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Original Research Article

Induction of labour in pregnancies with fetal demise: a randomised control trial

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ABSTRACT

Background: The present study aims at comparing efficacy and safety of two different regimens of induction of labour (IOL) in pregnancies with fetal demise.
Methods: A randomised controlled trial was conducted on 100 eligible pregnant women diagnosed with intrauterine fetal demise who were admitted in the labour ward of a tertiary care hospital.
Results: All participants were randomly divided into two groups in group A and group B. In Group A, IOL was done with transcervical Foley's catheter and vaginal misoprostol while in group B, mifepristone with vaginal misoprostol were used for IOL. During intrapartum period the mode of delivery, induction-delivery interval, total dose of induction agent used and amount of total blood loss were noted. Any side effect if present was also noted.
Conclusions: Comparing both the groups, Induction delivery interval was less in group A as compared to group B.

Keywords: Induction of labour, IUFD, Mifepristone, Misoprostol, Transcervical Foley's catheter

INTRODUCTION

Intrauterine fetal death is one of the most devastating obstetrics complications. Due to development of consumptive coagulopathy and other complication medical induction is recommended. IOL is higher in developed countries than in developing countries.[1] WHO has now recommended IUFD as a baby born with no sign of life at or after 28 weeks of gestation.[2] In India, MTP is allowed up to 24 weeks of pregnancy.[3] In this study, we have included pregnancies >24 weeks with documented IUFD and tried to evaluate comparative efficacy and safety of the two different regimes of IOL.

METHODS

A prospective, interventional randomized comparative study was conducted on 100 eligible pregnant women diagnosed with intrauterine fetal death after 24 weeks of gestation who were admitted in the labour ward and study conducted over a period of one year (January 2022 to December 2022).

The study was conducted primarily on 105 pregnant women diagnosed with intrauterine fetal death who were admitted in the labour ward. Five mothers were excluded from the study due to refusal of enrolment. Finally, a total of 100 pregnant women were randomly allocated into two groups.

Participants were briefed about the nature of the study and explained about the possible risks (if any) and the benefits of the study. After proper counselling and informed consent, all the selected participants were subjected to detailed history-taking, physical and obstetrical examination including Bishop's score.

Inclusion criteria

Inclusion criteria were women with gestational age of >24 weeks with IUFD who were willing to give written informed consent were recruited in this study.

Exclusion criteria

Exclusion criteria were pregnant women with multiple pregnancies, grand multipara, those having any contraindication for IOL (previous scar on uterus, any coagulation failure, placenta previa) were excluded. Patients with any other associated medical condition or disease which contraindicates the use of mifepristone like Adrenal insufficiency, severe anaemia, liver disease, hypertension, bronchial asthma, heart disease were also excluded.

For the induction of labour, Group A received transcervical foley catheter with vaginal misoprostol. The dose of vaginal misoprostol was 100mcg for 24-26 weeks and 50mcg for gestational age >26 weeks.[5] Women in group B received oral mifepristone with vaginal misoprostol. Mifepristone 200mg was administered on the first day and after 24 hours, vaginal misoprostol was given every 4 hourly. During intrapartum period, maternal vitals were monitored, antibiotic coverage were given and occurrence of any side effect like nausea, vomiting, diarrhea were observed. Induction-delivery interval time was noted and also need for surgical intervention was noted. Visual analogue scale (VAS) was used for assessment of pain intensity. Where 0=no pain, 1-3=mild, 4-6=moderate, 7-10=severe.[6] Successful induction was defined as normal vaginal delivery within 24 hours of IOL. If the fetus was undelivered in 24 hours, it was treated as failure.

Primary outcomes measured were the rate of successful delivery in 24 hours, induction delivery interval and need for surgical intervention. Secondary outcomes measured were amount of blood loss, need for blood transfusion and adverse effects related to drugs.

Sample size calculation

Proportion of IUFD pregnancy was 6.3% among deliveries conducted at hospital during 2019 (1 year).[4] With absolute error of 5%, power 80%, at 95% confidence level the minimum sample size were 100. Minimum sample of 100 IUFD pregnancy were taken and divided into two equal sample were 50 for each group.

Statistical analysis

Data was analysed using Medcalc 12.5. Software. Comparison of categorical variables were done using chi-square test. Differences were considered as statistically significant with a p-value <0.05.

RESULTS

The following are the tables and graphs which gives us the descriptive analysis of 100 patients in the study according to the distribution, age, parity, mode of delivery, induction-delivery interval, amount of blood loss, need for blood transfusion and side effect.

Table 1: Demographic distribution among participants.

Variables	Group A (%)	Group B (%)	P value
Age (Years)	25.2±4.3	24.74±3.9	0.56
PRIMI	24 (48)	27 (54)	
MULTI	26(52)	23(46)	
Gestational age (weeks)	32.96±4.3	32.88±4.0	0.92
BMI (Kg/m^2)	22.9±2.1	23.51±1.9	0.14

Table 1 show that study mean age of the participants was 25 years. Out of 100 participants, 51 participants were primigravida and 49 participants were multigravida. The mean gestational age was 32 weeks in both groups. The mean body mass index in both the groups was 23.2 kg/m^2.

Table 2: Participants distribution according to data of induction of labour.

Bishop's score	Group A (%)	Group B (%)	P value
≥3	32 (64)	37 (74)	0.28
<3	18 (36)	13 (26)	
Dose of misoprostol			
≤2	11 (22)	13 (26)	0.22
>2	39 (78)	37 (74)	

Table 2 show that the pre induction bishops score, group A had ≥3 score in 32 participants and <3 score in 18 participants. While in group B ≥3 score was seen in 37 participants and <3 score in 13 participants where 24% participants required ≤ 2 doses of misoprostol while 76% required > 2 doses.

Table 3: Maternal outcome.

Mode of delivery	Group A (%)	Group B (%)	P value
Normal delivery	43 (86)	46 (92)	0.34
LSCS	7 (14)	4 (8)	
Mean induction delivery interval (in hours)	13.2	15.8	0.003

Table 3 show that 92% of participants in group B delivered vaginally compared to 86% in group A. while other 14% participants had undergone caesarean section in group A as compared to 8% in the group B. Mean duration of induction delivery interval was found to be 13.2 hours in

group A compared to 15.8 hours in group B which was statistically significant.

Table 4 show that in group A < 500 ml blood loss was seen in 92% participants and >500 ml blood loss in 8% participants while in group B <500 ml blood loss in 94% participants and >500 ml blood loss in 6% participants was noted. Out of 100 participants 7 participants were required blood transfusion. Pain, nausea and vomiting were more common in group A.

Table 4: Blood loss, blood transfusion and side effect.

Blood loss	Group A (%)	Group B (%)	P value
<500 ml	46 (92)	47 (94)	0.69
≥500 ml	4 (8)	3 (6)	
Blood transfusion			
Yes	4 (8)	3 (6)	0.69
No	46 (92)	47 (94)	
Side effect			
Yes	8 (16)	5 (10)	0.37
No	42 (84)	45 (90)	

DISCUSSION

This prospective randomized study was conducted in the tertiary hospital among 100 eligible participants having >24 weeks of pregnancy with intrauterine foetal death. All of them were randomized into two groups and scheduled for induction of labour.

In present study mean age of the participants was 25 years. Out of 100 participants, 51 participants were primigravida and 49 participants were multigravida. The mean gestational age was 32 weeks in both groups. The mean body mass index in both the groups was 23.2 kg/m^2. In this prospective study participants in both groups were comparable with respect to age, parity, gestational age and BMI.

While comparing two study groups with pre induction bishop‟s score, group A had ≥3 score in 32 participants and <3 score in 18 participants. While in group B ≥3 score was seen in 37 participants and <3 score in 13 participants. Similar results were reported by Athawale et al in 2013.[7]

For IOL, 24% participants required ≤2 doses of misoprostol while 76% required >2 doses. Similar results were found in a study by Fonseca et al. [8]

There were 92% of participants in group B delivered vaginally compared to 86% in group A. while other 14% participants had undergone caesarean section in group A as compared to 8% in the group B. Similar results were found in other study.[8-11]

Mean duration of induction delivery interval was found to be 13.2 hours in group A compared to 15.8 hours in group B which was statistically significant. Similar results found in other study.[8-13]

In group A <500ml blood loss was seen in 92% participants and >500ml blood loss in 8% participants while in group B <500 ml blood loss in 94% participants and >500ml blood loss in 6% participants was noted. Out of 100 participants 7 participants were required blood transfusion. Similar findings were observed by Rezk et al in 2015.[14]

Pain, nausea and vomiting were more common in Group A, present in 100% and 12% respectively in Group A. Pain, nausea and vomiting were present in 100%, and 10% respectively in Group B. Similar results were observed by other study.[9,15]

This is one of the first studies to describe effect of IOL on pregnancies more than 24 weeks of pregnancy. Study was conducted by randomisation so allocation bias not seen in this study. Entire study was conducted by one observer, so inter-observer bias was minimised. Being a hospital-based study conducted in small sample size, the results cannot be extrapolated to the general population. Further large-scale, multi-centre randomized studies are needed before recommending these regimes for management IOL in pregnancies more than 24 weeks with IUFD.

CONCLUSION

We conclude that trascervical Foley's catheter with misoprostol was better than mifepristone with misoprostol for terminating pregnancies with fetal demise.

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Ethical approval: The study was approved by the Institutional Ethics Committee of Medical College and SSG Hospital Baroda, India (IECBHR/066-2022)

REFERENCES

1. Lydon-Rochelle MT, Cárdenas V, Nelson JC, Holt VL, Gardella C, Easterling TR. Induction of labor in the absence of standard medical indications: incidence and correlates. Medical care. 2007:505-12.
2. World Health Organization. Seventy-first world health assembly global strategy for women's, children's and adolescents' health (2016-2030): early childhood development status of women's, children's and adolescents' health, 2018. Available at: http://www.geastudy.org/. Accessed 06 January 2023.
3. Centre for Reproductive Rights. Factsheet: the medical termination of pregnancy (amendment) act, 2021. Available at: https://reproductiverights.org/wp-content/uploads/2022/09/India-FACTSHEET-MTP-Amendment-Act-9-22.pdf. Accessed 05 January 2023.
4. Tai NN, Mulchandani R, Modi DA, Rami B. A prospective study of intrauterine death cases at a

tertiary care hospital. Int J Reprod Contracept Obstet Gynecol. 2021;10(2):638.
5. FIGO. New FIGO Guidelines for Misoprostol Use, 2017. https://www.mhtf.org/2017/06/29/new-figo-guidelines-for-misoprostol-use. Accessed on 29 December 2022.
6. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual analog scale for pain (vas pain), numeric rating scale for pain (nrs pain), mcgill pain questionnaire (mpq), short-form mcgill pain questionnaire (sf-mpq), chronic pain grade scale (cpgs), short form-36 bodily pain scale (sf-36 bps), and measure of intermittent and constant osteoarthritis pain (icoap). Arthr Car Res. 2011;63(S11):S240-52.
7. Athawale R, Acharya N, Samal S, Hariharan C. Effect of mifepristone in cervical ripening for induction of labour. Int J Reprod Contracept Obstet Gynecol. 2013;2(1):35-8.
8. Fonseca MN, Sah V. Comparative study between sequential use of Foley catheter with vaginal misoprostol versus sequential use of oral mifepristone with vaginal misoprostol for second trimester medical abortion. Inter J Reprod Contracep Obstet Gynecol. 2018;7(11):4545-51.
9. Bhathena RK, Sheriar NK, Walvekar VR, Guillebaud J. Second trimester pregnancy termination using extraamniotic ethacridine lactate. BJOG: An Inter J Obstet Gynaecol. 1990;97(11):1026-9.
10. Bebbington MW, Kent N, Lim K, Gagnon A, Delisle MF, Tessier F, et al. A randomized controlled trial comparing two protocols for the use of misoprostol in midtrimester pregnancy termination. Ame J Obstet Gynecol. 2002;187(4):853-7.
11. Panda S, Jha V, Singh S. Role of combination of mifepristone and misoprostol verses misoprostol alone in induction of labour in late intrauterin fetal death: A prospective study. J Fam Reprod Heal. 2013;7(4):177.
12. Väyrynen W, Heikinheimo O, Nuutila M. Misoprostol-only versus mifepristone plus misoprostol in induction of labor following intrauterine fetal death. Acta obstetricia et gynecologica Scandinavica. 2007;86(6):701-5.
13. Modak R, Roy S, Biswas DK, Pal A, Mandal TK. Role of combination of mifepristone and misoprostol versus misoprostol alone in induction of labor in late intrauterine fetal death: A randomized trial. Int J Clin Obstetr Gynaecol. 2018;2:78-82.
14. Rezk MA, Abo-Elnasr M, Al-Halaby A. Combined use of intracervical foley catheter and vaginal misoprostol for termination of second trimester pregnancy: Clinical Obst. Gyn and Reprod Med. 2015;1(3):79-83.
15. Ranjan S, Sarojini A, Mohapatra I, Vivekanand A, Ranjan S. Comparison of intravaginal misoprostol alone and in combination with intracervical Foley's catheter for termination of second trimes-ter pregnancy-3 years study at a tertiary care hospital. Perspect Med Res. 2016;4:3-8.

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