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## **Induction of labour : Foley catheter revisited**

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# 7

## COST-EFFECTIVENESS OF INDUCTION OF LABOUR AT TERM WITH A FOLEY CATHETER COMPARED TO VAGINAL PROSTAGLANDIN E2 GEL (PROBAAT TRIAL)

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## ABSTRACT

**Objective:** To assess the economic consequences of labour induction with Foley catheter compared to prostaglandin E2 gel.

**Design:** Economic evaluation alongside a randomised controlled trial.

**Setting:** Obstetric departments of one university and 11 teaching hospitals in the Netherlands.

**Population:** Women scheduled for labour induction with a singleton pregnancy in cephalic presentation at term, intact membranes and an unfavourable cervix; and without previous caesarean section.

**Methods:** Cost-effectiveness analysis from a hospital perspective.

**Main outcome measures:** We estimated direct medical costs associated with healthcare utilisation from randomisation to 6 weeks postpartum. For caesarean section rate, and maternal and neonatal morbidity we calculated the incremental cost-effectiveness ratios, which represent the costs to prevent one of these adverse outcomes.

**Results:** Mean costs per woman in the Foley catheter group ( $n = 411$ ) and in the prostaglandin E2 gel group ( $n = 408$ ), were €3297 versus €3075, respectively, with an average difference of €222 (95% confidence interval –€157 to €633). In the Foley catheter group we observed higher costs due to longer labour ward occupation and less cost related to induction material and neonatal admissions. Foley catheter induction showed a comparable caesarean section rate compared with prostaglandin induction, therefore the incremental cost-effectiveness ratio was not informative. Foley induction resulted in fewer neonatal admissions (incremental cost-effectiveness ratio €2708) and asphyxia/postpartum haemorrhage (incremental cost-effectiveness ratios €5257) compared with prostaglandin induction.

**Conclusions:** FC and PGE2 labour induction generate comparable costs.

## INTRODUCTION

In 20–30% of all deliveries labour is induced for a variety of reasons, including hypertensive disorders, post-term pregnancy, intrauterine growth restriction and elective reasons.<sup>1-3</sup> A substantial proportion of women in whom labour is induced require cervical ripening because of an unfavourable cervix at the start of induction. Due to the large number of inductions, cervical ripening leads to substantial healthcare costs. Methods available for cervical ripening include administration of prostaglandin E<sub>1</sub> (misoprostol), prostaglandin E2 preparations (Prostin<sup>®</sup>, Cervidil<sup>®</sup>, Propess<sup>®</sup>) and mechanical methods such as sweeping of membranes and insertion of a Foley catheter.<sup>4-7</sup>

Prostaglandin E2 analogues were introduced in the 1980s, unfortunately without appropriately powered randomised controlled trials to prove their efficacy and safety. Nevertheless, vaginal application of prostaglandins has become a commonly used induction method in many industrialised countries, as it increases the likelihood of vaginal delivery within 24 hours.<sup>8</sup>

We recently performed a randomised trial on term induction of labour using a Foley catheter compared with prostaglandin E2 gel in women with an unfavourable cervix under the acronym PROBAAT.<sup>9</sup> This study showed a nonsignificantly higher rate of caesarean section after induction with a Foley catheter compared with induction of labour with prostaglandins. However, there were fewer operative deliveries due to fetal distress, a decreased need for maternal antibiotics during labour and fewer admissions to the neonatal ward. A meta-analysis including the PROBAAT trial and similar trials indicated significantly less hyperstimulation and postpartum haemorrhage (PPH) after induction with a Foley catheter.<sup>9-11</sup> Time to delivery was longer when a Foley catheter was used for cervical ripening.

The WHO induction guidelines recommend induction with a Foley catheter as one of the first-line methods, and the number of Foley inductions is increasing.<sup>12</sup> Despite the high frequency of labour induction and the recommendation of Kelly et al.<sup>13</sup> in their Cochrane review to incorporate cost analyses into trials investigating induction of labour, little is known about the economic consequences of different methods of induction.<sup>8,13,14</sup> To our knowledge evidence on the economic consequences of labour induction with a Foley catheter is lacking. Prostaglandin E2 gel itself is more expensive than a Foley catheter: on average €78 versus €14 per induction. Moreover, Foley catheter induction had favourable secondary outcomes in terms of fewer neonatal admissions, PPH and asphyxia compared with prostaglandin E2 gel induction, but longer admission time on the labour ward because of the relatively slow progression to active labour and birth. We therefore compared induction of labour using a Foley catheter with induction using prostaglandin E2 gel in an economic evaluation.

## METHODS

### Study design

The economic evaluation was conducted alongside the PROBAAT trial. This trial was a randomised controlled trial that compared induction of labour with a Foley catheter and induction of labour with vaginal prostaglandin E2 gel in pregnant women at term with an unfavourable cervix (Netherlands Trial Register NTR1646).<sup>9</sup> The protocol was approved by the Ethics Committee of the Academic Medical Centre in Amsterdam (MEC 08/310).

The PROBAAT trial was conducted in one academic and 11 nonacademic hospitals in the Netherlands. Pregnant women at term ( $\geq 37$  weeks of gestation) scheduled for induction of labour with a vital singleton pregnancy in cephalic presentation, intact membranes and an unfavourable cervix (Bishop score  $< 6$ ) were eligible for participation. Women younger than 18 years, with a previous caesarean section, a placenta praevia, a lethal fetal congenital anomaly or hypersensitivity for one of the products used for induction were excluded. After written informed consent, women were randomly allocated to either induction of labour with a Foley catheter or induction with vaginal prostaglandin E2 gel in a 1:1 ratio. Analyses were performed according to intention to treat. For further details we refer to the publication of the PROBAAT trial.<sup>9</sup>

The primary outcome, caesarean section rate, was comparable in both groups (23% versus 20%, relative risk [RR] 1.1, 95% confidence interval [95% CI] 0.87–1.5). Secondary outcomes were operative deliveries (caesarean section, vacuum or forceps extraction), maternal and neonatal morbidity and duration from start of induction to birth. Fewer operative deliveries for fetal distress were observed (12% versus 18%, RR 0.68, 95% CI 0.49–0.95), and fewer neonates were admitted to a neonatal ward (12% versus 20%, RR 0.60, 95% CI 0.43–0.83) after induction with a Foley catheter, and fewer mothers were in need of antibiotic treatment during labour (1% versus 3%, RR 0.36, 95% CI 0.32–1.36). Time to delivery was longer when labour was induced with a Foley catheter (median 29 hours [interquartile range 15–35] versus median 18 hours [interquartile range 12–33],  $P < 0.001$ ). A meta-analysis that combined the PROBAAT trial with other studies showed comparable caesarean section rates, with less hyperstimulation and less PPH ( $> 1$  l) after induction with a Foley catheter.

### Economic evaluation

For the cost analysis we used data from 819 of the 824 randomised women. In the Foley group 411 women were available for analysis, one woman was lost to follow-up. In the prostaglandin E2 gel group 408 women were available for analysis, after exclusion of three women because of a gestational age  $< 37$  weeks or a Bishop score  $> 6$  at randomisation. There were no other missing values for the primary clinical outcome. All but one (pH) of the secondary outcomes had  $< 1\%$  missing.

The economic evaluation was designed as a cost-effectiveness analysis, with caesarean section as the clinical outcome.<sup>15,16</sup> In line with the interpretation of the

results of the clinical study, where comparable caesarean section rates were found for Foley and prostaglandin induction, secondary outcomes have become more relevant for clinical decision making and were therefore also evaluated as clinical outcomes in this analysis. A hospital perspective was used, including effects and direct medical costs until 6 weeks postpartum only. Discounting of costs was unnecessary because all costs occurred within 1 year.<sup>15</sup>

## Resource use

Resource use was collected in the Case Record Form, and measured in the antenatal delivery and postpartum phases. In the antenatal phase, we documented admission time from randomisation to transfer to the labour ward. For the delivery phase and the postpartum phase, we included maternal and neonatal admissions (labour room, ward, and medium, high and intensive care), induction material, oxytocin for augmentation, medication use (antibiotics, tocolytics and pain medication), epidural and spinal anaesthetics, fetal blood sampling, mode of delivery, perineal lacerations, manual removal of the placenta and blood transfusion. Times of start of induction, rupture of membranes and start of active labour were also noted.

7

## Unit costs

Unit costs were estimated with different methods and sources, all according to recent guidelines on costing of healthcare services (Table 1).<sup>17</sup> All costs were expressed in 2009 euros and inflated where appropriate using the consumer pricing index.<sup>18</sup>

Unit cost estimates were retrieved from the financial department of one participating academic hospital and one participating nonacademic hospital. For maternal and neonatal admissions we used the unit costs per day admission reported by the Dutch costing guideline, and subtracted the costs that did not apply for our population (top-down approach). Costs for neonatal admission to the maternity ward were included in costs for the maternal admission. For time spent in the labour room and operating theatre, costs per hour were based on estimates of staff time, use of materials and overheads during a standard delivery (bottom-up approach).

Obstetric procedures were counted and valued separately to allow differentiation in associated costs between both induction groups. These included analgesia, third-stage delivery procedures such as suturing tears, manual removal of the placenta (top-down approach), vaginal instrumental delivery, fetal blood sampling and induction method (bottom-up).<sup>17</sup> Medication prices were obtained from the Dutch Pharmacotherapeutic Compass.<sup>19</sup>

## Analyses

Analyses were by intention to treat. Differences in resource use were tested using the nonparametric Mann–Whitney *U* test. Costs were calculated by multiplying the quantity of resource use and unit costs. Mean and median total costs per woman were calculated for the total trial period and split for the three delivery phases.

**Table 1.** Cost-analysis: units of resource use, unit costs, valuation method and volume source (2009 €)

	Unit	Unit cost	Valuation method (source)
<b>Admission mother</b>			
Ward*	day	359	Top-down calculation
Medium care*	day	545	Top-down calculation
ICU*	day	1,741	Top-down calculation
<b>Admission child</b>			
Maternal Ward*	day	359	Top-down calculation
Medium Care*	day	545	Top-down calculation
High Care*	day	1,461	Top-down calculation
Neonatal Intensive Care*	day	1,513	Top-down calculation
<b>Specialist care</b>			
Gynaecologist	hour	72	Dutch costing guideline <sup>16</sup>
Neonatologist	hour	72	Dutch costing guideline <sup>16</sup>
Paediatrician	hour	72	Dutch costing guideline <sup>16</sup>
<b>Other health care providers</b>			
Midwife	hour	35	Dutch costing guideline <sup>16</sup>
Home care	hour	33	Dutch costing guideline <sup>16</sup>
Nurse	hour	32	Dutch costing guideline <sup>16</sup>
<b>Induction methods</b>			
Oxytocin	gift	1	Dutch Pharmacotherapeutic Compass <sup>18</sup>
Prostaglandin E2 gel	gift	42	Dutch Pharmacotherapeutic Compass <sup>18</sup>
Foley catheter	unit	5	Dutch Pharmacotherapeutic Compass <sup>18</sup>
<b>Medication</b>			
Tocolysis**	gift	48	Dutch Pharmacotherapeutic Compass <sup>18</sup>
Antibiotic treatment during labour**	dose / day	32	Top-down calculation
Other medication during labour**	dose / day	2	Dutch Pharmacotherapeutic Compass <sup>18</sup>
Transfusion	gift	201	Dutch costing guideline <sup>16</sup>
<b>Analgesics during labour</b>			
Pethidine / Phenergan / Nubaine**	gift	3	Dutch Pharmacotherapeutic Compass <sup>18</sup>
Epidural/ Spinal**	procedure	167	Top-down calculation
<b>Delivery</b>			
Labour room*	hour	84	Bottom-up calculation
Theatre*	hour	145	Bottom-up calculation
Fetal blood sampling	procedure	16	Top-down calculation
CTG	procedure	30	Top-down calculation
Instrumental attempt	procedure	18	Top-down calculation
Episiotomy/Tear repair	procedure	18	Top-down calculation
Grade 4 tear/manual evacuation placenta	procedure	165	Top-down calculation
Vaginal delivery (total)	procedure	1,101	Top-down calculation

\*the mean of the unit cost for an academic hospital and a general hospital is presented

\*\*the mean of several methods /medication is presented



Costs were combined with the clinical outcomes by calculating incremental cost-effectiveness ratios (ICER). An ICER was defined as the ratio of the difference in costs and the difference in effectiveness between two interventions, which reflects the costs needed to obtain one extra unit in health outcome. We calculated ICERs for caesarean section rate, neonatal medium care/intensive care admission, postpartum haemorrhage and asphyxia. In this analysis the ICERs reflect the costs needed to prevent one caesarean section, one neonatal admission or one case of neonatal asphyxia or postpartum haemorrhage by using the Foley catheter.<sup>15,20</sup> Statistical uncertainty around the difference in mean costs and ICERs was expressed with 95% CI, estimated by 1000 bootstrap replications. Bootstrapping is based on generating multiple data sets using sampling with replacement from the original data and calculating the statistic of interest, in each set.<sup>20</sup> Uncertainty of the ICERs was visualised by plotting the cost-effectiveness plane and cost-effectiveness acceptability curves.<sup>21</sup>

Time spent in the labour room was calculated as the interval between admission to the labour room and birth, with addition of 1 hour recovery care. The costs of a caesarean section were estimated as the costs of 1 hour in the operating theatre, because the duration of occupation of the theatre was not documented.

### Sensitivity, scenario and subgroup analysis

The robustness of our findings was evaluated in multiple sensitivity analyses. In seven univariate models we examined the influence of assumptions and unit costs estimates, especially in ward occupation and neonatal admissions, as in these two the main cost differences were expected. Models 1 and 2 assessed the impact of expenses for personnel on labour room and operating theatre by varying time spent in labour room or operating theatre by midwives, residents and gynaecologists. Models 3 and 4 estimated cost differences in an academic and a nonacademic setting. In model 5 overall delivery costs were calculated using a top-down method. In model 6 we included extra costs for neonatal admissions in the maternal ward.

Additionally we performed three scenario analyses to evaluate the impact of reducing labour room occupation. In model 7, we assumed that all women are immediately admitted to the labour ward. In model 8, we assumed that after application of the Foley catheter or prostaglandin E2 gel women were admitted to the antenatal ward instead of the labour ward until active labour or rupture of membranes, while monitoring fetal condition and uterine activity. Model 9 examined a scenario in which all low-risk pregnant women (no growth restriction, no hypertension, no structural defects) were discharged to home with a 12-hourly control visit in the hospital after insertion of the Foley catheter.

Finally, we performed all these analyses *post hoc* in nulliparous and parous women separately. All statistical, economic and simulation analyses were performed using SPSS version 18.0 (Chicago, IL, USA) and MICROSOFT EXCEL 2003.

## RESULTS

### Resource use

Appendix S1 (see Supporting Information) presents average volumes of resources used and total costs in each group. In the Foley catheter group 96% of the women were induced with a Foley catheter, 9% received additional prostaglandin and 86% received oxytocin during labour. In the prostaglandin group all women were induced with prostaglandin, 1% received an additional Foley catheter and 59% received oxytocin. In the Foley induction group women spent more time in the labour room (mean 25.1 versus 20.8 hours,  $P < 0.001$ ), but neonates spent less time in medium/high care (0.51 versus 0.80 days,  $P < 0.001$ ). Other differences in resource use were insignificant.

### Costs

A summary of mean and median costs per woman is presented in Table 2. In the antepartum period the mean cost difference per woman was -€11. During delivery,

Table 2. Costs per woman (2009 €)

	Foley catheter (n = 411)		Prostaglandin E2 gel (n = 408)	
	Mean	Median (IQR)	Mean	Median (IQR)
Admission before ROM/active labour (ripening)	1,343	768 (415 – 1947)	1,106	637 (390 – 1473)
Admission after ROM/ active labour (delivery)	866	796 (569 – 1085)	754	678 (402 – 990)
Labour room (total)	2,097	1635 (966 – 2889)	1,736	1317 (786 – 2313)
Induction material	14	5 (5 - 14)	76	84 (42 - 84)
Medication during labour (incl. FBS)	87	26 (1 - 168)	86	18 (1 - 168)
Instrumental attempts and/or caesarean section*	35	0 (0-18)	31	0 (0-18)
Cost made in third stage delivery	64	18 (0 - 18)	60	18 (0 - 18)
Total delivery	2,409		2,112	
Maternal admission and home-care	602	540 (0 - 967)	613	563 (0 - 968)
Neonatal admission	286	0 (0 - 0)	350	0 (0 - 0)
Total postpartum	888		963	
Total direct medical costs	3,297		3,075	
Differential mean cost**				222
(95% CI)#				-157 to 633

IQR Interquartile range

ROM rupture of membranes

FBS fetal blood sampling

\*extra costs

\*\*Foley catheter minus Prostaglandin E2 gel

#non-parametric confidence interval based on 1000 bootstrap

more costs were generated in the Foley catheter group, mainly because of longer stays in the labour room (difference: €293). Costs related to the induction material favoured the Foley catheter group (difference: –€64). In the postpartum period, the mean cost difference per woman was –€71, especially due to medium care admissions (difference: –€115). The difference in costs for neonatal intensive care (€58 on average per induction) was predominantly generated by one neonate in the Foley group staying on the intensive care unit for 23 days, generating exceptionally high costs. Other substantial differences in costs were not found between the groups. Overall, when induced with a Foley catheter the mean costs per woman (€3297) were higher compared with induction with prostaglandin E2 gel (€3075), a difference of €222 (95% CI –€157 to €633), but the difference was not statistically significant.

### Cost-effectiveness

In combination with a small and nonsignificant difference in caesarean section rate in favour of prostaglandin E2 gel (23% versus 20%, RR 1.1, 95% CI 0.87–1.5), the ICER became negative (–€8759) and was therefore not informative. The findings based on probabilistic analyses reflect the combined uncertainty in cost

Table 3. Sensitivity and scenario analyses (2009 €)

Univariate sensitivity analyses					
Model	Description	PGE2	Foley	Diff	95% CI
0	Base case	3,075	3,297	222	-157 633
1*	Higher labour room (€166) and operation room (€290) costs	4,816	5,396	580	-9 1,198
2*	Lower labour room (€41) and operation room (€73) costs	2,185	2,223	38	-247 351
3*	Top-down calculation delivery	2,543	2,420	-123	-386 163
4*	Additional costs for neonate on maternal ward	3,464	3,780	316	-56 722
5*	All maternal admissions valued by using academic unit costs	3,656	3,830	174	-276 672
6*	All maternal admissions valued by using general unit costs	2,984	3,253	269	-81 630
Scenario analyses					
Model	Description	PGE2	Foley	Diff	95% CI
7*	Admission to labour ward from moment of induction	3,398	3,699	301	-48 682
8*	Admission to antenatal ward (+ CTG) until ROM/active phase	2,187	2,201	14	-261 350
9**	Outpatient induction and admission to labour ward in high risk pregnancies	3,075	2,313	-762	-1,075 -442

\*Scenario calculated in both arms

\*\*Scenario only calculated in Foley catheter induction arm

and effectiveness estimates, and are presented in the cost-effectiveness plane and cost-acceptability curves.

In the probabilistic analysis, 1000 random samples were drawn from our data set, and the resulting costs and effects were estimated for that sample. Each point in the cost-effectiveness plane represents the additional costs and health gain of Foley induction compared with prostaglandin induction (Figure 1). The ICER estimates for caesarean section rate are mainly located in the upper left quadrant (health loss is obtained at additional costs). However, the scatter spreads over all four quadrants, around the origin, indicating that our trial did not show significant differences in caesarean section rate (x-axis) and in costs (y-axis). In the cost-effectiveness plane, ICER estimates for neonatal admission and the composite outcome PPH/asphyxia are mainly located in the upper right quadrant (health gains are obtained at an additional cost). The cost to prevent one neonatal admission in the Foley group was €2708. The costs to prevent one composite outcome PPH and asphyxia was €5257.

Whether Foley induction is considered cost-effective depends on the willingness-to-pay for these health gains. Cost-effectiveness acceptability curves visualise the increasing probability that Foley inductions are cost-effective for the measured effect when increasing the willingness-to-pay threshold (Figure 2).

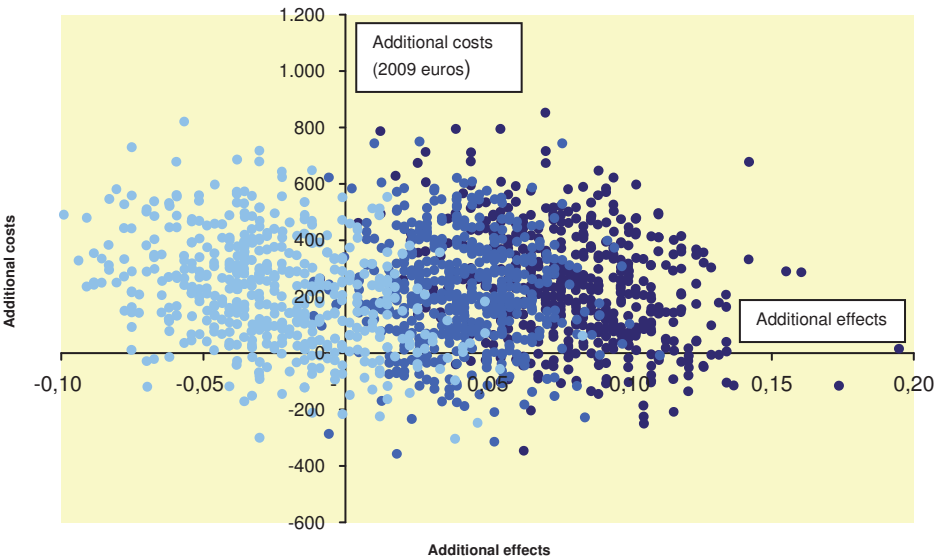


Figure 1. Cost-effectiveness plane. Each point in the cost-effectiveness plane represents the additional costs and health gain of Foley induction compared to prostaglandin induction (multiple samples from original dataset). Color represents clinical outcome measure:

- Caesarean section
- Composite PPH/asphyxia
- Neonatal medium/high care admission

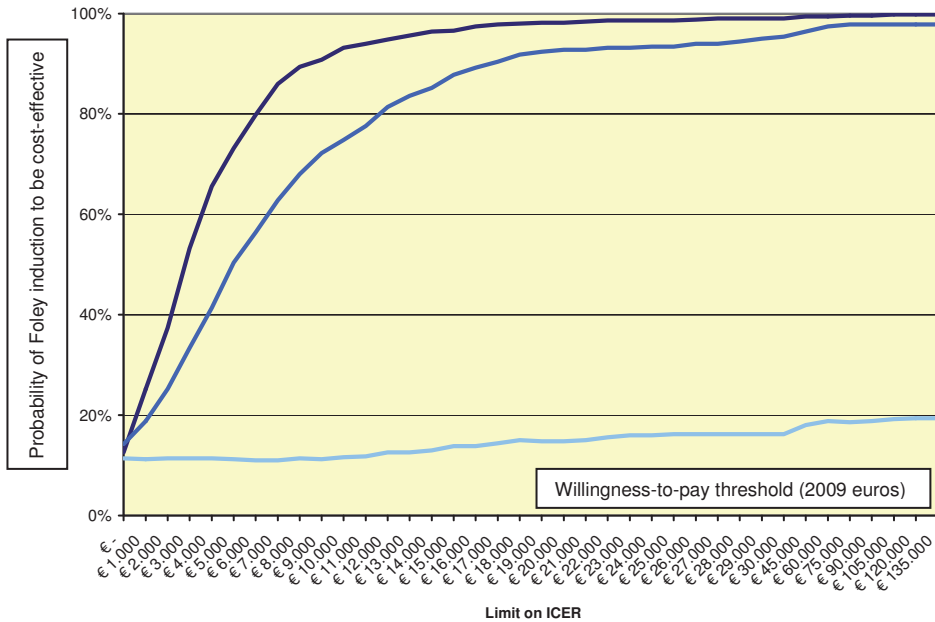


Figure 2. Cost-acceptability plot. Probability of Foley induction to be cost-effective for different clinical outcomes. The probability increases as result of an increase in willingness-to-pay. Color represents clinical outcome measure:

- Caesarean section
- Composite PPH/asphyxia
- Neonatal medium/high care admission

### Sensitivity, scenario and subgroup analysis

In Table 3 the results of the scenario and sensitivity analyses are shown. If labour room costs are increased from €80 to €115 and operating theatre costs from €140 to €224 per hour, then the difference would increase to €580 (95% CI –€9 to €1198), making prostaglandin E2 gel less costly (model 1). When assuming different unit costs in the models 2 to 6, the estimated differences in mean costs in favour of prostaglandin E2, gel remain small and insignificant.

Admission directly to the labour ward at start of induction (model 7) increased the mean costs in both groups, but more so in the Foley catheter group. When we assumed that women stayed at the antenatal ward during cervical ripening, costs in both groups reduced and the difference between the groups almost disappears to €14 (95% CI –€261 to €350, model 8).

When we assume discharge to home for low-risk women after insertion of the Foley catheter (model 9), the difference in costs would be clearly in favour of Foley catheter induction (–€762; 95% CI –€1075 to –€442).

A *post hoc* subgroup analysis showed that the overall costs of induction with a Foley catheter and prostaglandin E2 gel are comparable in nulliparous women,

whereas induction with prostaglandin E2 gel was associated with lower costs in multiparous women (see Supporting information, Appendix S2), mainly because of shorter time-to-delivery costs.

## DISCUSSION

### Principle findings

This study assessed the cost-effectiveness of induction of labour at term using a Foley catheter compared with prostaglandin E2 gel. The analysis was performed from a hospital perspective alongside the PROBAAT trial. Our analyses showed that the mean costs per woman were not significantly higher in women induced with a Foley catheter compared with women induced with prostaglandin E2 gel (mean difference €222; 95% CI –€157 to €633). Costs differences predominantly originated from duration of labour ward stay. The induction material was less expensive in the Foley catheter group.

The primary clinical outcome, caesarean section rate, was comparable in both groups. The incremental cost to avoid one admission to the neonatal ward or PPH/asphyxia by using a Foley catheter instead of prostaglandin E2 for induction were acceptably low.

Sensitivity analyses demonstrated that when estimates for resource use and unit prices are varied, the difference between both induction methods would remain low. Only when cervical ripening in the Foley catheter group would be carried out in an outpatient setting, would the Foley catheter become less costly (difference –€762; 95% CI –€1075 to –€442).

### Strengths and weaknesses

Strengths of our study are the prospective randomised design of the trial and prospective registration of resource uses, its large sample size and the diversity of participating hospitals. As extensive sensitivity analyses and scenario analyses showed consistent results, we can conclude that the model is robust against the most influential uncertainties.<sup>15,20,21</sup> Different scenarios for reducing the time spent in the labour room provide opportunities for reducing costs.

The study has also several limitations. First, cost-effectiveness analyses were performed for multiple clinical outcomes, in line with the presentation of the clinical results.<sup>9</sup> This provides insight into the ICERs of these outcomes separately, but makes it more difficult to interpret the results simultaneously. A common solution to deal with results from multiple outcomes/dimensions is to use an aggregate health metric such as the quality-adjusted life-year (QALY). Several conceptual points need to be taken into consideration. First, implications of caesarean section and vaginal delivery on future QALY measures are controversial, and may be valued differently by raters from different groups or countries. Furthermore we have to combine QALYs from mothers and newborns because the nature of intervention influences both, but there is little evidence on how this can be achieved. Finally, a QALY-

based analysis probably should incorporate a long-term (lifetime) perspective. At present, long-term outcomes—clinical as well as QALYs—are generally not incorporated in studies evaluating perinatal interventions.<sup>22</sup>

To facilitate studies such as the PROBAAT trial that address this long-term perspective, a systematic approach is advocated to developing prediction models to extrapolate short-term outcomes to a long-term horizon.<sup>23</sup>

Despite the short time horizon of the trial, we can speculate on the long-term impact on costs. After the index admission, medical costs are generated by healthcare utilization, as well as informal care and productivity loss (societal costs). Foley catheter induction results in less neonatal and maternal morbidity directly postpartum, so this strategy is likely to generate less medical and societal costs after discharge, and so becomes more cost-effective in the long term.

7

### Relation to other studies

To our knowledge this is the first economic evaluation that prospectively compared induction of labour strategies. In addition to our base-case analysis, we put forward the thought of outpatient Foley induction. Outpatient prostaglandin induction has been applied in multiple studies, because of the potential benefits, such as patient preference and lower costs. However there has been concern about adverse outcomes because of hyperstimulation and outpatient prostaglandin induction is therefore not recommended.<sup>24</sup> Outpatient Foley induction has recently been studied in Australia. Outpatient Foley induction resulted in shorter hospital stay before birth, whereas total induction to delivery time was similar.<sup>25</sup> The effects on healthcare cost by introducing outpatient Foley induction seem promising in our sensitivity analysis.

### Meaning of the results

Since the increase of Foley inductions, concerns have been raised about the potential increased costs, as a doctor has to insert the catheter and the relative inertia of the method, leading to a longer induction time than when induced with prostaglandin E2 gel. Our analysis shows that there are no significant differences in costs between Foley induction and prostaglandin E2 gel induction. In our opinion, induction with Foley catheter should be the preferred method of induction, because of the favourable short-term outcomes, the clinical usefulness and the comparable costs between Foley catheter and prostaglandin E2. As unit costs were estimated using Dutch reference prices and our cost calculations were based on the practice in the Netherlands, country-specific prices and assumptions need to be considered before generalising these results to other countries.

### Proposal for future research

It seems that Foley catheter induction could be less expensive in an outpatient setting, while remaining safe. The viability of such practice should be confirmed by trials appropriately powered to detect differences in maternal and neonatal outcomes.

## CONCLUSION

Induction of labour with a Foley catheter as compared to induction with prostaglandin E2 gel generates comparable healthcare costs. Given the clinical benefits of induction with a Foley catheter, we advise it as the treatment of choice for induction of labour at term.

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COSTS OF FOLEY CATHETER AND PROSTAGLANDIN E2 INDUCTION

Appendix S1. (2009 €)

	Unit	Foley catheter (n = 411)				
		% patients using care	Mean volume*	Mean Volume**	Total Costs (€)	Mean Costs pp (€)
Admission because of labour	days	35.3%	0.89	0.31	38,368	93
Admission because of labour (MC)	days	0.5%	11.99	0.06	7,787	19
Induction material (cath)	gift	96.1%	1.16	1.12	2,287	6
Induction material (PGE2)	gift	8.8%	1.78	0.21	3,586	9
Pethidine	unit (dag)	17.8%	-	-	221	1
Epiduraal	unit (proc)	39.7%	-	-	31,391	76
AB durante partu	gift/dag	8.3%	1,64	0.14	1,771	4
Other med durante partu	gift/dag	12.9%	1.42	0.18	124	0
Tocolysis	gift	5.1%	-	-	1,009	2
Oxytocine	gift	85.9%	-	-	205	0
Fetal blood sampling	proc/dag	11.9%	-	-	762	2
Labour room	hours	100%	25.1	25.1	861,748	2097
Instrumental attempts + instrumental deliveries	unit	12.5%	-	-	899	2
Caesarean delivery	unit	22.7%	-	-	13,490	33
(sub)total ruptuur	unit	1.7%	-	-	1,154	3
Episiotomy	unit	27.5%	-	-	3,244	8
Manual delivery placenta	unit	0,2	-	-	14,809	36
Packet cells	unit	1.9%	4.38	0.09	7,035	17
Total delivery phase					989,890	2408
Maternal admission IC	days	0,0	0	0	0	0
Maternal admission MC	days	2.9%	4.17	0.12	17,703	43
Maternal admission ward	days	63.3%	2.81	1.78	227,606	554
Maternal Home care	days	0,0	2,92	0,05	1,840	4
Neonatal admission IC	days	0.7%	10.24	0.08	46,791	114
Neonatal admission HC	days	0.2%	0.71	0.002	1,058	3
Neonatal admission MC	days	11.9%	4.24	0.51	67,414	164
Neonatal admission Ward	days	0.7% (3)	2.65	0.02	2,667	7
Total postpartum and direct follow-up (admissions)					365,080	888
Total costs					1,354,970	3,297

\*Of patients using care

\*\*Of all patients

COSTS OF FOLEY CATHETER AND PROSTAGLANDIN E2 INDUCTION

% patients using care	Prostaglandine E2 gel (n =408)			Mean Costs pp (€)	Diff (FC-PR)
	Mean volume *	Mean Volume**	Total Costs (€)		
34.8%	0.83	0.29	49,700	122	-28
0.2%	0.00	0.003	452	1	18
1.0%	1.50	0.02	40	0	5
99.7%	1.87	1.86	31,985	78	-70
19.9%	-	-	249	1	0
39.7%	-	-	31,057	76	0
10.1%	1.29	0.13	1,678	4	0
10.3%	1.13	0.12	78	0	0
5.6%	-	-	1,105	3	0
58.6%	-	-	139	0	0
12.0%	-	-	762	2	0
100%	20.8	20.8	708,457	1736	360
13.9%	-	-	1,005	2	0
20.1%	-	-	11,895	29	4
1.4%	-	-	989	2	0
33.1%	-	-	3,403	8	0
0,2	-	-	12,834	31	5
3.7%	2.40	0.09	7,236	18	-1
			863,065	2115	293
0.07%	1.04	0.01	4,134	10	-10
3.7%	2.65	0.10	15,119	37	6
68.9%	2.66	1.81	228,853	561	-7
0,0	4,04	0,05	1,820	4	0
1.0%	3.74	0.04	22,782	56	58
0,0	0	0	0	0	3
20.8%	3.82	0.80	113,757	279	-115
1.3% (5)	3.46	0.04	5,152	13	-6
			391,618	960	-71
			1,254,683	3,075	222

**APPENDIX S2.** Subgroup analysis

Costs were comparable in nulliparous women, whereas in multiparous women induction with prostaglandin E2 gel was less costly

Parity	Foley catheter (n = 411)		Prostaglandin E2 gel (n= 408)	
	n	Costs (2009 €)	n	Costs (2009 €)
0	268	3,690	263	3,652
1	99	2,686	99	2,074
2	34	2,386	35	1,830
3	8	2,094	7	1,287
4	0	-	3	1,045
5	1	-	1	-
6	1	-	0	-



