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Antimicrobial Utilization Patterns and Postoperative Outcomes in Otorhinolaryngology: A Prospective Observational Study

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ABSTRACT
Antimicrobial drugs play a crucial role in preventing postoperative infections, particularly in otorhinolaryngology (ENT) surgeries, where the risk of surgical site infections (SSIs) is high. Proper antimicrobial utilization is essential for reducing complications such as prolonged hospital stays and antimicrobial resistance (AMR). This study aimed to evaluate the patterns of antimicrobial drug use in postoperative ENT patients in a government hospital setting, identifying gaps in practice and promoting rational drug use. This prospective, cross-sectional, observational study was conducted over 12 months in the Department of Otorhinolaryngology at a government hospital in India. A total of 300 postoperative patients who underwent ENT surgeries and received antimicrobial therapy were included. Antimicrobial use, co-morbid conditions and adverse drug reactions (ADRs) were recorded. Data were analyzed using descriptive statistics and chi-square tests to assess associations between drug use, patient demographics and clinical outcomes. The most frequently prescribed antimicrobials were Amoxicillin+Clavulanic acid (16.25%), followed by Cephalosporins (26.61%) and Fluoroquinolones (6.72%). Males (57.33%) had a higher overall antimicrobial use compared to females (42.67%). Hypertension (25%) and diabetes mellitus (18.75%) were the most prevalent co-morbidities. Adverse drug reactions were observed in 34% of the patients, with nausea and vomiting being the most common. No significant gender differences in antimicrobial use or ADRs were found. Antimicrobials are widely used in postoperative ENT patients, with penicillin's and cephalosporins being the most common. The study highlights the need for adherence to antimicrobial stewardship programs to minimize inappropriate use and prevent antimicrobial resistance. Optimizing drug selection and duration of therapy can improve patient outcomes and reduce the incidence of ADRs.

INTRODUCTION

Antimicrobial drugs are critical in managing infections, particularly in the postoperative phase, where surgical wounds are vulnerable to microbial invasion. These drugs are routinely used to prevent or treat infections that can complicate recovery after surgeries, especially in the otorhinolaryngology (ENT) department. Postoperative infections can lead to complications such as prolonged hospital stays, increased healthcare costs, and higher mortality rates. Therefore, the proper selection and utilization of antimicrobials are essential to ensuring optimal patient outcomes[1-3].

Antimicrobials refer to agents that kill or inhibit the growth of microorganisms, including bacteria, viruses, fungi, and parasites. The use of antimicrobial drugs in the postoperative period is primarily prophylactic, aiming to prevent surgical site infections (SSIs) by targeting potential pathogens that could enter the body through the surgical wound[4].

Postoperative infections, particularly surgical site infections (SSIs), are one of the most common complications in surgical patients. The development of SSIs involves several factors, including the type of surgery, patient comorbidities and the microbial load at the surgical site. The contamination of surgical wounds by bacteria, such as Staphylococcus aureus, Pseudomonas aeruginosa and Enterococcus species, plays a key role in the pathogenesis of SSIs[5,6]. The use of prophylactic antimicrobials helps to reduce the microbial load, thus minimizing the chances of infection. However, the inappropriate use of these drugs, such as prolonged postoperative use or selection of broad-spectrum antibiotics, can lead to increased antimicrobial resistance, a significant global health concern[7,8].

In the field of otorhinolaryngology, surgeries often involve complex anatomical areas like the ear, nose, and throat, which are naturally colonized by various microorganisms. This makes patients undergoing ENT surgeries particularly susceptible to postoperative infections[9]. Procedures such as tonsillectomy, sinus surgery and laryngectomy carry inherent risks of infections that can be exacerbated by factors like poor immune status or pre-existing conditions[10]. The application of antimicrobials in these cases is essential to prevent infection and ensure successful recovery.

The overuse or misuse of antimicrobial drugs in postoperative patients is a growing concern. The lack of adherence to standard treatment guidelines can lead to unnecessary prolonged therapy, increased healthcare costs and the development of antimicrobial resistance[11]. Evaluating the utilization patterns of these drugs in postoperative patients is crucial to identify gaps in practice and promote rational drug use. This study is particularly important in a government hospital setting, where resources may be limited, and the population served is diverse in terms of health literacy and accessibility[12]. By assessing antimicrobial use in postoperative ENT patients, this study aims to contribute to the optimization of antimicrobial stewardship, which is vital to improving patient outcomes and combating the threat of antimicrobial resistance.

MATERIALS AND METHODS

This prospective, cross-sectional, observational study was conducted over 12 months at the Department of Otorhinolaryngology (ENT) in a government hospital in India. The study aimed to evaluate the utilization patterns of antimicrobial drugs in postoperative ENT patients, comparing prescribing practices with standard treatment guidelines. A total of 300 patients, aged 18 years and above, who underwent various ENT surgeries and received postoperative antimicrobial therapy, were included. Data were collected from patient medical records and recorded in a standardized case report form (CRF) to capture details of antimicrobial use, including drug type, dose, duration, and route of administration, along with any adverse reactions and clinical outcomes.

The study utilized convenience sampling and patients with incomplete medical records or those who did not receive postoperative antimicrobial therapy were excluded. Descriptive and inferential statistics were employed to analyze antimicrobial prescription patterns, co-morbidities and associated clinical outcomes. The appropriateness of antimicrobial use was assessed based on WHO and hospital guidelines, with ethical approval obtained from the Institutional Ethics Committee.

RESULTS AND DISCUSSIONS

This study, which analyzed 300 postoperative patients, examined various aspects such as age distribution, types of surgeries performed, co-morbid conditions, and the utilization of antimicrobial agents (AMAs) and drugs for managing co-morbidities. Below is a detailed summary of the results, including relevant statistical test values to support the findings.

Table 1: Gender wise Age Group Distribution of Patients with Different Surgery

	Patients		
Age group(years)	Male (%) (n=172)	Female (%) (n=128)	Total (%)
<21	22 (12.79)	16 (12.50)	38 (12.67)
21-30	52 (30.23)	34 (26.56)	86 (28.67)
31-40	40 (23.26)	38 (29.69)	78 (26.00)
41-50	30 (17.44)	24 (18.75)	54 (18.00)
>51	28 (16.28)	16 (12.50)	44 (14.67)
Total	172 (100.00)	128 (100.00)	300 (100.00)
Grand Total (%)	57.33	42.67	100
X^2- 2.3016 d.f =4 p= 0.6804			

The age distribution of the patients was similar between males and females, with the most common age group being between 21-30 years (28.67%),

followed by the 31-40 years group (26%) and 41-50 years (18%). Male patients made up 57.33% of the total sample, while female patients constituted 42.67%. The chi-square test performed to assess any significant differences in the age group distribution between genders yielded a chi-square test value (X^2) of 2.3016, with degrees of freedom (d.f.) equal to 4 and a p-value of 0.6804. This indicates that there was no statistically significant difference in the distribution of age groups between male and female patients, suggesting that both genders underwent surgery at similar ages.

Fig. 1: Distribution of Types of Surgery Gender Wise(n=300)

The distribution of types of surgeries showed that tonsillectomy was the most performed surgery, accounting for 29.07% of the total procedures. This was followed by adenoidectomy (23.26%) and tympanoplasty (15.12%). There was a slightly higher prevalence of certain surgeries in males compared to females, particularly mastoidectomy, which was performed in 15.12% of male patients compared to only 6.98% of females, and excision of mass, which was performed in 12.79% of male patients and 5.81% of females. The chi-square test for evaluating the association between gender and the type of surgery performed yielded a chi-square test value (X^2) of 7.6954, with degrees of freedom (d.f.) equal to 8 and a p-value of 0.4637. This indicates that the differences in surgery types between males and females were not statistically significant, suggesting that both genders had a relatively balanced distribution of surgeries.

Table 2: Co-Morbid Conditions in Patients (n=300)

Co-Morbid Conditions	Patients Male (%) (n=66)	Female (%) (n=62)	Total (%) (n=128)
Hypertension (HTN)	14 (21.21)	18 (29.03)	32 (25.00)
Epilepsy	2 (3.03)	2 (3.23)	4 (3.13)
Thyroid	2 (3.03)	6 (9.68)	8 (6.25)
Diabetes Mellitus (DM)	18 (27.27)	6 (9.68)	24 (18.75)
Tuberculosis	2 (3.03)	0 (0.00)	2 (1.56)
Gastritis	8 (12.12)	10 (16.13)	18 (14.06)
Ischemic Heart Disease (IHD)	4 (6.06)	12 (19.35)	16 (12.50)
Others	16 (24.24)	8 (12.90)	24 (18.75)
Total (%)	66 (100.00)	62 (100.00)	128 (100.00)
Grand Total (%)	51.56	48.43	100
t value =2.05, p value=0.312			

Out of the 300 patients, 128 (42.67%) were found to have co-morbid conditions. Hypertension (HTN) was the most prevalent co-morbidity, affecting 32 patients (25%), with a higher incidence in females (29.03%) compared to males (21.21%). Diabetes mellitus (DM) was more common in male patients, affecting 27.27% of males and only 9.68% of females, with a total of 24 cases (18.75%). Other co-morbidities such as gastritis were more evenly distributed, affecting 14.06% of the total population, with a slight female predominance (16.13% in females and 12.12% In males). The chi-square analysis yielded a t-value of 2.05 and a p-value of 0.312, showing no statistically significant difference in the prevalence of co-morbid conditions between genders. This suggests that, despite some gender-based variations in the specific conditions, the overall co-morbidity burden was similar in male and female patients.

A total of 714 antimicrobial agent (AMA) encounters were recorded in the study, with 398 encounters involving male patients (55.73%) and 316 encounters involving female patients (44.27%). The most used AMAs were penicillin's, with Amoxicillin + Clavulanic acid being the most frequently prescribed drug, accounting for 16.25% of the total AMA usage. Levofloxacin (6.72%) and Cefixime (9.52%) were other frequently prescribed drugs, indicating the preference for fluoroquinolones and cephalosporins in postoperative management. Cephalosporins were the most commonly utilized class, comprising 26.61% of the total AMA prescriptions. The statistical analysis showed no significant difference in the distribution of antimicrobial use between males and females, indicating that both genders received a similar range and frequency of AMAs for their postoperative care.

A total of 338 encounters involved the use of drugs for managing co-morbid conditions. The most commonly prescribed drugs were Metformin (6.51%) for managing diabetes and Hydrochlorothiazide (8.28%) for hypertension. There was a fairly even distribution of drug use between males and females, with 160 encounters (47.34%) involving male patients and 178 encounters (52.66%) involving female patients. Other frequently used drugs included Amlodipine (8.28%) for hypertension and Levetiracetam (5.92%) for epilepsy, with the latter being more commonly prescribed to female patients. Overall, there was no significant gender difference in the utilization of drugs for managing co-morbid conditions, suggesting that treatment patterns were similar for both male and female patients.

Table 3: Utilization of AMAs in Postoperative Patients at Government Hospital

S. No	Class of AMAs	Drugs Used	Patients Male (%)	Female (%)	Total Encounters
1	Penicillin's	Amoxycillin	14 (3.52)	8 (2.53)	22 (3.08)
		Amoxycillin +Clavulanic acid	62 (15.58)	54 (17.09)	116 (16.25)
		Ampicillin + Cloxacillin	16 (4.02)	10 (3.16)	26 (3.64)
2	Fluoroquinolones	Ciprofloxacin	12 (3.02)	6 (1.90)	18 (2.52)
		Norfloxacin	2 (0.50)	4 (1.27)	6 (0.84)
		Levofloxacin	26 (6.53)	22 (6.96)	48 (6.72)
3	Nitroimidazoles	Metronidazole	24 (6.03)	16 (5.06)	40 (5.60)
		Ornidazole	10 (2.51)	6 (1.90)	16 (2.24)
4	Tetracycline s	Doxycycline	20 (5.03)	18 (5.70)	38 (5.32)
5	Macrolides	Azithromycin	28 (7.04)	12 (3.80)	40 (5.60)
		Erythromycin	14 (3.52)	22 (6.96)	36 (5.04)
6	Cephalosporins	Cefaclor	18 (4.52)	10 (3.16)	28 (3.92)
		Cefixime	38 (9.55)	30 (9.49)	68 (9.52)
		Cefotaxime	20 (5.03)	16 (5.06)	36 (5.04)
		Cefadroxil	8 (2.01)	6 (1.90)	14 (1.96)
		Cefuroxime	4 (1.01)	2 (0.63)	6 (0.84)
		Ceftriaxone	20 (5.03)	18 (5.70)	38 (5.32)
7	Aminoglycan sides	Gentamicin	6 (1.51)	4 (1.27)	10 (1.40)
		Neomycin	4 (1.01)	0 (0.00)	4 (0.56)
		Amikacin	10 (2.51)	8 (2.53)	18 (2.52)
8	Antifungals	Clotrimazole	12 (3.02)	10 (3.16)	22 (3.08)
9	Others	Chloramphenicol	30 (7.54)	34 (10.76)	64 (8.96)
Total (%)			398 (100.00)	316 (100.00)	714 (100.00)

Table 4: Utilization of Drugs Used for Comorbidity in Post operative Patients at Government hospital

S. No	Class of Drugs	Other concomitant ly Drugs Used	Patients Male (%)	Female (%)	Total Encounters
1	Oral Hypoglycemics	Metformin	14 (8.75)	8 (4.49)	22 (6.51)
		Gliclazide	14 (8.75)	6 (3.37)	20 (5.92)
2	Anti- Hypertensives	Hydrochlorothiazide	18 (11.25)	10 (5.62)	28 (8.28)
		Amlodipine	8 (5.00)	20 (11.24)	28 (8.28)
		Enalapril	8 (5.00)	10 (5.62)	18 (5.33)
		Losartan	4 (2.50)	12 (6.74)	16 (4.73)
3					
	Antiepileptics	Levetiracetam	4 (2.50)	16 (8.99)	20 (5.92)
		Carbamazepine	12 (7.50)	4 (2.25)	16 (4.73)
4	Anti-Thyroid	Levothyroxine	6 (3.75)	12 (6.74)	18 (5.33)
5	Hematinic and Vitamins	Folic acid	10 (6.25)	10 (5.62)	20 (5.92)
		Vit. B6	10 (6.25)	14 (7.87)	24 (7.10)
6	NSAIDs	Paracetamol	8 (5.00)	4 (2.25)	12 (3.55)
		Diclofenac	6 (3.75)	10 (5.62)	16 (4.73)
7	Anti –Anginal	GTN	6 (3.75)	6 (3.37)	12 (3.55)
		IsosorbideMononitrate	2 (1.25)	2 (1.12)	4 (1.18)
8	Others	Sumatriptan	4 (2.50)	4 (2.25)	8 (2.37)
		Omeprazole	2 (1.25)	10 (5.62)	12 (3.55)
		Pantoprazole	8 (5.00)	14 (7.87)	22 (6.51)
		Antitubercular	16 (10.00)	6 (3.37)	22 (6.51)
Total (%)			160 (100.00)	178 (100.00)	338 (100.00)

Fig. 2: ADRsob served with AMAs (n=300)

The adverse drug reactions (ADRs) observed in patients treated with antimicrobial agents (AMAs) at the Government hospital are summarized in Table 6. A total of 102 patients, 42 males (41.18%) and 60 females (58.82%), experienced ADRs. The most reported ADR was nausea and vomiting, observed in 38 patients (37.25%), with a slightly higher incidence in females (33.33%) compared to males (42.86%).

The chi-square test (X^2) value was 6.8762 with 8 degrees of freedom and the p-value was 0.5500, indicating no statistically significant difference in ADRs between male and female patients. Overall, females experienced a slightly higher number of ADRs compared to males, but the distribution across different types of reactions was relatively balanced.

The use of antimicrobial agents (AMAs) in postoperative ENT patients is crucial for preventing surgical site infections (SSIs) and improving recovery outcomes. This study found that penicillins, fluoroquinolones and cephalosporins were the most frequently prescribed antimicrobials, with Amoxicillin+Clavulanic acid being the most common drug (16.25%). These findings are consistent with similar studies in otorhinolaryngology settings, which highlight the widespread use of broad-spectrum antibiotics such as cephalosporins in preventing SSIs due to their effectiveness against a wide range of pathogens. In a study by Sathiya[1] penicillins and cephalosporins were also the most frequently prescribed AMAs, with an emphasis on the need for adherence to standard guidelines to prevent antimicrobial resistance.

The inappropriate use of antimicrobials, including the unnecessary use of broad-spectrum agents and prolonged therapy, remains a significant concern. This study found that although antimicrobial prescriptions were mostly aligned with guidelines, there were instances of extended antibiotic use, which could contribute to the growing issue of antimicrobial resistance (AMR). Research by Khan[2] also found that inappropriate prophylactic antibiotic use, including prolonged postoperative therapy, can lead to resistance and increased healthcare costs. Furthermore, a study by Imamura[3] demonstrated that limiting antimicrobial use to the immediate perioperative period significantly reduces the risk of resistance without compromising patient outcomes .

The study also explored the impact of gender and co-morbidities on antimicrobial use and outcomes. Hypertension and diabetes mellitus were the most prevalent co-morbid conditions, affecting 25% and 18.75% of patients, respectively. Males were more likely to have diabetes, while females had higher rates of hypertension. These findings are consistent with a study by Uchiyama[4] which found that co-morbidities like hypertension and diabetes increase the risk of postoperative infections, thereby necessitating tailored antimicrobial prophylaxis strategies.

In terms of safety, this study reported a 34% incidence of adverse drug reactions (ADRs) related to antimicrobial use, with nausea and vomiting being the most common. Females experienced a slightly higher rate of ADRs than males, although the difference was not statistically significant. A similar pattern was observed in a study by Røder[7] where females exhibited a higher susceptibility to ADRs, particularly gastrointestinal issues, when treated with antimicrobial agents.

Overall, the study underscores the importance of rational antimicrobial use in postoperative ENT patients to prevent SSIs while minimizing the risk of AMR and ADRs. The findings align with those from other studies, highlighting the need for strict adherence to antimicrobial stewardship programs. This is especially critical in government hospital settings where resource constraints can exacerbate the misuse of antibiotics. The study reaffirms the need to optimize antimicrobial prescription practices, including the appropriate selection of drugs, proper dosing and limiting the duration of therapy to reduce the risk of resistance. By tailoring antimicrobial use to patient-specific factors such as gender and co-morbidities, healthcare providers can improve outcomes and minimize complications associated with antibiotic overuse.

CONCLUSIONS

This study highlights the frequent use of cephalosporins and penicillins, particularly Amoxicillin+Clavulanic acid, in postoperative ENT patients. While antimicrobial usage mostly adhered to guidelines, some inappropriate prolonged therapy was observed, raising concerns about antimicrobial resistance (AMR). Adverse drug reactions (ADRs) were common, emphasizing the need for better monitoring. To address these issues, hospitals should enhance antimicrobial stewardship, promote guideline-based prescribing and tailor treatments for patients with co-morbidities. The study's limitations include its single-center design, lack of long-term follow-up and a focus primarily on surgical site infections. Despite these, the findings stress the importance of rational antimicrobial use to prevent AMR and improve outcomes.

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