## Original Article:

# Comparative study of induction of labour with Foley's catheter inflated to 30 mL versus 60 mL

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## ABSTRACT

**Background:** The ripeness of the cervix is an important determinant of the success of induction of labour. One of the mechanical methods of cervical ripening is the use of a transcervical Foley catheter. In this study we compared the efficacy in induction of labour of two insufflation volumes of Foley catheter bulb 30 mL and 60mL.

**Methods:** This was a randomized, single-blind study conducted in 100 women, randomly allocated to the 30 mL group (n=50) and 60 mL group (n=50). Foley's catheter was removed after 12 hours if it was not spontaneously expelled. If the Bishop score was more than 6, oxytocin infusion was started. Labour was monitored and outcomes noted.

**Results:** Both groups had similar demographic profile, gestational age and indication for induction of labour. The primary outcome i.e., induction delivery interval was not statistically different in the two groups. The secondary outcomes i.e., Foley's catheter expulsion time, change in Bishop score, need for and dose of oxytocin, mode of delivery and neonatal outcome also did not show any statistically significant difference between the two groups.

**Conclusions:** Both 30 mL and 60 mL foley's catheter bulb insufflation volumes were comparable in inducing labour.

**Key words:** *Labour, induced, Urinary catheters insuflation*

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## INTRODUCTION

For centuries physicians have been intrigued by the process of parturition.[1] The cervix must remain closed during pregnancy to maintain pregnancy, yet open during parturition. It must perform its activity at the right time and in the right sequence within a reasonable period of time. Induction of labour is a common obstetric intervention and should be undertaken only when the risks of continuing the pregnancy to the mother, foetus or both are outweighed by the benefits of delivery. The main concern about induced labour is that it is more likely to end in caesarean section when compared to spontaneous labour.[2]

Over the last two decades there has been an abrupt increase in the labour induction rate, for a variety of indications including hypertensive disorders, post dated pregnancy, intrauterine growth restriction and elective reasons from 9.5% in 1990 to 21.2% in 2004.[3] An unripe cervix is a major impediment for the success of labour induction, [4] the status of which can be determined by the Bishop pelvic scoring system.[5] A low Bishop score in induced labour is associated with a high risk of caesarean section.[6] A variety of pharmacological and mechanical methods have been developed to ripen the unfavourable cervix. One of the mechanical methods is the use of transcervical Foley's catheter. Potential advantages of the Foley's catheter when compared with

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prostaglandins include lower cost, stability at room temperature, reduced risk of uterine tachysystole and appropriateness in outpatient setting.[5] Mechanical methods exert local pressure on the cervix, overstretching the lower uterine segment and indirectly stimulate the secretion of prostaglandins.

A recent review[7] reported that compared with prostaglandins, the balloon catheter was associated with a lower risk of uterine hyperstimulation with less foetal heart rate changes while the risk of caesarean section with the two methods was similar. The World Health Organization (WHO) induction guidelines recommend balloon catheter as one of the first line methods for induction of labour (moderate-quality evidence, strong recommendation).[7] The Foley catheter versus vaginal prostuglandin E2 gel for induction of labour at term (PROBAAT) trial[8] concluded that in women at term with an unfavourable cervix, induction of labour with Foley's catheter was equally effective as prostaglandins with less morbidity, but a longer time to delivery. Embry and Mollison[9] first used 26G Foley's catheter with a 50ml balloon in 1967. Since then, there is no consensus regarding the ideal volume required for inflating Foley's catheter balloon. Different authors reported using volumes ranging from 30 mL to 80 mL. Studies comparing balloon inflation sizes of 30-80 mL have been done which showed a higher rate of delivery within 24 hours in the higher volume group when compared to the lower volume group.[10] It has been postulated that the larger bulb causes release of larger amount of endogenous prostaglandins and also exerts more pressure on the cervix resulting in better ripening of the cervix.

The present study was undertaken to test the hypothesis that 60 mL Foley's catheter balloon improved the Bishop score better, shortened the induction-delivery interval and resulted in lower caesarean section rate than with 30 mL Foley's catheter balloon.

## MATERIAL AND METHODS

The study was conducted at the Government Maternity Hospital attached to Sri Venkateswara Medical College Tirupati, Chittoor District, Andhra Pradesh, India between January 2012 and January 2013. The Government Maternity Hospital, Tirupati is a teaching hospital catering to a large obstetric population from four districts. Annually nearly 14,000 deliveries are conducted at our hospital; of these, induction of labour constituted 15%.

The study was an interventional, randomized, single-blind study. After obtaining the approval of the Institutional Ethics Committee, pregnant women who required induction of labour were screened for inclusion in the study. Written informed consent was obtained from them. Obstetric ultrasonography was done in all women to confirm the presentation and placental location. Bishop score[5] was determined and noted. A computer based random number generator was used and the women were blinded to the group allocation. Subjects were allotted randomly to 30 mL or 60 mL Foley's balloon catheter volume groups. The investigators were not blinded as most of the times the investigators themselves conducted the procedure. Whenever the investigators were not available, postgraduate students who were trained conducted the procedure.

The study included both nulliparous and multiparous women with single live foetus in cephalic presentation, gestational age 37 weeks and above, with a Bishop score[5] less than 6.

Women with ruptured membranes, previous uterine scar, low lying placenta, contraindication to vaginal birth, inability to give consent, women with foetal anomalies and those unwilling to participate were excluded from the study.

Women were positioned as for standard speculum examination. Cervix was cleaned

with povidone iodine solution and a sterile 18F Foley's catheter balloon was placed under direct vision 5 cm into the endocervical canal in the extra amniotic space so that it was above the internal os. The operator then injected either 30 mL or 60 mL sterile saline into the bulb as per the random allocation. The external end of the balloon catheter was taped to the inner thigh without any traction and the patient returned to the waiting room. Vital parameters like pulse rate, temperature, uterine contractions and foetal heart rate were monitored every half-hourly and blood pressure was recorded every 2 hours.The women were instructed to inform the staff if the Foley's catheter was expelled or if they leaked amniotic fluid. Time of Foley's catheteter expulsion was noted. If the Foley's catheter was not expelled on its own, it was removed after 12 hours. The Bishop score[5] was calculated after the catheter was expelled or removed. If it was greater than 6, oxytocin drip was started at a dose of 2 μu/min and increased every 30 min by 1 μu/min until at least three contractions in 10 min, each lasting for 45-60 sec were established. The maximum dose of oxytocin used was 32 μu/min. As infusion pumps are not available in our hospital, oxytocin dose was adjusted by controlling the drip rate.

If there was no improvement in Bishop score[5] after 12 hours, another method of cervical ripening like vaginal misoprostol 25 μg or endocervical prostaglandin E2 gel (PGE2 gel) were resorted to. Progress of labour was plotted on a partogram and the outcomes noted.

### Statistical analysis

Statistical analysis was done using MS-Excel 2003, Epiinfo 7.1.2 and Stastical package for Social Sciences (SPSS) 20 (Trial version, IBM, Chicago, USA). Categorical variables were compared using Chi square test and continuous variables were compared using student's t-test. A p-value of less than 0.05 was considered statistically significant.

## RESULTS

Out of 100 women studied, 50 were randomly assigned to 30 mL group and the remaining 50 were randomly assigned to 60 mL group. Their demographic characteristics are shown in Table 1. There was no statistically significant

**Table 1: Demographic characteristics**

| | Foley's catheter bulb volume | | |
|---|---|---|---|
| | **30 mL** | **60 mL** | **p-value** |
| Age (years) | 23.0 ± 2.7 | 22.8 ± 3.0 | 0.703 |
| Socio-economic status | | | |
| low | 46 | 4 | |
| Middle | 45 | 5 | 0.727 |
| Parity | | | |
| Nullipara | 28 | 32 | |
| Multipara | 22 | 18 | 0.375 |
| Education | | | |
| Primary | 10 | 10 | |
| Secondary | 7 | 7 | 0.137 |
| College | 33 | 33 | |
| Gestational age (weeks)* | 40.1 ± 1.7 | 40.3 ± 0.9 | 0.529 |
| Indication for induction | | | |
| Oligoamnios | 7 | 11 | |
| PIH | 10 | 7 | |
| Post-dated pregnancy | 31 | 30 | |
| Others | 2 | 2 | 0.697 |

* data are presented as mean ± standard deviation

PIH = pregnancy induced hypertension

difference between the two groups in terms of age, the number of nullipara and multipara socio-economic status, education, and gestational age.

The most common indication for induction was post-dated pregnancy, followed by oligoamnios; pregnancy-induced hypertension; and others like decreased foetal movements and unstable lie. The indications for induction were comparable in both groups.

The outcome of induction of labour using Foley's catheter in both the groups is presented in Tables-2 and 3. There was no significant difference between the two groups in terms of change in Bishop's score.[5] The Foley's catheter was spontaneously expelled in 18 women in the 30 mL group and 19 women in the 60 mL group. In the remaining 63 patients, the Foley's catheter was not expelled and hence removed after 12 hours. There was no difference between the two groups in terms of expulsion/removal of Foley's catheter. Forty five women in each group required oxytocin.

One woman in 30 mL and two in the 60 mL group had no improvement in Bishop's score[5] after 12 hours. They were treated by other methods like PGE2 gel or misoprostol. There was no difference in the number of women who needed another method of cervical ripening in the two groups. The mean induction-delivery interval was comparable in the 30 mL and 60 mL groups (Table 1).

The neonatal outcomes are shown in Table 4. The mean birth weight (kg) was also comparable in the 30 mL group and 60 mL groups (2.9±0.5 vs 2.9±0.4). Further, there was no statistically significant difference in the birth weight, appearance pulse, grimace activity, respiration (APGAR) score[11] at 1 and 5 minutes, meconium stained liquor and neonatal intensive care unit (NICU) referral among the two groups.

## DISCUSSION

In the present study, there was no difference in the primary outcome i.e., induction-delivery interval between the two groups. The secondary outcomes i.e., time to Foley's catheter expulsion, change in Bishop score,[5] oxytocin requirement, maximum oxytocin dose, caesarean section rate, operative vaginal delivery rate APGAR[11] score at 1 and 5 minutes and meconium staining of liquor and NICU admission rate also did not differ in the two groups.

**Table 2: Comparison of outcomes**

| Variable | Foley's catheter bulb volume | | p-value |
|---|---|---|---|
| | 30 mL | 60 mL | |
| Change in Bishop's score* | 3.1 ± 1.2 | 2.9 ± 1.2 | 0.521 |
| Foley's catheter expulsion duration (minutes) | 380.8 ± 140.3 | 432.6 ± 191.1 | 0.356 |
| Oxytocin dose (μg/min)* | 11 ± 5.1 | 9.2 ± 4.6 | 0.125 |
| Induction delivery interval (hours)* | 18.9 ± 15.8 | 19.2 ± 21.1 | 0.775 |

*data are presented as mean ± standard deviation

**Table 3: Mode of delivery**

| Mode of delivery | Foley's catheter bulb volume | | p-value |
|---|---|---|---|
| | 30 mL | 60 mL | |
| Lower segment caesarean section | 10 | 7 | |
| Normal delivery | 39 | 37 | |
| Outlet delivery | 1 | 6 | 0.125 |

**Table 4: Neonatal outcome**

| Variable | Foley's catheter bulb volume | | p-value |
|---|---|---|---|
| | 30 mL | 60 mL | |
| Amniotic fluid | | | |
| Clear | 42 | 42 | |
| Meconium stained | 8 | 8 | 0.7856 |
| NICU referral | | | |
| Not referred | 48 | 46 | |
| Referred | 2 | 4 | 0.400 |
| Weight (kg) | 2.9±0.5 | 2.9±0.4 | 0.685 |
| APGAR score* | | | |
| At 1 min | 7.7±1.1 | 7.8±0.7 | 0.663 |
| At 5 min | 9.7±1.1 | 9.8±0.7 | 0.663 |

* data are presented as mean ± standard deviation

NICU= neonatal intensive care unit; APGAR score= appearance, pulse, grimace, activity and respiration score

Another study[12] also compared 30 mL Foley's catheter balloon with 60 mL Foley's catheter balloon. They did not find any difference in the induction-delivery interval, maximum oxytocin dose, caesarean section rate, rate of delivery within 24 hours and neonatal outcome between the two groups. Our results are in concurrence with the earlier report.[12] The only difference noted in the other study[12] was a higher median cervical dilation and a higher rate of delivery within 12 hours in the 60 mL group. This difference was noted only in nullipara. This could be due to the fact that they started oxytocin within 30 minutes of Foley's catheter balloon insertion, whereas in the present study, oxytocin was started only after the Foley's catheter was expelled or removed, that too only if the Bishop score[5] was more than 6. Another difference in methodology is that they[12] included all modes of delivery in analyzing the rate of delivery, whereas in the present study only vaginal deliveries were included.

A study from Sri Lanka[13] compared 84 women randomly assigned to 30 mL or 60 mL Foley's catheter balloon and found a higher change in Bishop score, higher likelihood of delivery within 30 hours and lower caesarean section rate in the 60 mL group, but this study[13] included only multiparous women with a gestational age of 40 weeks. The authors[13] left the Foley's catheter in situ for 24 hours if it was not spontaneously expelled. The authors found a higher rate of assisted vaginal delivery for fetal distress in the 60 mL group. In the present study too, the number of operative vaginal deliveries were higher in the 60ml group but the difference was not statistically significant.

Another study[14] compared 30 mL with 80 mL Foley's catheter balloon and found a higher post ripening cervical dilation, higher rate of delivery by 24 hours and less requirement of oxytocin in the 80 mL group. The caesarean section rate, as in the present study, did not show a statistically significant difference in the two groups .The difference in some of the outcomes may be due to the fact that they used 80 mL Foley's catheter balloon and traction was applied to the catheter.

In another study[15] 270 women were randomly assigned to three groups, namely, 30 mL Foley's catheter balloon with oxytocin, 80 mL Foley's catheter balloon with oxytocin and a third group received only oxytocin. They found that change in Bishop score,[5] rate of delivery in 24 hours and overall vaginal delivery rate were higher in the 80 mL group. These results are dissimilar

to those of the present study. In the previous study[15] they had applied 500 mL weighted bag to the Foley's catheter and also started oxytocin after 6 hours. This methodological difference might be the reason for the difference in results.

Most of the studies[12-15] including the present one, showed no difference in caesarean section rate between the two groups. An overall caesarean section rate of 22% was noted in an earlier study.[12] The overall caesarean section rate in the present study was 17%, which is comparable to the primary caesarean delivery rate at our institute. The most common indication for caesarean section was failure to progress, followed by foetal distress. These indications were consistent with observations recorded in an earlier study.[12]

The neonatal outcome, defined by the incidence of meconium stained liquor, 1 and 5min APGAR[11] score[11] and NICU admission rates were comparable in the two groups in all the studies[12-15] including the present one. So it can be inferred that inflation with a larger volume did not adversely affect the foetal outcome.

A meta-analysis[10] that combined all the studies comparing low volume and high volume Foley's catheters concluded that with high volume catheters the cervical ripeness and the likelihood of delivery within 24 hours was more compared with low volume catheters, but with no difference in mode of delivery and neonatal outcome. They felt that a large randomized trial with caesarean section as the primary outcome is warranted.

We did not record the patient's level of discomfort/pain during and after insertion of Foley's catheter. Our observations suggest that both volumes 30 mL and 60 mL are equally effective in inducing labour, but immediate augmentation with oxytocin may be necessary to shorten the induction delivery interval.

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