Effect of Boron-based Gel on Postpartum Episiotomy Wound Healing in Primiparous Pregnant Women

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Abstract

Objective: The present study aimed to determine the effects of boron-based gel on episiotomy wound healing and episiotomy pain in primiparous women.

Method: This retrospective study included 450 primiparous women who had a normal delivery with episiotomy at Private Nisa Hospital between January 2019 and March 2020. The participants were grouped as 150 women who used the Boron-Based Gel on the postpartum episiotomy site (cases-1), 150 women who used Beta Chlorhexidine Gel (cases-2), and 150 women who refused treatment or did not use any topical gel (controls). Wound healing status was evaluated on days 2, 5-7, and 10-14 after birth along with Redness, Edema, Ecchymosis, Discharge with Approximation (REEDA) Scale and the pain levels felt in the episiotomy area were evaluated using the Visual Analog Scale (VAS).

Results: No statistically significant differences were detected between the three groups in terms of age and other variables ($p>0.05$). The mean scores of VAS and REEDA on days 2, 5-7, and 10-14 after birth were significantly different in the Boron-Based Gel Group compared to Chlorhexidine Gel and control group ($p<0.001$).

Conclusion: It was found that the use of Boron-Based Gel increased episiotomy wound healing and reduced pain at significant levels.

Introduction

An episiotomy is a surgical incision made in the bulbocavernosus muscle in the second stage of the labor to facilitate labor, prevent unwanted tears, and preserve the perineal tonus (1, 2). When the literature was reviewed, the worldwide incidence of episiotomy was reported to be 41.5% in Iran, 50.4% in Israel, 53.8% in nulliparous women, and 46.2% in multiparous women in Poland (3–5). In a study that was conducted in Romania, the frequency of episiotomy was reported to be 71.4% and was found to be 92.7%, 73.2%, and 35% in the first, second, and third deliveries, respectively (6). In a study that was conducted in Turkey, the rate of episiotomy was reported to be 93.3% in primiparous women, and 30.2% in multipara women (2), and it was shown that the frequencies varied between 50.4% and 88.6% in primiparous and/or multiparous women (7–9).

An episiotomy may cause pain on the first day in 97% of primiparous women and the first seven days in 71% (10). Perineal pain developing after an episiotomy can impair the quality of life of the mother and affect mother-infant communication negatively (11). Episiotomy infection is one of the most serious postpartum complications occurring with fever, pain, and purulent discharge (1, 12). In a systematic review, the incidence of perineal trauma wound infection related to birth was found to be between 0.1% and 23.6%, and the incidence of wound dehiscence was found to be between 0.21% and 24.6% (12). It was reported that the healing process of this wound can take three months or more following birth (13). Many pharmacological and non-pharmacological methods (hot and cold showers, using dry heat with rays, lavender, aloe vera, chamomile, green tea, etc.) are used to accelerate the healing of the wound site in the episiotomy area (1, 14–17).

Boron, which is a very stable element, plays regulatory roles in the cell membrane and various enzymatic systems with its anti-inflammatory, antimicrobial, antioxidant, epithelializing, and angiogenesis-enhancing effects (18). Boron was also found to improve the extracellular matrix cycle and accelerate wound healing by facilitating the activity of enzymes such as elastase, trypsin, collagenase, and alkaline phosphatase in fibroblasts (19, 20). Although the wound healing effects of boron compounds were shown previously *in vivo* and *in vitro* (21, 22), no study investigated its effectiveness on episiotomy wound-healing.

The purpose of the present study was to evaluate the effectiveness of boron-based gel or chlorhexidine-based gel application on episiotomy wound healing in primiparous women who had a normal delivery.

Materials And Methods

Study design

The case-time control design, which is one of the hybrid designs, was used in the study (23,24). This study was conducted in Istanbul Private Nisa Hospital between April and October 2020. To conduct the study, the Clinical Research Ethics Committee of Istanbul Medipol University approved the study ((Reference number:10840098-604.01.01-E.14176, Date: 16/04/2020). The administration of Private Nisa Hospital where the study would be conducted gave its written permission to conduct the study before the data collection stage.

Study Population

The records of women who were hospitalized in the Obstetrics and Gynecology Service applying to the postpartum polyclinic between January 01, 2019, and March 31, 2020, were analyzed retrospectively in the study. As a general hospital protocol, some pharmacological drugs (cream, ointment, gels, etc.) that have effects on wound healing after episiotomy are prescribed. Women who used Boron-Based Gel or Beta Chlorhexidine Gel or did not apply any topical gel, had a normal birth, primiparous, and registered in digital media were evaluated in the study. The minimum sampling size of the study was calculated as 400 total sample size for three groups in the GPower 3.1.9.4 program (133) for each group (Effect size $f^2=0.25$, $\alpha=0.05$, 1- β err prob =0.95) (25). Considering possible data losses, it was decided to recruit 450 people for each group. Among the participants who met

the inclusion and exclusion criteria of the study, 150 women who used Boron-Based Gel on the postpartum episiotomy area were named as the cases-1, 150 women who used Beta Chlorhexidine Gel on the episiotomy area as the cases-2, and 150 women who refused the treatment or did not use/apply any topical gel as the control group.

Inclusion criteria

According to the inclusion criteria of the study, primiparous women who had spontaneous labor at 37-42 weeks, normal delivery, single fetus, mediolateral episiotomy, and second-degree perineal laceration were included in the study.

Exclusion Criteria

Those who had cesarean deliveries, manual placenta removal, third and fourth-degree perineal tears, long-term (>18 hours) rupture of membrane, abnormal postpartum hemorrhage or hematoma, irregular use of gels according to instructions, or developing side effects due to gels, those who had a history of disease disabling wound healing or those who used certain drugs (e.g. glucocorticoids, anticoagulants, chemotherapy, immunosuppressant, and radiotherapy), chronic systemic disease (heart, kidney and lung diseases, coagulation disorder, immune deficiency, connective tissue disorders, and diabetes), those with history of genital warts, those with symptomatic vaginitis, those using antibiotics after episiotomy, and those who had a history of perineal reconstructive surgery were not included in the study.

Data Collection Tools

The data were obtained retrospectively from hospital records in the present study. The REEDA and VAS Scale, which can be used and recorded in the hospital upon the request of the physician, were used in the study.

The REEDA Scale

The REEDA Scale, which indicates perineal wound healing, was developed by Davidson in 1974 and was used for the first time in Turkey by Üstünsöz in 1996 (26). Recovery is evaluated according to Redness, Edema, Ecchymosis, Discharge, Approximation in the perineal region with this scale. The sum of the scores obtained from the scale evaluated by giving points between 0 and 3 makes up the REEDA score. The lowest score is 0, and the highest score is 15. The highest score indicates the most serious perineal trauma (26,27).

Visual Analog Scale

The Visual Analog Scale (VAS) was originally developed and used by Bond and Pilowsky. In the VAS, which is evaluated with a 10 cm scale, “no pain” is graded with “0” points, and “the worst pain imaginable” is rated with “10” points. High scores indicate increased pain severity (28).

Procedures

The treatment ordered by the physician is applied during the postpartum hospital stay. Wound healing status is evaluated during the discharge from the hospital on days 2, 5-7, and 10-14 after birth. Mothers are called for the evaluation of weight, bilirubin, and hearing tests, and puerperal women are also invited to the obstetrics clinic for the healing follow-up of the episiotomy wound. For these reasons, the healing of the episiotomy wound of puerperal women who apply to the obstetrics clinic of the hospital is evaluated with the REEDA score, and the episiotomy pain is evaluated with the VAS score.

The creams, ointments, or gels recommended being applied on the episiotomy area after birth are in the form of applying these for 1 cm to the episiotomy (sutures) area after the perineal area is washed and dried under proper conditions as of the first day after birth twice a day for 10 days. This procedure is explained to the puerperal women by physicians or clinical nurses in detail.

Pharmacological drug forms used

Antimicrobial Boron-Based Gel and gel-containing Beta Chlorhexidine are generally used in hospital protocols.

Boron-Based Gel (Dermobor Gel: Istanbul, Turkey): The Boron-Based Gel is in the composition of a carbopol gel containing 2% Chlorhexidine, Sodium pentaborate pentahydrate (NaB), Poloxamer F68, and F127. NaB is an active ingredient involved in wound-healing and inhibits microbial growth in scar tissue along with Chlorhexidine (29).

Beta Chlorhexidine (Best Chlorhexidine Gel): The Chlorhexidine Gel contains 2% Chlorhexidine as the active ingredient, and is an effective antimicrobial (30).

Data Analysis

Descriptive statistics such as numbers (n), percentages (%), mean values, Standard Deviation (SD), median values, and Inter Quartile Range (IQR) were used in the analysis of the data. The conformity of the data to the normal distribution was tested with the Shapiro Wilk Test. The differences between the groups were checked with the Kruskal-Wallis Test, and in case significant differences were detected, the Dunn's Test was used to check

the differences between the two groups. The statistical significance level was taken as $p < 0.05$. The data were analyzed with the SPSS 22.0 Statistical Package Program.

Results

The statistical characteristics of the Boron-Based Gel, Chlorhexidine Gel, and control group are shown in Table 1. No significant differences were detected between the groups in terms of age, gestational age, BMI, the birth weight and head circumference of the infant, the length of the first, second, and third stages of labor, the duration and depth of the episode, and the length of vaginal or perineal episiotomy ($p > 0.05$).

Table 1
Statistical Characteristics of Boron-Based Gel, Beta Chlorhexidine Gel and Control group.

Variables	Case group-1 (Boron-Based Gel)	Case group-2 (Beta Chlorhexidine Gel)	Control group (n=150)	p-value*
	(n=150)	(n=150)		
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	
Age (year)	29.05 $\pm$ 3.64	29.11 $\pm$ 3.38	28.90 $\pm$ 3.46	0.757
Gestational age (week)	38.94 $\pm$ 1.07	38.95 $\pm$ 1.00	38.99 $\pm$ 1.03	0.970
BMI (kg/ m ²)	28.85 $\pm$ 3.28	28.71 $\pm$ 3.06	28.92 $\pm$ 3.32	0.937
Birth weight (gr)	3379.47 $\pm$ 399.87	3338.13 $\pm$ 385.33	3395.67 $\pm$ 399.95	0.617
Birth head circumference (centimeter)	34.32 $\pm$ 0.77	34.27 $\pm$ 0.81	34.31 $\pm$ 0.77	0.856
Labour				
Phase1 (sec)	7.85 $\pm$ 0.79	7.84 $\pm$ 0.81	7.81 $\pm$ 0.80	0.928
Phase 2(minutes)	30.49 $\pm$ 4.47	29.89 $\pm$ 4.17	30.31 $\pm$ 4.49	0.483
Phase 3(minutes)	11.59 $\pm$ 1.92	11.75 $\pm$ 1.90	11.69 $\pm$ 1.97	0.691
Episiotomy				
Times (minutes)	20.00 $\pm$ 4.45	19.91 $\pm$ 4.37	19.77 $\pm$ 4.43	0.885
Depth (millimeter (mm))	180.08 $\pm$ 24.62	182.21 $\pm$ 24.95	179.81 $\pm$ 25.68	0.481
Vaginal (mm)	218.03 $\pm$ 31.65	218.57 $\pm$ 32.35	219.90 $\pm$ 32.54	0.891
Perineal (mm)	239.07 $\pm$ 34.78	240.73 $\pm$ 35.66	238.07 $\pm$ 35.59	0.701
<i>*Kruskal Wallis Test</i>				

The assessment of the Boron-Based Gel Group, Chlorhexidine Gel Group, and control group in terms of variables (pain, redness, ecchymosis, edema, dehiscence, and discharge) is given in Table 2. Statistically significant differences were detected between the groups in terms of pain intensity on days 2, 5-7, and 10-14 after birth ($p < 0.001$). On day 2, the Boron-Based Gel Group was found to be different from the Chlorhexidine Gel and control group at statistically significant levels on day 2, and the Boron-Based Gel Group was found to be different from the Chlorhexidine Gel and control group at statistically significant levels on days 5-7 and 10-14 ($p < 0.05$) (the results are not shown in the tables).

Table 2

Assessment of cases groups and control group in terms of variables scores (pain, redness, ecchymosis, edema, dehiscence, and discharge)

	Case group-1 (Boron-Based Gel) (n=150)				Case group-2 (Beta Chlorhexidine Gel) (n=150)				Control group (n=150)				<i>p-value*</i>
	Min	Max	Median	IQR	Min	Max	Median	IQR	Min	Max	Median	IQR	
Pain level													
2nd day	3	10	5	2.00	3	10	6	2.00	4	10	7	1.00	<0.001
5th -7th days	0	7	3	2.00	0	8	4	3.00	2	8	4	1.00	<0.001
10th -14th days	0	4	1	1.25	0	7	2	2.00	0	7	3	2.00	<0.001
Redness													
2nd day	0	3	1	1.00	0	3	2	1.00	0	3	2	1.00	0.001
5th -7th days	0	3	1	0.00	0	3	2	1.00	0	3	2	0.00	<0.001
10th -14th days	0	2	1	1.00	0	3	2	1.00	0	3	2	0.25	<0.001
Ecchymosis													
2nd day	0	3	2	1.00	0	3	2	1.00	1	3	2	1.00	0.337
5th -7th days	0	3	1	1.00	0	3	2	1.00	0	3	2	1.00	<0.001
10th -14th days	0	3	1	1.00	0	3	2	1.00	0	3	2	1.00	<0.001
Edema													
2nd day	0	3	1	1.00	0	3	2	1.00	1	3	2	1.00	<0.001
5th -7th days	0	2	1	0.00	0	3	2	1.00	0	3	2	1.00	<0.001
10th -14th days	0	1	1	1.00	0	3	2	2.00	0	3	2	1.00	<0.001
Dehiscence													
2nd day	0	2	1	1.00	0	2	1	1.00	0	3	1	1.00	<0.001
5th -7th days	0	2	1	1.00	0	3	1	0.00	0	3	1	1.00	<0.001
10th -14th days	0	1	0	0.00	0	3	0	0.00	0	3	1	2.00	<0.001
Discharge													
2nd day	0	2	1	1.00	0	3	1	1.00	0	3	1	1.00	<0.001
5th -7th days	0	2	1	1.00	0	3	1	1.00	0	3	1	1.00	<0.001
10th -14th days	0	1	0	0.00	0	3	1	2.00	0	3	1	2.00	<0.001
<i>*Kruskal Wallis Test</i>													

Significant differences were determined between the groups on days 2, 5-7, and 10-14 in terms of redness ($p < 0.01$). Statistical differences were detected between the Boron-Based Gel Group and the Chlorhexidine Gel Group on day 2 ($p = 0.003$), and between the Boron-Based Gel Group and the control group ($p = 0.005$); however, no significant differences were detected between the Chlorhexidine Gel Group and the control group ($p = 0.418$). Statistical differences were detected between the Boron-Based Gel Group and Chlorhexidine Gel Group ($p < 0.001$) on days 5-7 and 10-14, and between Boron-Based Gel Group and control group ($p < 0.001$); however, no statistical differences were detected between the Chlorhexidine Gel Group and the control group ($p > 0.05$) (the results are not shown in the tables).

No statistically significant differences were detected between the groups in terms of ecchymosis on the 2nd day after birth ($p = 0.337$); however, significant differences were detected between the groups on days 5-7, and 10-14 ($p < 0.001$). Statistically significant differences were detected between the Boron-Based Gel Group and the Chlorhexidine Gel Group on days 5-7 ($p < 0.001$), and between the Boron-Based Gel Group and the control group ($p = 0.009$); however, there was a borderline significant difference detected between the Chlorhexidine Gel Group and the control group ($p = 0.050$). Statistically significant differences were detected between the Boron-Based Gel Group and Chlorhexidine Gel Group ($p < 0.001$) on days 10-14, and the Boron-Based Gel Group and the control group ($p < 0.001$); however, no significant differences were detected between the Chlorhexidine Gel Group and the control group ($p > 0.05$) (the results are not shown in the tables).

In terms of edema, significant differences were detected between the groups on days 2, 5-7, and 10-14 after birth ($p < 0.001$). Statistically significant differences were detected between the Boron-Based Gel Group and the Chlorhexidine Gel Group on day 2 ($p = 0.004$); between the Boron-Based Gel Group and the control group ($p < 0.001$); between the Boron-Based Gel Group and the Chlorhexidine Gel Group on days 5-7 and 10-14 ($p < 0.001$); and between the Boron-Based Gel Group and the control group ($p < 0.001$). However, no significant differences were detected between the Chlorhexidine Gel Group and the control group on days 2, 5-7, and 10-14 ($p > 0.05$) (the results are not shown in the tables).

In terms of dehiscence, significant differences were detected between the groups on days 2, 5-7, and 10-14 after birth ($p < 0.001$). The Boron-Based Gel Group was different from the control group at statistically significant levels on days 2, 5-7, and 10-14 ($p < 0.001$), and the chlorhexidine Gel Group was different from the control group at statistically significant levels ($p < 0.001$). It was found that the Boron-Based Gel Group was different from the Chlorhexidine Gel Group at statistically significant levels on days 5-7 ($p = 0.038$). However, no statistical differences were detected between the Boron-Based Gel Group and the Chlorhexidine Gel Group on days 2 and 10-14 ($p > 0.05$) (the results are not shown in the tables).

In terms of the discharge status, a significant difference was found between the groups on days 2, 5-7, and 10-14 after birth ($p < 0.001$). Statistically significant differences were detected between the Boron-Based Gel Group and the Chlorhexidine Gel Group ($p < 0.001$), and between the Boron-Based Gel Group and the control group ($p < 0.001$). However, no significant differences were detected between the Chlorhexidine Gel Group and the control group on days 2, 5-7, and 10-14 ($p > 0.05$) (the results are not shown in the tables).

The comparison of the REEDA Scores among the groups on days 2, 5-7, and 10-14 is shown in Table 3 in the Boron-Based Gel Group, Chlorhexidine Gel Group, and control group. Statistically significant differences were detected between the groups in terms of REEDA scores on the 2nd, 7th, and 10th days ($p < 0.001$). Statistically significant differences were detected between the Boron-Based Gel Group and the Chlorhexidine Gel Group on days 2, 5-7, and 10-14 ($p < 0.001$), and between the Boron-Based Gel Group and the control group ($p < 0.001$). However, no significant differences were detected between the chlorhexidine gel group and the control group on days 2, 5-7, and 10-14 ($p > 0.05$) (the results are not shown in the tables).

Table 3
In case groups and control group, 2nd day, 5-7th day, days and 10-14. comparison of REEDA scores on days

Days	Case group-1 (Boron-Based Gel) (n=150)					Case group-2 (Beta Chlorhexidine Gel) (n=150)					Control group (n=150)					p-value*
	Mean ± SD	Min	Max	Median	IQR	Mean ± SD	Min	Max	Median	IQR	Mean ± SD	Min	Max	Median	IQR	
2nd day	5.80 ± 1.69	2	11	6	2.00	7.15 ± 1.40	4	10	7	2.00	7.40 ± 1.83	3	13	7	3.00	<0.001
5th-7th days	4.99 ± 1.57	1	11	5	2.00	7.75 ± 1.68	3	14	8	2.00	7.83 ± 2.19	2	13	8	2.25	<0.001
10th-14th days	2.33 ± 1.33	0	7	2	2.00	6.71 ± 2.10	2	14	7	3.00	7.37 ± 2.54	2	14	7	3.00	<0.001
*Kruskal Wallis Test																

Discussion

The present study is the first in this field to investigate the effectiveness of Boron-Based Gel on episiotomy pain and wound-healing. The NaB in the Boron-Based Gel (Dermobor gel) that was used in the study is the active ingredient involved in wound-healing and has antimicrobial effects together with chlorhexidine (29). According to this study, better episiotomy healing and lower levels of pain were detected in patients who used Boron-Based Gel on the episiotomy area when compared to patients who used only chlorhexidine gel and the control group.

When the participants that were included in the study were examined in terms of socio-demographic and obstetric characteristics (i.e. age, gestational age, BMI, birth weight and head circumference of the infant, the length of the first, second, and third stages of labor, the duration and depth of the episiotomy, the length of the vaginal or perineal episiotomy), no significant differences were detected between the groups. These results, which show that the evaluation was made under similar conditions, were similar to the results of other studies that examined episiotomy pain and healing of the episiotomy site (16, 31).

When the literature was reviewed, a limited number of *in-vivo* and *in-vitro* studies were found on the effects of boron on wound-healing (29, 32, 33). Fibroblasts synthesize the extracellular matrix and collagen in animal connective tissue and play critical roles in wound-healing. In *in-vitro* studies using human fibroblasts, Boron was found to improve the extracellular matrix cycle by facilitating the activity of enzymes such as elastase, trypsin, collagenase, and alkaline phosphatase that are found in fibroblasts (19–21).

In their animal study, Demirci et al. found that the gel form that was obtained by combining Boron with some active biological polymers affected the healing of second-degree burn wounds positively in rats and showed antimicrobial activity against bacteria, yeast, and fungi (29). In another study, the Boron-Based Gel was applied in radiation-induced dermatitis in rats and it was found that it alleviated dermatitis by reducing the mRNA expression levels of Bax (Bcl-2-associated X) proteins (34).

When the studies that were conducted with human subjects were examined, Blech et al. found that the wound-healing was three times faster after applying a 3% Boric Acid solution to the wound site in 31 patients who had deep wound infection in the intensive care unit, and the wound healing was three times faster in those treated with Boric Acid when compared to the patients receiving traditional antiseptic, and that these patients returned to a normal care unit approximately three times faster (mean: 20 and 55 days, respectively) (35). In another study, Dermobor Cream was used in the treatment of diabetic foot ulcers, which is one of the chronic complications of diabetes and is highly resistant to treatment in case of infection, and it was shown to be effective in wound-healing (36). In the study that was conducted by Aysan et al. with 47 women who had breast cancer, they investigated the curative effects of boron in dermatitis developed by radiotherapy and applied Boron-Based Gel and gel-containing Vaseline to the breast skin four times a day after the day the radiotherapy started. They found faster and better healing in the breast skin of women who used Boron-Based Gel when compared to the placebo (Vaseline) group, and emphasized that this was because of the antioxidant and wound-healing effects of boron (33). In the present study, similar to the study of Aysan et al. (33), according to the REEDA score results in which episiotomy wound-healing and pain were evaluated, and according to VAS, it was found that the wound-healing was quite good and the level of pain in the episiotomy area was quite low in participants who used the Boron-Based Gel when compared to the participants in the chlorhexidine gel and control group. detected. It can be considered that this occurred because the Boron-Based Gel has effects accelerating episiotomy healing by increasing anti-inflammatory, antimicrobial, epithelialization, and angiogenesis properties.

Limitations

One of the limitations of the study was that all the factors that affected wound healing, such as nutritional status and physical activity levels of the subjects, could not be controlled because the study had a retrospective design. Since the different pharmacological or non-pharmacological methods used by the individuals and their decisions or recommendations were not known, the effects on wound-healing could not be determined. The application of scales by different people in episiotomy evaluation may have caused information bias. Another limitation of the study was that the results of the study can be generalized to its population.

Study strengths

To the best of our knowledge, this is the first study in this field conducted on the effectiveness of the Boron-Based Gel on episiotomy pain and wound-healing. The episiotomy type, repair method, repair agent, type of thread used, and the amount of anesthesia were the same for all subjects. No side effects were reported by the participants in the three groups. Also, no side effects, infections, or hypersensitivity were detected in the Boron-Based Gel Group.

Conclusion

It was determined in the present study that the use of Boron-Based Gel on the postpartum episiotomy site in primiparous patients accelerated episiotomy wound-healing and reduced pain. For this reason, the use of Boron-Based Gel on the episiotomy area can be an effective treatment. We recommend conducting additional prospective studies by using similar methods and a large cohort to confirm the findings of the present study. More studies are required by checking other confounding factors regarding the safety and efficacy of different doses of treatment, as well as potential side effects.

Declarations

Conflict of interest

All authors on this paper wish to declare that there is no conflict of interest.

Ethical approval

The Clinical Research Ethics Committee of Istanbul Medipol University approved the study ((Reference number:10840098-604.01.01-E.14176, Date: 16/04/2020).

Informed consent

The administration of Private Nisa Hospital where the study would be conducted gave its written permission to conduct the study before the data collection stage.

Disclosure Statement

The authors have no conflicts of interest to declare.

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