

Non-antibiotic prophylaxis in thyroid surgery.

Experience of a single Institution and revision of literature.



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Non-antibiotic prophylaxis in thyroid surgery. Experience of a single Institution and revision of literature.

AIM: To evaluate the incidence of SSI and systemic infectious complications in a consecutive series of patients undergoing thyroid surgery in the absence of prophylactic antibiotic (NO-AP).

METHODS: Prospective observational study including 77 patients who underwent total thyroidectomy and completion of previous hemithyroidectomy in NO-AP. The surgical intervention was performed by surgeons who were experienced in the procedure, and involved the use of Ligasure Harmonic Ethicon®, absorbable hemostat in oxidized regenerated cellulose (Tabotamp®), and skin incision suture device Skin Stapler®. The following risk factors were assessed: gender, age, BMI, alcohol consumption, habitual smoking, co-morbidities, ASA score, indication to surgery, duration of anesthesia and procedure length, type of surgical procedure, fever, white blood cells count, dosage of the pre-operative C Reactive Protein in the five first post-operative day, and histological diagnosis. The data were collected and processed using IBM SPSS software v.23.0.

RESULTS: No factors of increased infectious risk have been identified. No infectious surgical and systemic complications have been reported causes of prolongation of the length of the hospital stay.

Conclusions: Fever, neutrophilic leukocytosis and increased PCR cannot be assessed as predictive factors of infectious complication in thyroid surgery. The cutaneous antiseptics of the operative field with chlorhexidine gluconate, the improvement of the surgical technique, the protection of the cutaneous margins of incision, the use of new devices, the accurate hemostasis and the reduction of surgery time lead to a lack of SSIs and systemic infection complications in all patients undergoing thyroid surgery in NO-AP.

KEY WORDS: Antibiotic prophylaxis, Surgical site infections, Thyroid surgery, Thyroidectomy

Introduction

Surgical site infection (SSI) after thyroid surgery, performed for benign and malignant diseases, represents an

uncommon complication with an incidence reported in the literature between 0.09-2%^{1,2}.

For some authors the antibiotic-prophylaxis (AP) has no effect on the incidence of SSI, and it was extremely low even in patients classified as smokers, diabetics or in patients undergoing chronic steroid therapy^{3,4}. The aim of this study was to evaluate the incidence of SSI and systemic infection complications, in a consecutive series of patients undergoing total thyroidectomy (TT) or completion of previous hemithyroidectomy, without antibiotic-prophylaxis (NON-AP).

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Material and Methods

Prospective observational study conducted at the Surgery Operative Unit of University of Rome "La Sapienza", Faculty of Pharmacy and Surgery, Polo Pontino, "A. Fiorini" Hospital of Terracina.

The study was performed in accordance with the principles of the Helsinki Declaration.

The study included 77 patients, 57 F (average age 57.1 ± 13.9 years \pm ds, range 31-78 years), 20 M (average age 56.8 ± 12.0 years \pm ds, range 30-75 years) enrolled in the period between January 2018 and December 2019, subjected to open TT or completion of previous hemithyroidectomy.

All patients were not treated with AP. The following factors were evaluated: gender, age, BMI, current smoker, alcohol consumption, co-morbidities, ASA score, indication to surgery, cytological examination by ultrasound-guided fine needle aspiration (FNAC), type of surgical procedure, duration of anesthesia and operative time, fever, white blood cells count, dosage of the C Reactive Protein (CRP) pre-operative (pre-op) and in the following post-operative (p.o.) five days, and histological diagnosis.

The study included the following exclusion criteria: ASA Score > III, age < 18 years and > 85 years, antibiotic therapy performed 15 days prior to surgery, psychiatric disorders resulting in poor compliance, history of drug addiction, pregnancy, breastfeeding, refusal to sign off the informed consent form, chronic use of steroids, chemotherapy for malignant disease within 30 days prior to surgery, radiotherapy for malignant disease within 90 days prior to surgery, history of cardiac surgery, severe congestive heart failure, severe chronic obstructive pulmonary disease (COPD), patients in dialysis, and allergy to chlorhexidine. Patients underwent pre-op otolaryngological (ENT) evaluation and fibrolaryngoscopy with a flexible instrument in order to exclude a motor dysfunction of the true vocal cords (TVC).

The study protocol included the antiseptic preparation of the skin of the operating field with chlorhexidine gluconate and maintenance of antiseptic measures for the duration of the surgical procedure. In all cases, careful protection of the edges of the surgical incision was carried out. The surgery was performed under general anesthesia with orotracheal intubation (OTI) by surgeons experienced in the procedure, according to Kocher incision. In all cases, two suction drains were positioned at the end of surgery and removed after 72 hours. The surgical incision was sutured with SkinStapler F-35W device. Patient mobilization took place 6-8 hours after surgery.

For the p.o. analgesia, intravenous infusion of paracetamol 1000mg was used every 8 hours during the first 24 hours, and oral intake of paracetamol 1000g as needed in the following days. Patients were discharged in day III p.o., the metal agraphes removed in day V p.o. and replaced by steri-strips.

During hospitalization and outpatient follow-up at 7 and 30 days any SSIs and systemic infectious complications were assessed. Histological examination (EI) for the diagnosis of thyroid disease was always performed by the same two histologists.

The data was collected and processed using IBM SPSS v.23.0 software.

Results

The demographic and clinical characteristics of the sample are shown in Table I.

The cytological examination by ultrasound-guided needle aspiration (FNAC) was performed in 39 (50.6%) patients, the thyroid disease resulting as presumably benign lesion (TIR2) in 21/39(53.9%) patients, lesion with expected low-medium malignancy risk (TIR3A-B) in 12/39(30.8%) patients and lesion with high suspicion of malignancy and neoplastic lesion (TIR4-5) in 2/39(5.2%) patients.

Pre-op fibrolaryngoscopy showed bilateral TVC edema in 4(5.2%) patients, also associated with adduction deficits.

TT was performed in 72(93.5%) patients and the completion of previous hemithyroidectomy in 5(6.5%) patients. In all cases the indication to surgical treatment was represented by multi-nodular goiter, hyperfunctioning in 19(24.6%) patients, nonfunctioning in 58(75.3%) patients, and endotheracic in 10(12.9%) patients. Central compartment (CC) neck lymphadenectomy was performed by necessity in 11(14.3%) patients.

The duration of anesthesia and operative time were 100 min (range 60-140 min) and 77 min (range 40-125min), respectively. Post-operative hemorrhagic complication has not been described in any patient.

Body temperature rise (range 37-38.5 °C) was recorded in 9(11.7%) patients.

The WBC count (vn 4-10x10³/ul) and the CRP dosage (vn 0-0.5mg/dl) pre-op and in the first five days post-op are reported in Table I.

Histological examination revealed adenoma in 11(14.3%) patients, carcinoma in 7(9.1%) patients, and microcarcinoma in 4(5.2%) patients. Multinodular hyperplasia was present in 55(71.4%) patients and chronic lymphocytic thyroiditis in 22(28.6%) patients.

No SSIs and systemic infections were reported during the hospitalization and follow-up at seven and thirty days.

Discussion

Total thyroidectomy is recognized as a surgical treatment of choice in benign goiter and thyroid neoplasm^{5,6}. SSIs in thyroid surgery are considered serious complications although uncommon⁷.

Unlike what reported in the literature in patients with medical risks from comorbidities, in our study no

TABLE I - Clinical and demographic characteristics of patients

	N° patients(%) - Total 77		N° patients(%) - Total 77
Gender		FNAC	39(51)
M	20 (26)	TIR	
F	57(74)	I	4(10)
		II	21(54)
		III A-B	12(31)
		IV-V	2(5)
Age (years) average± ds range	57.0 ± 13.4 30-78	Surgical Procedures	
		Total Thyroidectomy Completion	72(94) 5(6)
		Central compartment lymphadenectomy	11(14)
Male Age (years) average± ds range	56.8 ± 12 30-75	Duration of Anesthesia (minutes) average± ds range	100 60-140
Female Age (years) average± ds range	57.1±13.9 31-78	Operative time (minutes) average± ds range	77 40-125
BMI		Fever (37-38,5°C)	9(12)
Normal	29(37)		
Overweight	27(35)		
Obese	21(27)		
Current smoker	28(36)	GB >10 [x10 ³ /ul] p.o.day	
		I	39(51)
		II	41(53)
		III	27(35)
		IV	6(8)
		V	11(14)
Alcohol habit	16(21)	PCR >0,5 [mg/dl] p.o. day	
		I	17(81)
		II	16(21)
		III	12(31)
		IV	7(9)
		V	4(10)
Comorbidity		Histological examination	
Hypertension	35(45)	Adenomas	11(14)
Cancer	15(19)	Carcinomas	7(9)
Diabetes mellitus	13(17)	I-PTMC	4(10)
Vasculopathy	12(15)	Hashimoto's thyroiditis	22(29)
mild-moderate COPD	10(13)		
Hepatic disease	7(9)		
Renal disease	6(8)		
Multiple sclerosis	3(4)		
	1(1)		
ASA score			
I	10(13)		
II	56(72)		
III	11(14)		
Indication to surgery			
Multi-nodular goiter	77(100)		
Toxic	19(25)		
Non-toxic	58(75)		
Intrathoracic thyroid	10(13)		

SSIs or systemic infectious complications were observed during hospital stay and follow-up at 7 and 30 days ^{8,9}.

In particular, diabetes mellitus insulin-dependent or non-insulin-dependent, mild-moderate chronic obstructive pulmonary disease (COPD), and the clinical history of malignancies and radio-chemotherapy treatments were not associated with any septic complications.

None of the other factors of increased infectious risk taken into consideration, such as age, gender, smoking, alcohol, BMI, duration of anesthesia and operative time, the histological findings of the thyroid lesion, CC lymphadenectomy, and unilateral or bilateral surgical procedure has been associated with local and/or systemic complications ⁷.

Also the routine positioning of two surgical drains in aspiration did not correlate with the increased incidence of SSIs reported by some authors ⁸⁻¹¹.

In our experience we have submitted all candidates for thyroid surgery to direct flexible fibrolaryngoscopy, considered the gold standard to evaluate the TVC function in thyroid surgery pre- and postoperatively ¹². TVC bilateral edema associated with deficiency of motility in adduction, probably due to habitual cigarette smoking and gastro-esophageal reflux disease (GERD), was the cause of p.o. dysphonia in 4 patients, unrelated to the surgical procedure. However, this condition did not favor the onset of upper respiratory tract infections.

As no SSIs and systemic infectious complications have been reported in this study, fever, increased circulating WBC and CRP cannot be assessed as predictive factors of local and/or systemic infection.

Surgical devices such as the bipolar coagulator, ultrasound instruments, and absorbable local haemostats contribute significantly to reducing intra-operative blood loss and operative time, in addition the skin incision suture device Skin Stapler contributes to the control of ischemic tissue suffering ^{13,14}.

SSIs following thyroidectomy with a clean surgical wounds are considered rare ⁷.

We also believe that preoperative skin preparation and skin decolonization of the operating field with safe and effective antimicrobial agent such as Clorexidina, maintenance of antiseptic measures throughout the surgical procedure, the improvement of sterilization procedures, the accuracy of the surgical technique, the reduced tissue manipulation, together with rapid patient mobilisation and short-term hospitalization contribute significantly to the control of infectious complications ¹⁵.

Similar to another study we conducted on AP in minimally invasive surgery, failure to find SSIs and other infectious complications in the examined sample does not justify the routine prophylactic use of antibiotics in ASA I, II, III patients ¹⁶.

AP should be considered in patients with ASA >3, at high risk of cardio-respiratory complications, with surgery lasting more than 180 minutes, in case of bleed-

ing with loss superior to 1500 ml, and when bilateral latero-cervical lymphadenectomy is performed ¹⁷.

Conclusion

Due to the current very low incidence of infectious complications, AP has no indication in thyroid surgery. In addition to being an uneconomic choice, the risk of antibiotic resistance and adverse events represent serious complications of this approach. AP should be limited to high-risk infectious patients only.

Riassunto

SCOPO: Le infezioni del sito chirurgico (SSIs) e le complicanze infettive sistemiche dopo chirurgia tiroidea sono di non comune riscontro. La profilassi antibiotica nei pazienti a basso rischio infettivo (ASA ≤ 3) sembra priva di significativi vantaggi sull'incidenza delle SSIs e delle complicanze settiche sistemiche. Scopo dello studio è stato quello di valutare l'incidenza delle SSI e delle complicanze infettive sistemiche in una serie consecutiva di pazienti sottoposti a chirurgia della tiroide in assenza di profilassi antibiotica (NO-AP).

PAZIENTI E METODI: Lo studio di tipo osservazionale prospettico includeva 77 pazienti (57 F; età media 57.1 anni; 20 M; età media 56.8) sottoposti a chirurgia tiroidea nel periodo Gennaio 2018-Dicembre 2019 presso l'ospedale universitario "A. Fiorini" di Terracina. Nessun paziente veniva sottoposto a profilassi antibiotica. L'intervento chirurgico era eseguito da chirurghi esperti della procedura e prevedeva l'utilizzo del Ligasure Harmonic Ethicon®, di emostatico riassorbibile in cellulosa ossidata e rigenerata (Tabotamp®) e dispositivo di sutura dell'incisione cutanea Skin Stapler®. Venivano valutati i seguenti fattori di rischio: sesso, età, BMI, consumo di alcool, fumo abituale, comorbidità, ASA score, indicazione all'intervento, durata dell'anestesia e dell'intervento chirurgico, procedura chirurgica adottata, febbre, conta dei globuli bianchi e dosaggio della Proteina C Reattiva pre-op e in I,II,III,IV,V giornata p.o, diagnosi istologica. I dati venivano raccolti ed elaborati mediante software IBM SPSS v.23.0.

RISULTATI: Una tiroidectomia totale è stata eseguita in 72 pz, completamento di pregressa emitiroidectomia in 5 pz, linfoadenectomia del compartimento centrale di "necessità" in 11 pz. In tutti i casi l'indicazione al trattamento chirurgico era rappresentata da gozzo multinodulare funzionante in 19 (24,6%) pz, non funzionante in 58(75.3%) pz, endotoracico 10(12.9%) pz. Non sono state riportate complicanze infettive del sito chirurgico e sistemiche causa di prolungamento della durata della degenza clinica. Pertanto la febbre, la leucocitosi neutrofila e l'aumento della PCR non possono essere valutati come fattori predittivi di complicanza infettiva.

CONCLUSIONI: Non sono stati identificati fattori di aumentato rischio infettivo. L'antisepsi del campo operatorio con Clorexidina gluconato, il miglioramento della tecnica chirurgica, la protezione dei margini cutanei di incisione, l'utilizzo dei nuovi devices, l'emostasi accurata e la riduzione dei tempi operatori si sono associati al mancato riscontro di SSI e di complicanze infettive sistemiche in tutti i pz sottoposti a chirurgia tiroidea in assenza di profilassi antibiotica.

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Commento e Commentary

PROF. NICOLA PICARDI

Già Ordinario di Chirurgia Generale

Le sole possibili cause di rischio infettivo in questa chirurgia – senza ipotizzare una scorretta preparazione del campo operatorio – sono legate a problemi intraoperatori di emostasi, con raccolte di sangue che anche se esigue, costituiscono sempre un pabulum. Questi elementi non sono presi in considerazione nello studio assumendo che in tutta la casistica citata l'esecuzione dell'intervento sia stato formalmente ineccepibile e privo di difficoltà.

Con i criteri di esclusione si sono eliminati tutti i possibili principali fattori di rischio di infezione del focolaio operatorio, che imporrebbero prudenza, perché un sia pur remoto pericolo di infezione postchirurgica potrebbe avere conseguenze maggiori. Non si può dimenticare però che si tratta di una chirurgia "pulita", e operando in un campo operatorio formalmente sterile i rischi di infezione sono di per sé trascurabili, ed i risultati dello studio erano prevedibili.

Probabilmente sarebbe utile lo stesso studio confrontando la popolazione individuata per questo studio con una popolazione esposta a fattori di rischio dati da diabete, alcolismo, dipendenza da droga analogamente non trattata con profilassi antibiotica. Il risultato potrebbe essere confermativo che osservando la sterilità del campo operatorio, anche in questi casi la profilassi antibiotica potrebbe confermarsi superflua.

* * *

The only possible causes of infectious risk in this surgery - without hypothesizing an incorrect preparation of the operating field - are linked to intraoperative problems of hemostasis, with collections of blood which, even if small, always constitute a pabulum. These elements are not taken into consideration in the study assuming that in all the cases mentioned, the execution of the intervention was formally flawless and without difficulties.

With the exclusion criteria, all possible main risk factors for infection of the operative outbreak have been eliminated, which would impose prudence, because even a remote danger of post-surgical infection could have greater consequences. It cannot be forgotten, however, that it is a "clean" surgery, and operating in a formally sterile operating field, the risks of infection are inherently negligible, and the results of the study were foreseeable.

The same study would probably be useful by comparing the population identified for this study with a population exposed to risk factors given by diabetes, alcoholism, drug addiction similarly not treated with antibiotic prophylaxis. The result could confirm that observing the sterility of the operative field, even in these cases antibiotic prophylaxis could prove superfluous.