Induction of labour : Foley catheter revisited

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SUMMARY

Prostaglandin analogues for induction of labour in women with an unfavourable cervix were introduced in the 1980s without good evidence of superiority over older methods, such as Foley catheter. The aim of this thesis was to investigate the use of Foley catheter as an induction agent in women with an unfavourable cervix at term, compared to pharmacological methods, mainly PGE2.

Chapter two describes the methods of induction of labour used in the Netherlands in 2010, before the PROBAAT study was finalised. We conducted a nationwide enquiry to investigate the methods of labour induction in women with and without a prior caesarean birth. We conducted a postal survey in all Dutch hospitals with a labour ward. The questionnaire contained questions concerning cervical ripening and induction of labour. We compared this survey to a similar Dutch survey conducted in 2006.

In 2010, prostaglandins were the preferred methods for cervical ripening in women without a prior caesarean delivery in all Dutch hospitals. Mechanical methods were used more often than in 2006, but only as a secondary method in women without prior caesarean.

Use of mechanical methods in women with a prior caesarean had increased rapidly between 2006 and 2010, with almost ¾ of Dutch hospitals using Foley catheter as a primary method for cervical ripening in these women. This corresponded with a decrease of prostaglandin use and elective repeat caesarean sections in women with prior caesarean birth with an indication for induction in the subsequent pregnancy.

Chapter three presents a systematic review and meta-analysis of studies comparing mechanical methods for induction of labour, including Foley catheter, to pharmacological methods, placebo or no intervention. The review includes 71 randomised controlled trials (39-588 women), with a total of 9722 women. We found that induction of labour using mechanical methods results in similar caesarean section rates as prostaglandins, for a lower risk of hyperstimulation. When compared with vaginal PGE2 preparations, a vaginal instrumental delivery is less often needed. Mechanical methods do not increase the overall number of women not delivered within 24 hours, however the proportion of parous women who did not achieve vaginal delivery within 24 hours was higher when compared to vaginal PGE2. Serious maternal and neonatal morbidity were infrequently reported and did not differ between the groups.

Compared with oxytocin, mechanical methods reduce the risk of caesarean section.

In Chapter four the results of the PROBAAT trial are presented. This was an open-label multicentre randomised controlled trial comparing Foley catheter to vaginal PGE2 gel for induction of labour in term women with an unfavourable cervix. Between February 2009 and May 2010, 824 women were allocated to either Foley catheter (n=412) or vaginal PGE2 gel (n=412). We found comparable caesarean

section rates for both methods. After induction with a Foley catheter, the overall number of operative deliveries for suspected fetal distress was lower, fewer mothers were treated with intrapartum antibiotics, and significantly fewer neonates were admitted to the neonatal ward. Induction with a Foley catheter seemed to cause less uterine hyperstimulation and post-partum haemorrhage, but this association was not statistically significant. The time from the start of the intervention to birth was longer when a Foley catheter was used than with prostaglandin E2 gel. A meta-analysis of similar studies, using comparable dosing regimen of PGE2 gel, showed no difference in caesarean section rates, and less hyperstimulation and post-partum haemorrhage in the Foley catheter group. We found no statistical difference in the umbilical-cord pH between the two groups when our results were pooled with earlier studies. We concluded that Foley catheter does not reduce the risk of caesarean section, but secondary outcomes are in favour of the Foley catheter, and therefore it should be considered as a primary method for induction of labour in term women with an unfavourable cervix.

In Chapter five, the results of a randomised controlled trial (PROBAAT-M) and meta-analysis of studies comparing Foley catheter to vaginal misoprostol are described. This small randomised controlled trial was conducted parallel to the PROBAAT study. In the same period as the PROBAAT study was conducted, we randomized women to Foley catheter (n=56) versus 25 mcg vaginal misoprostol tablets (n=64) (4-hourly). We found that caesarean delivery rates and vaginal instrumental deliveries were not different, but more caesarean deliveries were performed for failure to progress in the first stage after induction with a Foley catheter. When using a Foley catheter the time from start of induction to birth was significantly longer, and oxytocin augmentation was more often required. Maternal and neonatal secondary outcomes, including post partum haemorrhage and pH <7.10, did not differ significantly between the groups. In meta-analysis we found that Foley catheter compared to 4 hourly vaginal administration of 25 mcg misoprostol yields comparable caesarean delivery rates, reduced rates of vaginal instrumental deliveries and reduced hyperstimulation rates. Based on this we conclude that, despite the longer interval to birth, Foley catheter has some benefits over vaginal misoprostol.

Chapter six handles the comparison of Foley catheter versus 10 mg slow-release PGE2 inserts. This randomised controlled trial (PROBAAT-P) and meta-analysis of studies was also conducted parallel to the PROBAAT trial. We analysed 226 women, 107 received a Foley catheter and 119 inserts. Caesarean section rates were comparable. Secondary outcomes, including the time from the start of induction to birth, showed no differences. We observed no serious maternal or neonatal morbidity. Meta-analysis with two comparable studies confirmed a similar caesarean section rate, and showed fewer cases of hyperstimulation when a Foley catheter was used.

Chapter seven displays the data of an economic analysis and cost-effectiveness of Foley catheter and PGE2 gel. This cost-effectiveness study was conducted

alongside the PROBAAT study and handles, next to the main cost effectiveness question, different scenarios in which women are admitted to the antenatal ward or monitored as out-patient during ripening. Foley catheter and PGE2 gel inductions were found to generate comparable cost. However, Foley catheter induction resulted in less neonatal admissions and asphyxia/post-partum haemorrhage compared to prostaglandin induction, for an acceptable cost. In a scenario where Foley catheter is used in an outpatient setting, costs could be substantially reduced in favour of the Foley catheter, by reducing the time spent in the labour ward.

In Chapter eight a model for predicting caesarean birth in nulliparous women induced with an unfavourable cervix is presented. This model was a secondary analysis of the three PROBAAT studies (PROBAAT, PROBAAT-M and PROBAAT-P). We prospectively evaluated which combination of maternal, antenatal and pregnancy characteristics predicts the risk of emergency caesarean delivery best. After predictors were found to be associated with caesarean section in univariable analysis ($p<0.50$) the predictors of the multivariable logistic regression model were identified using backward selection. BMI, maternal height, maternal age, and gestational age were independent predictors for caesarean section. The model showed good calibration and moderate discrimination. After external validation, the model could be helpful in counselling of individual patients about their risk of emergency caesarean section after induction.

Chapter nine is a systematic review and meta-analysis of studies comparing different methods of cervical ripening and labour induction in women with a prior caesarean birth. In these women, induction of labour poses greater risks, including uterine rupture, than spontaneous labour or repeat caesarean section. For women who have had a previous caesarean delivery and who require induction of labour in a subsequent pregnancy, it is unclear which method of cervical ripening and labour induction is preferable. Two small randomised trials were included in the review, one of which was terminated prematurely due to safety concerns of uterine rupture. The available evidence from randomised controlled trials relating to methods of induction of labour for women with a prior caesarean section is inadequate, the available studies are underpowered to detect clinically relevant differences in the primary and secondary outcome.

Although data from randomised controlled trials are limited, lower quality data are available from prospective observational studies. The risk of uterine rupture, and subsequent maternal and neonatal morbidity is found to be significantly higher after induction with prostaglandin E2, when compared to spontaneous labour. The risks associated with misoprostol are less well documented; several case reports indicate an increased risk of uterine rupture. Induction using a Foley catheter is found to hold a lower risk than prostaglandins, one that is comparable to the risk after induction with favourable cervix, or even spontaneous labour.

Based on the information presented in the review, we conclude that there is insufficient information from randomised trials to base our clinical decision on. As

randomised trials are not likely to be undertaken, due to the outcomes of prior randomised trials, we propose large prospective cohort studies to help us find the answer to the question of how to induce women with prior caesarean who require cervical ripening.

The studies in this thesis demonstrate that Foley catheter yields similar caesarean section rates compared to vaginally administered prostaglandins, making both methods equally effective. Findings from RCTs and meta-analysis in this thesis show reduced side effects with Foley catheter, with comparable costs that could be further reduced in favour of Foley catheter when used in outpatient setting. This makes Foley catheter a superior method, with potential for outpatient cervical ripening, cervical ripening in low-resource settings, and cervical ripening in women with prior caesarean birth.