Role of Prophylactics Antibiotics in Clean Head and Neck Surgery in a Tertiary Care Center of Nepal: A Prospective Comparative Study

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ABSTRACT

Background: Surgical site infections are well recognized complications of any surgical procedures. In head and neck surgeries, prophylactic antibiotics are commonly used to prevent Surgical site infections, in contaminated and clean contaminated procedures. Guidelines advised against routine antibiotics use in clean surgeries, but in our setting, non-compliance is frequent, resulting excessive antibiotics use. Objective of the study was to compare the Surgical site infections rate between prophylactics antibiotics group and no antibiotics group in clean head and neck surgery.

Methods: It was a prospective comparative study conducted at a tertiary care centre of eastern Nepal. Patients were assigned to two groups, one receiving prophylactic antibiotics and another receiving no antibiotics.

Results: Out of 131 patients, 66 received prophylactic antibiotics and 65 did not. Thyroidectomy was the most common surgery. The surgical site infection rate was 6.06% in antibiotic group and 7.69% in no antibiotic group, the difference was not significant (p=0.744). The risk reduction of surgical site infection with use of antibiotics was 0.0163 and number need to treat was calculated to be 61.35 About 3% of the patients who were administered antibiotics experienced adverse drug reactions. Factors, such as gender, amount of blood loss, smoking, placement of drains had no significant impact on Surgical site infections rate.

Conclusions: Prophylactics antibiotics does not offer substantial advantages in preventing surgical site infections and are not advised for such procedures. Moreover, their use increases the financial burden and risk of adverse drug reactions to the patients.

Keywords: Adverse drug reaction; antibiotics; surgical site infections; thyroidectomy.

INTRODUCTION

Head and neck surgeries, like thyroidectomy and parotidectomy, are classified as clean surgery due to the absence of contact with the aerodigestive tract.[1] Surgical site infections (SSI) in head & neck region vary from 3.5% to 87%.[2] While antibiotics are effective in reducing SSI rates in contaminated surgeries, established guidelines discourage their use in clean head and neck surgeries.[3] Despite this, there is widespread non-compliance, with approximately 40% of clean head and neck surgeries receiving prophylactic antibiotics.[4]This trend is more prevalent among Asian surgeons compared to their European counterparts and is particularly pronounced in developing countries.[5] The unnecessary use of antibiotics results in increased costs, adverse drug reactions, and bacterial resistance. This study addresses the lack of literature on clean head and neck surgeries in developing regions, aiming to compare SSI rates between those receiving prophylactic antibiotics and those who do not, ultimately working towards minimizing unnecessary antibiotic use.

METHODS

A prospective comparative study conducted at BP Koirala Institute of Health Sciences (BPKIHS), over a period of 3 years from November 1, 2019, to October 30, 2022, Dharan, Nepal. Ethical approval was granted by Institutional Review Committee (IRC), BPKIHS (IRC/1582/019) before the study commenced. The study included all clean head and neck surgeries patients, but excluded patients with immunocompromised status,

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surgeries lasting over 4 hours, revision surgeries and previously irradiated necks, and intraoperative blood loss exceeding 1000ml.

A sample size of 128 (64 in each arm) was calculated using a power analysis of 80% to detect the 5% level of significance, based on the study done by Shkedy et al.[6] Written informed consent was obtained from all the patients before their participation in the study. Prior to the surgical procedures, a thorough clinical history, an examination of ear, nose and throat and essential diagnostics tests as well as tests for pre anesthetic checkup were systematically performed. Patients were randomly assigned to either the Prophylactic antibiotics group (Group A) or the Control group (Group B) using a lottery method. One of two designated nurse from otolaryngology operating theatre administered a single dose of intravenous cefazolin, 1 gram of antibiotics diluted in 100 ml of normal saline solution 30-60 minutes prior to the commencement of surgical procedures to patients in Groups A, while patients in group B did not receive any prophylactic antibiotics treatment.

The study's independent variables include age, sex, duration of surgery, blood loss, use of antibiotics. Whereas the surgical site infections, duration of hospital stay and adverse drug reactions to antibiotics, rate of readmission to the hospital within a month of surgery were outcome variables. The diagnosis of Surgical site infection was based on the criteria outlined in the Center for Disease Control and Prevention's guidelines for incisional surgical site infection.[7] SSI was defined as the presence of cellulitis or pus drainage requiring treatment with antibiotics.

Data were collected as per the performa. Pre-operative, intra-operative and post operative data up to one month were recorded. Data were entered in the Microsoft Excel 2007 (Microsoft, Redmond, WA, USA) and were analyzed using SPSS (Statistical Package for the Social Sciences) Version 20. The principal investigator periodically assessed the completeness of the data. Descriptive statistics represented as frequency, percentage, mean and standard deviation. An independent t-test was used to compare the mean of the numerical variables, while the Chi-square test and Fisher's exact test were applied to assess the associations between two categorical variables.

RESULTS

Out of the initial 147 patients for the study, 6 patients from antibiotic group and 10 patients from no antibiotic group were lost to follow up and subsequently excluded from the analysis. The final analysis was conducted on a total of 131, with 66 patients in the prophylactic antibiotics group and 65 in the no antibiotics group. Out of total131 patients, 77 patients were female and 54 were male (F:M = 1.42). The mean (SD) age was 39.24 (16.60) years. The mean (SD) age of the patients in antibiotics group was 39.29 (15.81) years and 39.20 (17. 49) years in no antibiotics group. There was no significant difference in baseline characteristics between the groups. (Table 1)

In both the groups, thyroidectomy was the most performed surgery, followed by excision of neck masses and parotidectomy. The category of neck mass excision encompassed procedures such as excision of branchial cysts, branchial sinuses/fistulas, paragangliomas, nerve sheath tumors etc. There was no significant difference between the nature of surgery performed in both the groups. (Table 2).

The mean duration of hospital stay in prophylactics antibiotics group was 2.86(0.97) days while it was 2.83(0.78) days in control group, the difference was not significant (p 0.186). No significant difference was observed between the groups regarding hematoma, seroma, nerve injury, amount of blood loss, drain placed after surgery. In the prophylactic antibiotics group, two patients (3.03%) experienced adverse reactions to the antibiotic, one developed rash in the extremities and another developed diarrhoea. No patients from either group were readmitted to the hospital within one month of discharge. (Table 3)

Four patients from the prophylactic antibiotics group experienced surgical site infections (SSI). Among them, two developed SSI following total thyroidectomy: a 52-year-old male on the 9th postoperative day (POD) and a 47-year-old female with controlled diabetes after 5 days of surgery. Additionally, a 43-year-old male developed SSI on the 8th POD following the excision of branchial cyst, and a 28-year-old female smoker developed SSI on the 3rd day of Sistrunk operation.

Similarly in the no antibiotic group, five patients developed SSI. A 30-year-old female had SSI on the 6th POD after right hemithyroidectomy. Another case involved a 38-year-old male who developed SSI after 8 days of total conservative parotidectomy. Additionally, a 56-year-old female had SSI after 7 days of excision of pleomorphic adenoma submandibular gland. Similarly, a 39-year-old male had SSI on the 4th POD of excision of branchial cyst, and a 41-year-old female had SSI after 11

days of excision of right vagal schwannoma. All patients with SSI were managed conservatively and received oral co-amoxiclav 625 mg three times a day for 7 days; none required further treatment.

The rate of surgical site infection in the antibiotics group was 6.06%, while it was 7.69% in no antibiotic group, the difference was not statistically significant (0.744). The risk reduction of surgical site infection with use of antibiotics was 0.0163 and number need to treat (NNT) was calculated to be 61.35. This implies that, on average, antibiotics would need to be administered to 61 patients to prevent single surgical site infection. (Table 4).

Table 1. Demographic profile of the patients (N=131).

Characteristics	Antibiotic group	No antibiotic group	P value
Gender			
Male	29	25	0.323
Female	37	40	
Mean age (SD) in years	39.29 (15.82)	39.20 (17.49)	0.976
Hypertension			0.446
Yes	20	18	
No	46	47	
Diabetes mellitus			
Yes	8	13	0.161
No	58	52	
Smoking			
Yes	25	23	0.105
No	41	42	
Alcohol			
Yes	21	23	0.402
No	45	42	
Drain			
Yes	34	34	0.662
No	32	31	

Table 2. Type of surgery (N=131).

Type of surgery	Total	Antibiotic Group	No antibiotic Group	P value
Thyroidectomy	50	27	23	0.770
Excision of Neck Mass	33	18	15	
Parotidectomy	26	12	14	
SMG excision	11	4	7	
Neck Dissection	6	2	4	
Sistrunk	5	3	2	

Table 3. Clinical characteristics of the patients. (N=131).

Characteristics	Antibiotic Group	No antibiotic Group	P value
Drain			
Yes	51.5%	47.69%	0.396
No			

Table 3. Clinical characteristics of the patients. (N=131).

Characteristics	Antibiotic Group	No antibiotic Group	P value
Hematoma			
Yes	2	3	0.493
No	64	62	
Mean (SD) Duration of surgery in minutes	132.32 (52.47)	124.94 (58.95)	0.296
Mean (SD) Blood loss in ml.	131.18(43.21)	132.31(59.17)	0.781
Mean (SD) duration of hospital stay in days.	2.86(0.97)	2.83(0.78)	0.186
Nerve injury	6.06%	4.61%	0.613
Seroma	4.54%	4.61%	1.00
Adverse reaction to antibiotics	3.03%	NA	NA

Table 4. Risk factors associated with surgical site infections. (N=131).

Characteristics	SSI	NO SSI	P value
Gender			
Male	7.4%	92.6%	1.00
Female	6.5%	93.5%	
Group			
Antibiotics	6.1%	93.9%	0.744
No Antibiotics	7.7%	92.7%	
Hypertension			
Yes	7.9%	92.1%	0.718
No	6.5%	93.5%	
Diabetes mellitus			
Yes	9.5%	90.5%	0.636
No	6.4%	93.6%	
Smoking			
Yes	11.9%	88.1%	0.145
No	4.5%	9.5%	
Alcohol			
Yes	6.8%	93.2%	1.00
No	6.9%	93.1%	
Drain			
Yes	7.7%	92.3%	0.744
No	6.1%	93.9%	

DISCUSSION

Despite the improved surgical technique, method of asepsis, sterilization, and operative set up, surgical site infection is the major contributing factor of morbidity, mortality and financial burden to patients, family and overall health care system, and is the third most common source of hospital acquired infection.[8]

Though guidelines recommend against the use of antibiotics in clean head and neck surgeries, non-adherence to guidelines is reported up to 40%. This is partly explained using prophylactics antibiotics in circumstances which are not covered by guidelines i.e., radical neck dissection and physician notion of my patient is different from others and needs antibiotics.[3] In most of the centres in Nepal, perioperative antibiotics are still administered for varying duration for clean head and neck surgical procedures. [9,10]

In our study there were a total of 131 patients, 66 patients in prophylactic antibiotics group and 65 patients in no antibiotic group. We had more female patients in the study, the proportion of female to male patient was 1.42:1. The average age of the patients was 39.29 (16.20) years. There were no significant differences between the groups in terms of demographic variables including age, smoking status, and rate of diabetes mellitus, hypertension, and other factors like duration of hospital stay, amount of blood loss, rate of complications and nature of surgeries performed.

Our study included a diverse range of surgical procedures such as thyroidectomy, salivary gland surgeries, excision of neck masses and neck dissection, and thyroidectomy was the most prevalent surgical procedure in both the groups. It is also worth noting that many prior studies primarily focused on thyroid and parathyroid surgeries when analysing SSI in the context of clean head and neck surgeries. [11-15] However, in a study conducted by Chiesa et al parotidectomy was the most frequently performed surgical procedure. [16]

In our study the incidence of surgical site infection was 6.06% in prophylactic antibiotic group and 7.69% in no antibiotic group, and the difference was not statistically significant (p value 0.744). It is noteworthy that the reported incidence of SSI in clean head neck surgery is usually less than 2%. [17] The higher SSI rate observed in our study may be attributed to inclusion of broad spectrum of surgical procedure. Our study was not limited to thyroidectomy, instead encompassed different surgeries including parotidectomy, neck dissection and excision of cyst, sinuses, and fistula. Though parotidectomy is clean surgery, some authors believe retrograde flow of saliva through Stenson duct contaminates the surgical field increasing the risk of SSI and advocate the routine use of prophylactic antibiotics.[6] Meccarielo G et al who included different spectrum of clean head and neck surgeries as our study registered SSI rate similar to our findings, with an SSI Incidence 6.5% in prophylactic antibiotics group and 7.9% in no antibiotic group and the difference was not significant.

Notably, some authors have suggested neck dissection, due to increased tissue exposure may entail a higher risk of SSI. Bergenfelz A et al reported postoperative infection rate of 1.6% in patients undergoing thyroidectomy but 5% in patients undergoing simultaneous neck dissections. [18]

Shkedy et al. found higher incidence of SWI after parotidectomies in female than male.[6] We did not find such difference, however, limited sample size precluded a subgroup analysis to focusing the specific surgical procedures including parotidectomies.

Nutritional status of the patient, presence of comorbidities, older age etc. are patient related factors whereas type and the duration of surgery, method of preoperative skin preparation, appropriate dose and timing of antimicrobial prophylaxis, use of drains , inadequate surgical instruments sterilization techniques , and quality of the operating theatre setup are external risk factors that may contribute to the Rate of SSI.[13,19] Some authors believe smoking, hypothyroidism and hypoalbuminemia increase the rate SSI.[20] In our study we were not able to detect significant differences in the rate of SSI between smokers and non-smoker, as well as patients with drains and those without drains. Additionally, we did not find an association between SSI rate and variables such as amount of blood loss, duration of hospital stays and comorbidities like diabetes mellitus and hypertension.

In the current study two patients developed adverse reactions to the antibiotics which were managed conservatively. In our study the risk reduction of surgical site infection with use of antibiotics was 0.0163 and number need to treat (NNT) was 61.35, which means we have to administer antibiotics in 61 patients to prevent one surgical site infection. Considering the low rate of SSI on one hand, and the potential of adverse events and development of drug-resistant organisms on the other and insignificant risk reduction with antibiotics, we feel routine use of prophylactic antibiotics clean head and neck surgeries is not recommended.

A key finding from our study is to underscore the significance of outcome auditing before implementing the change in practice. The study findings indicate that it is safe to change from conventional use of peri-operative antibiotics to a practice where no antibiotics are administered at all in clean head and neck surgical procedures. This change in practice not only diminishes the unwarranted use of antibiotics but also mitigates

associated financial burden and insurgence of antibiotic resistance.

The strength of the study includes comprehensive inclusion of wide range of head and neck surgeries encompassing thyroidectomy, parotidectomy, neck dissections and excision of cyst, sinuses, and fistulas. We believe our study provides significant value to the published literature with diverse inclusion of surgeries. Moreover, the study was conducted in the tertiary care center of developing nation where the standard practice entails one week of intravenous antibiotics followed by variable duration of oral antibiotics.

A Limitation of the study was relatively small sample size which precludes us from subgroup analysis to find out the effect different variables. Furthermore, we lacked data on variables such as hypothyroidism, hypoalbuminemia, obesity, and malnutrition and could not analyze their potential impact on SSI. However, it is worth noting that both the groups included similar patients profile leading us to conclude that these variables may not significantly alter the incidence of SSI in clean head and neck surgeries.

CONCLUSIONS

Based on the findings of the study, even in the operative set up of developing nations, prophylactics antibiotic does not offer significant advantages in preventing surgical site infections in clean head and neck surgeries. The routine use of antibiotics in such surgeries is not recommended. Additional multicentric studies with adequate sample size and comprehensive subgroup analysis of various risk factors will be helpful to gain the insight of effectiveness of routine antibiotics use in our context.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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