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REVIEW ARTICLE

Intraoperative cryoanalgesia on reducing post-tonsillectomy pain scales: a meta-analysis of randomized controlled trials

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Abstract

Objective To assess the effect of intraoperative cryoanalgesia on subjective pain scores of patients after tonsillectomy.

Methods A systematic review of PubMED, Web of Science, EMBASE was performed using the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) standards. For the first time, we included and quantitative synthesized English-language randomized controlled trials (RCT) evaluating patients of all age groups with benign pathology who underwent tonsillectomy with intraoperative cryoanalgesia versus without.

Results A total of 835 publications were identified, and 7 articles with 463 participants met our criteria were selected for meta-analysis. The standard mean difference for overall subjective pain score, subjective pain scores at postoperation Day1 (POD1), POD7 were −1.44 with 95% confidence interval (CI) [−2.17, −0.72], $P = .0001$; −1.20 with 95% CI [−1.89, −0.50], $P = .0007$; −0.90 with 95% CI [−1.46, −0.35], $P = .001$ respectively, both in favor of cryoanalgesia. Nevertheless, subgroup analysis by surgical technique showed no robust effect between hot technique and "relative" hot technique on overall pain: (−1.72, 95% CI [−2.71, −0.73]) vs. (−1.06, 95% CI [−2.20, 0.07]), p=.39; on POD1: (−1.56, 95% CI [−2.78, −0.33]) vs. (−0.97, 95% CI [−1.83, −0.11]), p=.39; and on POD7 (−1.11, 95% CI [−1.81, −0.40]) vs. (−0.89, 95% CI [−2.02, 0.25]), p=.13. The standard mean difference for postoperative secondary bleeding rate was 1.29 with 95% CI 0.37,4.52], $p = .06$, no difference in 2 groups.

Conclusion Limited evidence suggests that intraoperative cryoanalgesia during tonsillectomy leads to lower subjective pain score on overall, POD1 and POD7 without differences on post-operation bleeding rate.

Keywords Tonsillectomy · Intraoperative cryoanalgesia · Postoperative pain · Pain score

Introduction

Tonsillectomy is one of the most common processes performed in otorhinolaryngology for various reasons such as obstructive sleep apnea and chronic tonsillitis [1, 2]. But pain after tonsillectomy is a prominent concern all the time [3]. This type of pain is closely related to inflammation, edema and nerve irritation [4]. Many new tonsillectomy techniques and post-operation pain management for pain alleviating emerge these years, for example ultrasonically activated scalpel, bipolar scissors, coblation system through low temperature (60–100°C) and oral analgesics intake [5–8], however, uncontrolled disturbing pain often accompanies for weeks and impairs the post-surgery recovery, which probably increasing the duration of hospital stay, probability of complications and re-admission [9, 10].

Cryoanalgesia, applying low temperature to peripheral nerves to render them functionally inactive, has been widely utilized in both acute and chronic pain management elsewhere but not in otorhinolaryngology [11, 12]. Currently, clinical research focusing on effect of intraoperative cryoanalgesia for post-tonsillectomy pain is limited and no meta-ananlysis has examined the effect for pain alleviating. Therefore, the aim of this systematic review was to evaluate the effect of intraoperative cryoanalgesia in post-operation pain for patients with non-malignant tonsil conditions for

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the first time. We also sought to evaluate the secondary outcomes: is intraoperative cryoanalgesia effective on reducing post-operative bleeding rate?

Methods

Research protocol

The guidelines of the Cochrane Handbook for Systematic Reviews of Interventions besides the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) were adopted during the preparation of this research [13]. The study protocol was recorded in the International Prospective Register of Systematic Reviews (PROSPERO) under the registration number: [CRD42023494512]. Ethical approval was exempted because the present research was based on only published literature.

Literature search strategy

Three digital databases (PubMed, Embase, Web of Science) were systematically screened from inception until December 2023. The core search strategy comprised: (tonsillectomy* OR Adenoidectomy* OR "adenotonsillectomy") AND ("hypothermal" OR "hypothermic" OR "cryoanalgesia" OR "cryoanalgesic" OR "cold" OR "cold-water" OR "cold-saline" OR "cool" OR "cooling" OR "low temperature" OR" ice") AND (Pain, Postoperative* OR "postoperative pain" OR "Post-surgical Pain" OR "postoperative analgesia" OR "post tonsillectomy"). Supplementary Table 1 demonstrates the specific search strategy used in each digital database. To widen our search for relevant studies, we looked through the references of the eligible RCTs and recent reviews. Two coinvestigators independently searched the digital databases and disagreements were resolved by discussion with the principal investigator.

Eligibility criteria

Studies matching the following inclusion criteria were labeled as included: (i) Participants: human subjects of all ages who underwent palatine tonsillectomy (with or without adenoidectomy, uvulopalatoplasty) for benign conditions with cryoanalgesia (recurrent tonsillitis, sleep disordered breathing, tonsillar hypertrophy), Studies evaluating patients who underwent tonsillotomy (incomplete removal) or cryosurgical tonsillectomy (application of intense cold to destroy tonsillar tissue), and tonsillectomies performed for malignant pathology or active infection were excluded; (ii) Interventions: The intervention of interest was cryoanalgesia, which was defined as the intraoperative application of any cold medium or tool (e.g., water, saline or cryoprobe) into the oropharynx after tonsillectomy; (iii) Comparison: Included studies compared tonsillectomy patients who received intraoperative cryoanalgesia to those patients who underwent tonsillectomy and did not receive cryoanalgesia (iv) Outcomes: The primary outcome was postoperative pain, which was measured via Visual Analogue Scale (VAS). Secondary outcomes included postoperative complications (e.g., secondary bleeding) (v) Study design: RCTs. studies other than RCTs—such as case reports, observational studies, review, letters and non-English publication were excluded.

Quality assessment

The review authors assessed the methodological quality of the included trials. Any disagreements were resolved by discussion and consensus. We performed assessment of the risk of bias using the "Risk of Bias" tool as described in the Cochrane Handbook for Systematic Reviews of Interventions [14]. Each assessed domain and the overall quality of the study were given a specific score, which included either 'low', 'some concerns or 'high' risk of bias.

Data extraction and analysis

The reviewers extracted applicable data from each eligible study. Data abstracted included author's first name and the publication year, country, trial duration, sample size, demographic information, diagnosis, surgical type and surgical technique, intervention details, subjective pain scales, secondary bleeding rate, and patients' important outcomes as listed previously. The dichotomous data were analyzed using the Mantel–Haenszel method and pooled as odds ratio (OR) with 95% confidence interval (CI). The numerical data were analyzed using the Inverse-Variance method and pooled as mean difference (MD) or standardized mean difference (SMD) with 95% CI. The random-effects model was adopted in all analyses. Chi-square $p < .1$ and I-square > 50% suggested significant heterogeneity. Subgroup analyses were performed according to the surgical technique (monopolar, bipolar and welding as hot technique; coblation as "relative" hot technique) and post operation day 1, a representative post-surgery timepoint for recovery, and day 7, another representative timepoint for outpatient pain management and wound healing. For all purposes, statistical significance was determined as $p < .05$. The Review Manager (version 5.4) was adopted for all statistical analyses.

Results

Results of literature search

A total of 835 publications were queried (260 for Embase, 210 for pubmed, and 365 for web of science), and 320 duplicates were removed, and 515 abstracts were screened. After screening, the review, letter, non-English study and clinical studies that were unrelated to the inclusion criteria were removed, so 8 RCTs left met our inclusion criteria and full-text reviewed with 1 being excluded due to incomplete data [8, 15–21]. The remaining 7 RCTs were included in meta-analysis [15–21], as illustrated in the PRISMA flow diagram (Fig. 1).

Study characteristics

This review incorporated 499 participants consisted of adults and children world widely. The included RCTs infrequently reported the mean age and follow-up. 2 studies included both ages [15, 19], 3 studies were trials for adults [16–18], and another 3 studies were pediatrics trials [8, 20, 21], as presented in Table 1 with details. 4 studies underwent tonsillectomy diagnosed as recurrent tonsilitis [15, 18–20], 1 study as OSA [16], and 2 study as various reasons [17, 21]. As for surgical type, 5 trials merely underwent tonsillectomy [15, 17–20], 1 study underwent tonsillectomy ± adenoidectoy [21], and 1 underwent tonsillectomyop + uvulalatoplasty [16]. As for secondary bleeding rate, five studies provided this outcome, two of which had 0 occurrences [15–19]. As

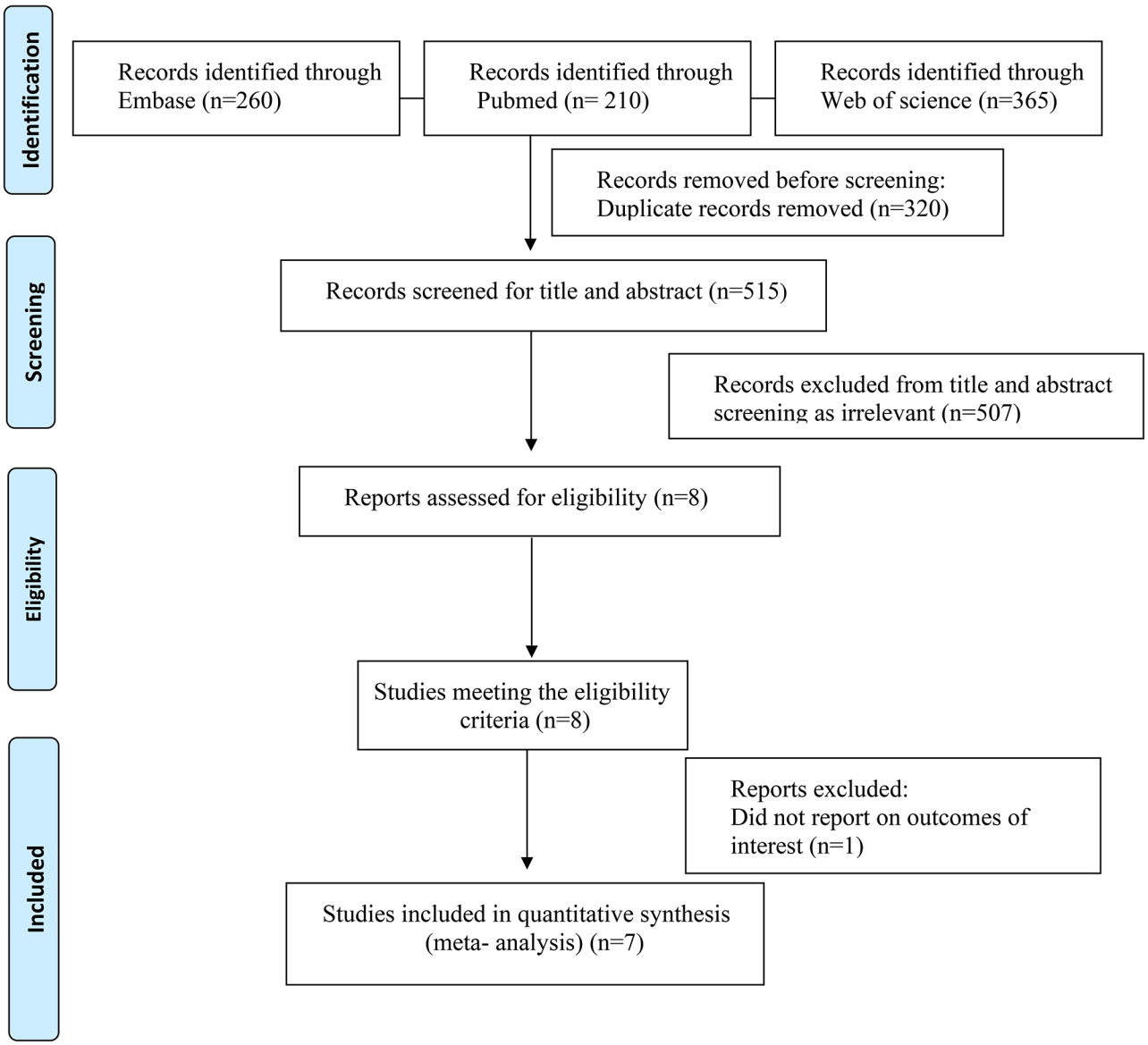

Fig. 1 PRISMA flowchart of literature review

Table 1 Summary of the baseline characteristics of the included studies and participants.

Study ID	Country	Trial duration	Age group	Arm	n	Age (years)	Sex, n M/F
Robinson 2000 [15]	New Zealand	February-May 1999	Both	CA	24	23 ± 6	8/16
				CON	23	22 ± 5	5/18
Horii 2011 [17]	Japan	NR	Adults	CA	79	32.3 ± 11.2	45/34
				CON	110	34.5 ± 12.5	62/48
Saban 2013 [20]	Turkey	NR	Pediatrics	CA	30	NR	16/14
				CON	30	NR	
Rotenberg 2013 [16]	Canada	September 2010 and February 2011	Adults	CA	9	39.0	6/3
				CON	9	44.4	6/3
Shin 2014 [19]	South Korean	March to October 2013	Both	CA	20	35.2	10/10
				CON	20	36.7	12/8
Vieira 2014 [8]	Brazil	June to November 2012	Pediatrics	CA	33	NR	NR
				CON	33	NR	NR
Lu 2020 [21]	China	January 2019 to December 2020	Pediatrics	CA	24	5.13 ± 1.54	12/12
				CON	24	5.25 ± 1.80	14/10
Liu 2023 [18]	China	2019 to December2020	Adults	CA	38	39.0 ± 13.5	15/23
				CON	23	32.3 ± 10.3	9/14

CA: cryoanalgesia; CON: control NR: not reported

for pain outcome measurement, only 1 study adopted FPS-R scale [21], the other used VAS scale. In terms of pain outcome, only 1 study didn't provide the outcome of interest [17], while others presented this outcome of interest with study characteristics as detailed in Table 2.

Assessment of risk of bias

Results of risk of bias assessment revealed an overall moderate risk of bias. Only three studies were low risk in the domains of randomization and allocation concealment [15, 16, 19], other studies didn't provide the details of random sequence generation, therefore, unclear risk of bias [5, 17, 20, 21]. As for selection bias, only 2 studies were low risk of bias [15, 16], the others were put some concerns. In terms of performance and detection bias, low risk of bias was put for all included studies. The details of other left domains of assessment were presented in supplementary Fig. 1.

Meta-analysis

The first meta-analysis compared overall subjective postoperative pain scores (Fig. 2) and included 6 studies. The standard mean differences, −1.44 with 95% CI [−2.17, −0.72], overall effect Z = 3.88 (*P* = .0001), was in favor of cryoanalgesia, with significant heterogeneity, $I^2 = 80\%$ (*P* = 0002). Subgroup analysis of tonsillectomy technique identified overall effects for hot technique and "relative" hot technique: mean difference − 1.72 with 95% CI [−2.71, −0.73], Z = 3.4 (*P* = .0007), mean difference − 1.06 with 95% CI [−2.20, 0.07], Z = 1.83 (*P* = .07). The test for subgroup differences was insignificant ($p > .05$) and significant heterogeneity was found within both groups.

The second meta-analysis compared subjective pain scores at POD1, which included 4 studies (Fig. 3). The standard mean differences, −1.20 with 95% CI [−1.89, −0.50], overall effect Z = 3.38 (*P* = .0007), was in favor of cryoanalgesia at postoperation day 1, with insignificant heterogeneity, $I^2 = 36\%$ (*P* = .20). Subgroup analysis of tonsillectomy technique identified overall effects for hot technique and "relative" hot technique: mean difference − 1.56 with 95% CI [−2.78, −0.33], Z = 2.49 (*P* = .001), mean difference − 0.97 with 95% CI [−1.83, −0.11], Z = 2.22 (*P* = .003), both in favor of cryoanalgesia at POD1. The test for subgroup differences was insignificant ($p > .05$). All subgroups had low heterogeneity.

The third meta-analysis compared subjective pain scores at POD7, which included 4 studies (Fig. 4). The standard mean differences, −0.90 with 95% CI [−1.46, −0.35], overall effect Z = 3.19 (*P* = .001), was in favor of cryoanalgesia at postoperation day 7, with insignificant heterogeneity, $I^2 = 40\%$ (*P* = .17). Subgroup analysis of tonsillectomy technique identified overall effects for hot technique and "relative" hot technique: mean difference − 1.11 with 95% CI [−1.81, −0.40], Z = 3.08 (*P* = .002) with low heterogeneity, mean difference − 0.89 with 95% CI [−2.02, 0.25], Z = 1.53 (*P* = .13) with significant heterogeneity. The test for subgroup differences was insignificant ($p > .05$).

The final meta-analysis compared postoperative secondary bleeding rate, which included 5 studies (Fig. 5). The standard mean differences, 1.29 with 95% CI [0.37,4.52], overall effect Z = 0.4 (*P* = .69), with low heterogeneity.

Table 2 Summary of the specific characteristics of the included studies

Study ID	Diagnosis	Surgical type	Surgical technique	Intraoperative cryoanalgesia method	Pain outcome measurement	Pain outcome result (mean ± SD) cryo vs con	Postoperative secondary bleed
Robinson 2000 [15]	Recurrent tonsilitis	Tonsillectomy	Bipolar	Cryoprobe	VAS (scale 0–10)	Overall cryo (4.3 ± 1.3) vs con (6.0 ± 1.8)	cryo 3/24 con 3/23
Horii 2011 [17]	Tonsilitis, OSA, IgA nephropathy	Tonsillectomy	Cryo = bipolar Con = cold dissection	Cold saline irrigation	VAS (scale 0–5)	NR	cryo 2/79 con 1/110
Saban 2013 [20]	Recurrent tonsilitis	Tonsillectomy	Thermal welding	Cold isotonic fluid irrigation	VAS (scale 0–10)	1st day 3.53 ± 2.81 vs 4.47 ± 2.50 7th day 1.40 ± 2.07 vs 2.47 ± 2.33 Overall 2.48 ± 2.18 vs 2.99 ± 1.79	NR
Rotenberg 2013 [16]	OSA	Tonsillectomyop + uvulalatoplasty	Monopolar cautery	Ice pack placement	VAS (scale 0–10)	Overall cyro (3.5 ± 1.85) vs control (6.9 ± 1.56)	0 for both group
Shin 2014 [19]	Recurrent tonsilitis	Tonsillectomy	Monopolar cautery	Cold saline irrigation	VAS (scale 0–10)	1st day 5.13 ± 2.27 vs 7.32 ± 2.12 7th day 2.33 ± 1.65 vs 3.46 ± 1.25 Overall 3.80 ± 1.49 vs 5.55 ± 2.00	cryo 1/20 control 1/20
Lu 2020 [21]	Recurrent tonsillitis or tonsilhypertrophy ± adenoid hypertrophy	Tonsillectomy ± adenoidectoy	Coblation	Ice water mixed saline for coblation	FPS-R scale	1st day 3.82 ± 2.32 vs 5.50 ± 2.69 7th day 0.71.±1.33 vs 2.29 ± 2.39 Overall 2.42 ± 1.12 vs 4.09 ± 1.10	NR
Liu 2023 [18]	Recurrent tonsilitis	Tonsillectomy	Coblation	Ice water mixed saline for coblation	VAS (scale 0–10)	1st day 2.20 ± 1.30 vs 2.90 ± 1.10 7th day 1.0.±1.10 vs 1.40 ± 0.90 Overall 1.36 ± 0.73 vs 1.87 ± 0.74	0 for both group

CA: Cryoanalgesia; CON: Control; NR: Not reported; VAS: Visual Analogue Scale; FPS-R: Face Pain Scale-revised; OSA: obstructive sleep apnea

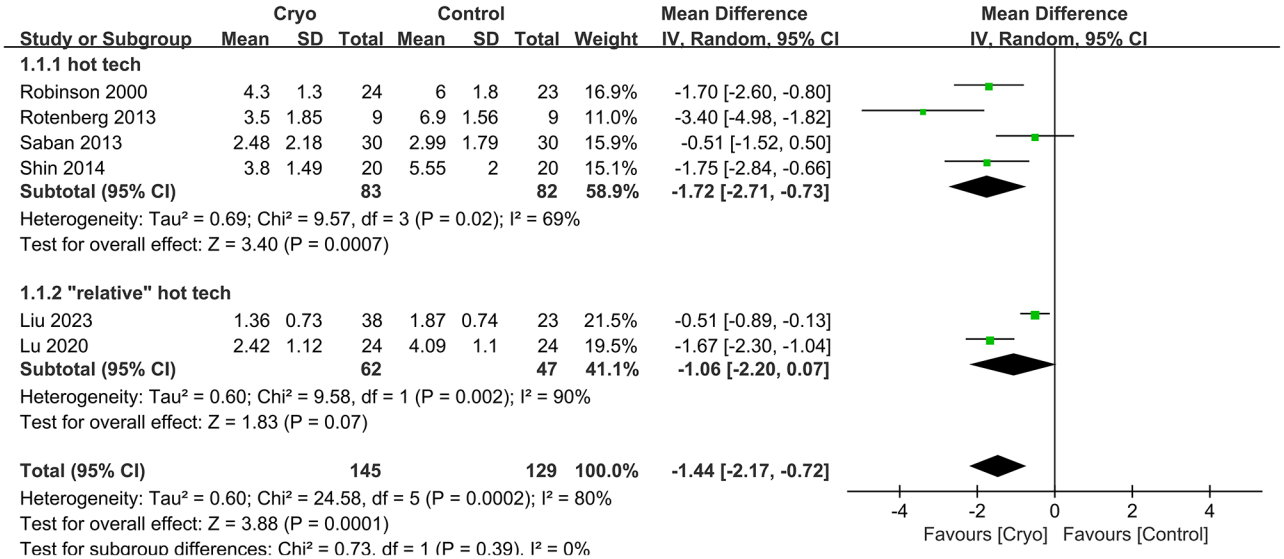

Fig. 2 Forest plot of studies comparing overall pain

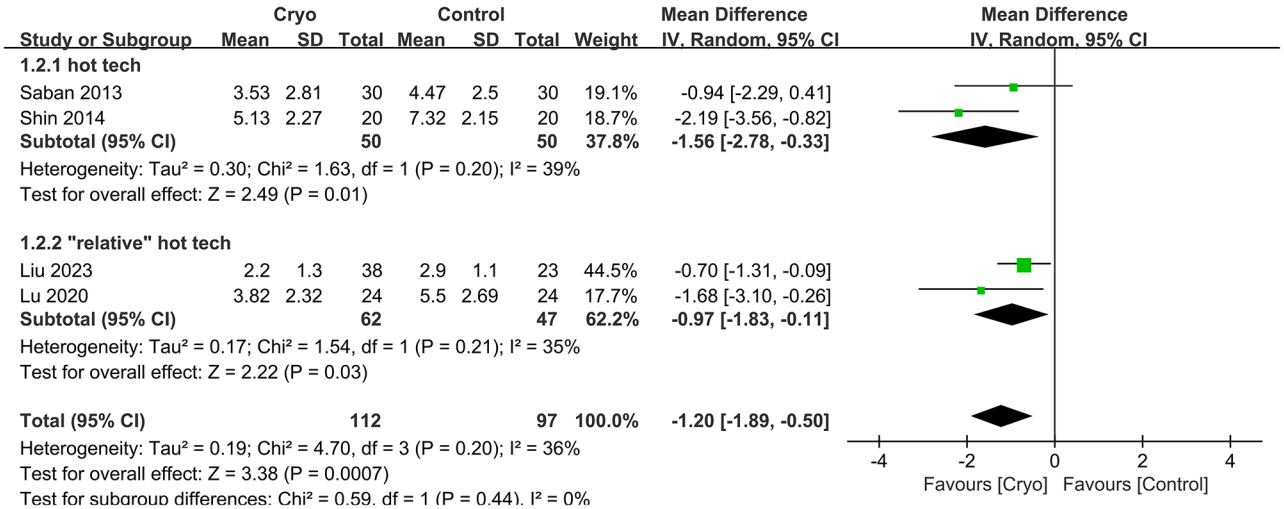

Fig. 3 Forest plot of studies comparing POD1 pain

Discussion

The present study systematically reviewed clinical trials of effect of intraoperative cryoanalgesia on post-tonsillectomy pain for the first time, which consisted of 8 studies and 7 were included in quantitative analysis. Overall post-surgery meta-analysis shows intraoperative cryoanalgesia has prominent reducing effect on post-tonsillectomy pain. Subgroup analysis according to the intraoperative heat by surgical instruments shows, in hot technique group (temperature beyond 100℃), intraoperative cryoanalgesia can significantly reduce the overall post operation pain, however in "relative" hot group, the significant effect is not existing. How cryoanalgesia in surgery reduces the post-tonsillectomy pain is not fully clear, possible mechanisms are through lessening adjacent tissue temperature, edema, inflammation, or de-sensitizing the pharyngeal nerve-fiber [11, 12], which may explain the subgroup differences of cryoanalgesia in 2 techniques. Nevertheless, the test for subgroup differences is insignificant and high heterogeneity occurs in both groups. Thus, concluding that intraoperative analgesia is more effective in hot technique (e.g., welding, monopolar cautery) than "relative" hot technique for tonsillectomy is not feasible or rational.

Post operation pain scale could change as post-surgical time goes. Choosing post-operation day 1 as a critical timeframe, another meta-analysis of 4 studies identified that intraoperative cryoanalgesia has significant effect on reducing post-tonsillectomy pain, the same effect seen in subgroup analysis as expected. Intraoperative cryoanalgesia has beneficial impact for post operation management in

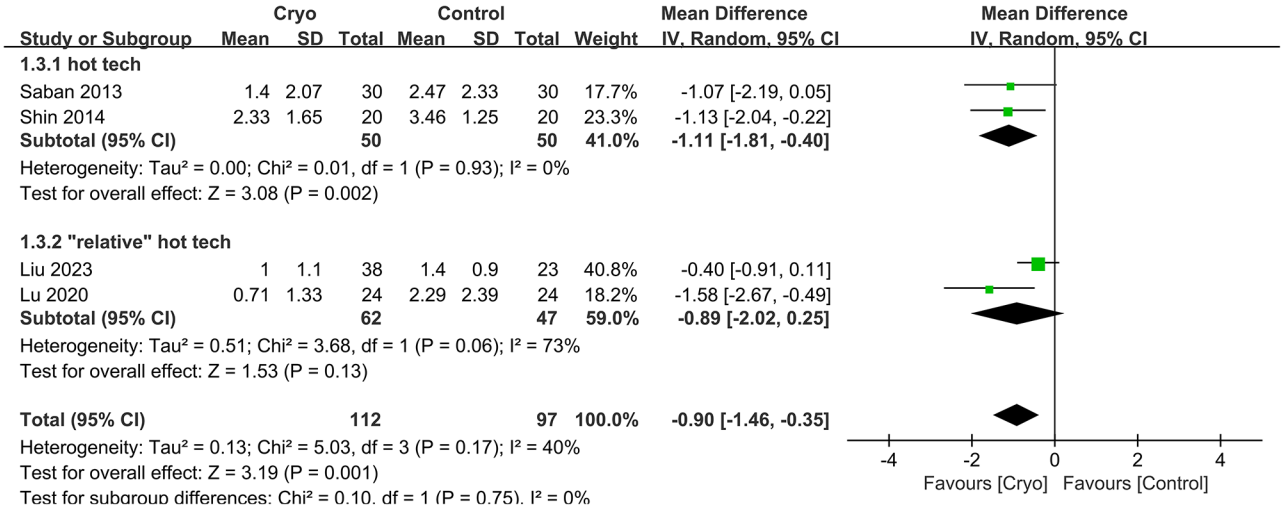

Fig. 4 Forest plot of studies comparing POD7 pain

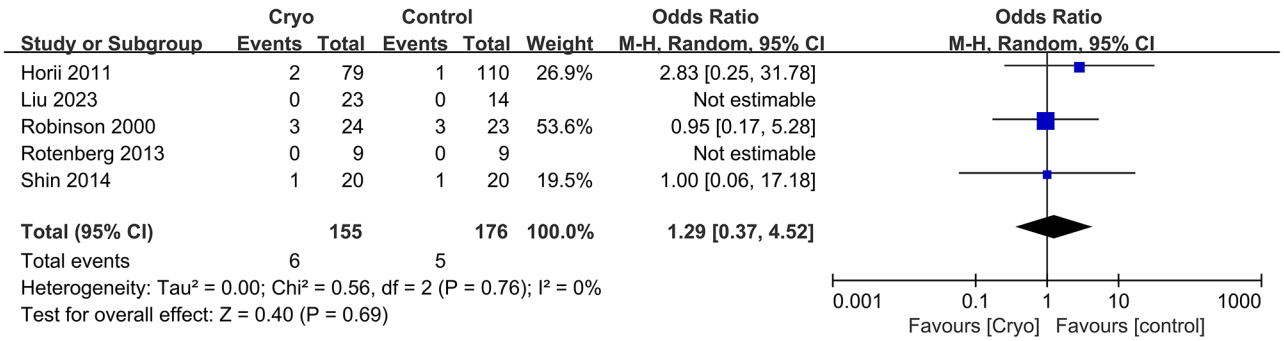

Fig. 5 Forest plot of bleeding rate

short-term, since less pain after operation, more water or food intake and subsequent robust recovery develops for operations like tonsillectomy. Interestingly, no significant differences were seen between hot technique group and "relative" hot group, which may indicate that intraoperative cryoanalgesia has similar analgesia effect regardless of surgical technique in short-term through lessening adjacent tissue edema and inflammation.

Additionally, on post-operation day 7, a representative timepoint for outpatient pain management and wound healing, intraoperative cryoanalgesia possess significant effect on lessening post-tonsillectomy pain. However, the same effect is not seen in "relative" hot technique group under sub-analysis. Possible reasons for this are that coblation tonsillectomy exceeds than other techniques in post-operation pain aspect [22, 23], plus, less heat generated in surgical process for coblation so cryoanalgesia is not as effective as in hot tonsillectomy. In theory, dropping down the temperature of surgical site can reduce the intraoperative blood loss through artery contraction and blood supply reduction, but no difference is observed in meta-analysis of post-operation secondary bleeding rate from 5 included studies. As palatine tonsil has a dense arterial branches supply from facial artery, greater palatine artery, ascending pharyngeal artery, and dorsal lingual artery [24], possible guessing involve that the contraction effect of low-temperature to these arteries is limited and not lasting or the temperature is not low enough.

Nevertheless, high heterogeneity among studies such as age, intraoperative cryoanalgesia method as well as surgical technique existed, and insufficient studies included in quantitative analysis. To account for this, Random effects statistical modeling, standard mean difference, and inverse variance weighting in the meta-analyses were utilized. Moreover, the risk of bias for included studies was low. In conclusion, intraoperative cryoanalgesia is effective in reducing post tonsillectomy pain from overall and POD1,7 pain meta-analysis. Further implications cannot be reached for surgeons to make specific surgical strategy and post tonsillectomy management. More high-quality clinical trials and standard intraoperative cryoanalgesia were required to clarify the exact beneficial in the future.

Strengths, limitations, and implications for future practice

We included clinical trials to ensure the highest level of evidence. Studies other than randomized clinic trials were excluded. This is considered the first meta-analysis studies that summarize the effect of intraoperative cryoanalgesia for tonsillectomy surgery. The main critical limitation is the small number of included studies and sample size, 1 of which study only included 9 patients each arm. In addition, age, the method of cryoanalgesia and surgical type contributes to the presence of heterogeneity among some outcomes which in return raise concerns about the certainty of the conclusion. However, this review could suggest surgeons to employ this simple and effective surgical "trick" in patients' management.

Conclusion

Limited evidence suggests that intraoperative cryoanalgesia during tonsillectomy leads to lower subjective pain score on overall, POD1 and POD7 without differences in post-operation bleeding rate. Subgroup differences on subjective pain score favor no preference between 2 groups. Further studies are warranted to draw conclusion with high certainty and help surgeons decision making and patients recovery.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00405-024-08817-4.

Author contributions Shipin and Yaping contributed to study conception, literature review, data analysis, and writing of initial draft. Yingli contributed to literature review, data collection. Yuedi contributed to revision of manuscript for editorial and intellectual contents. All authors read and approved the final draft of manuscript.

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Data availability The data that support this study are available from https://1drv.ms/x/c/df870d6d97d1ff51/EXXdDb5J-AZIm8DMI4xQIK0BW3hbqzl0ngAgCUbh0prNbg?e=0NqAtD.

Declarations

Ethical approval Not applicable.

Consent to participate Not applicable.

Consent for publication Not applicable.

Conflicts of interest Not applicable.

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