International Journal of Research in Medical Sciences
Adiele NA et al. Int J Res Med Sci. 2022 Jan;10(1):22-30
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20215030

Original Research Article

Profiling cervical ripening for induction of labour with Foley's balloon catheter in Ebonyi state, Nigeria: a randomized controlled trial

Nnabugwu Alfred Adiele[1]*, Christian C. Mgbafulu[1], Arinze Chidiebere Ikeotuonye[1], Christian Chidebe Anikwe[1], Joshua Adeniyi Adebayo[1], Nkemjika Miriam Adiele[2], Wilson Ndukwe Nwigboji[1], Ayodele Adegbite Olaleye[1], Amuchechukwu Veronica Nwafor[1], Lucky Osaheni Lawani[1]

[1]Department of Obstetrics and Gynaecology, Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State, Nigeria
[2]Department of Chemical Pathology, Enugu State University Teaching Hospital, Parklane, Enugu State, Nigeria

Received: 11 October 2021
Revised: 08 November 2021
Accepted: 12 December 2021

***Correspondence:**
Dr. Nnabugwu Alfred Adiele,
E-mail: nadiele2001@gmail.com

ABSTRACT

Background: The ripeness of the cervix is an important prerequisite to a successful labour induction. Use of extra-amniotic Foley catheter is a mechanical method of cervical ripening with proven efficacy. This study compared the difference in efficacy between 30 ml and 60 ml of water for inflation of Foley catheter balloon when used for cervical ripening during induction of labour.
Methods: A single-blind randomized controlled study where 260 term pregnant women with intact membranes and unfavourable cervix were selected for induction of labour and randomized into two equal groups (30 ml- and 60 ml-groups) from October, 2019 to July 2020. Each participant had cervical ripening with the catheter bulb inflated with either 30 ml or 60 ml of sterile water (as assigned to the individual). After achieving favourable cervix (BS ≥6), oxytocin titration was commenced and the labour monitored with the outcomes well documented and statistically analysed.
Results: Mean duration to favourable Bishop Score significantly reduced in the 60 ml group (10.8 hours±2.99) as against 12.7 hours±10.0 in 30ml group (p=0.038). Mean duration of active phase of labour was significantly reduced in 60 ml group (5.6 hours±2.4) as against 8.4 hours±3.2 in 30 ml group (p=0.010). Caesarean delivery rate was significantly reduced in the 60 ml groups (p=0.027).
Conclusions: The use of 60 ml inflated Foley's balloon catheter when compared with 30mls to ripen the cervix effectively reduced the duration to favourable Bishop Score, duration of the active phase of labour and the rate of Caesarean sections.

Keywords: Cervical ripening, Induction of labour, Foley's balloon catheter

INTRODUCTION

Labour is a physiological process characterized by sequence of uterine contractions that results in effacement and dilatations of cervix, leading to the expulsion of the fetus and other products of conception.[1,2] It's onset maybe spontaneous or induced. The incidence of labour induction has increased over the last decade; and about 25% of women will have their labour induced.[3,4] Labour induction rate varies within 9.5 to 33.7

percent of all pregnancies annually.[5] It is estimated that the rate had doubled between 1990 and 2006 and has continued to trend upwards.[6]

Maternal indications for labour induction include pre-eclampsia, eclampsia, placental abruption, chorioamnionitis, polyhydraminous, postdatism, chronic hypertension and renal disease in pregnancy.[7] Fetal indications are Rhesus isoimmunization, intrauterine death, unstable lie, fetal congenital anomaly and intrauterine growth restriction.[7] Non-medical indications may include none proximity to a health facility and/or transportation difficulties, prior history of precipitated labour. In such situations, the preferred gestational age should be greater or equal to 39 weeks.[5,8] Contraindications to the procedure are placenta previa, vasa previa, transverse fetal lie, previous classical caesarean section.[4,5]

Cervical ripening refers to the softening of the cervix that typically begins prior to the onset of uterine contractions and is required for cervical dilatation and delivery of the fetus and other products of conception.[9] It results from the series of complex biochemical processes that lead to rearrangement and realignment of the collagen molecules.[9] The cervix then thins, softens, relaxes and dilates in response to subsequent uterine contractions allowing the cervix to easily pass over the fetal presenting part during labour.[10,11] Apart from pharmacological methods of cervical ripening, mechanical methods exist including osmotic dilators, transcervical Foley and double balloon catheters. These work by directly causing cervical dilatation and also by releasing of endogenous prostaglandins and oxytocin.[12]

Transcervical Foley catheter placement has been established as a safe and effective modality in the setting of labour induction6. Foley catheter placement before the initiation of oxytocin has been shown to decrease the risk of caesarean delivery when compared with oxytocin alone.[13] Current evidence showed no difference in the duration of induction to delivery or risk of caesarean section when the efficacy of Foley catheter was compared to that of intravaginal prostaglandins.[6,14] Foley catheter use offers the advantage of lower cost, reversibility, stability at room temperature and decrease in the risk of tachysystole (with or without fetal heart changes).[12,13] It however has the potential side effects of premature rupture of membranes, chorioamnionitis, bleeding, increased patient discomfort, and displacement of presenting parts.[15] Multiple studies, however have not shown any consistent association between Foley catheter use and these risks.[16,17,18]

Since 1976, when transcervical Foley catheter for cervical ripening during labour induction was first described by Embrey and Mollison using a 26 guage Foley with 50 ml balloon, various balloon sizes ranging from 30 to 80 ml have been reported with varying results regarding the duration between insertion of catheter and cervical ripening, as well as the induction-delivery interval and the risk of caesarean delivery.[19] Some authorities have argued that higher balloon volumes stretch the cervix better and therefore achieve cervical ripening earlier than lower volumes with subsequent shorter induction-delivery intervals while others have found no difference between higher and lower volumes of catheter inflation.

As there is no consensus yet on the appropriate volume of water used to inflate catheter balloon for cervical ripening, this study was done to compare 30 ml and 60 ml of catheter balloon inflation in achieving cervical ripening and to assess maternal satisfaction. The findings of this study will help in the standardization of practice and comparison of results.

METHODS

This was a multi-center, single-blind randomized controlled study to compare the efficacy in labour induction of two insufflations volumes of Foley catheter bulb, 30 ml and 60 ml, at the Alex-Ekwueme Federal University Teaching Hospital Abakaliki (AE-FUTHA), Mile 4 Hospital Abakaliki and Mater Misericordiae Hospital Afikpo all in Ebonyi state, Nigeria. The study was conducted from October, 2019 to July, 2020.

Study background

Ebonyi state, located in the South Eastern Nigeria, was created on October 1, 1996. Abakaliki is the state capital and its population is about 438,700 and consists of different ethnic groups, predominantly Igbo. Afikpo is the second largest urban area in Ebonyi State with estimated population of 156,611 as at Nigerian 2006 Census. Generally, pregnant women in these two towns have strong aversion to cesarean delivery.

AE-FUTHA is the only Teaching Hospital in Ebonyi State. It's Obstetrics and Gynaecology department runs antenatal clinics managed by consultants and resident doctors with trained Nurses/Midwives. The hospital serves as a major referral center for Ebonyi and surrounding states. St. Patrick's Mile 4 Hospital is one of the mission hospitals in the state. It is managed by Consultant Obstetricians, resident doctors who are routinely posted from AE-FUTHA, medical officers and nurses. Mater Misericordiae Hospital Afikpo is one of the oldest missionary hospitals in Nigeria. It has well-developed Obstetrics and Gynecology Unit attended to by Consultant Obstetricians, resident doctors routinely posted from AE-FUTHA, medical officers and nurses.

Study population

This involved parturients at term (37 - 41+6 weeks' gestational age) with singleton, vertex presenting fetus and having intact membranes and unfavorable cervix, on admission for cervical ripening and labour induction with

extra-amniotic Foley's catheter. Women with the following conditions were excluded: ruptured fetal membranes, previous uterine surgery, placenta preavia, multiple pregnancy, HIV positive status, malpresenting fetuses, established labour, fetal structural anomaly and already favourable cervix. Patients that opted for epidural analgesia in labour or declined consent to the study were also excluded.

Sample size determination

The minimum sample size was determined using the formula for randomized controlled trials for equivalence study where primary outcomes are continuous variables as documented by Zhong.[20]

$N \text{ (size per group)} = 2 \times [(Z\ 1\text{-}\alpha/2 + Z\ 1\text{-}\beta) / \partial 0]^2 \times S^2$

Where: $Z\ 1\text{-}\alpha/2 = 1.96$

$Z\ 1\text{-}\beta = 0.845$

$\partial 0$ (clinically accepted margin from a related study, Delaney et al[14]) =1.0

S (polled standard deviation from a related study, Delaney et al14) = 2.7

$N = 2 \times [(1.96 + 0.845)/1]^2 \times (2.7)^2$

$N = 2 \times [2.805]^2 \times (2.7)^2$

$N = 2 \times 7.87 \times 7.29$

$N = 114.74$

$N \text{ (size per group)} \approx 115$

10% of the minimum sample size per group was added to correct for attrition, hence the final sample size was 130 for each arm.

Informed consent

The study objectives, procedure and full implication of participation were discussed with each participant before her signed consent is obtained. The participants were made to understand that declining participation had no consequences to receiving adequate care.

Randomization and concealment

A computer generated random-number using the software Research Randomizer was used in the randomization of the participants. Using this software, 130 numbers were randomly generated from a pool of 260 numbers (1 - 260) and these numbers were assigned to group A (30 ml group) while the remaining 130 were automatically assigned to group B (60 ml group). Group A received 30mls of sterile water instilled into size '20F Foley catheter (®U-MEC) after insertion into the intra-cervical, extra-amniotic compartment while Group B received 60mls of sterile water instilled into size '20F Foley catheter (®U-MEC) after insertion into the intra-cervical, extra-amniotic compartment.

Concealment was done in sequentially numbered opaque sealed envelopes (SNOSE). The numbers 1 to 260 were inscribed on brown envelopes and a piece of paper with the inscription '30' or '60' (depending on the group the number was assign to) was placed inside each envelope and sealed. The randomization and concealment were done by the researcher in conjunction with a statistician. All the envelopes were randomly kept in lockers that were accessible to all the members of the research team in the selected hospitals. After signing the informed consent, participants that met the inclusion criteria were given sequential study number and the corresponding numbered opaque sealed envelope was allocated to the patient.

Study procedure

Women scheduled for induction of labour were recruited from antenatal clinics, antenatal wards and accident/ emergency units of the selected facilities after been screened for inclusion into the study. The study was explained to the patient and a signed consent obtained. Clinical history and astute clinical examination were done to confirm the indication for the labour induction. Non-stress test (NST) was done with her lying comfortably on a couch and then connected to a cardiotocogram machine for 30 minutes while the fetal heart rate was monitored. Thereafter, an obstetric ultrasound was done by a Radiologist to ascertain the biophysical profile. Other ancillary investigations in preparation for labour induction were done.

By 6 pm, the patient was seen in the labour ward. She voided and emptied her bladder after which her privacy was secured using the ward screen with a female nurse present as a chaperon. The patient was placed in supine position and an abdominal examination done. The patient was then placed in a dorsal position and after cleaning the vulva with gauze soaked with savlon solution, a digital vaginal examination was done with sterile gloved fingers to assess the Bishop score. A sterile Cusco's speculum was gently passed into the patient's vagina, opened and retained to expose the cervix. Under direct vision, the anterior lip of cervix was held with a pair of sponge holding forceps to stabilize it and the ectocervix was cleaned with savlon. A sterile size '20 Foley catheter, held about 5 cm below the tip of its balloon end with another pair of sponge holding forceps, was inserted into the cervical canal under direct vision till it encountered the resistance of the fetal presenting part. With the help of an assistant, the catheter balloon was inflated with either 30mls or 60mls of sterile water (depending on the group allocated to the patient). The catheter was gently

pulled on to ensure it does not come out. The blades of the Cusco's speculum were released and the speculum was then removed gently from the patient's vagina. The external end of the catheter was strapped onto the medial aspect of patient's less dependent thigh under slight-moderate tension and the open end of the catheter was spigotted. The patient was then cleaned up and placed back to a supine position and the fetal heart rate rechecked for its normalcy. She was made comfortable in a left lateral position and observed in the labour ward for at least an hour for any undue vaginal bleeding, drainage of liquor or abnormal fetal heart rate. After this, she was transferred back to the antenatal ward and advised to report to the duty nurse once the catheter falls out. The clinical findings were explained to her.

By 6 am the next day (12 hours from time of catheter insertion), the patient was reviewed at the antenatal ward. History was taken to rule out any complication such as liquor drainage or bleeding per vaginam and the time the catheter fell off (if this occurred) was noted. She was then examined (with a female nurse present as chaperone). The ward screen was used to secure patient's privacy. An abdominal examination was done and the fetal heart rate rechecked for its normalcy. The bulb of the earlier inserted catheter was deflated and the catheter gently pulled out. After putting on a sterile glove, a repeat digital vaginal examination was done and the Bishop score reassessed. Patients that had attained a favorable cervix (BS ≥6) were transferred to labour ward and oxytocin titration commenced for labour induction according to our departmental protocol as detailed subsequently (see below). The time of catheter insertion/expulsion, cervical dilatation after expulsion, time taken to attain active phase parameters, duration of active phase of labour, delivery within 12 hours, mode of delivery, maternal and fetal outcomes were documented appropriately.

However, if the cervix remained unfavorable, the catheter was removed and re-inserted after 12 hours. In absence of serious urgency for labour induction, the procedure was repeated once more for favorable cervical transformation to occur. None of the participants had catheter inserted more than twice. Patients with urgent need for delivery, inadvertent rupture of fetal membranes or who did not attain favorable cervix after the required numbers of attempts were withdrawn from the study and an alternative mode of delivery decided by the managing consultant/unit. After delivery, the patients' level of satisfaction with the labour process was rated in the postnatal ward using a Likert scale before she was discharged home.

Oxytocin titration

An intravenous access was secured with a size 18 G cannular. Only oxytocin (Rotex®) was used in this study. The procedure was commenced by instilling 5 IU of oxytocin into 500 mls of 0.9% normal saline. This was connected to the intravenous cannular using the standard gauge blood giving set21. The titration was started at 10 drops/minute (5 miu/min) and increased by 10 drops every 30 minutes until at least 3 strong uterine contractions are achieved. The oxytocin drip was then maintained at the rate at which this was achieved. A synchronous amniotomy was done within 2 hours of commencement of oxytocin titration. The labour events were monitored with partograph21 and cardiotocogram. Parenteral analgesia with intramuscular pentazocin 30 mg was administered 4 hourly until cervical dilatation reaches 6 cm, after which subsequent analgesia was maintained with intramuscular tramadol 100 mg. Maternal vital signs were monitored every 30 minutes with digital vaginal examination to assess labour progress done every 4 hours. Patients that achieved full cervical dilatations were delivered by skilled birth attendants. However, those that required any form of instrumental delivery, including cesarean section, had such procedure done by either a consultant or a senior registrar. The APGAR scores at the 1st and 5th minutes of delivery were noted.[22] Records of events and outcomes were done. Each patient's social class was calculated and documented using her highest educational level and the profession of her husband as postulated by Olusanya et al.[23]

Outcome measures

Primary outcome measures included: time taken to achieve favorable Bishop Score, duration of active phase in each patient, induction-delivery interval, number of times the procedure was done before favorable cervix was attained; while the secondary outcomes were: mode of delivery, maternal complications, maternal satisfaction and fetal outcome.

Statistical analysis

Data were analyzed using Statistical package for social science (SPSS) software (version 20, Chicago II, USA). Numerical variables were presented as mean and standard deviation (Mean ± S.D), while categorical variables were presented as numbers and percentages. Chi-square test (X2) was used for comparison between groups for qualitative variables while student t-test was used for comparison between groups for quantitative variables. A difference with a $p<0.05$ was considered statistically significant.

RESULTS

Over the study duration of 9 months, 417 patients were assessed for eligibility into the study; 157 patients were excluded while 260 were included. This was equally distributed between the two arms of the study. Analysis of the data was done using per protocol concept.

Table 1 shows the socio-demographic parameters of the two arms with comparable means for age, booking status,

parity and occupation (p=0.675, 0.852, 0.622 and 0.788 respectively). The mean ages of the participants were 29.6 years±6.24 for 30ml arm and 29.0±5.58 for the 60 ml arm. (Table 1)

Table 1: Comparison of the participants' socio-demographic data.

Age (years)	30 ml arm (n=130)	60 ml arm (n=130)	P value
15-19	10	7	0.675
20-24	28	25	
25-29	21	30	
30-34	33	41	
35-39	29	22	
40-44	9	5	
Booking status	**n=130**	**n= 130**	
Booked	114	113	0.852
Unbooked	16	17	
Parity	**n=130**	**n =130**	
0	39	36	0.622
1-4	75	76	
≥5	16	18	
Occupation	**N = 130**	**N =130**	
Civil servant	49	47	0.788
Trader	39	46	
House wife	34	30	
Farmer	8	7	

Table 2: Comparison of various baseline parameters.

Parameters	30 ml arm (n=130)	60 ml arm (n=130)	P value
Gestation age (weeks) Mean ± SD	39.8±2.31	39.85±2.01	0.996
Mean frequency of catheter insertion Mean ± SD	1.35±0.47	1.06±0.17	0.00001

Table 2 shows the comparison of the gestational age on admission. This was comparable in both groups (p=0.996). The mean gestational ages for the participants in the study were 39.8 weeks±2.31 and 39.85 weeks±2.01 for 30 ml and 60 ml groups respectively. The mean frequency of catheter insertion was 1.35±0.47 for the 30ml arm while that of 60ml arm was 1.06±0.17 (p=0.00001) (Table 2).

Table 3 shows further comparison on baseline parameters. The social class and indications for induction of labour were comparable in both groups (p=0.763 and 0.194 respectively) (Table 3).

Table 3: Comparison of baseline parameters.

Parameters	30 ml arm (n=130)	60 ml arm (n=130)	P value
Social class	**frequency**		
1	8	10	0.763
2	45	43	
3	65	68	
4	12	10	
5	0	0	
Indication for iol	**n= 130**	**n =130**	
Preeclampsia	31	26	0.194
Postdatism	62	64	
Chronic kidney disease	4	1	
Chronic liver disease	1	4	
Diabetes mellitus	9	7	
Hypertensive heart disease	7	1	
Hypertension	10	13	
Fetal death	2	9	
Patient's wish	3	5	

Table 4: Comparison of labour and delivery parameters.

Events	30 ml arm	60 ml arm	P value
Mean Duration to favourable Bishop score (Hours) Mean ± SD	12.7 ± 10.0	10.8 ± 2.99	0.038
Mean Duration of active phase of labour (Hours) Mean ± SD	8.4 ± 3.2	5.6 ± 2.4	0.010
Mean Induction-Delivery interval (Hours) Mean ± SD	8.45 ± 3.87	6.65 ± 3.10	0.197
Maternal Satisfaction Score Mean ± SD	3.29 ± 0.37	3.53 ± 0.39	0.496

Table 4 shows the comparison of labour and delivery parameters. The mean duration to favourable Bishop's score for the 30ml arm was 12.7 hours±10.0 and that for 60ml arm was 10.8 hours±2.99. This was statistically significant (p=0.038). The mean duration of active phase of labour for the 30 ml arm was 8.4 hours±3.20; and 5.6 hours±2.40 for the 60ml arm. This was also statistically

significant (p=0.010). The mean induction - delivery intervals and mean maternal satisfaction were not statistically different with p-values of 0.197 and 0.476 respectively (Table 4).

Table 5: Comparison of labour and delivery parameters.

Parameters	30 ml arm (n=130)	60 ml arm (n=130)	P value	RR (95% C.I)
Mode of delivery				
Vaginal	92	108	0.027	0.852 (0.744-0.975)
C/Section	38	22		
Total number of C/sections: 60	38	22		
Indications for C/sections				
Inadequate contractions	13	2		
Fetal heart irregularities	10	12		
CPD due to persistent OPP	15	8		
Need for AOL	75	57	0.035	1.316 (1.031-1.679)
1ST minute APGAR				
< 7	29	19	0.130	1.261 (0.976-1.672)
≥ 7	101	111		
5TH minute APGAR				
< 7	0	0	1	1
≥ 7	130	130	1	1

Table 6: Multivariate analysis of duration of labour for the two groups.

Parameters	30 ml arm (n=130)	60 ml arm (n=130)	P value	RR (95% c.i)
Delivery ≤12 h				
All parturients	104	117	0.938	0.980 (0.594-1.619)
Nulliparae	22	26		
Multiparae	82	91		
Delivery > 12 h				
All Parturients	25	13	0.714	1.387 (0.44-4.36)
Nulliparae	8	3		
Multiparae	17	10		

Table 7: Comparison of maternal and fetal/neonatal complications.

Parameters	30 ml arm (n=130)	60 ml arm (n=130)	P-value	RR (95% c.i)
Cervical trauma	6	11	0.316	0.546 (0.208-1.431)
PPH	7	13	0.244	0.539 (0.222-1.306)
Ruptured uterus	0	0	1	1
Fetal heart irregularity	11	10	0.820	1.1 (0.484-2.500)
Neonatal seizures	4	8	0.376	0.661 (0.294-1.486)
Nicu admission	42	39	0.435	1.857 (0.615-1.196)
Neonatal death	7	4	0.540	1.75 (0.525-5.832)

Table 5 continues with the comparison of labour and delivery parameters. With regards to mode of delivery, vaginal delivery was achieved by 92 (70.8%) and 108 (83%) parturients of 30 ml and 60 ml arms respectively; while Caesarean delivery was conducted for 38 (29.2%) and 22 (17%) parturients of the 30ml and 60ml respectively. This difference was statistically significant (p=0.027; RR= 0.852; 95% C.I [0.744-0.975]).

Table 6 shows the multivariate analysis of duration of labour. Among the parturients in the 30 ml arm that achieved delivery within 12 hours in labour, 22 (16.9%) were nulliparae while 82 (63.1%) were multiparae. Comparably for the parturients in the 60ml arm, 26 (20%) were nulliparae while 91 (70%) were multiparae. This difference was not statistically significant (p= 0.938; RR= 0.980; 95% C.I [0.594 – 1.619]) (Table 6).

Table 7 shows the comparison of maternal and fetal/neonatal complications. With regards to maternal complications, out of 130 parturients randomized to the 30ml arm, six had cervical trauma and seven had postpartum haemorrhage; while out of 130 parturients randomized to the 60ml arm, eleven had cervical trauma and thirteen had postpartum haemorrhage. These were not statistically significant (p= 0.316; RR= 0.546 [CI: 0.208-1.431] and 0.244; RR=0.539[CI: 0.222-1.306] respectively).

DISCUSSION

The mean frequency of catheter insertion for the 30ml arm was 1.35±0.47 compared with 1.06±0.17 for the 60 ml arm. This was statistically significant and shows an increased likelihood of achieving cervical ripening with fewer catheter insertions using 60 ml inflated Foley's catheter. The mean duration to favorable Bishop Scores for the 30 ml group was 12.7±10.0 hours compared with 10.8±2.99 hours for the 60ml group. This was statistically significant and suggests that higher catheter balloon inflation may lead to more distension of cervix with more release of endogenous prostaglandins and faster ripening of the cervix. This finding was different from the study done by Indira et al who found no significant difference in the duration to favorable cervix when 30 ml and 60 ml Foley's catheter inflation were compared.[24] Indira et al conducted the study among Indians and used a smaller sample size (50 participants per arm) to arrive at its conclusion. This may have contributed to the difference in outcomes. None of the other studies accessed the duration to achieving favorable Bishop Score.[14,25,26] Again, the mean duration of active phase of labour for the 30 ml arm was 8.4 hours±3.2; and 5.6 hours±2.4 for the 60 ml arm. This was also statistically significant and suggests that the endogenous prostaglandins, probably released in higher quantity when 60 ml balloon inflation is used to achieve cervical ripening, further contribute to cervical dilatation during active phase of labour. This finding tallied with a similar study by Delany S14 which recorded a significant shortened active phase of labour in the 60 ml group. Both studies shared similar sample size and methodology and this may have contributed to the identical outcomes.

The mean induction – delivery interval for the 30ml group was 8.45 hours±3.87 and 6.65 hours±3.10 for the 60 ml group. The difference in the interval for the two groups was not statistically significant and this suggests that durations of latent phase and the 2nd stage of labour may be independent of the volume of catheter balloon inflation used during cervical ripening. This finding was similar with the results of studies conducted by Delany, Manish, Sandberg and Indira who all found no significant difference in the induction-delivery interval in the use of 30ml inflated Foley catheter for cervical ripening for induction of labour compared with the use of 60ml inflated Foley's catheter for the same procedure.[14,24,27,28] These three studies share similar sample size with the index study and this may have accounted for the similarity in their results.

Mode of delivery showed a statistically significant difference when the two groups were compared. Here 29% of the 30ml group delivered by caesarean section while only 17% of the 60ml group had caesarean delivery. This suggests that the use of 60 ml inflated Foley's catheter to achieve cervical ripening reduced the risk of caesarean section by about 15%. This finding is similar with that of Wijepal and Levy who recorded significant reduction in caesarean delivery rate among the 60 mls arm.[25,29] These similar results may be due to the fact that these studies, like the index study, excluded women with previous uterine surgeries. However, the above finding was different with that observed by Manish et al which showed no statistically significant difference in the mode of delivery in the two arms of the study.[27] This may be attributed to the fact that Manish et al recruited only high risks parturients with previous caesarean sections. This, no doubt, would influence the intrapartum decisions with low threshold for caesarean delivery.

The need for further increment in the oxytocin titration was recorded in 57.7% (75 participants) of the 30ml group while same was done for 43.8% (57 participants) of the 60 ml group. This difference was statistically significant and suggests that 60ml catheter inflation, through mechanical distension of the cervix and increased release of prostaglandins, enhanced the cervical dilation during labour thus minimizing the need for further increment in the oxytocin titration which is only indicated when the labour progress is adjudged to be poor. This agrees with the observation by Levy et al who found a statistically significant higher need for further increment in the oxytocin titration in the 30 mls arm.[29] Both studies shared similar sample size and methodology. None of the other reviewed studies accessed the need for augmentation.

The multivariate analysis of duration of labour for the two study groups showed no statistically significant difference in delivery within and after 12 hours for either nulliparae or multiparous mothers. These findings agreed with the study done by Delany which recorded no statistically significant difference in labour duration among parturients of different parities.[14] This similarity suggests that irrespective of the volume of catheter balloon inflation used the rate of cervical dilatation probably depends more on the intrinsic consistency of the cervix with minimal dependence on parity.

None of the fetomaternal complications evaluated in this study showed a statistically significant difference between the study groups. These findings were similar to that observed by Delany and Indira in their separate studies which showed no significant difference in the maternal and fetal/neonatal outcomes in the two study groups.[14,24] These similar outcomes can be explained by

the fact that the use of catheter balloon to achieve cervical ripening is generally known to be safe with low fetomaternal risks. Maternal satisfaction accessed in this study showed no statistically difference between the two study groups. This suggests that maternal perception of the labour process may be determined by multiple factors and not just on the chosen volume of Foley catheter balloon inflation. This was not assessed in any of the studies quoted above.

Limitation of the study: This study was limited by the subjectivity of the Bishop score as assessed by the researcher and the various research assistants.

CONCLUSION

This study demonstrated that the use of 60 ml inflated Foley's balloon catheter when compared with 30 mls for cervical ripening at the Alex-Ekwueme Federal University Teaching hospital Abakaliki, Mile 4 hospital Abakaliki and Mater Misericordiae Hospital Afikpo, effectively reduced the mean duration to favorable Bishop Score, mean duration of the active phase of labour and the rate of caesarean sections.

Recommendations

From this study, the use of 60 ml inflated Foley balloon catheter for cervical ripening in the process of induction of labour is recommended. This will assist in reducing the duration to achieving favorable cervix and the duration of the active phase of labour. It may also reduce the incidence of Caesarean sections especially in developing countries where aversion to Caesarean deliveries still persists. Further studies on the use of Foley catheter for cervical ripening are recommended so as to determine the standard catheter balloon volume that will lead to favorable fetomaternal outcomes.

ACKNOWLEDGEMENTS

I thank Dr Lawani LO (Consultant Obstetrician and Gynaecologist, AE-FUTHA) for his technical support and advice. The study was funded by the authors.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Carol LA, Ashley SR. Labour and delivery. In: Decherny AH, Nathan L. (eds). Current Diagnosis and Treatment in Obstetrics. 11th Edition. New York: McGraw Hills Medical Publishing Company. 2013;155.
2. Karjane NW, Ramus RM. Abnormal labour. Available at http://emedicine.medscape.com/article/273053-overview. Accessed on 24th July 2017.
3. Caughey AB, Sundaram V, Kaimal AJ, Cheng Yu, Gienger A, Little SE, et al. Maternal and neonatal outcomes of elective induction of labour. Evidence Report/technology Assessment. 2009;176:1-257.
4. Vrees RA, Kelly B. Induction of labour. Available at https://emedicine.medscape.com. April 12, 2018. Assessed on 1st February 2019.
5. Tenore JL. Methods of cervical ripening and induction of labour. Am Fam Physician. 2003;167(10):2133-28.
6. ACOG committee on practise Bulletins-Obstetrics. ACOG practice Bulletin No 107: Induction of labour. Obstet Gynecol. 2009;114(2):386-97.
7. Ede EE, Umeora OUJ. Induction and Augmentation of labour. In: Umeora OUJ, Eguji CC, Onyebuchi AK, Ezeonu PO. Our teachers: A comprehensive textbook of obstetrics and gynaecology. 1st Ed. St. Benedict printing and Publishing company. 2017;225-9.
8. Spong CY, Berghella V, Wenstorom KD, Mercer BM, Saade GR. Preventing the first caeserean delivery: Summary of a joint Eunice Kennedy Shriver National institute of child health and human development society for maternal-fetal medicine and American college of Obstetrician and Gynaecologists workshop. Obstet Gynecol. 2012;120(5):1181-93.
9. Goldenberg AE, Smith CV. Cervical ripening. Available at: https:// emedicine.medscape.com. Feb 28, 2018. Assessed on 4th February 2019.
10. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mo BW, Irion O, Boulvain M. Mechanical methods for induction of labour. Cochrane database syst Rev. 2012;3:cd001233.
11. Murphy DJ. Labour: normal and abnormal. In: Kenny LC, Myles JE. Obstetrics by ten teachers. 20th edition. CRC Press. 2017;193-232.
12. Gelber S, Sciscione A. Mechanical methods of cervical ripening and labour induction. Clin Obstet Gynaecol. 2006;49(3):642-57.
13. Boulvain M, Kelly A, Lohse C, Stan C, Irion O. Mechanical methods of induction of labour. The Cochrane database of systematic reviews. 2001;4:CD001233.
14. Delaney S, Shaffer BL, Brian L, Cheng YW, Vargas J, Sparks TN, et al. Labour induction with a Foley balloon inflated to 30mls compared with 60mls. A randomized controlled trial. Obstet Gynecol. 2010;115(6):1239-45.
15. Sherman DJ, Frenkel E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavorable cervix with extra-aminiotic catheter balloon: clinical experience and review. Obstet Gynecol. 1999;180:55-60.
16. Hill JB, Thigpen BD, Bofill JA, Magann E, Moore LE, Marth JN Jr. A randomized clinical trial comparing vaginal misoprostol versus cervical

Foley plus oral misoprostol for cervical ripening and labour induction. Am J Perinatol. 2009;26:33-8.
17. Prager M, Eneroth-Grimfors E, Edlund M, Marions L. A randomized controlled trial of intravaginal dinoprostone, intravaginal misoprostol and transcervical balloon catheter for labour indcution. BJOG. 2008;115:1443-50.
18. Sciscione A, Larkin M, O'shea A, Pollock M, Hofman M, Colmorgan G. Preinduction cervical ripening with the Foley catheter and the risk of subsequent preterm birth. Am J Obstet Gynecol. 2004;190:751-4.
19. Embrey MP, Mollision BG. The unfavorable cervix and induction of labour using a cervical balloon. J Obstet gynecol Br common W. 1967;74:44-8.
20. Zhong B. How to calculate sample size in Randomized Controlled Trials? Jour Thoracic Diz. 2009;1(1):51-4.
21. Umeora OUJ. Induction/ Stimulation/ Augmentation of labour. In: Umeora OUJ, Esike COU, Eze JN. The Guide: Protocols for management of Obstetrics and Gynaecological Patients in the tropics. 1st Ed. Uncle-Chyk Concepts. 2017;81-7.
22. Miller JL. Apgar Score. Available at: http://emedicine.medscape.com. 2018. Accessed on 19th January 2021.
23. Olusanya O, Okpere E, Ezimokhai M. The importance of social class in voluntary fertility control in a developing country. West Afr J Med. 1985;4(4):205-12.
24. Indira I, Latha G, Narayanamma VL. Comparative study of induction of labour with Foley catheter inflated to 30mls versus 60mls. J. Clin Sci Res. 2016;5:153-9.
25. Wijepala J, Najimundeen M. Comparism of 30mls and 60mls Foley catheter for cervical ripening. Euro Sci Jour. 2013;9(6):1857-881.
26. Delany S, Shaffer BL, Cheng YW, Vargas J, Sparks TN, Paul K, et al. Predictors of Caesarean delivery in women undergoing labour induction with a Foley ballon. J matern fetal neonatal Med. 2015;28(9):1000-4.
27. Manish P, Rathore S, Benjamin SJ, Abraham A, Jeyseelan V, Matheus JE. A randomised controlled trial comapring 30mls and 80 mls foley catherter for induction of labour after previous caeserean section. Available at https://journals.sagepub.com. Assessed on 17th March 2019.
28. Sandberg EM, Schepers EM, Sitter RLV, Huisman CMA, Wijngaarden WJV. Foley catheter for induction of labour filled with 30mls or 60mls: A randomised controlled trial . Eur J obstet Gynecol. Repro Biol. 2017;211:150-5.
29. Levy R, Kanengiser B, Furman B, ben Arie A, Brown D, Hagay ZJ. A randomized trial comapring a 30 mls and 80 mls foley catheter balloon for preinduction cervical ripening. AM J Obstet and Gynecol. 2004;191(5):1632-6.

Cite this article as: Adiele NA, Mgbafulu CC, Ikeotuonye AC, Anikwe CC, Adebayo JA, Adiele NM et al. Profiling cervical ripening for induction of labour with Foley's balloon catheter in Ebonyi state, Nigeria: a randomized controlled trial. Int J Res Med Sci 2022;10:22-30.