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# Meta-Analysis: Prophylactic Drainage and Bleeding Complications in Thyroid Surgery

Stephen A. Kennedy, MD, BSc, Robert A. Irvine, MD, FRCSC, Brian D. Westerberg, MD, MHSc, FRCSC, and Hongbin Zhang, MSc, MEng

## ABSTRACT

**Objective:** To conduct a comprehensive systematic review and high-quality meta-analysis to determine whether prophylactic drain placement reduces adverse bleeding events in thyroid surgery.

**Data Sources:** MEDLINE (OVID and PubMed), CENTRAL, CDSR, ACP Journal Club, DARE, EMBASE, PREMEDLINE, OLDMEDLINE, CINAHL, BIOSIS Previews, LILACS, KOREAMED, SAMED, IndMED, SIGLE, ScienceDirect, and INGENTACONNECT.

**Review Methods:** Studies for evaluation included all prospective trials assessing the use of drainage in thyroid surgery. We excluded case studies, retrospective studies, reviews, and studies that had a "selective" method of postoperative drainage that was not defined or was based on surgeon preference. Search strategies were broad and based on Cochrane Collaboration search filters. There was no language restriction. Article selection was conducted by two independent reviewers under QUORUM guidelines.

**Results:** Four hundred sixty-two articles were identified by the search strategy used, and 16 articles were included in the final review. Ten studies were randomized controlled trials, with 8 used for quantitative meta-analysis. No study showed a statistically significant benefit or harm with drain use. Meta-analysis of data estimated an odds ratio of 1.47 for reoperation for bleeding and 0.88 for visible hematoma for suction drains versus no drains. The results were not statistically significant, and 95% confidence intervals were wide.

**Conclusion:** The literature has insufficient evidence to recommend routine drainage in thyroid surgery. It is possible that drains may increase the risk of reoperation for bleeding, although the data are not statistically significant. If there is a benefit to drainage, absolute risk reductions of bleeding outcomes may not warrant routine use.

## SOMMAIRE

**Objectif:** Conduire une revue systématique complète et une méta-analyse de qualité pour déterminer si le placement prophylactique de drains réduit les complications hémorragiques après une chirurgie de la thyroïde.

**Source des données:** MEDLINE (OVID and PubMed), CENTRAL, CDSR, ACP Journal Club, DARE, EMBASE, PREMEDLINE, OLDMEDLINE, CINAHL, BIOSIS Previews, LILACS, KOREAMED, SAMED, IndMED, SIGLE, ScienceDirect, et INGENTACONNECT.

**Méthodes:** Nous avons évalué toutes les études prospectives étudiant l'utilisation de drains dans la chirurgie de la thyroïde. Nous avons exclu les séries de cas, les études rétrospectives, les revues et les études où la sélection du drainage n'était pas précisé ou laissé à la discrétion du chirurgien. Les stratégies de recherches étaient étendues et basées sur les filtres de recherche de la collaboration *Cochrane*. Nous n'avons pas mis de limite associée à la langue. La sélection des articles s'est faite par deux évaluateurs indépendants en utilisant les lignes directrices de QUORUM.

**Résultats:** Nous avons identifié quatre cent soixante-deux articles dont 16 ont été retenus pour l'évaluation finale. Des 10 essais contrôlés à allocation aléatoire, 8 ont été utilisés pour la méta-analyse. Aucune étude n'a montré d'avantage ou de désavantage à l'utilisation de drain. La méta-analyse des données a estimé le rapport de cotes à 1.47 pour un retour en salle d'opération pour un saignement et de 0.88 pour un hématome visible pour l'utilisation d'un drain par rapport à la non-utilisation. Les résultats n'étaient pas significatifs statistiquement et l'intervalle de confiance (95%) est très large.

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**Conclusion** La littérature ne présente pas assez de preuves pour supporter l'utilisation d'un drain après une chirurgie de la thyroïde. Il est même possible que les drains augmentent le risque de ré-intervention pour hémorragie, bien que ces données ne soient pas statistiquement significatives. Même s'il y a un bénéfice à drainer ces plaies, la réduction absolue du risque de complication hémorragique ne justifie pas son utilisation de routine.

**Key words:** *drainage, meta-analysis, thyroidectomy*

Postoperative hemorrhage is a rare but dreaded complication of thyroid surgery. Compression of neck structures by an expanding hematoma can lead to life-threatening airway compromise. The prophylactic application of a suction or passive drain appears to be an intuitive solution as it is thought to obliterate the dead space, prevent accumulation of excess blood and serum, and assist in the early detection of postoperative bleeding. However, some surgeons feel that retained blood in the wound bed often clots and blocks the drain, making it ineffective. Others are concerned that patient discomfort is heightened, infection risks increased, and hospital stays lengthened. Many elect not to use drains routinely, if at all. The complication of most concern remains postoperative hemorrhage requiring reoperation for bleeding.

Several prospective and retrospective studies have been done to examine the rates of adverse bleeding with and without surgical drains. No statistically significant benefit or harm has been shown, but studies have been underpowered.

The purpose of this study was to conduct a comprehensive systematic review and high-quality meta-analysis to determine whether prophylactic drain placement reduces adverse bleeding events in thyroid surgery. Meta-analysis was chosen to increase statistical significance and reduce the confidence interval margins of current estimates. We present a broad search of numerous international databases, article selection without language restriction under QUORUM guidelines,<sup>1</sup> and a quantitative synthesis of critically appraised relevant articles. Two meta-analyses were published prior to publication of this study, and their methods and findings are also discussed.<sup>2,3</sup>

## Methods

Studies eligible for this review were prospective observational studies, prospective cohort studies, and randomized controlled trials. Patients included were those undergoing various forms of thyroid or parathyroid surgery; interventions included closed suction drainage, passive gravity drainage, and/or no drainage; and outcome measures were the need for reoperation for bleeding and clinically apparent hematoma. Excluded articles included case

studies, retrospective reviews, studies without data on bleeding complications, and studies that had a "selective" method of postoperative drainage that was not defined or was based on surgeon preference.

The databases used included MEDLINE (OVID and PubMed), CENTRAL, CDSR, ACP Journal Club, DARE, EMBASE, PREMEDLINE, OLDMEDLINE, CINAHL, BIOSIS Previews, LILACS, KOREAMED, SAMED, IndMED, SIGLE, ScienceDirect, and INGENTACONNECT. Search strategies were broad and based on a modification of Cochrane Collaboration search filters.<sup>4</sup> Specific terms used in PubMed, for example, were (thyroidectomy OR thyroid gland OR thyroid diseases OR thyroid\*[all]) AND (drainage OR drain\*[all]) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method [mh] OR clinical trial [pt] OR clinical trials [mh] OR ("clinical trial" [tw]) OR ((singl\* [tw] OR doubl\* [tw] OR trebl\* [tw] OR tripl\* [tw]) AND (mask\* [tw] OR blind\* [tw])) OR (placebos [mh] OR placebo\* [tw] OR random\* [tw] OR research design [mh:noexp] OR comparative study [mh] OR evaluation studies [mh] OR follow-up studies [mh] OR prospective studies [mh] OR control\* [tw] OR prospectiv\* [tw] OR volunteer\* [tw]) NOT (animals [mh] NOT human [mh])).

The reference lists of relevant review articles and references of all identified articles were checked for more possible relevant studies. Hand searching was not performed.

A comprehensive list of articles was compiled from the various databases in Reference Manager software, and duplicates were removed. Two independent assessors (S.A.K. and R.A.I.) performed the article selection in a stepwise manner, first by title, then abstract, and then full-text review. Lists were recompiled between each step, and articles were not excluded unless both investigators rejected the studies. Medical colleagues provided translations for articles as needed. Disagreement on inclusion of full-text reports was resolved through consensus between the reviewers.

Two authors (S.A.K. and R.A.I.) critically appraised the articles and independently extracted the data. The methodologic quality was assessed based on the adequacy

of randomization, reproducibility of inclusion and exclusion criteria, clarity of population demographics, and statistical significance of the results. Study information was recorded in an electronic spreadsheet (*Excel*, Microsoft Corporation). Data on reoperation for bleeding and visible hematoma in each study were tabulated and provided to a research statistician (H.Z.). Analysis was conducted with SAS version 9.1 (SAS Institute, Cary, NC), and a random effects model was found to be appropriate. Quantitative meta-analysis of passive or gravity drainage was not performed owing to insufficient studies.

## Results

The search strategy was applied January 18, 2005, and 462 articles were identified. A flow diagram of article selection is shown in Figure 1. Fifty studies were retrieved for full-text review after exclusion for relevance. Of selected articles, one could not be found in full-text form.<sup>5</sup> Seventeen studies met the inclusion criteria for critical appraisal after full-text review. No study showed statistically significant benefit or harm with drain use in terms of bleeding outcomes.<sup>6-22</sup> Critical appraisal of the articles showed that the studies published by Teboul et al<sup>6</sup> and Peix et al<sup>7</sup> had identical results and many of the same authors, though published in different journals.<sup>6,7</sup> One was published in English<sup>7</sup> and the other in French,<sup>6</sup> so the English version was used for the meta-analysis.<sup>6</sup> Eight articles were found to have sufficiently similar methods and quality of published data to be included in the quantitative meta-analysis. Studies included in the meta-analysis and relevant data are included in Table 1. Other studies were excluded,<sup>15-22</sup> including two randomized controlled trials.<sup>15,16</sup> The results of statistical analysis,

including point estimates of absolute risks and odds ratios, are presented in Table 2. No statistically significant difference between drainage and no drainage was found in terms of reoperation for bleeding or visible hematoma.

## Discussion

In this meta-analysis, reoperation for bleeding occurred at a rate of approximately 0.77% and for visible hematoma at 6.5%. This appears to demonstrate the small risk of bleeding complications associated with this surgery. Calculated odds ratios of reoperation for bleeding and visible hematoma were 1.47 and 0.88 for drains versus no drains, although neither value was statistically significant. It is possible to conclude only that there is insufficient evidence of benefit or harm to drains in terms of bleeding outcomes.

This analysis of 907 patients is interesting because although comparisons are not statistically significant, it raises the possibility that drains actually increase the rates of reoperation for bleeding. There tends to be an assumption that drains must have some benefit, albeit small, but is it possible that they increase bleeding risk?

To answer definitively whether there is a benefit or harm to drainage in thyroid surgery, clinical studies will likely require a large number of subjects to detect it with statistical significance because the anticipated difference in absolute risk is small. Also, estimates of the standard deviation appear to be wide. A well-designed randomized controlled trial will likely require hundreds of, if not a few thousand, subjects.<sup>23</sup>

If a benefit to drainage does exist, consideration should also be given to the absolute risk reduction and therefore the number needed to treat (NNT) of the intervention.

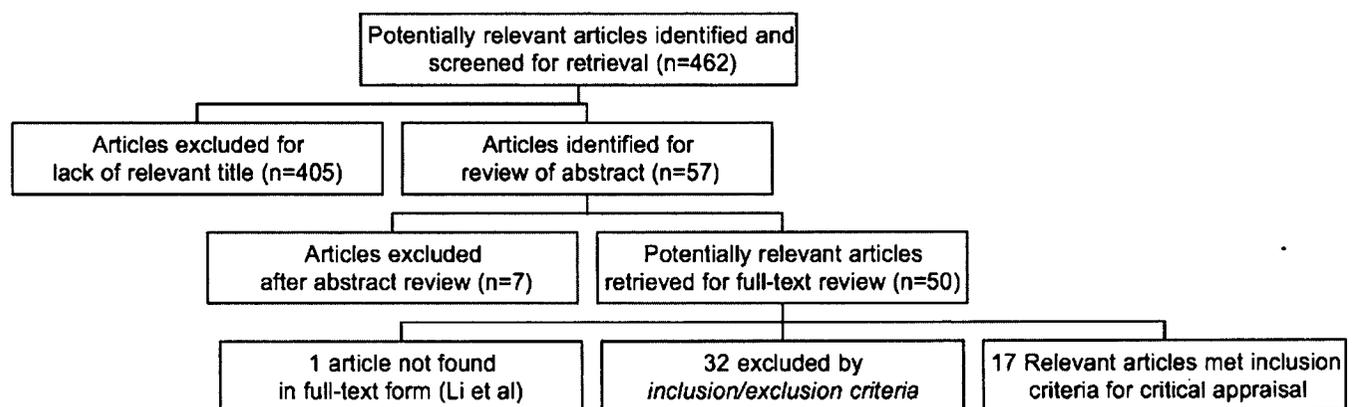


Figure 1. Flow diagram of article selection.

**Table 1.** Studies of Vacuum Drainage versus Nondrainage, with Data Used for Meta-Analysis

Study	Type	N	Reoperation for Bleeding	Visible Hematoma
Ayyash et al (1991) <sup>8</sup>	RCT			
	Vacuum drain	50	0	0
Hurtado-Lopez et al (2001) <sup>9</sup>	Undrained	50	0	0
	RCT			
	Vacuum drain	50	0	0
	Undrained	50	0	0
Kristoffersson et al (1986) <sup>10</sup>	Passive drain*	50	0	1
	RCT			
	Vacuum drain	50	0	1
Peix et al (1992) <sup>7</sup> /Teboul et al (1992) <sup>6</sup>	Undrained	50	0	0
	RCT			
	Vacuum drain	48	0	1
Pezzullo et al (2001) <sup>11</sup>	Undrained	49	0	3
	RCT			
	Vacuum drain	30	0	1
Schoretsanitis et al (1998) <sup>12</sup>	No drain	30	0	1
	RCT			
	Vacuum drain	100	2	5
Tubergen et al (2001) <sup>13</sup>	No drain	100	1	7
	RCT			
	Vacuum drain	52	2	13
Wihlborg et al (1988) <sup>14</sup>	No drain	48	0	14
	RCT			
	Vacuum drain	75	1	6
Summarized totals	No drain	75	1	4
	Vacuum drain	455	4	28
	No drain	452	3	31
	Total	907	7	59

RCT = randomized controlled trial.

\*Not included in totals.

Hypothetically, if we assume that drains decrease the risk of reoperation for bleeding by 1%, 100 drains would have to be inserted to prevent one reoperation, which is likely worthwhile. However, differences are probably less, meaning a larger NNT. Indeed, it is not clear whether this NNT

may even be a number needed to harm (NNH). Although speculative, the point estimate of the absolute risk reduction for visible hematoma in this meta-analysis of 907 patients correlated to an NNT greater than 300. The reoperation for bleeding number correlated to an NNH

**Table 2.** Absolute Risks of Reoperation for Bleeding and Visible Hematoma with Suction Drainage and No Drainage and Odds Ratios of Outcomes

Postoperative complication	Absolute Risk with Vacuum Drain, % (95% CI)	Absolute Risk with No Drain, % (95% CI)	Odds Ratio, Drains vs No Drains (95% CI)	p Value*
Reoperation for bleeding	1.02 (0.05–18.1)*	0.69 (0.19–2.61)	1.47 (0.26–8.28)	.62
Visible hematoma	2.08 (0.19–18.7)	2.36 (0.44–11.6)	0.88 (0.44–1.75)	.67

CI = confidence interval.

\*p value refers to calculation of the odds ratio.

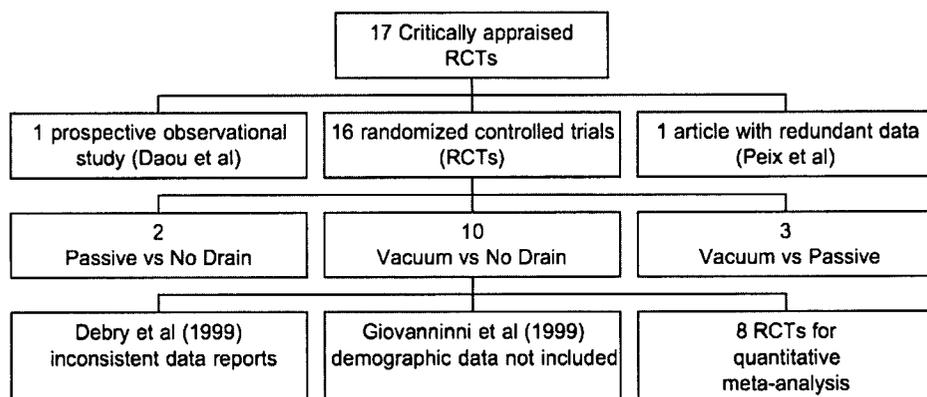


Figure 2. Flow diagram of article selection for quantitative meta-analysis. RCT = randomized controlled trial.

greater than 300. Are there better ways to prevent and manage postoperative bleeding?

Some surgeons continue to use drains because increased drain output can be an indicator of hemorrhage. No evidence exists in the literature to state whether this is an effective tool for monitoring bleeding. Anecdotal reports suggest that often drains get blocked with clotted blood and are unreliable. Clinical evidence such as wound bed fullness, dyspnea, and stridor is likely more sensitive and specific. It has been our practice that wounds after thyroid surgery receive no special care in terms of extubation, and we do not usually apply dressings, to allow for monitoring of skin swelling or fullness.

Two other meta-analyses were published on this topic prior to publication of this review. Pothier performed his meta-analysis alone, looking at all complications, and the point estimate of the odds ratio for suction drainage versus no drainage was 0.89.<sup>2</sup> In that study, the article by Pezzullo was not identified.<sup>11</sup> Corsten and colleagues looked at hematoma using the *PubMed* index only, calculating an odds ratio of 1.04.<sup>3</sup> In that analysis, the study by Tubergen and colleagues was not identified,<sup>13</sup> and both articles by Teboul and colleagues and Peix and colleagues were included, which we felt had redundant data.<sup>6,7</sup> The conclusions of the three studies were the same: there is insufficient evidence to say definitively whether there is a benefit or harm to the placement of drains.

Our study contributes further to the literature because our systematic review was comprehensive and our meta-analysis of high quality. Multiple medical literature databases were searched, study selection and data extraction were performed independently and in duplicate without language restriction, and identified studies were critically appraised before quantitative meta-analysis. This study may act as a starting point for production of further meta-analyses in the future.

Two additional randomized controlled trials have been identified in *PubMed* since the compilation of data in this study and are included in the References.<sup>24,25</sup>

## Conclusion

The literature contains insufficient evidence to recommend routine drainage in thyroid surgery. It is possible that drains may increase the risk of reoperation for bleeding, although the data are not statistically significant. If there is a benefit to drainage, absolute risk reductions of bleeding outcomes may not warrant routine use.

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