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Preoperative Single Dose Versus Conventional Antibiotic Prophylaxis in Thyroid Surgery

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Abstract:

Background: Surgical Site Infection (SSI) is the most frequent type of Health care-associated infections (HAI) in low- and middle-income countries and affects up to one-third of patients who have undergone a surgical procedure. SSI incidence is the second most frequent type of HAI in Europe and the United States of America.

Objective: This study aimed to compare the frequency of SSIs after thyroid surgeries with preoperative single dose antibiotic and conventional multi doses prophylaxis antibiotic regimens.

Methods: This randomized clinical trial was carried out in the Department of Otolaryngology and Head Neck Surgery, Chittagong Medical College Hospital from January 2020 to March 2021. Eighty-four patients who underwent elective thyroid surgery were randomly assigned into two equal groups of 42 each. They received either a single dose preoperative injectable antibiotic or a conventional antibiotic regimen for seven days. Patients were followed up till the 30th post-operative day to assess postoperative SSI and other complications.

Results: The majority of the patients were female (90%) and in the age group of 30 to 39 years (33%). Both groups were similar in terms of their demographic characteristics. The most common indication of the surgery was nodular goiter and most of the patients underwent hemithyroidectomy. The mean duration of operation was 120 minutes. No SSI or other major complications were observed in this study.

Conclusion: Preoperative single-dose antibiotic is comparable to conventional multi-dose prophylaxis antibiotic regimens in elective thyroid surgery.

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Introduction:

Surgical site infection (SSI) is defined as an infection that occurs within 30 days after surgery in the part of the body where the surgery took place. SSI is the most frequent type of Health care-associated infections (HAI) in low- and middle-income countries and affects up to one-third of patients who have undergone surgical procedures. SSI is the second most frequent type of HAI in Europe and the United States of America[1].

Surgical antibiotic prophylaxis (SAP) refers to the prevention of infectious complications by administering an effective antimicrobial agent before exposure to contamination during surgery[1].

Thyroidectomy is a clean head and neck procedure. With adequate sterilization, postoperative infections are uncommon and the reported incidence of SSI ranges from 0.09% to 1.6% [2,3,4,5].

International guidelines do not routinely recommend SAP after thyroidectomy, since unnecessary courses are often associated with pathogen resistance and superinfection, potential toxicity, increased cost, and hospital stay [6]. Despite these principles, many surgeons in the world routinely use antibiotic prophylaxis in thyroid surgery [7].

In our country, especially in public tertiary care hospitals, almost all surgeons routinely use surgical antibiotic prophylaxis after thyroid surgery. A previous study conducted in our setting demonstrated no difference in the incidence of SSI between routine antibiotic use and no use of antibiotic after thyroid surgery [8].

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In this study, we attempted to emphasize the optimal use of antibiotic prophylaxis. This study will help the surgeons to obviate the need for routine use of SAP.

Materials and Methods:

This randomized clinical trial was carried out in the Department of Otolaryngology and Head Neck Surgery, Chittagong Medical College Hospital, Chattogram from January 2020 to March 2021. The objective of this study was to compare the frequency of SSI after thyroid surgeries with a preoperative single dose antibiotic versus a 7-day antibiotic prophylaxis regimen. All adult patients between 20 and 65 years of age undergoing thyroid surgery during the study period were included in this study. Patients suffering from anaemia, diabetes or any chronic disease were excluded from this study. Patients were selected at random into either Group A or Group B. Group A Patients received a single dose of antibiotic half to 1 hour before surgery (intravenous ceftriaxone 50mg/kg body weight). Group B Patients received a single dose of antibiotic half to one hour before surgery (intravenous Ceftriaxone 50mg/kg body weight) and continued for 7 days (2 days intravenous Ceftriaxone 50mg/kg body weight in divided dose and later oral cefixime, 10mg/kg body weight/day for 5 days). All patients were told to take a bath using soap in the morning on the day of operation. All the necessary aseptic precautions were followed such as using autoclaved gowns, sterile disposable gloves, sterile instruments and drapes. Standard surgical scrub for 5 to 10 minutes using 10% povidone-iodine and 0.5% chlorhexidine gluconate solution was practiced before performing operations. All the procedures were carried out by the consultant surgeons. All wounds were irrigated with normal saline before closure. Drains were used in every case. Mupirocin 2% ointment was used for local application and wounds were closed with a sterile dressing. Wound dressing and drain off were done on the second postoperative day and checked for signs of wound infection. Patients were discharged on the second post-operative day and were followed up on 7th, 14th and 30th day after surgery for evaluation of wound conditions.

Data analysis was performed using the SPSS (Statistical Package for the Social Sciences) software, version 23.0.

Results:

Eighty-four patients were included in the study, 42 in each group. Two patients were dropped out from follow up in Group A. Age of the patient ranged from 20 to 65 years in both groups. The highest number of patients were in the 30-39 years age group (30% in Group A and 35.7% in Group B). Mean (±SD) age was 34.40 (±11.99) years and 35.70 (±11.78) years respectively. Both the groups were similar in terms of mean age distribution (p=0.178). [Table I]

Majority of the patients were female (90% in Group A and 90.5% in Group B). Female: Male ratio was 9:1 in group A and 9.5:1 in Group B. Both the groups were similar in terms of sex distribution (p=0.692) [Table II]. There were no statistical differences in mean BMI of the two groups (p=0.091). [Table III]

Multinodular goiter was the commonest indication in both groups, 47.5% and 59.5% respectively. [Table IV]. Most of the patients in both groups underwent hemithyroidectomy (40% and 45% respectively). [Figure 1].

Mean (±SD) duration of operation was 121.50 (±32.55) minutes and 120.63 (±31.75) minutes respectively from incision to closure. Differences were not statistically significant. (p=0.903). [Figure 2]

Two patients in each group developed temporary voice change in post-operative period. One patient in each group developed temporary hypocalcaemic tetany. [Table V] .There was no SSI in the study in any group [Table VI].

Table-I

Age distribution of the patients.

Age (years)	Group-A(n=40)	Group-B(n=42)	p value
Age groups			
20-29	10 (25%)	12 (28.6%)	
30-39	12 (30%)	15 (35.7%)	
40-49	7 (17.5%)	6 (14.3%)	
50-59	9 (22.5%)	7 (16.7%)	
≥60	2 (5%)	2 (4.8%)	
Mean (±SD)	34.40 (±11.99)	35.70 (±11.78)	0.178
Range	20-65	20-65	

Table-II

Sex distribution of the patients.

Sex Group-A(n=40)	Group-B(n=42)	p value	
Female	36 (90%)	38 (90.5%)	0.692
Male	4 (10%)	4 (9.5%)	

Table-III

BMI of the patients.

BMI, kg/m^2	Group-A(n=40)	Group-B(n=42)	p value
Mean (±SD)	23.23 (±4.57)	21.68 (±3.51)	0.091
Range	16.71-35.21	15.70-28.24	

Table-IV

Indications of operation.

Indications	Group-A(n=40)	Group-B(n=42)	P value
Solitary nodule	18 (45%)	14 (33.3%)	0.520
Multinodular goiter	19 (47.5%)	25 (59.5%)	
Papillary carcinoma	3 (7.5%)	3 (7.2%)	

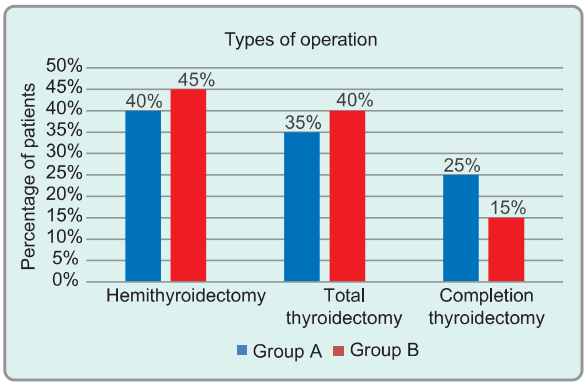

Figure 1: *Types of operation.*

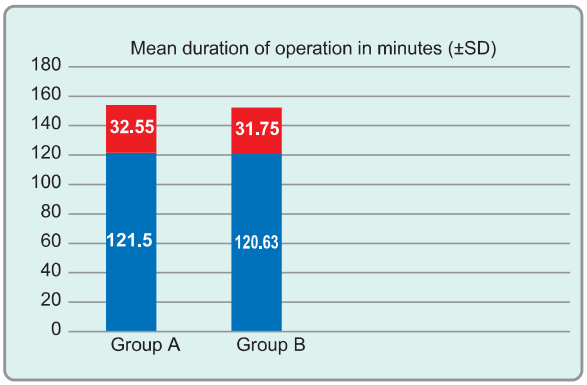

Figure 2: *Comparison of mean duration of operation between two groups*

Table-V

Postoperative complications

Complications	Group-A(n=40)	Group-B(n=42)	P value*
Voice change	2 (5%)	2 (4.8%)	1.0
Respiratory distress	0 (0)	0 (0)	NC
Heamatoma	0 (0)	0 (0)	NC
Hypocalcaemic tetany	1(2.5%)	1 (2.4%)	1.0

NC: Not calculable.

Table-VI

Postoperative complications related to SSI.

Complications	Group-A (n=40)	Group-B (n=42)	P value
Mild redness	3 (7.5%)	3 (7.1%)	1.0
Pain	18 (45%)	23 (54.8%)	0.689
Fever	2 (5%)	2 (4.8%)	1.0
Swelling	0 (0)	0 (0)	NC
Discharge	0 (0)	0 (0)	NC
Wound gap	0 (0)	0 (0)	NC

NC: Not calculable

Discussion

United States Centers for Disease Control and Prevention divided surgical wounds into four classes. Clean- an uninfected operative wound, Clean-contaminated- operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions, Contaminated- open, fresh, accidental wounds, Dirty or infected- old traumatic wounds with retained devitalized tissue or existing clinical infection or perforated viscera [1].

SSI rates with or without antibiotic prophylaxis in four types of wounds are - clean (1-2%, 1-2%); clean–contaminated (3%, 6-9%); contaminated- (6%, 13- 20%); dirty (7%, 40%) [9].

Patient characteristics and comorbidity play an important role in SSI. Coincident remote site infections, diabetes, cigarette smoking, use of systemic steroids, obesity, extremes of age, poor nutritional status, perioperative blood transfusion and prolonged pre and postoperative stay have all been shown to increase the risk of surgical site infection [10].

The routine administration of prophylactic antibiotics is standard in cases where a patient will have an artificial implant or foreign body implanted as part of the procedure, bone grafting procedures, and other surgeries with extensive dissections or expected high blood loss [11]. In the UK and other high-income countries, the use of SAP as a single dose within 1 hour of surgery has become routine practice [12].

Thyroid surgery is considered a clean procedure with a very low incidence of SSIs. In a Japanese prospective randomized trial conducted on antibiotic prophylaxis in thyroid and parathyroid surgery demonstrated that frequency of SSI was 0.09% in antibiotic prophylaxis group and 0.28% in the control group [13]. In another Japanese study incidence of SSI was 0.7%[14]. A study conducted in three medical college hospitals of Dhaka city demonstrated no difference in the incidence of SSI between routine antibiotic use and no use of antibiotics after thyroid surgery [8].

In a systematic review and meta-analysis, antibiotic prophylaxis was not found to be associated with significant prevention of SSI in clean thyroid and parathyroid surgery [15]. Authors in two Indian studies found no differences between routine use of antibiotic prophylaxis and no use of antibiotics [16,17]. In an Italian systematic review and meta-analysis Medas F et al found the incidence of SSI 0.6% in the case group and 0.4% in the control group [18]. In a Greek study, no statistically significant difference was found in patients who received and those who did not receive antibiotics, (0.4% vs 1.4% respectively, p=0.19). The authors also found that older age was the only variable associated with the development of SSIs (p=0.014) [19]. In a Korean study, authors didn't recommend routine use of antibiotic prophylaxis [20]. American Association of Endocrine Surgeons guidelines for the definitive surgical management of thyroid disease in adults didn't recommend SAP for standard transcervical thyroid surgery[21] .

Though international guidelines do not recommend the use of SAP in thyroid and parathyroid surgery, many surgeons in the world use SAP routinely. An international survey showed that the rate of SAP use varied from 8.8% for European surgeons to 27.9% among Americans surgeons and 58.3% by surgeons in Asia [15].

In our country, almost all surgeons traditionally use a single dose of pre-operative intravenous antibiotic followed by five to seven days of postoperative oral antibiotic. In the present study during 30 days from the thyroid surgery, no surgical site infection was observed. Some patients in both groups had few inflammatory signs such as redness in the incision area, pain and a rise of temperature. These might be related to postoperative inflammatory reactions. These reactions were managed with paracetamol and 2% mupirocin ointment.

In the current study, all the patients in both groups were inserted negative suction drain which was removed on the second postoperative day. In clinical practice, it is believed that the use of drains after thyroidectomy represents a risk factor for the development of infective complications. This notion is not supported by clinical data.

The analysis of several continuous moderators, including age, sex, BMI, indication, type, and duration of surgery, did not generate any significant results.

As per the results of the current study, there were no additional benefits in prolonging antibiotic administration. It results in financial burdens and harbors the possibility of antibiotic resistance.

Limitations: There was no control group without antibiotic prophylaxis. The benefit of using prophylactic antibiotic in thyroid surgery could not be determined in this study.

Conclusion: Preoperative single dose antibiotic is comparable to conventional multi doses prophylaxis antibiotic regimen in elective thyroid surgery. Drains did not represent a risk factor for the development of infections. Adherence to aseptic technique is the basic concept to combat postoperative surgical site infection.

Conflict of interest:
We have no conflict of interest to declare

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