ORIGINAL ARTICLE

Efficacy and safety of oral misoprostol for induction of labour

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Abstract

Objective: to assess the efficacy and safety of oral misoprostol for induction of labor.

Study design: prospective interventional case series

Place and duration: The study was conducted at Obstetrics and Gynaecology Department Ziauddin Hospital Kemari campus which is affiliated with Ziauddin University, from 1st January 2014 to31st December 2015.

Material and Method: Women with live singleton pregnancy of > 30 weeks gestation with cephalic presentation and bishop score <7 with an indication for induction of labor were recruited. Oral misoprostol 50 µg was given orally at 6 hourly interval for 4 doses followed by 24 hour rest and repetition of 50µg again at 6 hourly interval upto a maximum of 8 doses or till labor was induced. Feto-maternal outcome, mode of delivery and induction to delivery interval in hours was noted.

Results: The mean induction to delivery interval was 23.36 hours. 133 patients (67%) delivered within 24 hours. 67 patients (33.5%) delivered at >24 hours. Overall vaginal delivery was achieved in 165(83.5%) patients. 163 (81.5%) had spontaneous vaginal delivery, 2(1%) had forceps and 2(1%) had vaccum vaginal delivery while 33(16.5%) patients had to undergo cesarean section. There was no case of uterine hyper stimulation or rupture. There was no intrauterine death attributable to induction. The only neonatal death was in a 32 week severely preeclamptic patient.

Conclusion: Oral Misoprostol is safe and effective method of labor induction in third trimestor.

Keywords: labor, induction, misoprostol, maternal hyperstimulation, fetal distress, uterine rupture

Introduction:

Induction of labor is a method of artificially initiating the process of labor in cases where delivery is preferable over continuation of pregnancy1. These include pregnancy beyond 41 weeks of gestation, intra uterine growth restriction, hypertensive complications of pregnancy, diabetes in pregnancy[2] etc. In many countries, the rate of labor induction is more than 20%.[3]

Failure of induction has a significant consequence of delivery ending up in cesarean section. For this reason, the inducing agent should be effective and safe at the same time. Numerous agents have been inuse for this purpose and misoprostol is one of these.[4-7]

Misoprostol is a prostaglandin E1 analogue that was originally used for treatment of peptic ulcers.[8] Since 1990's it has been introduced as an abortificient and as labor inducing agent.

Although confidently used as abortificient in cases of missed miscarriage; since its introduction, there are fears regarding its use as a labor inducing agent at term and it has not gained widespread popularity and universal acceptance

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Table-1: The bishop score, indication for induction, mode of delivery and neonatal outcome.(n=200)

Bishop Score	No of Patients (n=200)	Indication for inductions	No of Patients (n)	Mode of delivery	(n)	Neonatal Factors		No of cases (n=200)
0	1(0.5%)	Post dates	109 (54.5%)	SVD	163(81.5%)	Neonatal Survival	Alive	191(95.5%)
1	1(0.5%)	Leaking	35 (17.5%)	VVD	2(1%)		Still birth	0(0%)
2	10(5%)	Pre-eclampsia	15 (7.5%)	FVD	2(1%)		IUD	8(4%)
3	44(22%)	Eclampsia	1 (0.5%)	LSCS	33(16.5%)	Apgar score	>7	182(91%)
4	84(42%)	Diabetes	9 (4.5%)	Total (n)	200		<7	9(4.5%)
5	52(26%)	Good size baby	1 (0.5%)			Neonatal complications	None	191(95.5%)
6	8(4%)	Decreaes featal	13 (6.5%)				Neonatal death	1(0.5%)
Total	200(100%)	Movements						
		IUGR	9 (4.5%)					
		Intrauterine deaths	8 (4%)					
		Total	200 (100%)					

for labor induction.[9] The major concerns are fear of hyper-stimulation leading touterine rupture and fetal distress. Misoprostol has the advantage of being an economical and heat stable method for induction of labor[10] that makes it a suitable agent for labor induction in third world countries like Pakistan. However, there is paucity of data from randomized controlled trials to determine the safe and efficacious dose of misoprostol.

The main aim of our study was to assess the safety and efficacy of oral misoprostol in multiple doses i.emore than 4 doses in a regimen involving a 24 hours rest period between the 4th dose and 5th dose with the objective of reducing caesarean section rate due to failed induction which is normally after the failure of onset of labour after 4 doses (24 hours) in most obstetric units. We therefore conducted this study to assess the efficacy and safety of oral misoprostol for labor induction.

Material and Methods:

We conducted a hospital based prospective interventional study, at Ziauddin Hospital Kemari Campus which is affiliated with Ziauddin University Karachi. It was conducted over a period of 24 months from 1st January 2014 to 31st December 2015. During this time period all patients who fulfilled the inclusion criteria were included in our study.

All patients with singleton pregnancy and gestational age> 30 weeks on the basis of last menstrualperiod or first trimester ultrasound scan and Bishop score <7; who needed induction of labor due to fetal or maternal indication were included in our study; after they gave consent. The indications for induction included post date pregnancy, leaking, pre eclampsia, eclampsia, gestational diabetes mellitus, intra-uterine growth restriction, intra-uterine dead baby, decreased fetal movement. Patients with a non reassuring fetal heart rate tracing, previous cesarean section vaginal bleeding and placenta previa were excluded from the study. Oral misoprostol 50μg was given orally at 6 hourly interval for maximum of 4 doses or till labor was induced, if labor was not established a 24 hour rest period was given and it was followed by repetition of 50 μg again at 6 hourly interval, upto a maximum total of 8 doses or till labor was induced. Failure of patients to establish labor after 8 completed doses was regarded as failed induction and baby was delivered by cesarean section. A post graduate trainee was assigned to fill data collection form in obstetric wards after the delivery. The data collection form contained data regarding age and parity of the patient, her bishop score, indication for induction, induction to delivery interval.

Maternal complications including hyper-stimulation and uterine rupture were recorded and

a note was also made of fetal complications like abnormal CTG, meconium staining of liquor, Apgar score at 1 and 5 minutes, intra uterine death and neonatal death . After obtaining the complete information, data analysis was carried out using the SPSS version 16. Results were collected and presented as a table.

Results:

A total of 200 participants were included in this study. The mean age of the study participants was 29.5 years.. Out of 200 participants 95(47.5%) were primi-gravidae and 105 (52.5%) were multi-gravidae.

Gestational age was 30 to 36+6 weeks in 17(8.5%) patients. Out of these, 8 were induced due to intra uterine death 5 had severe pre eclampsia and 4 had IUGR. In 73(36.5%) patients gestation was 37-40 weeks and 110 (55%)patients were >40 weeks.

Majority (54.5%) of the patients were induced because of post-date pregnancy followed by leaking in 17.5%. The mean Induction to delivery interval was 23.365 hours. 43 patients (21.5%) delivered within 12hours, 90 (45.5%) had delivery between 12 to 24 hours. 67 patients(33.5%) delivered after 24 hours.

Table 1 shows that 163(81.5%) patients had spontaneous vaginal delivery, 2(1%) had forceps and 2(1%) had vacuum vaginal delivery while 33(16.5%) patients had to undergo cesarean section. Of those who underwent cesarean section 6(3%) had failed induction, 9(4.5%) had abnormal CTG, 11(5.5%) were operated because of meconeum in the liquor, 6 had non progress of labor and 1(0.5%)developed obstructed labor. None of our patients developed maternal hyperstimulation and there was no case of uterine rupture. 6 Patients (3%) developed Primary PPH due to uterine atony. All of them were multi-gravidas.

Table 1 also summarizes fetal outcome of our study participants. 8 intra uterine deaths were all in those patients in whom induction was planned for the indication of intra-uterine dead baby. There was 1 neonatal death in whom mother was induced at 32 weeks due to severe pre-eclampsia. Neonatal admissions were done for observation in cases in whom the indication for induction was leaking and IUGR. 2 babies that developed meconeum stained liquor grade three were also admitted but were discharged in a satisfactory condition after management.

Discussion:

Induction of labour is a means of artificially initiating the process of labor in patients in whomcontinuation of pregnancy is a potential harm for the mother or fetus. Among the many different means for labor induction, prostaglandins are preferred in patients with low bishop scores.[11] Misoprostol is an in-expensive heat stable medication[12] however the dose, route of administration and frequency of doses of misoprostol are still under investigation.

In multi-gravidas generally the induction is more successful and has a shorter induction to delivery interval as compared to primigravidae.[13] In our study there were comparible primigravidae (47.5%) and multi-gravidae (52.5%). Thus the potential for bias among primi-gravidae and multi-gravidas is reduced. The criteria for induction in our study was a bishop score <7. Beuno concluded in his study that Bishop score is a significant predictor of induction success.[14] However, 96% of our patients had bishop score up to 5 and we were able to achieve successful vaginal delivery in 81.5% of patients induced with oral misoprostol. Furthermore, only 2.5% patients failed to establish labor and had cesarean for failed induction. Other studies also agree with our findings.[15-17] The induction to delivery interval ranged between 4-75 hours, with 67% delivering within 24 hours. One of the main factors can be our induction protocol in which we did not abandon induction after 4 doses, rather we gave 24 hours rest and repeated the doses in similar manner. This gave patients a better chance of delivering vaginally, particularly those who were induced at <37 weeks. The overall induction to delivery interval was shorter in patients who presented with leaking at <37 weeks. This is in accordance with theresults of Ilyas.[18]

Only 16.5% underwent cesarean section. Our findings are consistent with Zerco Alfirevic who concluded in his meta analysis that oral misoprostol has the lowest probabaility of cesarean section.[19] Our vaginal delivery rate of 81.5% is comparible with komala who reported a 94% success in achieving vaginal delivery with oral misoprostol.[20] Ratna Katri et al, also reported successful Vaginal delivery in 86% of her patients with oral misoprostol.[21] Chander also reports a similar result for his patients induced with oral misoprostol.[2] In Our study we found cesarean due to failed induction in 3% cases. This is in affirmance with the results of kamola.[20] However in contrast to his study we found relatively more cesareans for non progress of labour (18.18%)-1.56% in Kambolas study. We did not find any case of uterine hyper-stimulation or rupture, nor did we find any case of fetal mortality or serious morbidity attributable to misoprostol. Meconeum staining of liquor was seen in 5.5% and abnormal CTG in 4.5% of babies. However only 2 had grade three meconeum staining and were admitted in neonatal intensive care but were later discharged in a satisfactory condition. The only neo-natal death was that of a pre-term severly pre-eclamptic patient. Guerra reports increased maternal and peri-natal complications in his induced labours.[23] Studies of Oden[24] and de Aquino and Cecatti.[25] also showed significant maternal and fetal complications in misoprostol induced cases including tachysystole, meconium stained liquor and reduced APGAR, several other studies fail to report significant maternal or perinatal complications with oral misoprostol.[20,24,25] However results of Guerra in his study done in Latin America shows poorer maternal as well as perinatal outcomes in his induced labors.

Conclusion:

Oral misoprostol is safe and effective method of labor induction in the third trimester of pregnancy thus reducing the rate of cesarean section due to failed induction.

Conflict of interest: None

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Role and contribution of authors

Dr Urooh Malik, conceived the idea, collected the data, referenes and write the initial menuscript.

Dr Minahil, helped in collecting the data and references and also helped in introduction and methodolgy writing.

Dr Shahina Ishtiaq, critically review the article and did the useful changes.

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