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TO COMPARE SUBLINGUAL VERSUS PERVAGINAL MISOPROSTOL IN INDUCTION OF LABOUR AT TERM

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ABSTRACT

Background: Induction of labour, in modern obstetrics is an intervention devised to artificially begin the process of cervical dilatation, cervical effacement and uterine contractions, leading to the eventual birth of the baby. Induction of labour can be indicated by maternal or fetal, or both. **Material and Methods:** 360 women were included in the study where 25 µg of misoprostol, sublingually in group 1 was given and vaginally in Group 2. The progress of labor and foetal heart rate pattern in these patients was was monitored. Furthur doses of misoprostol were given every 6 hours. **Results and Conclusion:** 72.78% of the patients in the study belonged to 23-32 years of age. The two groups in my study were similar in obstetric variables (gestational age, parity, cervical effacement and cervical dilatation at the time of admission) and demographic variables. There bishop's score was markedly improved in both the routes in my study.

INTRODUCTION

The birth of a child has been a prominent event in the family of any civilization, culture, or society. Intense antenatal care along with the proper intra-partum care of the parturient woman safeguards the advent of the new born. The birth of a healthy child has always been regarded as a matter of pride and joy. Vaginal delivery is not only physiological but also the best option for the successful child birth.[1] Therefore, the obstetrician preferably lets nature follow its course and waits for labour to take place on its own. But, in some cases where this poses risk to maternal or fetal wellbeing obstetricians are required to carry out labour induction. Induction of labour, in modern obstetrics is an intervention devised to artificially begin the process of cervical dilatation, cervical effacement and uterine contractions, leading

to the eventual birth of the baby. Induction of labour can be indicated by maternal or fetal, or both

MATERIALS AND METHOD

This observational study was done at the Obstetrics And Gynaecology Department At Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha from 1st September 2017 to 31st August 2018.

INCLUSION CRITERIA

- Pregnancy with singleton live foetus with cephalic presentation
- term pregnancy
- uncomplicated twin pregnancy
- Oligohydramnios
- Gestational hypertension
- Gesational Diabetes Mellitus
- Pre mature rupture of membranes.

EXCLUSION CRITERIA

- Previous uterine surgery
- Major foetal malformation
- Parity >3
- Severe renal, hepatic failure
- Any medical disorder such as cardiac disease, glaucoma, convulsive disorder, asthma, severe anaemia
- Any contraindication to vaginal delivery like cephalopelvic disproportion
- Known hypersensitivity to prostaglandin.

All the women who were willing to participate in the study had to give an informed consent. Two groups were then divided depending upon the route of administration of the drug. Patients received tablets from envelope assigned to them and was instilled in the posterior fornix of the vagina under all aseptic precautions. Group 1 received 25 µg of misoprostol sublingually 6 hourly and the maximum dose was of six doses. Group 2 received 25 µg of misoprostol 6 hourly vaginally and the maximum dose was of six doses.

The patients underwent a per vaginum examination performed for the assessment of Bishop score followed by administration of 25 µg of misoprostol, sublingually in group 1 and vaginally in Group 2. The progress of labor and foetal heart rate pattern in these patients was was monitored. Furthur doses of misoprostol were given every 6 hours until there were regular uterine contractions (i.e.3-4 contractions every 10 minutes, lasting for 30-45 sec), cervical dilatation of >4 cm, Bishop score of >8 or evidence of hypertonus, tachysystole or hyperstimulation. In the event of tachysystole, uterine hypertonus or hyperstimulation, the woman was given left lateral and administration of oxygen was done by facemask at the rate of 6-8 liters per minute. Injection terbutaline 250 µg will be given by subcutaneous route in case of hyperstimulation and hypertonus.[2] The uterine contraction was monitored by palpation and FHS monitoring was done by auscultating intermittently as per protocol. NST tracing was taken in case of any event or features that suggest foetal distress. If the foetal heart rate was non reassuring, further doses of misoprost were witheld. When the patient enters the active phase of labour[3] management is done as per the intrapartum management protocol of the labour room. In case the patient did not deliver after a period of 24 hours, management was done as per the clinician on duty. If there was any side effect, like gastrointestinal side effects or fever were noted. Primary outcome measure included percentage of women delivering vaginally. The time taken from inducing the patient and the onset of labor and from onset of labour to delivery was also noted, the total number of doses of misoprostol(25µg) required, percentage of women who did not deliver in the span of 24 hours, the time taken from induction of the patient to her delivery, rate of maternal side effects (uterine tachysystole(percentage of foetal distress (meconium stained liquor or foetal heart rate abnormality)), neonatal Apgar score and their admission to NICU were taken as secondary outcomes.

Table 1: Comparison of Bishop Score in two groups on admission and at last dose of misoprostol.

Chisquare Test

	Bishop Score	SLM Group	VM Group	⍺2-value	p-value
On Admission	0 to 3	85(47.22%)	89(49.44%)	0.17	0.42 NS
	4 to 6	95(52.78%)	91(50.56%)		
	>6	0(0%)	0(0%)		
	Total	180(100%)	180(100%)		
	Mean±SD	3.68±0.73	3.66±0.73		
Last Dose of Misoprostol	0 to 3	4(2.22%)	4(2.22%)	0.920	0.62 NS
	4 to 6	75(41.67%)	84(46.67%)		
	>6	101(56.11%)	92(51.11%)		
	Total	180(100%)	180(100%)		
	Mean±SD	6.56±1.31	6.55±1.24		

In our study table no 4 shows that bishop's score at the time of admission was 0 to 3 in 85(47.22%) patients and between 4 to 6 in 95(52.78%) patients and more than 6 in none of the patients in slm group, while it was 0 to 3 in 89(49.44%) patients, 4 to 6 in 91(50.56%) and none of the patients had bishop's score more than 6 in vm group. The mean bishop's score at time of admission in slm and vm group was 3.68±0.73 and 3.66±0.73 respectively

No. OF MISOPROSTOL DOSES REQUIRED

Table 2: Distribution of woman according to number of doses in two groups.

No of doses	SLM Group	VM Group	⍺2-value
1 to 2	73(40.56%)	67(37.22%)	0.83 p=0.66,NS
3 to 4	100(55.56%)	103(57.22%)	
5 to 6	7(3.89%)	10(5.56%)	
Total	180(100%)	180(100%)	
Mean±SD	2.38±1.20	2.36±1.09	

Table 3: Distribution of patients in two groups according to duration of oxytocin infusion.

Duration of Oxytocin(hrs)	SLM Group	VM Group	⍺2-value
0.5-1.5	58(92.78%)	8(10.56%)	244.36 p=0.0001,SS
2-3	4(7.22%)	54(74.44%)	
3.5-4.5	0(0%)	10(15%)	
Total	62(100%)	72(100%)	
Mean ±SD	1.06±0.46	2.66±0.73	

In our study the results shows the duration of oxytocin in both the groups. 58(92.78%) patients in slm group and 8(10.56%) patients in vm group required oxytocin for 0.5 to 1 hr for delivery. There were 4 (7.22%) patients in slm group and 54 (74.44) % patients in vm group who required oxytocin for augmentation for 2-3 hrs. The p value in this case came out to be 0.0001. this is a significant value.

COMPARISON ACCORDING TO INDUCTION TO DELIVERY INTERVAL

Table 4: Comparison of induction to delivery interval in two groups.

Z-test for difference between two means.

Group	N	Mean (hrs)	Std. Deviation (hrs)	Std. Error Mean	z-value
SLM	180	7.88	4.73	0.35	9.10 p=0.0001,S
VM	180	12.78	10.63	0.79	

The mean induction to delivery time shows where in slm group it is 7.88 hrs with std deviation 4.73 and in vm group is 12.78 hrs with std deviation 10.63 and std error of mean 0.79. The p value came out to be 0.0001 which is found to be significant.

DISTRIBUTION ACCORDING TO MODE OF DELIVERY

Table 5: Distribution of woman according to mode of delivery in two groups.

Mode of delivery	SLM Group	VM Group	⨯2-value
Caesarean Section	26(14.44%)	23(12.78%)	0.98 p=0.61,NS
Instrumental Vaginal Delivery	8(4.44%)	12(6.67%)	
Vaginal Delivery	146(81.11%)	145(80.56%)	
Total	180(100%)	180(100%)	

Table 5 shows the delivery mode in both the groups the rate of vaginal delivery is almost same in both the groups while there were 26 (14.44%) patients in slm group who had undergone caesarean section and 23 (12.78%) patients who had to be taken for caesarean section. there were 8(4.44%) patients in slm group and 12(6.67%) patients in vm group who had instrumental delivery. 146(81.11%) patients in slm group and 145(80.56%) patients delivered vaginally in both the groups.

DISCUSSION

The present study shows that Bishop's score at the time of admission and the last dose of misoprostol in the two groups. In comparison with the study conducted by j madhu et al where bishop score of 1-2 had 19 women in case of sublingual misoprostol and 18 in case of

vaginal misoprostol groups while 3-4 bishop score was seen in 30 women who received sublingual misoprostol and 31 in vaginal group and it was similar in both the groups signifying that the route of induction does not determine the cervical ripening. A similar study was conducted by J Madhu et al where bishop score of 1-2 had 19 women in oral group and 18 in vaginal group while 3-4 bishop score was seen in 30 women in oral group and 31 in SLM group. No significant difference was found between the two groups.[4]

This denotes that the duration of oxytocin required in patients who were induced with sublingual misoprostol was less as compared to those with the patients who were induced vaginally.

This is in accordance with the study conducted by Siwach S et al where the duration of oxytocin required with misoprostol was 5.70±2.46 (hours).(123)

In our study the mean induction to delivery time shows where in slm group it is 7.88 hrs with std deviation 4.73 and in vm group is 12.78 hrs with std deviation 10.63 and std error of mean 0.79. The p value came out to be 0.0001 which is found to be significant.

This is in comparison to the study conducted by J Madhu et al where the induction to delivery time was less in slm group as compared to vm group. This is in comparison with the study conducted by jmadhu et al where time interval in slm was less compared to vm group and was statistically significant. Mean time interval in slm group was 11 hours 37 minutes±5 hours 56 minutes and that in vm it was 15 hours 14 minutes±6 hours 34 minutes. This was found to be significant statistically.[4]

our study shows the delivery mode in both the groups the rate of vaginal delivery is almost same in both the groups while there were 26(14.44%) patients in slm group who had undergone caesarean section and 23(12.78%) patients who had to be taken for caesarean section. there were 8(4.44%) patients in slm group and 12(6.67%) patients in vm group who had instrumental delivery.146(81.11%) patients in slm group and 145(80.56%) patients delivered vaginally in both the groups. the p value in this case came out to be 0.61 which is non significant. this shows that the mode of delivery does not vary with the route of administration of misoprostol.

This is in comparison with the study conducted by J.Madhu where 4 patients in slm and three patients in vm underwent instrumental vaginal delivery (outlet forceps).caesarean section was done for 12% in slm group and 14% in vm group.[4]

RESULTS AND CONCLUSION

Sublingual misoprostol is slightly better than vaginal misoprostol as it improves the cervical ripening Sublingual route of misoprostol has suggestively less time interval from inducing the patient to their delivery. Lesser number of doses of misoprostol were required in sublingual groupthan vaginal group to achieve adequate contractions. Very few patients had some minor side effects in both groups. None of them has any major side effects. The women who were induced with subingual misoprostol were more satisfied as the number of pervaginal examinations were less. There was no adverse effect on foetal heart rate and APGAR score. Misoprostol is more cost effective than any other induction agent so it should be used frequently. It also stable at room temperature and therefore not requiring any refrigeration. Hence the sublingual route of misoprostol is somewhat better than vaginal route and that why it should be put more into consideration and practice.

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