Drain Versus No Drain Placement In Hemithyroidectomy: A Case Control Study.

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Abstract:

Background

The use of drains in thyroid surgery is a common practice among surgeons, which is substantiated by the possibility of post-surgical hemorrhage. Thyroid being a highly vascular gland, any small hemorrhage can lead to serious life-threatening complications including venous edema of the airway, seroma and hematoma formation, which if detected early enough requires emergency decompression, in the absence of which may lead to fatal consequences. Use of drain prolongs the length of hospitalization and increases the rate of infection.[5,6,8,11–14].

Material And Method: The study was carried out on 60 euthyroid status patients who underwent 60 hemithyroidectomy after taking detailed history and general examination. Study conducted in a single unit conducted at MGM Medical College and M.Y. Hospital, Indore (M.P.) between December 2018 to February 2019. Patients were randomized into two groups i.e. 30 patients in Group A (drain) and 30 patients in Group B (no drain). Ultrasoundography done on postoperative day 1 and on postoperative day 3 for any collection and ultrasound guided aspiration of collection done if needed.

Results: Sixty patients underwent hemithyroidectomy and were randomly distributed into a drain or no drain group. There was a definite predominance of female patients than males in both groups. Four cases of postoperative collection in non-drained group and seven in with drain group. USG guided aspiration required in two patients in non-drain group and in five patients in drain group. Whereas four cases of wound dehiscence and five cases of wound infection occurred in the drained group. No patient needed re-operation for any complication. The mean hospital stay was significantly shorter in the non-drained group.

Conclusion: The present prospective case control study verify that in hemithyroidectomy for benign disease routine drain placement after surgery is not necessary and is not effective in decreasing the rate of postoperative complications. By contrast, the use of drain prolongs the postoperative pain, hospital stay and may be associated with an increased risk of infective complications. Placing wound drains is purely a surgeon’s choice based on experience and training, and not backed by enough clinical evidence, especially with the availability of advanced hemostatic techniques.

Keywords: Postoperative collection, Hemithyroidectomy, Hospital stay, Ultrasound

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I. Background:

It has been a controversial issue whether drainage should be used after thyroid surgery. Postoperative hematoma may lead to life-threatening airway compression. Majority of surgeons took for granted that drainage following thyroid surgery would obliterate the dead space and evacuate the accumulation of blood and serum. However, there is no supportive evidence so far. Insertion of a drainage tube did not benefit patients after thyroid surgery[1-3]. Several studies demonstrated that drainage did not reduce hematomas. And in case of severe bleeding, wound drainage may be obstructed by clots[4-6]. One study even found that more fluid collection and higher incidence of postoperative complications occurred in patients with drainage than those without drainage.[15]. The concern of postoperative complications such as the formation of hematoma or seroma, drives the surgeon’s decision to use drains. However, the argument against this is on the rare occurrence of postoperative bleeding[16,17]. Postoperative bleeding has been reported to be as low as 0.3–1 % in thyroid surgeries[18]. Furthermore, it has been suggested that clotted blood blocking the drain may cause more harm than benefit, as the surgeon may not be aware of a major bleeding, if it occurs[18]. Whether or not drains reduce
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the risk of hematoma in thyroid surgery, their placement may augment scarring in a cosmetically sensitive area and also add discomfort to the patient, and increase the cost of surgery[19,20]. Our goal in undertaking this study is to compare the outcomes of routine open drainage vs hemithyroidectomy without drainage and to develop an evidence-based surgical practice in hemithyroidectomy. The outcome measures included ultrasound assessment of fluid collection in the thyroid bed on postoperative day 1&3 and the rate of postoperative complications and length of hospital stay.

II. Material And Method:

The approval was taken from the ethical committee before initiating the study and informed consent was taken from the patients, we explained all surgical procedures and their possible consequences to the patients. The study was carried out on 60 euthyroid status patients who underwent 60 hemithyroidectomy after taking detailed history and general examination. Study conducted in a single unit conducted at MGM Medical College and M.Y. Hospital, Indore (M.P.) between December 2018 to February 2019. Patients were randomized into two groups i.e. 30 patients in Group A (drain) and 30 patients in Group B (no drain). Each operation was conducted under general anesthetic with endotracheal intubation. Surgeries were performed in the routine manner with a transverse midline incision for all cases. Postoperative care was routine. Tracheotomy trays were kept at the bedside as per our routine. Patients whom had active drain inserted were considered cases and patients without a drain were considered controls. In the drain group just before the closure, an active drain with negative pressure was brought out through a separate wound. Ultrasound of the neck was performed in both the groups on postoperative day 1 and day 3 each time by the same radiologist or under his supervision and ultrasound guided aspiration of fluid done in required cases. The calculation of the volume of the fluid collection in the operative bed was done by measuring the maximum diameter in three dimension. The drains were removed in all the patients after 3 days. All patients were observed for any postoperative pain, swelling, voice change, wound infection, wound dehiscence, length of hospital stay and collection (hematoma, seroma) were the outcomes measured per treatment arm. Using Chi square test, student t test, results were evaluated within a 95% confidentiality range and a p value of less than 0.05 was considered significant.

### Statistical Analysis

#### Distribution of Patients based on Gender

<table>
<thead>
<tr>
<th>Group</th>
<th>Without Drain</th>
<th>With Drain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>19 (64%)</td>
<td>19 (64%)</td>
</tr>
<tr>
<td>Male</td>
<td>11 (36%)</td>
<td>11 (36%)</td>
</tr>
</tbody>
</table>

#### Age

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>Median</th>
<th>Standard Deviation</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>With Drain</strong></td>
<td>20</td>
<td>50</td>
<td>32.13</td>
<td>34</td>
<td>6.85</td>
<td>0.6244</td>
</tr>
<tr>
<td><strong>Without Drain</strong></td>
<td>20</td>
<td>50</td>
<td>32.73</td>
<td>30</td>
<td>7.70</td>
<td></td>
</tr>
</tbody>
</table>

#### Analysis of POD1 and POD3 collection findings

<table>
<thead>
<tr>
<th>POD1 Collection</th>
<th>POD3 Collection</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>5 (45.5%)</td>
<td>11 (100%)</td>
</tr>
<tr>
<td>NO</td>
<td>4 (62.5%)</td>
<td>49 (100%)</td>
</tr>
</tbody>
</table>
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Above table shows that there are 5 (45.5%) cases found where POD3 collection is found after the finding of POD1 collection. Similarly, there are 45(93.75%) cases where POD 3 collection was found when there is no POD1 collection. This table represents the collective cases for both the cases. POD1 and POD3 collection findings based on Drain vs Non Drain Groups

It can clearly be seen from the above chart that there is no significant difference in the patients with Drain and No Drain groups when POD 1 collection is observed. However, we can see significant difference in the number of cases when POD 3 collection is observed.

<table>
<thead>
<tr>
<th></th>
<th>POD1 Collection</th>
<th>POD3 Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Drain</td>
<td>6 (54.5%)</td>
<td>24 (48%)</td>
</tr>
<tr>
<td>Without Drain</td>
<td>5 (45.5%)</td>
<td>25 (52%)</td>
</tr>
<tr>
<td>Total</td>
<td>11 (100%)</td>
<td>49 (100%)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.65</td>
<td>0.03</td>
</tr>
</tbody>
</table>

**Intervention Done**

<table>
<thead>
<tr>
<th></th>
<th>Intervention Done</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>With Drain</td>
<td>22 (73.3%)</td>
</tr>
<tr>
<td>Without Drain</td>
<td>24 (80%)</td>
</tr>
</tbody>
</table>

**Post-Operative Complications (p value: 0.026)**

<table>
<thead>
<tr>
<th>Complications</th>
<th>Wound Infection</th>
<th>Pain</th>
<th>Swelling</th>
<th>Dehiscence</th>
<th>Voice Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Drain(n=30)</td>
<td>3 (10%)</td>
<td>8 (27%)</td>
<td>3 (10%)</td>
<td>2 (6.7%)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Without Drain(n=30)</td>
<td>2 (6.8%)</td>
<td>5 (16%)</td>
<td>6 (20%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Here p-value is presented for total number of complication number. It suggests patients suffers less complications in without drain cases.

It is evident from the above chart that number of cases of post-operative complications are higher in the patients with Drain group than the patients in Without Drain group.

Hypothesis testing on the Post-operative complications and Hospital Stay

**III. Results**

Sixty patients underwent hemithyroidectomy and were randomly distributed into a drain or no drain group. There was a definite predominance of female patients, 19 of 30 (64%) female and 11 of 30 (36%) male in both the groups (Table 1). Median age of patients in drain group is 34 years while that in without drain group is 30 years (Table 2). Using student t test p-value =0.6244 that is greater 0.05 ,hence this difference is not significant. The distribution of age and gender is statistically similar in the both the groups as suggested by p-value(0.6224), which is calculated using student t-test.

Postoperative collection on POD 1 and POD3:
The present findings indicate no significant difference in collection on POD 1 between patients in the drain (p-value=0.65) and in no drain group. On POD 3,p-value=0.03(which is less than 0.05)concludes significant difference between two groups(Table 4). Intervention that is ultrasound guided aspiration not needed in 3 (10%) in with drain group 4(10.33%) in with out drain group .Intervention done in 5(16.67%) in with drain group and 2(0.67%) in without drain group (Table 6).

**Infection:**
The postoperative rate of infection was higher in the drain group (p-value = 0.014131, as the p-value which is less than 0.05 (confidence interval of 95%), we have sufficient evidence to reject null hypothesis. Thus, we can conclude that the chances of occurrences of Wound infection among patients with drain in more, which could be due to the drain itself, providing easy access for bacteria to the wound.

**Length of hospital stay:**
Table 8 summarizes the length of stay in the drain and no drain groups. Of note, mean duration of stay in hospital with drain group(4.67) is more than with no drain group(2.31 ).As the p-value(t-value -14.39,df =54.068,p-value=2.2e-16) is significantly less than 0.05 considering confidence interval of 95%, we have sufficient evidence to reject null hypothesis. Thus, we can conclude that the patient stays in hospital for lesser time in case of without drain. The main reason for prolonged stay in the drain group was because of too much
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drainage. Most of the patients with too much drainage, who were otherwise well, did not want to take the drain home to care for it themselves and it was not a feasible option for many because of distance to travel to the hospital. Also drain placement may be related to the higher infection rate, and the time needed to observe and remove the drain in drain group.

PAIN:
If we consider pain in between two groups, patients with drain group experience pain more than patients in without drain group (Chi-squared test for given probabilities data: observed X-squared = 1.5341, df = 1, p-value=0.2155). As the p-value is significantly greater than 0.05, we do not have sufficient evidence to reject null hypothesis.

Voice change:
If we compare voice change in between 2 groups, chances of Voice change among patients without drain in less. Chi-squared test for given probabilities data: observed X-squared = 3.682, df = 1, p-value =0.055 as the p-value is more than 0.05 (considering confidence interval of 95%) by very small margin, we can reject null hypothesis.

Wound dehiscence:
Comparing wound dehiscence in both groups patients we observed more number cases in patients with drain group (p-value =0.03169) with chance.

Post operative complication:
The adverse events reported in this study includes wound infection 3(10%) and pain 8(27%) higher in drain group as compared to without drain which is 2(6.8%),5(16%) respectively. Dehiscence 2(6.7%) and voice changes 3(10%) seen only in drain group. But swelling resulted more in without drain group 6(20%) than with drain group 5(16%). (Table 5). The p-value(0.026) for total number of complication suggests that patients suffers less complication in without drain cases.

IV. Conclusion
The present prospective case control study verify that in hemithyroidectomy for benign disease routine drain placement after surgery is not necessary and is not effective in decreasing the rate of postoperative complications. By contrast, the use of drain prolongs the postoperative pain, hospital stay and may be associated with an increased risk of infective complications. Placing wound drains is purely a surgeon’s choice based on experience and training, and not backed by enough clinical evidence, especially with the availability of advanced hemostatic techniques.

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