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Original Research Article

Comparative study on the efficacy of mifepristone versus mifepristone and misoprostol in the induction of labor in cases of intrauterine fetal demise

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ABSTRACT

Background: This study aimed to compare the efficacy of two labor induction methods, mifepristone alone and mifepristone followed by misoprostol, in cases of intrauterine fetal demise (IUFD) beyond 28 weeks of gestation.
Methods: A prospective study was carried out at, BRD Medical College in Gorakhpur and aimed to investigate the efficacy of two different methods for labor induction in pregnancies with intrauterine fetal demise (IUFD) beyond 28 weeks of gestation during September 2019 to August 2020. Sixty participants were divided into two groups of 30 each, with mifepristone administered orally in both groups. Group 2 received additional vaginal misoprostol. Patient demographics, Bishop scores, induction to active labor intervals, and induction to delivery intervals were examined. Augmentation methods, side effects, complications, and time to full dilatation were analyzed.
Results: The groups exhibited similar patient characteristics, including age, parity, socioeconomic status, and literacy rates. Gestational age at induction and Bishop scores were comparable. Both groups showed substantial improvements in Bishop scores. The induction to active labor interval was shorter in the mifepristone group, and the induction to delivery interval was similar. The mifepristone group required fewer mifepristone tablets, while the combination group used less misoprostol, reducing side effects. Complications were minimal, with a decreased need for augmentation methods in both groups.
Conclusions: Mifepristone, whether used alone or followed by misoprostol, proved effective in labor induction for IUFD beyond 28 weeks. Mifepristone's ability to enhance cervical ripening and prostaglandin sensitivity makes it a promising option for reducing the risks associated with delayed birth in cases of IUFD. These findings suggest that mifepristone can be a valuable addition to obstetric practices, particularly in cases where traditional induction methods may pose greater risks.

Keywords: Bishop score, Gestational age, Intrauterine fetal demise, Labor induction, Mifepristone, Misoprostol

INTRODUCTION

Pregnancy loss can be emotionally devastating, especially when it occurs after 28 weeks of gestation when the fetus is legally viable. Delays in spontaneous labor and delivery often necessitate a management plan that may include labor induction to reduce the risks associated with delayed birth. Beyond 28 weeks, inducing labor is crucial to mitigate the risks of psychological distress, sepsis, intrauterine infections, disseminated intravascular

coagulation (DIC), and an increased risk of consumptive coagulopathy.[1]

While there are various safe and effective medical and surgical interventions available for pregnancies under 28 weeks, labor induction beyond this point primarily involves medical methods. The combination of mifepristone and misoprostol is the preferred choice. Fetal death beyond 28 weeks is termed "intrauterine fetal demise" (IUFD). In roughly 25 to 35% of cases, the cause remains unknown, although maternal, placental, and fetal factors are known contributors.[2]

Spontaneous expulsion of the fetus occurs in approximately 80% of IUFD cases within three weeks. However, when fetal retention within the uterus occurs, it can lead to severe complications, including infections, DIC, and psychological distress.[3]

Mifepristone, also known as RU-486, was discovered in 1981 and has high affinities for progesterone receptors (PR), estrogen receptors (ER), and androgen receptors. It's commonly used in combination with prostaglandins for medical abortion.[4]

The pharmacokinetics of RU-486 post-oral administration involves rapid absorption, peaking at about one hour. RU-486 serum levels remain within the micromolar range for the next 24-48 hours, with detectable concentrations persisting up to day 10 after a 200 mg dose. RU-486 does not significantly affect the concentrations of other hormones in maternal or fetal circulation.[5] RU-486 sensitizes the myometrium to subsequent prostaglandin application and facilitates cervical ripening, making it valuable in scenarios like second-trimester abortion, labor induction at term or post-term, and cervical preparation for IUFD cases. It enhances cervical dilation and reduces mechanical resistance with fewer side effects compared to other methods.[4]

In contrast, misoprostol, a synthetic prostaglandin E1 analogue, is used for various medical purposes, including abortion and labor induction. It can be administered through different routes, with the mean time required for uterine tone increase shorter for oral and sublingual administration than for vaginal administration. Misoprostol use is associated with side effects, such as chills and hyperpyrexia, with a risk of uterine rupture, particularly in certain patient groups.

Given the potential benefits of mifepristone, this study explores its use for labor induction in IUFD cases. Mifepristone is not an oxytocic and doesn't lead to overstimulation of the uterus or the side effects seen with misoprostol.

This study aimed to compare the efficacy of two labor induction methods, mifepristone alone and mifepristone followed by misoprostol, in cases of intrauterine fetal demise (IUFD) beyond 28 weeks of gestation.

METHODS

The study was conducted at the labor room of BRD Medical College in Gorakhpur and aimed to investigate the efficacy of two different methods for labor induction in pregnancies with intrauterine fetal demise (IUFD) beyond 28 weeks of gestation. It was designed as a randomized controlled trial and took place over a one-year period, running from September 2019 to August 2020. The research involved a total of 60 participants, with an equal distribution into two study groups.

Inclusion criteria

Inclusion criteria encompassed women with confirmed singleton pregnancies experiencing IUFD or severe congenital malformations requiring pregnancy termination. These pregnancies had to be at or beyond 28 weeks of gestation, and the women needed to provide informed written consent for labor induction.

Exclusion criteria

Exclusion criteria involved the exclusion of women who did not provide consent, those with previous cesarean scars or other uterine scarring, and patients contraindicated for vaginal delivery. Also excluded were cases of multiple pregnancies with only one baby experiencing IUFD, women with hypersensitivity to mifepristone or misoprostol, and individuals with specific medical conditions such as renal impairment, chronic adrenal failure, or porphyrias.

The allocation of participants into the two groups was randomized using a block randomization method. The research was not blinded, meaning both the participants and researchers were aware of the group assignments. The two study groups were as follows:

Group 1: Women in this group received 200 mg of Mifepristone orally every 8 hours for a total of 48 hours. Group 2: Women in this group were administered 200 mg of Mifepristone orally, followed by vaginal administration of Misoprostol at a dosage of 50-100 mcg, repeated every 4 hours.

The study collected data on various aspects of labor induction, including Bishop's score before and after 12 hours of mifepristone administration, the induction to active labor interval, and the outcomes of labor induction. These outcomes included the method of delivery, which could be vaginal, instrumental, or via cesarean section. The research design adhered to high ethical standards and received clearance from the institutional committee of BRD Medical College, Gorakhpur.

RESULTS

In terms of demographics, Group 1 and Group 2 displayed similar characteristics. The majority of patients in both

groups were aged 20-25 years (60% in Group 1 and 63.33% in Group 2), with average ages of 25.62 years and 25.20 years, respectively. Parity distribution also showed resemblance, with primigravida patients comprising 36.66% in Group 1 and 53.33% in Group 2. There were no notable differences in socioeconomic status between the two groups, indicating comparable demographic profiles (Table 1).

Table 1: Demographics, parity, gravidity, and socioeconomic status comparison.

Characteristic	Group 1 (%)	Group 2 (%)
Demographics		
Age (years)		
<20	0	0
20-25	18 (60)	19 (63.33)
26-30	11 (36.6)	7 (23.33)
31-35	1 (3.33)	3 (10)
>35-40	0	1 (3.33)
Avg age (± SD)	25.62±3.08	25.20±4.42
Parity		
Primi	11 (36.66)	16 (53.33)
Gravida 2	8 (26.66)	6 (20)
Gravida 3	8 (26.66)	3 (10)
Gravida 4	2 (6.66)	0
Gravida 5	1 (3.33)	4 (13.33)
>G5	0	1 (3.33)
Mean gravidity (±SD)	2.13±1.10	2.13±1.65
Socioeconomic status		
Upper	0	0
Upper middle	1 (3.33)	1 (3.33)
Lower middle	9 (30)	7 (23.33)
Upper lower	8 (26.66)	7 (23.33)
Lower	12 (40)	15 (50)

The two groups, Group 1 and Group 2, showed similar characteristics in various aspects. Regarding the literacy rate, around 56.66% of patients in Group 1 were literate compared to 50% in Group 2. Gestational age at induction was also comparable between the groups, with the majority falling within 34-38 weeks. In terms of medical history and obstetric complications, no significant disparities were observed. Similarly, Bishop scores on admission and after 12 hours, as well as induction to active labor intervals, displayed no significant differences between the groups. These findings suggest overall similarity in patient characteristics and responses in both groups (Table 2).

Group 1 and Group 2 differed significantly in several induction-related parameters. The induction to active labor interval was notably shorter in Group 1 (11.55±5.34 hours) compared to Group 2 (18.44±6.38 hours). However, the induction to delivery interval was similar for both groups, with Group 1 at 18.44±6.38 hours and Group 2 at 18.10±5.72 hours. The number of mifepristone tablets used differed significantly, with more patients in Group 2 requiring 3 tablets (40%) compared to Group 1 (33.33%). Chi-square tests were performed for these parameters and yielded values of 13.63 and 9.632, respectively. Additionally, both groups displayed a similar rate of failed induction, with 3.33% in each group (Table 3).

Table 2: Summary of patient characteristics and outcomes.

Characteristic	Group 1 (%)	Group 2 (%)
Literacy rate		
Literate	17 (56.66)	15 (50)
Illiterate	13 (43.33)	15 (50)
Gestational age at induction		
28-30 wks	6 (20)	7 (23.33)
31-33 wks	9 (30)	3 (10)
34-38 wks	10 (33.33)	13 (43.33)
39-40 wks	4 (13.33)	5 (16.66)
>40 wks	1 (3.33)	2 (6.66)
Avg gestational age (wks, ± SD)	34.36±4.02	34.9±4.42
Medical history		
Heart disease	1 (3.33)	2 (6.66)
Anemia	4 (13.33)	1 (3.33)
Pulmonary edema	2 (6.66)	1 (3.33)
Jaundice	2 (6.66)	1 (3.33)
Hypothyroidism	1 (3.33)	0
None	5 (16.66)	16 (53.33)
Obstetric complications		
Severe oligohydramnios	3 (10)	3 (10)
Abruption	7 (23.33)	1 (3.33)
Preeclampsia	3 (10)	4 (13.33)
GDM	2 (6.66)	1 (3.33)
Bishop score on admission		
0-2	18 (60)	16 (53.33)
3-5	12 (40)	14 (46.66)
6	0	0
Mean Bishop score (± SD)	2.26±0.98	2.46±0.50
Bishop score after 12 hours		
0-4	3	2
5-8	19	23
>8	0	0
Already delivered	7	4
Mean Bishop score (±SD)	5.39±1.1	5.53±0.62
Induction to active labor interval		
0-8	11 (36.66)	9 (30)
9-16	14 (46.66)	19 (63.33)
17-24	4 (13.33)	1 (3.33)
Mean induction to active labor interval (±SD)	11.55±5.34	10.76±4.26

Table 3: Comparison of induction and medication usage.

Characteristic	Group 1 (%)	Group 2 (%)
Induction to active labor interval (hrs.)	11.55±5.34	18.44±6.38
Induction to delivery interval (hrs.)	18.44±6.38	18.10±5.72
Number of mifepristone tablets		
1 Tablet	6 (20)	1 (3.33)
2 Tablets	8 (26.66)	6 (20)
3 Tablets	10 (33.33)	12 (40)
4 Tablets	5 (16.66)	6 (20)
5 Tablets	0	3 (10)
6 Tablets	1 (3.33)	1 (3.33)
Chi square test	13.63	9.632
Failed induction	1 (3.33)	1 (3.33)

Table 4: Summary of induction, augmentation, side effects, complications, and time to full dilatation.

Characteristic	Group 1 (%)	Group 2 (%)	p-value
Methods of augmentation			
Oxytocin	8 (26.66)	14 (46.66)	0.03*
ARM (artificial rupture of membranes)	3 (10)	5 (16.66)	0.061*
None	19 (63.33)	11 (36.66)	0.04*
Side effects			
Diarrhea	1 (3.33)	3 (10)	0.51
Fever	0	2 (6.66)	1.03
Shivering	1 (3.33)	3 (10)	0.51
None	28 (93.33)	22 (73.33)	-
Complications			
PPH (postpartum hemorrhage)	3 (1)	7 (23.33)	1.127
Retained placenta	0	0	0
Uterine hyperstimulation	0	1 (3.33)	1.06
Uterine rupture	0	0	0
Maternal death	0	0	0
None	27 (90)	22 (73.33)	-
Time to full dilatation (hours)			
0-5 hours	14 (46.66)	13 (43.33)	0.071*
6-10 hours	12 (40)	12 (40)	-
11-15 hours	2 (6.66)	2 (6.66)	-
16-20 hours	1 (3.33)	2 (6.66)	-
Mean time to full dilatation (±SD)	6.86±3.48	7.03±4.52	-

Note: p-values marked with '*' indicate statistical significance

The data compares various characteristics and outcomes between two groups, Group 1 and Group 2. Group 1 had a slightly higher literacy rate, while Group 2 had a more diverse gestational age at induction. Medical history and obstetric complications varied between the groups. The Bishop score and induction to active labor intervals were similar, while Group 2 had a shorter induction to delivery interval. Group 1 required fewer mifepristone tablets. Finally, methods of augmentation, side effects, complications, and the time to full dilatation were analyzed, revealing some differences between the two groups, with statistical significance noted for specific parameters (Table 4).

DISCUSSION

In the realm of obstetrics, the quest for innovative labor induction methods is a persistent research focus. The study under discussion sought to explore the efficacy of mifepristone, an antiprogesterone drug, as a means of inducing labor and terminating pregnancies. This investigation divided 60 patients into two groups, each comprising 30 individuals. Below is a comprehensive summary of the key findings and implications of this study, along with references to prior research. The study's analysis of patient demographics revealed that the two groups shared similar age distributions. Most patients in both groups fell within the 20-25 age range, and statistical analysis indicated that maternal age did not exert a significant influence on the study's outcomes. This finding concurred with those from earlier research, such as Yelikar et al (22.96 versus 23yrs, p value>0.05) study, which reported analogous results.[6]

Parity distribution among the patients in Group 1 (36.66%) and Group 2 (53.33%) was essentially the same, with statistically insignificant differences. The mean gravidity also exhibited striking similarity between the two groups. These findings align with those of Yelikar et al (1.48±0.64 versus 1.62±0.44, p value= 0.659) and Oleg et al (28.72±4.89 versus 28.07±4.27, p>0.05), who reported analogous parity distributions and mean gravidity figures.[6,3]

Both groups had a high percentage of patients from lower socioeconomic backgrounds (40% versus 50%), and socioeconomic status exhibited no discernible correlation with group assignment. In terms of literacy, a similar percentage (56.66% versus 50%) of patients in both groups were literate, further underlining the lack of a significant effect of literacy on the study's outcomes. Unfortunately, no available studies could be found for a comparative analysis of socioeconomic status and literacy among the patients.

The gestational age at the onset of induction displayed no significant impact on the study's outcomes. Most patients in both groups (33.33% versus 43.33%) had gestational ages ranging from 34 to 38 weeks, and the mean gestational age in both the groups were (34.36±4.02 versus 34.9±4.42, p value>0.05) remarkably similar. These results were consistent with those reported by Damyanti et al (2012) but not with studies conducted by Yelikar et al

(2018) and Oleg et al (2015) which showed varying gestational ages at induction.[8,6,3]

The majority of patients in both groups (60% versus 53.33%) had initial Bishop scores falling within the 0-2 range, with the rest (40% and 46.66%) having scores of 3-5. While both groups exhibited significant improvements in Bishop scores, the mean scores after 12 hours (5.39±1.10 versus 5.53±0.62) were comparable. The study findings were in line with those of Athawale et al and Yelikar et al, who reported improved Bishop scores after mifepristone administration.[21,6]

The induction to active labor interval was comparable between the two groups (11.55±5.34 hours and 10.76±4.26 hours), with a slight non-significant deviation favoring the combination group. This finding contrasted with those of Yelikar et al (2018), who found statistically significant differences in induction to active labor intervals between mifepristone (approx. 26 hours) and placebo groups (29 hours).[6]

The mean induction to delivery intervals was akin in both groups, with a non-significant slight favor towards the combination group. Notably, when calculated for each group separately, these intervals were statistically significant. Both groups exhibited significant changes in induction to delivery intervals, indicating their effectiveness. These results mirrored those of previous studies conducted by Athawale et al (2009), Ahuja et al (2017), and Berkane et al (2005) which noted significant changes in Bishop scores and early deliveries after mifepristone administration.[21,19,17]

Both groups displayed a reduced need for augmentation methods, such as oxytocin and artificial rupture of membranes. A substantial percentage of patients in both groups delivered vaginally within 17 to 24 hours. Cesarean section rates were comparable between the two groups. This reduced requirement for cesarean sections aligns with the findings of Wing et al (2001).[7]

Both groups presented minimal side effects, with slightly fewer occurrences in the mifepristone group. Complications following drug delivery were minimal, including postpartum hemorrhage and uterine hyperstimulation. This is consistent with reports from Berkane et al (2005), Ahuja et al (2017), and Yelikar et al (2018) which all indicated fewer side effects and complications with mifepristone.[17,19,6]

This study has some limitations. The relatively small sample size, potentially impacting the generalizability of findings. Non- blinding introduces the potential for bias in outcome assessment. While socioeconomic factors were considered, the study did not extensively explore their nuances. Long- term follow-up data were lacking, limiting a comprehensive understanding of outcomes beyond immediate delivery. The study's scope primarily focused on the immediate labor induction period, leaving questions about postpartum and neonatal outcomes unanswered. Additionally, the exclusion of certain patient groups, such as those with specific medical conditions, may limit the applicability of findings to a broader population. These limitations highlight areas for consideration in the interpretation and application of the study's results.

CONCLUSION

In this study, 60 women with pregnancies complicated by intrauterine fetal demise were divided into two groups. The first group received mifepristone alone, while the second group received mifepristone followed by misoprostol. Most participants were between 20-25 years old and had lower socioeconomic status. Parity distributions were different between the groups but not statistically significant. Gestational ages ranged from 34-38 weeks, and both groups showed significant improvements in Bishop scores after 12 hours. The induction to active labor interval and the induction to delivery interval were similar between the groups, indicating their comparable effectiveness. The mifepristone group often succeeded with three tablets, and the combination group required fewer misoprostol tablets, reducing side effects. Mifepristone's ability to soften the cervix and enhance prostaglandin sensitivity makes it a promising option for labor induction, especially in cases of previously scarred uteri. Further research with larger sample sizes is needed for conclusive results.

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