



Journal Homepage: - www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/12742

DOI URL: <http://dx.doi.org/10.21474/IJAR01/12742>



RESEARCH ARTICLE

COMPARATIVE STUDY BETWEEN COMBINED USE OF INTRACERVICAL FOLEY CATHETER WITH VAGINAL MISOPROSTOL VERSUS VAGINAL MISOPROSTOL FOR MID TRIMESTER ABORTIONS IN PATIENTS WITH PREVIOUS CAESAREAN SECTIONS

Kanchan Sharma, Ranideepa and Anamika

Department of Obstetrics and Gynaecology, Patna Medical College And Hospital Patna.

Manuscript Info

Manuscript History

Received: 10 February 2021

Final Accepted: 16 March 2021

Published: April 2021

Key words:-

Intracervical foley's Catheter,
Misoprostol, Caesarean Section, Mid
Trimester Abortion

Abstract

Background: There is a gradual increase in second-trimester abortion because of wide scale introduction of prenatal screening programs detecting women whose pregnancies are complicated by serious fetal abnormalities such as aneuploidy, cardiovascular and skeletal malformation. It constitutes 10-15% of all induced abortions. With the global trend of raised cesarean section rate, obstetricians are faced with the challenge of termination of pregnancy in women with a scarred uterus. Termination of pregnancy in second trimester is associated with much more morbidity and mortality than when it is done in the first trimester. The various methods for second trimester termination of pregnancy are still controversial and the search for the ideal method which is the safest, easiest, cheapest and most effective is still going on. Search for alternative and effective method is the need of hour. In our study, we aimed at assessing the effectiveness and safety of intracervical foleys catheter with vaginal misoprost and comparing it with the vaginal misoprost for mid trimester abortions in patients with previous caesarean.

Methods: This was a prospective randomized controlled trial conducted on 108 women undergoing mid trimester abortions at Patna medical college and hospital in 2019. Patients were randomly allocated in 2 groups

Group I (intracervical foleys and Misoprostol group): Intracervical Foley catheter inserted with a standard regimen of moistened misoprostol tablets (200 µg) 6 hourly intravaginally was used.

Group II (misoprostol group): moistened misoprostol tablets (200 µg) 6 hourly inserted vaginally.

Procedure efficacy (defined as complete abortion within 48 hours of first dose of misoprostol), safety and reduction in side effects, acceptability, dose of misoprost required were assessed in both the groups.

Results: The induction to abortion interval was 24.16 ± 1.52 hours in the combined group compared to 45.76 ± 1.63 hours in the misoprostol group (P value < 0.021)

with success rate of 96% in the combined group and 80 % in misoprostol group.

Corresponding Author:- Kanchan Sharma

Address:- Department of Obstetrics and Gynaecology, Patna Medical College And Hospital Patna.

Total dose of misoprostol required in combined group was (682.33+₋245) micrograms and (1100 +₋ 212) micrograms in misoprost group with p value < 0.001

No significant difference as regard occurrence of adverse effects between the two groups.

Conclusions: Combined use of intracervical foley catheter and vaginal misoprostol is a novel safe, effective and acceptable method for termination of second trimester in patients with previous caesarean section pregnancy.

Copy Right, IJAR, 2021., All rights reserved.

Introduction:-

Abortion is defined as 'termination of pregnancy by any means before the fetus is viable'. Viability is now considered to be reached at 23–24 weeks of gestation, in India it is 28 weeks. Second trimester, or mid-trimester, is a period ranging from 13 to 28 weeks of gestation, which again is subdivided into an early period between 13 and 20 weeks and a late period between 20 and 28 weeks. In this review, we are limited to abortions up to 20 weeks gestation.

Worldwide mid-trimester abortion constitutes 10–15% of all induced abortions but is responsible for two-thirds of all major complications. With delay in the marriages leading to increased risk of aneuploidy and further advancements in medical science in the form of prenatal screening for fetal anomalies, mid trimester abortion is increasing day by day.

With the increasing trends of caesarean section, obstetricians now commonly face the problem to tackle termination of pregnancy in scarred uterus. This challenge further increases if it is mid trimester abortion with previous caesarean section.

Many studies are still undergoing so as to decide the safest method of mid trimester abortion in patients with previous caesarean sections.

Misoprostol is a synthetic prostaglandin E1 analogue. Originally used to inhibit peptic ulcer. It was first used in obstetrics to induce abortion in 1988. Now it is widely used for induction of labour, termination of pregnancy and management of postpartum haemorrhage but still its use in obstetrics is not approved by FDA.

The Foley's catheter traction is the cheapest, safest and successful mechanical method of cervical dilatation according to various studies. Transcervical extraamniotic intracervical foleys insertion causes mechanical stretching of the cervix and release of endogenous prostaglandins

This study aims to compare the safety and efficacy of two regimens in mid trimester abortion in patients with previous caesarean section either by using combination of intracervical foleys with vaginal misoprost and vaginal misoprost alone.

Methods:-

This was a prospective randomized controlled trial conducted during the period of January 2019 to January 2020 in the department of obstetrics and gynaecology in Patna medical college and hospital, Patna. The study recruited 108 patients, who were randomly allocated groups.

GROUP A :- 55 patients with previous caesarean undergoing mid trimester abortion with combined use of intracervical foleys catheter and vaginal misoprost 200 microgram every 6 hourly.

GROUP B:- 53 patients with previous caesarean undergoing mid trimester abortion with use vaginal misoprost 200 microgram every 6 hourly.

Inclusion Criteria:-

1. All women with previous 1 and previous 2 caesarean section needing termination between 13 to 20 weeks of gestation

2. singleton pregnancy Patients
3. who consent to be part of the study

Exclusion Criteria:-

1. Patients with more than 2 caesarean section
2. Classical caesarean section
3. Multiple gestation
4. Having complications in previous caesarean like endometritis etc
5. History of repair of rupture uterus
6. Other medical comorbidities like hypertension, diabetes mellitus etc

All women who presented through emergency or outdoor for therapeutic termination of pregnancy between 13 to 20 weeks of gestation having previous cesarean section and fulfilled inclusion criteria were included in the study. Patients in both the groups underwent thorough history taking, clinical examination, obstetric ultrasonography to confirm gestational age, congenital malformation, and placental localization

After taking informed consent, the group A patients were put in lithotomy position in examination room, vulva vagina were cleaned, sterile Sim's speculum was introduced in the vagina, holding anterior cervical lip with sponge holding forceps and with the help of another sponge holding forceps a Foleys catheter no 14 or 16 Fr passed in the cervix into the extra amniotic space and balloon was inflated with 30ml saline. A urine bag filled with 200ml saline was attached to the catheter for traction and in the same sitting T. misoprostol 200 microgram was applied vaginally. Misoprost administration was repeated at 6 hours interval. As soon as the catheter was expelled reassessment of the dilatation of the cervix was done.

In group B patients, with aseptic precautions 200µg misoprostol tablet was inserted in the posterior fornix every 6 hours till the expulsion or till maximum of six tablets were given.

The failure of the therapy was considered if there was no expulsion after 48 hours or there were serious side effects needing the treatment to be stopped.

Statistic Analysis

Pearson chi square & fisher's exact test were used to compare the categorical data between the two groups while Mann Whitney U test was used to compare the continuous data. P value < 0.05 is applied as statistically significant.

Table1:- maternal characteristics.

Maternal characteristics	Group A (combined group) N= 55	Group B (misoprostol group)	p value
Mean Age (years)	23.68	24.16	>0.05
Parity	2.5 +- 1.54	2.6+-0.88	>0.05
Mean Gestational age(weeks)	15.7+-1.66	16.4+-0.9	>0.05
Previous number of Lscs			>0.05
Previous 1	42	40	
Previous 2	13	12	

Table2 :- Indications for mid trimester abortions.

Indication	Group A (combined group) N= 55	Group B (misoprostol group) N=53	P value
Congenital anomalies	28	27	>0.05
Intrauterine death	27	26	>0.05

Table 3 :-Total dose of misoprostol required and induction to abortion interval.

Variables	Group A(combined)	Group B(misoprostol)	P value
Total dose of misoprost	682.33+-245	1100+-212	<0.001
Induction to abortion interval	24.16+-1.52	45.76+-1.63	<0.021

Table 4:- Complications due to intervention.

Complications	Group A(combined group) n= 55	Group B (misoprostol group) n= 53	P value
Nausea & vomiting	7(12.7 %)	9(16.3%)	p>0.05
Fever	1(1.81%)	2(3.7%)	p>0.05
Headache & giddiness	3(5.45%)	3(5.66%)	p>0.05
Rupture uterus	0	0	-
Excessive blood loss	2(3.6%)	4(7.5%)	P>0.05
Need for surgical intervention	1(1.8%)	3(5.6%)	p>0.05

Results:-

Total 108 women were randomly selected who were in second trimester (13 -20 weeks), attending OPD or emergency of Patna medical college, Patna with intrauterine death or with gross congenital anomalies incompatible with life. They were divided into two groups. Study group A received Foley's and misoprostol. Control group B received misoprostol alone.

The descriptive statistics of maternal demographic & obstetric characteristics are described in tables.

TABLE1. Both groups are comparable and showing no significant differences ($P>0.05$). most of the cases belonged to gestational age between 15 to 18 weeks ($p>0.05$). Out of 55 cases in GROUP A , 42 cases were previous 1 Lscs& 13 were previous 2 Lscs and in GROUP B , 40 cases were previous 1 Lscs& 12 cases were previous 2 Lscs. P value was insignificant with respect to previous caesarean status in both the groups.

TABLE2is showing indication for mid trimester abortion in both the groups . In group A out of 55 patients , 28 had congenital anomalies and 27 had intrauterine death and in GROUP B 27 had congenital anomalies in the fetus and 26 had IUD. Both the groups are comparable with respect to indication of mid trimester abortion(p value >0.05)

TABLE 3shows total dose of misoprost required and induction to abortion interval in both groups.

In GROUP A (combined group) total dose of misoprostol required was 682.33 +- 245 micrograms and in group B (misoprostol alone group) total misoprost required was 1100+_ 212 micrograms, p value <0.001 was significant, showing intracervical foley's catheter with vaginal misoprostol effectively reduces the dose of misoprostol required.

Induction to abortion interval was 24.16+_ 1.52 hours in group A whereas it was 45.76+_ 1.63 hours in group B (p value <0.021) showing that combined use of intracervical foley's with misoprostol is associated with shorter expulsion time and also resulting to shorter hospital stay in combined group with respect to group B.

TABLE4shows complications due to intervention in both the groups like nausea & vomiting, headache & giddiness, excessive bleeding, fever, need for surgical intervention , it was found that complications noted in both the groups were statistically not significant. There was no rupture of uterus in any group. 1 case in group A and 3 cases in group B required surgical intervention for complete evacuation of uterus.

Discussion:-

With the increasing global trend in caesarean section and limited evidence available on safe second term pregnancy termination in these women. Therefore, the decision to attempt pregnancy termination in the second trimester in

cases with previous uterine scar should be made on a case-by case basis, after consideration of the number of previous cesarean sections and gestational age, and availability of facilities to tackle emergency. In our study the overall dose of misoprostol required in combination with intracervical foley's catheter was significantly reduced in comparison to the doses required in case of misoprostol alone. Induction to abortion interval was also reduced in combined group in comparison to misoprostol alone group.

The most efficacious regimen for medical termination of second trimester pregnancy appears to be use of mifepristone followed by misoprostol. This regimen has an abortion rate of 97-99% in first 24 hours. In low resource setting mifepristone is non affordable or non available. Misoprostol is widely used for second trimester termination of pregnancy. However there is still a debate about the best route and dose with minimum induction to delivery interval and minimum side effects. In order to shorten the induction to delivery interval and to minimize the side effects of repeated dose of misoprostol, intracervical Foley's catheter combination is one of the better options. The purpose of our study was to compare the efficacy and outcome of misoprostol alone and in combination with intracervical Foley's catheter for medical termination of second trimester pregnancy. In this study the induction to delivery interval (IDI) was 24.16 + 1.52 hours in combined group which is significantly shorter than misoprostol alone group (45.76+1.63 hours). The side effects and complication was comparable without any significant difference. No uterine rupture observed in our study. The induction to delivery interval of misoprostol alone showed marked variation among various studies. It varies from 9 -47 hours, with success rate of 60-100%. Similar induction to delivery interval was observed by Shabana A et al., a study conducted at Egypt, in which induction to delivery interval in combined group was 15.6±5.4 hours which significantly shorter than misoprostol alone group (21.9±4.9) and Another study by A koury HA and et al., on 217 women of 15-24 weeks of gestation, compared the outcome of vaginal and oral misoprostol. The induction to delivery interval observed was longer for oral misoprostol group (30.5±14.4 hours) as compared to vaginal route (18.3±8.2hrs). There are very limited studies which compares the use of prostaglandin E1 tablet alone versus its combined use with Foley's catheter in terminating Midtrimester pregnancy with previous caesarean section.

A study conducted by Imran F et al., at Karachi, used 200 mcg misoprostol with hydroxyl ethyl gel for termination of pregnancy between 14- 24 weeks, found a success rate of 96% and induction to delivery interval 9.02±4.57 hours. Kooper smith study observed a low success rate of 60-70%²⁷. Ghorab et al., and Shabana A et al., observed a success rate of 100%⁸, ²⁸. These large variations in the outcome may be due to difference in the regimens used, routes of administration, indication, parity and the gestational age at the time of presentation. A study by Toptas et al., was conducted in a total of 91 pregnancies. Women between 13 to 26 gestational weeks were included in the study. Study participants received intravaginal misoprostol in combination with Foley's catheter (n=46) or intravaginal misoprostol alone (n=45). The authors concluded that combination of intravaginal misoprostol and extra amniotic Foley catheter for second trimester pregnancy termination does not provide additional efficacy with one case experiencing uterine rupture in the catheter group. Recently Razk et al., conducted comparative study including 90 pregnant women between 13 and 24 gestational weeks. Enrolled women were equally allocated into three groups. The first received vaginal misoprostol (n=30), the second received intracervical Foley catheter alone (n=30) and the third received both (n=30)³⁰. The induction to abortion interval was 7.5±1.25 h in the combined group, compared to 11.76± 1.63 h in the misoprostol group and 19.76±1.52 h in the catheter alone group.

Conclusion:-

Intracervical foley's catheter with Misoprostol is safe and more efficacious than misoprostol alone for second trimester pregnancy termination in women with previous cesarean section with no significant increase in side effects.

References:-

1. Champa SJ, Crispens M, Owen J. Complication of midtrimester pregnancy termination: The effect of prior caesarean delivery. *Am J Obstet and Gynaecol* 1996; 175:889-92.
2. Hackett GA, Reginald P, Paintin DB. Comparison of the Foley's catheter and dinoprostone for cervical preparation before second trimester abortion. *Br J ObstetGynaecol* 1989;96:1432-
3. Liu HS, Yu MH, Chang YK, Chu TY. Second and early third trimester pregnancy termination by extra amniotic balloon and intra cervical PGE2. *Int J GynaecolObstet* 1998; 60: 29-34.6.
4. Hamilton J. Historical Review of British Embrey MP, Mollison BG. The unfavourable cer-
5. vix and induction of labour using a cervical bal- loon. *J ObstetGynaecol Br Commonw* 1967; 74:44-8.

6. Ezimokhai M, Nwabinelli JN. The use of Foley's catheter in ripening of unfavourable cervix prior to induction of labour. *Br J ObstetGynaecol* 1980;87:281-6.
7. Pushpa, Sirichand, Sachdev. Termination of second trimester pregnancy: Comparison of prostaglandin vaginal pessaries vs. Foley's catheter insertion. *J Coll Physicians Surg Pak* 1999; 9:400-2.
8. Atad J, Hallak M, Auslender R, Porat-Packer T, Zarfati D, Abramovici H, et al. A randomized comparison of prostaglandin E₂, Oxytocin and double-balloon device in induction of labour. *ObstetGynecol* 1996;87: 223-7.
9. Yapar EG, Senoz S, Urkutur M, Batioglu S, Gökmen O. Second trimester pregnancy termination including foetal death: comparison of five different methods. *Eur J ObstetGynecolReprod Biol* 1996; 69: 97-102.
10. Atad J, Lissak A, Sorokin Y, Bornstein J, Auslender
11. Gemzell-Danielsson K, Lalitkumar S. Second trimester medical abortion with mifepristone-misoprostol and misoprostol alone: a review of methods and management. *Reprod Health Matters* 2008; 16: 162-172.
12. Bartlett LA, Berg CJ, Shulman HB, Zane SB, Green CA, Whitehead S, et al. Risk factors for legal induced abortion-related mortality in the United States. *ObstetGynecol* 2004; 103:729-37
13. Yapar EG, Senoz S, Urkutur M, et al: Second trimester pregnancy termination including fetal death: comparison of five different methods. *Eur J ObstetGynecolReprod Biol.* 1996; 69(2): 97-102.
14. Shabana A, Salah H, Kandil M et al. Termination of mid trimester pregnancies: misoprostol versus concurrent weighted Foley catheter and misoprostol. *F1000 research* 2012; 1:36-40.
15. Lohr PA, Hayes JL, Gemzell-Danielsson K.; Surgical versus medical methods for second trimester induced abortion. *Cochrane Database Syst Rev* 2008; CD006714.
16. KraliKowski. Extra-Amniotic PGF_{2a} in the termination of pregnancy. *S Afr Med J* 1994;84:321-22.
17. Bozkurt M. Combined oral and vaginal misoprostol use in therapeutic terminations at 14 to 28 weeks of gestation. *J Clin med Research* 2012; 4(9):104-108.
18. Sobia N, Nadra S. Role of Misoprostol for therapeutic termination of pregnancy from 10-28 weeks of gestation. *J Pak Med Assoc* 2007; 57:129-32.
19. Hamilton J. *Historical Review of British Obstetrics and Gynaecology.* Edinburgh and London: E & S Livingston Ltd; 1954;1800-950.
20. Embrey MP, Mollison BG. The unfavourable cervix and induction of labour using a cervical balloon. *J ObstetGynaecol Br Commonw* 1967; 74:44-8.
21. Imran F, Anser A, Danish N, Fatima N. Misoprostol for the purpose of mid trimester termination of pregnancy: A comparative study with prostaglandin F₂ alpha. *J Ayub Med Coll Abbotabad* 2010; 22: 87-91.
22. Ezimokhai M, Nwabinelli JN. The use of Foley's catheter in ripening of unfavourable cervix prior to induction of labour. *Br J Obstet Gynaecol.* 1980; 87:281-6.
23. Rezk M A, Abo-Elnasr M, Al-Halaby A. Combined use of intracervical foley catheter and vaginal misoprostol for termination of second trimester pregnancy: *Clinical Obst, Gyn and Reprod Med*, 2015; Volume 1(3): 79-83.
24. Thomas IL, Chenoweth JN, Tronc GN. Preparations for induction of labour of the unfavorable cervix with Foley catheter compared with vaginal prostaglandin. *Aust N Z J ObstetGynaecol.* 1986; 26(1): 30-5.
25. St Onge RD, Connors GT. Preinduction cervical ripening: A comparison of intracervical prostaglandin E₂ gel versus the Foley catheter. *Am J ObstetGynecol.* 1995; 172(2 Pt 1): 687-90.
26. Kierce MJ, Thiery M, Parewijck W, et al. Chronic stimulation of uterine prostaglandin synthesis during cervical ripening before the onset of labor. *Prostaglandins.* 1983; 25(5): 671-82.
27. A Koury HA, Hannch ME, Chitayat D, Thoma M, Winson E, Feoiois LE, et al. Randomized controlled trial of misoprostol for second-trimester pregnancy termination associated with fetal malformation. *Am J Obstet Gynecol.* 2004; 190; 755-62.
28. Liu HS, Yu MH, Chang YK, Chu TY. Second and early third trimester pregnancy termination by extra amniotic balloon and intra cervical PGE₂. *Int J GynaecolObstet* 1998; 60: 29-34.
29. Hamilton J. *Historical Review of British Liu HS, Yu MH, Chang YK, Chu TY. Second and early third trimester pregnancy termination by extra amniotic balloon and intra cervical PGE₂.* *Int J GynaecolObstet* 1998; 60: 29-34.
30. Hamilton J. *Historical Review of British Gomal Journal of Medical Sciences* January-June 2013, Vol. 11, No. 1 96 SurrayHalimi, et al.
31. Atad J, Lissak A, Calderon I, Sorokin T, Abramovici H, et al. Continuous extraovular prostaglandin F₂ alpha instillation for late pregnancy termination in patients with previous cesarean section delivery. *Int. J GynaecolObstet* 1986; 24:315-9.

32. Pushpa, Sirichand, Sachdev. Termination of second trimester pregnancy: Comparison of prostaglandin pessaries vs. Foley's catheter insertion. *J Coll Physicians Surg Pak* 1999; 9: 400-2.
33. Liu HS, Chang YK, CHU TY. Extra amniotic balloon with PGE2 versus extraovular Foley's catheter with PGF2 alpha in mid trimester pregnancy termination. *Int J Gynecol Obstet* 1998; 63: 51-5.
34. Mekbib TA. Induction of labour by condom Foley's catheter method in pregnant women with intra uterine foetal death. *Ethiop Med J* 1994; 32:107-13.
35. Halimi M. Therapeutics termination of second trimester pregnancy: A comparison of extra amniotic Foley's catheter balloon alone with combined use of Foley's catheter balloon and extra amniotic instillation of prostaglandin F2-alpha. *Postgrad Med J* 2004; 18: 408-18.

Conflict Of Interest

Authors declare no conflict of interest.

GRANT SUPPORT AND FINANCIAL DISCLOSURE

None declared.

18. Perry KG Jr, Rinehart BK, Terrone DA, Martin RW, May WL, Roberts WE. Second-trimester uterine evacuation: A comparison of intra-amniotic (15S)-15-methyl-prostaglandin F2alpha and intra vaginal misoprostol. *Am J Obstet Gynecol* 1999; 181(5 Pt 1) : 1057-61.

19. Fariha. A, Nadra. S, Naila I. Therapeutic abortion; Efficacy of intra-vaginal Misoprostol in comparison to extra amniotically administered prostaglandin F2 alpha. *Professional Med J* 2006; 13: 417-22.

20.