Title:

Off-label use of dinoprostone in women after 3 deliveries or more: efficacy and safety

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OBJECTIVE: The major risk factor for intrapartum uterine rupture is a previous cesarean delivery. This study aimed to ascertain the rate of uterine rupture in a trial of labor after cesarean section in women with and without prior vaginal birth

STUDY DESIGN: Electronic medical records of trials of labor after one previous cesarean section between the years 2003-2015 were reviewed. We included singleton deliveries at $\geq$24 weeks with vertex presentation.

The rate of uterine rupture among women who had at least one prior vaginal delivery was compared with the rate among women with no prior vaginal delivery. Multivariable analysis was used to control for confounders

RESULTS: A total of 9489 women underwent trial of labor after a cesarean section; 5752 (60.6%) of them had a prior vaginal birth. The risk for uterine rupture was 0.2% in the presence of a previous vaginal delivery versus 1% without a history of a prior vaginal delivery (p<0.001). Women with a prior vaginal delivery had a risk of uterine rupture that was one fifth that of women without a previous vaginal delivery (OR= 0.19; 95%CI 0.09- 0.38).

Women who previously delivered vaginally underwent labor induction more frequently (11.3 vs. 7.6%, OR 0.64, 95% CI 0.56-0.73, p<0.0001) and were significantly less likely to be delivered by cesarean in the index pregnancy (13.2 vs. 39.4%, OR 5.6, 95% CI 5.05-6.23, p<0.0001) than women who had not delivered vaginally.

Maternal hemorrhage, peripartum hysterectomy, fetal intrapartum fetal death and neonatal admission to the NICU did not differ significantly between the two groups.

Logistic regression modeling was used to control for possible confounders. Variables entered into the model included previous vaginal delivery, maternal age, gestational age at delivery, epidural administration, gestational diabetes melitus, labor induction, birth weight, and prolonged second stage of labor. When controlling for confounders only previous vaginal delivery remained statistically significant

CONCLUSION: Among women undergoing a trial of labor after cesarean section, women with a history of a prior vaginal delivery have a significantly lower risk for uterine rupture than women without a previous vaginal delivery. Therefore, a trial of labor after one cesarean section can be encouraged in the presence of a prior vaginal birth

778 Off-label use of Dinoprostone in women after 3 deliveries or more: efficacy and safety

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OBJECTIVE: According to the manufacture instructions, a history of 3 deliveries or more is a contraindication for the use of dinoprostone vaginal insert for induction of labor. The aim of this study was to determine the efficacy and safety of labor induction with dinoprostone slow release vaginal insert in women with history of 3 deliveries or more.

STUDY DESIGN: A retrospective cohort study of all pregnant women who underwent induction of labor with dinoprostone slow release vaginal insert in single tertiary care center. The study group included women with history of 3 deliveries or more and the control group included women with history of 2 vaginal deliveries or less. Insertion-to- delivery time, the rate of delivery within 24 hours, as well as the rates of Cesarean section, maternal and neonatal complication

were determined in both groups. Non-parametric statistics were used for analysis.

RESULTS: During the study period, 449 women were admitted for induction with dinoprostone slow release vaginal insert. Thirty three (7.3%) had $\geq$3 deliveries and 416 (92.7%) had less than 3 deliveries at admission. There were no significant differences in the median gestational age, BMI, GCT, birth weight and in the rate of chronic hypertension and gestational diabetes mellitus. As expected, maternal age was higher in the study group compared to controls (median 36; IQR 31-37 years vs. 31; IQR 28-36 years, respectively, p=0.001). Cervical dilatation was also greater in the study group compared to controls (1; IQR: 0-1.5 cm vs. 0; IQR: 0-1 cm, respectively, p=0.004).The insertion-to-delivery time was significantly shorter in the study group compared to controls (15.9; IQR: 9.4-34.5 hours vs. 28.8; IQR:15.9-47.9 hours, respectively, p=0.02). Similarly, the rate of delivery within 24 hours was also higher in the study group compared to controls (66.7% vs. 46.9%, respectively, p=0.03). There was no significant differences between study and control group in the rate of Cesarean section (12.1% vs. 18%) instrumental delivery (7.7% vs. 0%) or Apgar score. Regression analysis revealed that cervical dilatation (p=0.27) but not parity was significantly associated with insertion-to-delivery interval after adjustment for fetal head station, maternal age and birth weight.

CONCLUSION: Dinoprostone slow release vaginal insert is an efficient and safe method for induction of labor in women who had more than three deliveries.

779 National implementation of a decision aid/ prediction model on practice variation, VBAC and adverse outcome

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OBJECTIVE: In the Netherlands about 66% of the women with one prior caesarean starts a trial of labor. However, this varies from 46-94% and a negative relation between TOL and actual VBAC is observed. This large practice variation was irrespective of individual risk profiles. In the SIMPLE II we showed that a decision aid with a prediction model resulted in a shift from unplanned to planned CS without an effect on the VBAC rates. The aim of this implementation study is to study practice variation in vaginal birth after caesarean after nationwide implementation of the decision aid including a validated prediction model. Secondary outcome is the adverse outcome rate.

STUDY DESIGN: A multicentre cohort study was performed in 30 Dutch hospitals before (2013) and after (2017-2018) the introduction of the patient decision aid. A total of 1500 women with one prior caesarean section without a contraindication for a trial of labour were included.

RESULTS: Overall the practice variation reduced after the implementation of the patient decision aid. A reduction with a factor 1.5 was seen for planned CS rate (p=0.351). The practice variation for vaginal birth reduced with a factor 1.9 (p=0.125). The variation in unplanned CS rate was reduced with a factor 1.55 (p=0.351). Table 1 shows mode of delivery and complication rates before and after the introduction. There was no significant difference in amount of women with a TOL (66.3% vs 61.5% (p=0.082), but the number of women with VBAC reduced from 48.3% to 41.% (p=0.012).