DOI: https://doi.org/10.53350/pjmhs020231712843

ORIGINAL ARTICLE

Antibiotics! Does it make a Difference?

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ABSTRACT

Objectives: Breast surgeries are classified as clean surgeries but a higher infection rate of 3-15% is noted due to which prophylactic antibiotic is given before surgery. The aim of study is to determine the role of prophylactic antibiotics in malignant breast surgical cases to help in making local guidelines to prevent inadvertent of antibiotics.

Matrials and Methods: A Quasi Experimental study was conducted in breast unit of Khyber Teaching Hospital, with sample size of 42 in each group. The study was conducted in 6 months, from January 2023 to June 2023 after taking ethical approval from ethical review committee MTI, KTH.

Results: Mean age was comparable between groups (45.18±10.64 vs 49.39±12.02 years; p>0.05). SSI occurred in 13/42 (32.5%) patients without prophylaxis vs 11/42 (25.0%) with prophylaxis (absolute difference 7.5%; p>0.05). Complication severity was similarly low in both arms (Clavien–Dindo 1.23±0.42 vs 1.18±0.45; p>0.05). Although surgical mix differed (BCS 32.5% vs 11.4%; MRM 67.5% vs 88.6% in Groups A vs B, respectively), this did not translate into significant differences in SSI rate or severity.

Conclusions: Routine single-dose pre-operative amoxicillin–clavulanic acid did not significantly reduce SSI or alter complication severity following clean breast cancer surgery. These findings support a selective, risk-based approach to antibiotic prophylaxis alongside rigorous peri-operative asepsis, rather than universal prophylaxis.

Keywords: breast cancer surgery; surgical site infection; antibiotic prophylaxis; amoxicillin–clavulanic acid; quasi-randomized trial; Clavien–Dindo.

INTRODUCTION

Breast cancer is the most common type of cancer in women and is a leading cause of morbidity and mortality worldwide. The survival rate of breast cancer is improving as more cases are treatable now due to enhancement in screening and treatment modalities[1]. The treatment for breast cancer include surgery, chemotherapy, radiation therapy and hormonal therapy with surgery being the common treatment approach. Surgical interventions for breast cancer includes removing whole of breast along with axillary LN to wide excision with axillary LN removal or sentinel lymph node biopsy. Surgery for breast cancer can be done upfront or after receiving neo adjuvant chemo.

The common Post-operative adverse events after breast cancer surgery includes superfacial surgical site Infections, hematoma, flap necrosis and seroma among others, the leading cause has been shown to be SSIs. The potential risks of infection persists as with all other surgeries. It not only reduces the quality of life but also increases the postoperative stay plus it is financial burden to the patient and the hospital[1]. Between 3% and 15% of the breast cancer surgeries are associated with infections[2]. This is a higher rate than the 1-3% for clean surgical procedures[3].

Many factors play an important role in determining the development of post-operative wound infection like hospital and operating room conditions, experience of surgeon and skin antisepsis, Patient's factors also play an important role like advanced age, obesity, immunosuppressive and negative nutritional status, steroid use and recent surgery and blood sugar in diabetes and other comorbidities of the patient[4]. For these high risk groups, antibiotics prophylaxis is generally done but its use has still not shown reduction in the post-operative infection rates in breast surgeries[5].

Though breast surgeries are classified as clean surgeries but due to the higher infection rates than in other clean surgeries, antibiotics prophylaxis is used generally within one hour of incision. To determine the efficacy of antibiotics prophylaxis in breast surgeries, many randomized controlled trials have been conducted but shows conflicting result, some showing benefit but others showing no benefit[6]. National Institute of Health and Clinical Exellence (NICE) recommends that local protocols should be followed in breast cancer surgeries[7].

Recently PAUS trial was conducted in which single dose of prophylactic antibiotic was given at the time of surgery and wound infection rate was determined over the first post-operative month and concluded that there is no benefit of giving prophylactic antibiotics. We intend to conduct this study to determine the role of antibiotic prophylaxis in our unit in breast surgeries malignant and will help us in making local guidelines which will help us in preventing the inadvertent use of antibiotics.

MATERIALS AND METHODS

It's a Quasi experimental study conducted in Breast Unit, Department of Surgery, Khyber Teaching Hospital for 6 months, from January 2023 to June 2023.

Sample size: Sample size would be 42 in each group using 19% in control and 16% in interventional group, 95% confidence interval and 5% margin of error as calculated by WHO sample size calculator. Sampling Technique is consecutive non probability sampling technique.

SAMPLE SELECTION

Inclusion Criteria: Patients with invasive cancer over the age of 20 years were considered. Patients either had breast conserving surgery or Modified radical mastectomy, with either sentinel lymph node biopsy or axillary lymph node dissection.

Exclusion Criteria: Patient's having ulcerative (T4b) mass or history of surgery within past one month or patients allergic to penicillin were excluded.

DATA COLLECTION PROCEDURE: The study will be conducted after due hospital ethical and research board. All patients meeting the inclusion criteria will be admitted and their baseline investigations will be done. After taking informed consent for surgery, the purpose and benefits of the study will be explained to the patients and a separate written consent will be taken for the purpose of this study. The patients who consent to be included in the study will be placed randomly to both groups by lottery method. They would be instructed to stop any oral intake after midnight. Antibiotic would be given at the time of induction. Post-operatively patient will be monitored and after discharge in OPD with follow up at 7, 14 and 21 days.

Received on 28-10-2023
Accepted on 25-12-2023

RESULTS

A total number of 84 patients were included in this trial and were randomly assigned in two groups, group A and group B. Group A was the one which did not received antibiotics prophylaxis and group B received antibiotics prophylaxis. The mean age of patients in Group A (no antibiotic prophylaxis) was 45.18 ± 10.64 years, while in Group B (received pre-operative antibiotic) it was 49.39 ± 12.02 years. This indicates that patients in the antibiotic group were slightly older on average compared to those who did not receive prophylactic antibiotics. The difference in mean age between the two groups was not statistically significant ($p > 0.05$), suggesting that both groups were comparable in terms of age distribution as in table 1.

Out of the 84 patients included in the study, 13 (32.5%) developed postoperative wound infection in the no-antibiotic group (Group A), compared to 11 (25.0%) in the antibiotic group (Group B). Although the infection rate was numerically lower in patients who received prophylactic antibiotics, the difference between the two groups was not statistically significant ($p > 0.05$). The mean Clavien–Dindo score, which classifies the severity of postoperative complications, was 1.23 ± 0.42 in Group A and 1.18 ± 0.45 in Group B. This suggests that most complications were mild (Grade I–II) and that antibiotic prophylaxis did not significantly impact the severity or grading of wound complications.

The Bar chart I shows the observations of wound on each follow up visit and showing maximum patients had dry, clean wounds in both groups.

Table 1: Comparison of Age, BMI, and ASA Score between Groups A and B

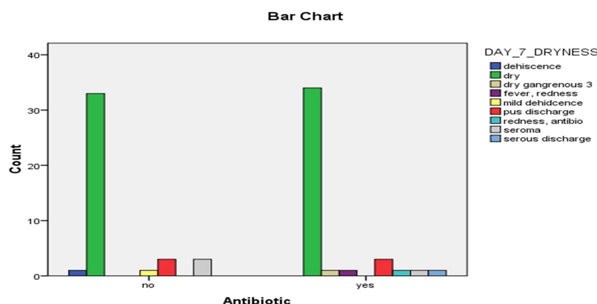
Variable	Group A (No Antibiotic, n=42)	Group B (Antibiotic Given, n=42)
Age (years)	45.18 ± 10.64	49.39 ± 12.02
BMI (kg/m²)	22.07 ± 1.86	21.99 ± 1.82
ASA Score	1.53 ± 0.68	1.34 ± 0.57

Table 2: Comparison of Wound Infection and Clavien–Dindo Score Between Groups

Parameter	Group A (No Antibiotic, n=42)	Group B (Antibiotic Given, n=42)
Number of patients with infection (n)	13	11
Infection Rate (%)	32.5%	25.0%
Mean Clavien–Dindo Score	1.23 ± 0.42	1.18 ± 0.45

Table 3: Distribution of Surgery Type between Antibiotic and Non-Antibiotic Groups

Surgery Type	Group A (No Antibiotic, n=42)	Group B (Antibiotic Given, n=42)
Breast Conserving Surgery (BCS)	13 (32.5%)	5 (11.4%)
Modified Radical Mastectomy (MRM)	27 (67.5%)	39 (88.6%)
Total	40	44



As shown in table 3, in the no-antibiotic group, 13 patients (32.5%) underwent Breast Conserving Surgery (BCS) and 27 (67.5%) underwent Modified Radical Mastectomy (MRM). In contrast, in the antibiotic group, only 5 patients (11.4%) had BCS while 39 (88.6%) underwent MRM. This indicates that a higher proportion of patients in the antibiotic group underwent more extensive procedures (MRM), likely due to a greater number of cases receiving neoadjuvant therapy. Although the surgical distribution differed between the two groups, this variation did not significantly affect overall wound infection rates or complication severity ($p > 0.05$).

DISCUSSION

Despite being labelled as clean surgery, surgical site infection is still regarded as most common complication after breast cancer surgery[8]. For patients with clean-contaminated wounds and contaminated wounds, Pre-operative antibiotics are given but for clean wounds without any additional risk factor, antibiotics are not given but for breast surgeries which are classified as clean surgeries, the infection rate is higher than in other clean surgeries. Post-operative infection can significantly reduce the quality of life but it can also increase financial burden to the patient, hospital and government. The rationale for antibiotic prophylaxis in breast surgery has long been debated, primarily because infection rates in breast cancer surgery cases (3–15%) are significantly higher than those seen in other clean surgical procedures (1–3%) [9, 10].

In this trial of ours, the administration of a single pre-operative dose of amoxicillin–clavulanic acid at induction was evaluated for its efficacy in preventing post-operative wound infection. The study outcomes showed no statistically significant difference in infection rates between the antibiotic and non-antibiotic groups, which is consistent with several previously published trials and meta-analysis. The PAUS trial and the Cochrane review by Jones et al. (2014) both concluded that routine prophylactic antibiotic administration does not substantially reduce SSI incidence in breast surgery patients[11, 12]. These findings collectively suggest that antibiotic prophylaxis may not be universally necessary in clean breast procedures.

Several explanations exist for this lack of observed benefit. First, the bacterial load in clean breast surgeries is typically minimal because of proper aseptic techniques, limited contamination, and effective preoperative skin preparation. Second, most postoperative infections are superficial and often occur due to patient-related factors—such as obesity, diabetes, smoking, poor nutritional status, or steroid use—rather than intraoperative contamination alone. Our findings reinforces the need to re-evaluate the antibiotics prophylaxis in breast cancer surgery.

In our trial, patients who underwent surgery after neoadjuvant chemotherapy (NAC) showed a slightly higher infection rate **(**30.6%**)** compared to those who had upfront surgery (27.8%)**.** No infections were observed among patients treated after neoadjuvant hormone therapy (NAHT)**.** However, the difference between NAC and upfront groups was not statistically significant ($p > 0.05$)**,** suggesting that type of preoperative treatment did not significantly influence wound infection risk in this group. Patients are immunocompromised after having Neoadjuvant chemo due to neutropenia and this leads to delayed wound healing and higher chances of infection[13].

Patients with high-risk characteristics—such as those undergoing re-operations, immediate reconstruction with implants, or those with diabetes or immunosuppression—may still benefit from targeted antibiotic coverage. However, indiscriminate use in all patients contributes to antimicrobial resistance, unnecessary cost, and potential side effects without significant clinical gain.

Pestoriza et all, in their study concluded that that smoking, COPD, ASA class severe, BMI >35 kg/m^2, length of stay are associated with increase rate of SSI following breast cancer surgery[14]. In our cohort of patients, most of the patients had ASA Grade I or II, only 6 patients had COPD and length of hospital stay mean was 2.3 days, all these features did not correlate with infection rates between the groups.

While this study was adequately powered, it is limited by its sample size and single-center design, which may affect generalizability. Additionally, only one antibiotic type and dose were evaluated, and the follow-up period was limited to 28 days. Future studies with larger populations and longer follow-up periods could provide more robust evidence and help identify subgroups that might benefit from prophylaxis.

CONCLUSION

In conclusion, our results suggest that routine pre-operative antibiotic prophylaxis may not significantly reduce the incidence of surgical site infection following clean breast cancer surgery. These findings align with international evidence advocating for a more selective, evidence-based approach to antibiotic use. Developing locally adapted infection-control protocols, focusing on high-risk patients, and emphasizing peri-operative asepsis may represent the most rational strategy for improving postoperative outcomes while curbing unnecessary antibiotic exposure.

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This article may be cited as: Wahid A., Ali I. S., Sahar S., Abbas H., Khan M. M., Antibiotics! Does it make a Difference?. Pak J Med Health Sci, 2023;17(12):843-845.