Pregnancy outcomes of induction of labor with metreurynter at or after 39 weeks of gestation in women with one previous cesarean delivery.

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Abstract

Objective: To elucidate the efficacy of induction of labor with metreurynter for women with one previous cesarean delivery.

Methods: A database was reviewed to identify women with singleton and vertex pregnancies who underwent trial of labor after one cesarean delivery (TOLAC) at or after 39 weeks of gestation between the years 2010 and 2016.

Results: Fifty-one women underwent induction of labor with metreurynter, and 230 women had spontaneous onset of labor pain. Successful TOLAC was observed in 95.2% (219/230) and 74.5% (38/51) of women with spontaneous onset of labor pain and induction, respectively ($p<0.001$). A case of uterine rupture was seen in a woman with induction, where the baby was born dead by cesarean section. Multivariable analysis demonstrated that induction of labor was an independent risk factor for successful TOLAC (adjusted odds ratio 0.21 and 95% confidence interval 0.07-0.65). Vacuum extraction (23.7% vs 6.8%, $p<0.001$) and amniotomy (55.3% vs 33.3%, $p=0.010$) were more frequent in women who had successful TOLAC with induction than those with spontaneous onset of labor.

Conclusion: Induction of labor with metreurynter decreases the success of TOLAC but is satisfactory in clinical practice based on its success rate. Induction of labor should be an option in women with TOLAC and no labor pain.

Keywords: Amniotomy, Induction, Metreurynter, TOLAC, VBAC.

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Introduction

Trial of labor after cesarean delivery (TOLAC) has been actively promoted as a method to reduce the proportion of cesarean delivery and the risk of operative morbidity and future pregnancy complications in women. From the perspective of medical economy, TOLAC is more cost-effective than elective repeat cesarean delivery in a variety of circumstances [1-3]. Therefore, current clinical practice guidelines support vaginal birth and trial of labor among women who have had a previous cesarean birth [4,5].

Physicians frequently encounter the dilemma of whether or not to induce labor when a woman with a history of cesarean delivery presents with spontaneously ruptured membranes or gets close to the due date with an unfavorable cervix and no labor pain. Although TOLAC in women with one previous low transverse cesarean is considered safe, the risk of uterine rupture associated with induction may be increased. It is commonly believed that women with a previous cesarean delivery who undergo induction of labor by pharmaceutical methods such as prostaglandin analogues and oxytocin are less likely to have vaginal birth after cesarean (VBAC) and have a slightly elevated risk of uterine rupture compared to women with spontaneous onset of labor [4,6,7]. While there are documented potential risks, induction of labor among women with TOLAC is considered by many obstetricians to be a part of clinical labor management [8,9]. Mechanical induction is another option to improve outcomes in women with TOLAC. Harper et al. reported that the risk of uterine rupture is similar in the case of spontaneous labor and when labor is induced with a favorable initial cervical exam and shorter time spent in active labor, suggesting that cervical ripening is important for successful TOLAC [10]. Several studies in the literature have shown that mechanical induction methods are as effective as pharmaceutical methods with lower the rates of uterine hyperstimulation and uterine rupture [11-13]. Most of these studies have used a Foley catheter with a balloon volume of less than 40 mL for the induction of labor. However, a Foley catheter is not a device designed for cervical ripening but for urological use in the first place. There is a paucity of information on the efficacy of metreurynter with a balloon volume of more than 70 mL.

The goal of this study was to elucidate the efficacy of induction of labor with metreurynter in women with one previous cesarean at or after 39 weeks of gestation.

Materials and Methods

Data were collected retrospectively from the medical records of all women who were admitted to the Japanese Red Cross Nagoya Daiichi Hospital for labor between the years 2010 and 2016. The hospital is a tertiary referral center with approximately 1,500 deliveries per year. The inclusion criteria were singleton and vital pregnancy with one previous lower

segment transverse cesarean delivery. The exclusion criteria were elective cesarean delivery, emergency cesarean delivery prior to a trial of labor, any other uterine surgeries related to gynecology, fetal presentation other than vertex, and fetal anomaly or abnormal karyotype. Cases with gestational ages at birth less than 39 weeks were also excluded because insufficient ripening of the cervical canal can affect labor progression. Gestational ages were established from menstrual history and confirmed by routine ultrasonographic examinations. Recurring indication for cesarean delivery was defined as the arrest of dilation or descent, which was thought to be disadvantageous for success of TOLAC. The study was approved by the Institutional Ethics Committee of the Japanese Red Cross Nagoya Daiichi Hospital.

The study population was divided into two groups, namely, induction and spontaneous onset of labor. After the women in the induction group were extensively counseled and had provided informed consent, they were induced with a metreurynter with a balloon volume of 70-100 mL, which was placed in the uterus until expulsion. In both groups, oxytocin administration was not routinely carried out but was commenced as an augmentation agent only if the cervix was 10 cm dilated but the labor was weak. Amniotomy was appropriately performed for labor augmentation. Analgesics were not given in our labor unit. Continuous electronic fetal monitoring was used throughout established labor. In case of non-reassuring fetal status or lack of labor progress, TOLAC was abandoned, and cesarean delivery was expedited.

The primary outcome was the rate of vaginal delivery after one cesarean section. The secondary outcomes were factors associated with failed TOLAC. In addition, labor parameters such as time of labor, operative delivery, blood loss at birth, and perineal laceration were examined in the case of successful TOLAC.

Statistical computations were performed with Statcel version 3 (OMS publishing Inc., Tokorozawa, Japan) and EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan; http://www.jichi.ac.jp/saitama-sct/SaitamaHP.files/statmedEN.html) [14]. Univariate analysis was performed with Student's t test, Mann-Whitney U test, Fisher's exact test, or chi-square test, when appropriate. Logistic regression analysis was used to assess the effects of confounding variables on successful TOLAC. The results were considered significant when two-tailed p values were less than 0.05.

Results

A total of 10,032 women delivered at our hospital during the study period. A total of 281 women met the criteria for inclusion in this study, 51 women for induction and 230 women for spontaneous onset of labor.

The demographic characteristics of the study population are shown in Table 1. The study groups differed in several characteristics. Women who underwent induction of labor were more likely to have recurring indication for cesarean section and higher gestational age at delivery. Women who delivered after spontaneous onset of labor were characterized by a higher number of previous vaginal births and VBAC. Successful TOLAC was observed in 95.2% (219/230) and 74.5% (38/51) of women with spontaneous onset of labor pain and induction, respectively ($p<0.001$). A case of uterine rupture was seen in a woman with induction, where the baby was born dead by cesarean section.

Table 1. *The demographic characteristics of the study population.*

	Induction	Spontaneous onset of labor	p value
	(n=51)	(n=230)	
Maternal age (y) [a]	33.5 ± 5.6	32.0 ± 4.6	0.050 [c]
Prepregnancy BMI [a]	21.6 ± 3.1	20.8 ± 3.0	0.067 [c]
Previous vaginal delivery ≥ 1, n (%)	1 (2.0)	21 (9.1)	0.144 [f]
Previous VBAC ≥ 1, n (%)	5 (9.8)	45 (19.6)	0.109 [f]
Indication for previous cesarean section, n (%)			0.017 [eh]
Recurring	17 (33.3)	43 (18.7)	
Non-recurring	27 (52.9)	157 (68.3)	
Unknown	7 (13.7)	30 (13.0)	
Metreurynter, n (%)	51 (100)	2 (0.9)	<0.001 [f]
Oxytocin for augmentation, n (%)	4 (7.8)	8 (3.5)	0.240 [f]
Mode of subsequent delivery, n (%)			<0.001 [e]
Vaginal delivery	38 (74.5)	219 (95.2)	
Cesarean section	13 (25.5)	11 (4.8)	
Gestational age at delivery (wk) [b]	41 (39-42)	40 (39-41)	<0.001 [d]
Indication for subsequent cesarean section, n (%)			0.122 [e]
Non-reassuring fetal status	6 (46.2)	3 (27.3)	
Lack of progress	7 (53.8)	5 (45.5)	
Maternal request	0 (0)	3 (27.3)	
Birth weight (g) [a]	3,209 ± 392	3,141 ± 387	0.257 [c]
Apgar score (5 min) <7, n (%) [g]	2 (3.9)	1 (0.4)	0.086 [f]
Infant sex, n (%)			0.046 [e]
Male	17 (33.3)	112 (48.7)	
Female	34 (66.7)	118 (51.3)	
Umbilical cord, n (%) [g]			
pH <7.10	5 (9.8)	9 (3.9)	0.145 [f]
Base excess <-12 mmol/L	4 (8.0)	4 (1.8)	0.037 [f]
Uterine rupture, n (%)	1 (2.0)	0 (0)	0.181 [f]

Data are expressed as the mean ± SD [a] or median (range) [b].

[c] Student's t test, [d] Mann-Whitney U test, [e] chi-square test, [f] Fisher's exact test.

[g] Some data are missing.

[h] Recurring vs non-recurring.

BMI, body mass index; VBAC, vaginal birth after cesarean.

Multivariable logistic regression analysis was used to validate whether the induction of labor was independently associated with failed TOLAC. Because a history of vaginal birth, especially if the vaginal delivery occurred after the cesarean, is known to be a factor for increased probability of success, and because recurring indication for cesarean delivery, older maternal age, and gestational age greater than 40 weeks are regarded as factors for decreased probability of success [4,5], these parameters were incorporated into the model as independent variables. Women with induction of labor were less likely to have successful TOLAC (adjusted odds ratio [aOR] 0.21, 95% CI [confidence interval] 0.07-0.65) compared with women with spontaneous onset of labor (Table 2).

Table 2. *Factors associated with successful TOLAC: multivariable analysis.*

Characteristic	Crude OR (95% CI)	Adjusted OR* (95% CI)
Age (y) ≥ 40	**0.14** (0.04-0.52)	**0.18** (0.04-0.78)
Gestational age at delivery (wk) ≥ 41	**0.17** (0.07-0.43)	0.47 (0.15-1.45)
Previous vaginal delivery ≥ 1	1.20 x 10^7 (0.00-infinite)	1.32 x 10^7 (0.00-infinite)
Previous VBAC ≥ 1	1.20 x 10^7 (0.00-infinite)	2.30 x 10^7 (0.00-infinite)
Recurring indication for cesarean section	**0.40** (0.16-0.99)	0.53 (0.19-1.46)
Induction of labor	**0.13** (0.05-0.32)	**0.21** (0.07-0.65)

Bold indicates statistically significant OR.

*Each odds ratio is adjusted for all other variables in the table.

OR, odds ratio; CI, confidence interval; VBAC, vaginal birth after cesarean.

Table 3 presents the outcomes of the women who had successful TOLAC. Vacuum extraction (23.7% vs 6.8%, p<0.001) and amniotomy (55.3% vs 33.3%, p=0.010) were more frequent in women with induction than in women with spontaneous onset of labor. There was no difference in the duration of first stage of labor between the groups. Women who were induced tended to have longer second stage of labor than women with spontaneous onset of labor (93 min vs 62 min), although the results were not statistically significant.

Table 3. *Maternal and neonatal outcomes for women who had a successful TOLAC.*

	Induction	Spontaneous onset of labor	p value
	(n=38)	(n=219)	
Maternal age (y) [a]	33.4 ± 5.4	31.9 ± 4.5	0.063 [c]
Prepregnancy BMI [a]	21.3 ± 2.9	20.6 ± 2.7	0.130 [c]
Previous vaginal delivery ≥ 1, n (%)	1 (2.6)	21 (9.6)	0.216 [f]
Previous VBAC ≥ 1, n (%)	5 (13.2)	45 (20.5)	0.377 [f]
Indication for previous cesarean section, n (%)			0.033 [eh]
Recurring	12 (31.6)	39 (17.8)	
Non-recurring	20 (52.6)	152 (69.4)	
Unknown	6 (15.8)	28 (12.8)	
Oxytocin for augmentation, n (%)	4 (10.5)	8 (3.7)	0.08 [f]
Vacuum extraction, n (%)	9 (23.7)	15 (6.8)	<0.001 [e]
Amniotomy, n (%)	21 (55.3)	73 (33.3)	0.010 [e]
Gestational age at delivery (wk) [b]	41 (39-42)	40 (39-41)	<0.001 [d]
Labor duration			
First stage (min) [a]	543 ± 428	548 ± 388	0.939 [c]
Second stage (min) [ag]	93 ± 157	62 ± 81	0.068 [c]
Blood loss at birth (g) [a]	337 ± 259	314 ± 332	0.695 [c]
Perineal laceration ≥ III, n (%)	0 (0)	2 (0.9)	1.000 [f]
Birth weight (g) [a]	3,170 ± 364	3,129 ± 389	0.541 [c]
Infant sex, n (%)			0.117 [e]
Male	13 (34.2)	105 (47.9)	
Female	25 (65.8)	114 (52.1)	
Apgar score (5 min) <7, n (%) [g]	1 (2.6)	1 (0.5)	0.275 [f]
Umbilical cord, n (%) g			
pH <7.10	2 (5.3)	7 (3.2)	0.627 [f]
Base excess <-12 mmol/L	1 (2.6)	4 (1.8)	0.557 [f]

Data are expressed as the mean ± SD [a] or median (range) [b].

[c] Student's t test, [d] Mann-Whitney U test, [e] chi-square test, [f] Fisher's exact test.

[g] Some data are missing.

[h] Recurring vs non-recurring.

BMI, body mass index; VBAC, vaginal birth after cesarean.

Discussion

Our induction method in women with previous cesarean delivery is unique in that pharmaceutical agents were not administered with the exception of the cases requiring augmentation, and mechanical devices were used. Because mechanical induction was less effective for induction of labor compared with pharmaceutical agents [15,16], our concern regarding the use of metreurynter for the induction of labor was whether it might increase the failure of TOLAC. In the present study, the rate of failed TOLAC in women with induction (25.5%) was significantly higher than that in women with spontaneous onset of labor (4.8%). Multivariable analysis demonstrated that induction of labor was an independent risk factor for successful TOLAC (aOR 0.21, 95% CI 0.07-0.65) as shown in previous reports [4,5,17]. However, these findings do not necessarily discourage the induction of labor. Considering that the expectant management for any woman with TOLAC is to undergo cesarean delivery if she does not go into labor, the success rate of 74.5% by induction of labor is satisfactory. Furthermore, the rate of success of TOLAC with metreurynter is comparable to previously reported data with an overall success rate of TOLAC ranging from 60% to 80% [5,18,19].

In addition to the probability of successful vaginal delivery, the risk of uterine rupture is of great concern in women undergoing TOLAC with induction. Unfortunately, there is no typical pattern of uterine rupture in tocogram, and therefore, close follow-up of uterine contractility is advised and hyperstimulation should be prevented [20]. Several authors have reported that in women with previous cesarean delivery, uterine ruptures are frequent during the induction of labor compared to women who experience spontaneous onset of labor [6,10,21]. One study of 20,095 women with a prior cesarean delivery found a rate of uterine rupture of 0.52% for spontaneous onset of labor, 0.77% for labor induced without prostaglandins, and 2.45% for prostaglandin-induced labor [22]. It is unclear whether the induction of labor affected the incidence of uterine rupture in the present study because only one out of 51 women with induction suffered from it. However, based on the rare occurrence of uterine rupture, our induction method by metreurynter with a balloon volume of 70-100 mL seems to be reasonable.

Mechanical methods of induction are becoming an option for women with previous cesarean deliveries because it promotes cervical ripening and the onset of labor with lower rates of uterine hyperstimulation [23,24]. Balloon catheters apply pressure on the internal cervical os and stretch the lower uterine segment, which results in the release of endogeneous prostaglandins [24]. In most studies reported, the volume of the inflated balloon inside the uterus was 30-40 mL in either single or double catheter. A higher volume of balloon is expected to exert higher pressure to the cervix. However, there are insufficient data available to indicate the optimal volume of balloon for induction of labor with a previous history of cesarean delivery. This is the first report to use metreurynter with a balloon volume of more than 70 mL. Considering the high rate of successful vaginal delivery and allowable range of uterine rupture in the present study as shown above, an unfavorable cervix should not solely discourage TOLAC in women with previous cesarean delivery, and mechanical induction with balloon catheters might replace pharmaceutical induction, especially when cervical ripening is required. Although the usefulness of double-balloon catheters for induction of labor in women with a previous cesarean delivery has been reported, a single balloon seems to be clinically enough based on safety, efficacy, and especially lower cost [25-28].

One of the disadvantages of balloon catheters is the high proportion of women requiring oxytocin for supplementation or augmentation [23]. Because oxytocin administration is not a standardized hospital protocol for TOLAC, augmentation with oxytocin was not used for more than 10.5% of cases with successful TOLAC by induction. However, amniotomy, which is a strong trigger for the onset of labor, and vacuum extraction were used significantly more often in the cases of successful TOLAC with induction compared to that with a spontaneous onset of labor (55.3% vs 33.3%, $p=0.010$; 23.7% vs 6.8%, $p<0.001$, for amniotomy and vacuum extraction, respectively). Furthermore, women with induction had a longer second stage of labor than women with spontaneous onset of labor (mean time 93 vs 62 min), although the data were not statistically significant. These findings suggest that induction with a balloon catheter by itself is not enough to ensure successful TOLAC. Membrane sweeping is an alternative method of mechanical dilation. Conflicting results have been presented with regard to its efficacy. Tan et al. reported that membrane sweeping at the onset of labor induction by dinoprostone administration or amniotomy increased the rate of vaginal delivery, reduced oxytocic drug use, and shortened the induction to delivery interval [29]. In contrast, Hamdan et al. reported that serial weekly membrane sweeping at term had no significant effect on the onset of labor in women with TOLAC [30]. The contradictory reports might be due to the differences in approach and strength of sweeping. Because the physiologic basis of membrane sweeping leading to labor is well established, membrane sweeping could be combined with metreurynter, especially when pharmaceutical agents are to be avoided.

Our study has several strengths. First, our study population was relatively homogeneous composed primarily of married Japanese women. Second, all information was obtained from a single institution, which eliminated the variability in medical protocols regarding the induction process, and the data were maintained in a prospectively managed database. However, there were several limitations to our approach. First, this study was retrospective in nature. Second, the sample size was relatively small. Third, the background parameters such as gestational age were not comparable between women with induction and women with spontaneous onset of labor. Also, Bishop Score was not assessed due to the lack of data. This inability could potentially bias the differences in the rate of successful TOLAC between the groups. Finally, all subjects were Japanese, which may limit the application of our results

to other races.

In conclusion, the induction of labor with metreurynter at or after 39 weeks of gestation in women with one previous cesarean delivery had lower rates of vaginal delivery compared to the spontaneous onset of labor. However, the success rate of TOLAC by induction was still 74.5% and clinically satisfactory because the expectant management for any woman with TOLAC was to undergo cesarean delivery if she did not go into labor. Our results can help women and physicians make decision regarding the use of induction in the absence of spontaneous onset of labor.

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Disclosure Statement

All authors declare that they have no conflict of interest.

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