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Research Article

EFFECTS OF OBSTETRIC GEL ON NEONATAL AND MATERNAL OUTCOMES IN NULLIPAROUS WOMEN

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Abstract:

***Objective:** The purpose of this study was to determine the effects of obstetric gel application on pregnant nulliparous women in the first and second stage of labor, to evaluate on the perineum with its protective effect, and the maternal and fetal outcomes related with this procedure.*

***Study Design:** A prospective and randomized controlled study.*

***Place and duration:** In the Obstetrics and Gynecology department of Sulaiman Al Habib Medical Group Hospital, Riyadh for one year duration from December 2017 to December 2018.*

***Methods:** Into two groups; between 37 and 41 weeks of gestation nulliparous women admitted to our hospital were randomly divided. The pregnant women were not given any induction during their labour; Normal amniotomy was performed as routine, but during delivery routine episiotomy was not done. In both groups, episiotomy need, perineal laceration, laboratory data, newborn data and birth stages were compared.*

***Results:** 200 total pregnant nulliparous females (n = 102 in Group I, in Group II: n = 98 spontaneous follow-up, treated with gel) who met the criteria of the study were evaluated. There was no difference in laboratory data, neonatal results and maternal demographic data. The 1st and 2nd stages of labor were statistically significant and shorter. In terms of need for episiotomy/procedure; there was no variation between the groups. As for the cases with mild perineal lacerations (first and second degree) and no fetal heart, the outcomes were better relatively in pregnant women with gel and there was no statistically significant variation in perineal lacerations at advanced stage (third and fourth grades).*

***Conclusion:** In nulliparous women, during delivery the use of obstetric gels leads to a significant reduction in the stage of labor and less tearing.*

***Key Words:** labor, obstetric gel, Labor facilitation.*

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INTRODUCTION:

For urinary incontinence and pelvic organ prolapse, the most important cause is fracture of pelvic floor especially levator ani muscle injury [1]. Many risk factors such as maternal age, pelvic floor dysfunction, fetal birth weight and Hormonal changes during pregnancy are considered as factors that explain the pelvic floor dysfunction [2]. Also, the 2nd stage and labor for long time are the most important obstetric factors for dysfunction of pelvic floor and injury. The second extended birth stage raises labor and is linked with the newborn's morbidity with undesirable peripartum [3]. Reducing vaginal delivery rates by applying a tweezers / vacuum or limited episiotomy procedure instead of routine method can help reduce damage to pelvic floor during delivery [4]. In addition, a randomized controlled trial and Cochrane analysis showed that perineal massage provides protection against pelvic floor injury before delivery or at birth and reduces perineal pain after postpartum. To facilitate vaginal delivery; Obstetric gels are made which are liquid based gels [5]. The aim of the method is to help in fetus delivery of the pregnant woman and protection of the pelvic floor and perineal area [6]. The obstetric gel reduces the resistance between the vagina and the fetus by the lubrication in the birth canal⁷. It has been published that by this way, the delivery duration is reduced by 31% (mean: 25 minutes) in multipara women and protects the pelvic floor, perineum and mother's vagina⁸. It has also been published that the obstetric gels used with perineal massage prevents significantly lacerations of perineum⁹. In our analysis, we evaluate the obstetric gel effects on delivery and perineum.

MATERIALS AND METHODS:

This prospective and randomized controlled study was held in the Obstetrics and Gynecology department of Sulaiman Al Habib Medical Group Hospital, Riyadh for one-year duration from December 2017 to December 2018.

The inclusion is as follows: nulliparous, 18-40 years, singleton, term, without obstetric and systemic pathology, vertex presentation, body mass index (BMI), 20 to 30 kg / m², without ongoing cervical surgery, There is no growth reduction, the birth weight estimated lies between 2000 and 4500 g and

no Fetal anomaly. We divided the subjects into two groups according to these criteria:

- Group I: the control group following the self-study; without obstetric gel.
- Group II: with obstetric gel Study group.

We use the method of random number in MedCalc to randomize patient groups. As a result, we applied the water and oil-based formula NatalisTM once to subjects. NatalisTM is a mixture of gel, hydroxyethyl cellulose, propylene glycol, NACL, xanthan gum and glycerol (which contains mainly glycerol and hydroxyethyl cellulose). Applying the gel to the cervix and neighboring area with the sterile disposable syringe and applicator applied, 15 ml, when labor 1st stage starts, in the active contraction's presence and cervical dilatation of 4 cm and monitoring protocol to examine routine primigravida. On other side, only standardized study protocol was applied for the control group of primigravida for pregnant women. Based on the actual amount of gel, we estimated that 105 patients used in both groups (n = 210); in Group I 3 patients and in Group II 7 patients were included in the operative emergency study due to fetal distress until the end of birth. In conclusion, 102 patients in Group I and 98 patients in Group II, respectively. In this analysis, additional epidural anesthesia was not given or analgesics and any additional procedures was not done that could prolong or affect the delivery stages. We used MedCalc statistical software for statistical analysis (version 13.3, Mariakerke, Belgium). To compare descriptive statistical methods we used Student's t-test (standard deviation, mean, minimum, ratio) and to compare the two groups quantitative data of parameters with Mann-Whitney U test and normal distribution for comparison of two parameter that did not show normal distribution. Chi-square test and Fisher's exact test were used for qualitative data comparison. The threshold for the results was significant and $p < 0.05$.

RESULTS:

In Table 1 the two groups demographic characteristics are summarized which are included in the study. Between the groups; no difference significantly was observed in terms of gestational week, BMI and age. The newborns mean birth weight

in Group I was 3259.56 ± 403.81 g and in Group II it was 3171.40 ± 390.12 g.

Table 1. Demographic data of the pregnant women.

	Min-max values		Mean and standard deviation		p
	Group I (n=102)	Group II (n=98)	Group I (n=102)	Group II (n=98)	
Maternal age (year)	18-38	18-37	23.36±4.33	23.31±4.73	0.663
Week of gestation	37-41	37-41	38.54±1.40	38.65±1.50	0.658
Maternal BMI (kg/m ²)	22.14-29.91	22.14-29.90	26.40±2.07	26.15±2.05	0.390

In Group I, three large neonates (2,94%) and 4 large neonates (4,08%) were observed in Group II with high weight than normal. When analysis of neonatal data was done, no strong variation was noted between the parameters given in (Table 2).

Table 2. Newborn values of the groups.

	Min-max values		Mean and standard deviation		p
	Group I (n=102)	Group II (n=98)	Group I (n=102)	Group II (n=98)	
1-min Apgar	6-9	8-9	8.89±0.46	8.85±0.22	0.581
5-min Apgar	8-10	9-10	9.92±0.33	9.97±0.173	0.327
Birth weight (g)	2480-4600	2480-4170	3259.56±403.81	3171.40±390.12	0.122
Head circumference (cm)	31-38	33-38	35.04±1.14	35.02±0.76	0.496

The data in both groups were statistically similar in terms of hematocrit and hemoglobin values between Group I and 2nd group before and after birth (Table 3).

Table 3. Hematologic results of the groups.

	Min-max values		Mean and standard deviation		p
	Group I (n=102)	Group II (n=98)	Group I (n=102)	Group II (n=98)	
Prenatal Hb (g/dl)	7-15	9-14	11.69±1.47	11.59±1.27	0.47
Prenatal Hct (%)	25-46	30-47	37.69±4.06	38.24±3.58	0.303
Postnatal Hb (g/dl)	6-14	7-13	9.88±1.50	9.73±1.37	0.563
Postnatal Hct (%)	23-44	22-42	32.12±4.08	32.68±4.11	0.331

In this analysis, we noted the first and second stages durations of the study as 233.79 ± 25.98 and 76.79 ± 14.92 minutes, in Group I. The duration of the 1st and 2nd stages of the study in Group II, was 216.01 ± 27.59 and 20.02 ± 16.09 minutes, respectively. When the two values were compared, we noticed significant variations statistically ($p < 0.001$) (Table 4). In this analysis without routine episiotomy, in Group I 24 pregnant women and in Group II 31 pregnant women required episiotomy while delivery.

Table 4. Labor stages of the groups.

	Min-max values		Mean and standard deviation		p
	Group I (n=102)	Group II (n=98)	Group I (n=102)	Group II (n=98)	
First stage of labor (minute)	178-312	158-292	234.83±26.38	215.10±26.61	<0.001
Second stage of labor (minute)	40-120	14-94	75.80±15.21	49.82±15.49	<0.001

In 91 pregnant women Perineal laceration was observed in the group; while, none was the 4th degree, and only 3 were the third grade. Perineal laceration was observed in 73 pregnant women in Group II; while the degree of tear was 4th degree, it was 3rd grade in two pregnant women.

Table 5. Grades of perineal lacerations and their distribution among the groups.

Perineal laceration grade	Group I (n=102)		Group II (n=98)		p
0 (no laceration)	11		25		0.009
Grade 1	71	Total n=88	55	Total n=71	0.015
Grade 2	17		16		
Grade 3	3	Total n=3	2	Total n=2	0.622
Grade 4	0		0		
Episiotomy need	24		31		0.209

Perineal laceration rates were statistically significantly minimum in the group in which the gel was administered ($p = 0.009$ for nonexistence and $p = 0.015$ for lacerations 1 and 2). In terms of advanced perineal lacerations there was no vast difference between the groups (3rd and 4th degree) ($p = 0.622$) (Table 5).

DISCUSSION:

It is supposed that between the baby and vagina friction force has major role in vaginal delivery, affected by the changes and companion with friction reducing agents like lubricants. In ancient Greece, Chiron encouraged the olive oil use during horse's delivery, which in veterinary medicine is a valid practice [10]. In our study; the pregnant women 27.38 ± 0.31 years was the mean age and the maximum number of patients in the 25 to 29-year-old group was highest. The 2014 Turkey Demographic and Health Survey (DHS) corresponded to the results. 64% of the jobs in Turkey was done by pregnant women age 30 and under [11]. Schaub et al and Ashwal et al. Similarly, Eren et al. To show the negative effects of teenage pregnancy is a serious problem in Turkey, 18 years of age due to the high perinatal problems as teenage pregnancy were not included in the six potential population [12]. In this analysis without any further procedure (caesarean, surgical and vaginal methods or Crystalline maneuver), the labor 1st stage was reduced within nineteen minutes ($p < 0.002$) and decreased by 26 minutes ($p < 0.001$) in 2nd stage [13]. This was statistically and clinically important. In our study, no epidural anesthesia was given so we not have done any additional procedures that might affect our cases birth stages. Stamp et al. They do a perineal massage in their work, thus shortening the labor in second stage by 11 minutes. Similarly, Schaub et al. The obstetric gel used Dianatal™ (polyacrylic acid-propylene glycol) in a multicentric randomized controlled trial and reported a significant reduction in perineal lacerations by shortening the second stage of

labor [14]. In a single use, we use a hydroxyethylcellulose and glycerol gel, a new gel format with water and oil-based formula. Neonatal and Maternal parameters and invasive procedure rates were not significant statistically in our results. In our analysis, we noted important results in terms of preservation of perineal integrity especially in rivet group ($p = 0.009$).

Rolinska et al. In order to determine the polyacrylic acid and propylene glycol effects on and pain during childbirth, we conducted studies in 47 pregnant women; However no significant outcome was noted. In our study, we did not investigate any psychological parameters except obstetric data [15]. In our study, we could not find an allergic reaction, infection or aspiration of the newborn due to the use of obstetric gel.

CONCLUSION:

In this analysis, it was noted that hydroxyethylcellulose-glycerol gel use decreased the 1st and 2nd stage of labor and decreased the reason of perineal laceration. We found that the obstetric delivery gel did not make a negative or positive variation for episiotomy, neonatal outcome and maternal blood loss. The power of this analysis was 77.8% in the post-hoc power analysis on type I / II error rate of 0.05 the basis for the use of gel and lacerations of the vagina. We supposed this is due to limited cases in our analysis. In our study, neonatal or maternal side effects were not observed due to the use of gel.

REFERENCES:

1. Le Ray, Camille, Hélène Collinot, Jade Merrer, Aude Girault, and François Goffinet. "676: Glucose supplementation to reduce labor duration among induced women with unfavorable cervix: GLUCOSHORT study results." *American Journal of Obstetrics & Gynecology* 220, no. 1 (2019): S447-S448.
2. Le Ray, Camille, Hélène Collinot, Jade Merrer, Aude Girault, and François Goffinet. "676: Glucose supplementation to reduce labor duration among induced women with unfavorable cervix: GLUCOSHORT study results." *American Journal of Obstetrics & Gynecology* 220, no. 1 (2019): S447-S448.
3. Prichard, Natasha, Anthea Lindquist, Richard Hiscock, Sophie Ruff, Stephen Tong, and Fiona C. Brownfoot. "High-dose compared with low-dose oxytocin for induction of labour of nulliparous women at term." *The Journal of Maternal-Fetal & Neonatal Medicine* 32, no. 3 (2019): 362-368.
4. Chowdhary, A., Bagga, R., Kalra, J., Jain, V., Saha, S.C. and Kumar, P., 2019. Comparison of intracervical Foley catheter used alone or combined with a single dose of dinoprostone gel for cervical ripening: a randomised study. *Journal of Obstetrics and Gynaecology*, pp.1-7.
5. Begley, C., K. Guilliland, L. Dixon, M. Reilly, C. Keegan, C. McCann, and V. Smith. "A qualitative exploration of techniques used by expert midwives to preserve the perineum intact." *Women and Birth* 32, no. 1 (2019): 87-97.
6. Zhao, Lei, Ying Lin, Ting-ting Jiang, Ling Wang, Min Li, Ying Wang, Guo-qiang Sun, and Mei Xiao. "Vaginal delivery among women who underwent labor induction with vaginal dinoprostone (PGE2) insert: a retrospective study of 1656 women in China." *The Journal of Maternal-Fetal & Neonatal Medicine* 32, no. 10 (2019): 1721-1727.
7. Meriwether, Kate V., Mark E. Lockhart, Isuzu Meyer, and Holly E. Richter. "Anal Sphincter Anatomy Prepregnancy to Postdelivery Among the Same Primiparous Women on Dynamic Magnetic Resonance Imaging." *Female pelvic medicine & reconstructive surgery* 25, no. 1 (2019): 8-14.
8. Schmidt, Markus, Maria Neophytou, Olaf Hars, Julia Freudenberg, and Maritta Kühnert. "Clinical experience with misoprostol vaginal insert for induction of labor: a prospective clinical observational study." *Archives of gynecology and obstetrics* 299, no. 1 (2019): 105-112.
9. Bahmani, S., Hesamy, K., Shahgheibi, S., Roshani, D. and Shahoei, R., 2019. Comparison of the Effect of Vaginal Capsule of Evening Primrose Oil and Misoprostol on Cervical Ripening of Nulliparous Women with Post-term Pregnancy. *Journal of Pharmaceutical Research International*, pp.1-9.
10. Subramaniam, Akila, Alan TN Tita, and Dwight J. Rouse. "Obstetric Management of Labor and Vaginal Delivery." *Chestnut's Obstetric Anesthesia E-Book* (2019): 393.
11. Ornat, Lía, Vanesa Alonso-Ventura, Juan Bueno-Notivol, Peter Chedraui, Faustino R. Pérez-López, and Health Outcomes and Systematic Analyses (HOUSSAY) Research Group. "Misoprostol combined with cervical single or double balloon catheters versus misoprostol alone for labor induction of singleton pregnancies: a meta-analysis of randomized trials." *The Journal of Maternal-Fetal & Neonatal Medicine* (2019): 1-16.
12. Envall, Niklas, Helena Graflund Lagercrantz, Jessica Sunesson, and Helena Kopp Kallner. "Intrauterine mepivacaine instillation for pain relief during intrauterine device insertion in nulliparous women: a double-blind randomized controlled trial." *Contraception* (2019).
13. Vora, Niraj, Ram Kalagiri, Lea H. Mallett, Jin Ho Oh, Umaima Wajid, Saef Munir, Natalie Colon, Venkata Nakta Raju, Madhava R. Beeram, and M. Nasir Uddin. "Proteomics and Metabolomics in Pregnancy—An Overview." *Obstetrical & gynecological survey* 74, no. 2 (2019): 111-125.
14. Katsurahgi, Shinji, Chizuko Kamiya, Kaoru Yamanaka, Reiko Neki, Takekazu Miyoshi, Naoko Iwanaga, Chinami Horiuchi et al. "Maternal and fetal outcomes in pregnancy complicated with Eisenmenger

syndrome." *Taiwanese Journal of Obstetrics and Gynecology* 58, no. 2 (2019): 183-187.

15. De Bonrosto Torralba, Carlos, Eva Lucía Tejero Cabrejas, Blanca Mar Envid Lázaro, Maria Jesús Franco Royo, Montserrat Roca Arquillué, and Jose Manuel Campillos Maza. "Low-dose vaginal misoprostol versus vaginal dinoprostone insert for induction of labor beyond 41st week: A randomized trial." *Acta obstetrica et gynecologica Scandinavica* (2019).