ORIGINAL ARTICLE

Comparison of drain versus no-drain strategy in Thyroidectomy

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Abstract

Objectives: To compare the effectiveness of keeping a drain vs no drain in thyroidectomy

Study design: Randomized controlled trial

Setting: Department of Surgery, Khyber Teaching Hospital, Peshawar.

Duration: July 15, 2020, to January 14, 2021

Material and Methods: Anesthesia fitness was obtained after consent. Surgery was performed in all cases by a consultant surgeon. Patients were examined on the first post-op day for hematoma. 1st post-operative day was detected by neck ultrasound on follow-up in both drain and non-drain groups. Results were analyzed on statistical package for social sciences (SPSS) version 20.

Results: A total of 216 patients were recruited for the study, half in each group. The mean age of patients in group-A (drain) and group- B (no-drain) was 41.84 years±9.4SD and 40.87 years ± 9.6SD respectively (P = 0.765). The efficacy in terms of no hematoma was observed in 85(78.7.7%) in group-A patients and 82(75.9%) in group-B patients. The P-value is 0.373, which is deemed statistically insignificant.

Conclusion: Our study showed that keeping a drain has no such role in reducing hematoma after thyroidectomy for benign thyroidal disorders.

Keywords: Hematoma, hemi-thyroidectomy, goiter, drain, total thyroidectomy

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Introduction:

Anatomically, the thyroid is a butterfly-shaped organ that sits at the base of the neck. A component of the endocrine system, it releases hormones into the circulation so that they may reach the cells of the body to regulate metabolism and control important bodily processes such as breathing, heart rate, body weight, and temperature, as well as menstruation cycles and much more. The thyroid gland utilizes iodine from our diet to produce two major active forms: Tri-iodo-thyronine (T4) and Thyroxine (T3). This gland is linked to multiple illnesses and ailments which can occur at any age resulting from a variety of causes - injury, disease, or nutritional deficit.[1-3]

Indications for thyroidectomy are manifold. Thyroid cancer, generally confirmed and diagnosed by fine-needle aspiration (FNA) of a nodule, is one of the most common indications. As mentioned in medical literature "Patients with Hürthle cells type of follicular neoplasm on a fine-needle aspiration require at least a hemi thyroidectomy (one lobe removed) on the ipsilateral side of the nodule, and may be a complete thyroidectomy if the histo-pathology report of the specimen shows evidence of malignancy."[4] Moreover, this procedure is also a potential option for people with symptomatic thyroid masses or goiters as well as patients with medically resistant Graves' disease or hyperthyroidism.[5]

Thyroid surgery, just like any other surgery, has its post-operative adverse events. Neck hematomas, an uncommon but hazardous complica-

tion, can occur due to improper hemostasis or the patient having a bleeding disorder and even though the annual occurrence is just 1%, it can asphyxiate the patient and cause airway obstruction.[6] After confirmation through bedside examination, the patient should be relocated to the operating room for an inspection of the wound site under anesthesia. If the patient is in respiratory distress as well then this warrants quick drainage of the hematoma (on bed side) followed by transfer to the operating room.

To avoid this, surgeons often utilize different types of surgical drains in all thyroid operations, and the use of a drain is even suggested in certain outdated reference texts.[7] However, for some clinicians, the use of drains is contentious, and they do not believe that they are frequently required. It should be noted that using a drain does not substitute precise hemostasis or avoid hematoma buildup. A suction drain may be implanted if a substantial defect or void remains after thyroidectomy, particularly in individuals with big goiters. The neck is then layered closed, with great attention paid to proper skin closure. According to research, "the usage of drains should be minimized if not needed. It has also been observed that using a drain following simple thyroid surgery is ineffective."[8-10] Therefore this study is aimed at determining the effectiveness of drain placement in preventing post-thyroidectomy complications and comparing the results with the control group where the drain wasn't used at all.

Material and Methods:

Study design: This randomized controlled trial was conducted in a tertiary care hospital in Peshawar from July 15, 2020, to January 14, 2021, after taking approval from the hospital's ethical and research committee. The sample size was 216 (108 in each group) using 99%[10] efficacy in the no-drain group, 92%[10] in the drain group, 95% confidence interval, and 80% power of the test, under the WHO sample size calculations. Non-probability consecutive sampling technique was used.

Data collection:

All patients who met the study's inclusion criteria were screened in the out-patient department (OPD) and admitted to the ward for additional evaluation. They were informed about the study's goal and purpose and were re-assured that it was being performed only for research and if they agreed, informed consent was acquired.

Routine baseline pre-operative tests such as complete blood picture, coagulation profile, liver tests, blood grouping, urine examination, blood sugar, ECG, serum electrolytes, and other necessary tests were carried out for all patients. The patients were divided into groups at random using a lottery system. Patients with drains were assigned to group-A, whereas those without drains were assigned to group-B. Surgical operations were carried out following general surgery regulations and by experienced general surgeons with at least 7 years of post-fellowship experience.

After surgery, all patients in both groups were kept under surveillance for 4 days. The drain was removed when drainage was less than 20ml in 24 hours. Ultrasound of the neck to assess the amount of collection of thyroid bed was done in all patients on 1st post-operative day by the same qualified radiologist having at least 5-years of experience. After a medical evaluation, patients were discharged on the 4th-day post-surgery.

Data analysis: The statistical calculations were done using SPSS version 20 software. Frequencies and percentages were calculated for categorical variables like gender, hematoma, and efficacy. Mean±SD were calculated for a continuous variable like goiter size and age for each group. A Chi-square test was applied for comparing efficacy on the 1st day post-operatively between the two groups. A, P-value <= to 0.05 was considered statistically significant. To investigate effect modifiers, efficacy was divided by age and gender. All of the findings were recorded in the form of tables.

Table 1: Gender wise comparison of both the groups

		Group			
		A	**B**	**Total**	**p-value**
Gender	Female	77	81	158	0.323
		71.3%	75.0%	73.1%	
	Male	31	27	58	
		28.7%	25.0%	26.9%	
		108	108	216	
		100%	100%	100%	

Table 2: Age-wise distribution in both the groups

		Group			
		A	**B**	**Total**	**p-value**
Age (in years)	<= 30.00	11	16	27	0.765
		10.2%	14.8%	12.5%	
	31.00 - 40.00	34	34	68	
		31.5%	31.5%	31.5%	
	41.00 - 50.00	42	38	80	
		38.9%	35.2%	37.0%	
	51.00+	21	20	41	
		19.4%	18.5%	19.0%	
Total		108	108	216	
		100%	100%	100%	
Mean(in years)±SD		41.84± 9.4	40.87±9.6	41.36 +9.5	

Table 3: Efficacy in both the groups

		Group			
		A	**B**	**Total**	**p-value**
Efficacy	Yes	85	82	167	0.373
		78.7%	75.9%	77.3%	
	No	23	26	49	
		21.3%	24.1%	22.7%	
Total		108	108	216	
		100%	100%	100%	

Results:

A total of 216 patients with visible or palpable enlargement of any size of the thyroid gland diagnosed clinically were added in the study. They were divided into 2 groups; groups-A and B each having 108 patients. Patients in whom drain was kept were allocated to group-A, and those in whom drain was not kept were allocated to group-B.

There were 31(28.7%) males and 77(71.3%) females in group-A and 27(25%) males and 81(75%) females in group-B (P-value = 0.323). The male to female ratio in groups A and B was 1:2.48 and 1:3 respectively. (Table no. 1)

The average age was 41.84years±9.4 SD in Group-A which contains 11(10.2%) patients having less than 30 years, 34(31.5%) patients between 31-40 years, 42(38.9%) between 41-50 years, and 21(19.4%) patients having age more than 50 years. While Group-B has an average age of 40.87years±9.6 SD and contains 16(14.8%) patients younger than or equal to 30 years, 34(31.5%) in 31-40 years, 38(35.2%) in 41-50 years, and 20(18.5%) patients have age more than 50 years of age. The age distribution among the group was insignificant with a p-value of 0.765. (Table no. 02)

In group-A with a suction drain placed in the pre-tracheal region, the efficacy in terms of no hematoma was observed in 85(78.7.7%) patients, and in group-B with no suction drain, effectiveness was noted in 82(75.9%) patients. The P-value is 0.373 which is considered to be statistically insignificant. (Table no.03)

The age distribution in both groups demonstrates that efficacy is higher in the younger age group and diminishes with age. Patients aged <=30 years old demonstrated potency in 9(81.8%) of Group-A patients and 13(81.2%) of Group-B patients. When we stratify the efficacy by age, we can observe that it is negligible in both groups. (Table no.04)

When Effectiveness was stratified among the gender in both the groups it showed that gender has no such role and the found statistically insignificant in both the groups. (Table no.05)

Discussion:

Despite advances in medical treatment and the high incidence of thyroid disease, some patients still require thyroid surgery at the end of their treatments. Having close anatomical relations to the trachea, jugular vein, carotid vessels, and the recurrent laryngeal nerve and a good blood supply from various sources is a precaution doctors are aware of, and the basic point that such

Table 4: Age-wise distribution of effectiveness in both the groups

			Efficacy		
			Yes	No	p-value
Age (in years)	<= 30.00	Group A	9	2	0.970
			81.8%	18.2%	
		Group B	13	3	
			81.2%	18.8%	
	31.00 - 40.00	Group A	29	5	0.720
			85.3%	14.7%	
		Group B	30	4	
			88.2%	11.8%	
	41.00 - 50.00	Group A	32	10	0.204
			76.2%	23.8%	
		Group B	24	14	
			63.2%	36.8%	
	51.00+	Group A	15	6	0.796
			71.4%	28.6%	
		Group B	15	5	
			75.0%	25.0%	

Table 4: Age-wise distribution of effectiveness in both the groups

			Efficacy		
			Yes	No	p-value
Gender	Female	Group A	61	16	0.348
			79.2%	20.8%	
		Group B	59	22	
			72.8%	27.2%	
	Male	Group A	24	7	0.452
			77.4%	22.6%	
		Group B	23	4	
			85.2%	14.8%	

surgeries require very accurate dissection and complete hemostasis.[11] Although authentic publications have agreed on the need for drains following thyroid procedures in exceptional circumstances such as retrosternal thyroid and cervical lymphatic dissection, the use of drains in simple thyroid surgery remains debatable.[12]

Most of the participants were young with a mean age(±SD)of 41.84 years±9.4 SD in the drain arm and 40.87 years±9.6 SD in the no-drain arm. The higher the percentage of females (73.1%) recruited in this study agrees with previous studies including the work of Tahsin et al,[13] and Davari et al,[14] in which "the majority of participants were females, 79.3% and 78.8% respectively".

In one analysis, it was found that there was no statistically significant difference in the frequencies of post-thyroidectomy hematoma whether or not suction drains were utilized or not, which is consistent with other studies as well.[15] Furthermore, drains did not give any additional advantages following thyroid surgery, according to a major study including between 250 and 400 patients.[16,17] Another research of 102 thyroid operations indicated that the use of drains was related with a greater accumulation of fluid on Day-one as measured by ultrasound. It is assumed that drains cause an inflammatory process, resulting in increased fluid production in the region.[18] Talmi also concluded that the use of vacuum drains in thyroid surgery to decrease post-operative hematoma formation has not been statistically proven yet.[19]

It is imperative to realize that preventing hematomas and seromas may be accomplished in a variety of ways, including identifying risk factors and employing suitable intra-operative methods. Harding et al. mentioned various risk factors leading to hematoma formation, broadly categorizing them into patient-related, thyroid pathology-related, and surgery-related factors. A history of bleeding problems, compliance with anti-coagulant medicines, and smoking are all patient-related variables. Furthermore, one analysis depicts no conclusive evidence that excessive vascularity in toxic multinodular glands and Grave's disease are linked to an increased risk of post-operative bleeding.[20] Using appropriate surgical methods, handling tissues carefully, and ensuring proper hemostasis intra-operatively are the most efficient ways to avoid problems related to hematoma and seroma development.[21,22]

The use of drains following thyroid surgery has also been shown to have no effect in two major non-randomized trials including 250 and 400 participants.[23,24] In our study, there was no collection noticed in the thyroid gland on ultrasound, although it was found in the vacuum drain. It might be due to the tube itself acting as a foreign body causing irritation and channeling

an inflammatory process. Moreover, the vacuum formed by the drain's negative suction may hinder the lymphatics from shutting off, increasing seroma production and drainage.[25,26]

Besides that, certain publications have demonstrated a probable link between drain insertion and ineffective consequences.[24,27]

Drains have typically been employed in the majority of thyroid surgical operations, however, there is no evidence to suggest that they are advantageous.[25,28-31] Our study found no benefit to using a drain regularly in such surgeries. Bleeding near the trachea reduces space, compressing the airway and causing severe edema in between the connective tissues of the larynx and throat. The result of such events is a situation called a suffocating hematoma, which needs rapid surgical intervention in the operating room. Statistics have shown that this complication occurs seldom, ranging from 0.3 to 2.5% of the time; but, when it happens, it poses a significant problem for both the surgeon and the anesthesiologist.[31] Patients with intra-thoracic goiter and Graves' disease have a higher risk of developing this complication.[31]

Such hematomas liable to cause asphyxiation often emerge a few hours after surgery, and the majority of patients describe coughing, vomiting, or nausea before the bleeding. This complication might be caused by the slippage of an inadequately placed suture, release of a vessel in which diathermy was employed for coagulation, or "drooling" of an insufficiently cauterized region.[31]

Conclusion:

This study supports that drains cannot replace precise dissection and proper hemostasis. The absence of drains was not related to any problems following thyroid surgery, although it may have reduced the patient's suffering. Only in exceptional circumstances of thyroidectomy is the use of a drain suggested.

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Role and contribution of authors:

Waleed Mabood, collected the data, references and did the initial write up.

Saeedullah Afridi, collected the data, and helped in introduction writing.

Amir Hamza, collected the references and helped in discussion writing.

Ibqar Azeem, collected the data, references and helped in interpretation of the data.

Shahid Khalil, critically review the article and made final changes.

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