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Original Research Article

Comparative study of foley's catheter and misoprostol versus mifepristone and misoprostol in induction of midtrimester abortions: a retrospective study

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ABSTRACT

Background: To compare the efficacy and safety of intracervical Foley's catheter and misoprostol versus mifepristone and misoprostol induction of midtrimester abortions.
Methods: I conducted a retrospective comparative study at a university affliated tertiary hospital at the postpartum unit of the department of obstetrics and gynaecology, Government Medical College, Amritsar from January 2022 to December 2023. Records were available for 80 patients who underwent midtrimester abortion. The enrolled women were allocated in two groups. Group A comprised women who underwent induction with combined intracervical Foley's catheter and misoprostol (n=42). Group B included women who underwent midtrimester abortion with mifepristone and misoprostol (n=38). The procedure efficacy and safety of the procedure were assessed.
Results: There was complete foetal expulsion in all cases in Group A (100%) while the success rate was 89.47%in Group B. The induction to abortion (IAI) interval was significantly shorter in Group A than Group B (6.66±1.1 versus 9.42±2.69hours, p=.000). Group A had shorter insertion to balloon expulsion time (7.80±0.87). The women with nulliparity, longer interpregnancy interval (>22 months), smaller gestational age (just 14 weeks) and lower Bishop Score before insertion (<2) had poorer outcome.
Conclusions: The present results confirmed that a combined mechanical and pharmacological approach for midtrimester abortions has comparable efficacy and safety to induction with vaginal mifepristone and misoprostol and can be safely recommended. Further, it reduces the total dosage of misoprostol required for termination and shortens the termination interval, thereby increasing the patient comfort and is more affordable.

Keywords: Foley catheter, Mifepristone, Misoprostol, Pregnancy termination

INTRODUCTION

Abortion is the expulsion or extraction of the foetus prior to 20 weeks gestation or a foetus weighing less than 500g when it is not capable of independent survival (WHO, The National Centre for Health Statistics). However, definitions vary widely according to state laws. However, the latest modification is the expulsion until 24 weeks of gestation. The midtrimester abortions (13-24 weeks) constitute about 10-15%of all induced abortions and are responsible for two-thirds of major abortion related complications. (WHO 1997). Worldwide 42 million legal abortions and 10 to 12 million clandestine abortion take place every year. According to the central health management and information (HMIS) system of NRHM in India, a total of 6.42 lakh abortions were recorded in the year 2006-07 and 11.06 lakh in 2008-09, of which midtrimeser abortions constitute 10.7 to 15%. MTPs or induced abortions are legalized in India according to the MTP Act, 1971 and may be performed

according to the rules made under this Act. The Medical Termination of Pregnancy Act (MTP) was passed by the Indian Parliament in August 1971 to permit wilful termination of pregnancy before the age of foetal viability for well-defined indications, so as to reduce high maternal mortality and morbidity due to illegal abortions. The Act was implemented in April 1972 all over India. The MTP Act has undergone a series of amendments over the decades to include a number of clauses so as to incorporate some new requirements and plug the lacunae in the existing Act so as to safeguard the physical and mental health of the pregnant woman. The latest amendment in the MTP Act was on 21st March 2021 wherein the main clause was increasing the age of wilful abortion to twenty four weeks of gestation, and even allowing abortion beyond twenty four weeks where such termination is necessitated by the diagnosis of substantial foetal abnormalities as recognised by the Medical board constituted by the State Government or Union Territory for this purpose.

Nowadays due to widespread use of antenatal screening techniques in detecting pregnancies complicated by major congenital malformations not compatible with life, there is a gradual increase in midtrimester abortions. There is no universally safe and effective method applicable to both first and second trimester induced abortions. The complications are less than 0.5% if termination is done before eight weeks of gestation and increase by 50% for every week of gestation after eight weeks. Second trimester pregnancy termination is associated with 3-5 times higher maternal and morbidity risks as compared to the first trimester termination but constitute 10-15% of all induced abortions.

However, with the amendment in the MTP Act in 2003 to facilitate provision of medical abortion and approval of the use of mifepristone (2002) and misoprostol for medical abortion by the drug controller in 2002, there has been a vast improvement in the methods of midtrimester abortions and have become safer and more accessible. However, there is no global agreement regarding the ideal method for induction of second trimester abortions.[1,2] Although the medical methods have been thoroughly assessed and considered the anchor of safe abortion care, the high cost of mifepristone can be a deterrent in low resource countries like India.[3]So in order to counter the high cost factor and at the same time shorten the induction to abortion interval and minimize the side effects of repeated doses of misoprostol, intracervical foley's catheter inflation in combination of misoprostol has been tried as a good alternative to the use of the combination of mifepristone and misoprostol.[4-7] The aim of the present study was to compare a combined mechanical and pharmacological approach by use of intracervical Foley's catheter and misoprostol for second trimester pregnancy termination to the combined use of mifepristone and misoprostol in terms of abortifacient efficacy in achieving vaginal expulsion in an expeditious manner with less maternal complications.

METHODS

Study place

The study was conducted at Bebe Nanki's mother and child care centre (BNMCCC), department of obstetrics and gynaecology, government medical college, Amritsar which is a tertiary obstetric referral hospital.

We retrospectively analyzed the case files of all patients who underwent second trimester abortion from the medical records section. The cases were subdivided into subgroups based on the method of midtrimester abortion used.

Study duration

The study was conducted from January 2022 to December 2023.

Inclusion criteria

The inclusion criteria of my study included 80 patients of age group of 18-35 years, singleton pregnancies of 13 to 26 weeks gestation terminating pregnancy for indication covered under the amended MTP Act, 1971 and given informed written consent to participate in the study.

These patients fulfilling the inclusion criteria were selected, appraised and assessed for methodological quality. Confirmation of gestational age by ultrasound was done and written informed consent was taken. The included studies were pooled for meta-analysis and the results were presented in risk ratio at a 95% confidence interval.

Exclusion criteria

However, the exclusion criteria were the patients with multiple pregnancies, grand multipara, having scarred uterus, cervical incompetence, genital infections, with underlying medical conditions like cardiac disease, diabetes mellitus, bronchial asthma, epilepsy, disseminated intravascular coagulation or liver disease, an intrauterine contraceptive device in utero, heavy smoker of more than 20 cigarettes per day, with known allergy to prostaglandins or already in the process of abortion.

Sample size

The sample size selected was 80 with Group A including 42 patients induced with intracervical Foley's catheter and misoprostol for midtrimester abortion. Group B had 38 patients induced medically with combination of mifepristone and misoprostol.

Group A

Induction was done with intracervical foley's catheter followed by intravaginal misoprostol 400 mcg after 24

hours of insertion. The size 14 or 16 Foley's catheter was inserted 3-4 cm into the cervix under proper antiseptic conditions and inflated with 25 ml of distilled water. Intravaginal misoprostol 400mcg was inserted into the posterior fornix every 4 hours up to a maximum of 6 doses.

Group B

Induction with oral mifepristone 200mg was followed by 400mcg of intravaginal misoprostol 24 hours later and then 400mcg vaginal misoprostol every 4 hours up to a maximum of 6 doses. The procedure efficacy (defined as complete abortion performed on site) was assessed. The primary endpoint was complete foetal expulsion with no subsequent intervention needed and expedition of the process of expulsion. The induction abortion interval of both the groups was studied. The critical outcome reported was ongoing pregnancy. The secondary outcomes included safety issues such as serious maternal complications (excessive bleeding due to incomplete expulsion necessitating surgical evacuation of the retained products of conception, blood transfusion, uterine rupture or cervical laceration, pelvic infection), patient acceptability (whether patients would opt for the same method again), satisfaction (whether patients were satisfied with the method) and side effects (e.g., nausea, vomiting, diarrhoea and fever).The appropriate method of statistical analysis was applied to study the efficacy of each method of induction. The descriptive statistics was used to calculate the mean, frequencies, standard deviation and Chi square test was used to compare the categorical variables of significance.

RESULTS

During the two-year study period, a total of 157 females in the reproductive age group underwent wilful pregnancy termination in the first and second trimesters of pregnancy for well-defined indications permitted under the amended MTP Act, 2021. 80 women underwent second trimester pregnancy termination hence the sample size of 80 was used in this study. The induction to abortion interval, misoprostol dose required for abortion, side effects of the drugs used, complication of abortion and analysis of complete abortion were considered as outcome variables. Foley's induction with misoprostol and mifepristone with misoprostol were considered the primary explanatory variables. Age, parity, marital status, socioeconomic status, gestational age and indications were other explanatory variables. The socio-demographic of the patients under study was determined by modified BG Prasad classification (2008). The median age of the study group was 26-30 years and 85% of the women were multigravidae. The mean induction-to-abortion interval in group A was 6.66 h (range 2.4-43.8 h). Nulliparous women took significantly longer time to abort (6.5 h in multiparous women compared to 7.6 h in nulliparous women; p<.0001). In Group B, the mean induction to abortion interval was 9.42h (range 4.1-65.5 h). In group B, two women (5.26%) failed to abort within 48 hours and surgical evacuation of the uterus was performed in two women (10.53%) for incomplete abortion or retained placenta. Multiparous women were less likely to need analgesic administration for pain relief, and to experience vomiting and diarrhoea than nulliparous women. Overall, 97.1% of the women in group A and 90% of the women in group B aborted within 24 hours and 100% of the women in Group A and 89.47% of the women in group B aborted within 36 hours respectively.

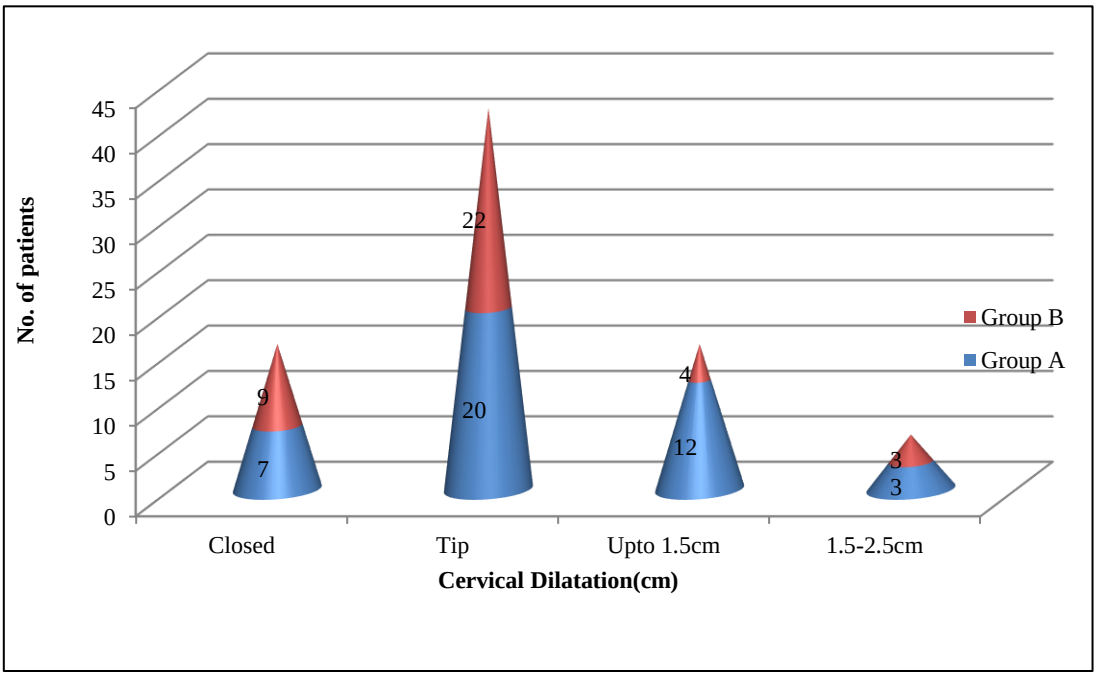

Figure 1: The cervical dilatation prior to induction in group A and B.

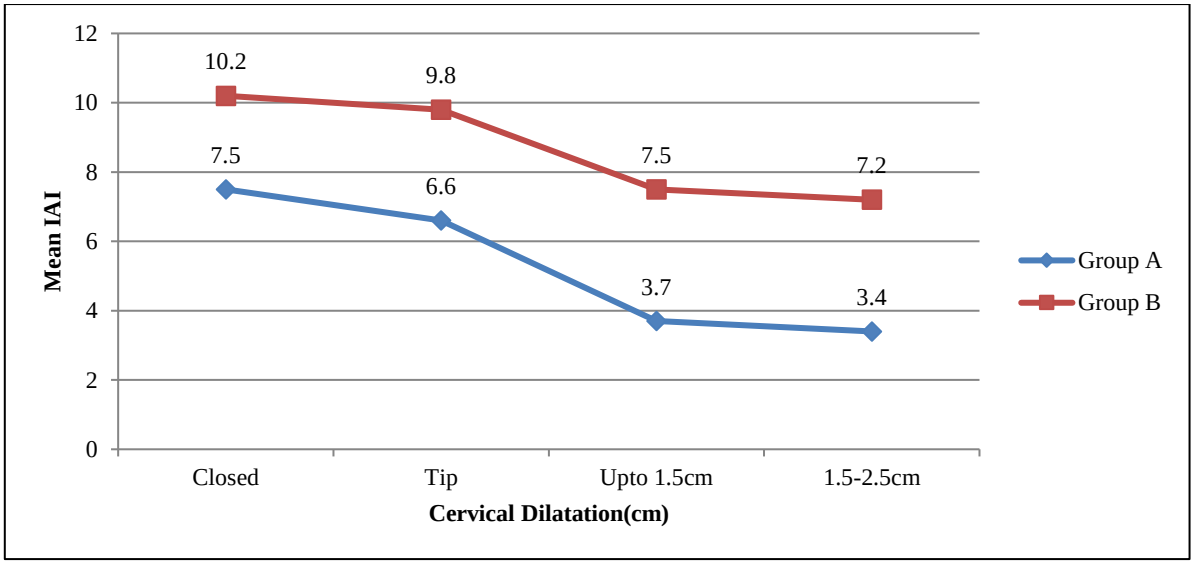

Figure 2: The relation of cervical dilatation to induction abortion interval (IAI) in Group A and B.

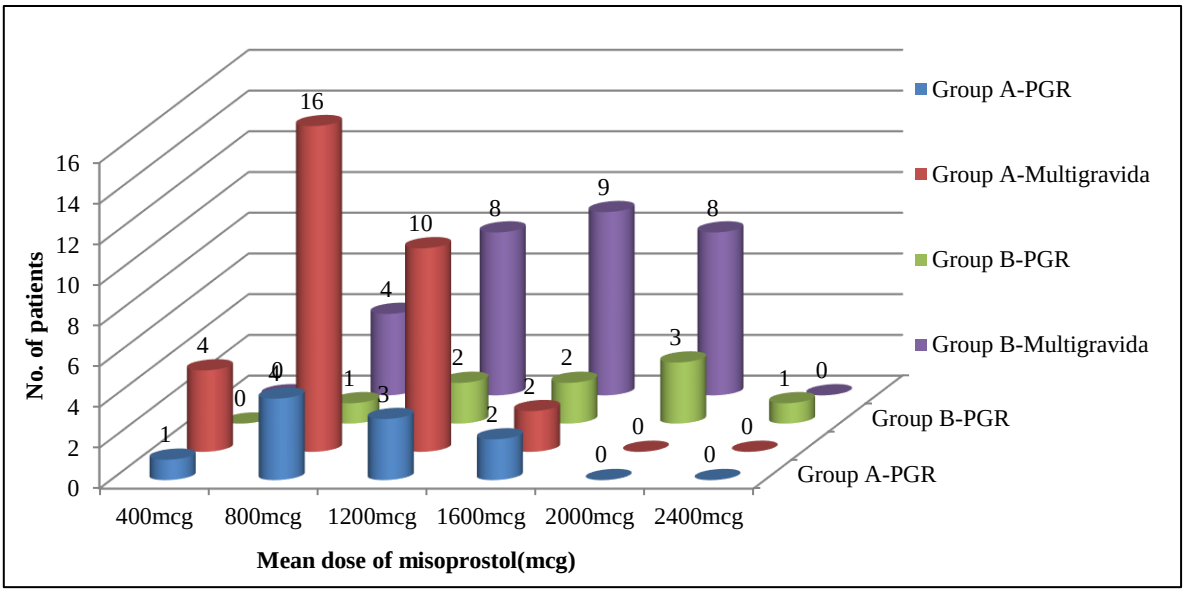

Figure 3: Mean dose of misoprostol needed for termination in Group A and B.

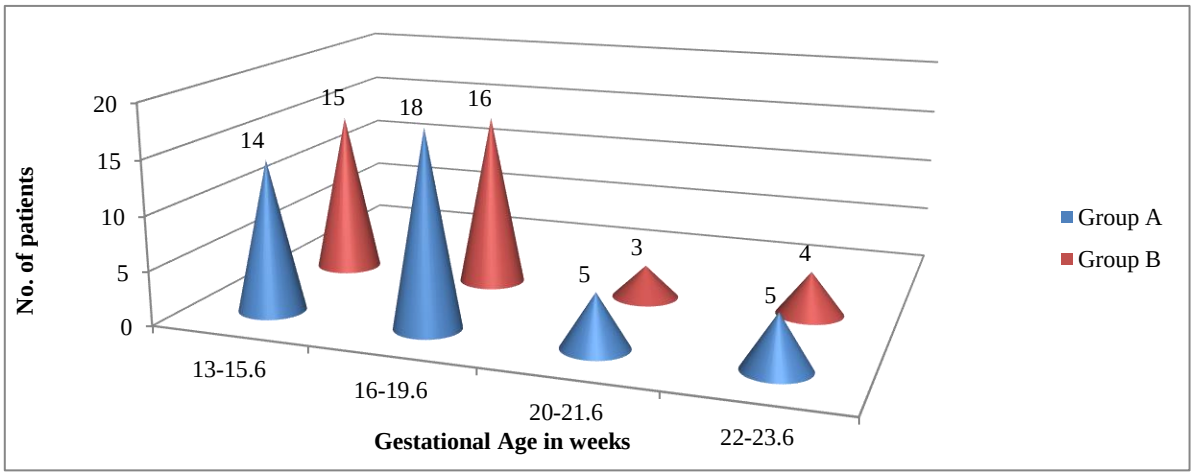

Figure 4: The comparative study of gestational age on induction to abortion interval in group A and B.

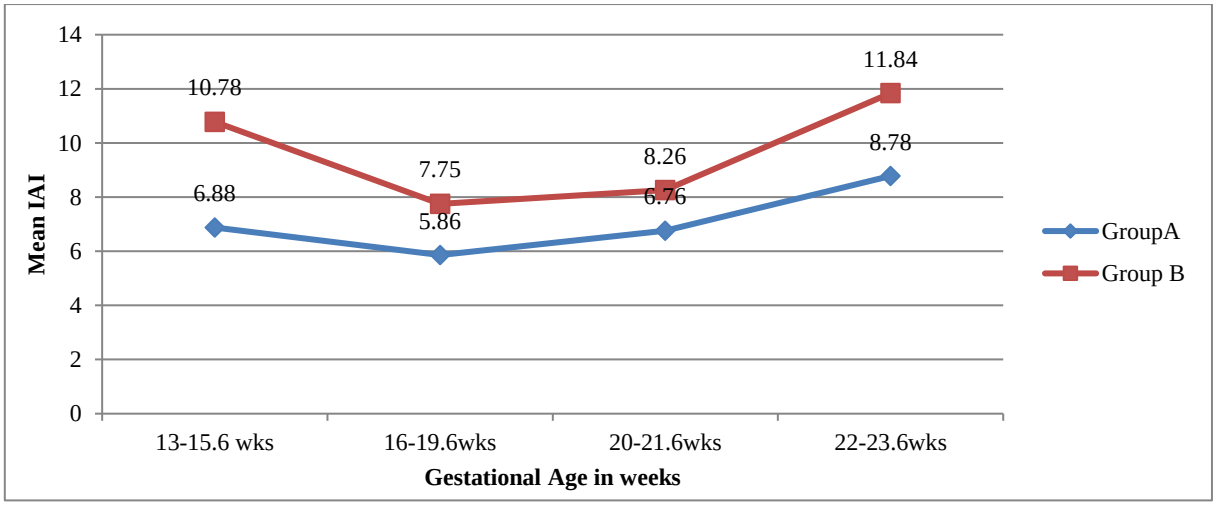

Figure 5: The comparative study of gestational age on induction to abortion interval in group A and B.

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

	Group A (n=42)	Group B (n=38)	Total (n=80)
Age (in years)			
<20	05 (11.91%)	05 (13.16%)	10 (12.50%)
20-25	12 (28.57%)	11 (28.95%)	23 (28.75%)
26-30	17 (40.48%)	15 (39.47%)	32 (40.00%)
>30	8 (19.04%)	07 (18.42%)	15 (18.75%)
Parity			
Primigravida	10 (23.81%)	09 (23.68%)	19 (23.75%)
G2	13 (30.95%)	11 (28.95%)	24 (30.00%)
G3	11 (26.19%)	07 (18.42%)	18 (22.50%)
G4	08 (19.05%)	11 (28.95%)	19 (23.75%)
History of prior midtrimester abortions	03 (7.15%)	02 (5.26%)	05 (6.25%)
Mean body mass index (kg/m2)	25.6±1.2	26.1±1.3	25.85±1.25
Gestational age at delivery (weeks)			
13-15 weeks 6 days	14 (33.33%)	15 (39.47%)	29 (36.25%)
16 weeks-19 weeks 6 days	19 (45.24%)	16 (42.11%)	35 (43.75%)
20 weeks-21 weeks 6 days	4 (9.52%)	3 (7.89%)	7 (8.75%)
22 weeks- 23 weeks 6 days	5 (11.91%)	4 (10.53%)	9 (11.25%)
Total	42 (100%)	38 (100%)	80 (100%)
Mean	18.62±2.20	17.92±2.10	18.27±2.15
Indications for midtrimester abortion			
Contraception failure	10	9	19
Congenital malformations	24	22	46
Anhydramnios	5	5	10
Unwed	3	2	05
Total	42	38	80

Table 2: Cervical dilatation and mean induction abortion interval in all the groups.

Cervical dilatation	Group A (n=42)		Group B (n=38)	
	No.	Mean IAI	No.	Mean IAI
Closed	07 (16.67%)	7.5	09 (23.68%)	10.2
Tip	20 (47.62%)	6.6	22 (57.89%)	9.8
Upto 1.5 cm	12 (28.57%)	3.7	04 (10.53%)	7.5
1.5-2.5 cm	03 (7.14%)	3.4	03 (7.90%)	7.2

Table 3: Comparative study of the mean misoprostol dosage in relation to parity in Groups A and B.

Mean dose of misoprostol (mcg)	Group A (n=42)			Group B (n=38)		
	Primigravida	Multigravida	Total	Primigravida	Multigravida	Total (n=80)
400	1 (2.38%)	4 (9.52%)	5 (11.91%)	0	0	0
800	4 (9.53%)	16 (38.10%)	20 (47.62%)	1 (2.63%)	4 (10.53%)	5 (13.16%)
1200	3 (7.14%)	10 (23.81%)	13 (30.95%)	2 (5.26%)	8 (21.05%)	10 (26.31%)
1600	2 (4.76%)	2 (4.76%)	4 (9.52%)	2 (5.26%)	9 (23.69%)	11 (28.95%)
2000	0	0	0	3 (7.90%)	8 (21.05%)	11 (28.95%)
2400	0	0	0	1 (2.63%)	0	1 (2.63%)

Table 4: Comparative study of gestational age on induction to abortion interval and completeness of abortion in Groups A and B.

Characteristics	Descriptive statistics (n=80)			
	Group A (n=42)	IAI	Group B (n=38)	IAI
Gestational Age				
13-15 weeks 6 days	14	6.88±1.88	15	10.78±2.96
16 weeks-19 weeks 6 days	18	5.86±0.36	16	7.75±2.71
20 weeks-21 weeks 6 days	05	6.76±0.96	03	8.26±2.56
22 weeks-23 weeks 6 days	05	8.78±1.60	04	11.84±1.68
Completeness of abortion	42 (100%)		34 (89.47%)	
Mean IAI		6.6±1.1		9.42±2.69

Table 5: Comparative study of the complications of the procedure adopted in Groups A and B.

Complications of the adopted procedure	Group A (n=42)	Group B (n=38)	Total (n=80)
Severe abdominal pain	05 (11.90%)	08 (21.05%)	13 (16.25%)
Fever with rigors and chills	03 (7.14%)	07 (18.42%)	10 (12.50%)
Shivering	02 (4.76%)	06 (15.79%)	08 (10.00%)
Nausea/Vomiting	05 (11.90%)	08 (21.05%)	13 (16.25%)
Diarrhoea	05 (11.90%)	12 (31.58%)	17 (21.25%)
Sepsis	0	02 (5.26%)	02 (2.50%)
Uterine rupture	0	0	0
Cervical lacerations	0	1	1
Incomplete abortion	0	02	02
Haemorrhage	04 (9.52%)	05 (13.16%)	09 (11.25%)
Failure of the method	0	02	02

Women in Group B needed more doses of misoprostol and were more likely to experience diarrhoea ($p<0.01$), vomiting ($p<0.01$) and shivering. ($p<0.01$).

DISCUSSION

Midtrimester abortions are associated with 3-5 times higher maternal morbidity and mortality as compared to first trimester abortions. Although, medical methods in the form of mifepristone and misoprostol are considered the anchor of safe abortion care, combining the pharmacological and mechanical methods in the form of intracervical Foley's catheter and misoprostol combination gives very good results.[7,8] Most of the women in both groups were in the age group of 26-30 years (40.00%) which was comparable to the results by Holla et al which showed mean age as 27.96±5.41 years. The study conducted by Fathalla et al, showed the mean age to be 25.9 years.[8] In the present study, 23 (28.75%) cases were in the age group of 20-25 years which was comparable to the study by Maninder et al which showed 36% of the cases in the same age group. 15 (18%) cases were above the age group of 30 years which was comparable to the study by Maninder et al which showed 18.75% cases to be older than 30 years. In this study, most patients were third gravid (22.50%) and fourth gravid (23.75%) in both groups. This was comparable to the study by Veena et al. which most of the women as third gravid and above, (53%).23.75% patients were primigravida similar to the study by Veena et al which had 17.8% cases as primigravidae.[10] 30% patients were second gravid as compared to the same study which had 28% second gravidae. In the present study, 35 (43.75%) patients were in the gestational age of 16-20 weeks while the study conducted by Bala Subramanian et al, 56% patients were in the age group of 13-16 weeks.[11] Studying the outcome

variable of the misoprostol dose required in the method combining Foley's catheter and misoprostol, 11.90% patients expelled with only 400 mcg of misoprostol, 47.62% with 800 mcg of misoprostol, 30.95% expelled with 1200mcg and only 9.53 % with 1600 mcg of misoprostol. This is comparable to the study by Fathalla et al, 13.4% expelled with 400mcg of misoprostol, 35.8% with 800mc, 19.4% with 1200mcg and 28.4% with 1600mcg dose of misoprostol.[8] However, in the method combining mifepristone with misoprostol, no case expelled with dose less than 800mcg. 13.16% expelled with dose of 800 mcg and 26.31% cases expelled with dose of 1200 mcg while 57.90% required dose of more than 1200 mcg for expulsion.

In the present study, the induction to abortion interval in Group A was 6.66 hrs which is comparable to the study by Rezk et al. which showed the average induction to abortion interval as 7.5±1.25 hours.[9] The study by Balasubramanian SR et al. also showed a comparable induction to abortion interval of 7 hours. However, the induction to abortion interval in Group B was 9.42 hrs which was comparable to the study by Rezk et al. which showed the induction to abortion interval in the similar group as 11.76±1.63 hours.[9] The present study showed a success rate of 100% in group A which is comparable to the study by Patel et al and Sharma et al. However, the study group combining mifepristone and misoprostol as abortifacients showed a success rate of 89.47%.[12,13]

In the group combining Foley's catheter induction with misoprostol, severe abdominal pain occurred in 11.90% cases, fever with rigors and chills in 7.14% cases, nausea and vomiting in 11.90% and diarrhoea in 11.90% cases. This is comparable to the study by Rezk et al which showed fever with rigors and chills in a similar study group in 13% cases and vomiting in 4% cases. In the second study group of mifepristone and misoprostol combination, severe abdominal pain occurred in 21.05% cases, fever with rigors and chills in 18.42% cases and vomiting in 21.05% cases which is comparable to the study by Balasubramanian et al, severe abdominal pain occurred in 28% cases and vomiting in 4% cases.[11]

In our study, none of the cases reported uterine rupture and sepsis in the group combining intracervical Foley's catheter and misoprostol which is similar to the study by Rezk et al. Failure of method occurred in no case which is similar to the study by Mohamed Rezk et al which showed 100% success rate without any failure.

The nulliparity, longer interpregnancy interval (>22 months), smaller gestational age (<14 weeks) and lower Bishop score before insertion (<2) were significantly associated with a higher likelihood of Foley's catheter balloon expulsion failure within 24 hours.[13-21] This compared favourably with the study by Ali et al, which showed similar results.[15] However, there were certain limitations in the present study. The nulliparous women, the women with longer interpregnancy interval or previous uterine surgery faced certain complications inherent to these factors which could not be segregated from the complications due to the procedures of induction of abortion while drawing conclusions and may have affected the results.

CONCLUSION

From the results of our study and review of literature, it can be safely concluded that a combined mechanical and pharmacological approach in the form of combined intracervical Foley's catheter and misoprostol in second trimester pregnancy termination has comparable efficacy and safety to the use of the combination of mifepristone and misoprostol. This method is more affordable in the low resource countries where achieving vaginal expulsion in midtrimester abortions in an expeditious manner with less maternal complications may prove to be a costly affair with mifepristone-misoprostol combination. Also, combining Foley's catheter with misoprostol reduced the total dosage of misoprostol required for termination and shortened the induction abortion interval, thereby increasing the patient's comfort by minimising the side-effects of mifepristone-misoprostol combination. Hence, this study implies that combining the use of intracervical Foley's catheter with misoprostol is safe, efficacious, cheap and hence preferred mode of termination in the second trimester of pregnancy.

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