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Foley Catheter in cervical priming for induction of labour in University Obstetric Unit, Colombo, Sri Lanka: a clinical audit with a patient satisfaction survey

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AUTHORS' CONTRIBUTION: **(A)** Study Design · **(B)** Data Collection · **(C)** Statistical Analysis · **(D)** Data Interpretation · **(E)** Manuscript Preparation · **(F)** Literature Search · **(G)** Funds Collection

SUMMARY

Introduction. The Foley catheter has shown to be a safe, effective and relatively feasible mechanical method of cervical priming in induction of labour (IOL). We evaluated indications, effectiveness, patient acceptability and outcomes of Foley catheter practicing according to the ward protocol in our unit.

Matherial i Method. A clinical audit with a patient satisfaction survey conducted in University Obstetric Unit, Colombo, Sri Lanka. Patients selected for IOL for Obstetric reasons were offered with Foley as per ward protocol. All the women had singleton pregnancies with cephalic presentation, intact membranes and period of gestation of 37 weeks or above. However, women with a history of caesarean section or previous uterine surgery, low-lying placenta and suspected fetal compromise were excluded from the study. In patients who had a Modified Bishop score (MBS) of less than 3, a 16Fr Foley catheter was inserted into cervical canal. Patient satisfaction for Foley insertion was assessed with regards to the degree of discomfort using a visual analogue scale (0-10).

Results. Fifty six women were primed with Foley catheters. Gestational diabetes and post term were commonest indications. Thirty two (57.1%) were nulliparous. During induction of labour, 53(94.6%) reported mild or no discomfort. Median (IQR) duration of Foley-in-situ was 30(23-48) hours. In Foley catheter only cases had 5 Caesarian sections and 31 vaginal deliveries and Foley/ prostaglandin group had 7 Caesarian sections and 13 vaginal deliveries. Subjects who had Foley only have a lesser chance of getting a caesarean section compared to those subjects who had Foley followed by prostaglandin (Relative risk = 0.40, 95% CI = 0.15- 1.09, P = 0.09).

Conclusions. Foley catheter is a good choice for pre-induction cervical priming in our unit with high patient comfort and can safely be applied instead of prostaglandins.

Key words: induction of labour; mechanical ripening; Foley catheter; audit; Sri Lanka

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INTRODUCTION

Induction of labour (IOL) is defined as the process of artificially stimulating the uterus to initiate labour [1]. IOL is common obstetric procedure with rising rates worldwide. Sri Lanka has a rate of IOL of 37.5%, which is one of the highest rates in the world [2]. In the United Kingdom, the rate of IOL ranges from 6 - 25% with the average being about 20% [3]. In USA the average rate of IOL is approximately 13% [4]. IOL has a significant impact on the birth experience of women. IOL is indicated if benefits of delivery outweigh the risk of continuing pregnancy.

At present, different methods are used for IOL in women with an unfavourable cervix. Mechanical methods such as transcervical extra-amniotic Foley catheter (FC) insertion and pharmacological methods such as vaginal prostaglandins, misoprostol are used for IOL in women with an unfavourable cervix for pre induction cervical priming [5-7]. During recent decades these mechanical methods have been substituted by pharmacological methods [8]. Mechanical methods of induction were developed to promote cervical ripening and the onset of labour by stretching the cervix. They are amongst the oldest methods to initiate labour [8]. The method most commonly used to identify readiness for onset of labour is the modified Bishop score which includes quantitative measures of consistency and dilation of the cervix, and station and position of the presenting part [9].

Recent Cochrane review has concluded that IOL using mechanical methods such as FC results in similar caesarean section rates as prostaglandins and yields a lower risk of hyperstimulation with or without foetal heart rate changes compared to prostaglandins [8]. As well as, FC gives fewer maternal and neonatal side-effects in comparison with vaginal prostaglan-

dins [8]. When compared with oxytocin, mechanical methods reduce the risk of caesarean section [8]. Mechanical methods are as effective in achieving delivery within 24 hours of intervention as any prostaglandins [8]. In terms of caesarean section, they are equally effective and have less side effects [7,8,10]. According to the limited data available, there is no evidence of an increased risk of infectious morbidity with mechanical methods [8]. Therefore it's good to consider for limited-resource settings with relatively lack of monitoring facilities. Potential advantages of mechanical methods over pharmacological ones may include wide availability, lower cost and reduction of some of the side effects [8].

Prostaglandin preparations used for cervical ripening are expensive and unstable, requiring refrigerated storage [11,12]. In a Nigerian study, they have stated that in Nigeria feasibility to use prostaglandins is very limited largely due to itshigher cost and inadequate infrastructure to maintain the narrow temperature range to keep its potency [13]. In some developing countries, conventionally cheap and feasible method for pre-induction cervical ripening is transcervical FC [11]. In experienced hands it is a safe and reliable method. But many practitioners find it cumbersome, somewhat archaic and esthetically suboptimal.

This is a well-researched topic in published literature. However, data on patient satisfaction or patient preferences in induction of labour are sparse [8]. Only one study reported on patient satisfaction and discomfort associated with insertion and cervical ripening in single balloon catheter, prostaglandins and double balloon catheter using a visual analogue scale [14]. In designing the study, we focused more on acceptability and local applicability of FC in our unit. We conducted a prospective audit at a University Obstetric Unit in a major Teaching Hospital in Sri Lanka. This audit was conducted to evaluate the indications, effectiveness, patient acceptability and outcomes of FC in pre-induction cervical priming in our unit.

MATERIALS AND METHODS

A clinical audit with a patient satisfaction survey conducted prospectively between July and September in 2013 in University Obstetric Unit, De Soya Hospital for Women (DSHW), Colombo, Sri Lanka. Women selected for IOL for Obstetric reasons were offered IOL with FC according to the ward protocol as described below. This ward protocol was developed according to the latest guideline on IOL published by Sri Lanka College of Obstetricians and Gynaecologists (SLCOG).

Ward Protocol for cervical priming with Foley catheter.

1. Decision for IOL was made by a consultant obstetrician for obstetric necessity.
2. In women who had a Modified Bishop Score (MBS) of less than 3, a 16Fr FC was inserted under aseptic conditions into cervical canal, position confirmed with ultrasound and balloon inflated with 50 ml of water.
3. The catheter was left undisturbed until spontaneous expulsion or no longer than 48 hours.

The selection of patients for FC was not affected by this study. We prospectively audited how FC use occurs over 03 months period. All the women had singleton pregnancies with cephalic presentation, intact membranes and period of gestation of 37 weeks or above. However, women with a history of caesarean section or previous uterine surgery, low-lying placenta and suspected fetal compromise were excluded from the study. Once decision for IOL was made, the study was introduced to the eligible women and consecutive consenting study participants were included in the study. MBS in all cases were assessed and all the FCs were inserted by a medical officer, by author MP himself. FC used initially and if no progress after 48 hours prostaglandin was used. It means, in women with MBS of less than 6 at 48 hours, 3 mg prostaglandin E2 vaginal tablet was

Tab. 1. Demographic details of the study participants

Pacjentki n=56	
Study participants	**n (%)**
Parity-0	32(57,1)
Parity-1	15(26,8)
Parity-2	5(8,9)
Parity-3	3(5,4)
Parity-4	1(1,8)
Period of gestation (weeks)	
37-40 + 6 days	32(57,1)
41≥	24(42,9)
Age (years)	
≤ 20	6(10,7)
21–25	12(21,4)
26–30	22(39,3)
31–35	14(25,0)
35<	2(3,6)

used subsequently. Maximum of 2 tablets of prostaglandin E2 were inserted vaginally 12 hours apart where needed. Prostaglandin insertion is done after informed written consent from the pregnant woman. Artificial rupture of membranes with or without intravenous oxytocin was used if MBS of 6 or more and the women were not in labour.

Data on indications for IOL, duration of Foley in-situ, insertion of additional prostaglandins and whether the artificial membrane rupture and oxytocin used or not, outcome of IOL (vaginal delivery or Caesarian section), degree of discomfort as assessed by visual analogue scale, duration of labour and maternal and fetal/neonatal complications were obtained. Patient satisfaction for Foley insertion was assessed with regards to the degree of discomfort using a validated visual analogue scale (0-10). Visual analogue scale is a simple assessment tool consisting of a 10-point line with 0 on one end, representing no discomfort, and 10 on the

Tab. 2. General outcomes of the audit

Parity	Cervical priming with Foley catheter alone. (n=36) n(%)	Total vaginal deliveries including instrumental deliveries (with Foley catheter and Prostaglandin vaginal tablets) (n=44) n(%)	Number of vaginal deliveries in Foley catheter only cases (n=31) n(%)	Average duration of Foley catheter-in-situ in hours (SD)	Average discomfort scoreaccording to 1-10 visual analogue scale (SD)
Parity-0	21(58,3)	26(59,1)	18(58,1)	29,8 (16,4)	1,7 (1,2)
Parity-1	9(25,0)	11(25,0)	7(22,6)	29,5 (17,8)	2,1(1,9)
Parity-2	4(11,1)	4(9,1)	4(12,9)	39,4 (9,2)	1,0 (0)
Parity-3	1(2,8)	2(4,5)	1(3,2)	38.7 (13,7)	1.7 (0,6)
Parity-4	1(2,8)	1(2,3)	1(3,2)	23,0 (0)	1,0 (0)

SD – Standard deviation

Tab. 3. Mode of delivery with other parameters

	Mode of delivery (n=56)						
	Normal vaginal delivery	Forceps	Caesarian section due to lack of progression of labour	Caesarian section due to foetal distress	Caesarian section due to failed induction of labour	Total number of Caesarian sections	Getting a caesarian section
Parity							Being nulliparous
Nulliparous (n=32)	25	1	2	2	2	6	RR = 0.75
Multiparous	18	0	2	2	2	6	95% CI = 0.28-2.04
							P = 0.81
Indication							Having an UP
UP (n=24)*	19	1	2	1	1	4	RR = 0.6
GDM	18	0	2	2	2	6	95% CI = 0.21-1.70
FGR	5	0	0	1	0	1	P = 0.49
Reduced AFI	1	0	0	0	0	0	
Past section	0	0	0	0	1	1	
For comparison							Having Foley only
Women who had Foley only (n=36)	30	1	2	2	1	5	RR = 0.40
							95% CI = 0.15- 1.09
Women who had Foley, then Prostaglandin	13	0	2	2	3	7	P = 0.09

* Relative risk assessed for this indication only. RR = Relative risk, 95% CI = 95% Confidence interval
UP – Women who have completed 41 weeks of gestation with otherwise uncomplicated pregnancies, GDM – Gestational Diabetes mellitus, FGR – Fetal growth restriction, AFI – Amniotic fluid index, Past section – Past history of caesarian section

other, representing the worst pain ever experienced. In this scale 1, 2, 3 for mild discomfort, 4, 5, 6 for moderate discomfort, 7 or more for severe discomfort were used when interpreting the degree of discomfort. Data analysis was done using standard statistical methods. Fisher's Exact Test was performed for significant testing among categorical variables (having a MBS of 6 or more and duration of Foley in-situ up to 48 hours). P value < 0.05 was considered as statistically significant for potential associations. Ethical aspects of patient satisfaction survey were assessed and approved by the Ethical Review Committee, DSHW, Colombo, Sri Lanka.

RESULTS

Our unit had a total of 910 deliveries during the study period. Fifty six consecutive cases which were primed with FC, prospectively recruited over three months. Informed consent was given by all of them and therefore, 56 cases were studied. According to Table 1, 32(57.1%) were nulliparous, 48 (85.7%) were between 21-35 years of age. Gestational diabetes and women who have completed 41 weeks of gestation with otherwise uncomplicated pregnancies were the commonest indications for IOL. Mean (SD) duration of FC in-situ was 31.4 (16.04) hours.

MBS of 6 or more was achieved in 36 (64.3%) subjects with Foley insertions out of 56. Rest of the 20 (35.7%) needed further intervention with vaginal prostaglandin E2. As presented in Table 2, 36 out of all (64.3%) had cervical priming only with FC and 31 of them (31/36, 86.1%) had vaginal deliveries and 5 (8.9%) had caesarian sections. Majority of subjects primed with FC only were nulliparous (21/36, 58.3%) and of them majority (18/21, 85.7%) delivered vaginally. Out of 21 nulliparas primed with Foley only, 15 (15/21, 71.4%) were uncomplicated pregnancies who have completed 41 weeks of gestation. From these fifteen, 13 delivered vaginally. In contrast, rest of the 20(35.8%) subjects had FC followed by additional vaginal Prostaglandin E2insertion. Thirteen of them (13/20, 65%) had vaginal deliveries. Of the 24 subjects who were induced due to completed 41 weeks of gestation with otherwise uncomplicated pregnancies, 17 (70.8%) had post-priming MBS of 6 or more with FC alone.

Relationship of Mode of delivery with other parameters has summarized in Table 3. Twenty out of 24(83.3%) of women who have completed 41 weeks of gestation with otherwise uncomplicated pregnancies delivered vaginally including single forceps delivery. Total vaginal delivery rate is 76.8 %(43/56). There were 12 (12/56, 21.4%) caesarian sections. Having a MBS of 6 or more was related to the duration of Foley in-situ (Fisher's Exact Test, $p=0.05$). During IOL 38 (66.6%) had no discomfort and 15(26.3%) had only mild discomfort (Table 4). FCwas deflated due to moderate discomfort in 3 women at 48 hours of insertion and they had MBS of more than 6 at the time of deflation and they have included in the analysis.

Tab. 4. Patient acceptability of Foley catheter as assessed with visual analogue scale (0–10)

Degree of discomfort (n=56)	Frequency (%)
No Discomfort	38 (66,6)
Mild Discomfort	15 (26,3)
Moderate Discomfort	3 (5,3)
Severe Discomfort	0
Subjects with mild or no discomfort (≤ 3 score in visual analogue scale) (n=53)	
Parity	
Nulliparous	30 (57,7)
Multiparous	23(42,3)
Mode of delivery	
Vaginal or forceps delivery	43(80,8)
Caesarian section	10 (19,2)

DISCUSSION

Our unit has an IOL rate of 11%, which is way below the national average but comparable to the rates reported by others [2]. Careful management strategies adhering to guidelines as an academic unit might have resulted this low IOL rate. Many studies have reported that both FC and prostaglandin E2 gel are equally effective in pre induction cervical ripening [8,15]. FC is a safe method of labor induction for the mother, fetus and newborn [16]. Our unit generally has a higher rate of prostaglandin use than FC for cervical priming, despite the ward protocol. That might be one reason for not getting a large sample for the study instead of 910 deliveries during the period.

In Sri Lanka conventionally most of the Obstetric Units are practicing IOL at 41 weeks of gestation for women with otherwise uncomplicated pregnancies. Latest guideline on IOL published by SLCOG has mentioned that IOL is recommended for otherwise uncomplicated, low-risk women who are known with certainty to have reached 41 weeks of gestation [17].

Furthermore, this guideline elaborates that it is good practice to assess foetal well-being around 40 weeks to select women for conservative management until 41 weeks gestation [17]. The World Health Organisation defines post term pregnancy as beyond 41 completed weeks from the first day of the last menstrual period [18]. This was later challenged because firstly, it was based on epidemiological data and secondly, it was calculated from the statistical distribution of the timing of delivery from the last menstrual period (LMP) [19]. Moreover, this definition did not consider the risk of pregnancy complications including stillbirth during late gestational ages. It is now accepted that gestational age assessment by LMP is not accurate [20]. Maturity of 39 week Asian fetuses are equal to that of a 41 week Caucasian fetus, implying that Asian fetuses mature sooner than Caucasians [19]. South Asian and black women have shorter length of gestation compared to Caucasian indicating the likelihood of high early perinatal complications in south Asian and black women [19]. Recent Sri Lankan study indicated that risk of stillbirth increases progressively after 38 weeks [21]. Therefore, typical "post-term pregnancies" could not be found.

FC is much cheaper when compared to vaginal prostaglandin tablets. A FC costs 90 LKR (0.7 USD), while 3 mg of prostaglandin costs about 1500 LKR (11.5 USD). Therefore it seems to be a bettercost effective method in developing countries like Sri Lanka. It has also shown to be a safe method in cervical priming and found to have same efficacy when compared with prostaglandins [7,8]. Some studies from developing countries on IOL have attempted to find out an economically feasible method as a cervical priming agent. Recently conducted PROBAAT trial in Netherlands, has evaluated cost-effectiveness of IOL at term with a FC compared to vaginal prostaglandin E2gel [22]. In the FC group has showed higher costs due to longer labour ward occupation and less cost related to induction material and neonatal admissions [22]. Foley catheter usage has showed a comparable caesarean section rate compared with prostaglandin induction and therefore the incremental cost-effectiveness ratio has not been informative [22]. FC use resulted in fewer neonatal admissions and asphyxia/postpartum haemorrhage compared with prostaglandin use [22]. They have concluded that FC and prostaglandin E_2gel labour induction generate comparable costs [22]. Interestingly, an Australian trial had reported different results which are more in favour of FC as a better cost-effective method. In that study the only difference in cost between the three groups (Foley, double balloon catheter and PGE_2) in this study relate to the cost of the cervical ripening device as there were no differences between groups in length of time in labour ward, mode of delivery, postnatal complications, duration of hospital admission or re-presentation to hospital after discharge [14]. The cost of ripening devices used in the trial were substantially lower for the Foley catheter (AUS$2.00) compared with the double balloon catheter (AUS$81) and PGE2 gel (AUS$124 for two doses) [14]. A study from India concluded that vaginal misoprostol is a cheap, highly effective, stable at room temperature and easy to administer agent for labor induction [11]. They have shown that misoprostol is superior to FC/oxytocin [11]. However few other studies concluded that the use of Foley catheter is as effective as misoprostol for cervical ripening [12,13]. A metaanalysis reported that vaginally administered misoprotol was more effective than dinoprostone vaginal insert for cervical priming and IOL and the safety profile of both drugs were similar [24]. [24]. This indicates that both FC and misoprostol has some advantages over prostaglandin. Although misoprostol is widely used worldwide for various indications in pregnancy, in Sri Lanka, it is not licensedat present [17]. Therefore FC becomes more important in IOL.

As shown in above results, subjects who were primed with FC followed by additional vaginal prostaglandins after 48 hours, had a high chance of getting a vaginal delivery (65%).We had to deflate FC at 48 hours in 16 subjects (28.6%) with a total vaginal delivery rate of 78.6%. Ekele BA et.al reported that most women (95%) would have expelled FC spontaneously within 72 hours of insertion and a 91% vaginal delivery rate [25]. According to our results nulliparous women reported 25/32, 78.1% vaginal delivery rate. Study done in Australia among nulliparous women had reported 45/110,41% of spontaneous vaginal delivery rate [15]. Nevertheless, as a conclusion of this trial they have mentioned that labour induction in nullipara with unfavourable cervices results in high caesarean delivery rates [14]. Although all methods (double balloon, single balloon and prostaglandin) in this study had similar efficacy, the single balloon catheter had offered the best combination of safety and patient comfort [14]. In our study, subjects who have comple-

ted 41 weeks of gestation with otherwise uncomplicated pregnancies and who were primed with FC alone (21/32) had reported 83.3% rate of vaginal delivery. Amongst who have completed 41 weeks, there were 15 nulliparous women reporting 13/15, 86.7% of vaginal delivery rate. This indicates that FC is a good option for the subjects with completed 41 weeks and especially nulliparous women in our unit.

However, a recent retrospective cohort study comparing nulliparous women with uncomplicated post term pregnancies with Foley catheter induction versus spontaneous labour has shown that Foley induction resulted in a six-fold increase in risk of caesarean section rate (odds ratio 6.2) [26]. But among parous women it was low and not significant [26]. In our study, we did not have a control group to compare. A recent Sri Lankan trial conducted among women with uncomplicated singleton pregnancies with 40 weeks and 6 days, has also shown that intracervical FC for 24 hours was better than two doses of 25 ìg misoprostol administered orally four hours apart, for pre induction cervical ripening in these prolonged pregnancies [12]. There Foley catheter has shown to be effective for both nulliparous and multiparous giving higher MBS and lower caesarean section rate. In our study, subjects who had Foley only have a lesser chance of getting a ceasarian section compared to those subjects who had Foley followed by prostaglandin (Relative risk = 0.40, 95% CI = 0.15- 1.09, P = 0.09). Although this is statistically not significant, it has an almost predictable result which might be confirmed with a better designed study.

Overall 53/56, 94.6% had mild or no discomfort with FC cervical priming indicating that FC has a good patient satisfaction.The only available study reporting patient satisfaction for FC using visual analogue scales (0–10) has shown thatFoley catheter had best patient comfort during insertion and ripening phase both [14]. In this study prostaglandin and FC had similar pain scores during insertion whereas during ripening phase FC had greater patient comfort than prostaglandins (pain score > 4, 36% in FC group Vs 63% in prostaglandin group, P < 0.001) [14].

CONCLUSIONS

According to this clinical audit, FC insertion is probably an effective method in cervical priming for IOL in our setting. It is also a good method for low resource settings in developing countries. That is because FC insertion is potentially cheaper and it gives a good patient comfort and also a high chance of vaginal delivery rate. FC alone could be an effective method of IOL for the subjects who have completed 41 weeks of gestation with otherwise uncomplicated pregnancies.

Cost-effectiveness in low resource settings and pregnant women satisfaction with FC has to be better evaluated by further well controlled trials. As limitations, we have not assessed the risk of infection. These data will be scientifically more sound, if the audit would have continued more longer duration. A relatively small sample size and being a single arm study might have an impact on results. There is no comparison with another method that can be used. Therefore claims cannot be made on relative effectiveness. Patient satisfaction would have been measured using more accurate validated tools.

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