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ORIGINAL ARTICLE

Comparison of postoperative infection rates by use of single-dose with multiple-doses of prophylactic antibiotics in thyroidectomy.

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ABSTRACT… Objective: To compare the postoperative wound infection rates in thyroidectomy patients receiving single-dose prophylactic antibiotics and multiple-dose regimens. **Study Design:** Prospective, Randomized Controlled Trial. **Setting:** Surgical Ward, Narowal Medical College/DHQ Teaching Hospital, Narowal. **Period:** 1st January 2024 to 31st December 2024. **Methods:** Patients undergoing elective thyroidectomy were randomized divided into two groups: Group A (single-dose) received a single ceftriaxone (1.0 g IV) 30 minutes before incision, and Group B (multiple-dose) received the same initial dose followed by three additional doses every 8 hours for 24 hours after surgery. Postoperative infections were evaluated on days 3, 7, and 30. Statistical analysis was performed using chi-square tests for categorical variables and t-tests for continuous variables. **Results:** A total of 200 patients were enrolled, with 100 in each group. Among them 156 were females and 44 were male with male to female ratio was 78:22 percent (3.54: 1). The overall infection rate was 2% (4/200). Group A had an infection rate of 3% (3/100), while Group B had an infection rate of 1% (1/100), with no statistically significant difference ($p = 0.312$. The cost of antibiotic therapy was significantly lower in Group A ($P < 0.001$). **Conclusion:** Single-dose prophylactic antibiotics are as effective as multiple-dose regimens in preventing postoperative infections in thyroidectomy, and lower costs.

Key words: Multiple-Doses, Postoperative Infection Rate, Prophylactic Antibiotics, Single-Dose, Thyroidectomy.

INTRODUCTION

Thyroidectomy is routinely performed general surgical procedure.[1] Postoperative surgical site infections are potential complications in any surgical procedure, including thyroidectomy.[2] Although thyroidectomy incision wounds are classified as a clean surgical wounds with a relatively lower risk of infection as in clean wounds, the administration of antibiotics has been a standard practice to further minimize this risk of infections after the surgery.[3] Prophylactic antibiotics aims to minimize microbial contamination during surgery and prevent subsequent surgical site infections, which can adversely affect patient outcomes and healthcare costs.[4]

In clean surgeries, despite the routine use of antibiotics, there is no consensus regarding the optimal dose and duration.[5] While single-dose antibiotic prophylaxis is supported by guidelines for many clean surgeries, some clinicians prefer extended antibiotic courses, believing they provide superior protection against infections.[6] This diversity in practice raises concerns about the overuse of antibiotics, potential adverse effects, and increasing cost without substantial evidence of additional benefit.[7]

OBJECTIVES

This study aims to address the postoperative infection rates in thyroidectomy patients who received a single perioperative dose of antibiotics with those who received multiple doses pre- and postoperatively using same antibiotics in all with similar spectrum and bioavailability. Patients according to potential commensals of neck area. This research aims to provide scientific evidence of recommendations for antibiotic

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prophylactic regimen by comparing surgical site infection rates and cost analysis between two groups in thyroidectomy. A better understanding of the efficacy of antibiotics dose regimens will help optimize patient care, reduce unnecessary antibiotic use, and contribute to global efforts against antimicrobial resistance.

METHODS

This prospective randomized controlled study was conducted over a period of one year between 1st January 2024 and 31st December 2024 at department of surgery Narowal medical college/DHQ Teaching hospital Narowal and involved patients undergoing total thyroidectomy for benign or malignant thyroid disease. Written informed consent was obtained from all patients, and the study adhered to the ethical guidelines outlined in the Declaration of Helsinki. Approval from the Institutional Review Board (IRB) was taken prior to study bearing no 349/NMCN dated 10/01/2024. A consecutive sampling method was employed to recruit eligible participants. The sample size was calculated using the formula for comparative studies.. Here = 1.96 for a 95% confidence level and 0.84 for 80% power. Assuming an expected difference of 5% and adjusting for potential attrition, the sample size was finalized at 200 patients.[8]

Patients aged ranging 15–60 years undergoing elective thyroidectomy were selected in inclusion criteria. Exclusion criteria were pre-existing infections, immunosuppression, known allergies to ceftriaxone, and recent antibiotic use (within 7 days prior to surgery). Patients who were unable to give consent were also excluded from study. Among 200 patients of total sample size, 154 were females and 46 were males and all patients were divided in two groups (A and B) by lottery single blind method. Group A (Single-Dose) was administered single dose of ceftriaxone (1.0 g IV) 30 minutes before the surgical incision. While Group B (Multiple-Dose) received ceftriaxone (1.0g IV) 30 minutes before the incision, followed by three doses every 8 hours for 24 hours.

The surgeons and nurses performed a standard preoperative surgical scrub for at least 2–5 min using appropriate antiseptic solutions. The entry of other personnel was restricted inside the operation theatre. All surgeries were performed by same team of surgeons in the same operation theatre with same technique of surgery. The operating surgeon washed and cleaned around the incision site before performing antiseptic skin preparation with an approved agent (povidoneiodine) for 2–5 min. The skin was prepared with an antiseptic antimicrobial preparation in concentric circles from the incision site in three coats. Single drain was placed in all patients and was removed after two days as per routine ward policy. Data was collected on predesigned proforma including patient age, sex, postoperative symptoms and signs, and complications of procedure according to Southampton's criteria (Table-I). Complete history and detailed physical examination of every patient was done pre and postoperatively. All the patients received the same pre and postoperative protocol and the method of closure of thyroidectomy wound was the same by using polypropylene 2/0 interrupted sutures and removed on fifth day postoperatively. Primary outcomes were measured as mainly incidence of surgical site infection (SSI) with standard signs and symptoms of infection like pain, swelling, redness, hot, tenderness within 30 days and secondary outcome variable studied was the cost of antibiotics used in both groups. Adverse events were be reported and managed properly.

Grade 0	Normal healing
Grade 1	Normal healing with mild bruising or erythema
Grade 2	Erythema plus other signs of inflammation
Grade 3	Clear or serous discharge
Grade 4	Pus
Grade 5	Deep or severe wound infection with or without tissue breakdown or hematoma requiring aspiration

Table-I

Southampton criteria+

Analysis

Descriptive statistics summarized baseline characteristics Data was analyzed with statistical

analysis program (IBM-SPSS-version 25). Shapiro wilk test was used to check the normality of data. Chi-square test was used to compare infection rates. P-value < 0.05 was considered statistically significant.

RESULTS

Demographic data of both groups were comparable in terms of age, gender distribution, post-operative infection rates and surgical duration (p > 0.05). (Table-II)

No	Age	Group A	Group B	Total
1	<20	08	06	14
2	21-30	16	20	36
3	31-40	24	24	48
4	41-50	36	38	74
5	51-60	16	12	28
Total		100	100	200

Table-II. Age distribution

The mean age is approximately 38.66 years in Group A and about 38.42 in group B. among total 200 patients,154(77%) were females and 46(23%) were males with a male to female ratio was I:3.35

The overall infection rate was 2% (4/200). Group A reported 3 infections (3%), while Group B reported 1 infection (1%). The difference was not statistically significant (p = 0.312). Table-III

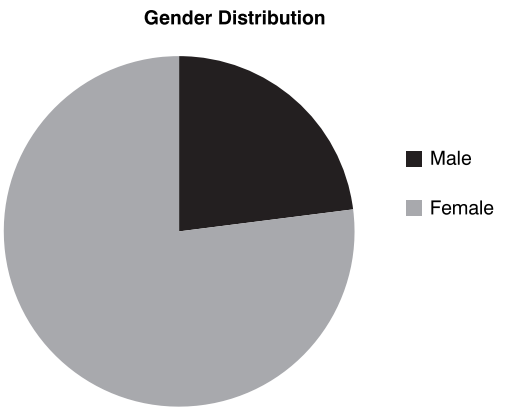

Figure-1

Total Number of Patients	Infection Rate	Group A N=	Percentage	Group B N=	Percentage	P-Value
200	4	3	3%	1	1%	0.312

Table-III. Infection rates

Adverse events related to antibiotics were more frequent in Group B (5% vs. 1%, p = 0.044). The cost of antibiotic therapy was significantly lower in Group A (mean cost Rs380 verses Rs1140, p < 0.001).The mean cost of antibiotics per patient was significantly lower in Group A compared to Group B (p < 0.001).

DISCUSSION

Antibiotics prophylaxis is an established strategy of surgical practice in specific operations to reduce postoperative surgical site infections and improve postoperative recovery.[9]

The findings of this study demonstrated that there is no significant difference in surgical site infection rates between single-dose and multiple-dose antibiotics regimens, this study validate previous evidence suggesting that single-dose antibiotic prophylaxis is sufficient for preventing postoperative infections in clean surgical procedures like thyroidectomy.[10] This reinforces the notion that extended antibiotic administration provides no additional benefit in clean surgeries.[11] Fabio medas ., et al. study supports the use of single-dose antibiotic prophylaxis as a safe and effective method for preventing infections in thyroid surgery.[12] Das s et al. findings describes no significant difference in surgical site infection rates between single and multiple-doses of antibiotic prophylaxis in thyroidectomy.[13] Rao VV., et al found that single-dose antibiotic prophylaxis is sufficient to prevent postoperative infections in thyroidectomy patients.[14] A study by Polistena A. et al supports the use of single-dose antibiotic prophylaxis as a safe and effective method for preventing infections in thyroid surgery.[15] This supports the results of Oliveira G. et al. research indicating that multiple-dose antibiotic prophylaxis does not significantly reduce infection rates compared to a single preoperative dose in thyroidectomy patient.[16] A study by cabuncal et al favor that postoperative antibiotic is not needed

in patients undergoing elective thyroid surgery.[17]

So all these studies favors this study results which is against the routine uses of multiple dose of antibiotics in routine settings. Additionally, the higher rate of adverse events observed in the multiple-dose group is consistent with the findings of Zhang Q who reported increased gastrointestinal disturbances and allergic reactions with prolonged antibiotic use. These adverse effects, though generally mild, can impact patient comfort and satisfaction, further advocating for the use of a single-dose regimen.[18]

Cost-effectiveness analysis in this study also mirrors the observations of Costabella F (2023), who highlighted the economic advantages of single-dose prophylaxis in reducing healthcare expenditure without compromising clinical outcomes.[19] Prophylactic antibiotics is of no use in minimizing the incidence of surgical site infection in thyroid surgery and should be abandoned. It also put negative impact on costs and risk of developing antibiotic resistance. It is particularly relevant in resource-limited settings where minimizing costs and high standards of care is priority.[20]

While this study gives scientific evidence supporting single-dose prophylaxis, it is essential to consider potential limitations, including the relatively small sample size and the single-center design. Future multicenter studies with larger populations are needed to validate these findings and explore the generalizability of single-dose regimens across diverse patient demographics and surgical settings.

CONCLUSION

Single-dose prophylactic antibiotics provide equivalent protection against postoperative infections as multiple-dose regimens in thyroidectomy while reducing adverse events and costs. This study results support and recommend the routine use of single-dose antibiotic prophylaxis in clean surgical procedures such as thyroidectomy and discourage the use of multiple doses of antibiotics.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Muhammad Zafar Mengal:** Study Design, data collection.
2	**Muhammad Najam Iqbal:** Data analysis.
3	**Muhammad Anwar:** Proof reading.
4	**Uzma Shaheen:** Reference writing.
5	**Muhammad Muneeb Saqlain Bajwa:** Methods writing.
6	**Rehan Hameed:** Article writing.