ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 6, Issue – 2, April- 2023, Page No. : 183 - 189

Study of medical termination of pregnancy beyond 12 weeks in a tertiary care centre with respect to efficacy and safety of mifepristone-mechanical traction-misoprostol based 2 regimens

[1]Dr. Snehal Govind Kumbhar, Department of Obstetrics and Gynaecology, Byramjee Jeejeebhoy Medical College and Sassoon General Hospital, Pune, Maharashtra, India 411001

[2]Dr. Arun Ambadkar, Department of Obstetrics and Gynaecology, Byramjee Jeejeebhoy Medical College and Sassoon General Hospital, Pune, Maharashtra, India 411001

[3]Dr. S. G. Tambe, Department of Obstetrics and Gynaecology, Byramjee Jeejeebhoy Medical College and Sassoon General Hospital, Pune, Maharashtra, India 411001

Corresponding Author: Dr. Snehal Govind Kumbhar, Department of Obstetrics and Gynaecology, Byramjee Jeejeebhoy Medical College and Sassoon General Hospital, Pune, Maharashtra, India 411001

How to citation this article: Dr. Snehal Govind Kumbhar, Dr. Arun Ambadkar, Dr. S. G. Tambe, "Study of medical termination of pregnancy beyond 12 weeks in a tertiary care centre with respect to efficacy and safety of mifepristone-mechanical traction-misoprostol based 2 regimens", IJMACR- April - 2023, Volume – 6, Issue - 2, P. No. 183 – 189.

Type of Publication: Original research Article

Conflicts of Interest: Nil

Abstract

Objectives: To assess the effectiveness and safety of two different regimens based on Mifepristone, mechanical traction and Misoprostol for medical termination of pregnancy beyond 12 weeks.

Methods: Observational Retrospective study in 304 patients at a tertiary care centre.

Results And Conclusion: Of the 304 women, 3 patients chose surgical method for termination in view of history of previous 2 LSCS, while rest patients were terminated with institutional protocols using Mifepristone-Mechanical traction-Misoprostol protocol. Of these, 25 women aborted with single dose of misoprostol 200 mcg and rest aborted successfully within five doses of misoprostol. Nearly ≥90 % women underwent complete abortion. Women with previous 2 LSCS had statistically significant difference in induction to abortion interval when used 2 different regimens under study. There was no need of hysterotomy and only 1% cases needed blood transfusion post-procedure proving methodologies used in this study to be safe & efficacious.

Keywords: Medical termination of pregnancy, Mifepristone, Misoprostol, Mechanical traction, hysterotomy.

Introduction

The subject of an ideal method of midtrimester pregnancy termination that is both safe and effective, has been frequently discussed and evaluated. Different drugs

came into prominence over the years starting from quinine, ergot alkaloids, hypertonic saline, urea, ethacridine lactate and many of them have faded into oblivion. Karim and Filshie [1, 2] first reported the use of prostaglandin administration.Mifepristone, 200 mg, is just as effective for this purpose as 600 mg (3). A common protocol was developed using mifepristone and misoprostol that is now recommended by the Royal College of Obstetricians and Gynecologists (RCOG) and the WHO (4,5).

Materials And Method

A retrospective observational study carried out at department of obstetrics and gynaecology at Byramjee Jeejeebhoy Medical College and Sassoon General Hospital, Pune, Maharashtra, in 304 patients over a period of 18 months and the collected data analysed over 2 months. Patients from gynaecology OPD and ANC ward with gestational age beyond 12 weeks who were admitted in the hospital and undergone the procedure after written informed consent, were traced in the hospital records.Institutional regimen protocols were regimen (A) Mifepristone 200 mg followed by Dinoprostone gel 0.5 mcg per vaginally and mechanical traction per vaginally 48 Hr later further followed by Tab Misoprostol 200 mcg 4 Hrlyper vaginally and (B) Mifepristone 200 mg 2 doses 24 Hr. apart with second dose followed by Dinoprostone gel and mechanical traction per vaginally 24 Hr. later further followed by tab Misoprostol 200 mcg 4 Hrly per vaginally. Outcomes were measured in terms of • Induction to abortion interval • Dose of medicine required (Government supply drugs will be used) • Rate of complete abortion • Failure to achieve complete abortion with intended method and need for surgical evacuation like dilation & evacuation or hysterotomy• Excessive blood loss either measured /estimated by clinically relevant drop in hemoglobin

Results

Total 304 cases were studied in which 253 MTPs were carried out by regimen A and 49 MTPs were carried out by regimen B. 3 of the total studied MTPs were directly by hysterotomy and were not planned for medical methods based purely on patients' choice after explaining high risk consent due to history of previous 2 LSCS. Mean induction abortion interval by regimen A and B are respectively 13 and 14 Hr respectively as per table 1.While as shown in table 2, nearly 50% of the patients undergoing MTPs by either of the regimens took 13 to 18 Hr. While nearly 8% and 7% of the study patients had induction abortion interval less than/equal to 6 Hr and more than 18 Hr respectively. Nearly 45% and 37%patients took time less than 19 Hr in regimen 3 and 4 respectively.

Table 1: Average comparison of induction to abortion interval

Schedule	Induction to abortion interval		P
	Mean	SD	
Regimen A (N=253)	13.38	4.039	0.16
Regimen B (N=49)	14.27	4.410	
Total	13.52	4.107	

Table 2: Distribution of Induction to abortion interval

Induction to abortion interval		Schedule		Total	P
		Regimen A (N=253)	Regimen B (N=49)		
≤ 6 Hrs	Number	20	5	25	0.133
	%	7.9%	10.2%	8.3%	
7 to 12 Hrs	Number	95	13	108	
	%	37.5%	26.5%	35.8%	
13 to 18 Hrs	Number	123	24	147	
	%	48.6%	49.0%	48.7%	
19 to 24 Hrs	Number	15	7	22	
	%	5.9%	14.3%	7.3%	

In patients with previous 2 LSCS, mean induction to abortion intervals by regimen 3 & 4 are 17 Hr and 13 Hr respectively which are statistically significant.

Table No 3: Average comparison of Induction to Abortion Interval in cases with 2 LSCS (Hours).

Induction to Abortion Interval in cases with 2 LSCS (Hours)	Regimen A (N=51)		Regimen B (N=12)		P
	Mean	SD	Mean	SD	<0.01
	17.3	5.6	12.8	6.3	

None in the study population required hysterotomy for termination of pregnancy in view of failed induction. Average pre procedure and post procedure haemoglobin level distribution studied in the population as in table 4.Only 1.3% in the study population required blood transfusion as a result of anaemia due to intra or post procedural haemorrhage.

Table No 4: Average comparison of Pre Hb and Post Hb between study groups

Schedule		pre- Hb	Post- Hb
Regimen A (N=253)	Mean	10.27	9.83
	SD	1.27	1.25
Regimen B (N=49)	Mean	10.35	9.99
	SD	1.43	1.43
Total	Mean	10.28	9.85
	SD	1.29	1.28
P		0.67	0.41

Nearly 6% and 10% of the study population had incomplete abortion in category of regimen A and B respectively.In this study , routine ultrasonography was done as part of institutional protocol after 48 Hr of expulsion of conceptus and placenta to rule out retained products of conception(RPOC) . Nearly 93 % of the study population had complete abortion with either of the regimen.Particularly regimen A and B have rate of complete abortion as 93.7% and 89.8% , respectively.

Table 5: Distribution of complete abortion between study groups.

Complete abortion		Regimen A (N=253)	Regimen B (N=49)	Total	P
No	Number	16	5	21	0.328
	%	6.3%	10.2%	7.0%	
Yes	Number	237	44	281	
	%	93.7%	89.8%	93.0%	

Table No 6: Incomplete abortions and further interventions done

Size of RPOCs		Regimen A (N=16)	Regimen B (N=5)	Total Incomplete abortions (N=19)
RPOC≤1 cm	Number	9	2	11
	%	56.25%	40.0%	96.4%
RPOC>1 cm	Number	7	3	10
	%	43.75%	60.0%	3.6%

Discussion

This forms main aim of the study. In the studied population, average IAI in group of regimen A was 13 Hr and group of regimen B was 14 Hr. Nearly half of the population had IAI in between 13 to 18 Hr. Only 8% to 10% female had IAI less than 6 Hr .14% of the regimen B group had IAI more than 18 Hr while 6% of the regimen A group had IAI of more than 18 Hr. Women with history of previous 2 LSCS are the most difficult cases usually due to unfavourable Bishop at the time of induction. Hence IAI in such cases is of utmost importance to the practicing gynaecologist. Also, they often land up into hysterotomy due to failure of induction. In this study, in cases with previous 2 caesarean sections, IAI by the regimen A and regimen B are 17 Hr and 13 Hr respectively ,which is statistically significant; thus, we can say that Tab Mifepristone given twice prior induction has better results. The mean induction-to-abortion interval increases by 4 h after 20 weeks GA(6).In a study (7), the mean IAI for cervical traction with simultaneous vaginal Misoprostol and tab Mifepristone 200 mg per orally followed by 24 Hr later vaginal tab Misoprostol were studied and were found to be 20 Hr and 54 Hr, respectively. Both the regimens were followed by tab Misoprostol 200 mcg per vaginally 4 Hrly. This study implicated statistically significant reduction in IAI when cervical traction used in combination with tab Misoprostol vaginally; which can be attributed to time gap of 48 Hr between tab Mifepristone and tab Misoprostol administration in the second regimen. But prior method required more dose of tab Misoprostol (mean dose of 4.2 in first regimen of the study) than the second one (1.5 in the second regimen of the study) which was again found to be statistically significant. The results were comparable with the results obtained by Bhathena et al, Prachasilpchai et al(8,9) and Allahbadia, Agarwal et al(10,11).But in another study at Tamilnadu(12),no difference in mean IAI was found in both the methods with both methods having average IAI of nearly 8 Hr.

Intra or post procedural complication, mainly haemorrhage, were studied on the basis of need of blood

transfusion post procedure depending on the symptomatic severity of anaemia and lab results. In this study , as per institutional protocols, termination of pregnancy being elective procedure, all the patients were optimised hemodynamically including pre procedural blood transfusion for optimization of Haemoglobin. In this study only 1.3% of the cases required blood transfusion.Another study states that heavy bleeding which requires blood transfusion was only less than 1%(13), while another study in Tamilnadu(14) showed that, 15% of women required blood transfusion.

Hysterotomy is an incision opening that opens the endometrial cavity usually via abdominal route for completion of procedure of abortion. With the wide use of medical methods of second trimester abortion, hysterotomy is seldom required as an elective procedure.1 However, it may be indicated in certain situations like haemorrhage in second trimester and failed induction, especially with the increase of patients with previous uterine surgeries.In this study , no patient required hysterotomy for termination of pregnancy in view of failed induction or suspected uterine rupture with the regimen under study.Another study(15) at PGIMER ,Chandigarh , revealed 3.8% rate of need of hysterotomy in all mid trimester abortions below 26 weeks of gestational age out of which 13.46% of the total hysterotomies performed were due to failure of induction(7 out of 52 hysterotomies in the study group).In the same study, 13.36 % & 1.9% of the hysterotomies were done due to history of previous 2 LSCS & suspected uterine rupture with peritoneal collection ,respectively.

Retained products of conception (RPOC) are estimated to occur in about 1% of term pregnancies and much more frequently after miscarriage or termination of pregnancy (TOP) worldwide(16,17,18). For treatment of RPOC, curettage has long been used to stop bleeding, eliminate infection or prevent long-term complications(19), and recent studies showed a high curettage rate ranging from 30.8% to 59% after second trimester TOP(20,19,21,22).In this study , routine ultrasonography was done as part of institutional protocol after 48 Hr of expulsion of conceptus and placenta to rule out retained products of conception(RPOC) . Nearly 93 % of the study population had complete abortion with either of the regimen. This corresponds to the results in a study(23),where surgical intervention was needed in nearly 8% of the studied population. Particularly regimen A and B have rate of complete abortion as 93.7% and 89.8% , respectively. Presence of RPOC were further managed either medically (when size of RPOC ≤ 1cm) or surgically by curettage (when size of RPOC > 1cm).56 % and 40 % of the regimen A and B group had RPOC ≤ 1cm size which were managed by keeping Tab Misoprostol 200 mcg per vaginally(medical method).Nearly 44% and 60% of the regimen A and B group had RPOC > 1cm size which needed curettage.

Limitations

Since this study is a record based retrospective study, it is heavily reliant on accurate recording of information at the first point of contact during the hospital stay. No follow up could be done if there were mistakes in the hospital record entries or if the data was insufficient the population sample was not necessarily representative of the situation at the community level.

Conclusion

1. Nearly half of the population had induction to abortion interval between 13 to 18 Hr.

2. In case of previous 2 LSCS, regimen B group had significantly lower induction abortion interval than regimen A. So, pretreatment with 2 doses of 200 mg of tab Mifepristone prior induction should be preferred especially in scarred uterus.
3. With the regimens under study, rate of complete abortion was nearly 93% with 1.3% required blood transfusion.
4. None had required hysterotomy for failed induction or uterine rupture, even in the previously scarred uterus.

Abbreviations

- MTP - Medical Termination of Pregnancy
- TOP – Termination of Pregnancy
- CVS – Cardiovascular System
- CNS – Central Nervous System
- GIT – Gastrointestinal Tract
- Tab – Tablet
- Inj – injection
- D & E – Dilation & Evacuation
- IAI – Induction to Abortion Interval
- Pv – Per vaginal
- LSCS – Lower Segment Cesarean Section
- RMP – Registered Medical Practitioner
- RCOG – Royal College of Obstetrician
- SFP – Society of Family Planning
- WHO – World Health Organization
- Mg – milligram
- Mcg – microgram

Acknowledgement: Department of Obstetrics and Gynecology, at Byramjee Jeejeebhoy Medical College and Sassoon General Hospital, Pune, Maharashtra.

Ethical Approval: The study was approved by the Institutional Ethics Committee

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