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Original Research Article

Role of combination of mifepristone and misoprostol versus misoprostol alone in the management of late intrauterine fetal death

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ABSTRACT

Background: Intrauterine fetal death (IUFD) occurs in 1% of pregnancies and has devastating consequences. Previous methods for inducing labor in IUFD involved oxytocin and prostaglandins. The combination of mifepristone and misoprostol is commonly used for early first-trimester termination. This study aimed to compare the effectiveness of mifepristone and misoprostol combination versus misoprostol alone for labor induction in intrauterine fetal death.
Methods: A randomized controlled clinical trial was conducted at Sir Salimullah Medical College, Mitford Hospital, Dhaka, from January 2017 to June 2017. Sixty-four pregnant women with intrauterine fetal death after 28 weeks of gestation were included. Participants were randomly assigned to either group-I (mifepristone and misoprostol) or group-II (misoprostol alone). Statistical analyses were performed using statistical package for the social sciences (SPSS) version 20.0 for Windows.
Results: The mean age was 27.7±5.6 years in group I and 27.5±4.3 years in group II. Majority of patients in group I were housewives (87.5%), while in group II, it was 78.1%. Most patients in group I (56.3%) came from lower-income families, compared to 65.6% in group II. The gestational age did not significantly differ between the groups. The induction to delivery interval was significantly shorter in group I (8.6±2.0 hours) compared to group II (15.1±3.5 hours). The dose administration pattern of misoprostol differed significantly between the groups.
Conclusions: Both methods are equally safe and effective for managing intrauterine fetal death. However, the combination of mifepristone and misoprostol showed greater efficacy in terms of reducing the induction to delivery interval and requiring a lower dose of misoprostol.

Keywords: Misoprostol, Mifepristone, IUD

INTRODUCTION

"Tear in eyes but milk in blessing". This describes the greatness of motherhood. To achieve motherhood women are ready to go through labor pain which is described often as more severe than the pain of angina. Every woman wants to get a live baby when she becomes pregnant. Unfortunately, sometimes something goes wrong and a baby dies in utero, which is the most undesirable consequence of any pregnancy. Intrauterine fetal death is encountered in 1% of all pregnancies.[1] The definitions of intrauterine fetal death (IUFD) vary among different countries. For our context, it is defined as antepartum death occurring beyond 28 weeks of gestation. When a fetal death occurs, spontaneous expulsion will usually occur in about 80% of cases within 2 weeks of fetal demise.[2] So expectant managements is an option if desired by the patient and is unlikely to result in the adverse medical

outcome. But prolonged expectant management poses a risk of developing intrauterine infection especially when membranes are ruptured and if the dead fetus is retained in the uterus for more than 4 weeks it can lead to consumptive coagulopathy and disseminated intravascular coagulation.[3] However, moderate to severe maternal anxiety had been found to occur if labor has failed to start 24 hours after diagnosis.[4]

Thus, social and maternal desires and a moderate risk of maternal complication compel the caregiver to induce labor soon after diagnosis aiming for safe and speedy delivery. Before the introduction of prostaglandins, various methods have been tried in the management of IUFD. Now prostaglandins have revolutionized the management of intrauterine fetal death. The therapeutic effect of prostaglandins is limited by their side effect. These effects are dependent on the type of prostaglandin and the route of administration. They can be used by oral, sublingual, intramuscular, vaginal, and rectal routes. Misoprostol, a synthetic analog of prostaglandin E_1 is widely used because of its low cost, stability at room temperature, and ease of administration. Oral misoprostol administration for labor induction with an IUFD was first described in Sao Paulo, Brazil.[5] Mifepristone is an antiprogesterone steroid that competes with progesterone at the receptor level and is widely used for 1st and 2nd trimester termination of pregnancy.[6-9] The role of mifepristone for uterine priming was first reported by Cabrol et al.[10] Subsequently it was observed that a combination of mifepristone and misoprostol for induction of labor in late intrauterine death is more effective and safe regimen and the induction to delivery interval is shorter than studies using mifepristone or misoprostol alone.[11,12]

Mifepristone administration before misoprostol increases the sensitivity of the uterus to prostaglandins and ripens the cervix, thereby allowing the lower doses of misoprostol to induce expulsion of the fetus, so that side effects related to misoprostol were less. However, the optimum combination of mifepristone and misoprostol for induction has not been established yet. This study has been done to find out the efficacy and safety of the combined regimen with mifepristone and misoprostol or misoprostol alone in the delivery of a fetus following IUFD.[11,12] The research will continue in this direction to find out the near-ideal method to induce labor after intrauterine fetal death. This active approach will virtually eliminate the possibility of consumption coagulopathy.[3]

Objectives

General objective of the study was to assess whether the combination of mifepristone and misoprostol is superior to misoprostol alone for the induction of labor in intrauterine fetal death.

Specific objectives of the study were: to determine the success rate of delivery in both groups, and to compare the induction delivery interval in both groups.

METHODS

This randomized controlled clinical trial was conducted at the department of obstetrics and gynecology, Sir Salimullah Medical College, Mitford Hospital, Dhaka, from January 2017 to June 2017. A total of 64 pregnant women with intrauterine fetal death after 28 weeks of gestation, admitted to the hospital, were selected as the sample size based on the inclusion criteria. The study employed a random sampling technique. Eligible women, who provided informed written consent, underwent detailed clinical examination and ultrasound confirmation of intrauterine fetal death. They were then randomized into group-I and group II using a lottery system. Patients in group-I received a single oral dose of 200 mg mifepristone and were allowed to stay in the ward. After 36-48 hours, 50 mcg of misoprostol was inserted into the posterior vaginal fornix and repeated at 4-hour intervals, with a maximum of 6 doses if required. In group II, only 50 mcg of misoprostol was administered vaginally at 4-hour intervals according to the same dosage schedule. Statistical analyses were performed using the statistical package for social sciences (SPSS) version 20.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Descriptive analysis was conducted, calculating mean values for continuous variables and presenting quantitative observations as frequencies and percentages. Unpaired t-tests were used to compare continuous variables between the combination of mifepristone and misoprostol group and the misoprostol alone group. The chi-square test was employed to compare categorical data, such as clinical signs and symptoms. A significance level of $p<0.05$ was considered statistically significant. Ethical clearance was obtained from the ethical committee of Sir Salimullah Medical College, Mitford Hospital, Dhaka. Privacy and confidentiality of the participants were strictly maintained. The inclusion criteria for this study included gravid women between 28 to 42 weeks of pregnancy with intrauterine fetal death who were not in active labor and expressed willingness to terminate the pregnancy through medical management. On the other hand, the exclusion criteria comprised grand multiparity (parity >4), women with ruptured membranes or evidence of infection, previous intramural uterine incision (cesarean section, myomectomy), known allergy to misoprostol and mifepristone, evidence of coagulopathy, and women with chronic systemic steroid administration or adrenal disease, bronchial asthma, seizure disorder, or cardiovascular disease.

RESULTS

It was observed that half (50.0%) of the patients in group I and almost two third (62.5%) of patients in group II belonged to the age group between 26 to 35 years. The mean age was found 27.7±5.6 years in group I and 27.5±4.3 in group II. The majority (87.5%) of patients were housewives in group I and 25 (78.1%) in group II. Most (56.3%) patients come from low-income families in group I and 21 (65.6%) in group II. The difference was

statistically not significant (p>0.05) between the two groups (Table 1).

Table 1: Distribution of the study patients by demographic variables (N=64).

Variables	Group-I (n=32)		Group-II (n=32)		P value
	n	%	n	%	
Age (in years)					
19-25	12	37.5	10	31.3	
26-35	16	50.0	20	62.5	
35-40	4	12.5	2	6.25	
Mean±SD	27.7±5.6		27.5±4.3		[a]0.873[ns]
Range (min, max)	19, 40		19, 37		
Occupational status					
Housewife	28	87.5	25	78.1	[b]0.320[ns]
Service	4	12.5	7	21.87	
Socio-economic status					
Low (≤6821)	18	56.3	21	65.6	[b]0.576[ns]
Lower middle (6828-26852)	9	28.1	7	21.9	
Higher middle (26859-83018)	5	15.6	3	9.4	
High (≥83024)	0	0.0	1	3.1	

ns=Not significant, [a]p value reached from unpaired t-test, [b]p value reached from Chi-square test, group I=combination of mifepristone and misoprostol, group II=misoprostol alone

Almost three fourth (71.9%) of the patients were multi gravida in group I and 25 (78.1%) in group II. The difference was statistically not significant (p>0.05) between the two groups (Table 2).

Table 2: Distribution of the study patients by gravida (N=64).

Gravida	Group-I (n=32)		Group-II (n=32)		P value
	n	%	n	%	
Primi	9	28.1	7	21.9	0.563[ns]
Multi	23	71.9	25	78.1	

ns=Not significant, p value reached from the Chi-square test

The majority (84.4%) of patients belonged to gestational age ≤36 weeks in group I and 29 (90.6%) in group II. The difference was statistically not significant (p>0.05) between the two groups (Table 3).

It was observed that the majority (40.6%) of patients Bishop's score was 7-8 in group I and group II respectively. Followed by 10 (31.3%) was 5-6 in group I and 4 (12.5%) in group II, 6(18.7%) was 9-10 in group I and 13 (40.6%) in group II, 3 (9.4%) was >10 in group I and 2 (6.3%) in group II. The mean Bishop's score was found 7.6±2.0 in group I and 8.3±1.6 in group II. The difference was statistically not significant (P>0.05) between the two groups (Table 4).

Table 3: Distribution of the study patients by gestational age (N=64).

Gestational age (weeks)	Group-I (n=32)		Group-II (n=32)		P value
	n	%	n	%	
≤36 (preterm)	27	84.4	29	90.6	
37-40 (term)	5	15.6	3	9.4	
Mean±SD	32.6±3.2		33.3±3.0		0.370[ns]
Range (min, max)	28, 39		28, 39		

ns=Not significant, p value reached from the unpaired t test

Table 4: Distribution of the study patients by Bishop's score (N=64).

Bishop's score	Group-I (n=32)		Group-II (n=32)		P value
	n	%	n	%	
5-6	10	31.3	4	12.5	
7-8	13	40.6	13	40.6	
9-10	6	18.7	13	40.6	
>10	3	9.4	2	6.3	
Mean±SD	7.6±2.0		8.3±1.6		0.122[ns]
Range (min, max)	5, 11		5, 11		

ns=Not significant, p value reached from the Chi-square test

In this study, 7 (21.9%) patients in group I and 15 (46.9%) in group II required augmentation by injection oxytocin. The difference was statistically significant (p<0.05) between the two groups (Table 5).

Table 5: Distribution of the study patients who required additional intervention (N=64).

Augmentation by oxytocin	Group-I (n=32)		Group-II (n=32)		P value
	n	%	n	%	
Augmentation required	7	21.9	15	46.9	0.036[s]
Augmentation not required	25	78.2	19	53.1	

s=Significant, p value reached from the Chi-square test

It was observed that the majority (59.4%) of patients in group I, received the 2nd dose (4 hours) followed by 7 (21.9%) 3rd dose (8 hours), 4 (12.5%) 1st dose (0 hours) and 2 (6.3%) received 4th dose (12 hours). In group II, most (40.6%) of the patients, received the 3rd dose (8 hours) followed by 10 (31.3%) 4th dose (12 hours), 5 (15.6%) 5th dose (16 hours) and 4 (12.5%) received 2nd dose (4 hours). The difference was statistically significant (p<0.05) between the two groups (Table 6).

The majority (87.5%) of patients belonged to the induction to the delivery interval of 7 to 12 hours in group I and 8 (25.0%) in group II. The mean induction to the delivery interval was found 8.6±2.0 in group I and 15.1±3.5 in

group II. The difference was statistically significant (p<0.05) between the two groups (Table 7).

Table 6: Distribution of the study patients by number of doses (misoprostol) (N=64).

Dose (misoprostol) (in hours)	Group-I (n=32)		Group-II (n=32)		P value
	n	%	n	%	
1st dose (0)	4	12.5	0	0.0	0.563ns
2nd dose (4)	19	59.4	4	12.5	
3rd dose (8)	7	21.9	13	40.6	
4th dose (12)	2	6.3	10	31.3	
5th dose (16)	0	0.0	5	15.6	
6th dose (20)	0	0.0	0	0.0	

s=Significant, p value reached from the Chi-square test

Table 7: Distribution of the study patients by induction to delivery interval (N=64).

Induction to delivery interval (in hours)	Group-I (n=32)		Group-II (n=32)		P value
	n	%	n	%	
≤6	4	12.5	0	0.0	
7-12	28	87.5	8	25.0	
>18	0	0.0	24	75.0	
Mean±SD	8.6±2.0		15.1±3.5		0.001s
Range (min, max)	5.2, 12.3		8.4, 21.3		

s=Significant, p value reached from the unpaired t test

DISCUSSION

In this current study half (50.0%) of the patients in group I and almost two third (62.5%) of patients in group II belonged to the age group between 26 to 35 years. The mean age was found 27.7±5.6 years in group I and 27.5±4.3 in group II, which were similar between the two groups. Gupta et al found the mean age was 28.4±5.4 years in group A and 27.5±4.5 in group B. However, Chaudhuri and Datta found the mean age was lower i.e. 24.5±5.0 years in group I and 23.3±3.8 in group II.[12] Panda et al found that the mean age was 27.9±4.6 years in the combination group and 26.8±6.6 years in the misoprostol group.[13] The difference was not statistically significant (p>0.05) between the two groups). The above findings are consistent with the current study. In this present study, it was observed that the majority of patients were housewives in both groups, which were 87.5% and 78.1% in group I and group II respectively. Lipika found housewives 72.0% and service holders 28.0% in the misoprostol group, which closely resembled the present study.[14] In this current study it was observed that most (56.3%) patients came from a low-income family in group I and 65.6% in group II. The difference was statistically not significant (p>0.05) between the two groups. Another study from Begum observed that more than a half (52.0%) of the patients came from the low-income group followed by (38.0%) from a low-middle class group, 4 (8.0%) from the upper-middle class and 1 (2.0%) from the high-income group.[24] In this present study, it was observed that almost three fourth (71.9%) of the patients were multi gravida in group I and 78.1% in group II. The difference was statistically not significant (p>0.05) between the two groups. Sharma et al found multigravida 55.0% in group I and 70.0% in group II, which is similar to the current study.[15] Similar observations regarding gravidity were also made by Gupta et al.[16] All these results support the present study. In this present study majority (84.4%) of patients in group I and 90.6% in group II belonged to ≤36 weeks of gestation. The mean gestational age was 32.6±3.2 weeks and 33.3±3.0 weeks in group I and group II respectively. The difference was statistically not significant (p>0.05) between the two groups. Gupta et al found the mean gestational age 32.4±6.4 weeks in group I and 31.2±6.2 weeks in group II.[16] The difference was statistically not significant (p>0.05) between the two groups, which closely resembled the present study. Similarly, Panda et al found the mean gestational age was 33.63±1.1 weeks in the combination group and 34.0±0.9 weeks in the misoprostol group.[13] The mean difference was not statistically significant (p>0.05) between the two groups. In another study, Fairley et al observed that median gestational age was found 28 weeks with a range from 24 to 40 weeks in group one and 21 weeks with a range from 24 to 41 weeks in group two, which are comparable with the current study.[17] In this current study, the majority 40.6% of patients Bishop's score was 7-8 in group I and group II respectively. Followed by 31.3% who were 5-6 in group I and 12.5% in group II, 18.7% who were 9-10 in group I and 40.6% in group II, 9.4% was >10 in group I and 6.3% in group II. The mean Bishop's score was found 7.6±2.0 in group I and 8.3±1.6 in group II. The difference was statistically not significant (p>0.05) between the two groups. Similarly, Gupta et al found the mean Bishop's score was 3±1.6 in group I and 2.6±1.8 in group II.[16] The difference was not statistically significant (p>0.05) between the two groups. Sharma et al observed 80.0% had Bishop's score of 0-3 in the two groups.[15] The mean Bishop's score was found 1.45±1.60 in group I and 2.1±1.20 in group II. The difference was not statistically significant (p>0.05) between the two groups. In another study, Chaudhuri and Datta showed the mean pre-induction Bishop's score was found 2.4±1.3 in group I and 2.6±1.1 in group II.[12] The difference was not statistically significant (p>0.05) between the two groups. In this present study, it was observed that only 21.9% of patients in group I and 46.9% in group II required augmentation by injection oxytocin. Augmentation by oxytocin was significantly (p<0.05) higher in group II. Similarly, Gupta et al found 6.6% of patients needed oxytocin in group I, and 19.4% needed it in group II.[16] In another study Panda et al observed no patients needed oxytocin in the combined regimen group and 11.5% of patients needed oxytocin in the misoprostol group, which is consistent with the current study.[13] In this present study, it was observed that the majority (59.4%) of patients in group I, received 2nd dose (4 hours) followed by 21.9% received 3rd dose (8 hours), 12.5% 1st dose (0 hours), and 6.3% received 4th dose (12

hours). In group II, most (40.6%) of the patients, received the 3rd dose (8 hours) followed by 31.3% 4th dose (12 hours), 15.6% 5th dose (16 hours), and 12.5% received the 2nd dose (4 hours). The difference was statistically significant ($p<0.05$) between the two groups. The number of doses of misoprostol required was significantly less in the mifepristone group which can be explained due to its pharmacodynamics. Similarly, Gupta et al observed the mean number of doses of misoprostol was 2.9±1.2 in group I and 4.2±1.3 in group II.[16] The mean number of doses was significantly ($p<0.05$) less in group I. Panda et al showed the mean number of doses of misoprostol was 1.69±.73 in the combination group and 3.2±1.16 in the misoprostol group.[13] Praveena et al found the number of misoprostol doses used in each group was not statistically significant when compared.[18] Minimum and maximum doses were the same in both groups. The mean dose was less (1.75) in group I though the difference was not statistically significant. Similarly, in another study, Sharma et al found the mean number of doses of misoprostol was 1.6±0.92 in group I and 3±0.95 in group II.[15] The difference was statistically significant ($p<0.05$) between the two groups. In this present study majority (87.5%) of patients had an induction delivery interval of 7 to 12 hours in group I and 8 (25.0%) in group II. The mean induction to the delivery interval was found 8.6±2.0 in group I and 15.1±3.5 in group II. The mean induction to the delivery interval was significantly ($p<0.05$) lesser in group I. In Gupta et al study, induction to the delivery interval was less in the group pretreated with mifepristone.[16] The present study is consistent with the study of Väyrynen et al and Sharma et al.[15] Induction to the delivery interval was shortest (7 hours) in the study of Fairley et al, while it was maximum (12.8 hours) in the study of Väyrynen et al.[17,19,28] In Gupta et al study it was 9.8 hours in a combination regimen.[16] Panda et al showed the Induction to the delivery interval was 8.46±3.03 in the combination group and 15±4.14 in the misoprostol group.[13] Praveena et al found the mean induction to delivery interval (IDI) in hours were 10.55 and 12.55 in groups A and B, respectively which was not statistically significant.[18] The minimum was 1.5 hours which was in group B and the maximum was 26.50 hours, which was also in group B. Mean IDI was 11.65 hours. Combinations of mifepristone and misoprostol are widely employed in the management of first and second-trimester termination of pregnancy and miscarriage.[7,11] Fairley et al demonstrated that the extension of this regimen to women with late IUD is both safe and effective and supports the use of this combination.[17]

All the women in their study delivered vaginally with the shortest median induction to delivery interval being in group one at 7 hours. By using a higher dose of misoprostol, the authors achieved a median induction to-delivery interval 1.5 hours shorter than that previously reported.[11] In another study Panda et al observed that the mean induction to the delivery interval was found 8.46±3.03 hours in the combination group and 15± 4.14 hours in misoprostol.[13] The findings closely resembled the present study.

Limitations

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community. The follow-up period after vaginal delivery was too short as patients were discharged early, thus evaluation of complications could not be done thoroughly.

CONCLUSION

This study concluded that, both methods are equally safe and effective in the management of intrauterine fetal death but the combination of mifepristone with misoprostol is more effective in terms of reduction of induction delivery interval, and requirement of a lesser dose of misoprostol.

Recommendations

Further studies should be conducted involving a large sample size and multiple centers.

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