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COMPARISON OF OUTCOMES BETWEEN 25MCG AND 50MCG DOSING REGIMENS OF VAGINAL MISOPROSTOL FOR LABOUR INDUCTION AT TERM.

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ABSTRACT

Background: Misoprostol is a prostaglandin E-1 analogue which induces uterine contractions and cervical dilatation to reduce primary cesarean section and improve final outcome regarding subsequent pregnancies. **Aim:** The purpose of this study was to evaluate the effectiveness of different doses of vaginal misoprostol for medical induction of labor and compare the side effects of the two doses. **Materials and Methods:** A Prospective study conducted for the period one year (2022- 2023) at Tishreen University Hospital in Lattakia-Syria. The study included 100 pregnant women at full term who had indication for induction of labor, and were divided into group A (50): women were administrated 25 µg of vaginal misoprostol, and group B(50): women were administrated 50 µg of vaginal misoprostol. **Results:** The mean age was 26.33±1.88 years, without significant differences between the two groups regarding age, gestational age, obstetric history, body mass index, status of cervix, etiology of labor induction, and mean induction -abortion interval. The rate of induction success was 88% in group A versus 94% in group B without significant difference, p:0.6. Vaginal delivery was observed more frequently in group B(78% versus 74%, P:0.2) without presence of significant difference between two groups regarding complications (p> 0.05). The rate of responsive to induction was higher in pregnant women in the following cases: advanced age, low body mass index, gestational age group (40-42 weeks), Bishop score (5-6) and multiparous but without significant difference(p>0.05). **Conclusion:** Our study findings suggest that misoprostol in low dose represents a safe and effective alternative to high doses for induction of labor at full term.

KEYWORDS: Labor, induction, full term, misoprostol.

INTRODUCTION

Labor refers to regular and painful uterine contractions that lead to progressive dilation and effacement of cervix.[1] Induction of labor is defined as techniques used for stimulating uterine contractions to perform delivery prior to spontaneous onset of the contractions.[2] It is a critical life-saving intervention that reduces adverse outcomes. Worldwide, it is a relatively common practice. The frequency of labor induction in the United States is rising from 9.5% in 1990 to 29.4% in 2019.[2]

It is indicated when allowing the pregnancy to continue is at least as risky for mother and/or fetus as delivery. It is carried out for a number of reasons ranging from medical necessity to convenience. The main indications for labor induction are: prolonged gestation, premature rupture of membranes, fetal growth restriction and maternal health problems such as pre-eclampsia and diabetes mellitus.[3]

There are many methods for induction of labor, which range from chemical to surgical and mechanical techniques. The choice of methods depends on individual clinical factors, national guidelines and local protocol, as well as advantages and disadvantages of different methods.[4,5] Misoprostol is a prostaglandin E1 analogue which is considered an important drug in obstetric and gynecologic practice due its uterotonic and cervical ripening activity. It is useful in the management of postpartum hemorrhage, abortion and induction of labor.[6] There are many methods for administration of misoprostol which includes: vaginal, oral and sublingual.[7] Several clinical trials revealed that vaginal misoprostol is more effective in inducing labor than

oxytocin without increasing in the maternal and fetal morbidity. In addition to, many studies demonstrated that low doses of vaginal misoprostol are equal in efficiency to high ones. Therefore, the objectives of the study were to: 1- detect the effectiveness of vaginal misoprostol 25 µcg versus 50 µcg in inducing labor in pregnant women at term. 2- to compare the complications between the two groups.

PATIENTS AND METHODS

This is a comparative prospective study of a group of pregnant women at term attending department of Obstetrics and Gynecology at Tishreen University Hospital in Lattakia-Syria during one-year period (2022-2023). The inclusion criteria were: women with viable singleton intrauterine pregnancy in a cephalic presentation, Bishop score lower than 6, with an indication for termination of pregnancy and without contractile activity of uterus. The exclusion criteria were: fetus large for gestational age, malpresentation, multiple pregnancy, severe polyhydramnios, previous sensitivity to prostaglandins, previous uterus surgery, presence of renal failure, asthma, or heart disease.

The following workup included: history, physical examination and laboratory investigations were performed. Patients were randomized into two groups: group I (50 women) who received25 µg of vaginal misoprostol and group II (50 women) who received 50 µg of vaginal misoprostol. Patients were followed up until delivery with monitoring uterine contraction activity and fetal heart by fetoscope. Final outcomes were reordered and compared between two groups.

Ethical consideration: All patients were provided a complete and clear informed consent after discussion about the study. This study was performed following the Declaration of Helsinki.

Statistical Analysis

Statistical analysis was performed by using IBM SPSS version20. Basic Descriptive statistics included means, standard deviations(SD), median, Frequency and percentages. To examine the relationships and comparisons between the two group, chi-square test was used. Independent t student test was used to compare 2 independent groups. All the tests were considered significant at a 5% type I error rate($p<0.05$), β:20%, and power of the study:80%.

RESULTS

The study included 100 pregnant women at term who underwent induction of labor with vaginal misoprostol. Ages range from 18 to 36 years, with a mean age 26.33±1.8 years. As table one shows, the age group (20-30 year) represented the most frequent group followed by >30 and < 20 in group I versus group II as follow;(66% vs 70%), (20% vs 18%) and (14% vs 12%) respectively, p:0.5. Distribution of the women according to the BMI in group I versus group II was as follow; underweight (4% vs 2%), normal (52% vs 54%), overweight (28% vs 26%), and obesity (16% vs 18%),p:0.2. The mean gestational age was 40.9±2.3 in group I vs. 40.3±3.1in group II, p:0.6. The group <40 week represented the most frequent group followed by 40-42 and >42 in group I versus group II as follow;(56% vs 62%),(42% vs 36%)and (2% vs 2%) respectively,p:0.3.

Table 1: Demographic characteristics of the study population by comparison of the two group.

Variables	Group I Vaginal misoprostol 25 mcg (n=50)	Group II Vaginal misoprostol 50 mcg (n=50)	P value
Age (years)	26.2±3.6(18-43)	25.9±4.1(20-39)	0.6
Age groups			
<20	7(14%)	6(12%)	
20-30	33(66%)	35(70%)	0.5
>30	10(20%)	9(18%)	
BMI(kg/m^2)			
Low weight	2(4%)	1(2%)	
Normal	26(52%)	27(54%)	
Overweight	14(28%)	13(26%)	0.2
obesity	8(16%)	9(18%)	
Gestational age	40.9±2.3	40.3±3.1	0.6
Gestational age group(weeks)			
<40	28(56%)	31(62%)	
40-42	21(42%)	18(36%)	0.3
>42	1(2%)	1(2%)	

Majority of the cases were multiparous (68% in group I versus 72% in group II, p:0.9). The total mean and standard deviation of the Bishop score in the group I and II was respectively 3.1±1.5 versus 2.9±1.4 , p:0.6, and the score 3-4 was detected frequently, followed by 5-6 and 1-2 in group I versus group II as follow;(58% vs 64%),(26% vs 22%) and (16% vs 14%) respectively,p:0.2. In group I versus group II, prolonged pregnancy represented the most common indication for induction of labor (44% vs 38%, p:0.6), followed by

premature rupture of membrane (32% vs 28%,p:0.2), oligohydramnios(18% vs 22%,p:0.1), pre -eclampsia(4% vs 8%,p:0.5), and intrauterine fetal death(2% vs 4%,p:0.1). Mean of the time from induction to delivery was 13.9±3.7 in group I versus 13.6±3.1 in group II without significant difference, p:0.2. Approximately half of the patients were in the time group 13-24; 48.6% in group I versus 51.3% in group II,p:0.6.

Table 2: Obstetric characteristics of the study population by comparison of the two group.

Variables	Group I Vaginal misoprostol 25 mcg (n=50)	Group II Vaginal misoprostol 50 mcg (n=50)	P value
Obstetric status			
Nulliparous	16(32%)	14(28%)	0.9
Multiparous	34(68%)	36(72%)	
Bishop score			
1-2	8(16%)	7(14%)	
3-4	29(58%)	32(64%)	0.2
5-6	13(26%)	11(22%)	
Indication of labor induction			
Post-term	22(44%)	19(38%)	0.6
Premature rupture of membrane	16(32%)	14(28%)	0.2
Oligohydramnios	9(18%)	11(22%)	0.1
Pre -eclampsia	2(4%)	4(8%)	0.5
Intrauterine fetal death	1(2%)	2(4%)	0.1
Induction -delivery time			
1-12	15(40.6%)	16(41.1%)	
13-24	18(48.6%)	20(51.3%)	0.6
>24	4(10.8%)	3(7.6%)	

Number of vaginal misoprostol doses that used in induction of labor ranged from one to two, three, and four doses in group I versus group II as follow;(8% vs 14%), (32% vs 30%), (40% vs 44%) and (20% vs 12%) respectively without significant difference between two groups, p:0.3. The prevalence of success of induction of labor was 88% in group I versus 94% in group II, p:0.6. 37 cases (74%) delivered vaginally in group I versus 39 cases (78%) in group II. Failure of labor induction represented the most frequent etiology of cesarean section in group I(12%) followed by fetal distress(8%) and failure of progress(6%), whereas fetal distress represented the most etiology in group II(14%) followed by failure of labor(6%) and failure of progress(2%), p:0.2. There was no significant difference between two groups regarding complications(p>0.05). Fetal distress represented the most frequent complication in group I(8%), followed by meconium stained amniotic fluid(6%), post-partum bleeding(4%) and uterine hypertonus(2%), whereas in group II fetal distress represented the most frequent complication (14%) followed by meconium stained amniotic fluid(8%), post-partum bleeding(4%),uterine hypertonus(4%) and uterine tachysystole (2%).

Table 3: Obstetric outcome of the study population by comparison of the two group.

Variables	Group I Vaginal misoprostol 25 mcg (n=50)	Group II Vaginal misoprostol 50 mcg (n=50)	P value
Outcome of induction			
Success	44(88%)	47(94%)	0.6
Fail	6(12%)	3(6%)	
Route of delivery			
Vaginal	37(74%)	39(78%)	
Cesarean section			
Failure of induction	6(12%)	3(6%)	0.2
Fetal distress	4(8%)	7(14%)	
Failure of progress	3(6%)	1(2%)	
Complications			
Uterine tachysystole	0(0%)	1(2%)	0.9
Uterine hypertonus	1(2%)	2(4%)	0.1
Fetal distress	4(8%)	7(14%)	0.3
Meconium stained amniotic fluid	3(6%)	4(8%)	0.7
Post- partum bleeding	2(4%)	2(4%)	1

As shown in table (4), variables such as age, BMI, gestational age, Bishop score, and obstetric status were associated insignificantly with the outcome of induction of labor, in which success of induction was increased with advanced age of mother, decreasing of BMI, advanced gestational age, high grade of Bishop score and in multiparous (p>0.05).

Table 4: Association between results of labor induction and characteristics of the study population.

Variables	Group I Vaginal misoprostol 25 mcg (n=50)		Group II Vaginal misoprostol 50 mcg (n=50)	
	Success	**Failure**	**Success**	**Failure**
Age groups				
<20	5(71.4%)	2(28.6%)	5(83.3%)	1(16.7%)
20-30	30(90.9%)	3(9.1%)	33(94.3%)	2(5.7%)
>30	9(90%)	1(10%)	9(100%)	0(0%)
BMI(kg/m^2)				
Low weight	2(100%)	0(0%)	1(100%)	0(0%)
Normal	25(96.1%)	1(3.9%)	26(96.3%)	1(3.7%)
Overweight	12(85.7%)	2(14.3%)	12(92.3%)	1(7.7%)
Obesity	5(62.5%)	3(37.5%)	8(88.9%)	1(11.1%)
Gestational age group(weeks)				
<40	24(85.7%)	4(14.3%)	29(93.5%)	2(6.5%)
40-42	19(90.5%)	2(9.5%)	17(94.4%)	1(5.6%)
>42	1(100%)	0(0%)	1(100%)	0(0%)
Bishop score				
1-2	5(62.5%)	3(37.5%)	5(71.4%)	2(28.6%)
3-4	26(89.7%)	3(10.3%)	31(96.6%)	1(3.1%)
5-6	13(100%)	0(0%)	11(100%)	0(0%)
Obstetric status				
Nulliparous	13(81.2%)	3(18.8%)	13(92.9%)	1(7.1%)
Multiparous	31(91.2%)	3(8.8%)	34(94.4%)	2(5.6%)

DISCUSSION

This comparative study of 100 pregnant women at full term who underwent induction of labor assessed efficiency of vaginal misoprostol 25 µcg versus vaginal misoprostol 50 µcg in induction, as well as the safety of each dose.

Our clinical trial demonstrated that majority of women were in the age group 20-30 year and BMI ranged from normal to overweight. Gestational age <40 week represented the most frequent group and majority of women were multiparous. Prolonged pregnancy represented the most indication for labor induction, and induction-delivery time was in the range 13-24 hour in approximately half of the women. Number of doses that used was two (most frequently) followed by three doses in the two groups. The rate of success was higher in group II without presence of significant differences between two groups, and failure induction represented the most frequent indication for cesarean section in group I versus fetal distress in group II. There was no significant difference between two groups regarding complications which was more frequent in group II regardless obstetric status. Various studies have provided evidence for outcome of labor induction by misoprostol 25 µcg versus 50 µcg.

Bharathi et al (2013) demonstrated in a study conducted in 100 pregnant women at full term who underwent induction of labor either by vaginal misoprostol 25 µcg(50 cases) versus vaginal misoprostol 50 µcg(50 cases) that induction-delivery time was significantly shorter with increasing dose(9.45 versus 14.5 hour, p:0.001). The rate of vaginal delivery was higher with lower doses (72% versus 50%, p:0.001) with lower rate of induction failure (16% versus 38%). Complications were observed more frequently with high dose especially uterine tachysystole and uterine hypertonus.[8]

Adebayo et al (2017) demonstrated in a study conducted in 184 pregnant women at full term who underwent induction of labor either by vaginal misoprostol 25 µcg(92 cases) versus vaginal misoprostol 50 µcg(92 cases) that prolonged pregnancy represented the most frequent indication for induction in two groups without significant difference between groups regarding induction-delivery time(0.8), delivery during 24 hours(0.1), frequency of cesarean section delivery(p:0.7) and maternal and fetal complications.[9]

Aggarwal et al(2018) showed in a study conducted in 100 pregnant women at full term who underwent induction of labor either by vaginal misoprostol 25 µcg (50 cases) versus vaginal misoprostol 50 µcg(50 cases) that induction-delivery time didn't differ significantly between two groups(p:0.9). The rate of delivery after one dose was lower in 25 µcg group (38% versus 42%), but with increasing the rate of delivery in this group after

repeating dose. There was no significant difference between two groups regarding maternal and fetal morbidity and method of delivery(p>0.05).[10]

Srilaxmi (2020) showed in a study conducted in 120 pregnant women at full term who underwent induction of labor either by vaginal misoprostol 25 µcg (60 cases) versus vaginal misoprostol 50 µcg(60 cases) that prolonged pregnancy was the most frequent indication for induction in two groups without presence of significant difference of vaginal delivery between two doses(80% versus 83.3%,p:0.6). The rate of complications was higher with increasing the dose (6.6% versus 3.3%, p>0.05).[11]

Garg et al (2021) demonstrated in a study conducted in 100 pregnant women at full term who underwent induction of labor either by vaginal misoprostol 25 µcg versus vaginal misoprostol 50 µcg that pre -eclampsia was the most frequent indication for induction in two groups with presence of significant difference between two groups (50 µcg versus 25 µcg) regarding number of women who delivered after one dose(40% versus 20%,p:0.008) and delivery during less than 12 hours(41.8% versus 22.7%, p:0.01). Perineal tear, post-partum hemorrhage, and tachysystole were observed more frequently with high doses without significant differences between two groups(p>0.05).[12]

In summary, low dose of vaginal misoprostol was an effective method for labor induction as high dose and can safely be implemented.

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