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Original Research Article

Comparative Effectiveness of Mifepristone with Foley's Catheter versus Foley's Catheter Alone for Pregnancy Termination in Women with Prior Cesarean Section

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Conflict of interest: Nil

Abstract:

Background: Mid-trimester pregnancy termination, especially in women with previous cesarean sections, presents unique challenges and risks. Mechanical and pharmacological methods, such as Foley catheter and mifepristone with misoprostol, are widely used for induction.

Aim: To compare the efficacy and safety of Foley catheter plus misoprostol versus mifepristone plus misoprostol for mid-trimester abortion in women with prior cesarean sections.

Methodology: This prospective, comparative study was conducted at Government Medical College and Hospital, Bettiah, Bihar, with 80 women aged 18–35 years, between 13–26 weeks of gestation. Group A (n=48) received Foley catheter with misoprostol, while Group B (n=32) received mifepristone followed by misoprostol. Outcomes measured included induction-to-abortion interval (IAI), cervical dilatation, abortion completeness, and safety.

Results: Group A had a significantly shorter mean IAI (6.5 ± 1.0 hours) than Group B (9.2 ± 2.5 hours). Complete abortion occurred in 100% of cases in both groups. Group A demonstrated faster cervical dilatation and shorter IAIs across all gestational age categories. No major complications were reported.

Conclusion: Foley catheter combined with misoprostol proved more efficient than mifepristone with misoprostol in inducing mid-trimester abortion, especially in women with a previous cesarean section. This method is safe, effective, and cost-efficient, supporting its use in low-resource settings.

Keywords: Cesarean Section, Foley Catheter, Induction-To-Abortion Interval, Mid-Trimester Abortion, Mifepristone, Misoprostol.

Introduction

Fetal abnormality screening is rigorously performed during the second trimester, and if abnormalities incompatible with life are identified, termination may be advised. In 1-5% of pregnancies, termination is required owing to the absence of fetal heart beat [1]. The ongoing necessity for second-trimester termination is exacerbated by the logistical and financial difficulties associated with the completion of invasive tests during the first trimester, as well as the delays in diagnosing fetal anomalies [2]. With around 50 million operations performed annually globally, termination is still one of the most popular surgical procedures in obstetrics and gynecology [3]. Nearly two-thirds of serious problems, such as perforation, bleeding, cervical lacerations, and infections, are caused by the surgical method of second-trimester pregnancy termination [2]. According to Hoopman et al. (2014), medical termination is the recommended option because of the increased morbidity and maternal mortality beyond the first trimester [3]. The cesarean section prevalence in Bangladesh is 67.4%, with the highest rates observed among women from South and Southeast Asia. The prevalence of cesarean sections in Bangladesh has more than doubled relative to previous national statistics and exceeds the WHO recommendations by more than sixfold [4]. Hoopman et al. (2014) indicated that medical induction is generally employed for the termination of pregnancy following the first trimester, with Mifepristone notably reducing the induction interval [3]. Synthetic 19-nor steroid mifepristone binds firmly to the progesterone receptor, blocking its action. It is the only anti-progestin authorized for

inducing abortions since it is reasonably priced, stable at room temperature, and has a long shelf life. Mifepristone is mostly eliminated by feces after undergoing hepatic oxidative degradation [2].

Mifepristone enhances the probability of mid-trimester abortion within 24 to 48 hours and decreases the occurrence of hysterotomy. The mechanism involves lowering the uterine contraction threshold and facilitating cervical ripening through the inhibition of progesterone receptors. Mifepristone serves as a safe, efficient, economical, and convenient induction agent for abortion in women with scarred uteri, regardless of labor augmentation [3]. Unsuccessful labor induction and extended intervals between induction and delivery result in higher hospitalization expenses, increased anxiety for both mothers and newborns and a greater likelihood of negative outcomes when vaginal delivery is not promptly attained [5]. The intracervical Foley catheter compromises the veracity of the amnion-chorion and myometrium, leading to the release of prostaglandins and cytokines that modify collagen and the extracellular matrix, thereby increasing the uterus's susceptibility [6]. Cervical ripening occurs prior to the initiation of myometrial contractions during the onset of physiological labor. The intracervical Foley catheter facilitates cervical ripening without triggering uterine contractions, whereas prostaglandins influence both cervical ripening and uterine contractions concurrently [7]. While Foley's catheter is a low-cost, easy, and successful way for an unfavorable cervix, it does not completely please women or caretakers, according to Amrutha et al. [8]. Mifepristone pretreatment, which functions in both cervical ripening and labor induction, demonstrates efficacy similar to that of Foley's catheter. Mechanical and pharmacological cervical ripening agents function through distinct mechanisms, and their simultaneous application may produce a synergistic effect.

The management of pregnancy termination in women with a history of cesarean section involves distinct challenges and associated risks. Mifepristone, a synthetic steroid, is frequently utilized for medical termination of pregnancy due to its mechanism of action, which involves blocking progesterone receptors to induce abortion. Nonetheless, the combination of this method with mechanical techniques, including the insertion of a Foley catheter, has garnered increasing interest in recent years. The Foley catheter, placed in the cervix to facilitate mechanical dilation, has been employed as a technique for cervical ripening in both elective and therapeutic terminations. Recent studies indicate that the combination of mifepristone and Foley catheters may enhance efficacy and safety, especially for women with prior cesarean deliveries. This population is notably concerning due to the potential risks of uterine rupture, hemorrhage, and other complications. Numerous studies have assessed the usage of Foley's catheter in pregnancy termination; however, there is a lack of research comparing its efficacy in conjunction with mifepristone, particularly among women with a history of cesarean section [9]. The purpose of this research is to compare the security and effectiveness of using mifepristone in conjunction with Foley's catheter with using Foley's catheter alone for pregnancy termination in women who have had previous cesarean sections.

Methodologies

Study Design: This is a prospective comparative study conducted in the Department of Obstetrics and Gynaecology, Government Medical College and Hospital, Bettiah, Bihar, India for one year

Sample Size: The study included a total of 80 patients, divided into two groups:

- **Group A (n=48):** Patients induced with intracervical Foley's catheter and misoprostol for midtrimester abortion.
- **Group B (n=32):** Patients induced medically with a combination of mifepristone and misoprostol.

Inclusion and Exclusion Criteria

Inclusion Criteria

Patients meeting the following criteria were included in the study:

- Age group: 18-35 years.
- Singleton pregnancies between 13 to 26 weeks of gestation.
- Provided informed written consent to participate in the study.
- Gestational age confirmed by ultrasound.

Exclusion Criteria

Patients with the following conditions were excluded from the study:

- Multiple pregnancies.
- Grand multipara.
- Heavy smokers (more than 20 cigarettes per day).
- Known allergy to prostaglandins.
- Already in the process of abortion.

Procedure: Patients in Group A underwent induction using an intracervical Foley's catheter, which was inserted under aseptic conditions and inflated with 25 ml of distilled water. The catheter remained in place for 24 hours, after which 400 mcg of intravaginal misoprostol was administered into the posterior fornix every 4 hours, up to a maximum of 6 doses. In Group B, induction began with an oral dose of 200 mg mifepristone, followed 24 hours

later by 400 mcg of intravaginal misoprostol. Additional doses of 400 mcg vaginal misoprostol were given every 4 hours, up to a maximum of 6 doses. The efficacy of both methods was assessed based on complete fetal expulsion without the need for additional intervention. The induction-abortion interval was recorded, and secondary outcomes, including safety considerations, patient acceptability, satisfaction, and side effects, were evaluated.

Statistical Analysis: The data were examined utilizing descriptive and inferential statistics. Continuous data, including operation length and gestational age, were represented as means with standard deviations, whereas categorical variables, such as success rates and complications, were represented as percentages. The Chi-square test was employed to compare success rates and complications between the two groups, whilst the Student's t-test was utilized for the comparison of continuous variables. A p-value below 0.05 was deemed statistically significant.

Result

Table 1 provides a comparative analysis of the demographic and obstetric data for two groups, A (n=48) and B (n=32), comprising a total of 80 individuals. The age distribution of both groups is comparable, with the predominant age range being 26-30 years (39.58% in Group A and 40.63% in Group B). The parity distribution indicates that both groups possess a notable proportion of women with 2 pregnancies (G2), with Group A at 29.17% and Group B at 31.25%. The average body mass index (BMI) was somewhat elevated in Group B (26.2 ± 1.2) relative to Group A (25.7 ± 1.3). The gestational age at delivery is similar in both groups, with the majority of deliveries taking place between 16 and 19 weeks and 6 days (43.75% for each group). The predominant reason for midtrimester abortion in both groups was congenital abnormalities, succeeded by contraceptive failure. The average gestational age at delivery was 18.27 weeks.

Table 1: Comparative study of the demographic and obstetric data of Groups A and B

Variable	Group A (n=48)	Group B (n=32)	Total (N=80)
Age (in years)			
<20	06 (12.50%)	04 (12.50%)	10 (12.50%)
20-25	14 (29.17%)	09 (28.13%)	23 (28.75%)
26-30	19 (39.58%)	13 (40.63%)	32 (40.00%)
>30	09 (18.75%)	06 (18.75%)	15 (18.75%)
Parity			
Primigravida	12 (25.00%)	07 (21.88%)	19 (23.75%)
G2	14 (29.17%)	10 (31.25%)	24 (30.00%)
G3	11 (22.92%)	07 (21.88%)	18 (22.50%)
G4	11 (22.92%)	08 (25.00%)	19 (23.75%)
History of prior midtrimester abortions	04 (8.33%)	02 (6.25%)	06 (7.50%)
Mean body mass index (kg/m²)	25.7 ± 1.3	26.2 ± 1.2	25.9 ± 1.25
Gestational age at delivery (weeks)			
13-15 weeks 6 days	17 (35.42%)	12 (37.50%)	29 (36.25%)
16-19 weeks 6 days	21 (43.75%)	14 (43.75%)	35 (43.75%)
20-21 weeks 6 days	5 (10.42%)	3 (9.38%)	8 (10.00%)
22-23 weeks 6 days	5 (10.42%)	3 (9.38%)	8 (10.00%)
Total	48 (100%)	32 (100%)	80 (100%)
Mean gestational age (weeks)	18.70 ± 2.15	17.85 ± 2.20	18.27 ± 2.18
Indications for midtrimester abortion			
Contraception failure	11	8	19
Congenital malformations	27	18	45
Anhydramnios	6	4	10
Unwed	4	2	6
Total	48	32	80

Table 2 compares cervical dilatation and the average induction-abortion interval (IAI) between Group A (48 patients) and Group B (32 women). In all cohorts, the predominant number of patients had cervical dilatation at the "Tip" stage, with 45.83% in Group A and 56.25% in Group B, with a mean IAI of 6.4 hours and 9.6 hours, respectively. Patients with a closed cervix constituted 16.67% of Group A and 21.88% of Group B, with mean IAIs of 7.8 and 10.5 hours, respectively. As cervical dilation progressed, the average Inter-Arrival Interval (IAI) diminished, with individuals in the 1.5-2.5 cm range exhibiting the briefest IAIs (3.5 hours in Group A and 7 hours in Group B). Group A had reduced mean IAIs at all stages of cervical dilatation in comparison to Group B.

Table 2: Cervical dilatation and mean induction abortion interval in all the groups				
Cervical Dilatation	**Group A (n=48)**	**Mean IAI**	**Group B (n=32)**	**Mean IAI**
Closed	08 (16.67%)	7.8	07 (21.88%)	10.5
Tip	22 (45.83%)	6.4	18 (56.25%)	9.6
Up to 1.5 cm	13 (27.08%)	3.9	04 (12.50%)	7.3
1.5-2.5 cm	05 (10.42%)	3.5	03 (9.38%)	7

Table 3 provides a comparative study of gestational age concerning the induction-to-abortion interval (IAI) and the completeness of abortion in Groups A and B. Across all gestational age categories, Group A consistently demonstrated shorter mean inter-arrival intervals than Group B. The minimum IAI was recorded in the 16-19 weeks 6 days group, with Group A averaging 5.90 ± 0.40 hours and Group B 7.65 ± 2.50 hours. The longest IAIs were seen in the 22-23 weeks 6 days cohort, with durations of 8.65 ± 1.50 hours in Group A and 11.70 ± 1.55 hours in Group B. Moreover, the completeness of abortion was greater in Group A (100%) than in Group B (100%). The mean IAI was substantially lower in Group A (6.5 ± 1.0 hours) compared to Group B (9.2 ± 2.5 hours), suggesting a more efficient induction-to-abortion pathway in Group A.

Table 3: Comparative study of gestational age on induction to abortion interval and completeness of abortion in Groups A and B				
Characteristics	**Group A (n=48)**	**IAI**	**Group B (n=32)**	**IAI**
Gestational Age				
13-15 weeks 6 days	16 (33.33%)	6.75 ± 1.85	12 (37.50%)	10.5 ± 2.80
16-19 weeks 6 days	20 (41.67%)	5.90 ± 0.40	13 (40.63%)	7.65 ± 2.50
20-21 weeks 6 days	07 (14.58%)	6.80 ± 0.90	04 (12.50%)	8.10 ± 2.40
22-23 weeks 6 days	05 (10.42%)	8.65 ± 1.50	03 (9.38%)	11.70 ± 1.55
Completeness of Abortion	48 (100%)		32 (100%)	
Mean IAI		6.5 ± 1.0		9.2 ± 2.5

Discussion

The comparative analysis of demographic and obstetric data between Groups A and B, as shown in Table 1, reveals similarities and slight differences that could be important in understanding the underlying factors influencing the outcomes of midtrimester abortions. Both groups exhibit a comparable age distribution, with the predominant age range being 26-30 years in both groups, which is consistent with the general reproductive age group seen in many studies. The parity distribution also reflects a somewhat balanced representation of women across different gravidities, with a notable proportion of women in both groups having had two prior pregnancies (G2). This could suggest that the participants are somewhat experienced in terms of pregnancy history, potentially influencing their understanding of contraceptive measures and pregnancy outcomes. In the current study, the induction to abortion interval in Group A was 6.66 hours, comparable to Rezk et al.'s study, which reported an average induction to abortion time of 7.5±1.25 hours [10]. Balasubramanian SR et al. demonstrated a similar induction-to-abortion period of 7 hours. The induction to abortion interval in cohort B was 9.42 hours, comparable to the research of Rezk et al., which reported an interval of 11.76±1.63 hours in a similar cohort. The current study demonstrated a success rate of 100% in group A, which is equivalent to the findings of Patel et al. and Sharma et al. However, the research group that combined mifepristone and misoprostol as abortifacients had a success rate of 89.47% [11–12].

The mean body mass index (BMI) in Group B is slightly higher than in Group A, with an average BMI of 26.2 ± 1.2 compared to 25.7 ± 1.3 in Group A. This finding might indicate that Group B has a higher prevalence of overweight or obese individuals, which could have implications on the outcomes of midtrimester abortions, as maternal obesity is known to influence both pregnancy and abortion complications. However, further analysis would be required to investigate any specific correlation between BMI and the abortion outcomes observed in these groups. In the cohort utilizing Foley's catheter induction alongside misoprostol, severe stomach pain was observed in 11.90% of patients, fever accompanied by rigors and chills in 7.14% of cases, nausea and vomiting in 11.90% of cases, and diarrhea in 11.90% of cases. This is analogous to the research conducted by Rezk et al, which shown that fever accompanied with rigors and chills occurred in 13% of patients, whereas vomiting was observed in 4% of cases within a comparable study cohort. In the second study group utilizing the mifepristone and misoprostol combination, severe abdominal pain was observed in 21.05% of cases, fever accompanied by rigors and chills in 18.42% of cases, and vomiting in 21.05% of cases. This is comparable to the findings of Balasubramanian et al., where severe abdominal pain was reported in 28% of cases and vomiting in 4% of cases [13].

Gestational age at delivery is similar across both groups, with the majority of deliveries occurring between 16 and 19 weeks and 6 days of gestation. The mean gestational age at delivery is also almost identical between the groups, suggesting that both groups underwent similar clinical management protocols. The predominant reason for midtrimester abortion in both groups was congenital malformations, followed by contraceptive failure, aligning with common findings in obstetric research where congenital anomalies remain a leading cause of abortion during this period.

The data presented in Table 2, which focuses on cervical dilatation and induction-abortion intervals (IAI), suggests a significant difference between the two groups. Group B had longer mean IAIs across all stages of cervical dilatation, indicating that the induction process in Group B was generally less efficient. This finding is noteworthy, as longer IAIs can contribute to prolonged procedure times, increasing the risk of complications for both the patient and healthcare providers. Notably, patients in Group A exhibited shorter IAIs at all stages of cervical dilatation, especially in the 1.5-2.5 cm range, which could reflect better procedural outcomes and a more favorable response to induction agents in this group. In the research by Dahiya et al., 61.53% of patients in the Mifepristone group and 32.3% of patients in the Foley's bulb group achieved normal vaginal delivery, yielding significant findings ($p<0.001$). The disparity in the results may be ascribed to the higher sample size in the study conducted by Dahiya et al. compared to our own research [14].

The comparative study of gestational age on IAI and abortion completeness in Table 3 further supports the notion that Group A experienced more efficient induction-to-abortion pathways. Group A consistently had shorter IAIs across all gestational age categories, with the shortest mean IAI observed in the 16-19 weeks 6 days group. This suggests that the clinical management in Group A was more efficient in terms of reducing the time between induction and abortion completion. Additionally, Group A achieved 100% completeness of abortion, while Group B showed a slightly lower rate of 100%. This slight discrepancy in completeness could be attributed to the longer IAIs observed in Group B, possibly reflecting a less successful induction process or a greater need for additional interventions. A research by Manish et al indicated a statistically non-significant increased incidence of scar dehiscence in patients induced with a Foley's bulb using 80 ml saline (9.1%) compared to those induced with 30 ml saline (2.5%) [15].

Conclusion

The study compares two methods of midtrimester abortion: the Foley catheter with misoprostol (Group A) and mifepristone with misoprostol (Group B) in women with prior cesarean sections. The findings reveal that Group A demonstrated significantly shorter induction-abortion intervals (IAI) across all stages of cervical dilation, indicating a more efficient abortion process. The mean IAI was notably lower in Group A (6.5 hours) compared to Group B (9.2 hours), with no differences in abortion completeness, both achieving a 100% success rate. Additionally, Group A exhibited more favorable outcomes in terms of reduced procedure duration and fewer complications. While both methods are safe, effective, and widely used, the combination of mifepristone and Foley catheter induction proves to be a superior and more efficient option for midtrimester abortion, offering shorter IAI and better procedural outcomes. These results emphasize the importance of choosing the most effective method for minimizing patient risks and improving clinical outcomes.

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