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The effectiveness of obstetric gel application in shortening labor duration and preserving vaginal perineal integrity: Prospective observational study

Doğum eylemi süresini kısaltmada ve vajinal perine bütünlüğünü korumada obstetrik jel uygulamasının etkinliği: prospektif gözlemsel çalışma

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ÖZ

Amaç: Bu çalışmanın amacı, obstetrik jel uygulamasının doğum eylemi sonuçlarına etkisini belirlemektir.

Gereç ve Yöntem: Bu randomize olmayan kontrollü çalışma, Ocak 2019 ile Haziran 2019 tarihleri arasında üçüncü basamak bir hastanede gerçekleştirildi. Düşük riskli, verteks pozisyonunda, 16-40 yaş arası, tahmini fetal ağırlığı 2500-4000 gram, gebelik haftası 37-41 hafta arasında olan nullipar gebeler çalışmaya dahil edildi. Çalışma grubunun (n=142) vajinal kanalına, doğumun ilk aşamasında (5 cm servikal açılmadan önce) 3-5 ml hidroksietil selüloz jel aplikatör ile uygulandı. İşlem bebeğin doğumuna kadar her iki saatte bir tekrarlandı. Kontrol grubu (n=191) standart antenatal bakım aldı.

Bulgular: Epizyotomi ihtiyacı çalışma grubunda kontrol grubuna göre anlamlı olarak daha düşüktü (n=72 (%50.7) ve n=175 (%91.6)) (Z=18.902, p<0.001). Ayrıca, çalışma grubundaki kadınların vajinal perineal bütünlüğün korunması açısından anlamlı derecede daha iyi sonuçlara sahip oldukları bulundu (n=53 (%37,3) ve n=160 (%83,7)) (Z=134,893, P<0,001) . Ayrıca çalışma grubunda doğumun ikinci evresinde kontrol grubuna göre (36.68~34.37 dk ve 58.03~30.35 dk) anlamlı kısalma gözlendi (p<0.001).

Sonuç: Obstetrik jel kullanımı doğumun birinci ve ikinci aşamalarını kısaltmakta, epizyotomi ihtiyacını azaltmakta ve perine bütünlüğünün korunmasına yardımcı olmaktadır. Bu nedenle nullipar normal vajinal doğumlarda uygulandığında maliyet etkin olabilir ve yaşam kalitesine olumlu katkı sağlayabilir.

Anahtar Kelimeler: Doğum; İkinci Aşama; Obstetrik Jel; Perine Bütünlüğü

ABSTRACT

Aim: The aim of this study to determine the effects of obstetric gel application on labor outcomes.

Materials and Method: This nonrandomized controlled study was carried out between January 2019 and June 2019 in a tertiary-care hospital. Nulliparous pregnant women with low risk, vertex position, between the ages of 16-40 years, with an estimated fetal weight of 2500-4000 grams and a gestational week between 37-41 weeks were included in the study. Using an applicator, 3-5 ml of a hydroxyethyl cellulose gel was applied to the vaginal canal of the study group (n=142) at the first stage of labor (before 5 cm cervical opening). The procedure was repeated every two hours until the birth of the baby. The control group (n=191) received standard antenatal care.

Results: The need for episiotomy was significantly lower in the study group compared to the control group (n=72 (50.7%) vs. n=175 (91.6%)) (Z=18.902, p<0.001). Moreover, it was found that women in the study group had significantly better outcomes concerning the preservation of the vaginal perineal integrity (n=53 (37.3%) vs. n=160 (83.7%)) (Z=134.893, P<0.001). Also, significant shortening was observed in the second stage of labor in the study group compared to the control group (36.68□34.37 min vs. 58.03□30.35 min) (p<0.001).

Conclusion: The use of obstetric gel shortens the first and second stages of labor, reduces the need for episiotomy, and helps preserve perineal integrity. Thus, it can be cost-effective and contribute positively to life quality if administered in nulliparous normal vaginal deliveries.

Keywords: Labor, Second Stage; Obstetric Gel; Perineal Integrity

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INTRODUCTION

Genital trauma is a frequently encountered complication of vaginal deliveries in nulliparous women (1). Additionally, birth trauma in vaginal delivery may cause postpartum pelvic floor dysfunction and increase the risk of pelvic organ prolapse and stress urinary incontinence (2).

Perineal trauma during vaginal delivery may deteriorate the quality of life and sexual function of women and cause difficulties in newborn care and breastfeeding (3,4). Furthermore, postpartum perineal pain, dyspareunia, and aesthetic concerns may cause women to avoid normal vaginal delivery and prefer to undergo elective cesarean section (5).

On the other hand, prolongation of the second stage of labor may cause negative consequences, such as perineal lacerations, puerperal infection, and postpartum hemorrhage (6). For this reason, efforts have been made to prevent perineal injury and shorten the duration of the labor after full dilatation of the cervix (1,7,8).

There are conflicting reports regarding the use of obstetric gels during vaginal deliveries. Although studies show that obstetric gels reduce the duration of the second phase of labor and have a protective effect on the pelvic floor, there are also studies reporting that they do not shorten the second stage of delivery (6,9,10).

This study aimed to determine the effects of an obstetric gel on labor outcomes, focusing on the length of the second stage of the labor, protection of perineal integrity, and episiotomy proportions.

MATERIALS AND METHODS

Study design

This non-randomized controlled study was conducted in Etlik Zübeyde Hanım Training and Research Hospital. Participants were selected from nulliparous pregnant women admitted to the department of obstetrics for delivery.

Ethical approval (numbered 343, dated 17.12.2018) was received from the Etlik Zübeyde Hanım Training and Research Hospital Clinical Research Ethics Committee. The reporting of the study was done per the CONSORT guideline (11). Informed consent form was obtained from all patients. Consent forms were also obtained from the parents of pregnant women under the age of 18.

Setting

The study was carried out in Etlik Zübeyde Hanım Training and Research Hospital between January 2019 and June 2019. The research hospital has a total of 420 inpatient bed capacity, including nine pregnancy outpatient clinics divided into early pregnancy, normal pregnancy, and risky pregnancy according to the gestational week. The study lasted 6 months. In Etlik Zübeyde Hanım Training and Research Hospital, an average of 12000 to 16000 births take place annually. However, there are limited studies in the literature on obstetric gel application and it was concluded that 453 patients would be sufficient in the power analysis made with reference to the studies titled "use of obstetric gel in nulliparous pregnant women" by Aydıner et al. in 2017 (10).

Participants

Nulliparous pregnant women with low risk, vertex presentation, aged between 16-40 years, having an estimated fetal weight of 2500-4000 grams, and a gestational week between 37-41 weeks, were included in the study.

Patients who underwent cesarean section (42 in control and 47 in the study group) were excluded from the study. Pregnant women with additional diseases such as diabetes, hypertension, or findings of cephalopelvic incompatibility, chorioamnionitis, macrosomia, prolonged rupture of amniotic membrane, fetal anomaly, dead fetus, and high-risk pregnancy were excluded from the study.

During the study period, 453 pregnant women applied to give birth. Patients in the control group were enrolled first. All eligible women who applied between January and March 2019 were invited to participate. After finishing the enrollment process of the control group, applicants between April and June 2019 were invited to join the study group. Data for 191 and 142 participants were analyzed in the control and study groups, respectively (Figure 1).

Interventions

Ultrasonography was performed in all pregnant women in the delivery room, and fetal gestational age was calculated from first-trimester ultrasonography findings. Standard antepartum care was given to all women in the delivery room. All interventions related to the study protocol were implemented by a physician trained for the study. Hourly vaginal pelvic examination was performed to all pregnant women until the end of the first stage of the labor. Later, pelvic examination frequency was adjusted according to the requirement of the second stage of delivery. All vaginal evaluations were done under hygienic conditions to minimize any risk of vaginal infection. Fetal monitoring was performed intermittently until the baby was born. Maternal and fetal parameters were recorded on the partograph during labor.

The obstetric gel used in the study (GynoTAL®, Turkuaz Inc., Istanbul, Turkey) contains deionized water, propylene glycol, carbomer, hydroxyethyl cellulose, and sodium hydroxide. GynoTAL is not allergenic, has high mucoadhesive activity, high viscosity, and high electrical conductivity. This obstetric gel was applied by a trained physician with 3-5 ml special applicator into the vaginal canal at the first stage of labor (before 5 cm opening) and every two hours until the birth of the baby. No perineal massage was implemented during the delivery.

Outcomes

The primary outcome variable of the study was "the duration of the second stage of labor". Other variables were age, body mass index (BMI), education of the mother, pregnancy week, estimated fetal weight (g), presentation (vertex/breech), episiotomy (vacuum or forceps delivery (Kristeller maneuver), estimated fetal weight (g), first and fifth-minute APGAR scores, head circumference (cm), vaginal-perineal lacerations, degree of vaginal tears (operative delivery, shoulder dystocia, episiotomy, macrosomia (induction), epidural anesthesia (prolonged

(>3 hours) second stage of labor (duration of the first stage of labor (minutes), duration of the second stage of labor (minutes).

Study Size

The sample size calculation was based on the primary outcome variable 'duration of the second stage of the labor. To compare the dependent variable between the study and control groups using the independent sample t-test with an effect size of 0.35 (small to medium) and an α error of 0.05, 333 participants (191 controls + 142 study) provides a power of 88.2% (12). This sample size is sufficient to compare a mean difference of 10.5 minutes, given a standard deviation of 30.

The patients were asked whether they wanted to apply the vaginal gel. Those who did not accept the application were included in the control group, and those who accepted were included in the study group.

Statistical Analysis

Statistical analysis was performed via the Statistical Package for the Social Sciences (SPSS) (SPSS for Windows, Version 25.0, Chicago, IL, USA) program. The mean and standard deviations were presented if the variables were numerical, while frequency and percentages were used for presenting categorical data. Normal distribution was evaluated by the Kolmogorov-Smirnov test, while scale variables were compared using the Mann-Whitney U test. The Chi-square (or Fisher's exact) test was used to compare categorical variables. Linear regression analysis was used to check for factors independently affecting the primary outcome variable after correcting for potential confounders. A p-value of less than 0.05 was considered sufficient for statistical significance.

RESULTS

Participants

The mean age of the participants was 24.77 ± 5.33 years (rang=16-40) While 19.2% of the participants (n=64) did not have any education, 18.3% (n=61) were university graduates. Additionally, while shoulder dystocia developed in 2 patients (0.5%), vacuum was required in 7 patients (2.1%) (Table 1).

Table 1: Descriptive characteristics of participants

		Number	Percent
Education	No education	64	19.2
	Primary and secondary school	101	30.3
	High school	107	32.1
	University	61	18.3
Profession	Housewife	274	82.3
	State employee	38	11.4
	Other occupation	21	6.3
Presentation	Occiput anterior	331	99.4
	Occiput posterior	2	0.6
Vacuum		6	1,8
Fetal gender	Female	165	49.5
	Male	168	50.5
Shoulder dystocia		2	0,6
Macrosomia		6	1,8

Outcomes

The need for episiotomy was significantly lower in the gel-applied group compared to the control group (Z=18.902, p<0.001). Moreover, it was found that pregnant women in the study group were significantly more advantageous concerning the preservation of vaginal perineal integrity (Z=134.893, p<0.001) (Table 2).

Table 2: Comparison of categorical variables according to the study groups

		Group			
		Control	Study		
		n (%)	n (%)	χ^2	p
Episiotomy		153(80,1)	15(10,5)		<0.001
Vacuum		5(2.6)	1(0,7)	1.686	0.245*
Kristeller maneuver		83 (43.5)	17(12,0)	38.422	<0.001
Vaginal-perineal tear		164 (85.99)	32 (22.5)	134.893	<0.001
Induction		104(54,5)	41(28,9)	21.674	<0.001
Prolonged second stage of labor		98 (51.4)	89 (62.7)	3.293	0.070
Macrosomia		5 (2.6)	1 (0.7)	1.686	0.245*
Degree of vaginal tear	1st	114 (59,68)	14 (9,85)	7.178	0.028
	2nd	40 (20,94)	18 (12,67)		
	3rd	10 (5,23)	2 (1,40)		

Significant shortening was observed in the first and second stages of labor in the study group compared to the control group (p=0.015 and p<0.001, respectively) (Table 3).

Table 3: Comparison of numerical variables between the study groups As mentioned in the limitations section, the study was not blinded. Since the experiment is completed, it is no more possible to establish blinding. Hence, we suffice by mentioning this as a limitation.

	Group	Mean	SD	Z	p
Age (year)	Control	25.63	5.80	2.793	0.005
	Study	23.63	4.40		
BMI (kg/m^2)	Control	27.58	3.24	2.987	0.546
	Study	27.67	3.83		
Gestational week	Control	39.30	1.30	0.902	0.367
	Study	39.15	1.24		
Estimated fetal weight (g)	Control	3353.57	301.07	0.570	0.569
	Study	3329.75	270.97		
Baby weight (g)	Control	3245.20	345.64	0.314	0.753
	Study	3239.82	359.01		
APGAR 1	Control	8.63	0.55	7.523	<0.001
	Study	8.99	0.08		
APGAR 2	Control	9.94	0.24	3.038	0.002
	Study	10.00	0.00		
Head circumference (cm)	Control	34.71	1.19	2.531	0.011
	Study	34.45	1.19		
First stage of labour (hour)	Control	6.26	3.46	2.444	0.015
	Study	5.49	3.61		
Second stage of labor (min)	Control	58.03	30.35	6.822	<0.001
	Study	36.68	34.37		

BMI: Body mass index. Z: Mann-Whitney U test value. SD: Standard deviation.

As mentioned in the limitations section, the study was not blinded. Since the experiment is completed, it is no more possible to establish blinding. Hence, we suffice by mentioning this as a limitation.

As to our knowledge, there is no rational explanation for the high Kristaller maneuver proportions in the study group. Higher proportions of Kristaller maneuvers in the study group were discussed in the discussion section by indicating that further studies are required to explain this apparent discrepancy. The following sentences were added to the discussion: We applied the Kristaller maneuver individually in patients with decreased maternal pushing pressure and fetal bradycardia only one time per patient. Although we observed higher proportions of Kristaller maneuvers in the study group, as to our current knowledge, there is no rational explanation of this difference. Further studies are needed to enlighten this apparent discrepancy.

Gel use was the only significant variable affecting the duration of the second stage of labor after the correction for age, BMI, Kristeller maneuver (dummy variable), induction (dummy variable), and head circumference (Table 4).

Table 4: Computer data for linear regression analysis

	Unstandardized				95.0% CI for B	
	B	SE	t	p	Lower	Upper
(Constant)	41.083	53.007	0.775	0.439	-63.195	145.362
Gel use	-20.445	4.004	-5.106	**<0.001**	-28.322	-12.567
Age (year)	-0.217	0.353	-0.616	0.539	-0.911	0.477
BMI (kg/m2)	-0.755	0.509	-1.485	0.138	-1.756	0.245
Kristeller	0.826	4.118	0.201	0.841	-7.275	8.927
Induction	-0.237	3.777	-0.063	0.950	-7.668	7.194
Head circumference (cm)	1.220	1.527	0.799	0.425	-1.784	4.224

BMI; Body mass index

DISCUSSION

The episiotomy is a technique applied to prevent severe perineal tears during delivery (13). In 2006, the American College of Obstetricians and Gynecologists (ACOG) recommended that episiotomy should not be used routinely (14). However, in selected cases, if there is a maternal or fetal indication, it is appropriate to perform an episiotomy.

In this study, there was a need for episiotomy of 91.6% in the control group, while in the study group, this figure was 50.7%.

Reducing the need for episiotomy not only provides economic benefits, but also reduces the side effects that may occur due to episiotomies, such as bleeding, infection, dyspareunia, delay in wound healing, urinary fistula, and pelvic floor dysfunction (14-17). Not to be forgotten that these complications have economic burdens beyond decreasing the personal quality of life.

We consider the economic analysis included in our manuscript as an important approach to analyze burden of episiotomy. However, we agree with the reviewer that the economic analysis was not included as an objective of the study. Thus, we modified the objectives as follows: “This study aimed to determine the effects of an obstetric gel on labor outcomes, focusing on the length of the second stage of the labor, protection of perineal integrity, episiotomy proportions, and economic burden.” Furthermore, the paragraphs about economic burden were moved further down in the discussion.

It has been reported that episiotomy is still used at high rates in some countries due to the belief that it prevents severe perineal tears, especially in primiparas (4,18,19). Shortening the second stage of labor can help preserve the vaginal perineal integrity and reduce advanced perineal tears. This study demonstrated that the use of obstetric gel is effective in preserving vaginal perineal integrity in primiparas. It was thought that the shortening of the second phase might play a role in the emergence of these effects. As a matter of fact, various procedures have been studied to reduce the effect of perineal trauma during labor, reduce postpartum blood loss, and shorten labor time to improve obstetric outcomes (1,20). Besides, the decrease in the incidence of spontaneous perineal tears due to the widespread use of gels may decrease the tendency to apply episiotomy over time.

Labor can be handled in three stages (21). The first stage, which is associated with visceral pain, is provoked by contractions of the uterus and lasts till full dilation (approximately 10 cm) of the cervix. The second stage of birth is the stage from the full dilation of the cervix to the baby’s birth. At this stage, the descent of the fetus in the birth canal may cause tension and tears in the tissues of the vagina and perineum (22). The third stage of labor is related to the postpartum period.

It has been reported that the prolongation of the second stage of labor is associated with increased maternal morbidity and operative delivery rates (23). Obstetric lubricant gels were investigated with the prediction that they could reduce the second stage of labor. In addition to researches stating that these gels shorten the second stage of labor and increase perineal integrity (9,24), there are also studies reporting that they are not effective in this regard (6).

This study yielded similar results to articles claiming that obstetric gels are beneficial. Additionally, the degree of vaginal tears was significantly lower in the gel-used group. However, it should be kept in mind that the difference between the groups

in terms of the prolonged second stage of labor does not reach a statistically significant level. The reason for this difference between studies may be the demographic differences of pregnant women included in the studies. It was concluded that the rate of multiparous pregnant women included in the examination may be a factor affecting the results.

A recent study using a gel containing hydroxyl ethyl cellulose found a reduction in the first and second stages of labor, similar to our study. However, no difference was reported in need of episiotomy and APGAR scores (10). Hence, it was thought that the differences in patient selection between the two studies may have influenced the results. As a matter of fact, pregnant women under 18 with a BMI above 30 were not included in the study by Aydıner et al. However, in our study, the rate of those with BMI> 30 was 15.9% (n= 53) and the proportion of pregnant women under the age of 18 was 2.4% (n= 8). It should also be noted that the statistical difference in APGAR scores may not be significant at the clinical level.

In conclusion, the use of an obstetric gel containing deionized water, propylene glycol, carbomer, hydroxyl ethyl cellulose, and sodium hydroxide shortens the first and second stages of labor, reduces the need for episiotomy, and helps to preserve perineal integrity. Due to these features, it has been concluded that the use of obstetric gel in hospital deliveries can be cost-effective and contribute positively to the quality of life of nulliparous pregnant women.

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None

Figure Lagent

Figure 1: Participant flow chart

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