

Vaginal Application of K-Y Gel During Labor in Nulliparous, Term Pregnant Women: A Case Control Study.

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ABSTRACT

Background: Labor process involves a friction process between fetal head and maternal pelvic floor and perineum which seems to be inevitable. Repeated vaginal birth with a lengthy second stage is a significant risk factor for pelvic floor and perineal injuries and related pathological outcomes.

Purpose: This study aimed to assess maternal and fetal outcomes in nulliparous pregnant women after vaginal application of K-Y gel during the active period of labor as facilitating vaginal delivery can hopefully reduce perineal and pelvic floor injuries.

Methods: A prospective case-control study including 220 primiparous, term pregnant women hospitalized to the Obstetrics and Gynecology Department in the first stage of labor. Participants were divided into two groups: Group I (n =110) got regular antepartum care (Control group) and group II (n =110) received K-Y gel in addition to standard antepartum care (Study group). Maternal and fetal outcomes were documented and examined.

Results: The length of the second stage and the duration of the active phase were significantly shorter in the study group (P = 0.001). In the study group, the proportion of deliveries with intact perineum was significantly greater (P = 0.008). The mean Apgar score at one minute was significantly higher in the study group than in the control group (P = 0.029). In the study group, there were fewer perineal lacerations (OR 1.61; 95% CI of 0.95 - 2.75, P = 0.079). Other data and results were similar across the two groups, with no statistically significant differences.

Conclusion: The administration of K-Y gel vaginally during labor in primiparous women shortens the length of the active phase and second stage of labor and increases the proportion of women who deliver with an intact perineum.

Keywords: Nulliparous, Active labor, Perineal lacerations, K-Y gel, Episiotomy, Second stage.

INTRODUCTION

Vaginal birth is a significant risk factor for damage to the pelvic floor muscles, which may result in pelvic organ prolapse and urine incontinence ^[1, 2]. Prolonged second stage of labor is the leading cause for that and for increased fetal morbidity ^[3].

In addition, extended second stage heightens the requirement for operational vaginal delivery and associated complications ^[4]. Development and use of obstetric gels with variable structures are reported in the literature. Their use aimed for more rapid labors and less perineal injury through lubricant effect and decreasing friction between fetal head and birth canal ^[5-7]. So, its use is reported to shorten labor duration but the effects on perineum are conflicting with lack of evidence.

This study aimed to assess maternal and fetal outcomes in nulliparous pregnant women after vaginal application of K-Y gel during the active period of labor to facilitate vaginal delivery can hopefully reduce perineal and pelvic floor injuries.

MATERIALS AND METHODS

A prospective case-control study was conducted on women who were admitted to the Obst. and Gyn. Dep. at Maternity Hospital of Menoufia University, in the period between January and May 2023.

After a thorough description of the study's aims, all women who met the inclusion criteria and volunteered to participate were screened for eligibility.

Inclusion criteria: 18–40 years of age, primiparous, term, singleton pregnancy, vertex presentation, and estimated fetal weight between 2500 g and 4000 g by obstetric ultrasound.

Exclusion criteria: Women having any obstetric and systemic illness, those who underwent cervical surgery, BMI ≥ 30 kg/m², induced labors, those with documented fetal anomalies or growth restriction and those with documented chorioamnionitis or pre-labor rupture of membranes.

• **Group I:** The control group (n = 110) whose labors received standard ante- and intra-partum care without application of K-Y gel.

• **Group II:** The study group (n = 110) in whom K-Y gel (*K-Y Jelly Johnson & Johnson 82 gm. Active ingredients*) was applied along with the standard care.

All interventions including standard intra-partum care and vaginal application of K-Y gel was carried out by the attending resident or specialist who was oriented by the study protocol. Throughout the initial stage of labor, a vaginal examination was conducted every two hours. The frequency of vaginal inspection was modified based on the development of labor. For every vaginal examination, sterile gloves were utilized. The partograph was used to capture maternal and fetal data during labor. The neonatologists who received the infant for evaluation, resuscitation, and reporting of the Apgar score were unaware of the research.

K-Y gel (K-Y Jelly Johnson & Johnson 82 gm. Active components) that is translucent, water-based, physiologically inert, and electrically conductive was employed for the investigation. It is composed of glycerol, hydroxyethyl cellulose, gluconolactone, chlorhexidine, sodium hydroxide, gluconate, methylparaben, and sterile water. Using a sterile syringe, K-Y gel was administered vaginally around the cervix sporadically from the initiation of active phase of labor (when the cervix is at least 5 cm dilated) until delivery of the infant. During regular sterile vaginal examinations, which are part of the standard care, 3–5 ml of K-Y gel was supplied and disseminated throughout the vagina every two hours. The first stage of labor begins when the cervix is at least 5 centimeters dilated in the presence of vigorous uterine contractions (three or more contractions in ten minutes) and concludes when the cervix is completely dilated. The second stage of labor begins when the cervix is completely dilated and concludes when the fetus is delivered [6]. According to the opinion of the physician, episiotomy was not performed regularly during the second stage of labor unless the perineum was overstretched or threatening to rip. Perineal lacerations were described as any situation requiring perineal suturing other than an episiotomy. It should be highlighted that there was an overlap between the number of patients who had episiotomy and those who developed perineal lacerations. In the present investigation, no further therapies, such as epidural anesthetic or extra analgesics, that may impact the length of labor were used.

Outcomes: Maternal outcomes included the duration of the second stage of labor, the duration of the active phase, the method of delivery, the number of perineal lacerations, the necessity for episiotomy, and the proportion of patients delivered with an intact perineum (with neither episiotomy nor perineal lacerations). Among the fetal outcomes were admissions to the NICU and infant APGAR scores.

Sample size calculation was based on review of past literature [6], who found significant shortening of the second stage duration in women with application

of obstetric gel group when compared to control group (45 ± 34 min vs. 58 ± 31 min, respectively; p = 0.005). Using version 6 of the statistics and sample size pro tool, the sample size was determined to be 198 women. The study's reliability is 80% and its degree of assurance is 95%. To account for potential dropouts, the research recruited 220 female participants. Using a computer-generated random number table, all participating women were randomly allocated to one of two groups during the first stage of labor.

Ethical approval: Medical Ethics Committee of Menoufia Faculty of Medicine gave its approval to this study (IRB No. 5-2023 OBG 12). All participants gave written consents after receiving all information. The Helsinki Declaration was followed throughout the study's conduct.

Statistical Analysis

Data were tabulated and processed using SPSS version 23 on a personal computer compatible with IBM (SPSS Inc., Released 2015). V. 23.0 of IBM SPSS statistics for Windows (Armonk, New York: IBM Corporation). To summarize normally distributed quantitative data, mean ± SD were utilized, and the student's t-test was used to compare the two groups. The Mann Whitney test was used to evaluate quantitative variables between two non-normally distributed sets of data. While qualitative data were provided as numbers and percentages. Categorical outcomes were compared using the Chi-square test. The odds ratio and confidence interval (CI) at 95 percent were computed for each groups' outcome measures. P value at ≤ 0.001 indicated a high significance, whilst p value ≤ 0.05 indicated significance.

RESULTS

The length of the second stage and the duration of the active phase were considerably shorter in the study group, although there was no significant difference in terms of maternal age, gestational age at delivery, maternal weight, and height (Table 1).

Table (1): Patient characteristics of the study population

Baseline Criteria	Cont. Grp (n=110)	Study Grp. (n=110)	Test of significance	P value
Age (years)	24.6 ± 2.5	24.4 ± 2.8	T = 0.56	0.577
Gestational age (weeks)	39.2 ± 1.6	39.1 ± 1.4	T = 0.49	0.622
Maternal weight (kg)	68.2 ± 6.8	67.1 ± 8.5	T = 1.06	0.290
Maternal Height (cm)	159.1 ± 7.9	158.8 ± 8.2	T = 0.28	0.783
Duration of the 2 nd stage (min)	86.0 ± 51.0	56.0 ± 48.0	U = 4.49	<0.001
Duration of the active phase (hours)	3.6 ± 1.8	2.7 ± 1.5	U = 4.03	<0.001

T: Student's t-test

U: Mann-Whitney test.

Table (2) showed a significant higher percentage of delivery with intact perineum in the study group than the control group (p = 0.008). There was no significant differences between the two groups regarding oxytocin augmentation, Cesarean section rate, need for episiotomy, perineal lacerations, and postpartum endometritis.

Table (2): Maternal outcomes

Maternal outcomes	Cont. Gr (n=110)	Study Grp. (n=110)	χ^2	P – value	OR (95% CI)
Oxytocin augmentation	62 (56.4%)	65 (59.1%)	0.17	0.682	0.89 (0.73-1.23)
Cesarean section rate	31 (28.2%)	25 (22.7%)	0.86	0.353	1.15 (0.73-2.45)
Need for episiotomy	35 (31.8%)	32 (29%)	0.19	0.660	1.14 (0.64-2.02)
Perineal laceration Grade 1 & 2	66 (60.0%)	53 (48.2%)	3.09	0.079	1.61 (0.95-2.75)
Perineal laceration Grade 3	5 (4.5%)	3 (2.7%)	0.52	0.471	1.70 (0.40-7.29)
Delivery with intact perineum	15 (13.6%)	31 (28.2%)	7.04	0.008*	0.40 (0.20-0.80)
Postpartum endometritis	0 (0%)	1 (0.9%)	1.09	0.296	----

OR: Odd's ratio. CI: confidence interval. χ^2 : Chi-square test.

Regarding fetal outcomes, table (3) showed a significant higher mean value of Apgar score at 1 minute in the study group (p = 0.029), while other fetal outcomes including birth weight, neonatal head circumference, Apgar score at 5 minutes and NICU admission were almost similar in the two groups.

Table (3): Fetal outcomes

Fetal outcomes	Cont. Grp (n=110)	Study Grp. (n=110)	Test of significance	P value
Birth weight (kg)	3.3 ± 0.5	3.4 ± 0.4	T = 1.64	0.103
Neonatal head circumference (cm)	33.7 ± 2.1	33.1 ± 3.1	T = 1.68	0.094
Apgar score at 1 minute	7.8 ± 1.3	8.2 ± 1.4	T = 2.20	0.029
Apgar score at 5 minutes	9.1 ± 0.9	9.3 ± 0.7	T = 1.84	0.067
NICU admission	1 (0.9%)	2 (1.8%)	$\chi^2 = 0.34$	0.561
Birth injury	0 (0%)	0 (0%)	NA	NA

SD: standard deviation NA: not applicable; T: Student's t-test; χ^2 : Chi-square test.

DISCUSSION

Labor process involves a friction process between fetal head and maternal pelvic floor and perineum, which seems to be inevitable [8, 9]. Repeated vaginal birth with a lengthy second stage is a significant risk factor for pelvic floor and perineal injuries and related pathological outcomes [1, 2].

The use of lubricant material is known to reduce friction forces and consequently reducing the duration of labor and perineal injury. Regarding patient variables such as mother age, gestational age, maternal weight, and maternal height, there were no significant variations between the two research groups. No birth injuries happened in both groups and there was no significant differences regarding other fetal outcomes in terms of birth weight, neonatal head circumference, APGAR scores and NICU admissions. The second stage of labor and the whole active phase were significantly shorter in group 2 (study group) indicating the promising lubricant effect on the duration of labor thus reducing time of friction between the fetus and maternal tissues and consequently pelvic and perineal injuries. In the current study, there was important outcome where the number of women delivered with intact perineum was significantly higher in the study group. Fortunately, there was no complete perineal tears (grade 4) in the study population, five patients and three patients in group 1 and group 2 respectively had third degree perineal tear while regarding grade one and two perineal lacerations, there was thirteen more patients in group 1. Although not reaching statistical significance, this difference is to be considered [OR: 1.61 at 95 % CI of (0.95-2.75)] and this can be attributed to the lubricant effect and shorter durations of the active phase and second stage of labor resulting in a shorter duration of friction fetal head and perineum. The shorter labor active phase and second stage duration revealed in the current study is correlating with previous reports done in both nulliparous and multiparous women [6], and reports done only in nulliparous women like the current study [7, 10].

On the other hand, a study done on 200 pregnant women by Ashwal *et al.* [11] found that obstetric gel was used safely during labor but without significant effects on the duration of labor or on the rate of perineal lacerations outcomes that are not correlating with the findings of the current study and this difference especially in the effect on the duration of labor active phase and second stage may be due to the different structure of the used lubricant and the different method of application; gel applied by hands in the vagina only during the second stage while in the current study it was applied using syringe starting with the onset of active phase and repeated till delivery.

In 2018, a meta-analysis was done for three randomized trials and this analysis included 512 participants and revealed that use of lubricant gel while in labor at term had no effect on the length of the

second stage of labor and was not associated with significant reduction of the risk of perineal lacerations [12]. This is contrary to the current study outcomes regarding the duration of labor and delivery with intact perineum, while this meta-analysis correlates, to a certain degree, with the current study outcomes regarding the rate of perineal laceration that don't have significant differences even with more perineal lacerations in the control group.

In the literature, the influence of a protracted second stage of labor and total labor time on mother and fetal outcomes is evident [3, 6, 13].

There are studies that used K-Y gel or obstetric gel with similar structure like the one used in the current study [10, 14] and they are in agreement with the current study regarding shortening the duration of both active phase and second stage of labor without significant effect on the rate of perineal integrity and lacerations.

Fetal outcomes were not significantly different in the current study population except for Apgar score at one minute which was significantly higher in group 2 that used K-Y gel that not correlating with some reports [10]. This positive effect on fetal outcome can be attributed shorter labor duration specially the second stage and this correlates with some other reports [6].

The effect of lubricant gel on the duration of the second stage is evidenced by the results of the current study and literature but the positive effect on the perineum is still conflicting and the differences can be attributed to different structures of the used gel, different methodologies and study populations. There is no robust evidence regarding gel use during labor on fetal and neonatal outcomes and wider studies are needed to drag firm conclusions regarding perineal protection and neonatal outcomes.

The standardized obstetric management and the number of the study population and matched demographic data between the study and control groups constitute points of strength to the present study. Meanwhile, the lack of a long term follow up to record late effects on the power of perineal and pelvic floor muscles constitutes unintended limitation to the present study. Future research should focus on conducting a multicenter randomized controlled study on the effect of K-Y gel use during labor on labor information, short- and long-term perineal and pelvic floor effects and fetal outcomes.

CONCLUSION

Vaginal application of K-Y gel during labor in nulliparous women has promising effects in the form of significant reduction of the duration of the active phase and second stage of labor, significant increase in the percentage of delivery with intact perineum and less perineal injuries.

- **Financial support and sponsorship:** Nil
- **Conflict of Interest:** Nil

REFERENCES

1. **Dietz H (2004):** Levator function before and after childbirth. *Aust N Z J Obstet Gynaecol.*, 44: 19–23.
2. **Morgan D, Cardoza P, Guire K et al. (2010):** Levator ani defect status and lower urinary tract symptoms in women with pelvic organ prolapse. *Int Urogynecol J.*, 21: 47–52.
3. **Cheng Y, Hopkins L, Laros R et al. (2007):** Duration of the second stage of labor in multiparous women: maternal and neonatal outcomes. *Am J Obstet Gynecol.*, 196: 1-6.
4. **Eason E, Labrecque M, Wells G et al. (2000):** Preventing perineal trauma during childbirth: a systematic review. *Obstet Gynecol.*, 95: 464–71.
5. **Beckmann M, Stock O (2013):** Antenatal perineal massage for reducing perineal trauma. *Cochrane Database Syst Rev.*, 4: CD005123. doi: 10.1002/14651858.CD005123.pub3.
6. **Seval M, Yüce T, Yakıştıran B et al. (2017):** Effects of obstetric gel on the process and duration of labor in pregnant women: Randomised controlled trial. *J Obstet Gynaecol.*, 37: 714-8.
7. **Schaub A, Litschgi M, Hoesli I et al. (2008):** Obstetric gel shortens second stage of labor and prevents perineal trauma in nulliparous women: a randomized controlled trial on labor facilitation. *J Perinat Med.*, 36: 129-35.
8. **Manassiev N (1997):** Head-to-cervix force: an important physiological variable in labor. *Br J Obstet Gynaecol.*, 104: 272–3.
9. **Sallam H, Abdel-Dayem A, Sakr R et al. (1999):** Mathematical relationships between uterine contractions, cervical dilatation, descent and rotation in spontaneous vertex deliveries. *Int J Gynaecol Obstet.*, 64: 135–9.
10. **Aydiner B, Kiyak H, Mete F et al. (2017):** Use of obstetric gel in nulliparous pregnant women: Maternal and neonatal outcomes. *Perinatal Journal*, 25 (3): 127–32.
11. **Ashwal E, Aviram A, Wertheimer A et al. (2016):** The impact of obstetric gel on the second stage of labor and perineal integrity: a randomized controlled trial. *J Matern Fetal Neonatal Med.*, 29: 3024-9.
12. **Aquino C, Saccone G, Troisi J et al. (2019):** Use of lubricant gel to shorten the second stage of labor during vaginal delivery. *J Matern Fetal Neonatal Med.*, 32: 4166-73.
13. **Cheng Y, Hopkins L, Caughey A (2004):** How long is too long: Does a prolonged second stage of labor in nulliparous women affect maternal and neonatal outcomes? *Am J Obstet Gynecol.*, 191: 933-8.
14. **Albers L, Sedler K, Bedrick E et al. (2005):** Midwifery care measures in the second stage of labor and reduction of genital tract trauma at birth: a randomized trial. *J Midwifery Womens Health*, 50: 365–72.