THE JOURNAL OF OBSTETRICS AND GYNECOLOGY OF INDIA

The Journal of Obstetrics and Gynecology of India (July–August 2018) 68(4):294–299
https://doi.org/10.1007/s13224-017-1041-0

ORIGINAL ARTICLE

A Randomized, Open-labelled, Interventional Study to Evaluate the Incidence of Infection with or Without Use of Prophylactic Antibiotics in Patients of Episiotomy in a Normal Vaginal Delivery

Amrita N. Tandon[1] · **Asha R. Dalal**[1,2]

Received: 9 July 2017 / Accepted: 31 July 2017 / Published online: 11 August 2017

About the Author

Dr. Amrita N. Tandon works as a Speciality Medical Officer (SMO) in the Department of Obstetrics and Gynaecology at the BYL Nair Charitable Hospital in Mumbai. She has completed her postgraduation from the same institute. She takes special interest in infertility and endoscopy and is set to pursue further specialisation in the same. She is an active Youth Council Member in MOGS and is also a member of the Sexual Medicine Committee, FOGSI. Besides academics, she also takes keen interest in music and is trained in Hindustani classical singing.

Abstract

Aim The aim of this study was to compare the incidence of infection in patients of episiotomy with or without the use of prophylactic antibiotics and to compare other morbidities associated with episiotomy and the role of antibiotics in their prevention and treatment.

Design This open-labelled, randomized, interventional study was conducted in the Department of Obstetrics and Gynaecology at BYL Nair Charitable Hospital, Mumbai, Maharashtra, from October 2014 to October 2015. Three hundred women subjected to episiotomy during normal vaginal delivery in the labour ward from BYL Nair Charitable Hospital fulfilling specific criteria were enrolled in this study and randomly divided into two study groups A and B. In group A, 5-day course of prophylactic antibiotics including tablet cefixime 200 mg BD and tablet metronidazole 400 mg TDS was given, and in group B, prophylactic antibiotics were not given. The two groups were followed up for a period of 5-days postpartum and observed for signs and symptoms of infection.

Main Outcome Presence of infection, i.e. presence of any positive finding including redness/pain/swelling/wound

Dr. Amrita N. Tandon is a Speciality Medical Officer, Department of Obstetrics and Gynaecology, BYL Nair Charitable Hospital, Mumbai, India; Asha R. Dalal is a Head of Department at Department of Obstetrics and Gynaecology, Sir H.N. Reliance Foundation and Research Centre, Mumbai, India, and Ex Professor and Head of Department at Department of Obstetrics and Gynaecology, BYL Nair Charitable Hospital, Mumbai, India.

✉ Amrita N. Tandon
amrita.tandon15@gmail.com

Asha R. Dalal
ashard@hotmail.com

[1] Department of Obstetrics and Gynaecology, BYL Nair Charitable Hospital, Mumbai, India

[2] Department of Obstetrics and Gynaecology, Sir H.N. Reliance Foundation and Research Centre, Mumbai, India

discharge or wound gape in group A (with antibiotics), was 0.7%, and in group B (without antibiotics) was 2%. The *p* value by Fischer's exact test was 0.622 which is not significant. Hence, there was no increased incidence of infection in either group, whether antibiotics were given or not.

Conclusion To summarise, in our study, it was seen that prophylactic antibiotics did not decrease the incidence of infection in episiotomy following normal vaginal delivery in uncomplicated cases, but further studies are required to evaluate this topic and come to a more definitive conclusion.

Keywords Episiotomy · Prophylactic antibiotics · Vaginal delivery · Antibiotic resistance · Episiotomy infection

Introduction

Antibiotic prophylaxis is one of the methods to reduce the risk of post-partum infections. The purpose of antibiotic prophylaxis is to reduce the colonisation pressure of micro-organisms introduced at the time of operation to a level that the patient's immune system is able to overcome. Role of prophylactic antibiotics is said to be effective in reducing post-operative puerperal morbidity after caesarean section in a Cochrane review [1].

There are increasing public health concerns about emerging antibiotic resistance following misuse or overuse of antibiotics in the obstetric population and the possibility of inadequate response to treatment of puerperal infections due to early exposure to under-effective antibiotic prophylactic regimens. Given the large proportion of women experiencing uncomplicated vaginal birth, a universal application of antibiotics to such women has the potential to lead to substantial clinical benefits in terms of reducing infection risk, but could also lead to direct harm to the woman and indirect harm to the general public with increasing resistance to antibiotics [2].

The increasing trend of using prophylactic antibiotics may increase the risk of hospital-acquired infections after normal vaginal birth if not accompanied by improvements in the quality of hygiene and infection control measures. However, evidence is unclear about the added effect of antibiotic prophylaxis in the prevention of post-partum infections after an uncomplicated vaginal birth [3].

In contrast, some studies did show that antibiotic prophylaxis reduces the risk of infection after normal vaginal delivery and operative vaginal delivery [4]. Neither is there a consensus regarding the routine use of prophylactic antibiotics for vaginal delivery with episiotomy, nor is there a good study to prove that prophylactic antibiotics are useful in uncomplicated episiotomy wounds. So further studies are required to determine the exact role of prophylactic antibiotics in vaginal delivery with episiotomy.

Aims and Objectives

1. To compare the incidence of infection in patients of episiotomy with or without the use of prophylactic antibiotics.
2. To compare other morbidities associated with episiotomy and the role of antibiotics in their prevention and treatment.

Materials and Methods

This open-labelled, randomized, interventional study was conducted in the Department of Obstetrics and Gynaecology at BYL Nair Charitable Hospital, Mumbai, Maharashtra, from October 2014 to October 2015.

Study Population

Three hundred women subjected to episiotomy during normal vaginal delivery in the labour ward from BYL Nair Charitable Hospital fulfilling the criteria as listed below were enrolled in this study and divided into two groups.

Inclusion Criteria

All patients who were given episiotomy during a normal vaginal delivery.

Exclusion Criteria

- Extension of episiotomy as a third- or fourth-degree perineal injury.
- Anaemia with haemoglobin (Hb) <8 gm%.
- Leaking per vaginum >24 h.
- Women who have received antibiotics in intrapartum period.
- Patients with systemic diseases like heart disease, diabetes mellitus, jaundice, hypertension in pregnancy, and chronic renal disease.
- All patients of induction of labour.

Pre-procedure Evaluation

All patients were assessed before the procedure. Investigations including complete blood count (CBC) were made available. Thorough systemic and local examination was done to rule out prior infection and the mentioned high-risk conditions.

Method of Randomization

Computer-generated randomization was done to allocate patients to groups A and B.

Methodology

After obtaining approval from institutional ethical committee, study protocol was explained to all potential participants in the antenatal period in their ninth month of pregnancy. Informed consent was obtained from each participant, explaining them the possible risks and benefits of the study. In the peripartum period, prior to delivery, the participants were allocated a group, according to computer-generated randomization as study groups A and B. In group A, 5-day course of prophylactic antibiotics including tablet cefixime 200 mg BD and tablet metronidazole 400 mg TDS was given, and in group B, prophylactic antibiotics were not given. Both groups received oral analgesics, a combination of paracetamol, diclofenac and serratiopeptidase for 5-days, oral antacid ranitidine and local application of antiseptic agent povidone iodine ointment. The patients were taught methods of local hygiene around the episiotomy site.

The two groups were followed up for a period of 5-days postpartum and observed for signs and symptoms of infection. In case of any complication, free rescue medication in the form of appropriate antibiotics (cefixime and metronidazole) was given to the participants.

Statistical Analysis

Complete blood count (CBC) values were compared by the unpaired t-test. The study parameters were compared using non-parametric tests like Fischer's exact test, Chi-square test and Mann–Whitney test.

Following outcomes were studied in the study groups:

Pain (day 1 to day 5): this was analysed by the presence or absence of pain in the form of yes or no and further graded according to visual analogue scale (VAS) score for pain on a scale of 1–10.

Other local factors: *redness, swelling, wound discharge and wound gape*: the presence or absence of the above-mentioned factors was used to analyse the outcome in both groups from day 1 to day 5 postdelivery and on follow-up day 10.

Type of discharge: it was further categorised into: serous, sero-purulent and purulent.

Systemic factor in the form of presence or absence of *fever* was used from day 1 to day 5 postdelivery and follow-up day 10. Presence of any of the above indicators of infection was further corroborated by CBC on day 3, and later if indicated.

Results and Discussion

After analysis of the data, no change was observed in the mean CBC values in the symptomatic patients on day 3 as compared to day 1 using unpaired t-test (p value for Hb 0.755, WBC 0.237, platelets 0.241, hence not significant; Table 1).

As shown in Table 2, based on the p values by Fischer's exact test, the incidence of pain, redness and swelling was not increased in the 'no antibiotic' group.

Wound discharge (serous discharge) was present in one subject in the 'no antibiotic' group.

None of the patients in group A had wound discharge. p value by Fischer's exact test for this was 0.99 which is not significant.

Table 1 Comparison of CBC values on day 1 and day 3 between group A and group B

Group	Day 1				Day 3			
	Mean	SD	N	p value	Mean	SD	N	p value
Hb								
A	11.404	1.0899	150	0.301	10.4		1	0.755
B	11.609	1.251	150		10.56	0.4041	3	
WBC								
A	8448.635	2159.5954	150	0.222	11,000		1	0.237
Platelets								
B	8743.461	2008.6773	150		8300	1400	3	
PPPp								
A	230.12	63.425	150	0.625	214		1	0.241
B	226.61	60.795	150		322.67	57.073	3	

Table 2 Comparison of study parameters between group A and group B

Criteria	Present/absent	Group A	Group B	Total	*p* value
Pain	Absent	149 (99.3)	148 (98.7)	297 (99)	0.99
	Present	1 (0.7)	2 (1.3)	3 (1)	
Redness	Absent	149 (99.3)	147 (98)	296 (98.7)	0.622
	Present	1 (0.7)	3 (2)	4 (1.3)	
Swelling	Absent	149 (99.3)	148 (98.7)	297 (99)	0.99
	Present	1 (0.7)	2 (1.3)	3 (1)	
Wound discharge	Absent	150 (100)	149 (99.3)	299 (99.7)	0.99
	Present	0 (0)	1 (0.7)	1 (0.3)	
Type of discharge	Absent	150 (100)	149 (99.3)	299 (99.7)	0.99
	Serous discharge	0 (0)	1 (0.7)	1 (0.3)	
Wound gape	Absent	149 (99.3)	147 (98)	296 (98.7)	0.622
	Present	1 (0.7)	3 (2)	4 (1.3)	
Fever	Absent	150 (100)	150 (100)	300 (100)	NA
	Present	0 (0)	0 (0)	0 (0)	
Total		150 (100)	150 (100)	300 (100)	

Wound gape was present in one subject of group A, and three subjects of group B (*p* value 0.622) which is not significant. Hence, there was no increased incidence of wound gape in the group that did not receive antibiotics.

None of the study subjects had fever in the 5-day study period in either of the groups.

It was found that the presence of pain by VAS score was significant in the 'no antibiotic' group (*p* value 0.026) but the incidence of pain, redness, swelling, wound discharge and wound gape by Fischer's exact test was not significantly higher in the 'no antibiotic' group as compared to the group which received antibiotics (Table 3).

The three subjects in group B were given a course of rescue antibiotics as per the protocol. The length of hospital stay was the same as the other subjects, and there was no need for readmission or secondary suturing in the subjects who had a wound dehiscence.

On follow-up day 10, wound was healthy in 90.7% subjects, 8.3% were lost to follow-up, and 1% had partially healed wounds.

The three subjects in group B with wound gape on follow-up had partially healed wounds, but superficial gape was still present which was left to heal by secondary intention. One subject in group A who had a superficial wound gape on day 2 of episiotomy was also discharged on day 5 and on follow-up had a healthy wound which had healed (*p* value 0.217) which was not significant. These patients were called for weekly follow-up, and by fourth week of follow-up, they had completely healed wounds (Table 4).

Presence of infection, i.e. presence of any positive finding including redness/pain/swelling/wound discharge or wound gape, was not found to be significantly different between the two groups (*p* value 0.622). Hence, there was no increased incidence of infection in either group, whether antibiotics were given or not (Table 5).

Table 3 Use of VAS score for comparison of pain between groups A and B

Group	N	Mean	SD	SE mean	*p* value by Mann–Whitney U test
VAS score					
A	150	0.81	0.610	0.050	0.026
B	150	0.97	0.618	0.050	

Table 4 Day 10 follow-up status

	Group		Total	*p* value by Chi-square test
	A	B		
Day 10 status				0.217
Subjects lost to follow-up				
Count	13	12	25	
% within group	8.7	8.0	8.3	
Subjects with healthy wounds				
Count	137	135	272	
% within group	91.3	90.0	90.7	
Subjects with partially healed wounds				
Count	0	3	3	
% within group	0.0	2.0	1.0	
Total				
Count	150	150	300	
% within group	100.0	100.0	100.0	

Table 5 Comparison of infection rate between group A and group B

	Group		Total	*p* value by Fischer's exact test
	A	B		
Infection				0.622
No				
Count	149	147	296	
% within group	99.3	98.0	98.7	
Yes				
Count	1	3	4	
% within group	0.7	2.0	1.3	
Total				
Count	150	150	300	
% within group	100.0	100.0	100.0	

The purpose of this study was to evaluate the need for prophylactic antibiotics in an episiotomy wound following normal vaginal delivery in a tertiary care setting.

A study from India showed that over 90% of women giving birth vaginally receive antibiotics before hospital discharge. This includes the use of a wide range of antibiotics (amoxicillin, ampicillin, cephalosporins, fluoroquinolones or a combination of antibiotics), different routes (oral, intramuscular, intravenous) and duration of administration (average of three to four days) [5].

Routine antibiotic prophylaxis is not recommended after an episiotomy or repair of an obstetric laceration. However, infection increases the risk of perineal repair breakdown, particularly for higher-order (third- or fourth-degree) lacerations [6]. Because breakdown of higher-order lacerations may result in incontinence of stool or flatus, sexual dysfunction or rectovaginal fistula, the use of prophylactic antibiotics in this setting has been evaluated.

The Royal College of Obstetricians and Gynaecologists (RCOG) recommends routine prophylaxis owing to the severity of the outcomes following infection [7].

A prospective, randomized, placebo-controlled study was carried out at Santa Clara Valley Medical Centre and Stanford University Medical Centre's Lucile Packard Children's Hospital. The conclusion drawn from this study was that by 2-weeks postpartum, patients who received prophylactic antibiotics at the time of third- or fourth-degree laceration repair had a lower rate of perineal wound complications than patients who received placebo [8].

The American College of Obstetricians and Gynecologists (ACOG) does not recommend universal prophylaxis due to lack of evidence. Advantages of widespread use of prophylactic antibiotics have to be balanced against the disadvantages, such as potential adverse effects for the mother and the baby, including disruption of the normal microbial flora, increased risk of resistant bacterial infections, allergic reactions, as well as increased health costs [9].

A prospective comparative study was carried out in Kasturba Medical College, Manipal University, to evaluate the pattern of antimicrobial agent use in hospital deliveries. Caesarean section and episiotomy were the commonest prophylactic indications. The conclusion drawn from this study was that there was a need for an urgent review on rational use of antimicrobial for prophylaxis and that preference is to prescribe a single antimicrobial agent with a wide spectrum of activity and not a combination of drugs so as to avoid possible adverse reactions, suprainfections and decreased patient compliance [10].

A protocol for review has been recently published in the Cochrane Database of Systematic Reviews whose objective is to assess whether the routine administration of prophylactic antibiotics to women after normal (uncomplicated) vaginal birth, compared with placebo or no antibiotic prophylaxis, reduces post-partum maternal infectious morbidities and improves outcomes [11].

Conclusion

The aim of our study was to compare the incidence of infection in patients of episiotomy with or without the use of prophylactic antibiotics and to compare other morbidities associated with episiotomy and the role of antibiotics in their prevention and treatment.

In our study, it was seen that the use of prophylactic antibiotics did not decrease the incidence of infection in patients of episiotomy following normal vaginal delivery in uncomplicated cases. The morbidities associated with episiotomy were also not found to be increased in subjects who were not given antibiotic prophylaxis. Further studies are required to evaluate this topic and come to a more definitive conclusion.

Compliance with Ethical Standards

Conflict of interest Amrita N Tandon and Asha R. Dalal declare that they have no conflict of interest.

Informed Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as reviewed in 2008.

Human and Animal Rights This article does not contain any studies with animal subjects.

References

1. Smaill F, Hofmeyr GJ. Antibiotic prophylaxis for cesarean section. Cochrane Database Syst Rev. 2002. doi:10.1002/14651858.

2. WHO. Antimicrobial resistance: global report on surveillance. Geneva: WHO; 2014.
3. Hussein J, Mavalankar DV, Sharma S, et al. A review of health system infection control measures in developing countries: what can be learned to reduce maternal mortality. Global Health. 2011;7:14 **(PUBMED: 21595872)**.
4. Tharpe N. Postpregnancy genital tract and wound infections. J Midwifery Women's Health. 2008;53:236–46. doi:10.1016/j.jmwh.2008.01.007.
5. Sharma M, Sanneving L, Mahadik K, et al. Antibiotic prescribing in women during and after delivery in a non-teaching, tertiary care hospital in Ujjain, India: a prospective cross-sectional study. J Pharm Policy Pract. 2013;6:9.
6. American College of Obstetricians and Gynaecology. ACOG practice bulletin. Episiotomy. Clinical management guidelines for obstetrician-gynecologists. Number 71, April 2006. Obstet Gynecol. 2006;107(4):956–62.
7. Fernando RJ, Williams AA, Adams EJ, on behalf of the Guidelines and Audit Committee of the Royal College of Obstetricians and Gynaecologists. The management of third- and fourth-degree perineal tears. London: RCOG; 2007. Green-top guideline No. 29.
8. Buppasiri P, Lumbiganon P, Thinkhamrop J, et al. Antibiotic prophylaxis for third- and fourth-degree perineal tear during vaginal birth. Cochrane Database Syst Rev. 2014;. doi:10.1002/14651858.
9. American College of Obstetricians and Gynecologists. ACOG practice bulletin no. 120: use of prophylactic antibiotics in labor and delivery. Obstet Gynecol. 2011;117(6):1472–83.
10. Adiga MNS, Alwar MC, Pai MRSM, et al.. Pattern of antimicrobial agents use in hospital deliveries: a prospective comparative study. Online J Health Allied Sci. 2009;8(4):10.
11. Bonet M, Ota E, Chibueze CE, et al. Routine antibiotic prophylaxis after normal vaginal birth for reducing maternal infectious morbidity. Cochrane Database Syst Rev. 2016;. doi:10.1002/14651858.CD012137.