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Original Research Article

Efficacy and safety of labor induction by oral versus vaginal misoprostol–study of 200 cases in private setup

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ABSTRACT

Background: Labour induction is an important obstetric procedure aimed at achieving vaginal delivery when pregnancy extends beyond term or the cervix is unfavorable. Misoprostol, a prostaglandin E1 analogue, is commonly used due to its effectiveness, low cost, and ease of storage. It can be administered orally or vaginally, with varying efficacy. This study compares the safety and efficacy of both routes for cervical ripening and labour induction.

Objective: To evaluate the efficacy and safety of vaginal versus oral misoprostol for third-trimester cervical ripening and labour induction in 200 patients at Mahavir Hospital, Surendranagar, Gujarat.

Materials and Methods: This prospective study enrolled 200 pregnant women requiring labour induction with misoprostol between October 2023 and September 2024. Participants were assigned to either vaginal or oral misoprostol (25 micrograms). Labour progress was monitored using WHO partographs. Primary outcomes included induction-to-delivery interval and mode of delivery, while secondary outcomes included maternal and neonatal outcomes and complications.

Results: Vaginal misoprostol was more effective for cervical ripening and reduced caesarean section rates compared to oral misoprostol. Of the 200 women, 100 received vaginal misoprostol, and 100 received oral misoprostol. Spontaneous vaginal delivery rates were similar (67% for oral, 68% for vaginal), and both routes showed higher spontaneous vaginal delivery rates (68%) compared to caesarean sections (12%). The vaginal group had a shorter induction-to-delivery interval. Additionally, more oral misoprostol patients (42) required multiple doses than vaginal misoprostol patients (55). Minimal side effects were reported.

Conclusion: Misoprostol, especially when administered vaginally, is a safe and effective method for labour induction. Vaginal misoprostol showed slightly better efficacy, reduced caesarean section rates, and shorter induction times compared to oral misoprostol. Ongoing monitoring is essential to ensure safety and improve outcomes for both mothers and babies.

1. Introduction

In today's modern obstetrics practice, induction of labour is one of the most key procedures.[1] This procedure is widely performed when continuation of pregnancy is hazardous to the mother and fetus or there is need to cut shorten the labour time. It is the artificial induction of uterine contraction before its spontaneous onset for purpose of delivery of the fetoplacental unit. The success of labour induction largely depends on the cervical factor, maternal health or bishop's score at the time of induction of labour.[2] A successful induction of labour refers to the vaginal delivery of the healthy baby, in desirable time with minimum maternal side effect or truma.

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Misoprostol drug is a prostaglandin E1 analogue molecule. It is a new agent for induction and cervical ripening and uterotonic properties.[3] It is less expensive, stable at room temperature with very less side effects and can be easily administered through oral, vaginal, route.[4] Most clinical trials have used 25 microgram every six hours vaginally and orally.[5]

1.1. Bishop score

Bishop scoring system is based on digital cervical examination of the patient with a zero (0) point which is minimum and 13 point which is maximum. This system uses cervical dilation, its position, effacement, consistency, and fetal station. Cervical dilation, effacement, and station are given 0 to 3 points, while cervical position and consistency are given o to 2 points.[6,7] Bishop score of 8 or greater is considered to be favourable for induction, or chances of vaginal delivery with induction is similar to spontaneous labour. A score 6 or less is considered to be unfavourable if an induction is indicated cervical ripening agents may be taken in use.[8]

Score	Dilation (cm)	Position of cervix	Effacement (%)	Station (-3 to +3)	Cervical consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Mid posterior	40-50	-2	Medium
2	3-4	Anterior	60-70	-1,0	Soft
3	5-6	-	80	+1,+2	-

2. Materials and Methods

This was prospective comparative study conducted in Scientific Research Institute, Surendranagar, Gujarat from October 2023 to September 2024. Study population comprised of 200 subsequent pregnant women.

25 microgram misoprostol vaginally and orally in alternative manner used every 6 hourly for maximum of five doses.

2.1. Inclusion criteria

1. Singleton intrauterine pregnancy
2. Full term pregnancy
3. Adequate pelvis size
4. Bishop score more than 6
5. No uterine contraction
6. Reactive non stress test
7. Previous LSCS
8. Multiparity (first baby vertex presentation)

2.2. Exclusion criteria

1. Malpresentation of fetus
2. Previous more than 1 caesarean section
3. Cephalopelvic disproportion of pelvic
4. Non- reactive non stress test
5. Placenta previa
6. Abruptio placenta
7. Vaginal delivery: any contraindicated

Step by step detailed history of all the patient is taken, followed by general physical examination of all the patients was done. Obstetrical examination included lie of baby, presentation of fetus, fundal height, fetal heart sound, per vaginal examination for assessing bishop's score and pelvis type. Antenatal ultrasound and required blood investigations were done to ensure correct gestational age and anaemia status of mother respectively. Duration, intensity and frequency of uterine contraction were observed and plotted on partograph. Study population was examined and vaginal 25 microgram misoprostol was placed in posterior fornix after moistening with normal saline. Similarly in every alternative patient tablet of 25 microgram misoprostol is given orally. Per vaginal examination done every 6 hourly to note the changes in the cervical dilatation and effacement status. To minimize the infection unnecessarily, per vaginal examination is avoided. Before each successive dose of 25 microgram misoprostol fetal heart monitoring was done and induction continued only if there is no fetal distress. Progress of labour charted on partograph. Induction was stopped when the adequate uterine contraction of at least 3 contraction/10 min each of 40sec duration is achieved. All patients were augmented with 2.5 Unit of Oxytocin in second stage of labour, another 2.5 unit of oxytocin was given in third stage for easy progression of labour. A further induction was withhold in cases of tachysystole, hyper tonus or hyper stimulation of uterus or non-reactive CTG not corrected by primary measures. If the patient did not enter active labour six hour after last dose the induction was considered to have failed and caesarean section was performed to avoid further maternal or fetal complications.

3. Result

Our study shows that the use of vaginal misoprostol results in more effective cervical ripening and induction of labour and to reduce rate of caesarean section and increasing rate of vaginal delivery compared to orally given misoprostol. Table 1 shows the of the study group with regards to maternal age and parity. In our study we included 200 pregnant women group in which 100 (50%) women were 25 micrograms of misoprostol tablet given vaginally and 100(50%) were given same dose orally. All patients were among age group of 20-30 years. Table 2 shows comparison of primary outcomes, spontaneous vaginal delivery with oral misoprostol (67%) and with vaginal misoprostol (68%) and instrumental vaginal delivery with oral misoprostol (21%) and with vaginal misoprostol (21%). Both with

Table 1: Demographic distribution of study populations

Characteristics	**Group (n=200)**
Maternal age	years 20-30 years
Parity	
a) Primipara	128 (64%)
b) Multipara	72 (36%)

Table 2: Primary outcome variables

Mode of delivery	**Oral route**	**Vaginal route**
Vaginal delivery	55 (67%)	81 (68%)
LSCS	10 (12%)	14 (11%)
Instrumental delivery (vacuum/ forceps)	17 (21%)	23 (21%)
Induction to delivery interval		
Vaginal delivery within 24 hours	(70%)	(85%)
Other parameters		
Uterine hyper stimulation	5% (5/100)	10% (10/100)
Haemorrhage	2% (2/100)	1% (1/100)

Table 3: Secondary outcome variables

No. of doses	**Vaginal delivery after oral route**	**Vaginal delivery after vaginal route**
1	5 (9%)	8 (9%)
2	8 (14%)	18 (22%)
>2	42 (77%)	55 (69%)

Table 4: NICU admission: 29(21%).

Indications for NICU admission	**With oral route**	**With vaginal route**	
Meconium stained liquor	5 (5%)	3 (3%)	8 (4%)
Delayed cry	5 (5%)	3 (3%)	8 (4%)
Fetal distress	6 (6%)	7 (7%)	13 (13%)
Total	16 (16%)	13 (13%)	29 (21%)

vaginal and oral route in sum spontaneous (normal) vaginal delivery rate is higher (68%) than caesarean section (12%). There was less induction to delivery interval in vaginal group compared to caesarean section, and among the vaginal delivery group, comparison done according to interval within 12 hours and within 24 hours vaginal delivery after induction. The secondary outcomes are given in Table 3. 42 patients among orally proffered group require more than 2 doses of misoprostol to effect delivery and 55 patients among vaginally proffered group require more than 2 doses of misoprostol to effect delivery. Very less side events were encountered during our study.

4. Discussion

Misoprostol 25 microgram for induction of labour has been very promising. Misoprostol administered vaginally is slightly more effective as conventional methods then orally for induction of labour at term or near term. Distribution according to demographic characteristic in our study population was almost similar to various studies.[9–12] This study shows that women who receive misoprostol vaginally experience slightly faster induction to delivery then orally given misoprostol.[13] Time taken for induction to vaginal delivery was significantly less in vaginal group as demonstrated by various studies, because vaginal misoprostol is absorbed quickly and removed slowly from body which makes it available to act for a longer time as compared to oral resulting in rapid progression of labor.[13] There is wide clinical experience with this agent and a large number of published reports supporting its safety and efficacy when used appropriately and in proper dose. Vaginal misoprostol significantly reduces the time interval from induction to delivery and increases chances of eventless vaginal delivery.[14]

5. Conclusion

As per 2013 SOCG guidelines which says that misoprostol is safe and effective agent for induction in labour with intact membrane for impatient. This is somewhat confirmed with our study with more recent data, as analysed we concluded that vaginal misoprostol appears to be slightly more efficacious and safe for cervical ripening and labour induction then oral misoprostol. Vaginal misoprostol tablet is most effective in achieving vaginal

Table 5: Other study data

Outcome	Route	Rehman et al[10] (50mcg PO vs. 25mcg PV)	J Anice et al[9] (50mcg PO vs. PV)	Jindal et al[15] (50mcg PO vs. PV)	Pandya et al[12] (25 mcg PO vs. PV)	Present study (25 mcg PV)
Vaginal delivery	Oral	58%	83.3%	74.5%	-	67%
	Vaginal	64%	76.8%	90.38%	68%	68%
Vaginal instrumental	Vaginal	-	-	-	20%	21%
	Oral	30%	16%	25.49%	-	21%
Caesarean section	Vaginal	29%	19%	9.62%	12%	21%
	Oral	21.22+2.4	27.3(18.8)	16.47%	-	11%
Induction to vaginal delivery interval	Vaginal	20.15+3.1	19.0(11.9)	9.79%	36%	85%
	Oral	27.27%	78%	-	-	70%
Oxytocin administration	Vaginal	23.6%	50%	-	-	-
	IV	-	-	-	-	-

births relatively rapidly then oral route. Misoprostol is considered as a safe agent for labour induction by world health organization (WHO). As per 2011 WHO guidelines WHO recommended misoprostol for induction of labour except in those with previous 2 LSCS (lower segment caesarean section). We have to assess patient's safety data and monitoring requirements, to ensure safe and better outcomes for pregnant women fetuses and neonates with use of misoprostol in induction of labour.

6. Source of Funding

None.

7. Conflict of Interest

None.

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