A comparative study of combination of intracervical foley's catheter and intravaginal misoprostol versus intravaginal misoprostol alone for induction of labour

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Abstract

Aims & Objective: The goal of induction of labour is to achieve vaginal delivery in a safe timely manner, to prevent unnecessary LSCS and for safe neonatal outcome. The main objective of this study is to compare combination of intracervical Foley's catheter and intravaginal misoprostol with intravaginal misoprostol alone for induction of labour.

Materials and Methods: A prospective randomized study was conducted on 200 patients with term singleton pregnancy admitted in the Department of Obstetrics and Gynaecology of Government Medical College and Rajindra Hospital Patiala from November 2014 to July 2016, for induction of labour with Bishop score ≤ 4 and were randomly allocated to Group A and Group B. Group A consisted of 100 women in whom intracervical 16F Foley's catheter was inserted along with 25 microgram intravaginal misoprostol. Group B also had 100 participants who received 25 microgram misoprostol intravaginally. Misoprostol was repeated 4 hourly and maximum of 5 doses were given in both the groups. Multiple variables including induction delivery interval (IDI), mode of delivery, maternal and foetal outcome were analyzed.

Result: 86% of the patient in group A and 88% of the women in group B delivered vaginally. IDI was shorter in Group A (14.58±6.67 hours) than Group B (19.11±10.20 hours) which was statistically significant.

Conclusion: The combination of intracervical Foley's catheter and intravaginal misoprostol for cervical ripening and induction of labor appears to be a safe and more effective method compared to intravaginal misoprostol alone in parturient at term with unfavorable cervices.

Keywords: Foley's catheter, Misoprostol, Induction of labor, Intracervical, Intravaginal.

Introduction

Labour is a sequence of uterine contractions that results in effacement and dilatation of cervix and voluntary bearing down efforts leading to expulsion per vaginum of the products of conception.[1] Induction of labour is a common procedure in obstetrics. It is defined as initiation of labour by artificial means prior to spontaneous onset at viable gestational age with aim of achieving vaginal delivery in pregnant women.[2] The goal of induction of labour is to achieve vaginal delivery in a safe timely manner, to prevent unnecessary caesarean section and for safe neonatal outcome.[3] Mostly labour sets in spontaneously but for various obstetrical and medical indications it needs to be induced when the benefits either to the mother or the foetus outweighs those of continuing the pregnancy.[4] In developed countries, rate of induction of labour has doubled and it accounts for 25% of all deliveries.[5]

Methods of induction of labour include mechanical, surgical, pharmacological and combined methods. Mechanical methods are among the oldest and most important approach used for induction of labour.[2] It includes Foley's catheter, hygroscopic laminaria tent and extra amniotic saline infusion. Mechanical methods lead to separation of membrane from lower uterine segment which leads to release of lytic enzymes, indirectly stimulating the production of prostaglandins.[6] Pharmacological agents include prostaglandins (PG) E2 and E1, relaxin, oxytocin and mifepristone. Misoprostol is a synthetic analogue of prostaglandin E1.[7] Originally it was developed as gastrocytoprotective agent. It is used by sublingual, oral, buccal, vaginal and rectal route. Vaginal route significantly improves cervical ripening and the rate of vaginal delivery within 24 hours.[8] It is being widely used for induction of labour, abortion, prevention and treatment of postpartum haemorrhage.

One of the effective methods of cervical ripening in unripe cervix is combination of mechanical methods with prostaglandins. As mechanical devices result in cervical dilatation and PG agents soften and efface the cervix, the combination of the two methods may result in a greater degree of cervix ripening and successful labour induction.

With this assumption in mind many studies were conducted in different parts of the world. All came with different results. The present study was conducted on 200 women to compare the efficacy of combination of Foley's bulb and vaginal misoprostol with vaginal misoprostol alone for induction of labour

Materials and Methods

The present study was conducted in Department of Obstetrics and Gynaecology, Government Medical College & Rajindra Hospital Patiala. 200 women with indication for induction of labour were enrolled in the

study after fulfilling the inclusion and exclusion criteria. After proper counselling, a written informed consent was taken.

The women with term singleton pregnancy, cephalic presentation, intact membranes and unfavourable cervix i.e. Bishop score less than 4 were included in the study. The women with previous uterine surgery (LSCS or myomectomy), placenta previa, CPD and allergy to prostaglandins were excluded from the study. The study was conducted in a total of 200 women with 100 women in each group. In Group 1 women a 16F Foley's catheter was inserted through internal cervical os under all aseptic precautions and filled with 30-60 ml of sterile water. Catheter was then pulled against os and taped to inner side of the thigh. Simultaneously they received 25 micrograms of misoprostol per vaginum in posterior vaginal fornix which was repeated every four hours for a maximum of 5 doses. Catheter was removed after 24 hours if it was not expelled or the women didn't go into labour. Group B women received 25 micrograms of misoprostol per vaginum in the posterior fornix every four hour for a maximum of 5 doses. Subjects were observed for foetal heart sounds and initiation of labor. Partograph was maintained when the subjects went into labour. Women who didn't go into labour even four hours after maximum dose of misoprostol were considered as failed induction and were excluded from the study. The two groups were then compared with respect of induction to delivery interval, mode of delivery, maternal side-effects and fetal outcome.

Statistical Analysis

At the end of the study, the data was collected and analyzed by using Student t-test and Chisquare test. A p value of < 0.05 was considered significant.

Results

Of the total 200 women studied, 100 were assigned to each group. Both group were comparable with respect to maternal age, parity, period of gestation and Bishop score at time of induction. (Table 1)

Table 1: Subjects characteristics in both groups

Variables	Group 1	Group 2	p value	Significance
Age	24.32±3.35 yrs	24.35 ± 3.30 yrs	0.107	NS
Primigravidae	72%	59%	0.053	NS
Period of Gestation	39.069 ±1.596 wks	39.166 ±1.602 wks	0.679	NS
Bishop Score	3.0700±.76877	3.5600±.68638	0.124	NS

Preeclampsia/APE (Antepartum eclampsia), postdated pregnancy and APH (Antepartum haemorrhage) were the leading indications for induction of labour. Pre-eclampsia/APE was observed in 46% and 44% of the women in Group 1 and 2 respectively. The second most common indication was post-dated pregnancy accounting for 25% of cases in Group 1 and 30% in Group 2. Antepartum Haemorrhage (11% in Group 1 and 12% in Group 2) was the other main indication in remaining of the subjects.

Two women in Group 1 and one woman in Group 2 didn't go into labour even after 125µg (i.e. maximum of 5 doses) of misoprostol and the intracervical catheter was removed after 4 hours of observation of last dose of misoprostol. They were induced by alternate method of induction, one of them delivered vaginally and two underwent LSCS due to foetal distress. They were considered as cases of failed induction.

In Group 1, among 98% women who had successful induction, 85.71% women had vaginal delivery while 14.29% underwent LSCS (lower segment caesarean section) due to foetal distress or NPOL (non-progress of labour) whereas In Group 2, among 99% of women with successful induction, vaginal delivery occurred in 88.89% cases and 11.11% landed up in LSCS despite good uterine contractions due to foetal distress or NPOL. The p value was non-significant (Fig. 1)

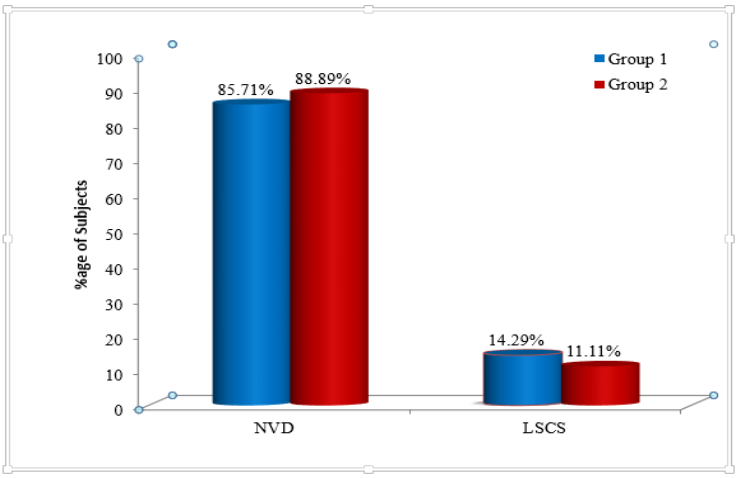

Fig. 1: Outcome of induction of labour in subjects with successful induction

In Group 1 nearly 50% of subjects delivered in less than 12 hours whereas in Group 2 only 29.55% delivered within 12 hours. In Group 1 majority of the cases (91.67%) delivered within 24 hours and only 8.33% of the women needed > 24 hours to deliver whereas in other group, 22.73% delivered in >24 hours. The mean induction delivery interval (IDI) in Group 1 came out to be 14.58±6.67 hours while in Group 2 it was 19.11±10.20 hours. *p*-value was significant showing that subjects in Group 1 took shorter time to deliver than the subjects in Group 2. (Table 2)

Table 2: Distribution of subjects according to induction delivery interval

Time in hours	Group 1		Group 2	
	No.	%age	No.	%age
6-12 hours	42	50.00	26	29.55
>12-24hours	35	41.67	42	47.72
>24hours	7	8.33	20	22.73
Total	84	100.00	88	100.00
Mean ± S.D	14.58±6.67		19.11±10.20	
p value	0.014			
Significance	S			

(The above table includes 84 women in Group 1 and 88 women in Group 2 with successful induction and vaginal delivery)

The mean amount of misoprostol required in Group 1 was 76.78 µg and 86.36 µg in Group 2. The *p* value was significant showing that mean amount of drug required for induction of labour in Group 1 was lesser than Group 2 (Fig. 2)

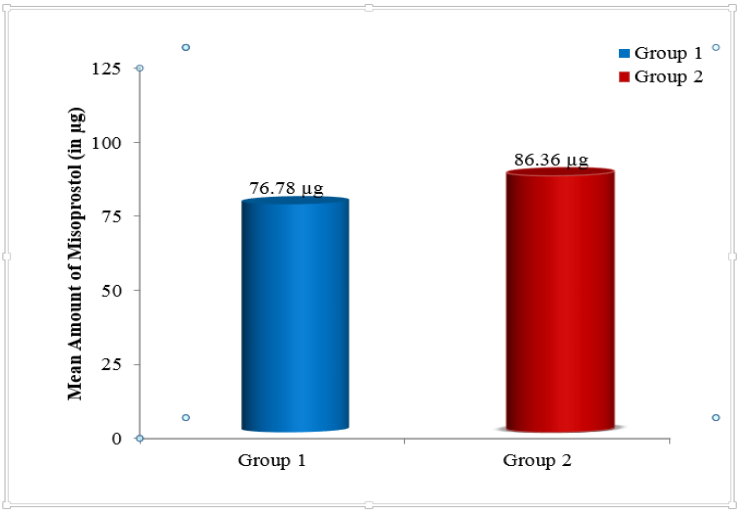

Fig. 2: Amount of misoprostol required in both the groups

Neonatal complications in the form of mild birth asphyxia were seen in 9.18% of the neonates in Group 1 and 12.12% of the neonates in Group 2. Neonatal jaundice occurred in 4.08% of the newborn in Group 1 and 4.04% in Group 2. Around 2% of the newborn in both groups had hypoglycaemia (Table 3).

Table 3: Maternal and neonatal outcomes

Variables		Group 1 (In %age)	Group 2 (In %age)
Neonatal complications	Birth Asphyxia (mild)	9.18	12.12
	Neonatal jaundice	4.08	4.04
	Hypoglycaemia	2.04	2.02
Maternal side effects	Hypertonic uterine action	6.12	5.05
	PPH	1.02	2.02
	Nausea & Vomiting	6.12	5.05
	Shivering	2.04	2.02
	Rupture uterus	0	0
	Chorioamnionitis	0	0

(The above table excludes the newborn of the women with failed induction)

Maternal side-effects in form of, hypertonic uterine action was observed in 6.12% of the cases in Group 1 and 5.05% of the cases in Group 2. The other less common side-effects were postpartum haemorrhage, shivering, nausea and vomiting. No case of chorioamnionitis was seen in our study (Table 3).

Table 4: Induction delivery interval of subjects in various studies

Author name and year of study	Group 1	Group 2	*p* value	Significance
Chung JH et al (2003)[9]	16.6 ± 8.2 hrs	17.5 ± 9.3 hrs	0.46	NS
Ande AB (2012)[12]	514 ± 175 mins	627 ± 268 mins	0.014	S
Carbone JF (2013)[3]	15.3 66.5 hrs	18.368.7 hrs	0.03	S
Lanka S (2014)[13]	26.52 hrs	27.64 hrs	0.65	NS
Kehl S (2015)[11]	32.43 hrs	22.46 hrs	0.004	S
Charaya E (2016)[2]	11.76±5.89 hrs	14.54±7.32 hrs	0.018.	S
Present Study (2016)	14.58±6.67 hrs	19.11±10.20 hrs	0.014	S

Discussion

Induction of labour is a commonly practiced nowadays in obstetrics to artificially initiate cervical dilatation, effacement and uterine contractions. Induction of labour with unfavorable cervix results in prolonged labour and increased rate of cesarean section. With time various methods of induction of labour came into practice. In an effort to find a better way to induce labour, various studies have been conducted all over the world. We conducted a study in our department and found that use of combination of the Foley's catheter and vaginal misoprostol for induction of labour shortened induction-to-delivery time by an average of 5 hours compared with vaginal misoprostol alone in cases with unfavourable Bishop score. No differences were observed in labour complications or adverse neonatal and maternal outcomes.

Among the two groups, 85.71% cases had successful vaginal delivery without aid in Group 1 while LSCS was required in 14.29% of cases after successful induction. 88.89% cases delivered vaginally in Group 2, while 11.11% had LSCS after successful induction. These results are comparable to study by Charaya E[2] and Baron B[10] whereas Chung JH et al[9] and Carbone JF[3] studies have shown higher caesarean rates. The studies by Kehl S[11] and Ande AB[12] showed lesser LSCS rate in combination group.

In the present study, the mean induction delivery interval in Group 1 came out to be 14.58±6.67 hours while in Group 2 it was 19.11±10.20 hours. *p* value was statistically significant. The present study is consistent with studies done by Carbone JF[3], Ande AB[12] and Charaya E,[2] who also found induction delivery interval lower in combined regimen groups as compared to subjects who were given only misoprostol and the difference was statistically significant. In studies conducted by Lanka S[13] and Chung JH[9] the IDI was lesser in combination group (Group 1) but statistically non-significant. The IDI was higher in the combination group than the misoprostol group in the study conducted by Kehl S[11] as he gave misoprostol after 24

hours of intracervical catheter insertion and that too by oral route (Table 4).

In our study, 91.67% cases delivered within 24 hours in Group 1 whereas 77.27% cases delivered within 24 hours in Group 2. This result shows that combination of misoprostol with intracervical catheter results in more percentage of vaginal deliveries within 24 hours. Our results are concordant with the studies done by Charaya E[2] and Carbone JF.[3] But in the study conducted by Baron B[10] only 45% and 40% of the women delivered within 24 hours in Group 1 and Group 2 respectively as in his study the misoprostol was not given simultaneously with intracervical catheter. Also the dose of misoprostol was lower (20 µg) and it was given through oral route.

This implies that induction to delivery interval is shorter when induction is done with combination of Foley's catheter and vaginal misoprostol than vaginal misoprostol alone.

The incidence of hypertonic uterine action in our study was 6.12% and 5.05% in Group1 and Group 2 respectively which was comparable to the study conducted by Baron B,[10] but much lesser than the incidence found in the study by Chung et al (2003).[9]

Conclusion

It is concluded from the present study that intracervical Foley's catheter and misoprostol combination is better than misoprostol alone for induction of labour in cases with unfavourable Bishop score. The induction delivery interval and mean amount of misoprostol are reduced in the combination group. However, rate of caesarean section, maternal side-effects and fetal complications were comparable in both groups. Hence combination of Foley's catheter and vaginal misoprostol is a good option for patients with unfavourable Bishop score undergoing induction of labour.

References

1. Archie C, Roman A. Normal and abnormal labor and delivery. In: Decherney A, Nathan L, Nerilaufer, Roman A, eds. In: Lange current diagnosis and treatment in obstetrics and gynaecology. McGraw Hill, USA. 14th edn., 2013.p.154-62.
2. Charaya E, Dahiya K. Comparative study of combined Foley Bulb and Vaginal Misoprostol with Vaginal Misoprostol alone for cervical ripening and Induction Labour Research Article Br J Med Health Res. 2016;3(5) ISSN: 2394-967.
3. Carbone JF, Tuuli MG, Fogertey PJ, Roehl KA, Macones GA. Combination of Foley Bulb and Vaginal Misoprostol Compared With Vaginal Misoprostol Alone for Cervical Ripening and Labor Induction A Randomized Controlled Trial. Obstet Gynecol 2013 Feb.; 121 (2 pt-1):247-52.
4. Promila J, Gill BK, Bala T. A Comparison of Vaginal Misoprostol versus Foley's catheter with oxytocin for induction of labour. J Obstet Gynecol India Jan/Feb;57 (No 1);p.42-7.
5. National Collaborating Centre for Women's and Children's Health. Induction of Labour. London, UK: RCOG Press;2008.
6. Josie L.Tenore.: Methods for Cervical Ripening and Induction of Labour. Am Fam Physician. 2003 May 15;67 (10): 2123-8.
7. Misoprostol. Available at: http://www.drugs.com/ monograph/ misoprostol.html). The American Society of Health-System Pharmacists. Retrieved Feb 20,2015.
8. Hofmeyr GJ, Gülmezoglu AM, Pileggi C. Vaginal misoprostol for cervical ripening and induction of labour. Cochrane Database Syst Rev 2010;CD000941.
9. Chung JH, Huang WH, Rumney PJ, Garite TJ, Nageotte MP. A prospective randomized controlled trial that compared misoprostol, Foley catheter and combination miosprostol-Foley catheter for labor induction. Am J Obstet Gynecol 2003;189:1031–5.
10. Baron B Matonhodze , G Justus Hofmeyr, Jonathen Levin: labour induction at term –a randomised trail comparing foley's catheter plus titrated oral misoprostol solution, titrated oral misoprostol solution alone, and dinoprostone. May 2003 , vol. 93, no.5 SAMJ.
11. Kehl S, Ziegler J, Schleussner E, Tuschy B, Berlit S, Kirscht J, Weiss C, Siemer J, Sutterlin M. Sequential use of double balloon catheter and oral misoprostol versus oral misoprostol alone for induction of labour at term(CRB trial): a multicentre , open label randomized control trial. BJOG 2015;122:129-36.
12. Ande AB, Ezeanochie CM, Olagbuji NB Induction of labor in prolonged pregnancy with unfavorable cervix: comparison of sequential intracervical Foley's catheter-intravaginal misoprostol and intravaginal misoprostol alone. Arch Gynaecol Obstet 2012 Apr; 285(4):967-71. doi: 10.1007/s00404-011-2094-4. Epub 2011 Oct.
13. Lanka S, Surapaneni T, Nirmalan PK. Concurrent use of Foley catheter and misoprostol for induction of labor: a randomized clinical trial of efficacy and safety.jObstet Gynaecol Res. 2014 Jun;40 (6):1527-33. doi: 10.1111/jog.12396.