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Original Research Article

Comparison of Mifepristone-Misoprostol versus Dinoprostone -Misoprostol for Second-Trimester Pregnancy Termination: A Randomized Controlled Trial

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ABSTRACT

Background: Second-trimester abortions account for 10–15% of induced abortions globally. Misoprostol is widely used due to its efficacy and accessibility, with sublingual administration often preferred for convenience. Cervical priming with oral mifepristone (inducing collagen breakdown) or endocervical dinoprostone/PGE2 gel (promoting cervical remodelling) may improve outcomes, but comparative data are limited. **Methods:** This open-label randomized controlled trial compared two regimens: Group A (oral mifepristone + sublingual misoprostol) versus Group B (endocervical PGE2 gel + sublingual misoprostol) in 50 participants (13–24 weeks gestation, Bishop score <5). Primary outcome was abortion success within 24 hours; secondary outcomes included safety, induction-to-abortion interval, and patient satisfaction. **Results:** Group A demonstrated a significantly shorter mean induction-to-abortion interval (16.5 vs 26.5 hours, $p<0.01$) with greater temporal consistency (SD 6.2 vs 12.1 hours) compared to Group B. While 88% (22/25) of Group A cases completed within 24 hours (median 18h), Group B showed prolonged expulsion (median 23h), with 32% (8/25) exceeding 24 hours including two outliers >48h. Both groups required similar misoprostol doses (mean 4.0 vs 4.88), though Group B exhibited higher central tendency (median/mode=5 vs 4) and greater variability in dosing requirements. The frequency distribution of completion times did not differ significantly between groups ($p=0.23$). **Conclusion:** The mifepristone-misoprostol regimen was more efficient for mid-trimester abortion than PGE2-misoprostol regimen, providing faster completion with fewer doses, though with more side effects. While PGE2 showed greater variability in outcomes and blood loss, both protocols were effective. Mifepristone is preferable where available, with PGE2 remaining a viable alternative.

Keywords: Mifepristone, Misoprostol, Dinoprostone, Sublingual, Second trimester, Induced Abortion

INTRODUCTION

Globally, 10-15% of induced abortions occur in the second trimester, with misoprostol being the preferred agent due to its efficacy, affordability, and ease of administration(1)(2)(3). Its dose-dependent myometrial effects influence uterine contractility, though tachysystole remains a clinical consideration(4). Both sublingual and vaginal routes show comparable efficacy, though sublingual administration is often favoured for its convenience, reduced discomfort, and enhanced privacy (5). Prior cervical priming with mifepristone (which induces collagen degradation via matrix metalloproteinase-2) or PGE2 gel (which promotes extracellular matrix remodelling through interleukin-8-mediated neutrophil activation) may improve outcomes(4)(6). While mifepristone followed by sublingual misoprostol is a well-established regimen for mid-trimester abortion(7), endocervical PGE2 (Dinoprostone) gel with misoprostol has been less rigorously studied (8)(9)(10). Given the lack of robust comparative data on efficacy, safety, and patient experience between these protocols, this randomized controlled trial aims to evaluate both regimens systematically.

Methods

This open-label randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology at Gauhati Medical College & Hospital. Pregnant individuals seeking mid-trimester termination (13–24 weeks gestation, confirmed by LMP and ultrasonography) were enrolled after baseline investigations (blood group, haemoglobin, platelet count, and viral markers). Inclusion criteria were Pregnancy between 13 to 24 weeks gestation with a Bishop score <5 and no active uterine contractions, while exclusion criteria included uterine scarring (like Post CS, Post myomectomy), PPROM, Multiple pregnancy, cardiac disease and uterine anomalies. Using computer-generated randomization, 50 participants were allocated equally to two groups: Group A received oral mifepristone (200 mg) followed after 36 hours by sublingual misoprostol (400 mcg every 4 hours, max 6 doses), while Group B received

endocervical PGE2 gel (0.5 mg) followed after 6 hours by the same misoprostol regimen. Patients with no expulsion after 6 doses of misoprostol were given 24 hours rest and reinitiated with misoprostol for a maximum of 6 doses. The primary outcome was successful abortion within 24 hours of misoprostol initiation; secondary outcomes included safety (side effects), patient satisfaction (Visual Analogue score for pain), induction-to-abortion interval, and need for additional interventions. Data were analysed using appropriate statistical methods. Ethical approval and written informed consent were obtained.

Results

Age: Group B's mean age (28.25) was slightly higher than Group A's (27.08), though both shared the same median (27.5). Group A had greater variability (range: 19 vs. 13; SD: ~6.42 vs. ~4.36), more younger individuals (age 18 appearing five times), and a higher maximum age (37 vs. 36). Group B was more tightly clustered with fewer extremes (23–36). However, no significant differences were found in mean age ($p = 0.475$) or overall distribution ($p = 0.42$). (Table 1)

	Group A	**Group B**
Mean (Average)	~18w 2d	~17w 6d
Median	18w 4d	18w 0d
Range	13w 2d – 23w 4d	13w 6d – 22w 2d
Standard Deviation	±3w 1d	±2w 6d
Mode (Most Frequent)	17w (4 counts)	20w 6d, 19w 5d (3 each)
p-value (Mann-Whitney)	0.48(Not significant statistically)	

Table 1

Religion:

There was no statistically significant difference in religious distribution between Group A and Group B (p value=0.207). (Fig 2)

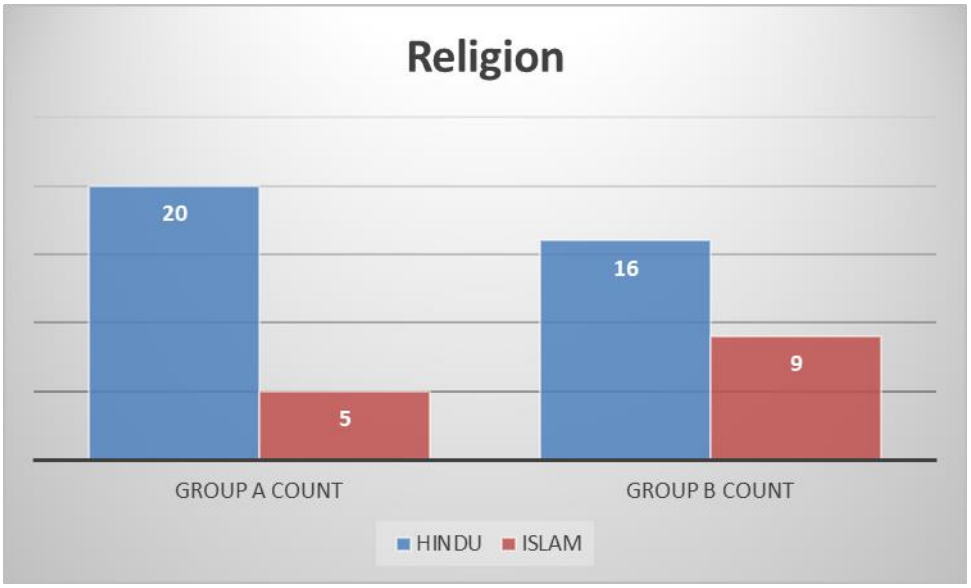

Fig 2

Gestational age:

Group A had a slightly higher mean (~18w 2d vs. ~17w 6d) and median(18w 4d vs. 18w0d) , but the difference was not statistically significant (p=0.48). Both groups had similar distributions across key gestational age thresholds. (Table 1) (fig 3)

Fig 3

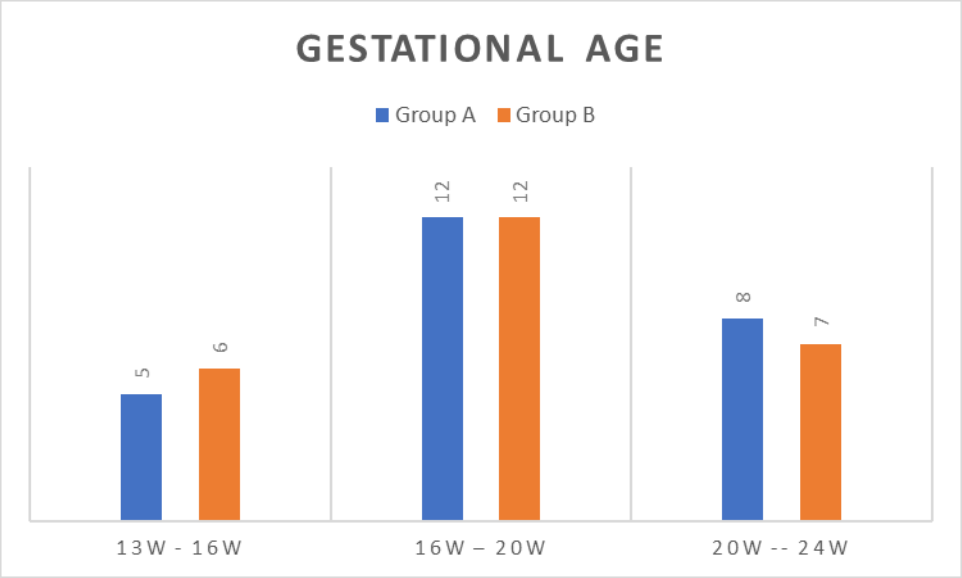

Fig 3

BMI:

The mean BMI of Group A (22.79) was slightly lower than Group B (23.47), but the difference was small. There was no statistically significant difference between median BMI of Group A and Group B, P value=0.29, Mann-Whitney U Test (Wilcoxon Rank-Sum Test). (Table 2)

BMI	Group A	Group B
Mean	22.79	23.47
Median	21.5	22.52
Std Dev	4.89	5.42
Min	16.8	18.18
Max	30.8	34.7
Range	14	16.52

Table 2

Parity:

Group B had a slightly higher mean parity count (1.2 vs. 1.0). Group A had more variability (higher standard deviation) due to an outlier (a case with 4 parity). Both groups had the same median (1), suggesting a similar central tendency. Group A had more cases with 0 parity and one extreme case (4). Group B had more cases with 2 parity and fewer zeros. However, there was no statistically significant difference in parity counts between Group A and Group B at the 5% significance level. U statistic = 268.5, p-value = 0.186 (Mann-Whitney U Test) (Fig 4)

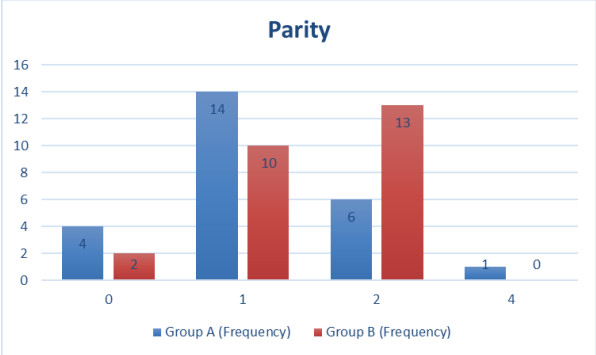

Fig 4

INDICATION OF MTP:

Both groups were dominated by "self-Choice" cases (~60-67%). Group A had slightly more Fetal Anomaly cases (8 vs. 6). Missed Abortion was rare in both groups (3 vs. 2).Group B had a marginally higher proportion of elective

("Self-Choice") terminations. Group A had more medically indicated (Fetal Anomaly + Missed Abortion) cases (45.8% vs. 33.3%). There was no significant statistical difference in indications for termination of pregnancy between the groups, p value 0.69 (Fig 5)

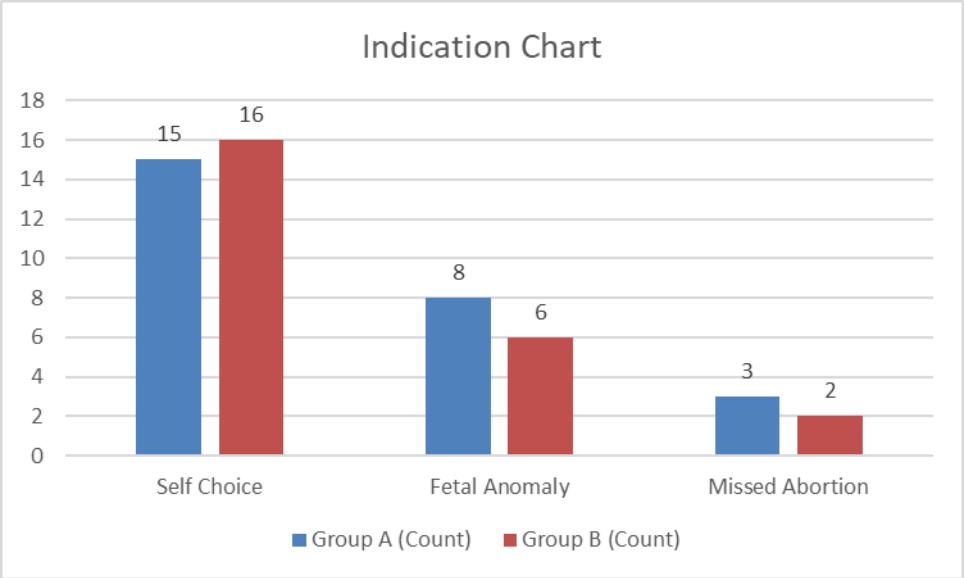

Fig 5

Induction-Abortion Interval:

The mean induction (misoprostol) to abortion (expulsion) interval in Group A was 16.5h and in Group B was 26.5h. The median in Group A was 18h and in Group B was 23h. Group B (~12.1) had twice the variability of Group A (~6.2). Group B (48.4h) spans much longer durations than Group A (26h). Mann-Whitney U test confirms a significant difference ($p < 0.01$). Group B included 2 extreme cases (>48h), while Group A had none. (Table 3)

Metric	Group A (n=25)	Group B (n=25)	Statistical Test
Mean (hours)	16.5	26.5	
Median (hours)	18	23	
Minimum (hours)	4	9.6	
Maximum (hours)	30	58	
Range (hours)	26	48.4	
Standard Deviation	~6.2	~12.1	
Mann-Whitney U Test	—	—	$p < 0.01$

Table 3

Frequency Distribution of Induction-to-Expulsion Times

In Group A, 88% of cases (22/25) completed within 24 hours. Only 3 cases (12%) took 25–30 hours (none exceeded 48 hours). In Group B, 68% (17/25) finished within 24 hours, but 32% (8/25) took longer. 2 extreme outliers (8%) exceeded 48 hours. No significant difference ($p=0.23 > 0.05$) in frequency distributions between groups (Chi-square Test) was found. (Fig 6)

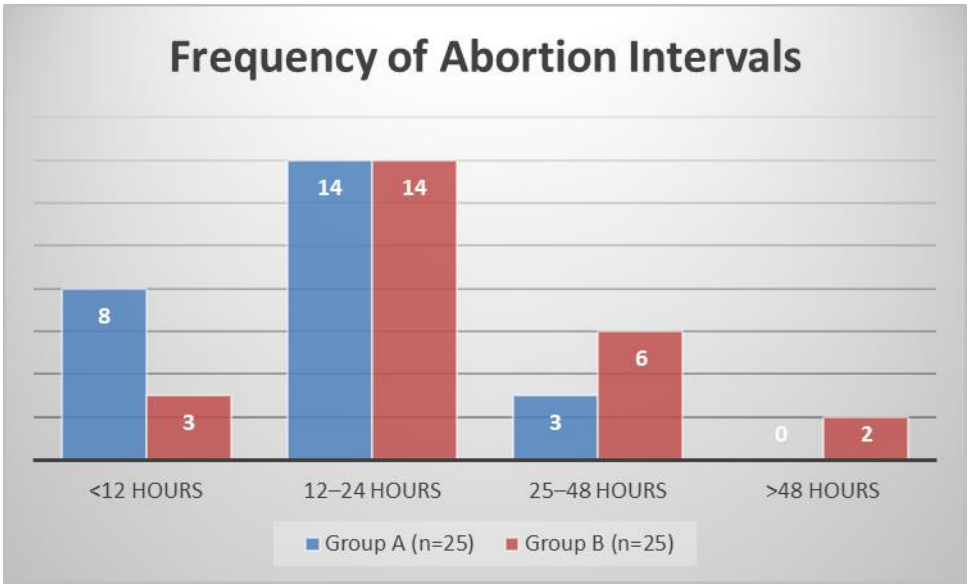

Fig 6

Misoprostol Doses:

Group B's mean of misoprostol dose was 4.88 and Group A's was 4.00.. Central Tendency: Group A was centered at 4 (both median and mode), while Group B was centered at 5 (median and mode = 5, appearing 10 times). Spread of Doses: Group A's doses range from 1 to 6, while Group B's range from 2 to 8. The difference in dose distributions between the 2 groups is statistically significant ($p < 0.05$). (Mann-Whitney U Test, U statistic= 203.5, p value= 0.018, two- tailed). (Table 4)

Statistic	Group A (n=25)	Group B (n=25)
Mean	4	4.88
Median	4	5
Mode	4 (8 times)	5 (10 times)
Minimum	1	2
Maximum	6	8
Range	5 (1- 6)	6 (2 - 8)

Table 4

Group A required a mean misoprostol dose of 1,552 ± 576 mcg (range 400-2,400 mcg), while Group B required a significantly higher mean dose of 1,808 ± 712 mcg (range 800-3,200 mcg), representing a 16.5% increase. Group B showed greater dose variability and included higher maximum doses (3,200 mcg versus Group A's 2,400 mcg maximum), with 20% of patients receiving the highest dose category. The difference in means was not statistically significant ($p \sim 0.14$). (Table 5)

Group	**Mean ± SD** (Miso dose)	Range (Min–Max)	Median
A	**1,552 ± 576 mcg**	400–2,400	1,600
B	**1,808 ± 712 mcg**	800–3,200	2,000

Table 5

Hb Loss:

Group B had a mean Hb loss of 1.29 g/dL compared to Group A which was 0.69 g/dL. Group B also shows much higher variability (SD = 0.93 vs. 0.45). The median Hb loss is close in both groups (0.6 vs. 0.7), but Group B has a wider range (0.1–2.5 vs. 0.2–1.7. Mann-Whitney U Test: $U \approx 180$, $p \approx 0.008$ (significant difference). Rank-biserial $r \approx 0.5$ (moderate

effect). (Table 6)

Statistic	Group A	Group B
Mean (Hb loss)	0.692	1.292
Median	0.6	0.7
Std Dev	0.453	0.928
Min	0.2	0.1
Max	1.7	2.5
Range	1.5	2.4

Table 6

PAIN SCORE:

Group A had a mean pain score (VAS) of 5.56 compared to Group B which was 6.56. Group B showed less variability (Std Dev = 1.15) than Group A (Std Dev = 2.16). Group A had a wider range (3-10), including extreme values (10), while Group B was more clustered (5-8). The difference is statistically significant ($p < 0.05$). T-test Output : t-statistic ≈ -2.06, p-value ≈ 0.045 (assuming equal variances not assumed due to differing std devs). (Table 7)

Statistic	Group A	Group B
Mean	5.56	6.56
Median	5	7
Mode	4, 5	5, 7, 8
Std Dev	2.16	1.15
Range	7 (3-10)	3 (5-8)
Min	3	5
Max	10	8

Table 7

Side effects:

Nausea was slightly more frequent in Group A (28%) vs. Group B (24%) Vomiting was marginally higher in Group A (12%) vs. Group B (8%). Fever & Shivering was 3× more common in Group A (24%) vs. Group B (8%). "No side effects" were more frequent in Group B (52%) vs. Group A (36%). Group A had higher rates of fever/shivering (24% vs. 8%), but this was not statistically significant with n=25. Group B had fewer side effects overall (52% no side effects vs. 36%), but again, this was not significant. No major safety concerns differ between groups, though trends suggest Group A may be slightly less tolerable. (Table 8)

Side Effect	Group A (%)	Group B (%)	P value
Nausea	28% (7/25)	24% (6/25)	0.24
Vomiting	12% (3/25)	8% (2/25)	1.0
Fever & Shivering	24% (6/25)	8% (2/25)	1.0
No Side Effects	36% (9/25)	52% (13/25)	0.4

Table 8

Discussion

The study population demonstrated comparable baseline characteristics between the two treatment groups (A & B), with no significant differences observed in demographic or clinical parameters including maternal age, parity, religious affiliation, body mass index (BMI), or gestational age at termination ($p>0.05$ for all comparisons). Importantly, the indications for pregnancy termination were similarly distributed between groups, and the mean gestational ages showed no statistically significant variation, ensuring that subsequent outcome comparisons between the treatment protocols were not confounded by these potential influencing

factors.

In our study, Group A (Mifepristone + Misoprostol) showed a significantly shorter and more predictable induction-to-abortion interval compared to Group B (PGE2 + Misoprostol), with a 10-hour shorter mean (16.5h vs. 26.5h), a 5-hour shorter median (18h vs. 23h), and lower variability (SD ~6.2 vs. ~12.1). Group B also had a much wider range (48.4h vs. 26h) and included two outliers exceeding 48 hours, none of which occurred in Group A. The difference was statistically significant (Mann-Whitney U, $p < 0.01$), indicating greater consistency and efficiency with mifepristone. These findings are consistent with Kapp (2007), who reported a 12.13-hour reduction in abortion time with mifepristone + misoprostol compared to misoprostol alone (11). However, our results contrast with Tanwar et al. (2020), who observed a non-significant shorter interval in the PGE2 + misoprostol group (6.50 ± 3.54h) versus mifepristone + misoprostol (7.33 ± 2.5h; $p = 0.344$), suggesting possible variability due to differing protocols(10). Bhattacharjee N et al. (2008) found no significant difference in induction-abortion interval or 48-hour success rates between sublingual and vaginal routes(5). Similarly, Tang OS et al. (2005) reported comparable 48-hour success rates between routes, though vaginal administration had a significantly higher 24-hour success rate(12). Ragip A. Al (2015) further supported the vaginal route's efficacy, showing a significantly shorter induction-to-abortion interval compared to the buccal route (25 ± 17h vs. 40 ± 29h; $p = 0.001$) (13). Overall, our findings underscore the superior consistency and efficiency of the mifepristone-based regimen, while highlighting the influence of drug combinations and administration routes on outcomes. (Fig 7)

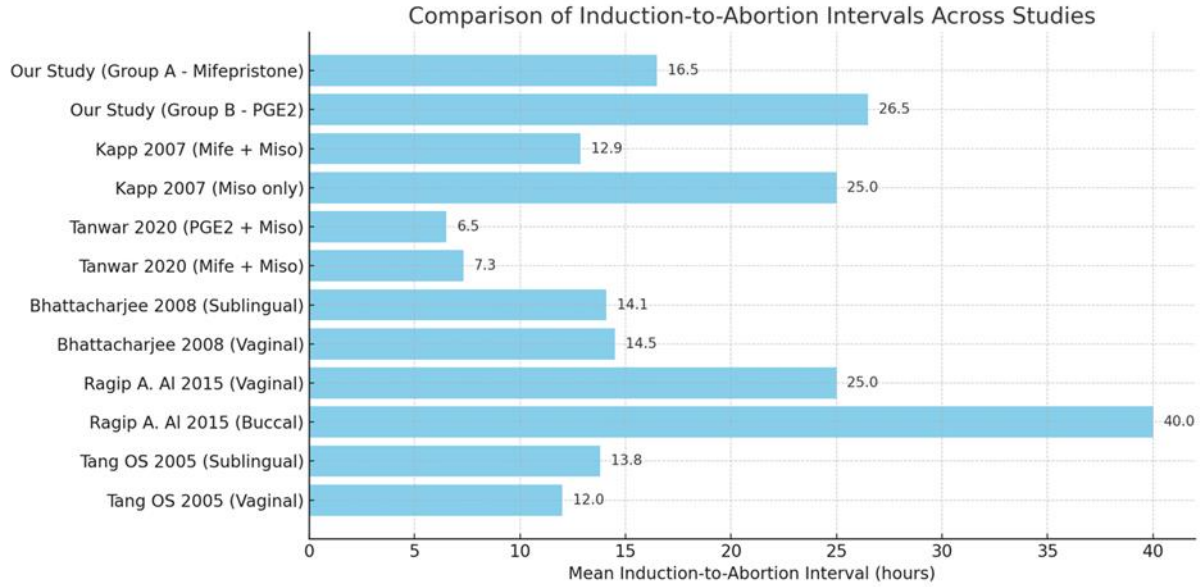

Fig 7

In this study, a greater proportion of participants in Group A (mifepristone) achieved abortion completion within 24 hours (88%, 22/25) compared to Group B (PGE2) (68%, 17/25). Notably, only 12% (3/25) of Group A cases extended to 25–30 hours, with none exceeding 48 hours. In contrast, Group B had 32% (8/25) of cases lasting longer than 24 hours, including two outliers that exceeded 48 hours. While the Chi-square test did not show statistical significance in the distribution of durations ($p = 0.23$), the presence of extreme delays in Group B highlights a clinically relevant concern, warranting further investigation into potential predictive factors for delayed outcomes. These results align with findings by Tanwar et al. (2020), who reported a slightly higher success rate for complete abortion within 15 hours in the mifepristone group (92%) compared to the PGE2 plus misoprostol group (88%), reinforcing the notion that mifepristone-based regimens may provide more predictable and timely outcomes(10). Similarly, Bhattacharjee et al. (2008) found no statistically significant difference between sublingual and vaginal misoprostol routes in complete abortion rates at 24 hours (64.03% vs. 61.59%, $p = 0.767$) or 48 hours (79.14% vs. 82.01%, $p = 0.651$) (5). Conversely, Ragip A. Al (2015) demonstrated significantly higher abortion rates in the vaginal group compared to the buccal group at both 24 hours (63% vs. 42%, $p = 0.014$) and 48 hours (91% vs. 68%, $p = 0.001$), emphasizing the role of administration route in

determining efficacy and timing (13). Overall, our findings support the clinical advantage of mifepristone for faster and more consistent abortion outcomes. (Table 9)

Study/Group	**24h Success Rate (%)**	**48h Success Rate (%)**
Our Study - Group A (Mifepristone)	88% (22/25)	100% (25/25)
Our Study - Group B (PGE2)	68% (17/25)	92% (23/25)
Tanwar et al. (2020) - Mifepristone	92%	–
Tanwar et al. (2020) - PGE2+Misoprostol	88%	–
Bhattacharjee et al. (2008) - Sublingual	64.03%	79.14%
Bhattacharjee et al. (2008) - Vaginal	61.59%	82.01%
Ragip A. Al (2015) - Vaginal	63%	91%
Ragip A. Al (2015) - Buccal	42%	68%

Table 9

Our study demonstrated significantly greater misoprostol requirements in the PGE2 gel plus misoprostol group (Group B) compared to the mifepristone plus misoprostol group (Group A). Group B required a mean of 4.88 doses (1,808 ± 712 mcg) versus Group A's 4.00 doses (1,552 ± 576 mcg), representing a 22% increase (Δ256 mcg; Mann-Whitney U = 203.5, p = 0.018). Group B also showed higher median dosing (5 doses/2,000 mcg vs 4 doses/1,600 mcg) and greater variability, with a dose range of 2-8 doses (800-3,200 mcg) compared to Group A's 1-6 doses (400-2,400 mcg), including high-dose outliers (7-8 doses/2,800-3,200 mcg) not observed in Group A. These findings align with Ngai et al.'s (2000) report of higher oral versus vaginal misoprostol requirements (1,734 ± 1,113 mcg vs 812 ± 550 mcg, p = 0.0001) and Ragip A. Al's (2015) findings of greater buccal dose requirements (median 5 doses, range 1-18) compared to vaginal administration (median 3 doses, range 1-14; p < 0.001), collectively highlighting how both pretreatment medication and administration route significantly influence misoprostol dosing requirements (13,14).

Our study found that Group B (PGE2 protocol) was associated with significantly greater mean haemoglobin loss (1.29 g/dL) compared to Group A (mifepristone protocol; 0.69 g/dL, p=0.008), with a moderate-to-large effect size (r≈0.5), despite similar median losses (0.6 vs. 0.7 g/dL). Group B demonstrated greater variability (SD 0.93 vs. 0.45) and a wider range of Hb loss (0.1-2.5 g/dL vs. 0.2-1.7 g/dL), suggesting the presence of outliers with clinically significant blood loss. These findings contrast somewhat with Tanwar et al. (2020), who reported lower mean Hb decreases in their PGE2 group (0.68±0.42 g/dL) compared to mifepristone (0.91±0.47 g/dL), though this difference was not statistically significant (p=0.071)(10). Notably, both studies observed that most patients (72-88%) experienced ≤1 g/dL Hb reduction regardless of protocol, but our data revealed that PGE2 use may carry greater risk of substantial blood loss (>2 g/dL) in certain patients. This discrepancy between studies may reflect differences in population characteristics, PGE2 dosing regimens, or management protocols, highlighting the need for careful monitoring when using PGE2, particularly in settings where anaemia is a concern. The collective evidence suggests that while both protocols are generally safe, mifepristone may offer more predictable haemoglobin outcomes with fewer extreme cases of blood loss.

This study also found that Group A (MTP Protocol A) reported significantly lower mean pain scores (5.56) compared to Group B (6.56, p=0.045), suggesting a potential advantage in pain reduction with Protocol A, though with important nuances in the pain experience patterns between groups. While Group B demonstrated more consistent pain responses (SD=1.15, range 5-8), Group A showed greater individual variability (SD=2.16, range 3-10), including some extreme high pain reports that may reflect unique patient responses or protocol-specific effects. These findings align with Ragip A. Al's (2015) observation of lower pain scores in vaginal (6.6±1.6) versus buccal (7.3±1.4, p=0.01) misoprostol administration, collectively indicating that both the choice of primary protocol (MTP A vs B) and specific medication route (vaginal vs buccal) can meaningfully influence pain experiences during abortion care (13). The greater variability in Group A's pain

scores, despite its lower mean, suggests that while Protocol A may be preferable for reducing average pain levels, clinicians should remain attentive to the possibility of severe pain in certain patients, potentially warranting individualized pain management approaches. These pain outcome differences between protocols add an important dimension to protocol selection considerations, alongside factors like efficacy and completion rates.

Our study observed that Group A (mifepristone pretreatment) showed a non-significant trend toward higher side effect frequencies compared to Group B, including slightly increased nausea (28% vs. 24%) and vomiting (12% vs. 8%), and a particularly notable threefold difference in fever/shivering (24% vs. 8%) - a pattern potentially attributable to mifepristone's systemic effects, though these differences did not reach statistical significance (n=25/group). While Group B demonstrated better overall tolerability (52% side effect-free vs. 36% in Group A), these findings contrast with literature showing more pronounced route-dependent variations: Tang et al. (2003) reported significantly higher fever/chills and gastrointestinal effects with sublingual versus vaginal administration, while von Hertzen et al. (2008) found comparable side effect profiles except for fever, which increased significantly with vaginal dosing after repeated administration (39.7% vs. 29.9% sublingual, p=0.008)(12,15). Our results suggest that pretreatment choice (mifepristone vs. alternative) may influence side effect patterns differently than administration route alone, with mifepristone potentially predisposing to more systemic reactions like fever, though larger studies are needed to verify these observations and clarify whether the modest increases in side effects with mifepristone regimens outweigh their established efficacy advantages.

Conclusion

The mifepristone-misoprostol regimen proved more efficient than PGE2-misoprostol for mid-trimester abortion, offering faster completion times and more predictable outcomes with fewer doses required. While both protocols were effective, mifepristone-misoprostol was associated more side effects like nausea, vomiting, fever, whereas PGE2-misoprostol showed more variable results with some prolonged cases and more blood loss. Clinical choice should balance these factors against patient needs and medication availability, with mifepristone being preferable where accessible. These results contribute to growing evidence supporting mifepristone-based regimens as the preferred option when accessible, while acknowledging PGE2 as a viable alternative in resource-limited settings. However, our conclusions should be interpreted with consideration of the limited sample size.

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Ethical approval*: The study was approved by the Institutional Ethics Committee, Gauhati Medical College*

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