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# Vaginal prostaglandin $E_2$ versus double-balloon catheter for induction of labour for vaginal birth after caesarean section: A Retrospective Cohort Study

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## Abstract

### OBJECTIVE

To compare the success of the double-balloon catheter (DBC) versus prostaglandin gel (PGE2) for induction of labour in women with one previous caesarean section.

### DESIGN

Retrospective cohort study using routinely collected maternity data in a Tertiary NHS hospital, North West England, UK. Women with a live singleton cephalic pregnancy

induced using DBC or PGE2 after one previous birth by caesarean section from 1st April 2017 to 1st July 2019 were included. The core outcomes assessed were the inability to perform artificial rupture of membranes, requirement of oxytocin, vaginal birth and uterine rupture.

**RESULTS**

208 women met the inclusion criteria, 127 were induced using the DBC and 81 using PGE2. The two groups were well matched for demographics and characteristics. Women induced for prolonged ruptured membranes with PGE2 were excluded from the study leaving 127 managed with DBC and 69 with PGE2. There were no significant differences observed between the two groups. Vaginal birth rates were 52.7% for the DBC and 66.6% for the PGE2 (relative risk 0.79 (confidence interval 0.63 - 1.00); P=0.05). A single uterine rupture was reported following DBC usage.

**CONCLUSIONS**

The DBC and PGE2 appear to be equally effective for induction of labour in women with one previous caesarean section.

**KEYWORDS:** VBAC, Induction, Double Balloon Catheter, Prostaglandin

## Introduction

Induction of labour is an increasingly common obstetric intervention, rising from 20.4% of births in 2007-8 to 32.6% in 2017-18 in England.[1] Overall rates of caesarean section have also risen in the UK from 19.7% in 2000 to 26.2% in 2015 and this trend is being reflected globally.[2] Approximately half of women who have had a Caesarean

section opt for a vaginal birth after a caesarean section (VBAC) in the subsequent pregnancy, which is generally considered safe.[3] It is therefore not surprising that obstetricians find themselves increasingly considering induction of labour in women who have had a previous caesarean section.

Vaginal birth after one caesarean section has a well recognised risk of uterine rupture of approximately 1 in 200 (0.5%) after spontaneous labour and a likelihood of successful VBAC of 72-75%.[4,5] The Royal College of Obstetricians and Gynaecologists (RCOG) cautiously advise on induction of labour in women attempting VBAC stating a 2-3 fold increased risk of uterine rupture in association with the use of prostaglandins and oxytocin.[4] The RCOG have suggested considering the use of mechanical methods as they are associated with a lower risk of uterine rupture, although the recent National Institute for Health and Care Excellence (NICE) evidence update on induction of labour advises against the use of mechanical methods in women with an unscarred uterus.[4,6] The NICE update on intrapartum care of women with a previous caesarean section makes no comment with regards to induction of labour while the NICE induction of labour guideline advocates the use of prostaglandins for VBAC induction.[7,8] A Cochrane Review concluded that there was not enough good quality evidence to determine the optimal method for induction of labour in a women with a previous caesarean section.[9] This was mirrored by a recent systematic review published in December 2019.[10] International bodies vary in their recommendations; some UK and German guidelines advocate the use of PGE2 (Dinoprostone gel) whereas Canadian and French guidelines advise avoidance. All mention the option of mechanical methods, to reduce risk of uterine rupture.

We performed the first direct comparison of the double-balloon catheter (DBC) and PGE2 in order to review the success and safety of each method for induction of labour for women who have had one previous caesarean section.

## Methods

We reviewed all patients who underwent induction of labour between 1st April 2017 and 1st July 2019 coded to have had a previous caesarean section at Liverpool Women's Hospital, a large tertiary unit in the UK. Only singleton live pregnancies with a cephalic presentation were included with no contraindication to VBAC. Each patient's electronic record was then checked individually to confirm evidence that there had been a single delivery by caesarean section prior to an induction of labour with either PGE2 or DBC.

This 27-month period was selected because during this time the hospital transitioned from the use of PGE2 gel (Dinoprostone 1mg, Prostin) (April 2017 and October 2018) to DBC (Cook Medical, cervical ripening balloon) (November 2017 and July 2019) as the method of induction for women with a previous caesarean section. During the cross over period of both methods being in use allocation was based on availability of equipment and a clinician trained to insert a DBC only. There was no other policy change with regards to induction of labour during this period of time. The DBC was inserted as per the manufacturer's guidelines with 80mls in each balloon and remained in situ for 12 hours or until spontaneous expulsion. If safety criteria were met the patient would be managed as an outpatient. DBC was contraindicated in the presence of ruptured membranes. PGE2 gel was administered as per the manufacturer's guidelines into the posterior fornix, initially 1mg followed by a further 1mg 6 hours later if required. Women induced with PGE2 with ruptured membranes

were excluded from the study. After completion of cervical ripening, with either PGE2 or DBC, an artificial rupture of membranes (ARM) was performed and a variable rate oxytocin infusion commenced, unless regular uterine activity was established.

Maternal demographic details were collected along with maternity details of previous pregnancies (parity, previous vaginal births, previous VBACs, indication for previous caesarean section). Data was collected for the index pregnancy including BMI, gestational age at delivery, indication for induction of labour; Bishop score prior to induction of labour and birth weight.

Core outcomes assessed were inability to perform ARM, need for oxytocin, vaginal birth and uterine rupture. Indication for emergency caesarean delivery and maternal and neonatal outcomes were also recorded (epidural use, blood loss, Apgar <7 at 5 minutes, arterial pH<7.10, admission to NICU).

Statistical analysis was performed on continuous data, mean and standard deviation were calculated in the presence of Gaussian distribution and the median and interquartile range for skewed data. Statistical difference was assessed using the T-Test or Mann-Whitney U test. Categorical data was expressed as the total number followed by percentage and relative risk, 95% confidence intervals and P values were calculated. Statistical significance was accepted at a P value <0.05.

## Results

There were 208 eligible women who underwent induction of labour, after one previous birth by caesarean section, between 1st April 2017 and 1st July 2019. 81 underwent induction of labour with PGE2 and 127 with DBC. 12 women in the PGE2 group were induced for prolonged rupture of membranes and these were excluded from the study,

leaving 69 women in the PGE2 group. No women with ruptured membranes were induced with DBC.

Maternal demographics and characteristics were compared across the 2 groups and are displayed in Table 1. There were no statistically significant differences seen between the groups' demographics. Indications for previous caesarean sections and for induction of labour were generally well matched across the two groups. The attending clinician determined indications for induction of labour or caesarean section. Maternal reasons would include maternal request, mental health issues, symphysis pubis dysfunction. Fetal distress would be defined as a cardiotocograph (CTG) trace classified as pathological according to NICE guidelines either with or without conformation with a fetal blood sample. A higher proportion of women had an unknown indication for previous caesarean birth and were induced for other indications in the PGE2 group. There were no other significant differences seen in maternal characteristics between the two groups including parity, gestation at delivery, previous vaginal births, births after caesarean section and bishop score.

The induction of labour outcomes are displayed in Table 2. One woman (0.8%) in the DBC group was unable to have an ARM performed compared to 2 women (2.9%) in the PGE2 group (RR 0.27 (CI 0.03 – 2.94); P=0.28). There was no significant difference observed in oxytocin usage between the groups (63.8% Vs 55.1%, RR 1.16 (CI 0.90 – 1.49); P=0.25) or caesarean sections performed for unsuccessful inductions of labour (11.7%% Vs 21.7%, P=0.25). There was no significant difference observed in vaginal births between the 2 methods, RR 0.79 (CI 0.63 – 1.00); P=0.05. Of the women achieving a vaginal birth there was no difference in the risk of requiring an assisted delivery (20.9% Vs 19.6%, RR 1.07 (CI 0.51 – 2.26); P=0.86) or in the duration of labour (5hrs 28mins Vs 4hrs 32mins, P=0.20). 48.0% of women delivered by caesarean

section in the DBC group compared to 33.3% in the PGE2 group (RR 1.42 (CI 0.97 – 2.07); P=0.07). There were no significant differences observed between any indications for caesarean birth. There were no differences between the groups concerning the use of epidurals, blood loss or uterine rupture.

There was a single uterine rupture in a woman induced with a DBC. This woman had a DBC inserted but was unable to have an ARM performed after 24 hours. The patient declined caesarean section and requested the DBC again. The DBC was inserted again and remained in for less than 4 hours and then an ARM was performed followed by an oxytocin infusion. An emergency caesarean section was performed due to failure to progress in the 1st stage of labour at 4cm dilatation. Uterine rupture was identified at caesarean. The rupture was approximately 6cm in length and described as the full width of the previous uterine scar. The baby was born in good condition and blood loss was 500mls. There were no maternal or neonatal complications.

All babies delivered were live born and neonatal outcomes are displayed in Table 3. Birth weight was comparable across the groups (3277.3g Vs 3317.4g, P=0.63). There was no significant difference between groups for adverse neonatal outcomes including Apgar score <7 at 5 minutes, umbilical artery pH <7.10 or admission to the neonatal intensive care unit.

## Discussion

Our cohorts are well matched for age, BMI, ethnicity, previous vaginal births, indication for previous caesarean section and bishop score, all of which have been shown to influence a women's chance of successful VBAC and possible risk of uterine rupture.[3,11,12] Success rates for vaginal birth after caesarean were 52.7% for the DBC and 66.6% for PGE2 (RR 0.79 (0.63 – 1.00); P=0.05), showing both methods to

be comparably effective. This is a similar success rate, for the DBC, shown by a recent Danish cohort study.[13]

There continues to be a lack of good quality data directly comparing PGE2 against mechanical balloon catheters, specifically the double-balloon catheter, for induction of labour in VBAC patients. The use of PGE2 in combination with the DBC for induction in VBAC women has been reported but with no advantage over PGE2 alone.[14] The closest comparisons to our work are 3 papers comparing the use of PGE2 against the Foley catheter (FC) in VBAC. A 2002 retrospective cohort study presents similar results to ours when comparing PGE2 (n=55) to the Foley catheter (n=161) for induction in women aiming for VBAC.[15] Both groups were well matched and both methods were shown to be equally effective. There were no uterine ruptures observed in either group or significant differences in adverse events. The largest of these 3 studies was performed in Canada in 2000.[16] Similar success between PGE2 and the Foley catheter was reported but they raised concerns with regards to safety within the PGE2 group. There were significantly more uterine ruptures in the PGE2 group (2.9%, p=0.004) compared to the Foley catheter (0.76%), oxytocin alone (0.73%) and spontaneous labour (0.45%) groups. To put these results into context it is worth noting that one of the diagnostic criteria for uterine rupture was severe fetal heart rate abnormality alone. There was also potential for a high dose of PGE2 to have been administered (up to 6mg), much higher than that used in most current practice. Lastly, a small cohort study of 70 patients from India compared PGE2 gel (0.5mg, max 2 doses 12 hours apart) against the Foley catheter and the results suggested comparable safety and efficacy.[17] Vaginal birth was lower in the PGE2 group (60.0%) compared to the FC group (71.4%). The poorer performance of PGE2 may relate to the particularly low dose used in this study.

A second purpose of this study was to review the safety profile of each method, acknowledging the study was underpowered to draw any firm conclusions. There were no significant differences between any of the neonatal outcomes assessed; Apgar <7 at 5 minutes, umbilical artery pH<7.10 and admission to NICU. There was no evidence of reduced safety in maternal outcomes between the 2 groups with only a single uterine rupture in a woman with a DBC.

Since the move toward the avoidance of PGE2 there has been some growing evidence suggesting safety with the use of low dose PGE2 with VBAC. Unfortunately, some evidence hasn't been widely applicable though, as it has included administration over a prolonged regime (7 days) or only grand multiparous women.[18,19] Sangwan et al compared outcomes of women with spontaneous labour verses induction of labour with PGE2 gel (0.5mg, max 3 doses 6 hours apart) after one previous Caesarean section.[20] There was only 1 (0.5%) uterine rupture out of 220 women in the spontaneous group and 1 (0.9%) rupture in 115 women in the induction group. Of those that ended up with repeat caesarean delivery, 3 (10.3%) had evidence of scar dehiscence in the spontaneous group verses 5 (12.5%) in the induction group.

We present novel data, comparing the DBC to PGE2 for VBAC induction. There has been a randomised control trial (RCT) assessing 3mg Dinoprostone against DBC which recruited 10 women with a previous caesarean section into each arm of the study. Vaginal birth was achieved by 5 (50%) of women in the DBC arm and 4 (40%) in the PGE2 arm, and there were no admissions to the neonatal unit.[21] The numbers were too small to draw any conclusions about the effect of VBAC. Therefore, our study adds much needed data to help answer the question of superiority between these 2 commonly used and recommended methods of induction in VBAC.

We acknowledge the limitations of our study design and that the cohort numbers are not large enough to power for rare events such as uterine rupture and adverse neonatal outcomes. Therefore, we echo the on-going calls for the need for a sufficiently powered RCT to assess these agents in VBAC but stress how difficult this challenge is. In order to achieve appropriate power for a RCT to compare these methods in VBAC, using the primary outcome of uterine rupture, over 18,500 women would need to be recruited and randomised. This highlights the research challenge faced.

We suggest that either DBC or PGE2 could be offered for induction of labour for women attempting VBAC. We demonstrated no differences in the proportion of women having caesarean births for unsuccessful induction of labour or delay in the 1st stage of labour, suggesting the two methods are equal for the purpose of achieving induction of labour. This is further supported by no difference seen in the number of women who were unable to have an ARM performed or who needed oxytocin.

## Conclusion

Our data suggests broadly similar outcomes between DBC and PGE2 in VBAC induction of labour. Unfortunately, it is impossible to draw real conclusions about the superiority of either induction agent due to the retrospective nature and limited data available. We suggest that until clear evidence of benefit is available from appropriately powered RCTs that either PGE2 or DBC could be considered for VBAC induction after discussion with the woman as part of informed consent.

### Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Disclosure of interests

None

## Funding

None

## Contribution to authorship

AS conceived the study and design. JS and SB collected the data. SB conducted the analyses. SB and JS wrote the paper and AS commented on the drafts. All authors approved the final version for publication.

## Ethics

As this study involved analysis of existing anonymised data for service evaluation ethical approval was not required. Necessary hospital approvals were obtained.

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**Table 1. Demographic data and characteristics of women**

| | **DBC** (n=127) | **PGE2** (n=69) | **P value** |
|---|---|---|---|
| **Age** (years; mean, SD) | 31.2 (5.07) | 30.5 (5.27) | 0.36 |
| **BMI** (kg/m2; mean, SD) | 27.7 (6.08) | 28.6 (5.80) | 0.32 |
| **Ethnicity** | | | |
| White | 91 (71.7%) | 52 (75.4%) | 0.58 |
| Asian | 16 (12.6%) | 4 (5.8%) | 0.13 |
| Black | 13 (10.2%) | 8 (11.6%) | 0.76 |
| Other | 7 (5.5%) | 5 (7.2%) | 0.64 |
| **Parity** (median, IQR) | 1(1-2) | 1 (1-2) | 0.67 |
| **Gestational age at delivery** (weeks; mean, SD) | 38.9 (1.36) | 38.7 (1.72) | 0.37 |
| **Previous vaginal births** | 58 (45.7%) | 31 (44.9%) | 0.91 |
| **Previous vaginal birth after caesarean section** | 20 (15.7%) | 15 (21.7%) | 0.30 |
| **Indication for Previous Caesarean Section** | | | |
| Unsuccessful Induction of Labour | 13 (10.2%) | 6 (8.7%) | 0.74 |
| 1st Stage Delay | 15 (11.8%) | 3 (4.3%) | 0.08 |
| 2nd Stage Delay | 5 (3.9%) | 3 (4.3%) | 0.89 |
| Malpresentation | 17 (13.4%) | 11 (15.9%) | 0.63 |
| Fetal Distress | 34 (26.8%) | 13 (18.9%) | 0.21 |
| Fetal Growth Restriction | 2 (1.6%) | 0 (0%) | 0.29 |
| Multiple Pregnancy | 0 (0%) | 1 (1.5%) | 0.18 |
| Hypertensive Disease | 2 (1.6%) | 2 (2.9%) | 0.54 |
| Placenta Praevia | 5 (3.9%) | 1 (1.5%) | 0.33 |
| Maternal Reason | 1 (0.8%) | 2 (2.9%) | 0.26 |
| Fetal Abnormality | 0 (0%) | 0 (0%) | 0.76 |
| Cord Prolapse | 1 (0.8%) | 0 (0%) | 0.45 |
| Unknown | 32 (25.2%) | 27 (39.1%) | **0.04** |
| **Indication for Induction of Labour** | | | |
| Maternal Reason | 49 (38.6%) | 19 (27.5%) | 0.12 |
| Reduced Fetal Movements | 13 (10.2%) | 10 (14.5%) | 0.37 |
| Prolonged Pregnancy | 14 (11.0%) | 5 (7.2%) | 0.39 |
| Small for Gestational Age/Fetal Growth Restriction | 16 (12.6%) | 7 (10.1%) | 0.60 |
| Diabetes | 16 (12.6%) | 9 (13.0%) | 0.94 |
| Hypertensive Disease | 4 (3.1%) | 3 (4.3%) | 0.66 |
| Other | 15 (11.8%) | 16 (23.2%) | **0.04** |

| | | | |
|---|---|---|---|
| **Bishop Score Prior to Induction of Labour** (mean, SD) | 3.5 (1.56) | 3.3 (2.50) | 0.49 |

*SD = Standard Deviation, IQR = Inter Quartile Range*

**Table 2: Induction of labour outcomes**

| | **DBC** (n=127) | **PGE2** (n=69) | **Relative Risk (95% CI); P value** |
|---|---|---|---|
| **Unable to Perform ARM** | 1 (0.8%) | 2 (2.9%) | 0.27 (0.03 – 2.94); 0.28 |
| **Oxytocin Commenced** | 81 (63.8%) | 38 (55.1%) | 1.16 (0.90 – 1.49); 0.25 |
| **Epidural** | 44 (34.6%) | 18 (26.1%) | 1.33 (0.84 – 2.11); 0.23 |
| **Vaginal Birth** | 67 (52.7%) | 46 (66.6%) | 0.79 (0.63 – 1.00); 0.05 |
| *Assisted Delivery* | 14/67 (20.9%) | 9/46 (19.6%) | 1.07 (0.51 – 2.26); 0.86 |
| **Duration of Labour** (hr:min; mean, SD) | 05:28 (03:58) | 04:32 (03:30) | P = 0.20 |
| **Birth by Caesarean Section** | 60 (48.0%) | 23 (33.3%) | 1.42 (0.97 – 2.07); 0.07 |
| **Indication for Caesarean Section** | | | |
| Unsuccessful Induction of Labour | 7 (11.7%) | 5 (21.7%) | P = 0.25 |
| 1st Stage Delay | 31 (51.7%) | 10 (43.5%) | P = 0.51 |
| 2nd Stage Delay | 3 (5.0%) | 0 (0.0%) | P = 0.28 |
| Fetal Distress | 10 (16.7%) | 4 (17.4%) | P = 0.94 |
| Maternal Reason | 3 (5.0%) | 1 (4.3%) | P = 0.89 |
| Other | 6 (10.0%) | 3 (13.0%) | P = 0.70 |
| **Estimated Blood Loss** (ml; mean, SD) | 516.2 (394.34) | 544.8 (423.31) | P = 0.64 |

*CI = Confidence Interval, ARM = Artificial Rupture of Membranes, ml = millilitre, SD = Standard Deviation*

**Table 3: Neonatal outcomes**

| | DBC | PGE2 | Relative Risk (95% CI); P value |
|---|---|---|---|
| **Birth Weight** (grams; mean, SD) | 3277.3 (558.24) | 3317.4 (529.92) | P = 0.63 |
| **Apgar score <7 at 5 minutes** | 1/125 (0.8%) | 0/69 (0%) | 1.67 (0.07 – 40.37); 0.75 |
| **Umbilical artery pH <7.10** | 4/102 (3.9%) | 1/50 (2.0%) | 1.96 (0.23 – 17.09); 0.54 |
| **Admission to NICU** | 7/127 (5.5%) | 3/69 (4.3%) | 1.27 (0.34 – 4.75); 0.72 |

*SD = Standard Deviation, NICU = Neonatal Intensive Care Unit*