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ARAŞTIRMA / RESEARCH

A model to predict the risk of infected episiotomy in low-risk women

Düşük riskli kadınlarda enfekte epizyotomi riskini öngören bir model

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Abstract

Purpose: Infected episiotomy (IE) is a rare complication of vaginal delivery. However, the practical use of the risk factors involved in the development of IE is unclear. The aim of this study is to create a risk scoring model to be applied in clinical practice with the risk factors we will determine so as to predict the development of IE.

Materials and Methods: All women who were delivered vaginally with mediolateral episiotomy within a 1-year period were included in this retrospective study. While 42 women (cases) with the diagnosis of IE were eligible for inclusion in the study and formed the case group, randomly selected 168 women in whom IE was not detected formed the control group. Possible risk factors for the development of IE were evaluated by multivariate regression analysis.

Results: The analysis revealed 5 significant independent factors related to IE. Among these factors, 5 points were given to current smoking presence, 4 points to weight gain during pregnancy ≥11.5 kg, 3 points to postpartum neutrophil to lymphocyte ratio ≥10.4, 2 points to presence of diabetes mellitus, and 1 point to presence of hospitalization before active phase of labor. And a cut-off value of 5.5 was found to be moderately effective in predicting IE.

Conclusion: Consequently, this five-variable model can predict the presence of IE with significant efficiency. In the presence of these variables, the clinician can identificate the patients at risk of IE. In this way, individualized patient risk assessment and situation-specific counseling can be made.

Keywords:. Episiotomy, infection, risk score, postpartum complications

Öz

Amaç: Enfekte epizyotomi (EE) vajinal doğumun nadir bir komplikasyonudur. Ancak, EE'nin ortaya çıkmasında rol oynayan risk faktörlerinin pratikte kullanımı belirsizdir. Bu çalışmanın amacı, EE gelişimini tahmin etmek için belirleyeceğimiz risk faktörleri ile klinikte uygulanabilecek bir risk skorlama modeli oluşturmaktır.

Gereç ve Yöntem: Bu retrospektif çalışmaya 1 yıllık süreç içerisinde mediolateral epizyotomi ile vajinal yolla doğum yapan kadınlar dahil edildi. EE tanılı çalışmaya alınmaya uygun olan 42 kadın vaka grubunu oluştururken, rastgele seçilen ve EE saptanmayan 168 sağlıklı kadın kontrol grubunu oluşturdu. EE gelişimi için olası risk faktörleri çok değişkenli regresyon analizi ile değerlendirildi.

Bulgular: Yapılan analizde EE ile ilişkili 5 önemli bağımsız faktör bulundu. Bu faktörlerden 5 puan mevcut sigara içme durumuna, 4 puan gebelikte ≥11.5 kg kilo alımına, 3 puan postpartum nötrofil-lenfosit oranı ≥10.4'a verildi. Diyabetes mellitus varlığına 2 puan ve doğumun aktif evresinden önce hastaneye yatış varlığına 1 puan verildi. 5.5 cut-off değeri EE'yi tahmin etmede orta derecede etkili bulunmuştur.

Sonuç: Bu beş değişkenli model, yüksek bir etkinlikle EE varlığını predikte edebilir. Bu değişkenlerin varlığında, klinisyenler EE riski taşıyan hastaları belirleyebilir. Bu sayede bireyselleştirilmiş hasta risk değerlendirilmesi ve danışmanlık yapılabilir.

Anahtar kelimeler: Epizyotomi, enfeksiyon, risk skoru, postpartum komplikasyonlar

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INTRODUCTION

Episiotomy is the surgical expansion of the vaginal orifice by an incision during the last part of the second stage of labor and is commonly performed in obstetric practice to avoid anal sphincter and perineal lacerations as well as fetal complications[1]. Although routine episiotomy is no longer recommended[2], the overall prevalence of episiotomy varies between countries[3]. While it is often below 30% in westernized countries, it is over 70% in East Asia countries[4]. Whereas episiotomy seems like an innocent procedure, women who experience episiotomy may have problems with infection and wound dehiscence[5].

Infected episiotomy (IE) is rare among the complications of vaginal delivery. In many cases, it is treated with antibiotic therapy, effective analgesia, or hospitalization. However, in severe cases, surgical procedures such as debridement and re-suturation are performed[6]. IE can be a source of physical, psychological, and social problems for women. In the short term, it may cause pain and discomfort at the wound site, urinary retention, defecation problems, and limitation of physical activity. In the long term, it may impair the quality of life of women by causing psychological problems such as postpartum depression and sexual problems such as dyspareunia[7,8].

It is an extremely rare cause of mortality, but an infected perineal wound is a potential route for systemic infection where sepsis and septic shock can develop[9,10]. In addition, it increases the admissions to health centers and the duration of hospitalization, and it can cause an additional burden on health services and economic loss. Therefore, it is important to prevent and appropriately treat IE. There are studies reporting that these infections will be reduced by taking certain precautions[11-14]. The basic precautions are to comply with aseptic rules during performing and suturing the episiotomy and to administer prophylactic antibiotics to high-risk women, especially women with 4th-degree perineal tears. However, antibiotics are often used as a routine approach. Asepsis is indispensable, but unnecessary antibiotic use in low-risk women will lead to medical problems such as side effects and resistance development, and an increased cost. Thus, it is important to know who might have an IE. This can be predicted by identifying possible risk factors and utilizing risk scoring systems developed with those factors.

A number of risk factors have been identified for the development of IE, but to the best of our knowledge, no risk scoring system has been previously developed that can be used to predict. We hypothesized that a risk scoring model may predict the presence of IE with considerable efficiency. So individualized patient risk assessment and implementation of appropriate strategies to reduce infection may be ensured. On that account, the aim of this study was to determine a risk score model to predict the development of IE in the low-risk population.

MATERIALS AND METHODS

This retrospective study was approved by the ethics committee of Ankara City Hospital (08.06.22/16). Ankara City Hospital is located in the capital of our country and is one of the centers where 20-30 vaginal deliveries are performed daily, referring to the obstetric field and providing specialist training in this field.

Study population

Women with singleton pregnancy at term (> 37 weeks of gestation) who were delivered vaginally with the help of right mediolateral episiotomy in our hospital during a 1-year period were included in this study.

The data of all pregnant women was obtained from the hospital records. In our hospital, the data of inpatients and patients who apply to outpatient clinics are filled into files by residents and recorded in the system at the same time. It is also controlled by the responsible specialist of the clinic. The pregnant women with insufficient data, additional perineal lacerations other than an episiotomy, 3rd and/or 4th-degree perineal injury, and instrumental delivery were excluded from the study.

All episiotomies except 3rd or 4th-degree perineal tears were performed and repaired by residents who have completed at least 1 year of similar training program. Only women with 3rd and 4th-degree perineal lacerations were given antibiotics and were repaired by specialist obstetricians. The hospital records of all women for the postpartum 6-week period were re-evaluated and women hospitalized with a pre-diagnosis of IE were grouped for case group selection. The diagnosis of all IE was

confirmed by the presence of a detected pathogen that could be associated with the infection in the swab culture sample taken from purulent discharge at the wound site. Other women without IE or any infective complications were reserved for control group selection. A total of 49 IE records were reached. 42 of them were selected as eligible for inclusion in the study and formed the case group.

Demographic data form

Prenatal demographic characteristics, obstetric histories, body weight, and height at the beginning of pregnancy (body mass index (BMI) was calculated using the weight (kg) / height^2 (m^2) formula), active smoking during pregnancy, systemic diseases developed during pregnancy follow-up and weight they gained during pregnancy were recorded. The examination findings and laboratory measurements were recorded when they were hospitalized for delivery. Information about labor follow-up was investigated. Cervical dilatation of 6 cm with adequate uterine contractions was considered the onset of active labor, and the time from this moment to the moment of delivery was calculated as the duration of active labor. Birth weights and head circumferences of each newborn were recorded. Birth weight > 4000 g was classified as macrosomia. Laboratory measurements of all women in the early postpartum period before discharge were also evaluated. In the laboratory measurements, the presence of Hemoglobin< 10 g / dl was noted as anemia.

Statistical analysis

The sample size of the study was determined according to the results of the central limit theorem [15]. This sample size estimation was performed by using G*Power version 3.0.10 (Franz Faul, Universitat Kiel, Kiel, Germany). Since we identified 42 cases, we aimed to have 168 women in the control group. We randomly selected these 168 women using a computer program from the records (in whom IE was not detected) reserved for selection of the control group. As a result, our study population consisted of 210 women.

SPSS 20.0 statistical software (SPSS, Inc., Chicago, IL, USA) program was used to analyze the collected data. Continuous data and categorical data were presented as mean ± standard deviation (SD) and number (%), respectively. Continuous variables were analyzed by Independent Student's t test and Chi-square tests were used for the analysis of categorical variables. When p values of a continuous variable were less than 0.05 in the t test, a receiver operating characteristic (ROC) curve was created to determine the cut-off values of that significant quantitative variable. Multivariate analysis through binary logistic regression analysis was performed to identify the significant independent factors that helped to predict IE. Then we established a risk score model according to these significant factors. Each independent factor was scored from 1 to 5 according to the Wald value. The factor with the smallest Wald value was given 1 point, while the highest one was given 5 points. Finally, the factors were used collectively to calculate a patient's risk score for IE. Risk scores for all patients were entered into a ROC curve analysis again to assess the cut-off point for the prediction of IE. P values of less than 0.05 were considered to indicate statistical significance.

RESULTS

During the study period, 2811 vaginal deliveries with mediolateral episiotomy were performed in our hospital. Forty-nine (1.7%) women were hospitalized with the diagnosis of IE. Forty-two of these 49 women constituted the case group. 7 patients were excluded due to missing data in the patient files and hospital system. Non-adjusted comparisons of the characteristic features using univariate analysis between case and control groups were shown in Table 1.

Accordingly, in the case group mean BMI, weight gain during pregnancy, and postpartum neutrophil to lymphocyte ratio (NLR) were higher than in the control group, while the mean cervical dilatation measurement at hospitalization was lower. In addition, obesity, current smoking, diabetes mellitus (DM), hospitalization before the active phase of labor, pre and postpartum anemia, and labor induction were more common in the case group. ROC curve analysis determined the best cut-off values for weight gain during pregnancy, cervical dilation measurement at hospitalization, and postpartum NLR as 11.5 kg (Area under the curve (AUC)=0.757; p<0.001), 3.5 cm (AUC=0.688; p<0.001) and 10.4 (AUC=0.763, p<0.001), respectively.

Table 1. Characteristics features of the groups

	Cases (n=42)	Controls (n=168)	p
Age (years)	26.13±5.35	26.36±3.57	0.798
Adolescent pregnancy <20years-old	1 (2.4)	12 (7.1)	0.252
Education level >primary school	27 (64.3)	122 (77.2)	0.088
Gravida (n)	1.29±0.55	1.41±0.71	0.286
Multigravida (n)	10 (17.5)	47 (29.7)	0.449
Parity (n)	1.05±0.22	1.13±0.48	0.264
Primiparity (n)	40 (95.2)	144 (91.1)	0.384
BMI (kg/m^2)	32.40±3.36	29.84±3.02	**<0.001**
Obesity (BMI≥30kg/m^2)	33 (78.6)	68 (43.0)	**<0.001**
Weight gain during pregnancy (kg)	17.36±5.72	12.47±5.05	**<0.001**
Weight gain during pregnancy≥11.5kg	40 (95)	82 (51.9)	**<0.001**
Current smoking	13 (31.0)	18 (11.4)	**<0.001**
Diabetes mellitus	9 (21.4)	14 (8.9)	**0.023**
Cervical dilatation at hospitalization (cm)	3.26±1.95	4.68±2.26	**<0.001**
Cervical dilatation <3.5 cm at hospitalization	24 (57.1)	47 (29.7)	**0.001**
Hospitalization before active phase of labor	38 (90.5)	93 (58.9)	**<0.001**
Premature rupture of membrane	13 (31.0)	41 (25.9)	0.516
Prepartum hemoglobin level (g/dl)	11.44±1.31	11.78±1.39	0.158
Prepartum anemia (Hemoglobin<10g/dl)	16 (38.1)	30 (19.0)	**0.009**
Prepartum NLR	5.39±2.36	6.08±2.67	0.128
Duration of active phase	5.24±1.92	4.48±1.90	0.053
Labor induction/augmentation	34 (81.0)	99 (62.7)	**<0.001**
Meconium-stained amniotic fluid	8 (19.0)	33 (19.6)	0.912
Birth weight (gr)	3392.38±338.10	3323.52±426.68	0.334
Macrosomia (>4000gr)	1 (2.4)	11 (7.0)	0.267
Head circumference of newborn (cm)	34.36±2.01	34.54±1.30	0.481
Postpartum hemoglobin level (g/dl)	10.75±1.27	11.26±1.39	0.062
Postpartum anemia (Hemoglobin<10g/dl)	26 (61.9)	56 (35.4)	**0.002**
Postpartum NLR	13.49±5.49	9.28±4.45	**0.001**
Postpartum NLR ≥10.4	31 (73.8)	52 (32.9)	**<0.001**

Values were presented as mean±standard deviation and number (%).
n: number, BMI: Body mass index, kg: kilogram, m^2: square meter, cm: centimeter, g/dl: grams per decilitre, gr: gram, NLR: Neutrophil to lymphocyte ratio.
p<0.05 was considered statistically significant

Multivariate logistic regression analysis revealed that presence of weight gain during pregnancy ≥11.5 kg (Wald=9.363, p=0.002), current smoking (Wald=12.320, p<0.001), DM (Wald=5.423, p=5.423), hospitalization before active phase of labor (Wald=4.605, p=0.032), and postpartum NLR ≥10.4 (Wald=8.807, p=0.003) were significant independent factors related to IE (Table 2). Among these factors, 5 points were given to current smoking presence, 4 points to weight gain during pregnancy ≥11.5 kg, 3 points to postpartum NLR ≥10.4, 2 points to the presence of DM, and 1 point to the presence of hospitalization before active phase of labor. The total risk score's role to predict the presence of IE was further evaluated by using a ROC curve, which had a cut-off value of 5.5 score with a sensitivity of 73.8%, a specificity of 75.0%, a positive predictive value of 42.5%, a negative predictive value of 92.0% and an accuracy of 74.8%. The AUC was 0.775 (95% CI 0. 708-0.841, p< 0.001, Fig. 1).

Table 2. Multivariate logistic regression analysis of factors for infected episiotomy

	Wald	SE	p	Exp(B) [%95 CI for Exp(B)]
BMI≥30 kg/m2	1.283	0.564	0.257	1.89 (0.63-5.72)
Weight gain during pregnancy ≥11.5 kg	9.363	0.605	**0.002**	6.36 (1.95-20.81)
Current smoking	12.320	0.627	**<0.001**	0.11 (0.03-0.38)
Diabetes mellitus	5.423	0.673	**0.020**	0.21 (0.06-0.80)
Cervical dilatation <3.5 cm at hospitalization	0.087	0.513	0.768	1.16 (0.43-3.18)
Hospitalization before active phase of labor	4.605	0.753	**0.032**	0.18 (0.04-0.86)
Prepartum anemia (Hemoglobin<10g/dl)	1.970	0.607	0.160	2.35 (0.71-7.72)
Labor induction	0.148	0.599	0.700	0.79 (0.25-2.57)
Postpartum anemia (Hemoglobin<10g/dl)	2.657	0.548	0.103	2.44 (0.84-7.15)
Postpartum NLR ≥10.4	8.807	0.518	**0.003**	4.66 (1.69-12.85)
p<0.05 was considered statistically significant				

BMI: Body mass index, kg: kilogram, m^2: square meter, cm: centimeter, g/dl: grams per decilitre, NLR: Neutrophil to lymphocyte ratio.

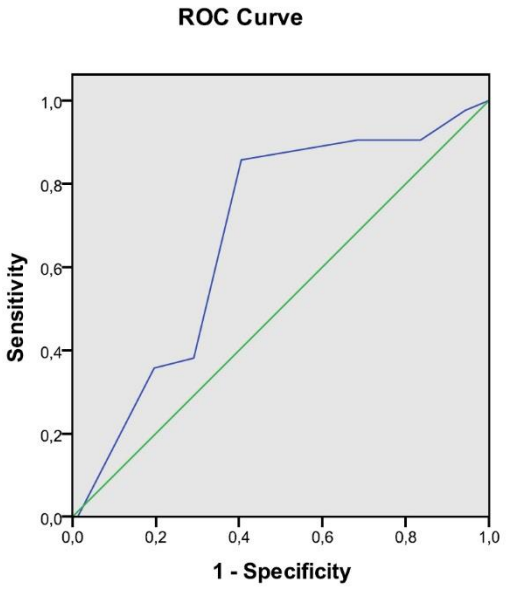

Figure 1. Receiver operating characteristic curve. Receiver operative curve compares the sensitivity and specificity of total model scores for infected episiotomy. Total score of 5.5 was detected as cut-off value with a sensitivity of 73.8%, a specificity of 75.0%

DISCUSSION

In this current study, the incidence of IE was found to be 1.7 %. This rate has been quite variable in the literature, ranging from 0.1% to 23.6% and increasing especially with the presence of 4th-degree perineal lacerations and after instrumental deliveries[5,16,17]. This large variation can be explained by the fact that studies in this field have different designs and follow-up periods (between 3 weeks and 6 months) and do not have a standard definition for the presence of infection. Nevertheless, the relatively low and acceptable rate in our study can be attributed to the fact that our hospital is a referral center, therefore its medical facilities and hygienic conditions are appropriate, and our study population consists of low-risk women having no anal sphincter damage or instrumental delivery.

Many prepartum factors such as advanced maternal age, smoking, malnutrition, obesity, DM, and immunodeficiency; intrapartum factors such as prolonged labor-membrane rupture, operative vaginal delivery, 3rd or 4th-degree perineal laceration; postpartum factors such as suboptimal hemostasis, lack of antisepsis or contamination at the wound site, and poor individual hygiene for wound care have been reported to be associated with the formation of IE in the literature [7,18]. In this study, five significant factors were determined. These were, weight gain ≥11.5 kg during pregnancy, smoking, DM, hospitalization before active labor, and a postpartum NLR ≥ 10.4. It has been reported that obesity or excessive weight gain, poor glycemic control or DM, smoking or alcohol abuse may facilitate bacterial colonization by reducing tissue perfusion and oxygenation, possibly with vascular dysfunction in the surgical field. These may also negatively affect tissue healing by disrupting the inflammatory response and easing the infection formation [19-21]. On the other hand, prolonged hospitalization may increase the risk of contamination with hospital flora, which harbors a large number of microorganisms. In

general, it is well known that the probability of developing hospital-acquired infections increases rapidly as the length of stay in the hospital increases, and data suggest that the length of stay before surgery is a risk factor for the development of wound infection [22,23]. Neutrophils and lymphocytes are important factors in biophylaxis against infection. In the initial stage of bacterial infections, neutrophil counts increase while lymphocyte counts decrease. Thus, increased NLR is considered a possible sign of contamination [24,25]. Indeed, similar to our findings, the increase in NLR detected after some surgical operations have been reported as a useful marker for detecting postoperative infections [26,27].

These factors are similar to and suggestive of the possible factors previously reported. Therefore, it can be thought that detecting them does not have an additional benefit for the literature. On the other hand, it would be beneficial to be able to transform these into a useful tool for clinical practice. In our study, which we started with this aim, we found that the risk scoring model created with the possible factors we identified had moderate effectiveness in predicting postpartum IE. Thus, we think that our current study may be useful in terms of clinical practice as its findings are both first and important. Namely, the available evidence for the use of prophylactic antibiotics in the prevention of infections after episiotomy is uncertain. Indeed, a recent Cochrane review reported that there is insufficient evidence to evaluate the clinical benefits or harms of routine antibiotic prophylaxis for episiotomy repair after vaginal delivery [6]. Antibiotics given unnecessarily in this situation may be associated with poorer outcomes, exposing women and breastfed infants to the risk of antibiotic-related side effects, increasing healthcare costs, and leading to the emergence of antibiotic resistance. On the contrary, preventative antibiotics, or prophylaxis, which are given when necessary, might reduce wound infections after episiotomy and improve maternal well-being. Therefore, it should be well determined in which cases antibiotics should be given. We think that our study can guide clinical practice on this subject. With relatively low sensitivity and specificity values, low positive predictive value, and high negative predictive value, our scoring system mainly indicates which women should not be given antibiotic prophylaxis. Based on this, prophylaxis may not be applied to women with scores below the threshold value and a joint decision can be taken by discussing the benefits-harms with women having scores above the threshold in clinical practice. However, additional studies are needed to confirm the clinical applicability of our findings.

Our study has some limitations. Firstly, because of its retrospective design, there may have been a potential bias associated with patient selection and missing patient information. Secondly, it has data from a single center. Although our hospital is a referral center, due to its localization, patients from the nearby geography mainly apply to this center. Therefore, our model should be tested in different geographical areas in order to be applicable to large populations. Finally, some other influencing factors were not taken into consideration, such as the mother's socioeconomic status or approach to wound care.

Many scoring models have been developed to predict the outcome of surgery, but choosing the right model is difficult. The ideal model should be accurate, objective, and easy to use. Unfortunately, there has been no perfect model in use so far. Nevertheless, these tools are useful for determining whether presurgical modification of risk factors or changes in surgical approach should be considered. We also performed a risk score modeling for IE in this study. As a result this model, which consists of five variables, can predict the presence of IE with considerable efficiency. Identification of patients at risk of IE allows for individualized patient risk assessment, implementation of appropriate strategies to reduce infection, administration of necessary antibiotic prophylaxis, and situation-specific counseling. Further prospective studies are needed to evaluate the applicability and accuracy of the model in clinical practice.

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