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- **Title:** Could Post-thyroidectomy bleeding be the clue to modify the concept of postoperative drainage? A Prospective Randomized Controlled Study
- **Tentative Article Number:** ASJSUR_2017_287
- **Authors:** Ali Al-Qahtani, Tarek Osman

is formally accepted by Asian Journal of Surgery, and it will approximately be published in 2018.

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ORIGINAL ARTICLE

Could post-thyroidectomy bleeding be the clue to modify the concept of postoperative drainage? A prospective randomized controlled study

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Received 2 July 2017; received in revised form 2 August 2017; accepted 28 August 2017

KEYWORDS
Thyroid;
Thyroidectomy;
Post thyroidectomy bleeding;
Surgical drains

Summary
Purpose: To unveil the real effect of surgical drains on the outcomes of thyroidectomy for benign thyroid disorders.

Methods: A prospective randomized study was conducted at Abha Private Hospital, Saudi Arabia on 108 patients suffered from benign thyroid disorders undergoing elective thyroidectomy from 1 August 2015 to 28 February 2017. Patients were allocated randomly into drainage group (A) and non-drainage group (B). The demographic data, operation (type and duration), postoperative complications, histopathological results and length of stay were assessed, documented and statistically verified to check its significance.

Results: A total of 108 patients were enrolled in the study; 94 females and 14 males with mean age of 38.02 years, two patients developed hematoma (1.85%); one in each group and another two patients had seroma with no significant difference between both groups, the mean length of stay was significantly higher in group (A) (p = 0.001).

Conclusion: This prospective study verified that routine drainage adds no significant advantage in the prevention of post-thyroidectomy bleeding, but it prolongs hospitalization. This aids in changing the concept from the “wide” use of drains into the “wise” use in selected patients with risk factors of bleeding.

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https://doi.org/10.1016/j.asjsur.2017.08.004
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Please cite this article in press as: Al-Qahtani AS, Abouzeid Osman T, Could post-thyroidectomy bleeding be the clue to modify the concept of postoperative drainage? A prospective randomized controlled study, Asian Journal of Surgery (2017), https://doi.org/10.1016/j.asjsur.2017.08.004
1. Introduction

Thyroid gland is a highly-vascularized endocrine organ, any hematoma within the closed paratracheal space can occlude the venous and lymphatic drainage that consequently leads to laryngopharyngeal edema and airway obstruction,\(^1\) therefore, post-thyroidectomy hematoma could be a life-threatening sequelae.\(^2\)

Post-thyroidectomy hematoma has been variously reported in literature (0.1–6.5\%) with an average of 1\% in large endocrine centers,\(^3\) it mostly occurs within 2–6 h postoperatively.\(^4,5\) However, the onset may be delayed up to the 13th day.\(^6\)

The possible causes include the slippage of an improperly applied ligature due to retching, vomiting, Valsalva maneuver, increased venous and/or arterial pressure. It was shown to be associated with anticoagulant medications and hematologic diseases.\(^7\)

The bleeding source may be from the subcutaneous tissue, infrahyoid muscles, upper pole, residual thyroid tissue, internal jugular vein, or tissues adjacent to the recurrent laryngeal nerve. Sometimes the bleeding source is not evident during wound re-exploitation.\(^8\)

The key for successful management depends on early detection and immediate proper intervention before airway obstruction occurs; early detection relies on high index of suspicion in the first golden post-operative hours. The presence of sweating, tachycardia, irritability and confusion reflects early hypoxia, whereas ecchymosis, neck swelling, choking sensation, dyspnea, difficult phonation and stridor constitute the late symptoms and signs.\(^9\) The surgical drain is usually blocked with clotted blood, a common problem that turns the drain into a misleading tool. So, the clinical picture of the patient is much more sensitive and specific in the diagnosis of Postoperative hematoma than drain discharge.\(^10\)

The scientific research investigating post-thyroidectomy drainage could be broadly classified into 3 groups: The first group of authors are convinced with the routine drainage; their research is designed to compare the negative suction drains and natural drains.\(^10,11\) The second group are not convinced with drains, that's why their research is based on the "no-drain concept",\(^12,13\) whereas the third group tried to compare the rates of bleeding with and without drains.\(^14-19\)

Nevertheless, these controversial studies are still not convincing to many surgeons due to its retrospective design as well as the exclusion of both Graves’ disease and the retrosternal goiters. This prospective randomized study was conducted to evaluate the role of drainage post-thyroidectomy for all benign thyroid disorders including Graves’ disease and the retrosternal goiters.

2. Methods

Upon Approval of the Institutional Review Committee of the hospital, a prospective randomized study has been conducted at Abha Private Hospital, Kingdom of Saudi Arabia, on 108 patients suffered from benign thyroid diseases underwent thyroidectomy in a single unit from 1 August 2015 to 28 February 2017. Patients of either gender, aged 14–75 years who had benign thyroid disorders and are candidates for thyroidectomy were enrolled in this study, exclusion criteria included bleeding disorders, history of neck malignancy, previous neck surgery or radiotherapy, and those unfit for general anesthesia.

Patients were evaluated by neck ultrasound, thyroid hormone profile, fine needle aspiration cytology (FNAC), and routine preoperative blood investigation. Patients signed the preoperative written informed consent and were scheduled for either lobectomy plus an isthmectomy or total thyroidectomy according to their disease. The preoperative demographic and clinical data were documented.

All patients were classified according to the block randomization method into either drain group (group A) or non-drain group (group B), this involves balancing of the number of patients recruited to both arms of the study after every 10 recruits. So, it ensured that if the study had been stopped early, there would have been almost the same number of patients in both groups.

All procedures were done by one of the authors under general anesthesia using the same conventional technique, with separate ligation of the branches of the superior thyroid artery, middle thyroid vein and inferior thyroid artery. Furthermore, hemostasis was achieved with bipolar electrocautery. The operating surgeon was informed to put drain or not just before muscle closure. We used natural (Penrose drain) (Sewoon Medical Co., Cheonan, Korea). The specimen was sent for histopathological examination.

Group (B) patients were discharged usually after one day of operation while Group (A) patients were discharged after drain removal, this was achieved when drainage fluid was less than 15 mL over eight hours. At discharge, all subjects were instructed to report any post-operative swelling.

Other relevant data as type of surgery, duration, intra-operative blood loss, drain use, postoperative hematoma, and length of stay were also documented in a standard form, and were verified to check its statistical significance. Standard descriptive statistics were used to summarize the demographic and clinical data, surgical operations and outcomes. The statistical analysis was done using the Statistical Package for Social Science Version 16 software package (SPSS, Inc., Chicago, Illinois, USA). Statistical significance was set at P-value <0.05.

3. Results

During the period of study, 108 patients underwent thyroidectomy, 94 females and 14 males (female: male ratio of 7:1.6) with mean age of 38.02 years (range 14–72 years). Both groups were consisted of 54 patients. There was no statistically significant difference in the age, gender, and histopathological results of the patients of both groups (Table 1).

No significant differences were found among both groups regarding type of the operation, operative time in minutes and operative blood loss (Table 2). Postoperative hospital stay is markedly increased in group (A) (37.3 h (range 21.4–72.6 h) versus 21.2 h (12.4–59.3 h) in group (B) with significant difference between both groups (p = 0.001 & 95% confidence intervals) (Fig. 1)).
Table 1  Demographic data and pathological diagnosis.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group (A) Drain Group</th>
<th>Group (B) Non-drain Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (mean ± SD)</td>
<td>38.02 ± 12.96</td>
<td>39.59 ± 10.42</td>
<td>0.489</td>
</tr>
<tr>
<td>Gender:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males: n (%)</td>
<td>6 (11.1%)</td>
<td>8 (14.8%)</td>
<td>0.776</td>
</tr>
<tr>
<td>Females: n (%)</td>
<td>48 (88.9%)</td>
<td>46 (85.2%)</td>
<td></td>
</tr>
<tr>
<td>Pathologic diagnosis:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Multi-nodular goiter: n (%)</td>
<td>19 (35.2%)</td>
<td>17 (31.5%)</td>
<td>0.952</td>
</tr>
<tr>
<td>2) Graves’ disease: n (%)</td>
<td>8 (14.8%)</td>
<td>7 (13.0%)</td>
<td></td>
</tr>
<tr>
<td>3) Hashimoto’s thyroiditis: n (%)</td>
<td>7 (13.0%)</td>
<td>8 (14.8%)</td>
<td></td>
</tr>
<tr>
<td>4) Solitary thyroid adenoma: n (%)</td>
<td>20 (37.0%)</td>
<td>22 (40.7%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2  Operative data (type of the operation, operative time in minutes, and operative blood loss in ml) and post-operative hospital stay in hours.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group (A) Drain Group</th>
<th>Group (B) Non-drain Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of operation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total thyroidectomy: n (%)</td>
<td>34 (62.9%)</td>
<td>32 (59.3%)</td>
<td>0.844</td>
</tr>
<tr>
<td>Lobectomy plus isthmectomy: n (%)</td>
<td>20 (37.1%)</td>
<td>22 (40.7%)</td>
<td></td>
</tr>
<tr>
<td>Operative duration: (mean ± SD)</td>
<td>(54.72 ± 15.16) min</td>
<td>(56.05 ± 14.42) min</td>
<td>0.641</td>
</tr>
<tr>
<td>Operative blood loss: (mean ± SD)</td>
<td>(168.24 ± 76.64) ml</td>
<td>(175.19 ± 87.45) ml</td>
<td>0.662</td>
</tr>
<tr>
<td>Postoperative hospital stay: (mean ± SD)</td>
<td>(37.30 ± 11.51) h</td>
<td>(21.20 ± 4.99) h</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Figure 1  Error bar showing arithmetic mean and 95% confidence intervals of the study groups (A: drain group and B: non-drain group).
Two patients developed Postoperative hematoma (1.85%); one patient in each group, there was no significant difference in the rate of bleeding between the two groups, both patients were treated with conservative treatment. Two cases of seroma, one in each group, they had been diagnosed in the follow up and were treated with aspiration. No cases developed surgical site infection in this series.

4. Discussion

Since it has been introduced in 1940s, suction drain was commonly used in most of surgical operations including thyroidectomy. Many researchers reevaluated its role in different surgical procedures as cholecystectomy and intestinal surgery.

Ardito et al. analyzed the outcome of their 10 years’ experience on 1217 patients underwent thyroidectomy. However, they suggested drains’ value in removing blood, they documented that drains were not helpful in the cases which developed bleeding.

Although, there is no scientific evidences to support the benefit of drains, surgeons continued to use as it is thought to obliterate the dead space, facilitate flaps repositioning, drain off any formed fluid, and help in the early detection of bleeding. This assumption was reinforced by the observation that drain usually brings effluent. By time, this proved to be wrong, and the presence of the drains was the irritant factor that triggers local inflammation and seroma formation.

In two recent studies comparing negative and natural drainage post-thyroidectomy, it was shown that closed suction drainage increased drainage volume than natural drain. This could be attributed to the fact that negative pressure prevents the injured lymphatics to seal off and hence increase drain output, and they recommended the use of natural drain if needed. Moreover, this negative pressure may cause ligatures slippage or suck the fresh clot in the thyroid bed, and hence increase the risk of hemorrhage.

Some investigators argued against the concept of dead space stating that the surrounding pliable tissues collapse around the thyroid bed at the end of the operation obliterating any dead space, and or seroma to be formed in a given cavity, the pressure within this cavity must be higher than the atmospheric pressure or the walls of this cavity must be rigid enough to counteract the external pressure which is difficult to occur.

This change in the concept of post-thyroideectomy drainage was initially surprising to the surgical community, especially when Ariyanayagam et al. published their 15 years’ clinical trial conducted on 259 patients assigned to non-drain thyroidectomy with less than 1% complication rate. This trial clearly establishes the safety of non-drainage concept.

Many arguments were published all over the world, suggesting abandonment of the routine placement of drains post-thyroidectomy. The largest series studied this issue was a retrospective analysis on 1066 patients over about 17 years, in which, Ozlem et al. found no value of the old concept of routine drainage.

In this series, minor bleeding occurred in two patients (1.85%); the first patient was 61 years old female suffered from large multinodular goiter, she underwent total thy-roideectomy without placing drains, and developed mild neck swelling 10th hour after surgery with superficial prominent dark-colored bruising.

The second one was 38 years old lady had Graves’ disease with failed medical treatment for 2 years. She underwent total thyroidectomy with drain use, drain was removed in the second day with only 23 cc effluent, and patient was discharged. After 2 days, patient returned to us with neck swelling, and mild pressure sensation. Both patients had stable vital data, no signs of hypoxia or respiratory distress, they had been kept under observation for 2 days without intervention. Seroma developed in another 2 cases one in each group (1.85%), and was aspirated without further sequelae.

There is no statistical difference between the 2 groups denoting that the routine use of natural drains does not appear to reduce the rate of bleeding, seroma or re-operation rates after uncomplicated thyroidectomy, these results are in accordance with that concluded by some previous studies. Furthermore, the use of drain was associated with significant increase in the length of hospital stay ($P = 0.001$) which is the same concluded by some other trials.

4.1. Surgical impact

1) Abandon the old concept of routine drainage in uncomplicated thyroidectomy in low risk patients and so decrease the rate of drain-associated complication.

2) Develop a new concept "wise use of drain" by determining the high-risk patients who will benefit from drain insertion. The preoperative risk stratification is still considered a matter of controversy. Up to date, no consensus about the risk factors of bleeding. However, it is significantly associated with male gender, older age, obesity, smoking, antithrombotic agents, coagulopathy, postoperative hypertension (systolic pressure $> 150$ mmHg), Graves’ disease, malignant tumor, total thyroidectomy (due to more dissection), subtotal thyroidectomy (due to vascularized remnant tissue), lymph node dissection, and blood transfusion on the day of surgery.

A recent study using the American inpatient database added thyroiditis, and chronic renal disease as predictors for post-thyroidectomy hematoma occurrence.

Lang et al. found those with dominant nodule size $> 3$ cm had approximately 4.5 times higher risk for bleeding than those $< 3$ cm. Some demonstrated that postoperative drain output is more related to intraoperative blood loss rather than the extent of surgery. Some authors are convinced that drains should only be used in complicated cases, large goiters, retrosternal goiters and wet operative field at the end of the procedure.

3) Direct the research towards the innovation and the development of a real preventive measures for the postoperative hematoma (rather than drains). These
measures could be broadly classified into 3 categories: hemostatic materials, new energy devices, and the minimally invasive approach.

Fibrin glue is a biological adhesive material reconstituted from human fibrinogen, it offers a comparative advantage over suction drain by decreasing the incidence of bleeding and seroma formation and shortening the hospital stay.\textsuperscript{17,25} Collagen human fibrinogen human Thrombin patch (CFTP) and Bio-absorbable oxidized cellulose are also effective in decreasing effluent drainage.\textsuperscript{2} Epinephrine spray minimizes capillary and venous bleeding without marked systemic complications. The new energy devices as the Harmonic Focus\textsuperscript{®} (Ethicon Inc., Cincinnati, OH, USA) and Ligasure\textsuperscript{®} (Covidien Inc., Autosuture, Mansfield, USA) have been shown to be more effective in ensuring less bleeding and less postoperative fluid. Minimally invasive techniques and robotic surgery decreased the rate of bleeding in several RCTs.\textsuperscript{2,6,26} Other measures as pressure dressing and tranexamic acid had no additional value in the control of perioperative bleeding.\textsuperscript{22}

The limitation of this study is that emerged from a single-center experience. Further study of the previously mentioned risk factors and determination of specific criteria for drain use are important objectives for future research. Although the number of study subjects in the present study is relatively small raising the potential limitation of type II error, yet similar studies in the same subject failed to show any significant differences.

5. Conclusion

This prospective randomized study verified that drainage had no significant advantage in the prevention of post thyroidectomy bleeding for benign thyroid disorders, but it prolongs hospitalization. Therefore, the old concept of "Wide use of drains "must be abandoned and replaced with the new concept "Wise use of drains" in selected patients with risk factors of bleeding.

Conflicts of interest

None declared.

Financial disclosures

This study was not funded or granted by any companies.

Authors’ contribution

Authors equally contributed to this article, in the design study, data collection and analysis, literature review, and manuscript writing.

Acknowledgment

The authors would like to acknowledge Prof. Ahmad Mahfouz from the department of family and community medicine, King Khalid University for his valuable assistance with the statistical analysis.

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