Surgical Site Infection Following Episiotomy Repair in Relation to Routine Use of Postpartum Antibiotic Prophylaxis in Low Risk Population: A Randomized Controlled Trial

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Abstract

Background: Antibiotic prophylaxis may lower the incidence of wound infections following an episiotomy, especially in circumstances like midline episiotomy, incision extension, or environments with a high baseline risk of infection following vaginal delivery, which are linked to a higher risk of postpartum perineal infection. Nevertheless, there is conflicting data at this time about the benefit of prophylactic antibiotics in avoiding infections after an episiotomy.

Objective: Evaluation of whether regular prophylactic antibiotic medication to women after an uncomplicated vaginal delivery, as opposed to not administering any antibiotic prophylaxis, lowers postpartum maternal infectious morbidities and improves outcomes.

Methods: A total of 200 pregnant women with who underwent elective episiotomy repair were enrolled and divided into two equal groups; study group received oral antibiotics in a dose of 625gm twice daily for 3 days after delivery and control group didn't receive postpartum antibiotics. We followed up her through a telephone call weekly for 6 weeks asking about fever, discharge, vaginal pain, dysuria, vulval swelling, redness and pelvic pain. Maternal readmission to hospital, puerperal sepsis, urinary tract infection, endometritis, serious infectious complications was compared between study groups.

Results: No differences were noted between study groups regarding all study parameters. Routine antibiotics after episiotomy had no role in prophylaxis against wound complications, maternal fever, puerperal infection and maternal readmission.

Conclusion: Administration of prophylactic systemic antibiotic post episiotomy is not effective to prevent wound infection.

Keywords: Surgical Site Infection; Episiotomy; Postpartum Antibiotic.

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Introduction

In Approximately 200 000 of the projected 300 000 women who died in 2017 were in subSaharan Africa, illustrating the unacceptable global rate of maternal mortality [1].

Sepsis caused by maternal infection is a major factor in these fatalities. However, there are little data about the prevalence and etiology of maternal infection [2].

Women who are supposed to have simple vaginal deliveries may be more susceptible to bacterial infections if they have a number of pre-existing medical issues. These include illnesses such group B streptococcus infections, bacterial vaginosis, anemia, and malnourishment [3].

Furthermore, the risk of infection in the puerperium may be raised by complications related to labor and delivery (such as prolonged rupture of the membranes, prolonged labor, genital tract lacerations, and retained products of conception) or by interventions by the provider (such as frequent vaginal examinations, operative vaginal birth (using forceps or a vacuum), and episiotomy) [4].

An episiotomy is a planned incision made on the perineum during the second stage of labor, which is considered when there are signs that if it is not performed, there might be a substantial rupture of the perineum [5].

A spontaneous vaginal delivery, or SVD, is when a woman gives birth to her child via the birth canal (the vagina) without the need for forceps, vacuum extraction, or a cesarean section. This may happen when the mother is not using any medications or other methods to induce labor. Approximately four million vaginal births occur in the United States annually, with the majority being spontaneous [6].

One of the key variables influencing medical outcomes is socioeconomic status (SES). Poor SES has been linked to insufficient medical treatment and unfavorable results. Low SES may raise a woman's chance of unfavorable pregnancy outcomes [7].

Infection-prone obstetrical operations, including as caesarean sections, manual placenta removal, and the repair of third- or fourth-degree perineal injuries, should be avoided by antibiotic prophylaxis. Anatomically speaking, episiotomies resemble a second-degree perineal laceration, involving [5].

the connective tissue, underlying muscles, and vaginal mucosa, and may not justify the regular use of preventive antibiotics [8].

Prophylactic antibiotic usage for episiotomies seems to vary much, nevertheless. As far as we are aware, there is no research on the use of prophylactic antibiotics for episiotomies in 3 high-income countries, and clinical guidelines do not suggest using them in the absence of infection. However, prophylactic antibiotic use appears to be very common in certain lowincome countries, where most women undergo episiotomies and receive them [9].

The risk of episiotomy infection is reduced by general infection control practices such hand hygiene, aseptic surgical methods, site cleaning, and sterilization of tools used in the procedure [10].

Methods

From September 2022 to May 2023, a randomized controlled clinical study was carried out at the Obstetrics and Gynecology Department of the Faculty of Medicine, Ain Shams University Hospitals. The following conditions were met by expectant mothers who visited the labor ward:

Patients who had an uneventful vaginal delivery, had elective episiotomy repair, and showed no signs of continuing antibiotic use throughout the postpartum phase met the inclusion criteria.

Patients with prolonged rupture of membranes (PROM >24 hours), chorioamnionitis, prolonged second stage of labor (>2 hours), third- or fourth-degree vaginal tears, retained or manual placenta removal, post-partum

hemorrhage, anemia, diabetes, and immunocompromised status were among the exclusion criteria.

Sampling Method

Women who met the eligibility requirements were randomly allocated to either group using systematic random selection. Two hundred opaque envelopes were serially numbered, and the matching letter representing the assigned group was placed inside each envelope in accordance with the randomization table. Next, each envelope was sealed and placed within a single box. Using MedCalc ® version 13, a computergenerated randomization sheet was used for the randomization process.

Sample size justification

A sample size of 100 women per group was required to detect a difference between the two groups, using the Pass 11 software to calculate the sample size. Power was set at 80%, a-error at 0.05, and the incidence of infection in the control group was assumed to be 10% and in the intervention group to be 2%.

Ethical considerations

Before being recruited in the research, the patient's information and informed permission were obtained. The patient gave her assent to participate after being given a clear explanation of the purpose, scope, and potential drawbacks of the clinical trial. In the case report, the patient's initials were the only information included. The investigators stored any additional documents containing the patient's identity in a safe location. To make records identifiable, the scientists kept a personal patient identification list, which included patient initials matched to matching patient names. The protocol and all related paperwork were declared for ethical and research approval by the council of the OB/GYN department at Ain Shams University before the study started, and any compliance with local regulations was followed. There is no proof that the research intervention is detrimental.

Study procedures

The patients underwent a thorough history taking of clinical value, a general examination with a focus on the "Leopold maneuvers" of the obstetric abdominal examination, and standard investigations in accordance with the inclusion and exclusion criteria. Measurements of the traditional fetal biometric parameters were made using ultrasonography during the antenatal ultrasound examination.

The patients were divided into two groups: the study group (n = 100) received coamoxiclav in the form of a film-coated tablet called Megamox® (clavulanic acid 125 mg + amoxicillin 500 mg). produced in Saudi Arabia by AL-Jazeera Pharmaceutical and imported by Hikma Importation) twice a day for three days after birth, with a control group of one hundred patients not receiving postpartum antibiotics (n = 100).

As per the local hospital protocol, all women were positioned in the lithotomy position and then had their lower abdomen skin, thighs, and vagina sterilized with povidone iodine upon being moved to the labor room. Before head delivery, straight scissors were used to make an incision on the head's crowning and when the perineum was at its most stretched and ready to rupture. Local lidocaine was given at the episiotomy line and fourchette. Sim's speculum and two ovum forceps were used to inspect the whole vaginal wall and cervix after the full delivery of the baby, placenta, and membranes.

The extent of the episiotomy-cut wound was assessed before it was closed in layers (two muscle layers and the vaginal wall) with a continuous vicryl 2/0 suture that allowed for total homeostasis. With a subcuticular 2/0vicryl suture, the skin was sealed. Before the patient was sent to the post-natal ward for a two-hour surveillance of postpartum hemorrhage, a regular per-rectum examination was performed. Following a 12- to 24hour period, the patient was examined for any signs of local episiotomy hematoma, discomfort, or

excessive vaginal bleeding before being sent home with a follow-up card.

Follow up

Investigations, such as CBC, urine analysis, wound swabs for cultures, and chest x-rays, were sometimes required to confirm the diagnosis since infections might be diagnosed based on non-specific symptoms and indications.

The main result was an infection at the episiotomy site (edematous, erythematous, wound edge with pain, frankly purulent material, or wound dehiscence), and the secondary results included serious infectious complications like septic shock, bacteremia, systemic infection, fever (body temperature of 38 degrees Celsius or higher) occurring on any two occasions in the first 10 days postpartum, excluding the first 24 hours, puerperal infection, urinary tract infection, and endometritis.

Statistical Analysis

Numerical data that was normally distributed was statistically expressed as mean ± standard deviation (± SD), but data that was not normally distributed was expressed as median and range or inter-quartile range (IQR).

Results

Table 1: Demographic characteristics of study groups.

Demographic data	Total (n=200)	Group (1) (n=100)	Group (2) (n=100)	Test value	Pvalue
Age (years) Mean±SD Range	 24.12±4.68 17-40	 24.43±4.71 17-39	 23.81±4.64 17-40	0.878	0.350
BMI [wt/ (ht) ^A2] Mean±SD Range	 24.81±3.10 19.1-33.3	 25.03±2.60 19.1-33.3	 24.58±3.53 22.6-33.3	1.030	0.311
BMI [wt/ (ht) ^A2] Mean±SD Range P2 PG	 19 (9.5%) 33 (16.5%) 8 (4.0%) 140 (70.0%)	 9 (9.0%) 20 (20.0%) 3 (3.0%) 68 (68.0%)	 10 (10.0%) 13 (13.0%) 5 (5.0%) 72 (72.0%)	2.152	0.542
GA "wks." Mean±SD Range	 39.01±1.09 37-41.6	 39.04±1.06 37-41.6	 38.98±1.13 37-41	0.150	0.699

There i s no statistically significant difference between groups according to demographic data, about Age (years), BMI [wt/ (ht) A2], Parity and GA "wks.", with p-value (P=0.350; P=0.311; P=0.542 ad P=0.699) (Table 1).

Table 2: Comparison between Group (1) and Group (2) according to Membrane rupture to delivery time

Membrane ruptures to delivery time (hrs.)	Total (n=200)	Group (1) (n=100)	Group (2) (n=100)	Test value	Pvalue
Mean±SD	6.30±2.38	6.63±2.41	5.97±2.35	0.775	0.380
Range	0.08-23	0.08-23	0.17-21.5		

There is no statistically significant difference between groups according to membrane rupture to delivery time "hrs", with p-value (p=0.380) (Table 2).

Table 3: Comparison between Group (1) and Group (2) according to Admission to delivery time

Admission to delivery time (hrs.)	Total (n=200)	Group (1) (n=100)	Group (2) (n=100)	Test value	Pvalue
Mean±SD	6.13±2.28	6.30±2.62	5.96±2.92	0.312	0.577
Range	1.25-25	1.25-25	1.25-21		

There is no statistically significant difference between groups according to admission to delivery time "hrs.", with p-value (p=0.577) (Table 3).

Table 4: Comparison between Group (1) and Group (2) according to Length of 1st stage of labour

Length of 1st stage of labour (hrs.)	Total (n=200)	Group (1) (n=100)	Group (2) (n=100)	Test value	Pvalue
Mean±SD	4.05±2.35	4.00±2.05	4.09±2.02	0.074	0.786
Range	0.67-17.5	0.67-17.5	0.92-11.33		

There is no statistically significant difference between groups according to length of 1st stage of labour "hrs", with p-value (p=0.786) (Table 4).

Table 5: Comparison between Group (1) and Group (2) according to Length of second stage of labour

Length of second stage of labour (min.)	Total (n=200)	Group (1) (n=100)	Group (2) (n=100)	Test value	Pvalue
Mean±SD	38.4±22.8	39.6±22.2	37.2±18.0	0.413	0.423
Range	4-120	5-120	4-120		

There is no statistically significant difference between groups according to length of second state of labour "hrs.", with p-value (p=0.423) (Table 5).

Table 6: Comparison between Group (1) and Group (2) according to complications

Complications	Total (n=200)	Group (1) (n=100)	Group (2) (n=100)	Test value	Pvalue
Wound Complication					
Erythematous Oedematous Purulent material	7 (3.5%) 3 (1.5%) 6 (3.0%)	3 (3.0%) 1 (1.0%) 2 (2.0%)	4 (4.0%) 2 (2.0%) 4 (4.0%)	1.715	0.788
Maternal Fever	0 (0%)	0 (0%)	0 (0%)	0.000	1.000
Serious Infectious complications	0 (0%)	0 (0%)	0 (0%)	0.000	1.000
Maternal Re-dmission	0 (0%)	0 (0%)	0 (0%)	0.000	1.000
Puerperal Infection	0 (0%)	0 (0%)	0 (0%)	0.000	1.000

Regarding complications from episiotomy wounds, the difference between the two groups was not statistically significant with a p-value of >0.05 in the presence of wound infection (erythematous, edematous, and purulent discharge).suggesting there was no statistically significant correlation between the preventative use of antibiotics and a decrease in the incidence of wound infections. There were no instances of maternal readmission, puerperal infections (endometritis, urinary tract infection), or severe infectious consequences (bacteremia, systemic infection, septic shock) in either group. In neither group did any occurrences of maternal fever occur (Table 6).

Table 7: Association between infection rate according duration of ROM in each group.

ROM	Infection rate				Total		x2	pvalue
	Non Infection		Infection					
	No.	%	No.	%	No.	%		
Group 1								
<18 hrs.	88	93.6%	6	100.0%	94	94.0%	0.407	0.523
>18 hrs.	6	6.4%	0	0.0%	6	6.0%		
Group 2								
<18 hrs.	85	93.4%	9	100.0%	94	94.0%	0.631	0.427
>18 hrs.	6	6.6%	0	0.0%	6	6.0%		
All group								
<18 hrs.	173	93.5%	15	100.0%	188	94.0%	1.035	0.309
>18 hrs.	12	6.5%	0	0.0%	12	6.0%		

x^2: Chi-square test for Number (%) or Fisher S exact test, when appropriate p-value >0.05 is insignificant

There is no statistically significant association between infection rate according ROM in each group and all group, with p-value (p>0.05).

Table 8: Association between infection rate according to Length of 1st stage of labour and Length of second stage of labour in each group

Stage	Infection rate				Test value	pvalue
	Non Infection		Infection			
	Mean	±SD	Mean	±SD		
Group 1						
Length of 1st stage of labour (hours)	3.91	1.60	5.38	2.21	0.526	0.470
Length of second stage of labour	0.65	0.39	0.68	0.24	0.862	0.355
Group 2						
Length of 1st stage of labour (hours)	3.96	1.89	5.40	2.81	3.291	0.073
Length of second stage of labour	0.58	0.26	1.06	0.55	0.599	0.441
All group						
Length of 1st stage of labour (hours)	3.94	1.28	5.39	2.86	2.390	0.124
Length of second stage of labour	0.62	0.30	0.91	0.30	0.308	0.579

Using: t-Independent Sample t-testfor Mean±SD; p-value >0.05 is insignificant

There is no statistically significant association between infection rate according to Length of 1st stage of labour and Length of second stage of labour in each group and all group, with p-value (p>0.05).

Discussion

In Our findings demonstrated that all research parameters were similar across study groups. Following an episiotomy, routine antibiotic use had little bearing on preventing wound complications, mother fever, puerperal infection, or readmission of the mother. In terms of demographic information, such as mother age, BMI, parity, gestational age at delivery, membrane rupture to delivery time, admission to delivery time, and duration of the first and second phases of labor, no differences were found between the research groups.

In 2022, Mohamed et al. conducted a comparison of the incidence of infectious morbidity among parturient women who had an uncomplicated vaginal delivery and were given regular local treatment alone vs a preventive course of oral antibiotics post-episiotomy. They came to the same conclusion as us—that prophylactic systemic antibiotic therapy is ineffective in preventing wound infection after an episiotomy. There was no statistically significant difference in the total wound complications after episiotomy between the antibiotic and non-antibiotic groups (7.8%-6.7%), as compared to our findings (6% vs 8%). There were no occurrences of atypical lochia or maternal fever reported on the second visit [11].

Up until 2021, the WHO, ACOG, and other organizations did not recommend antibiotic prophylaxis for women undergoing episiotomies. This makes it one of the contentious topics for obstetricians. According to ACOG Practice Bulletin No. 120 in 2011 and Bonet et al. in 2017, there was insufficient evidence to support routine antibiotic prophylaxis for episiotomy repair following a normal birth in order to reduce maternal or fetal infectious morbidity. As a result, the Cochrane Library recommended conducting more RCTs in 2016. [12,13].

Although exact statistics on the prevalence of episiotomy in Egypt are unavailable, both public and private institutions often perform the procedure. The primary conclusions of our research show that the incidence of infection in patients with episiotomies after a typical vaginal birth of low-risk parturient women was not significantly reduced by the administration of preventive antibiotics. Additional-

ly, a significant proportion of women would likely be exposed to antibiotics needlessly because to the very high rate of episiotomies.

According to Ramirez et al.'s 2020 report, the CDC advised against prescribing unnecessary antibiotics because they can have a number of negative effects on the mother and the newborn, including upsetting the microbiota, antibiotic resistance, an increased risk of drug poisoning, hypersensitivity reactions, and needless costs [14].

In line with the current investigation, Garala and Nambiar (2019) found no statistically significant differences between the two groups that got or did not receive antibiotics after an episiotomy with relation to puerperal pyrexia, wound infection, and length of hospital stay [15].

Apart from instrumental vaginal delivery, Akram et al. (2019) and Tandon and Dalal (2018) reported using various antibiotic types, single or multiple doses, in different studies, such as amoxi-clavulinic acid, cefoxine metronidazole combination, and chloramphenicol. They all concluded that there was no benefit of antibiotic prophylaxis after episiotomy repair [16, 17].

Despite their recommendation, Knight et al. (2019) link the high infection rate in the control group to the possibility of microorganisms entering the genital tract during operative vaginal delivery. They also link this procedure to longer labor, more vaginal examinations, bladder catheterization prior to the procedure, more perineal lacerations, and the use of episiotomies, all of which increase the risk of infection [18].

The incidence of episiotomy site infection was compared in two groups of primiparas with and without taking prophylactic antibiotics after a normal vaginal delivery. Goodarzi et al.'s 2020 RCT, which contrasted with our study, found that the antibiotic group had a better wound healing as indicated by a lower healing score than the placebo group. However, they used chromic sutures and midline episiotomy, both of which enhance the risk of infection [19].

In 2022, Sirilak et al. set out to ascertain the prevalence of postpartum infections as well as the consequences and variables linked to antibiotic prophylaxis in women who had vaginal deliveries. They agreed with us, backed the practice standards, and gave the medical staff peace of mind that no more than 10% of women giving birth naturally would need the use of antibiotics. The incidence of postpartum infection did not significantly vary between individuals who received antibiotics and those who did not. There was no statistically significant difference in the number of postpartum infections reported between 11 of 792 women without antibiotic prophylaxis and 3 of 117 individuals receiving them [20].

The risk of urinary tract infections, wound infections, and length of hospital stay in women treated with antibiotics was not different from that of those who received a placebo or no antibiotics, according to a 2017 systematic review by Bonet et al. on the use of antibiotics to prevent infection in women after delivery [13].

In the 2018 research by Tandon and Dalal, the infection-related symptoms were 0.7 and 2% in the groups receiving antibiotic treatment and the untreated group, respectively.

Infection symptoms did not vary statistically significantly between the two groups ($p<0.622$) [17].

In 2016, a research conducted in Sirilampang, Thailand, the results of complications in postpartum sepsis were not different between the groups receiving antibiotic treatment and those not receiving any [21].

According to Sangprappai's 2011 report, neither group had postpartum infections, with 57 women receiving amoxicillin treatment and 56 not receiving it. In this investigation, the criteria for assessing infections were comparable. These trials' findings demonstrated that, in women who gave birth normally,

the outcome of postpartum infection did not change depending on whether or not antibiotics were used. Therefore, unless a patient has a third or fourth degree tear, antibiotic prophylaxis should not be used to prevent postpartum infections in women who give birth vaginally [22].

According to a 2017 study by Bonet et al, there was no statistically significant difference in the use of antibiotics in episiotomy for infected wounds between the groups receiving antibiotic treatment and those not [20].

According to WHO recommendations from 2015, women with episiotomy lesions should not get antibiotic prescriptions as an empirical therapy for postpartum infections [23].

the American College of Obstetricians and Gynecologists does not advise against using antibiotics to prevent postpartum infections [24].

Conclusion

It is ineffective to prevent wound infection after an episiotomy by administering a prophylactic systemic antibiotic. In conclusion, even though it's a fairly prevalent practice in low-income countries, giving oral antibiotics to low-risk patients after their episiotomies are unnecessary and have not been shown to lower the incidence of postpartum infections.

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