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Original Research Article

Use of low dose misoprostol for induction of labour in a secondary hospital setting: a retrospective cohort study of a unique induction protocol

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ABSTRACT

Background: Induction of labour is a procedure often used in pregnant women where there are clear medical indications. There are various modalities of induction of labour which differ in outcomes and complications. Our aim was to look at how effective our protocol using misoprostol was in achieving delivery within 24 hours of the start of induction, the induction delivery interval, Caesarean section rates and its indications using Robsons classification, uterine hyperstimulation with FHR changes and oxytocin augmentation and its duration.
Methods: This was a retrospective study which looked at the mode of induction and outcomes of women during the period from 1st February, 2021 to 31st July,2021.
Results: There were 2574 deliveries in the period February 1st, 2021 to July 31st, 2021. We found more nulliparous women and obese women in the induced group. The main indication for induction was past dates and the mean induction to delivery interval among the women being induced was 32 hours (SD: 22.58). There were significantly higher women who experienced PPH and Caesarean sections were 2.100 (1.577- 2.793) times higher among women who were induced.
Conclusions: Induction protocols need to be developed taking into consideration the advantages as well as complications associated with it and then tailor it according to infrastructure and personnel available.

Keywords: Induction of labour, Misoprostol, Low resource setting

INTRODUCTION

Induction of labour is defined as process of artificially stimulating the uterus to start labour. As induction of labour is not without risks, the WHO recommends induction to be performed when there are clear medical indications and when potential benefits outweigh the risks.[1]

The accepted indications of induction of labour include past dates, prelabour rupture of membranes, hypertensive disorders of pregnancy and intrauterine growth restriction.[2] Induction of labour when compared to expectant management at or beyond term is associated with a small reduction in perinatal deaths and caesarean sections as well as fewer NICU admissions and fewer babies with low Apgar scores compared.[3] Induction following premature rupture of membranes (PROM) has been shown to reduce chorioamnionitis, endometritis and neonatal ICU (NICU) admissions.[4]

Success of induction depends mainly on the favourability of the cervix. This is usually assessed using the Bishops score. An unripe cervix indicates a low possibility of successful vaginal delivery.

Rates of induction of labour have been steadily going up. The rates of labour induction in the U.S have been quoted

between 20-34% and still rising.[5] These have been attributed to both physician as well as patient factors. The epidemiology of labour induction in low-income countries is not well described, though in some settings they may be as high as observed in high income countries.[1]

There are various methods used for induction of labour. These include pharmacological agents (oxytocin, prostaglandins), or mechanical methods (introduction of Foley's catheters, sometimes with the injection of saline; double balloon inflatable catheters introduced into the extra-amniotic space, or laminaria tents made from sterile sea-weed or synthetic hydrophilic materials, introduced into the cervical canal that achieve a gradual stretching of the cervix; and digital sweeping or stripping of membranes). Although mechanical methods carry less risk of uterine hyperstimulation than pharmacological methods, they are probably somewhat less effective than oral or vaginal prostaglandins.[6]

Misoprostol is a synthetic prostaglandin that can be given orally or vaginally. In most countries misoprostol has not been licensed for use in pregnancy, but its unlicensed use is common (for a variety of obstetric indications, including labour induction) because misoprostol is cheap, stable at room temperature and effective in causing uterine contractions.

There is some evidence to show that oral misoprostol is superior to the vaginal route. The recent Cochrane review that studied low dose oral misoprostol has confirmed that low dose oral misoprostol resulted in fewer vaginal deliveries in 24 hours and with less uterine hyper stimulation with fetal heart changes without an increase in overall caesarean section rate as compared to vaginal misoprostol.[7]

In a rural setup where monitoring of labour is not as rigorous as in tertiary centres, we have tried using a low dose misoprostol protocol at longer intervals of administration. This mode of induction is novel in the fact that it is used at 12 hourly intervals and is a combination of both oral as well as vaginal misoprostol. This protocol has been in use in the hospital for about 8 years and was adopted considering the limited resources in the hospital and to avoid unnecessary vaginal examinations which would increase chance of infections.

Our aim was to look at how effective our protocol was in achieving delivery within 24 hours of the start of induction, the induction delivery interval, caesarean section rates and its indications using Robsons classification, uterine hyperstimulation with FHR changes and oxytocin augmentation and its duration. We also looked at maternal outcomes such as uterine rupture, post-partum hemorrhage, maternal death, chorioamnionitis and Meconium-stained amniotic fluid as well as neonatal outcomes such as Meconium aspiration syndrome (MAS), perinatal death and birth asphyxia.

METHODS

The Community Health and Development Hospital is a 140 bedded secondary care level hospital under the Department of Community Health of Christian Medical College in Vellore, Tamil Nadu. The department has been providing primary and secondary level maternal and child health services for over 40 years, focussing primarily on the residents of Kaniyambadi block, which is a rural development block in Vellore district. The services also extend to the surrounding areas of Vellore town as well as to residents of adjoining districts who wish to seek care at the hospital. Another area of primary focus is the tribal population of the Jawadhi hills which span over 4 panchayats in Vellore district and 11 in Thiruvanamalai district. Both out-patient and in-patient facilities are available at the hospital for different health conditions. The out-patient clinic includes both general services and speciality clinics for maternal and child health as well as communicable and non-communicable chronic diseases.

Obstetric services can be availed by anyone registered in the antenatal clinic at the base hospital or in the various mobile clinics that cater to the residents of Kaniyambadi block and the Jawadhi hills. The maternal health related services provided include 24-hour labour room facility for normal and assisted delivery, operation theatre and Caesarean sections under spinal anaesthesia and an established referral system to the Obstetrics and Gynaecology department at Christian Medical College Hospital (tertiary health care centre).The labour room is run by a team comprising of resident in Community Health and an intern along with two nurses in consultation with an obstetrician or consultant in family medicine or community health. Data concerning deliveries, the risk factors associated, and birth outcomes are recorded during pregnancy and childbirth in out-patient as well as in-patient records and entered into an electronic database. This electronic database with respect to base hospital as well as community data has been maintained over the last 25 years.

Time period

The electronic database yielded information on baseline characteristics, risk factors, mode of delivery and outcomes of women delivering in the hospital. Information regarding induction method, number of doses and duration of labour were abstracted retrospectively from the medical records. The cohort chosen were women who delivered between 1st February, 2021 and 31st July,2021.

Mode of induction

Women who needed induction of labour were assessed for favourability of cervix. Those with an unfavourable cervix were induced with 25mcg Misoprostol given orally 12 hours apart. If a woman still had an unfavourable cervix, she was given 25mcg Misoprostol vaginally 12 hours apart. At the end of both oral and vaginal Misoprostol, if

the cervix was still unfavourable, a Foley catheter was introduced intracervically and the bulb inflated with 30 ml of sterile water. This was followed by artificial rupture of membranes and oxytocin augmentation 12 hours later.

This protocol has been followed for about eight years. The method of induction followed in our hospital was made after considering the resources available. Patients being induced are monitored in the wards closely and are shifted to labour room once contractions start. In the labour room, these women are monitored for vital signs every hour and the fetal heart is monitored using continuous electronic fetal monitoring. Electronic fetal monitors are used due to the large number of patients who need monitoring. The combined route was opted for to decrease the number of vaginal examinations done on the patient. The doses were given at 12 hourly intervals to ease the burden of monitoring on the residents and nurses.

Outcomes

Post partum haemorrhage, uterine rupture and death were included as composite poor maternal outcomes and birth asphyxia, meconium aspiration syndrome, early neonatal death, neonatal sepsis and transient tachypnoea of the new born were included in composite poor neonatal outcomes.

Statistical analysis

Data entry was done into Microsoft Excel, and analysis was done using SPSS version 24.0. Continuous variables were expressed as mean and standard deviation and discrete variables as frequencies and proportions. The associations were determined using Chi-square test, Odds Ratio with 95% CI and a p-value of <0.05 was considered to be statistically significant.

RESULTS

There were 2574 deliveries in the time period February 1st, 2021 to July 31st, 2021. Data were available from the charts of 2522 women (98%). Of these, data for 250 women who were delivered by elective caesarean section were excluded from the analysis. Of the remaining 2272 women, labour was induced in 1116 women (49%), while 1156 (51%) went into spontaneous labour.

Baseline characteristics (Table 1) showed some expected differences between the groups of women. The mean age of the women who were induced was 24.99 (SD:4.3) years compared to 24.56 (4.092) years among those who had spontaneous labour and were similar between groups. The groups of women also did not differ significantly for common medical co-morbid risk factors affecting delivery outcomes. However, there were more nulliparous women among those who were induced, compared to those who experienced spontaneous labour (67% versus 56%; p <0.00001). There were also more obese women (70.8%) among those induced compared to 59.7% among those experiencing spontaneous labour (p<0.00001).

Table 1: Baseline characteristics.

		Induced (n=1116) N (%)	Spontaneous (n=1156) N (%)
Age	<20	155 (13.9)	193 (16.7)
	21-25	500 (44.8)	528 (45.7)
	26-30	332 (29.7)	336 (29.1)
	31-35	110 (9.9)	85 (7.4)
	Above 36	19 (1.7)	14 (1.2)
Parity	Nulliparous	746(66.9)	646(55.9)
	1	228(25.8)	416(36.0)
	2-3	82(7.4)	93(8.1)
	4 and more	0	1(0.01)
BMI	Underweight (<18.5)	7 (0.6)	13 (1.2)
	Normal (18.5-22.9)	156 (14)	246 (21.9)
	Overweight (23-24.9)	162 (14.6)	194 (17.2)
	Obese (≥25)	788 (70.8)	672 (59.7)
		*Missing: 3	*Missing: 31
Medical risk factors	GDM on diet	84 (7.5)	91 (7.9)
	GDM on OHA	125 (11.2)	119 (10.3)
	GDM on insulin	7 (0.6)	8 (0.7)
	Anaemia	37 (3.3)	37 (3.2)
	Hypothyroidism	57 (5.1)	53 (4.6)
	Hypertension	45 (4)	42 (3.6)
	Asthma	10 (0.9)	8 (0.7)

BMI: Body Mass Index, GDM: Gestational diabetes mellitus, OHA: Oral hypoglycemic agent.

The main indication for induction of labour was past dates 500 (45.2%) followed by pre labour rupture of membranes 328 (29.4%). The other indications for induction of labour include gestational diabetes 166 (14.9%), hypertensive disorders 44 (3.9%), intrauterine growth restriction 23 (2.1%), intrauterine fetal demise 11 (1%), infertility 8 (0.7%), oligohydramnios 8 (0.7%), decreased fetal movement 5 (0.4%), bad obstetric history 4 (0.3%), ante partum haemorrhage 3 (0.3%) and multiple gestation 3 (0.3%).

Among the women who were induced, 510 women (45.7%) were given vaginal misoprostol in addition to oral misoprostol for induction of labour. Foleys were used in 176 women (15.8%) in addition to misoprostol and 6 (0.5%) women had only foleys inserted (Table 2).

The mean induction to delivery interval among the women being induced was 32 hours (SD: 22.58) with a median of 26 hours (IQR: 33). Among the women induced, 521 (46.7%) delivered within 24 hours, 335 (30%) delivered

within 24 to 48 hours and 191 (17.1%) delivered between 49 and 72 hours.

Among the women who were induced, 703 (63%) were augmented with oxytocin compared to 507 (43.9%) among those who presented with spontaneous labour. An equal number of women received Inj. Terbutaline for hyperstimulation with foetal heart rate changes in both the induced as well as the ones with spontaneous labour. There were seven in each group.

Table 3 shows the maternal and neonatal outcomes in both groups. The number of still born foetuses in the induced group was 12 which includes 11 who were induced for Intrauterine foetal demise. There were significantly higher women who experienced PPH in the induced group. This includes a woman who had atonic PPH and had to undergo a caesarean hysterectomy.

There was one maternal death in a mother who had induction of labour. She had sudden intrapartum collapse (desaturation with hypotension) a few hours after augmenting with oxytocin. Amniotic fluid embolism was suspected.

Table 2: Method of induction and doses of misoprostol.

	Number of doses	Number (1116)	Percentage
Oral MISO	0	20	1.8
	1	326	29.2
	2	744	66.7
	3	26	2.3
PV MISO	0	606	54.3
	1	222	19.9
	2	283	25.4
	3	5	0.4
Foleys	Yes	176	15.8
	No	940	84.2
Total doses	1	325	29.1
	2	281	25.2
	3	216	19.4
	4	280	25.1
	5	8	0.7
	Only Foleys	6	0.5

The doses of oral and vaginal misoprostol are indicative only of that particular route of administration.

Table 3: Maternal and fetal outcomes.

Outcome	Induced (n=1116)	Spontaneous (n=1156)
Mode of delivery		
Normal	795 (71.2)	935 (80.9)
Operative vaginal delivery	170 (15.2)	154 (13.3)
Caesarean section	149 (13.4)	79 (6.8)
Vaginal breech delivery	2 (0.2)	8 (0.7)
Birth outcome		
Live born	1104 (98.9)	1151 (99.6)
Still born	12 (1.1)	5 (0.4)
Birth weight		
Low birth weight (<2.5kg)	156 (14.0)	185 (16.0)
Normal (2.5-3.99kg)	952 (85.3)	965 (83.5)
Macrosomia (≥ 4kg)	8 (0.7)	6 (0.5)
Adverse maternal outcomes		
Postpartum haemorrhage	34 (3)	20 (1.7)
Uterine rupture	1 (0.08)	0
Death	1 (0.08)	0
Adverse neonatal outcomes		
Birth asphyxia	14 (1.3)	6 (0.5)
Meconium aspiration	5 (0.4)	5 (0.4)
Early Neonatal death	4 (0.4)	3 (0.3)
Neonatal sepsis	1 (0.08)	1 (0.08)
Transient tachypnoea	10 (0.8)	15 (1.3)

Birth asphyxia was identified by an Apgar score of less than 7 at 5 minutes. There were 14 (1.3%) neonates who had asphyxia in the induced group compared to 6 (0.5%) in the group with spontaneous labour. The proportions did not differ significantly between the groups

Table 4: Maternal and neonatal outcomes.

Risk factor	Category	Induced (n=1116)	Spontaneous (n=1156)	Chi-square	Odds ratio (95% ci)	P-value
Mode of delivery	Caesarean section	149 (13.4%)	79 (6.8%)	26.715	2.100 (1.577-2.793)	0.001
	Non-caesarean section	967 (86.6%)	1077 (93.2%)			
Birth weight	Low birth weight	156 (14.0%)	185 (16.0%)	1.825	0.852(0.677 - 1.074)	0.177
	Birthweight above 2.5kg	960 (86.0%)	971 (84.0%)			
Composite maternal outcomes	Poor maternal outcomes	36 (3.1%)	20 (1.7%)	4.241	1.785 (1.021-3.120)	0.039
	Good maternal outcomes	1082 (97.0%)	1136 (98.3%)			
Composite neonatal outcomes	Poor neonatal outcomes	34 (3.0%)	30 (2.6%)	0.423	1.179 (0.716-1.941)	0.516
	Good neonatal outcomes	1082 (97.0%)	1126 (97.4%)			

Table 5: Robsons classification of caesarean sections.

Robsons class		Size of the group	CS in each group	Contribution of each group
1	51/696	27%	7.3%	1.9%
2	129/662	25.7%	19.4%	5%
3	11/554	21.5%	1.9%	0.4%
4	10/282	10.9%	3.5%	0.38%
5	182/182	7%	100%	7%
6	26/28	1%	92.8%	1%
7	4/7	0.2%	57.1%	0.15%
8	21/39	1.5%	53.8%	0.8%
9	0	0	0	0
10	22/124	4.8%	17.7%	0.8%
Total	456/2574			

Table 6: Misoprostol dosage vs caesarean rate, composite maternal outcomes, composite neonatal outcomes.

	Caesarean	Not-caesarean	Chi-square for trend	P-value
Only foleys (0)	2 (33.3)	4 (66.7)	14.458	<0.001
1	25 (7.7)	300 (92.3)		
2	42 (14.9)	239 (85.1)		
3	19 (8.8)	197 (91.2)		
4	60 (21.4)	220 (78.6)		
5	1 (12.5)	7 (87.5)		
Total	149	967		
	Poor maternal outcomes	Good maternal outcomes	Chi-square for trend	p-value
Only foleys (0)	0 (0)	6 (100)	7.716	0.005
1	6 (1.8)	319 (98.2)		
2	5 (1.8)	276 (98.2)		
3	8 (3.7)	208 (96.3)		
4	14 (5.0)	266 (95.0)		
5	1 (12.5)	7 (87.5)		
Total	34	1082		
	Poor neonatal outcomes	Good neonatal outcomes	Chi-square for trend	p-value
Only foleys (0)	0 (0)	6 (100)	1.027	0.311
1	5 (1.5)	320 (98.5)		
2	12 (4.3)	276 (95.7)		
3	8 (3.7)	208 (96.3)		
4	9 (3.2)	266 (96.8)		
5	0	8 (100)		

Caesarean sections were 2.100 (1.577- 2.793) times higher among women who were induced compared to those in spontaneous labour. (Table 4) Among those who were induced, 148 (13.3%) underwent Caesarean section of which 64 (43.2%) was for non-reassuring foetal status, 41 (27.7%) was for failed induction and 30 (20.2%) was for non-progress of labour. Among those with spontaneous labour, 79 (6.8%) underwent Caesarean section of which 25 (31.6%) was for non-reassuring foetal status and 11 (13.9%) was for non-progress of labour.

All 2574 deliveries have been included in table 5 which looks at Robsons classification for Caesarean section. The overall caesarean section rate was 17.7%.

Table 6 shows the relationship of number of doses of misoprostol to caesarean section rates and maternal and neonatal composite outcomes. There was a trend suggesting that the risk of having a caesarean section increased with the number of misoprostol doses. (p value <0.001) poor maternal outcomes also appeared to increase with the number of misoprostol doses. (p value 0.005).

DISCUSSION

Almost half of the women (49%) had labour induced. This is a very high rate of induction compared to other rates across the world. Increasing rates of induction have been reported in the UK, the USA, Canada and Australia since the early 1990s. In the USA, the labour induction rate doubled between 1992 and 2006, from 11.4% to 22.5%, and the caesarean delivery rate increased by nearly 50%, from 22.3% in 1992 to 31.1% in 2006.[8,9] In Australia, induction of labour rates varied upto 44%.[13] The high rate of induction in our hospital can be attributed to many factors. Many of our women do not have a first trimester ultrasound to confirm dates and are often induced once they reach 40 weeks and 3 days which is calculated by their LMP. The WHO recommends induction of labour only at 41 weeks. This does not apply to settings where gestational age cannot be reliably calculated.[1]

The main indication for induction in our study was past dates. The classification of past dates here includes anyone who has crossed 40 weeks of gestation. Induction of labour has been recommended at or beyond 41 weeks as it will decrease perinatal mortality and decrease meconium aspiration syndrome.[4] Our reason for inducing at 40 weeks and 3 days includes many factors like distance the woman has to travel to access the hospital, unavailability of a dating scan and the induction protocol we have adopted which may last up to 72 hours.

In our study, the mean induction to delivery interval among the women being induced was 32 hours with a median of 26 hours. This is using a prolonged induction protocol and was suitable for the kind of infrastructure and personnel available in our setting. Most other studies show a shorter induction to delivery interval.

Our study showed higher 2.1 times higher chance of caesarean section among women being induced. This is to be expected as women who are induced have unfavourable cervix. A study in Australia among nulliparous women showed no clear association between hospital induction rates and intrapartum CS, maternal or neonatal morbidity, although there was a slightly higher risk of neonatal morbidity at early term births among hospitals with high IOL rates.[9]

In a study which looked at the factors and outcomes associated with labour induction in Latin America, they found an association between induced labour and the postpartum use of uterotonic drugs, the occurrence of perineal laceration, puerperal hysterectomy, admission to an intensive care unit and duration of hospitalisation >7 days.[10] The same study also showed that some adverse perinatal outcomes were also higher, such as low 5-minute Apgar score, very low birthweight, admission to neonatal ICU and delayed initiation of breastfeeding. The WHO Global Survey on Maternal and Neonatal health showed that induction was associated with increased odds of admissions to ICU (Africa) and NICU (Asia), but not increased odds of fetal or neonatal mortality.[11] Our study also showed significantly higher incidence of Post partum haemorrhage with one woman undergoing peripartum hysterectomy. There were slightly higher poor composite maternal outcomes seen in the group of women who were induced. We also had a higher number of birth asphyxias in the induced group. The poor maternal outcomes were more with higher number of doses of misoprostol.

In the systematic review done by Hofmeyer et al they stated that, when misoprostol was compared to conventional methods of cervical ripening, although no differences in perinatal outcome were shown, the studies were not sufficiently large to exclude the possibility of uncommon serious adverse effects.[12]

The recent systematic review by Alfirevic and Weeks indicates that oral misoprostol is as effective as vaginal misoprostol in achieving vaginal delivery.[13] Given safety is a concern, oral misoprostol is preferred over vaginal especially in situations where the risk of ascending infection is high and the lack of staff means that women cannot be intensely monitored. In centres where misoprostol is used for labour induction, maternal and perinatal outcome should be audited regularly to ascertain whether there is an association with rare adverse events, such as uterine rupture and perinatal and maternal death.

Limitation

This was a retrospective study done to look at advantages and disadvantages of the above said protocol. Both the above groups were not strictly comparable considering one group was induced and the other went into spontaneous labour.

CONCLUSION

The rates of induction of labour are increasing in different parts of the world including LMICs. This study looks at a novel protocol which was tailored to a low resource setting. The induction to delivery interval was slightly longer but suitable for our setting considering the reduced number of health personnel available.

There were higher rates of caesarean section, post-partum haemorrhage as well as birth asphyxias among the women induced. Induction protocols need to be developed taking into consideration the advantages as well as complications associated with it and then tailor it according to infrastructure and personnel available.

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