ORIGINAL ARTICLE

Comparative Evaluation of Oral Misoprostol, Vaginal Misoprostol and Intracervical Folley's Catheter for Induction of Labour at Term

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Abstract

The present study was undertaken to compare the safety and efficacy of intra-vaginal misoprostol, oral misoprostol and intra cervical catheter balloon for induction of labour at term in terms of interval from induction to birth, mode of delivery, maternal complication, neonatal outcome and to find out failure rate in induction of labour in all the group. Each of the three groups were allotted 30 pregnant women at term who were considered for induction of labor. The observations were made with regard to induction delivery interval, mode of delivery, any complications, APGAR score & failure of induction. Mean induction delivery interval was shortest (10:35 hrs) in vaginal misoprostol group with increased LSCS rate in Oral Misoprostol & Foley's Catheter group. Also failure of induction was not to be seen in vaginal misoprostol group. Vaginal Misoprostol for induction of labour appears to be safe & effective method with least complications.

KeyWords

Misoprostol, Induction of Labour, Induction Delivery Interval

Introduction

The artificial termination of pregnancy beyond 28 weeks of gestation or before the onset of spontaneous labour by initiating uterine activity by independent stimulus that aims to secure a vaginal delivery is called as induction of labour (IOL) (1). The incidence of IOL has been reported to be 50% in 1993 (2) and has further increased due to PIH, postdatism, IUGR and congenital malformations.

Use of Foley's Catheter as a mechanical method of IOL had its advantages of simplicity, cost effectiveness, reversibility and minimal side effects (3). Exogenously administered Prostaglandins are relatively newer Pharmacological agents used for IOl. Initially PGE_2 gel was used intracervically but due to its high cost and cold storage problems, it is being replaced by newer PGE_1 tablets for effective and safe induction. Misoprostol (PGE_1) tablets acts as effective myometrial stimulant, is quiet stable in vivo and is rapidly absorbed orally and vaginally. Well controlled studies indicated its efficacy via oral route (4). More recent data shows that vaginal administration of PGE_1 tablets is sufficient & more efficacious to induce labour at term (5) and appears to be more effective than conventional methods of cervical ripening and labour induction (6). Although , Misoprostol administered by the bucal/sublingual routes having advantage of rapid onset of action & greatest bioavailability have been suggested (7).

Hence in view varying studies and with the idea to provide some relevant data to give new direction in the management of induction of labour in full term the present study was done to compare the safety and effectiveness of oral misoprostol, vaginal misoprostol and intracervical foley's catheter for cervical ripening & IOL in women with unripe cervices.

Matreial and Methods

The study was conducted on 90 pregnant women at term in deptt of obst. & Gynae, SMGS Hospital, Jammu over a period of one year. After getting full informed consent, the subjects were randomly assigned to three groups viz : Oral misoprostol (Group-I), vaginal

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misoprostol (Group-II) and intracervical foley's catheter (Group-III), thus each group getting 30 subjects. A detailed history followed by general physical examination was done to rule out any cardio-respiratory, hepatic and renal disease, obstetrical examination included P/A - for fundal height, lie, presentation and fetal heart sound. P/V - examination was done for assessing bishop's score and pelvis. Routine biochemical investigations include ABO/ Rh, Hb, BT, CT, Urine examination and obstetrical USG was done.

Inclusion Criteria

- 1st or 2nd gravida with single live fetus in cephalic presentation with indication for IOL like postdatism, PET, chronic hypertension, congenital abnormalities etc.
- Gestational age 37-42 weeks.
- Bishops score of 5 or less
- Absence of uterine contractions.

Exclusion Criteria

- Previous uterine surgery
- Non reassuring fetal heart rate tracing
- IUGR, Oligohydramnios
- Placenta Praevia, Multifetal pregnancy
- Fetal malpresentation, cord prolapse
- Any evidence of Chorioamnionits, active Herpes
- Estimated Fetal weight > 4kg
- Renal or Hepatic disease (Group I&II)

Group I - Patients received 50 ugm PGE_1 tablets orally.

Group II - Patients were inserted 25 ugm PGE_1 tablets in posterior veginal fornix aseptically

GroupIII - IOL was done with intracervical inflation of No. 16 or No.18 Bardias Foley's Catheter with 35 C.C of Normal Saline aseptically. In group I & group II, doses were repeated every 4 hours to a maximum of 5 doses (if required) until patients went into active labour & augmentation with oxytocin was done, or non reassuring fetal heart tracings developed, or no response/ failure of induction occurred. In group III, catheter was kept till it was spontaneously extruded or after 16 hours was taken out, Bishop's score assessed followed by amniotomy & oxytocin augmentation. During whole intrapartum period strict mointering of fetal heart rate rhythm was done & uterine activity was moniterd for tachysystole, hypertonus & hyper stimulation syndrome. Induction of labour was considered to have failed when cervix was unfavourable for amniotomy after 24 hours or after 5 doses of misoprostol.

Results

The different indications for which the patients were induced were postdatism (48.8%), PIH (33.3%), PROM (16.66%) and others (1.11%). *Table I* shows the Bishop's Score of the patients in the present study which was <3 in 86.66% patients and 3-5 in 13.3% cases indicating all have unfavourable score prior to induction. The mean induction delivery interval (IDI) was shortest in Vaginal Misoprostol (Group II) patients i.e. 10.35 hours *(Table 2)*. It was concluded that prolonged IDI had adverse effect on outcome of labour resulting in high LSCS rate & failure of induction in Group I&III.

Table 3 also shows that there was no case of failure of induction in Vaginal misoprostol group as against 16.6% failure in each of Group I & Group III patients. With regard to the need of augmentation with titrated doses of oxytocin only 23.30% patients required oxytocin in Group II whereas in Group I& Group III Oxytocin was needed in 56.6% and 86.66% cases respectively. One minute Apgar Score <7 was found in one baby (3.3%) in each Group I & Group II but in 3 babies (10%) in Group III. But at 5 minutes only one baby from Group I & Group III had APGAR score of <7 which needed NICU admission for less than one week. No baby from Group II needed NICU admission. Negligible complications occurred in the form of tachysystole in one patient (3.3%) inGroup I, hypertonus in one patient (3.3%) in Group II & only one patient had vomiting in GroupI. After analysing *Table 4* & keeping all parameters into consideration, it can be concluded that Group II i.e. Vaginal Misoprostol Group is most favourable with shortest IDI, reduced LSCS rate, no failure rate, minimal need for oxytocin, lower maternal and fetal complications which was the primary objective of the study.

Statistical Analysis

The data was analysis with the help of computer software SPSS120 for windows. The data represented as percentage as well as mean & SD as being appropriate. Statistically significant difference were evaluated using Chi square test. A p value of <.05 was considered as statistically significant.

Discussion

IOL is an integral component of any maternity practice and is often taken up in the interest of mother and fetus. The initial test of trial for any method of unfavorable cervix into favourable one & in the present study the change in the mean Bishop's Score was 4.0±0.2, 4.0 ± 0.3 and 3.9±0.3 respectively for Group I,II & III. Wing *et al* (5) concluded mean pre-induction Bishop's Score as 2 in Group I & II. Bishop's Score was 3 before redosing in both the groups.

In the present study the mean induction delivery interval was least in vaginal misoprostol group, being 10.35 hrs,

Table 1: Initial Bishop's Score

Bishop's	Group I		Group II		Group III	
Score	No.	%	No.	%	No.	%
<3	26	86.67	27	90	25	83.33
3-5	4	13.33	3	10	5	16.66
Total	30	100	30	100	30	100

Chi²(2) 0.50 p 0.74 (Non Significant)

Table 2: Introduction Delivery Interval

Time	Group I		Group II		Group III	
Hours	No.	%	No.	%	No.	%
0-6	2	6.6	4	13.31		
0-12	5	16.6	15	50	2	6.66
12-24	6	20	7	23.3	8	26.6
>24	4	13.3			7	23.3

Mean induction delivery interval was Group I-15.05 hours Group II-10.35 hours Group III-22.14 hours
Chi²(2) 15.81 p = .0003 (Significant)
For analysis data analysed as <12 hr and >than 12 hr

the result being highly significant with P <0.0003. Similar results were been in study of Sanchez-Ramos (8) where mean IDI was 11.5 hours. However, Wing *et al* (5) found IDI for this group as 22.05 hours. The better results of the present study could be attributed to low body weight & body surface area of the patients in our country. The shorter IDI in group II could be explained on the bases of greater oxytocic effect on uterus via vaginal route due to direct access to myometrium by cervical canal. With regards to outcome, Group II showed 86.6% successful outcome i.e Vaginal delivery with healthy mother & baby and with no case of failure of induction, Similar results were seen in study conducted byShetty *et al* (9) wherein 80% Group II patients delivered vaginally. Need for oxytocin augmentation was significantly high in Foley's catheter group (86.6%) & least in Vaginal Misoprostol group. Chuck *et al* (10) also observed the minimal titrated oxytocin need in vaginal misoprostol group.

No baby in Group II needed NICU admission, clearly ruling out any adverse affect of the drug on the neonate's health even though one baby in each of the other two groups needed NICU admission but discharged in healthy condition. Careful monitering of labour is essential for reducing neonatal complications.

Conclusion

There is no doubt that IOL confers benefit in various material & fetal conditions. The present study has emphasized on the fact that Misoprosol is perfect substitute for PGE_2 gel, it being cheaper & more stable at room temperature, Moreover our study corroborates the effectiveness & safety of Vaginal Misoprostol 25 ugm for IOL at term when compared to Oral Misoprostol 50 ugm & intracervical foley's catheter.

Table 3: Clinical Outcome of Induction of Labour

Group	Successful		Unsuccessful			
	No.(%)	Total %	LSCS	%	Failure	%
Group I	17(56.6)	13 (43.3)	8	26.6	5	16.6
Group II	26 (86.6)	4 (13.3)	4	13.3	nil	
Group III	17 (56.6)	13 (43.3)	8	26.6	5	16.6

Chi²(2) 8.10 p = .01 (Significant)

Table 4: Comparative Evaluation Between Groups

Groups	G-I	G-II	G-III
Mean IDI (hours)	15.05	10.35	22.14
Successful V. Delivery (%)	56.6	86.6	56.6
LSCS (%)	26.6	13.3	26.6
Failed induction (%)	16.6		16.6
Need for Oxytocin (%)	56.6	23.3	86.6
A/S <7 at 5 minutes (%)	3.3		3.3
Admission to NICU (%)	3.3		3.3
Maternal Complications	6.6%	3.3%	

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