

Comparison between Medical and Mechanical Method (Foley's) of Termination of Pregnancy in second trimester in Previously Scarred Uterus

Dr. Poonam Mani¹, Dr. Vidushi²

¹Professor, Department of Obstetrics & Gynecology, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, U. P.;
Corresponding Author Email: [poonam.mani\[at\]grediffmail.com](mailto:poonam.mani[at]grediffmail.com)

²Junior Resident, Department of Obstetrics & Gynecology, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, U. P.

Abstract: ***Background:** Obstetricians are faced with the difficulty of ending pregnancies in women who have scars on their uteruses because to the global trend of an increased prevalence of cesarean sections. The present study compares mifepristone against Foley's catheter for termination in uteri with prior scarring which will help the obstetricians in deciding which procedure has less complications and better efficacy that will enhance the quality of life of women having second trimester abortions. **Aim & Objectives:** To assess the safety and effectiveness of using mifepristone versus Foleys bulb for termination of pregnancy in previous LSCS and hysterotomy and compare the efficacy of medical versus mechanical induction and potential risks or adverse effects. **Material and Methods:** 40 pregnant women with the gestational age of 12 - 28 weeks participated in this hospital - based observational research which lasted for 12 months at Muzaffarnagar Medical College & Hospital in Muzaffarnagar, Uttar Pradesh. Chi square and t test were used in the statistical analysis of the data. **Results:** The participants ranged in age from 20 - 35 years old. Both Group M and Group B comprised the highest percentage of patients in age group 26 - 30 years i. e.55% and 50% respectively. Mean induction to interval of labour (in hrs), induction to augmentation interval, and induction to interval of delivery (in hrs) was more in Group B than the mifepristone group (Group M) ($p < 0.05$). In Mifepristone group, maximum reported complication was fever i.e. 4 cases experienced fever while in Foleys Bulb group, 7 cases had need for instrumentation (suction and evacuation). **Conclusion:** Mean induction to labour interval (in hrs), induction augmentation interval, and induction to delivery interval (in hrs) was more in Foleys bulb group (Group B) than the mifepristone group (Group M), being statistically significant. So, we conclude that mifepristone can be a better method for termination of pregnancy in scarred uterus as compared to Foley's catheter.*

Keywords: Mifepristone, Foley's bulb, Scarred uterus, Prev. C - section, Abortion, Termination of pregnancy (TOP).

1. Introduction

With the global trend of increasing cesarean section rate, obstetricians face the challenge of termination of pregnancy in women with a scarred uterus. ^[1] This becomes a lot challenging due to increased cesarean rates. In second trimester termination could be medical or surgical but advancement in medicine have introduced more effective methods like manual vacuum aspiration (MVA) of products of conception and cervical ripening in second trimester with prostaglandin preparations and replaced high morbidity surgical procedures. ^[2]

Maternal as well as fetal factors in termination of pregnancy are indicated in post caesarean cases, these factors being intrauterine death causes complications during intrapartum period, diabetes, hypertension, infection, genetic and congenital abnormalities, dysfunctional placental, and pregnancy continuing beyond 40 weeks. This is a catastrophic event with lasting consequences on all of society. ^[3]

The Foley catheter affects the cervix through direct mechanical action and the release of endogenous prostaglandins, and it is enhanced by traction use. ^[4] Misoprostol is a synthetic prostaglandin E1 analogue, first used in 1985 in obstetrics to induce abortion. ^[14] Since mifepristone and Foley's bulb improve cervical ripening and facilitate cervical effacement and ripening, there is no evidence of scar rupture. It takes 36 to 48 hours for

Mifepristone to prime the cervix, makes it suitable for misoprostol to work upon. Abortions performed in the second trimester led to high morbidity and mortality. Therefore, it is urgent to find the best way to perform a second trimester abortion without any problems. ^[5]

The present study compares the safety and efficacy of mifepristone against Foley's catheter for pregnancy termination with prior uterine scarring which will help the obstetricians in deciding which procedure has less complications and better efficacy in second trimester abortions to enhance the quality of life in women.

Aim & Objectives:

- 1) To find out safest and effective methods for termination in pregnancy in scarred uterus.
- 2) To compare the effectiveness of medical method (mifepristone) and mechanical induction (Foley's catheter) in abortion in women with previous LSCS and hysterotomy as well as the possible complications and side effects.

2. Material and Methods

This was a hospital based prospective study done in the Department of Obstetrics & Gynaecology, Muzaffarnagar Medical College & Hospital, Muzaffarnagar. 40 booked pregnant females between 12 - 28 weeks of gestation with previous LSCS or hysterotomy who presented to OPD/ Emergency for termination of pregnancy for intrauterine

Volume 13 Issue 9, September 2024

Fully Refereed | Open Access | Double Blind Peer Reviewed Journal

www.ijsr.net

fetal demise in Muzaffarnagar Medical College & Hospital, Muzaffarnagar; were included in the study by simple random sampling. Study was done for a period of 12 months i. e. July, 2023 to June, 2024.

They were given mifepristone (Group M) or Foley's bulb (Group B) to terminate the pregnancy. Progress of labor of patients in either group was studied and their outcome was recorded. Both groups were given misoprostol once their bishops score was more than or equal to 6. Cases with complete expulsion and cases which needed surgical exploration like dilatation and evacuation were evaluated. A variable was considered to be statistically significant if the value of $p < 0.05$.

Inclusion criteria:

- All antenatal women with previous LSCS who presented to OPD /Emergency for termination of pregnancy
- Intrauterine fetal demise as indication for termination of pregnancy
- Singleton pregnancy
- Period of gestation beyond 12 weeks till 28 weeks
- Bishops Score < 6

Exclusion criteria:

- Period of gestation < 12 weeks and > 28 weeks
- Medical or obstetrical complications which preclude vaginal delivery
- Medical conditions: heart disease, chronic renal failure, chronic adrenal failure, on long term steroid therapy.
- Inter conception period of < 6 months
- Previous classical / T - shaped Caesarean section.
- Conditions like Cervicovaginal Infection, PPRM along with Chorioamnionitis and bleeding PV at the time of examination

Ethical approval was taken from the institute's ethical committee and written informed consent was taken from all the participants. Observations were expressed in the form of tables and figures. $p < 0.05$ was considered significant.

3. Results

The participants in this study ranged in age from 20 - 35 years old. Both Group M and Group B comprised the highest percentage of patients in age group 26 to 30 years i. e. 55% and 50% respectively. Mean age was 27.49 years. Both Group M and Group B comprised the highest percentage of patients having gestational age of 17 to 23 weeks (40% and 55% respectively). Mean gestational age was 19.85 weeks. In both Group M and B, maximum patients had parity P2 - P3 i. e. 55% and 45% respectively. In the mifepristone group, 85% patients had LSCS history and 15% had previous hysterotomy while in Foleys bulb group, 75% had prev. LSCS and 25% had previous hysterotomy. (Table 1, Figure 1)

Mean induction to interval of labour (in hrs), induction to augmentation interval, and induction to interval of delivery (in hrs) was more in Group B than the mifepristone group (Group M). It was found to be significant as p value was less than 0.05. (Table 2)

The complications in both the study groups were reported as: Mifepristone: 4 cases experienced fever, 3 had need for instrumentation and UTI, only 1 case reported blood transfusion need and 2 cases had vaginal discharge. Foleys Bulb: 7 cases had need for instrumentation (suction and evacuation), 2 cases reported fever, 4 cases required blood transfusion, 02 cases had ICU admission, 4 cases had vaginal discharge and 6 cases had UTI. (Table 3)

4. Discussion

In the present study, both group M and group B comprised the highest percentage of patients aged 26 to 30 (55% and 50% respectively). In a study done by Fonseca MN et al (2018), 77.77% of the women in group A and 83.32 % of the women in group B were in the age group of 21 - 30 years. [6] A study done by Tomar Y et al (2023) also had most of the patients enrolled between 26 - 30 years of age. [7] These findings were similar to the finding of our study. In the present study, the test yielded a chi - square statistic of 1.34 with a p - value of 0.72. In a study done by Kusumam V. N. et al (2018), the test gave a p value equals to 0.84. [8] A study done by Saleh et al (2020) yielded p value of 0.125. [9] A study done by Kara et al (2023) yielded p value of 0.722. [10] All these studies reveal same non - significant relationship as our study.

The participants in present study had gestational age of 12 - 28 weeks. Both Group M and Group B comprised the highest percentage of patients having gestational age of 17 to 23 weeks i. e. 40% and 55% respectively. There was non - significant relationship between these two categorical variables. The same non - significant ($p > 0.05$) finding between gestational weeks and study groups was found in the studies done by Kusumam V. N. et al (2018), Kanta S et al (2020) and Saleh et al (2020) [8, 11, 9]

In the present study, 85% and 90% cases respectively from group M and B were unbooked. The test yielded a p - value of more than 0.05. This indicated that the relationship between these two categorical variables was not significant.

The current study found that Group B had higher mean induction to labor interval (in hours), induction augmentation interval, and induction to delivery interval (in hours) than the mifepristone group (Group M). There was a significant difference ($p < 0.05$). In a study done by Fonseca MN et al (2018), the mean induction abortion interval in group A (mifepristone and Foley's bulb) was 20.11 hours, while the mean induction abortion interval in group B (mifepristone and misoprostol) was 54.77 hours and this difference between the induction abortion intervals of the two groups was found to be statistically significant. [6] According to a research by Dahiya K et al. (2020), women who had previously had one cesarean section were at a lower risk while undergoing labor induction with mifepristone and a balloon catheter. Compared to a balloon catheter, mifepristone exhibited higher rates of cervical ripening and vaginal delivery. But there was no difference in induction to active phase of labour interval, induction - delivery interval in both groups. [12] The findings of these studies were similar to the finding of present study.

In a study done by CM Domerose et al., 2012 severe complications was seen in 8.1%, including silent uterine rupture, atonic and secondary hemorrhages, and peritonitis. Induction - expulsion failure occurred in 9.9% of cases. [13] A study done by Andrikopoulou M et al (2016) provides evidence that PGE1, PGE2, and mechanical methods are efficacious for achieving vaginal delivery in women with previous caesarean delivery. [14] The findings of these studies were almost similar to the finding of present study.

5. Conclusion

Mean induction to labour interval (in hrs), induction augmentation interval, and induction to delivery interval (in hrs) was more in Foleys bulb group (Group B) than the mifepristone group (Group M), being statistically significant. So, we conclude that mifepristone can be a better method for termination of pregnancy in scarred uterus as compared to Foley's catheter.

Limitations of the study:

In our study, women were included only from one hospital that represented a sample from a single geographical area.

Relevance of the study:

This study is very helpful as it will help the obstetricians in deciding which procedure has less complications and better efficacy in second trimester abortions to enhance the quality of life in women.

Funding: No funding sources.

Conflict of interest: None declared.

Authors Contribution: The study was done under the continuous and expert guidance of Dr. Poonam Mani (Professor).

References

- [1] Niino Y. The increasing cesarean rate globally and what we can do about it. *Bioscience trends*.2011 Aug 31; 5 (4): 139 - 50.
- [2] Patil B. *A Comparative Study of Manual Vacuum Aspiration with Medical Method of Management for Incomplete and Missed Abortion* (Doctoral dissertation, Rajiv Gandhi University of Health Sciences (India)).
- [3] Kuthe A. Intra - uterine Fetal Death. A Practical Guide to Third Trimester of Pregnancy & Puerperium.2016 Apr 30.
- [4] David HP. Acceptability of mifepristone for early pregnancy interruption. *Law, Medicine and Healthcare*.1992 Oct; 20 (3): 188 - 94.
- [5] Bingham D, Jones R. Maternal death from obstetric hemorrhage. *J Obstet Gynecol Neonatal Nurs*.2012; 41: 531–539.

- [6] Fonseca MN, Sah V. Comparative study between sequential use of Foley 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.
- [7] Tomar Y, Najam R, Singh M. Effectiveness of mifepristone versus balloon catheter in induction of labour in women with previous caesarean sections: a randomised comparative study. *Int J Reprod Contracept Obstet Gynecol* 2023; 12: 88 93.
- [8] V. N, Kusumam & Khan, Naseema & V. G, Sruthi. (2018). Comparison of effectiveness of mifepristone misoprostol combination versus mifepristone Foley EAS (Extra - amniotic instillation of saline) combination in second trimester pregnancy termination. *Indian Journal of Obstetrics and Gynecology Research*.5.530 - 534.10.18231/2394 - 2754.2018.0119.
- [9] Saleh HS, El - Kadosi MEH, Sherif HE. Misoprostol only or in combination with intra cervical Foley's catheter for termination of the second trimester demise pregnancy in patient with previous caesarean sections. *Obstet Gynecol Int J*.2020; 11 (6): 381–385. DOI: 10.15406/ogij.2020.11.00540.
- [10] Kara Ş, Gök K, Köse O, Bostancı MS, Özden S. Investigation of the Effectiveness of Misoprostol and Foley Catheter Use Alone or Together in Second Trimester Pregnancy Terminations. *Eur Arch Med Res* 2023; 39 (4): 229 - 234.
- [11] Swarn Kanta, Pooja Sharma, Sandeep Sharma, Mandeep Sharma. Comparison of intravaginal misoprostol alone and in combination with intracervical foley's catheter for termination of second trimester pregnancy at a tertiary care hospital. *MedPulse – International Medical Journal*. October 2018; 5 (10): 100 - 102. <http://www.medpulse.in>.
- [12] Dahiya K, Yadav N, Dahiya P, Nandal I. Comparative study of mifepristone versus balloon catheter for cervical ripening and induction of labour in previous caesarean section. *Int J Reprod Contracept Obstet Gynecol* 2020; 9: 2504 - 7.
- [13] Domröse CM, Geipel A, Berg C, Lorenzen H, Gembruch U, Willruth A. Second - and third - trimester termination of pregnancy in women with uterine scar—a retrospective analysis of 111 gemeprost - induced terminations of pregnancy after previous cesarean delivery. *Contraception*.2012 Jun 1; 85 (6): 589 - 94.
- [14] Andrikopoulou M, Lavery JA, Ananth CV, Vintzileos AM. Cervical ripening agents in the second trimester of pregnancy in women with a scarred uterus: a systematic review and metaanalysis of observational studies. *Am J Obstet Gynecol*.2016 Aug; 215 (2): 177 - 94. doi: 10.1016/j.ajog.2016.03.037. Epub 2016 Mar 25. PMID: 27018469.

Tables & Figures:

Table 1: Comparison of Socio - demographic profile in groups M & B:

Variables	Group Frequency		Chi square	P value
	Mifepristone (n=20) (%)	Foleys bulb (n=20) (%)		
Age Category				
20 - 25	06 (30%)	05 (25%)	0.64	0.73
26 - 30	11 (55%)	10 (50%)		
31 - 35	03 (15%)	05 (25%)		
Gestational Age				
12 - 16 wks	06 (30%)	05 (25%)	0.96	0.62
17 - 23 wks	08 (40%)	11 (55%)		
24 - 28 wks	06 (30%)	04 (20%)		
Parity				
P1	07 (35%)	07 (35%)	0.87	0.65
P2 - P3	11 (55%)	09 (45%)		
>P3	2 (10%)	4 (20%)		

Mean age: 27.49 years

Mean gestational age: 19.85 weeks

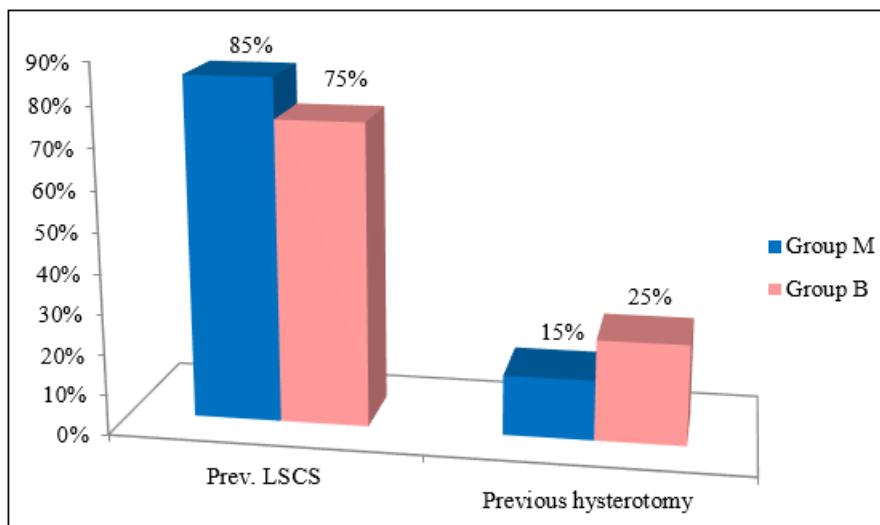


Figure 1: Distribution of participants according to surgical history

Table 2: Test for significance between induction intervals and study groups:

Group		Induction to Labour Interval (in hrs)	Induction augmentation interval	Induction to delivery interval (in hrs)
Mifepristone	Mean	19.7	2.3	25.9
	SD	5.6	0.8	8.1
Foleys bulb	Mean	24.2	2.9	31.1
	SD	5.5	1.1	7.9
t test		3.20	2.48	1.93
p value		0.003	0.019	0.043

Table 3: Correlation between Complications and study groups:

Complications	Mifepristone		Foleys Bulb		Chi square value	P value
	N (20)	%	N (20)	%		
Fever	4	20%	2	10%	4.38	0.49
Blood transfusion	1	5%	4	20%		
ICU admission	0	0%	2	10%		
Discharge per vaginally	2	10%	4	20%		
UTI	3	15%	6	30%		
Need for instrumentation	3	15%	7	35%		