

Comparing the Incidence of Episiotomy Site Infection in Two Groups of Primiparas with and without Taking Prophylactic Antibiotics After Normal Vaginal Delivery Referred to Bent Al-Huda Hospital in Bojnourd

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ABSTRACT

Background & Objective: Episiotomy is the most prevalent surgery in midwifery which can lead to infection or delay in wound healing like any other wound. Prophylactic antibiotics are currently prescribed after episiotomies in most Iranian centers. According to global efforts as well as WHO strategies to reduce antibacterial resistance, antibiotics are only prescribed when there is a definite medical indication and the benefit of taking them outweighs the harm. Therefore, this study aimed to compare the incidence of episiotomy site infection in two groups of primiparas with and without taking prophylactic antibiotics after normal vaginal delivery at Bent Al-Huda Hospital in Bojnourd.

Materials & Methods: This double-blind randomized clinical trial was conducted on 140 primiparas (70 women in two groups, i.e., cephalexin and placebo capsules) at Bent Al-Huda Hospital in Bojnourd. After episiotomies, the patients took the prescribed medication every 6 hours for 7 days. The wound healing assessment was done by applying the REEDA scale (redness, edema, ecchymosis, discharge, and approximation of wound edges) seven days after the delivery. SPSS 18 were used to analyze the data. P-values below 0.05 were considered significant.

Results: On the seventh day after the delivery, the two groups were different in terms of healing score based on the REEDA scale, and statistically significant differences were observed. The healing score was lower in the antibiotic group compared to the placebo group, indicating a better wound healing.

Conclusion: The results showed the effectiveness of prophylactic antibiotics in treating episiotomy wounds.

Keywords: Episiotomy, Infection, Prophylactic Antibiotics



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Introduction

The ultimate goal of medical sciences concerning childbirth is terminating all pregnancies ensuring maternal and neonatal health because maintaining the health of these two will guarantee the health of the community. To achieve this ultimate goal, efforts are being made to medically intervene in the process of normal vaginal delivery in favor of the mother and neonate. One of these interventions is episiotomy (1).

Episiotomy is a surgical incision of a mother's perineum that accelerates the second stage of labor by enlarging the pelvic outlet and prevents severe perineal rupture. This incision is made by sterile scissors or a surgical razor blade and is repaired with sutures. Episiotomy is one of the most common surgeries in the

world (2) and the most prevalent midwifery surgery (1) performed in approximately 15% to 95% of deliveries (3). Prevalence of episiotomy was reported 90% and 19.4% in developing countries and the United States, respectively (4).

Accurate information on the prevalence of episiotomy in Iran is not available (3); however, it is a prevalent practice in Iranian hospitals (5). During a study carried out in Tehran in 2000, Nasiri reported a prevalence of 95.8% (6), and Rezazadeh and Ghaffari reported a prevalence of 88% in Tehran in 1996 (7). Even though the routine use of episiotomy has declined in developed countries, studies have demonstrated that women in Asian countries, due to their short perineum

and strong tissue, are prone to large ruptures of the perineum during vaginal delivery so that applying this method is still common (4).

Like any other surgical incision, episiotomy involves risks including pain, hemorrhage, infection, abscesses, hematoma, damages to the sphincter, anal mucosa, fistula between the anus and vagina, and painful intercourses (8). Due to the effective role of the perineal muscles in normal activities, incising this area is associated with great discomfort for the mother and causes fatigue, insomnia, difficulty in sitting and cuddling the neonate, and disturbances in the emotional relationship between the mother and the neonate. Hence, wound healing and faster recovery are of particular importance. These relieve the mother's pain and discomfort and help her to return to her daily activities quickly (4). Episiotomy, like any other wound, can lead to infection and delayed healing. Infection occurrence can be due to the mother's body microbial flora (the vagina, gastrointestinal tract, and skin) or external microorganisms (infected medical staff conducting the delivery, poor surgical techniques, and infected instruments and delivery environment). It clinically manifests with fever, local pain, hyperthermia, redness, ecchymosis, and discharge from the incision site, and is sometimes associated with perineal abscesses, delayed wound healing, or wound opening (9).

There is little information on the prevalence of post-episiotomy infection. However, its prevalence seems to be low and is estimated to be between 0.3% and 5% (9, 10, 11, 12).

Prescribing prophylactic antibiotics may reduce the incidence of postpartum episiotomy site infection, especially when the risk of postpartum infection is high (9). Prescribing prophylactic antibiotics is recommended to prevent the infectious side effects of midwifery procedures, such as cesarean section incision, manual removal of the placenta, and the third- and fourth-degree perineal rupture repair. Since the episiotomy is anatomically similar to a second-degree rupture of the perineum, there may be no justification for the routine use of antibiotics (13). Post-episiotomy infection can be minimized by complying with infection control criteria, such as applying aseptic surgery techniques, having a non-infectious environment, and sterilizing the episiotomy instruments (9).

There is no clear evidence of prophylactic antibiotics playing a role in preventing the episiotomy wound infection. Indeed, most women who undergo an episiotomy do not suffer from its side effects; however, a small number of women may experience pain and delayed recovery associated with the infection while using prophylactic antibiotics for episiotomy seems very diverse. In developed countries, there are no clinical recommendations for taking prophylactic antibiotics after an episiotomy in the absence of infection; in contrast, in developing countries, the majority of women who undergo an episiotomy receive prophylactic antibiotics (9).

This purposeless antibiotic prescription brings about many side effects for both the mother and the neonate such as disrupting the microbial flora, antibiotic resistance, increased risk of drug poisoning, hypersensitivity reactions, and unnecessary expenses (14). This study is significantly important because it stops us from unneeded prescription of antibiotics. Based on global efforts as well as the World Health Organization (WHO) strategies employed to reduce antibacterial resistance, antibiotics are only prescribed when there is a definite medical indication and the benefit of taking them outweighs the harm (9).

Nowadays, in most Iranian medical centers, contrary to WHO recommendations, prophylactic antibiotics are prescribed to prevent the episiotomy site infection in all women after childbirth. Due to the side effects of antibiotics, health centers try to decrease their unnecessary use. Accordingly, the present study aimed to investigate and compare the incidence of episiotomy site infection in primiparas in two groups receiving antibiotics and placebo at Bint Al-Huda Hospital in Bojnourd to reduce excessive antibiotic usage.

Materials and Methods

This double-blind randomized clinical trial was carried out on 140 primiparas in two months at Bint Al-Huda Hospital. The mothers were randomly divided into two groups, i.e., study (70 subjects) and control (70 subjects) groups. Initially, the objectives of conducting this study were explained to the participants and their written consent to participate in the study was obtained. In both groups, after complete cervical dilatation and observing 3-4 cm of the fetal head in diameter, the midline episiotomy was performed with mayo-harrington after performing local anesthesia with 5 ml of 2% lidocaine (pasargad chemi alvand company, Iran) in the perineal area. Immediately after the delivery and before the episiotomy repair, the area was washed by normal saline serum. Then, the repair was done using 0 suture thread (supa chromic 0) for the inner layers and 0-2 thread for the outer layers. Episiotomy repair durations and the incision sizes were recorded. Necessary recommendations for wound care including keeping the perineal area dry and clean (washing the area with a local cleanser daily) as well as medication and placebo, were explained. All of the participants were prohibited from taking topical antibiotics during the follow-up period (3, 4). In the case group, 500 mg cephalexin capsules were prescribed every 6 hours for 7 days. In the control group, the placebo was used in a form similar to cephalexin. On the seventh day after the delivery, all the participants' healing process and episiotomy incision infection (redness, bruising, edema, infectious discharge, and approximation of wound edges) were assessed by a medical specialist using the REEDA scale in the lithotomy status and applying an examination lamp. Subsequently, the total score of wound healing was calculated (3).

Data collection tools included a questionnaire on demographic, pregnancy, and childbirth characteristics as well as the wound healing scale (REEDA). Data collection methods included observation, interview,

examination, and study of the patients' medical records. For carrying out all of which, the researcher was physically present in the hospital. The questionnaire on demographic, pregnancy, and childbirth characteristics included demographic information, maternal age, gestational age, number of pregnancies, and the information on the duration of the labor, episiotomy appearance, and repair time.

The REEDA scale is an international scale for wound healing and has been used in most national and

international research papers. Its validity and reliability have been proven in previous studies. This scale includes 5 variables of redness, edema, ecchymosis, discharge, and approximation of wound edges. In this scale, based on the Likert criterion for each variable, a score from 0 to a maximum of 3 is considered. The scores obtained from each variable are added together. The total score ranging 0-15 indicates the degree of wound healing. The lower the REEDA score, the better the wound healing ([Table 1](#)).

Table 1. Comparing means± standard deviations of age, BMI, and neonatal weight of the study groups

Variable	Group	N	M±SD	P-value
Age	Antibiotic	70	23.97±4.6	0.446
	Placebo	70	23.35±4.8	
BMI	Antibiotic	70	26.81±3.9	0.292
	Placebo	70	26.06±4.3	
Neonatal weight (gr)	Antibiotic	70	3234.28±370.2	0.929
	Placebo	70	3228.42±400.7	

To ensure the reliability of the questionnaire on demographic, pregnancy, and childbirth characteristics, the concurrent evaluation method was applied. Initially, the information form was completed simultaneously by the researcher and an assistant in the research environment for 10 qualified units, and then the correlation coefficients were calculated between the small variables determined by examination.

To describe the descriptive variables of the study, the central indicators and data distribution and frequency were used. Afterwards, to compare the quantitative variables with normal distribution and homogeneity of variances, an independent t-test was applied between the two groups. In cases of abnormal distribution, the Mann-Whitney U test was used. To compare and relate the quantitative and qualitative variables between the groups, the chi-square test and one-way ANOVA (Tukey) were used, respectively. In all calculations, P-value<0.05 was considered as the significance level.

Results

In this study, using a random number table, 140 primiparas were assigned to two groups, each including 70 women receiving antibiotics and placebo after episiotomies. Both groups were compared in terms of age, body mass index (BMI), and neonatal weight, which did not indicate any statistically significant differences ([Table 1](#)).

The mothers were also examined for their place of residence. The number and percentage of subjects who lived in urban and rural areas were also assessed ([Table 2](#)). As can be seen, in the antibiotic-treated group, 44 subjects (62.9%) lived in urban areas and 26 subjects (37.1%) lived in rural areas; however, in the placebo-treated group, 43 subjects (61.4 %) were urban dwellers and 27 subjects (38.6%) were rural dwellers. In terms of living in urban or rural areas, the mothers showed almost the same results in both groups.

Table 2. Comparing the place of residence of the study groups

Group	Place of residence	Urban areas	Rural areas
		Number (Percent)	Number (percent)
Antibiotic		44 (62.9%)	26 (37.1%)
Placebo		43 (61.4%)	27 (38.6%)
Total		70	70

Moreover, the patients were compared in terms of their level of education. The results of which are presented in [Figure 1](#).

The mothers were also compared in terms of the length of the episiotomy incision. The mean incision length in the antibiotic and the placebo groups were

3.38 ± 0.88 and 3.21 ± 0.56 cm, respectively. These showed no statistically significant differences ([Table 3](#) and [Figure 2](#)).

Episiotomy infection was assessed by the REEDA scale ([Table 4](#), [Figure 3](#), and [Figure 4](#)).

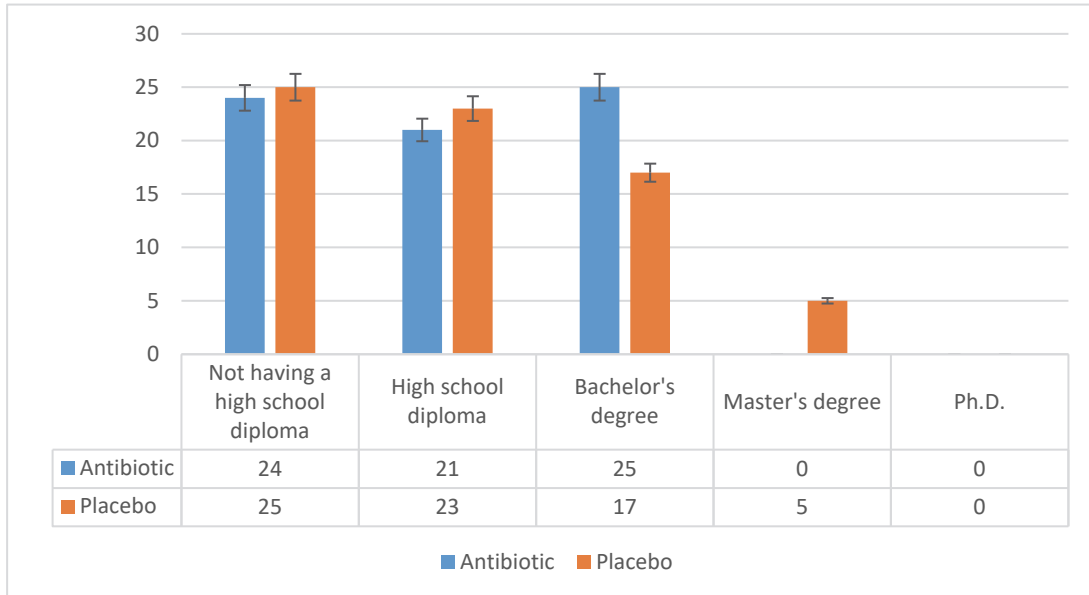


Figure 1. Comparing the frequency of their level of education based on the number of people in the study groups

Table 3. Indicating the frequency distribution of episiotomy incision length based on the number of people in the study groups

Group \ Incision length	≥ 2-3 cm	≥3-4 cm	≥ 4-5 cm	≥ 5-6 cm	≥ 6-7 cm	≥ 7-8 cm
Antibiotic	0	55	7	4	3	1
Placebo	0	60	5	5	0	0

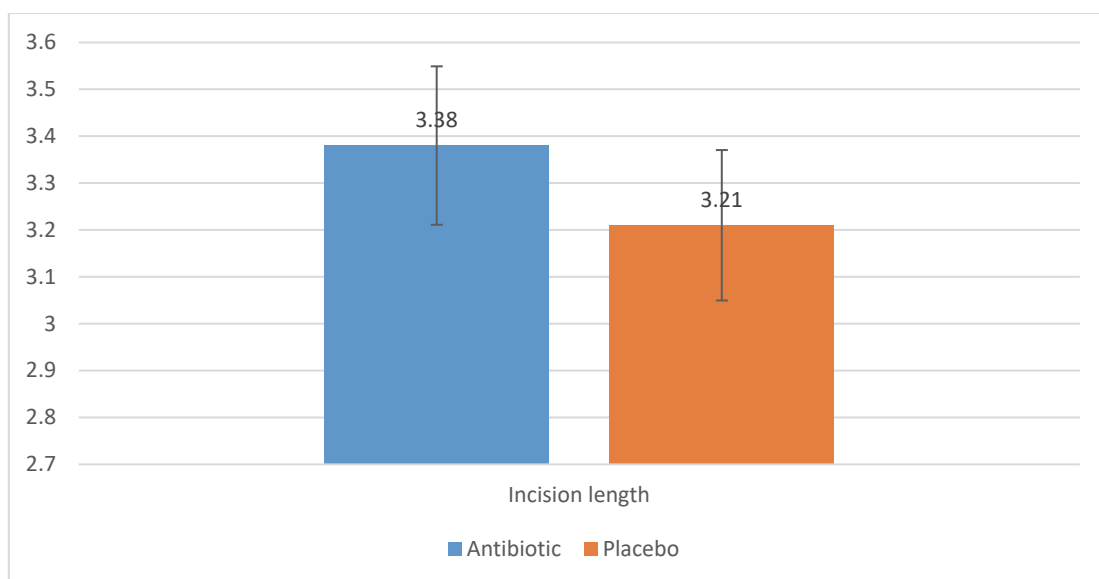
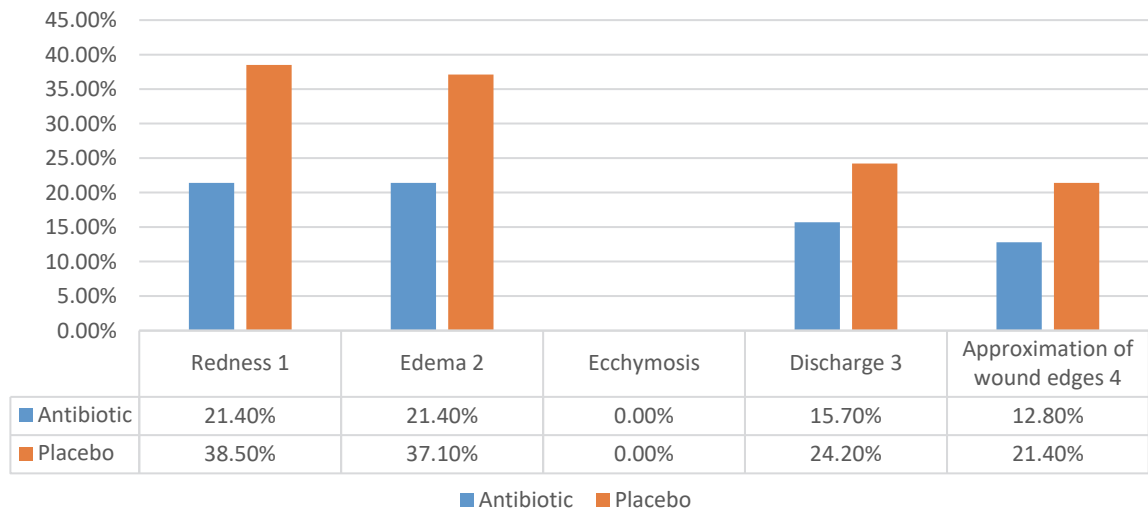


Figure 2. Indicating the frequency distribution of mean incision length \pm standard deviation in cm according to the studied groups

Table 4. Investigating the frequency distribution of the number of people based on the REEDA scoring system for each study group

The REEDA factors	Scoring system	Antibiotic	Placebo
Redness	0-None	55	43
	1-Within 0.25 cm of the incision bilaterally	11	19
	2-Within 0.50 cm of the incision bilaterally	2	8
	3-Beyond 0.50 cm of the incision bilaterally	2	0
Edema	0-None	55	44
	1- Less than 1 cm from the incision	14	19
	2- 1 to 2 cm from the incision	1	7
Discharge	3- Greater than 2 cm from the incision	0	0
	0-None	53	59
	1-Serum	8	8
	2-Serous	3	9
Approximation of wound edges	3-Bloody-purulent	0	0
	0-None	55	61
	1-Less than 3 mm	1	0
	2-Skin and subcutaneous fat separation	14	7
	3-Skin, subcutaneous fat, and fascial layer separation	0	2

**Figure 3.** Comparing the frequency distribution of the REEDA scale criteria obtained by the study groups on the 7th day after the delivery

- 1- If the patients had ≥ 0.25 cm redness on the 7th day after the delivery.
- 2 - If the patients had ≥ 1 cm swelling from the incision on the 7th day after the delivery.
- 3- If the patients had serous, bloody, or purulent discharge on the 7th day after the delivery.
- 4 - If the patients had a ≥ 3 mm opening of the incision on the 7th day after the delivery.

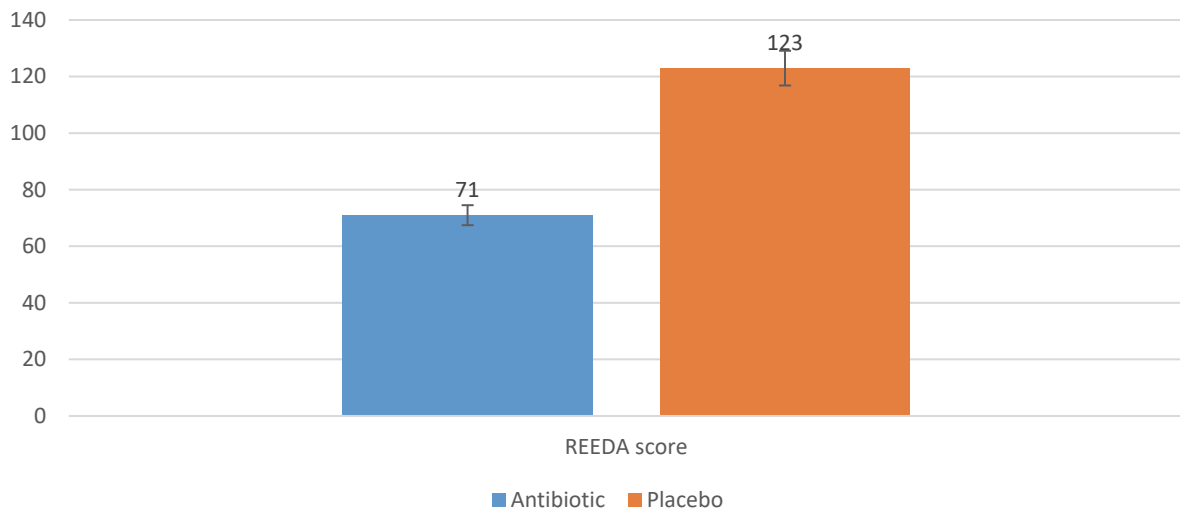


Figure 4. Comparing the frequency distribution of the total REEDA scale scores of the study groups on the 7th day after the delivery

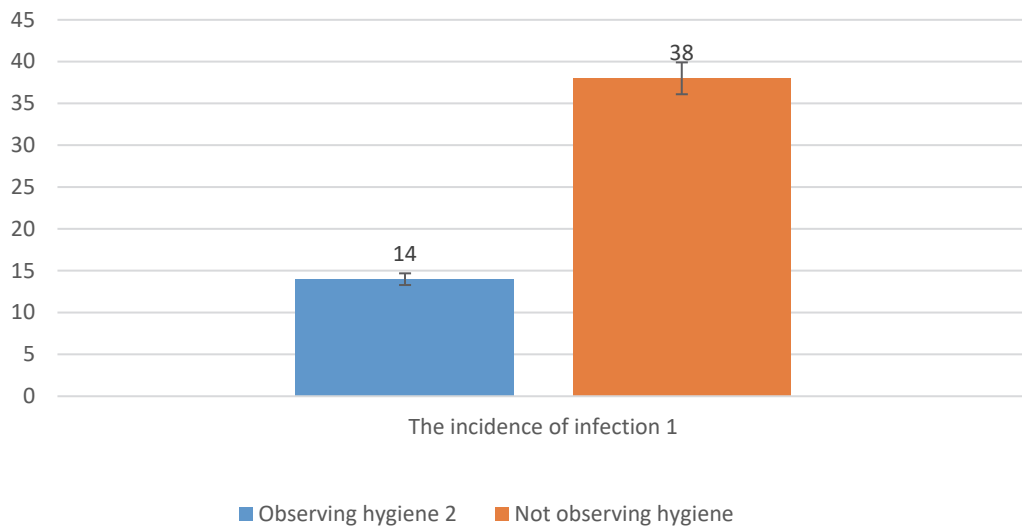


Figure 5. Checking the frequency of episiotomy site infection separately based on observing and not observing the hygiene procedures

- 1- It indicates the presence of cellulite, discharge, or delay in wound healing.
- 2- It indicates keeping the perineum area dry and washing it with shampoo.

Examining the episiotomy infection by the REEDA scale indicated that the two groups had statistically significant differences on the seventh day in terms of redness, edema, discharge, and approximation of wound edges ($P < 0.05$).

The two groups were identical in terms of ecchymosis. No ecchymosis was reported in either group. [Figure 3](#) has compared the frequency distribution of the REEDA scale criteria.

Furthermore, the sum of the REEDA scale scores showed that there was a statistically significant difference between the two groups seven days after the delivery ([Figure 4](#)).

The mothers were also tested for observing hygiene procedures in the perineal area, including keeping it dry and washing it locally with shampoo ([Figure 4](#)).

Among these 140 women, 21 women (15%) did not observe the hygiene procedures, of which 8 women

(38%) were infected. Moreover, 119 women (85%) observed the hygiene procedures, of which 17 women (14%) were infected. The infection rate was significantly higher among the women who did not observe the hygiene procedures.

The mothers were also screened for treatment costs and hospitalization duration. Re-hospitalization was required for two out of 140 patients for 2 days in the gynecology ward and their wounds were again repaired in the operating room, both of whom were antibiotic takers.

No cases of infectious disease (septicemia, infectious shock, laparotomy, or hysterectomy due to infection or hospitalization in the intensive care unit (ICU)) were observed in the two groups.

No side effects of antibiotics including nausea, vomiting, skin rash, and anaphylactic shock were observed in the mothers and the neonates.

Discussion

Nowadays, episiotomy is one of the most widely used surgeries during vaginal deliveries, which facilitates removing the fetus and results in pain in patients, especially primiparas. Its other side effects include fatigue, insomnia, difficulty in sitting and cuddling the neonate, and disturbances in the postpartum emotional relationship between the mother and the neonate (4). In a systematic review study, Shahrahmani *et al.* conducted 36 clinical trials on pain reduction and recovery of episiotomy wounds in Iran in 2015, which were registered at the Clinical Trials Center and received a score of 3 or more on the Jadad scale. Most of these studies focused on the effects of herbal medicines (15), and the role of antibiotics was not investigated. This indicates that few studies have been conducted in this field in Iran.

In the present study, the incidence of episiotomy wound infection in the groups receiving prophylactic antibiotics and placebo was investigated and compared. The results of the current study showed that the incidence of episiotomy infection was significantly higher in the placebo group. Ehdæivand *et al.* demonstrated that prophylactic antibiotic usage significantly reduced the incidence of episiotomy infection (16). Makvandi *et al.* also proved that the topical use of postpartum antibiotics significantly improved wound healing (3). While both studies conducted in Iran confirmed the findings of the present study, Fouelifack *et al.* did not find a significant difference between the antibiotics and placebo groups (17). Tondon *et al.* examined 3000 women who underwent episiotomies and suggested that prophylactic antibiotics did not reduce the prevalence of episiotomy infection (18). Additionally, Ayesha *et al.* showed that post-episiotomy prophylactic antibiotics usage is not necessary (19). However, it should be noted that these studies, which indicated the contradictory results, were

performed with larger sample numbers. In a study examining 73 women who underwent episiotomies, Bonet *et al.* did not demonstrate any clear association between prescribing prophylactic antibiotics and reduced wound opening and infection and mentioned that further studies were required (9).

The patients did not show significant statistical differences in terms of individual characteristics and neonatal weight. Lavaf *et al.* also agreed with this study in terms of demographic and midwifery characteristics (5).

The lengths of incisions in patients were reported to be 3.38 ± 0.88 cm in the antibiotic group and 3.21 ± 0.56 cm in the placebo group. Furthermore, Makvandi *et al.* reported a mean episiotomy incision length of 3.47 ± 0.93 cm (1).

Conclusion

The incidence of infection was significantly lower in the perineal hygiene group. No similar studies were found, with the results of which this finding could be compared.

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Conflict of Interest

Authors declared no conflict of interests.

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