorter induction to the delivery interval [8].

Many clinical trials were conducted to evaluate the role of vaginal IMN either alone [20,21] or in combination with prostaglandins [22,23] for cervical ripening and labour induction with proved efficacy.

The use of vaginal IMN was reported with a significant increase in headache, severe enough to interrupt the study [24]. This may be due to repeated dosage in this trial (two to three doses); in our study, we use only one IMN tablet once, and 10 out of 18 patients required analgesics in our study which is comparable to previous studies [21,25].

Based on the results obtained from a previous study in our hospital [26] comparing the use of intracervical Foley catheter versus IMN tablets, we decided to use both agents for induction of labour in order to decrease the induction to delivery interval and to decrease the side effects of prolonged catheter placement namely pyrexia, and headache caused by repeated doses of IMN.

In our study, the caesarean delivery rate, maternal complications and fetal-neonatal outcome were comparable in the two groups.

Inability to include women with past history of labour dystocia and non-use of epidural analgesia were the main limitations of our study.

In conclusion, the combined use of intracervical Foley catheter and vaginal IMN tablets seems safe and effective novel method and superior to intracervical Foley catheter alone for induction of labour in women with one previous caesarean section at term. Future research should address maternal acceptability, cost-effectiveness of labour induction and the length of convalescence after delivery in women delivered vaginally compared to those undergoing repeat elective caesarean section.

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Disclosure

We certify that no actual or potential conflicts of interest in relation to this article exist.

Bibliography

1. Ananth CV., *et al*. "The association of placenta previa with history of cesarean delivery and abortion: a meta-analysis". *American Journal of Obstetrics and Gynecology*177.5 (1997): 1071-1078.
2. Wu S., *et al.* "Abnormal placentation: twenty-year analysis". *American Journal of Obstetrics and Gynecology* 192.5 (2005): 1458-1461.
3. Silver RM.,*et al*. "Maternal morbidity associated with multiple repeat cesarean deliveries". *Obstetrics and Gynecology* 107.6 (2006) :1226-1232.
4. Smith GC.,*et al*. "Factors predisposing to perinatal death related to uterine rupture during attempted vaginal birth after caesarean section: retrospective cohort study". *BMJ*329.7462 (2004): 375.
5. Jozwiak M and Dodd JM. "Methods of term labour induction for women with a previous caesarean section".*Cochrane Database of Systematic Reviews*28.3 (2013): CD009792.
6. Chwalitz K and Garfield RE. "Nitric oxide as the final mediator of cervical ripening". *Human Reproduction*13.2 (1998): 245-248.
7. Ledingham MA., *et al*. "Nitric oxide donors stimulate prostaglandin F (2 alpha) and inhibit thromboxane B (2) production in the human cervix during the first trimester of pregnancy". *Molecular Human Reproduction*5.10 (1999): 973-982.
8. Ziyauddin F., *et al*. "Transcervical Foley Catheter Versus the Vaginal Prostaglandin E2 Gel in the Induction of Labour in aOne previous caesarean section – A Clinical Study". *Journal of Clinical and Diagnostic Research* 7.1 (2013):140-143.
9. Guise JM., *et al*. "Vaginal birth after cesarean: new insights on maternal and neonatal outcomes". *Obstetrics and Gynecology* 115.6 (2010): 1267-1278.
10. Landon MB., *et al*. "Maternal and perinatal outcomes associated with a trial of labor after prior cesarean delivery". *New England Journal of Medicine* 351.25 (2004): 2581-2589.
11. Landon MB., *et al*. "The MFMU Cesarean Registry: factors affecting the success of trial of labor after previous cesarean delivery". *American Journal of Obstetrics and Gynecology* 193.3 (2005): 1016-1023.
12. Mozurkewich EL and Hutton EK. "Elective repeat cesarean delivery versus trial of labor: a meta–analysis of the literature from 1989 to 1999". *American Journal of Obstetrics and Gynecology* 183.5 (2000): 1187-1197.

13. Chauhan SP., *et al*. "Maternal and perinatal complications with uterine rupture in 142,075 patients who attempted vaginal birth after cesarean delivery: a review of the literature". *American Journal of Obstetrics and Gynecology* 189.2 (2003): 408-417.

14. McNally OM and Turner MJ. "Induction of labour after one previous caesarean section". *Australian and New Zealand Journal of Obstetrics and Gynaecology* 39.4 (1999): 425-429.

15. Kayani SI and Alfirevic Z. "Uterine rupture after induction of labour in women with previous caesarean section". *BJOG*112.4 (2005): 451-455.

16. Nuthulapaty FS., *et al*. "The association of maternal weight with cesarean risk, labor duration, and cervical dilation rate during labor induction". *Obstetrics and Gynecology* 103.3 (2004): 452-456.

17. Grobman WA., *et al*. "Development of a nomogram for prediction of vaginal birth after cesarean delivery". *Obstetrics and Gynecology*109 (2007): 806-812.

18. Brill Y and Windrim R."Vaginal birth after Caesarean section: review of antenatal predictors of success". *Journal of Obstetrics and Gynaecology Canada* 25.4 (2003): 275-286.

19. Ravasia D., *et al*. "Uterine rupture during induced trials of labor in women with a previous cesarean delivery". *American Journal of Obstetrics and Gynecology* 183.5 (2000):1176-1179.

20. Eddama O., *et al*. "The cost-effectiveness of outpatient (at home) cervical ripening with isosorbidee mononitrate prior to induction of labour". *BJOG* 116.9 (2009):1196-1203.

21. Yazdizadeh H., *et al*. "The impact of isosorbidee mononitrate on cervical ripening and labor induction in primiparous women with term pregnancy: A double-blind, randomized, controlled trial". Iranian Journal of Nursing and Midwifery Research 18.3 (2013):246-250.

22. Wolfler MM., *et al*. "Induction of labor at term using isosorbidee mononitrate simultaneously with dinoprostone compared to dinoprostone treatment alone: a randomized, controlled trial". *American Journal of Obstetrics and Gynecology* 195.6 (2006):1617-1622.

23. Abdellah MS., *et al*. "Intravaginal administration of isosorbidee mononitrate and misoprostol for cervical ripening and induction of labour: a randomized controlled trial". *Archives of Gynecology and Obstetrics*284.1 (2011):25-30.

24. Hatanaka AR., *et al*. "Interruption of a study of cervical ripening with isosorbidee mononitrate due to adverse effects". *Clinical and Experimental Obstetrics & Gynecology*39.2 (2012):175-180.

25. Bullarbo M., *et al*. "Outpatient vaginal administration of the nitric oxide donor isosorbidee mononitrate for cervical ripening and labor induction postterm: a randomized controlled study". *American Journal of Obstetrics and Gynecology*196.1 (2007): 50.e1-55.

26. Rezk M., *et al*. "Intracervical Foley Catheter Versus Vaginal Isosorbide Mononitrate for Induction of Labor in Women with Previous One Cesarean Section". *Journal of Clinical Gynecology and Obstetrics*3.2 (2014):55-61.

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