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Original Research Article

A prospective clinical trial on comparison of thyroidectomy done with or without drain

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ABSTRACT

Background: The practice of using the drain in thyroidectomy is common to avoid complications like a hematoma. Many surgeons use drain following thyroid surgery with an intention to evacuate the collected serum and blood. Objective was to evaluate the necessity of routine drainage and advantages in thyroidectomy.
Methods: Prospective, non-randomized clinical trial was conducted for a duration of 1 year in 60 patients attended hospital. Patient were divided into two groups (Group WD and Group D). Epi-info version 7.0 was used for analysis. P<0.05 is considered statistically significant.
Results: As seen the surgery was common in females which was significant (p<0.05) with the average age of 44 years in patients treated without drain while 42 years with drain. The most common diagnostic indication was found to be thyroid nodule. length of stay in hospital was less in patients were surgery was done with drain (2 days) (p<0.05).
Conclusions: Significant reduction in length of hospital stay in drainage group compared to non-drainage group. So suction drainage should be done as a routine procedure.

Keywords: Clinical trial, Haematoma, Colorectal, Thyroidectomy, Suction drain

INTRODUCTION

Thyroid surgery was first conveyed in the 1800s.[1] The initial skill with this procedure was poor, with a reported 40% mortality rate.[1] By the early 1900s, enhanced technique had decreased the mortality to 3%.[1] The four major complications include neck hematoma. The overall complication rate is low at approximately 4%.[2] The motivation for using a neck drain is to try to avoid, or identify early, the potentially life-threatening complication of a neck hematoma and to prevent seroma formation. 75% of hematomas usually occur within the first 6 hours after the operation and the rest occur in the next 6 to 24hours.[3] Hemorrhage can be life threatening which makes most of the surgeons to put the drain in thyroid surgery though the actual incidence is only 0.3-1%.[4] Several studies have been performed over the years examining the usefulness and necessity of post- operative drains; most of these have shown that they do not provide any protective benefit. In terms of experience, the incidence of postoperative hematomas and seromas seemed to be very low. So, this clinical trial was planned to investigate if repetitive drain use in thyroidectomy was necessary and its duration of stay of patients in hospital.

METHODS

This was a prospective non-randomized clinical trial type of study. This study was conducted at Department of Surgery, Tertiary care Hospital, Ezhamkulam, Kerala. This study was conducted from January 2017 to January 2018 (1 year). All patient who were admitted for variety diagnoses, including multi- nodular goitre, papillary carcinoma, and follicular carcinoma or, for a definitive

diagnosis, a thyroid nodule was taken as study population. 60 patients who were admitted during the study period for the above causes were taken as the respective sample size. Which were further divided in 2 groups 30 each with drain and without drain. Purposive sampling technique was used.

Inclusion criteria

All patient who gave consent and who were to undergo either total/hemi/complete thyroidectomy were included in the study.

Exclusion criteria

Those patients who didn't give informed consent. Those Patients with known bleeding disorders. Patients with massive goitres or nodules >6cm in size. Patients for whom lateral neck dissection was required were excluded.

Methodology

Among the two groups WD group is without drain and D group is with drain. All procedures were performed by the same team to avoid any discrepancy at a tertiary care teaching facility that includes a wide demographic and has a very large catchment area. Each operation was conducted under general Anaesthesia with endotracheal intubation. Operations were performed in the routine manner with a transverse midline incision for all cases. A closed suction drains with negative pressure kept in each patient in group D. Post-operatively at 24hours surgeons checked the volume of fluid assemblage in wound bed and drain discretely with ultrasonography using B mode of 7.5Mhz by the same radiologist. All group D patients had less than 50ml collection in the drain after 24hours hence drain removed after 24hours from all the patients. Written informed consent was taken.

Statistical analysis

Recorded observations were analysed using Epi info software (version 7.0). The descriptive procedure was used to display univariate summary statistics for several variables in terms of frequency and proportion. The crosstabs procedure was used to measure of association for two-way tables. Unpaired student t-test and Chi-square test was used and $p<0.05$ is considered statistically significant.

RESULTS

Shows demographic parameters of the patients in two groups. As seen the surgery was common in females which was significant ($p<0.05$) with the average age of 44 years in patients treated without drain while 42 years with drain. All the surgery done were total thyroidectomy which was significant. Mostly the patient was from urban area (Table 1).

Table 1: Demographic details of study participants (n=60).

Parameters	Group WD (N=30)	Group D (N=30)	P-value
Age	44±14.5 years	42±12.60 years	0.22
Sex			
Male	10	12	0.01*
Female	20	18	
Area of residence			
Urban	13	26	0.11
Rural	17	4	
Type of surgery			
Total	30	30	0.001*
Hemi	0	0	

*p<0.05 is statistically significant.

As seen nearly all the indications were seen and it was found that the most common diagnostic indication was thyroid nodule which highly significant followed by papillary carcinoma in patients without drain and follicular carcinoma in patients with drain but not significant (Table 2).

Table 2: Diagnostic indication for thyroid surgery (n=60).

Indication	Group WD (N=30)	Group D (N=30)	P-value
Multinodular goitre	8	6	0.11
Papillary carcinoma	10	6	0.27
Follicular carcinoma	4	8	0.33
Thyroid nodule	8	10	0.002*

*p<0.05 is statistically significant.

The post-operative complications are very minimal in patients with drain (group D) only wound infection was seen only in single patient but as compared to patients without drain the most common complication was found to be suture reaction but it was not found to be significant. As the sample size is too low to determine the significance of this complication (Table 3).

Table 3: Postoperative complications in both the groups (n=60).

Complications	Group WD (N=30)	Group D (N=30)	P-value
Haematoma	0	0	0.0
Seroma	1	0	0.346
Suture reaction	2	0	0.33
Wound infection	1	1	0.06
Nerve injury	0	0	0.0

As seen length of stay in hospital was less in patients were surgery was done with drain (group D). As compared most of the patient were stayed only for 2 days in patients with drain which was significant. Hospital stay for 3 days was seen in most of the patient with and without drain and was significant also (p<0.05) (Table 4).

Table 4: Duration of stay in hospital (n=60).

Days in hospital	Group WD (N=30)	Group D (N=30)	P-value
0 days	0	0	0.0
1 day	1	1	0.316
2 days	2	16	0.02*
3 days	15	10	0.001*
5 days	10	2	0.21
7 days	3	1	0.44

*p<0.05 is statistically significant.

DISCUSSION

The present was female preponderance. Drains have been routinely used in most of the thyroid surgeries including hemithyroidectomy but there is limited evidence to support their use.[5-7] Hematoma is the significant complication in most of the studies. But not in the present study. This is a very challenging complication for which immediate surgical evacuation in operation-theatre is mandatory.[8] Possible causes for this are slippage of an improperly applied suture and improperly cauterized area. Two large nonrandomized studies of 250 and 400 patients have also recognized that no benefits of using the drains in thyroid surgery.[9,10] The reason for this may be an inflammatory effect of drain itself. Few studies have pragmatic infective complications with the use of drain, but we didn't find such associations with drain use in present study.[11,12] According to Corsten et al, drain use in thyroid surgeries is not evidenced based.[6] According to Khanna et al, no significant reduction in the fluid collection in the operative wound in patients with suction drain by ultrasonography.[7]

Currently, most patients are discharged home post-thyroid surgery in less than 48 hours. Short-stay thyroid surgery has become routine in many centres and is usually defined by the American insurance industry as discharge less than or equal to 23hours from the operation. Our average length of stay was 3 day in the no drain group and 2 days in the drain group. For comparison, Schoretsanitis and colleagues had an average of 1.6 days in the no drain group and 3.4 days in the drain group and Marohn and LaCivita both did not use drains and had mean stays of 1.06 days and 1.2 days, respectively.[13,14]

It is important to note that the complication rate is very surgeon and site specific. Two of the biggest factors in performing a complication-free thyroid operation are surgeon expertise and his or her diligence at ensuring perioperative hemostasis. Routine drain use is never a substitute for these factors.[15]

CONCLUSION

The present prospective clinical trial was found that use of drain is necessary for thyroid surgeries as duration of stay along with complication are lesser and effective in preventing any post-operative complication of thyroid surgery. Prevention of complications depends more on the experience of surgeon, meticulous hemostasis and attention to finer details during surgery as it reduces pain and discomfort to the patient hence reduces hospital stay without increasing morbidity.

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