VAGINAL MISOPROSTOL VERSUS TRANSCERVICAL FOLEY'S CATHETER AND INTRAVENOUS OXYTOCIN FOR LABOUR INDUCTION

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ABSTRACT

Objectives: To compare efficacy and safety of 50 mg vaginal Misoprostol with transcervical Foley's catheter and intravenous oxytocin for labor induction.

Method(S): 150 women at term gestation, with Bishop score ≤ 4, with various indications for labor induction were randomly allocated to receive either Misoprostol vaginally 6 hourly (maximum 4 doses) or transcervical Foley's catheter with intravenous oxytocin (2 mU/minute to a maximum of 32 mU/minute or till the woman goes into active labour).

Results: In Misoprostol group induction-delivery interval was significantly less (11.58 vs 19.45 hours) and successful induction significantly higher (98% vs 78%) as compared to catheter/oxytocin group. Eighty-eight percent of the women delivered within 24 hours of induction in misoprostol group whereas in the other group 72% delivered within 24 hours. Eighteen percent of women delivered with a single dose of misoprostol while 28% required the maximum dosages of oxytocin.

Conclusion(S) : Vaginal misoprostol is a cheap, highly effective and easy to administer agent for labour induction.

Key words : vaginal misoprostol, intracervical catheter and oxytocin, induction of labor.

INTRODUCTION

Modern obstetrics aims at improving the safety of the mother and the fetus during antenatal period as well as parturition. The aim of induction of labour is to perform safe vaginal delivery. Spontaneous labour and vaginal delivery is preceded by a cascade of synchronized events, which leads to ripening of cervix.[1]. Induction is the process of starting labour by uterine stimulation. It should be used when it is thought that the baby will be saferto deliver than in utero.

From 15% to 20% of all pregnancies require induction of labour [1]. Many women who require induction of labour present with an "unripe" cervix[2]. Labour induction in the presence of an unfavorable cervix is professional folley and associated with prolonged labor and increased incidence of chorioamnionitis and cesarean section. Hence, the use of cervical ripening agents prior to conventional methods of induction is now a standard practice [3].

Moving preinduction cervical ripening from an inpatient to an outpatient setting appears to decrease cost significantly[4]. Furthermore, 50% of all patients requiring induction of labour may be eligible for outpatient cervical ripening (4). Multiple studies have attempted to perform cervical ripening in an

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outpatient setting [5].

Oxytocin and prostaglandins are the agents most frequently used for induction of labour [6].Oxytocin is the commonest induction agent used worldwide. It has been used alone, in combination with amniotomy or following cervical ripening with other pharmacological or non-pharmacological methods. Although oxytocin is widely accepted as a safe and effective initiator of uterine contractions, its success depends on the preinduction cervical score [7] . Prior to the introduction of prostaglandin agents, oxytocin was used as a cervical ripening agent as well.

In developed countries oxytocin alone is more commonly used in the presence of ruptured membranes whether spontaneous or artificial. In developing countries where the incidence of HIV is high, delaying amniotomy in labour reduces vertical transmission rates and hence the use of oxytocin with intact membranes warrants further investigation. [8]

Misoprostol (Misotac–200mcg, SIGMA) is a prostaglandin E1 analogue marketed for use in the prevention and treatment of peptic ulcer disease. It is inexpensive, easily stored at room temperature and has few systemic side effects. It is rapidly absorbed orally and vaginally. Although not registered for such use, Misoprostol has been widely used for obstetric and gynecological indications, such as induction of abortion and of labour [9,10].

Intravaginal Misoprostol is effective, simple to administer, requires continuous monitoring once administered.misoprostol is fraught with adverse effects including fever, nausea and vomiting, diarrhoea, and hyperstimulation that may lead to tachysystole, uterine rupture and fetal morbidity and mortality [11].

Prostaglandins act on the cervix to enable ripening by a number of different mechanisms. They alter the extra cellular ground substance of the cervix. They cause an increase in elastase, glycosaminoglycan, dermatan sulfate, and hyaluronic acid levels in the cervix. A relaxation of cervical smooth muscle facilitates dilation. Finally, prostaglandins allow for an increase in intracellular calcium levels causing contraction of myometrial muscle [12,13].

In developing countries, conventionally cheap a and feasible method used for preinduction cervical ripening is transcervical Foley's catheter. In experienced hands it is a safe and reliable method of inducing cervical ripening and even labour. But many dangers are encountered as accidental rupture of membranes, cord prolapse, chorioamnionitis, and pyrexia because of infection [14].

MATERIALS & METHODS

The protocol of this study was approved by the local ethical committee of the institution and all participants consented before inclusion in the study.

150 consented pregnant women were enrolled in the study in the period from February 2006 to January 2008 in the Obstetrics and Gynecology Department Mansoura University Hospital, Mansoura-EGYPT. Thorough history taking, general and local examinations were done. They were routinely examined to evaluate the Bishop score and confirm fetal vertex presentation. A reactive nonstress test prior to induction of labour was confirmed in all cases.

All the cases had various indications for induction of labour with singleton pregnancy at term, in cephalic presentation, intact membranes, Bishop score ≤ 4 and volunteered to participate in the trial. We excluded women with uterine surgeries, multifetal gestation, nonreassuring fetal heart tracings, thyrotoxicosis, heart disease, bronchial asthma and known hypersensitivity to prostaglandins.

The participants were assigned to two groups (woman's choice).

The First:

Received 50 mcg (1/4 of the scored tablet Misotac - 200, SIGMA) intravaginal Misoprostol 6 hourly for a maximum of 4doses or till the woman went into active labour. If she did not go in active labour in 24 hours the method was declared as failed. During induction if the woman developed tachysystole (≥ 6 uterine contractions per 10 minutes for two

consecutive 10 minutes), hypertonus (contractions lasting for ≥ 120 seconds) or hyperstimulation (tachysystole or hypertonus associated with abnormal fetal heart recordings) the next dose of misoprostol was withheld and the tablet was removed if still in the posterior fornix.

The Second:

First, counsel the patient and obtain her informed consent. Prior to examination, ensure that a sonogram reading does not show signs of placenta previa,There were no visible lesions and provide appropriate intravenous antibiotic therapy during the ripening and later induction processes.

16F Foley's catheter was introduced just beyond the internal os and its balloon was inflated with 30 mL of sterile water. Traction was applied by taping the distal end of the catheter to the medial aspect of thigh[15].

Simultaneously, oxytocin infusion (syntocinon 5 IU\ml Novartis PharmaAG, Basle Switzerland) was started with an initial dose of 2 mU/minute and increased the dose by 2mU/minute every 30 minutes till the woman went into active labour (three contractions of good intensity per 10 minutes lasting for 45-60 seconds) or the maximum dose of 32 mU/minute was reached after 8 hours. This dose was continued till onset of labour and delivery or its failure inspite of 24 hours of administering this maximum dose. If labour started, the dose being administered was continued till delivery. If labour failed to start at the end of 24 hours, the maximum dose of oxytocin drip used was discontinued and the method was considered as failed.

During induction, fetal heart rate was monitored by Doppler and uterine contractions monitored manualty. In both groups, if a woman developed fetal heart abnormalities, continuous monitoring of fetal heart was done with a tocodynamometer. Those who did not go in to active labour inspite of the maximum dose of misoprostol or oxytocin, were to be terminated by cesarean section.

The main measures of efficacy of successful induction were the number of women who achieved active labour within 24 hours of induction and their induction-delivery interval.

Statistical analysis

Median and range were computed. Continuous variables were compared using the Fisher's Z test and discrete data with the c2 test. Analysis was performed using statistical software SPSS version 13.

RESULTS

Maternal demographic characteristics and indications for induction were similar in the two groups (Table I), 72 of the 80 (90%) women went into active labour while 8 (10%) failed as they did not achieve active labour with maximum dose of Misoprostol. In the oxytocin group, 54 (77.14%) of the 70 women achieved active labour and 16 (22.84%) failed (P= 0.016) (Table II).

Induction-delivery interval was significantly shorter in the Misoprostol group than that in the catheter/oxytocin group (12.47 hours vs. 18.35 hours; P = 0.000036). Also, greater number of women (68 = 85%) delivered within 24 hours of the start of induction in Misoprostol group than those in the catheter oxytocin group (49 = 70%) (P = 0.013) (Table II). With Misoprostol, four hyperstimulation occurred while one was seen in the catheter/oxytocin group (Table II).

The majority of women in both groups delivered vaginally (72/80 in Misoprostol group vs 54/70 in the catheter/oxytocin group); (P=0.016) and fetal distress was the most common indication for cesarean section (4/80 in Misoprostol group v/s 11/16 in catheter oxytocin group, P = 0.205) (Table III).

There were no significant differences in the neonatal outcomes between the two groups. All the neonates were born alive with Apgar score of nine at five minutes. But a woman in the second group lost her fetus by meconium aspiration. Only 4 babies in oxytocin group and two in Misoprostol group required admission to the neonatal intensive care unit (Table IV).

Table (I): Demographic characteristics and indications for labour induction.

	Group I (Misoprostol) (n = 80)	Group II (Catheter/ Oxytocin) (n = 70)
Age (yrs.) (median -range)	27 (18-34)	28 (21-37)
Primigravida number	45	42
Gestation (weeks) (median -range)	39.00 (37-41)	38.00 (37-41)
Preinduction cervical score (median -range)	4 (2-4)	3 (2-4)
Post term number (-percentage)	20 (25%)	18 (25.71%)
Hypertension number (-percentage)	28 (35%)	24 (34.28%)
Intrauterine growth restriction number (-percentage)	5 (6.25%)	3 (4.28%)
Diabetes mellitus number (-percentage)	9 (11.25%)	10 (14.28%)

Table (II): Outcome of labour induction.

	Group I (Misoprostol) (n = 80)	Group II (Catheter/Oxytocin) (n = 70)	P value
Successful induction number (- percentage)	72 (90%)	54 (77.14%)	0.016*
Successful Induction-delivery interval (hours) (median -range)	12.47 (7-33.5)	18.35(6.25-35)	0.000036*
Number delivered within 24 hours number (-percentage)	68 (85%)	49 (70%)	0.013*
Hyperstrimulation number	4	1	0.112

* Significant p < 0.05

Table (III): mode of delivery and indications of caesarean section .

	Group I (Misoprostol) (n = 80)	Group II (Catheter/Oxytocin) (n = 70)	P value
Normal Vaginal	68	53	0.075
Instrumental delivery	4	1	0.112
Cesarean section	8	16	0.016*
Indication of cesarean section:			
Fetal distress	4	11	0.205
Cervical dystocia	3	5	0.364
Maternal distress	1	0	0.361

* Significant p < 0.05

Table (IV): Neonatal outcome.

	Group I (Misoprostol) (n = 80)	Group II (Catheter/Oxytocin) (n = 70)	P value
Apgar at 1 minute	8	7	
Apgar at 5 minutes	9	9	
Meconium staining of liquor	2	3	0.272
Admission to neonatal intensive care unit	2	4	0.158
Live birth	80	69	0.142
Still birth	0	1	0.142

* Significant p < 0.05

DISCUSSION

Induction of labour is widely carried out all over the world in cases where continuation of pregnancy is hazardous to both the mother and \ or the fetus. In Assiut University Hospital, Assiut, Egypt, which is a referral facility, in 1998, there was one case of induction of labour daily, giving an annual induction rate of nearly 6%. This figure rose to 7.8 % in 1999, 13% by the year 2003 and 18% in year 2005 [16].

In our study, successful induction with vaginal Misoprostol could be achieved in 90% while with catheter/oxytocin in 77.14%. This result is in agreement with Promila J et al [17] who stated that as a cervical ripener and labour inducing agent, vaginal Misoprostol is highly effective, inexpensive and superior to catheter/oxytocin and with Adeniji AO et al who indicated that Undoubtedly, intravaginal Misoprostol has advantages over transcervical Foley catheter in pre-induction cervical ripening[18]. However, Sciscione AC et al [19] and Adeniji OA et al [20] concluded that Foley catheters are effective and similar to intravaginal Misoprostol for preinduction cervical ripening with aggressive management of labour.

Though Misoprostol may show some promise as an effective agent for labour induction, it cannot be recommended for routine use as concluded by Hofmeyer GJ et al [21]. Similarly Caliskan E et al observed that in women with an unfavorable cervix, the addition of extra-amniotic saline infusion to a transcervical Foley catheter does not improve efficacy for labour induction [22].

In our study, induction delivery interval was 12.47 hours with Misoprostol and 18.35 hours with catheter oxytocin. Also, 85% of women delivered within 24 hours in Misoprostol group compared to 70% in the catheter/oxytocin group. This result is in agreement with Caliskan et al [23] who studied 91.3% of their cases who delivered within 24 hours with sublingual Misoprostol and also with Toppozada MK et al [24] who stated that The vaginal route of administration induced a higher success rate in a shorter time interval using a lower dose but was associated with more abnormal FHR patterns and instances of uterine hyperstimulation. So it is recommended to use the vaginal approach with cardiotocographic monitoring.

In the present study, Misoprostol did not significantly increase the incidence of meconium passage which was in 2 cases and 4 cases with catehter/oxytocin. This is consistent with Kramer RL et al [25] data who observed that during labour even 100 mcg Misoprostol did not significantly increase the incidence of meconium passage. Contrarily, Manley JS et al [26] found that increased risk of meconium passage and uterine contractile abnormalities occurred in the Misoprostol group.

We concluded that vaginal Misoprostol is highly

effective, easy to administer and superior to catheter/oxytocin in cervical ripening and induction of labour.

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