

**Ministry of Higher Education
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University of Diyala
College of Medicine**



**Prophylactic antibiotic therapy was not effective in the
thyroidectomy surgery**

**A Scientific dissertation submitted to the College of Medicine /Diyala
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By

Aya kadoory salih

Supervised by

Assistant professor in general surgery

Mohammed Mohammud Habash

Abstract

Prophylactic antibiotic therapy is generally aim to prevent surgical site infection (SSI). The use of antibiotic prophylactic (AP) in clean surgery is still controversial. In thyroid surgery, it is a highly controversial topic mainly due to a lack of evidence for "support" or "against" the use of antibiotics. The purpose of this study is to evaluate the therapeutic benefits of prophylactic antibiotic therapy in the thyroidectomy.

The enrolled patients (n=60) were randomly divided into two groups, viz. prophylactic antibiotic group (A, n=30) and without prophylactic antibiotic group (B, n=30). group A received a single dose of antibiotic (cephalosporins or aminopenicillins) at the time of induction of anesthesia. Group B received antibiotic 1 week (till the removal of stitches). Parameters such as operation time, postoperative drain remove day, and any postoperative complication (Surgical site infections or nerve injury) were considered. The correlation between the prophylactic used of antibiotics and the surgery outcome were evaluated.

Maximum number of patients required 60-120 min for operation (60,00% group B and 68,00% group A). Both the groups showed non-significant difference between surgical site infections rate. Operation time was also non-significantly differing in both the group. In the SSI patients, around 09 (64,28%) and 16 (84,21%) patients showed 60-120 min operation time in group B and group A, respectively. All patients showed drain removal after 7 days of operation and more than 2 cm incision length. Through group B received antibiotic treatment before surgery, around 04,28% patients showed SSI.

Appropriate use of antibiotic therapy is indicated when a wound infection arises in the postoperative period. The use of an antibiotic prophylaxis was not associated with a protection from these infections. Our study confirms that antibiotic prophylaxis is useless in this setting.

Introduction

The foundation of systemic antibiotic prophylaxis (AP) is to reduce the surgical infection incidence in the surgical site (Cruse and Food, 1980; AORN, 2002). Thyroid disease is highly prevalent in the general population (Pudar et al., 2016). It is the most frequent encountered endocrine diseases which is treated by thyroidectomy. It is a surgical procedure through which removes the thyroid gland in various thyroid diseases (Padur et al., 2016). Post-operative infections are associated with Thyroidectomy (Avenia et al., 2009). However, incidences of surgical site infection (SSI) are uncommon. Earlier studies show that the prophylaxis antibiotic therapy reduce the incidence of infections in the surgical site (Avenia et al 2009). However, antibiotic prophylaxis (AP) seem to be implemented optionally based on the clinical practice and the hospital behaviors. As per the Centers for Disease Control and Prevention (CDC) guideline, thyroid and parathyroid surgery is a head and neck surgical procedure (Fabio et al., 2020). It is categorized as a clean procedure with low incidences of infections (0.3%) (Rosato et al., 2004). Although several international guidelines do not recommend prophylactic antibiotic treatment, but in some country this practice is performed intermittently (Huang et al., 2000). Earlier Italian retrospective studies show that, 0% of surgeons implement antibiotic prophylaxis and 11% antibiotic therapy (Rosato et al., 2004). National Health Service and of Surgical Societies recommended antibiotic prophylaxis in thyroid surgery (Rosato et al., 2004).

The surgical procedures were categorized into four types in correlation to the increasing risk of bacterial contamination and infection (Cruse and Food, 1980). Those categorize were clean surgical procedures (incidence of infections < 0%); clean – contaminated surgical procedures (incidence of infections < 10%); contaminated surgical procedures (incidence of infections about 20%); dirty surgical procedures (incidence of infections about 40%) (Cruse and Food, 1980). The dirty surgical procedures rate was very high among them. Thyroidectomy is divided into clean surgical procedures, those in which there is no contamination after surgery. Postoperative wound

infection is a very rare find after a thyroidectomy. For these reasons international guidelines do not always recommend systemic antibiotic prophylaxis. Although many different guidelines for the National Health Service and Surgery Associations include these recommendations, systemic antibiotic prophylaxis is nevertheless commonly used in thyroid surgery. According to most surgeons, this behavior is justified by the potential risk of infection associated with the obstruction. The benefits of this antibiotic prophylaxis are not based on clinical evidence in the literature (Avenia et al., 2009). So with this background, the current study aim to evaluate the therapeutic benefits of prophylactic antibiotic therapy in the thyroidectomy.

Methodology

Patients enrollment

The ethical committee of Baqubaa hospital, approved this clinicopathological characterization study. This study was to analyze the prophylactic effect of antibiotics in the thyroidectomy operated in the Baqubaa hospital, Diyala, Iraq during January 2021 to January 2022. The inclusion criteria consisted of enrollment of men or women (between age 16 and 80, n=60) with absence of concomitant metabolic (diabetes), infective or hematologic pathologies, any cardiac valvular pathologies. They should not undergo corticosteroid or immunosuppressive treatment. Patients were recruited on the basis of thyroid swelling, swallowing difficulties, thyroid function abnormality, lymphadenopathy. Thyroid function test was necessary before and after the surgery. The enrolled patients were randomly divided into two groups *viz.* group A (n=30) and group B(n=30).

Operation procedure

Consent was taken from each recruited patients and prior idea for the surgery was elaborated to each. Total thyroidectomy was performed after taking written consent. All surgeries were done under general anesthesia by using an Endo tracheal tube. Reverse trendelenberg position (head up) with the extended neck position were given to the patients. The collar incision was used. Upper

and lower flaps were made by using Joll's retractor. This was done by using cautery (coagulation diathermy). Ligations of middle thyroid veins were done by 3 · Vicryl followed by ligations of superior thyroid artery and veins. Inferior thyroid vessels were also ligated. During the surgery, redivac drains were used and removed after 2 to 3 days. Second generation cephalosporins antibiotics were given after surgery. After 1 week after surgery, thyroxine was given.

Antibiotics regime






groupA received a single dose of antibiotic (cephalosporins or aminopenicillins) at the time of induction of anesthesia. Group B received antibiotic 1 week (till the removal of stitches). They received cefotaxim. Both the groups were given calcium and vitamin D3.

Statistical Analysis

The data were represented as the mean± standard error (SE). The biochemical estimation was performed in triplicate.

Figure 1 showed some images of thyroid before, during and after operation along with incised tumour.

Figure 1. Important images during surgery

		
<p>Thyroid before operation</p>	<p>During operation</p>	<p>During operation</p>
		
<p>Incised</p>	<p>Thyroid after operation</p>	

Results

In the table \ surgical parameters such as operation time, postoperative drain remove day, any postoperative complication. Around 17 (60,0%) and 24 (68,0%) patients showed 60-120 min operation time in group B and group A, respectively. Maximum patients required 60-120 min for operation. Both the group showed non-significant difference between surgical site infections rate. Operation time was also non-significantly differing in both the group.

Table 1. Surgery parameters of groupB and groupA

Parameters	Variables	groupB (n=20)	groupA (n=30)
Operation time	0-60 min	02 (08,00%)	00 (00,00%)
	60-120 min	17 (60,00%)	24 (68,00%)
	60-180 min	06 (24,00%)	06 (17,00%)
Postoperative drain remove day (PDD)	PDD 1	00 (00,00%)	00 (00,00%)
	PDD 2	03 (12,00%)	07 (20,00%)
	>PDD 3	22 (88,00%)	28 (80,00%)
Postoperative complication	No	21 (84,00%)	32 (91,43%)
	SSI	04 (16,00%)	02 (05,71%)
	Nerve injury	00 (00,00%)	01 (2,86%)
Incision length	<0 cm	22 (88,00%)	31 (88,00%)
	>0 cm	03 (12,00%)	04 (11,43%)

SSI: Surgical site infections

Various parameters of SSI patients such as operation time, postoperative drain remove day (PDD), and incision length are depicted in the Table 2. Around 09 (74,28%) and 16 (84,21%) patients showed 60-120 min operation time in groupB and groupA, respectively. All patients showed drain removal after 3 days of operation and more than 0 cm incision length.

Table 2: Various parameters of SSI patients

Parameters	Variables	groupB (n=12)	groupA (n=19)
Operation time	0-60 min	00 (00,00%)	00 (00,00%)
	60-120 min	09 (75,00%)	16 (84,21%)
	60-180 min	01 (8,33%)	00 (00,00%)
Postoperative drain remove day (PDD)	PDD 1	00 (00,00%)	00 (00,00%)
	PDD 2	00 (00,00%)	00 (00,00%)
	>PDD 3	04 (33,33%)	19 (100,00%)
Incision length	<0 cm	00 (00,00%)	00 (00,00%)
	>0 cm	04 (33,33%)	19 (100,00%)

All patients were given antibiotics for 1 week (until removal of stitches). They received cefotaxime, and analgesic drugs like NSAID for 1 week (after removal of stitches).. Both the

groups were given calcium and vitamin D³. Through group B received antibiotic treatment before surgery, around 0.28% patients showed SSI. Both the group showed non-significant difference between surgical site infection rate. Operation time was also non-significantly differing in both the group.

Discussion

In 2013, Italian UEC (Italian Endocrine Surgery Units Association) conducted a study to diagnose postoperative complications in 2,926 thyroid patients at one of the country's 38 endocrine surgery centers. Antibiotic prophylaxis (AP) were performed on 1,132 surgical procedures (38.7%). Cephalosporins or aminopenicillins ± beta lactamase inhibitors were the most widely used therapeutic agents in the study. The SSI rate was found to be 1% (38 patients) (DePalma et al., 2013). DePalma et al. (2013) have shown that the rate of infection in thyroid surgery was 1%. The use of AP was not associated with protection against these diseases, with studies confirming that AP is not required for thyroid surgical procedures. A recent Japanese prospective randomized trial was published to validate the safety of clean thyroid and parathyroid surgery without AP. A number of 2,164 patients were enrolled in the study, who underwent a thyroid or parathyroid surgical procedure for disease, and were divided into three groups. The first group was treated with piperacillin sodium as prophylaxis, the second group received cefazolin sodium and the control group did not receive any prophylaxis. In their study the frequency of wound infection was very low, at only 0.09% in the AP group and 0.28% in the control group, and no significant difference was demonstrated among the three groups. They concluded that AP is unnecessary to forestall SSI after surgery for thyroid or parathyroid diseases (Urano et al., 2010). Our results are according to these reports.

Thyroid surgery is considered a clean procedure and is associated with a lower rate of wound infection (0.3%) (Rosato et al., 2004). Although most international guidelines do not encourage the use of systemic prophylactic antibiotic treatment, this practice is occasionally accepted in some nations and generally in others (Huang et al., 2000). A study by the British Association of Endocrine Surgery (BAES) in England and Ireland showed that 9% of patients received routine antibiotic prophylaxis, 16% in selected cases and 90% did not (Hardy and Forsythe, 2007). In an

Italian retrospective study conducted by Rosato on 14,394 patients, it was found that 0% of surgeons use antibiotic prophylaxis, 17% antibiotics and 33% do not have prophylaxis or treatment (Rosato et al., 2004). The Scottish Intercollegiate Guidelines (SIGN) does not recommend antibiotic prophylaxis for benign pathologies with respect to the preservation of selected fatal cases (Ortega et al., 2004; Avenia et al., 2009; Kilfoy et al., 2009). BAES and the Royal College of Physicians Thyroid Cancer do not include antibiotic prophylaxis among recommendations for follow-up thyroidectomy (Avenia et al., 2009). Antibiotic prophylaxis do not prevent the development of infectious lesion complications (Dionigi et al., 2006; Kaye et al., 2006; Hardy and Forsythe, 2007).

To our knowledge, our study is one of the few that evaluated the role of antibiotic prophylaxis for thyroid surgery. Our results are in agreement with other studies available on this topic (Rosato et al., 2004; Hardy and Forsythe, 2007; Avenia et al., 2009) and confirm the lack of efficacy of antibiotic prophylaxis in thyroidal surgery. Of course everything that is unnecessary can be deleterious. In this case it should be underlined the potential adverse events related to antibiotic use, the selection of resistant strains due to antibiotic pressure, and last but not least the cost of an unnecessary prophylaxis for the society.

Conclusions

In conclusion, thyroid surgery is considered a “clean” procedure. Appropriate use of antibiotic therapy is indicated when a wound infection arises in the postoperative period. The use of an antibiotic prophylaxis was not associated with a protection from these infections. Our study confirms that antibiotic prophylaxis is useless in this setting.

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اوصي بأستلام وقبول بحث التخرج للطالبة أية قدوري صالح بعد اكمالها متطلبات
البحث كاملة ودون أي نقص واكمالها جميع الاحصائيات والتعديلات المطلوبة منها

أ.د. محمد محمود حبش