COBLATION^o Intracapsular Tonsillectomy compared with total tonsillectomy: a systematic literature review and meta-analysis¹

Summary

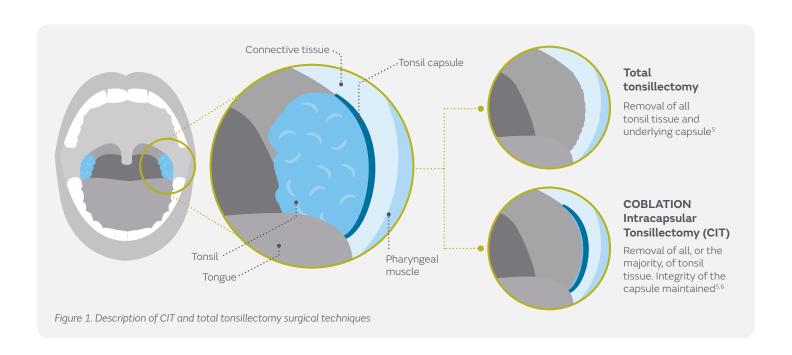
- COBLATION Intracapsular Tonsillectomy (CIT) has been proposed to improve post-operative recovery and reduce post-operative morbidity compared with total tonsillectomy²⁻⁴
- This systematic literature review and meta-analysis evaluated the outcomes of CIT in comparative studies versus total tonsillectomy techniques
- Results showed that CIT offered significant improvements in post-operative morbidity compared with total tonsillectomy, including reduced likelihood of post-tonsillectomy haemorrhage, reduced pain, and faster return to normal activity and diet, while maintaining the efficacy of the procedure

Introduction

Total tonsillectomy, involving the removal of all tonsil tissue and the underlying capsule (Figure 1), has traditionally represented the standard surgical treatment for obstructive sleep apnoea (OSA) and recurrent tonsillitis. However, intracapsular tonsillectomy, involving removal of all or the majority of tonsil tissue but maintaining the integrity of the underlying capsule, so is becoming more popular as 20% of paediatric otolaryngologists now perform intracapsular tonsillectomies in the USA.

COBLATION Technology can be used to ablate tissue during an intracapsular tonsillectomy in a procedure termed COBLATION Intracapsular Tonsillectomy (CIT; Figure 1). CIT has been proposed to reduce post-operative morbidity compared with traditional total tonsillectomy.²⁻⁴ Some authors have suggested that residual tissue preserved in intracapsular tonsillectomy techniques such as CIT may act as a 'biological dressing' to protect the underlying pharyngeal musculature (Figure 1) and reduce post-operative pain.^{8,9}

This report summarises the systematic literature review and meta-analysis, on the post-operative outcomes of CIT in comparative studies versus total tonsillectomy, published in <u>OTO Open</u>.



Methods

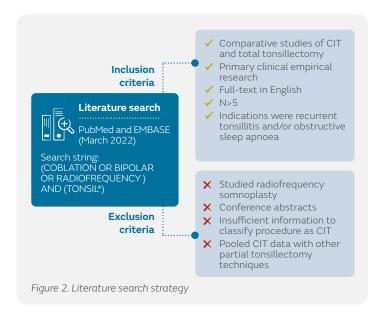
Literature search

A systematic literature search was conducted to identify comparative studies evaluating CIT and total tonsillectomy. Articles were screened for suitability according to the inclusion and exclusion criteria outlined in Figure 2.

CIT was defined as a clear intention to remove all, or the majority, of tonsil tissue whilst maintaining the integrity of the underlying capsule.⁶

Data extraction

Data including study and patient characteristics, procedural information and clinical outcomes were extracted from relevant articles. Key outcomes of interest included: post-operative pain, time taken to pain-free and analgesia-free, time taken to return to normal activity and diet, efficacy and post-tonsillectomy haemorrhage rates.



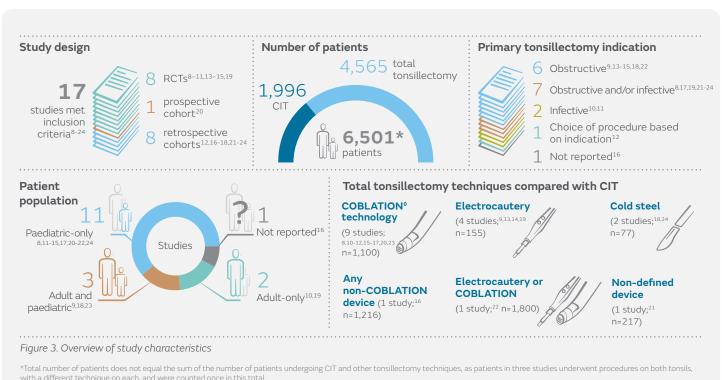
Meta-analysis

Meta-analyses were performed for variables of interest between experimental and control procedures. For further details on meta-analysis methods, see Appendix 1.

Results

Literature identified

Initial searches identified 1,287 articles. Following screening, 17 relevant studies⁸⁻²⁴ were included in the analysis (Figure 3). Further details on the characteristics of included studies are provided in Appendix 2.



with a different technique on each, and were counted once in this total.

CIT = COBLATION Intracapsular Tonsillectomy; RCT = randomised controlled trial.

Results (cont.)

Pain

Absolute pain

Eleven studies 8-12,14,15,17-20,24 reported on absolute pain scores. All studies found lower pain scores for CIT at one or more follow-up visit. Meta-analyses were conducted to evaluate post-operative pain scores at day 1 (within the first 24 hours) and week 1 (between 5 and 8 days).

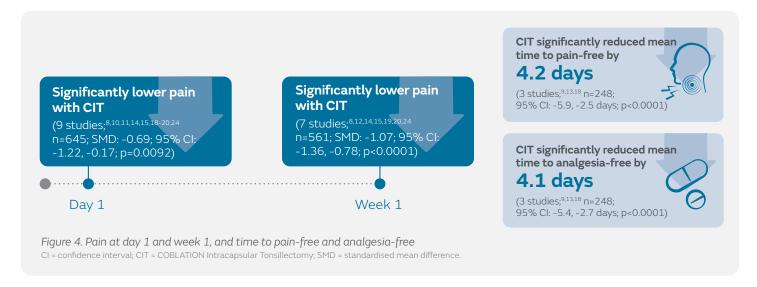
Pain scores at day 1 and week 1 were significantly lower for CIT when compared with total tonsillectomy (p=0.0092 and p<0.0001, respectively; Figure 4).

Time to pain-free and analgesia-free

Three studies^{9,13,18} reported on time to pain-free and analgesia-free. All studies found significantly faster time to both pain- and analgesia-free for CIT compared with total tonsillectomy.

In the meta-analysis, CIT significantly reduced time to pain-free by a mean of 4.2 days (p<0.0001; Figure 4) and time to analgesia-free by a mean of 4.1 days (p<0.0001; Figure 4).

Five additional studies ^{12,14,15,22,24} reported other analgesia-related outcomes, including the proportion of patients requiring analgesia and analgesia use at specific time points post-operatively. Three studies ^{12,15,22} reported significant improvements with CIT, while two studies ^{14,24} reported no significant differences between CIT and total tonsillectomy with COBLATION° but one study did not provide quantitative data.



Return to normal

Activity

Three studies^{9,13,18} reported on time to return to normal activity for CIT compared with total tonsillectomy, and all studies reported this to be significantly faster for the former.

In the meta-analysis, CIT significantly reduced time to return to normal activity by a mean of 2.8 days (p<0.0001; Figure 5).

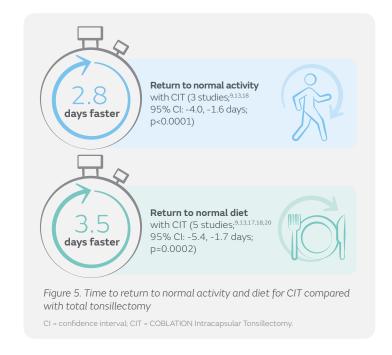
Two additional studies^{14,15} reported that more patients were able to return to activity at specific time points following CIT compared with total tonsillectomy.

Diet

Five studies^{9,13,17,18,20} reported on time to return to normal diet for CIT compared with total tonsillectomy.

In the meta-analysis, CIT significantly reduced time to return to normal diet by a mean of 3.5 days (p=0.0002; Figure 5).

Three additional studies^{12,14,15} reported that more patients were able to return to normal diet at specific time points following CIT compared with total tonsillectomy.



Efficacy

Three studies^{12,13,21} reported on outcomes related to the efficacy of surgical procedures to treat OSA or obstructive tonsillar hypertrophy. No significant differences between CIT and total tonsillectomy for any efficacy outcome measures were observed (Table).

Study	Comparator	Efficacy measure	Results
Braverman et al. (2015) ¹²	Total tonsillectomy using COBLATION° technology	OSA-18 score Freedom from obstructive sleep apnoea symptoms	 Similar mean post-operative OSA-18 scores (CIT: 25.5; total COBLATION tonsillectomy: 24.6 All patients free from OSA symptoms with both techniques
Chan et al. (2004) ¹³	Total tonsillectomy using electrocautery	Recurrence of obstructive symptoms	No significant difference in improvements in obstructive symptoms at 3 or 12 months post- operatively
Mukerji et al. (2021) ²²	Total tonsillectomy using electrocautery or total COBLATION tonsillectomy	• AHI	No significant differences in parental report of symptom improvement, post-operative AHI improvement or OSA symptoms with both techniques

Risk of PTH significantly lower with CIT

(10 studies;^{13-19,21,22,24} n=6,039; RR: 0.36; 95% Cl, 0.16 – 0.81; p=0.0131)



No significant difference in total PTH rates requiring operating room management (7 studies; 9.14.15.17-19.21 n=1,322; RR 0.52; 95% CI, 0.19 – 1.39; p=0.19)



Figure 6. Risk of PTH for CIT compared with total tonsillectomy

CI = confidence interval; CIT = COBLATION Intracapsular Tonsillectomy; RR = risk reduction; PTH = post-tonsillectomy haemorrhage.

Complications - post tonsillectomy haemorrhage (PTH)

The incidence of PTH was reported in 13 studies, ^{9-11,13-19,21,22,24} though two of these studies ^{10,11} did not provide sufficient information to compare rates between techniques.

A statistically significant lower risk of PTH was observed with CIT compared with total tonsillectomy (10 studies; $^{13-19,21,22,24}$ n=6,039; relative risk [RR]: 0.36; 95% confidence interval [CI], 0.16 – 0.81; p=0.0131; Figure 6), however, no statistical differences were identified when considering total PTH rates requiring operating room management (7 studies; $^{9,14,15,17-19,21}$ n=1,322; RR 0.52; 95% CI, 0.19 – 1.39; p=0.19; Figure 6).

Other complications

Eleven studies $^{9,12-15,17,18,20,22-24}$ reported complications other than PTH. One of these studies 17 did not provide sufficient information to determine which procedure the events were associated with.

Across all techniques the most commonly reported complications were dehydration, nausea, fever and infection. Complication rates between CIT and total tonsillectomy were similar in five studies^{9,14,15,18,24} and lower for CIT in four studies.^{12,13,20,22}

Conclusion

This meta-analysis of comparative studies demonstrates that CIT leads to reduced post-operative morbidity and likelihood of post-tonsillectomy haemorrhage compared with total tonsillectomy, including reduced pain and faster return to activity, while maintaining the efficacy of the procedure.

Considerations

No study included in the systematic literature review was identified to be at high risk of bias, despite most included comparative studies being of relatively small size.

References

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Appendix 1. Details of the methodology for data synthesis and meta-analysis

Meta-analyses were performed in R (statistical software) for comparisons of variables of interest between the experimental and control procedures. For binomial outcomes, a RR with a 95% CI was reported as the summary statistic. For continuous outcomes, a mean difference (if reported on the same scale) or standardised mean difference using Hedges g correction (if reported on different scales) with a 95% CI was reported as the summary statistic. Heterogeneity of included studies was assessed using the I² statistic; the fixed effect model was utilised when I²<50% and the random effects model when I²>50%.

controlled trial	Level 2: Prospective, comparative Level 3: Retrospective comparative	Study, year	Control procedure(s)	Number of patients						
				Overall	СІТ	Control(s)	Indication(s)	Population	Mean age (years)	Outcomes reported
		Arya et al. 2003 ¹⁰	Total COBLATION ^o tonsillectomy	14*	14	14	Infective	Adult	Overall: 31.9	Absolute pain at Day 1
		Arya et al. 2005 ¹¹	Total COBLATION tonsillectomy	18*	18	18	Infective	Paediatric	Overall: 9	Absolute pain at Day 1
		Chan et al. 2004 ¹³	Total tonsillectomy using electrocautery	55	27	28	Obstructive with no history of recurrent tonsillitis	Paediatric	CIT: 6.4 Total: 5.9	Time to pain free and duration of analgesia use Time to return to normal activity Time to return to normal diet Total incidence of PTH
		Chang et al. 2005 ¹⁴	Total tonsillectomy using electrocautery	101	52	49	Obstructive with no history of recurrent tonsillitis	Paediatric	CIT: 6.4 Total: 6.2	Absolute pain at Day 1 and Week Total incidence of PTH Incidence of PTH requiring OR management
		Chang et al. 2008 ¹⁵	Total COBLATION tonsillectomy	69	34	35	Obstructive with no history of recurrent tonsillitis	Paediatric	CIT: 6.2 Total: 6.1	Absolute pain at Day 1 and Week Total incidence of PTH Incidence of PTH requiring OR management
		Hall et al. 2004 ¹⁹	Total tonsillectomy using electrocautery	28*	28	28	Obstructive and/ or infective	Adult	NR	Absolute pain at Day 1 and Week 1 Average pain over 1 week Total incidence of PTH Incidence of PTH requiring OR management
		Lu et al. 2017 ⁸	Total COBLATION tonsillectomy	90	48	42	Obstructive and/ or infective	Paediatric	Overall: 5.3	 Absolute pain at Day 1 and Week 1
		Wilson et al. 2009 ⁹	Total tonsillectomy using electrocautery	103	53	50	Obstructive with no history of recurrent tonsillitis	Adult & paediatric	CIT: 5.8 [†] Total: 6.1 [†]	Time to pain free and duration of analgesia use Time to return to normal activity Time to return to normal diet Incidence of PTH requiring OR management

controlled trial Level 2:	tive,	Level 3: Retrospective comparative	Study, year	Control procedure(s)	Number of patients						
	Level 2: Prospec compara				Overall	CIT	Control(s)	Indication(s)	Population	Mean age (years)	Outcomes reported
			Junaid et al. 2019 ²⁰	Total COBLATION ^o tonsillectomy	101	23	78	Obstructive and/or infective (tendency for experimental to be only used on obstructive)	Paediatric	NR	 Absolute pain at Day 1 and Week 1 Time to return to normal diet
			Braverman et al. 2015 ¹²	Total COBLATION tonsillectomy	80	43	37	Obstructive with (control) or without (CIT) history of recurrent tonsillitis	Paediatric	CIT: 4† Total: 5†	Absolute pain at Week 1
			Divi et al. 2005 ¹⁶	Total COBLATION tonsillectomy Total tonsillectomy using devices other than COBLATION	1,758	303	239 (COBLATION) 1,216 (non- COBLATION)	NR	NR	NR	Total incidence of PTH
			Duarte et al. 2014 ¹⁷	Total COBLATION tonsillectomy	415	157	258	Obstructive and/ or infective	Paediatric	Overall: 6.7	Average pain over 1 week Time to return to normal diet Total incidence of PTH Total incidence of PTH requirin OR management
			Friedman et al. 2003 ¹⁸	Total tonsillectomy using cold steel	100	50	50	Obstructive without history of recurrent tonsillitis	Adult & paediatric	CIT (adult): 31.1 Total (adult): 27.2 CIT (paediatric): 6.3 Total (paediatric): 4.2	Absolute pain at Day 1 Time to pain free and duration analgesia use Time to return to normal activ Time to return to normal diet Total incidence of PTH Incidence of PTH requiring OR management
			Heward et al 2021 ²¹	NR	498	281	217	Obstructive and/ or infective	Paediatric	NR	Total incidence of PTH Incidence of PTH requiring OR management
			Mukerji et al 2021 ²²	Total tonsillectomy using electrocautery or total COBLATION tonsillectomy	2,267	467	1,800	Obstructive and/ or infective	Paediatric	6.23 (3.43) 6.82 (3.54)	Total incidence of PTH Duration of analgesia use
			Naidoo et al 2021 ²³	tonsillectomy	730		379	Obstructive and/ or infective	paediatric	7.0 (0.8 – 74.3) 6.9 (0.7 – 66.8)	Revision surgery
			Tremlett et al 2020 ²⁴	Total tonsillectomy using cold steel	74		27	Obstructive and/ or infective	Paediatric	3.5 3.4	Total incidence of PTH Time to pain free Time to return to normal activ Time to return to normal diet

*In this study, each patient underwent both intracapsular and total tonsillectomy, with a different technique used on each tonsil. For each patient, data from both tonsils were included in meta-analyses. †Represents median patient age. CIT = COBLATION Intracapsular Tonsillectomy; NR = not reported; OR = operating room; PTH = post-tonsillectomy haemorrhage.

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use. Post-tonsillectomy haemorrhage (PTH) is a potentially serious complication that has been reported in literature for both adult and paediatric patients.