DOI: https://doi.org/10.53350/pjmhs22163573

ORIGINAL ARTICLE

Randomized Clinical Trial for Comparison of Drain Versus no Drain Thyroidectomy

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ABSTRACT

Drains have been traditionally used routinely after thyroidectomy despite limited evidence to suggest any benefit. In many facilities, drains are routinely inserted after thyroidectomy with the aim of preventing hematoma formation and accumulation of seroma.

Objective: To compare the outcome of drain versus no drain after thyroidectomy in patients presenting with clinically benign lesions of thyroid

Methods: Study design is Randomized control trail. Settings are Department of Surgery, Mayo University Hospital Ireland. Study was completed in 6 months after the approval of synopsis 13-07-2015 to 31-05-2016. After taking approval from Hospital Ethical Committee, 60 patients fulfilling the inclusion criteria were selected from ward of Department of Surgery, Mayo University Hospital Ireland. Informed consent was taken. The demographic information was obtained. Patients were randomly divided in two groups by using lottery method. In group A, drain was inserted after surgery while in group B, no drain was inserted. All surgeries were done by a single surgical team. After surgery patients were shifted to ward and were followed-up there. At time of discharge, duration of hospital stay was noted. Patients were advised to follow-up in OPD after 7 days of surgery. Patients were assessed for seroma and hematoma formation.

Results: Mean age of women in Group-A and in Group-B was 43.73±10.51 years and 40.23±9.07 years. In Group-A there were 13(43.3%) male and 17(56.7%) females while in Group-B there were 18(60%) male and 12(40%) females. In Group-A mean hospital stay of patients was 5.80±1.42 days and in Group-B mean hospital stay of patients was 3.76±1.10 days. In Group-B patients rate of hematoma and seroma formation was low as compared to that of Group-A patients but this difference was not statistically significant.

Conclusion: Outcome of thyroidectomy is better in terms of shorter hospital stay, and other post operative complications in patients without drain. Now the controversy is clear that thyroid surgery without drain results in good outcome for patients. So there is no beneficial aspect seen in patients with the use of drain after thyroidectomy.

Keywords: Thyroidectomy, outcome, drain, benign lesions, thyroid disease.

INTRODUCTION

Thyroidectomy is one of the most commonly performed procedures in neck operations. Several complications can occur per-operatively or post-operatively. Some complications such as hypocalcemia and recurrent laryngeal nerve palsy can be quite disturbing for patients in their permanent form and can prolong hospital stay adding to patient's morbidity[1]. An acute complication of this procedure is the formation of compressive hematoma, although being rare (1-2.5%).[2] Leyre et al in their retrospective study of 6830 thyroidectomy cases identified 70 hematomas only.[3] Several authors have analyzed the factors which could be the predisposing or causative factors for hematoma formation.[3, 4] Godballe et al through a study identified old age, male gender, malignancy and extent of surgery as the risk factors for bleeding.[5] Usually the bleeding occurs within the first 6 hours and the reactionary heamorrhage has been rarely reported after 24 hours from surgery.[6]

Several studies have pointed out negative effects of putting suction drainage. Gungor et al conducted an elaborate retrospective analysis of 280 thyroidectomy cases comparing the closed suction type and open penrose drain. In this comparative study they experienced post-op bleeding in closed suction group in 3.4% cases and none in the other group. The hypothesis that this drain could itself be a cause of post-op bleeding.[7] One study has found that with drain mean hospital stay was 7.4±2.6days while without drain was 4.6±1.2 days (P=0.002). There were 8.3% cases with drain who developed hematoma and 16.6% developed seroma while without drain, 25% developed hematoma and 16.6% developed seroma. The difference was no significant and results showing that without drain, there are more complications.[8]

But another study has reported that with drain mean hospital stay was 2.41±0.89days while without drain was 1.71±0.76 days (P=0.0008). There were 2.9% cases with drain who developed hematoma and 8.8% developed seroma while without drain, no one developed hematoma and 5.9% developed seroma. The difference was no significant and results showing that without drain, there are less chances of complications.[9]

Rationale of this study is to compare the outcome of drain versus no drain after thyroidectomy in patients presenting with clinically benign lesions of thyroid. In literature controversial results have been observed which create a misperception about the use of drain in thyroidectomy surgeries. Moreover, no local evidence were found in literature which can help us in deciding whether to use drain after thyroidectomy. So we want to conduct this study to find the role of absence of drain is effective in developing less complications. This will help us to improve our practice and we will be able to implement the method to go without drain in future to prevent complications.

MATERIAL AND METHODS

Study Design is Randomized control trial. Setting are held in Department of Surgery, Mayo University Hospital Ireland. Study Duration is 6 months after approval of my synopsis (Date: from 13-07-2015 to 31-05-2016). Sample size of 60 cases; 30 cases in each group is calculated with 95% confidence level, 80% power of test and taking magnitude of hospital stay i.e. 2.41±0.89 days with drain while 1.71±0.76 days without drain in patients underwent thyroidectomy. Non probability purposive sampling.

Inclusion Criteria: Patients of age 25-60 years of either gender, clinically and sonographically diagnosed case of MNG, Solitary nodule ASA I & II

Exclusion Criteria:

Patients with Anaplastic CA diagnosed with FNAC (on medical record)

Recurrent Goitre(on medical record)

Bleeding Tendencies (PT>20sec, aPTT>15 sec, INR>2)

Diabetes mellitus (BSR>186mg/dl), hypertension (BP≥140/90mmHg)

Data Collection: After taking approval from Hospital Ethical Committee,60 patients fulfilling the inclusion criteria were selected from ward of Department of Surgery, Mayo University Hospital Ireland. Informed consent was taken. The demographic information like age, sex and address was obtained. Patients were randomly divided in two groups by using lottery method. In group A, drain was inserted after surgery while in group B, no drain was inserted. All surgeries were done by a single surgical team. After surgery patients were shifted to ward and were followed-up there. At time of discharge, duration of hospital stay was noted. Patients were advised to follow-up in OPD after 7 days of surgery. Patients were assessed for seroma and hematoma formation (as per operational definition). All the data was collected on a pre-designed Performa (attached).

Data Analysis: The data was entered in SPSS version 22.0 and analyzed. Study variables like age, tumour size and hospital stay was analyzed by calculating mean and standard deviation. Frequency and percentage was calculated for seroma formation and hematoma. Frequency of seroma and hematoma was compared in both groups by applying Chi Square test and mean hospital stay was compared by using t-test. P value ≤0.05 was considered significant.

RESULTS

Mean age of women in Group-A and in Group-B was 43.73±10.51 years and 40.23±9.07 years. Minimum and maximum age of patient in Group-A was 26 and 60 years while in Group-B it was 26 and 56 years. (Table-1)

In Group-A there were 13(43.3%) male and 17(56.7%) females while in Group-B there were 18(60%) male and 12(40%) females (Table-2)

In Group-A mean hospital stay of patients was 5.80±1.42 days and in Group-B mean hospital stay of patients was 3.76±1.10 days. Minimum and maximum hospital stay in Group-A was 4 and 8 days. While in Group-B minimum and maximum hospital stay of patients was 2 and 5 days respectively. (Table-3)

In Group-A hematoma formation was seen in 8(26.7%) patients and in Group-B it was seen in 4(13.3%) patients only. Although in Group-B patients rate of hematoma formation was less as compared to that of Group-A patients but this difference was not statistically significant. i.e. (p-value=0.197)(Table-4)

Table-1: Age Distribution of Patients

	Drain	No Drain
N	30	30
Mean	43.73	40.23
SD	10.51	9.07
Minimum	26.00	26.00
Maximum	60.00	56.00

Table-2: Gender Distribution of Patients

	Drain	No Drain
Male	13(43.3%)	18(60%)
Female	17(56.7%)	12(40%)
Total	30	30

Table-3: Descriptive Statistics for Hospital Stay of Patients

	Drain	No Drain
N	30	30
Mean	5.80	3.76
SD	1.42	1.10
Minimum	4.00	2.00
Maximum	8.00	5.00

t-test= 6.180 p-value= 0.000

Table-4: Hematoma In Patients

Hematoma	Drain	No Drain
Yes	8(26.7%)	4(13.3%)
No	22(73.3%)	26(86.7%)
Total	30	30

Chi-Square Test= 1.66
p-value= 0.197

Table-5: Seroma Formation in Patients

Seroma formation	Drain	No Drain
Yes	8(26.7%)	4(13.3%)
No	22(73.3%)	26(86.7%)
Total	30	30

Chi-Square Test= 1.66 p-value= 0.1978

In both treatment groups no statistically significant difference was seen for seroma formation. i.e. (Group-A: 26.7% vs. Group-B: 13.3%). i.e. (p-value=0.197)(Table-5)

DISCUSSION

It is believed that many surgeons use a drain following thyroid surgery to obliterate the dead space and evacuate collected blood and serum. This is further reinforced by the fact that postoperative drains usually yield fluid. Hemorrhage can be life threatening, thus necessitating an immediate reoperation. This fear prompts surgeons to use a routine drain after any type of thyroid surgery. Although the rate of bleeding might increase in a subtotal thyroidectomy due to vascularized remnant tissue, postoperative bleeding is actually quite rare and occurs in only 0.3–1% of patients after a thyroidectomy.[53] Many studies have suggested that drains may be blocked with clotted blood; therefore, the surgeon is not alerted even if major bleeding occurs.[58, 71] In addition, numerous studies have also failed to show any benefits of drainage in thyroid surgery.[60]

Seroma Formation: In this study frequency of seroma formation in patients with and without drain was 26.7% and 13.3% respectively. Although no statistically significant association was seen between seroma formation and treatment groups. Patients with drain had higher frequency for seroma formation. P.L. Chalya in his study reported that 16.6% of patients in drain and 16.6% of patients in non drain group had seroma.[8] Ugur Deveci reported seroma formation in 4(2%) cases in no drain group and 3(1.5%) cases in drain group.[62] Recently a local study reported a statistically significant seroma formation as 1.47% in drain and 4.41% in non drain group[72] . P.L. Chalya, Ugur Deveci and results of local study did not show any significant association of seroma formation in patients with and without drain and the same results were obtained in this study. Although the frequency of seroam formation was quite as that of these studies due to the difference in sample size.

Kalemera Ssenyondo E has reported high frequency of seroma formation in patients with drain and without drain group undergoing thyroidectomy. i.e. 60% vs. 40%.[9] Kalemera Ssenyondo findings are in line with the results of this study as he also showed a higher frequency of seroma formation in patient who underwent drain. Zahid Ali Memon in his study reported that there were no cases of seroma formation in either the drain or non drain group, which coincides with the fact that seroma formation does not specifically occur when drains are not used. No patients in any group had to undergo aspirations (except for a case hemorrhage). Conversely, the placement of drains itself can lead to seroma formation since the drain is a foreign object.[73]

There are also very low chances of postoperative seromas forming in the absence of drains but they can be observed and allowed to resorb themselves or, if severe, aspirated.[74] Drains have been also suggested when the dead space is large and the possibility of seroma formation is high[75]. Drain usage has been questioned after various types of surgeries with much larger potential dead spaces in other areas such as colorectal, plastic surgery, vascular and orthopedics. These procedures are now routinely not drained. Previous reports have also reported that the drain being a foreign body may induce reactive fluid formation, thus encourage formation rather than preventing fluid collection.[76-80]

Hematoma Formation: Classic teaching in surgery has dictated that drains should be used routinely after thyroid surgery so as to prevent postoperative complications by evacuating postoperative hematoma or lymphatic fluid in the thyroid bed and to alert the surgeon to early postoperative

bleeding.[51, 81]. In this study it was seen that patients with drain had high frequency of hematoma formation as compared to the patients in the non drain group. i.e. 26.7% vs. 13.3%. But no statistically significant difference was present for hematoma formation in relation to drain and no drain. i.e. p-value=0.197. Ugur Deveci in his study reported the frequency of hematoma as 1% and 1.5% in without drain and with drain.[62] P.L. Chalya in his study reported the frequency of hematoma as 8.3% in drained group and 25% in non drained group.[8] P.L. Chalya results contradicting to the results of this study as in this study frequency of hematoma was higher in drain group while P.L. Chalya reported higher frequency of hematoma in non drain group.

In a meta-analysis, Corsten et al. concluded that the use of suction drains in thyroid surgery to prevent postoperative hematoma is not evidence based[62]. Hyoung et al reported the incidence of hematoma formation post- thyroidectomy to be varying between 0.3-4.3%.[51] Tahsin et al reported that post-thyroidectomy bleeding is as rare as 0.3%-1.0%.[53] Both Hyoung reported a very low frequency of hematoma formation post-thyroidectomy. While in this study in both treatment groups i.e. drain and no drian group frequency of hematoma formation is quite high. The fear of an hematoma enlarging and obstructing the airway and causing difficulty in breathing, prompts many surgeons to use drains routinely after any type of thyroid surgery. The main reason is to drain off a possible postoperative haematoma, which may compress the airway and produce respiratory failure.[53, 81] Meticulous hemostasis and an adequate surgical technique are the keys for avoiding hemorrhage and hematoma formation.

Hospital Stay: In this study it was observed that patients in which drain was inserted among them mean hospital stay was 5.80 days while patients in which drain was not inserted their mean hospital stay was 3.76 days. As per p-value patients with no drain had significantly shorter hospital stay. Ugur Deveci in his study also reported that performing a thyroidectomy without the use of drain decreased the length of hospital stay. The average length of hospital stay was 1.10 (1−3)±0.33 days for group 1 and 1.53 (1−6)±0.80 days for group 2[62]. Tahsin Colak also reported shorter hospital stay with non drain thyroid surgery.[53] Muthaa in his study reported that patients in the non-drained group had a significantly shorter length of hospital stay compared to those in drained group (p-value = 0.001). On average, patients in the non-drained group stayed in hospital for 1.2 days [SD 0.06] and those in the drained group stayed on for 3.2 days [SD 0.12][82]. Ugur Deveci, Tahsin Colak and Muthaa results regarding shorter hospital stay with no drain is consistent with the results of this study. However mean hospital stay very. Results of a local study from Pakistan also supports that without using drain results in shorter hospital stay as compared to the use of drain in thyroid surgery. i.e. (1.5 days without drain vs. 3.4 days with drain).[83]

Short stay thyroid surgery has become routine in many centers and is usually defined by the American Insurance Industry as discharge less than or equal to 23 hours > from the operation. LoGerfo is routinely discharging patients < 8 hours. Average length of stay was 0.85 days (about 21 hours) in no drain group and 2 days in drain group[84].

Nuraydin Ozlem also reported that the average postoperative hospital stay of the drained group was significantly longer than that of the non-drained group.[85] Keeping in mind al these results it can be said that drainage caused a longer hospital stay and may increase the surgical site infection rate. Similarly results of this study suggest that insertion of drain after the thyroid surgery increases the hospital stay of the patients. These results are consistent with the above mentioned studies results. Most studies have revealed that drainage is unnecessary after routine thyroid surgery.[8, 9, 62] However, many of these studies had a small number of patients and a retrospective design. This prospective study contains the largest number of patients on this topic in the literature. Keeping in mind the results of this study it can be believed that thyroidectomies without drains are safe for differentiated thyroid cancer, Graves' disease, and other toxic goiters.

CONCLUSION

Outcome of thyroidectomy is better in terms of shorter hospital stay, and other post-operative complications in patients without drain. Now the controversy is clear that thyroid surgery without drain results in good outcome for patients. So there is no beneficial aspect seen in patients with the use of drain after thyroidectomy.

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