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Original Research Article

Efficacy and safety of mifepristone as a sole induction agent in intrauterine fetal demise in scarred and unscarred uterus

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ABSTRACT

Background: Termination of pregnancy in the second and third trimester due to intrauterine fetal demise (IUFD) or lethal fetal anomalies requires safe and effective methods of induction of labour. Mifepristone, an antiprogestin, has been used for cervical ripening and labour induction. This study aimed to evaluate the efficacy and safety of mifepristone as a sole agent for induction of labour in pregnancies beyond 20 weeks of gestation in women with both scarred and unscarred uterus.

Methods: This prospective clinical study was conducted in the Department of Obstetrics and Gynaecology at Shaheed Hasan Khan Mewati Government Medical College, Nalhar, Haryana over a period of one year after approval from the institutional ethics committee. A total of 54 antenatal women with gestational age >20 weeks requiring termination due to intrauterine fetal demise, lethal fetal malformation or PPROM were included. Tablet mifepristone 200 mg was administered orally at 12-hour intervals for a maximum of three doses. Patients were monitored for onset of labour and delivery. Primary outcome measured was successful vaginal delivery following induction with mifepristone alone. Secondary outcomes included induction-delivery interval, requirement of additional uterotonics and maternal complications.

Results: Most patients belonged to the age group of 18–24 years (48.14%), and the majority were multiparous. Scarred uterus was present in 24.07% of cases while 75.93% had unscarred uterus. A total of 87.04% of women delivered within 72 hours of the first dose of mifepristone without the need for additional uterotonics. Additional induction methods such as misoprostol or intracervical Foley's catheter were required in 12.96% of cases. The majority of patients (59.25%) delivered between 24–72 hours following the first dose of mifepristone. No cases of uterine rupture, scar dehiscence, retained products of conception, or requirement of caesarean section or hysterotomy were observed.

Conclusions: Mifepristone is an effective and safe agent for induction of labour in pregnancies beyond 20 weeks with intrauterine fetal demise or lethal fetal anomalies in both scarred and unscarred uterus. Its use is associated with a high rate of successful vaginal delivery with minimal maternal complications.

Keywords: Mifepristone, Induction of labour, Intrauterine fetal demise, Scarred uterus, Second trimester termination

INTRODUCTION

The importance of safe induction of labour cannot be emphasized enough in obstetrics. With the emergence of better diagnostic techniques and earlier detection of congenital malformations and intrauterine fetal demise, the frequency and need for induction of labour is increasing. India continues to bear a substantial burden of stillbirths and intrauterine fetal deaths. Recent national estimates suggest a stillbirth rate of approximately 14.7 per 1,000 total births. Such cases often require induction of labour, particularly in the second and third trimester, when

expectant management may increase the risk of infection, coagulopathy, psychological distress, and maternal complications.[1]

We have guidelines, recommendations and various studies regarding the use of different agents and modalities for induction of labour. Management of termination involves inducing labour and a safe delivery with minimal complications. Mifepristone (RU 486) is a steroidal antiprogestin which is orally active and has a long half-life of 25 to 30 hours. It acts by competing with progesterone for receptor binding.[2] It increases uterine activity and causes cervical effacement and dilatation for pregnancy termination. Few studies suggest that enzyme prostaglandin dehydrogenase, which is the main inactivating enzyme for prostaglandins, is under progesterone control. Hence antiprogestins like mifepristone may have a role to increase the prostaglandin concentration within the tissue.[3,4] Given these benefits this study explores the use of mifepristone as the sole inducing agent in women with period of gestation more than 20weeks for fetal demise, lethal fetal anomalies Ours is a tertiary care center in a remote, rural area. Most of the patients who present to us are multiparous with associated conditions like moderate to severe anaemia. Other concern is the increasing prevalence of patients with scarred uterus owing to increasing caesarean section rates. Aim of this study is to evaluate the role of mifepristone as the only agent to induce labour in pregnancies at gestation >20 weeks in both scarred as well as unscarred uterus.

METHODS

The study was a prospective clinical study, conducted in the Department of obstetrics and gynaecology at SHKM Medical College, Nalhar, Haryana for 1 year after approval from institutional ethics committee. Study comprised of 54 antenatal women at gestational age greater than 20 weeks requiring termination of pregnancy due to various reasons like intrauterine fetal demise, lethal fetal malformation and PPROM. These included patients with both scarred and unscarred uterus over a period of one year from October 2024 to September 2025.

Inclusion criteria

Singleton pregnancy, gestational age more than 20 weeks, absence of any features of labour (Bishop's score <6).

Exclusion criteria

Multiple pregnancy, sepsis, coagulation disorder, impaired renal or hepatic function. Detailed history, examination and investigations including complete blood count, liver function tests, renal function tests, coagulation profile, ultrasonography were done for all patients before starting treatment. After counselling and written informed consent tab mifepristone 200mg was given orally, 12 hrs apart. Total 3 doses were given over a period of 36 hours. Patients were monitored after last dose of mifepristone, for next 48 hours for vitals, contractions or bleeding, leaking per vaginum. If the labour did not start in 48 hours after the last dose, then additional prostaglandins or mechanical methods were started as per labour room protocol. Primary outcome was measured as onset of labour and vaginal delivery within 48 hours of last dose. Secondary outcomes were need for additional uterotonics, scar dehiscence or rupture and retained products of conception. Data was entered in an excel sheet and statistical analysis was carried out by the statistical software SPSS version 25.0.

RESULTS

Most of our patients were in the age group of 18-24 years (48.14%) with maximum cases falling in the parity of gravida 2- gravida 5(72.22%). 24.07% patients had scarred uterus and 75.93% had unscarred uterus. Majority of the patients were in second trimester with period of gestation, 20-28 weeks (37.03%) (Table 1). 44.44% of patients had mild anemia. Patients with moderate (18.51%) (5) and severe anemia (3.7%) were also induced after correction of anemia with blood transfusion.

Table 1: Distribution of women according to period of gestation.

POG (in weeks)	Scarred uterus	Unscarred uterus
20-28	3 (5.55%)	17 (31.48%)
>28-32	5 (9.25%)	9 (16.66%)
>32-37	4 (7.40%)	10 (18.51%)
>37	1 (1.85%)	5 (9.25%)

Table 2: Induction delivery interval.

Induction delivery interval (from first dose of mifepristone to delivery)	
<12 hours	5 (9.25%)
>12-<24 hours	10 (18.51%)
>24-<72 hours	32 (59.25%)
>72 hours	7 (12.96%)
Yes	0
No	54

Maximum patients (87.04%) delivered within 72 hours since the first dose of tab mifepristone (Table 2). Without any additional uterotonics (Table 3). 12.96% women required additional uterotonics in the form of tab misoprostol or intracervical foleys catheter (Table 3). Maternal outcome was satisfactory for 100% cases and no surgical intervention was required in the form of caesarean section or hysterotomy.

After 24 hours of delivery all the patients were screened for retained products of conception by sonography and there was no evidence of retained products in any case.

Table 3: Doses of mifepristone required for successful induction of labour and requirements of any additional uterotonics with adverse effects.

Doses of mifepristone required for IOL	
1	5 (9.25%)
2	10 (18.51%)
3	39 (72.22%)
Need of additional uterotonics for IOL	
Yes	5 (t. Misoprostol) 2 (intracervical Foleys catheter)
No	47 (87.03%)
Need for C-section\hysterotomy	

DISCUSSION

The initial studies using mifepristone to induce labour in 2nd and 3rd trimester were done in 1985 by Cabrol et al.[5] The pilot study was done on 11 women with IUFD at gestation greater than 18 weeks. Tab mifepristone 200mg was given twice daily for 2 days. Successful induction in 81% with mean induction delivery interval was 39+/-12.5 hours. This was followed by a placebo controlled multicentric study in 1990.[6] 48 pregnant females with IUFD at gestation more than 16 weeks were included in the study. Tab mifepristone 200mg was given thrice a day for two days. Success rate was 63%.

In 1992, another placebo-controlled trial was done by Frydmen et al in 120 pregnant females at gestation more than 37.5 weeks.[7] Tab mifepristone 200mg was given on day 1 and 2 of 4-day observation period. Out of these 41 subjects entered spontaneous labour in which 31 had mifepristone and 10 were in control group ($p<0.001$). They concluded mifepristone as a suitable agent for induction at term. In 1994, Leladier et al conducted a double-blind placebo-controlled trial on 32 pregnant females at gestation >37.5 days with previous caesarean section.[8] Tab mifepristone 200 mg was given on day 1 and 2 of 4-day observation period. Out of these 13 subjects passed into labour in which 11 had mifepristone and 2 were in control group ($p<0.01$). they concluded mifepristone to be a safe drug for induction at term with previous LSCS.

In 2009, Cochrane systemic review on mifepristone for induction of labour, ten trials (1108) were included. Hapangama et al found that mifepristone treated women were more likely to be in labour or to have a favorable cervix at 48 hours (risk ratio 2.41; 95% CI 1.96 to 5.92).[9] The authors concluded that mifepristone is better than placebo in reducing caesarean sections done for failed induction of labour. Therefore, more trials are required comparing mifepristone with other cervical ripening agents. Thereafter many studies have been done on the use of mifepristone as cervical ripening agent at term and comparing mifepristone with mifepristone plus misoprostol combination.[10-15] In a letter to the editor, a group of authors recently reported that they often use mifepristone 36hrs before misoprostol (200 mcg every 3 or 6 hrs) to induce the expulsion in non-viable pregnancies in the second and third trimester.[16]

In our study, we observed that mifepristone is associated with a favorable outcome. Out of 54 women, 41 delivered spontaneously without the need of additional uterotonic. The results were comparable to study by Arora et al the induction to delivery interval was calculated from first dose of mifepristone till delivery.[17] In our study 24.07% (13) patients had scarred uterus and 11.1% (6) women were at gestational age >37 weeks.

The induction was successful with mifepristone alone. Intracervical Foley's catheter induction and misoprostol were required in 2 and 5 cases respectively. These patients belonged to late second trimester. Intracervical foley's catheter induction was required in cases with previous LSCS i.e. 1 case of previous 2 LSCS and 1 case of previous 3 LSCS respectively. This varied among patients with maximum patients (59%) delivering between 24-72 hrs from first mifepristone dose. This difference could be due to difference in parity and gestational age of patients. Studies by Padayachi et al, Cabrol et al show similar results.[5-18]

There was no incidence of scar dehiscence or rupture in our study. None of the patients had retained products of conception and no patients required hysterotomy or cesarean section. Past studies by Padayachi et al and Cabrol et al have got similar results.[5-18]

In one case that we have not included in our study we have given extended doses of mifepristone (6 doses) and the patient went into labour that is also one area we can study for future references. The limitation of this study is the small sample size but it can provide a structure for further research in using mifepristone alone for induction of labour, more so in scarred uterus.

CONCLUSION

Mifepristone is an effective labour inducing agent in late second trimester and third trimester with fetal demise of lethal fetal anomalies in both scarred and unscarred uterus with reduced need for prostaglandins. The administration of drug is also safe without any increase in detrimental effects on mother.

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

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