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Could subcutaneous rifampicin administration be an effective approach for reducing episiotomy infections?

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Abstract. – OBJECTIVE: The aim of this prospective cross-sectional study was to investigate whether cleaning the episiotomy line with rifampicin solution before suturing will reduce infection and wound dehiscence in women who had vaginal delivery with episiotomy.

PATIENTS AND METHODS: A prospective cross-sectional study was conducted with a total of 400 primigravida patients. In the study group, irrigation with rifampicin of the subcutaneous tissue of the episiotomy incision was applied, and in the control group, there was no irrigation. Patients were evaluated for infection at the 1st, 3rd week, and 1-month controls. The groups were compared according to episiotomy infection and wound dehiscence rates.

RESULTS: The episiotomy infection rate of the whole group was 8.5%, the wound dehiscence rate was 3.75%, and the average time of occurrence of the infection was 5.35±2.21 days. The most common infection findings were local pain and purulent discharge at 4.75%. In the control group, where the infection occurred earlier, the infection and wound dehiscence rates were significantly higher [11.5% *vs.* 5.5%; 6.0% *vs.* 1.5% ($p<0.05$)]. Purulent discharge was the most common finding in the control group, and local pain in the study group, but no significant difference was found between the two groups in terms of findings ($p<0.05$). When only the patients who developed episiotomy infection were evaluated among themselves, the only significant difference was found in wound dehiscence, which was higher in the control group ($p<0.05$).

CONCLUSIONS: Considering the high rates of episiotomy in our country, subcutaneous irrigation with rifampicin is a good option that can be kept in the foreground due to its low cost and ease of application.

Key Words:
Episiotomy, Rifampicin, Infection, Wound dehiscence, Irrigation.

Introduction

Episiotomy is a planned surgical incision applied to the perineum and posterior vaginal wall in women in the second stage of labor[1]. The first episiotomy was performed by Sir Fielding Ould in 1742 with the logic of widening the birth canal in order to minimize trauma to the mother during birth[2]. Initially, it was used especially in deliveries that needed to be accelerated, but it has become an increasingly preferred method with the increase in hospital deliveries. Reducing the possibility of severe perineal tears and sphincter injury, preserving the functions of pelvic floor muscles and reducing the risk of fecal and urinary incontinence, and especially protecting premature fetuses from head trauma, can be counted as the indications for opening episiotomy. The conditions in which episiotomy is most necessary are shoulder dystocia and operative vaginal deliveries[3]. In recent years, routine episiotomy has gradually begun to be replaced by selective episiotomy due to both a lack of long-term benefits and objective, evidence-based data on when it should be performed. Especially in developed countries, procedures have started to move away from routine episiotomy, due to the fact that most of the lacerations that occur during delivery in the perineum do not lead to negative results and that the selective application of episiotomy, except in cases where operative delivery is required, leads to a decrease in serious perineal/vaginal traumas[4]. Compared to lacerations, undesirable anatomical results (such as asymmetry, fistula and skin tags), greater weakness in the pelvic floor muscles, extension of the incision leading to third- and fourth-degree tears, damage to Bartholin's gland, increase in blood loss, severe perineal laceration from the episiotomy scar in subsequent deliveries, and a high risk of infection

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and wound dehiscence (separation of the episiotomy) can be counted among the disadvantages of episiotomy[5].

In our country, episiotomy is typically conducted in primigravidas, with very few exceptions. This practice is driven by concerns about potential complications arising from a high number of births and the conservative stance adopted by physicians. However, quantifying its percentage is challenging due to the absence of precise statistical data. Although there is no clear data on the frequency of wound infection due to episiotomy in our country, the frequency reported as 0.8%-11% in developed countries in the world is as high as 25% in developing countries[6,7]. A wound infection that develops after episiotomy not only disrupts the comfort of the mother but also reduces the mother's quality of life and brings an extra financial burden due to the need for extra antibiotic treatment, frequent hospital visits, and even hospitalization. Therefore, in places like our country, which has high birth rates and where it is difficult to break the resistance of doctors in routine episiotomy practice, it is especially important to emphasize the development of infection after episiotomy and to reduce the occurrence of this risk.

However, routine antibiotic prophylaxis is not recommended for the prevention of episiotomy infection. Although the effect of topical antibiotic use in gynecological surgeries or cesarean section on reducing wound infection has been investigated in the literature, its effects on episiotomy infection have not been investigated. As a topical antibiotic, rifampicin is one of the most commonly used agents in skin and soft tissue infections in terms of both cost and effectiveness. Rifampicin is an antibiotic from the rifamycin group, which has a strong bactericidal effect on both Gram-negative and Gram-positive bacteria.

The aim of this study was to investigate whether cleaning the episiotomy line with rifampicin solution before suturing would reduce episiotomy infection and wound dehiscence in women who had vaginal delivery with episiotomy.

Patients and Methods

This prospective cross-sectional study was conducted at Dr. Sami Ulus Gynecology and Children's Hospital, a tertiary education and research hospital in Ankara, between May 2022 and December 2022. Ethics committee approval was obtained from the same hospital on 12/17/2020 with No. E-20/12-58. All procedures applied in the study were within the ethical standards of the Helsinki Declaration (1964 and later amendments). All patients were informed in detail regarding the study, and their informed written consent was obtained.

Patient Selection

A total of 400 primigravida patients, 200 in the study group and 200 in the control group, were involved in the study. Patients who had conditions that may adversely affect wound healing, such as chronic diseases, immunologic problems, immuno-suppressive therapy, and active smoking, were not included in the study. Additionally, during the detailed examination of the episiotomy line after delivery and separation of the placenta, patients with 3rd and 4th-degree lacerations were excluded from the study.

Applied Episiotomy Protocol

All the patients included in the study were taken to the delivery table during the crowning; they were covered with a sterile drape, and the perineum was washed with a 10.0% povidone-iodine solution. After the area was anesthetized with local anesthetic (1% lidocaine) before the episiotomy, the mediolateral episiotomy (the incision is made at the vaginal introitus in a lateral direction) was opened using sterile scissors during crowning. The episiotomy incision was started from the hymenal ring in the midline and continued in the lateral direction at an angle of 45 degrees with a length of 3-5 cm. Following the delivery of the infant and the separation of the placenta, the incision line was cleaned again with 1% povidone-iodine solution in all patients, contaminated sterile drapes were replaced with new ones, and the episiotomy line was evaluated in detail according to the laceration degree of the perineum. In the study group, irrigation with 1 ampoule of rifampicin (Rif/250 mg, 3 ml) of the subcutaneous tissue of the episiotomy incision was applied. A continuous non-locking suturing technique was used to appose the vaginal wall and muscle layers (Vicryl Rapide No.: 1), and a continuous subcuticular technique (Vicryl Rapide No.: 2/0) was used for the skin layer.

All patients were kept in the hospital for 24 hours after delivery, the episiotomy line was checked before discharge, and they were informed in detail about perineal care. All patients were warned to come to the hospital immediately in case of purulent discharge, elevated temperature,

color change, severe pain in the episiotomy line, or in the case of wound dehiscence and were called for control at the end of the 1st week, 3rd week, and 1st month. When the patients came for control, the episiotomy line was examined, and it was noted whether there were signs of infection or dehiscence. CDC criteria were used for the diagnosis of episiotomy infection. Surgical site infection (SSI) is defined by the Centers for Disease Control and Prevention as a wound infection that occurs within 30 days of an operative procedure[8]. When any of the following conditions were observed on the episiotomy line, it was considered an episiotomy infection: the presence of elevated temperature, severe local pain, purulent discharge, color change from the site of incision, or wound dehiscence. Patients with severe infection or wound dehiscence were hospitalized and treated.

Although all patients came to the 1st and 3rd week controls, 8 patients from the control group and 5 patients from the study group did not attend the 1st month control. Patients were contacted by phone and asked if they had any infections-like symptoms. The examination findings of both groups when they came to the 1st week, 3rd week, and 1st month follow-up control were noted by the researcher. Apart from this, verbal information was obtained from the patients at each visit, and their files were examined in detail. The examination findings, if any, were noted. After all data were obtained, the groups were compared according to episiotomy infection and wound dehiscence rates.

Statistical Analysis

SPSS 26 package (IBM Corp., Armonk, NY, USA) program was used in the evaluation of statistical analysis. Kolmogorov test was used to determine the suitability of the data for normal distribution. Parametric tests were used for normally distributed data; otherwise, analyses were done with non-parametric tests. Pearson- χ^2 cross tables were used to analyze the relationships between two qualitative variables. The Mann-Whitney U test was used to compare two independent groups as a nonparametric test. $p<0.05$ were considered to be statistically significant.

Results

The socio-demographic characteristics and the birth statistics of the groups are shown in Table I. The groups were similar in terms of age, employment, educational and co-educational status, and average monthly income ($p>0.05$). No statistically important differences were found between the study groups according to birth weeks, fetal weight, and fetus gender ($p>0.05$).

When the whole study group was examined in terms of episiotomy infection, the infection rate was determined as 8.5% (34 out of 400), wound dehiscence as 3.75% (15 out of 400), and the average time of occurrence of the infection was found to be 5.35±2.21 days. The most common infection findings were local pain and purulent discharge at 4.75% (Table II).

When the study groups were compared according to episiotomy infection, wound dehiscence rates, and mean time of onset of infection, a statistically significant difference was found between the groups. The infection (11.5% *vs.* 5.5%) ($p=0.049$) and wound dehiscence (1.5% *vs.* 6.0%) ($p=0.035$) rates were higher in the control group and occurred earlier when compared with the study group (4 days *vs.* 7 days) ($p=0.006$). In addition to the high infection rate, wound dehiscence was found to be statistically significantly higher in the control group (1.5% *vs.* 6.0%) ($\chi^2=4.433$, $p=0.035$) (Table III).

When only the patients who developed wound infection were evaluated in terms of wound infection findings, the only statistically significant difference between the groups was found in wound dehiscence. Wound dehiscence was significantly higher in the control group (27.3% *vs.* 52.2%) ($\chi^2=4.433$, $p=0.035$). When other wound infection findings were examined, purulent discharge was the most common finding in the control group and local pain in the study group, but no significant difference was found between the two groups in terms of findings ($p<0.05$) (Table IV).

Discussion

In this study, which we conducted to examine whether cleaning the episiotomy line with rifampicin has a reducing effect on episiotomy infection and wound dehiscence, we found that rifampicin had a positive effect on both reducing the development of episiotomy infection, wound dehiscence and delaying the onset of infection.

The World Health Organization (WHO) does not recommend routine or liberal use of episiotomy in spontaneous vaginal deliveries and states that keeping the episiotomy rate around 10% is a good target to be followed[9]. In this direction, with

Table I. The socio-demographic characteristics and birth statistics of the groups.

Variable	Study group (n = 200)	Control group (n = 200)	Statistical analysis probability*
Age (median, min-max)	25.0 [20.0-35.0]	25.0 [20.0-35.0]	Z = -0.295 *p* = 0.768
Employment			
• Employed	154 (77.0%)	155 (77.5%)	χ^2 = 0.014
• Unemployed	46 (23.0%)	45 (22.5%)	*p* = 0.905
Education			
• Primary	32 (16.0%)	31 (15.5%)	χ^2 =0.065
• High	125 (6.5%)	124 (62.0%)	*p* = 0.968
• University	43 (21.5%)	45 (22.5%)	
Co-Education			
• Primary	18 (9.0%)	19 (9.0%)	χ^2 = 0.067
• High	126 (63.0%)	127 (63.5%)	*p* = 0.967
• University	56 (28.0%)	54 (27.0%)	
Average monthly income			
• < Minimum wage	12 (6.0%)	13 (6.5%)	χ^2 = 0.119
• Minimum wage	74 (37.0%)	71 (35.5%)	*p* = 0.942
• > Minimum wage	114 (57.0)	116 (58.0%)	
Birth Week (median, min-max)	39.0 [37.0-41.0]	39.0 [37.0-41.0]	Z = -0.728 *p* = 0.467
Birth Week (%)			
• 37	37 (18.5%)	25 (12.5%)	χ^2 = 9.209
• 38	55 (27.5%)	51 (25.5%)	*p* = 0.056
• 39	44 (22.0%)	65 (32.5%)	
• 40	38 (19.0%)	43 (21.5%)	
• 41	26 (13.0%)	16 (8.0%)	
Fetal Weight (median, min-max)	3,376.55 [2,680.0-41.00]	3,280.0 [2,670.0-4,100.0]	Z = - 1.250 *p* = 0.211
Fetus gender			
• Girl	98 (49.0%)	97 (48.5%)	χ^2 = 0.010
• Boy	102 (51.0%)	103 (51.5%)	*p* = 0.920

*: Pearson-χ^2, Mann-Whitney U.

Table II. Episiotomy infection frequency and findings of the entire study group.

Variable	Whole group
Episiotomy infection	
• Yes	34 (8.5%)
• No	366 (91.5%)
Average time of infection (median)	5.35 ± 2.21 (days)
Wound dehiscence	
• Yes	15 (3.75%)
• No	385 (96.2%5)
Purulent discharge	
• Yes	19 (4.75%)
• No	381 (95.25%)
Local Pain	
• Yes	19 (4.75%)
• No	381 (95.25%)
Color Change	
• Yes	12 (3.0%)
• No	388 (97.0%)
Elevated temperature	
• Yes	10 (2.5%)
• No	390 (97.5%)

the application of selective episiotomy policies, especially in developed countries, episiotomy rates have decreased worldwide in recent years. However, episiotomy rates vary considerably not only between countries but also within countries from region to region. Graham et al[10], in their study published in 2005, examined episiotomy rates that included both primiparous and multiparous worldwide between 1995-2003. They stated that the lowest rate was 9.7% in Sweden and the highest rate was 100% in Taiwan. Although the rate was given as 64% for Turkey in the same study, 9 of every 10 primiparas can still expect to receive an episiotomy as a result of the routine application of episiotomy in many centers in our country, especially in primigravida deliveries.

Complications such as pain, progression of perineal lacerations, and dyspareunia are undoubtedly the main reasons for moving away from episiotomy in recent years[11]. Episiotomy infections are also among the leading problems, as this delays

Table III. The socio-demographic characteristics and birth statistics of the groups.

Variable	Study group (n = 200)	Control group (n = 200)	Statistical analysis probability*
Episiotomy infection			
• Yes	11 (5.5%)	23 (11.5%)	$\chi^2 = 3.889$
• No	189 (94.5%)	177 (88.5%)	$p = 0.049$
Average time of infection (median, min-max)	7.0 [4.0-11.0]	4.0 [2.0-8.0]	Z = -2.774
			$p = 0.006$
Wound dehiscence			
• Yes	3 (1.5%)	12 (6.0%)	$\chi^2 = 4.433$
• No	197 (98.5%)	188 (94.0%)	$p = 0.035$

*: Pearson-χ^2, Mann-Whitney U.

the postpartum recovery of the patient, requires long-term hospitalization, reduces mobility, and can cause more advanced and serious infections when not properly treated[12]. Episiotomy infection rates given worldwide in the literature show a wide variation. In studies that investigated episiotomy infection rates, Khan et al[5] stated the rate as 8.9% in Pakistan, Salmanov et al[12] as 17.7% in Ukraine, and Ononuju et al[13] as 1.9% in Nigeria. In their study, Humphreys et al[14], in which they investigated the factors that increase the risk of infection after operative vaginal delivery, stated that episiotomy is one of the most important risk factors that increase infection and reported the episiotomy infection rate as 16.4%. Larsson et al[15] examined 2,144 births in Sweden and reported that both the infection rates were higher and the healing period was delayed in the episiotomy group compared to the patients with spontaneous perineal laceration, and gave the episiotomy infection rate as 10%. Compared to the literature, our study group's 8.5% episiotomy infection rate is not very high, considering that 9 out of 10 pregnant women undergo this procedure in our country.

Regardless of the rates of episiotomy infection, considering both the quality of life of the mother and the morbidity it may cause, it is clear that infection should be prevented, and the rates should be reduced. Although an episiotomy can be considered a clean-contaminated wound, the normal vaginal, intestinal, and skin flora can contaminate the wound. However, the practitioner, a poor surgical technique, contaminated surgical equipment, and poor wound care of the patient can also cause infection[16]. Despite all standard aseptic techniques applied at birth, postpartum infections still continue to be an important cause of maternal morbidity.

Table IV. Comparison of wound characteristics of the study and control groups.

Variable	Study group (n = 200)	Study group (n = 200)	Statistical analysis probability*
Wound dehiscence			
• Yes	3 (27.3%)	12 (52.2%)	$\chi^2 = 5.993$
• No	8 (72.7%)	11 (47.8%)	$p = 0.014$
Color Change			
• Yes	4 (36.4%)	8 (34.8%)	$\chi^2 = 0.008$
• No	7 (63.6%)	15 (65.2%)	$p = 0.928$
Elevated temperature			
• Yes	3 (27.3%)	7 (30.4%)	$\chi^2 = 0.036$
• No	8 (72.7%)	16 (69.6%)	$p = 0.850$
Purulent discharge			
• Yes	4 (36.4%)	15 (65.2%)	$\chi^2 = 2.513$
• No	7 (63.6%)	8 (34.8%)	$p = 0.113$
Local pain			
• Yes	5 (45.5%)	14 (60.9%)	$\chi^2 = 0.717$
• No	6 (54.5%)	9 (39.1%)	$p = 0.397$

*: Pearson-χ^2, Mann-Whitney U.

The common view in the literature is that accurate episiotomy care is important in terms of easier and shorter healing of the episiotomy incision and prevention of progressive complications[17]. In the literature, many methods have been tried in the care of episiotomy, including prophylactic antibiotics, antiseptic solutions, dry/wet hot-cold applications, laser and light therapy, aromatic oil, and phytotherapy. However, due to the use of many different care products and differences in the methodologies of the studies, there is not a clear consensus on episiotomy care today. The results of prophylactic oral antibiotic use and antiseptic solutions, which are the most researched applications in the literature to reduce the risk of episiotomy infection, are also contradictory. Tandon and Dalal[18] conducted a study with 300 patients to examine the effect of prophylactic antibiotic use in episiotomies and stated that the use of prophylactic antibiotics did not reduce the rate of episiotomy infection. Similarly, Bonet et al[19], in their systematic review in which they examined the effects of antibiotic prophylaxis after episiotomy repair with normal vaginal delivery on endometritis, urinary tract, and episiotomy infections, concluded that the data was insufficient to determine the clinical benefit of routine administration of antibiotic prophylaxis for episiotomy. Considering the relatively low frequency of episiotomy infections, the negative effects of antibiotic use on the mother and the baby, and the antibiotic resistance that may be caused by the widespread use of antibiotics, it can be said that the routine use of oral antibiotics after delivery with episiotomy is not a very appropriate approach. Due to these concerns about the use of oral antibiotics, antiseptic solutions that can be applied to the wound area have come to the fore, but studies[20,21] show that these solutions are not as effective as expected in preventing episiotomy infection. Yılmaz et al[20], in their study where they compared the effect of saline and rivanol on recovery during episiotomy care, stated that saline was much more effective. Eko et al[21] investigated the effects of sitz-bath and iodine antiseptic (betadine) solution on wound healing, infection, and pain in perineal and vaginal tears that occur after normal vaginal delivery and stated that patient compliance was higher in the betadine group, but it did not have an extra advantage in wound healing.

Based on all these findings, in our study, we found a significant decrease in episiotomy infection (11.5% *vs.* 5.5%) and wound dehiscence (1.5% *vs.* 6.0%) in the group whose subcutaneous tissue was irrigated with rifampicin. The infection rate was higher in the study group and occurred earlier when compared to the control group. To the best of our knowledge, we could not find a similar example for episiotomy infection in the literature, but there are examples where the effects of rifampicin were examined, especially in other surgical incisions of obstetrics and gynecology. In their prospective, randomized controlled study, Karuserci et al[22], compared the effect of saline, saline-rifampicin and saline-10% povidone-iodine on superficial surgical site infection rates in benign gynecological surgeries and determined that superficial tissue infections were significantly higher in the saline group. In the same study, the infection rate in the rifampicin group was found to be lower than in the povidone-iodine group but this was not statistically significant. They concluded that rifampicin is a good alternative, especially due to the low risk of allergic reactions and sterilization problems compared with povidone-iodine. Ata et al[23] compared the effect of systemic antibiotic prophylaxis and topical rifampicin on surgical site infection in 100 patients who underwent abdominal/laparoscopic hysterectomy and cesarean section. As a result of the study, they determined that the effect of rifampicin on wound infection was as effective as systemic antibiotic treatment, but they stated that larger prospective studies are needed in order for topical rifampicin application to replace systemic prophylactic antibiotic treatment.

Another remarkable finding from our study was that wound dehiscence was significantly lower in the rifampicin-irrigated group compared to the control group (1.5% *vs.* 6.0%). In the literature, wound dehiscence after episiotomy varies considerably in prevalence, ranging from 0.3% to 11.0%[10,24]. Our rate of 3.75% in the entire study group is also compatible with the general literature, and this wide variation can be explained by the differences in the rates of patient follow-up after episiotomy and episiotomy rates around the world. Wound dehiscence can affect the patient's life both psychologically and socially, leading to a serious deterioration in the quality of life. The limitation of movement in the patient can cause problems in breastfeeding and baby care, and situations such as long hospitalization and surgical intervention cause many financial and moral burdens. Considering both the low infection rate in the rifampicin group and the decrease in wound dehiscence, we believe our findings are significant.

The fact that our study group was a homogeneous group with similar sociodemographic characteristics, and that all the deliveries were not performed by the same team can be shown as the limitations of our study. However, our study has several strengths that need to be highlighted. Firstly, the prospective design of the study ensured that there was no patient loss. Secondly, the majority of the study group showed up for the controls, making our results more reliable. Thirdly, we used CDC criteria in the diagnosis of wound infection, which is a recognized standard. Finally, the high number of patients included in the study is a reflection of the high rate of episiotomy in our country, which is actually undesirable.

Conclusions

In conclusion, episiotomy infection rate and wound dehiscence were significantly reduced when irrigation with rifampicin was performed during episiotomy. Undoubtedly, the most important thing in reducing episiotomy infections is the application of selective episiotomy. However, in countries such as our country, where birth rates are high and doctors cannot easily give up their habits, it is important to prevent episiotomy infection, which reduces the patient's quality of life as much as possible. Considering the maternal side effects, cost, and antibiotic resistance that may arise due to widespread oral antibiotic use, the inadequacy of topical antiseptic agents, the relative inadequacy of the effects of topical antiseptic solutions on the infection, due to its low potential side effects, low cost and ease of application with episiotomy, use of rifampicin is a good alternative to reduce infection rates.

Conflict of Interest
The authors declare that they have no conflict of interests.

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Authors' Contribution
E.Y., Ç.S., and Z. VY designed, analyzed, and wrote the article. O.Ö, M.F.D., and T.Ç. collected and performed studies.

Informed Consent
Informed consent was obtained from all subjects involved in the study.

Ethics Approval
Ethics committee approval was obtained from Dr. Sami Ulus Education and Research Hospital Ethics Committee on 12/17/2020 with No. E-20/12-58.

Data Availability
The data presented in this study are available upon request from the corresponding author.

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