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Cervical maturation in breech presentation: Mechanical versus prostaglandin methods.

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Abstract

Objective: Breech presentation at term accounts for around 5% of births. Few studies have evaluated the effectiveness of different induction methods for breech presentations. We aim to compare the mode of delivery after induction by intra cervical dilatation balloon compared to prostaglandin (PGE2) in breech presentation. We also evaluated the risk factors associated with a failure of induction.

Methods: Single-center retrospective study from January 2000 to December 2020 including all women induced from 36 weeks, breech presentation, with a single pregnancy without contraindication to vaginal delivery and with an unfavorable cervix (Bishop<6). The primary endpoint was the mode of delivery. Failure of induction was defined as the need of a cesarean section.

Results: One hundred seventy six patients were included, 96 in the balloon group and 80 in the prostaglandin group. The cesarean section rate in the balloon group was not significantly different from the prostaglandin group (34.4% vs. 26.3%, p= 0.24). Fifty percent of the patients in the balloon group required additional maturation with prostaglandins after the balloon was dropped or removed. In our overall population, the factors associated with induction failure were nulliparity (OR= 3.144; CI95%: (1.496-6.661)) and BMI > 30 kg/m^2 (OR= 3.15 CI95%: (1,374 - 7,224)).

Conclusion: Mode of delivery after mechanical methods in breech delivery induction appears similar to prostaglandins. However, it should be noted that in half of the cases, additional maturation with prostaglandin was necessary, calling into question the value of the mechanical methods. Factors associated with cesarean were maternal characteristics (nulliparity and BMI > 30 kg/m^2) but not induction method.

Keywords

Breech, induction, prostaglandins, mechanical, cesarean

Introduction

Breech presentation at term accounts for around 5% of births (1). Vaginal delivery for this presentation has been widely debated. The 2000 international multicenter randomized Term Breech Trial report by Hannah et al. initially found a decreased risk of neonatal morbidity and mortality in the scheduled cesarean section group versus the vaginal delivery group; however, the two-year follow-up study of this cohort of children showed no significant between-group differences (2,3). Since then, others have demonstrated the safety of vaginal delivery in breech presentation. Indeed, the French–Belgian multicenter observational study (PREMODA) found no significant differences in neonatal morbidity or mortality between the vaginal delivery and scheduled cesarean section groups (4).

Regarding vaginal birth policies, the labor induction question arises. Most international guidelines, including the US, Australian, and British guidelines, either do not recommend or do not mention labor induction in such cases (5–7). Nevertheless, several studies on this subject have been published. Most compared induced versus spontaneous labor, and none found significant differences in cesarean section rate or neonatal morbidity or mortality (8–10). As such, French guidelines have concluded that there is no contraindication to labor induction when the criteria for the acceptance of vaginal delivery are met (i.e., normal maternal pelvimetry, no fetal head hyperextension, and estimated fetal weight of 2500–3800 g) (1). However, this recommendation was made with a low level of evidence.

In induction cases, the use of mechanical methods versus prostaglandins has been widely discussed. A meta-analysis of nine randomized studies (cumulative 1,866 patients) comparing double balloon versus prostaglandin induction found no significant difference in vaginal delivery rate (11). However, all included studies

concerned cephalic presentations, and none evaluated breech presentation specifically.

Therefore, the main objective was to compare the mode of delivery after induction by intra cervical dilatation balloon compared to prostaglandin (PGE2) in breech presentation. We secondary evaluated the risk factors associated with a failure of induction.

Materials and Methods

This single-center retrospective study was conducted in Lille, France (a Level III maternity hospital with more than 5,600 deliveries annually) from January 2000 to December 2020.

The inclusion criteria were single pregnancy with breech presentation (frank or complete), induction of labor with unfavorable cervix (Bishop < 6), and gestational age ≤ 36 weeks. Exclusion criteria were medical termination of pregnancy, intrauterine death, fetal malformation, and spontaneous labor.

The trial of labor protocol in breech presentation cases has been previously published (12). Briefly, vaginal delivery was considered appropriate when three conditions were met: the difference between the promonto-retropubic diameter and the bi-parietal diameter was greater than 15mm, the difference between the transverse median diameter and the bi-parietal diameter was greater than 25mm, and the difference between the interspinous diameter and the bi-parietal diameter was greater than 0mm. In all other situations, vaginal delivery was considered inappropriate. A further condition for vaginal delivery was an estimated fetal weight below 3800g in nulliparous women (there was no cutoff for multiparous women). A woman in spontaneus labor with no previous pelvimetry was only eligible for vaginal delivery if the ultrasound-estimated fetal weight was < 2500 g or she had history of a vaginal delivery of an infant weighing > 3800 g.

Two induction groups were compared: (i) prostaglandins (PGE2, period 1, from 2000 to 2010) and (ii) mechanical methods (single or double balloon), which were introduced in our center during 2010 (period 2, from 2010 to 2020). The induction procedure in the prostaglandin group was as follows: fetal heart monitoring for a minimum of 30 min followed by vaginal release dinoprostone or prostaglandin gel 1

mg or 2 mg. The vaginal sustained-release dinoprostone was left in place for a maximum of 24 h. If, at the end of 24 h, the cervix was favorable and Bishop score of > 6, induction was continued with oxytocin in the labor ward, as necessary. If Bishop score was < 6, a second line of induction with prostaglandin gel was used. The prostaglandin gel was left in place for a maximum of 6 h. After 6 h, the cervix was reassessed, and management depended on Bishop score.

In the balloon group, the induction protocol was as follows: fetal heart monitoring for a minimum of 30 min, followed by placement of the intracervical dilatation catheter. This catheter was either a single balloon inflated with 50 cc of physiological serum or a double balloon inflated from 50 cc to 80 cc with physiological serum. The choice between these two was made by the attendant physician. Fetal heart monitoring was performed for 2 h. The balloon remained in place for a maximum of 12 h. If the patient lost the balloon before, and the cervix was favorable, induction continued in the labor ward. If, after 12 h from insertion, the cervix was still not favorable, induction was continued with a prostaglandin (vaginal sustained-release dinoprostone or gel).

Statistical analysis

Our primary endpoint was to compare the mode of delivery (i.e cesarean section rates) in the two groups. Our secondary endpoint was to evaluate the factors associated with failed induction in the overall population. Failed induction was defined as need for cesarean.

Categorical variables are reported as frequency (percentage) and continuous variables as mean ± standard deviation (SD) in case or normal distribution, or median (interquartile range [IQR]) otherwise. Normality was assessed graphically and using the Shapiro–Wilk test. Between-group comparisons (balloon group vs. prostaglandin

group) were made using chi-square or Fisher exact probability tests for categorical variables and Student's *t* test or Mann–Whitney *U* test for continuous variables (according to normality). A multivariate analysis was conducted, with factors selected based on their clinical relevance in a logistic regression model. Odds ratio and 95% confidence interval are reported to show effect size. All statistical tests were performed at the two-tailed α level of 0.05. Data were analyzed with SAS software version 9.4 (SAS Institute Inc., Cary, NC).

Ethics

This study received favorable opinion of the Ethical Committee for Research in Obstetrics and Gynecology (CEROG) CEROG 2021-OBS-0903.

Results

During the study period, 96,371 births occurred, among which 3,101 were breech presentations (Figure 1). Cesarean before labor was performed in 1,240 of the breech cases (40.0%). Of those with vaginal attempts (n = 1861), 176 (9.4%) were induced and included: 96 in the balloon catheter group and 80 in the prostaglandin group. Table 1 presents the sample characteristics. The only statistically significant difference between the two groups was average body mass index (BMI) (24.0 [IQR, 21.3 to 29.8] vs. 21.7 [IQR, 20.0 to 25.5] kg/m^2, p = 0.010), with no significant between-group difference for BMI > 30 kg/m^2 (p = 0.32).

In both groups, the most frequent indications for induction were prelabor rupture of membranes and fetal growth restriction (Table 2). We observed a significant difference in the number of induction labor lines. In the balloon catheter group, a secondary or greater induction line was necessary in half the cases (46.0% vs. 12.0%, p < 0.001). There was no significant difference in the rates of fetal heart rate abnormalities or uterine hyperkinesia/hypertonia.

Table 3 shows obstetrical and neonatal outcomes. Significantly longer latency phase duration was observed in the balloon group (4.0 [IQR, 1.0 to 5.5] vs. 1.5 [IQR, 0.4 to 3.0] h, p < 0.001). Oxytocin was used significantly more frequently in the balloon group (80.2% vs. 66.7%, p = 0.049) with a higher total dose compared with the prostaglandin group (750 [IQR, 45 to 1920] vs. 210 [IQR, 0 to 1200] mUI). Cesarean section rates did not differ significantly between balloon and prostaglandin groups (34.4% vs. 26.3%, p = 0.24). Episiotomy rate was higher in the first period of the study i.e in the prostaglandins group (55.9 vs 19.0, p<0.001). Regarding neonatal outcomes, mean arterial pH was lower in the mechanical method group (7.18 vs. 7.22, p = 0.008). However, there was no significant difference in arterial pH < 7.10.

Factors associated with labor induction failure were evaluated for all induction methods (Table 4). Nulliparity and a BMI > 30 kg/m^2 were the two factors significantly associated with an increased risk of failed induction (OR = 3.144 [95% CI, 1.496 to 6.610] and OR = 3.15 [95% CI, 1.374 to 7.224], respectively). Induction methods did not affect the risk of induction failure (balloon vs. prostaglandin; OR = 1.68 [95% CI, 0.838 to 3.367].

Discussion

Main findings

In this study, comparing cervical ripening by mechanical versus prostaglandin methods in term breech presentation cases, we found no significant difference in the mode of delivery between the two groups. However, labor duration, oxytocin use, and patient discomfort were higher in the mechanical group.

Interpretation

There is limited evidence on the safety and outcomes of breech labor induction. In this study, the overall cesarean section rate was 30%. Several studies have compared cesarean section rates in induction versus spontaneous labor for breech presentation cases. Bleu et al. found a cesarean section rate of 20% in their induction group versus 14% in spontaneous labor cases, although the difference was not statistically significant. The absence of a statistically significant difference was likely due to a lack of power (8). That study was also conducted at our center, during a period when induction was only performed with prostaglandins.

Marzouk et al. also compared obstetrical outcomes for spontaneous initiation and induction in breech presentations. In their study, cervical ripening or labor induction was performed for premature rupture of membranes, postdates, oligohydramnios, or maternal pathology. They used dinoprostone 0.5 mg (Prepidil®), oxytocin (Syntocinon®), or misoprostol (Cytotec®). The decision regarding cervical preparation method was made after evaluating local conditions (e.g., cervix, vaginal examination) by the head of the obstetrics department responsible for the labor room. There was no significant omnibus difference in cesarean section rates between the two groups. However, secondary analysis comparing cesarean section rates between cephalic

and breech presentations in labor induction showed a significant difference, with a significantly higher cesarean section rate in the breech compared with the cephalic presentation group (12.8% vs. 1.82%, respectively, $p < 0.01$) (10).

A recent retrospective cohort study of 1,054 singleton live fetuses compared the outcomes of spontaneous and induced breech deliveries. The induction rate was 21.0% in women with planned vaginal births and was stable during the study period. The frequency of intrapartum cesarean section was 48.0% for induced labor versus 45.7% for spontaneous labor ($p = 0.64$). In their center, the induction procedure started with a balloon catheter, misoprostol, or dinoprostone administered vaginally in women with an unripe cervix. In women with a ripe cervix, the recommendation for cephalic induction was amniotomy, followed by oxytocin infusion. However, amniotomy was usually avoided as a first-line procedure in breech inductions because of the risk of umbilical cord prolapse (13).

In these studies, no comparisons were made between induction methods. Thus, our results can only be compared with studies that evaluated mechanical and prostaglandin methods in cephalic presentations. For example, the PROBAAT randomized controlled trial compared misoprostol induction versus transcervical Foley catheter in cephalic presentations. The cesarean section rates did not differ significantly (22% vs. 20% RR = 0.90 [95% CI, 0.54 to 1.50], $p = 0.68$) (14). Similarly, the meta-analysis of nine randomized studies described above did not find any difference in vaginal delivery rates between prostaglandin or double transcervical balloon inductions (11).

Finally, we also evaluated the factors associated with induction failure. The two factors that emerged were nulliparity and obesity (BMI > 30 kg/m^2). These factors have been identified in many previous studies. For example, Levine et al. included

this information in their score to predict induction outcome. They found maternal BMI at delivery, height, parity, gestational age > 40 weeks at induction, and modified Bishop score to be independent risk factors for cesarean delivery among women undergoing labor induction with an unfavorable cervix (15). An observational study published in 2009 also highlighted these factors, and added others (e.g., maternal age > 30 years, Bishop score < 5, gestational age at term < 38 or > 41 weeks, and fetal weight > 3500 g) (16). A 2015 literature review also found nulliparity and obesity to be risk factors for failed induction (17). In a retrospective cohort of over 1.2 million women at term, elective induction in multiparous women was associated with a high vaginal delivery rate of 97% versus 76.2% for nulliparas (18).

Strengths and limitations

Our study is original due to the comparison of prostaglandins to balloons in breech presentation. Few studies have addressed breech induction, probably because of practice heterogeneity. In France, where breech vaginal delivery and induction are allowed, an observational study across 94 maternity units showed that only 10.6% of the units induced breech deliveries in cases with an unfavorable cervix (19).

Our study is not without potential biases. This was a retrospective analysis of data covering the past 20 years at one center. This may be explained by the low prevalence of induced term breech deliveries. Management in labor ward have evaluated during this period and may also influence our results (for example the episiotomy rate). External validity may also be questioned because of the use of a cephalopelvic confrontation protocol to allow vaginal delivery.

Conclusion

Mode of delivery after mechanical methods in breech delivery induction appears similar to prostaglandins. However, it should be noted that in half of the cases, additional maturation with prostaglandin was necessary, calling into question the value of the mechanical methods. Factors associated with cesarean were maternal characteristics (nulliparity and BMI > 30 kg/m^2) but not induction method.

Conflict of interest: Charles Garabedian is consultant for Ferring

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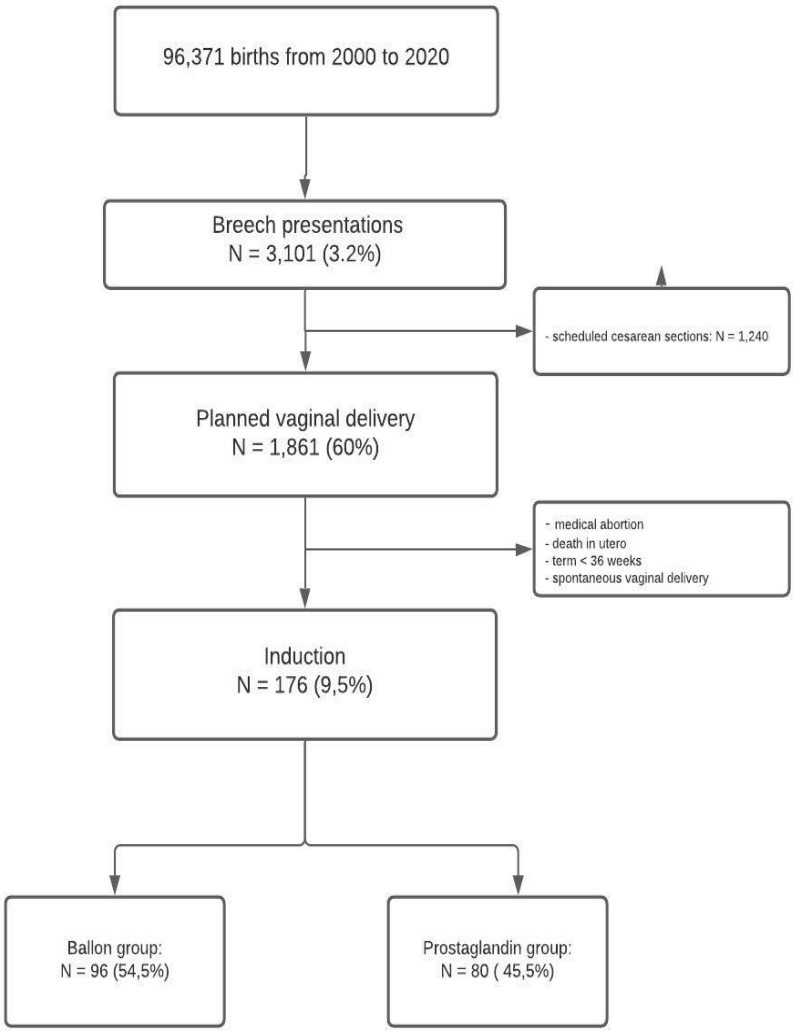

Figure 1. Study flowchart

Table 1. Sample characteristics

	Mechanical induction n = 96	Prostaglandins N = 80	p
Gestational age at delivery (weeks)	38.3 (36.9 to 39.6)	38.6 (37.3 to 40.4)	0.20
BMI	24.0 (21.3 to 29.3)	21.7 (20.0 to 25.5)	0.010
> 30 kg/m2	24 (25)	15 (18.8)	0.32
Maternal history			
Diabetes	5 (5.2)	3 (3.8)	0.73
Uterine malformation	5 (5.2)	1 (1.3)	NA
Scarred uterus	1 (1.0)	1 (1.3)	NA
Chronic hypertension	4 (4.2)	2 (2.5)	NA
Smoking	9 (9.5)	11 (13.7)	0.38
Nulliparous	47 (49)	48 (60)	0.14
Initial Bishop score	2.0 (1.0 to 4.0)	3.0 (1.0 to 5.0)	0.46
Breech presentation			
Complete	21 (22.6)	14 (17.5)	0.41
Frank	72 (77.4)	66 (82.5)	

Results presented as number (percentage) or mean ± standard deviation

NA, not applicable; BMI, body mass index

Table 2. Methods of cervical ripening

	Mechanical induction n = 96	Prostaglandins n = 80	p
Indication			
PROM	6 (6.2)	5 (6.2)	0.51
Prelabor rupture of membrane	20 (20.8)	22 (27.8)	0.28
Term	12 (12.5)	10 (12.5)	1
Preeclampsia	9 (9.3)	6 (7.5)	0.38
Diabetes	5 (5.2)	4 (5)	1
Fetal growth restriction	27 (28.0)	13 (16.1)	0.62
Number of ripening agents used:			
1	50 (52.1)	68 (85.0)	< 0.001
2 or more	46 (47.9)	12 (15.0)	
Complication:			
FHR abnormalities	15 (15.6)	5 (6.2)	0.036
Hyperkinesia	7 (7.2)	6 (7.5)	0.52
Hypertonia	0 (0.0)	3 (3.7)	NA

Results presented as number (percentage) or mean ± standard deviation
PROM, premature rupture of membranes
FHR, fetal heart rate

Table 3. Obstetrical outcomes

	Mechanical induction (n = 96)	Prostaglandins (n = 80)	p
Duration (h)			
Latent phase	4.0 (1.0 to 5.5)	1.5 (0.4 to 3.0)	< 0.001
Active phase	2.0 (0.5 to 2.8)	2.0 (0.5 to 4.0)	0.15
Complete dilatation	0.5 (0.0 to 1.0)	0.5 (0.2 to 1.0)	0.15
Duration of pushing efforts (min)	7.0 (0.0 to 17.0)	7.0 (7.0 to 17.0)	0.14
Fetal heart rate abnormalities	28 (29.1)	13 (16.2)	0.063
Intrauterine infection	1 (1.04)	2 (2.5)	NA
Oxytocin	73 (80.2)	48 (66.7)	0.049
Total dose (mUI) / ml	750 (45 to 1920)	210 (0 to 1200)	0.014
Cesarean during labor			
Latent phase dystocia	33 (34.4)	21 (26.3)	0.24
Active phase or second stage	12 (36.4)	5 (23.8)	0.33
dystocia	7 (21.2)	7 (33.3)	0.32
Umbilical cord prolaps	1 (3.0)	1 (4.8)	NA
Elective	2 (6.1)	0	NA
Vaginal delivery	63 (65.6)	59 (73.8)	0.24
Perineal tear	29/63 (65.9)	14/59 (28.0)	< 0.001
I–II	29/29 (100)	12/14 (85.7)	
III–IV	0	2/14 (14.3)	
Episiotomy	12/63 (19.0)	33/59 (55.9)	
Postpartum hemorrhage			
500–1000 mL	3 (3.1)	2 (2.5)	NA
> 1000 mL	6 (6.2)	2 (2.5)	
pH at birth			
Mean	7.18 ± 0.09	7.21 ± 0.09	0.008
< 7.10	17 (17.7)	10 (12.5)	0.34
Apgar < 7 at 5 min	6 (6.3)	2 (2.5)	0.29
Neonatal weight (mean)	2961 ± 560 g	3032 ± 545 g	0.40
Transfer to neonatal intensive care unit	1	0	NA

Results presented as number (percentage) or mean ± standard deviation

Table 4. Multivariate analysis of risk factor of induction failure

	ORs adjusted	95% Confidence Interval
Balloon vs. prostaglandins	1.680	(0.838 to 3.367)
Nulliparity	3.144	(1.496 to 6.610)
BMI > 30 kg/m2	3.150	(1.374 to 7.224)
Rupture of membranes vs. intact membranes	0.600	(0.278 to 1.292)
Complete vs. Frank	1.781	(0.706 to 4.496)

ORs adjusted, odds ratio adujsted; BMI, body mass index

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