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Original Research Article

## Management of stillbirths: an observational analysis at a rural tertiary care centre in Kerala, India

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### ABSTRACT

**Background:** Stillbirth is a distressing event, both for the expecting mother and the obstetrician. Several maternal, social and circumstantial factors influence its occurrence. These women with intrauterine fetal death need to be treated in a considerate manner. Our aim was to analyse different methods of induction, management of labour and their outcomes in women with antepartum fetal demise.

**Methods:** All women admitted to a tertiary care centre with intrauterine fetal death after 22 weeks during the study period of 24 months were recruited. Maternal sociodemographic characteristics and relevant investigations were studied. Induction of labour was achieved with mechanical and pharmacological methods. Stillborn babies, placentae and umbilical cord were examined after delivery.

**Results:** There were 175 women with IUFD admitted during the study period. The stillbirth rate was 38.6 per 1000 live births. 148 women (84.57%) required induction of labour while 16 women had spontaneous onset of labour. Among the 44 women with previous Cesarean section, 11 underwent elective Cesarean section. 19 women (57.6%) out of 33 cases of trial of labour after Cesarean had a successful vaginal delivery. There were 2 cases of rupture uterus and 10 women required ICU admissions. Intrauterine growth restriction was the leading cause of stillbirth (41.8%) followed by hypertensive disorders (27.7%).

**Conclusions:** Present study has shown that vaginal birth can be achieved in most women with mechanical and pharmacological methods of induction within a reasonable period of time.

**Keywords:** Management of labour, Misoprostol, Previous caesarean, Stillbirths

### INTRODUCTION

Stillbirth can be a devastating experience to the bereaved parents and family members. It can result in immediate and long-lasting psychological effects on the mother. The health care providers too, have to overcome a complex situation where a probable cause and contributory factors involved have to be identified and a suitable method of termination of pregnancy suggested. The reported incidence of stillbirths varies significantly between studies from different countries and depends on

the definitions used. Out of a global estimate of 2.6 million stillbirths in 2015 with a stillbirth rate of 18.4 per 1000 births, majority occurred in the developing world and India accounted for the highest number of stillbirths.<sup>1</sup> A wide range of maternal, social and circumstantial factors influence its occurrence.

Stillbirth (SB) is defined as a fetus with no signs of life prior to the complete expulsion or extraction from its mother, and after a pre-defined duration of gestation; after delivery it is confirmed that the fetus does not

show any evidence of life and cannot be resuscitated. The minimum gestational age cut-off defining stillbirths vs. miscarriage generally varies from 20 to 28 weeks of gestation based on available medical care and health infrastructure.<sup>2</sup> The Brighton Collaboration Stillbirth Working group recommends making explicit a working definition of SB to capture all events, for example early (after 22 weeks) vs late (after 28 weeks) stillbirths.<sup>3</sup> Stillbirths are referred to as antepartum stillbirths when it occurs before the onset of labour and intrapartum stillbirth after the onset of labour.

In the stressful situation of an intrauterine fetal death (IUFD), the options are either to await the onset of spontaneous labour or to induce labour. It may take several weeks for spontaneous expulsion. Retention of the fetus can be associated with emotional distress, intrauterine infection if membranes are ruptured and a time related risk of consumptive coagulopathy. Management of labour and finding the cause of fetal death is difficult.

This becomes more difficult when intrauterine fetal death occurs in a woman with a prior Cesarean delivery. The surgical methods of inductions may precipitate infection. Oxytocin induction is more likely to fail as the uterus is less sensitive to oxytocin remote from term. Occasionally, mechanical methods using a cervical balloon, and rarely, surgical procedures such as hysterectomy and Cesarean section may be needed. Though both Mifepristone-Misoprostol Combination Regimen and Misoprostol-alone Regimen for induction of labour in IUFD have been recommended by different international associations, there is no consensus regarding the ideal regimen.<sup>4,5</sup>

The purpose of this study was to analyze methods of induction, management of labour and their outcomes in women with antepartum fetal demise.

## METHODS

This was a cross sectional study done in the Department of Obstetrics and Gynecology at Government Medical College, Thrissur, Kerala, India. All women with antepartum intrauterine death at or more than 22 weeks (fetal weight 500 gms or more if gestational age was not known) admitted to our Hospital between March 2014 to February 2016 were recruited for the study.

### *Inclusion criteria*

- All consecutive women with an IUFD consenting to take part in the study were included.

### *Exclusion criteria*

- Women with a history of attempted feticide or admitted after having delivered a stillborn elsewhere, were excluded.

The study protocol was accepted by the Institutional Review Board. Informed consent was obtained from all the subjects. The diagnosis of intrauterine death was confirmed on ultrasound by the absence of fetal heart pulsation. Gestational age was confirmed by either reliable dates or a first trimester ultrasound. When gestational age was not known, stillborn babies weighing more than 500gms when delivered. Maternal demographic data, medical and surgical history, and obstetric history were collected using a structured proforma. Women were examined and relevant investigations were done. Cervical favourability was assessed using the Bishop's score. The mode of induction of labour was decided upon by the previous obstetric history and Bishop's score. Induction of labour with mifepristone-misoprostol combination regimen was as follows. A single oral dose of 200mg mifepristone was given initially. Oral misoprostol, 100µg, was given 48 hours later for gestations between 22 and 34 weeks. Following administration of the first dose, a further two doses of misoprostol (100µg each) were given orally every 6 hours. For gestations over 34 weeks, 50µg of misoprostol was administered in a similar manner. If the first course was unsuccessful, the woman was not given any further labour inducing agents for the next 24 hours. A second course was then administered starting with the first oral dose of misoprostol. Misoprostol alone regimen was used in women who were multiparous or when the cervix was favourable. In women with a previous cesarean, Foley catheter with Extra Amniotic Saline (EAS) Infusion for cervical ripening was used followed by Prostaglandin E2 gel or misoprostol if required. Augmentation of labour was done with oxytocin if needed. Repeat Cesarean delivery was done electively when trial was contraindicated. Subsequent to induction, uterine contractions, pulse, blood pressure, temperature and systemic symptoms were monitored. Uterine tachysystole (six contractions in a 10-minute period for two consecutive 10-minute periods) and hyper tonicity (a single uterine contraction with a duration of more than two minutes) were watched out for and recorded. Maternal complications such as uterine rupture, postpartum endometritis and requirement for blood and blood component therapy were noted. After delivery, the stillborn baby, placenta and umbilical cord were examined and recorded.

### *Statistical analysis*

Data were analyzed using SPSS 10.1 for statistical Package (SPSS Inc. Chicago, Illinois, USA). Variables that were normally distributed are presented as means with standard deviations and ranges. The induction delivery interval was used as the dependent variable.

## RESULTS

There were 203 stillbirths and 5264 total live births during the study period of 24 months. 175 cases of stillbirths that fulfilled the criteria were recruited.

Stillbirth rate was 38.6 per 1000 live births. Demographic and obstetric characteristics are presented in Table 1.

**Table 1: Demographic and obstetric characteristics of the women with IUFD.**

Characteristics	No.
Rural population	81.36%
Unbooked status	12.42%
Low socioeconomic status	89.83%
Age in years	27.28±4.27
Parity (multi and primi)	59.32 & 40.68%
Gestation at induction in weeks	30.96±3.75
Bishop's score	4 (2-9)
Birth weight (g)	1311.77±546.9
Induction to delivery interval (hours)	18.54±6.08

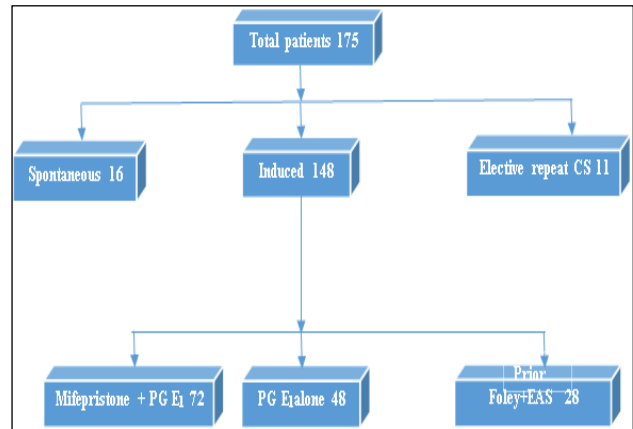
Categorical variables are presented as n %, continuous variables as mean ± SD and median [range]. Sixteen women (9.69%), including 5 women with prior Caesarean section had spontaneous onset of labour while awaiting investigation results and arrangement of cross-matched blood. 148 women (84.57%) required induction of labour. The induction to delivery interval reflects the time interval between first doses of misoprostol to expulsion of fetus. The induction delivery interval varied from 5 hours 43 minutes to 42 hours 25 minutes with a mean of 18 hours 54 minutes±6 hours 8 minutes. In women (120) with an unscarred uterus, Mifepristone - Misoprostol combination regimen was used for induction of labour in 72 (60%) subjects, while Misoprostol alone was the mode of induction in 48(40%) women. All women had successful induction of labour, requiring misoprostol doses ranging from 50 to 400 µg. The mean dose of misoprostol required to achieve established labour in pregnancies above 34 weeks was 125µg while that for gestational age between 22 and 34 weeks was 250µg. Table 2 shows the relationship between gestational age at induction and the dose of misoprostol required to establish labour. Twenty-eight women (16.96%) required augmentation with oxytocin for inefficient uterine contractions.

**Table 2: Relationship between dosage requirement of Misoprostol and gestational age.**

Gestational age (weeks)	Dosage range (µg)	Mean dosage (µg)
22-34	100-400	250±75.6
>34	50-250	125±45.4

Tachysystole or hypertonicity did not occur in any of these women. The most common side effects were cramping, nausea, vomiting, diarrhoea, pyrexia and shivering. Twenty-one women required analgesia during labour. The mode of management of labour in IUFD is shown in Figure 1. There were 44 women (24.8%) with prior Caesarean delivery and antepartum stillbirth. Among them 33 (75%) were given trial of labour after Caesarean section (TOLAC), while 11 women underwent

elective repeat cesarean section. The indications for repeat caesarean section included placenta praevia in 4 women, abruptio placentae in 2, previous two or more cesarean sections in 2, suspected macrosomia in 1 subject and antepartum eclampsia in 2 women.



**Figure 1: Mode of management of labour in IUFD.**

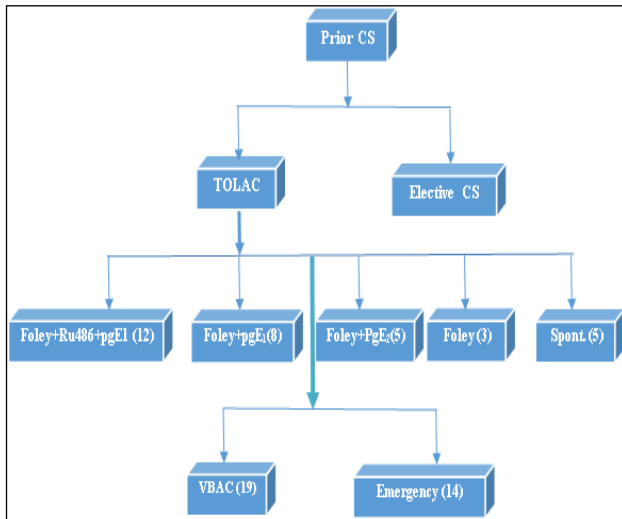
Among the TOLAC group, 19 women (57.67 %) achieved successful VBAC (vaginal birth after Caesarean) when trial of labour was attempted, while 14 (42.33%) of them underwent repeat emergency sections. Mode of induction of labour in women with prior one Caesarean section is given in Table 3.

**Table 3: Mode of induction in previous caesarean with IUFD given TOLAC.**

Mode of induction	No. of women with previous CS and IUFD
Foley EAS + Mifepristone+ Misoprostol	12 (36.4%)
Foley EAS + misoprostol	8 (24.2%)
Foley EAS + PGE <sub>2</sub> gel	5 (15.2%)
Foley EAS alone	3 (9%)
Spontaneous labour	5 (15.2%)
Total	33

Foley catheter with extra amniotic saline infusion was used only in cases with prior CS. Two women with a previous caesarean delivery who underwent labour induction had rupture of the uterus. The women with uterine rupture had an average gestational age of 31.56 weeks and the average birth weight of their babies was 2034 grams. Both these women had labour induced with Foley + EAS insertion followed by prostaglandin E<sub>2</sub> gel application in posterior fornix and labour augmentation with oxytocin. Both women had repair of the ruptured scar and bilateral tubal ligation. The mode of management of labour in IUFD with prior CS is shown in Figure 2. The rate of blood transfusion was 8%. A total of 10 (5.7%) women required ICU admissions for conditions like uncontrolled hypertension, HELLP syndrome and for hemodynamic monitoring. One woman in the induced group with an unscarred uterus

required manual removal of retained placenta. Among the induced group with a scarred uterus, two women required hysterectomy for atonic postpartum haemorrhage (PPH) following Emergency Caesarean section. There were no maternal deaths in this cohort of patients.



**Figure 2: Mode of termination of IUD in prior caesarean section.**

There were 49 (27.7%) women whose pregnancy was complicated by hypertension while 26 (14.7%) women had Gestational Diabetes mellitus. Other pre-existing maternal diseases like thyroid disease, seizure disorder, chronic hypertension, renal disease and connective tissue disease were also present. The commonest cause for stillbirth was IUGR (41.8%) followed by hypertensive disorders (27.7%).

## DISCUSSION

In the current study, a large majority (84.57%) of women with an IUD required induction of labour. Most of them received prostaglandin analogues along with mifepristone. A combination of mifepristone and misoprostol was a very effective and safe method of induction of labour in IUD in present study. Most of these subjects had a successful induction resulting in vaginal delivery with few complications. The prolonged time interval from induction of labour to expulsion of the dead fetus are not acceptable to many women. The combined regimen of mifepristone with a prostaglandin analogue results in a synergistic effect. Uterine sensitivity to prostaglandins is known to increase with advancing gestation<sup>6</sup>. This predisposes women to develop tachysystole to uterotonic agents. Since authors used a reduced dose (50µg) for women more than 34 weeks gestational age, it did not have tachysystole or hypertonic uterine contractions in any of the present patients. Authors had limited the dose of misoprostol to a maximum of 4 doses in 24 hours with the fourth dose being given only to a very few women. Using mifepristone prior to misoprostol is of value in reducing

the induction delivery interval as well as in the total dose of misoprostol required. Improved patient acceptability and reduced risk of introducing intrauterine infection are potential advantages of oral misoprostol over vaginal misoprostol.<sup>7</sup> Authors had two cases of obstetric hysterectomies for atonic PPH and one woman needed manual removal of placenta. Present study population being from a tertiary care center included women with other comorbidities. Even though there were ICU admissions for uncontrolled hypertension, HELLP syndrome and hemodynamic monitoring, there were no maternal deaths. The ideal treatment regimen and optimum dosage for better management of IUD is yet to be established. Surgical methods may invite infection. Oxytocin is less effective for induction of labour.<sup>8</sup> RCOG recommends a combination of mifepristone and prostaglandin combination which is also endorsed by the NICE guidelines especially for late IUD.<sup>4,5</sup> WHO recommends oral or vaginal misoprostol for induction.<sup>9</sup> The dosage regimens used in present study were most often mifepristone and misoprostol. The results of this study are similar to the findings in other reports.<sup>10</sup>

In present study, women with IUD and prior caesarean section, trial of labour following induction with EAS instillation and prostaglandins was found to be effective. 33 women were given trial of labour. 28 of these women had induction of labour with mechanical and pharmacological methods while 5 women had spontaneous onset of labour. Authors could achieve successful vaginal delivery in 19 (57.67%) of the 33 women with prior Caesarean who were given a trial. Authors had two cases of rupture uterus in the TOLAC group. The frequency of uterine rupture in this study of 3.56% is similar to the reported rates of uterine rupture in women with previous caesarean delivery who underwent induction of labour.<sup>11,12</sup> In women with IUD and prior caesarean delivery, prevention of maternal morbidity is important. Repeat caesarean delivery, in women who plan future pregnancies, may increase the risk of uterine rupture, placenta accreta and morbidity related to multiple abdominal surgeries. Women who deliver successfully vaginally have less postpartum discomfort, shorter hospital stay and shorter periods of disability than women who undergo repeated caesarean delivery.<sup>13</sup>

Growth restriction was the most common condition (41.8%) associated with stillbirth in present study. Hypertensive disorders of pregnancy (27.7%) was the second most significant condition associated with stillbirth followed by diabetes mellitus (14.7%). Congenital malformations were present in 15% of cases. Most of these were due to open neural tube defects. Knowing the cause of stillbirth is very important for the management of future pregnancies.<sup>14</sup> In the current study, psychological outcome was not addressed. It is well known that complex emotional factors are associated with fetal loss. The woman herself or her relatives are often not able to decide between induction and watchful expectancy because of the emotional impact of an IUD.

Once intrauterine death is confirmed, majority of women hope for expulsion of the dead fetus as early as possible. Hence induction of labour is often accepted. Late IUFD poses particular difficulties as it is sudden and unexpected. Women with a dead fetus in utero need an empathetic approach and every effort must be made to identify a cause for the IUFD. Counseling these women regarding future pregnancies may have to be based on these conclusions. The cross-sectional nature of data collection precludes recall bias. Ideally randomized controlled trials are needed to establish optimum dosage schedules of drugs used for induction. This may not be feasible following intrauterine death in view of the large number of patients required and the complexity of emotional factors associated.

## CONCLUSION

Stillbirth is one of the most undesirable outcomes of pregnancy. It makes the mother emotionally unstable. The health care provider needs to find a cause for the fetal death and decide on an optimal management strategy. Present study has shown that vaginal birth can be achieved with mechanical and pharmacological methods of induction in most women with IUFD within a reasonable period. Women with previous Caesarean, without any contraindications for TOLAC can be safely offered mechanical ripening followed by pharmacological methods to deliver vaginally. Vaginal birth carries the potential advantages of early recovery and quicker return to daily routine. The current study may aid in counselling women with intrauterine fetal death regarding the mode of delivery and management of future pregnancies to prevent these unfortunate events.

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