Observational Study of Neonatal Safety for Outpatient Labour Induction Priming with Dinoprostone Vaginal Insert

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Abstract

Objectives: To evaluate the safety of outpatient induction with dinoprostone insert in low-risk labour inductions for premature rupture of membranes or postdates gestation.

Methods: This retrospective cohort study compared outpatient labour induction priming with inpatient induction in terms of neonatal safety, mode of delivery, and obstetrical parameters. The sample included all inductions for premature rupture of membranes or postdate gestation. The analysis used logistic regression. The statistical power of the sample was 80% to detect a difference of 5.6% for the composite neonatal safety outcome (5-minute Apgar score <7 and NICU admission for >12 hours or transfer to a level III nursery).

Results: Compared with the inpatient cohort (n = 568), the outpatient cohort (n = 611) included more postdate gestations (93% vs. 67%) with less cervical dilatation (0.5 cm vs. 1.0 cm) and larger infants (3705 g vs. 3551 g). There were no differences in measures of neonatal safety or mode of delivery. The outpatient cohort required more dinoprostone inserts (1.59 vs. 1.23) and were less likely to deliver within 24 hours (OR 0.24, 95% CI 0.17 to 0.34) but were also less likely to deliver by CS (OR 0.71, 95% CI 0.54 to 0.95), after adjusting for obstetrical parameters.

Conclusion: An outpatient model of labour induction using dinoprostone inserts is feasible and safe.

Résumé

Objectifs : Évaluer l'innocuité du recours aux insertions vaginales de dinoprostone pour induire un déclenchement artificiel du travail en cas de rupture prématurée des membranes ou de grossesse après terme chez des patientes externes dans un contexte de faible risque.

Méthodologie : Cette étude de cohorte rétrospective a comparé le déclenchement artificiel du travail chez des patientes externes et des patientes hospitalisées sur le plan de l'innocuité néonatale, du mode d'accouchement et des paramètres obstétriques. Ont été inclus dans l'échantillon tous les déclenchements attribuables à une rupture prématurée des membranes ou à une grossesse après terme. Une analyse de régression logique a été utilisée. L'étude avait une efficacité statistique de 80 % et a permis de détecter un écart de 5,6 % dans les résultats combinés relatifs à l'innocuité néonatale (indice d'Apgar à 5 minutes <7 et admission à l'UNSI pendant >12 heures ou transfert vers une pouponnière de niveau 3).

Résultats : Comparativement à la cohorte de patientes hospitalisées (n = 568), la cohorte de patientes externes (n = 611) a été associée à un plus grand nombre de grossesses après terme (93 % c. 67 %), à une dilatation cervicale plus faible (0,5 cm c. 1,0 cm) et à des bébés plus lourds (3 705 g c. 3 551 g). Aucune différence n'a été observée sur le plan de l'innocuité néonatale et du mode d'accouchement. Les patientes externes ont eu besoin d'un plus grand nombre d'insertions vaginales de dinoprostone (1,59 c. 1,23) et étaient moins susceptibles d'accoucher en moins de 24 heures (RC : 0,24; IC à 95 % : 0,17–0,34), mais aussi d'accoucher par césarienne (RC : 0,71; IC à 95 % : 0,54–0,95), après un ajustement pour tenir compte des paramètres obstétriques.

Conclusion : Un modèle de déclenchement artificiel du travail chez les patientes externes au moyen d'insertions vaginales de dinoprostone est réalisable et sûr.

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The induction of labour is a well-established means of decreasing perinatal morbidity for both maternal and neonatal indications. Prostaglandins and oxytocin are the commonly used agents.[1] Yet the success of an induction is dependent on the characteristics of the cervix. Consequently, induction methods that prime the cervix are preferable, including mechanical dilatation and prostaglandins.[2] The safety of these approaches balances different parameters,

which for prostaglandins include uterine hyperstimulation with potential fetal compromise.[3–5] A variety of delivery methods for prostaglandins are described, including dinoprostone inserts (Cervidil; Ferring Pharmaceuticals, Saint-Prex, Switzerland), which continuously release 10 mg of dinoprostone at a rate of 0.3 mg/hour.[6–8] This delivery method allows for prompt removal with rapid resolution of hyperstimulation. Even though studies show no difference in the rates of hyperstimulation compared with other delivery methods, the rapid removal may confer a safety advantage related to rapid reversal.[5]

The ease of removal of the dinoprostone insert opens the possibility of a patient removing it herself if she perceives hyperstimulation. This potential for patient intervention supports the concept of induction priming outside the hospital. In 2009, we published a retrospective cohort study comparing outpatient dinoprostone inserts to inpatient induction in low-risk patients.[9] There were no serious complications or differences in neonatal outcomes. Yet the study left unanswered questions about efficacy and safety. Recent systematic reviews of outpatient labour induction noted feasibility and high maternal satisfaction but insufficient data to quantify adverse events.[10–12]

To address this gap, we decided to revisit our prior work. To maximize assessment of neonatal safety, we sought to increase the sample size while improving generalizability through consistency of indication for induction of labour. The most common indications in our previous study (60%) were postdate gestation and premature rupture of membranes at term. Dinoprostone is an evidence-based approach for both indications.[13,14] Consequently, the objective of this investigation was to assess the safety and effectiveness of outpatient induction with dinoprostone inserts in low-risk inductions for PROM or postdates gestation.

METHODS

This investigation was a retrospective cohort study carried out at St. Paul's Hospital, a tertiary maternity unit in Vancouver. The Research Ethics Board of the Providence Health Research Institute, an affiliate of the University of British Columbia Research Ethics Board, approved the investigation (H10-01048). Based on our prior study, we estimated a composite neonatal safety outcome of approximately 15%.[9] Assuming a clinically significant absolute difference in this outcome of 5%, the necessary sample size was 1160 to achieve 80% power with an alpha level of 0.05. The study sample was drawn from all women undergoing induction of labour between July 1, 1998, and March 31, 2012, for the following two indications: PROM at term gestation or postdate gestation at >41 weeks. Eligible patients were identified in the discharge database using the code "induction of labour." Patients were added to the study sample if they met study inclusion and exclusion criteria based on the chart audit of identified records. Inclusion criteria included singleton gestations >37 weeks that were induced using dinoprostone vaginal insert for indications of PROM or postdate gestation (>41 weeks' gestation). Exclusion criteria included multiple gestations, prior CS, and preadmission intrauterine fetal demise. Because the inclusion period for this study overlapped that of our prior study, 793 patients in this study were also reported in the prior study.[9] This includes 387 inpatients (240 postdate and 147 PROM) and 406 outpatients (371 postdates and 35 PROM).

Trained research abstractors collected data from the electronic medical records. All pregnancies and deliveries in British Columbia are captured in the Perinatal Data Registry, a quality controlled database that uses a standardized data entry form with defined clinical parameters. Research abstractors drew data points from these forms with augmented data from the remainder of the chart. All data were entered directly into an electronic database. To ensure data quality, we performed a 10% re-abstraction.

Neonatal safety was the primary outcome of interest. We analysed 5-minute Apgar score <7 and NICU admission for >12 hours or transfer to a level III nursery. We also created a composite neonatal safety outcome that included 5-minute Apgar score <7 and NICU admission >12 hours or transfer to level III nursery. During the early part of the study period, the authors' institution admitted all infants delivered by CS to the NICU during the mother's recovery. Excluding these healthy neonates was the basis for the 12-hour cutoff for NICU admissions. Secondary outcome measures included length of induction; mode of delivery; and more specific interventions, including the number of dinoprostone inserts used, epidural use, and oxytocin use. We also created a dichotomous variable, delivery within 24 hours of the first dinoprostone insert.

St. Paul's Hospital is an inner city hospital, serving an ethnically and economically diverse population. It is a teaching hospital associated with the University of British Columbia, and the obstetrical unit has provincial designation as a level III maternity centre with approximately 1800 deliveries per year. There is a level II nursery that provides care for babies >32 weeks' gestation. Family doctors, midwives,

ABBREVIATION

PROM premature rupture of membranes