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MATERNAL-FETAL MEDICINE

Double-balloon catheter and sequential vaginal prostaglandin E2 versus vaginal prostaglandin E2 alone for induction of labor after previous cesarean section

Sven Kehl[1,2] · Christel Weiss[3] · Michael Wamsler[4] · Jana Beyer[5] · Ulf Dammer[1] · Jutta Heimrich[1] · Florian Faschingbauer[1] · Marc Sütterlin[2] · Matthias W. Beckmann[1] · Ekkehard Schleussner[5]

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Abstract
Purpose To evaluate the efficacy of inducing labor using a double-balloon catheter and vaginal prostaglandin E2 (PGE2) sequentially, in comparison with vaginal PGE2 alone after previous cesarean section.
Methods A total of 264 pregnant women with previous cesarean section undergoing labor induction at term were included in this prospective multicentre cohort study. Induction of labor was performed either by vaginal PGE2 gel or double-balloon catheter followed by vaginal PGE2. The primary outcome measure was the cesarean section rate.
Results The cesarean section rate was 37 % without any statistically significant difference between the two groups (PGE2: $n = 41$, 37 % vs. balloon catheter/PGE2: $n = 41$, 42 %; $P = 0.438$). The median (range) number of applications of PGE2 [2 (1–10) versus 1 (0–8), $P < 0.001$] and the total amount of PGE2 used in median (range) mg [2 (1–15) vs. 1 (0–14), $P = 0.001$] was less in the balloon catheter/PGE2 group. Factors significantly increasing risk for cesarean section were "no previous vaginal delivery" (OR 5.391; CI 2.671–10.882) and "no oxytocin augmentation during childbirth" (OR 2.119; CI 1.215–3.695).
Conclusions The sequential application of double-balloon catheter and vaginal PGE2 is as effective as the sole use of vaginal PGE2 with less applications and total amount of PGE2.

Keywords Induction of labor · Double-balloon catheter · Prostaglandin E2 · Dinoprostone · Previous cesarean section · Scarred uterus

Introduction

As the rate of cesarean section continues to rise, 25 % of pregnant women with a previous cesarean delivery develop an indication for induction of labor in a subsequent pregnancy [1]. The choice between elective cesarean section, awaiting spontaneous onset of labor and induction of labor is difficult, as risks and benefits have to be considered carefully. Current sources of information are limited to non-randomized trials [2–4].

Women should be informed about the potential increased risk of uterine rupture associated with any induction and the decreased probability of achieving vaginal birth after cesarean delivery (VBAC) [5–9]. Data about which method of induction of labor is best in a scarred uterus are sparse. There are inhomogeneous recommendations by national guidelines. The National Institute for Health and Clinical Excellence (NICE) in United Kingdom recommends vaginal prostaglandin E2 (PGE2) for induction of labor in women who had a previous cesarean section [7]. The Society of Obstetricians and

✉ Sven Kehl
sven.kehl@gmail.com

1 Department of Obstetrics and Gynecology, Erlangen University Hospital, Universitätsstraße 21-23, 91054 Erlangen, Germany

2 Department of Obstetrics and Gynecology, University Medical Center Mannheim, Heidelberg University, Heidelberg, Germany

3 Department of Medical Statistics and Biomathematics, University Medical Center Mannheim, Heidelberg University, Heidelberg, Germany

4 Department of Obstetrics and Gynecology, Hospital Memmingen, Memmingen, Germany

5 Department of Obstetrics, Jena University Hospital, Jena, Germany

Gynecologists of Canada (SOGC) and the French College of Obstetricians and Gynecologists (CNGOF) stated that medical induction of labor with PGE2 is associated with an increased risk of uterine rupture and should not be used except in rare circumstances [6, 9]. The American College of Obstetricians and Gynecologists (ACOG) suggested to avoid sequential use of PGE2 and Oxytocin [5]. The German Society of Gynecology and Obstetrics advocated intracervical PGE2 for cervical ripening and vaginal PGE2 or Oxytocin in a favorable cervix [8]. Balloon catheter can be used in an unfavorable cervix even in women with a history of cesarean section [4–6, 9–11]. There is clear consensus that misoprostol is associated with an increased risk of uterine rupture in a scarred uterus and should be avoided [5–9]. The decision on which method of induction should be used depends on several factors. Clinical endpoints such as safety profile, operative delivery rates, cost-effectiveness, and woman's expectations have to be taken into account. Neither balloon catheters nor prostaglandins are licensed for labor induction after previous cesarean section and patients have to be informed about this. For women with prior cesarean section, the safety but also the probability of successful vaginal delivery is important. Most previous studies have consistently shown that women with a scarred uterus who are induced have a 15-20 % lower chance of vaginal birth in comparison with spontaneous onset of labor [12–16]. The risk of uterine rupture is higher among those whose labor is induced [12, 17, 18], especially when prostaglandins are used (1.4 %, OR 1.67) [19–21]. However, in many countries, vaginal PGE2 has been used for induction of labor in a scarred uterus for years. More and more investigations show good success with the utilization of balloon catheters with only a slightly increased risk for uterine rupture (0–1.6 %) [4, 11, 22–24]. Lower risk of complications and the same efficacy are aspects in favor of balloon catheters. It is not known, whether a combination of pharmaceutical and mechanical methods is beneficial in this situation. Despite a combination of balloon catheter and prostaglandin is not approved by the manufacturer, there have been published promising results in patients without a history of cesarean section [25, 26]. The aim of this study was therefore to evaluate the efficacy of the induction of labor using a double-balloon catheter and vaginal PGE2 sequentially, in comparison with vaginal PGE2 alone.

Materials and methods

This prospective cohort study was undertaken at four hospitals in Germany between January 2012 and December 2013. Pregnant women with singleton pregnancies and a prior cesarean section at term (≥259 days of gestation) for induction of labor were included. Exclusion criteria were breech presentation, structural or chromosomal fetal abnormality, intrauterine fetal death, placenta previa, or any other contraindication to vaginal delivery. Only cases with previous transverse uterotomy were considered. If the previous cesarean section was not performed by a transverse uterotomy, labor was not induced in the participating hospitals.

The study was approved by the Ethics Committee at Erlangen University, Erlangen, Germany. All study participants were briefed about off-label use of balloon catheter and PGE2 for labor induction after previous cesarean section and written informed consent was given.

Gestational age was assessed from the menstrual history and confirmed by measurement of fetal crown–rump length at a first-trimester scan. The Bishop score was assessed by a midwife or a physician before induction of labor.

Induction of labor was performed either by vaginal PGE2 gel (MINPROSTIN® Vaginalgel 1 mg/−2 mg; Pfizer Pharma, Berlin, Germany) or double-balloon catheter (Cook Medical, Cervical Ripening Balloon; Cook OB/GYN, Bloomington, Indiana, USA) and vaginal PGE2 sequentially based on physicians' preference.

Six hours after the initial dosage of 1 mg, 2 mg PGE2 was given vaginally. Twenty-four hours after the start of PGE2 administration, dosages of 2 mg in the morning and after 6 h was given if necessary.

The double-balloon catheter was placed in accordance with the manufacturer's instructions. Both balloons were filled with 80 mL of saline. The external end of the device was taped without traction to the woman's thigh. It was removed after 12 h if the double-balloon catheter did not fall out spontaneously. A reason for removing the catheter earlier than 12 h after placement was the request by the woman but not rupture of the membranes. If labor did not start after mechanical ripening, the woman received vaginal PGE2 the next morning, 24 h after the insertion of the catheter, as described above.

Artificial rupture of the membranes and oxytocin administration were not carried out routinely in the participating hospitals. In case of premature rupture of the membranes (PROM) labor was induced after at least 12 h.

The primary outcome measure was the cesarean section rate. Other outcome parameters were induction-to-delivery interval, proportion of VBAC within 24 and 48 h and failed induction (defined as no VBAC within 72 h). Moreover, neonatal [umbilical artery pH less than 7.1, Apgar score less than 7 at 5 min, meconium-stained amniotic liquor, abnormal cardiotocography (CTG), postpartum transfer to neonatal intensive care unit, chorioamnionitis, infection of the newborn] and maternal outcome (endometritis and uterine rupture) were also evaluated. The data were obtained concurrently with woman care and were recorded by the research team.

Student's *t* test or Mann–Whitney *U* test have been used to compare groups of continuous normally or not normally distributed variables, respectively. The Chi^2 test or Fisher's exact test were performed to analyze proportions. For ordinal scaled data Cochran–Armitage trend test were used. Furthermore, a multiple logistic regression analysis with binary outcome has been performed to evaluate which factors contribute to an increased risk for cesarean section. In each test, a significance level of 5 % was used. All statistical calculations were done with SAS software, release 9.3.

Results

During the 2-year study period, 13,608 women delivered at the participating institutions and 264 women met the inclusion criteria. The trial profile is shown in Fig. 1.

Table 1 demonstrates the demographic and baseline characteristics in cases without PROM in the PGE2 and the balloon catheter and PGE2 group. There were significantly more women with at least one previous vaginal delivery in the PGE2 group ($n = 46$, 41 % vs. $n = 21$, 21 %; $P = 0.002$).

In total, 54 women had labor induction for PROM. The baseline characteristics were similar to those without PROM [age 32.9 ± 5.2 years, body mass index 29.1 ± 6.1, parity median 1 (1–3), gestational age 276.6 ± 7.6, birthweight 3362.6 ± 417.5, bishop score 3 (0–9)].

The indications for induction of labor are given in Table 2. There were no significant differences between the two groups. Cases with PROM were not considered in this table. Induction of labor for PROM was performed in 52 women with PGE2 and in two with the balloon catheter and PGE2.

The primary outcome parameter was the cesarean section rate. There were 98 cesarean sections necessary (37 %) without any difference between the two groups in the total collective of 264 women. In Table 3, outcome parameters excluding cases with PROM are depicted. In all 210 cases, cesarean section rate was not different (PGE2: $n = 41$, 37 % vs. balloon catheter/PGE2: $n = 41$, 42 %; $P = 0.438$). The indications for cesarean section were similar in the PGE2 group [failed induction ($n = 8$), arrest of labor ($n = 11$), abnormal CTG ($n = 15$), maternal request ($n = 6$), suspected uterine rupture ($n = 1$)] and in the balloon catheter/PGE2 group [failed induction ($n = 6$), arrest of labor ($n = 17$), abnormal CTG ($n = 10$), maternal request ($n = 4$), suspected uterine rupture ($n = 1$), others ($n = 3$)].

Approximately 50 % of the vaginal deliveries were within 24 h and about 80 % within 48 h. In 31 % of all inductions with the balloon catheter no further methods of labor induction were necessary, and the catheter was extruded spontaneously in 18 women (18.6 %). The total amount of PGE2 used ($P = 0.001$) and the number of applications ($P < 0.001$) were less when starting labor induction with balloon catheter.

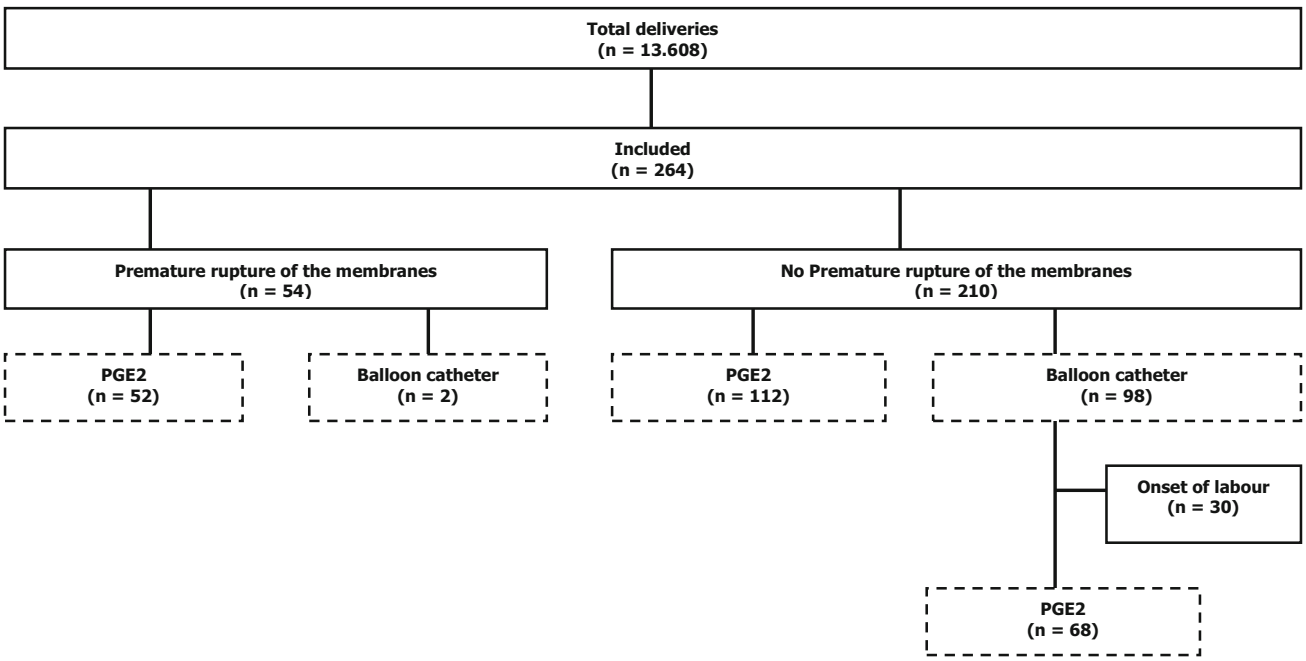

Fig. 1 Trial profile

Table 1 Baseline demographics and pregnancy characteristics

Characteristics	PGE2 ($n = 112$)	Balloon catheter and PGE2 ($n = 98$)	P value
Age (years)	34.1 ± 5.3	33.2 ± 4.7	0.184
Maternal height (cm)	166.6 ± 6.1	167.8 ± 5.5	0.134
Maternal weight (kg)	83.8 ± 14.2	85.9 ± 16.5	0.328
Body mass index	29.6 ± 5.2	28.6 ± 6.3	0.218
Pregnancy	3 (2–8)	2 (2–8)	0.443
Parity	1 (1–5)	1 (1–3)	0.002
Previous vaginal delivery	46 (41 %)	21 (21 %)	0.002
Gestational age (days)	281.8 ± 7.9	282.4 ± 8.1	0.579
Birthweight (grams)	3525.0 ± 474.3	3563.0 ± 564.7	0.598
Child's sex	Male: 48 %	Male: 47 %	0.917
	Female: 52 %	Female: 53 %	
Bishop score	3 (0–8)	2 (0–9)	0.064
Hypertensive disorder (n, %)	7 (6.3 %)	11 (11.2 %)	0.199
Gestational diabetes (n, %)	18 (16.1 %)	17 (17.5 %)	0.779

Data are median (range) or in mean with standard deviation. Cases with premature rupture of the membranes are not considered

PGE2 Prostaglandin E2

$P < 0.05$ was considered significant

Table 2 Indications for inducing labor

Indication	PGE2 ($n = 112$)	Balloon catheter and PGE2 ($n = 98$)	P value
Pregnancy at or beyond 41 weeks	50 (45 %)	46 (47 %)	0.739
Gestational diabetes	16 (14 %)	13 (13 %)	0.831
On request	16 (14 %)	11 (11 %)	0.509
Suspected fetal macrosomia	5 (4 %)	4 (4 %)	1.000
Fetal growth restriction, placental insufficiency	3 (3 %)	7 (7 %)	0.194
Abnormal cardiotocography	3 (3 %)	3 (3 %)	1.000
Oligohydramnios	4 (4 %)	3 (3 %)	1.000
Preeclampsia, hypertensive disorder, HELLP syndrome	5 (4 %)	7 (7 %)	0.404
Other	5 (4 %)	3 (3 %)	0.726

Data are presented as absolute and relative frequencies. Cases with premature rupture of the membranes are not considered

PGE2 Prostaglandin E2

$P < 0.05$ was considered significant

Outcome parameters are demonstrated according parity in Table 4. There was also less PGE2 necessary in the balloon group (No previous vaginal delivery: $P = 0.006$, previous vaginal delivery: $P = 0.007$) with less vaginal applications of PGE2 (No previous vaginal delivery: $P = 0.001$, previous vaginal delivery: $P = 0.004$). The cesarean section rate is lower in women with at least one previous vaginal delivery [PGE2: 8 (17 %) vs. 33 (50 %), balloon catheter/PGE2: 2 (10 %) vs. 39 (51 %)].

When labor was induced for PROM ($n = 54$), 16 cesarean Sects. (30 %), six surgical vaginal deliveries (11 %) and 32 normal vaginal deliveries (59 %) were performed. Except one, all vaginal deliveries were within 48 h. The median of number of applications of PGE2 was 1, and the median total amount of PGE2 used 1 mg. The outcome parameter was also excellent after PROM (arterial pH < 7.10: $n = 0$, BE < -12: $n = 0$, postpartal transfer of the newborn: $n = 0$, uterine rupture: $n = 0$). The two cases with labor induction using balloon catheter after PROM resulted in uncomplicated vaginal deliveries.

In the univariate analyses, parity and bishop score have been revealed as significant factors influencing the

Table 3 Outcome parameters

Outcome parameter	Total ($n = 210$)	PGE2 ($n = 112$)	Balloon catheter and PGE2 ($n = 98$)	P value
Mode of delivery (n, %)				
Normal vaginal delivery	105 (50 %)	58 (52 %)	47 (48 %)	0.736
Operative vaginal delivery	23 (11 %)	13 (12 %)	10 (10 %)	
Cesarean section	82 (39 %)	41 (37 %)	41 (42 %)	
Induction-delivery-interval (min; median)	1441 (225–9719)	1352 (353–9175)	1496 (225–9719)	0.081
Induction-delivery-interval (hours; median)	24.0 (3.75–162.0)	22.5 (5.9–152.9)	24.9 (3.75–162.0)	
Vaginal delivery within 24 h (*n*, %)	62 (50 %)	37 (54 %)	25 (44 %)	0.240
Vaginal delivery within 48 h (*n*, %)	104 (83 %)	58 (85 %)	46 (81 %)	0.494
Failed induction[a] (no VBAC within 72 h; *n*, %)	9 (7 %)	6 (9 %)	3 (5 %)	0.511
Onset of labor after balloon cather before PGE2 application (*n*, %)	30 (31 %)	–	30 (31 %)	–
No. of applications of PGE2 (median, range)	2 (0–10)	2 (1–10)	1 (0–8)	<0.001
Total amount of PGE2 used (mg; median, range)	2 (0–15)	2 (1–15)	1 (0–14)	0.001
Arterial pH < 7.10 (*n*, %)	5 (2 %)	3 (3 %)	2 (2 %)	1.000
BE < −12 mmol/l (*n*, %)	3 (1 %)	2 (2 %)	1 (1 %)	1.000
Apgar score at 5 min < 7 (*n*, %)	4 (2 %)	3 (3 %)	1 (1 %)	0.625
BE < −12 and Apgar score at 5 min < 7 (*n*, %)	1 (1 %)	1 (1 %)	1 (1 %)	1.000
Abnormal cardiotocography (*n*, %)	62 (30 %)	37 (33 %)	25 (26 %)	0.217
Epidural anesthesia (*n*, %)	76 (36 %)	40 (36 %)	36 (37 %)	0.878
Oxytocin (*n*, %)	92 (44 %)	45 (40 %)	47 (48 %)	0.257
Meconium-stained amniotic liquor (*n*, %)	36 (17 %)	21 (19 %)	15 (15 %)	0.509
Chorioamnionitis (AIS) (*n*, %)	2 (1 %)	2 (3 %)	0	0.501
Postpartal transfer of the newborn (*n*, %)	17 (16 %)	8 (17 %)	9 (15 %)	0.806
Infection of the newborn (*n*, %)	2 (1 %)	2 (2 %)	0	0.500
Uterine rupture (*n*, %)	1 (0.5 %)	1 (0.9 %)	0	0.499

Cases with premature rupture of the membranes are not considered

BE base excess, *PGE2* Prostaglandin E2

[a] Cases with cesarean section are excluded

cesarean section rate (Table 5). According multiple logistic regression analysis, factors significantly increasing risk for cesarean section are "no previous vaginal delivery" ($P < 0.001$, OR 5.391; CI 2.671, 10.882) and "no oxytocin augmentation during childbirth" ($P = 0.08$; OR 2.119; CI 1.215, 3.695). The higher the Bishop score the lower is the risk for cesarean section (OR 0.833 per score unit; CI 0.713, 0.974).

Discussion

The rates of cesarean section and induction of labor are rising. Therefore, the number of pregnant women with a scarred undergoing labor induction is incrementing as well. Unfortunately, there is no consensus on the best regime in this situation. Vaginal PGE2 [7, 8] and balloon catheters [5, 6, 9] were recommended by international guidelines.

This study assessed the application of a double-balloon catheter the day before starting vaginal PGE2 and the exclusive use of vaginal PGE2 for induction of labor in women with previous cesarean section. Our study design was not randomized. The only statistically significant difference between the two groups (PGE2 vs. balloon catheter and PGE2) was the number of previous vaginal deliveries. Therefore, multiple logistic regression analysis has been used in order to adjust for this factor. Our analyses show that both strategies were equally effective and safe. The cesarean section rate was 37 and 42 % when using vaginal PGE2 only or double-balloon catheter with sequential PGE2. Rates of successful VBAC vary from one study to another. The 63 and 58 % success rates in this trial are similar to previous investigations [4, 11, 22–24, 27–31].

Main factors increasing the risk for cesarean section were no previous vaginal delivery, no oxytocin augmentation during childbirth and a low bishop score. Previous

Table 4 Outcome parameters in relation to parity

Outcome parameters	No previous vaginal delivery			Previous vaginal delivery		
	PGE2 ($n = 66$)	Balloon catheter and PGE2 ($n = 77$)	*P* value	PGE2 ($n = 46$)	Balloon catheter and PGE2 ($n = 21$)	*P* value
Mode of delivery (n, %)						
Normal vaginal delivery	24 (36 %)	29 (38 %)	0.939	34 (74 %)	18 (86 %)	0.643
Operative vaginal delivery	9 (14 %)	9 (12 %)		4 (9 %)	1 (5 %)	
Cesarean section	33 (50 %)	39 (51 %)		8 (17 %)	2 (10 %)	
Induction-delivery-interval (min; median)	1620.5 (420–5707)	1593.0 (225–9719)	0.316	1021.5 (353–9175)	1309.0 (402–4159)	0.215
Vaginal delivery within 24 h (*n*, %)	15 (47 %)	13 (34 %)	0.281	22 (61 %)	12 (63 %)	0.882
Vaginal delivery within 48 h (*n*, %)	26 (81 %)	30 (79 %)	0.810	32 (89 %)	16 (84 %)	0.682
Failed induction[a] (no VBAC within 72 h; *n*, %)	3 (9 %)	3 (8 %)	1.000	3 (8 %)	0	0.544
Onset of labor after balloon catheter cather before PGE2 application (*n*, %)	–	20 (26 %)	–	–	10 (48 %)	–
No. of applications of PGE2 (*n*, %; median, range)	2 (1–10)	2 (0–8)	0.001	2 (1–9)	1 (0–5)	0.004
Total amount of PGE2 used (mg; median, range)	2 (1–15)	2 (0–14)	0.006	2 (1–9)	1 (0–9)	0.007
Arterial pH < 7.10 (*n*, %)	3 (5 %)	2 (3 %)	0.662	0	0	–
BE < -12 (*n*, %)	2 (3 %)	1 (1 %)	0.593	0	0	–
Apgar score at 5 min < 7 (*n*, %)	3 (5 %)	1 (1 %)	0.335	0	0	–
BE < -12 and Apgar score at 5 min < 7 (*n*, %)	1 (2 %)	1 (1 %)	1.000	0	0	–
Abnormal cardiotocography (*n*, %)	23 (35 %)	21 (27 %)	0.298	14 (30 %)	4 (19 %)	0.329
Epidural anesthesia (*n*, %)	29 (44 %)	32 (42 %)	0.774	11 (24 %)	4 (19 %)	0.761
Oxytocin (*n*, %)	32 (48 %)	37 (48 %)	0.959	13 (28 %)	10 (48 %)	0.122
Meconium-stained amniotic liquor (*n*, %)	15 (23 %)	12 (16 %)	0.277	6 (13 %)	3 (14 %)	1.000
Chorioamnionitis (*n*, %)	1 (2 %)	0	1.000	1 (2 %)	0	1.000
Postpartum transfer of the newborn (*n*, %)	5 (14 %)	9 (20 %)	0.498	3 (7 %)	0	0.082
Infection of the newborn (*n*, %)	2 (3 %)	0	0.211	0	0	–
Uterine rupture (*n*, %)	1 (1.5 %)	0	0.215	0	0	–

Cases with premature rupture of the membranes were not considered. $P < 0.05$ was considered significant

BE base excess, *PGE2* Prostaglandin E2

[a] Cases with cesarean section were excluded

vaginal delivery is known to increase the rate of successful VBAC [4, 10, 11, 14, 28, 32–35].

There was no routine administration of oxytocin in this study. In 44 %, oxytocin was given during the course of childbirth. Labor augmentation is possible after previous cesarean section even though oxytocin itself was found to be an independent risk factor for uterine rupture in multivariate analyses [36]. But no use of oxytocin increased the risk for cesarean delivery in the present study. This was also found in other trials [28]. A high Bishop score, indicating a favorable cervix, decreased the risk for cesarean section.

Induction of labor because of PROM is very effective as it is already a strong triggering factor for onset of labor in term pregnancies [37]. Additional methods may therefore be of minor importance for which reason double-balloon catheter was not routinely used in this situation.

After inducing labor with the double-balloon catheter, onset of labor started in 31 % before application of PGE2. In women with previous vaginal delivery 48 % got into labor. Without previous vaginal delivery, only 26 % were in labor and the cervix was still unfavorable. The commonly used procedure was to switch to oxytocin and

Table 5 Univariate analysis for mode of delivery

Parameter	Cesarean section ($n = 98$)	Vaginal delivery ($n = 166$)	*P value*
Maternal age	33.8 ± 5.3	33.3 ± 4.9	0.480
Maternal height	166.8 ± 5.7	167.4 ± 6.1	0.478
Maternal weight	86.1 ± 17.0	83.9 ± 14.5	0.278
Body mass index	29.4 ± 6.1	28.9 ± 5.6	0.489
Parity	1 (1–5)	1 (1–5)	<0.001
Previous vaginal delivery	13	68	<0.001
Birthweight	3567 ± 542	3470 ± 477	0.131
Gestational age >279	64	112	0.719
Bishop score	2 (0–7)	3 (0–9)	0.008
Hypertensive disorder	8	11	0.641
Gestational diabetes	17	20	0.255
Indication for induction of labor			
Abnormal CTG	2	4	1.000
Gestational diabetes	14	15	0.188
Hypertensive disorder, preeclampsia	4	8	1.000
Fetal growth restriction	6	4	0.181
Suspected fetal macrosomia	4	5	0.730
Pregnancy at or beyond 41 weeks	33	63	0.485
On request	12	15	0.406
Premature rupture of the membranes	19	41	0.320
Others	3	5	1.000
Induction of labor with balloon catheter	41	59	0.305
Oxytocin	36	80	0.070
Epidural anesthesia	32	63	0.286
Previous cesarean section for arrest of labor	23	29	0.236

continued with that method [38, 39]. Since induction of labor with oxytocin in an unfavorable cervix is associated with an increased operative delivery rate [40], the potential benefit of using sequential PGE2 might be explained by its better efficacy in this unfavorable cervical condition. There were less vaginal applications of PGE2 necessary in the balloon group, and the total amount of PGE2 used was also smaller.

The potential increased risk of uterine rupture associated with any induction should be borne in mind [5–9]. Further trials demonstrated uterine rupture rate between 0 and 1.6 %, which is similar to this investigation [4, 11, 22–24]. The risk was higher, when using prostaglandin than oxytocin or balloon catheter [20, 21].

Uterine rupture was defined as a disruption of the uterine muscle and visceral peritoneum. Disruption of the uterine muscle with intact serosa was defined as uterine dehiscence. It is necessary to promptly recognize the uterine rupture and to deliver the fetus since it is linked to severe perinatal morbidity (hypoxic-ischemic encephalopathy), perinatal mortality and severe maternal complications (e.g., postpartum hemorrhage) [17, 20, 41]. Then, neonatal harm could be prevented [42].

There were no adverse maternal or neonatal events in this investigation, aside from the one uterine rupture. In that case, two doses of 1 mg PGE2 were given for labor induction and labor was augmented with oxytocin. Emergency cesarean section was conducted for suspected uterine rupture. Uterine rupture was confirmed during surgery and the newborn had to be transferred to neonatal intensive care unit for fetal asphyxia [pH 6.87, BE −19 mmol/l, Apgar score (after 5 min) 2]. Safety profile, cost-effectiveness, and the women's expectations need to be taken into account in addition to effectivity data. Induction of labor using balloon catheter or vaginal PGE2 has been reported to be methods well accepted by women [43, 44]. When inducing labor in women with previous cesarean section the potentially increased risk of uterine rupture and the decreased probability of achieving VBAC have to be considered. Uterine rupture is more likely after PGE2 application. When beginning labor induction with balloon catheter in 26 % (no previous vaginal delivery) to 48 % (at

least one previous vaginal delivery) no PGE2 gel was necessary. Less vaginal applications of PGE2 and less total PGE2 used after labor induction with balloon catheter might reduce the risk for uterine rupture. The sample size in this investigation was too small to show the difference. There was only one uterine rupture in the PGE2 group. Jozwiak et al. [45] showed that labor induction using balloon catheter might reduce maternal and neonatal side effects, especially infections, too. In this non-randomized trial, the two groups were not equal and this difference could not be demonstrated. The PROBAAT-S Trial, a national ongoing prospective observational cohort study in the Netherlands which plan to include 1500 women, compare the application of single-balloon catheter with prostaglandin for labor induction after previous cesarean section [46]. The results of this and further trials are necessary to create the basis for evidence-based recommendations. Randomized trials are necessary to evaluate potential advantages of sequential labor induction after previous cesarean section.

Overall, induction of labor with PGE2 and balloon catheter is possible to achieve vaginal delivery with little risk for adverse events. The sequential application of double-balloon catheter and vaginal PGE2 is as effective and safe as the sole use of vaginal PGE2 with less applications and total amount of PGE2.

Compliance with ethical standards

Conflict of interest There are no conflicts of interest.

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