

The application of drains in thyroid surgery

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Abstract: It has been shown that the use of drain in thyroid surgery does not reduce the reoperation rate for hemorrhage. The aim of this systematic review was to update the knowledge of the role of drain in thyroid surgery in term of postoperative complications, pain and hospital length of stay (LOS). A systematic search was performed in the PubMed and Embase database to identify all randomized controlled trials (RCTs) comparing clinical outcomes in patients who underwent thyroidectomy or lobectomy with or without drainage. The primary outcome was reoperation rate for bleeding; the secondary outcomes were development of hematoma, seroma, and wound infection; postoperative pain evaluated by Visual Analogue Scale (VAS) at the postoperative day (POD) 1, and hospital LOS. Risk ratios (RRs) and 95% confident intervals (95% CI) were used for dichotomous variables; mean differences (MDs) and 95% CI for continuous variables. Statistical heterogeneity was evaluated and its degree was quantified by the I² statistic. Twenty RCTs were included, with 2,204 patients enrolled. No difference was found between the two groups in term of reoperation [RR 1.13 (0.43, 2.95); I² =0%], hematoma [RR 1.18 (0.71, 1.95); I² =0%], and seroma [RR 0.82 (0.44, 1.53); I² =0%]. Patients with drain had higher postoperative pain [MD 1.91 (1.30, 2.53); I² =97%], prolonged hospital LOS [MD 1.34 (0.91, 1.76) days; I² =98%], and increased wound infection rate [RR 2.82 (1.36, 5.86); I² =0%], even though the latter was not confirmed in the sensitivity analysis including only studies with ≥100 patients per trial. The use of drain after thyroid surgery increase postoperative pain and hospital LOS, with no decrease of reoperation rate, hematoma and seroma formation. An increased wound infection rate in patients with drain is suggested, but a large RCT should be performed to confirm this correlation.

Keywords: Drainage; meta-analysis; postoperative complications; randomized controlled trial (RCT); thyroidectomy

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Introduction

Neck hematoma after thyroid surgery is a potentially life threatening complication, and drains are commonly used for early detection of postoperative bleeding. However, in some cases the drain may be blocked by clotted blood and the hemorrhage may be highlighted by neck swelling and respiratory symptoms. In these cases the drain does not

provide any benefit and may offer a false sense of tranquility until symptoms appear. Recently, in a systematic review and meta-analysis, Woods *et al.* showed a reoperation rate for neck hematoma after thyroid and parathyroid surgery of 1% in patients with drain and 0.4% in those without drain and they concluded that the use of drains does not decrease the risk of reoperation for neck hematoma [risk ratio (RR) 1.90;

95% confidence interval (CI) 0.87–4.14] (1). Furthermore, they showed and increased wound infection rate and postoperative pain and prolonged hospital length of stay (LOS) in patients with drain (1), and these conclusions are supported by a more recent meta-analysis (2).

The aim of this meta-analysis was to update the knowledge of the role of drain in thyroid surgery in term of reoperation for bleeding, postoperative complications (i.e., wound infection, hematoma, seroma), postoperative pain and hospital LOS including randomized controlled trials (RCTs) published until 2017.

Methods

Eligibility criteria

The PRISMA-P 2015 statement (3) and the PICO method were followed for this systematic review, specifically:

- (I) Participants: patients who underwent total or near total thyroidectomy or lobectomy;
- (II) Intervention: drain usage;
- (III) Comparator: no drain usage;
- (IV) Outcomes: the primary outcome was reoperation for bleeding. The secondary outcomes were postoperative complications (i.e., hematoma, wound infection, seroma), postoperative pain evaluated by Visual Analogue Scale (VAS) at the postoperative day (POD) 1, and hospital LOS;
- (V) Type of study: RCTs.

No limitation regarding publication date was considered; only articles in English language were included.

The exclusion criteria were: (I) no RCTs; (II) studies including parathyroid surgery; and (III) studies including lymph node dissection (central or lateral neck dissection) due to the greater extension of surgery compared to thyroidectomy or lobectomy alone that may influence the primary and secondary outcomes of the present meta-analysis.

Information sources and search strategy

Two databases were used (i.e., PubMed and Embase) for a systematic search performed on March 2017, using the Mesh terms as follow:

- (I) “Thyroidectomy”[Mesh] AND “Drainage”[Mesh]
- (II) “Thyroid Gland”[Mesh] AND “Drainage”[Mesh]

Study records

Two independent investigators (Mattia Portinari, Paolo Carcoforo) evaluated titles and abstracts of all identified articles, and the full text of those that met the inclusion criteria was assessed. In case of multiple studies from the same authors and institutions, only the most recent article was included to avoid data duplication.

According to the aim of this review, the rate of reoperation for bleeding, hematoma, wound infection, seroma, the postoperative pain at the POD 1, and the hospital LOS were reported.

Risk of bias in individual studies

The Cochrane Collaboration’s tool was used to assess the quality and the risk of bias of RCTs, specifically were evaluated randomization procedure and allocation concealment, blinding, description of withdrawals and dropouts, and other source of bias (4). Of note, it is quite difficult to obtain blinding in case of drain use, thus blinding of participants and personnel was considered appropriate if the treatment assignment (drain versus no drain) was defined immediately before the wound closure (performance bias), instead blinding of outcome assessment was judged appropriate if the data collection was done by one observer who did not participate in the surgery (detection bias).

Statistical analysis

Data are presented as mean (standard deviation) for hospital LOS and postoperative pain at POD 1. RRs and 95% CI were used for dichotomous variables, otherwise mean differences (MDs) and 95% CI for continuous variables. Statistical heterogeneity was evaluated and its degree was quantified by the I^2 statistic to choose the model for meta-analysis: random-effect for $I^2 > 50\%$; fixed-effect for $I^2 \leq 50\%$. Meta-analysis was performed when data for an outcome were available from four or more studies. Sensitivity analyses were performed including the following studies: (I) studies with low risk of selection bias and performance bias; (II) studies in which patients with coagulation disorders or anticoagulant therapy were not excluded; (III) studies in which patients with huge goiter or substernal goiter were not excluded; and (IV) studies with ≥ 100 patients per trial.

Data analysis was performed with Review Manager

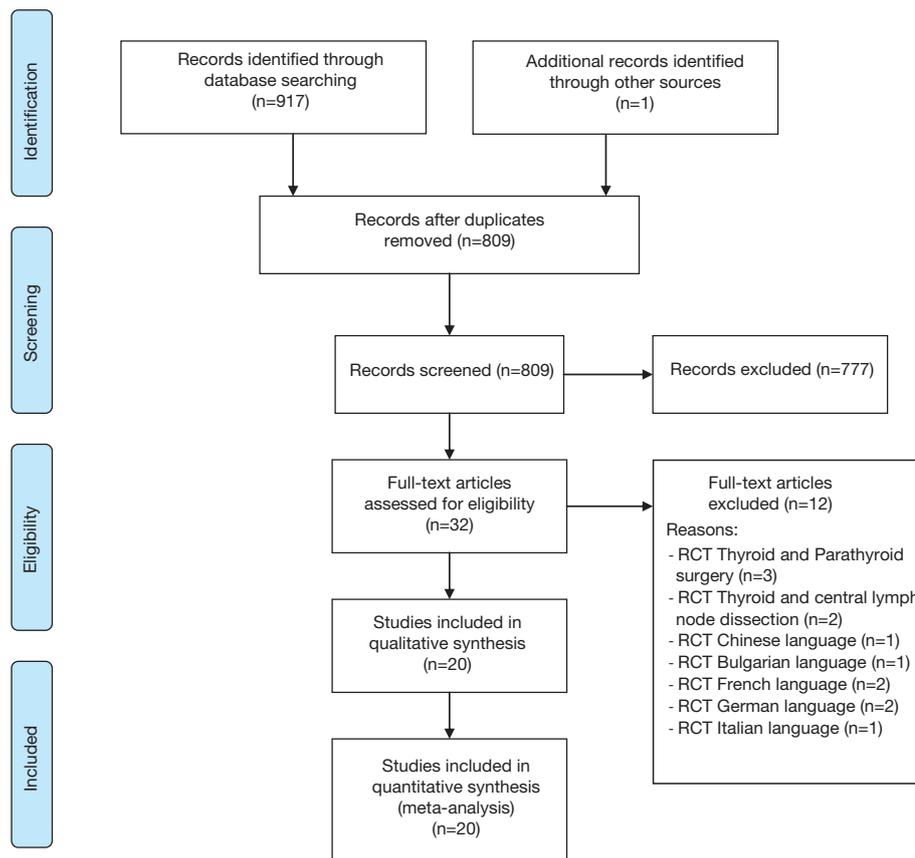


Figure 1 Flow chart illustrating the systematic search and the selection process of the articles.

(RevMan) for Windows. Version 5.3. Copenhagen: the Nordic Cochrane Centre, the Cochrane Collaboration, 2014.

Results

Selection process of the articles

Twenty out of 809 articles were included in the qualitative and quantitative synthesis (Figure 1), and their details are shown in Table 1. Among the 20 studies included, a total of 2,204 patients were enrolled, 1,131 in the drain group and 1,073 in the no drain group. The sample size was <100 patients per trial in 12 (60%) of the included studies, from 100 to 200 patients in 7 (35%) studies and 400 patients in 1 (5%) study (Table 1). Exclusion criteria were the presence of coagulation disorder in 9 studies, anticoagulant therapy in 2 studies, and the presence of a huge goiter or substernal goiter in 6 studies (Table 1).

Risk of bias

The risk of bias of the included studies is shown in Figures 2 and 3. The random sequence generation was unclear in 3 studies (15%), the allocation concealment in 7 studies (35%), and the blinding of participants and personnel in 8 studies (40%). The blinding of outcome assessment was described only in three studies, in which one observer who did not participate in the surgery performed the data collection.

Outcomes

Reoperation for bleeding

The reoperation rate for bleeding was low in both group of patients with (0.64%) and without drain (0.58%), and there was no difference between the two groups in the risk of reoperation [RR 1.13 (0.43, 2.95); $I^2=0\%$] (Figure 4).

Table 1 Characteristics of included studies

Author	Year	Country	Sample size	Type of surgery	Exclusion criteria
Wihlborg (5)	1988	Sweden	150	Total or near total thyroidectomy or lobectomy	Lymph node dissection, sternotomy
Peix (6)	1992	France	97	Lobectomy	Coagulation disorders, previous neck surgery
Schoretsanitis (7)	1998	Greece	200	Near total thyroidectomy or lobectomy	Not described
Debry (8)	1999	France	100	Total thyroidectomy or lobectomy	Lymph node dissection
Hurtado-López (9)	2001	Mexico	150	Total or near total thyroidectomy or lobectomy	Not described
Pezzullo (10)	2001	Italy	60	Total or near total thyroidectomy or lobectomy	Previous neck surgery or neck irradiation
Khanna (11)	2005	India	102	Total thyroidectomy or lobectomy	Coagulation disorders, lymph node dissection
Suslu (12)	2006	Turkey	135	Total or near total thyroidectomy	Coagulation disorders, lymph node dissection, huge goiter with mediastinal extension
Colak (13)	2008	Turkey	116	Total thyroidectomy or lobectomy	Coagulation disorders, thyroid cancer
Ishaq (14)	2008	Pakistan	60	Total thyroidectomy or lobectomy	Coagulation disorders, lymph node dissection, Graves' disease
Musa (15)	2010	Nigeria	67	Near total thyroidectomy	Goiter with intrathoracic extension, lymph node dissection
Chalya (16)	2011	Tanzania	62	Total thyroidectomy	Coagulation disorders, huge goiter, thyroid cancer, lymph node dissection
Memon (17)	2012	Pakistan	60	Lobectomy	Total or near total thyroidectomy, thyroid cancer, previous thyroid surgery
Neary (18)	2012	Ireland	93	Total thyroidectomy or lobectomy	Coagulation disorders, lymph node dissection, sternotomy, age <18 years
Asgari (19)	2013	Iran	66	Total or near total thyroidectomy or lobectomy	Lymph node dissection, parathyroidectomy
Deveci (20)	2013	Turkey	400	Total thyroidectomy or lobectomy	Anticoagulant therapy, substernal goiter, lymph node dissection
Kalemera (21)	2013	Uganda	68	Total or near total thyroidectomy or lobectomy	Recurrent goiter, infiltrating thyroid cancer, diabetes, hypertension
Muthaa (22)	2013	Kenya	90	Total thyroidectomy or lobectomy	Anticoagulant therapy, previous thyroid operation, Graves' disease
Nawaz (23)	2015	Pakistan	68	Total thyroidectomy	Coagulation disorders, infiltrating thyroid cancer, lymph node dissection, substernal goiter, American Society of Anesthesiologists score ≥ 3
Afzal (24)	2015	Pakistan	60	Lobectomy	Coagulation disorders, huge goiter, thyroid cancer

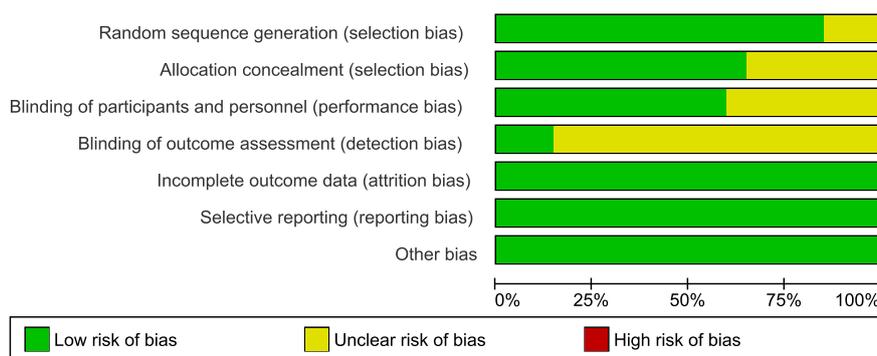


Figure 2 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Hematoma and seroma

The rate of hematoma (2.9% in drain group versus 2.6% in no drain group) and seroma (2.7% in drain group versus 3.2% in no drain group) were comparable in both group and no difference was found in the risk of hematoma [RR 1.18 (0.71, 1.95); $I^2=0\%$] and seroma [RR 0.82 (0.44, 1.53); $I^2=0\%$] (Figures 5,6).

Wound infection

A higher wound infection rate was found in the drain group compared to the no drain group (2.6% versus 0.7%, respectively) with a RR of 2.82 [(1.36, 5.86); $I^2=0\%$] (Figure 7).

Postoperative pain (POD 1)

The postoperative pain was evaluated at the POD 1 only in 9 out of 20 studies. Patients in the drain group had higher VAS score compared to patients in no drain group [MD 1.91 (1.30, 2.53); $I^2=97\%$] (Figure 8).

Hospital LOS

Patients in the drain group experienced a prolonged hospital LOS compared to patients in the no drain group [MD 1.34 (0.91, 1.76) days; $I^2=98\%$] (Figure 9).

Sensitivity analysis and publication bias

The increased risk of wound infection, the higher postoperative pain at POD1 and prolonged hospital LOS in patients with drain compared to those without drain were confirmed performing the meta-analysis either including only studies with low risk of selection bias and performance bias or comprising only studies in which patients with huge goiter or substernal goiter were not excluded (Table 2).

The increased risk of wound infection was not proved performing the meta-analysis either including only studies in which patients with coagulation disorder or anticoagulant therapy were not excluded or only studies with ≥ 100 patients per trial (Table 2).

No difference between two groups was found in term of reoperation rate, hematoma and seroma formation in the four sensitivity analyses (Table 2).

The funnel plot regarding the primary outcome of the present meta-analysis (reoperation for bleeding) did not suggest significant publication bias (Figure S1).

Discussion

This systematic review and meta-analysis shows that the use of drain in thyroid surgery increase the risk of wound infection, cause higher postoperative pain and prolong hospital LOS, with no decrease of reoperation rate, hematoma and seroma formation. These findings are consistent with previous meta-analyses (1,2). However, including in the meta-analysis only studies with ≥ 100 patients per trial, no difference was found in term of wound infection between the two groups (drain versus no drain).

The absence of differences between the two groups in term of risk of reoperation for bleeding and risk of hematoma formation was confirmed also performing the meta-analysis including only studies in which patients with high risk of hemorrhage (i.e., coagulation disorders, anticoagulant therapy, huge goiter or substernal goiter) were not excluded (Table 2), and this support the safety of no use of drain after thyroidectomy or lobectomy.

Regarding the hospital LOS, patients without drain were sent home if there were lack of clinical evidence of any collection in the neck; instead in the drain group, the

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Afzal 2015	+	?	?	?	+	+	+
Asgari 2013	+	?	?	?	+	+	+
Chalya 2011	+	+	+	?	+	+	+
Colak 2008	+	+	+	?	+	+	+
Debry 1999	+	+	?	?	+	+	+
Deveci 2013	+	+	?	?	+	+	+
Hurtado-López 2001	+	?	?	?	+	+	+
Ishaq 2008	?	?	+	?	+	+	+
Kalemera 2013	+	+	+	?	+	+	+
Khanna 2005	+	+	+	?	+	+	+
Memon 2012	+	+	+	+	+	+	+
Musa 2010	+	?	?	?	+	+	+
Muthaa 2013	+	+	+	?	+	+	+
Nawaz 2015	+	+	+	+	+	+	+
Neary 2012	+	+	+	?	+	+	+
Peix 1992	+	+	+	+	+	+	+
Pezzullo 2001	+	+	+	?	+	+	+
Schoretsanitis 1998	+	+	?	?	+	+	+
Suslu 2006	?	?	?	?	+	+	+
Winlborg 1988	?	?	+	?	+	+	+

Figure 3 Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

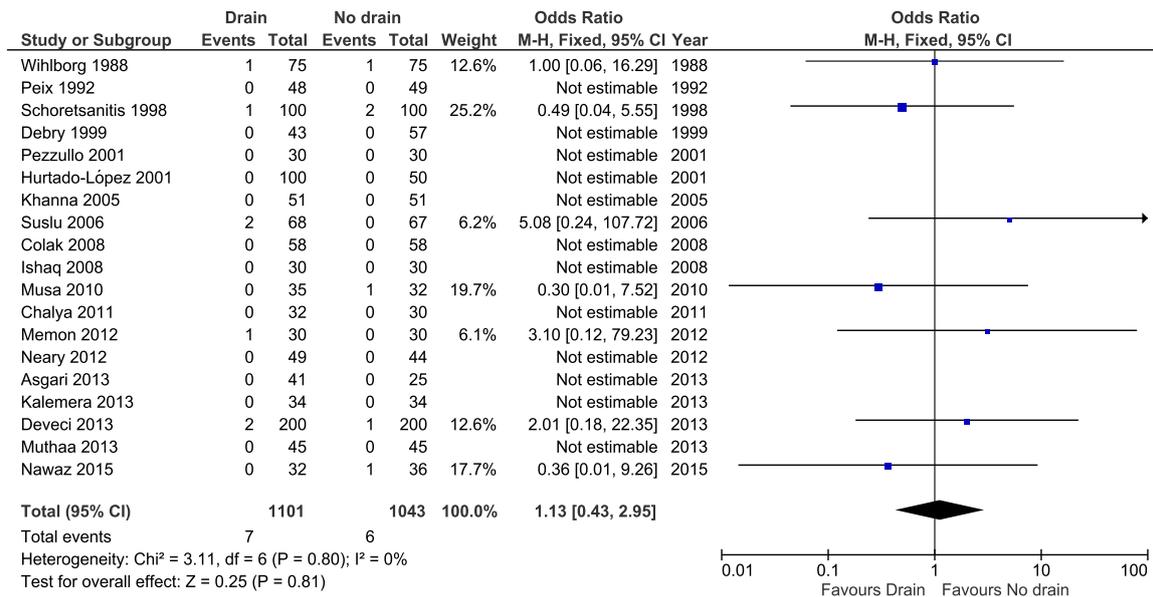


Figure 4 Forest plot of comparison: drain versus no drain for thyroid surgery. Outcome: reoperation for bleeding. Mantel-Haenszel (M-H) fixed-effect model (Fixed) for meta-analysis.

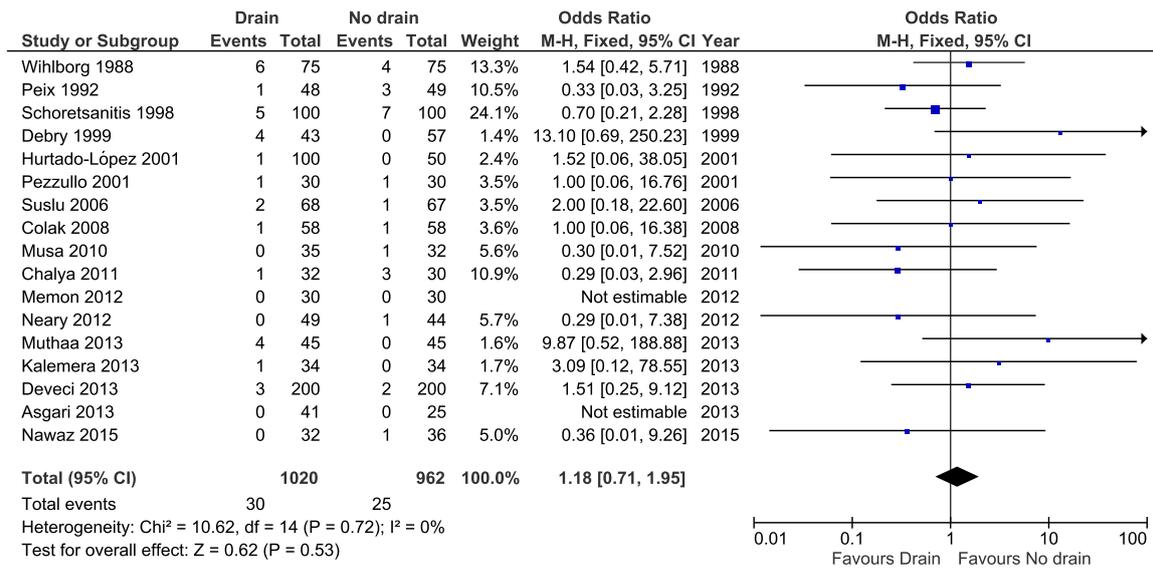


Figure 5 Forest plot of comparison: drain versus no drain for thyroid surgery. Outcome: hematoma. Mantel-Haenszel (M-H) fixed-effect model (Fixed) for meta-analysis.

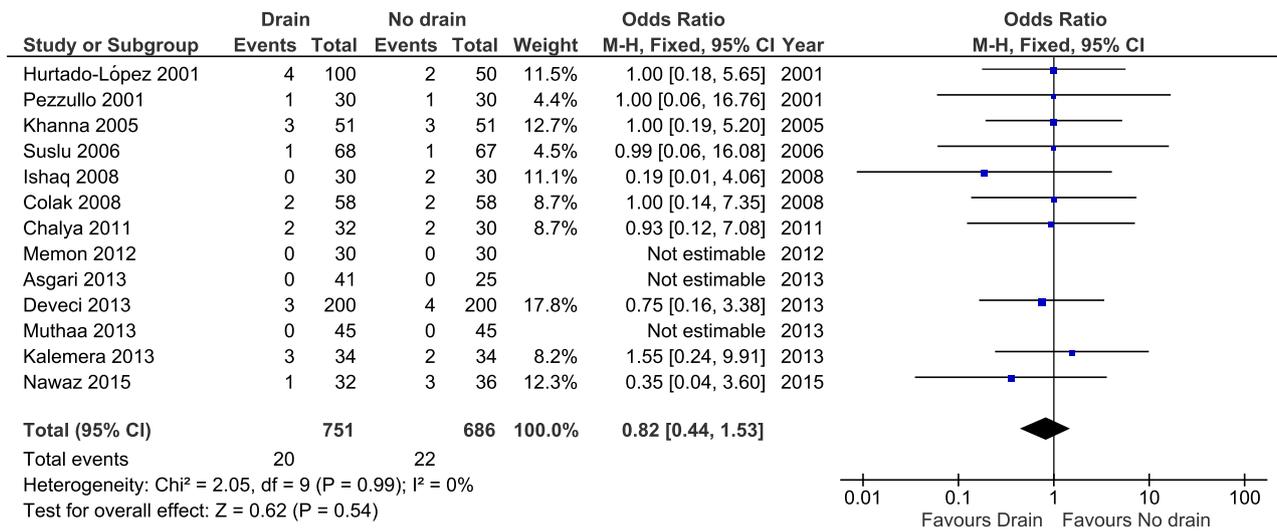


Figure 6 Forest plot of comparison: drain versus no drain for thyroid surgery. Outcome: seroma. Mantel-Haenszel (M-H) fixed-effect model (Fixed) for meta-analysis.

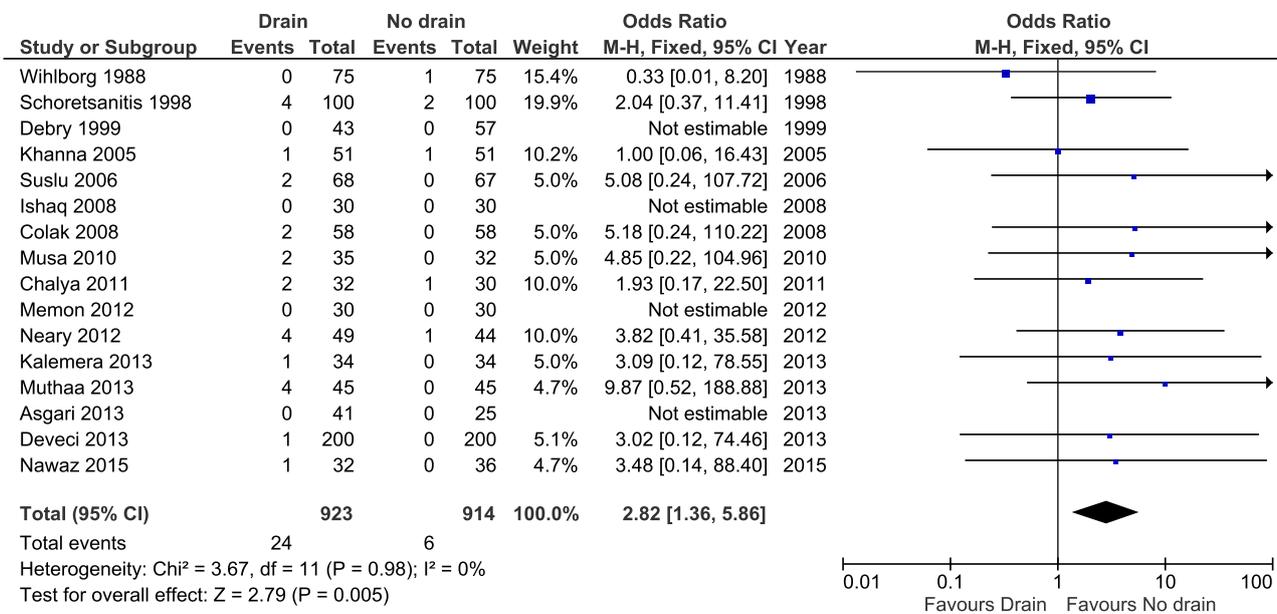


Figure 7 Forest plot of comparison: drain versus no drain for thyroid surgery. Outcome: wound infection. Mantel-Haenszel (M-H) fixed-effect model (Fixed) for meta-analysis.

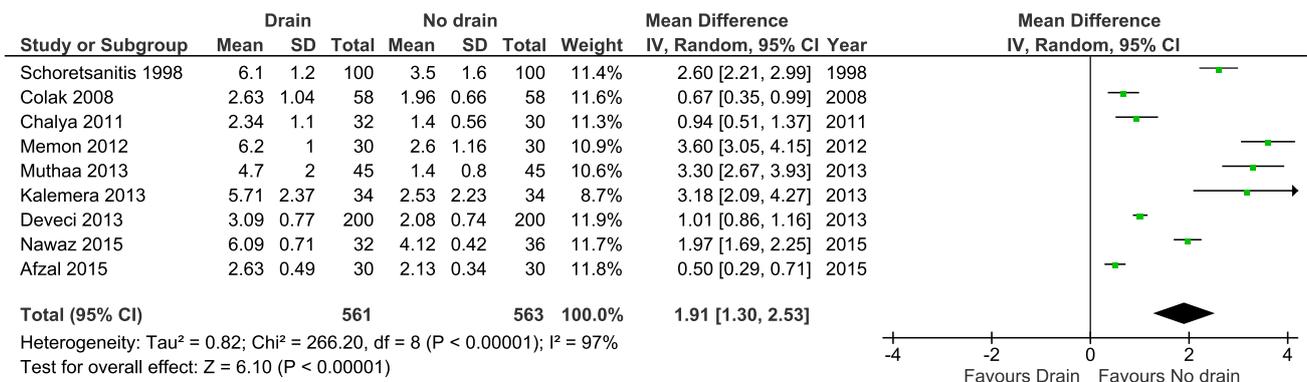


Figure 8 Forest plot of comparison: drain versus no drain for thyroid surgery. Outcome: postoperative pain evaluated by VAS at the POD one. Inverse-variance (IV) random-effect model (Random) for meta-analysis. VAS, Visual Analogue Scale; POD, postoperative day.

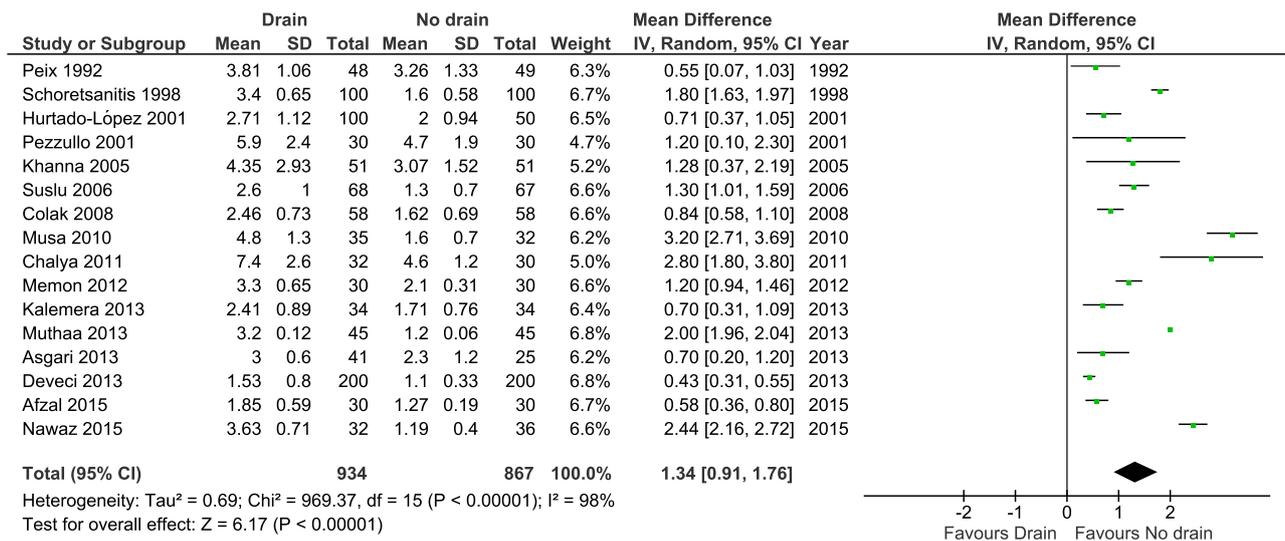


Figure 9 Forest plot of comparison: drain versus no drain for thyroid surgery. Outcome: hospital LOS. Inverse-variance (IV) random-effect model (Random) for meta-analysis. LOS, length of stay.

drain was removed when the output was low and patients were discharged without drain. Furthermore, as suggested by some Authors the presence of drains may increase the amount of fluid collection by their sole presence (9,11), even though the rate of seroma was not significantly different between the two groups. Thus, the presence of drain may influence itself the duration of hospital stay due to the need of monitoring the fluid drainage, with a demonstrated disadvantage related to the higher postoperative pain in these patients.

Limitation of the systematic review

Firstly, the results of the included RCTs may be influenced by the difficulty of blinding in case of drain usage, however the blinding of participant and personnel was considered adequate if the allocation was done immediately before wound closure, because this method guaranteed the blinding of the surgeon during the surgical procedure. Secondly, as reported by Rerkasem *et al.*, the blinded outcome assessment is not always possible in RCTs of surgical procedures, and the allocation concealment is one of the most critical

Table 2 Sensitivity analyses for all outcomes—meta-analysis was performed when data for an outcome were available from four or more studies

Outcomes	Studies with low risk of selection bias and performance bias	Studies in which patients with coagulation disorders or anticoagulant therapy were not excluded	Studies in which patients with huge goiter or substernal goiter were not excluded	Studies with ≥ 100 patients per trial
Reoperation	10 studies; 816 patients; RR 1.06 (0.14, 7.82); $I^2 = 0\%$	9 studies; 921 patients; RR 0.78 (0.21, 2.94); $I^2 = 0\%$	14 studies; 1,412 patients; RR 1.00 (0.22, 4.45); $I^2 = 0\%$	7 studies; 953 patients; RR 1.28 (0.31, 5.24); $I^2 = 0\%$
Hematoma	9 studies; 714 patients; RR 0.91 (0.40, 2.08); $I^2 = 0\%$	9 studies; 921 patients; RR 1.34 (0.68, 2.66); $I^2 = 0\%$	12 studies; 1,250 patients; RR 1.37 (0.76, 2.49); $I^2 = 0\%$	6 studies; 851 patients; RR 1.45 (0.72, 2.91); $I^2 = 0\%$
Wound infection	8 studies; 659 patients; RR 3.46 (1.26, 9.49); $I^2 = 0\%$	7 studies; 711 patients; RR 1.88 (0.59, 5.99); $I^2 = 0\%$	11 studies; 1,105 patients; RR 2.59 (1.07, 6.25); $I^2 = 0\%$	6 studies; 803 patients; RR 1.93 (0.68, 5.47); $I^2 = 0\%$
Seroma	8 studies; 626 patients; RR 0.93 (0.41, 2.08); $I^2 = 0\%$	5 studies; 404 patients; RR 1.19 (0.37, 3.77); $I^2 = 0\%$	9 studies; 772 patients; RR 0.92 (0.41, 2.04); $I^2 = 0\%$	4 studies; 503 patients; RR 1.00 (0.38, 2.61); $I^2 = 0\%$
Hospital LOS	9 studies; 723 patients; MD 1.42 (0.94, 1.90) days; $I^2 = 96\%$	7 studies; 671 patients; MD 1.36 (0.80, 1.92) days; $I^2 = 94\%$	10 studies; 1,009 patients; MD 1.11 (0.69, 1.52) days; $I^2 = 97\%$	5 studies; 703 patients; MD 1.19 (0.69, 1.68) days; $I^2 = 93\%$
Pain score on POD1 (VAS)	6 studies; 464 patients; MD 2.23 (1.29, 3.18); $I^2 = 96\%$	–	5 studies; 534 patients; MD 2.65 (1.37, 3.93); $I^2 = 97\%$	–

RR, risk ratio; VAS, Visual Analogue Scale; MD, mean difference; POD, postoperative day.

methodological factors in reducing bias (25). Of note, among the included studies some quality information were unclear (i.e., the random sequence generation in 15% of the studies, the allocation concealment in 35% of the studies, and the blinding of participants and personnel in 40% of the studies) and this may affect the results of the meta-analysis. However, a sensitivity analysis including only studies with low risk of selection bias and performance bias (10 studies) was performed, and the results were consistent with the findings obtained by including all studies. Thirdly, in 60% of the included studies the number of patients were < 100 , and there could be potential inherent biases due to the small sample size. Furthermore, as stated by Rerkasem *et al.*, a single large RCT will usually produce more reliable evidence than a meta-analysis of multiple small RCTs (25). Interestingly, the sensitivity analysis including only studies with ≥ 100 patients per trial showed that the use of drain does not increase wound infection rate. Of note, on the basis of the pooled results of wound infection rate in both patients with (2.6%) and without drain (0.7%) after thyroid surgery, a RCT with a large sample size should

be performed to identify a significantly clinical difference between two groups. Fourthly, only articles in English language were included.

Conclusions

The use of drain after thyroid surgery increase postoperative pain and hospital LOS, with no decrease of reoperation rate, hematoma and seroma formation. This meta-analysis suggests an increase wound infection rate in patients with drain, however a large RCT should be performed to confirm this finding.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Supplementary

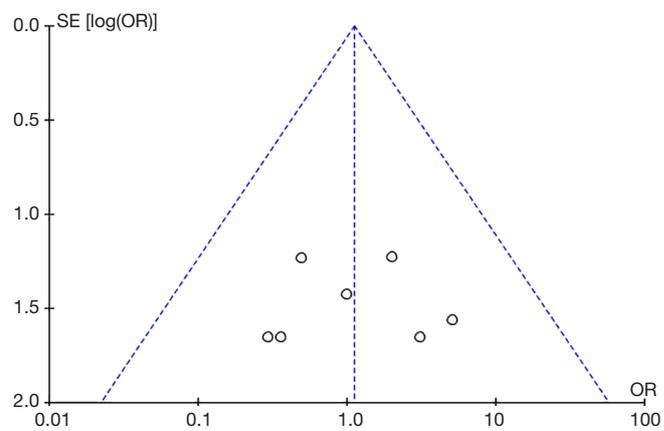


Figure S1 Funnel plot of comparison: drain versus no drain for thyroid surgery. Outcome: reoperation for bleeding (primary outcome).