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COMPARISON BETWEEN VAGINAL AND SUBLINGUAL ADMINISTRATION OF MISOPROSTOL USE FOR LABOR INDUCTION IN PRIMIPAROUS

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ABSTRACT

Background: Increased rate of caesarean sections recently due to cervical immaturity، increased incidence of fetal distress during labour، and lack of knowledge of the best drug and the optimal method for induction of labor، and in view of this، we conducted an observational prospective study to compare the sublingual and vaginal misoprostol in the induction of labor in full-term breech women. **Objective:** The main objective of this study was to compare the vaginal and sublingual administration of misoprostol to induce labor in in full-term Primigravida who are indicated for termination of pregnancy in terms of efficacy، safety، and recorded side effects on the mother and fetus. **Materials and Methods:** This study is a prospective study. The study included pregnant women attending the Department of Obstetrics and Gynecology at Tishreen University Hospital (TUH) in Lattakia. In the period from the beginning of March 2022 until the end of February 2023، for those who have met the criteria for admission. The women in the study sample were divided into two groups as follows: The first group included 50 women who were induction of labor by giving misoprostol 25 mcg every 4 hours sublingually The second group included 50 women. Induction of labor was performed by giving misoprostol 25 mcg every 4 hours vaginally. **Results:** The two groups were controlled for the following variables The woman's age، weight، gestational age، and Bishop's index of success were variable with respect to these variables. The advanced age، higher body mass index، younger gestational age، and lower Bishop's index were associated with lower rates of success in the two groups without having a statistically significant significance. The success of misoprostol was 86% in sublingual administration and 80% in vaginal administration. Normal delivery occurred in 78% in sublingual administration and 72% in vaginal administration without a statistically significant difference. There was a convergence in the time required for labor to occur between the two methods of administration in the time required for labor to occur starting from administration and in the number of misoprostol doses required for labor to occur، and there was no significant statistical difference, As for the general side effects (digestive and hyperthermia)، they were higher in the sublingual route than in the vaginal route، without a statistically significant difference. In the complications associated with labor and delivery، the most common of these complications was the presence of meconium in the amniotic fluid in 16% of women who used misoprostol under the tongue، compared to 14% in vaginal use، without a statistically significant difference. Fetal distress also occurred in 6% of the sublingual use versus 2% of the vaginal use، without a statistically significant difference. As for the rest of the complications، such as inertia bleeding، perineal and cervical tears، it was higher in the vaginal administration group، but without a statistically significant difference. As for the newborn's Apgar in the first fifth minute، it was close in the two groups without a statistically significant difference Conclusion The current study confirmed the effectiveness of giving misoprostol 25 mcg every 4 hours in cervical ripening and induction of labor in full-term breech women، and that there is no preference between the two methods of vaginal or sublingual administration in terms of average duration of induction، success of induction of labor، and maternal and neonatal complications.

KEYWORDS: Labor, Labor Induction، Misoprostol, Bishop's Index.

INTRODUCTION

Increased rate of caesarean sections recently due to cervical immaturity، increased incidence of fetal distress during labor، and lack of knowledge of the best drug and the optimal method for induction of labor، and in view of this، we conducted an observational prospective study to compare the sublingual and vaginal misoprostol in the induction of labor in full-term breech women.

Induction of labor It is a stimulation procedure for uterine contractions in order to initiate labor with or without rupture of the amniotic membranes, while induction of labor is defined as stimulation and stimulation of spontaneous uterine contractions that are not effective enough and cause failure of cervical dilatation and later descent. The cervix undergoes a series of physical and chemical changes at the end of pregnancy, which is clinically called cervical ripening. Unfortunately, cervical ripening may not occur in some patients when childbirth is necessary or when labor begins. Here, labor induction often fails and we have to resort to cesarean delivery.

Misoprostol: It is a synthetic analogue of prostaglandin E1. It has been used for long periods in the treatment of peptic ulcers. It has properties that are characteristic of cervical ripening and induction of labor.

The importance of the research lies in trying to reduce caesarean sections, avoid parental complications, and change the obstetric management of the woman in subsequent pregnancies. And in showing the benefit of misoprostol in ripening the cervix to obtain effective labor and choosing the most appropriate, safest, most useful, useful and accepted method by women.

MATERIAL AND METHODS

The study was conducted at the labor ward of Tishreen University Hospital in Lattakia-Syria for one year (2022-2023*).*

Study design

It Was Prospective Study.

Inclusion criteria

- Primigravida
- Gestational age 37 gestational weeks or more
- Single and cephalic pregnancy
- Bishop index less than 6
- No effective uterine contractions, less than two within 10 minutes
- The presence of indications for termination of pregnancy (absence of fetal pulse, prolonged pregnancy, rupture of amniotic fluid membranes
- Absence of cardiovascular, hepatic and renal diseases
- The condition of the fetus is reassuring
- Informed consent

Exclusion criteria

- Prematurity
- A defective presentation or multiple pregnancies
- Amniotic oedema or a clear fetal megaloplex
- Active labour
- History of uterine surgery Venereal bleeding (defective placenta accreta - idiopathic)
- Active herpes infection
- Disproportion of the two fetuses
- An amniotic infection

Methods

The research sample included 100 women primigravida attending the Labor Division and the Women's Clinic in the Department of Obstetrics and Gynecology at Tishreen University Hospital in Lattakia during the time period 2022-2023, and the investigators included the criteria for inclusion in the research. The age of the women ranged from 18 to 42 years, and the average age was 26.33 ± 6.2 years.

The first group included 50 patients with odd numbers who were given 25 mcg misoprostol under the tongue every 4 hours.

The second group included 50 patients with even numbers who were given 25 mcg vaginal misoprostol every 4 hours.

The research topic was explained, the patient's questions were answered, and her informed consent was taken. This is after adjusting her achievement of the entry criteria into the study.

Secondly, the evaluation of the patient through ultrasound imaging. A complete evaluation before each dose in terms of the presence of: uterine contractions, listening to the fetal pulse, estimating the degree of maturity of the cervix according to the Bishop's index, pelvic evaluation.

Thirdly, misoprostol is applied to each patient according to her group, and the induction is stopped if o Presence of more than two effective uterine contractions within 10 minutes o Fetal pulse disorder o Signs of amniotic infection. If uterine contraction or uterine entrapment occurs, labor stops are applied.

Successful induction means the development of active labor or the occurrence of labor within 24 hours of the start of induction or the arrival of the Bishop's index greater than or equal to 8.

Failed induction means failure to develop active labor after the completion of 4 doses of induction or 24 hours after the start of regular induction.

The patient was monitored by the research doctor, and the clinical condition of the patient was followed up until delivery, where the uterine contractions were followed

by palpation and the fetal heartbeat was followed using continuous electronic monitoring, all information about the patient and about the results of induction and complications were recorded on special forms through which the results were studied in detail.

Data analysis

This study is a randomized clinical trial Statistical analysis was done using IBM SPSS statistics (version 20). Descriptive statistics: Quantitative variables with measures of central tendency and measures of dispersion. qualitative variables with frequencies and percentages The following tests were used to study the relationship between the two research groups: Independent T Student test to compare the mean of two independent groups. Chi-Square or Fisher exact test to study the relationship between qualitative variables. The results are statistically significant with a p-value >0.05. Adopting the program (IBM SPSS statisticsVersion20) to calculate statistical coefficients and analyze results.

RESULTS

The two groups were controlled for the following variables The woman's age، weight، gestational age، and Bishop's index of success were variable with respect to these variables. The advanced age، higher body mass index، younger gestational age، and lower Bishop's index were associated with lower rates of success in the two groups without having a statistically significant significance.

The success of misoprostol was 86% in sublingual administration and 80% in vaginal administration.

Normal delivery occurred in 78% in sublingual administration and 72% in vaginal administration without a statistically significant difference. There was a convergence in the time required for labor to occur between the two methods of administration in the time required for labor to occur starting from administration and in the number of misoprostol doses required for labor to occur، and there was no significant statistical difference.

As for the general side effects (digestive and hyperthermia)، they were higher in the sublingual route than in the vaginal route، without a statistically significant difference.

In the complications associated with labor and delivery، the most common of these complications was the presence of meconium in the amniotic fluid in 16% of women who used misoprostol under the tongue، compared to 14% in vaginal use، without a statistically significant difference.

Fetal distress also occurred in 6% of the sublingual use versus 2% of the vaginal use، without a statistically significant difference.

As for the rest of the complications، such as inertia bleeding، perineal and cervical tears، it was higher in the vaginal administration group، but without a statistically significant difference.

As for the newborn's Apgar in the first fifth minute، it was close in the two groups without a statistically significant difference.

Conclusion The current study confirmed the effectiveness of giving misoprostol 25 mcg every 4 hours in cervical ripening and induction of labor in full-term breech women، and that there is no preference between the two methods of vaginal or sublingual administration in terms of average duration of induction، success of induction of labor، and maternal and neonatal complications.

Table 1: Distribution differences between the two research groups according to age groups.

Age group (year)	The research sample		Total	P-value
	vaginal route	sublingual route		
<20	10(20%)	6(12%)	16	>0.05
20-30	32(64%)	41(82%)	73	
>30	8(16%)	3(6%)	11	

Table 2: Distribution differences between the two research groups according to the body mass index.

(BMI) kg/m²	The Research Sample		Total	P-value
	Vaginal Route	Sublingual Route		
<18.5	1(2%)	2(4%)	3	>0.05
18.5-30	41(82%)	39(78%)	80	
>30	8(16%)	9(18%)	17	

Table 3: Distribution differences between the two research groups according to gestational age.

Gestational age	The research sample		Total	P-value
	Vaginal Route	Sublingual Route		
>40	26(52%)	30(60%)	56	>0.05
40-42	23(46%)	18(36%)	41	
>42	1(2%)	2(4%)	3	

Table 4: Distribution differences between the two research groups according to Bishop's index.

(BISHOP INDEX)	The Research Sample		Total	P-value
	Vaginal Route	Sublingual Route		
Mean ± SD	3.4±1.2	3.5±1.4		0.2
1-2	15(30%)	14(28%)	29	0.5
3-4	30(60%)	32(64%)	62	0.5
5-6	5(10%)	4(8%)	9	0.5

Table 5: Distribution differences between the two research groups according to the cause of labor induction.

(Reason for induction of labor)	The research sample		Total	P-value
	Vaginal Route	Sublingual Route		
prolonged pregnancy	24(48%)	21(42%)	45	0.6
PPROM	16(32%)	22(44%)	38	0.08
fetal death	10(20%)	11(22%)	21	0.1
Oligohydramnios	9(18%)	4(8%)	13	0.06

Table 6: Distribution differences between the two research groups according to the result of labor induction.

Rresult of induction of labor	vaginal route	sublingual route	Total	P-value
Success	40(80%)	43(86%)	83	0.6
failure	10(20%)	7(14%)	17	0.6

Table 7: The time between the initiation of misoprostol administration and the onset of labor.

The time between the start of administration and the occurrence of delivery (hours)	The research sample		Total	P-value
	vaginal route	sublingual route		
1-12	13(26%)	9(18%)	22	>0.05
12-24	23(46%)	29(58%)	52	
>24	14(28%)	12(24%)	26	

Table 8: The number of doses of misoprostol used.

The number of doses	The research sample		Total	P-value
	vaginal route	sublingual route		
1	10(20%)	13(26%)	23	>0.05
2	12(24%)	18(36%)	30	
3	16(32%)	14(28%)	30	
4	12(24%)	5(10%)	17	

Table 9: Distribution differences between the two research groups according to the method of birth.

Delivery	The research sample		Total	P-value
	Vaginal Route	Sublingual Route		
Vaginal	**36(72%)**	**39(78%)**	**75**	**>0.05**
Cesarean section	14(28%)	11(22%)	25	>0.05
• Fetal distress	2(4%)	3(6%)	5	
• Failed labor induction	10(20%)	6(12%)	16	
• Labor does not progress	2(4%)	1(2%)	3	
• Placental abruption	0(0%)	1(2%)	1	

Table 10: Apgar Score.

APGAR SCORE		The research sample		Total	p- value
		vaginal route	sublingual route		
First Minute	<6	2(4%)	5(10%)	7	0.2
	6 ≥	48(96%)	45(90%)	93	
Fifth minute	<6	0(0%)	1(2%)	1	0.6
	6 ≥	50(100%)	49(98%)		

Table 11: Side effects.

Side effects	Vaginal Route	Sublingual Route	Total	P-value
Digestive	4(8%)	9(18%)	13	0.06
Hyperthermia	3(6%)	5(10%)	8	0.3

Table 11: The complication.

The Complication	The research sample		Total	P-value
	Vaginal Route	Sublingual Route		
Meconium in the Amniotic Fluid	7(14%)	8(16%)	15	0.4
Fetal Distress	1(2%)	3(6%)	4	0.5
Inertia Bleeding	6(12%)	1(2%)	7	0.1
Cervical Rupture	6(12%)	4(8%)	10	0.5
Perineal Tear (Grade3)	3(6%)	1(2%)	4	0.3

Table 12: Relationship of success or failure of treatment with age groups.

Age Groups (Years)	Vaginal Route		Sublingual Route	
	Success	Failure	Success	Failure
< 20	9(90%)	1(10%)	6(100%)	0(0%)
20-30	28(87.5%)	4(12.5%)	36(87.8%)	5(12.2%)
>30	5(62.5%)	3(37.5%)	2(66.7%)	1(33.3%)

Table 13: Relationship of success or failure of treatment with BMI (kg/m^2).

(BMI) kg/m^2	vaginal route		sublingual route	
	Success	Failure	Success	Failure
<18.5	1(100%)	0(0%)	2(100%)	0(0%)
18.5-30	32(78.1%)	9(21.9%)	36(92.3%)	3(7.7%)
>30	4(50%)	4(50%)	6(66.7%)	3(33.3%)

Table 14: Relationship of success or failure of treatment with(Gestational age.

(Gestational age)	Vaginal Route		Sublingual Route	
	Success	Failure	Success	Failure
<40	19(73.1%)	7(26.9%)	26(86.7%)	4(13.3%)
40-42	20(86.9%)	3(13.1%)	17(94.4%)	1(5.6%)
>42	1(100%)	0(0%)	2(100%)	0(0%)

Table 14: Relationship of success or failure of treatment with (BISHOP INDEX).

(BISHOP INDEX)	vaginal route		sublingual route	
	Success	Failure	Success	Failure
1-2	10(66.7%)	5(33.3%)	11(78.6%)	3(21.4%)
3-4	26(86.7%)	4(13.3%)	30(93.8%)	2(6.2%)
5-6	5(100%)	0(0%)	4(100%)	0(0%)

DISCUSSION

The present study is a controlled prospective study, this study was conducted on 100 women who were admitted to Tishreen University Hospital in Lattakia and who fulfilled the conditions and criteria of the study. The two groups were controlled for the following variables: The woman's age, weight, gestational age, and Bishop's index of success were variable with respect to these variables. Induction of labor in breech women has been a necessary recommendation in several previous reports. Its aim is to reduce the rate of initial cesarean section in breech women. However, these recommendations are still hampered by fear of complications of induction and resorting directly to cesarean section. There are several drugs used to induce labor, including prostaglandins, including misoprostol, which has been used since ancient times to induce labor, with different doses and different methods of administration. This study was conducted to compare the vaginal and sublingual routes of administration in terms of efficacy and safety The two groups were controlled for the following variables: The woman's age, weight, gestational age, and Bishop's index of success were variable with respect to these variables. The advanced age, higher body mass index, younger gestational age, and lower Bishop's index were associated with lower rates of success in the two groups without having a statistically significant significance.

The success percentage of misoprostol was 86% in sublingual administration and 80% in vaginal administration. Normal delivery occurred in 78% in sublingual administration and 72% in vaginal administration without a statistically significant difference. There was a convergence in the time required for labor to occur between the two methods of administration in the time required for labor to occur starting from administration and in the number of misoprostol doses required for labor to occur the general side effects (hyperthermia and vomiting) were present in both routes of administration, and in the sublingual route more, but without a statistically significant difference. This is consistent with a previous study in Iran in 2016 and a study in Egypt in 2009 As for the effects related to labor and delivery, the presence of meconium in the amniotic fluid and fetal pain was higher in the sublingual route, while inertia bleeding and vaginal and perineal tears were higher in the vaginal route without a significant statistical difference. This differs with the Iran 2016 study, which showed that meconium is higher in the sublingual route with There is an important statistical difference.

As for the newborn, the first- and fifth-minute Apgar's were similar between the two groups.

CONCLUSIONS

The application of misoprostol at a dose of 25 mcg every 4 hours showed significant effectiveness in ripening the cervix and inducing labor in full-term breech women with no serious complications for the mother or the newborn, and that there was no preference between the two methods of vaginal or sublingual administration in terms of the following variables:

- Successful induction of labor
- Average duration of induction
- The number of misoprostol doses Associated maternal complications
- Fetal morbidity

Recommendations

It is recommended to use misoprostol in the induction of labor at a dose of 25 mcg in the induction of labor in full term pregnant women due to its significant effectiveness in cervical ripening provided that there is no contraindication to its use and it is cheap and easy to use The two methods of vaginal and sublingual administration are effective and safe, and either of them can be used to ripen the cervix and induce labor in breech women.

Conducting a prospective study in which the results of the use of different doses of misoprostol were compared, as well as the different vaginal, sublingual, oral, buccal and rectal methods.

Recommendation for pharmaceutical companies to manufacture misoprostol capsules and pills in low doses for ease of use (25 mcg)

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