Modern Technology–Assisted vs Conventional Tonsillectomy

A Meta-analysis of Randomized Controlled Trials

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Objective: To systematically review evidence regarding modern technology–assisted tonsillectomy pertaining to operative time, intraoperative and postoperative bleeding, postoperative pain, and other outcomes.

Design: A systematic search for randomized controlled trials comparing total tonsillectomies performed using vessel sealing systems (VSS), Harmonic Scalpel (HS), or radiofrequency ablation (ie, Coblation) with the conventional technique of cold steel and/or electrocautery dissection (CS/EC). Estimation of odds ratios and 95% confidence intervals (CIs), weighted mean differences (WMD), or standardized mean difference (SMD), as appropriate.

Patients: Thirty-three randomized controlled trials studying a total of 3139 patients were included in this meta-analysis.

Main Outcome Measures: Operative time, perioperative and postoperative bleeding, and postoperative pain.

Results: For the VSS group compared with the CS/EC group, operative time was significantly shorter (WMD), –4.09 minutes; 95% CI, –7.43 to –0.75 minutes; 760 patients), perioperative bleeding was significantly less (SMD, –1.67; –2.80 to –0.53; 355 patients), and postoperative bleeding was significantly less (odds ratio, 0.28; 0.13 to 0.61; 792 patients). Pain on the first and seventh postoperative days was significantly less in the VSS group (SMD, –1.73; 95% CI, –3.07 to –0.39; 740 patients; and SMD, –1.46; –2.35 to –0.57; 684 patients; respectively). For the HS group compared with the CS/EC group, the only studied outcome that differed significantly was perioperative bleeding, which was significantly less in the HS group (WMD –37.71 mL; 95% CI, –52.98 to –22.43 mL; 535 cases). No difference was noted between the Coblation and CS/EC groups for any of the studied outcomes.

Conclusions: For tonsillectomies, the Coblation and HS techniques do not provide any significant advantage compared with CS/EC. Synthesis of the limited and heterogeneous data regarding VSSs showed a significant benefit in all studied outcomes.

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TONSILLECTOMY IS ONE OF the oldest and most commonly performed otorhinolaryngologic procedures.[1] The advent of antimicrobial therapy[2] and the establishment of specific surgical indications[3] have substantially decreased the number of tonsillectomies. In 2003 and 2004, a total of 50 531 patients underwent tonsillectomy within English National Health Service trusts, of whom 49 765 (98.5%) were elective admissions,[4] with a significant health care expenditure aggravated by the cost of postoperative morbidity.[5] Modern tonsillectomy is a safe procedure. The conventional technique is cold steel and/or electrocautery dissection (CS/EC). However, postoperative morbidity in terms of pain, bleeding, and return to normal activity and diet is notable. Thus, a variety of techniques and approaches have been tested over the years. Yet, no definite consensus has been reached regarding the optimal technique with the lowest morbidity rates.

Recent advances in surgical instrumental technology have introduced energy-based devices that are able to simultaneously dissect tissue and seal vessels. The patented energy-based vessel sealing systems (VSS) designed for tonsillectomy use different technologies to provide a similar dissection-ligation effect. The LigaSure Vessel Sealing System (LS) (Valleylab, Boulder, Colorado) is a hemostatic electrosurgical device that consists of a handpiece with a ratcheted scissors mechanism that grasps and compresses the tissue and an electrosurgical generator that senses the density of the tissue bundle, automatically adjusting the amount of en-

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ergy to deliver the optimal amount to denature collagen and elastin within the vessel wall and connective tissue.[6] The Thermal Welding System (TWS) (Starion Instruments Corp, Saratoga, California), instead of using electric current, uses heat and pressure to simultaneously fuse and divide soft tissue and blood vessels. The manufacturer claims that it produces less heat and minimizes collateral tissue damage. It consists of a simple electrically resistant heating wire driven by low-voltage direct current.[7] The third device of this type is the BiClamp (BC) (Erbe Elektromedizin GmbH, Tübingen, Germany), which combines bipolar coagulation with high-frequency current modulation automatically regulated and dosed according to tissue impedance. The manufacturer claims that it results in pulse-and-pause duration that offers gentle coagulation, avoiding carbonization. The coagulation induces vessel wall swelling and sealing of the lumen.[8]

The Harmonic Scalpel (HS) (Ethicon Endo-Surgery Inc, Cincinnati, Ohio), another device that has been used to safely perform tonsillectomies, uses ultrasonic energy to vibrate its blade at 55 kHz, providing simultaneous cutting and coagulation of the tissue. This vibration transfers energy to the tissue and leads to superficial denaturation and coagulation of protein by heating the tissue. The temperature of the surrounding tissue reaches 80°C. The manufacturer claims that this procedure results in precise cutting with minimal thermal damage.[9]

Finally, radiofrequency ablation (ie, cold ablation) is a technology that has been used successfully in various surgical specialties.[10] Bipolar radiofrequency ablation, referred to by the trade name Coblation (ArthroCare Corp, Sunnyvale, California), was designed for head and neck surgery; it ablates and coagulates soft tissue by generating a field of ionized sodium molecules. The ionized plasma layer between the device tip and the tissue is produced by a radiofrequency current that passes through a medium of normal saline at a temperature of 40°C to 70°C. This process breaks molecular bonds and produces a melting tissue effect. The manufacturer claims that the lower temperature provides important benefits, such as improved precision cutting and minimal thermal damage in tissue.[11]

Many studies have been published regarding the use of all these surgical techniques and devices. However, the reported results are, in many cases, conflicting and controversial. Thus, we sought to systematically review and synthesize the available evidence regarding modern technology–assisted total tonsillectomy pertaining to operative time, intraoperative and postoperative bleeding, postoperative pain, and other clinical outcomes. We then compared them with the conventional technique of CS/EC by performing a systematic review and meta-analysis of randomized controlled trials (RCTs).

METHODS

DATA SOURCES

This meta-analysis was conducted according to the guidelines issued by the Quality of Reporting of Meta-analyses conference.[12] To identify relevant RCTs, we systematically searched PubMed for articles dated through July 14, 2010, and the Cochrane Central Register of Controlled Trials for the key word *tonsillectomy* using only articles published after January 1, 1990. Furthermore, we reviewed the references of the included RCTs to identify additional resources. We did not seek abstracts of conference proceedings.

STUDY SELECTION

Two of the authors (V.G.A. and M.S.S.-S.) independently performed literature searches to locate potentially eligible reports. All RCTs comparing total tonsillectomies performed using VSS (ie, LS, TWS, and BC), HS, or Coblation with tonsillectomies performed using the conventional technique of CS/EC and reporting on operative time, intraoperative and postoperative bleeding, postoperative pain, and other clinical outcomes were considered for inclusion in this meta-analysis. The RCTs reporting on subtotal (ie, intracapsular) tonsillectomies were excluded. Thus, techniques such as microdebrider and laser-assisted tonsillectomy were excluded. Furthermore, we excluded case series reporting on fewer than 10 patients. Finally, we excluded RCTs pertaining to the use of Argon Plasma Coagulation (Erbe Elektromedizin GmbH), a technology that has been used for tonsillectomy after successfully having been used in endoscopic procedures.[13] Argon Plasma Coagulation–assisted tonsillectomy never has been a widely used technique and has been almost abandoned today.

DATA EXTRACTION

Two reviewers (V.G.A. and M.S.S.-S.) independently collected from all eligible articles the first author, year of publication, country of origin, age range of study population, number of patients enrolled, tonsillectomy techniques compared, and studied outcomes. Detailed data regarding operative time, intraoperative and postoperative bleeding, postoperative pain, and other clinical outcomes were tabulated. Also, we individually assessed randomization, generation of random numbers, details of the double-blinding procedure, information regarding withdrawals, and concealment of allocation to evaluate the methodologic quality of each RCT according to a modified Jadad score.[14] One point was awarded for the specification of each criterion; the maximum score that a study could achieve was 5.

ANALYZED OUTCOMES AND DEFINITIONS

The outcome measures for this meta-analysis were operative time, intraoperative and postoperative bleeding, and postoperative pain. Postoperative bleeding was defined as any primary and secondary bleeding reported by the authors of an RCT.

DATA AND STATISTICAL ANALYSES

Statistical analyses were performed using Review Manager (RevMan, version 5.0.24, for Linux; Nordic Cochrane Center, Cochrane Collaboration, Copenhagen, Denmark). The heterogeneity among the RCTs was assessed with the I^2 statistic and a χ^2 test; $P<.10$ was defined to note statistical significance in the analysis of heterogeneity. Publication bias was assessed according to funnel plot asymmetry. Continuous outcomes were analyzed using weighted mean difference (WMD) or standardized mean difference (SMD) if different scales were used to calculate the same outcome[15] and 95% confidence intervals (CIs). The SMD is necessary to standardize the results of the studies to a uniform scale before they can be combined; it expresses the size of the intervention effect in each study relative to the study variability.[15] Pooled odds outcomes of this meta-

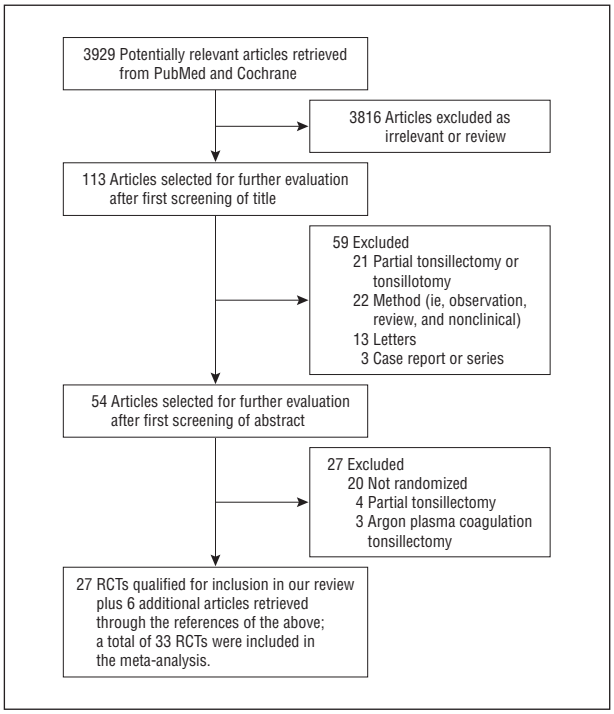

Figure 1. Flow diagram of the reviewed studies. RCTs indicates randomized controlled trials.

analysis were calculated by using a fixed-effects model or the DerSimonian-Laird random-effects model if statistically significant heterogeneity was noted.

RESULTS

SELECTED RCTs

In **Figure 1**, we present a flow diagram describing the selection process followed to identify the pool of RCTs included in the meta-analysis. The PubMed search yielded 3929 potentially relevant articles; the search using the Cochrane Central Register of Controlled Trials did not reveal any additional relevant RCTs. An additional 6 articles were retrieved using the references cited in the retrieved articles. In total, 33 articles[16-48] fulfilled the inclusion criteria for this meta-analysis.

CHARACTERISTICS OF THE SELECTED STUDIES

In **Table 1**, we summarize the main characteristics of the studies included in this meta-analysis: 33 RCTs studying a total of 3139 patients (median, 68; range, 20-316). Seven studies compared tonsillectomies performed using VSS (ie, 4, 2, and 1 studies for TWS, LS, and BC, respectively) with tonsillectomies performed using CS/CS. Eleven and 16 studies compared conventional tonsillectomy using CS/EC with tonsillectomies performed using HS and Coblation, respectively. Eleven studies were conducted among children only and 8 among adults only. Fourteen studies had a mixed-age population. Five studies randomized tonsils instead of patients. Regarding quality score, 16 of 33 RCTs achieved a score of 3, 3 studies achieved a score of 4, and 1 study achieved the maximum score of 5. The rest of the included studies had a low score of 1 or 2 points.

MAIN OUTCOMES DATA EXTRACTION

In **Table 2**, we present various clinical outcomes summarized by our study. Data regarding operative time, perioperative and postoperative bleeding, and postoperative pain were reported by most of the included studies; thus, a meta-analysis was feasible. Return to normal diet and activity, patient satisfaction, need for analgesics, tonsillar fossa healing, postoperative nausea and vomiting, need for antibiotics, and other complications, such as hematoma and taste changes, were reported only by certain studies.

META-ANALYSIS

In **Figure 2**, we present a meta-analysis comparing outcomes of tonsillectomies performed using VSS with tonsillectomies performed using the conventional technique (ie, CS/EC). Operative time was significantly shorter in the VSS group (WMD, –4.09 minutes; 95% CI, –7.43 to –0.75 minutes; 760 patients). Perioperative bleeding was noted to be less using VSS compared with the conventional technique (SMD, –1.67; 95% CI, –2.80 to –0.53; 355 patients). Moreover, VSS yielded significantly less postoperative bleeding compared with the conventional technique (odds ratio [OR], 0.28; 95% CI, 0.13 to 0.61; 792 patients). Pain on the first and seventh postoperative days was significantly less in the VSS group (SMD, –1.73; 95% CI, –3.07 to –0.39; 740 patients; and SMD, –1.46; –2.35 to –0.57; 684 patients, respectively).

In **Figure 3**, we present the meta-analysis comparing outcomes of tonsillectomies performed using HS with tonsillectomies performed using CS/EC. No significant difference was found between the compared groups regarding operative time (WMD, –0.10 minutes; 95% CI, –6.26 to 6.05 minutes; 655 cases), postoperative bleeding (OR, 0.78; 95% CI, 0.50 to 1.23; 1473 cases), and averaged postoperative pain (SMD, –0.38; 95% CI, –1.20 to 0.43; 517 cases). However, perioperative bleeding was significantly less in the HS group (WMD, –37.71 mL; 95% CI, –52.98 to –22.43 mL; 535 cases).

In **Figure 4**, we present the meta-analysis comparing outcomes of tonsillectomies performed using Coblation with tonsillectomies performed using the conventional technique. No significant difference was found between the compared groups for any of the studied outcomes: operative time (WMD, –0.35 minutes; 95% CI, –2.84 to 2.13 minutes; 406 cases), perioperative bleeding (WMD, –4.22 mL; 95% CI, –14.39 to 5.95 mL; 292 cases), postoperative bleeding (OR, 0.99; 95% CI, 0.58 to 1.69; 1092 cases), and postoperative pain (SMD, –1.56; 95% CI, –3.48 to 0.35; 313 cases).

COMMENT

The main finding of this meta-analysis of RCTs is that the Coblation and HS tonsillectomy techniques that have been used during the past decade in an attempt to de-

Table 1. Main Characteristics of Studies Included in the Systematic Review

Source	Country	Quality Score	Study Population, Age, y	No. of Patients	Compared Tonsillectomy Techniques
Silvola et al,[16] 2011	Finland	3	16-65	60	VSS (TWS) vs EC
Lee et al,[17] 2008	South Korea	3	2-61	215	VSS (BC) vs EC
Sezen et al,[18] 2008	Turkey	1	3-28	50	VSS (TWS) vs CS
Lachanas et al,[19] 2007	Greece	2	Adults	161	VSS (LS) vs HS
Stavroulaki et al,[20] 2007	Greece	3	Adults	32	VSS (TWS) vs CS
Karatzias et al,[21] 2006	Greece	2	17-56	150	VSS (TWS) vs EC
Lachanas et al,[22] 2005	Greece	2	16-46	200	VSS (LS) vs CS
Cushing et al,[23] 2009	Canada	3	6-47	114	HS vs EC
Leaper et al,[24] 2006	New Zealand	2	6-15	204	HS vs EC
Parsons et al,[25] 2006	United States	3	Children	134	HS vs Coblation vs CS
Kamal et al,[26] 2006	England	1	3-69	190	HS vs CS
Oko et al,[27] 2005	England	3	5-13	122	HS vs CS
Collison and Weiner,[28] 2004	United States	2	Children	28	HS vs CS
Willging and Wiatrak,[29] 2003	United States	3	3-18	120	HS vs EC
Sheahan et al,[30] 2004	Ireland	3	16-31	21	HS vs EC
Walker and Syed,[31] 2001	United States	2	1-19	316	HS vs EC
Akural et al,[32] 2001	Finland	3	17-48	28	HS vs EC
Aksoy et al,[33] 2010	Turkey	3	>10	50	Coblation vs EC
Parker et al,[34] 2009	England	5	4-16	70	Coblation vs CS/EC
Roje et al,[35] 2009	Croatia	3	3-16	72	Coblation vs EC
Magdy et al,[36] 2008	Egypt	4	18-34	40	Coblation vs CS/EC
Hasan et al,[37] 2008	Finland	3	18-55	40	Coblation vs EC
Shapiro and Bhattacharyya,[38] 2007	United States	3	2-16	47	Coblation vs CS
Mitic et al,[39] 2007	Norway	3	4-12	40	Coblation vs EC
Tan et al,[40] 2006	Singapore	4	>18	67	Coblation vs EC
Noordzij and Affleck,[41] 2006	United States	2	>18	48	Coblation vs EC
Polites et al,[42] 2006	Australia	2	16-41	20	Coblation vs EC
Ragab,[43] 2005	Egypt	3	9-16	200	Coblation vs CS
Philpott et al,[44] 2005	England	4	Adults	92	Coblation vs CS
Stoker et al,[45] 2004	United States	1	3-12	99	Coblation vs EC
Shah et al,[46] 2002	United States	1	4-7	34	Coblation vs EC
Bäck et al,[47] 2001	Finland	3	18-65	37	Coblation vs CS
Temple and Timms,[48] 2001	England	2	4-12	38	Coblation vs EC

Abbreviations: BC, BiClamp; CS, cold steel; EC, electrocautery dissection; HS, Harmonic Scalpel; LS, LigaSure; TWS, Thermal Welding System; VSS, vessel sealing systems.

crease postoperative morbidity in terms of pain and bleeding do not provide any significant advantage over the conventional CS/EC technique. The only outcome that differed significantly in tonsillectomies performed using HS compared with those using CS/EC was perioperative bleeding. However, it is commonly accepted that this variable does not have any measurable clinical significance. Regarding postoperative bleeding and pain in tonsillectomies performed using HS, the meta-analysis plot (Figure 3) identified 2 outlier studies[19,26] reporting significant benefits that were not verified by the total OR and SMD, respectively. However, none of the 16 RCTs comparing Coblation with CS/EC showed significant benefits regarding postoperative bleeding. This finding was verified by the meta-analysis, including a total of 1092 patients; no benefit of Coblation over CS/EC was observed regarding the most important clinical outcome of postoperative bleeding. Regarding other outcomes, the pooled population was considerably smaller: 406, 292, and 303 patients for operative time, perioperative bleeding, and postoperative pain, respectively. Thus, results should be considered cautiously. In all outcomes, HS and Coblation were at least equivalent to the conventional technique. However, equivalence may not be enough to justify a change in the current clinical practice.

The meta-analysis of the RCTs reporting the use of VSS showed a statistically significant difference in favor of this technique compared with CS/EC for all studied outcomes: operative time, perioperative bleeding, and, most important, postoperative bleeding and pain. Of interest, none of the included VSS studies was highly powered enough to show statistical significance in the clinical outcome of postoperative bleeding. Synthesis of the available evidence from 792 patients included in 7 RCTs showed that the meta-analysis has higher statistical power to detect an effect on the rare but clinically important outcome of postoperative bleeding. Furthermore, 4 of the 5 studies[18-22] that evaluated pain in the first postoperative day showed that it was significantly less for the VSS group. One study[17] did not show any significant difference, and another[16] showed that pain was significantly greater in the VSS group. Combining all the available evidence helps resolve such controversies and reach a safer conclusion regarding postoperative pain.

This systematic review has included 4 studies of TWS,[16,18,20,21] 2 studies of LS,[19,22] and 1 study of BC[17] that have not equally addressed all the outcomes included in

Table 2. Data Extracted From the Included Randomized Controlled Trials Regarding Outcomes of the Meta-analysis

Source	Operative Time, Mean (SD), min	Intraoperative Bleeding, Mean (SD), mL	No. of Patients With Postoperative Bleeding/Total No. of Patients	Pain Score, Mean (SD)	Other Outcome Information and Scores[a]
				VSS vs CS/EC	
Silvola et al,[16] 2011	15 (5) vs 13 (5)	18 (36) vs 11 (14)	0/31 vs 3/27	POD 1: 2.3 (1.9) vs 1.1 (1.3) ($P = .01$); MU: 10-point scale; Analgesia: NS differences	In the VSS group, recovery after discharge was significantly shorter, less pain was reported, interference with daily activities was significantly less, and patient satisfaction was significantly higher compared with the monopolar group; Various adverse events after discharge (ie, constipation, tiredness, nausea, and abdominal pain): 26/31 vs 23/27
Lee et al,[17] 2008	Children: 12.0 (3.9) vs 14.8 (4.3) ($P < .01$); Adults: 15.6 (7.0) vs 20.5 vs 7.9 ($P < .01$)	Children: 1.58 (0.66) vs 2.04 (0.75) ($P < .01$); Adults: 1.92 (0.83) vs 2.27 (0.87) ($P < .05$); Grade of blood loss, scale of I to V: grade I (none), grade II (<20 mL), grade III (20-<50 mL), grade IV (50-100 mL), and grade V (>100 mL)	Children: 0/45 vs 3/47 ($P = .24$); Adults: 4/60 vs 9/63 ($P = .24$)	POD 1—child: 0.67 (0.71) vs 1.06 (0.94) ($P = .02$); adult: 3.78 (1.24) vs 4.10 (1.25) ($P = .17$); POD 7—child: 0.47 (0.63) vs 1.13 (1.94) ($P = .001$); adult: 2.98 (2) vs 5.08 (2.18) ($P < .001$); POD 14—child: 0.11 (0.38) vs 0.43 (0.65) ($P = .006$); adult: 0.97 (1.34) vs 1.79 (1.84) ($P = .005$); Pain did not differ significantly on POD 31 in any of the compared groups; MU: 4-point visual analog pain scale with pictures of faces for children and 10-point visual analog pain scale for adults	Normal activity (in days)— Children: 2.93 (1.32) vs 3.83 (2.19) ($P = .02$); Adults: 3.52 (1.52) vs 5.83 (2.54) ($P < .001$); Other perioperative complications (ie, minor hematoma, anterior pilar tearing, posterior pilar perforation, and taste change)—Children: 3/45 vs 5/47 ($P = .71$); Adults: 10/60 vs 21/63 ($P = .04$); Mean dietary score was significantly higher in the VSS group in PODs 7 and 14 for children and adults
Sezen et al,[18] 2008	21.5 (8.81) vs 36.44 (12.07) ($P < .01$)	17.28 (13.35) vs 132.4 (56.9)	0/25 vs 0/25	Pain in VSS group was significantly higher for PODs 1 and 2 ($P < .01$); For PODs 3-7, NS difference; MU: Wong-Baker FACES Pain Scale for patients younger than 7 years and visual analog scale for others	Return to normal activity: NS difference; Mean suture number: 0 vs 3 ($P < .01$); Poor appetite on POD 1: 4% vs 48% ($P < .01$)
Lachanas et al,[19] 2007	15.54 (1.47) vs 21 (1.10) ($P < .001$)	0 vs 73 (20.11) ($P < .001$)	Primary bleeding: 0/50 vs 1/37 ($P < .001$); Secondary bleeding: 1/50 vs 1/37 ($P < .001$)	POD 1: 4.83 (1.3) vs 7.98 (0.67) ($P < .001$); POD 3: 4.75 (1.79) vs 7.75 (0.79) ($P < .001$); POD 5: 4.35 (1.45) vs 6.08 (1.26) ($P < .001$); POD 7: 3.33 (1.4) vs 5.33 (1.25) ($P < .001$); POD 10: 1.33 (1.18) vs 3.00 (0.71) ($P < .001$); Overall mean pain score: 3.72 (1.37) vs 6.03 (0.88) ($P < .001$); MU: 10-point visual analog scale	NA
Stavroulaki et al,[20] 2007	NA	9.4 (5.20) vs 158.44 (30.40) ($P < .001$)	0/16 vs 3/16 ($P = .08$)	POD 1: 6.031 (2.41) vs 8.375 (1.58) ($P = .003$); POD 2: 5.812 (2.22) vs 7.562 (2.18) ($P = .03$); POD 3: 5.593 (2.27) vs 7.312 (1.92) ($P = .03$); POD 4: 4.875 (1.70) vs 6.531 (2.40) ($P = .03$); POD 7: 3.218 (2.23) vs 4.656 (2.42) ($P = .03$); PODs 5-10: NS difference; Cessation of significant pain (pain score of >7) occurred 3 days earlier in VSS ($P = .007$); MU: 10-cm visual analog scale	Analgesic use was higher in CS group; Mean No. of acetaminophens: 4.38 (4.29) vs 6.88 (5.63) ($P = .17$); Postoperative nausea and vomiting: NS difference; Tonsillar fossa healing: NS difference
Karatzias et al,[21] 2006	22.67 (0.38) vs 22.23 (0.20) ($P > .50$)	No measurable bleeding vs 16 (range, 0-45 mL)	Primary hemorrhage: 0/81 vs 1/69; Secondary hemorrhage: 1/81 vs 3/69	POD 1: 8.86 (0.15) vs 9.54 (0.07) ($P < .001$); POD 3: 8.26 (0.16) vs 9.26 (0.09) ($P < .001$); POD 5: 7.90 (0.19) vs 9.12 (0.12) ($P < .001$); POD 7: 6.65 (0.23) vs 7.54 (0.18) ($P < .001$); POD 10: 2.20 (0.15) vs 4.03 (0.19) ($P < .001$); POD 14: 1.04 (0.09) vs 2.51 (0.26) ($P < .001$); Overall mean pain score: 5.82 (0.16) vs 7.00 (0.15) ($P < .001$); MU: 10-point visual analog scale	Mean return to diet (d): 8.44 (0.12) vs 12.01 (0.30) ($P < .001$); Peritonsillar and uvula edema: 0/81 vs 7/69 (resolved in 24 hours with no additional medication)

(continued)

Table 2. Data Extracted From the Included Randomized Controlled Trials Regarding Outcomes of the Meta-analysis (continued)

Source	Operative Time, Mean (SD), min	Intraoperative Bleeding, Mean (SD), mL	No. of Patients With Postoperative Bleeding/Total No. of Patients	Pain Score, Mean (SD)	Other Outcome Information and Scores[a]
			VSS vs CS/EC		
Lachanas et al,[22] 2005	15 (1.43) vs 21 (1.09) ($P<.001$)	No measurable bleeding vs 125	Primary hemorrhage: 0/108 vs 1/92; Secondary hemorrhage: 2/108 vs 2/92	POD 1: 4.60 (1.66) vs 7.93 (0.64) ($P<.001$); POD 3: 6.01 (1.95) vs 7.76 (0.73) ($P<.001$); POD 4: 6.19 (1.43) vs 6.12 (1.27) ($P<.001$); POD 7: 3.67 (1.88) vs 5.38 (1.25) ($P<.001$); POD 10: 1.33 (1.18) vs 2.99 (0.70) ($P<.001$); POD 14: 0 vs 0.33 (0.47); Overall mean pain score: 3.63 (0.91) vs 5.09 (0.54) ($P<.001$); MU: 10-point visual analog scale	Peritonsillar edema: 21/108 vs 0/92 (resolved in 24 hours with no additional medication)
			HS vs CS/EC		
Cushing et al,[23] 2009	NA	NA	1/114 vs 0/114; 1 tonsil removed using HS and the other using EC	Averaged pain at rest: 26.4 (28.8) vs 27.3 (29.3) (NS difference); Averaged pain on swallowing: 33.7 (32.3) vs 35.2 (32.4); Pain at rest—POD 10: mean difference, 5.8 ($P=.04$); PODs 1-9 and 11-14: NS difference; Pain with swallowing—PODs 1, 6, 7, and 8: mean score differences, 7.2, 8.4, 8.2, and 7.8 ($P=.02$, .002, .03, and .04), respectively; PODs 2-5 and 9-14: NS difference; MU: 100-mm nonhatched visual analog pain scale	Delayed postoperative dehydration or poor oral intake: none
Lachanas et al,[19] 2007	14.84 (1.38) vs 21 (1.10) ($P<.001$)	5 (2.77) vs 73 (20.11) ($P<.001$)	Primary bleeding 1/43 vs 1/37 ($P<.001$); Secondary bleeding 2/43 vs 1/37 ($P<.001$)	POD 1: 4.91 (1.25) vs 7.98 (0.67) ($P<.001$); POD 3: 4.50 (1.75) vs 7.75 (0.79) ($P<.001$); POD 5: 4.21 (1.31) vs 6.08 (1.26) ($P<.001$); POD 7: 3.29 (1.3) vs 5.33 (1.25) ($P<.001$); POD 10: 1.29 (1.25) vs 3.00 (0.71) ($P<.001$); Overall mean pain score: 3.64 (1.32) vs 6.03 (0.88) ($P<.001$); MU: 10-point visual analog scale	NA
Leaper et al,[24] 2006	Median (IQR), 12 (9-16) vs 12 (10.14) ($P=.35$)	Median (IQR), 5 (5-15) vs 5 (5-13) ($P=.27$)	9/103 vs 11/101 ($P=.60$)	Median (IQR)—Child pain score: 4.7 (4.4-4.9) vs 4.2 (4.0-4.4) ($P=.002$); Child worst pain: 6.9 (6.7-7.1) vs 6.2 (6.0-6.5) ($P<.001$); Child pain with swallowing: 5.9 (5.6-6.1) vs 5.2 (5.0-5.5) ($P<.001$) Adult pain score: 4.5 (0.1-0.6) vs 4.2 (4.0-4.4) ($P=.008$); Adult worst pain: 6.5 (6.3-6.7) vs 6.0 (5.8-6.2) ($P=.002$); Adult pain with swallowing: 5.3 (5.1-5.5) vs 5.0 (4.8-5.2) ($P=.02$); MU: 10-point visual analog pain score	NA
Parsons et al,[25] 2006	31.5 (9.9) vs 21.0 (6.7) ($P<.001$)	18.2 (24.5) vs 11.3 (12.8) (NS difference)	1/44 vs 2/43 (NS difference)	4.66 (1.67) vs 4.30 (2.10) (NS difference); MU: Wong-Baker FACES Pain Rating Scale	Within 10 PODs, 80.3% of patients achieved normal food intake ($P=.08$) and 91.8% reached normal activity level: NS difference; Postoperative telephone calls, 3/17 vs 10/19 ($P=.053$)
Kamal et al,[26] 2006	14.9 (1.94) vs 26.16 (1.91)	6.2 (2.54) vs 49.38 (3.4) ($P=.05$)	2/120 vs 12/70	Grades 4-6: 51.5% vs 80%; MU: 1-6 grades	Similar anesthesia requirements; Antibiotic prescription: 12.7% vs 34%
Oko et al,[27] 2005	16.2 (4.41) vs 16.7 (3.74) (NS difference)	3.0 (6.88) vs 33.1 (31.26) ($P<.001$)	8/61 vs 6/61 (NS difference)	Averaged pain score: 1.8 (1.046) vs 1.5 (0.994) ($P=.003$); POD 1: 2.04 vs 1.69 ($P=.047$); POD 3: 2.24 vs 1.77 ($P=.008$); POD 5: 2.09 vs 1.77 ($P=.08$); POD 7: 1.71 vs 1.33 ($P=.08$); POD 9: 1.02 vs 0.89 (NS difference); MU: Bieri Faces Pain Scale	Dietary intake scores: POD 1: 0.58 vs 0.4 ($P<.001$); POD 3: 0.6 vs 0.5 ($P=.33$); POD 5: 0.62 vs 0.4 ($P=.02$); POD 7: 0.56 vs 0.25 ($P<.001$); POD 9: 0.27 vs 0.13 ($P=.006$); 4-point visual analog dietary scale; Readmission rates with pain and dehydration were 3-fold more common in HS (4.9% vs 1.6%, $P=.62$)
Collison and Weiner,[28] 2004	10.9 (1.66) vs 7.7 (1.2) ($P=.002$)	6.2 (4.14) vs 58.8 (11.31) ($P<.001$)	3/28 vs 0/28; 1 tonsil removed using HS and the other using CS	3 Hours postoperatively, mean pain score, 3.5 vs 4.4 ($P=.004$); POD 7: 2.7 vs 2.6 (NS difference); MU: 10-point visual analog scale	NA

(continued)

Table 2. Data Extracted From the Included Randomized Controlled Trials Regarding Outcomes of the Meta-analysis (continued)

Source	Operative Time, Mean (SD), min	Intraoperative Bleeding, Mean (SD), mL	No. of Patients With Postoperative Bleeding/Total No. of Patients	Pain Score, Mean (SD)	Other Outcome Information and Scores[a]
			VSS vs CS/EC		
Willging and Wiatrak,[29] 2003	8.7 (1.29) vs 4.55 (0.4) ($P<.001$)	Only 2 patients from the HS and 1 from the EC group lost 1 mL of blood intraoperatively (NS differences)	6/61 vs 3/59 ($P=.49$); 2 patients in HS and 1 in EC group required surgical intervention	PODs 1, 2, 3, and 14: less pain with HS ($P=.04$, $P=.01$, $P=.02$, and $P=.04$), respectively; MU: Wong-Baker FACES Pain Rating Scale	Ability to eat, drink, or swallow and amounts consumed: NS difference; Pain when speaking or level of ability to talk: NS difference; Level of daily activity: lower for HS on POD 1 ($P=.01$); Adverse events, dehydration, and fever: NS difference
Sheahan et al,[30] 2004	NA	NA	Secondary hemorrhage: 1/21 vs 1/21; 1 tonsil removed using HS and the other using EC	PODs 1, 2, and 7 and week 3: NS difference; MU: 10-point visual analog scale	NA
Walker and Syed,[31] 2001	NA	Minimal bleeding for both	Secondary hemorrhage: 1/155 vs 3/161	NA	Return to regular diet within 1 POD: 44.3% vs 22.7% ($P=.004$); Return to regular diet within 3 PODs: 74.2% vs 46.7% ($P=.001$); Return to normal activity, POD 1: 27.8% vs 12.0% ($P=.01$); Return to normal activity, POD 3: 49.5% vs 22.7% ($P=.001$); Readmission for dehydration: 2/155 vs 4/161
Akural et al,[32] 2001	7 vs 7	0 vs 21	1/14 vs 1/14	Pain score—at rest: at 0-10 hours, 12.3 vs 24.8 ($P=.002$); first week, NS difference; Second week, 11.5 vs 6.8 ($P=.002$); With swallowing: at 0-10 hours, 32.5 vs 50.5 ($P=.001$); first week, NS difference; second week, 16.8 vs 9.8 ($P=.003$); Day's worst—first week: NS difference; second week: 18 vs 11.75 ($P=.002$); Day's average—first week: NS difference; second week: 9.3 vs 5.5 ($P=.004$); Day's least—2.5 vs 0.5 ($P=.01$); Otalgia—first week: NS difference; second week: 10 vs 7 ($P=.002$); MU: 10-point numerical rating score	Requirement for analgesia; Paracetamol and codeine consumption persistently high during the first week; From POD 7, codeine consumption decreased compared with POD 1; From POD 8, paracetamol consumption decreased
			Coblation vs CS/EC		
Aksoy et al,[33] 2010	7.3 (1.5) vs 8.1 (1.6) ($P=.03$)	Minimal bleeding for both groups	1/25 vs 2/25	3.3 (1.4) vs 3.7 (1.4), NS difference; MU: 10-point visual analog pain scale	PODs 5, 10, and 14: Tonsillar fossa healing scores: NS difference
Parker et al,[34] 2009	NA	NA	NA (excluded if postoperative bleeding occurred)	PODs 1-10: NS differences; MU: Wong-Baker FACES Pain Rating Scale and Derbyshire Children's Hospital Paediatric Pain Chart	Analgesics requirement: fewer analgesics for Coblation group in the first 24 hours
Roje et al,[35] 2009	NA	10.83 (3.41) vs 27.08 (13.22)	0/36 vs 0/36	NA	Analgesics use, d—mean (range): 4 (0-9) vs 5 (1-8) ($P<.05$); Return to normal activity (d)—mean (range): 2 (1-7) vs 4 (1-9) ($P<.001$); Mean depth in mm of thermal damage to tonsillar tissue: 428.58 (47.4) vs 841.17 (39.7)
Magdy et al,[36] 2008	Coblation vs CS: median (range), 10.5 (7-35) vs 14.5 (10-30) ($P=.20$) Coblation vs EC: 12 (7-40), 10 (6-20) ($P=.98$)	Coblation vs CS: median (range), 5 (0-10) vs 22.5 (10-75) ($P<.001$) Coblation vs EC: median (range), 5 (0-10), 12.5 (0-25) ($P=.21$)	Coblation vs CS: 0/20 vs 0/20; Coblation vs EC: 0/20 vs 0/20	Coblation vs CS: significantly lower in the coblation group for PODs 1 and 4-7; Coblation vs EC: significantly lower in the Coblation group for PODs 1-13; MU: 10-point visual analog pain scale	Tonsillar fossa healing—Coblation vs CS: NS difference; Coblation vs EC: POD 7, median (range), faster healing in the Coblation group ($P=.004$)
Hasan et al,[37] 2008	Median (range), 20.5 (11-45) vs 12 (6-19)	Median: 20 vs 5	1/20 vs 4/20	Daily median pain score: NS difference for all PODs; MU: 10-point visual analog scale	Patient-controlled analgesia device median doses: 10 vs 4 ($P=.04$)
Shapiro and Bhattacharyya,[38] 2007	5 (0.97) vs 7.8 (1.1) ($P<.001$)	Significantly lower in the Coblation group ($P<.001$); Graded blood loss comparison	1/23 vs 0/24	Pain between the compared groups: NS difference	Return to normal activity: NS difference

(continued)

Table 2. Data Extracted From the Included Randomized Controlled Trials Regarding Outcomes of the Meta-analysis (continued)

Source	Operative Time, Mean (SD), min	Intraoperative Bleeding, Mean (SD), mL	No. of Patients With Postoperative Bleeding/Total No. of Patients	Pain Score, Mean (SD)	Other Outcome Information and Scores[a]
			VSS vs CS/EC		
Mitic et al,[39] 2007	25.6 vs 26.6 (NS difference)	28.25 vs 62.25 (significant difference)	0/20 vs 0/20	6.2 vs 9.6 days with pain score higher than 2 ($P<.001$); MU: 5-point visual analog pain scale	Return to normal activity: 6.6 vs 8.5 ($P<.001$); Measure used: 5-point visual analog scale; Nutrition score: 6.8 vs 8.9 ($P<.001$); Measure used: 5-point visual analog scale
Tan et al,[40] 2006	NA	NA	2/29 vs 0/38	Daily pain: 3.6 (1.4) vs 3 (1.2) ($P=.32$); MU: 10-point visual analog pain scale	Return to normal activity (d): 7.9 (4.9) vs 10 (6.3) ($P=.06$); Return to normal diet (d): 11.1 (3.8) vs 12.5 (4) ($P=.04$); Return to painless swallowing (in days): NS difference; Use of analgesia tablets per days: NS difference; Satisfaction score: NS difference
Noordzij and Affleck,[41] 2006	8.22 (0.6) vs 6.33 (0.48) ($P=.11$)	2.44 (0.58) vs 5.39 (0.66) ($P=.007$)	1/48 vs 3/48; 1 tonsil removed using Coblation and the other using EC	Averaged pain score for 14 days: 3.32 (0.1) vs 3.93 (0.1) ($P<.001$); MU: 10-point visual analog pain scale	Tonsillar fossa healing: NS difference
Polites et al,[42] 2006	NA	NA	1/20 vs 2/20; 1 tonsil removed using Coblation and other using EC	POD 1: 3.89 (2.60) vs 6.89 (2.05) ($P<.001$); POD 2: 4.84 (2.57) vs 6.47 (2.25) ($P=.005$); POD 3: 5.32 (2.43) vs 6.47 (2.14) ($P=.02$); For PODs 4-10: NS difference; MU: 10-point visual analog pain scale	NA
Parsons et al,[25] 2006	28.9 (13.5) vs 21.0 (6.7) ($P<.001$)	21.5 (32.6) vs 11.3 (12.8) ($P=.15$)	1/47 vs 2/43 ($P=.69$)	Mean pain score: 3.27 (1.42) vs 4.30 (2.10) ($P=.02$); MU: Wong-Baker FACES Pain Rating Scale	Marginal difference noted regarding food intake ($P=.08$); No significant difference regarding time to resume normal activity ($P=.96$); Postoperative telephone calls, 6/25 vs 10/19 ($P=.053$)
Ragab,[43] 2005	8.5 vs 15.5 ($P<.001$)	13 vs 82 ($P<.001$)	1/100 vs 3/100	POD 1: 8.5 vs 9 ($P<.05$); MU: 10-point visual analog pain scale	Return to regular diet, return to normal activity, and analgesia required: NS difference
Philpott et al,[44] 2005	NA	NA	11/46 vs 8/46	Pain score: Derbyshire Children's Hospital Paediatric Pain Chart differences for all postoperative days; MU: 6-point visual analog pain scale for pain, otalgia, and swallowing	Otalgia, analgesia, and swallowing scores: NS differences for all PODs; Return to normal activity: NS difference; Return to regular diet significantly faster for the CS group ($P=.03$)
Stoker et al,[45] 2004	7.8 (4.9) vs 8 (2.7) (NS difference)	98% vs 89% had <15 mL of bleeding	1/44 vs 1/45	Freedom from analgesics or pain: NS difference; Patients treated using Coblation tended to discontinue prescription narcotic use sooner ($P=.07$); MU: Wong-Baker FACES Pain Rating Scale	Return to normal activity: NS difference; Return to normal diet: NS difference; Postoperative calls for mild bleeding, pain, vomiting, fever, dehydration, no eating, or coughs: 14/44 vs 23/45 ($P=.08$); Posterior and anterior pillar swelling was more frequent in ES group ($P=.06$ and .03)
Shah et al,[46] 2002	16.32 (3.2) vs 23.8 (7.9) ($P=.002$)	83.8 (46.4) vs 90.9 (35.3) (NS difference)	1/17 vs 0/17	Pain score: NS differences; MU: Bieri Faces Pain Scale	Return to normal activity and NS difference; Return to normal diet: NS difference
Bäck et al,[47] 2001	27 vs 18 ($P<.001$)	80 vs 20 ($P=.02$)	9/18 vs 8/19 (NS difference)	NS differences; MU: 0-100–mm vertical line visual analog pain scale	Need for analgesia: NS difference; Swelling sensation, difficulty drinking, eating, opening mouth, and speaking: NS difference
Temple and Timms,[48] 2001	NA	NA	0/18 vs 0/20	POD 1: 4.3 vs 6.4; POD 7: 1.1 vs 6.6; POD 9: 1.0 vs 4.3; PODs 1-9: significant differences ($P<.001$); MU: 10-point visual analog pain scale	Return to normal diet (d): 2.4 vs 7.6 ($P<.001$)

Abbreviations: CS, cold steel; EC, electrocautery dissection; HS, Harmonic Scalpel; IQR, interquartile range; MU, measures used; NA, not applicable; NS, nonsignificant; POD, postoperative day; VSS, vessel sealing systems.

[a] Mean (SD) except where otherwise indicated.

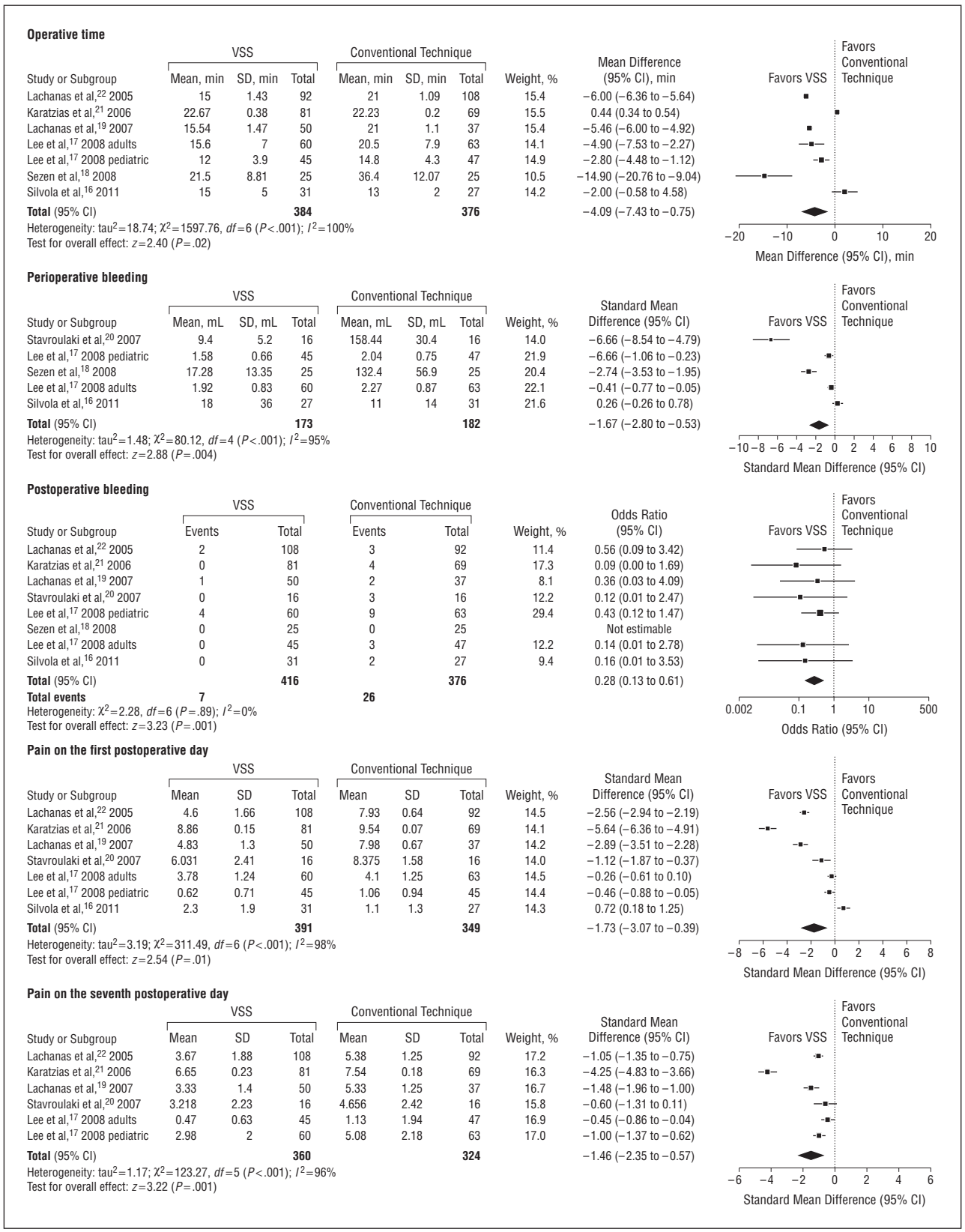

Figure 2. Meta-analysis comparing outcomes of tonsillectomies performed using vessel sealing systems (VSS) with tonsillectomies performed using the conventional technique (cold steel and/or electrocautery). CI indicates confidence interval.

the meta-analysis. Thus, splitting the VSS RCTs into subgroups would not permit us to draw any meaningful conclusions. When further evidence from ongoing or future studies of these devices is available, it would be useful to perform subanalyses of the different VSS devices, as well as a comparative analysis. Vessel sealing systems consti-

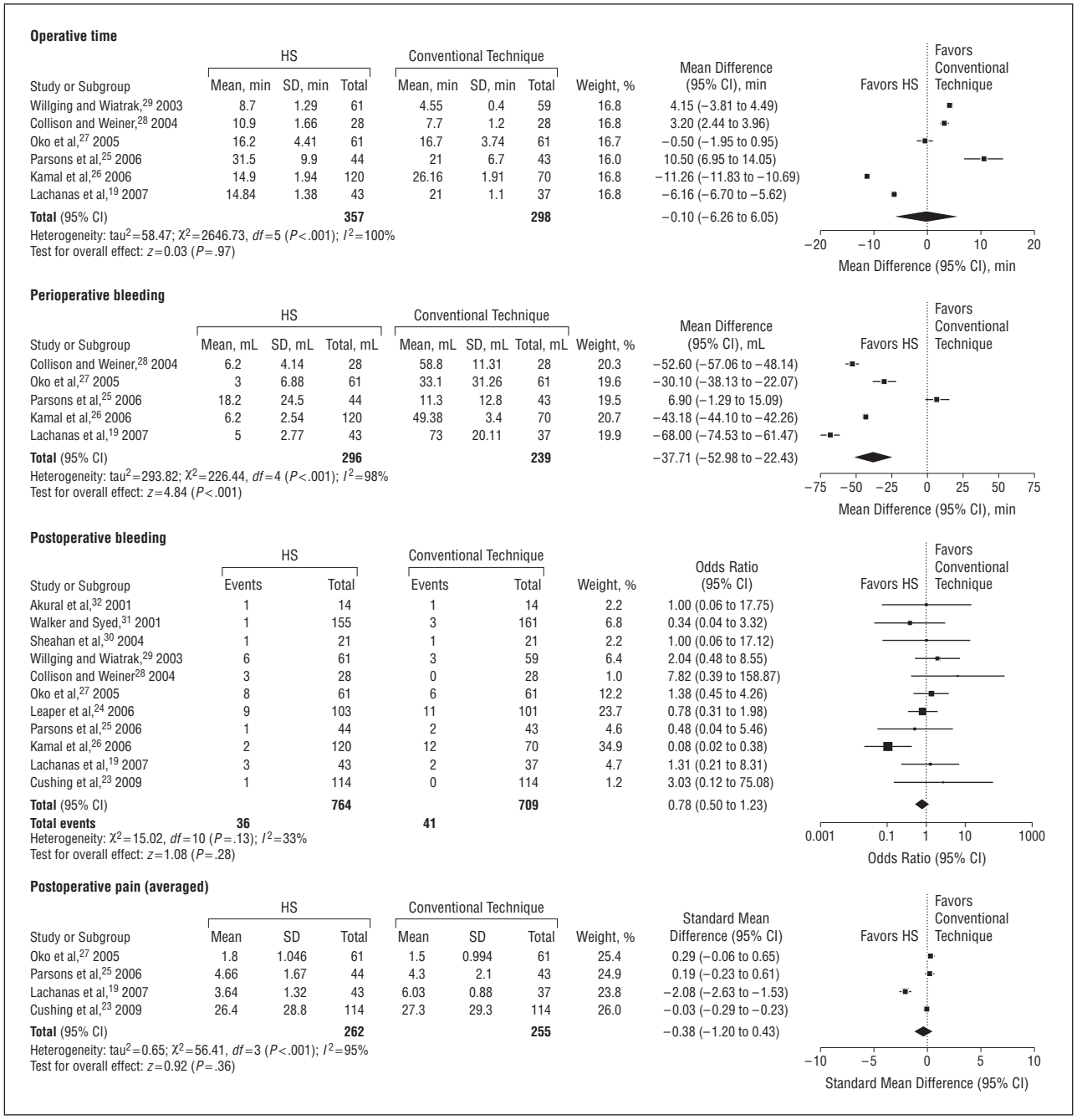

Figure 3. Meta-analysis comparing outcomes of tonsillectomies performed using Harmonic Scalpel (HS) with tonsillectomies performed using the conventional technique (cold steel and/or electrocautery). CI indicates confidence interval.

tute a new technique; therefore, one should consider many issues before trying to implement it in everyday clinical practice: cost, training issues, the learning curve for novice surgeons and additional morbidity associated with the procedure, and, most important, limited evidence to support a change from the use of CS/EC, the tonsillectomy procedure that has proven safe for several decades.

Regarding the quality score, 20 of 33 RCTs achieved a score of 3 or higher, which is generally acceptable for inclusion in a meta-analysis. Only 4 studies[18,26,45,46] had a low score of 1 and accounted for less than 12% of the weight of the meta-analysis. This finding may be attributed to the nature of this surgical intervention that does not permit double-blinding for most of the studied outcomes. Thus, we chose to maintain a lower threshold for inclusion and to include the studies with weak evidence. Other methodologic issues regarding the included RCTs pertain mainly to the data collection methods used (ie, questionnaires, daily diaries, and visual analog scales) and short follow-up periods. These issues may have introduced a degree of bias in our analysis that needs to be acknowledged.

The results of this study should be considered in view of several limitations. The included studies have significant methodologic heterogeneity, and various scales were used to measure postoperative pain and perioperative

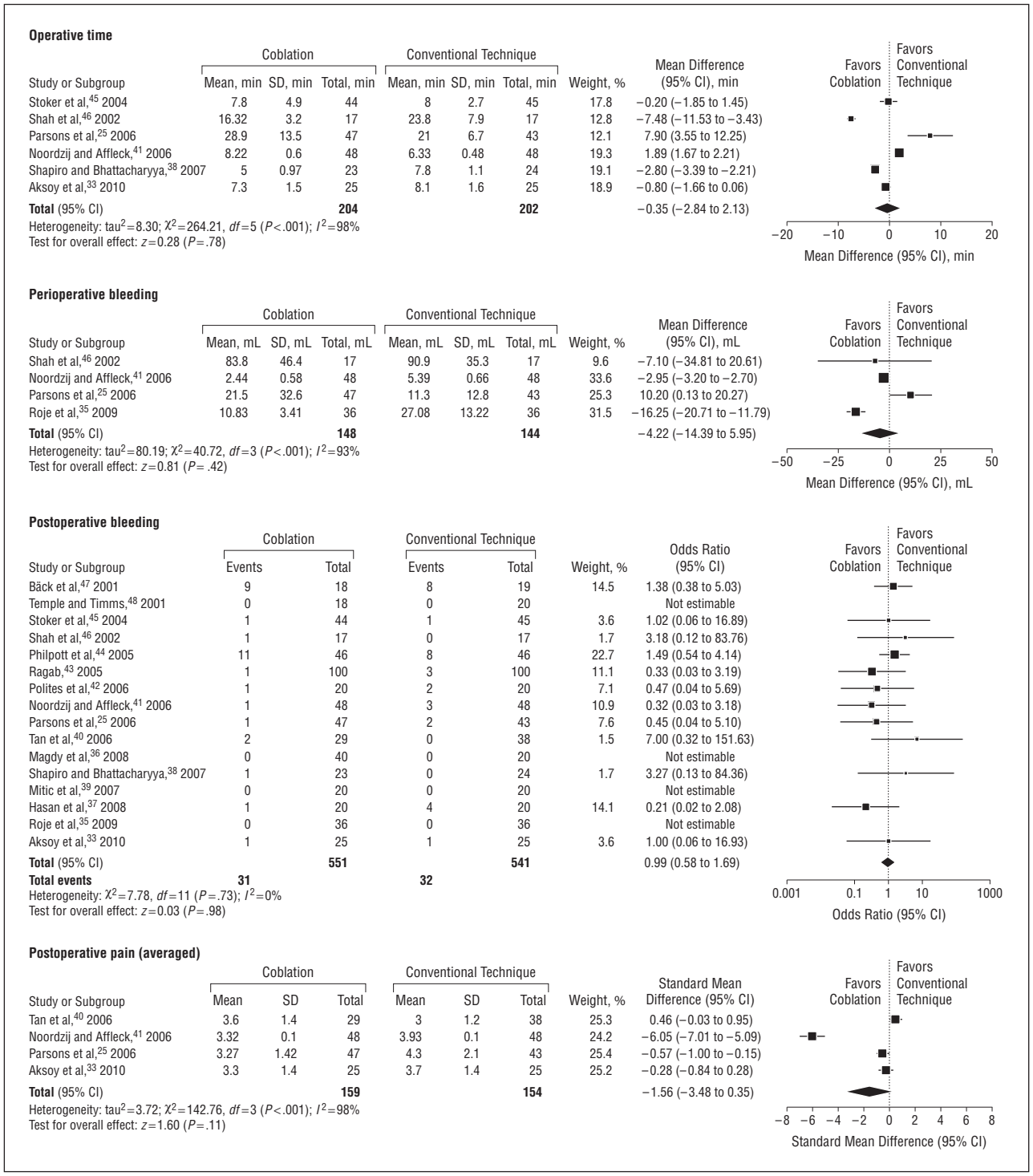

Figure 4. Meta-analysis comparing outcomes of tonsillectomies performed using Coblation with tonsillectomies performed using the conventional technique (cold steel and/or electrocautery). CI indicates confidence interval.

bleeding. To overcome this limitation, the SMD was calculated if different scales were used to measure the same outcome.[14] The SMD is appropriate for depicting significant differences but does not provide any meaningful quantification. In general, for continuous outcomes (eg, pain scores, blood loss, and operative time), the noted statistical heterogeneity was significant. The random-effects model was used to deal with this issue. However, the clinical diversity of the included studies was not strong.

The absence of outliers, especially for the VSS analysis, may indicate a certain degree of publication bias and may be attributed to the fact that many of the included studies were sponsored by the manufacturers of the relevant devices. However, we did not note any significant funnel plot asymmetry for postoperative bleeding in any of the pooled analyses. In all cases, the well-described selective publication of RCTs[49] and the "file drawer effect"[50] also should be acknowledged when interpreting the re-

sults of this meta-analysis. Moreover, the quality score of the included RCTs is relatively low, which may be attributed to the nature of this surgical intervention that does not permit double-blinding for most of the studied outcomes. Finally, as previously mentioned, the VSS analysis pooled studies of 3 different devices; manufacturers often claim that their products have unique characteristics that make them more efficient than those of their competitors. The available evidence that directly compares different VSS devices in tonsillectomy[51] and in other surgical procedures[8] shows that these devices are, in fact, similar or equivalent in terms of surgical effectiveness and clinical outcomes. Still, the results of this analysis should be interpreted with caution.

In conclusion, despite its limitations, this meta-analysis provides evidence that the use of Coblation and HS for tonsillectomy is equivalent to the use of the conventional CS/ES technique. Surgeon experience, training, and preferences, as well as cost-effectiveness criteria, should be considered. However, statistical synthesis of the limited available data regarding VSS showed a significant benefit in all studied outcomes. Well-designed and well-performed RCTs are warranted to further investigate the effectiveness of VSS techniques for tonsillectomy.

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Author Contributions: All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Alexiou. *Acquisition of data:* Alexiou and Salazar-Salvia. *Analysis and interpretation of data:* Alexiou, Salazar-Salvia, Jervis, and Falagas. *Drafting of the manuscript:* Alexiou and Salazar-Salvia. *Critical revision of the manuscript for important intellectual content:* Alexiou, Jervis, and Falagas. *Statistical analysis:* Alexiou. *Administrative, technical, and material support:* Salazar-Salvia. *Study supervision:* Jervis and Falagas.
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