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ORIGINAL RESEARCH

Comparative Study of the Safety and Effectiveness of Misoprostol in Induced Midtrimester Abortions in Patients with or without Previous Caesarean Sections -A Retrospective Study

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ABSTRACT

Background: To compare the safety and efficacy of misoprostol in induction of midtrimester abortions in women with or without uterine scar due to previous caesarean section to achieve expeditious vaginal expulsion with minimal maternal complications. **Methods:** We conducted a retrospective cohort based comparative study at a tertiary care academic medical centre at the postpartum unit of the department of obstetrics and gynaecology, Government Medical College, Amritsar from January 2022 to December 2024. 155 patients who underwent termination of pregnancy between 13 and 24 weeks of pregnancy were identified to develop two contemporous cohorts based on the presence or absence of previous caesarean scar. The outcome data of women undergoing midtrimester abortion with history of at least one previous caesarean section (n= 52) (Group A) was compared with a cohort of women undergoing midtrimester abortion with history of previous vaginal deliveries (n=103) (Group B). The procedure efficacy and safety of the procedure were assessed. **Results:** Out of 52 women with history of previous caesarean sections, 34 had previous one caesarean birth, 15 women had previous two caesarean deliveries, and 3 had previous three caesarean sections. There was relatively higher number of women with previous uterine scar for induction of midtrimester abortions due to higher referrals of such cases at this tertiary hospital. Women with prior caesarean sections were significantly older; mean age 33years [interquartile range 27-37] P = < .001 as compared to women with previous vaginal deliveries (23 years[interquartile range 18-26])and are also of increased parity. The mean gestational age was 14.6weeks [interquartile range 13.8-20.4 weeks] in women with previous caesarean births as compared to women with previous vaginal deliveries of 15.2weeks [interquartile range 14-20.4 weeks]P =.54 The presence of the uterine scar did not affect the induction to abortion(IAI) interval, the completeness of the abortions or the ensuing complications like the amount of blood loss. Also, the presence of the caesarean scar did not impact the dose of misoprostol needed to induce and complete the process of abortion. The longer interpregnancy interval (>22 months), lesser gestational age(just 14 weeks) nulliparity and lower Bishop Score (<2) at the time of misoprostol usage in both the groups were significantly associated with a poorer outcome. **Conclusion:** The present results confirmed that the presence or absence of the caesarean scar did not significantly affect the induction abortion interval or the completion of midtrimester abortions. There was no increase in the complication rate in women with previous caesarean scar undergoing midtrimester abortion with misoprostol.

Keywords: Misoprostol, pregnancy termination, Caesarean scar.

INTRODUCTION

The midtrimester abortions contribute to about 10-15% of all induced abortions(WHO;1997) but are responsible for two-thirds of abortion related complications and a three fold higher morbidity. About 42 million legal abortions and 10 to 12 million clandestine abortions take place throughout the world every year. According to the central health management and information (HMIS) system of NRHM in India, about 6.42 lakh abortions were

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recorded in the year 2006-07 and 11.06 lakh in 2008-09. 10.7 to 15% of these abortions occurred in the second trimester.

In modern obstetric practice, due to the widescale introduction of antenatal screening programs to detect severe foetal anamolies in the second trimester, there is a gradual increase in midtrimester abortions[1] as the women have an option to terminate the ill fated pregnancy. The latest amended MTP Act on 21st March 2021 has increased the age of wilful abortion to twenty four weeks of gestation, and even allowed abortion beyond twenty four weeks if serious foetal anamolies not compatible with life are diagnosed. This and the approval of the use of pharmacological agents like misoprostol and mifepristone for medical abortion by the drug controller in 2002, has made the medical methods of midtrimester abortions safer and more acceptable.

The rate of caesarean births has significantly increased in recent years. No uniform consensus exists regarding the ideal method for induction of midtrimester abortions in women with previous caesarean sections[2,3]. Although the medical methods may be flaunted as the anchor of safe abortion care, there is very little literature available regarding the safety and efficacy of using misoprostol for induction of midtrimester abortions in women with previous uterine scar.[3-5]

The aim of the present study was to retrospectively analyze all cases where misoprostol had been used for second trimester pregnancy termination in women with previous caesarean scars to achieve vaginal expulsion safely in an expeditious manner with least maternal complications.

MATERIAL AND METHODS

We conducted a retrospective cohort based comparative study at a university affliated tertiary care hospital at the postpartum unit of the department of obstetrics and gynaecology, Government Medical College, Amritsar from January 2022 to December 2024. 155 patients who underwent termination of pregnancy between 13 and 24 weeks of pregnancy during this period were identified and their case files from the medical records section were analyzed to develop two contemporous cohorts based on the presence or absence of previous caesarean scar. The outcome data of women undergoing midtrimester abortion with history of at least one previous caesarean section (n= 52) (Group A) was compared with a cohort of women undergoing midtrimester abortion with history of previous vaginal deliveries (n=103) (Group B). The procedure efficacy and safety of the procedure were assessed.

The inclusion criteria of my study included 155 patients of age group of 18-35 years, singleton live intrauterine pregnancies of 13 to 26 weeks gestation terminating pregnancy for indication covered under the amended MTP Act, 1971 and had given informed written consent to participate in the study. Their detailed history, physical examination and confirmation of gestational age by clinical examination and ultrasound was evaluated from the available medical records. The included studies were pooled for meta-analysis and the results were presented in risk ratio at a 95% confidence interval. However, the exclusion criteria were the patients with pregnancy less than 13 weeks and more than 26 weeks, multiple pregnancies, grand multipara, scarred uterus, severe anaemia, 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, any contraindications to the use of misoprostol like uncontrolled bronchial asthma, with known allergy to prostaglandins, carrying a dead foetus or already in the process of abortion.

The sample size selected was 155 with Group A including 52 patients with previous caesarean section induced with intracervical Foley's catheter and misoprostol for midtrimester abortion.

Group B had 103 patients with previous vaginal deliveries without any uterine scar, induced for second trimester abortion with intracervical Foley's catheter and misoprostol.

In both the groups, induction was done with intracervical foley's catheter followed by intravaginal misoprostol 400mcg inserted into the posterior fornix every 4 hours upto a maximum of 5 doses. The size 14 or 16 Foley's catheter was inserted 3-4 cm into the cervix under proper antiseptic conditions and inflated with 25ml of distilled water.

After misoprostol administration, pulse, blood pressure and temperature were recorded fourly. The procedure efficacy (defined as complete abortion performed on site) was assessed. The primary outcome was complete foetal expulsion with no subsequent intervention needed and induction-abortion interval (AI). Secondary outcomes were the successful vaginal abortion rate, the percentage of abortions in 24 h and the rates of surgical removal of the placenta. The critical outcome reported was ongoing pregnancy. The 'efficacy' was analyzed on the basis of completeness of procedure, total number of doses of misoprostol required, need for surgical evacuation of the retained products of conception in cases of incomplete abortion and evidence of other complications. The other parameters studied were complications (cervical laceration, uterine rupture, pelvic infection, thromboembolic events), 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).If the patient did not abort after five doses, 4hr after the last dose, she was labelled as 'failure' and alternative methods were used for abortion. The statistical analysis was applied to study the demographics and the efficacy of the chosen method. The mean, frequencies and the

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standard deviation was calculated by descriptive statistics. Chi square test was used to compare the categorical variables of significance.

RESULTS

During the two year study period, a total of 376 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. The sample size of 155 was used in this study of induced midtrimester abortions in patients with or without caesarean sections.

The socio-demographic of the patients under study was determined by modified BG Prasad classification(2008).The median age of the study group was 26-30years and 85% of the women were multigravidae. There was no statistical difference in any of these parameters (age, parity,previous obstetrical history, mean gestational age between the two groups).

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

	Group A(n=52)	**Group B(n=103)**	**Total(n=155)**
Age(Years)			
16-20	03(5.77%)	12(11.65%)	15(9.68%)
21-25	16(30.76%)	32(31.06%)	48(30.97%)
26-30	25(48.08%)	43(41.75%)	68(43.87%)
31-35	06(11.54%)	12(11.65%)	18(11.61%)
>36	02(3.85%)	04(3.88%)	06(3.87%)
Parity			
Primigravida	8(15.39%)	27(26.21%)	35(22.58%)
G2	21(40.38%)	41(39.81%)	62(40.00%)
G3	19(36.54%)	28(27.19%)	47(30.32%)
G4	04(7.69%)	07(6.79%)	11(7.10%)
Previous abortions	15(28.85%)	25(24.27%)	40(25.81%)
Mean body mass index(kg/m2)	25.8±1.2	26.1±1.3	25.98±1.25
Gestational age at delivery(weeks)			
13-15wks6days	20(38.46%)	41(39.81%)	61(39.20%)
16wks-19wks6days	23(44.23%)	45(43.69%)	68(43.20%)
20wks-21wks6days	5(9.62%)	12(11.65%)	17(10.40%)
22wks- 23wks6days	4(7.69%)	5(4.85%)	9(7.20%)
Total	52(100%)	103(100%)	155(100%)
Mean	18.61±2.20	17.91±2.10	18.28±2.15
Indications for midtrimester abortion			
Contraception failure	12(23.08%)	29(28.16%)	41(26.45%)
Congenital malformations	31(59.62%)	61(59.22%)	92(59.35%)
Anhydramnios	6(11.54%)	10(9.71%)	16(10.32%)
Unwed	4(6.25%)	3(2.91%)	07(4.52%)
Total	52	103	155

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

Cervical dilatation	**Group A(n=64)**		**Group B(n=61)**	
	No.	**Mean IAI**	**No.**	**Mean IAI**
Closed	9(17.31%)	7.5	17(16.51%)	7.2
Tip	25(48.08%)	6.8	54(52.43%)	6.5
Upto 1.5cm	15(28.85%)	4.1	25(24.27%)	3.5
1.5-2.5cm	03(5.76%)	3.4	07(6.79%)	3.2

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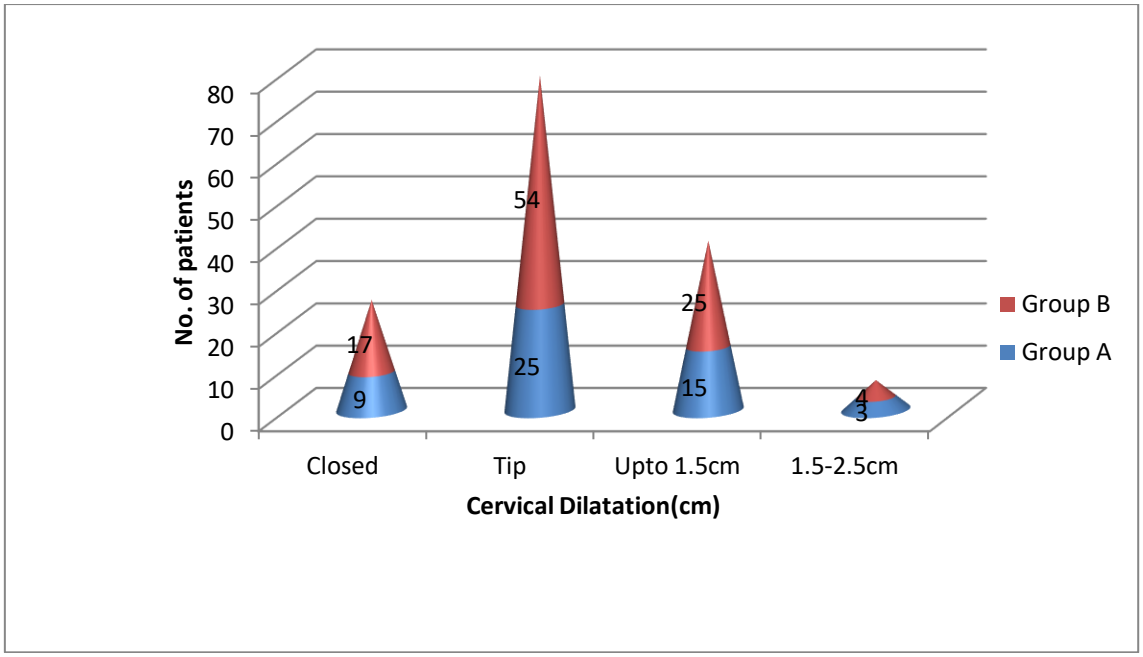

Fig 1 shows the cervical dilatation prior to induction in Group A and B:

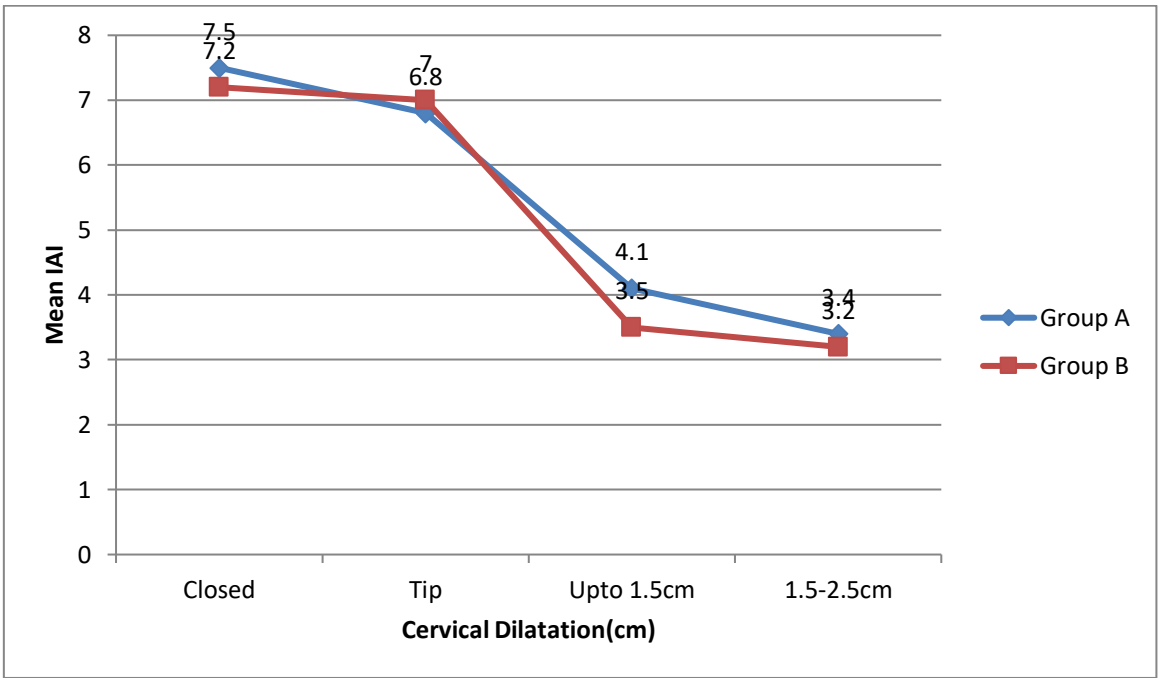

Fig 2 shows the relation of cervical dilatation to induction abortion interval (IAI) in Group A and B:

The mean induction-to-abortion interval in Group A was 6.8±1.1 h (range: 2.8-43.8 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). The mean induction to abortion interval in Group B was 6.46±1.69h (range: 2.1-45.5h. Multiparous women were less likely to need analgesic administration for pain relief, and to experience vomiting and diarrhoea than nulliparous women. Overall, 47(90.38%) women in Group A and 96(93.20%) women in Group B aborted within 24 hours. 49(94.23%) of the women in Group A and 99(96.15%)of the women in Group B aborted within 36hours respectively. Three women(5.77%) with previous uterine scar failed to abort within 48 hours and two needed surgical evacuation of the uterus for incomplete abortion or retained placenta. In Group B, four women (3.85%) failed to abort within 48 hours and six women landed with retained placental bits which needed surgical removal.

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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=52)			Group B(n=103)		
	Primigravida	Multigravida	Total(n=52)	Primigravida	Multigravida	Total (n=103)
400	0(0.00%)	1(1.92%)	1(1.92%)	1(0.97%)	2(1.94%)	3(2.92%)
800	4(7.69%)	20(38.47%)	24(46.15%)	4(3.88%)	27(26.21%)	31(30.10%)
1200	5(9.62%)	16(30.77%)	21(40.39%)	8(7.77%)	39(37.86%)	47(45.63%)
1600	3(5.77%)	1(1.92%)	4(7.69%)	7(6.80%)	10(9.71%)	17(16.50%)
2000	1(1.92%)	1(1.92%)	2(3.85%)	2(1.94%)	3(2.92%)	5(4.85%)

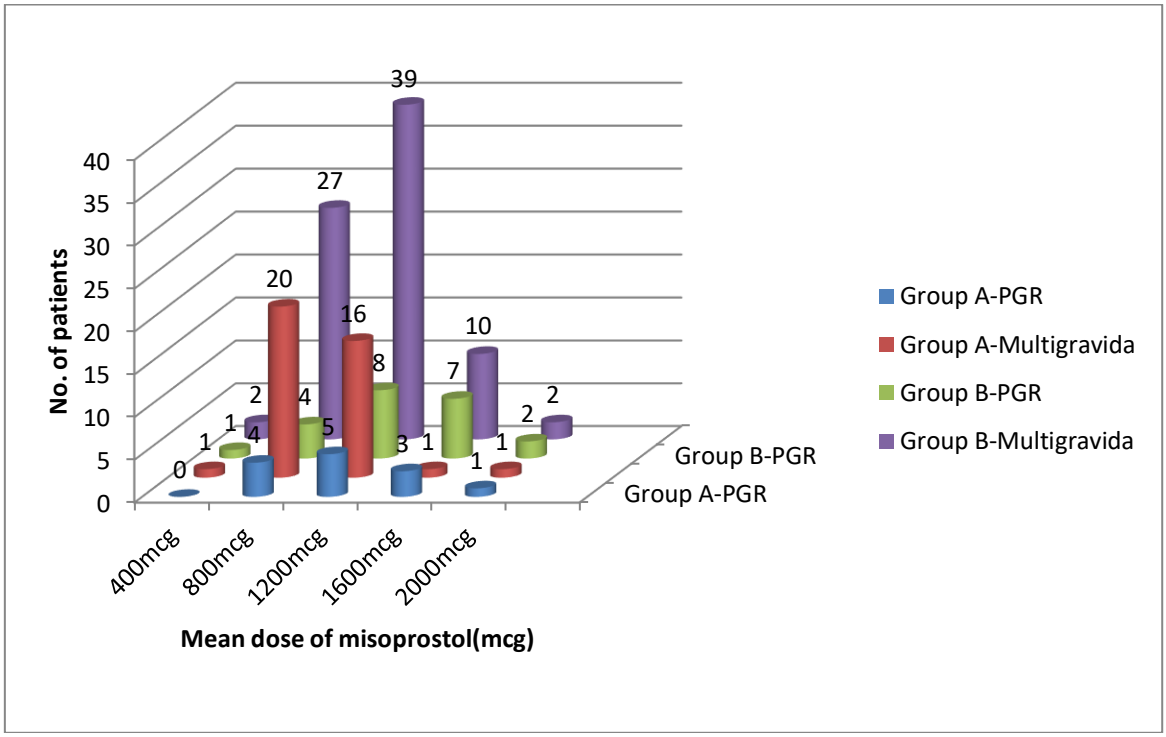

Fig 3 shows mean dose of misoprostol needed for termination in Group A and B:

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=155)			
	Group A(n=52)	IAI	Group B(n=103)	IAI
Gestational Age				
13-15wks6days	20(38.46%)	6.82±1.88	39(37.86%)	6.76±2.96
16wks-19wks6days	16(30.77%)	5.88±0.36	37(35.92%)	5.77±2.71
20wks-21wks6days	10(19.23%)	6.77±0.96	19(18.45%)	6.28±2.56
22wks-23wks6days	06(11.54%)	8.74±1.60	08(7.77%)	8.88±1.68
Completeness of abortion<48h	47(90.39%)		93(90.29%)	
Mean IAI		6.8±1.16		6.46±2.69

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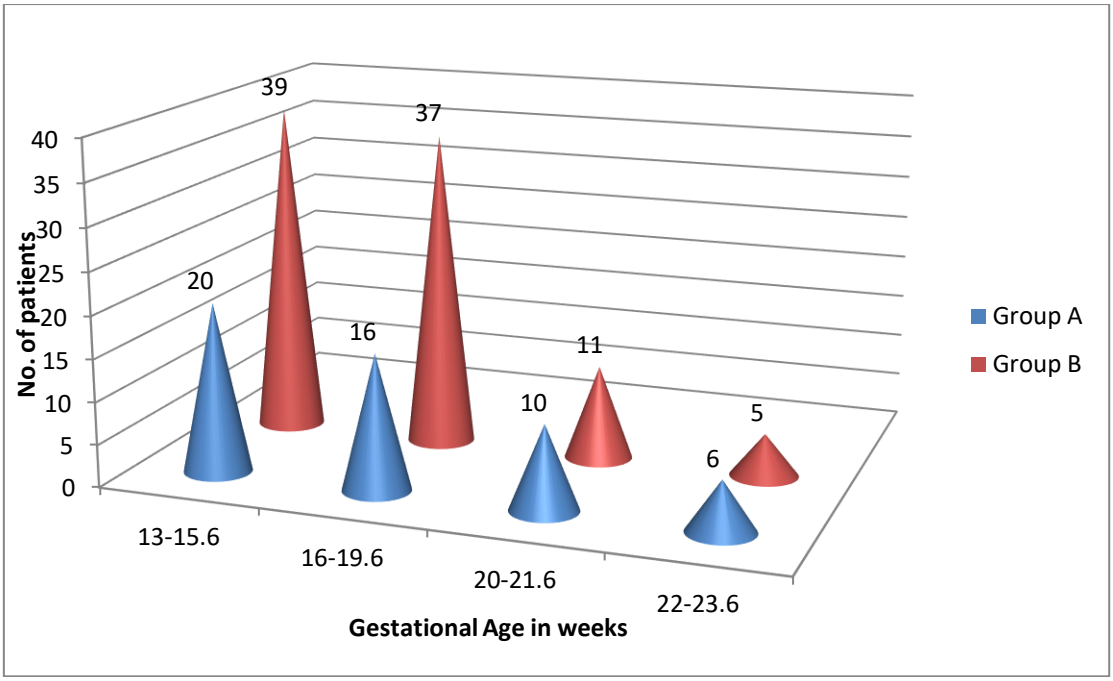

Fig 4a and b: showing the comparative study of gestational age on induction to abortion interval in Group A and B:

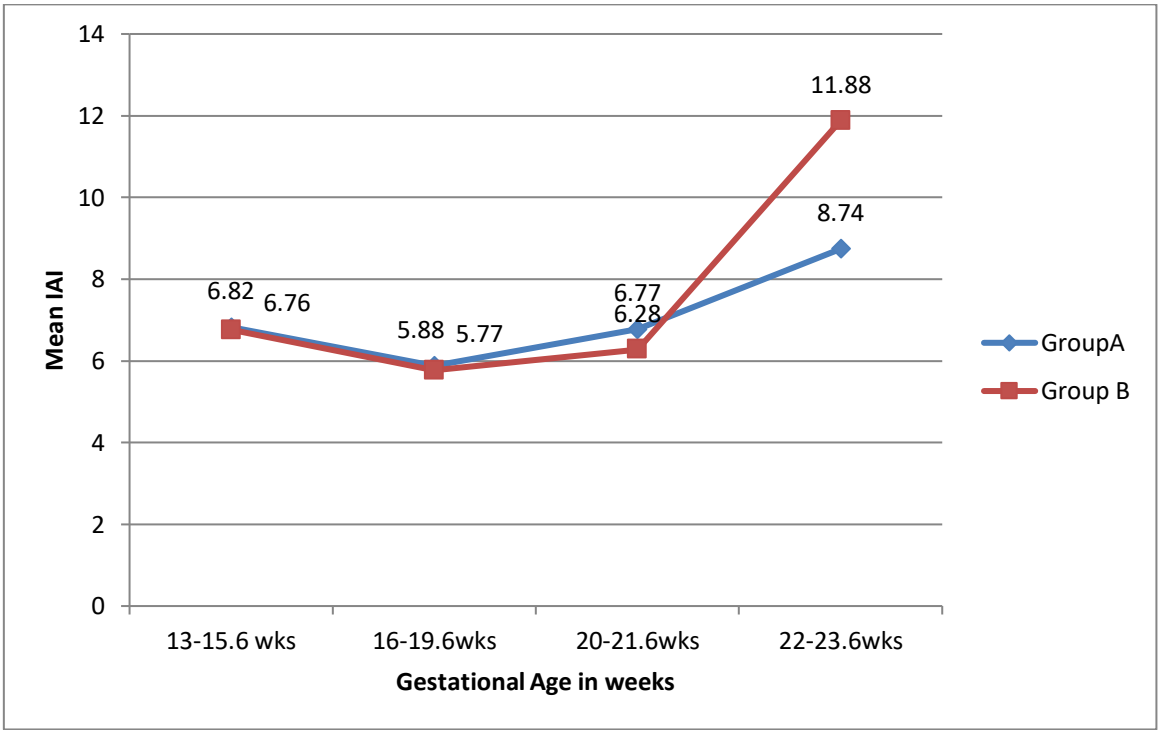

Table 5: Comparative study of the complications of the procedure adopted in Groups A and B:

Complications of the adopted procedure	Group A(n=52)	Group B(n=103)	Total(n=155)
Severe abdominal pain	6(11.53%)	10(9.71%)	16(10.32%)
Fever with rigors and chills	5(9.62%)	9(8.74%)	14(9.03%)
Shivering	04(7.69%)	9(8.74%)	9(5.81%)
Nausea/Vomiting	04(7.69%)	5(4.85%)	19(12.26%)
Diarrhoea	05(9.62%)	10(9.71%)	15(9.68%)
Sepsis	02(3.85%)	05(4.85%)	07(4.52%)
Cervical lacerations	3(5.77%)	1(0.97%)	4(2.58%)

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Incomplete abortion	3(5.77%)	04(3.88%)	07(4.52%)
Haemorrhage	07(10.94%)	6(5.83%)	13(8.39%)
Failure of the method	3(5.77%)	04(3.85%)	07(4.52%)

DISCUSSION

There is a progressive increase in the incidence of caesarean sections in modern obstetric practice coupled with an increase in the incidence of induction of midtrimester abortions due to early detection of foetal anamolies with ultrasound. This has raised the concern of the safety and effectiveness of induction of second trimester terminations in patients with prior caesarean sections[5-8] as unsupervised midtrimester abortions are usually associated with 3-5 times higher maternal morbidity and mortality as compared to abortions in the first trimester[9,10].

Misoprostol, a synthetic prostaglandin (PGE_1) analog has revolutionized the success rate of midtrimester abortions. Combining the pharmacological and mechanical methods in the form of intracervical Foley's catheter and misoprostol combination gives very good results. In induction of abortions in second trimester in women with previous caesarean section[11], uterine rupture associated with the use of misoprostol does not appear to occur with such frequency as that observed at term[11-13]. Also, cases of rupture of the uterus in induced midtrimester abortions are also known in patients without any uterine scars[15-16].

Most of the women in both groups in our study were in the age group of 26-30 years (43.87%) which was comparable to the results by Holla R[17] et al which showed mean age as 27.96±5.41 years. The study conducted by Fathalla MM[18] et al showed the mean age to be 25.9 years. In the present study, 48(30.97%) cases were in the age group of 21-25 years which was comparable to the study by Maninder K et al which showed 30% of the cases in the same age group. 24(15.48%) cases were above the age group of 30 years which was comparable to the study by ManinderK et al which showed 18.75% cases to be older than 30 years.

In this study, most patients were third and fourth gravid(37.42%)in both groups. This was comparable to the study by Veena[19] et al where most of the women were third gravid and above(53%). 22.58% patients were primigravida similar to the study by Veena[20] et al which had 23.8% cases as primigravidae. 40.00% patients were second gravid as compared to the same study which had 28% second gravidae.

In the present study,68(43.20%) patients were in the gestational age of 16-20 weeks while the study conducted by BalaSubramanian SR et a[20], 56% patients were in the age group of 13-16weeks.

In the present study, the induction to abortion interval in Group A was 6.82±1.88 h and in Group B was 6.76±2.96 h which is comparable to the study by Rezk MA et al[21] which showed the average induction to abortion interval as 7.5±1.25 hrs. The study by Balasubramanian SR et al[20] also showed a comparable induction to abortion interval of 7 hours. Also, Desai et al reported a similar induction abortion interval of 7.9 h. There were no significant differences in failure rate and need for surgical intervention in both the groups. There was also no significant difference in the termination outcome between these two groups.

The present study showed almost similar success rate of 90.38%in Group A and 93.20% in Group B with foetal expulsion in less than 24h.This is comparable to the study by Patel U et al and Sharma N et al. However, three women(5.77%) in Group A and four (3.85%)in Group B failed to abort within 48h.

In the group with previous uterine scar, severe abdominal pain occurred in 11.53% cases, fever with rigors and chills in 9.62 % cases, nausea and vomiting in 7.69% and diarrhoea in 9.62% cases. This is comparable to the study by Mohamed Rezk[21] et al which showed fever with rigors and chills in a similar study group in 13% cases and vomiting in 4% cases. In Group B, severe abdominal pain occurred in 9.71% cases, fever with rigors and chills in 8.74% cases and vomiting in 4.84% cases. However,the study by Balasubramanian SR[20] et al showed severe abdominal pain occurred in 28% cases and vomiting in 4% cases.

In our study, no case reported uterine rupture or sepsis in either group which is similar to the study by Mohamed Rezk et a[21]. Sajjan[22] et al have reported complete avulsion of the cervix from the lower part of the uterus as a rare complication with intravaginal misoprostol. Cervical laceration occurred in three(5.77%) patients with previous caesarean scar and only one(0.97%) in patients without previous uterine scars. This may be more linked to the indication being cervical dystocia in these patients of previous caesarean sections. Also, the cases of incomplete abortions was a little higher in the patients with previous caesarean scars with subsequent haemorrhage, necessitating surgical evacuation in these patients.

The nulliparity, longer interpregnancy interval(>22months), smaller gestational age(<14 weeks)[16] and lower Bishop score before insertion(<2) were significantly associated with a lesser likelihood of abortion within 24 hours. This compared favourably with the study by Ali MK et al which showed similar results

A recent 2017 publication by FIGO on their updated recommendations for misoprostol concluded that misoprostol is safe and effective for induced midtrimester abortionsd in women with previous caesarean or other transmural uterine scars as evidence from studies show the risk of uterine rupture is <0.3%(95% confidence interval 0.08-1.67%), of hysterectomy of 0% and need for transfusion of 0.2%.Our studies and findings are in keeping with

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these guidelines. However, Pluchon and Winer[23] recommend that caution be exercised when using misoprostol on a scarred uteri with a reduction in dosage. Cloquer[24]et al has recommended a decreased dosage of 100µg in patients with previous caesarean scar.

However, there were certain limitations in the present study. The women with previous uterine surgery, the women with longer interpregnancy interval and the nullipara 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. Also,there are insufficient data on risk with more than three prior caesarean birth or with prior classical caesarean birth.

CONCLUSION

The given trial highlights the safety and effectiveness of misoprostol for induced midtrimester abortions in women with previous caesarean section or other trasmural uterine scars. There was no observed difference in any termination outcome in women with or without caesarean scars. The presence of the uterine scar did not affect the induction to abortion(IAI) interval, the completeness of the abortions or the ensuing complications. Also, the presence of the caesarean scar did not impact the dose of misoprostol needed to induce and complete the process of abortion.

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DECLARATIONS:

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Conflict of interest: There is no conflict of interest, financial or otherwise.

Ethical approval: The study was approved by the Institutional Ethics Committee.

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