**Publication summary** 

# COBLATION<sup>o</sup> Intracapsular Tonsillectomy compared with total tonsillectomy: a systematic literature review and meta-analysis<sup>1</sup>

# Summary

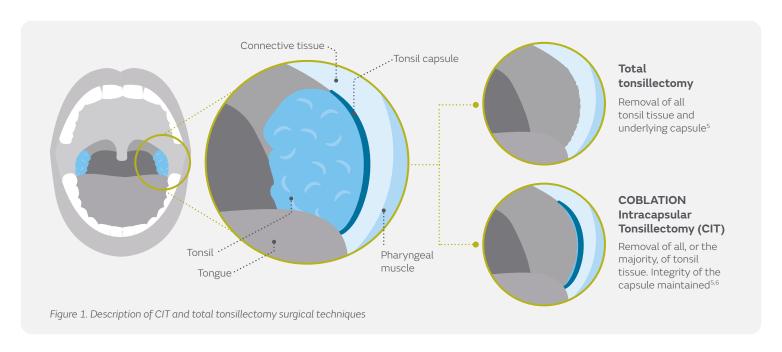
- COBLATION Intracapsular Tonsillectomy (CIT) has been proposed to improve post-operative recovery and reduce post-operative morbidity compared with total tonsillectomy<sup>2–4</sup>
- This systematic literature review and meta-analysis evaluated the outcomes of CIT in comparative studies versus total 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.<sup>2-4</sup> 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.<sup>8,9</sup>

This systematic literature review and meta-analysis evaluated the post-operative outcomes of CIT in comparative studies versus total tonsillectomy.



# **Smith-Nephew**

#### Methods

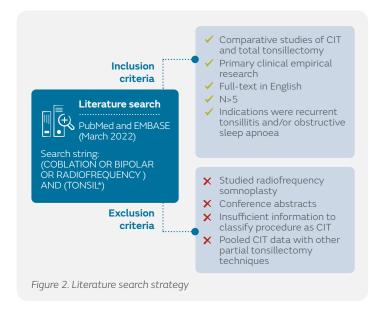
#### Literature search

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.<sup>6</sup>

#### 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.



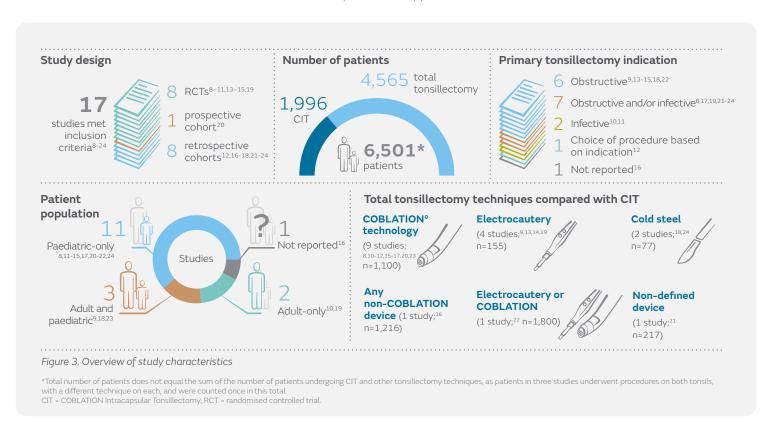
# Meta-analysis

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 studies<sup>8-24</sup> were included in the analysis (Figure 3). Further details on the characteristics of included studies are provided in Appendix 2.



# Results (cont.)

#### Pain

#### Absolute pain

Eleven studies<sup>8-12,14,15,17-20,24</sup> 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).

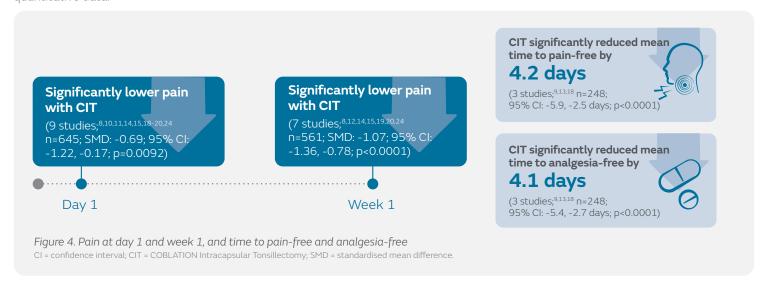
Pain scores at day 1 and week 1 were significantly lower for CIT when compared with total tonsillectomy (p=0.0092 and p<0.0001, respectively; Figure 4).

# Time to pain-free and analgesia-free

Three studies<sup>9,13,18</sup> 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<sup>9,13,18</sup> 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).

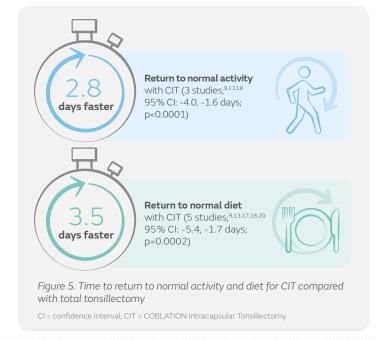
Two additional studies<sup>14,15</sup> reported that more patients were able to return to activity at specific time points following CIT compared with total tonsillectomy.

#### 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<sup>12,14,15</sup> reported that more patients were able to return to normal diet at specific time points following CIT compared with total tonsillectomy.



#### **Efficacy**

Three studies<sup>12,13,21</sup> 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).

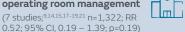
Study	Comparator	Efficacy measure	Results		
Braverman et al. (2015) <sup>12</sup>	Total tonsillectomy using COBLATION°	OSA-18 score Freedom from obstructive sleep	Similar mean post-operative OSA-18 scores (CIT: 25.5; total COBLATION tonsillectomy: 24.6)  All patients from OSA prophers with both		
	technology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

# Risk of PTH significantly lower with CIT

(10 studies;<sup>13-19,21,22,24</sup> n=6,039; RR: 0.36; 95% CI, 0.16 – 0.81; p=0.0131)



No significant difference in total PTH rates requiring operating room management





 ${\sf CI=confidence\ interval;\ CIT=COBLATION\ Intracapsular\ Tonsillectomy;\ RR=risk\ reduction;\ PTH=post-tonsillectomy\ haemorrhage.}$ 

## Complications - post tonsillectomy haemorrhage (PTH)

The incidence of PTH was reported in 13 studies, <sup>9-11,13-19,21,22,24</sup> though two of these studies <sup>10,11</sup> 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. 12,13,20,22 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.

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

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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%.

Level 2: Prospective, comparative Level 3:	rative		Number of patients							
Level 2: Prospective, comparative Level 3: Retrospective comparative	Study, year	Control procedure(s)	Overall	CIT	Control(s)	Indication(s)	Population	Mean age (years)	Outcomes reported	
	Arya et al. 2003 <sup>10</sup>	Total COBLATION <sup>o</sup> tonsillectomy	14*	14	14	Infective	Adult	Overall: 31.9	Absolute pain at Day 1	
	Arya et al. 2005 <sup>11</sup>	Total COBLATION tonsillectomy	18*	18	18	Infective	Paediatric	Overall: 9	Absolute pain at Day 1	
	Chan et al. 2004 <sup>13</sup>	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 <sup>14</sup>	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 1     Total incidence of PTH     Incidence of PTH requiring OR management	
	Chang et al. 2008 <sup>15</sup>	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 1     Total incidence of PTH     Incidence of PTH requiring OR management	
	Hall et al. 2004 <sup>19</sup>	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 <sup>8</sup>	Total COBLATION tonsillectomy	90	48	42	Obstructive and/ or infective	Paediatric	Overall: 5.3	<ul> <li>Absolute pain at Day 1 and Week 1</li> </ul>	
	Wilson et al. 2009°	Total tonsillectomy using electrocautery	103	53	50	Obstructive with no history of recurrent tonsillitis	Adult & paediatric	CIT: 5.8 <sup>†</sup> Total: 6.1 <sup>†</sup>	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	

Appendix 2. Details of	f studies identifie	ed via systematic	literature review
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Randomised controlled trial Level 2: Prospective,	2: active, arative	Level 3: Retrospective comparative	Study, year	Control procedure(s)	Number	of pat	ients				
	Level Prospe				Overall	CIT	Control(s)	Indication(s)	Population	Mean age (years)	Outcomes reported
			Junaid et al. 2019 <sup>20</sup>	Total COBLATION <sup>o</sup> tonsillectomy	101	23	78	Obstructive and/or infective (tendency for experimental to be only used on obstructive)	Paediatric	NR	<ul> <li>Absolute pain at Day 1 and Week 1</li> <li>Time to return to normal diet</li> </ul>
			Braverman et al. 2015 <sup>12</sup>	Total COBLATION tonsillectomy	80	43	37	Obstructive with (control) or without (CIT) history of recurrent tonsillitis	Paediatric	CIT: 4 <sup>†</sup> Total: 5 <sup>†</sup>	• Absolute pain at Week 1
			Divi et al. 2005 <sup>16</sup>	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 <sup>17</sup>	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 requiring OR management
			Friedman et al. 2003 <sup>18</sup>	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 of analgesia use     Time to return to normal activities. Time to return to normal diet     Total incidence of PTH     Incidence of PTH requiring OR management
			Heward et al 2021 <sup>21</sup>	NR	498	281	217	Obstructive and/ or infective	Paediatric	NR	Total incidence of PTH Incidence of PTH requiring OR management
			Mukerji et al 2021 <sup>22</sup>	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 <sup>23</sup>	Total COBLATION tonsillectomy	730	351	379	Obstructive and/ or infective	Adult & paediatric	7.0 (0.8 – 74.3) 6.9 (0.7 – 66.8)	Revision surgery
			Tremlett et al 2020 <sup>24</sup>	Total tonsillectomy using cold steel	74	47	27	Obstructive and/ or infective	Paediatric	3.5 3.4	Total incidence of PTH Time to pain free Time to return to normal activit 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.