

## Mechanical induction versus drug induction in termination of Pregnancy with IUFD in Tertiary Hospital

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**Abstract: Introduction:** Now-a-days oral mifepristone or oral misoprostol, oxytocin and surgical method or foley catheters these three are the common methods are use for termination of IUFD pregnancy. **Objective:** Our main objective was to estimate the effectiveness of mechanical induction versus drug induction in termination of pregnancy with IUFD. **Method:** This randomized clinical trial study was done at tertiary medical college and hospital from 2016 to 2018. During the study all patients were divided into two groups by simple lottery method. Group-I was the misoprostol group, where misoprostol vaginal tablet was used for cervical ripening. Group-II was Foley's catheter group, where cervical ripening was done by using intra cervical extra amniotic Foley's catheter. Group-III oxytocin, Group-IV combined method drug and Foley catheter.

**Results:** Combination of balloon catheter PG, Oxytocin showed better result than only PGE<sub>1</sub> & or PGE<sub>2</sub>.

**Conclusion:** To arrive at a definite conclusion, it is suggested that a long-term study with larger number of subjects need to be carried out to make a plan of action in the selection of method of induction of labour for pregnant women.

**Keywords:** IUFD, Misoprostol, Foley catheters.

### I. Introduction

Intrauterine fetal death (IUFD) is defined by as fetal death at 28 weeks gestation or later in south Asian countries and 22 weeks or more in outside the world which indicates no fetal heartbeat detected after 28 weeks gestation, while missed abortion states to the event occurring prior to 28 weeks gestation. Intrauterine fetal death is also termed stillbirth, which means that after induction of labor, a fetus without spontaneous breath, heartbeat, or movement was delivered. The total number of global stillbirths is 3.2 million annually. The prevalence of intrauterine fetal death differs from 5–32/1000 between nations; stillbirth rates in developing countries are higher than in developed countries. These consequences may represent different levels of healthcare among district, geographically-defined communities between countries.

For pregnancies of gestational age between 12-14 weeks in case of abortion, the World Health Organization recommends the following medications for termination of IUFD pregnancy: oral mifepristone or oral misoprostol or combination of both, when mifepristone is not available and Surgical abortion via manual vacuum aspiration or intra cervical Foley catheter is an alternative option recommended by WHO for pregnancies up to 12-14 weeks in gestational age . But now a days these methods are also used in later weeks of pregnancy for induction of labour.

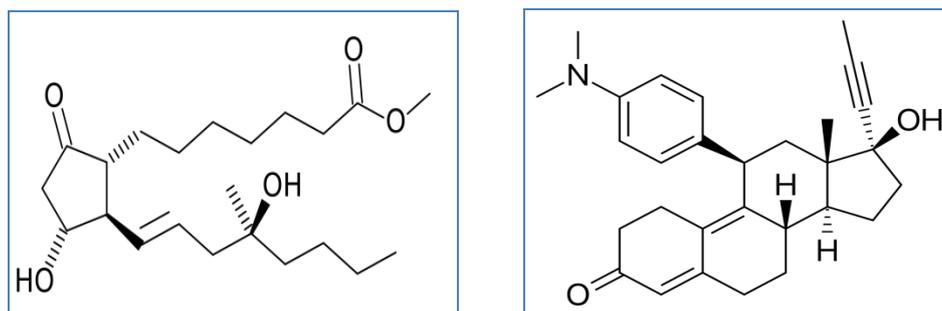
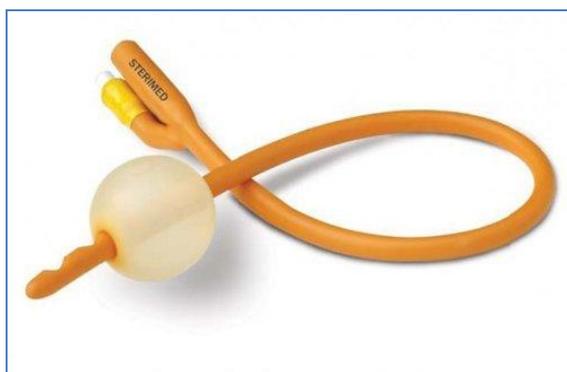


Figure-1a and 1b: molecular structure mifepristone and misoprostol

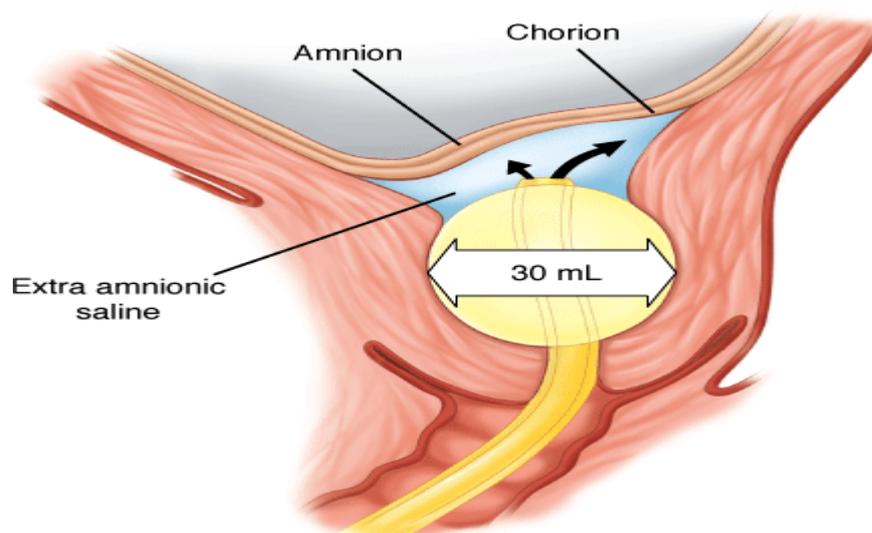
Mifepristone is a 19 nor-steroid which has greater affinity for progesterone receptors than does progesterone itself. It thus blocks the action of progesterone at the cellular level. The pharmacokinetics of mifepristone are characterized by rapid absorption and a long half-life of 25 to 30 hours. Key metabolites also have high affinity to progesterone receptors. Mifepristone now has an established role in termination of pregnancy (in combination with prostaglandins) during the early first, and the second trimesters. Mifepristone is also being investigated as a possible contraceptive agent. Misoprostol is a PGE1 analogue that was originally approved for the prevention and treatment of peptic ulcers because of its anti gastric acid secretory properties and its various mucosal protective properties. It can be administered via several routes including oral, buccal, sublingual, vaginal and rectal. Once administered, it rapidly de-esterifies to its active form, misoprostolic acid. This is 85% albumin-bound and has a half-life of approximately 30 minutes. It is excreted in urine as inactive metabolites. The combination of mifepristone and misoprostol in the management of intrauterine fetal death is one of the major advances in modern clinical practice, with safety and efficacy. A standard Foley catheter or a proprietary Cook cervicalripening balloon are the most commonly used mechanical methods of cervical ripening for the induction of labour. Because of the risks associated with pharmacological agents, the use of mechanical methods is on the rise in women with a previous caesarean section and other uterine scars. Foley catheter is a flexible tube that passes through the urethra and into the bladder to drain urine. It is the most common type of indwelling urinary catheter. The tube has two separated channels or lumens running down its length. <sup>[1]</sup>



**Figure-2: Foley catheter**

One lumen, open at both ends, drains urine into a collection bag. The other has a valve on the outside end and connects to a balloon at the inside tip. The balloon is inflated with sterile water when it lies inside the bladder to stop it from slipping out.<sup>[2]</sup> In this study our main objective is to evaluate the effectiveness of mechanical induction versus drug induction in termination of pregnancy in pregnant women with IUD. Now a days recommended dose of misoprostol after 24 weeks 400 mg single or 600 mg single dose can be given but combined treatment give better result. For labour induction Foley catheter introduced intra cervically but should be placed outside the amniotic membrane. Catheter balloon is infiltrated with 20 -30 ml distilled water for pressure effect which help to release natural prostaglandins to initiate labour and also cause cervical dilatation.

**Figure-3**



Source: Cunningham FG, Leveno KJ, Bloom SL, Hauth JC, Rouse DJ, Spong CV: *Williams Obstetrics, 23rd Edition*: <http://www.accessmedicine.com>  
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**Figure-4**

## II. Objective

### General objective:

- To estimate the effectiveness of mechanical induction versus drug induction in termination of PG with IUFD.

## III. Methodology

### Study type:

- This study was a randomized clinical trial.

**Sample size:** Total sample size was 215.

### Study place and period:

- This study was conducted at tertiary medical college and hospital from 2016 to 2018.

### Method:

- The methods and purpose of the study were explained to the patients and only those who agreed were finally selected. Written consent was taken from each respondent. The inclusion criteria were intact membrane, singleton pregnancies, cephalic presentation, low Bishop score ( $\leq 5$ ) and pregnancies after the age of viability. Patients with vaginal infection, placenta previa, low-lying placenta, unexplained vaginal bleeding, presentation other than head and previous caesarean section were excluded from the study. A total patients were randomly selected for this study. All patients came during the study period were included. All patients were divided into two groups by simple lottery method. Group-I was the misoprostol group, where misoprostol vaginal tablet was used for cervical ripening. Group-II was Foley's catheter group, where cervical ripening was done by using intracervical extra amniotic Foley's catheter.

### Statistical analysis:

- Statistical Package for Social Sciences (SPSS) version 20 for windows was used to analyze the data. Descriptive statistics were computed. Chi-square test was carried out to assess association of qualitative data. To compare the mean differences between the groups student's t-tests and ANOVA were done. Strength of associations and their corresponding 95% confidence interval (CI) were calculated. Statistical significance was defined as  $p < 0.05$ . Multivariate analysis Linear regression was done.

## IV. Result

The following figure-5 shows that most of the patients (35%) were in the age group of 36-41 and the lowest (15%) were in the age group of 18-23.

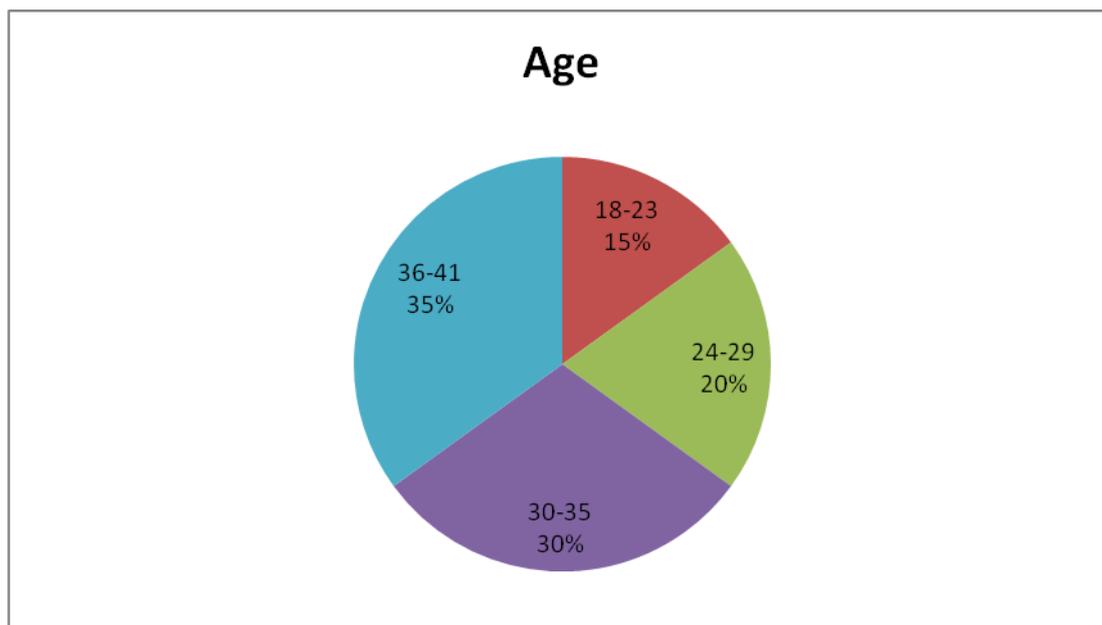


Figure-5: Age group of the patients

Table-1: Socio economic conditions of Patients

Profession	Percentage
House wife	70%
Service holder	30%
Family income	
20,000-29,000	60%
30,000-39,000	20%
40,000-49,000	10%
50000+	10%

Table-2: Causes of IUD

Causes	Percentage
DM & GDM	60%
PE & Eclampsia	25%
Others	10%
Congenital anomaly	5%

The following table-3 shows the outcome of Combine method (Balloon catheter and oxytocin) is highest 90% and only Misoprostol (PGE<sub>1</sub>) is lowest.

Table-3: Misoprostol PGE<sub>1</sub>, Balloon catheter and oxytocin

Cervical dilatation up to 4-6 cm in 6 hours	Percent
Misoprostol (PGE <sub>1</sub> )	30%
Balloon catheter	60%
Combine method (Balloon catheter and oxytocin)	90%
Only oxytocin	40%

Among the 215 patients the complications were follows:

Table-4: Complications

Complication	Percent
Scar rupture	1%
Infection	8%

The following table-5 shows the outcome of different methods:

**Table-5: Outcome of different methods**

Methods	Percent
Misoprostol (PGE <sub>1</sub> )	31%
Balloon catheter	65.5%
Combine method (Balloon catheter and oxytocin)	88.5%
Only oxytocin	42%

Only balloon catheter showed better result than only PGE<sub>1</sub>, but combination of balloon catheter and Oxytocin showed better result.

C/S needed only 8% patients due to following reasons:

- Previous C/S or complication.
- Obstetrical indications.

### V. Discussion

Nascimento. M.I. et al (2014) in their study showed that the Subgroups A (misoprostol or Oxytocin), B (misoprostol and Oxytocin), and C (Foley catheter alone or combined with misoprostol and/or Oxytocin) were formed according to the applied methods. Nine out of 163 cases ended with cesarean section. The incidence of cesarean section was 3.5 per 1,000 people-hours, meaning that a pregnant woman with IUFD had a 15.6% risk of cesarean section during the first 48 hours of clinical management to anticipate childbirth. The conditions significantly associated with the mode of delivery were placental abruption (HR: 44.97), having two or more previous cesarean deliveries (HR: 10.03), and mechanical method with Foley catheter (HR: 5.01).<sup>[3]</sup>

Nzewi et al (2014) showed in their article about the combination of mifepristone and misoprostol in the management of intrauterine fetal death is one of the major advances in modern clinical practice, with safety and efficacy reported by numerous observational and non-randomised controlled trials.<sup>[4-8]</sup> However, certain issues remain unresolved regarding its use. These include the optimum dose of both mifepristone and misoprostol, the best route of administration of misoprostol and the most effective interval between the administrations of both drugs. Published studies report a mean induction to delivery interval of 10–19 hours with the use of the misoprostol-only regimen and a shorter induction to delivery interval of 7–10 hours with the use of the combination mifepristone– misoprostol regimen.<sup>[8-14]</sup>

**Table 6. Suggested induction of labour regimen**

Clinical condition	Regimen <sup>a</sup>	Evidence base
Gestation 24–27 weeks <sup>b</sup>	Mifepristone 200 mg for all gestations from 24 weeks	Royal College of Obstetricians and Gynaecologists 2011, <sup>9</sup> Dodd and Crowther 2006, <sup>18,40</sup>
	Misoprostol 100lg 6-hourly	
	Maximum 5 doses/course	
	Misoprostol 50lg 6-hourly	
Gestation ≥28 weeks <sup>b</sup>	Mifepristone–misoprostol interval 36–48 hours	Expert opinion
	Regimen of misoprostol as above (≥28 weeks)	
Previous uterine scar	Repeat course of misoprostol only as above	Expert opinion
Failed induction of labour	>12-hour gap between courses	
	Total misoprostol dose not to exceed 1000lg for gestation 24–27 weeks, and not to exceed 500 lg for gestation >28 weeks (i.e. maximum of 2 full courses)	
	Consider alternative options thereafter, but avoid further pharmacological interventions for previous uterine scar	
Retained placenta	Complete full course of misoprostol as prescribed, unless significant bleeding	Expert opinion

<sup>a</sup>Suggested regimen based on simplicity, best available evidence and a common sense approach. <sup>b</sup>Third trimester is defined as ≥27 weeks of gestation.

Nzewi et al (2014) showed A standard Foley catheter or a proprietary Cook cervical ripening balloon

are the most commonly used mechanical methods of cervical ripening for the induction of labour.<sup>[15]</sup> Because of the risks associated with pharmacological agents, the use of mechanical methods is on the rise in women with a previous caesarean section and other uterine scars.<sup>[16]</sup> A 2012 Cochrane review that analysed 71 published randomised controlled trials ( $n=9722$  women) reported similar vaginal delivery rates with lower risk of hyper stimulation with the use of mechanical methods than with other pharmacological methods for induction of labour.<sup>[15]</sup> Subgroup analysis of women with caesarean section or other uterine scars was not reported.

## VI. Conclusion

To arrive at a definite conclusion, it is suggested that a long-term study with larger number of subjects need to be carried out to make a plan of action in the selection of method of induction of labour for pregnant women. This methods are more cost effective then the other methods and should be done with proper monitoring.

## Reference

- [1]. Heikinheimo O. Clinical pharmacokinetics of mifepristone. *Clin Pharmacokinet* 1997;33:7–17.
- [2]. Watkinson G, Hopkins A, Akbar FA. The therapeutic efficacy of misoprostol in peptic ulcer disease. *Postgrad Med J* 1988;64(Suppl 1):60–77.
- [3]. Nascimento M.I., Cunha A.A, Muri Oliveira S.R.S., Clinical management of the induction of labor in intrauterine fetal death: evaluation of incidence of cesarean section and related conditions. *Rev Bras epidemiol*, Jan-Mar, 2014; 203-216
- [4]. Wagaarachchi PT, Ashok PW, Narvekar NN, Smith NC, Templeton A. Medical management of late intrauterine death using a combination of mifepristone and misoprostol. *BJOG* 2002;109:443–7.
- [5]. Vayrynen W, Heikinheimo O, Nuutila M. Misoprostol-only versus mifepristone plus misoprostol in induction of labour following intrauterine fetal death. *Acta Obstetrica et Gynecologica* 2007;86:701–5.
- [6]. Fairley TE, Mackenzie M, Owen P, Mackenzie F. Management of late intrauterine death using a combination of mifepristone and misoprostol-experience of two regimens. *Eur J Obstet Gynecol Reprod Biol* 2005;118:28–31.
- [7]. Jannet D, Aflak N, Abankwa A, Carbonne B, Marpeau L, Milliez J. Termination of 2nd and 3rd trimester pregnancies with mifepristone and misoprostol. *Eur J Obstet Gynecol Reprod Biol* 1996;70:159–63.
- [8]. Stibbe KJM, De Weerd S. Induction of delivery by mifepristone and misoprostol in termination of pregnancy and intrauterine fetal death: 2nd and 3rd trimester induction of labour. *Arch Gynecol Obstet* 2012;286: 795–6.
- [9]. Bugalho A, Bique C, Machungo F, Faáundes A. Induction of labor with intravaginal misoprostol in intrauterine fetal death. *Am J Obstet Gynecol* 1994;171:538–41.
- [10]. Chittacharoen A, Herabutaya Y, Punyavachira P. A randomized trial of oral and vaginal misoprostol to manage delivery in cases of fetal death. *Obstet Gynecol* 2003;101:70–3.
- [11]. Draycott T, Hawkes N, Read MD. Induction of labour with vaginal misoprostol after intrauterine death from 24 weeks gestation. *J Obstet Gynecol* 1996;16:517–8.
- [12]. Srisomboon J, Singchai S. A comparison between 25 lg and 50 lg of intravaginal misoprostol for labour induction. *J Med Assoc Thai* 1998;81:779–83.
- [13]. Dodd JM. Misoprostol for the induction of labour at term. PhD thesis. Department of Obstetrics and Gynaecology, Faculty of Health Sciences, University of Adelaide, 2005.
- [14]. Fletcher HM, Wharfe G, Simeon D, Mitchell S, Brown D. Induction of labour with intravaginal misoprostol versus dinoprostone in intrauterine death: a retrospective study. *Journal of Obstetrics & Gynaecology* 1996;16:155–8.
- [15]. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O, Boulvain M. Mechanical methods for induction of labour. *Cochrane Database Syst Rev* 2012;(3): CD001233.
- [16]. Huisman CMA, Jozwiak M, De Leeuw JW, Mol BW, Bloemenkamp KWM. Cervical ripening in the Netherlands: a survey. *Obstetrics and Gynecology International* 2013; Article ID 745159; DOI: 10.1155/2013/745159.

Dr. Fahmida Sultana. "Mechanical induction versus drug induction in termination of Pregnancy with IUFD in Tertiary Hospital." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, vol. 18, no. 3, 2019, pp 66-71.