



## PRACTICE OF PRESCRIPTION ANTIBIOTIC PROPHYLAXIS IN HEAD AND NECK TUMOR EXCISION: A RETROSPECTIVE STUDY

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### Abstract:

Since antibiotic prophylaxis standards are frequently not followed, antimicrobial stewardship programmes should focus on improving this area. We looked specifically at clean-contaminated head and neck tumour excision and found that the intervention was linked to altered perioperative prescription and surgical outcomes, including the risk of surgical site infections. One hundred patients who had clean-contaminated head and neck tumour excisions at Mayo Hospital in Pakistan between January 1, 2022, and January 1, 2024 were the subjects of a retrospective analysis. Patients were split into two groups: pre-intervention (before the education campaign) and post-intervention (after it). We examined surgical outcomes, intraoperative and postoperative variables, and patient demographics and illness features. Prior to the intervention, patients were prescribed more topical chloramphenicol ointment ( $P < .000$ ), more oral nystatin ( $P < .001$ ), and longer courses of preventive antibiotics (median [interquartile range],  $P < .000$ ). Following the intervention, the patients exhibited increased incidence of donor site infections ( $P < 0.005$ ) and recipient infections ( $P < .001$ ). Patients received shorter doses of preventive antibiotics, more of the suggested cefazolin-metronidazole regimen, and fewer topical medicines after the information campaign. But there was also a greater incidence of surgical site infections in the patients.

**Keywords:** antibiotics prophylaxis, head and neck, tumor excision, surgical site infection

### INTRODUCTION

Prophylaxis, which can be classified as primary, secondary, or eradication, is the term used to describe the prevention of an infection. The term "primary prophylaxis" describes the defense against an early infection. The prevention of an infection's recurrence or reactivation is known as secondary prophylaxis [1]. The goal of surgical antibiotic prophylaxis guidelines is to strike an optimal balance

between preventing surgical site infections and causing side effects [2] or drug-resistant organism selection [3]. Adherence to guidelines is frequently not at its best. Antimicrobial stewardship programs promote evidence-based prescribing, emphasizing the reduction of unnecessary broad-spectrum antibiotic prescriptions and the limitation of antibiotic duration, the latter of which is frequently especially important for surgical prophylaxis. In order to achieve peak tissue levels at the time of incision, a single dose is advised for the majority of surgical procedures [4]. However, there is a lack of data to support prophylactic regimens for certain surgical operations, thus extrapolation may not be suitable. This leaves open the potential that alternative antibiotics or longer courses of therapy may be more effective for particular surgeries. Specifically, longer-term or wider-spectrum regimens might work better for more intricate and contaminated surgical procedures. Few controlled studies exist to inform the practice of providing perioperative antibiotics to patients having head and neck malignancies removed [5]. In contrast to other less complex surgical procedures in the head and neck or other body areas, these patients frequently undergo complex surgical excision, extensive neck dissection, and free flap reconstruction. Because these procedures involve a breach of the upper airway epithelial barrier and exposure to oral and pharyngeal bacterial flora, they are commonly referred to as clean-contaminated procedures [6]. When it comes to surgical practice and antimicrobial prophylaxis for these surgeries, extended antibiotic courses lasting seven to ten days—or until drain tubes are removed—are typical. The high incidence of surgical site infections (SSI) in this population [7, 8] and the necessity to avoid the serious repercussions of infection, including as delayed wound healing, wound breakdown, creation of fistulas, and flap loss, have influenced this approach. The national guidelines for Australia [9] suggest administering a single intravenous (IV) dosage of cefazolin 2g 60 minutes prior to surgical excision, along with 500 mg of metronidazole up to 120 minutes before to surgical excision. In September 2012, Mayo Hospital in Lahore, Pakistan, launched a focused teaching program with the goal of aligning surgical antibiotic prophylaxis with hospital guidelines, following audits that revealed inadequate adherence to protocols. The intervention included actions at every level of the unit, such as collaborative ward rounds with the antimicrobial stewardship (AMS) and surgical teams, alterations to the resident handbook, and unit presentations to all consultant and resident personnel. It promoted the avoidance of topical antibiotics, the use of shorter antibiotic courses, and the use of more targeted-spectrum antibiotics. We conducted a retrospective analysis to find out if the education campaign affected the prescription of antibiotics during the perioperative period for patients having their head and neck tumors removed, and to look into whether these modifications to perioperative care were linked to alterations in the results of the surgery.

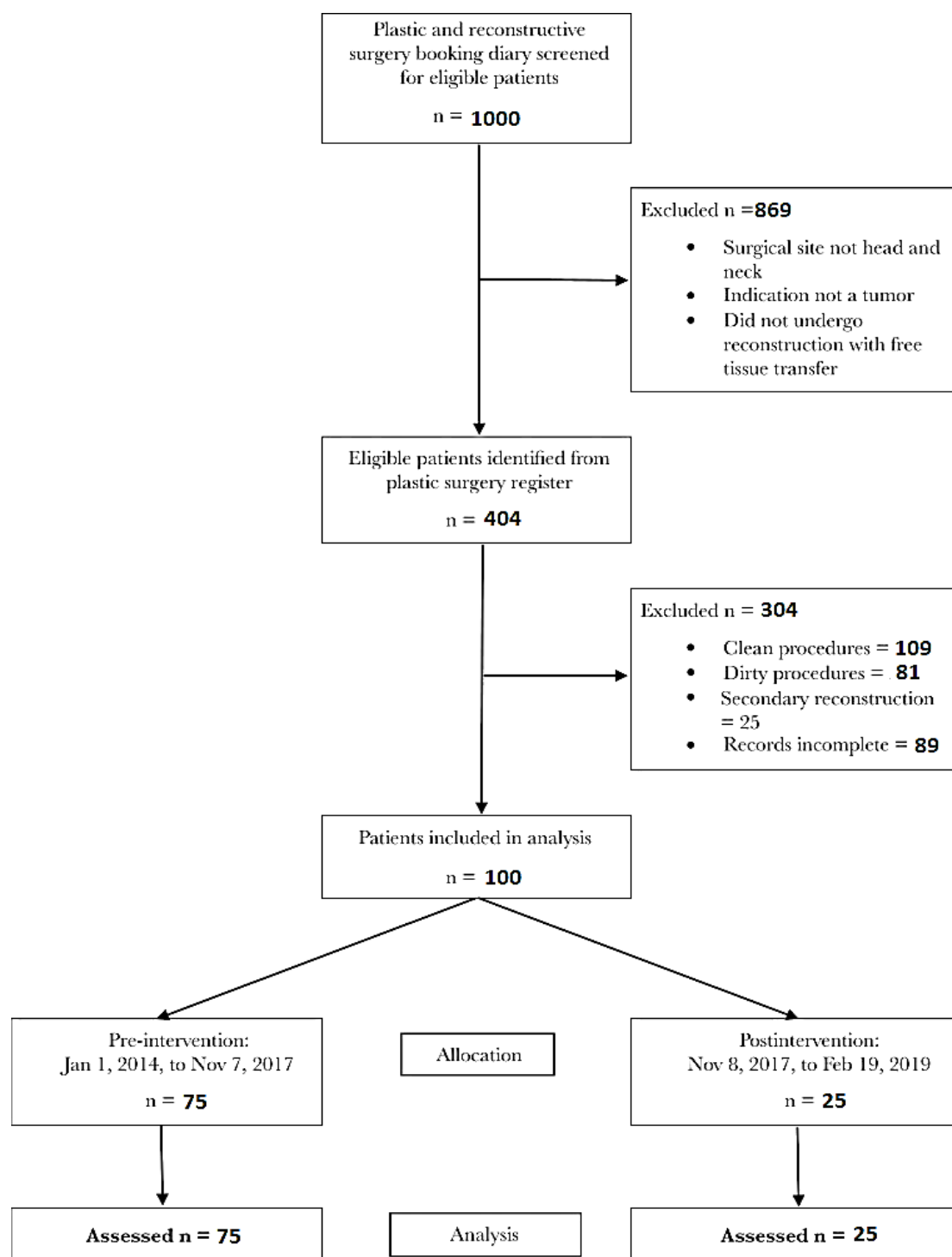
## **METHODS**

Patients who had clean-contaminated [10] head and neck tumour excisions at the Mayo Hospital in Pakistan between January 1, 2022, and January 1, 2024 were the subjects of a retrospective study. The KEMU/Mayo Hospital Ethical Review board in Lahore, Pakistan, gave the study approval. There were no criteria in our study that required patient permission. The department of oral and maxillofacial surgery produced a list of eligible patients. Patients with surgical wounds classified as clean, contaminated, or dirty by the Centres for Disease Prevention and Control (CDC) [10] were not included in our analysis because their rates of surgical site infections (SSIs) differ and their local guidelines [11] recommended different prophylactic antibiotic regimens. Additionally, patients with incomplete or missing medical data (discharge summary, anaesthetic chart, operation report, and medication) or those with secondary reconstruction were not included in our analysis. Three authors methodically retrieved data from both electronic and hard copy medical records. The date on the anaesthetic chart when antibiotics were first administered (as well as when the postoperative antibiotic regimen, which included oral tail) was either stopped, changed to a different antibiotic regimen, or there was a clearly documented change in indication, was used to determine the duration of antibiotic prophylaxis. The length of antibiotic prophylaxis was determined by analysing medication and discharge reports. The intervention promoted the application of national guidelines for perioperative antibiotic prophylaxis [11], which include refraining from topical antimicrobial

prophylaxis such as oral nystatin drops and topical chloramphenicol ointment (unless for incisions near the eyes) and using postoperative antibiotic prophylaxis of cefazolin and metronidazole for up to 24 hours. An alternative suggested to keep wounds wet and promote healing was liquid paraffin. The intervention started and went after every level within the unit. The oral and maxillofacial surgery department's resident staff, consultants and chemists gave a presentation to all of them to kick things off. The resident handbook was revised to include the established policies. At the start of every new resident rotation, residents received the handbook. Throughout the year, junior department members based on wards, an infectious disease physician, and a pharmacist participated in joint ward visits. Individual patient reviews and continuous educational reinforcement of guidelines were conducted. Within 30 days after the procedure, the following surgical outcomes were recorded: length of stay in the hospital, death, return to theatre, nonsurgical site infections (including sepsis, UTIs, and pneumonia), recipient and donor SSIs, and sepsis. Deep SSIs were characterized by the CDC guidelines [12] as those that occurred within 30 days following the surgery and were connected to one or more of the following: Purulent drainage from the deep incision; B) wound dehiscence on its own or a wound intentionally opened by a surgeon; C) an abscess involving the deep incision detected by imaging, histology, or inspection; and D) a surgeon or doctor diagnosing SSI. For instance, even though a patient did not match criteria A, B, or C, they would still meet criterion D if it was noted in their discharge statement that they had a deep SSI or collection. Two authors independently calculated the SSI, which was then reviewed by all authors. When there were questions, all writers discussed the examples and came to a consensus on the classification. Every patient's data field was gathered, but only the first CDC infection criterion that the patient satisfied was recorded; for instance, if a patient satisfied criterion A, it was not specified if they also met the other criteria. Only one author (Sejuti Sarker Tinny) examined the data. With frequency (%) presented, binary and categorical data were compared using the chi-square test. The Mann-Whitney U test was used to compare continuous variables with uneven variance that was provided as median (interquartile range [IQR]). The Student t test was used to compare continuous variables that were given as mean (SD). The Pearson r test was utilised to analyse correlations. Statistical significance was defined as an alpha error of less than 0.05. Version 0.9 of Jamovi was utilised to produce statistical evaluations and statistics [13].

## RESULTS

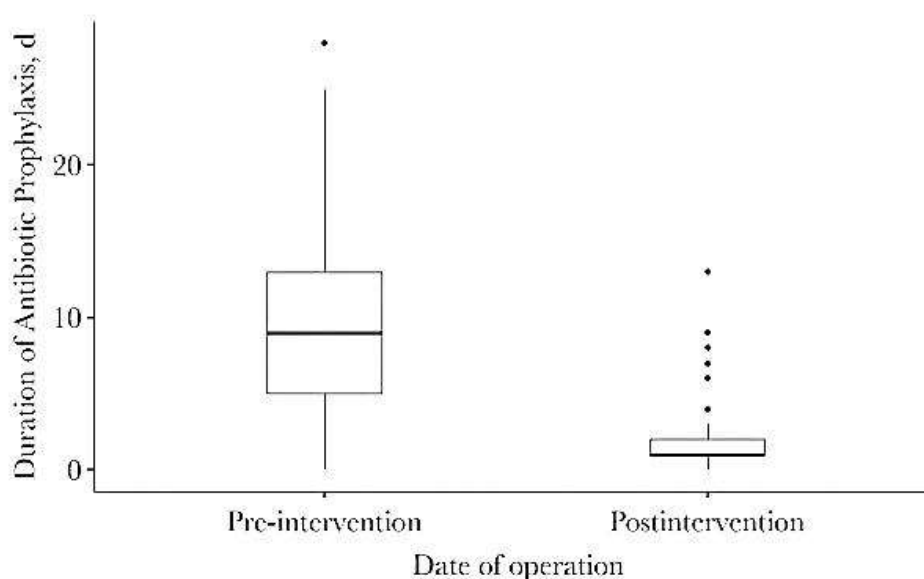
404 of the 1000 procedures that were recorded involved tumours of the head and neck (Figure 1). Of these, 304 surgeries were ignored because the patient was having secondary repair (n = 25), the operative sites were declared clean (n = 109) or polluted (n = 81), or the medical records were insufficient (n = 89). One hundred patients receiving clean-contaminated therapies were included in the statistical analysis. The demographics and disease characteristics of the enrolled people are detailed in Table 1. Due to missing data points, the total number of data entries for each variable is provided. The features of the intraoperative and postoperative periods are shown in Table 2. Data on antibiotic use were obtained in 100 of the patients that were included. The prophylactic antibiotic treatment ranged widely in duration, from 0 to 28 days. The average (standard deviation) duration of antibiotic prophylaxis during the experiment was 7.6 (5.8) days. The length of the prescription period was shown against time (Figure 2).



**Figure 1: The patient screening diagram displays the overall number of charts checked, the total number of patients eliminated at various points during the procedure, and the final count of patients included in the study.**

Based on the dates the education campaign started and the pattern in prescribing that we had seen, we divided into two groups: a pre-intervention group that comprised people who had not yet started the education programme and a post-intervention group that included those who had. Included in this were 25 patients following the intervention and 75 patients before it. Although the patients' demographic and clinical features were identical between the two groups, their tumour stages (T-stages) were considerably more advanced after the intervention. The two groups' mean surgery durations, donor and recipient sites, tracheostomy durations, and recipient drain tube and by mouth durations were comparable; although, patients' post-intervention metalware attachment rates were

higher (45.8%;  $P = .005$ ). Antibiotic prophylaxis varied across the two groups; pre-intervention cefazolin monotherapy was the most common regimen (45.7%), whereas post-intervention cefazolin-metronidazole was the most common regimen (50.6%;  $P < .001$ ). Prior to intervention, the majority of patients were prescribed lengthy courses of antibiotics (median [IQR], 9 [8] days) (Figure 2).



**Figure 2:** A box plot that contrasts the patient medians from before and after the intervention.

Interquartile ranges (IQRs) are represented by boxes, data within 1.5 IQRs of the nearest quartile are represented by whiskers, and single points are considered outliers.

**Table 1: Characteristics of patients**

Characteristic	Total (%) N = 100	Pre-intervention (n= 75)	Post-intervention (n= 25)	<i>P</i> -value
		Total (%)	Total (%)	
<b>Gender</b>				
Male	61.3	59.1	65.1	.004
Female	38.7	40.9	34.9	
<b>America Society of Anesthesiologist (ASA) classes</b>				
Class-I	9.9	9.7	9.9	.030
Class-II	42.1	42.6	39.0	
Class-III	46.4	47.0	49.4	
Class-IV	1.7	1.7	1.7	
Class-V	0.0	0	0.0	
<b>Tobacco use</b>				
Never Use	49.5	48.8	52.1	.661
Previous history	31.1	30.7	32.4	
Current usage	19.4	20.5	15.5	
<b>Diabetes</b>	12.3	13.1	9.6	.341
<b>Other cardiovascular risk factors</b>				
<b>Hypertension</b>	17.8	17.4	19.2	.768
<b>Hypercholesterolemia</b>	5.8	4.4	11.0	
<b>Hypertension and hypercholesterolemia</b>	24.3	26.1	17.8	
<b>Disease type</b>				
<b>SCC</b>	84.6	83.7	87.6	.086
<b>Adenocarcinoma</b>	1.8	1.6	2.8	
<b>Other carcinomas</b>	5.2	5.6	1.4	
<b>Sarcoma</b>	1.8	1.6	2.7	

<b>Melanoma</b>	0.9	0.8	4.1	
<b>Benign</b>	5.5	6.7	1/73 (1.4)	
<b>Tumor stage</b>				
<b>I</b>	18.3	21.9	5.9	.003
<b>II</b>	27.9	30.3	19.6	
<b>III</b>	10.5	7.3	21.6	
<b>IV</b>	43.2	40.4	52.9	
<b>Age at surgery, y No. (Mean [SD])</b>	100(60.4 [14.6])	86 (59.9 [15.0])	25 (62.0 [13.2])	.256
<b>Body mass index, kg/m<sup>2</sup> No. (Mean [SD])</b>	99 (27.1 [6.00])	85 (27.2 [5.9])	25 (26.6 [6.45])	.466
<b>Pre-op albumin No. (Mean [SD])</b>	72 (37.9 [5.46])	43 (37.8 [4.87])	16 (38.0 [7.13])	.665

**Table 2: Intraoperative and Postoperative Features**

Characteristic	Overall	Pre-intervention	Postintervention	P
	Total (%)	Total (%)	No./Total (%)	
<b>Mucosal incision</b>				
Oral cavity	93.8	94.0	93.2	.846
Larynx or pharynx	11.7	11.9	11.0	
Nasal or sinus	2.8	2.8	2.8	
<b>Bony resection</b>				
Nil	25.2	27.0	19.2	.142
Mandible	44.3	43.7	46.6	
Maxilla	10.2	9.9	11.0	
Mandible and maxilla	16.9	17.1	16.4	
Other	3.4	2.4	6.8	
<b>Neck dissection</b>				
Nil	12.9	15.1	5.5	0.321
Unilateral	68.6	66.7	75.3	
Bilateral	18.5	18.3	19.2	
Metalware insertion	44.3	32.5	45.8	.005
Chloramphenicol ointment use	10.2	21.9	0	<.000
Nystatin use	16.9	36.7	12.3	<.001
<b>Intraoperative antibiotic choice (from anesthetic chart)</b>				
Cefazolin monotherapy	45.7	47.9	38.4	<0.011
Cefazolin-metronidazole	50.6	48.0	58.9	
Other	4.0	4.1	2.7	
<b>Postoperative antibiotic choice (from medication chart)</b>				<.001
Cefazolin	47.2	57.2	13.7	
Cefazolin-metronidazole	45.3	34.2	83.6	
Other	7.5	8.6	2.7	
<b>Duration of antibiotic prophylaxis, d</b>	322 (7 [9])	250 (9 [8])	72 (1 [1])	<.000

## DISCUSSION

There was an unanticipated rise in the rate of recipient SSIs despite the fact that the education effort was successful in getting more patients to follow the prescribed regimen of cefazolin and metronidazole, shorter antibiotic courses, and decreased use of topical antimicrobials. Engaging local providers was a remarkable success of the change prescription intervention. Various issues such as professional hierarchy, varying perceptions of risks and anxieties, and a lack of surgeon engagement and accountability have been identified as obstacles to modifying surgical antibiotic prescribing practices [14]. The fact that the intervention was continuous, with joint ward rounds conducted all year long, and that there was extensive interaction with the unit at all levels were two of our study's strongest points. Our study's main conclusion is that auditing results is crucial while making practice changes. It is imperative to provide evidence that a practice modification is both safe and beneficial

in the particular setting. The study's recipient SSI rate increased dramatically following the information campaign, even though it was similar to previous research [15]. This could be due to a number of factors. Initially, following the intervention, patients were having surgery for T-stage tumours, which may have been brought on by better surgical methods that allowed for the surgical management of more advanced instances. They also inserted metalware more frequently, which increases the risk of infection [16]. Second, head and neck reconstruction cases are extensive, involving multiple surgical teams and various opportunities for sterile barriers to be breached. It's possible that the two groups' intraoperative sterile barrier maintenance differed. Lastly, it's possible that prolonged prophylactic antibiotic regimens do indeed guard against SSI. The World Health Organisation [18], the CDC [5], the Scottish Intercollegiate Guidelines Network (SIGN) [19], and the American Society of Health-Systems Pharmacists (ASHP) [17] are among the other guidelines that advise against continuing antibiotic prophylaxis after wound closure in clean-contaminated head and neck surgery, even in the presence of a drain. It has been proposed that guidelines undervalue the complexity of micro-vascular reconstruction in comparison to other head and neck procedures, given the increased risk of SSIs associated with complex head and neck surgery involving micro-vascular reconstruction [20, 21]. Extended antibiotic prophylaxis in head and neck surgery has not been shown to provide any discernible benefits, according to the majority of other trials [22–24]. It is necessary to balance the possible advantages of prolonged antibiotic prophylaxis against the possibility of adverse effects and the development of antibiotic resistance [25, 26]. Antibiotics not only eradicate the bacteria that cause SSIs but also eradicate normal flora, which allows drug-resistant bacteria to proliferate more easily [2]. Multidrug-resistant organism infections have been linked to higher rates of morbidity and mortality, longer hospital stays, and higher medical expenses [27]. Similar to previous research, we discovered that a limited percentage of recipient SSIs were caused by multidrug-resistant pathogens [28, 29]. For this reason, we did not examine how the incidence of multidrug-resistant organisms changed before and after the intervention. Interestingly, the education campaign may have contributed to the decline in patients receiving oral nystatin postintervention, but it's also possible that the longer antibiotic courses changed the oral microbiome and allowed *Candida* to overgrow, which is why oral candidiasis was more common in the pre-intervention group [30]. It is difficult to assess this because there is insufficient documentation regarding the use of nystatin drops as a therapeutic or preventative measure. Antibiotic selection is unlikely to have contributed in any way to the higher risk of SSIs following intervention. Combining cefazolin with metronidazole, which offers extra anaerobic coverage (rate of recipient SSI 9.5% for cefazolin + metronidazole vs 18.6% for cefazolin monotherapy), has been proven to be more successful than cefazolin alone which primarily covers gram-positive aerobes [31, 32]. However, local recommendations and practices vary regarding the type of antibiotic used to prevent surgical site infections (SSIs) during head and neck oncological surgery. As an illustration, the ASHP [12] advises ampicillin-sulbactam or cefazolin for broad-spectrum antibiotic prophylaxis. Similar to this, the SIGN [14] suggests using ampicillin-sulbactam or another broad-spectrum antibacterial cover for both aerobic and anaerobic species. One of the limitations of our study is the lack of documentation regarding the usage of antibiotics. This made determining whether they were being administered as a therapy or as a preventative challenging. As a result, we had to use a standardised technique to calculate the duration of preventive antibiotics after the fact. Nevertheless, we found that prophylactic antibiotics ranged widely from 0 to 28 days. The fact that we had to rely on proper reporting of SSIs in patient documents presents another research restriction. Deep SSI criteria A through C could be evaluated objectively, but criterion D was more arbitrary. The increased number of patients who satisfied criterion D after the intervention may have been explained by the education campaign making doctors more cognizant of infections and improving the reporting of SSIs. Lastly, because our analysis was retrospective in nature, we were unable to take into consideration certain confounders, such as patients' postintervention metalware installation and more advanced tumour stages (T-stages). Thus, it is improbable that this could have contributed to a rise in SSIs after the intervention.

## CONCLUSION

Prophylactic antibiotic use is crucial in reducing SSI in the context of head and neck cancer. Based on available data, cephalosporins appear to be the most effective alternatives. Furthermore, there is no benefit to long-term prophylaxis over short-term prophylaxis. In conclusion, it's critical to administer the proper antibiotic prophylaxis to patients who have been diagnosed as allergic appears to be unsuccessful in this regard. The prophylactic antibiotic prescribing education campaign in the surgical department resulted in shortened prophylactic antibiotic courses, increased adherence to the advised cefazolin and metronidazole regimen, and decreased usage of topical antimicrobials. But there was also a greater incidence of SSIs. A prospective trial is required to evaluate the effectiveness of intraoperative-only regimens compared with protracted regimens because of the disparity between guidelines and actual practice and the paucity of evidence supporting single-dose regimens in difficult head and neck surgery including excision.

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