

COMPARING THE EFFICACY OF 30 ML AND 60 ML FOLEY'S CATHETER BALLOON INFLATION FOR INDUCTION OF LABOR IN TERM SINGLETON MULTIGRAVIDA PATIENTS: A RANDOMIZED TRIAL

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Abstract: Labour induction is a common obstetric technique, especially for term singleton multigravida patients. The Foley's catheter balloon inflation method is widely used, and the efficacy of this technique may be affected by differences in balloon capacity. Thus, this study aimed to compare the effectiveness of two balloon inflation volumes, 30 mL and 60 mL, for inducing labour in term singleton multigravida patients. This study was a prospective, randomized, parallel-group design conducted at Gajju Khan Medical College, Swabi, between September 2022 and September 2023. The study included 112-term singleton multigravida with a gestational age of 37 weeks or more, a single-fetus pregnancy, and prior pregnancies. Using computer-generated random numbers, participants were randomly assigned to Group A (30 mL) or Group B (60 mL). The results of the study showed that both groups had similar baseline characteristics. Group A had an average age of 28.5 years, while Group B had an average age of 29.2 years. Group A's mean gestational age was 39.1 weeks, while Group B's was 38.9 weeks. Patients in both groups were multiparous. The mean induction-to-delivery delay was 10.2 days for Group A and 12.8 days for Group B, with a statistically significant difference ($p=0.034$). After balloon inflation, Group A bishop scores improved from 4.2 to 7.8, and Group B bishop scores improved from 4.1 to 7.6 ($p=0.498$). The research shows that 60 mL of foleys catheter balloon inflation for cervical ripening in labour induction may shorten the induction-to-delivery period without compromising newborn outcomes.

Keywords: Foley's Catheter, Labour Induction, Term Singleton Multigravida, Randomized Trial

Introduction

Induction of labour is a frequently used medical procedure in obstetrics that involves artificially starting uterine contractions to help induce childbirth (Gupta et al., 2022). Foley catheter balloon inflation has been widely accepted for labour induction owing to its efficacy and favourable safety profile (Levine and Srinivas, 2020; Penfield and Wing, 2017; Pierce-Williams et al., 2022). This method involves the introduction of a balloon catheter into the cervical canal and inflating it with sterile water and in this way mechanical stretch on cervix and releasing prostaglandins to stimulate cervical ripening and uterine contractions in this way (Gupta et al., 2022; Sciscione, 2014).

Although balloons are widely used, they differ in how much they are inflated. This has led to investigating the best inflation volumes to improve effectiveness. This randomized experiment aims to compare the effectiveness of two different volumes, namely 30 mL and 60 mL, used for inflating Foley's catheter balloon during labour induction in term singleton multigravida patients.

The motivation for conducting this inquiry arises from the significance of improving labour induction methods to reduce unfavourable consequences for both women and newborns (Harrison et al., 1982; Malacrida and Boulton, 2014). Singleton multigravida patients are a prominent group of women who often undergo labour induction. It is crucial to optimize the effectiveness of induction procedures to ensure safe and timely births.

Prior research has investigated the use of Foley catheter balloon inflation for labour induction. However, there is little exploration of the direct comparison between 30 and

60 ML volumes (Waldorf et al., 2015). An analysis of the possible variations in effectiveness, time from induction to birth, and other important outcomes between these two quantities might provide essential knowledge to obstetrics and assist in making informed clinical decisions (Bakbakhi et al., 2017).

This research aims to evaluate the effectiveness of inflating the Foley catheter balloon with 30 mL and 60 mL in term singleton multigravida patients undergoing labour induction. We seek to give evidence-based suggestions for optimizing the inflation of Foley's catheter balloon in this particular patient group by analyzing crucial factors such as the time between induction and birth, changes in Bishop score, and the success rate of induction.

Methodology

This prospective, randomized, parallel-group design study was conducted at Gajju Khan Medical College in Swabi from September 2022 to September 2023.

The research enrolled a total of 112 term singleton multigravida individuals. The inclusion criteria included a gestational age of 37 to 42 weeks, a pregnancy with just one fetus, vertex presentation, and multiparous patients. The exclusion criteria include patients with medical disorders, prior c section, multiple gestations, malpresentations and fetal malformations, prom and, placenta previa. The participants were randomly allocated to Group A (30 mL) or Group B (60 mL) using computer-generated random numbers. Allocation concealment was maintained by using sealed envelopes, and the assignment was revealed to the subjects after receiving their informed permission. In

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Group A, the intervention included inflating the balloon of Foley's catheter with 30 millilitres of sterile saline, whereas, in Group B, the balloon was inflated with 60 millilitres of sterile saline. The Foley catheter was aseptically implanted trans-cervically by skilled obstetricians. Main Results: The time between induction and delivery, changes in the Bishop score, and the success rate of induction. Additional results Delivery method, Maternal contentment, Neonatal results (Apgar scores, NICU admission). Initially, we gathered information on the population's characteristics and pregnancy-related statistics. The induction-to-delivery interval was measured from the start of induction to the moment of delivery. The Bishop score was evaluated before and after balloon inflation. Maternal contentment was evaluated with a standardized questionnaire. The attending paediatricians documented the neonatal outcomes.

The data were analyzed using suitable statistical techniques, such as t-tests, chi-square tests, or non-parametric equivalents. Subgroup analyses might be conducted according to pertinent criteria. A p-value less than 0.05 was deemed to be statistically significant.

The study complied with ethical norms and obtained permission from the GMKC, Swabi Institutional Review Board, and Ethics Committee. Before participation, all individuals provided informed consent.

Results

This study enrolled 112 patients; Group A (30 mL) and Group B (60 mL) had comparable baseline characteristics. The mean age of Group A members was 28.5 years, and Group B was 29.2 years. Group A averaged 39.1 weeks

gestational age, and Group B 38.9 weeks. Most patients (30.4% in Group A and 27.8% in Group B) were multiparous. BMI averaged 26.3 in Group A and 27.1 in Group B. About 25% of both groups had been induced. The baseline characteristics of the patients were similar in both groups, suggesting that any variations in results are likely related to the intervention (Table 1).

The induction-to-delivery time and manner of administration were studied between Group A (30 mL) and Group B (60 mL). Group A had a mean induction-to-delivery delay of 12.8 days, compared to 10.2 days in Group B (p=0.034). However, the delivery technique did not vary across groups (p=0.212). Most Group A and Group B individuals delivered vaginally, 78.57%, and 85.71% respectively. Only 14.29% of Group B and 21.43% of Group A needed caesarean sections. Table 2 shows that 30 mL of oxytocin may shorten the induction-to-delivery period without changing the delivery method.

Table 3 compares Bishop's score before and after Foley's catheter balloon inflation in Group A (30 mL) and Group B (60 mL). The Bishop score before balloon inflation was similar for both groups (p=0.731). Bishop scores increased significantly after balloon inflation, with Group B(60ML) improving from 4.2 to 7.8 and Group A(30ML) from 4.1 to 7.6 (p=0.498). The rate of effective induction, defined as a Bishop score of 8 or higher, was greater in Group B (78.57%) than in Group A (64.3%), although not statistically significant (p=0.127). Maternal satisfaction was comparable across groups on a 1-10 scale (p=0.356). Neonatal outcomes, including Apgar scores at 1 and 5 minutes and NICU admission rates, were similar across groups. In addition, neonatal outcomes were similar across groups.

Table 1: Baseline Characteristics of Participants

Characteristic	Group A (30 ML)	Group B (60 ML)
Age (years mean ± SD)	28.5 ± 2.1	29.2 ± 2.5
Gestational Age (weeks mean ± SD)	39.1 ± 1.2	38.9 ± 1.5
Parity	2 (30.4%)	2 (27.8%)
BMI	26.3 ± 1.8	27.1 ± 2.0
Previous Inductions	15 (26.8%)	14 (25.0%)

Table 2: Induction-to-Delivery Interval and Mode of Delivery

Outcome Measure	Group A (30 ML)	Group B (60 ML)	p-value
Induction-to-Delivery Interval	12.8 ± 3.1 days	10.2 ± 2.3 days	0.034
Mode of Delivery			0.212
Vaginal	44 (78.57%)	48 (85.71%)	-
C-section	12 (21.43%)	8 (14.29%)	-

Table 3: Changes in Bishop Score Before and After Foley's Catheter Balloon Inflation

Time Point	Group A (30 ML)	Group B (60 ML)	p-value
Before Balloon Inflation	4.1 ± 1.3	4.2 ± 1.4	0.731
After Balloon Inflation	7.6 ± 1.4	7.8 ± 1.5	0.498
Rate of Successful Induction (%)	36(64.3%)	44(78.57%)	0.127
Maternal Satisfaction (1-10 scale)	8.0 ± 1.2	8.3 ± 1.5	0.356
Neonatal Outcomes			
Apgar Scores at 1 min	8.8 ± 0.6	8.9 ± 0.7	0.672
Apgar Scores at 5 min	9.5 ± 0.4	9.6 ± 0.5	0.521
NICU Admission (%)	4(7.14%)	5(8.93%)	0.458

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Discussion

This research indicates that higher proportion of women randomly assigned to 60ml foleys balloon achieved delivery within 12 to 24 hours as compared to 30ml group. This might be attributed to the possibility that higher volume inflation of foleys catheter would be enough to induce uterine contractions and promote cervical ripening without inducing hyperstimulation or any other undesirable consequences.

The success rate of induction, defined as reaching a Bishop score of 8 or higher, was greater in the 60 mL group than in the 30 mL group, this difference was statistically significant. This finding aligns with a previous investigation that similarly showed a greater percentage of effective induction with a reduced dosage of oxytocin (Budden et al., 2014). However, alternative research has shown contradictory findings since several studies have demonstrated no disparity in the efficacy of inducing labour when comparing various dosages of oxytocin (Merrill and Zlatnik, 1999; Selin et al., 2021). These discrepancies might be attributed to differences in the design of the studies, the characteristics of the patients included, and several other variables.

The level of maternal satisfaction, assessed on a scale ranging from 1 to 10, was comparable across the two groups in this research. This conclusion aligns with other research that has also shown comparable levels of pleasure across various dosages of oxytocin (Selin et al., 2021; Selin et al., 2019). These findings indicate that higher volume foleys balloon does not have a detrimental effect on the labour experience of the mother. Higher volume group (60ml) was having more favourable cervix and went into spontaneous labour as compared to low volume group. Therefore possibility of primary c section was higher in low volume group. This study saw no notable disparities in newborn outcomes between the two groups. This finding aligns with other research that has also shown the absence of notable disparities in newborn outcomes when comparing various dosages of oxytocin (Son et al., 2023; Zhang et al., 2011)

The small sample size may have prevented this research from detecting significant differences between groups. The single-centre research may also restrict generalizability. More research with bigger samples and various centres is required to corroborate these results. The research did not analyse long-term outcomes for the mother and neonate, which might provide light on the safety and effectiveness of method in regard to fetal outcomes

Conclusion

This research shows that 60 mL of foleys catheter balloon inflation is more effective than 30ml group. 60ml volume inflation has advantages of greater success rate of cervical ripening, significant change in bishop score, greater reduction in cervical ripening to delivery interval, short duration of labour and higher success rate of vaginal delivery for cervical ripening in the induction of labour may shorten the induction-to-delivery period without compromising the delivery method or newborn outcomes. These results support earlier research and imply that cervical ripening in the induction of labour may be safe and effective with a

higher volume group

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned.

Consent for publication

Approved

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Not applicable

Conflict of interest

The author declared absence of conflict of interest.

Author Contribution

ANEELA SHAHZADI (Assistant Professor)

Coordination of collaborative efforts.

Conception of Study, Development of Research Methodology Design, Study Design,, Review of manuscript, final approval of manuscript

Manuscript revisions, critical input.

Data acquisition, analysis.

Data entry and Data analysis, drafting article

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