Systematic Review of Randomized Controlled Trials Comparing Intracapsular Tonsillectomy With Total Tonsillectomy in a Pediatric Population

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Objective: To perform a systematic literature review and data synthesis of level-1 evidence comparing recovery-related outcomes after intracapsular tonsillectomy (IT) (any technique) with those of total tonsillectomy (TT) (any technique) in a pediatric population.

Data Sources: Two independent reviewers searched the following databases: Ovid MEDLINE, including old MEDLINE and pre-MEDLINE, EBM reviews, Books@Ovid and Journals@Ovid, the Web of Science with Conference Proceedings, and references from indexed articles.

Study Selection: Inclusion criteria were randomized controlled trials conducted on a pediatric population comparing IT performed by any technique of dissection with TT, also performed by any technique of dissection. Two independent reviewers determined included trials with difference of opinion resolved by a third reviewer.

Data Extraction: Independent data extraction by 2 reviewers on the following outcomes: postoperative pain, analgesic use, recovery time, diet, bleeding rate, infection, and regrowth rate requiring further surgical intervention.

Data Synthesis: Heterogeneity of outcome measures and lack of reporting of raw data precluded formal meta-analysis. For quantitative data that could be extracted, pooled data analysis was performed using nonparametric tests.

Conclusion: Recovery-related outcomes for IT were superior to TT (secondary hemorrhage rate, number of days until pain free) in a pediatric population with obstructive symptoms (level-1 evidence).


Much has changed in both the indications and techniques for performing tonsillectomy over the past 2 centuries. Guillotine tonsillectomy, originally introduced by Philip Physick in 1828,1 was in effect a partial tonsillectomy, which was later superseded by total tonsillectomy (TT), performed with the same instrument, owing to concerns about recurrent infection in the residual tonsillar tissue.2,3 Total tonsillectomy was described in 1906 and rapidly became the preferred method of tonsil excision using sharp dissection.3 The introduction of electro surgical devices in 1887 initially provided a means of improved hemostasis. Later, with the development of diathermy and nonvolatile inhalational anesthetics, electrocautery gained acceptance as a preferred method of tonsillar dissection.4 More recently, surgeons have used the harmonic scalpel, laser, microdebrider, coblation, and radiofrequency, with the aim of reducing postoperative pain and morbidity.

Since the advent of antibiotics and improved guidelines for monitoring and observation of infection, the rate of surgery for infection has been declining, while sleep-disordered breathing has become the most common indication for tonsillectomy in the pediatric population.5,6 In parallel with this development has been a renewed interest in the value of intracapsular tonsillectomy (IT). Its proponents cite equivalent outcomes for obstructive symptoms, with the possible benefit of reduced pain and morbidity because there is no breach of the tonsillar capsule or underlying pharyngeal musculature. The risks associated with this technique are infection in the tonsillar remnant and regrowth of tonsillar tissue.

Over the past decade numerous clinical trials have been undertaken to compare IT with TT techniques for the relief of sleep-disordered breathing. Previous au-
thor have shown that IT is as effective as TT, when evaluating clinical outcomes of sleep-disordered breathing. In the present study, we evaluated the postoperative recovery period and performed a systematic review of all the available level-1 evidence to guide treatment in this patient subset. While the data extracted from these trials could not be assessed with a formal meta-analysis and most of the trials would be excluded from a purist analysis such as a Cochrane review, we still believe that there is value in an examination of the available evidence for the otolaryngologic community.

METHODS

OBJECTIVE

To perform a systematic literature review and data synthesis of the best published evidence to compare recovery-related outcomes after IT (any technique) with those of TT (any technique) in a pediatric population.

DATA SOURCES

Two independent reviewers (J.W. and Y.E.) searched the following databases: Ovid MEDLINE (1948–June, week 3, 2011); search terms were (“tonsillectomy” [MeSH terms] OR “tonsillectomy” [all fields] AND “methods” [subheading] OR “methods” [all fields] OR “methods” [MeSH Terms]). A keyword search was also performed using the following terms: tonsilotomy [all fields] OR intracapsular [all fields] AND “tonsillectomy” [MeSH terms] OR “tonsillectomy” [all fields] OR partial [all fields] AND “tonsillectomy” [MeSH terms] OR “tonsillectomy” [all fields] OR subcapsular [all fields] AND “tonsillectomy” [MeSH terms] OR “tonsillectomy” [all fields].

STUDY SELECTION

Inclusion criteria were randomized controlled trials (RCTs) conducted on a pediatric population (age <16 years), comparing IT performed by any technique of dissection with TT, also performed by any technique of dissection. The indication for tonsillectomy was for sleep-disordered breathing in all trials. The outcomes assessed included postoperative pain, analgesic use, recovery time, diet, bleeding rate, and infection and regrowth rate requiring further surgical intervention.

DATA EXTRACTION

Data extraction was performed by 2 independent reviewers (J.W. and Y.E.) on the following outcomes: scores from pain rating scales, number of days until pain free, days of analgesic use, number of analgesics doses, days until return to normal activity, days until resumption of normal diet, number of posttonsillectomy bleeding episodes (primary and secondary), number of postoperative throat infections and orontisillitis cases requiring antibiotics, and recurrence of sleep-disordered breathing requiring further surgery.

DATA SYNTHESIS

For quantitative data that could be extracted, pooled data analysis was performed using nonparametric tests on IBM SPSS Statistics software (SPSS Inc.). For χ² analysis, Yates correction factor was used if at least 1 cell of the table had an expected count smaller than 5 to prevent overestimation of statistical significance for small data.

RESULTS

Articles were screened independently by both reviewers. When there was a conflict of opinion, a third reviewer (M.G.S.) decided the outcome, which was required in 1 case. Thirty-five articles were then examined in full text, of which there were 19 RCTs that met the inclusion criteria. Three RCTs were then excluded because they did not examine the outcomes of interest (2 studies) or because of tonsil reduction technique (1 study) (Table 1). Radiofrequency tissue volume reduction via probe insertion into the tonsil was not considered to be equivalent to IT. Of the 16 included articles (Table 2), 2 reported on 1 dataset with short- and long-term follow-up. There was 1 study in which the age range was between 6 months
and 22 years, with the mean age of 5 and 6 years in the intervention groups. The consensus between reviewers was to include this trial, which had a large number of patients enrolled with only a few over the age limit of 16 years.16

In 3 studies,10,19,23 children had experienced bouts of tonsillitis in addition to sleep-disordered breathing.

The number of participants in the 16 included studies was 1312, 699 in the partial tonsillectomy group and 635 in the TT group. Some participants acted as their own control in a matched pair study, thus a small number were included in both groups.

In the 16 included studies, techniques used for IT included microdebrider (6 studies), coblation (4 studies), laser (2 studies), radiofrequency sling and/or Surgitron, 1.7 MHz (Ellman International Inc) (3 studies), bipolar electrocautery (1 studies), and cold steel (1 study) (1 study had 2 IT intervention groups: coblation and microdebrider).16 Techniques for TT included electrocautery (9 studies), sharp dissection (6 studies), and coblation (1 study).

The distribution of length of follow-up in the included studies was less than 6 months (9 studies),10,12-18,25 6 to 12 months (3 studies),19,21,23 13 to 24 months (3 studies),2,20,22 and 25 to 36 months (1 study).24

<table>
<thead>
<tr>
<th>Study</th>
<th>Source</th>
<th>Size, No. of Patients</th>
<th>Blinding</th>
<th>Technique of Randomization</th>
<th>Outcome Measure</th>
<th>Method of Follow-up</th>
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<tr>
<td>Sobol et al12</td>
<td>74</td>
<td>Single</td>
<td>Blocks of 10, sealed envelope, stratified 2 surgeons</td>
<td>Pain, diet, activity, bleeding</td>
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<td>10 d</td>
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<td>Lister et al13</td>
<td>25</td>
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<td>Pain, diet, activity, bleeding, recurrence</td>
<td>NR</td>
<td>1 mo</td>
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<td>40</td>
<td>Single</td>
<td>Blocks of 4</td>
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<td>7 d</td>
</tr>
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<td>Bitar and Rameh2</td>
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<td>Pain, diet, activity, bleeding, recurrence</td>
<td>Office visit, prospective</td>
<td>20 mo</td>
</tr>
<tr>
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<td>NR</td>
<td>&gt;7 d</td>
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<td>Coin toss, in blocks of 6 (3:3 ratio) following enrollment</td>
<td>Pain, diet, activity, bleeding, recurrence, infection</td>
<td>Office visit, prospective</td>
<td>1 y</td>
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<tr>
<td>Densert et al20</td>
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<td>Questionnaire, prospective</td>
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<tr>
<td>Ericsson et al24</td>
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<td>Zelen’s method</td>
<td>Recurrence, infection</td>
<td>1-y office visit, 3-y questionnaire, prospective</td>
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<td>Pain, diet, activity, bleeding</td>
<td>NR</td>
<td>7 d</td>
</tr>
</tbody>
</table>

Abbreviations: NA, not applicable; NR, not reported.

*Reporting on the same data set.

OUTCOMES

Postoperative Pain

Fifteen trials reported results for postoperative pain using pain rating scales. Numerous scales were used by investigators in an attempt to compare pain between groups. These included Wong Baker Faces (0-5 scale) (6 studies), Wong Baker Faces (0-10 scale) (5 studies), Faces pain scale (0-6 scale) (1 study), Faces pain scale (1-5 scale) (1 study), visual analog scales (2 studies), and verbal or numerical pain response scales (mild, moderate, severe, or 1-5 scale) (2 studies). The time range of assessment was from 0 to 14 days.

Pain response scores were examined. Four studies reported no difference in postoperative pain, and 9 described significantly less postoperative pain in the IT group. Two other studies described less pain in the IT group, but there was no statistical test of significance reported to support the assertion. Owing to the heterogeneity of the measurement instruments and the lack of raw data, it was not possible to compare these statistically.

Six studies reported the mean number of days before resolution of pain between groups. When pooling the
means for these studies, the mean (SD) was 5.0 (0.83) days in the partial tonsillectomy group (n = 263) and 7.6 (2.14) days in the TT group (n = 208). The Mann-Whitney test demonstrated a significant difference between both groups P = .045 (2-tailed).

Analgesic Use

Eleven of the 16 studies reported on analgesic use. Outcomes were measured as the number of medication doses given per day; however, results were not comparable statistically owing to different indications for dosing, parental instructions, types of medication used, and time frame of dosing. Of these 11 studies, 10 found that there were significantly fewer doses of analgesic given in the IT group. One study found that there was no difference between groups.

Return to Normal Activity

Ten of the 16 studies reported return to normal activity and compared results between groups. Overall, 8 studies found that the IT group returned to normal activity significantly earlier than the TT group. Two studies found no difference.

Seven studies reported on the days until normal activity was resumed. The pooled mean (SD) was 4.1 (1.54) days in the IT group (n = 469) and 6.6 (2.19) days in the TT group (n = 404). Results from the Mann-Whitney test showed no significant difference between groups (P = .06) (2-tailed).

The remaining 3 studies reported the proportion or percentage in each group who had resumed normal activity between days 1 and 7. Two of these trials reported that significantly more participants in the IT group had returned to normal activity than the TT group. The other study found no difference.

Diet

Twelve of the 16 studies compared postoperative oral intake between groups. Overall, 9 of these studies found a significantly earlier return to diet in the IT group. Three studies found no difference in the resumption of diet between groups.

Six studies reported days until resumption of normal diet. One of these studies found no difference between groups. The other 5 studies reported a significantly earlier return to normal diet in the IT group. The pooled mean (SD) days until return to normal diet was 4.0 (1.04) days in the IT group (n = 420) and 6.2 (1.83) days in the TT group (n = 361). Results from the Mann-Whitney test showed no significant difference between groups (P = .053) (2-tailed).

Two studies reported the percentage of the group who returned to a normal diet on days 1 to 2, 3 to 4, and 5 to 6 and found the IT group had a significantly higher proportion consuming a normal diet. One study reported on the percentage of time between days 1 and 7 that participants ate less than normal, normal, or more than normal and found that the IT group ate significantly more than the TT group.

Two studies reported the time until oral intake was first resumed postoperatively, with no difference between the IT and TT groups.

Postoperative Bleeding

The complication of postoperative bleeding both primary and secondary was reported for all datasets from the included studies.

- Primary hemorrhage: In the IT group, 3 of 699 patients required intervention for primary bleeding. In the TT group, 1 of 635 patients had primary bleeding. Yates χ² analysis showed no significant difference between the groups (Yates P = .69).

- Secondary hemorrhage: In the IT group, 5 of 699 patients had a secondary hemorrhage, while the number in the TT group was 13 of 635 patients. Results from χ² analysis showed a significant difference between both groups (P = .04).

OUTCOMES STRATIFIED BY THE IT SURGICAL TECHNIQUE

Microdebrider

Six studies compared IT performed with the microdebrider (n = 357) with TT (n = 346). For the TT technique, the majority were performed with electrocautery (n = 326) and a small number with cold steel (n = 20). Four of these studies reported outcomes for the mean number of days of analgesic use (IT, 4.4 days; TT, 6.7 days), the mean number of days until resumption of normal diet (IT, 3.9 days; TT, 5.6 days), and the mean number of days until resumption of normal activity (IT, 2.9 days; TT, 5.1 days). Two studies reported the mean number of days until pain free (IT, 4.7 days; TT, 5.3 days). There were no episodes of primary hemorrhage in either group. The rate of secondary hemorrhage for the IT group was 4 of 357 and for TT 7 of 346. Results from χ² analysis shows no statistical difference in the secondary hemorrhage rate between groups (P = .51).

Coblation

Four studies compared IT performed with coblation (n = 159) with TT (n = 161). In the TT group, the technique used was EC (n = 126) and coblation (n = 35). Two studies reported outcomes for the mean number of days of pain (IT, 5.5 days; TT, 8.32 days), the mean number of days of analgesic use (IT, 5.1 days; TT, 8.4 days), the mean number of days until resumption of normal diet (IT, 4.6 days; TT, 6.9 days), and the mean number of days until resumption of normal activity (IT, 4.8 days; TT, 7.3 days). The other 2 studies examined outcomes in terms of percentage who returned to normal activity or diet between days 1 to 6. In both of those studies, the IT group had improved outcomes in terms of earlier return to diet and activity. When pain scores were compared between groups, the IT group had less pain than the TT group.

There were no episodes of primary hemorrhage in either group. The rate of secondary hemorrhage for the IT group was 1 or 159, and for TT, 3 of 161.
Radiofrequency

Three studies compared IT performed with radiofrequency using a sling and/or Surgitrone (n=133) with TT (n=118). In the TT group, the technique used in all cases was cold steel. Two studies reported outcomes for the mean number of days of pain (IT, 4.9 days; TT, 8.6 days), mean number of days of analgesic use (IT, 4.6 days; TT, 7.7 days), and the mean number of days until resumption of normal activity (IT, 6 days; TT, 9 days). The third study reported long-term outcomes using one of these datasets.

The rate of primary hemorrhage was 2 of 133 for IT and 0 of 118 for TT. For secondary hemorrhage the rate was 0 of 133 for IT and 3 of 118 for TT.

Laser

Two studies reported results comparing IT with laser (n=41) with TT (n=40). Total tonsillectomy was performed by electrocautery in half of the cases, with the remainder cold steel. Both studies reported less pain in the IT group when evaluated with the Faces pain scale (1-5 scale) or Wong Baker Faces pain scale (0-5 scale). One study reported the mean days until pain free (IT, 5 days; TT, 8 days). There were no cases of primary or secondary hemorrhage.

Other Techniques

One study reported results for IT with bipolar (n=18) compared with TT using electrocautery (monopolar) (n=21). This study reported no difference in pain scores between groups, with the same proportion returning to normal activity on days 1, 3, 5, and 7 and no difference on time to resuming oral intake. There were no cases of primary or secondary hemorrhage.

One study reported results for IT with cold steel (n=40) compared with TT using cold steel (n=41). Average pain scores were the same between both groups measured to day 9. The total number of analgesic doses given per day was less in the IT group. There was no difference in time to return to daily activities or in visual analog scores for quality of life. There was 1 case of primary hemorrhage in both groups and no cases of secondary hemorrhage.

RECURRENTNESS OF SLEEP-DISORDERED BREATHING

None of the studies reported preoperative or postoperative polysomnographic data. Of the 16 studies, 8 reported results for regrowth of tonsillar tissue and recurrence of sleep-disordered breathing. One study reported these results after only 1-month follow-up at an office visit and reported no evidence of recurrent symptoms or tonsillar tissue in either group. Of the 7 studies with longer follow-up (range, 6 months–3 years), in the IT group (n=269), 4 children had evidence of regrowth of tonsillar tissue and snoring and 1 required completion tonsillectomy for ongoing poor weight gain, episodic tonsillitis, and snoring without apnea.24 In the TT group (n=250), 2 children had ongoing snoring, with none showing evidence of tonsillar tissue and none requiring further tonsil surgery. The Yates $\chi^2$ for snoring ($P = .75$) and further surgery ($P = .97$) showed no significant difference between the IT and TT groups.

COMMENT

Otolaryngologists are continuing to advance surgical techniques with the aim of reducing postoperative pain and morbidity in tonsillectomy while still achieving optimum long-term results. To date, this is still a very contentious area of practice, and in the quest to improve the postoperative course after tonsillectomy, many different surgical techniques and devices have been championed. More recently, this hotly debated topic has evolved further to include the difference between 2 different operations, IT and TT.

In 2003, Koltai et al26 reported success using IT in the treatment of children with sleep-disordered breathing with reduced postoperative pain and faster recovery. Subsequent studies have substantiated these findings.27-29 Sorin et al30 examined outcomes in 278 patients after IT and cited the regrowth rate of tonsillar tissue with snoring as 3.2%. Two patients in that series (0.7%) developed obstructive symptoms requiring completion tonsillectomy.30

The purpose of this systematic review was to examine the available level-1 evidence to compare recovery-related outcomes between IT and TT. In terms of postoperative recovery, IT had significantly faster resolution of pain, and the majority of studies reported earlier return to normal diet, earlier return to normal activity, and less use of analgesics compared with the TT group.

In addition, there was no difference in the rate of primary hemorrhage between groups, and for secondary hemorrhage, the IT group had a significantly lower bleeding rate.

When stratifying results by surgical technique, a trend to better recovery-related outcomes for IT were reported for the microdebrider, coblator, radiofrequency sling and/or Surgitron, and laser. The smaller population after stratification often precluded formal statistical analysis. Bipolar and cold steel partial tonsillectomy did not appear to have the same benefit.

Much of the apprehension from otolaryngologists about IT stems from concerns about infection in the tonsillar remnant and the presence of residual tonsillar tissue rather than recovery-related outcomes. The benefit of reduced time of convalescence or risk of bleeding must be weighed against these concerns. There is a value judgment that should be
made with parents regarding this issue, where the benefit of shortened duration of pain by 2 to 2.5 days and the reduced risk of secondary hemorrhage must be compared with the risk of leaving the tonsillar remnant behind. In these circumstances some parents may prefer TT.

The population included in this study consisted of children with sleep-disordered breathing. The findings in 8 of these trials suggest no significant difference in the rate of sleep-disordered breathing after IT compared with TT. The efficacy of IT for the relief of obstructive symptoms must be questioned in the absence of preoperative and postoperative polysomnography.

Several studies examining outcomes after IT have been reported with polysomnographic data that demonstrate that partial tonsillectomy in combination with adenoectomy is an effective means of reducing the apnea-hypopnea index in children with obstructive sleep apnea to normal levels. Intracapsular tonsillectomy and adenoectomy has also been shown to have equivalent outcomes to TT and adenoectomy when evaluated with polysomnographic data in a retrospective cohort study of 30 patients.

Data from 4 of the included RCTs suggest no significant difference in the rate of tonsillitis between IT and TT groups. These results must be interpreted with caution, given the small number of participants and the relatively short length of follow-up. There are few studies that have examined this parameter because of difficulty in obtaining reliable follow-up data and because the study populations have usually been children with obstructive sleep apnea, where primary outcomes have focused on recovery or relief of sleep-disordered breathing.

The duration of trials is an important issue. Nine of the 16 trials reported follow-up of 1 month or less. The remaining 7 trials had follow-up between 6 months and 3 years. Regrowth of lymphoid tissue may occur over years, and only 3 of these trials had follow-up greater than 1 year. Two of those trials obtained follow-up data via questionnaire, which is not an ideal assessment tool, and 1 via clinical examination. To definitively address the issues of infection rates and obstructive symptoms, trials need to have long time frames of assessment, ideally with preoperative and postoperative polysomnography.

The greatest difficulty in forming best practice guidelines from an analysis of available RCTs is the lack of standardization of outcomes and a lack of reporting of raw data. When key outcomes were reported, the heterogeneity of measurement instruments made comparisons problematic and precluded meta-analysis.

In some cases data were reported that was unlikely to be related to the type of tonsillectomy technique used, such as emesis or nausea in the recovery room, or the time until first intake of fluid, which may be influenced by a multitude of confounding variables, such as method of anesthesia, type of pain relief, and recovery room protocols, for example.

Sound knowledge of the current literature and its deficiencies is the best means to designing better long-term studies to address these important clinical questions.

In conclusion, examination of the level-I evidence comparing IT with TT for the management of obstructive symptoms in a pediatric population shows equivalent or superior recovery-related outcomes (ie, secondary hemorrhage rate, number of days until pain free) for IT in the postoperative period.

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Author Contributions: Dr Walton had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Walton, Ebner, Stewart, and April. Acquisition of data: Walton and Ebner. Analysis and interpretation of data: Walton, Ebner, and April. Drafting of the manuscript: Walton and Ebner. Critical revision of the manuscript for important intellectual content: Walton, Ebner, Stewart, and April. Statistical analysis: Walton, Ebner, and Stewart. Administrative, technical, and material support: Walton, Stewart, and April. Study supervision: Stewart and April.

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REFERENCES


