Original Article

A Comparison of 30-, 50-, and 60-mL Foley Catheter Balloon Volume and Time to Achieve Cervical Ripening for Labor Induction: A Triple-Blind Randomized Controlled Trial

KO Cousin, PN Ebeigbe

Department of Obstetrics and Gynaecology, Delta State University Teaching Hospital, Otefe, Oghara, Delta State, Nigeria

Abstract

Background: Cervical ripening is one of the most important determinants of the outcome of induction of labor. The findings of studies on the most efficacious inflatable catheter balloon volume for pre-induction cervical ripening have been inconclusive. **Aim:** To compare the efficacy of the use of different intracervical Foley catheter balloon volumes (30-, 50-, and 60-mL) on cervical ripening. **Subjects and Methods:** This study was a triple-blind randomized controlled trial. Two hundred and sixteen women with a Bishop score ≤5 at term were randomly assigned into three groups (1:1:1) to receive an intracervical single size eighteen Foley balloon catheter inflated either with 30-mL (control arm) or 50-mL and 60-mL (intervention arm) of sterile saline which was retained for a duration of 12 h. The primary outcome measures were the mean change in Bishop score and achieving a Bishop score of ≥6 at the twelfth-hour post-Foley catheter balloon insertion. **Results:** In the total study population and among nulliparous women, the 50-mL and 60-mL balloons compared with the 30-mL Foley catheter balloon achieved a statistically significantly greater mean change in Bishop scores at the twelfth hour\post-insertion (P = 0.005 and P = 0.001), while the 60-mL balloon compared with the 30-mL and 50-mL balloons achieved statistically significant higher mean change in Bishop scores among multiparous women (P = 0.047 and P = 0.003) and cervical dilatation irrespective of parity (P = 0.003 and P = 0.002), at the twelfth-hour post-insertion. The larger catheter balloons were also associated with a statistically significant greater chance of having an induction to delivery interval of <12 h in nulliparous women P = 0.003. **Conclusion:** The findings of this study showed that the larger single Foley catheter balloon volumes (50-mL and 60-mL) aside from being well tolerated and acceptable have the ability to induce faster changes in Bishop score, produce higher cervical dilation, and thus likely reduce significantly the total labor induction process compared to the 30-mL single catheter balloon volume irrespective of parity.

Keywords: *Cervical ripening, Foley balloon catheters, Labor induction, Volume*

Received: 09-Apr-2022;
Revision: 25-May-2023;
Accepted: 07-Jun-2023;
Published: 03-Aug-2023

Introduction

Induction of labor (IoL) is one of the most commonly performed obstetric interventions worldwide.[1,2] Its reported incidence globally has been on the increase over the last decade and is estimated to be about 20 to 30% of all deliveries.[2-4] Successful IoL depends on several factors such as parity, Bishop score, the position of the vertex, and the method of induction. Among these, the Bishop score seems to be of cardinal importance.[5]

Access this article online

Quick Response Code:

Website: www.njcponline.com

DOI: 10.4103/njcp.njcp_251_22

Address for correspondence: Dr. KO Cousin, Department of Obstetrics and Gynaecology, Delta State University Teaching Hospital, Otefe Road, Off Benin-Warri Express Way, Oghara, Delta State, Nigeria.
E-mail: cousin5kay@gmail.com

How to cite this article: Cousin KO, Ebeigbe PN. A Comparison of 30-, 50-, and 60-mL foley catheter balloon volume and time to achieve cervical ripening for labor induction: A triple-blind randomized controlled trial. Niger J Clin Pract 2023;26:871-80.

The goal of cervical ripening is to facilitate the process of cervical softening, thinning, and dilatation with a resultant reduction in the rate of failed induction and induction to delivery time.[6] Induction of labor when done in the setting of an unfavorable cervix results in increased maternal or neonatal morbidities, longer lengths of hospital stay, and ultimately to increased cost of care.[7] The three most commonly used methods for cervical ripening in Nigerian women are the intracervical Foley catheter, misoprostol, and prostaglandins. Foley catheter is widely used because of its many unique properties which include its low cost, reversibility, stability at room temperature, reduced risk of uterine tachysystole, and abnormal fetal heart rate (FHR) changes.[8,9] Furthermore, its use is not contraindicated in pregnant women with a previous lower segment uterine scar.[10]

Several authors have compared different Foley catheter balloon distention volumes (as large as 80-mL) to the 30-mL balloon volume, in an effort to improve the overall efficacy of the Foley balloon catheter for cervical ripening. Higher inflatable volumes were hypothesized to produce higher prostaglandin secretion, induce larger cervical dilatation, and thus shorten cervical ripening. Many of the studies did not involve randomization and used open-label designs exposing the results to the influence of confounding variables and bias. The findings have been inconsistent, with some showing better efficacy with higher inflatable volumes[11-13] while others did not.[14-16]

The aim of this study was to compare the efficacy of the use of different intracervical Foley catheter balloon volume (30-, 50-, and 60-mL) on cervical ripening among women at term undergoing cervical ripening for labor induction, at the twelfth-hour post-insertion using the mean change in Bishop score and the achievement of a Bishop score equal to or more than 6, as primary outcome measures.

Materials and Methods

This was a multi-arm triple-blind randomized controlled study tailored according to the "CONSORT 2010 guideline"[17] that compared the efficacy of the use of different single Foley catheter balloon volumes (30-, 50-, and 60-mL) and time to achieve cervical ripening at the twelfth hour, post-Foley catheter balloon insertion, among pregnant women at term, undergoing labor induction using the 30-mL balloon volume as control. The study was performed in two tertiary health centers (Delta State University Teaching Hospital Oghara and Central Hospital Warri, Delta State Nigeria) after approval by the Hospital Research Ethics Committees of both hospitals.

Both hospitals are closely affiliated and have joint accreditation for the training of medical students and postgraduates in obstetrics and gynecology and share management protocols. The proposal and protocol for the study were subjected to blinded external formative assessment by the Faculty of Obstetrics and Gynaecology of the National Postgraduate Medical College of Nigeria, and following directed revisions, the study protocol was approved before the study was commenced.

The ethical approval for this study (reference no: HREC/PAN/2019/069/0350 and CHW/ECC VOL 1/203) was obtained from the institutional research ethics committees of Delta State University Teaching Hospital Oghara and Central Hospital Warri, Delta State Nigeria. A written informed consent was also obtained from each participant before recruitment into the study.

The study population included 216 pregnant women at term who were scheduled for induction of labor but were found to have an unfavorable cervical score (≤5) between June 1, 2020, and March 31, 2021. The sample size was determined using the formulae for comparative studies proposed by Charan and Biswas.[18] A power analysis calculated before the initiation of the study based on assumptions made on prior published work[11] showed that 72 women, respectively, were needed in each study arm to demonstrate a 20% difference in the primary outcome of a Bishop score ≥6 at the time of catheter removal with 80% power and $\alpha = 0.05$.

To be included in the study, pregnant women had to have a height of at least 1.5 meters, be carrying a singleton fetus at a gestational age of 37 completed weeks to 42 completed weeks with an estimated fetal weight less than 4.0 kg, have intact membranes, not have any contractions in ten minutes, have a Bishop score of 5 or less, have a reassuring pre-induction fetal cardiotocography, not have any contraindication to vaginal delivery, and not have any ongoing medical disorders like severe pre-eclampsia/eclampsia, cardiac disease, or uncontrolled diabetes mellitus.

The participants were randomly allocated into one of the three study arms to receive a transcervical single-size 18 Foley balloon catheter inflated either with 30-mL (control arm) or 50-mL and 60-mL (intervention arm) of sterile saline to be retained for a maximum duration of 12 h. Randomization was done using a random permutated blocking technique[19] with a block size of eighteen stratified by parity (nulliparity versus multiparity) in 1:1:1 ratio.

The study population, outcome assessors, and data analysts were blinded to assigned randomization as follows: After initial assessment of the Bishop

score and correct placement of the intracervical Foley catheter under aseptic condition, the managing physician inflated the Foley catheter balloon with 30-mL of sterile saline for all study participants and subsequently stepped out of the labor ward suite. Further inflation or not of the Foley balloon was done by a designated independent research assistant (not part of the outcome assessors) in possession of the master's copy of random numbers. For participants randomly assigned to the 30-mL arm, the designated independent research assistant briefly attached a prefilled syringe to the placed Foley catheter but did not inflate the balloon with any additional saline. However, for participants randomly assigned to the 50-mL or 60-mL arm, the Foley balloon was further inflated by 20-mL and 30-mL, respectively. The allocation assignment was only revealed to the outcome assessors and data analysts, after data analysis.

The Bishop's score was reassessed at the twelfth hour by the outcome assessors after the deflation of the catheter balloon by a labor ward charge nurse who was not part of the research team. With no improvement in the Bishop score (≥6), a pharmacological method of cervical ripening was commenced. In all three arms, the Foley catheter was discontinued for the following reasons: if a spontaneous rupture of membrane occurred, if balloon ruptures or was spontaneously expelled, women entered the active phase of labor, severe pain perception, any unexplained vaginal bleeding or if fetal distress was suspected. For those whose cervices were assessed to be ripe, but did not enter into spontaneous labor during the ripening process (12 h), oxytocin titration was commenced after artificial rupture of the membrane following the departmental protocol.

A self-administered numeric pain rating scale (NPRS) and a five-point Likert-like scale were administered to each participant during the process of cervical ripening, following delivery or before discharge to assess the degree of pain perception and satisfaction with the different Foley balloon catheter management arm.

The primary outcome measures were the mean change in Bishop score and achieving a Bishop score of ≥6 at the twelfth-hour post-Foley catheter balloon insertion. Secondary outcome measures included the mean change in cervical dilation from baseline value at the twelfth-hour post-insertion, Foley catheter insertion to expulsion interval, induction to delivery interval, catheter balloon rupture, iatrogenic membrane rupture, need an for additional ripening agent, vaginal delivery rate, cesarean section rate, participants' perception of pain during the ripening process, need for analgesia during the ripening process, and participants' satisfaction with the use of the various inflatable catheter balloon volumes.

Data were analyzed with the Statistical Package for the Social Science (SPSS) software (version 25.0; Chicago, Illinois, USA). An intention to treat method of analysis was employed. Descriptive statistics were expressed as means with standard deviation and ranges for continuous variables and as percentages and frequencies for categorical variables. The *t*-test was used to analyze the difference between means, while ANOVA (analysis of variance) and Bonferroni *post hoc* test were used to analyze the relationship between categorical variables. Multivariate regression analysis was performed to investigate the effect of different potential confounding variables on independent prediction of success of cervical ripening. Statistical significance was set as $P < 0.05$. The results were displayed using flowcharts and tables.

Results

During the study duration, 275 women were assessed for eligibility, 216 met the inclusion criteria, and 59 patients were excluded. The intervention was discontinued in fifteen participants, with seven assigned to the 30-mL group and four each assigned to the 50-mL and 60-mL groups, respectively. The reasons for discontinuing the intervention were fetal distress (3), uncontrolled hypertension (3), and maternal decision (2). All 216 randomized subjects were analyzed. [Figure 1]

The three catheter groups were similar with regard to maternal age, religion, parity, body mass index, and gestational age at delivery. A statistically significant majority of study participants assigned to the 30-mL group had a primary level of education and were unemployed compared to the 50-mL and 60-mL groups, $P = 0.001$, 0.003 [Table 1]. However, after both variables were subjected to multivariate logistic regression analysis, they did not add statistically significantly to the prediction of the mean change in Bishop score ($R^2 = 0.115$, $F = 3.347$, $P = 0.218$) and achieving a Bishop score of ≥6 ($R^2 = 0.043$, $F = 3.161$, $P = 0.206$) at the twelfth hour post-Foley catheter balloon insertion as P was >0.05 in all cases.

In the total study population, at the twelfth-hour post-insertion, the mean change in Bishop scores was found to be statistically significantly higher among study subjects assigned to the 50-mL and 60-mL compared to the 30-mL Foley catheter balloon group with $P = 0.006$ and 0.000, respectively. There were no differences across the three catheter groups in the proportion of women who had a Bishop score of ≥6 at twelfth-hour post-insertion [Table 2].

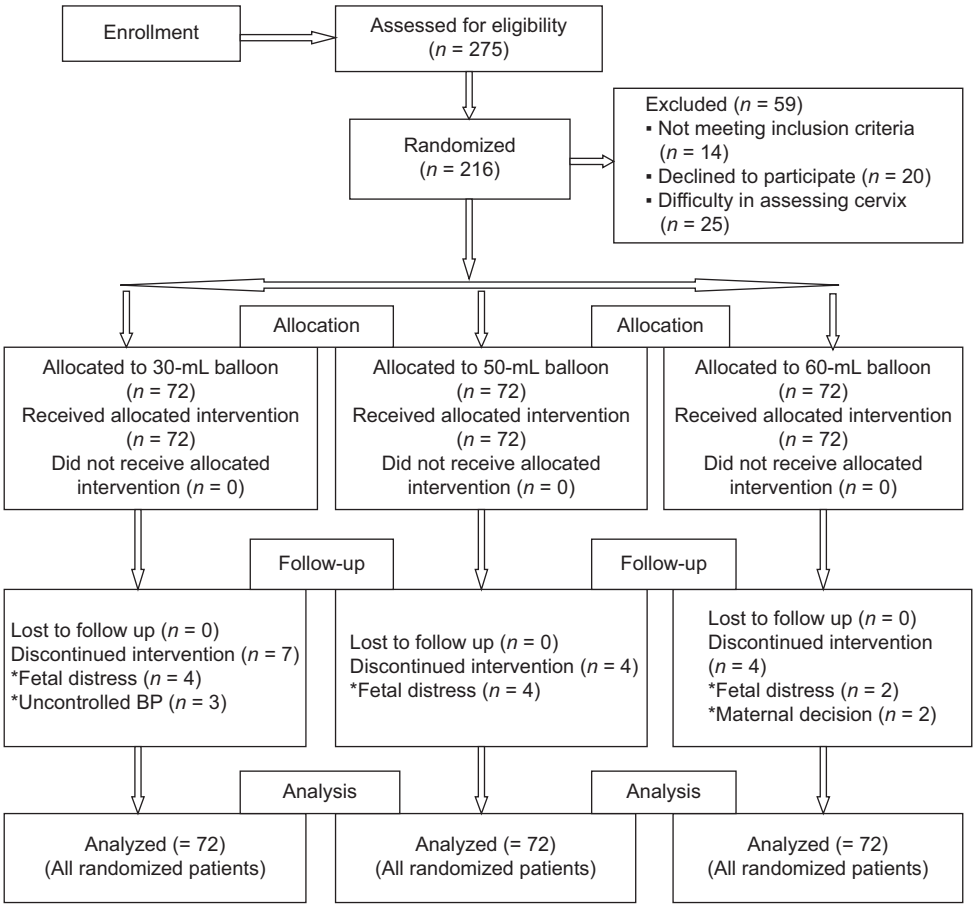

Figure 1: CONSORT flowchart of the randomization and follow-up of study participants

Among the nulliparous study subjects, the Bishop scores a showed statistically significant higher mean change in Bishop's score in the 50-mL and 60-mL compared to the 30-mL Foley catheter balloon group $P = 0.011$ and 0.001 [Table 3], while among multiparous study participants, the Bishop scores showed statistical significance in the 60-mL compared to the 30-mL and 50-mL Foley catheter balloon group with respect to the mean change in Bishop scores, $P = 0.000$ and 0.039 [Table 3]. There were no differences across the three catheter groups in those who achieved a Bishop score of ≥6 at the twelfth-hour post-insertion irrespective of parity [Table 3].

With respect to the cervical dilatation, among nulliparous study subjects, the 60-mL group showed statistically significant higher values compared to the 30-mL and 50-mL groups as regards the mean change in dilatation $P = 0.000$ and 0.003. Similarly, among multiparous subjects, the 60-mL group showed a statistically significant higher mean change in cervical dilatation $P = 0.001$ [Table 4] compared to the 30-mL group.

The meantime, in hours, between insertion and expulsion/removal of the Foley catheter did not differ significantly between the three Foley catheter groups regardless of parity [Table 4]. An induction to delivery interval of <12 h was found to be statistically significant among nulliparous subjects in the 50-mL and 60-mL compared to the 30-mL group = 0.013 [Table 4]. The induction to the delivery interval was similar among multiparous subjects across the three catheter groups. In addition, the vaginal delivery and cesarean section rates were similar across the three catheter groups irrespective of parity [Table 4].

The study found that irrespective of the Foley catheter balloon volume used, there was no difference among those who required an additional ripening agent and those who did not (42.6% vs. 57.4%) among the nulliparous study subjects. However, a statistically significant majority of multiparous study subjects did not require an additional ripening agent (75.0%) compared to those who did (25.0%), $P = 0.025$ [Table 4]. A statistically significant majority of subjects reported having mild pain ($P = 0.003$) in the 30-mL group as against moderate pain perception in the 50-mL and 60-mL catheter groups; $P = 0.048$ [Table 4]. Despite the majority of subjects experiencing discomfort and varying levels of pain

Table 1: Baseline biodemographic and clinical characteristics of the study population

	30-mL		50-mL		60-mL		Total		Test statistics	*P*
	n	%	*n*	%	*n*	%	*n*	%		
Age (years)										
>20	3	4.2	0	0.0	0	0.0	3	1.4	χ^2=13.174	0.125
20–25	23	31.9	17	23.6	12	16.7	52	24.1	χ^2=15.275	0.160
25–29	17	23.6	22	3-.6	24	33.3	63	29.2	χ^2=23.851	0.243
30–34	15	20.8	23	31.9	25	34.7	63	29.2	χ^2=28.221	0.091
≥35	14	19.4	10	13.9	11	15.3	35	16.2	χ^2=3.391	0.151
Mean	27.96±6.03		28.79±4.88		29.33±4.41		28.69±5.16		*t*=1.303	0.274
Marital status										
Single	14	19.4	9	12.5	7	9.7	30	13.9	χ^2=3.019	0.132
Married	58	80.6	63	87.5	65	90.3	186	86.1	χ^2=4.944	0.077
Educational status										
Primary	14	19.4	3	4.2	0	0.0	17	7.9	χ^2=25.812	*0.001
Secondary	29	40.3	30	41.7	26	36.1	85	39.4	χ^2=24.314	0.056
Tertiary	29	40.3	39	54.2	46	63.9	114	52.8	χ^2=13.331	0.080
Occupation										
Unemployed	16	22.2	7	9.7	2	2.8	25	11.6	χ^2=16.864	0.003
Employed										
Unskilled	33	45.8	28	38.9	29	40.3	90	41.7	χ^2=24.689	0.053
Skilled	23	31.9	37	51.4	41	56.9	101	46.8	χ^2=11.958	0.097
Religion										
Christian	46	63.9	57	79.2	49	68.1	152	70.4	χ^2=11.006	0.093
Atheists	12	16.7	7	9.7	13	18.1	32	14.8	χ^2=6.493	0.116
Muslim	12	16.7	5	6.9	4	5.6	21	9.7	χ^2=10.679	0.052
Traditionalist	2	2.8	3	4.2	6	8.3	11	5.1	χ^2=9.263	0.240
Parity										
Para 0	36	50.0	36	50.0	36	50.0	108	50.0	χ^2=0.000	1.000
Para 1–4	36	50.0	36	50.0	36	50.0	108	50.0	χ^2=0.000	1.000
BMI (kg/m^2)										
25–29	25	34.7	32	44.4	35	48.6	92	42.6	χ^2=3.162	0.224
30–34	41	56.9	35	48.6	28	38.9	104	48.1	χ^2=4.391	0.197
>35	6	8.3	5	6.9	9	12.5	20	9.3	χ^2=3.824	0.384
Mean±SD	31.17±2.75		30.33±2.33		30.69±2.59		30.69±2.58		*F*=2.072	0.128
Mean EGA at delivery in weeks (Mean±SD)	39.58±1.34		40.04±1.26		39.85±1.15		39.85±1.26		*t*=2.578	0.078

*FGR=Fetal growth restriction|EGA=Estimated gestational age|CS=Cesarean section|SD=Standard deviation |χ^2=Pearson Chi-square test. |*t*=Student's *t*-test

Table 2: Primary outcome measures of total study population

	30-mL (*n*=72)		50-mL (*n*=72)		60-mL (*n*=72)		Total		Test statistics	P
Mean change in Bishop's scores at 12 h post-insertion (Mean±SD)	4.18±2.18		5.49±2.62		6.42±2.73		5.36±2.67		*F*=14.311	*0.003 *0.006[a] *0.000[b] 0.083[c]
Bishop scores at 12 h post-insertion										
≥6	47	100	53	100.0	59	100.0	159	100.0	χ^2=1.490	0.222

F=Coefficient of ANOVA|*P* = Probability value | *=Probability value of statistical significance|[a] = Comparison between 30-mL and 50-mL study group using Bonferroni *post hoc* correction|[b] = Comparison between 30-mL and 60-mL study group using Bonferroni *post hoc* correction|[c] = Comparison between 50-mL and 60-mL study group using Bonferroni *post hoc* correction

perception during the cervical ripening process, a majority did not require the need for analgesia compared to those who did; 62% (134) vs 38% (82). Our study found no incidences of Foley catheter balloon rupture or iatrogenic membrane rupture at insertion or during the study duration.

Table 3: Relationship between parity and primary outcome measures of total study population

	30-mL (*n*=72)		50-mL (*n*=72)		60-mL (*n*=72)		Total		Test statistics	P
Mean change in Bishop's scores at 12 h post-insertion Para 0 (*n*=108) (Mean±SD)	3.42±2.17		5.25±2.79		5.75±2.86		4.81±2.79		*F*=7.877	*0.001 *0.011[a] *0.001[b] 1.000[c]
Bishop scores at 12 h post-insertion ≥6	16	44.4	25	69.4	27	75.0	68	63.0	χ^2=0.489	0.143
Mean change in Bishop's scores at 12 h post-insertion Para 1–4 (*n*=108) (Mean±SD)	4.94±1.94		5.72±2.45		7.08±2.44		5.92±2.44		*F*=8.057	*0.001 0.457[a] *0.000[b] *0.039[c]
Bishop scores at 12 h post-insertion ≥6	31	86.1	28	77.8	32	88.9	91	84.3	χ^2=0.734	0.512

F=Coefficient of ANOVA|*P* = Probability value | *=Probability value of statistical significance|[a] = Comparison between 30-mL and 50-mL study group using Bonferroni *post hoc* correction|[b] = Comparison between 30-mL and 60-mL study group using Bonferroni *post hoc* correction|[c] = Comparison between 50-mL and 60-mL study group using Bonferroni *post hoc* correction

As regards participant's satisfaction, there were no differences in the satisfaction level across the three catheter balloon groups. A generality of study participants felt "Somewhat Satisfied" with their management arms corresponding to an average sentiment level of 2.2 on the five-point Likert scale [Table 5].

Discussion

The results of this triple-blind randomized controlled trial showed that there was no statistically significant difference among the three Foley catheter balloon groups in the pattern of baseline clinical and sociodemographic variables such as maternal age, parity, body mass index, and gestational age at delivery which are documented confounders that could have impacted on the primary and secondary study outcomes.[5,20,21] Two sociodemographic variables, primary level of education and being unemployed though statistically significant, are not known cofounders and did not add to the prediction of the primary outcome measures after subjection to multivariate regression analysis. This demonstrates that the randomization process was effective in controlling for the effect of possible confounding variables on the results of the study.

A major finding of this study was that in the total population, there was similar efficacy in achieving a Bishop score of ≥6 at the twelfth-hour post-insertion across the three catheter balloon volume groups. However, the 50-mL and 60-mL single Foley catheter balloons were significantly more efficacious than the 30-mL balloon in achieving a greater mean change in the Bishop's score. The findings are in agreement with the reports of Wijepala *et al.*[13] and Kashanian *et al.*,[12] who compared the 60-mL and 30-mL and the 80-mL and 30-mL single Foley catheter balloons in their respective studies. However, the findings are in contrast to the findings of by Manish *et al.*[15] and Indira *et al.*[16] who found no statistical significant difference in the mean change in Bishop's score when the 30-mL and 60-mL and the 80-mL and 30-mL single Foley catheter balloon volumes were compared. It is likely that the difference between the findings of this study and those of Manish *et al.*[15] and Indira *et al.*[16] are because both studies were not adequately powered to detect/show significant differences in the outcome measures under study

The above findings suggest that though all three catheter balloon types are equally effective in achieving a Bishop score ≥6, the larger balloon types are more likely to produce a greater mean change in Bishop scores and may in turn shorten the overall time for the induction process. This is most likely because with an increased surface area of the larger balloon, there was a more effective mechanical stretch of the cervix and increased release of endogenous prostaglandins which in turn hastened the process of ripening[9,22]

Analysis of the primary outcome measures according to parity showed that there was no difference in the proportion of those who achieved a Bishop score ≥6 across the three catheter groups in both the nulliparous and multiparous study subjects. However, as regards the mean change in Bishop score, the 50-mL and

Table 4: Secondary outcome study measures of total study population

	Mean±SD				Test statistics	*P*
	30-mL	50-mL	60-mL	Total		
Mean change in cervical dilatation						
Para 0	1.83±1.34	2.39±0.93	3.47±1.73	2.56±1.52	t=13.589	*0.003 0.268[a] *0.000[b] *0.003[c]
Mean change in cervical dilatation						
Para 1-4	1.31±1.24	1.69±0.86	2.28±1.21	1.76±1.18	t=6.444	*0.002 0.426[a] *0.001[b] 0.086[c]
Insertion to expulsion/removal interval						
Para 0	11.96±0.19	11.63±0.66	10.94±1.85	11.54±1.16	t=2.266	0.109
Para 1-4	11.58±0.70	11.54±0.74	11.40±0.83	11.51±0.76	t=0.514	0.599
Induction to delivery interval (hours)						
Para 0 (<12)	12 33.3	24 66.7	25 69.4	61 56.5	χ^2=11.828	*0.013
(>12)	24 66.7	12 33.3	11 30.6	47 43.5	χ^2=7.427	*0.001
Para 1 – 4 (<12)	21 58.3	20 55.6	27 75.0	68 63.0	χ^2=3.450	0.181
(>12)	15 41.7	16 44.4	9 25.0	40 37.0	χ^2=5.283	0.172
Use of additional ripening agent						
Para 0 (Yes)	20 55.6	15 41.7	11 30.6	46 42.6	χ^2=3.522	0.078
(No)	16 44.4	21 58.3	25 69.4	62 57.4	χ^2=4.217	0.115
Para 1 – 4 (Yes)	14 38.9	9 25.0	4 11.1	27 25.0	χ^2=7.407	*0.025
(No)	22 61.1	27 75.0	32 88.9	81 75.0	χ^2=6.328	0.055
Vaginal delivery						
Para 0	25 48.1	33 53.2	29 47.5	87 49.7	χ^2=0.493	0.788
Para 1 – 4	27 51.9	29 46.8	32 52.5	88 50.3	χ^2=0.728	0.673
Cesarean section						
Para 0	11 55.0	3 30.0	7 63.6	21 51.2	χ^2=2.576	0.227
Para 1 – 4	9 45.0	7 70.3	4 36.4	20 48.8	χ^2=0.563	0.315
Latrogenic membrane rupture						
Yes	0 0.0	0 0.0	0 0.0	0 0.0	–	–
No	72 100.0	72 100.0	72 100.0	216 100	χ^2=0.000	1.000
	30-mL	50-mL	60-mL	Total	Test statistics	*P*
Catheter balloon rupture						
Yes	0 0.0	0 0.0	0 0.0	0 0.0	–	–
No	72 100.0	72 100.0	72 100.0	216 100	χ^2=0.000	1.000
Pain perception						
Yes	53 73.6	46 63.9	36 50.0	135 62.5	χ^2=8.652	*0.003
Mild	39 73.6	21 45.7	15 41.7	75 55.6	χ^2=10.382	[+]0.013
Moderate	14 26.4	25 54.3	21 58.3	60 44.4	χ^2=13.573	[+]0.048
Severe	0 0.0	0 0.0	0 0.0	0 0.0	-	-
No	19 26.4	26 36.1	36 50.0	81 37.5	χ^2=1.492	*0.047
Need for analgesia						
Yes	24 33.3	27 37.5	31 43.1	82 38.0	χ^2=1.455	0.463
No	48 66.7	45 62.5	41 56.9	134 62.0	χ^2=4.934	0.513
Need for analgesia						
Satisfied	19 26.4	21 29.2	21 29.2	61 28.2	χ^2=9.486	0.131
Somewhat satisfied	29 40.3	25 34.7	25 34.7	79 36.6	χ^2=3.542	0.127
Neither Satisfied/dissatisfied	17 23.6	25 34.7	25 34.7	67 31.0	χ^2=2.317	0.281
Somewhat dissatisfied	7 9.7	1 1.4	1 1.4	9 4.2	χ^2=14.713	0.057
Dissatisfied	0 0.0	0 0.0	0 0.0	0 0.0	-	-

[A] = Comparison between 30-mL and 50-mL study group using Bonferroni post hoc correction| [B] = Comparison between 30-mL and 60-mL study group using Bonferroni *post hoc* correction | [C] = Comparison between 50-mL and 60-mL study group using Bonferroni *post hoc* correction

*Statistical significance | [+] = Statistical significance between mild and moderate pain perception. | χ^2=Pearson Chi-square test. | t=Student's t-test

Table 5: Interpretation of the five-point Likert scale for 30-mL, 50-mL, and 60-mL groups

Sentiment Level (SL)	Numerical Value (NV)	Responses (R)	Total (NV X R)
30-mL GROUP			
Satisfied	1	19	19
Somewhat satisfied	2	29	58
Neither satisfied/dissatisfied	3	17	51
Somewhat dissatisfied	4	7	28
Dissatisfied	5	0	0
For 30-mL: (N X V)/TR=156/72=2.5			
50-mL Group			
Satisfied	1	21	21
Somewhat satisfied	2	25	50
Neither satisfied/dissatisfied	3	25	75
Somewhat dissatisfied	4	1	4
Dissatisfied	5	0	0
For 50-mL: (N X V)/TR=150/72=2.1.			
60-mL Group			
Satisfied	1	21	21
Somewhat satisfied	2	25	50
Neither satisfied/dissatisfied	3	25	75
Somewhat dissatisfied	4	1	4
Dissatisfied	5	0	0
For 60-mL: (N X V)/TR=150/72=2.1. Total average=2.5+2.1+2.1/3=2.2			

60-mL Foley catheter balloons were significantly more efficacious than the 30-mL balloon in nulliparous subjects, while the 60-mL Foley catheter balloon was significantly more efficacious than the 30-mL and 50-mL balloons in multiparous subjects. This finding suggests that larger catheter balloon catheters have the ability to produce greater changes in the Bishop score than the 30-mL balloon catheter.

The findings of this study as regards the secondary outcome measures showed that the 60-mL Foley catheter balloon produced greater mean changes in the cervical dilatation at 12 h post-insertion compared to the 30-mL and 50-mL Foley catheter balloons in nulliparous subjects and the 30-mL Foley catheter balloon volume only among multiparous subjects. Levy *et al.*[11] and Delaney *et al.*[9] demonstrated similar findings in their respective studies comparing the 30-mL catheter balloon to the 60-mL and 80-mL balloons. Similarly, the findings of this study as regards the induction to the delivery interval were consistent with those of Delaney *et al.*,[9] Levy *et al.,*[11] and Wijepala *et al.*[13] Indira *et al.*,[16] however, found a comparable mean induction without the to delivery interval in their study comparing the 30-mL and 60-mL catheter balloon groups irrespective of parity. The contrasting finding by Indira *et al.* could be because their sample size was small and, therefore, may not have been adequately powered to show significant differences in the outcome measured. The above findings suggest that a larger balloon volume may produce much greater and faster cervical dilatation and thus shorten the longest period in the labor curve, that is, the latent phase before 6 cm.[9,14]

This study found no differences in the three catheter balloon volumes as regards the insertion to expulsion interval, vaginal delivery, and cesarean section rates, respectively, irrespective of parity. This could be explained from the findings of this study that the three catheter balloon volume groups showed similar efficacy in achieving a Bishop score of ≥6 at the twelfth hour post-insertion, in addition to the fact that all subsequent management followed the same departmental protocol.

The comparable mean time (in hours) between insertion and expulsion or removal of the Foley catheter balloon in this study was consistent with those found by Delaney *et al.*,[9] Indira *et al.,*[16] and Levy *et al.*,[11] when comparing the 30-mL and 60-mL and 30-mL and 80-mL Foley catheter balloon, respectively. Likewise, the similar vaginal delivery and cesarean section rates across all Foley catheter balloon groups in this study were consistent with the findings of Delaney *et al.*,[9] Indira *et al.,*[16] and Manish *et al.*,[15] but was inconsistent with the findings of Wijepala *et al.*[13] whose study reported a significantly higher vaginal delivery and lower cesarean section rates in their 60-mL group when compared to the 30-mL group. This contrasting finding could likely be because the gestational age at entry into the study by Wijepala *et al.* was set at 40 weeks and 2 days; hence, the finding cannot be generalized for other term gestations.

Similarly, this study found no incidence of Foley catheter balloon and iatrogenic membrane rupture during the study duration. Delaney *et al.*,[9] Indira *et al.*,[16] Kashanian *et al.,*[12] and Manish *et al.*[15] reported similar findings despite over inflating the catheter balloon beyond the manufacturer's required limit. This was in contrast to the study by Sandberg *et al.*[22] who reported that the Foley catheter balloon ruptured 12 times in the 60-mL group compared to the 30-mL group. This may have arisen from either structurally faulty Foley catheters.

As observed in the findings of this study, a statistically significant majority of multiparous women did not require an additional ripening agent across the three catheter balloon groups. There was however no difference in this parameter among nulliparous women. The findings in the multiparous study subjects were consistent with that of Indira *et al.*[16] who compared the 30-mL and 60-mL Foley catheter balloon volumes. These observations can clearly be explained by the findings of this study that a majority of multiparous women achieved Bishop score's ≥6 at the twelfth-hour post-insertion. Similarly, a statistically significant majority of women in the 30-mL group reported having mild pain intensity in contrast to the 50-mL and 60-mL catheter group subjects who had moderate pain intensity. The finding on moderate pain intensity associated with the 60-mL catheter balloon volume type was similar to the observation of the study by Wijepala *et al.*[13]

This study found no differences in the proportion of women who had analgesia administered regardless of the catheter balloon volume used for the ripening process. Previous studies including that of Wijepala *et al.* did not assess/compare the proportion of women who had analgesia administered using different Foley catheter balloon volumes for cervical ripening. Similarly, there was no observed significant difference in the various satisfaction levels across the three Foley catheter groups even when parity was considered. This was consistent with the findings of Dombrovsky *et al.*,[23] who found no difference in their study participant's satisfaction level, when the 10-, 30-, and 70-mL catheter balloon volumes were compared.

From the aforementioned, the findings of this study suggest that larger catheter balloon volumes produce greater mean changes in the Bishop scores, more advanced cervical dilatation, and shorter induction to delivery interval with similar pain rating scores and satisfaction levels. The findings of this study can thus be generalized to clinical settings where pregnancy and childbirth are cared for in routine clinical practice because the randomization process was shown to be effective, and its triple-blind design eliminated treatment allocation, study arm ascertainment, treatment intervention as well as outcome reporting biases.[24,25] In addition, the application of a self-administered numerical pain rating scale (NPRS)[26,27] and a five-point Likert-like scale,[28] to assess the participant's perception of pain and satisfaction with respect to the different Foley catheter balloon volumes, strengthens the safety and applicability of using larger single Foley catheter balloon volumes for pre-induction cervical ripening.

This study was not without its limitation as the potential for both intra- and inter-observer variability in the assessment process may not have been completely eliminated and entirely controlled for. This was however recognized at the outset of the study and was mitigated by training all research assistants on the specific protocols adopted in the assessment of the primary and secondary outcome measures.

In conclusion, the findings of this study showed that the larger single Foley catheter balloon volumes (50-mL and 60-mL) aside from being well tolerated and acceptable have the ability to induce faster changes in Bishop score, produce higher cervical dilation, and thus likely reduce significantly the total labor induction process compared to the 30-mL single catheter balloon volume irrespective of parity.

Based on the findings of our study, we recommend inflating the single Foley catheter balloon to either 50-mL or 60-mL for pre-induction cervical ripening in both nulliparous and multiparous women, as they are safe, acceptable, and have the potential to shorten the labor induction process.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Diederen M, Gommers JSM, Wilkinson C, Turnbul D. Safety of the balloon catheter for cervical ripening in outpatient care: Complications during the period from insertion to expulsion of a balloon catheter in the process of labour induction: A systematic review. BJOG 2018;125:1086–95.
2. Jozwiak M, van de Lest HA, Burger NB, Dijksterhuis MG. Cervical ripening with Foley catheter for induction of labour after cesarean section: A cohort study. Acta Obstet Gynaecol Scand 2014;93:296–301.
3. Jozwiak M, ten Eikelder M, Oude Rengerink K, de Groot C, Feitsma H, Spaanderman M, *et al*. Foley catheter versus vaginal misoprostol: randomized controlled trial (PROBAAT-M Study) and systematic review and meta-analysis of literature. Am J Perinatol 2014;31:145–56.

4. Zhu L, Zhang C, Cao F, Liu Q, Gu X, Xu J, *et al*. Intracervical foley catheter balloon versus dinoprostone insert for induction cervical ripening: A systematic review and meta-analysis of randomized controlled trials. Medicine (Baltimore) 2018;97:e13251. doi: 10.1097/MD.0000000000013251.
5. Arulkumaran S, Talaulikar V. Failed induction of labour: Strategies to improve the success rates. Obstet Gynaecol Surv 2011;66:717–28.
6. Fruhman D, Gavard JA, Amon E, Flick KVG, Miller C, Gross G. Tension compared to no tension on a Foley transcervical catheter for cervical ripening: A randomized controlled trial. AJOG 2017;216:P67.E1-9.
7. Connolly KA, Kohari KS, Factor SH, Rekawek P, Miller MR, Smilen BS, *et al*. A randomized trial of foley balloon induction of labor trial in multiparas (FIAT-M). Am J Perinatol 2017;34:1108–14.
8. American College of Obstetricians and Gynaecologists. Practice bulletin clinical management guidelines for obstetrician-gynecologists: Induction of labor. Obstet Gynecol 2009;114:368–97.
9. Delaney S, Shaffer BL, Cheng YW, Vargas J, Sparks TN, Paul K, *et al*. Labour induction with a Foley balloon inflated to 30 mL compared with 60 mL: A randomized controlled trial. Obstet Gynaecol 2010;115:1239–45.
10. Berndl A, El-Chaar D, Murphy K, McDonald S. Does cervical ripening at term using a high volume foley catheter result in a lower caesarean section rate than a low volume foley catheter? A systematic review and meta-analysis. J Obstet Gynaecol Can 2014;8:678–87.
11. Levy R, Kanengiser B, Furman B, Ben Arie B, Brown D, Hagay Z. A randomized trial comparing a 30-mL and an 80-mL Foley catheter balloon for preinduction cervical ripening. Am J Obstet Gynaecol 2004;191:1632–6.
12. Kashanian M, Nazemi M, Malakzadegan A. Comparison of 30-mL and 80-mL Foley catheter balloons and oxytocin for preinduction cervical ripening. Int J Gynaecol Obstet 2009;105:174–5.
13. Wijepala J, Najimudeen M. Comparison of 30 ML and 60 ML Foley catheter for cervical ripening. Eur Sci J 2013;9:180–94.
14. Schoen CN, Saccone G, Backley S, Sandberg EM, Gu N, Delaney S, *et al*. Increased single-balloon foley catheter volume for induction of labor and time to delivery: A systematic review and meta-analysis. Acta Obstet Gynaecol Scand 2018;97:1051–60.
15. Manish P, Rathore S, Benjamin SJ, Abraham A, Jeyaseelan V, Mathews JE. A randomised controlled trial comparing 30 mL and 80 mL in Foley catheter for induction of labour after previous caesarean section. Trop Doct 2016;46:205–11.
16. Indira I, Latha G, Lakshmi Narayanamma V. Comparative study of induction of labour with Foley's catheter inflated to 30 mL versus 60 mL. J Clin Sci Res 2016;5:153–9.
17. Moher D, Hopewell S, Schulz KF, Montori V, Devereaux PJ, Elbourne D, *et al*. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c889.
18. Charan J, Biswas T. How to calculate sample size for different study designs in medical research ? Indian J Psychol Med 2013;35:121–6.
19. Broglio K. Randomization in clincal trials. Permuted blocks and stratification. J Am Med Assoc 2018;319:2223–4.
20. Baños N, Migliorelli F, Posadas E, Ferreri J, Palacio M. Definition of failed induction of labor and its predictive factors: Two unsolved issues of an everyday clinical situation. Fetal Diagn Ther 2015;38:161–9.
21. Leduc D, Biringer A, Lee L, Dy J. SOGC Clinical Practice Guideline: Induction of Labour. J Obs Gynaecol Can 2013;35:840–57.
22. Sandberg EM, Schepers EM, Van Sitter RL, Huisman CMA, Van Wijngaarden WJ. Foley catheter for induction of labour filled with 30 mL or 60 mL: A randomized controlled trial. Eur J Obstet Gynecol Reprod Biol 2017;211:150–5.
23. Dombrovsky I, Kristina R, Stowe RJ, Okpekpe C, Valenzuela G. A Randomized controlled trial of 10, 30, and 70 mL ttranscervical foley catheters for cervical ripening during induction of labour: Time to delivery and patient satisfaction: Is bigger better? 2020. Available from: https://www.arrowheadregional.org/.
24. Abdelhamid A. Bias in RCTS: Confounders, selection bias and allocation concealment. Middle East Fertil Soc J 2005;10:258–61.
25. Karanicolas PJ, Farrokhyar F, Bhandari M. Blinding: Who, what, when, why, how? Can J Surg 2010;53:345–8.
26. Childs JD, Pira SR, Fritz J. Responsiveness of the numerical pain rating scale in patients with low back pain. Spine (Phila Pa 1976) 2005;30:1331–4.
27. Williamson A. Pain: A review of three commonly used pain rating scales. Issues Clin Nurs 2005;14:798–804.
28. McLeod SA. Likert scale definition, examples and analysis. Available from: https://www.simplypsychology.org/likert-scale.html. 2008.