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Evaluation of the effectiveness of obstetric lubricant gel in labor in nulliparous and primiparous women: a randomized controlled study

Nullipar ve primipar kadınlarda doğumda obstetrik lubrikan jelin etkinliğinin değerlendirilmesi: Randomize kontrollü çalışma

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ABSTRACT

Aim: Our hypothesis was that lubricating gels used at the beginning of the active phase of labor could reduce the incidence of episiotomies and shorten the duration of labor. This study aims to investigate and confirm this theory with a randomized controlled trial.

Material and Methods: A prospective randomized controlled trial was conducted at obstetrics and gynecology department of a university hospital between January 2017 and April 2017. The study included 102 nulliparous and 93 primiparous singleton pregnancies. 50 primiparous women and 47 nulliparous patients were randomly assigned to the obstetric gel group. Obstetric gel was applied to participants in the study groups at the beginning of the active phase of labor. Outcomes were episiotomy rates and duration of labor.

Results: Episiotomy rates were significantly lower in nulliparous obstetric gel group (36.1% and 63.6%, p=0.005). The duration of the active phase of the first and second stage of labor was significantly lower in the obstetrical gel groups compared to the control groups in both parities (150±86 and 203.5±134, p=0.021, 28.8±18.2 and 62.6±53.8, p<0.001 in nulliparous and 143.4±61.4 and 185.3±97.2, p=0.016, 21.5±14.8 and 36.9±34.1, p=0.006 in primiparous, respectively).

Conclusion: The application of obstetric gel shortened the duration of the active phase of the first stage of labor and the duration of the second stage of labor. In addition, we observed that episiotomy rates were reduced by the use of obstetric gel in the nulliparous group.

Keywords: Episiotomy; labor; obstetric gel; parturition; second stage of the labor

ÖZ

Amaç: Çalışmanın amacı doğumun aktif fazının başlangıcında kullanılan kayganlaştırıcı jellerin epizyotomi insidansını azaltabileceğini ve doğum süresini kısaltabileceğini göstermektir. Bu çalışma, bu teoriyi randomize kontrollü bir çalışma ile doğrulamayı amaçlamaktadır.

Gereç ve Yöntemler: Ocak 2017 ile Nisan 2017 tarihleri arasında bir üniversite hastanesinin kadın hastalıkları ve doğum kliniğinde prospektif randomize kontrollü bir çalışma olarak yürütülmüştür. Çalışmaya 102 nullipar ve 93 primipar tekil gebelik dahil edildi. 50 primipar kadın ve 47 nullipar hasta randomize edilerek obstetrik jel grubuna dahil edilmiştir. Çalışma gruplarındaki katılımcılara doğumun aktif fazının başında obstetrik jel uygulanmıştır. Sonuçlar gruplar arasında epizyotomi oranları ve doğum süresilerinin farkının değerlendirilmesidir.

Bulgular: Epizyotomi oranları nullipar obstetrik jel grubunda anlamlı olarak daha düşük olarak bulunmuştur (%36.1 ve %63.6, p=0.005). Doğumun birinci ve ikinci evresinin aktif fazının süresi her iki paritede de obstetrik jel gruplarında kontrol gruplarına kıyasla anlamlı olarak daha düşük saptanmıştır (150±86 ve 203.5 ±134, p=0.021, nulliparlarda 28.8±18.2 ve 62.6±53.8, p<0.001 ve primiparlarda sırasıyla 143.4±61.4 ve 185.3±97.2, p=0.016, 21.5±14.8 ve 36.9±34.1, p=0.006).

Sonuç: Obstetrik jel uygulaması doğumun birinci evresinin aktif fazının süresini ve doğumun ikinci evresinin süresini kısaltmıştır. Ayrıca, nullipar grupta obstetrik jel kullanımı ile epizyotomi oranlarının azaldığını gözlemlenmiştir.

Anahtar Kelimeler: Epizyotomi; doğum; obstetrik jel; parturisyon; doğumun ikinci evresi

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INTRODUCTION

The first stage and second stages of labor are the two phases of vaginal birth. The latent phase and the active phase are additional divisions of the first stage of work. The point at which there is a noticeable rise in the rate of cervical dilatation is known as the active phase of labor. Cervical dilation of 6 cm be considered the start of the active phase of labor. When the cervical dilation is complete, the second stage of labor begins and finishes with the delivery of the newborn (1). It has been demonstrated that there is an increased risk of adverse maternal and neonatal outcomes in cases of protraction and arrest disorders, including cesarean delivery, chorioamnionitis, postpartum hemorrhage, fetal acidosis, and neonatal intensive care unit (NICU) admission (2). In a retrospective study of 19,000 patients, it was shown that when the definition of prolongation of the 2nd stage of labor was increased by 1 hour, cesarean section rates decreased, but neonatal acidemia, NICU admission and 3rd-4th degree perineal injuries increased (3).

Multiple adaptive chances are needed for vaginal delivery. Vaginal delivery has been described as a potentially stressful experience by Nygaard (4). Many strategies have been put forth to lessen the traumatic impact of childbirth. Warm compresses and perineal massage have been recommended as ways to stretch and soften the perineum (5). Additionally, it has been discovered that increasing the number of midwives can aid to lessen perineal damage during labor (6). The perineum is traumatized by episiotomy in addition to the stress caused by vaginal delivery. It is no longer recommended that routine episiotomy be performed and the decision to perform an episiotomy is at the discretion of the clinician at the time of delivery. The limited use of episiotomy has been demonstrated to reduce the risk of perineal and vaginal injury (7, 8).

Reducing the trauma associated with vaginal birth has recently become a significant topic of interest. There are a limited number of studies in the literature investigating the use of lubricant gels. The effects of using lubricant gels remain unclear and continue to be a subject of debate (9). It has already been hypotized that obstetric gel could help reduce friction during labor. Thus the duration of labor may be shortened and perineal trauma may be reduced (10). Contradictory findings exist regarding the use of lubricant gels during labor. While some studies, such as those by Seval et al. (11) and Azardish et al. (9) , suggest that lubricant gels shorten labor stages and reduce episiotomy rates, a meta-analysis found no significant impact on the duration of the second stage of labor (10).

The objective of this study is to investigate and confirm the hypothesis that the application of lubricant gels at the beginning of the active phase of labor may reduce the duration of delivery and episiotomy rates The objective of this study is to investigate and confirm this hypothesis through a randomized controlled trial.

MATHERIALS AND METHODS

Pregnant women who were admitted to obstetrics and gynecology department of the university hospital for vaginal delivery between January 2017 and April 2017 were assessed for eligibility. This study was conducted in accordance with the ethical standards set by the Declaration of Helsinki. The institutional ethics committee of the university approved the study (approval no: 09-606-18) and written informed consent has been obtained from all patients. The study included nulliparous and primiparous singleton pregnancies between 37 and 41 weeks + six days of gestation and vertex presentation of the fetus with an estimated birth weight of 2000–4500 g. The study excluded multiparous pregnancies and women who had previously undergone a cesarean section, as well as those with contraindications to vaginal delivery. PG E1 or PG E2 was not used for cervical dilatation. Patients requiring medication for cervical dilatation were not included in the study. NCT number is NCT06069596. It was obtained retrospectively.

The participants were separated into two distinct categories, namely nulliparous and primiparous, on the basis of their parity status. Each cohort comprised 110 participants initially. The nulliparous and primiparous groups were randomly assigned to either the study or control group in a 1:1 ratio using a computer-generated randomization program to ensure a randomized and unbiased selection process. The randomization procedure was conducted in a double-blind manner, with the investigators responsible for the study remaining unaware of the allocation until the conclusion of the study. All participants in the study received the standard antepartum care regimen in the delivery room. A total of 25 patients were lost to follow-up during the course of the study. Consequently, obstetric lubricant gel was administered to patients in the study groups, which included 47 nulliparous and 50 primiparous patients. Clinical care of the participants was provided by same team of physicians with no changes about study protocol. Patients did not undergo routine amniotomy. However, in patients who did not have spontaneous rupture of amniotic membranes during the progression of the active phase, amniotomy was performed when cervical dilatation was 8-9 cm. Continious fetal monitoring was performed until the delivery. No patient received epidural anesthesia during labor. Maternal and fetal parameters was recorded by partograph during labor. APGAR scores were evaluated by a neonatologist who was not informed about the study and the groups. At the onset of the active phase of labor, a specially designed applicator was

used to administer obstetric lubricant gel to the vaginal canal. The study utilized a highly viscous, isotonic gel with a mildly acidic pH ranging from 6.0 to 6.7. This gel comprised hydroxyethylcellulose, propylene glycol, and glycerin. The packaging included a sterile 15 ml syringe and a flexible applicator.

The active phase of the first stage of labour was defined as starting with cervical dilation of 3–5 cm or more, in the presence of active uterine contractions (>200 Montevideo units), ending with complete cervical dilation. The second stage of labour was defined as starting when cervical dilation is complete and ending with fetal delivery. The primary outcome was duration of active phase and second stage of labor while the secondary outcomes were observation of type of the delivery (cesarean or vaginal delivery), episiotomy rates, ocytocin requirement, analgesic requirement, birth weight and APGAR scores of the newborns.

Statistical Analysis

Data analyzes were performed by using SPSS Version 21.0 (IBM Corporation, Armonk, NYC, USA). Samples were tested with Shapiro Wilk to determine normality of distributions. According to the results, non parametric tests were preferred. Continuous variables were compared with Mann Whitney U test. Categorical variables were compared with Chi square test or Fisher's exact test where appropriate. A P value of <0.05 was considered statistically significant. The sample size calculation based on previously published data (12) revealed that this study needs recruit at least 84 persons for each group to have 80% power with 5%.

RESULTS

Flowchart of this study is shown in Figure 1. Between January 2017 and April 2017, a total of 220 patients who applied for delivery participated to the study. All the participants were divided into two groups based on their parity. Nulliparous and primiparous pregnant women were randomized using a computer system. Twenty five patients were lost to follow up during the labor. The numbers of patients in the obstetric gel groups were 47 and 50, respectively (Figure 1).

There were no significant differences between the groups in terms of age, gestational age, body mass indexes, cesarean rates, oxytocin induction, bishop scores at the time of gel application and APGAR scores in both parity groups (Table 1). In nulliparous women, fetal birth weights were similar in both groups, although the fetal birth weights in primiparous control group were higher than the obstetric gel group (3418 ± 421 grams and 3245 ± 383 grams, p=0.042, respectively). While, episiotomy rates were significantly lower in nulliparous obstetric gel group (36.1% and 63.6%, p=0.005, respectively), there was no significant difference in primiparous group (36% and 29.1%, p=.449, respectively). The duration of the active phase of the first stage and the second stage of the labor were significantly lower in obstetric gel groups compared to the control groups in both parity (150±86 mins and 203.5±134 mins, p=0.021, 28.8±18.2 mins and 62.6±53.8 mins, p<0.001 in nulliparous, and 143.4±61.4 mins and 185.3±97.2 mins, p=0.016, 21.5±14.8 mins and 36.9±34.1 mins, p=0.006 in primiparous, respectively). APGAR scores were similar across

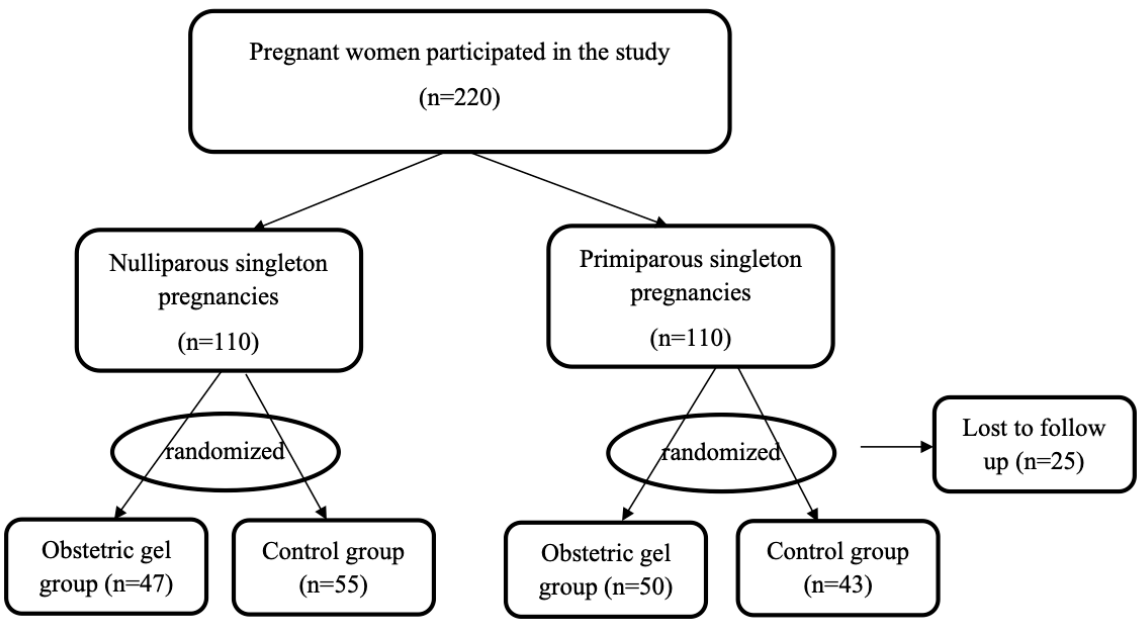

Figure 1. Flow chart of the study

Table 1. Patients characteristics and outcome variables of the study population

	Nulliparous			Primiparous		
	Obstetric gel group (n=47)	Control group (n=55)	P value	Obstetric gel group (n=50)	Control group (n=43)	P value
Age, years, mean ± SD	26.7±4.7	26.4 ±5.1	0.917	26.9±5.1	27.7±4.7	0.759
Gestational age, days, mean ± SD	273.4±6.1	271.7±5.8	0.892	271.1±4.3	275.5±8.3	0.436
BMI, kg/m², mean ± SD	30.66±4.44	29.96±4.11	0.410	29.73±4.30	31.33±4.49	0.084
Cesarean section, n(%) -fetal distress -failure to progress	6(12.7%) 3(6.3%) 3(6.3%)	12(21.8%) 5(9.0%) 7(12.8%)	0.231	2(4%) 2(4%) 0	4(7.2%) 3(5.2%) 1(2%)	0.470
Episiotomy rates, n(%)	17(36.1%)	35(63.6%)	**0,005**	18(36%)	16(29.1%)	0.449
Ocytocin induction, n(%)	22 (46.8%)	27(49.1%)	0.818	15(30%)	19(34.5%)	0.619
Bishop score*, mean ± SD	9.76±0.86	9.65±0.88	0.524	9.66±0.86	9.69±0.96	0.851
Duration of the active phase of the first stage, min, mean ± SD	150±86	203.5±134	**0.021**	143.4±61.4	185.3±97.2	**0.016**
Duration of the second stage, min, mean ± SD	28.8±18.2	62.6±53.8	**<0.001**	21.5±14.8	36.9±34.1	**0.006**
Fetal weight, g, mean ± SD	3284±448	3250±377	0.793	3245±383	3418±421	**0.042**
APGAR 1, mean ± SD	7.32±1.47	7.48±0.9	0.472	7.85±0.91	7.55±0.88	0.529
APGAR 5, mean ± SD	8.95±0.97	8.96±0.47	0.692	9.26±0.44	9.01±0.75	0.524

*Bishop score at the time of gel application
‡ Mann-Whitney U, T test or Chi-square test SD: Standard deviation

all groups. No side effects were observed with the use of obstetric lubrican gel.

DISCUSSION

The findings of the present study demonstrated that the duration of the active phase of the first stage of labor and the duration of the second stage of labor were shorter in the obstetric gel groups. Additionally, the rate of episiotomy was found to be significantly lower in the obstetric gel group among nulliparous women.

A limited number of studies have been published on this topic. In a randomized controlled trial (RCT) published by Schaub et al. in 2008, it was demonstrated that the application of the obstetric gel resulted in a notable reduction in the duration of the second stage of labor (12). Although the use of lubrican gel resulted in a reduction in the duration of the first stage of labor and the total duration of labor, these findings were not statistically significant. Additionally, the author indicated that the incidence of perineal tears was lower in the group that received the obstetric gel. No adverse effects were observed. Aydın et al. also reported similar findings. The durations of the first and second stages of labor were found to be shorter in the obstetric gel group compared to the control group (13). In an RCT conducted by Seval et al. in 2017, it was observed that the mean duration of the second stage of labor was significantly shorter in the obstetric gel group compared to the control group, regardless of the number of previous pregnancies (45±34 minutes and 58±31 minutes, respectively; p=.005) (14). Among nulliparous women, the mean duration of the second stage of labor was found to be shorter in the study group compared to the control group (53±52 mins and 83±42 mins, respectively; p = 0.003). However, no statistically significant difference was observed between the two groups in multiparous women with regard to the duration of the first and second stages of labor. Additionally, the authors indicated that the 5-minute APGAR scores of the study group were significantly higher than control group. No significant difference was observed in the duration of the active phase of the first stage of labor. In a recent RCT, Azarkish et al. investigated the effects of an obstetric gel on the length of labor and perineal trauma in primiparous women (9). The study reported that the mean duration of the total length of labor, the first stage, and the second stage were significantly shorter in the obstetric gel group compared to the control group in primiparous women. Furthermore, the authors have indicated that perineal health was notably superior in the obstetric gel group. The percentage of women who underwent episiotomy and experienced perineal trauma was significantly lower in the obstetric gel group compared to the control group. Additionally the authors stated that the mean duration of the first stage of labor was reported to be 141.64±77.89 minutes in the obstetric gel group

and 190.02±117.60 minutes in the control group. Furthermore, the duration of the second stage of labor was 37.62±18.24 in the study group and 43.69±16.24 in the control group. A systematic review and meta-analysis published in 2022 demonstrated that the utilization of lubricant gel was associated with a reduction in the occurrence of perineal trauma, the administration of episiotomy, and second-degree perineal laceration, in addition to a shorter second stage of labor (15) .

In contrast with these findings, Ashwal et al. reported no reduction in the durations of the stages of labor following the administration of an obstetric gel. The mean lengths of the active and second stages of labor were 157 minutes and 48 minutes, respectively, in the obstetric gel group and 219 minutes and 56 minutes, respectively, in the control group (16). The authors noted that these differences did not achieve statistical significance. In the cited study, the groups were randomly assigned, regardless of the number of previous pregnancies. The Ashwal et al. study included both nulliparous and multiparous women in its groups. One hypothesizes that a significant difference would have been identified between the groups had the groups been divided in accordance with parity. Furthermore, the authors indicated that while the obstetric gel group exhibited lower rates of grade II perineal tears and episiotomy compared to the control group, there were no statistically significant differences between the groups in terms of rates of episiotomy and grade II perineal tears. Furthermore, Aquino and colleagues published a meta-analysis that included three studies that are referenced in this article. The authors indicated that the application of obstetric gel does not result in a reduction in the length of labor. However, the authors also stated that the use of lubricant gel could potentially reduce perineal trauma by reducing friction through a purely physical effect, thereby decreasing the opposing force during vaginal birth (10). Furthermore, the study indicated that the rates of operative vaginal births and cesarean sections did not differ between the obstetric gel and control groups. Additionally, the use of obstetric gel did not result in a reduction in the duration of the second stage of labor. In a recently published expert opinion, the authors posit that perineal massage and stretching of the perineum with a water-soluble lubricant gel during the second stage of labor are associated with an increased rate of intact perineum and a decreased rate of severe perineal trauma and episiotomy. The authors recommend perineal massage as a technique to reduce severe perineal trauma during the second stage of labor (17). It was reported that perineal massage was associated with a 51% reduction in the incidence of severe perineal trauma and a 44% reduction in the requirement for episiotomy (18). It is nevertheless recommended that obstetric gel should not be used as a lubricating gel in the absence of perineal massage (17).

The present study findings indicate that the obstetric gel did not affect the rates of cesarean section. However, the length of the active phase of the first stage of labor and the length of the second stage of labor were shorter in the obstetric gel group. A prospective randomized controlled study with different groups, such as an obstetric gel group, an obstetric gel group with perineal massage, and a control group, may provide greater clarity. Additionally, the rate of episiotomy was found to be significantly lower in the obstetric gel group among nulliparous women.

Study Limitations

Our study has several limitations. One limitation was the degree of standardization of the methodology. To maximize standardization, all patients were consistently monitored and received gel application by the same team. However, a higher level of standardization could have been achieved if all interventions and follow-ups were performed by a single specialist. The lower mean birth weight of the infants in the obstetric gel group, as compared to the control group, among primiparous pregnant women may have influenced the study results in a manner that favored the study group. This represents a potential limitation of the study. Our study also has several strengths. The present study was a prospectively designed randomized controlled trial with group allocation based on patient parity.

CONCLUSION

In the present study, we have found that the application of obstetric gel shortened the duration of the active phase of the first stage of the labor and the duration of the second stage of the labor. In addition, we have observed that episiotomy rates were reduced by using obstetric gel in nulliparous group.

Conflict of Interest

The authors declared no conflict of interests.

Ethics Committee Approval:

The institutional ethics committee of the university approved the study (Ankara University Ethics Committee) and written informed consent has been obtained from all patients.

NCT number is NCT06069596. It was obtained retrospectively.

The study was presented as an oral presentation at EBCOG-TJOD 2017 in Turkey.

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