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Buccal versus Intravaginal Administration of Misoprostol for Labor Induction

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Abstract

Objective:

The purpose of this study is to compare the efficacy of misoprostol that is administrated in the buccal pouch with the intravaginal route.

Study design:

Ninety eight pregnant women with a singleton live gestation. Bishop score of < 5, gestational ages of > 37 wks were randomized receives misoprostol that would be placed either in the buccal pouch or vagina. In the oral group were initially given 100 µg of misoprostol orally this was repeated every 3-4 hours until occurrence of active and progressive labor while in vaginal group we insert 25 µg in the vagina using a water as a lubricant and the labor and fetal outcome was compared in both groups.

Results:

The hours from drug administration to vaginal delivery were significantly not different between the buccal and vaginal group (1120 ± 128) versus (1412 ± 140) respectively, 28 patient in buccal group versus 35 delivered vaginally in vaginal group.

The neonatal outcomes between the two groups were similar and there were no statistical difference between the two groups.

(P = not significant). So, buccal misoprostol is effective for cervical ripening as dose the vaginal administration.

Introduction

Induction: is a method of artificially or prematurely stimulating labor in a women [1].

Induction should only be undertaken for significant medical reasons, but some feel that doctors show increasing propensity toward induction simply for personal convenience or to relieve load on hospital facilities [induction] enables doctors to practice day light obstetrics [2].

Methods of Induction

Methods of inducing labor include [3].

- Membrane sweep, also known as membrane stripping.
- Artificial rupture of the membranes (ARM)
- Cervically – applied prostaglandin, such as dinoprostone .
- Intravenous administration of synthetic oxytocin preparations.
- Natural inductions → which may include use of herbs, castor oil.

If an induction causes complications during labor, a cesarean section is almost always conducted [4]. Of note, induction rates have shown large variation induction rates being found in white, non Hispanic women (25.3%), women with more than 12 years of education (24.6%) and women with private ensurance (24.5%) [5].

Bishop`s score is a pre-labor scoring system to assist in predicting whether induction of labor will be required. A score of 5 or less suggest that labor is unlikely to start without induction [6].

Prostaglandins are the current agent of choice that has been shown to have utility in promoting and labor initiation.

Misoprostol (PGE1) analogue, which is methyl ester (a synthetic) analogue of natural prostaglandin E1. Administrated vaginally and its peak plasma concentration of misoprostotic acids are achieved in less than 30 minutes. It is a thermostable drug and is relatively inexpensive [7].

Although vaginal application of PGE1 (misoprostol) has been validated as reasonable means of induction, there is patient resistance to the digital examination necessary for placement of the drug.
So a method of administration that would provide effective drug absorption without the inconvenience of serial vaginal examinations and without regards of nausea with effective uterine contractility would be useful.

Aim of the study

The purpose of this study is to compare the efficacy and the safety of misoprostol that was administrated in the buccal space with the more used intravaginal route.

Materials and Methods

It is a prospective comparative study conducted during the period from January 2007 to June 2008 at Basrah Maternity and Child Hospital. Patients participant in this study were required to sign in formal consent forms. Patients were eligible in the study if they presented with indication for induction and carrying a single live fetus, more than 37 wks of gestation with cephalic presentation. Any pelvic contracture, vaginal birth contraindications, prostaglandins hypersensitivity were excluded.
All the pregnant mothers included in the study were reviewed and approved and vaginal examination confirmed a Bishop score of less than 5 consent was obtained.
The patients studied were 98 divided into two groups: buccal and vaginal. The buccal group of 45 patients were initially given 100µg of misoprostol buccally, repeated every (3-4) hours until occurrence of active and progressive labor, that's to say, about three uterine contractions every 10 minutes and ask the patient to swallow the tablet after 30 minutes while in the vaginal group 53 patients received 25 µg of misoprostol placed at the posterior vaginal fornix`s using water as a lubricants, the need for repeated dosing was done until active labor was achieved followed with repeated monitoring of fetal heart rate and uterine contractility and the labor, neonatal outcome of both groups was compared. The primary outcome measure was the time from induction initiation to vaginal delivery. Secondary outcome variables include the mode of delivery and neonatal outcome were studied.
Data were analyzed by using the T test and X2 test.

Results

A total of 98 women were included in this study 45 patients were given Buccal misoprostol and 53 were given vaginal misoprostol. Table – No- 1 shows the indications for induction of labor between the two groups the reasons for ripening and induction most frequently post date were similar between the two groups.

Table -1-

Induction Indications

Induction	Buccal =45		Vaginal = 53	
	n	%	n	%
Postdate	14	31.1	16	30.1
PROM	12	26.6	15	28.3
PE	11	24.4	13	24.5
D.M	3	6.6	5	9.4
IUGR	4	8.8	3	5.6
Other	1	2.2	1	1.8

Table -2-

Parity and mode of delivery in the vaginal and buccal misoprostol groups

	Buccal = 45		Vaginal = 53	
Parity	n	%	n	%
Nulliparous	30	66.6	31	56.3
Multiparous (Mode of delivery)	15	33.4	22	41.5
N.V.D	28	62.2	35	66.03
Vacuum	6	13.3	4	7.5
Forceps	2	4.4	1	1.8
Cesarean	9	20	13	24.5

P value was N.S

There was no significant difference between the two groups in regards to the mode of delivery and C.S rate.

Table -3-

Outcome of labor in the buccal and vaginal misoprostol groups.

	Buccal =45		Vaginal =53		p-value
	n	%	n	%	
Interval from drug administration to uterine contraction (min± SD)	31±2.1		29±1.8		N.S
Induction initiation to vaginal delivery (min)	1120±128		1412±140		N.S
Number of administration	1.6±0.9		1.1±0.8		N.S
P.P.H	3	6.6	5	9.4	N.S
Meconium	9	20	8	15.2	N.S
Use of pitocin to Augment labor	5	11.1	6	11.3	N.S
Fetal distress	7	15.5	12	22.6	N.S

Meconium was reported to be higher in the oral group when compared with vaginal route however this difference neither did nor appear to be statistically differing.

Table -4-

Neonatal outcome in the vaginal and buccal misoprostol groups.

Neonatal	Buccal = 45		Vaginal = 53		P-value
	n	%	n	%	
Apgar score <7 at 5 minute	2	4.4	3	5.6	N.S
Birth weight (kg)	3.4 ± 0.4		3.3±0.5		N.S
NICU	8	17.7	13	24.5	N.S

NICU neonatal intensive care unite

No statistical difference between the two studied groups in regards to neonatal outcome.

Discussion

The results of this study indicate that misoprostol administration in the buccal space is effective as the vaginal administration for cervical ripening of labor induction which suggest like PGE2 misoprostol PGE1 is absorbed and active through mucus membrane of the oral cavity [8].

The misoprostol plasma level are detected by 30 minutes and persist for hours and this was in agreement with our finding when uterine contraction started half an hour after administration of buccal and vaginal PGE1 (misoprostol) [9].

The buccal pouch shares some of the same favorable vascular properties as the other mucus membrane; therefore, it is not surprising that this route of administration would be effective. One critical question concerning this route of administration, however, is the amount of gastrointestinal absorption that occurred. Although our patients were asked to swallow at 30 minutes, it is unlikely that gastrointestinal absorption alone was responsible for the uterine activity because around (82%) of the buccal groups started uterine contraction between buccal administration and swallowing which suggest a rapid trans-mucosal absorption. Buccal absorption eliminates exposure to gastrointestinal secretions in first pass liver metabolism, and earlier onset of uterine activity compared with buccal administration would be expected [9].

Also simply because there is residual un-dissolved tablet in the buccal space doesn`t confirm that active drug has not been absorbed because the tablet is not designed for mucus membrane application. This suggest the active ingredient can be absorbed over the mucus membrane [10].

In our study there was no statistical difference in labor and neonatal outcome in both studied groups, so our findings indicate that in closely supervised hospital setting with adequate monitoring buccal misoprostol a potential to induce labor as safely and effectively as the vaginal route and buccal route of misoprostol has a rapid onset to avoid the need for repeated vaginal examinations. Can be used in patients who are unable to eat and are highly effective as a cervical ripening agent. It may be an ideal method of cervical ripening in women with unripe cervices and premature rupture of membranes which allows wash out of misoprostol vaginally, and additional researches are needed to categorically determine the most effective dosing and timing intervals remaint be determined.

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