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Research Article

Foley's Catheter Balloon with Sequential Misoprostol for Induction of Mid Trimester Abortions- An Observational Study

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ABSTRACT

Background: The utilization of the Foley catheter method has demonstrated a faster abortion process compared to using misoprostol alone, reducing the time from induction to delivery. However, concerns exist regarding the infection risk associated with the Foley catheter technique, particularly in cases of prolonged prelabour rupture of membranes.

Objectives: To evaluate the safety and effectiveness of combining the Foley catheter bulb with sequential misoprostol for the induction of second-trimester abortions.

Methods: We conducted a prospective observational study on women seeking pregnancy termination between 13-28 weeks of gestation. Twenty participants underwent foley catheter followed by induction with misoprostol. The primary focus was on the duration from induction to abortion. Secondary outcomes included rates of complete abortion, need for surgical placenta removal, and occurrence of complications.

Results: Our study revealed that 70% of participants were in the 20-30 years age group, with 45% being primiparous. Approximately 25% had a history of abortions for various reasons, and 55% had previous childbirth experiences, including 20% who had cesarean sections and 10% who had vaginal deliveries. The mean durations from induction to bulb expulsion, bulb expulsion to abortus expulsion, and induction to product expulsion were 8.75 hrs, 6.4 hrs, and 14.05 hrs, respectively. The rate of complete abortion was 80%, with 20% requiring surgical placenta removal. Some participants encountered minor complications like fever (30%), severe pain (VAS scale ≥ 5) (85%), and the need for blood transfusions (10%). No major complications were reported.

Conclusion: The combined use of Foley catheter balloon and misoprostol sequentially is a safe, effective, and well-tolerated approach for terminating pregnancies in the second trimester, without a significant increase in adverse effects or maternal risks.

Keywords*: Foley catheter, abortion, misoprostol, complications, parous*

INTRODUCTION

Second trimester or mid-trimester, is a period ranging from 13 to 28 weeks of gestation. Second trimester abortions constitute 10–15% of all induced abortions worldwide but are also responsible for two-thirds of all major abortion-related complications.[1] There has been a rising trend of mid- trimester abortions with increased use of antenatal screening tests in modern obstetrics detecting serious fetal abnormalities.

Congenital abnormalities and Missed abortions are commonest indications for mid-trimester abortions.[2] The risk of complications associated with abortions increase with increasing gestational age making second trimester abortions challenging for the obstetricians.

Many studies have described Medical, Mechanical and Surgical methods for second trimester abortions, but there is no consensus about which is the best.[2] The most efficacious regimen for second trimester abortions appears to be the use of a combination of mifepristone, followed by misoprostol showing 97–99% rate of abortion within 24 hours.[3] Considering higher cost of Mifepristone, misoprostol alone have been shown to be effective, although a higher total dose is needed and is less effective than the combined regimens.[4]

Some of the studies have described the effectiveness of Foley's catheter in cervical ripening and its mechanical stretching increasing the release of prostaglandins. Hence, the safety, efficacy and acceptability of use of Foleys catheter bulb with sequential use of misoprostol in induction of second trimester abortions has been studied in the given sample size.

MATERIALS AND METHODS

A prospective observational study was conducted on women seeking pregnancy termination between 13-28 weeks of gestationin Department of Obstetrics and Gynecology, Shimoga Institute of Medical Sciences, Shimoga. About 20 cases constituted the sample size. Clearence from institutional ethics committee was obtained before the study was started. An informed, bilingual consent was obtained from all the patients before including them in to the study.

Pregnant women between 13-28 weeks pog with various indications for mid trimester abortions were included in to the study. The cases with Congenital uterine anamolies, Multiple pregnancies, Women with renal disease, heart disease, severe anemia,
porphyrias, epileptic disorders, Placenta previa/Low lying placenta were excluded from the study

The information regarding demographic information (age, gestational age, etc.), Medical history and obstetric history. Induction – Abortion Interval, Induction to expulsion[of foleys bulb]Interval, Complete abortion rate , Complications like [-Pain, excessive bleeding ,retained products of conception] ,need for surgical intervention were taken as outcome measures.

RESULTS

Table 1: Demographic characteristics of enrolled study participants

	N	%
Age group (Years)		
20-25	7	35
26-30	7	35
More than 30	6	30
Body mass index (BMI)		
Normal	6	30
Overweight	7	35
Obese	7	35
Co-morbidities		
Hypothyroidism	2	10
Pregnancy-induced hypertension (PIH)	3	15
Hypertension (HTN)	1	5

The mean age of the study population was found to be 27.6 ±4.9 years, and 70% of the people comes under 20-30 age group. The Body mass index was calculated and 70% of the cases had more than normal BMI and mean BMI was found to be 23.7 ±2.8 kg/m^2. Nearly 30% of the study population had co-morbidities such as hypothyroidism, PIH and HTN.

Table 2: Maternal characteristics of enrolled study participants

	N	%
Parity		
Primi	9	45
Abortion	6	30
Parous	5	25
Gestational age (weeks)		
15-20	9	45
20-25	7	35
25-28	4	20
History of previous delivery		
Vaginal delivery	2	10
Lower (uterine) segment caesarean section (LSCS)	3	15
Abortion	6	30
No history	9	45

Menstrual disorder		
Regular	18	90
Polycystic ovary syndrome	2	10
Unintended pregnancy		
No	18	90
Yes	2	10
Anamolous fetus		
No	10	50
Yes	10	50
Fetal death		
No	16	80
Yes	4	20

In our study, majority (45%) of the women were primiparous and 30 % of the womens had previous history of termination and only 25% of the women were multigravida. The average gestational age was found to be 20.85 ± 4.1 weeks and most (45%) of the pregnancies were terminated between 15 -20 weeks of gestation. Approximately 25% had a history of abortions for various reasons, and 55% had previous childbirth experiences, including 20% who had cesarean sections and 10% who had vaginal deliveries.

Polycystic ovary syndrome was found to in 10% of the cases in the menstrual disorder catgaries and the medical terminations due to Unintended pregnancy, anamolous fetus and featal death were found to be 10, 50 and 20% respectively.

Table 3: Dose of Misoprostol and Induction abortion interval

	N	%
Misoprostol dosage in MCG (microgram)		
200	3	15
200-600	13	65
600-1000	2	10
1000-1500	1	5
More than 1500	1	5
Number of misoprostol dose		
1 dose	3	15
2 dose	6	30
3 dose	7	35
4 dose	2	10
5 dose	1	5
More than 5 dose	1	5
Time Interval between Induction to bulb expulsion (HRS)		
Within 6 hrs	9	45
6-12 hrs	7	35
12-24 hrs	4	20
Time Interval between bulb expulsion to expulsion of abortus		
Within 6 hrs	12	60
6-12 hrs	6	30
12-24 hrs	2	10
Time Interval between Induction to expulsion of products		
Within 6 hrs	1	5
6-24 hrs	17	85
More than 24 hrs	2	10

Twenty participants underwent foley catheter followed by induction with misoprostol. For induction of labour, majaority (65%) of the cases were adimistrate with 200-600 mcg of misoprostol and labour was induced with in 3 doses of misoprostol in 80% of the cases. The mean durations from induction to bulb expulsion, bulb expulsion to abortus expulsion, and induction to product expulsion were 8.75±5.5hrs, 6.4±4.3hrs, and 14.05±7.3hrs, respectively. In 45% of the cases, the time interval between Inductions to bulb expulsion was observed within 6 hrs and the time interval between bulb expulsion to abortus within 6 hrs was found to be 60%. The time interval between inductions to expulsion of product within 24 hrs was found to be 90%.

Table 4: Outcome and Maternal complications of the study participants

	N	%
Outcome of termination		

Incomplete termination	3	15
Complete termination	16	80
Failure	1	5
Method of removal of placenta		
Spontaneous	16	80
Surgical	4	20
Fever		
No	14	70
Yes	6	30
Blood transfusions		
No	18	90
Yes	2	10
Nausea and Vomiting		
No	9	45
Yes	11	55
Pain scale		
4	3	15
5	4	20
6	7	35
7	6	30

In our study, the rate of complete termination was 80% of the cases and 20%of the cases requiring surgical placenta removal. Some participants encountered minor complications like fever (30%), Nausea and Vomiting (55%), severe pain (VAS scale ≥ 5) (85%), and the need for blood transfusions (10%). No major complications were reported.

DISCUSSION

The use of an intracervical Foley catheter may act in addition to its mechanical effect; increase the release of prostaglandin and/or oxytocin secondary to localized inflammation.

The study was undertaken to study the safety, efficacy, and acceptability of the use of a Foley catheter bulb with sequential use of misoprostol in the induction of second trimester abortions.

A gradual increase in second-trimester abortion is due to the wide scale introduction of prenatal screening programs detecting women whose pregnancies are complicated by serious fetal abnormalities such as neural tube defects, i.e., anencephaly, fetal death, and unintended pregnancy.

In our study, the average age of the study cohort was determined to be 27.6 ±4.9 years, which shows most of the women having an abortion are between the ages of 20-30 years which is similar to what was found by Rezk et al., Mahajan et al., and Agarwal et al. [3, 5–6]. The majority (45%) of the female participants were primiparous, whereas in Sankalpa et al., study, multiparous participants were more than primiparous. [7]

The mean gestational age was determined to be 20.85 ± 4.1 weeks, with most pregnancies (45%) being concluded between the 15th and 20th weeks of gestation. Around 25% reported a record of abortions for diverse causes, whereas 55% had previous parturition encounters, with 20% undergoing cesarean sections and 10% opting for vaginal deliveries, which was similar to the Fonseca et al., Rezk et al., and Sankalpa et al., studies. [2-3,7]

The medical terminations resulting from unintended pregnancy, anomalous fetus, and fetal death were reported at rates of 10%, 50%, and 20% respectively in our study. According to Fonseca et al., [2] the most common indication for termination was congenital malformation in the fetus (47.22%), followed by terminations due to failure of contraception in multiparous women (38.88%). Medical terminations due to missed abortions (8.3%) and intrauterine fetal demise (5.5%) were among the other indications.

In our study, the mean dose of misoprostol required for successful abortion with Foley catheter insertion was found to be 600 µg which was similar to Agarwal et al. study [6], whereas in the Fonseca et al., and Prachasilpchai et al, [8] studies, it was reported as 800 µg.

According to Monika et al., and Abdou et al., studies [9–10], the mean induction to abortion interval ± standard deviation was found to be 17.29 ± 3.58 h and 14.80 ± 4.51 hrs, respectively, which was slightly comparable with our study's (14.05 ± 7.3 hrs) results.

Within our investigation, complete termination was observed in 80% of cases, while 20% necessitated surgical removal of the placenta, which was similar to previous studies. [2, 10]

In our study. Several participants experienced minor complications such as fever (30%), nausea and vomiting (55%), severe pain (VAS scale ≥ 5) (85%), and the requirement for blood transfusions (10%). Notably, no major complications were documented. Whereas pain, nausea, and vomiting were present in 100%, 22.22%, and 16.66%, respectively in the Fonseca et al., study. [2].

CONCLUSION

Studies have demonstrated encouraging outcomes when utilizing Foley catheter balloons in conjunction with sequential misoprostol for mid-trimester abortions, showcasing a reduction in the duration of induction to abortion, total misoprostol dosage needed, and length of hospitalization. Research has underscored the effectiveness and safety of Foley catheter balloons for cervical ripening in various obstetric contexts, encompassing the induction of labor in primiparas with differing cervical conditions. Despite apprehensions regarding the potential for infection, particularly in instances of prolonged prelabour rupture of membranes, comparative analysis has revealed that the overall efficacy and safety profile of the Foley catheter vis-à-vis oral misoprostol for cervical ripening subsequent to premature rupture of membranes (PROM) are comparable. These results substantiate the utilization of Foley catheter balloons alongside misoprostol for mid-trimester abortions, underscoring its capacity to enhance outcomes and streamline the abortion procedure.

The findings derived from this observational investigation demonstrate that the concurrent application of an intracervical Foley catheter and vaginal misoprostol presents a new, secure, efficient, and well-received approach for concluding a mid- or second trimester pregnancy, which is akin to a mifepristone-misoprostol combination protocol but with reduced expenses and absence of extra maternal hazards.

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REFERENCE

1. Drey EA, Foster DG, Jackson RA, Lee SJ, Cardenas LH, Darney PD. Risk factors associated with presenting for abortion in the second trimester. Obstet Gynecol. 2006 Jan;107(1):128-35.
2. Fonseca MN, SahV. Comparative study between sequential useof Foleys catheter with vaginal misoprostol versus sequential use of oral Mifepristone with vaginal misoprostol for second trimester medical abortion. Int J Reprod Contracept Obstet Gynecol 2018;7:4545-50.
3. Rezk M, Abo-Elnasr M, Al-Halaby A. Combined use of intracervical Foley catheter and vaginal misoprostol for termination of second trimester pregnancy: a three-year observational study. Clin Obstet Gynecol Reprod Med. 2015;1(3):79-83.
4. Ngai SW, Tang OS, Ho PC (2000) Randomized comparison of vaginal (200 microg every 3 h) and oral (400 microg every 3 h) misoprostol when combined with mifepristone in termination of second trimester pregnancy. *Human Reproduction* 15: 2205-2208.
5. Mahajan P, Sharma N, Sharma P. Study to compare the effectiveness of intravaginal misoprostol alone with combined use of intravaginal misoprostol and intracervical Foley's catheter for termination of mid trimester pregnancy. Int J Reprod Contracept Obstet Gynecol. 2020;9:2560-5.
6. Agarwal P, Gandhi S, Indora P. Comparative study of combination of misoprostol with Foleys bulb compared with misoprostol alone for termination of second trimester pregnancy.Int J ReprodContraceptObstetGynecol 2022;11:2459-65.
7. Sankalpa AJ, Jayanthy T, Sanvithi A.A retrospectivestudy on various methods used in second trimesterMTP at KIMS hospital and research centre, Bangalore. Int J Reprod Contracept Obstet Gynecol 2022;11:2208-12.
8. Prachasilpchai N, Russameecharoen K, Borriboonhirunsarn D. Success rate of Second Trimester Termination of pregnancy. J Med Assoc Thai. 2006;89(8):115-9.
9. Monika, Yadav., Urmila, Mahala. A prospective study to compare combined use of intravaginal misoprostol and intracervical foley catheter versus intravaginal misoprostol alone for termination of mid-trimester pregnancy in department of obstetrics and gynaecology sms medical college, jaipur. Asian Journal of Pharmaceutical and Clinical Research, (2023). doi: 10.22159/ajpcr.2023.v16i7.47446
10. Abdou, Saeed, Ait-Allah., A, Abdullah., Hany, F., Sallam. Transcervical Foley's Catheter Balloon with Misoprostol versus Misoprostol Alone for Cervical Ripening and Induction of Midtrimesteric Abortion in Women with Unfavorable Cervix. Aswan University Medical Journal, (2022).;2(1):1-9. doi: 10.21608/aumj.2022.237798.