Do we need antibiotic prophylaxis in non-reconstructive breast surgery?

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Abstract

Introduction

Breast surgery is a clean surgery with variation in the reported incidence of surgical site infection (SSI) (2% to 38%) which in higher than expected in a clean surgery. Due to a higher reported incidence of SSI, there are variable protocols regarding the usage of antibiotics. Therefore, the objective of this study was to compare the incidence of infection after breast surgery with or without use of perioperative antibiotics.

Methods

This prospective study included 68 patients who underwent non reconstructive elective breast surgery and were randomized equally into two groups who received or who did not receive perioperative antibiotics. Demographic profile and factors which increase the incidence of SSI were recorded. All patients were followed until the wound healing was complete. SSI was diagnosed based on CDC criteria and wounds were graded according to Southampton wound score.

Results

Mean age, etiology of breast lesions, presence of risk factors and duration of drain kept was comparable among groups. No patient developed SSI in either group according to CDC criteria and developed only minor complications according to Southampton wound score ($p > 0.05$). In addition there was no significant interaction on two way mixed models ANOVA between use of antibiotics and on wound healing (p 0.101).

Conclusions

This study highlights that wound healing is not dependant on the use of perioperative antibiotics. Therefore, rational and effective use of antimicrobial agents for the prevention of SSI in clean breast surgeries will decrease the development of antibiotics related complications, antibiotic resistance and the cost of treatment.

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Introduction

The incidence of surgical site infection (SSI) for breast surgery is much higher (2% to 38%) than the reported incidence of SSI for other clean surgical procedures (3.4%) [1-4]. Prevalence of SSI for modified radical mastectomy has been reported as high as 36% and it has been reported in up to 53% for women who were treated for breast cancer with immediate reconstruction [2-5]. Any patient developing SSI will have delayed wound healing, prolongation of hospital stay, delay in adjuvant treatment, poor patient satisfaction, antibiotic related complications, and also increase in the total cost of treatment.

The prophylactic perioperative antibiotics in both benign and malignant breast diseases have been used in an effort to decrease the incidence of SSI. The beneficial effect of administration of prophylactic antibiotics for reducing the incidence of SSI from 14% to 3.4% in patients undergoing breast and axillary procedure has been demonstrated in various studies and is also recommended by Joint Commission of Surgical Care Improvement Project (SCIP) [6,7]. Current guidelines recommend a single dose of perioperative antibiotic prophylaxis and antibiotics in postoperative period for maximum duration of 24 hrs [8]. However, there are reports where preoperative antibiotics did not decrease the incidence of SSI following breast surgery for both benign or malignant diseases [9,10]. Hence, whether antibiotics decrease SSI following breast surgery is unanswered as SSI can also be decreased by adhering to the principles of asepsis, meticulous surgical technique, control of theatre environment and optimization of patient clinical status before surgery. Therefore, it was decided upon to study the incidence of postoperative wound infection and clinical outcome in patients who underwent elective breast surgery in a tertiary care centre with or without use of perioperative antibiotics.

Methods

A prospective study was carried out in the department of Surgery in a tertiary care centre in North India. Sixty eight patients who underwent non reconstructive elective breast surgery for various indications were included after obtaining ethical clearance from the Institute. Patients were randomized into two equal groups using the sealed envelope method.

Patients in group A were given 2 doses of Inj. Amoxycillin1000 mg + clavulanic acid 200 mg, first dose- 30 min prior to surgery and second dose- 6-8 hours' post-surgery. Patients in group B were not given antibiotics before or after the surgery.

Demographic profiles of each patient and factors which can increase the incidence of SSI were recorded. Smoking status was characterized as non smoker, current smoker, or prior smoker. Body mass index (BMI) at the time of surgery, presence of diabetes, hypothyroidism and corticosteroid use (as tablet, intravenous or inhaler) were also recorded. History of earlier breast cancer-related therapies such as prior breast surgery, neoadjuvant chemotherapy, and radiation therapy to the ipsilateral breast, was also recorded. Laboratory investigations including haemoglobin and serum protein levels were also recorded. Surgery type was defined as excision for phylloides tumor, enucleation for fibroadenoma, unilateral or bilateral mastectomy with or without axillary dissection. Duration for which the drain kept was also recorded in number of days.

All surgeries were performed by the trained surgeons under general anaesthesia following strict aseptic techniques. Wounds were irrigated with normal saline before closure with skin staples or ethilon and thereafter sterile dressing was applied which was removed after 72 hours. Wound status was assessed in outpatient clinic on postoperative day (POD) 3, 5, 7, 10, 14. Patients who had a negative suction drain after total mastectomy +/- axillary clearance; daily drain output was measured. Drain was removed once drain output was < 20 ml for two consecutive days. All patients were followed for 30 days or until the wound healing was complete, whichever was earlier. SSI was diagnosed based on CDC criteria and wounds were graded according to any complication and its extent through Southampton wound score [11,12].

Statistical analysis

All data was analysed by SPSS data processing software (Statistical Package for the Social Sciences, version 26). All quantitative variables were estimated using measures of central location (mean, median) and measures of dispersion (standard deviation and standard error). For normally distributed data, means were compared using Student's T-Test. For skewed data, Mann – Whitney U test was applied. Categorical variables were described as frequencies and proportions. Proportions were compared using Chi square test or Chi square with Yate's correction or Fisher's exact test whichever was applicable. A p value of <0.05 was considered significant. Two way mixed model ANOVA was used to observe if there was any interaction between type of intervention and Southampton healing scores at various points of time after the surgery.

Results

Of 68 patients, 34 patients received antibiotics (group A) and 34 patients did not receive antibiotics (group B). Demographic profile of both groups is shown in Table 1. Both groups were comparable in terms of etiology for which patient underwent breast surgery (Table 1). Also, presence of various risk factors for SSI such as anaemia, diabetes mellitus, hypothyroidism, and receipt of neoadjuvant treatment was comparable among two groups (Table 1).

No patient had preoperative low serum albumin (<3.5 g/dL), history of steroid intake, history of smoking or history of radiation to ipsilateral breast in either group. In group A the mean duration of drain kept after surgery was 7 days while it was 8 days in group B (p=0.34).

SSI comparison in both groups

No patient in either group developed SSI based on CDC guidelines. Based on Southampton wound score, minor complications (grade I&II) were present in 13 patients in group A on POD 3, 5 and 7; and in group B minor complications (grade I&II) were present in 14 patients on POD 3, in 12 patients on POD 5 and in 6 patients on POD 7. However, they were not clinically or statistically significant (Table 2, Figures 1 & 2). Wound healing was comparable among two groups on POD 14 and 30. No patients developed major complications (Grade III, IV, and V) among both groups.

There was no significant interaction on two way mixed model ANOVA between group variables i.e. the type of intervention given by antibiotic or no antibiotic in perioperative period and time after the surgery on post operative day 3, 5, 7, 14 and 30 [$F(2.132)=2.33$, $p=0.101$, $\eta 2=0.o34$]. This indicates that use of perioperative antibiotics is not significantly different when we consider the interaction on wound healing on different post operative days implying that administering or not administering antibiotic does not affect the rate of healing in any way.

Discussion

In this study, none of the 68 patients developed SSI following breast surgery for both benign and malignant indications who received or who did not receive perioperative prophylactic antibiotics. Patients in either group developed only minor complications according to Southampton wound score despite the presence of risk factors among both groups. This was in contrast to the reported SSI rate of 2-38% for clean breast surgeries in various studies [1-4].

Reported high incidence of SSI following breast surgery is usually attributed to the presence of obesity, diabetes, history of receipt of neoadjuvant chemotherapy, previous radiation

Table 1. Demographic profile and risk factors between two groups

Variables	Group A (n=34)	Group B (n=34)	Test of Comparison
Mean Age (years) mean±SD	49.03±11.51	47.79±15.70	t (66) = 0.38, p=0.71
Females (n)	34	33	Fischer's Exact value =01.00
Males (n)	00	01	
Breast lesion aetiology			
a) Infiltrating ductal carcinoma, n (%)	29 (85.30%)	29 (85.30%)	Chi square value (with Yate's Correction) = 0.12, p=0.73
b) Fibroadenoma, n (%)	02 (5.88%)	05 (14.70%)	
c) Intraductal papilloma, n (%)	01 (2.94%)	00	
d) PhyllodesTumor, n (%)	01 (2.94%)	00	
e) BRCA mutation (underwent bilateral prophylactic mastectomy), n (%)	01 (2.94%)	00	
Risk Factors			
a) Diabetes mellitus, n (%)	01 (02.94%)	04 (11.76%)	Fisher's Exact = 0.356
b) Hypothyroidism, n (%)	06 (17.64%)	02 (05.88%)	Fisher's Exact = 00.26
c) Hb (g/dL) median	11.30	11.00	Mann Whitney U Value (-00.92) =504.00, p=0.36
d) Body mass index (Kg/m^2) mean±SD	24.10±03.30	23.27±04.12	Student t value (66) =0.91, p=0.3
e) Neoadjuvant chemotherapy, n (%)	08 (23.50%)	07 (20.60%)	Fisher's Exact Value = 01.00
f) Drain duration (days) Median (IQR)	7.00 (3.00)	8.00 (3.00)	Mann Whitney U test U (0.95) =512.50, p=0.34

Table 2. Southampton wound scores at post-operative day 3, 5 and 7 in both groups

Variable	Group A Median (Interquartile range)	Group B Median (Interquartile range)	Test of comparison (Mann Whitney U test)
Southampton wound score at post operative day 3	00.00 (Q1= 0, Q3= 1.25)	00.00 (Q1= 0, Q3= 2.00)	U (0.49) = 613.00, p=0.63
Southampton wound score at post operative day 5	00.00 (Q1= 0, Q3= 06.00)	00.00(Q1= 0, Q3= 01.75)	U (-0.34) = 524.50, p=0.74
Southampton wound score at post operative day 7	00.00 (Q1= 0, Q3= 4.00)	00.00 (Q1= 0, Q3= 0.00)	U (-01.84) = 460.00, p=0.07

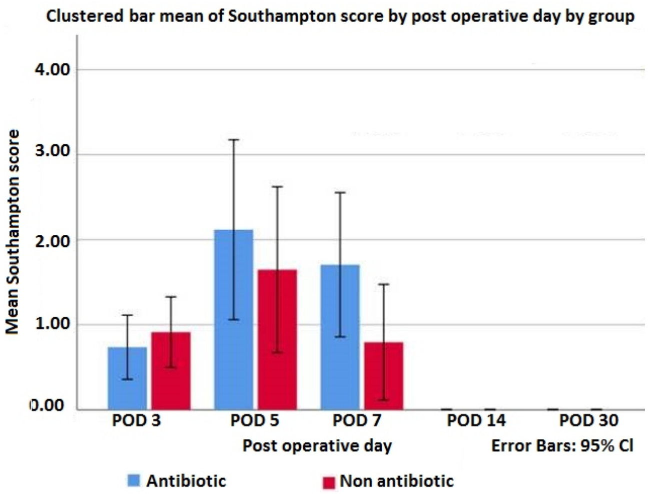

Figure 1. Clustered bar of Southampton score

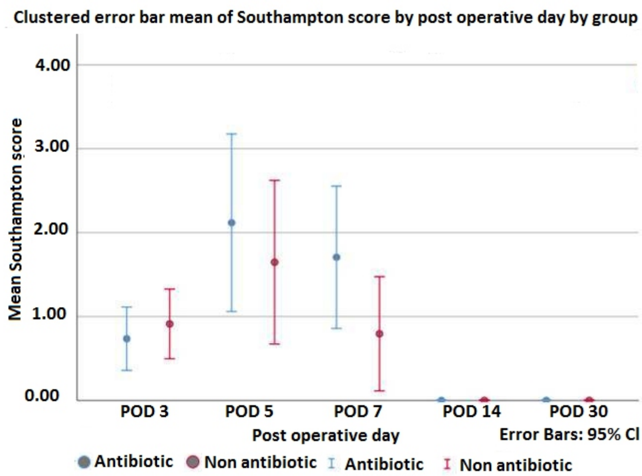

Figure 2. Clustered error bar of Southampton score

exposure, smoking or prolonged duration of drain kept following surgery. Duration of keeping the drainage tube is variable based on the drain output; longer the drain kept, more are the chances of developing bacterial colonization which also increases the incidence of SSI. Felippe et al., in a prospective study on 354 patients reported 17% incidence of SSI among women who were discharged with a drain after breast cancer surgery [3].

Bacterial colonization of the drain was found in 33% and 80.8% on POD 7 and POD 14 respectively; and Staphylococcus aureus was the most commonly isolated organism. SSI was caused by the same bacterial species which was previously isolated from the drainage fluid.

On multivariate regression analyses the authors found that bacterial colonization of the drain along with an age of 50 years and flap necrosis was independently associated with a higher incidence of SSI. It was also reported in the literature that antibiotics are prescribed to the patients till the time drain was removed. Therefore, it is the individual practice which varies among surgeons regarding the duration to continue antibiotics. Antibiotic prophylaxis can be given either perioperatively or as a routine prophylaxis after surgery for 5 to 7 days or till the time drain is present. In the present study, duration of drain kept or presence of risk factors like obesity, diabetes and receipt of neoadjuvant chemotherapy has not affected the outcome or increased the incidence of infection in either group.

In a study conducted by Edward et al., involving 425 breast cancer patients who underwent various non reconstructive breast procedures it was observed that SSI was significantly less likely to develop with administration of postoperative prophylactic antibiotics as compared to those receiving only perioperative antibiotics (3.4% and 14%, respectively) [6]. They reported that patients who were diabetic or obese or had previous radiation or chemotherapy exposure or among cases where the drain stayed for > 14 days were not at risk of SSI; though smoker and elderly females were at increased risk of SSI if they did not receive antibiotic prophylaxis. In the present study none of the patient in either of the group was a smoker and a mean age was 49.03± 11.51 years and 49.03± 11.51 years in groups A and B respectively. Conversely, Crawford et al., concluded in a retrospective analysis that SSI rate did not decrease with and without use of antibiotic prophylaxis; increased risk of SSI was associated with BMI >25 kg/m2[13]. However, in this study relation of BMI with SSI was not detected.

The optimal use of antibiotics in patients undergoing surgery is essentially important as misuse of potent antimicrobial agents may lead to allergic reactions, drug toxicity, super infections with Clostridium difficile, increase in healthcare cost and colonization by highly resistant strains of bacteria [14]. The risks of developing adverse events with drug prophylaxis are more frequently observed with a prolonged course of therapy as compared to a single dose of administered perioperative antibiotic. In congruence to this statement, Throckmorton et al., observed a 0% antibiotic therapy related complications among patients who had received merely a single preoperative antibiotic dose after breast surgery in comparison to 5.5% patients who had received postoperative prophylactic antibiotics [15].

Therefore, prolonged usage of antibiotics should be discouraged until there is a specific clinical indication to continue therapy. The risk of postoperative wound infection is the lowest after clean surgical procedures and prophylactic systemic antibiotics are not indicated for patients undergoing clean surgeries. However, majority of surgeons still use prophylactic antibiotics in clean surgical procedures because of undue fear of infection which prevails in their mind.

It is not only the antibiotics use which prevents SSI; there are other factors which decrease the occurrence of SSI such as aseptic techniques, meticulously performed surgery, operating theatre environment, instruments, and patient's own microbial flora. Skin flora (Streptococcous species, Staphylococcus aureus, Coagulase negative staphylococci) is the main source of SSI in clean surgeries [16]. Poor compliance with infection control practices is a significant cause for SSI; therefore, use of antiseptic techniques in the operating room plays a crucial role. Meticulously performed procedures following aseptic techniques are vital in decreasing the incidence of SSI in clean surgeries.

A small sample size is a limitation of this study. Though, results of the current study cannot influence the current practice but it does suggest a change to the existing clinical practice. A prospective study with larger patient numbers is required to further establish the actual benefit of prophylactic antibiotics in breast surgery which will help to identify the indications for selective antibiotic use.

Conclusion

This study highlights that wound healing was not dependant on the use of perioperative antibiotics. Therefore, rational and effective use of antimicrobial agents for the prevention of SSI in clean breast surgeries will decrease the development of antibiotic related complications, antibiotic resistance and the cost of treatment.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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