A cross-sectional analytical study to evaluate need of prophylactic antimicrobials in patients undergoing normal vaginal delivery with episiotomy before and after implementation of antimicrobial policy

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<u>Abstract</u> Aim - The aim of this study was to evaluate need of prophylactic antimicrobials in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy. Design - This Cross-sectional, Analytical, Observational study was conducted in Obstetric ward of Bharati Vidyapeeth (Deemed to be) University Medical College and Hospital, Sangli, Maharashtra from May 2019 to August 2019. Women admitted in Obstetrics ward and subjected to episiotomy during normal vaginal delivery in this time duration of 4 months were included in the study after obtaining written informed consent. Change in rate of infection in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy was observed. Patients were divided into 2 study groups A and B. Result: - Presence of infection was evaluated by presence of study parameters like redness, pain, swelling, wound discharge, wound gape, fever. Rate of infection in group A subjects was 8% while in group B subjects was 16%. As sample size was small, Fisher's exact test was used to calculate statistic p value. By Fisher's exact test p value was 0.667 which was not significant. Thus, there was neither decrease in rate of infection in patients who were given prophylactic antimicrobials nor increase in rate of infection in patients who were not given any prophylactic antimicrobials. Conclusion: - Objective of our study was to compare change in infection rate in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy. From our study it was concluded that there was neither decrease in infection rate in patients who were given prophylactic antimicrobials nor increase in infection rate in patients who were not given any prophylactic antimicrobials. Key words: Antimicrobials, Antimicrobial resistance, Prophylactic antimicrobials, Normal vaginal delivery, Episiotomy.

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INTRODUCTION

Medicines used to prevent and treat bacterial infections are known as Antimicrobials. When bacteria change in response to the use of these medicines antimicrobial resistance occurs. Antimicrobial resistant bacteria cause infections that are harder to treat than those caused by non-resistant bacteria. Antimicrobial resistance causes increased medical expenses, prolonged stay in hospital, and increases mortality. Antimicrobial resistance will remain a major threat if there are no changes in behaviour. Changes in behaviour includes actions to reduce the spread of infections through vaccination, hand washing, good hygiene¹. Episiotomy is intended incision

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infections around the time of childbirth. Use of antimicrobials for prophylaxis and treatment, is the most common intervention used for preventing morbidity and mortality related to maternal infection. Nowadays in clinical practice it is commonly seen that there is misuse of antimicrobials for obstetric conditions and procedures, thus carries risks of maternal infection. Inappropriate use of antimicrobials among women giving birth has lead to emergence of resistant strains of bacteria which consequently has implications on global health. The WHO global strategy for containment of antimicrobial resistance underscores the importance of appropriate use of antimicrobials at different levels of the health system to reduce the impact of antimicrobial resistance, while ensuring access to the best treatment available⁴. Considerable maternal and perinatal morbidity and mortality may result because of bacterial infections occurring during labour, childbirth and the puerperium.Prophylactic antimicrobials may reduce incidence of wound infection after an episiotomy particularly in conditions which are more prone to develop postpartum perineal infection, like midline episiotomy, extension of the incision5.

AIM

To evaluate need of prophylactic antimicrobials in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy.

OBJECTIVES

- 1. To compare change in infection rate in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy.
- 2. To identify signs of infection in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy.
- 3. To assess risk factors provoking infection.

MATERIALS AND METHODS

This Cross-sectional, Analytical, Observational study was conducted in Obstetric ward of Bharati Vidyapeeth (Deemed to be) University Medical College and Hospital, Sangli, Maharashtra from May 2019 to August 2019. **Study Population** Women admitted in Obstetric ward and subjected to episiotomy during normal vaginal delivery fulfilling the criteria mentioned below were included in the study after obtaining written informed consent and were included in the study after obtaining written informed consent and were divided into two study groups.

Inclusion Criteria

Patients who were given episiotomy during a normal vaginal delivery.

Exclusion Criteria

Patients with systemic diseases like diabetes mellitus, heart disease, tuberculosis, hypertensive disorders of pregnancy, jaundice, liver disorders, and renal diseases.

Methodology

Study was conducted in Obstetric ward of Bharati Vidyapeeth (Deemed to be) University Medical College and Hospital, Sangli, Maharashtra after obtaining approval from Institutional Ethical Committee. All patients who were given episiotomy during a normal vaginal delivery were included in the study after obtaining written informed consent. Patients were divided into 2 groups:

Group A included patients undergoing normal vaginal delivery with episiotomy before implementation of Antimicrobial policy and who were given prophylactic antimicrobials for a duration of 5 days i.e. Capsule Ampiclox 500 mg thrice a day and tablet metronidazole 400 mg thrice a day.

Group B included patients undergoing normal vaginal delivery with episiotomy after implementation of Antimicrobial policy and who were not given any prophylactic antimicrobials. In both group of patients, episiotomy was given under strict aseptic preventive measures. Patients of both groups were given oral analgesics, а combination of diclofenac and serratiopeptidase for 5 days, oral antacid ranitidine and local application of antiseptic agent povidone iodine ointment. Maintenance of local hygiene around episiotomy suture site was taught to the patients. Patients were followed for a period of 5 days after delivery to observe if they developed any signs and symptoms of infection. If patient developed any complications then immediately rescue medications in form of antimicrobials (capsule Ampiclox 500 mg thrice a day and tablet metronidazole 400 mg thrice a day) were given.

Statistical Analysis

Complete Blood Count (CBC) parameters of symptomatic patients of Group A and Group B were compared using paired student t-test. Study parameters were evaluated by Fisher's exact test. Change in infection rate was compared by Fisher's exact test and risk factors provoking infection were also compared by Fisher's exact test.

RESULTS

CBC Parameters	Group	Mean	SD	Ν
Hb	А	11.024	0.923	25
	В	11.34	0.774	25
TLC	А	8180	1743.8	25
	В	7600	1412.74	25
Platelets	А	295760	56427.89	25
	В	341440	46924.66	25

т nts

Hb - Haemoglobin, TLC - Total leucocyte count

Table 1 shows Mean and Standard deviation of CBC Parameters of group A and group B patients on Day 2 after delivery. Mean Hb of group A patients was 11.024 and of group B patients was 11.34, while Mean TLC of group A patients was 8180 and of group B patients was 7600. Mean Platelets of group A patients were 295760 and of group B patients were 341440. After analysis of data, CBC Parameters of symptomatic patients of group A and group B were compared on day 2 and day 4 after delivery (Table 2).

Table 2 Comparison of CBC parameters of symptomatic patients of group A and group B on day 2 and day 4 after delivery

CBC Parameters	Group	Day2		Day4		Significance (p value)
		Mean	SD	Mean	SD	
Hb	А	9.9	0.99	9.6	0.85	0.205
	В	9.975	0.95	9.75	0.79	0.098
TLC	А	10350	1202.08	11800	282.84	0.269
	В	10100	1503.33	11575	590.9	0.076
Platelets	А	312500	10606.6	312500	17677.67	0.99
	В	306000	83940.46	298750	83703.35	0.093

No change was observed in mean CBC values of group A and group B symptomatic patients on day 2 and day 4 using paired student t test. In group A patients p value for Hb was 0.205, for TLC was 0.269 and for platelets was 0.99 which were not statistically significant while in group B patients p value for Hb was 0.098, for TLC was 0.076 and for Platelets was 0.093 which were also not statistically significant. Study parameters were evaluated by Fisher's exact test as sample size was small (Table 3).

Table 3: Evaluation of parameters studied in group A and group B								
Study Parameter	Present/ Absent	Group A N(25)	Group B N(25)	Total	Significance (p value)			
Redness	Present	2	4	6	0.6671			
	Absent	23	21	44				
Pain	Present	1	3	4	0.6092			
	Absent	24	22	46				
Swelling	Present	1	3	4	0.6092			
	Absent	24	22	46				
Wound Discharge	Present	1	3	4	0.6092			
	Absent	24	22	46				
Wound Gape	Present	2	4	6	0.6671			
	Absent	23	21	44				
Fever	Present	1	3	4	0.6092			
	Absent	24	22	46				

Pain, swelling, wound discharge and fever was observed in 1 patient of group A (patients undergoing normal vaginal delivery with episiotomy before implementation of Antimicrobial policy and who were given prophylactic antimicrobials) and in 3 patients of group B (patients undergoing normal vaginal delivery with episiotomy after implementation of Antimicrobial policy and who were not given any prophylactic antimicrobials). p value of these 4 parameters by Fisher's exact test was 0.609 which was not statistically significant. Redness and wound gape was noted in 2 patients of group A and in 4 patients of group B. p value by Fisher's exact test was 0.667 which was not statistically significant.As per protocol 4 patients of group B were given rescue medications immediately as they developed positive findings suggestive of infection.

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 Table 4 Comparison of Infection rate between group A and group B

Infection	Group A N(25)	Group B N(25)	Total	Significance (p value)
Present	2 (8%)	4 (16%)	6	0.6671
Absent	23 (92%)	21(84%)	44	

As seen in Table 4, infection ensued in 2 study subjects out of 25 subjects of group A who were given prophylactic antimicrobials before implementation of Antimicrobial policy while infection ensued in 4 study subjects out of 25 subjects of group B who were not given any prophylactic antimicrobials after implementation of antimicrobial policy. Accordingly infection rate was 8% in group A study subjects while it was 16% in group B study subjects. Fisher's exact test was used for comparing change in infection rate between two study groups. p value was 0.667, which was not significant statistically. Thus infection rate was not increased in either group of patients whether prophylactic antimicrobials were given or not given.

Risk Factor	Infection Present/ Absent	Group A N(25)	Group B N(25)	Total	Significance (p value)
Anaemia	Present	1	2	3	0.226
	Absent	5	1	6	
PROM	Present	0	1	1	0.4
	Absent	3	1	4	
Extension of Episiotomy as 3rd or 4th degree perineal tear	Present	1	1	2	1
	Absent	1	0	1	

Table 5 shows assessment of risk factors provoking infection. Anaemia was present in 1 patient of group A out of 25 patients while it was present in 2 patients of group B out of 25 patients. p value by Fisher's exact test was 0.226 which was not significant statistically. Premature rupture of membranes (PROM) was present in 1 patient of group B while it was not present in any patient of group A. p value by Fisher's exact test was 0.4 which was not significant statistically. Extension of episiotomy as 3rd or 4th degree perineal tear was seen in 1 patient of group A and also in 1 patient of group B. p value by Fisher's exact test was 1 which was statistically insignificant.

DISCUSSION

The goals of this study were to compare change in infection rate and to identify signs of infection in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy and to assess risk factors provoking infection. A similar study was conducted in India at BYL Nair charitable hospital, Mumbai. Aims were to compare incidence of infection in patients of episiotomy with or without use of prophylactic antibiotics and to compare other morbidities associated with episiotomy and the role of antibiotics in their prevention and treatment ⁶.A protocol for review has been recently published in Cochrane Database of Systematic review in which it was concluded that use of antibiotics did not reduce the incidence of urinary tract infections, wound infection or length of maternal hospital stay. Antibiotics are not a substitute for infection prevention and control measures, around the time of childbirth and the postpartum period7. A prospective cohort study was conducted in Department of Gynecology and Obstetrics at central hospital of Yaounde for a period of 6 months. The conclusion drawn from this study was that Antibiotics should not be prescribed for perineal wounds in order to contain the healthcare costs⁸. The Royal College of Obstetricians and Gynaecologists

(RCOG) recommend use of prophylactic antibiotics to reduce the risk of postoperative infections and wound dehiscence⁹. The American College of Obstetricians and Gynecologists (ACOG) recommend that use of antibiotics to prevent infections during the antepartum, intrapartum and postpartum periods is different than the use of antibiotics to treat established infections. Concerns about the emergence of resistant strains of common bacteria in addition to the emergence of strains with increased virulence, have resulted in increased scrutiny of use of antibiotics particularly in hospital setting. Cost is a consideration in the use and choice of prophylactic agents¹⁰.

CONCLUSION

Aim of our study was to evaluate need of prophylactic antimicrobials in patients undergoing normal vaginal delivery with episiotomy, before and after implementation of Antimicrobial policy. From our study it was concluded that there was neither decrease in rate of infection after giving prophylactic antimicrobials nor increase in rate of infection in patients who were not given any prophylactic antimicrobials. So, more research is needed to evaluate this topic to give some firm conclusion.

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