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To evaluate the efficacy of oral misoprostol solution (prostaglandin E_1) for induction of labour

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Abstract

Background: Induction of labour is an intervention that artificially initiates uterine contractions leading to progressive dilatation and effacement of cervix and expulsion of fetus prior to spontaneous onset of labour.

Methods- This study was carried out in Labour ward at Apollo BGS Hospitals, a tertiary health care centre in Kuvempunagar, Mysore. 50 patients with an indication for induction of labour was receive 0.5 mg intracervical dinoprostonegel and repeated for a maximum of 3 doses every 6 hours as needed. 50 patient with an indication for labour induction was receive with 20ml [20 microgm] oral misoprostol solution and repeated every 2 hourly until adequate uterine contractions occurred [3 contractions per 10 min lasting 30-40 second].

Results: Neonatal outcomes were also similar between the two treatment groups. The percentage of infants requiring admission to the intensive care unit and the proportion of meconium stained liquor is slightly less in cerviprime gel than in oral misoprostol solution (4% vs 8%) (p- 0.40) and not much difference meconium stained liquor between two groups (4% vs 8%). Apgar scores @1min and 5 min were similar.

Conclusion: Misoprostol is cheaper than other preparations of prostaglandins and has few side effects. It does not require refrigerated transport or storage and easy to use when compared with the dinoprostone gel. The disadvantages of the dinoprostone are it requires refrigeration and is expensive; more over it causes discomfort to the patient when used intracervically.

Keywords: Labour, Induction, Misoprostol and Dinoprostone

Introduction

Currently, there are pharmacological (administration of prostaglandins or isosorbide mononitrate) and mechanical (insertion of balloon catheters or cervical dilators) methods for cervical ripening. Prostaglandins are considered the most effective agent in women with an unfavourable cervix, these molecules being effective for both cervical ripening and the induction of labour. Their main adverse effect is excess uterine activity with or without cardiotocographic abnormalities, and these effects are route of administration and dose dependent.[1-3]

Misoprostol, a synthetic analogue of prostaglandin E1, is indicated for the prevention and treatment of peptic ulcer disease. This drug stimulates the endometrium,

induces uterine contractions and is effective for cervical ripening . In addition, its low cost and the fact that can be stored at room temperature make it a key drug for the induction of labour in developing countries. Misoprostol can be administered by various routes: buccal, oral, rectal, sublingual and vaginal. The dose and duration of administration of this drug, however, have not yet been well defined.[4-6]

Materials And Methods

Study Setting

This study was carried out in Labour ward at Apollo BGS Hospitals, a tertiary health care centre in Kuvempunagar, Mysore.This is the tertiary referral centre for perinatal care serves an almost 1000 annual births. Our induction rate is around 20% with approximately 500 inductions per Year.

Study Duration: This study was carried out for 2 years from July 2017 to May 2019.

Study design: Hospital based observational study.

Study Population1 Study Area: 100 Patients getting admitted to labour ward of OBG Department of Apollo BGS Hospitals, Mysore with an indication for induction of labour.

Study Population: The study was conducted on women getting admitted to labour ward of OBG Department of APOLLO BGS HOSPITAL,Mysore and those women meeting inclusion criteria of study and willing to participate in study.

Ethical clearance was taken from the Ethical Clearance Committee.100 cases was taken for study as calculated by the sample size. The patients getting admitted to labour ward of OBG Department of APOLLO BGS HOSPITAL, ysoren,between 37 weeks to 40 weeks of gestational age with an indication for induction of labour. Those fitting in to inclusion criteria was included in study. Informed consent will be taken after explaining the procedure.

50 patients with an indication for induction of labour was receive 0.5 mg intracervical dinoprostonegel and repeated for a maximum of 3 doses every 6 hours as needed.

50 patient with an indication for labour induction was receive with 20ml [20 microgm] oral misoprostol solution and repeated every 2 hourly until adequate uterine contractions occurred [3 contractions per 10 min lasting 30-40 second].

Statistical Analysis

Statistical analysis was performed using MS Excel and R-3.5.1 software.

All the tests of significance are carried out at 5% level of significance.

The statistical methods used are:

a. Non parametric test - Wilcoxon rank sum test

Abbreviations:

p-value – probability val

b. The Chi square test,

Results

Mode of delivery	Cerviprime Gel	Oral Misoprostal Solution	Chi-square value	Significance	
Spontaneous Vaginal delivery	36(72%)	43(86%)	3.73	P=0.155	NS
Instrumental vaginal delivery	5(10%)	4(8%)			
LSCS	9(18%)	3(6%)			

Table 1: Mode of delivery

In both groups, the majority of women had spontaneous vaginal delivery, 72% with cerviprime gel, and 86% with oral misoprosol solution. The instrumental delivery rate was10%and 8% in cerviprime gel and oral

misoprostol solution group respectively. The LSCS rate was 18% and 6% with cerviprime gel and oral misoprostol solution group respectively. There was no statistically significant difference (p=0.155).This figure (4-1) clearly indicates that both misoprostol and dinoprostone produce more delivery by spontaneous vaginal methods compared to caesarean and instrumental methods.

Table 2: Induction to vaginal delivery interval

Induction to Vaginal delivery interval (hrs)	Cerviprime Gel	Oral Misoprostol Solution	Chi square value	Significance	
<12	7(14%)	9(18%)	11.6	P=0.008	Significant
12-24	21(42%)	34(68%)			
24-36	19(38%)	7(14%)			
>36	3(6%)	0(0%)			

Table show number of patients delivered vaginally within 12 hours, 24 hours and >36 hours. There was significant difference in the number of patients delivered within 12 hours, 24 and 36 hours between both the groups. 14% in cerviprime gel group and 18% in oral misoprostol solution group delivered within 12 hours and 42% in cerviprime gel group and 68% in oral misoprostol solution group within 12-24 hours. The proportion of patients delivered within 24-36 hours was 38%% in the cerviprime gel group and 14% in the 38% in oral misoprostol solution group (p=0.008). The percentage of patients was slightly more in cerviprime gel than in oral misoprostol solution (6% vs. 0%) among the patient delivered more than 36hours.

Table 3: Fetal outcome

Indictors	Cerviprime Gel	Oral Misoprostol Solution	Chi-sqaure value	P – value	Significant
Liqour Meconium stained Clear	2(4%) 48(96%)	4(8%) 46(92%)	0.709	0.4	NS
NICU admission Yes No	2(4%) 48(96%)	4(8%) 46(92%)	0.709	0.4	NS

Apgar score <7	Cerviprime Gel	Oral Misoprostol solution	Significance	
	No. of patients (n)=50	No. of patients (n)=50		
@1min	8.42±0.64174	8±0.4517	2.81e-04	Significant
@5min	8.54±0.50345	8.9±0.3030	4.23e-05	Significant

Neonatal outcomes were also similar between the two treatment groups. The percentage of infants requiring admission to the intensive care unit and the proportion of meconium stained liquor is slightly less in cerviprime gel than in oral misoprostol solution (4% vs 8%) (p- 0.40) and not much difference meconium stained liquor between two groups (4% vs 8%). Apgar scores @1min and 5 min were similar.

Discussion

This following sub-section describes the discussions about the results obtained in this study that was described in Results and Analysis along with the other published works.

Labour induction is one of the most common obstetrics procedures with its incidence being 20% with all pregnant patients. Recently, prostaglandins are commonly used as a cervical agent as it shortens the induction delivery interval, and reduces the maternal morbidity associated with the prolonged labour. Both the drugs are associated with the hyper stimulation with the fetal heart rate changes.[15-18] This study was performed in 100 patients in a observational way to assess the induction–delivery interval and effectiveness

of oral misoprostol solution and 0.5 mg of intracervical dinoprostone (used as cervical ripening agent).

Table 4: Comparison of mode of delivery in different study

Study and year	Misoprostol			Cerviprime Gel		
	Vaginal delivery	Instrumental delivery	LSCS	Vaginal delivery	Instrumental deliverey	LSCS
Present study	86%.7%	8%	6%	72%	10%	18%
Xiu Wang et al [7](2016)	85.5%	12.1%	14.2%	81.9%	17.8%	18%
Agarwal et al.[8] (2003)[97]	NA	NA	26.6%	NA	NA	15%
G.J. Hofmeyer [9] et al.(1999)	82%	0%	18%	74%	2%	24%

Most of the patient delivered vaginally in both the groups, but the more in misoprostol group as compared to cerviprime gel and the rate of instrumental delivery was more in cerviprime gel group than in misoprosto group. The instrumental delivery was indicated more commonly for failure of secondary maternal forces. There was no significant difference between the rates of cesarean delivery between the two groups. This study is similar to Xiu Wang et al(2016)[7], and Agarwal et al. (2010)[8] and in G.J. Hofmeyer et al. (1999)[9] vaginal delivery was more in misoprostol as compared to cerviprime gel and no instrumental delivery was done Agarwal et al. (2003)[8] studies the rate of the vaginal delivery has not mentioned.

Table 5: Comparison of fetal outcome with other studies

Study	APGAR<7@1MNT		APGAR<7@5MNT	
	Misoprostol	Dinoprostone	Misoprostol	Dinoprostone
Present study	4(36.4%)	6(42.9%)	0	0
Xiu Wang et al (2016)[7]	8	9	3	3
Shakya et al. (2010)[10]	11	6	0	1
G.J. Hofmeyer [9]et al. (1999)	5	2	0	0

The number of neonates with 1-minute Apgar scores < 7 was small, and no neonate had a 5-minute Apgar score < 7 in both the study group. The number of newborn babies admitted to the NICU were very less in both the grups and it was 6 newborns in misoprostol and 4 cerviprime gel group.The main reasons for admission were meconium staining of amniotic fluid and respiratory distress.The pediatric unit admits newborns for observation for 1-2 days when ever there is meconium staining of amniotic fluid. But, none of these neonates were resuscitated or died. The present study observation is well agreed with the G.J. Hofmeyer (1999)[9], Xiu Wang et al.(2016) [7]and Shakya et al. (2010)[10] with respect of apgar score and meconium passage. However, there was no NICU admission in the other studies because the babies were observed alongside of the mother.

Conclussion

Misoprostol is cheaper than other preparations of prostaglandins and has few side effects. It does not require refrigerated transport or storage and easy to use when compared with the dinoprostone gel. The disadvantages of the dinoprostone are it requires refrigeration and is expensive; more over it causes discomfort to the patient when used intracervically.

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