Ibrahim Card Med J 2022; 12 (1): 25-29

Comparative Outcome between Intracervical Catheterization and Vaginal Misoprostol in the Induction of Labour in Intrauterine Fetal Death

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ABSTRACT

Background & Objective: Induction of labour (ILO) is a standard obstetric approach to terminate the pregnancy. But it is always a challenge to many an obstetrician and is more so when the cervix is unfavourable. The intrauterine fetal death (IUFD) itself does not constitute an indication for cesarean section and surgery should be reserved for specific conditions, since it increases maternal morbidity without any fetal advantage. The present study was undertaken to make a comparative evaluation of the outcome of intracervical Foley's catheter insertion and vaginal misoprostol in the induction of labour in pregnant women with IUFD.

Methods: This study was a comparative cross-sectional study conducted in the Department of Obstetrics and Gynecology, Sir Salimullah Medical College & Mitford Hospital over a period of one year between January to December 2013. A total 68 single-tone pregnant women with gestational age > 24 weeks, intact membrane and IUFD confirmed by sonography were consecutively included in the study. However, cases with temperature > 38°C, placenta previa, chorioamnionitis, vaginal bleeding were excluded from the study. The recruited patients were randomly assigned to intracervical catheterization (ICC) and vaginal misoprostol (VMP) groups. While the independent variable was induction of labour, the outcome variables were time to induction, interval from induction to full-dilatation and thinning of the cervix (effacement) and time needed from induction to delivery.

Results: More than one-quarter (27.9%) of the patients were 20 or < 20 years. The patients were predominantly primipara (63.2%). Around two-thirds of the patients in either study groups received 10 – 20 units of oxytocin with no significant intergroup difference in terms of oxytocin needed (p = 0.793). The difference between the two groups in terms of pethidine needed to get rid of the labour pain was not statistically significant (p = 0.278). Time to induction in majority of the patients of both groups was 13 or < 13 hours and there was no significant difference between the groups in terms of time to induction (p = 0.380). About one-third (32.4%) of VMP group required < 15 hours from induction to full-dilatation (effacement) of cervix as opposed to only 11.8% of the ICC group (p = 0.014). Over half (52.9%) of the VMP group delivered their dead fetus in < 18 hours as compared to 41.2% of the ICC group (p = 0.331).

Conclusion: The study concluded that vaginal misoprostol is more effective and safe for cervical ripening and labour induction than Foley's catheter in pregnant women with IUFD. Type and amount of analgesia needed and oxytocin required between VMP and ICC groups do not differ significantly.

Key words: Intracervical catheterization, vaginal misoprostol, induction of labour, IUD etc

ORIGINAL ARTICLE

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INTRODUCTION:

Induction of labour (IOL) is a standard obstetric approach by which pregnancy is terminated. It should be considered when further prolongation of pregnancy might expose the mother or fetus or both to certain risk and when vaginal delivery is not contraindicated. Common indications of IOL are prolonged pregnancy, diabetes mellitus, RH-isoimmunisation, preeclampsia, chronic hypertension, IUGR, congenital malformation of fetus and intrauterine death.[1] Intrauterine fetal death (IUD) refers to fetal death after the age of viability before the onset of labour. Once diagnosis of fetal demise is confirmed, the pregnancy should be terminated. The principal concern is how to provide the most effective, easy to use, safest and less expensive way to terminate the pregnancy. Termination of pregnancy through vaginal route requires ripening of cervix, which can be accomplished by the following way: a) using oxytocin drip, b) intravaginal, intracervical or extraamniotic application of prostaglandins, c) intravaginal administration of oestradiol, d) intracervical placement of catheter balloon, e) stripping the membrane & f) amneotomy etc.[2]

Misoprostol, a synthetic prostaglandin E1 analogue, is a promising agent in cervical ripening. Possible advantages of misoprostol may be its cost-effectiveness, ease of administration, well tolerability and most notably its dual action in cervical ripening and uterine contraction.[3] According to WHO 2002 guidelines, induction of labour should be done with misoprostol in highly selected situations, such as, in severe pre-eclampsia or eclampsia when the cervix is unfavourable and a caesarean is unsafe, or there is in-utero fetal death in woman who have decreasing platelets and no spontaneous labour takes place after four weeks. Misoprostol has been extensively studied and widely used for pre-induction cervical ripening and labour induction (at 3rd trimester, especially at low Bishop's score), evacuation of the uterus after pregnancy failure or for various medical reasons (2nd trimester), and primary postpartum haemorrhage.[4] Kirby and associates[5] demonstrated that vaginal administration of PGE1 tablets is efficacious to induce labour at term and appears to be more effective than conventional methods of cervical ripening and labour induction.

Use of the Foley's catheter for termination of pregnancy was first described by Krause in 1833.[6] In 1967, Embrey and Mollison reported a 94% successful induction rate in 100 women with Foley's catheter.[7,8] The use of Foley's catheter balloon alone has shown better results in achieving cervical ripening than 3 mg dinoprostone vaginal passery and it is also very economical.[9,10] Mechanical methods of cervical ripening act primarily by dilating and stretching the lower uterine segment and cervix. Cervical ripening with an extra amniotic catheter balloon has advantages of simplicity, low cost, reversibility and lack of systemic or serious side effects.[11] However, there are limited studies which compared the outcome (efficacy and safety) of two methods of induction – intrauterine balloon catheter and vaginal misoprostol, particularly in the context of Bangladesh to come to a conclusion about the superiority of one method to the other. The present study was designed to make a comparative evaluation of the outcome of intrauterine Foley's catheter insertion and vaginal misoprostol in cervical ripening and induction of labour in pregnant women with IUFD.

METHODS:

This comparative cross-sectional study was conducted on pregnant women with IUFD admitted in the Department of Obstetrics and Gynecology, Sir Salimullah Medical College & Mitford Hospital (SSMC & MH) over a period of one year between January to December 2013. A total 68 single-tone pregnant women with gestational age > 24 weeks (on the basis of LMP or sonography at first trimester), intact membrane and IUFD (confirmed by sonography) were consecutively included in the study. However, cases with temperature > 38°C, placenta previa, chorioamnionitis, vaginal bleeding were excluded from the study. The recruited patients were randomly assigned to ICC and VMP groups. The direct mechanical dilatation and endogenous release of prostaglandin are the mechanism of cervical ripening by Foley's catheter.[11] The VMP group received 50 microgram of misoprostol tablet at

posterior fornix of vagina at 6 hourly interval up to induction of labour. While the independent variable in the present study was induction (using medications or mechanical tools to begin the process of labor that hasn't organically occurred in the body after the fetal demise) method, the outcome variables were time to induction, interval from induction to full-dilatation (dilated to 10 cm) of the cervix and time needed from induction to delivery.

Data were collected from the study subjects using a semi-structured questionnaire containing the variables of interest. and were analyzed with the help of software, Statistical Package for Social Science (SPSS), version 21. The test statistics used to analyze the data were descriptive statistics and Chi-squared (χ^2) probability test. The level of significance was set at 5% and p-value < 0.05 was considered significant.

RESULTS:

Table 1 shows the distribution of the IUD cases according to age and parity. Over one-quarter (27.9%) of the patients were 20 or < 20 years, 57.4% 21 – 30 years and 14.7% > 30 years old. The patients were predominantly primipara (63.2%). About 45% of the ICC group were at 30 weeks of gestation, 45% of the VMP group were at 31 – 36 weeks of gestation. In both the methods of induction, the median gestational age was 32 weeks (Fig. 1).

Around two-thirds of the patients in either of the study groups received 10 – 20 units of oxytocin with no significant intergroup difference (p = 0.793) (Table II). More than three-quarters (77.4%) of the patients in the ICC group and 57.7% in the VMP group required 75 mg of pethidine to control delivery pain. A few patients (12.9%) in the ICC group and about one-quarter (23.1%) in the VMP group needed 150 mg of pethidine. The difference between the two groups in terms of pethidine required to get relief from the labour pain was not statistically significant (p = 0.278) (Table III). Comparison of outcome between the two groups revealed that time to induction in majority of the patients of both groups was 13 or < 13 hours and there was no significant difference between the groups in terms of time to induction (p = 0.380). About one-third (32.4%) of VMP group required < 15 hours from induction to full-dilatation (effacement) of cervix as opposed to only 11.8% of the ICC group (p = 0.014). Over half (52.9%) of the VMP group delivered their dead fetus in < 18 hours as compared to 41.2% of the ICC group (p = 0.331).

Table I. Distribution of patients by age and parity

Demographic characteristics	Frequency	Percentage
Age group (years)		
≤ 20	19	27.9
21 – 30	39	57.4
31 – 40	10	14.7
Parity		
Primipara	43	63.2
Multipara	25	36.8

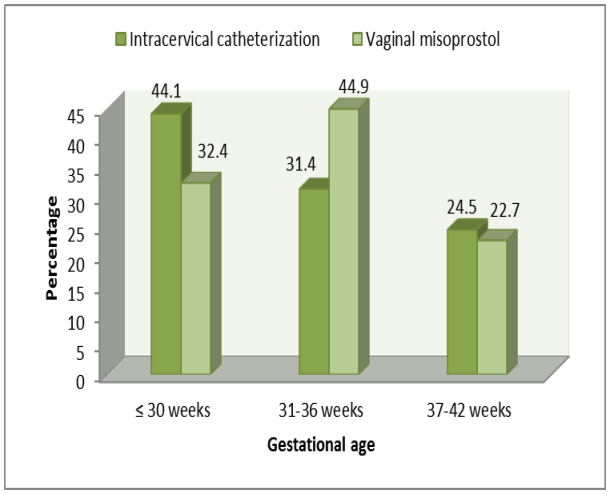

Fig. 1: Distribution of the patients according to gestational age in both groups.

Table II: Association between method of induction and amount of oxytocin needed

Amount of oxytocin	Group		p-value
	ICC (n = 34)	VMP (n = 34)	
5 unit	11(32.4)	10(29.4)	0.793
10 – 20 unit	23(67.6)	24(70.6)	

Figures in the parentheses denote corresponding percentage. Data were analyzed using **Chi-square** (χ^2) **Test** and were presented as **n(%).**

Table III: Comparison of amount of pethidine required in each group

Dose of pethidine	Group		p-value
	ICC (n = 34)	VMP (n = 34)	
50 mg	3(9.7)	5(19.2)	
75 mg	24(77.4)	15(57.7)	0.278
150 mg	4(12.9)	6(23.1)	

Figures in the parentheses denote corresponding percentage. Data were analyzed using **Chi-square** (χ^2) **Test** and were presented as **n(%).**

Table IV: Distribution of the patients according to the interval from induction to starting of labour pain in both method

Outcome variables	Group		p-value
	ICC (n = 34)	VMP (n = 34)	
Time to induction (hours)			
≤ 13 hours	25(73.5)	28(82.4)	0.380
> 13 hours	9(26.5)	6(17.6)	
Interval from induction to full dilatation of cervix (hours)			
< 15	4(11.8)	11(32.4)	0.041
≥ 15	30(88.2)	23(67.6)	
Induction to delivery time (hours)			
< 18	14(41.2)	18(52.9)	0.331
≥ 18	20(58.8)	16(47.1)	

Figures in the parentheses denote corresponding percentage. Data were analyzed using **Chi-square** (χ^2) **Test** and were presented as **n(%).**

DISCUSSION:

This comparative evaluation of outcome of pregnant women with IUFD was conducted in the Department of Obstetrics and Gynecology, SSMC & MH with the objective of comparing the effectiveness of ICC and VMP as a priming agent to induce labour. The primary outcome variables were time to induction (from intervention of induction method to start of labour pain), interval from induction to full-dilatation of cervix, interval from induction to delivery, type and amount analgesia needed, oxytocin required each method of labour induction.

It was found that more than half (57.3 %) of the IUD cases were in their 2nd decade of life, with mean age being 25.2 ± 5.3 years. This is quite similar with another study conducted in our country by Ferdous et al[12] where it was 25.3 ± 5.1 years. The patients were primarily primipara (63.2 %), which bears consistency with the findings of Ferdous et al.[12] In our study the mean gestational age in ICC and VMP groups were 32.5 ± 4.1 and 32.3 ± 4.2 weeks respectively. In Ferdous's[12] study the mean gestational ages in ICC and VMP groups were somewhat higher (36.2 ± 4.9 and 36.4 ± 5.0 weeks respectively).

There was no significant difference between the study groups in terms of time to induction with majority of the patients in either group required < 13 hours. The mean interval from induction to onset of labour pain was 12 ± 4.2 hours in ICC and 10.2 ± 4.5 hours in VMP groups. So VMP had shorter interval from induction to onset of labour pain in comparison to ICC method. Consistent with the findings of our study, Ferdous et al,[12] also showed shorter interval (13.6 ± 5.0 hours) from induction to onset of labour pain in patients who received VMP than those who were induced by intracervical catheterization (15.2 ± 3.6 hours). However, induction to effacement (induction to full-dilatation with thinning of the cervix) was significantly earlier in the VMP group than that in the ICC group. A sizable portion of the VMP group had shorter interval from induction to effacement as opposed to only 12% of the ICC group. The mean interval from induction to full-dilatation of cervix was 21.1 ± 7.6 hours and 19.1 ± 7.8 hours in ICC and VMP groups respectively. This was quite similar with the study of Ferdous et al.[12] In case of interval from induction to delivery, over half of the VMP group required < 18 hours to evacuate their uterus compared to 41.2% of the ICC group. Ferdous[12] showed that vaginal misoprostol had shorter interval from induction to delivery (20.0 ± 2.8 hours) than that required by patients of ICC (21.2 ± 2.3 hours).

Around two-thirds of the patients in either of the study groups received 10 – 20 units of oxytocin and there was no significant difference between the groups in terms oxytocin received. Majority (77.4%) of the ICC group required > 75 mg of pethidine to control pain, whereas only 57.7% of the VMP group required the same amount of pethidine for the same

purpose. A few patients in the ICC group and about one-quarter (23.1%) in the VMP group however, needed 150 mg of pethidine.

CONCLUSION:

From the findings of the study, it can be concluded that vaginal misoprostol is an effective mode of induction of labour than intracervical catheterization in pregnant women with IUFD. Although interval from induction to full-dilatation (effacement) of the cervix is significantly shorter in the VMP group than that in the ICC group, the time to induction and interval from induction to delivery are not significantly heterogeneous. Type and amount of analgesia needed, oxytocin required between VMP and ICC groups do not differ significantly. However, further long-term prospective study with larger samples is recommended to validate the findings of the present study.

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