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How to Decide for Drain Placement in Thyroidectomy: Qualitative Exploration to Formulation of a Decision Tree

Talat Waseem, Safia Zahir, Zaitoon Zafar, Muhammad Hasham Ashraf

IMPORTANCE Contrary to significant clinical evidence, many surgeons still use drains following a thyroidectomy for several reasons, including intent to prevent postoperative hemorrhage and seroma formation. Quality of hemostasis, size of gland, quality of thyroid tissue and its dissection, presence of adhesions and extent of surgery may all influence surgeon's decision to use a drain. The aim of this study is to qualitatively explore the reasons for use of drains in thyroidectomy, to evaluate given reasons in a clinical setting and finally, to develop a consensus decision tree.

METHODS We conducted a thematic analysis following a focused group discussion among panel of endocrine surgical experts (n=8) to explore the factors which influence the decision to place a drain following thyroidectomy. To validate these findings, we conducted a prospective randomized clinical trial on patients undergoing thyroid surgery. Patients were randomly assigned to a drain group (n = 112) or a no-drain group (n = 100). Postoperatively, we evaluated visual analogue scale pain scores, postoperative analgesic requirements, self-reported scar satisfaction at 6 weeks and complications associated with surgery including hemorrhage and seroma formation. E-Delphi technique was used to develop a consensus on the proposed decision tree.

RESULTS Thematic analysis of the focused group discussion of panel of endocrine surgeons revealed various factors involved in the decision of placing or not placing a drain. Reasons included quality of dissection, size of gland, extent of dissection, thyrotoxicosis associated tissue friability and thyroiditis, or cancer associated fibrosis. Technique of dissection and experience were considered to be the most important determinant of postoperative hemorrhage. Purpose of drain placement was not to prevent hemorrhage, but to provide a sense of comfort to the operating surgeon. Clinical trials revealed no significant impact of drains in prevention of hemorrhage, however, drain placement was significantly associated with lower rates of postoperative seroma formation. Subgroup analysis showed a higher association of seroma formation to extent of surgery, size of gland and thyrotoxicosis. A decision tree to aid decision making for drain placement during thyroidectomy is being proposed here.

CONCLUSIONS The decision to place the drain should be selective. Size of the gland, extent of dis-section, thyrotoxicosis and quality of hemostasis are important determinants for the decision of drain placement justifying the selective use of drains. The frequency of life-threatening post-thyroidectomy bleeds remains low and drain placement might not be required for smaller thyroid nodules. Short term drain placement for 12-24 hours reduces seroma formation and, thus, need for needle aspiration in patients undergoing thyroidectomy.

KEY WORDS Thyroidectomy, Drain Placement, hemorrhage, seroma formation

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Emerging evidence challenges routine use of drains in many surgical procedures because of higher infection rates, discomfort and prolonged hospital stays [1–5]. Their clinical utility has been questioned in colonic and biliary surgery and in fact their use has reduced significantly [1,6,7]. Thyroid surgery is no exception. Following these lines many studies have discouraged the use of drains, even in the neck, with the belief that drains do not prevent hemorrhage[7–14]. The evidence is statistically convincing however the practice has lagged, in opposition to literature recommendations. Many surgeons still use drains after performing thyroid surgery and have a selective approach[15]. Early recognition of hemorrhage, fear of formation of neck hematoma or prevention of seroma formation are the three most cited reasons for placing drains in neck[16]. On the contrary, drains can augment infection, may influence the wound scar quality, can lead to more pain, and may prolong hospital stay[9,16,17].

This discrepancy between literature recommendations and prevalent practices potentiates the need for randomized trials but despite many randomized trials, many aspects of the drain placement decision still remain unexplored. To explore reasons for drain placement we here employ the qualitative approach and examine the perceptions and their scientific justification. To further corroborate our qualitative findings, we conducted a randomized controlled trial. The objective of the study is to critically probe the reasons for placing a drain following neck surgery and with the eventual aim to minimize the gap between theory and practice.

METHODS

Ethical approval for the study was obtained through institutional review board. Mixed method study design was chosen, with stage 1 comprising a qualitative approach and stage 2 comprising quantitative data collection in clinical setting, where findings of the first stage were validated in quantitative fashion. In stage 3, based on the data, a proposed decision tree was circulated among the panel of experts to build consensus through e-Delphi technique as described previously 18. Qualitative research has the power to explore details of the experiences and perceptions and may work where quantitative research has limitations. Focus group discussion (FGD) which is a very comprehensive qualitative data collection technique, was used here, as described previously, in this study to explore perceptions and experiences of expert endocrine surgeons about drain placement[19]. To identify prevalent themes in drain placement, challenges, advantages and disadvantages, extensive literature review was done and a discussion guide was made for the FGD session. Open ended and closed ended questions were formulated for discussion. Descriptive exploratory qualitative study using a conventional content analysis method was performed. Purposive sampling of the eight (n=8) experts was done to include the surgeons who are well trained and have extensive experience in endocrine surgery and have performed at least 200 thyroidectomies. Our sample size conforms to literature recommendations [19]. Focus group discussion was conducted in standard fashion with the point of saturation as described previously by Strauss [20]. The session was audio-recorded. A qualitative content analysis was performed as described previously by Graneheim and Lundman [21]. Analytical process started by using verbatim transcription and identifying the participants' views. Themes, subthemes and categories were identified and negotiated between the team members to generate inter-rater reliability. As of any qualitative research the quality of study was ensured on the criteria of credibility, transferability, dependability, and confirmability.

In stage 2 of the study, a prospective randomized clinical trial was conducted following principles of the CONSORT flow diagram. The trial involved patients undergoing elective thyroidectomy with or without drain. The patients having small and moderate sized glands were included in the study and the patients with large or huge glands were excluded from the study. General demographics of the participants, disease, gland size, clinical status and clinical diagnosis parameters were recorded as per norms. The randomization was through the lottery method. The primary study end point was seroma formation and hemorrhage necessitating re-exploration. Secondary end points included postoperative pain (assessed by visual analgia scoring and analgesia requirements according to the WHO analgesia ladder system) at 24 hours, drain output and length of hospital stay. Patients requiring extensive surgery like sternotomy, thyroidectomy for huge glands, neck dissection and with history of any bleeding disorder were excluded. Both surgeons and the patients were blinded to randomization. Two surgeons employed the same operative technique to provide uniformity. Meticulous hemostasis was ensured prior to closure. Suction drain was used prior to closure for the drain group. Preoperative analgesia was standardized. Type and length of surgery recorded. Operative time, blood loss, postoperative drain volume, analgesia requirements, histological diagnosis and recurrence over a period of at least 6 months recorded. Postoperative pain was assessed through visual analogue scoring ranging from 0-10. Postoperative complications like acute life-threatening post-thyroidectomy bleed, neck hematoma and symptoms of hypocalcemia, were recorded both throughout the hospital stay and at the first scheduled clinic appointment after surgery (6 weeks postoperatively). A wound infection was diagnosed if purulent discharge exuded from the wound or a painful, spreading erythema indicative of cellulitis existed. At six weeks, patient satisfaction with scarring was assessed by subjective patient ranking on a scale from 0 to 10.

In Stage 3, e-Delphi technique was used as described previously to build expert consensus on proposed decision tree for drain placement in 2 rounds.

Statistical Analysis of Results

The data was analyzed using SPSS version 21 (SPSS, Inc, Chicago, IL, USA). Data normality was tested using the Kolmogorov-Smirnov test. Fisher's exact test or Pearson Chi2 values were used to determine significant difference between the groups. For linear data with means, Mann-Whitney U test was used as appropriate. A value of $P < 0.05$ was considered to be statistically significant. Inter-rater agreement and concordance were calculated based in Fleiss's kappa values with cut off of 0.8.

RESULTS

The study consists of three stages: first stage encompasses qualitative portion and the second stage is a quantitative study in form of a randomized controlled trial. Figure 1 shows the flow of the study and its two stages. In third stage we propose a consensus decision tree based on data. Extensive preliminary literature review was done, based on which themes and subthemes were identified to understand

the reasons of drain placement. A discussion guide was formulated to standardize the discussion. Eight experts in endocrine surgery participated in Focus Group Discussion (FGD). The themes explored have been summarized in the Table 1.

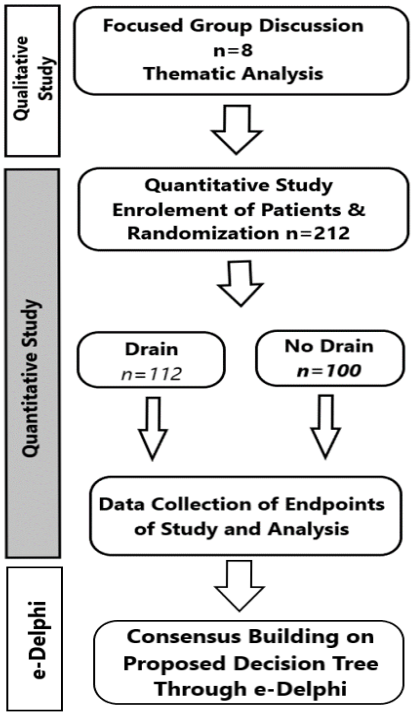

Figure 1: The Flowchart shows the overview of the study steps and its qualitative and quantitative components.

Theme	Subtheme	Representative Statements
actors influencing Placement of Drain	Hemorrhage & Apprehension of Bleed	*"Well it is all about fear of bleed"* *"Conventionally I have believed in drains in neck surgery-It is reassuring and it does not hurt me or the patient"*
	Size & Extent of Dissection	*"For smaller glands I may be able to skip the drain but for the larger glands, usually it becomes harder for me to avoid a drain"* *"I think size of the gland and toxicity often force me to put in drain"*
	Friability & Fibrosis	*"Toxic glands are quite friable and the surrounding tissues are also hyper-vascular and they bleed to touch. Invariably I would have to place a drain in these cases"* *"Preoperative Lugol's Iodine treatment partially reduces vascularity of the gland and reduces friability of the gland however I always put a drain in such cases"*
	Adhesions	*"Adhesions are also important, whether they are due to malignant thyroidal lesion or thyroiditis related fibrosis, they all lead me to put in a drain"*
	Seroma Formation	*"For smaller glands, there are lower chances of seroma development-these are probably the cases where we can avoid the drain"* *"Seroma formation may also be linked to body's response to dissection and the sutures used for tying vessels".* *"When there is extensive area of dissection for example in total thyroidectomy for large glands, there is higher chance of bleed and seroma formation if we don't put in a drain"*
Prevention of Hemorrhage	Technique & Quality of Hemostasis	*"It all depends on technique, careful dissection and quality of hemostasis"* *"I had few bleeds in my career and they all were related to technical failure and that was mostly slippage of ligature of a vein; I always tie twice!"* *"Whenever I re-explored for bleed mostly it was due to missing on either small lateral or inferior thyroid vein and drain did not prevent neck hematoma formation"*
Advantages of Drain Placement	Reassurance	*"It is quite reassuring for me"* *"I am not sure if it would prevent hemorrhage but it keeps me calm and reassured"*
	Possible Prevention of Hemorrhage	*"The drains frequently have from few mls to up to few hundred ml of blood which shows that it is probably beneficial somehow to have it probably we would need a huge to trial to prove it statistically, however"*
	Reduction of Seroma Formation	*"It does reduce the incidence of postoperative seroma formation"*
Disadvantages of Drain Placement	Discomfort & Pain	*"Well it does add to patient discomfort"* *"Patient have more pain when a drain is there and the patients without drain are more comfortable"*
	Hospital Stay	*"However, I don't think it should add significantly to patient hospital stay"*
Avoiding Drain Placement	Smaller Glands-Minimal Dissection	*"For smaller non-toxic lobes I usually avoid drains"* *"Good hemostasis is the key for me to decide in favor of not putting the drain"*
Need or Reassurance?	Reassurance	*"it is both reassuring to put in a drain and it also prevents the postoperative seroma formation"*
	Prevention of Seroma Formation	*"I think it is ok to put in a drain for 12-24 hours or so, it is not only reassuring for me but also reduces the incidence of postoperative seroma formation"*

Table 1: Thematic analysis of qualitative interviews exploring the need for drain placement following thyroidectomy

Factors influencing the decision of drain placement were explored. Contrary to what the literature states, the fear and apprehension of neck hematoma needing evacuation still has some role to play in decision making. This varies between surgeons and few believe in the literature evidence but would still like to decide on case to case basis. One participant said: "Well this is all about fear of bleeding". This notion was expressed by another participant in following words: "conventionally I have believed in drains in neck surgery—It is reassuring and it does not hurt me or the patient". This highlights the potential role of personal biases playing in the decision of drain placement. When further scrutinized one participated in favor of placing drain claimed: "the drains frequently have from few mls. [milliliters] to up to few hundred ml of blood which shows that it is probably beneficial somehow to have it— we would

probably need a huge trial to prove it statistically, however". This does merit further investigation.

Gland size and extent of dissection play an important role in terms of apprehension about hemorrhage and the seroma formation as well as described by one participant: "For smaller glands I may be able to skip drain but for the larger glands, usually it becomes harder for me to avoid [it]" and"when there is extensive area of dissection for example in total thyroidectomy for large glands, there is higher chance of bleed and seroma formation if we don't put in a drain". For smaller glands, surgeons tended to avoid placing drains.

Third salient determinant for placement of drain that emerged was friability and the fibrosis of gland or adhesions to the surrounding structures. According to one participant, "toxic glands are quite friable and the surrounding tissues are also hyper-vascular and they bleed to touch. Invariably I would have to place a drain in these cases". When asked if there was any way to reduce the vascularity of the gland, one participant responded: "preoperative Lugol's Iodine treatment partially reduces vascularity of gland and reduces friability of gland however I always put a drain in such cases". Similarly, fibrosis and adhesions can also influence the resection bed and may lead to decision of the drain placement. In words of one expert surgeon, "adhesions are also important, whether they are due to malignant thyroidal lesion or thyroiditis related fibrosis, they all lead me to put in a drain".

The size of the gland and extent of dissection and quality of hemostasis also correlate positively to postoperative seroma formation. "For smaller glands, there are lower chances of seroma development— these are probably the cases where we can avoid the drain". One participant pointed towards the varying responses of the patient's immune system to dissection and the sutures used for tying vessels…… "seroma formation may also be linked to body's response to dissection and the sutures used for tying vessels". Area of dissection clearly was pointed as the a potentially decisive aspect. As per one surgeon: "When there is extensive area of dissection for example in total thyroidectomy for large glands, there is higher chance of bleed and seroma formation if we don't put in a drain"

Quality of hemostasis would often dictate surgeons to use or not to use the drain following thyroid surgery as explained by one endocrine surgeon this way: "It all depends on technique, careful dissection and quality of hemostasis","I had few bleeds in my career and they were all related to technical failure and that was mostly slippage of ligature of a vein; I always tie twice!" Ligature of the veins is the most frequent cause of hematoma as described by one participant: "whenever I re-explored for bleed mostly, it was due to missing on either small lateral or inferior thyroid vein and drain did not prevent neck hematoma formation".

Frequent advantages outlined by the participants included personal reassurance, possible prevention or early detection of hemorrhage, reduction in the incidence of seroma formation and reduction in postoperative pain and discomfort.

Measurement Parameter		Drain Group (n=112)	No Drain Group (n=100)
Age		49.32±11.6	47.35±10.77
Gender			
	Female	88.2%	83.5%
	Male	11.8%	16.5%
Diagnosis			
	Suspicious Solitary Nodule	60 (54%)	73 (73%)
	MNG Involving one lobe	31 (28%)	16 (16%)
	MNG	21 (19%)	11 (11%)
Histological Diagnosis			
	Benign Follicular Lesion	70 (62%)	64 (64%)
	Benign Hyperplastic Glands	21(19%)	13 (13%)
	Follicular Carcinoma	8 (7%)	14 (14%)
	Papillary Carcinoma	13 (12%)	8 (8%)
	Hashimoto's Thyroiditis	0	1 (1%)
Clinical Status			
	Euthyroid	74 (66%)	82 (88%)
	Hypothyroid	5 (4%)	4 (4%)
	Toxic Adenoma	33 (30%)	16 (16%)
ASA Status			
	ASA-I	100 (89.2%)	92 (92%)
	ASA-II	4 (3.5%)	4 (4%)
	ASA-III	5 (4.4%)	2 (2%)
	ASA-IV	3 (2.6%)	2 (2%)
Gland Size WHO Classification (1974)			
	WHO Class I	0	0
	WHO Class II	1 (0.8%)	7 (7%)
	WHO Class III	98 (87.5%)	82 (82%)
	WHO Class IV	13 (11.6%)	11 (11%)
Type of surgery			
	Lobectomy and Isthmectomy	91(90.1%)	87(87%)
	Total Thyroidectomy	21(9.9%)	13 (13%)
Mean length of surgery (minutes)		92.5±31.8	81.8±24.5

Table 2: General Patient Characteristics either having or not having drain

The representative statements have been outlined in the Table 1. Similarly, postoperative discomfort and potential lengthening of the hospital stay were considered as the potential disadvantages. One participant concluded by illuminating: "I think it is ok to put in a drain for 12-24 hours or so, it is not only reassuring for me but also reduces the incidence of postoperative seroma formation".

To further expand the findings of qualitative analysis and to put them to clinical perspective, we ran a randomized controlled trial. CONSORT protocol was followed and eventually 112 patients were randomized to drain group and 100 to the no-drain group. The general characteristics of the patients have been summarized in Table 2.

Measurement parameter	Drain group	No Drain group	P-value
Per-operative mean blood loss	39.86±24.75	42.95±25.06	0.135
Postoperative Drain Output	50.17±41.50	-	-
Mean length of postoperative stay (Hours)	25.91±9.87	21.82±3.57	0.773
Mean pain score (maximum = 10)	3.1±1.1	2.3±0.4	0.051*
Median postoperative analgesic requirements as per WHO pain ladder	Level II	Level II	0.341
Complications			
Wound infection	0.9%	1.2%	0.063
Hematoma requiring drainage	0.5%	0.9%	0.472
Seroma formation requiring drainage	1.4%	11.3%	0.000*
Transient hypocalcemia	0.9%	1.1%	0.936
Permanent hypocalcemia	0%	0%	-
Transient recurrent laryngeal Nerve compromise	2.8%	3.2%	0.265
Permanent recurrent laryngeal nerve compromise	0%	0%	-
Recurrence (Over period of at least 6 months-7 years)	0%	0%	-
Others (RTI)	0.3%	0.02%	0.634
Mean satisfaction with scar (maximum = 10)	7.9	8.3	0.640
Satisfaction with overall hospital stay (maximum = 10)	8.1	8.7	0.982

Table 3: Study endpoints summarized in both groups with and without drain

The primary endpoints included postoperative hemorrhage and neck hematoma formation, pain scoring, hospital stay and seroma formation (Table 3). Rest of the complications including hypocalcemia, recurrent laryngeal nerve compromise, recurrence over a period of at least 6 months and wound infection were also assessed.

Group without drain had significantly lower postoperative pain and discomfort as opposed to drain group (3.1±1.1 vs. 2.3±0.4; $p<0.05$) however postoperative analgesia requirement was not statistically different. Similarly, rate of seroma formation in postoperative period was significantly higher in the group receiving no drains (1.4% vs. 11.3%; p value <0.00). Despite a good quality hemostasis, average drain output was 50.17±41.50 ml in drain group probably forming the impetus for subsequent seroma formation.

Rest of the parameters like operative time, per-operative blood loss, hematoma requiring draining, would infection, postoperative hypocalcemia, RLN compromise and recurrence were not statistically different between two groups. Mean satisfaction with scar or overall hospital stay were not statistically different either (Table 3).

To explore the reasons of the higher seroma rate in no drain group, sub group analysis was done which showed size of the gland, extent of dissection and toxicity of the gland to be related to higher rates of seroma formation (Table 4). The size of the gland was the strongest predictor of seroma formation with Pearson Chi2 value of 11.99 and $p<0.002$.

In stage 3 of the study, the above data was shared in form of a report along with a proposed decision tree for the drain placement during thyroidectomy. The consensus was developed through 2 rounds on the decision tree with Fleiss's kappa value of 0.83. Figure 2, shows a proposed algorithm for the drain placement in thyroidectomy.

	Factor	Pearson Chi2 Value	Significance
1	ASA Status	0.759	0.859
2	Toxicity	4.289	0.04*
3	Fibrosis	6.634	0.07
4	Histological Diagnosis	5.963	0.11
5	Size of Gland	11.99	0.002*
6	Extent of Surgery	6.402	0.05*

Table 4: Subgroup Analysis: Factors Affecting Seroma Formation

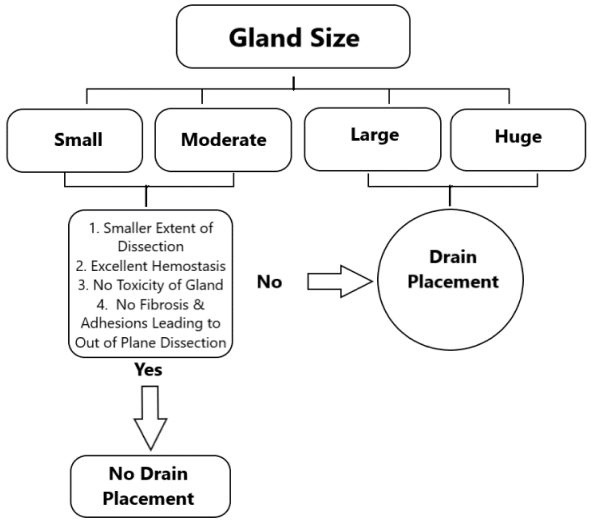

Figure 2: Proposed Drain Placement Decision Tree

DISCUSSION

Hematoma rates are generally low ranging from 0-2.6% and the ones requiring intervention are even less than 1.5%. Most hematomas develop in early postoperative period i.e. 75% within first 6 hours and rest in 6-24 hours[7,22]. Though the incidence of the hematomas is low but they can be potentially life threatening; thus, creating a reason for drain placement. Placement of drain though may be assuring for some, does not prevent the need for exploration if the patients really develop postoperative neck hematoma. Extensive literature review persistently shows that drain placement does not prevent hemorrhage [7,8]. Our study here further corroborates the findings of the previous literature and the incidence of postoperative hemorrhage without drains remains low. Contrary to evidence in literature stating that instituting drains following thyroid surgery may not prevent hemorrhage, quite a few of the surgeons still use drains for especially larger thyroid glands requiring extensive dissection. They feel reassured with drain placement citing four prominent reasons: firstly, most of the times following drain placement, even after quality hemostasis, some blood always pours into the drains; secondly, it gives a chance to pick hemorrhage early; thirdly it does reduce the incidence of postoperative seroma formation and fourthly it does not harm the patient even if nothing pours into the drain16. This 'conventional strategy' prevails among most of endocrine surgeons and may be coined as surgical wisdom by some [5,23]. Moreover, apprehension of bleed still persists among endocrine surgeons and their personal perceptions do play a role in the decision of drain placement.

Drain placement, however, does reduce the incidence of postoperative seroma formation and has thus been proposed to have selective use of drain by Saha et al [8,15]. This study further strengthens the literature evidence and propagates for placement of short-term drain for 12-24 hours as quoted by one endocrine surgeon in this study.

This study has explored the reasons for higher incidence of seroma formation whom did not have drain. Quality of hemostasis and expertise in securing hemostasis can be a significant factor in preventing postoperative hemorrhage as well as seroma formation[24]. The gland size and the extent of dissection exclusively correlate with higher incidence of seroma formation. Another reason could be related to toxicity and vascularity of gland. Friability and fibrosis of gland and adhesions may also be important influencers but they could not reach any statistical significance. The decision of using drain should be scientific and based on the factors which have been identified through this study and existing literature.

Instead of advocating no drains for all thyroidectomies, it appears prudent to commend for selective drainage following thyroidectomy. The algorithm, here proposed, promotes the decision of putting drain on the bases of quality of hemostasis, size of gland, extent of dissection and vascularity of gland. For large and huge glands (WHO Class IV and beyond), it would be probably be more prudent to place a drain as there would be higher chances of seroma formation and higher probability of life-threatening hematoma formation in neck.

There are certain limitations in this study. The study has primarily enrolled smaller and moderate size glands in clinical trial; hence the quantitative data is not sufficient enough to predict the rates of hemorrhage and seroma formation in those individuals. Moreover, qualitative data by principle is based on opinions and experiences and may not sufficiently prove exclusively that surgeon experience or perceptions are reflections of reality.

In conclusion, intent of earlier detection of hemorrhage, fear of postoperative hemorrhage and seroma formation were found to be the most common reasons for drain placement. The decision of placing a drain or not should be individualized and should correlate with extent of dissection, size of gland, quality of hemostasis, extent of adhesions either related to any inflammatory condition or malignancy and the vascularity of the gland. It remains safe to skip drain placement in small to moderate size glands provided the quality of hemostasis is superb and risk factors for seroma formation are not present.

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