European Journal of Obstetrics & Gynecology and Reproductive Biology 211 (2017) 150–155

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Full length article

Foley catheter for induction of labour filled with 30 mL or 60 mL: A randomized controlled trial

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ARTICLE INFO

Article history:
Received 16 June 2016
Received in revised form 14 February 2017
Accepted 16 February 2017

Key message:
No difference was seen regarding the effectiveness of induction of labour with a Foley catheter filled with 60 mL or 30 mL, but although underpowered, a higher rate of deliveries within eight hours after amniotomy was observed for multiparous and a significantly lower caesarean section rate for nulliparous

Keywords:
Induction of labour
Foley catheter
Delivery
Maternal outcomes
Neonatal outcomes

ABSTRACT

Objectives: One of the methods used to induce labour is the placement of a transcervical Foley catheter (FC). The aim of this randomized controlled study was to assess in term pregnant women with an unfavourable cervix, whether there is a difference in efficacy between the two most commonly used insufflation volumes of FC (30 mL and 60 mL).
Study design: Randomized controlled trial.
Results: Women were randomized to induction of labour with a Foley catheter filled with 30 mL or with 60 mL. Primary outcome was delivery within eight hours after amniotomy. Secondary outcomes included the time interval between placement of the Foley and amniotomy, the mode of delivery, complications and neonatal outcomes. In total, 174 women (87 in each arm) were randomized. The number of deliveries within eight hours after amniotomy was not significantly different between the two groups (40.7% versus 48.83%, OR = 0.71(CI; 0.39–1.3)). Sub-analysis showed that more multiparous women in the 60 mL group delivered within eight hours (93.10% versus 65.22%, OR = 7.2 (CI; 1.35–38.37)). For the nulliparous, the 30 mL Foley catheter was associated with a higher caesarean section rate (31.75% versus 15.52% (OR 2.53; CI; 1.1–6.2)). The 60 mL Foley catheter was also associated with a higher chance of spontaneous labour after placement (OR 2.35; CI; 1.1–5.1), a shorter time interval for cervical ripening (OR = 4.5; CI: 1.2–16.7) and less blood loss. (p = 0.002). The Foley catheter ruptured twelve times in the 60 mL group whereas this did not happen once in the 30 mL group. One case of umbilical cord prolapse was observed in the 60 mL group. No differences in neonatal outcomes and patient satisfaction were seen.
Conclusions: For our primary outcome, no difference was observed between the Foley catheter balloon filled with 60 mL and the one filled with 30 mL. Yet, a Foley catheter filled with 60 mL was associated in multiparous women with a higher rate of deliveries within eight hours after amniotomy and in nulliparous with a significantly lower caesarean section rate. These latest findings should be interpreted with cautious as underpowered.

Introduction

Induction of labour is a common obstetrical procedure: in 2010, 20.9% of all deliveries in the Netherlands were induced [1]. Compared to a spontaneous onset, induction of labour is associated with prolonged labour, more instrumental deliveries and a higher caesarean section rate [2,3]. As a result, it is important to ascertain which method of induction is the most effective and offers the best outcomes. Since the publication of the 'PROBAAT trial' in 2011 [4] the use of a transcervically placed Foley catheter (FC) to induce labour has increased dramatically [5]. That study reported a similar success rate of induction of labour with a FC filled with 30 mL compared to intravaginal prostaglandins, but with less maternal and neonatal side effects.

Embrey and Mollison first published the use of a FC for cervical ripening in 1967 [6]. Since then, various amounts of volume for insufflation of the balloon have been used and reported on. Most studies used 30 mL of normal saline to fill the balloon because it was thought that more volume would increase the balloon diameter only minimally and thus would not lead to any additional cervical dilatation. Contrarily, others believed that insufflation of the balloon up to 80 mL would not only enhance cervical dilatation but also would promote more endogenous prostaglandin

Abreviations: FC, Foley catheter.
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http://dx.doi.org/10.1016/j.ejogrb.2017.02.019
0301-2115/

secretion. Although some studies may suggest better outcomes with a FC with a high volume [7–9], the protocols used in those studies varied so much that it is near impossible to compare outcomes. As a result, we designed this randomized controlled study to evaluate, in term pregnant women with an unfavourable cervix, whether there is a difference in efficacy between low and high volume FC. As low volume, 30 mL was chose as most commonly used, for high volume, we chose 60 mL, based on the most recent RCT published on the topic [8].

Material and methods

The protocol of this trial was reviewed and accepted by the local institutional review board on 26th of November 2013 (METC Zuidwest Holland, number NL44078.098.13). The trial was registered in the Dutch clinical trial register (www.trialregister.nl, number NTR5578). Between 1 February 2014 and 1 January 2015, all term pregnant women in the Bronovo Hospital (teaching hospital) that met the inclusion criteria were asked to participate in the study. Inclusion criteria were: term pregnant women (> = 37 weeks) with an indication for induction of labour, an unfavourable cervix (Bishop score <6) [10], singleton pregnancy, vertex position and intact membranes. Exclusion criteria were pregnant women younger than 18 years, women with an allergy to latex, prior caesarean delivery or other contra-indications for induction of labour. During the outpatient visit where the date of induction was set, patients were given oral and written information by the doctor.

If patients agreed to participate, they were asked to sign the informed consent form. Women were then randomized to induction with a FC filled with 30 mL or with 60 mL. This was done using a randomization list to compute a sequential list, which corresponded to opaque, sequentially numbered envelopes which held the treatment method. These were opened at start of induction. Blinding of the volume inserted into the balloon was

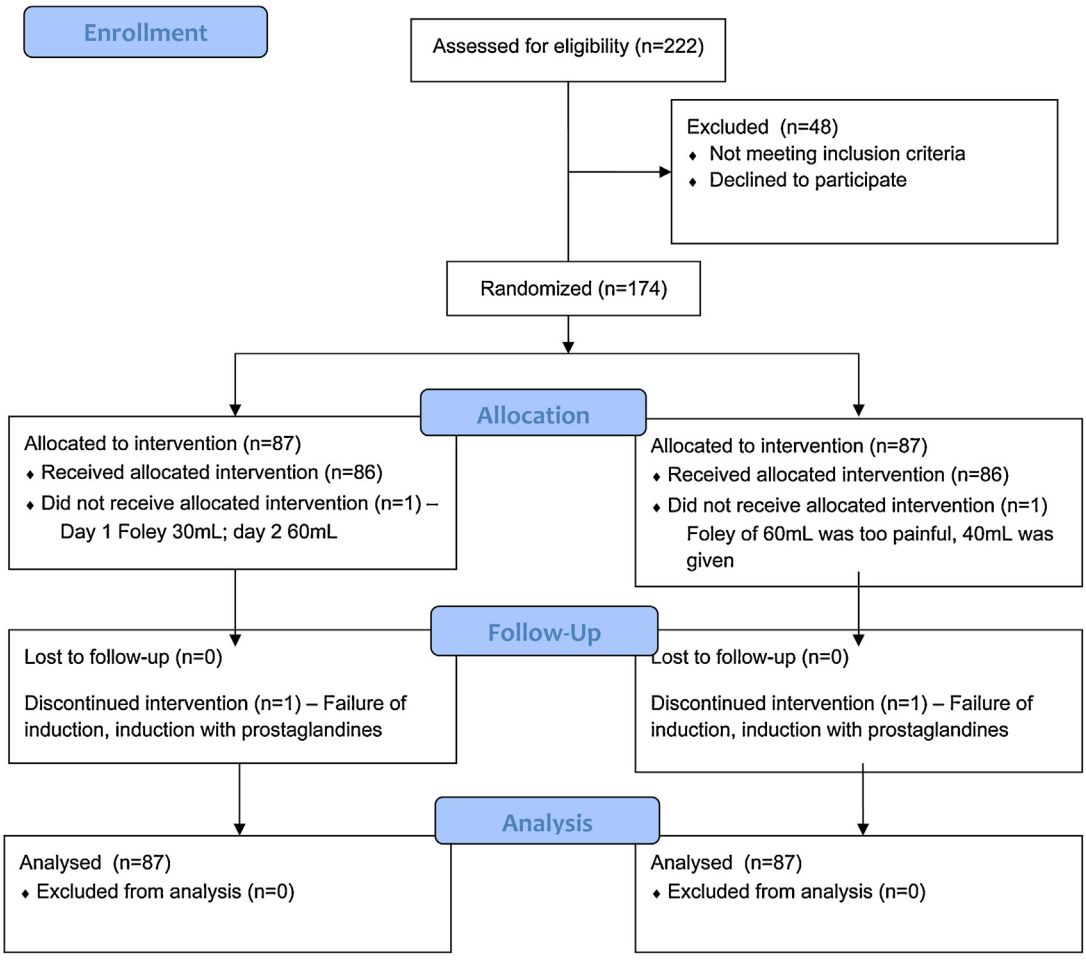

Fig. 1. CONSORT 2010 Flow Diagram.

not possible as it was logistically difficult to realize at our department. We accepted this as it was thought that because of the setup of the trial non-blinding was unlikely to exert influence on the outcomes.

The transcervical placement of the FC was performed according to local guidelines. A vaginal swab was taken to detect any vaginal infection as it was thought that this could affect outcome. No traction was applied to the balloon after correct placement was assured.

Amniotomy was performed after spontaneous expulsion of the FC or when the Bischop score was >6. If a patient was not in labour after the expulsion of the FC the attending staff was free to decide to postpone amniotomy when intact and to start oxytocin the following morning in order to facilitate 'day-time' delivery as much as possible. If the balloon was not expulsed spontaneously after 24 hours, the patient was re-examined the next morning, and, depending on the Bishop score, the decision was made to perform an amniotomy or to continue with the FC. If necessary, oxytocin was started one hour after amniotomy. If after two days the cervix was still not favourable, induction with FC was considered to have failed and the responsible gynaecologist decided on further management.

After delivery and before discharge all patients were asked to fill in a questionnaire about their experience during induction and labour. The questionnaire was self-developed and consisted of six questions and an open space for comments. A five-point Likert scale was used and a score of 4 or 5 was considered as a positive result.

The primary outcome of the study was the rate of deliveries within eight hours after amniotomy. We chose eight hours as the main outcome measure as we aimed for daytime delivery and tried mimic our normal practice as much as possible. Amniotomy was only performed with a Bishop score of at least six points, Secondary outcomes were the days of induction with FC, the number of spontaneous labour offset after FC placement, the number of ruptured FC, the cervical dilatation after FC expulsion, the use of oxytocin, the need of epidural analgesia, the mode of delivery, the time from amniotomy to delivery and the time of second stage, obstetric complications (e.g. umbilical cord prolapse, postpartum haemorrhage) and neonatal outcomes (e.g. Apgar score, meconium and umbilical artery cord gas). Sub-analyses were performed separately for primiparae and multiparae. Also, baseline characteristics of the included patients were extracted from the medical records.

Statistical analysis was performed using SPSS software (IBM SPSS Statistics for Windows, version 20.0, Chicago). The outcomes of the two groups were compared to each other using Wilcoxon rank-sum test, univariate regression analysis and Chi-square where appropriate. Analysis was done by intention-to-treat.

A power calculation to ascertain the required group size was performed based on the available literature [7–9]. Unfortunately, there is a scarcity of data on this subject which can be used to design a trial comparing Foley catheters for induction of labour with different volumes. Nevertheless, and to provide more data on the subject, we accepted it to be enough to base assumptions on and calculate sample sizes. Two groups of 87 women were needed to demonstrate an increase in deliveries from 45% to 66% within eight hours after amniotomy with a power of 0,8 and an alpha <0.05 (alpha error 5%, beta error 20%). Statistical significance was denied as a probability value of > 0.05.

Table 1
Baseline characteristics.

	Group with FC filled with 30 mL (n = 87)	Group with FC filled with 60 mL (n = 87)
Nulliparous	63 (72.4)	58 (66.7)
Multiparous	24 (27.6)	29 (33.3)
Para 1	19 (79.2)	22 (75.9)
Para 2	4 (16.7)	5 (17.2)
Para 3	1 (4.2)	1 (3.4)
Para 4	0	1 (3.4)
Gestational age	39.57 (1.43)	39.84 (1.40)
Age	32.51 (5.08)	32.93 (4.62)
BMI	25.20 (4.75)	23.88 (3.88)
Ethnicity		
Caucasian	69 (79.3)	68 (78.2)
Indian/Pakistani	5 (5.75)	5 (5.75
African	4 (4.6)	4 (4.6)
Mediterranean	8 (9.2)	8 (9.2)
Asian	1 (1.15)	2 (2.29)
Indication for induction of labour		
Post-date	23 (26.4)	29 (33.3)
Elective/other	14 (16.1)	23 (26.4)
Hypertension	18 (20.7)	14 (16.1)
Suspected foetal macrosomia	15 (17.2)	11 (12.6)
Suspected foetal growth restriction	11 (12.6)	8 (9.2)
Bishop 1 before Foley placement	2.16 (1.39)	2.10 (1.38)
Bishop 2 before amniotomy	4.69 (1.46)	4.73 (1.91)
Vaginal culture (N = 165)	(N = 81)	(N = 84)
GBS	7 (8.64)	9 (10.71)
Candida	19 (23.46)	12 (14.29)
Others[a]	1 (1.23)	7 (8.33)

All data are presented as mean (SD) or as number (percentages).
FC = Foley catheter; GBS – beta-hemolytic streptococ.

Results

Baseline characteristics of the included patients

During the study period 537 women were admitted for induction of labour. Of these, 222 women had a Bishop score of less than six and were potential candidates for the study. Forty-eight of them did not meet the inclusion criteria or declined participation. In total 174 women were included in the study and randomized to either a FC of 30 mL or 60 mL (Fig. 1). Three patients (two in the 60 mL group, one in the 30 mL) did not achieve enough cervical ripening after FC placement and subsequently received prostaglandins. In two women, the decision to induce with prostaglandins was made 24 hours after FC placement, as per judgment of the clinician on duty. In one woman, randomized to a 30 mL balloon, the balloon was changed after 24 hours against protocol to 60 mL because cervical ripening was deemed insufficient. One woman in the 60 mL group had a FC insufflated to only 40 mL as it could not be filled further due to pain.

In Table 1 the baseline characteristics of the two groups are shown. At baseline and after 24 hours of cervical ripening, no differences in Bishop scores between the two groups were observed.

Primary outcome: Delivery within 8 hours

No difference was seen between the groups for our primary outcome, the number of deliveries within eight hours after amniotomy (40.7% in the 30 mL versus 48.8% in the 60 mL group, OR = 0.71 (CI; 0.39–1.3), Table 2). Sub-analysis showed that multiparous women induced with a 60 mL FC delivered significantly more often within eight hours as compared to those induced with a 30 mL balloon (93.1% versus 65.2% versus, OR = 7.2 (CI; 1.35–38.37)).

Secondary outcomes

Table 2 further summarizes the delivery results. In the 30 mL group, 14% did not have a favourable cervix 24 hours after FC placement compared to 3.45% in the 60 mL group (p = 0.023). In the group with a FC of 60 mL, the balloon ruptured 12 times, whereas this did not happen once in the 30 mL group. Twenty-four women

Table 2
Induction and delivery results.

	Group with FC filled with 30 mL (n = 87)	Group with FC filled with 60 mL (n = 87)	OR 95% CI	P-value
Delivery within 8 hours after amniotomy	34 (40.47)	42 (48.83)	0.71 (0.4–1.3)	0.274*
Primiparae	19 (31.14)	15 (26.31)	0.79(0.35–1.76)	0.563*
Multiparae	15 (65.22)	27 (93.10)	7.2 (1.35–38.37)	0.021*
Days of induction of labour (days)				
0 or 1	74 (86.05)	84 (96.55)	4.54	0.023*
> 1	12 (13.95)	3 (3.45)	(1.23–16.71)	
Spontaneous labour before amniotomy	12 (13.79)	24 (27.59)	2.35 (1.09–5.07)	0.030*
Ruptured FC balloon	0	12 (13.85)		–
Oxytocin use during labour	85 (97.7)	80 (91.95)		0.168
Epidural analgesia	56 (65.12)	56 (65.12)		0.983
Delivery mode				
Vaginal delivery	66 (75.86)	76 (87.36)	2.19 (0.99–4.94)	0.054*
Spontaneous	51 (58.62)	60 (68.96)		
Ventouse	15 (17.24)	16 (18.39)		
Caesarean section	21 (24.14)	11 (12.64)		
Primiparae	20 (31.75)	9 (15.52)	2.53 (1.04–6.15)	0.040*
Multiparae	1 (4.17)	2 (6.90)	1.70(0.15–20.02)	0.672*
Caesarean section				
Indications Primiparae				036
Failure to progress (1)	16 (80)	4 (44.44)		
Nonreassuring foetal heart rate (2)	1 (5)	0		
(1) + (2) combined	1 (5)	5 (55.56)		
Failed ventouse	1 (5)	0		
Malpresentation	1 (5)	0		
Indications Multiparae				0.642
Failure to progress	1 (100)	1 (50)		
Umbilical cord prolaps	0	1 (50)		
Time interval amniotomy/delivery (hours)	09:18 (4:00)	08:23 (4:21)		0.163
Primiparae	10:06 (3:57)	10:21 (3:43)		0.723
Multiparae	07:09 (3:23)	4:32 (2:32)		0.003
Time 2nd stage of labour (hours)	00:37 (00:29)	00:49 (00:40)		0.047
Primiparae	00:46 (00:27)	1:03 (00:40)		0.02
Multiparae	00:18 (00:25)	00:23 (00:26)		0.509
Estimated blood loss (mL)	568.31 (471.91)	388.56 (251.21)		0.002
Complications				
>500 mL blood loss	30 (34.48)	16 (18.39)		0.016
Umbilical cord prolapse	0	1 (1.15)		–
Perineal tear grade 3 or 4	1 (1.15)	1 (1.15)		–

FC = Foley catheter; all data are presented as mean (SD) or as number (percentages).
* Results from univariate regression analyse.

(27.6%) went spontaneously into labour after placement a 60 mL FC compared to 12 (13.8%) in the 30 mL group (p = 0.03). No difference was seen with respect to oxytocin requirement (92% vs. 97.7%, p = 0.17). Sixty-five percent of the women had an epidural.

Concerning the mode of delivery, 75.9% of the women in the 30 mL group delivered vaginally, compared to 87.4% in the 60 mL group (OR 2.19 (CI; 0.99–4.90)). Nulliparous women induced with a 30 mL FC had a significant higher rate of delivery by caesarean section (31.8% versus 15.5%, OR 2.53 (CI; 1.04–6.15)). The most common indication for caesarean section was 'failure to progress' with or without a non-reassuring foetal heart rate pattern. For multiparous women, two had a caesarean delivery due to failure to progress (one in each arm) and one women in the 60 mL group had an umbilical cord prolapse after amniotomy for which an uncomplicated emergency caesarean section was carried out. This woman had had an induction of labour with a 60 mL balloon and because of a persistently unripe cervix after two days, prostaglandin vaginal gel was given. Of the two other women who were induced with prostaglandins, one had a vaginal delivery and one a caesarean section for failure to progress.

No difference was seen for the overall time between amniotomy and delivery. Though, sub-analysis for multiparae showed a significantly shorter time (7h09 min versus 4h32 min, p = 0.003). For those who delivered vaginally, the second stage of labour was significantly shorter in the 30 mL group (37 min vs. 49 min, p = 0.047).

The amount of blood loss was significantly lower in the 60 mL group (586 (471.91) vs. 388 (251.21)mL, p = 0.002). Also, a significant difference was seen between the two groups for haemorrhage of more than 500 mL (34.5% versus 18.4%). No differences were seen for neonatal outcomes (Table 3). The response rate to the postpartum questionnaire was 87.4% and no differences were reported between the groups (Table 4).

Discussion

Induction of labour with an FC has been shown to offer similar outcomes and several advantages compared to other techniques [4]. In most hospitals, the balloon is filled with 30 mL, though studies have demonstrated benefits of higher volumes [7–9,11]. In our study, no difference was found between the 30 mL and 60 mL groups for our primary outcome, delivery within eight hours after amniotomy. Sub-analysis for multiparous women showed a higher delivery rate within eight hours, leading to an overall shorter delivery time and less often need of oxytocin. For nulliparous women a lower rate of caesarean deliveries was observed in the group induced with a balloon filled with 60 mL. Additionally, induction of labour with a balloon of 60 mL was associated with a shorter time interval of cervical ripening, a higher chance of spontaneous labour and less blood loss. A presumed disadvantage of a high volume balloon is an increased risk of umbilical prolapse and malpresentation [7,8]. We encountered one case of umbilical cord prolapse after failed induction with a 60 mL balloon and subsequent use of prostaglandins. To assess the actual risk of these complications, more studies with higher numbers of participants will need to be performed. The balloon in the 60 mL group ruptured twelve times, an event that did not occur in the 30 mL group.

In contrast to other studies we did find differences in complication rates between the study groups [7–9,11]. Firstly, a higher rate of postpartum haemorrhage (> = 500 mL) in the 30 mL group was shown. The association between prolonged labour and/or caesarean section and increased blood loss could be speculated to be causal in the difference found. Secondly, our study showed a higher caesarean section rate for nulliparous women induced with a 30 mL balloon (31.8% vs. 15.5%) and compares surprisingly high to the national average. In 2010, the Dutch caesarean delivery rate for all women was 16.9% and for nulliparae 19.2% [15]. The reason for caesarean section in nulliparae was in 75% of the cases 'failure to progress' during the first stage of labour. Nine women (5.17%) did not progress to more than 4 cm of cervical dilatation. For those women, it can be questioned whether the cervix was favourable enough at amniotomy in the first place.

A limitation of our study is that patients and clinicians were not blinded to the volume used, potentially leading to bias. Additionally, interpretation of secondary findings needs to be done with caution, as the study was not powered for these outcomes. Given the small differences between the groups found in our study, one could argue whether the sample size was too small. The power calculation was based on the available scarce literature on the subject when the study was designed and at the time not deemed to be insufficient. A new trial on the subject would have to take our results into the sample size calculation. However, given our results, one could question whether such a trial would be of clinical importance when large numbers are needed to show a difference. Strengths of our study include its randomized controlled design and the no loss to follow-up.

To date four randomized controlled trials comparing the FC filled with 30 mL to 60 mL or 80 mL for induction of labour have been performed [7–9,11]. The results of three trials were summarized in a meta-analysis by Berndl et al. which concluded in favour of a high-volume balloon [12]. In contrast, one recently published randomized controlled trial found no difference in the effect of various balloon insufflation volumes or duration of placement (12 hours versus 24 hours) [11].

In all these studies the protocols adhered to were different and all, in turn, differed from the current Dutch national guideline. In the studies by Kashanian et al. and Levy et al., the FC was removed six or twelve hours after insertion, respectively, and oxytocin infusion was subsequently started regardless of cervical dilatation [7,9]. In the study by Delaney et al. oxytocin was started within 30 minutes after FC placement [8]. Gu et al. defined their primary endpoint as the number of deliveries within 24 hours after placement but in one of the arms the FC was left in place for 24 hours if labour did not ensue spontaneously, thus excluding

Table 3
Results neonates.

	Group with FC filled with 30 mL (n = 87)	Group with FC filled with 60 mL (n = 87)	P value
Birth weight (grams)	3650 (521.5)	3599,6 (469.8)	0.713
Meconium	7 (8.05)	7 (8.05)	1.000
pH umbilical artery	7,23 (0.09)	7,27 (0.07)	0.070
Base Excess umbilical artery	− 5,7 (2.96)	− 4,49 (2.80)	0.162
Apgar score			
1 min	8,9 (0.58)	9,07 (0.46)	0.292
5 min	9,71 (0.46)	9,90 (0.31)	0.084
10 min	9,91 (0.28)	10.00	0.117

FC = Foley catheter; all data are presented as mean (SD) or as number (percentages).

Table 4
Results from post-partum questionnaire.

	Group with FC filled with 30 mL	Group with FC filled with 60 mL	P value
Did patient feel she was well informed about the induction method?	70 (97.22)	77 (96.24)	1.000
Did patient experience in general pain with the FC?	32 (46.38)	42 (55.26)	0.32
Did patient experience pain during FC placement?	7 (9.86)	17 (21.79)	0.841
Did patient experience pain when urinating with FC in place?	5 (6.94)	11 (13.92)	0.193
Did patient experience pain during labour?	40 (57.14)	45 (56.96)	1.000
Were patients overall satisfied with the treatment?	68 (98.55)	74 (92.50)	0.091

FC: Foley catheter; all data are presented as number (percentages).

almost all these women from the primary outcome analysis. Our policy was to site the FC in the morning and to perform an amniotomy not before the following morning unless there was a reason to do so. An advantage of postponing amniotomy after expulsion of the balloon until the following day is that daytime delivery can be aimed for, which seems associated with better outcomes [13,14]. It can be questioned if a shorter interval of, for instance, 12 hours (by siting the balloon in the evening and aiming for amniotomy the following morning), would not yield similar outcomes. As in our study 96.6% of the women in the 60 mL group had a favourable cervix after 24 hours, the efficacy of a shorter placement to amniotomy interval needs to be addressed in future studies. A shorter priming time means a shorter hospital stay. This may not only lead to cost reduction but is likely to enhance patients' satisfaction as well. Many of our patients reported in the open section of the questionnaire that they experienced the waiting time before amniotomy as unpleasant and boring.

Conclusion

For our primary outcome, no difference was observed between a FC filled with 60 mL and 30 mL. Yet, a FC filled with 60 mL was associated in multiparous women with a higher rate of deliveries within eight hours after amniotomy and in nulliparous with a significantly lower caesarean section rate. Although the study was not powered for these outcomes, these results might be relevant and need to be studied further. On the other hand, women should be counselled about the increased risk of FC rupture in the 60 mL group.

Conflict of interest

None of the authors have conflicts of interests to disclose.

Funding

None.

Author Agreement

All authors have seen and approved the final version of the manuscript being submitted. All authors warrant that the article is the authors' original work, hasn't received prior publication and isn't under consideration for publication elsewhere.

Acknowledgements

We thank all the participants and the staff in the Bronovo Hospital that helped us complete this trial.

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