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Original Research Article

Comparative Study of 25 µg Vaginal Misoprostol V/S Cerviprime Gel for Induction of Labour at Term

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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:*** The average number of cerviprime gel doses given per patient was 1.42 ± 0.6417, whereas the average number of oral misoprostol solution doses given per patient was 4.52±1.2162 ($p < 0.001$). ***Conclusion:*** In conclusion, we found that both misoprostol and dinoprostone are useful and safe drugs for cervical ripening and labour induction when used at flexible doses and at intervals of 6 hours between doses in a low-risk population with unfavourable cervices. However, misoprostol offers the advantages of more rapid labour and less cost

Keywords: Labour, Induction, Misoprostol and Dinoprostone.

INTRODUCTION

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. In some 5-25% of pregnancies, there comes a time when the fetus and/or mother would be better off if delivery was conducted. Prostaglandin analogue has been emerged for use in labour induction. Prostaglandins alter the extracellular ground substance of the cervix, ripen the cervix and also increase the activity of collagenase in the cervix. They also allow for an increase in intracellular calcium levels, causing contraction of myometrial muscle. The FDA revised its labeling for misoprostol in April 2002 from "contraindicated in pregnancy" to "contraindicate in pregnancy for the treatment and prevention of NSAID induced ulcers". Currently, two prostaglandin analogs PGE1 (Misoprostol) and PGE2 (Cerviprime gel) are available for the purpose of cervical ripening.

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, Mysore, between 37 weeks to 40 weeks of gestational age with an indication for induction of labour. Those fitting in to inclusion criteria were 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

Table-1: Demographic characteristics of the cerviprime gel and oral misoprostol solution

Indicators	Cerviprime Gel	Oral Misoprostol Solution	Significance*	
	No of patients (n) =50	No of patients (n) =50		
Age(yrs)	25.26±3.8269	26.50 ± 2.7423	p=0.066	NS
Gestational age(days)	271.5 ± 11.8084	267.6 ± 10.3053	p= 0.083	NS

Table shows that the mean age of the patients included in the present study were 25.26± 3.8269 and 26.50 ± 2.7423 in cerviprime gel and oral misoprostol solution respectively. The mean gestational age at induction in cerviprime gel and oral misoprostol solution treated groups were 271.5 ± 11.8084 and 267.6± respectively.

Table-2: Effect of misoprostol and dinoprostone on cervical ripening and time intervals to delivery

Indicators	Cerviprime Gel	Oral Misoprostol Solution	Significance	
Preinduction bishops score(mean)	4.14 ± 0.8332	4.4 ± 0.8329	p=0.122	NS
Post induction bishops score (mean)	5.7 ± 1.1473	10.04 ± 1.6031	P<0.0001	S
Indution to pain interval	8.106 ± 5.1483	3.26 ± 0.8992	P <0.0001	S
Induction to delivery interval (hrs)	22.38± 9.1626	16.2 ± 6.6394	P<0.0001	S

Number of doses of misoprostol and dinoprostone used for the induction

The maximum doses used for the induction of labour may vary between 1-3 in cerviprime gel and 1-8 in oral misoprostol solution depending upon the bishop's score and uterine contraction. The doses were repeated every 6th hourly in cerviprime gel before active labour have started and 2nd hourly in oral misoprostol solution till moderate contraction have started. After giving the additional doses of oral misoprostol solution or cerviprime gel, fetal monitoring by CTG for one hour and monitoring of uterine contraction for tachysystole and hyperstimualtion was performed.

Table 3: Number of doses of cerviprime gel and oral misoprostol solution used

Number of doses	Cerviprime Gel	Oral Misoprostol solution	Significance	
	No. of patients (n) = 50	No. of patients (n) = 50		
	1.42 ±0.6417	4.52±1.2162	<0.001	Significant
1	33 (66%)	0		
2	13 (26%)	0		
3	4 (8%)	12 (24%)		
4	0	12 (24%)		
5	0	19 (38%)		
6	0	3 (6%)		
7	0	3 (6%)		
8	0	1 (2%)		

The table showed the number of doses of cerviprime gel and oral misoprostol solution used for the induction for labour. The average number of cerviprime gel doses given per patient was 1.42 ± 0.6417, whereas the average number of oral misoprostol solution doses given per patient was 4.52±1.2162 ($p < 0.001$). Majority 33 out of 50(66%) of the cerviprime gel treated patients received single dose and in oral misoprostal solution treated group no patients out of 50 received single dose. The percentage of patients who received two; three and four doses in cerviprime gel treated groups were 26%, 8%, and 0%respectively, whereas the number in oral misoprostol solution treated group were 0%, 24% and 24%. In oral misoprostol solution majority of patients 38% were given 5 doses and 6, 7 and 8 doses were 6%, 6% and 2%.

DISCUSSION

Majority of the patients involved in the present study were between 26 and 30 years of age 68% in oral misoprostol solution and 44% in cerviprime gel group. The mean age was 25.26±3.8269 in cerviprime gel and 26.50±2.7423 in oral misoprostol solution group similar to Patil Kumar P *et al.* [2] and Xiu Wang *et al*. study [3].

The mean gestational age at induction in oral misoprostol solution and cerviprime gel treated groups were 267.6 ± 10.3053 and 271.5 ± 11.8084, respectively. The gestational age between 37-39 weeks was more in oral misoprostol solution group (44%) than in cerviprime gel groups and (22%). Gestational age of >40 weeks were slightly more in the cerviprime gel group 58% when compared with oral misoprostol solution group (<36%). Pandis *et al.* [4] results are slightly different (with difference of one week) because of inclusion and exclusion criteria.

Most of the induction of labour 34% was done for postdated pregnancy in cerviprime gel group and 8% in oral misoprostol solution group and around 30% in cerviprime gel group and 54% in oral misoprostol solution group were performed electively for safe confinement for the patients staying far away from the hospital who has come to the hospital at term gestation with fear or discomfort. Pandis *et al*. [4], Patil Kumar P. *et al.* [3] and G.J. Hofmeyr *et al.* [5] study has showed difference from present study as the induction of labour was performed in majority with post dated pregnancy.

Effect of misoprostol and dinoprostone on cervical ripening and time intervals to delivery

The following table shows that there was a significant improvement in the bishop's score after the induction and it was more with the oral misoprostol solution when compared with the cerviprime gel. Misoprostol was more effective than PGE2 in producing cervical changes ($p<0.0001$). This change in the bishop's score was more in present study (misoprostol in solution form and oral route) to that in Agarwal *et al.* [5] and Shakaya *et al.* [6] (misoprostol in tablet form and vaginal route) study.

Table-4: Comparison of Post bishops score after induction with other study*

Study	Misoprostol	Cerviprime Gel	Significant
Present study	10.04 ± 1.6031	5.7 ± 1.1473	P<0.0001
Shakaya *et al*. [6]	4.90±5.48	5.58±2.0	0.22

*Bishops score after 6 hours after induction

CONCLUSION

In conclusion, we found that both misoprostol and dinoprostone are useful and safe drugs for cervical ripening and labour induction when used at flexible doses and at intervals of 6 hours between doses in a low-risk population with unfavourable cervices. However, misoprostol offers the advantages of more rapid labour and less cost.

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