Assessment of Routine Drainage in Elective Thyroid Surgery. A Prospective Randomized Study

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Abstract:

Background: At the end of thyroidectomy surgery, there was an area of some debate about insertion of closed suction drain before closure. The decision of routine use of drain depends on the surgeon's training, experience, and personal preference. Many surgeons prefer to place drain to minimize dead space collection and to prevent or reduce the post-operative hematoma that may be life-threatening so, the insertion of drains was generally accepted, although there are many studies that show no difference in the rate of complication with or without drain insertion. Moreover drain insertion may be accompanied by many hazards such as more hospital stay and post-operative pain. So, the concept of routine use of drain should be revised in the light of recent reports that test the real need for its use.

Aim of the study: this study aimed to assess if there was actual benefit from the use of drain in thyroid surgery and to evaluate the necessity of its use in thyroid surgery and to detect hazards of its use. Patients and methods: between June 2015 and July 2018, a prospective randomized study included 78 patients from those had elective thyroid surgery in Al-Hussien University Hospital for different indications. Patients had been categorized into 2 groups; group A (39 patients) for thyroidectomy without insertion of drain and group B (39 patients) for thyroidectomy with insertion of suction drain. In the study, results including: post-operative pain, hospital stay and complications (including wound infection, seromas, post-operative bleeding, hematoma, recurrent laryngeal nerve (RLN) palsy or hypoparathyroidism) were documented. Follow up after patient discharge was done until healing of wounds to detect post-operative complications. **Results:** the overall postoperative complications rate in the study was low (13 patients) in the two groups. In the non-drained group, there were one case of hematoma (2.5 %), 2 cases of seroma (5.1 %), one case of RNL palsy (2.5 %), one case of transient hypoparathyroidism (2.5%) and no cases of wound infection, whereas in the other group, there were 2 cases of hematoma (5.1%), 3 cases of seroma (7.6%), 2 case of RNL palsy (5.1%), 2 case of transient hypoparathyroidism (5.1 %) and no cases of wound infection. There was no statistical significance between both groups as regard incidence of complications. In the non- drained group, 37 patients (94.8 %) were discharged at the next day after surgery while in the drained group 2 patients (5.1%) only were discharged in the next day and the remaining patients were discharged after removal of drain after 48 hours. The mean hospital stay for the non- drained group was 1.2±1 days and the mean hospital stay for the drained group was 2.1 ± 1 days. **Conclusion:** in the study, use of drain in thyroid surgery did not have significant effect on the rate of incidence or prevention of postoperative complications. In serious postoperative bleeding, the drain which usually has small pores often become blocked be blood clots and become useless. On contrary, insertion of drain prolongs patient hospital stay and increases postoperative pain. So, routine use of drain in elective thyroid surgery should be prohibited. Key words: drain, thyroidectomy, post-oprative complications.

Introduction

In most thyroidectomies, drainage is very low and in the case of incomplete drainage of large volume of collection, seroma or hematoma is unavoidable. Also we should notice the fact that adequate haemostasis could never be replaced by insertion of drains ^[1]. In spite of these facts, drains are still routinely inserted by most surgeons in thyroidectomy ^[2]. The use of drain is a tradition and belief on surgeons rather than evidence based trials and it depends on the surgeon's experiences and practice. The main purpose of drain use is to prevent post-operative complications by draining post-operative hematoma or lymphatic fluid collection and to alert the surgeon to early post-operative bleeding ^[3]. Surgeons adopting the concept of routine drainage noted that some thyroidectomies with a dry surgical dissection have still developed significant post-operative collection and drainage. They keep all patients overnight with a drain for two purposes: 1) to drain excess collections; 2) to detect active bleeding in those who may develop a postoperative hematoma ⁴. It might be accepted that the use of drain in the past decades was to some extent needed due to high rate of post-operative

haematomas which is a life threatening condition^[5]. In the present days, bleeding and haematoma that threatens life and needs urgent reoperation to control bleeding became a rare complication ^[6]. This may be due to great improvement of operative techniques and haemostatic devices over the past decades and postoperative morbidity and mortality rates have further decreased. Life-threatening postoperative bleeding with compression of air passages and suffocation became avoidable in most patients ^[7,8]. Although it is logical that drain prevents post-operative hematomas, this has not been reported and is recently disputed by many researchers in last two decades. In many studies it has been reported that rates of post- operative seroma and hematoma show no significant differences in patients with and without drains ^[9]. Seromas and minimal hematomas developing postoperatively are less serious and generally do not produce any respiratory distress. They could be easily aspirated in the outpatient office with minimal morbidity ^[10].Moreover, some researches have shown that drains could increase the rate of some post-operative morbidity such as pain¹¹, wound infections ^[12] and can also lead to increased length of hospital stay ^[13,14]. Some researchers have indicated that the overall cost of thyroid surgery is significantly reduced [15] of drains without the use In the light of these facts, the value of drain in elective thyroid surgery might be now questionable and needs more research to assess the necessity of its use in all cases.

Aim of the study:

To assess the value of drainage in thyroid surgery and evaluate the necessity of its use routinely in all thyroid surgery cases and also to detect hazards and disadvantages of its use.

Patients and methods:

Between June 2015 and July 2018, 78 patients had been selected to enter the study from the patients coming to the outpatient surgery clinic in Al-Hussien University Hospital with thyroid disease and decision of surgery (total, sub-total, hemi or near total thyroidectomy) was taken for them. The patients were examined clinically after full history taking and investigated for diagnosis and preoperative preparation and the. Indications of surgery included simple multinodular goiter (MNG), controlled toxic goiter, solitary thyroid nodule (STN), thyroiditis (discovered in histopathology), cancer thyroid without radical dissection (all cases were discovered from histopathology after surgery) and recurrent nodular goiter after previous thyroidectomy. **This study was approved by the Ethics Board of Al-Azhar University.**

• Inclusion criteria:

- 1. Adult patients \geq 18 years old
- 2. Benign or malignant thyroid disease indicated for any type of thyroidectomy.
- 3. Elective thyroidectomy surgery

• Exclusion criteria:

- 1. Patients < 18 years.
- 2. Malignant thyroid disease indicated for nodal dissection.
- 3. Emergency cases as bleeding, suffocation and complicated cyst.

The 78 patients had been categorized into 2 groups; group A (39 patients) for thyroidectomy without insertion of drain and group B (39 patients) for thyroidectomy with insertion of suction drain. Patients were categorized blindly and every patient did not know in each group he was preoperatively. In the study, postoperative pain and need for analgesic administration, hospital stay, and complications including wound infection, seromas, post-operative bleeding, hematoma, recurrent laryngeal nerve (RLN) palsy or hypoparathyroidism, all these results were documented. Postoperative pain was recorded with a visual analogue scale (VAS) from 0 (no pain) to 10 (worst imaginable pain) on the postoperative day (POD) 0 and POD 1 if the patient was not discharged. Follow up was done until healing of wounds to detect complications. Patients were discharged when they have no complications and no longer required intramuscular analgesics after the drain was pulled, if drained. This work was applied after the Ethical Committee approval. Informed patient consents had been guaranteed from every patient included in the study.

Statistical analytic tests as χ^2 test had been performed for the gender, diagnosis of the patient, amount of analgesic needed, hospital stay, and complication rates. Student t-test had been performed for the age, hospital stay and VAS score. P-values and standard deviation had been calculated.

Results:

The 78 patients were involved in the study with a mean age of 39.53 years. The non-drained group consisted of 15 (38.5%) men and 24 (61.5%) women. The drained group consisted of 17 (43.6%) men and 22 (56.4%) women.

Table 1 showed the results of Chisquare test of association between the groups and gender (sex), the value of chi square is 1.147 with p-value =0.563, which means that there was no significant relation at level of significance =0.05.

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гаше г	- 1116	e cross	тяріе о	и зех ни	юнн	groups:	$A \equiv HOH$	агашеа	yrom).	. D =	агашеа	yron	
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				Sex	Total	
			female	male		
		Count	24	15	39	
Group	A	%	61.5%	38.5%	100.0%	
Group	6	Count	22	17	39	
	В	%	56.4%	43.6%	100.0%	
Total		Count	45	32	78	
		%	57.7% 41.0%		100.0%	
	Pearson Ch	ni-Square	1.147			
	P-va	lue	0.563			

The mean ages for the non-drained group was 39.05 while the mean ages for the drained group was 40 years where the oldest patient is 61 years old and the youngest is 23 as shown in table 2. **Table 2: descriptive Statistics of age in both groups**

Descriptive Statistics of age in both groups											
Group	N	Minimum	Maximum	Mean	Std. Deviation						
А	39	23	60	39.05	9.364						
В	39	23	61	40.00	8.246						

The indications for surgery included simple multinodular goiter disease (MNG), solitary thyroid nodule (STN), controlled toxic goiter, thyroiditis, cancer thyroid and recurrent nodular goiter (RNG). Table 3 showed the results of chi-square test of association between the group and diagnosis, the value of chi square was 1 with p-value =0.148, which means that there was no significant relation between the diagnosis of the patient and the groups at level of significance =0.05.

			Diagnosis								
			MNG	CON.TOX	STN	REC.NG	Thyroiditis	Cancer			
	Δ	count	14	6	8	4	5	2			
	Λ	%	35.9%	15.4%	20.5%	10.3%	12.8%	5.1%			
Group	В	count	13	6	8	5	5	2			
	2	%	33.3%	15.4%	20.5%	12.8%	12.8%	5.1%			
Total		count	27	12	16	9	10	4			
Total		%	34.6%	15.4%	20.5%	11.5%	12.8%	5.1%			
Pearsor	n Chi-So	quare	1								
Р	-value		0.148								
Sig	nificanc	e	insignificant at α=0.05								

Table 3: the cross table of diagnosis and the group

From previous data analysis, there was no significant difference in the gender, age and indication of surgery between the two groups.

The overall postoperative complications rate in the study was low, 13 patients, in both groups; 5 patients in non-drained group and 9 patients in the drained group. In the non-drained group, there were one case of bleeding and heamatoma (2.56 %), 2 cases of seroma collection (5.1 %),one case of

recurrent laryngeal nerve (RNL) palsy (2.56 %), one case of transient hypoparathyroidism (2.56 %) and no cases of wound infection, whereas in the other group, there were 2 cases of bleeding (5.1 %), 3 cases of seroma (7.62 %), 2 cases of RNL palsy (5.1 %), 2 case of transient hypoparathyroidism (5.1 %) and no cases of wound infection.

Table 4 demonstrated that the percentage of each type of complications all over the study.

Table 4: the percentage of each type of complications

Complication	Percent
Bleeding	3.8%
Seroma	6.4%
Infection	0%
Transient hypoparathyriodism	3.8%
RNL palsy	3.8%

Table 5 showed result of t-test and pvalues for each complication to detect if there is a significant difference between the two groups or not at a level of significance= 0.05. For bleeding, the value of the test was -0.582 with p-value 0.562 which means that there was no significant difference between patients of both groups. Comparing results for seroma showed that value of the test was 0.421 with p-value 0.675 which means that there was no significant

difference between groups. As regard transient hypoparathyriodism, it appears that value of the test was 0 with p-value 1 which means that there was no significant difference between patients with drain and those without. Also for RNL palsy, the value of the test is 0.582 with p-value 0.562 which means that there is no significant difference between patients who did use drain and who did not considering RNL palsy.

		t-test for Equality of Means						
	<i>P</i> value	df	Sig. (2- tailed)	Mean Difference	Std. Error Difference	95% Co Interva Diffe	nfidence l of the rence	
						Lower	Upper	
Transient Hypoparathyriodism	0.000	76	1.000	0.000	0.051	-0.101	0.101	
RNL inj.	-0.582	76	0.562	-0.026	0.044	-0.113	0.062	
Seroma	0.421	76	0.675	0.000	0.061	-0.122	0.122	
Bleeding	-0.582	76	0.562	-0.026	0.044	-0.113	0.062	

Table 5 showed result of t-test and p-values for each complication

* t cannot be computed for infection because standard deviations of both groups are 0.

From previous table it was concluded that there was no statistical significance between both groups as regard incidence of complications.

Post-operative pain was estimated by visual analogue scale (VAS) and every patient had a score from 0-10 at the surgery day (POD 0) and the day after (POD 1) then the mean was calculated for every patient. The patients with scores from 0-3 were described as having mild pain, those with score from 4-6 were described as moderate pain group and patient was

considered having sever pain if the score was 7 or more.

Table 6 showed that in group A (without drain) 79.5% of patients had mild pain while 12.8% had moderate pain and 7.7% severe pain. On the other hand, in group B (with drain) 64.1% of patients had mild pain while 20.5% had moderate pain and 15.4% have severe pain. Although there was no significant relation between pain and groups in the test, it was clear that more severe pain was observed in the drained group and milder pain was noticed in the non-drained patients.

Group * pain Cross tabulation test									
				Total					
			MILD	MODERATE	SEVERE				
Group A		Count	31	5	3	39			
		%	79.5%	12.8%	7.7%	100.0%			
	В	Count	25	8	6	39			
		%	64.1%	20.5%	15.4%	100.0%			
Total Co		Count	56	13	9	78			
		%	71.8%	16.7%	11.5%	100.0%			
pear	son chi sq	uare	2.335						
	p-value		0.311						
	sig		not significant						

Table 6: pain cross tabulation of pain in both groups

In the non- drained group, 37 patients (94.8 %) were discharged at the next day after surgery while 2 patients (5.1%) only were discharged in the next day and the remaining patients of drained group were discharged after

removal of drain after 48 hours. The mean hospital stay for the non- drained group was 1.2 ± 1 days and the mean hospital stay for the drained group was 2.1 ± 1 days.



Fig. 2: thyroidectomy without insertion of drain (healed wound without local complications)



Fig. 3: thyroidectomy with insertion of drain

Discussion:

Although numerous randomized trials revealed that drainage is unnecessary after routine thyroid surgery this result might not yet be directly accepted in practice Complication rates of these studies were comparable with literature ^[2,16,17,18]. The complication rate in the work was low reflecting that generally the post-operative complications after thyroid surgery remains low whether drain was used or not.

In this study, complication rates were observed as regard to hematoma and seroma between groups were comparable. These results may be due to use of the same haemostatic procedures in patients of both groups. Serious hemorrhage occurred in 3 patients; one in the non-drained group and 2 in the drained group. 2 patients needed surgical revision for exploration and control of the source of bleeding (slipped upper pole ligature in a patient of drained group and anterior jugular vein in that of non-drained group). The 3rd patient was managed by conservative treatment and no surgery needed. Unfortunately, drain did not alert the surgeons in the cases of the drained group as no marked collection was noticed in the drain (70 cm in one case and 30 cm in the other case). The collected blood in the operative bed clotted led to obstruction of the drain pores as Hemorrhagic fluid collected several hours (3 hours & 4 hours in both cases) after surgery. This may indicate that presence of drain does not detect early bleeding in all cases. This fact limits the expected benefits from the use of drain as we agree that drain alerts the surgeon to severe hemorrage which became rare after elective thyroidectomy. Also this draws attention to notice that the most important indicator that bleeding degree and amount collected requires emergency interference is incidence of dyspnea, suffocation or stridor, not the amount of blood in the drain. Thus, neck drainage did not prevent life-threatening hemorrhage and the decision to re-operate was made when dyspnea developed, not according to the amount of blood in the drain. So, in the drained patient with delayed minor bleeding no urgent surgical intervention was needed as no dyspnea, suffocation nor stridor was observed. Venous bleeding was seen and controlled at the time of surgery.

Moreover, if drain was decided, wide drain was better used as narrow drain can easily become blocked with clotted blood ^[5].

This study showed that 5 patients had seromas (6.41% of all patients in the study) constituting 19.3% of all complications; two patients of the non-drained group and 3 patients of the drained group. These patients were only conservative measures treated by and medication, but 2 cases needed needle aspirations twice. In other studies, it had been reported that the incidence of seromas and hematomas was similar in patients with or without drains. Most hematomas occurs within two to six hours after surgery although there had been reports of them occurring up to 24 hours postoperatively ^[2,17]. A late minimal haematoma may be treated with needle aspiration with no need for surgery if not affecting respiration.

Although this study showed no infection in either group of, a possible relationship between drain insertion and infective complications was observed in other studies when researchers noticed that incidence of infection was more in the drained group so, they adopted the belief that drains may predispose to infective complications^[18,19].

Similar results were reported by Ariyanayagam *et al.*; Kristoffersson *et al.* and Tabaqchali *et al.* who stated that drains might be associated with possible infection $[^{20,21.23}]$. The fact that wound infections developed in patients with drains supports the belief that drains predispose the area to infective complications $[^{3,20,23}]$.

Other complications were successfully managed with no need for surgical interference.

The incidence of hypoparathyroidism and recurrent laryngeal nerve (RLN) palsy reported in this work appeared to have no relation to insertion of drain. Nerve palsy occurred in 2 cases of the drained group (one recurrent after previous subtotal was thyroidectomy with marked fibrosis and the other was in a very difficult case appeared to have lymphocytic thyroiditis). The only case with nerve injury in the non- drained group occurred in a case of Hashimoto thyroiditis and the operation was bloody and difficult too. In general, incidence of hypoparathyroidism and recurrent laryngeal nerve injury was more in the drained group, may be due to presence of more difficult and complex cases (toxic, inflammatory and recurrent cases) included in this group.

In this work, it was reported that postoperative pain was more severe in drained group and accompanied by limited neck movement and discomfort. In this group there was more need for analgesics both in doses and duration of administration.

In **Colac** *et al.* study, postoperative pain dramatically decreased in most of the nondrained patients, especially in POD 1. These results showed that drains insertion might be directly associated with increasing postoperative discomfort of the patient by increasing postoperative pain. This is reflected in patient satisfaction and early discharge, independently of any complications ^[9].

The hospital stay of patients after surgery was definitely more in the drained group. In this study, most patients of drained group needed one more day to discharge from hospital than those with no drain. In the nondrained group, 37 patients were discharged at the next day after surgery while in the drained group, 2 patients only were discharged in the next day and the remaining patients of were discharged after removal of drain after 48 hours. The mean hospital stay for the nondrained group was 1.2±1 days and the mean hospital stay for the drained group was 2.1±1 days. The decision to discharge patient is not only related to drainage but also to postoperative pain, satisfaction and, comfort of the patient. Previous studies established similar results as regard prolonged hospital stay in drained patients with increased pain and need for analgesia ^[8,11,22,23,24]. From the previous reports, researchers had verified that the overall cost of thyroidectomy is significantly decreased without the use of drains due to earlier discharge, less pain, less need for analgesics and more patient satisfaction.

Conclusion:

Although most surgeons routinely insert drains after thyroidectomy to prevent hemorrhage and to detect life- threatening bleeding which was a rare complication, the drain usage appeared to have to significant effect in reduction of post-operative complication and, moreover, it leads to increase in post-operative pain, analgesic needs and prolongs the hospital stay. Thus, the insertion of drain in elective thyroidectomy should be abandoned.

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