|| ISSN(online): 2589-8698 || ISSN(print): 2589-868X ||
International Journal of Medical and Biomedical Studies
Available Online at www.ijmbs.info
PubMed (National Library of Medicine ID: 101738825)
Index Copernicus Value 2018: 75.71
Original Research Article
Volume 4, Issue 2; February: 2020; Page No. 137-142

TO COMPARE THE EFFECTIVENESS OF EXTRA-AMNIOTIC SALINE INSTILLATION THROUGH FOLEY CATHETER PRIOR TO ORAL MISOPROSTOL WITH ORAL MISOPROSTOL ALONE IN INDUCING LABOUR IN PREGNANCIES >28 WEEKS WITH INTRAUTERINE FOETAL DEATH- A RANDOMIZED CONTROLLED TRIAL AT TERTIARY CARE HOSPITAL BIKANER.

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Article Info: Received 24 January 2020; Accepted 11 February 2020
DOI: https://doi.org/10.32553/ijmbs.v4i2.944
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Conflict of interest: No conflict of interest.

Abstract

Background: The present study aims to compare the results of EASI followed by oral misoprostol and oral misoprostol alone for induction of labour in pregnancies of more than 28 weeks with intrauterine foetal death.

Methods: The present observational and prospective study is an attempt to compare the efficacy of extra-amniotic saline instillation with Foley catheter prior to oral misoprostol and oral misoprostol alone in induction of labour of pregnancies more than 28 weeks with intrauterine fetal death.

Results: Most of the cases delivered vaginally in both study groups. The mean induction delivery time in group I was higher than group II and the results were statistically significant on comparing both groups. In group I, 78% cases were delivered within 24 hours whereas in group II 96% cases delivered within 24 hours of induction. There was no significant difference in the mean number of required misoprostol in both groups ($p>0.05$). Need of supplementation with oxytocin was more in group I as compared to group II and the p value is significant ($p<0.01$). Mean birth weight in group I was 2.25 ± 0.75 kg and in group II was 2.27 ± 0.77 kg. Maximum number of babies had birth weight between 1.52-2.50 kg with 44% in group I and 40% in group II ($p>0.05$). Only 4 cases had uterine tachysystole and only 1case had postpartum pyrexia. Very few complications were recorded in both the study groups ($p>0.05$).

Conclusion: We concluded that oral misoprostol tablet alone is more effective at inducing and setting up the active labour in pregnancies of >28 weeks with intrauterine foetal death than EASI followed by oral misoprostol. It is inexpensive, has a long shelf life, can be easily stored at room temperature and patient remains ambulatory after induction with oral misoprostol. Oral misoprostol alone seems to have an edge over extra-amniotic saline instillation followed by oral misoprostol in all aspects.

Keywords: Misoprostol, Extra-amniotic saline, Induction of labour.

Introduction

Induction of labour assigns the course of artificial cervical ripening and initiating uterine contractions followed by active labour with the aim of completing a vaginal delivery[1]

There are different methods of inducing labour which includes both pharmacological medication and mechanical or physical method. Pharmacological methods include prostaglandin E_2 (dinoprost), a prostaglandin E1 analogue (misoprostol) and intravenous oxytocin. Whereas mechanical methods encompass membrane stripping, artificial rupture of membranes, extra-amniotic saline infusion, transcervical balloons, and hygroscopic cervical dilators[2]. In cases of IUFD, the ideal method for the induction of labour should not only be effective and safe, but should also be affordable to avoid additional financial burden arising from a wasted pregnancy[3].

Mechanical methods are amongst the oldest methods used to initiate labour. During the last decades medication such as PGE_2, misoprostol and oxytocin have partly replaced mechanical methods. Mechanical methods for induction promote cervical ripening and onset of labour by stretching the cervix. In extra-amniotic saline infusion (EASI) method saline is infused via Foley catheter that is placed through internal cervical os, into the space between internal os and placental membranes. It acts probably by dual mechanism of action through local release of endogenous prostaglandins and mechanical dilatation of cervix[2].

Misoprostol is a synthetic prostaglandin E_1 (PGE_1) , It has been used for induction of labour and may be

administered orally, vaginally or sublingually. It increases the vaginal delivery rate within 24 hours[4].

The present study aims to compare the results of EASI followed by oral misoprostol and oral misoprostol alone for induction of labour in pregnancies of more than 28 weeks with intrauterine foetal death.

Material and Methods

The present study was conducted in the Department of Obstetrics and Gynaecology, S.P. Medical College associate Associated group of hospitals, Bikaner, Rajasthan.

Study design: Prospective randomized comparative study.

Study period: from 1st October. 2018 to 30th Sep 2019.

Study population: The study group comprised of pregnant female with intrauterine foetal death >28 weeks attending Obstetrics and Gynaecology Department in S.P. Medical College Bikaner, consenting to participate in the study , 100 women (50 in each group) met within the inclusion criteria were included.

Inclusion criteria

1. Singleton gestation
2. Gravida 1 or 2
3. Intact membranes
4. Bishop score less than 4
5. Gestational age >28 weeks to 40 weeks

Exclusion criteria

1. APH due to either placenta praevia or abruptio placenta
2. Active genital herpes infection
3. Invasive Cervical carcinoma
4. Hypersensitivity to cervical ripening agents
5. Transverse lie,
6. Glaucoma,
7. Severe local infection
8. Patients in spontaneous labour
9. Patients with inadequate pelvis
10. Malpresentations
11. Patients with previous LSCS
12. Latex allergy

Sampling methods: Random sampling

Methodology The trial was included women both booked and unbooked women admitted after 28 weeks of gestation and above with a clinical diagnosis of intrauterine foetal death which was confirmed by ultrasound scan.

After taking written & informed consent and fulfilling inclusion criteria women were randomized to either Group I or Group II.

Group I was consists of 50 women, these women were induced by extra- amniotic saline instillation with Foley catheter prior to oral misoprostol. Women assigned to this group were inserted 12-14 F Foley catheter beyond the internal os under direct visualization. Balloon was inflated with 30ml normal sterile, water outlet of the catheter was connected to a normal saline bottle through a drip set. The amount of saline infused was 10 ml/week gestation. The catheter was placed by trapping it to the medial aspect of the thigh. Maximum of six hours of induction was done by normal saline instillation then for further induction 50 microgram oral misoprostol was given four hourly.

Group-II consists of 50 women randomized to this group were given 50 microgram of misoprostol tablet orally with water every four hours. Maximum six doses were given. Assessment of cervical dilatation and effacement was done every four hours.

Data Analysis

To collect required information from eligible patients a pre-structured pre-tested Proforma was used. The statistical analysis was performed using the Mean, Standard Deviation, Chi square test and T-test. Variations of $p<0.05$ were considered to be statistically significant.

Observations

Table 1: Socio-demographic profile

Variable	Group I	Group II	p-value
Age (Yrs)	23.56±3.12	23.30±4.21	0.727
Rural : Urban	27:23	33:17	0.221
ANC Registered cases	20(40.00%)	23(46.00%)	0.545
Gravida I:2	37:13	32:18	0.280

In our study both group were comparable.

Table 2: Distribution of cases according to Bishop score at the time of induction

Bishop Score	Group I		Group II		Total	
	No.	%	No.	%	No.	%
0	29	58.0	16	32.0	45	45.0
1	7	14.0	23	46.0	30	30.0
2	13	26.0	7	14.0	20	20.0
3	1	2.0	4	8.0	5	5.0
Mean	0.72		0.98			
SD	0.92		0.89			
t	1.429					
p-value	0.156					

Mean Bishop score in group I and group II was 0.72 and 0.98 respectively. Both groups are comparable with respect to Bishop score at the time of induction and p value is not significant. Induction was done in all cases with unfavorable Bishop score (p=0.156).

Table 3: Distribution of cases according to mode of delivery

Mode of Delivery	Group I		Group II		Total	
	No.	%	No.	%	No.	%
LSCS	2	4.0	1	2.0	3	3.0
Vaginal	48	96.0	49	98.0	97	97.0
χ^2	0.344					
p-value	0.558					

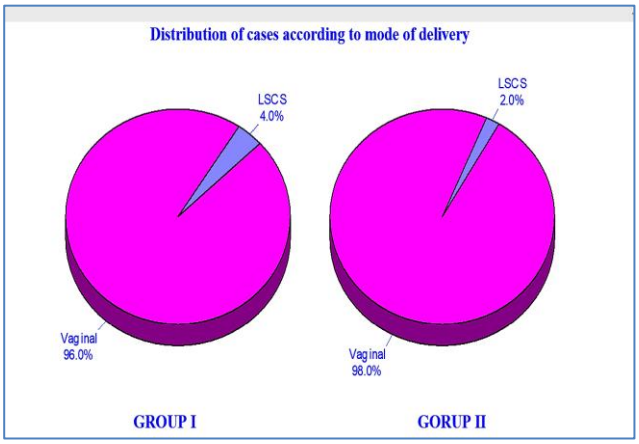

Table 4: Distribution of cases according to induction delivery time (hrs)

Induction Delivery Time (hrs)	Group I		Group II		Total	
	No.	%	No.	%	No.	%
<5	0	-	3	6.0	3	3.0
6-10	9	18.0	28	56.0	37	37.0
11-15	18	36.0	11	22.0	29	29.0
16-20	10	20.0	5	10.0	15	15.0
21-24	2	4.0	1	2.0	3	3.0
>24	11	22.0	2	4.0	13	26.0
Mean	16.88		10.99			
SD	7.27		5.18			
t	4.655					
p-value	<0.001					

The mean induction delivery time in group I was 16.88 hour and in group II was 10.99 hour. The results were compared statistically and p value found to be significant (p<0.001).

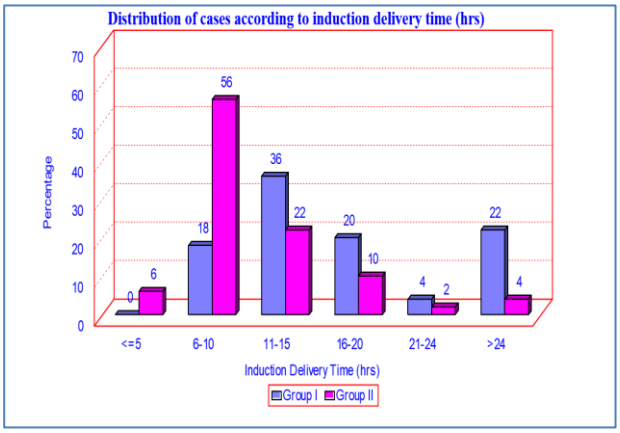

Table 5: Distribution of cases according to number of 50µg misoprostol required

Number of 50µg Misoprostol	Group I		Group II		Total	
	No.	%	No.	%	No.	%
1	11	22.0	9	18.0	20	20.0
2	24	48.0	23	46.0	47	47.0
3	8	16.0	6	12.0	14	14.0
4	2	4.0	8	16.0	10	10.0
5	1	2.0	2	4.0	3	3.0
6	4	8.0	2	4.0	6	6.0
Mean	2.40		2.54			
SD	1.37		1.30			
t	0.525					
p-value	0.601					

Mean number of 50µg misoprostol required in group I was 2.40±1.37 while in group II it was 2.54±1.30. On applying student 't' test, the difference was found statistically insignificant (p>0.05).

Table 6: Distribution of cases according to need of oxytocin for augmentation

Need of Oxytocin for augmentation	Group I		Group II		Total	
	No.	%	No.	%	No.	2
Required	18	36.0	6	12.0	24	24.0
Not required	32	64.0	44	88.0	76	76.0
χ^2	7.895					
p-value	0.005					

Table 6: shows distribution of cases according to need of oxytocin for augmentation, it reveals that 36% of cases in group I whereas 12% cases in group II required augmentation with oxytocin. This shows that significantly less number of cases in group II required augmentation with oxytocin and the p value is significant (p=0.005).

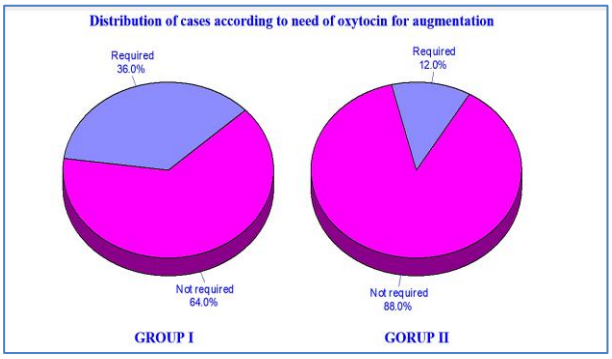

Table 7: Distribution of cases according to birth weight (kg)

Birth Weight (kg)	Group I		Group II		Total	
	No.	%	No.	%	No.	%
<1.5	8	16.0	10	20.0	18	18.0
1.51-2.50	22	44.0	20	40.0	42	42.0
2.51-3.00	14	28.0	11	22.0	25	25.0
>3.00	6	12.0	9	18.0	15	15.0
Mean	2.25		2.27			
SD	0.75		0.77			
T	0.153					
p-value	0.879					

The difference in birth weight between two groups was not significant in our study (p=0.879).

Table 8: Distribution of cases according to intrapartum and postpartum maternal complications

Maternal Complication	Group I		Group II		Total		χ^2	P
	No.	%	No.	%	No.	%		
Uterine Tachysystole	3	6.0	1	2.0	4	4.0	1.042	0.307
Postpartum Pyrexia	0	-	1	2.0	1	1.0	1.010	0.315
Postpartum Haemorrhage	0	-	0	-	0	-		

Out of 100 cases, 3 cases in group I and 1 case in group II had uterine tachysystole. Postpartum pyrexia was found in 1 case of group I. This difference was found statistically insignificant (p>0.05 in all).

Discussion

The present observational and prospective study is an attempt to compare the efficacy of extra-amniotic saline instillation with Foley catheter prior to oral misoprostol and oral misoprostol alone in induction of labour of pregnancies more than 28 weeks with intrauterine fetal death.

In our study, one hundred cases were randomly selected and grouped into group I and group II, of 50 each. Group I was induced by extra-amniotic saline instillation with Foley catheter followed by oral misoprostol and group II with only oral misoprostol. The induction delivery interval, vaginal delivery within 24 hours, mode of delivery, intrapartum and postpartum maternal complications, dose of oral misoprostol required and need of oxytocin for augmentation of labour were compared between the two group.

Maximum number of cases in our study had gestational age between 33-36 weeks with 38% in group I and 52 % in group II. Mean gestational age by ultrasound was 34.16 weeks in group I and 35.10 weeks in group II.

In comparison to study conducted by Mahomed and Jayaguru[5], where mean gestational age was 30.30 weeks and 29.20 weeks in two study groups, our cases were of higher gestational age. In our study induction was done in late intrauterine foetal deaths (>28 weeks). Overall there was no significant difference was found in the gestational age of both the groups, similar to previous studies[6](p = 0.372).

Mean Bishop score in group I and group II was 0.72 and 0.98 respectively. All patients had unfavourable Bishop score at the time of induction. Both groups are statistically comparable and p value is not significant (p=0.156). The finding is consistent with previous studies[5,6,7].

In our study, overall 3% of cases underwent caesarean deliveries. 4% in the extra-amniotic saline instillation followed by oral misoprostol and 2% in oral misoprostol alone group. Incidence of caesarean delivery was similar in both the groups and this finding was consistent with previous studies[5,7]. Overall 97 cases were delivered vaginally out of these ,48 cases were in group I and 49 were in group II. There was no significant difference in the mode of delivery either vaginal or caesarean delivery between the two groups (p=0.558). Most of the cases in our study delivered vaginally in both the groups. This finding is consistent with the finding of study conducted by Vengalil et al[8], in which induction of labour done in viable pregnancy by oral misoprostol and extra-amniotic saline infusion in two different groups. This observation indicates that both the induction methods used in our study are equally good in term of mode of delivery as caesarean delivery for dead fetus is performed only to ensure maternal health. Otherwise surgery for a fetal demise always put extra morbidity, emotional stress and financial burden to both patient and treating obstetrician.

In our study, in group I most of the cases (36%) delivered between 11-15 hours while in group II maximum number of cases (56%) delivered between 6-10 hours of the induction. In group I only 18% cases delivered in 6-10 hours of induction and 6% cases in group II delivered in <5 hours of induction. In group I, 20% cases delivered between 16-20 hours whereas in group II only 10% women took this time to get delivered.

Mean induction delivery time in group I was 16.88 hours and in group II was 10.99 hours. This difference was found to be significant (p<0.001) because in group I transition to active labour occurred late by misoprostol as it was given after initial six hours of extra-amniotic saline instillation in comparison to group II where induction was started with oral misoprostol only. Extra-amniotic saline instillation helped in cervical priming but for establishing the active labour misoprostol was required. In the study conducted by Barrilleaux et al[6], induction was done in viable pregnancy and no significant difference was found in the induction delivery interval in oral misoprostol group and combination group of Foley catheter and oral misoprostol.

In our study, overall 87% cases delivered within 24 hours. In group I, only 78% cases and in group II 96% cases delivered within 24 hours. (p=0.007)This difference was found statistically significant and indicates that extra-amniotic saline instillation followed by oral misoprostol took more time for effective stimulation of labour in case of unfavourable cervix.

Vengalil et al[8] observed that majority of cases(81%) in their study, delivered in less than 24 hours from initiation of induction which is similar to our study where overall 87% cases delivered within 24 hours of induction. They observed that there were no significant differences in median time to delivery between misoprostol group and extra-amniotic saline infusion group which is significant between our study groups.

In the study of Chen[7], Barrilleaux et al[6] no significant difference was observed when the both groups compared on the basis of delivery within 24 hours and median time of delivery.

Mohmad and Jayaguru[5] observed that most of the cases in their study delivered within 24 hours of extra-amniotic saline infusion.

In our study, average number of 50µg misoprostol required in group I was 2.40±1.37 whereas in group II, it was 2.54±1.30. Most of the cases (47%) including both groups required two misoprostol of 50µgm. It indicates that in both the groups same number of 50µgm misoprostol was required for induction even when the initial induction was done by extra-amniotic saline infusion in group I.

In present study the requirement of oxytocin for supplementation in group I is significantly higher (p=0.005). 36% cases in group I required oxytocin as compared to 12% in group II, it is comparable to previous studies[7].

Overall 42% babies had birth weight between 1.51-2.50 kg including both groups. In group I, 8% and in group II 20% babies had birth weight of less than 1.5 kg. There was no significant difference in the mean birth weight of group I (2.25kg) and group II (2.27kg) (p=0.879). This is similar to other studies[5].

In our study, the intrapartum and postpartum complications were very less and only 4 cases had uterine tachysystole in either group. Overall only1 case of postpartum pyrexia was found in group II. No case of postpartum haemorrhage was recorded in either group. This difference was found statistically insignificant similar to other studies[8]. It signifies that both the induction methods are safe in view of maternal intrapartum and postpartum complications.

Conclusion

Our study depicts that both extra-amniotic saline instillation followed by oral misoprostol and oral misoprostol alone are safe, effective and non invasive regimes for induction of labour in more than 28 weeks of pregnancies with intrauterine foetal death.

After extra-amniotic saline instillation there was significant improvement in Bishop score as it helped in cervical ripening but for transition to active labour oral misoprostol was required. Cases in the EASI group complained of the discomfort of the vaginal insertion of the catheter and wetness of the bed from the leakage of saline, but not unduly troubled by this.

Thus it can be concluded that oral misoprostol tablet alone is more effective at inducing and setting up the active labour in pregnancies of >28 weeks with intrauterine foetal death than EASI followed by oral misoprostol. It is inexpensive, has a long shelf life, can be easily stored at room temperature and patient remains ambulatory after induction with oral misoprostol. Oral misoprostol alone seems to have an edge over extra-amniotic saline instillation followed by oral misoprostol in all aspects.

Our study is very small, larger and multicentric studies are required to justify the results of extra-amniotic saline instillation followed by oral misoprostol or misoprostol alone in the induction of labour in pregnancies of more than 28 weeks with intrauterine foetal death.

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