

Comparison of patient satisfaction amongst sublingual and pervaginal misoprostol administration in induction of labour at term.

¹Dr. Archana Suneja, MBBS, DGO, DNB Obstetrics and Gynaecology

²Dr. Mayank Dutta, MBBS, MS Orthopaedics

Corresponding Author: Dr. Mayank Dutta, MBBS, MS Orthopaedics

Citation this Article: Dr. Archana Suneja, Dr. Mayank Dutta, “Comparison of patient satisfaction amongst sublingual and pervaginal misoprostol administration in induction of labour at term”, IJMSIR- August - 2022, Vol – 7, Issue - 4, P. No. 109 – 117.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Labour induction incidence has seemed to rise over the past few decades. Rate of induction of labour in Asian and Latin American countries is of 30 % of all pregnancies following induction of labour, the proportion of women delivering vaginally is found one in 4. Induction comes along with many maternal complications consisting of uterine scar rupture, uterine rupture, uterine hyper- stimulation, chorioamnionitis, and postpartum haemorrhage from uterine atony. Foetal demise and foetal complications are rare complications of induction of labour.

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 labour and foetal heart rate pattern in these patients was monitored. Further doses of misoprostol were given every 6 hours according to the bishops score assessment.

Results and conclusion: There was a significant proportion (p= 0.001) of women who were satisfied in sublingual misoprostol group (95.65%) as compared to vaginal misoprostol group (83.33%) in terms of route of

administration and were satisfied with their labour experience. Despite of labour being a painful process more women in sublingual misoprostol group had a positive attitude towards induction of labour in their subsequent pregnancies. Gestation age, parity, induction to delivery interval was similar in both the groups.

Keywords: Sublingual misoprostol, per vaginal Misoprostol, satisfaction, labour.

Introduction

Induction of labour, being the oldest interventions in obstetrics, dates back to the ancient Greece, where the labour was particularly induced in women having a narrow pelvis in order to prevent the excessive growth of the foetus. Post term pregnancy, intra uterine growth retardation, premature rupture of membranes, and hypertensive disorders are clinical indications. According to the WHO guidelines, in the rural areas of the developing countries like India, where the hospitals are too far from home (1)and it becomes a potent risk to wait for spontaneous labour to occur at home, labour induction can be done at term in low risk women(2).

Successful induction of labor includes certain factors namely, cervical score of patient, parity status and pre induction BMI(3).

97 percent multiparas and 76 percent nulliparas delivered vaginally by elective vaginal induction as reported by Consortium on Safe Labour by the investigators but the induction with ripe cervix was more successful(4). ARM and the use of oxytocin was seen to be more helpful in women with a ripe cervix. The situation when a woman is in labor and the cervix is not dilated is a challenge for the obstetrician.

The failure rates and increased complications are associated with these cases as compared to spontaneous labor. As a consequence of improper dilatation of cervix in such cases shoulder dystocia occurs. Hence it has been long recognised that this poses a challenge in the women with unripe cervix

Materials and methods

This study is an Observational study which has been conducted in the Department of Obstetrics and Gynaecology at Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha from September 2017 to August 2018.

Inclusion criteria

- Singleton live foetus in cephalic presentation
- Gestational age ≥ 34 weeks
- Postdated pregnancy ($>41+0$ weeks) or post term pregnancy ($>42+0$)
- Pregnancy with Oligohydramnios
- Gestational hypertension >38 weeks.
- Antepartum haemorrhage: abruption placentas,

Exclusion criteria

- Any uterine surgery
- foetal malformations
- Ante partum haemorrhage

- Severe renal, hepatic failure
- Placenta praevia
- Any medical disorder such as cardiac disease, glaucoma, convulsive disorder, asthma, severe anaemia
- Any contraindication to vaginal delivery like cephalopelvic disproportion, severe intrauterine growth induction (IUGR), oligohydramnios (<3 cm), clinically suspected chorioamnionitis or history of unclean vaginal examination,

- 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.

Group 1 received 25 μ g of misoprostol sublingually 6 hourly and the maximum dose was of six doses.

Group 2 received 25 μ g of misoprostol 6 hourly vaginally and the maximum dose was of six doses.

Bishop score is assessed by per vaginal examination followed by administration of 25 μ g of misoprostol, sublingually in group 1 and vaginally in group 2.

Labour progress is then monitored including foetal heart rate, contractions (intensity and frequency) and thereafter further doses of misoprostol were decided.

As the patient enters the active phase of labour 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 is done as per the clinician on duty.

If there was any side effect, like gastrointestinal side effects or fever were noted.

Patient's experience of labour is recorded as the baby delivers.

Observations and results

Booking status

Table 1: Distribution of woman according to booking status in two groups

Booking Status	SLM Group	VM Group	χ^2 -value
Booked	165(91.67%)	159(88.33%)	1.11
Unbooked	15(8.33%)	21(11.67%)	p=0.29, NS
Total	180(100%)	180(100%)	

Unbooked: <3 visits after 20 weeks of gestation.

Booked: At least having three visits in pregnancy after 20 weeks of gestation.(131)

Graph 1: Distribution of woman according to booking status in two groups

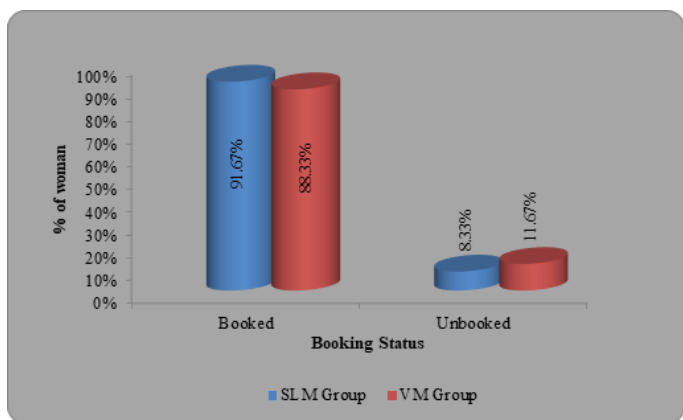


Table no 1 shows that 165 (91.67%) patients in SLM and 159(88.33%) patients in VM group were booked.

- There were 15(8.33%) patients in SLM group and 21(11.67%) in VM group who were induced with sublingual misoprostol and vaginal misoprostol respectively and were unbooked.
- The p value was 0.29 which came out to be non-significant.
- There were more booked patients found in our study as the follow up in our hospital is comparatively good due to the services provided and there are regular buses and vehicles for the patients' convenience.

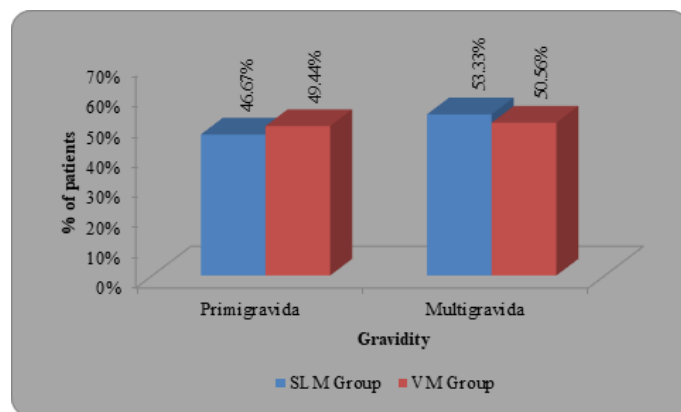
- There was no significant difference found with respect to booking status between the two groups.

Gravidity wise distribution

Table 2: Distribution of patients in two groups according to parity

Gravidity	SLM Group	VM Group	χ^2 -value
Primigravida	84(46.67%)	89(49.44%)	0.27
Multigravida	96(53.33%)	91(50.56%)	p=0.59, NS
Total	180(100%)	180(100%)	

Graph 2: Distribution of patients in two groups according to gravidity



- Table No 2 shows the distribution of patients according to gravidity.
- There are 84(46.67%) women in slm group who are primigravida while the vm group includes 89(49.44%) women who were primigravida.
- Multigravida consisted of 96(53.33%) women in slm group and 91(50.56%) in vm group.
- The p value came out to be 0.59 which is non-significant.
- Thus there is no significant difference between the parity of the women in two groups, whether the women is induced with sublingual misoprostol or per vaginal misoprostol the incidence of gravidity is same in both the groups.

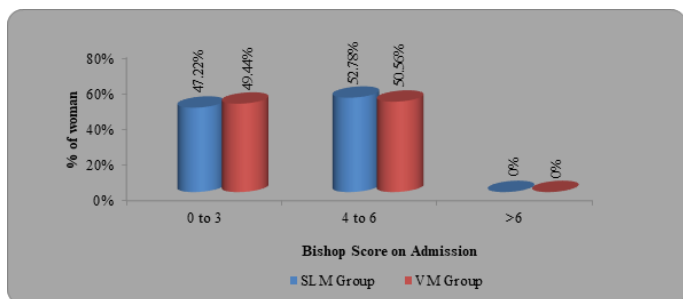
Bishop score in both the groups

Table 3: Comparison of Bishop Score in two groups on admission and at last dose of misoprostol

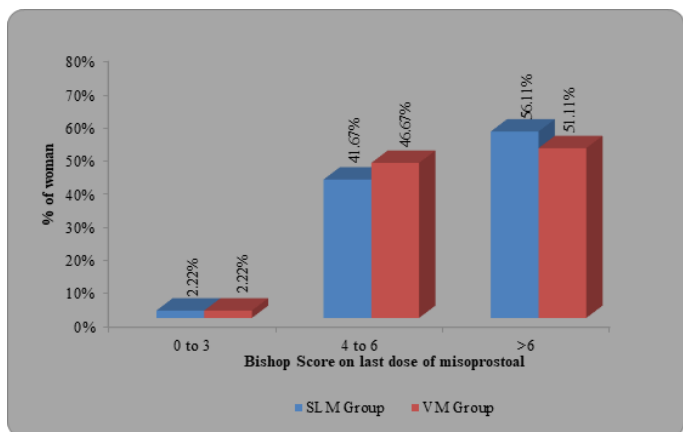
- Chi square Test

	Bishop Score	SLM Group	VM Group	χ^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		

Graph 3: Comparison of Bishop Score in two groups on admission in two groups.



Graph 4: Comparison of Bishop Score in two groups on last day of misoprostol in two groups



- Table No 3 shows that Bishop’s score at the time of admission was 0 to 3 in 85(47.22%) patients in SLM

group and 89 (49.44%) patients induced with sublingual and vaginal misoprostol respectively.

- In this table on admission, 95 (52.78%) patients were induced with SLM misoprostol and 91(50.56%) patients with vaginal misoprostol whose bishop’s score was between 4 to 6.
- There was no patient whose bishop’s score was >6 .
- After the last dose of misoprostol there were 4(2.22%) patients in both the sublingual as well as vaginal group whose bishops score remained 0 to 3 .
- There were 75 (41.67%) patients in SLM group and 84(46.67%) patients in VM group who were induced with misoprostol and their bishop score was between 4 to 6 after the last dose of misoprostol.
- 101(56.11%) patients in SLM group and 92(51.11%) patients in VM group had bishop’s score >6 after the last dose of misoprostol.
- The mean bishop score in SLM group at the time of admission was 3.68±0.73 and VM group was 3.66±0.73.

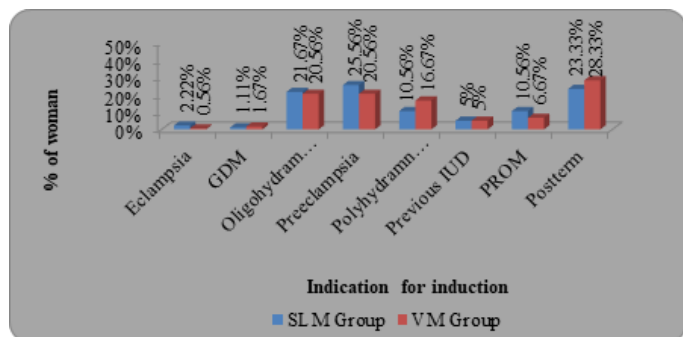
- The mean bishop score in SLM group at the time of admission was 6.56 ± 1.31 and VM group was 6.55 ± 1.24 .
- The p value between both the groups on admission came out to be 0.17 which was non-significant. This signifies that the bishop's score does not vary with the route of administration of the drug.
- The p value of the two groups at the last dose of misoprostol was 0.62 which was not significant concluding that the Bishop's score does not depend on the route of misoprostol.

Indication of induction

Table 4: Distribution of woman according to indication for induction in two groups.

Indication for induction	SLM Group	VM Group	χ^2 -value
Eclampsia	4(2.22%)	1(0.56%)	7.95 p=0.3 3, NS
GDM	2(1.11%)	3(1.67%)	
Oligohydramnios	39(21.67%)	37(20.56%)	
Preeclampsia	46(25.56%)	37(20.56%)	
Polyhydramnios	19(10.56%)	30(16.67%)	
Previous IUD	9(5%)	9(5%)	
PROM	19(10.56%)	12(6.67%)	
Post term	42(23.33%)	51(28.33%)	
Total	180(100%)	180(100%)	

Graph 5: Distribution of woman according to indication for induction in two groups.



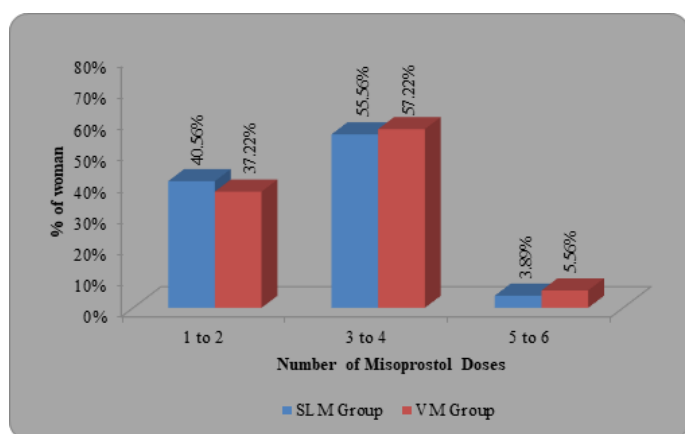
- Table 4 shows the indications for which the patients were induced with either sublingual or pervaginal misoprostol.
- There were 4 (2.22%) patients in SLM group and 1(0.56%) in VM group who were induced due to eclampsia sublingually and pervaginally respectively.
- 2 (1.11%) patients in SLM group and 3 (1.67%) patients in VM group were induced with sublingual and pervaginal misoprostol respectively with GDM.
- 39(21.67%) women with oligohydramnios and 37 (20.56%) patients with oligohydramnios were induced with sublingual and pervaginal misoprostol respectively.
- In SLM group 46(25.56%) women with preeclampsia and 37(20.56%) women in VM group who were diagnosed with pre-eclampsia were induced with sublingual and vaginal misoprostol respectively.
- 19 (10.56%) patients with polyhydramnios in SLM group and 30 (16.67%) patients with VM were induced with misoprostol.
- There were 9 patients in both the groups comprising of 5% patients in both the groups who were induced in view of previous childiud.
- 19 (10.56%) patients with PROM in SLM group and 12 (6.67%) patients with PROM were induced with sublingual and vaginal misoprostol respectively.
- The most common indication for induction in both the sublingual and misoprostol group was post-dated pregnancy which accounted to 42(23.33%) patients in SLM group and 52(28.33%) patients in VM group who were induced with misoprostol.
- Though the p value came out to be non-significant(0.33) but the most common cause of induction in either of the two groups was post-dated pregnancy.

No. Of misoprostol doses required

Table 5: Distribution of woman according to number of doses in two groups.

No of doses	SLM Group	VM Group	χ^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 \pm SD	2.38 \pm 1.20	2.36 \pm 1.09	

Graph 6: Distribution of woman according to number of doses in two groups.



- Table 5 shows the number of doses of misoprostol required for the induction of labour.
- 73(40.56%) patients in SLM group and 67 (37.22%) patients in VM group required 3-4 doses of misoprostol for labour.
- There were 100 (55.56%) patients in SLM group and 103(57.22%) in VM group who required 5 to 6 doses of misoprostol.
- In this table 5 (3.89%) patients in SLM group and 10(5.56%) patients in VM group required 5 -6 doses of misoprostol.
- The mean dose in SLM misoprostol 2.38 \pm 1.20 and in VM was 2.36 \pm 1.09. The p value came out to be 0.66 which was not significant .

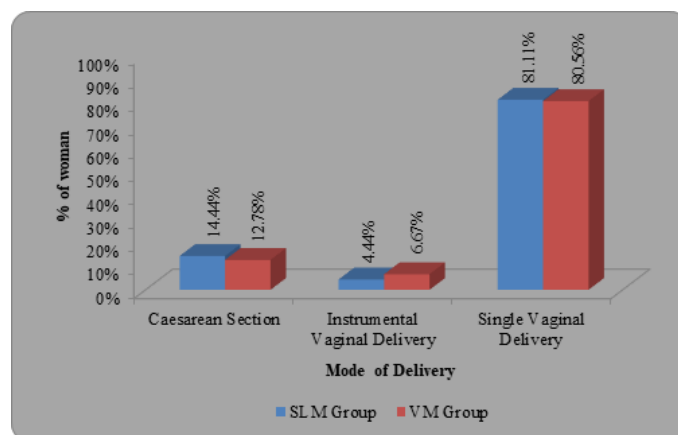
- This concludes that the total number of misoprostol in both the groups is comparable and the mean came out to be similar.

Distribution according to mode of delivery

Table 6: Distribution of woman according to mode of delivery in two groups

Mode of delivery	SLM Group	VM Group	χ^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%)	

Graph 7: Distribution of woman according to mode of delivery in two groups



- Table 6 shows the distribution according to the mode of delivery in two groups .
- 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.

Distribution according to patient satisfaction

Table 7: Distribution of patients in two groups according to patient satisfaction

Patient Satisfaction	SLM Group	VM Group	χ^2 -value
Not Satisfied	8(4.44%)	30(16.67%)	14.24 p=0.001, S
Satisfied	172(95.56%)	150(83.33%)	
Total	180(100%)	180(100%)	

Graph 8: Distribution of patients in two groups according to patient satisfaction

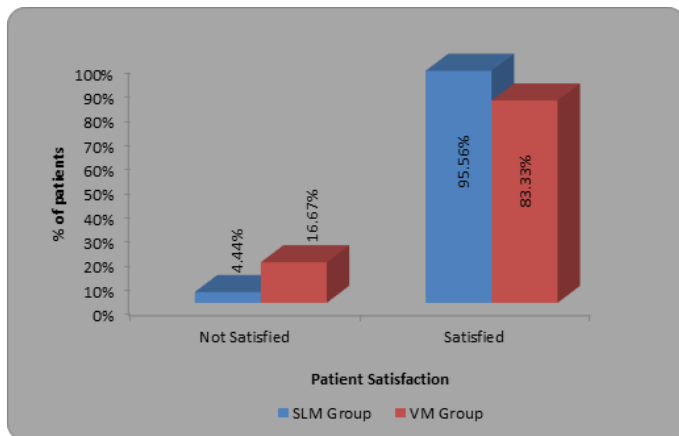


Table no 7 shows the patient satisfaction in both the groups.

95.56 % patients were satisfied in slm group while 83.33% in vm group;

The p value is 0.001 and it came out to be significant.

Discussion

This study was conducted in the department of obstetrics and Gynaecology, Acharya Vinoba Bhave Rural Hospital, Jawaharlal Nehru Medical College Sawangi

(Meghe), Wardha for the comparison of misoprostol as given sublingually and pervaginally for inducing labor at term.

Comparison of booking status of the two groups

The result observed in our study were subjected to statistical analysis. The tests used were by student’s chi-square test odd’s ratio and ‘t’ test. The results in our study shows that there were 324 (90%) patients who were booked while only 36(10%) patients were unbooked.

There was a study conducted by M Sunita et al where 30 were booked and 20 were unbooked accounting to 60% and 40 % respectively.(1)

Thus the patients who were booked were found more frequently to be induced than those compared with the unbooked patients. The rate of booked patients is more in our hospital as the follow of the patients is better due to the various services of transportation and counselling provided by our hospital.

Gravidity wise distribution

In our study table no 2 shows the distribution of patients according to gravidity. There are 84 (46.67%) women in slm group who are primigravida while the vm group includes 89(49.44%) women who were primigravida. Multigravida consisted of 96(53.33%) women in slm group and 91(50.56%) in vm group. The p value came out to be 0.59 which is non-significant. Thus, there is no significant difference between the parity of the women in two groups, whether the women is induced with sublingual misoprostol or per vaginal misoprostol the incidence of gravidity is same in both the groups.

This is in comparison with the study conducted by J. Madhu, where 70% of patients in slm group and in vm group 72% of patients were seen to be primigravida.(1)

The number of doses of misoprostol in two groups

The present study shows the number of doses of misoprostol required for the induction of

labour.73(40.56%) patients in SLM group and 67 (37.22%) patients in VM group required 3-4 doses of misoprostol for labour. There were 100 (55.56%) patients in SLM group and 103(57.22%) in VM group who required 5 to 6 doses of misoprostol. In this table 7 (3.89%) patients in SLM group and 10(5.56%) patients in VM group required 5 -6 doses of misoprostol. The mean dose in SLM misoprostol 2.38 ± 1.20 and in VM was 2.36 ± 1.09 . The p value came out to be 0.66 which was not significant. This concludes that the total number of misoprostol in both the groups is comparable and the mean came out to be similar. The p value was 0.66 which is not significant.

This is in comparison with the study conducted by J. Madhu et al where the mean number of doses required in slm group was 1.86 ± 1.088 and that in vm group was 2.96 ± 1.442 and this was statistically significant.(2)

Bishop's score on admission and at the last dose of misoprostol

The present study shows that Bishop's score at the time of admission and the last dose of misoprostol in the two groups. 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. 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.(1)

Mode of delivery between the two groups

The present 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.(3)

According to patient's satisfaction

In our study Table no 21 shows the patient satisfaction in both the groups. 95.56 % patients were satisfied in SLM group while 83.33% in VM group. The p value is 0.001 and it came out to be significant. This is in comparison with the study conducted by nassar et al in which the patient satisfaction with misoprostol administered sublingually or vaginally for labour induction at term there is preference for the sublingual route of

administration than vaginal route of misoprostol despite the higher rate of adverse effects experienced in this group. the sublingual route was more preferred than the vaginal route as the vaginal route was more embarrassing. Other studies, however, reported similar satisfaction rates with both routes. The sublingual route was due to the unpleasant taste and the GI adverse effects experienced.

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 group than 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 sublingual misoprostol were more satisfied as the number of pervaginal examinations were less.

Summary

Our study concludes that though both the routes of administration of misoprostol give similar results, there is an edge with sublingual misoprostol as there is lesser side effects, more patient satisfaction lesser oxytocin use and lesser induction to delivery time.

References

1. ACOG Issues Revision of Labor Induction Guidelines - ACOG [Internet]. [cited 2016 Oct 9]. Available from: <http://www.acog.org/About-ACOG/News-Room/News-Releases/2009/ACOG-Issues-Revision-of-Labor-Induction-Guidelines>. 42.
2. Wing DA, Tran S, Paul RH. Factors affecting the likelihood of successful induction after intravaginal misoprostol application for cervical ripening and labor

induction. Am J Obstet Gynecol. 2002 Jun;186(6):1237-1240-1243. 45.

3. Laughon SK, Zhang J, Grewal J, Sundaram R, Beaver J, Reddy UM. Induction of labor in a contemporary obstetric cohort. Am J Obstet Gynecol. 2012 Jun;206(6): 486.e1-9. 46.
4. Danish N, Fawad A, Abbasi N. Assessment of pregnancy outcome in primigravida: comparison between booked and un-booked patients. Journal of Ayub Medical College Abbottabad. 2010;22(2):23–25.
5. Mishra S, Chaudhary V, Sudhir S. A study of induction of labour at term with different prostaglandins. Prostaglandins. 2015;4(45):04.
6. Hangaraga US. Comparison of sublingual versus vaginal routes of misoprostol in induction of labor. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 2017;6(7):3062–3066.