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Original Article

Effect of post episiotomy antibiotics on maternal infectious morbidity (clinical trial)

Gynecology & Obstetrics

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ABSTRACT

Background: Episiotomy is a surgical wound done with sterile scissors to widen the vaginal opening. There is little information on the prevalence of post-episiotomy infection worldwide. Contrary to WHO recommendations, prophylactic antibiotics are still prescribed in many hospitals including our hospital, to prevent the episiotomy site infection in all women after childbirth.

Aim: To compare infectious morbidity rates between parturient women with uncomplicated vaginal birth who received either a prophylactic course of oral antibiotics post-episiotomy in addition to routine local care versus those who received routine local care only.

Methodology: A randomized trial conducted in the labour room of Al-Zahraa University Hospital, Cairo, Egypt within a 15 months duration. We recruited 630 pregnant ladies admitted for a non-complicated vaginal birth and indicated for episiotomy. Cases were randomly assigned after delivery and at discharge into two groups. Group A: prescribed on discharge oral antibiotics twice daily for 5 days after the delivery and routine episiotomy care, Group B: received routine episiotomy care only. Primary outcomes: Episiotomy wound infection and endometritis, and secondary outcomes: Episiotomy wound dehiscence or gapping, Puerperal infection or adverse effects of antibiotics.

Results: We reported a 7.5 % prevalence of wound infection in total study participants. Episiotomy overall wound complications were 7.8 %-6.7% in antibiotic and non-antibiotic group respectively with no statistical difference. On the second visit, no cases were reported with abnormal lochia or maternal fever.

Conclusion: It is concluded that administration of prophylactic systemic antibiotic post episiotomy is not effective to prevent wound infection.

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Key word: Episiotomy, vaginal birth, antibiotic.

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INTRODUCTION

Episiotomy is a surgical wound done with sterile scissors to widen the vaginal opening to facilitate vaginal births, and to prevent maternal and fetal complications. Although current evidence recommended for episiotomy only when indicated in order to shorten 2nd stage of labour and to prevent perineal trauma, still it is the most frequently procedure done in obstetric wards and it is still done as a routine in many hospitals [1].

Episiotomy, like any other wound, can lead to infection and delayed healing. Perineal infections are associated with wound dehiscence, need for repair, and perineal pain, and influence women's quality of life and sexual wellbeing. Contrary to WHO recommendations, prophylactic antibiotics are prescribed in many hospitals including our hospital, to prevent the episiotomy site infection in all women after childbirth. There is little information on the prevalence of post-episiotomy infection worldwide. However, its prevalence seems to be low and is estimated to be varied between 0.3% and 7.5% [2].

In consistence with Duggal et al, 2008[3], we define wound infection as presence of two of three parameters: perineal pain, purulent discharge and wound gap. The aim of this study is to compare infectious morbidity rate between parturient women who had an uncomplicated vaginal birth and were received prophylactic course of oral antibiotics post-episiotomy in addition to routine local care and who were received routine local care only.

PATIENTS AND METHODS

Quasi-Randomized trial study (parallel group study with 1:1 randomization) conducted at labour room of Al-Zahraa University Hospital within 15 months duration from December 2019 to February/2021.

Randomization done as follows: women admitted in delivery room at Monday, Thursday and Friday given no prophylaxis and those admitted at Saturday, Sunday and Tuesday received antibiotic prophylaxis. Approval of ethical committee was obtained from quality education assurance unit, Al-Azhar university faculty of medicine, Egypt, with IRB number (2018122001).Verbal consent was taken from all cases before participation in this study. The nature and aim of this work were fully discussed to all women who were included in the study.

Sampling method

Consecutive sampling (non-probability sample).

Sample size justification

Based on previous Knight et al.[4] study, we assumed rate of infection in the test group to be 11% and that for placebo group to be 19%% and an effect size of 8% would be of interest, with a two-sided significance of 0.05 and a power of 0.8, we used the following formula: $n = 2 (Z\alpha + Z [1-\beta]) 2 \times p \times q/d 2$ [5].

- $Z(1-\alpha)$ = is the critical value of the normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96).
- $Z(1-\beta) = Z\beta$ is the critical value of the normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84). So we will select 12 subjects for each group P is the Average of P1(proportion of clinical pregnancy/per embryo transfer in group 1) and P2 (proportion of clinical pregnancy/per embryo transfer in group 2)
- q is 1-p
- d is the effect size

The total sample size calculated is 300 in each group and we considered 5% dropouts, so we recruited a total sample of 630 patients.

Participants: At labour ward, after admission and after confirming inclusion criteria women given information about the study aims informed verbal consent taken.

Setting: Inpatient and outpatient

Inclusion Criteria

All pregnant women at full or preterm admitted for non-complicated vaginal birth and indicated for episiotomy. In our department episiotomy is indicated routinely for primigravida and in multigravida whose perineum maximally stretched and about to tear.

Exclusion criteria

Patients with chronic medical illness like diabetes, asthma or tuberculosis, anemia, Immuno-compromised patients, patients on anticoagulants therapy Women allergic to antibiotics, women undergo VBAC, patients with extending episiotomy or with vaginal wall lacerations or with cervical tear, women with History of receiving antibiotics during the preceding 7 days, patients with severe vaginal infection, women scheduled for prolonged induction of labour, women with PROM >4 hours and prolonged total duration of labour more than 12 hours.

Intervention: Cases randomly assigned after delivery and at discharge into two groups, both of them instructed for local hygiene instructions according to NHS patient leaflet and to come 1 week (1st visit) later and at 40 days post-delivery (2nd visit) again to check for wound complication. If she did not come, the first author call her on mobile and ask her about every study outcome.

- ***Group A*:** prescribed on discharge oral antibiotics,(clavulanic acid 125 mg + amoxicillin 500 mg) twice daily for 5 days after the delivery. In addition to local episiotomy care: (local antiseptic, local antibiotic cream /1-2times daily after washing, change sanitary pads regularly. Washing hands both before and after going to the toilet or on changing sanitary pads and avoid constipation). To contact if stitches become painful or smelly if the wound does not heal.
- ***Group B:*** received routine episiotomy care: (local antiseptic, local antibiotic cream/3 times daily after washing, change sanitary pads regularly. Washing hands both before and after going to the toilet or on changing sanitary pads and avoid constipation). To contact if stitches become painful or smelly if the wound does not heal.

On shifting woman to labour room all women subjected to: sterilization of lower abdominal skin, both thigh and vagina as local hospital policy with povidone iodine after positioning at lithotomy position, local lidocaine injected at episiotomy line and fourchette, straight scissor used for incision on crowning of head and when the perineum shown maximally stretched and going to tear before head delivery. After complete delivery of baby, placenta and membranes, we examined whole vaginal wall and cervix using sim's speculum and two ovum forceps. Episiotomy cut wound then examined for its extent and closed in layers (vaginal wall,2 muscle layers by continuous vicryl 2/0 suture with complete homeostasis- skin closed by sub-cuticlar 2/0vicryl suture). Then PR examination done routinely before shifting the patient to post natal ward for 2 hours watching for post-partum hemorrhage. After 12-24 hours, the patient checked for local episiotomy hematoma or pain, excessive vaginal bleeding and then discharged with follow up card after 1 week (check for primary outcomes) and after 40 days to check for secondary outcomes.

Outcome Measures

- **Primary outcome**: Episiotomy wound infection (including edema, erythema, serosanguinous, or frankly purulent discharge).
- **Secondary outcomes:**

- Episiotomy wound dehiscence or gapping.
- Puerperal infection: defined in International classification of diseases and WHO as an infection of the genital tract occurring at any time between the onset of rupture of membranes or labour, and

the 42nd day postpartum in which two or more of the following are present:

- ✓ Pelvic pain, fever (oral temperature 38.5°C or higher on any occasion).
- ✓ Abnormal vaginal discharge, e.g. presence of pus, the abnormal smell of the discharge.
- ✓ Delay in the rate of reduction of the size of the uterus (involution).

- Adverse effects of antibiotics (maternal: allergic reaction, nausea, vomiting, diarrhea, skin rashes, anaphylaxis.

Statistical analysis

Data collected were reviewed.Coding and statistical analysis of the collected data were done by using SPSS program (statistical package of social science; SPSS Inc., Chicago, IL, USA) version 16 for Microsoft Windows. Descriptive statistics: Mean and standard deviation were calculated to measure central tendency and dispersion of quantitative data.Numbers and percentages were used to describe qualitative data. Analytic Statistics: Comparing groups was done using student's t-test to compare between two quantitative variables while qualitative data were compared by using Chi-square(X^2) test, fisher's exact test was used instead when more than 20% of cells have expected frequencies<5.The level of significance was taken at p-value of <0.05. Results were represented in tables and graphs.The relative risk (RR), and odds ratio (OR)with 95% confidence interval (CI) is used to estimate the precision of the OR.

RESULTS

In the present study we reported a 7.5 % prevalence of wound infection in total study participants. Both groups were comparable regarding maternal age, BMI, education level and employment status as shown in table (1), 72% and 69% of studied groups respectively were multipara, total sample in both groups had irregular ANC(antenatal care) visits (<4 visits all through pregnancy), and most of them were full term(96.5%-93.3%) with no statistical difference table (2). Table 3 showed that almost all cases in both groups had spontaneous onset of labour and intact membranes were found in 86.8% - 90% respectively with no significant difference. Episiotomy all wound complications were 7.8 %-6.7% respectively in antibiotic and non-antibiotic groups , gapped wound and/or discharge 12 cases in each group with no statistical difference. In the second visit, no cases reported abnormal lochia, maternal fever or maternal mortality as shown in table (4). Table (5) showed no significant increased risk of episiotomy wound infection without the use of antibiotics and the estimated number to treat is 2227 to get one patient got the benefit. Table (6) showed that no statistical difference between the two studied groups regarding NICU admission due to infection neonatal mortality and no recorded cases of antibiotic hypersensitivity or toxicity.

Table (1): Socio-demographic data among the studied sample

Groups Socio-demographic data	Patients with antibiotic (n=317)	Patients without antibiotic (n=313)	Significant test	P value
Age /years (mean± SD)	26.31 ± 5.26	26.43 ± 5.83	t=0.28	0.777
BMI	33.4 ± 4.35	33.6 ± 5.26	t=0.13	0.341
Education - Educated - Not educated	 287 (90.5%) 30 (9.5%)	 281 (89.8%) 32 (10.2%)	χ^2=0.10	0.750
Employment - House wife - Employed	 317 (100%) 0 (0.0%)	 312 (99.7%) 1 (0.3%)	χ^2=1.01	0.498

t: Student t test, χ^2: Chi square

Table (2): Antenatal data among the studied sample

Groups Antenatal data	Patients with antibiotic (n = 317)	Patients without antibiotic (n=313)	Significant test	P value
Parity - Nulliparous - Multiparous	 87 (27.4%) 230 (72.6%)	 95 (30.4%) 218 (69.6%)	χ^2=0.65	0.420
No. of children: - < Two - ≥Two	 169 (73.5%) 61 (26.5%)	 178 (81.8%) 40 (18.2%)	χ^2=6.23	0.012
Regular Antenatal care - Yes - No	 0 (0.0%) 317 (100.0%)	 0 (0.0%) 313 (100.0%)	-	-
Gestational age/weeks - Mean± SD - Preterm - Full term	 38.75±1.35 11 (3.5%) 306 (96.5%)	 38.88±1.50 21 (6.7%) 292 (93.3%)	t=1.12 χ^2=3.42	0.262 0.064

t: Student t test, χ^2: Chi square

Table (3): Onset of labour and membranes among the studied sample

Groups / Natal data	Patients with antibiotic (n=317)	Patients without antibiotic (n=313)	Significant test	P value
Onset of delivery				
- Induced	5 (1.6%)	3 (0.95%)	χ^2=0.48	0.724
- Spontaneous	312 (98.4%)	310 (99.4%)		
Membrane				
- Ruptured<4hour	42 (13.2%)	31 (9.9%)	χ^2=1.72	0.190
- Intact	275 (86.8%)	282 (90.1%)		

t: Student t test, χ^2: Chi square

Table (4): Post-natal data among the studied sample

Groups / Post-Natal data	Patients with antibiotic (n=317)	Patients without antibiotic (n=313)	Significant test	P value
Wound complication (First visit)				
- Yes	27 (7.8%)	21 (6.7%)	χ^2=0.73	0.392
- Gapped wound and/or discharge	12	12		
- Skin dehiscence	15	9		
- No	290 (91.5%)	292 (93.3%)		
wound complication (second visit)				
- Healed Wound and no fever	317 (100%)	313 (100%)	-	-
Abnormal lochia 1st visit				
- Yes	0 (0.0%	0 (0.0%	-	-
- No	317 (100%)	313 (100%)		
Maternal fever 1st visit				
- Yes	0 (0.0%	0 (0.0%)	-	-
- No	317 (100%)	313 (100%)		
Maternal Mortality:				
- Yes	0 (0.0%)	0 (0.0%	-	-
- No	317 (100%)	313 (100%)		

χ^2: Chi square

Table (5): Relative and odds ratio of wound infection among studied groups

	Wound infection	No wound infection	Total
Antibiotic	12	305	317
No antibiotic	12	301	313
Total	24	606	630
Relative risk	0.99	CI 0.45-2.16	P value = 0.975
Odds ratio	0.98	CI 0.436-2.23	P value = 0.975
NNT	2227		

(Table 6): Neonatal outcomes among the studied sample

Groups / Outcome data	Patients with antibiotic (n=317)	Patients without antibiotic (n=313)	Significant test	P value
NICU admission due to infection				
- Yes	7 (2.2%)	8 (2.6%)	χ^2=0.08	0.774
- No	310 (97.8%)	305 (97.4%)		
Neonatal mortality				
- Yes	4 (1.3%)	2 (0.6%)	χ^2=0.65	0.686
- No	313 (98.7%)	311 (99.4%)		

χ^2: Chi squareχ^2: Chi square

DISCUSSION

Whether to prescribe antibiotic prophylaxis after normal vaginal delivery or not in women with episiotomy is one of the controversial issues for obstetrician till 2021; WHO, ACOG, and others not suggesting it. Cochrane library at 2016 advised to conduct more RCTs as there was no clear evidence to give routine antibiotic prophylaxis for episiotomy repair after normal birth to decrease maternal or fetal infectious morbidity[1] [6].

Precise data on the predominance of episiotomy in Egypt is not available; however, it is a prevalent practice in public and private hospitals. We included 630 women divided into two groups that compared

infectious morbidity rate after uncomplicated vaginal birth who received or not prophylactic course of oral antibiotics post-episiotomy.

The main findings indicate that the use of prophylactic antibiotics did not cause significant reduction in the incidence of infection in patients with episiotomy following normal vaginal delivery of low risk parturient women.. In addition, the relatively high prevalence of episiotomies in our hospital, would mean that an important number of women would be exposed to antibiotics, probably unnecessarily. CDC 2020 recommended That, unnecessary antibiotic prescription leads to 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 .

In the present study, the maternal morbidities like episiotomy wound infection (discharge and gapping) associated with episiotomy were not significantly increased in subjects who were not received antibiotic prophylaxis. Skin dehiscence although it was more found in the antibiotic group (15 versus 9) it is related mainly to operator skills not due to infection as it was not associated with any signs or symptoms of infection and they need to change her antibiotic. No cases of puerperal endometritis were reported in either the antibiotic or control group. Antibiotics prophylaxis even for assisted vaginal delivery the Cochrane review in 2017 found only one acceptable randomized controlled trial (RCT) with small participant numbers, although there was a relative reduction in risk of endometritis or maternal length of stay it was not statistically significant. Therefore they recommended a well-conducted RCT.

In our department episiotomy is done routinely for primigravida and in multigravida whose perineum maximally stretched and about to tear, and antibiotic given also as a routine after normal vaginal labour with episiotomy or without episiotomy. One of strength point in our study is relatively large sample size in addition to the selection criteria, women recruited, randomized and allocated into two groups after labour and after make sure that all of recruited women has no risk for infection. Also all episiotomies included in our study were of 2nd degree involving the vaginal mucosa, connective tissue and underlying muscles repaired by continuous suturing technique as it preferred according to Cochrane systematic review 2012, and it was medio-lateral to lower the risk of infection. Another point of strength is the strict instructions given for post episiotomy care for each woman and in details [7].

Data was obtained in second visit via telephone interviews, and 24% of women could not be contacted via the cell phone. Although all episiotomies done by residents but the variability of the skill of the operator could not be adjusted, that may account for cutting too laterally and damaging other structures or making a ragged incision. Regarding the technique of repair and the type of suture used for episiotomy repair were similar in both groups. Another weak point in our research is that blinding was restricted to outcome assessor only and due to limited fund the antibiotic given not based on culture. In agreement with the present study, Nirav et al. [8] reported that regarding puerperal pyrexia, wound infection and duration of hospital stay there was no statistical difference between both groups those received or not received antibiotic after episiotomy. Different antibiotic types, single or multiple doses used in different studies as amoxilclavulinic acid, cefoxine metronidazole combination and chloramphenicol and they all concluded that no benefit of antibiotic prophylaxis after episiotomy repair except for instrumental vaginal delivery [9,10]. Although they recommend it but they relate the high infection rate in control group to the fact that operative vaginal delivery can introduce microorganisms into the genital tract, is associated with longer labour, more vaginal examinations, with bladder catheterization before the procedure, and with more perineal lacerations and use of episiotomy, all of which can increase the risk of infections [11]. In contrast to our study a recent RCT conducted by Goodarzi et al. [12]. compared the incidence of episiotomy site infection in two groups of primiparas with and without taking prophylactic antibiotics after normal vaginal delivery and they concluded that the healing score was lower in the antibiotic group compared to the placebo group, indicating a better wound healing. But they used the midline episiotomy and chromic sutures was used which carry increased risk of infection.

Prophylactic antibiotics was established in the 1960s**,** when experimental data established that antibiotics had to be in the circulatory system at a high enough serum level before incision to be effective, in our and most similar studies antibiotic prescribed after episiotomy incision, and we found no difference in wound infection rate, In addition based on global efforts as well as the World Health Organization (WHO) strategies employed to reduce antibacterial resistance, antibiotics should only prescribed when there is a definite medical indication [13].

CONCLUSION

We concluded there is no need to give systemic antibiotic to low risk parturient women after episiotomy incision to prevent wound infection .

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الملخص العربي

تأثير المضاد الحيوي بعد شق العجان على حالة الأم المرضية (تجربة سريرية)

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ملخص البحث

المقدمة: شق العجان هو جرح يتم إجراؤه بمقص معقم لتوسيع فتحة المهبل. هناك القليل من المعلومات حول انتشار عدوى ما بعد شق العجان في جميع أنحاء العالم. خلافًا لتوصيات منظمة الصحة العالمية ، لا تزال المضادات الحيوية الوقائية موصوفة في العديد من المستشفيات بما في ذلك مستشفانا ، لمنع عدوى شق العجان للسيدات بعد الولادة.

الهدف: الهدف من الدراسة هو مقارنة معدل الإصابة بتلوث الجرح وغيرها من مضاعفات بين النساء الحوامل ذات الولادة المهبلية غير المصحوبة بمضاعفات اللاتي تلقين اما الدورة الوقائية للمضادات الحيوية عن طريق الفم بعد شق العجان بالإضافة الى الرعاية الموضعية الروتينية واللاتي تلقين رعاية موضعيه روتينية فقط.

الطرق: دراسة تجريبيه شبه عشوائية أجريت في غرفة الولادة بمستشفى جامعة الزهراء ، القاهرة ، مصر في غضون 15 شهرًا. تم قبول 630 سيدة حامل للولادة المهبلية غير المصحوبة بمضاعفات والتي خضعت الى شق العجان. يتم توزيع الحالات بشكل عشوائي بعد الولادة وعند الخروج إلى مجموعتين.

المجموعة أ: يتم وصف المضادات الحيوية عن طريق الفم مرتين يوميًا لمدة 5 أيام بعد الولادة والرعاية الروتينية لشق العجان ، المجموعة ب: تلقي الرعاية الروتينية لشق العجان فقط.

النتائج الأولية: عدوى جرح شق العجان أو حمى النفاس، ونتائج ثانوية: عدم التئام الجرح بشكل تام او استمرارية بقاء العدوى، عدوى النفاس أو الآثار الجانبية للمضادات الحيوية.

النتائج: بعد عمل الدراسة تبين ان معدل انتشار عدوى الجرح حدث بنسبة 7.5٪ في إجمالي المشاركين في الدراسة. بحيث كانت مضاعفات الجرح الكلية لشق العجان 7.8٪ -6.7٪ في مجموعة المضادات الحيوية وغير المضادات الحيوية على التوالي مع عدم وجود فرق إحصائي. في الزيارة الثانية، لم يتم الإبلاغ عن أي حالات مصابة بحمى النفاس أو غيرها من مضاعفات.

الاستنتاجات: استنتج أن إعطاء المضادات الحيوية الوقائية بعد بضع الفرج ليس فعالاً لمنع عدوى الجرح.

الكلمة المفتاحية: شق العجان، الولادة المهبلية ، مضاد حيوي.

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