

OBSTETRICS

Prostaglandin vaginal gel induction of labor comparing amniotomy with repeat prostaglandin gel

Michael Beckmann, MBBS, FRANZCOG;
Sailesh Kumar, MBBS, FRANZCOG, CMFM, FRCOG, FRCS, PhD;
Vicki Flenady, RN, RM, MMedSci, PhD; Ellen Harker, MBBS

OBJECTIVE: The purpose of this study was to compare 2 inductions of labor protocols.

STUDY DESIGN: Women with live singleton pregnancies at $\geq 37 + 0$ weeks gestation who were booked for prostaglandins 2 (PGE₂) vaginal gel induction with a modified Bishop's score of < 7 were eligible for inclusion. After an evening dose of PGE₂ vaginal gel, women were assigned randomly the next morning into the amniotomy or repeat-PGE₂ group. The amniotomy group underwent artificial rupture of membranes (ARM), regardless of modified Bishop's score, and received further PGE₂ doses only if ARM was not technically possible. The repeat-PGE₂ group received further PGE₂ (to a maximum of 3 doses) until a modified Bishop's score ≥ 7 occurred, when an ARM was performed. In both groups, Syntocinon was commenced once membranes were ruptured. The primary outcome measure was time from commencement of induction until birth.

RESULTS: Two hundred forty-five women were assigned randomly into either the amniotomy ($n = 121$) or repeat-PGE₂

group ($n = 124$). The time for induction of labor—to-birth was > 5 hours shorter in the amniotomy group (24.8 vs 30.0 hours; mean difference, 5.2 h; 95% confidence interval, -2.5 to -7.8). Fewer women in the amniotomy group remained undelivered after 24 hours (47.1% vs 67.7%; $P < .01$). However, the likelihood of an in-hours birth and the length of hospital stay were no different between the groups. There was no difference in the mode of birth or any of the secondary outcomes.

CONCLUSION: After an initial dose of PGE₂ vaginal gel, an amniotomy (once technically possible) is associated with a shorter induction of labor—to-birth time compared with the use of repeat doses of PGE₂. Administering more PGE₂ with the aim of starting contractions or making the cervix "more favorable," appears to have no clinical advantage.

Key words: cervical ripening, induced labor

Cite this article as: Beckmann M, Kumar S, Flenady V, et al. Prostaglandin vaginal gel induction of labor comparing amniotomy with repeat prostaglandin gel. *Am J Obstet Gynecol* 2015;213:859.e1-9.

More than 25% of women now undergo induction of labor (IOL).¹⁻⁴ One of the most common methods of commencing an IOL is to use vaginal prostaglandin (PGE₂ vaginal gel)

then perform an artificial rupture of membranes (ARM) followed by a Syntocinon infusion.⁵ It is well-established that, in commencing an IOL, cervical priming of an unripe cervix is of value; however, if the woman is not in labor 6 hours after administration of PGE₂ vaginal gel, there is much variation in practice. Some clinicians give more PGE₂ vaginal gel and then perform an ARM once the modified Bishop's score is ≥ 7 ; others give no more PGE₂ vaginal gel and attempt an ARM, regardless of the modified Bishop's score. Proponents of giving more PGE₂ vaginal gel argue that the likelihood of failed IOL is lower, maternal satisfaction is higher, need for Syntocinon is reduced, and discomfort is less if the cervix is more favorable before ARM. Supporters of an "early ARM" approach believe that clinical outcomes are unchanged and that the IOL-to-birth

time is delayed unnecessarily by giving more PGE₂ vaginal gel. In the United States,³ Australia,⁶⁻⁹ and the United Kingdom,² clinical practice guidelines provide no evidence-based recommendations regarding subsequent dosage and frequency of PGE₂ vaginal gel for cervical priming. There is very little objective data of the value of repeated dosing of PGE₂ vaginal gel; the single randomized controlled trial that addressed this question reported no difference in the duration of induced labor or any clinical outcomes.¹⁰

This study investigated women who underwent IOL who had already received an initial dose of PGE₂ vaginal gel. The aim of this study was to determine whether there is advantage or disadvantage in continuing to administer more PGE₂ rather than perform an ARM, if technically possible.

From the Department of Obstetrics and Gynecology, Mater Health Services (all authors), and Mater Research Institute and the University of Queensland School of Medicine (Drs Beckmann and Kumar), Brisbane, QLD, Australia.

Received April 27, 2015; revised June 12, 2015; accepted July 29, 2015.

Supported by a \$30,000 seeding grant from the JP Kelly Foundation.

The authors report no conflict of interest.

Corresponding author: Michael Beckmann, FRANZCOG. Michael.Beckmann@mater.org.au

0002-9378/\$36.00

© 2015 Elsevier Inc. All rights reserved.

<http://dx.doi.org/10.1016/j.ajog.2015.07.043>

MATERIALS AND METHODS

A randomized controlled trial was undertaken at Mater Health Services Brisbane between March 2010 and August 2013. All women with live singleton pregnancies at or beyond 37 + 0 weeks gestation who were booked for IOL with the use of PGE₂ vaginal gel and with a modified Bishop's score <7 were considered eligible for inclusion in the study. Exclusion criteria included multiple pregnancy, previous cesarean delivery or other uterine surgery, major fetal congenital abnormality or fetal death, any contraindications to vaginal birth (eg, active genital herpes, major placenta praevia), maternal age <18 years, or inability to consent for whatever reason. The trial protocol was registered (ACTRN:12613000370707), and ethics approval was granted from the Mater Health Services Human Research Ethics Committee (Ref 1315M).

After an initial dose of PGE₂ vaginal gel in the evening (2 mg for nulliparous women, 1 mg for multiparous women), women were reviewed at approximately 6:00 AM the next morning. Immediately before their cervical assessment, participants were assigned randomly into either the amniotomy group or repeat-PGE₂ group. Women in the amniotomy group underwent ARM regardless of modified Bishop's score and received further doses (1 mg PGE₂, at 6-hour intervals, to a maximum of 3 doses) only if ARM by an experienced clinician was not technically possible at each review. Women who were assigned randomly to the repeat-PGE₂ group continued to receive further doses (1 mg PGE₂, at 6-hour intervals, to a maximum of 3 doses) until the modified Bishop's score was ≥7, at which time an ARM was performed. In both groups, a Syntocinon infusion was commenced as soon as the membranes were ruptured. The infusion was commenced at a rate of 1 mU/min and was increased in increments of 4 mU/min every 30 minutes to a maximum rate of 32 mU/min, until 3-4 contractions every 10 minutes were achieved. Active management of the third stage was used. The trial protocol is summarized in [Figure 1](#).

The primary outcome measure was the length of time from commencement

of IOL until birth. The *commencement of IOL* was defined as the time the first dose of PGE₂ was inserted. Secondary outcome measures included birth "in-hours," mode of birth, use of epidural analgesia in labor, need for broad-spectrum antibiotics in labor, admission of baby to nursery, postpartum hemorrhage, uterine hyperstimulation with fetal heart rate changes, women's experience and satisfaction with IOL, and duration of hospital admission. The concept of an "in-hours" birth was used as a measure of both the duration of induced labor and safety, recognizing the frequently reported association between evening/nighttime births and increased adverse perinatal outcomes.^{11,12} An "in-hours" birth was defined as a birth that occurred between 8:00 AM and 5:00 PM. *Uterine hyperstimulation with fetal heart rate changes* was defined as any event of excessive uterine activity (>5 contractions in 10 minutes)² at which time PGE₂ vaginal gel was removed from the vagina or acute tocolysis was administered. A combination of visual inspection by clinicians and weighing of pads/linen was used to estimate postpartum blood loss. Need for broad-spectrum antibiotics in labor was recorded as a surrogate marker of chorioamnionitis. The outcomes of women's experience and satisfaction with IOL are the subject of subsequent publication and are not reported here.

Randomization (1:1) into the 2 study arms was according to a computer-generated random allocation list. Sealed sequentially numbered opaque envelopes were prepared by Mater Medical Research Institute. At the time of the morning review after an initial dose of PGE₂ vaginal gel, the envelopes were opened by the midwife caring for the woman after confirming verbal consent. Given the nature of the intervention, it was not possible to blind either clinicians or women to their allocation.

Assuming a type-1 error of 0.05 and a power of 80%, a sample size of 125 women per group was calculated to detect a difference of 5 hours (20.5-15.5 hours) in the time from first dose of PGE₂ vaginal gel until birth. These assumptions were based on an unpublished clinical

audit that measured a change in policy at Mater Health Services from the use of a multiple-dose PGE₂ vaginal gel protocol to an early amniotomy protocol that was associated with a 5- to 6-hour reduction in the time from IOL to birth. Statistical analyses of primary and secondary outcomes were performed according to the intention-to-treat principle but have also been presented as-per-protocol. The chi squared tests, Fisher exact test, independent samples *t*-tests, and Mann-Whitney *U* tests have been used to compare categorical, categorical (small cell numbers), normally distributed, and nonnormally distributed continuous outcomes, respectively, with the use of StataSE software (version 10.1; StataCorp, College Station, TX). Comparisons were deemed statistically significant at a probability level of .05.

Overall, a protocol violation was identified in 39% of cases, with more protocol violations occurring in the repeat-PGE₂ group than in the amniotomy group (65 vs 36). Many protocol violations represented a delay to undertake a review or delay to commence Syntocinon. In the absence of an agreed standard, ">4 hours delay" was chosen as the discriminator as to whether a protocol violation had occurred ([Table 1](#)).

RESULTS

Between March 2010 and August 2013, there were 2057 women booked for PGE₂ vaginal gel IOL at Mater Health Services, Brisbane, Australia who were eligible for inclusion. Two hundred sixty-seven women were approached by the medical officer on the evening of their IOL, of whom 22 declined to participate. Sealed opaque envelopes were prepared, and 250 of the envelopes were opened. However, data were available for only 245 eligible women; it is not known the reason that these 5 additional envelopes were opened, which was not recognized until recruitment was ceased. Of the 245 women who were assigned randomly, 124 were allocated to the repeat-PGE₂ group and 121 to the amniotomy group. Outcome data were available for all 245 participants. The flow of participants is presented in the

Download English Version:

<https://daneshyari.com/en/article/6143861>

Download Persian Version:

<https://daneshyari.com/article/6143861>

[Daneshyari.com](https://daneshyari.com)