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Laser tonsil treatment under local anesthesia: a patient-friendly effective alternative?

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Citation

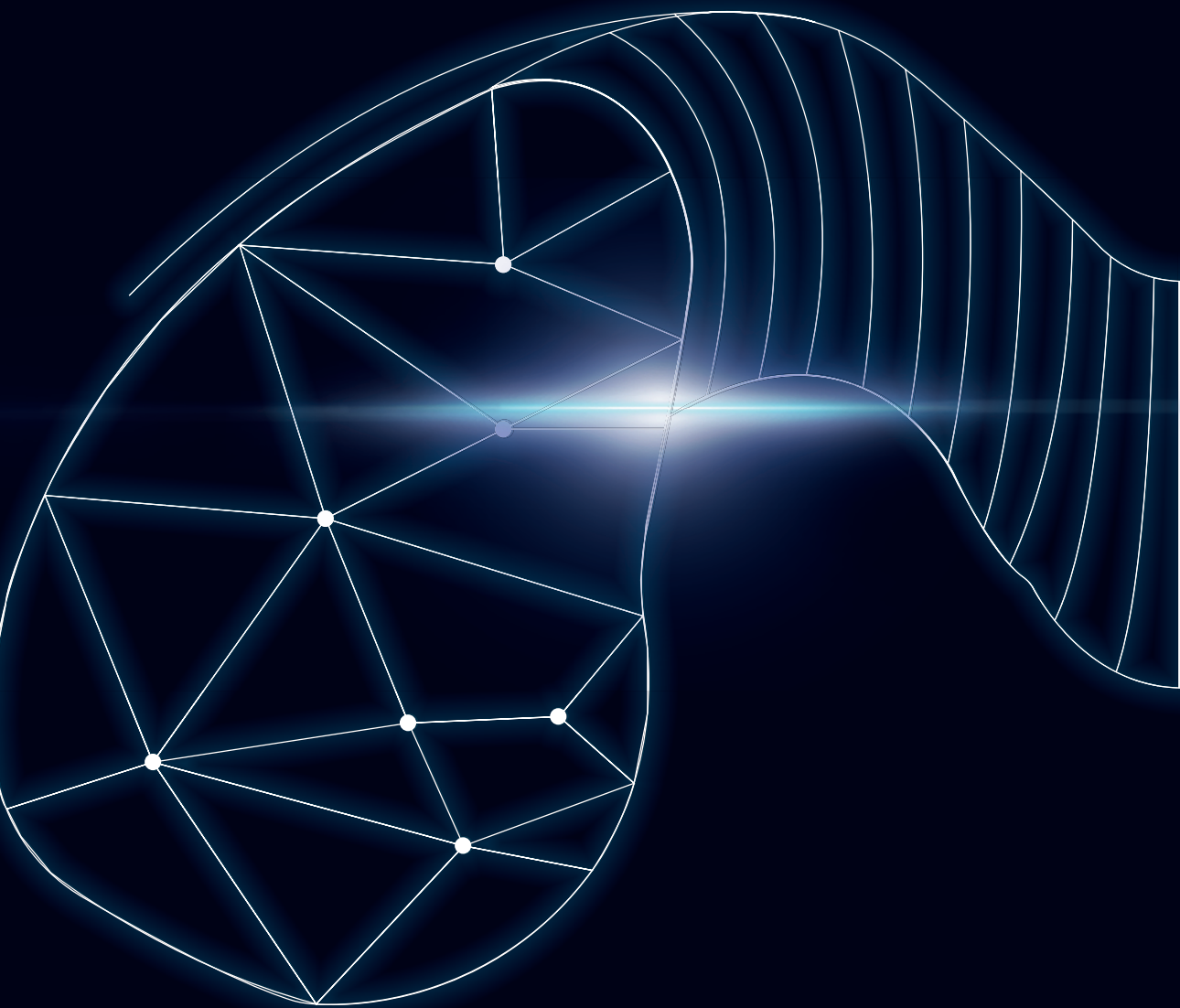
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CHAPTER 3

Post-operative morbidity and 1-year outcomes in CO₂-laser tonsillotomy versus dissection tonsillectomy

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ABSTRACT

Objective: In this study a type of partial tonsil surgery, CO₂-laser tonsillotomy, was compared to regular tonsillectomy. The effectiveness and post-operative recovery rate of both interventions in adult patients was assessed by using a questionnaire.

Study design: Prospective follow-up non-randomized cohort study.

Method: One hundred and seven adults were included; 46 tonsillectomies and 61 tonsillotomies were performed. Patients in the tonsillectomy group underwent general anesthesia, while tonsillotomy was performed in an ambulatory setting with local anesthesia. Post-operative questionnaires were administered by mail after 2 weeks, 6 months, and 1 year to assess recovery rate and symptom recurrence.

Results: In total, 72.5% of patients were cured from their initial symptoms after tonsillotomy. Three patients (7.5%) required re-surgery for their initial complaints. After tonsillectomy, 97.2% of patients were cured. Both groups showed equally high satisfaction scores after treatment. Post-operative evaluation after 2 weeks showed a mean pain-intensity score of 5.4 (Visual Analogue Scale 0–10) after tonsillotomy and a mean pain-intensity score of 7.7 after tonsillectomy. The post-operative use of analgesics was twice as long in the tonsillectomy group compared to the tonsillotomy group and the tonsillectomy group required twice as many days for full recovery. After tonsillectomy a higher rate of major post-operative hemorrhage was seen.

Conclusion: CO₂-laser tonsillotomy is associated with a shorter and less painful recovery period. Both surgical methods are equal in terms of long-term satisfaction, although tonsillotomy comes with a higher recurrence rate of mild symptoms. A strict pre-operative patient selection for CO₂-laser tonsillotomy is necessary.

INTRODUCTION

In the Netherlands, conventional dissection tonsillectomy (TE) is performed when conservative treatment fails in adults with tonsillar disease. After TE, post-operative morbidity remains a major clinical problem.^{1,2} The high prevalence of long-lasting post-operative pain and risk of post-operative hemorrhage have made otorhinolaryngologists search for other alternative techniques. New techniques for removing the pharyngeal tonsils are developing and primarily consider partial removal, so-called tonsillotomy. As opposed to TE only the tonsillar crypts, which play a major role in infection, are securely ablated.

A prospective pilot study investigating the effect of CO₂- laser tonsillotomy (TO) in adult patients has been initiated at the ENT department in the HagaZiekenhuis, with the first promising results published in 2009 by Datema et al.³ To assess proper potential of TO, there is need for a comparison with TE. The primary aim of this prospective study is to compare TO and TE with respect to post-operative morbidity and success rates. Initially a prospective randomized trial was started (SMOKE study). Unfortunately, as the Haga-Ziekenhuis was the only centre in the Netherlands performing the outpatient laser tonsillotomy, patients travelled from far to have the TO performed and many could not be motivated to participate in a randomized trial. Therefore, the study design was changed to the next best, which is this cohort study. The goal of this study is to determine the position of TO in the treatment of tonsillar disease in otolaryngological practice in the Netherlands

MATERIALS AND METHODS

Participants (figure 1)

This study was conducted between September 2012 and January 2014. The study population existed of recruited patients more than 16 years of age suffering from established recurrent tonsillitis (defined as more than five episodes of tonsillitis a year, according to the national guideline⁴), halitosis, tonsilloliths, tonsillar hyperplasia causing partial airway obstruction, or dysphagia. Exclusion criteria for TO were a strong gag reflex, inability to keep the mouth open, and previous tonsillotomy. Specific exclusion criteria for both procedures were a history of peritonsillar abscess and bleeding disorders. In the study period 193 outpatients were diagnosed with any 'adenoid and tonsillar disorder'. Of these patients, 114 were indicated for TE or TO. Seven patients already underwent tonsil surgery once before and were, therefore, excluded from participation in this study. Eventually, 107 patients were included and either allocated to TE or had a freedom of

choice (**Figure 1**). All patients were provided with clear information about both procedures, so a deliberate choice could be made. Thirty-six patients (33.6%) were excluded for TO and were advised to undergo TE. The TE group consisted of 46 patients (n = 46) and TO was performed in 61 patients (n = 61).

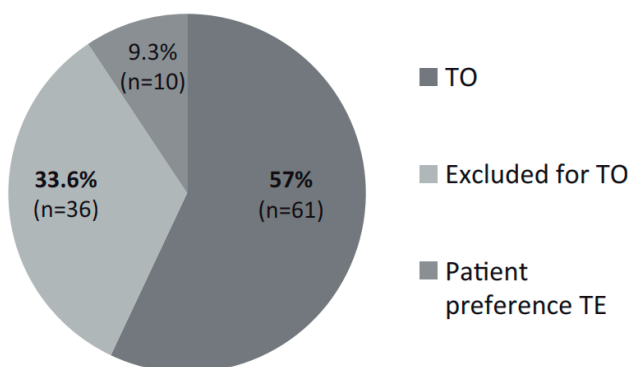


FIGURE 1. DISTRIBUTION OF TONSILLECTOMY (TE) AND TONSILLOTOMY (TO) IN PATIENTS

TABLE 1. DEMOGRAPHIC CHARACTERISTICS FOR TE AND TO AFTER INCLUSION

Characteristic	TE (n = 46)	TO (n = 59)	Total, n (%)	Level of significance
Gender, n (%)				NS
Male	15 (32.6%)	13 (22.0%)	28 (26.7%)	
Female	31 (67.4%)	46 (78.0%)	77 (73.3%)	
Mean age, years (SD)	25.3 ($\pm$ 7.9)	29.7 ($\pm$ 9.6)		p = 0.014
Smoking status, n (%)				NS
Unknown	3 (6.5%)	5 (8.1%)	8 (7.6%)	
Yes	11 (23.9%)	11 (18.6%)	22 (21.0%)	
No	32 (69.6%)	43 (72.9%)	75 (71.4%)	
Working in environment with children, n (%)				NS
Unknown	9 (19.6%)	10 (17.2%)	19 (18.1%)	
Yes	3 (6.5%)	6 (10.2%)	9 (8.6%)	
No	34 (73.9%)	43 (72.9%)	77 (73.3%)	
Ethnicity, n (%)				NS
Unknown	6 (13.0%)	2 (3.4%)	8 (7.6%)	
Caucasian	33 (71.7%)	53 (89.8%)	86 (81.9%)	
Asian	—	1 (1.7%)	1 (1.0%)	
East-European	7 (15.2%)	3 (5.1%)	10 (9.5%)	
Indication surgery, n (%)				p = 0.0012
Recurrent tonsillitis	41 (89.1%)	40 (67.8%)	81 (77.1%)	
Tonsillolithiasis	3 (6.5%)	13 (22.0%)	16 (15.2%)	
Halitosis	5 (8.5%)	5 (8.5%)	5 (4.8%)	
Partial airway obstruction	2 (4.4%)	—	2 (1.9%)	
Dysphagia	—	1 (1.7%)	1 (1.0%)	
Tonsil size, n (%)				p = 0.003
Unknown	13 (28.3%)	2 (3.4%)	15 (14.3%)	
Friedman 1	2 (4.3%)	21 (35.6%)	23 (21.9%)	
Friedman 2	20 (43.5%)	26 (44.1%)	46 (43.8%)	
Friedman 3	10 (21.7%)	8 (13.6%)	18 (17.1%)	
Friedman 4	1 (2.2%)	2 (3.4%)	3 (2.9%)	

Level of sign. = level of significance; NS = Not significant.

Intervention

Trained surgeons performed both procedures. TO was performed as ambulatory surgery in OR, meeting specific criteria for performing laser treatments.⁵ Available was a F125 Laser tube by Lumenis, which was set at 25 W in the continuous mode and distributed focused laser energy with a beam diameter of 3 mm. Patients were positioned in a half-supine position, wearing protective glasses and a nose peg. Tonsillar tissue was exposed using a double wooden tongue blade. Local anesthesia was accomplished with Xylocaine 2%/Adrenaline 1:80,000 injected directly into the tonsils and tonsillar pillars. The crypts were evaporated in a sweeping motion until complete cryptolysis was achieved. Patients were instructed to hold their breath during activation of the laser and smoke was evacuated using a smoke evacuator. In case of hemorrhage, hemostasis could be achieved by bipolar coagulation. TE was planned in day care or short clinical stay. Hemostasis was achieved with gauzes or bipolar coagulation if necessary. All patients received standard post-operative care and were discharged with the advice to use paracetamol 1000 mg 4-times a day and diclofenac 50 mg 3-times a day if necessary.

Outcome

Primary outcome variables of the study were post-operative pain scores, using a Visual Analogue Scale (VAS), rate of patient recovery and long-term outcome. A best- and worst case outcome analysis was performed. Secondary outcome variables were per operative results, complications and patient satisfaction. Patients were interviewed at 2 weeks, 6 months, and 1 year post-operatively using a questionnaire that was sent by e-mail after telephone contact (**Appendix**). Any post-operative complications and visits were extracted, if possible, from the patient's medical file.

Statistics

All data were collected in a custom MS-Access database. Statistical analysis was performed with SPSS Statistics for Windows, version 20.0. All statistical significance was set at $p < 0.05$. A descriptive analysis was performed. Quantitative group data differences were analysed using an unpaired t-test or Mann-Whitney U-test, with multiple linear regressions performed to adjust for age and gender. Associations between categorical variables were analysed using a Chi-square-test or Fisher's exact test. Logistic regression was performed if applicable. Missing data were handled by pairwise deletion.

RESULTS

Demographic data is presented in **Table 1**. A follow-up flowchart is presented in **Figure 2**. TO was terminated in two patients due to excessive gag reflexes. These patients were not included in the further post-operative analyses.

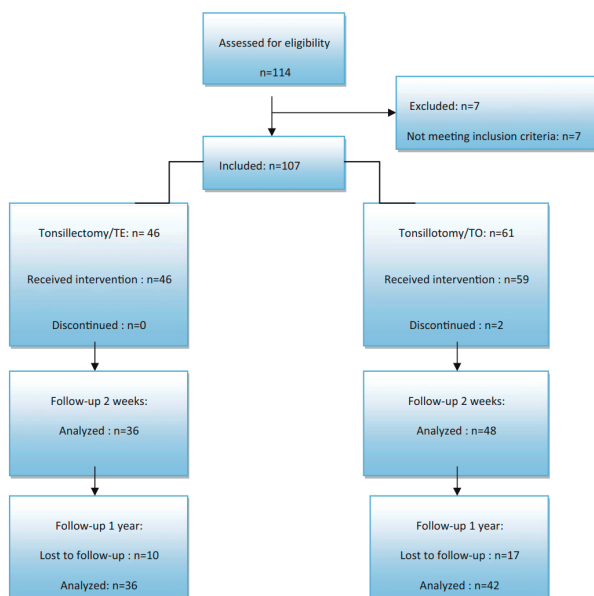


FIGURE 2. FLOWCHART OF TONSILLECTOMY (TE; N = 46) AND TONSILLOTOMY (TO; N = 61) PATIENTS THROUGH STUDY PERIOD.

Per Operative Results

Total operation time was calculated as evaporation time needed in TO and as the time from insertion of the mouth gag until removal in TE. Mean evaporation time in TO was 17.1 ± 6.6 min vs 22.4 ± 6.8 min in TE ($p = 0.002$, Mann-Whitney U-test). Mean blood loss in TE was 177.7 ml (range = 50–500 ml), vs 0 ml in TO ($p < 0.001$, Mann-Whitney U-test). After TO all patients were discharged directly after surgery. After TE the majority of patients were discharged the same day, but eight patients (17.4%) needed an overnight stay ($p < 0.001$, Fisher's exact test).

Post-operative Pain (Figure 3)

Mean pain scores during the first 2 weeks after surgery were based on a Visual Analogue Scale (VAS), ranging from no pain to worst imaginable pain (0–10). TO patients scored 5.4

(range = 0–9) and TE patients scored 7.7 (range = 2–10) ($p < 0.001$, Mann-Whitney U-test). The TO group used analgesics for 5.4 days (95% CI = 4.2–6.5, SE = 0.6), the TE group used analgesics for 9.9 days (95% CI = 8.7–11.2, SE = 0.6) ($p < 0.001$, Mann-Whitney U-test). TE patients predominantly used non-steroidal anti-inflammatory drugs in combination with paracetamol (62.9%). TO patients mainly used paracetamol only (51.1%).

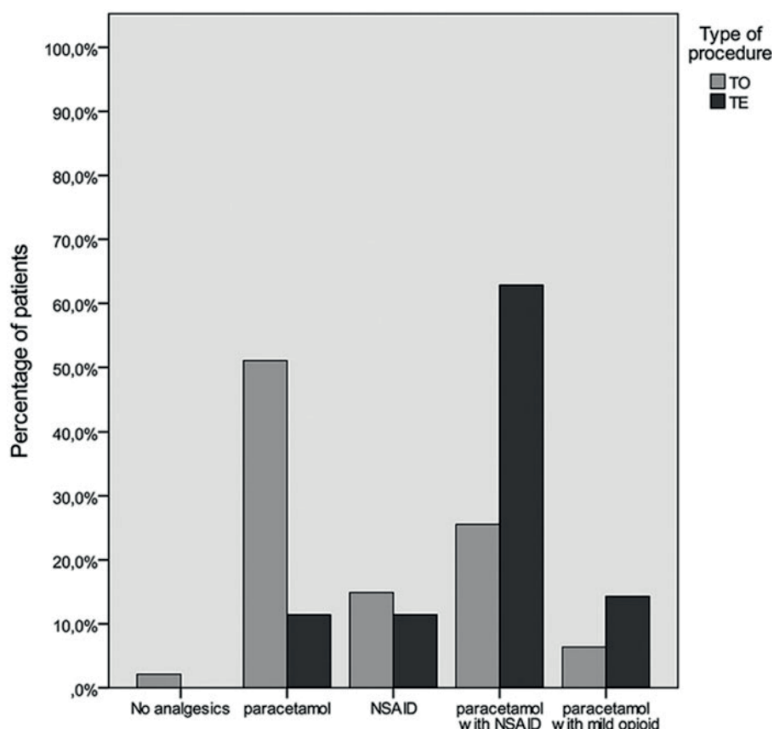


FIGURE 3. DIAGRAM SHOWING THE PERCENTAGE OF PATIENTS IN BOTH TREATMENT GROUPS USING A TYPE OF ANALGESIC DRUG. TE: TONSILLECTOMY; TO: TONSILLOTOMY; NSAID: NON-STEROIDAL ANTI-INFLAMMATORY DRUG (DICLOFENAC 50 MG OR IBUPROFEN 200/400 MG); PARACETAMOL + MILD OPIOID (PARACETAMOL 325 MG/ TRAMADOL 37.5 MG OR PARACETAMOL 500 MG/ CODEINE 10–20 MG).

Unscheduled Contact with Physician

Five patients (10.2%, $n = 5/49$) consulted a physician after TO compared to 14 patients (35.0%, $n = 14/40$) after TE ($p = 0.005$; 95% CI = 1.53–14.67; Odds ratio = 4.7). These contacts were telephone calls or visits to the outpatient department, general practitioner or emergency department for questions about pain or post-operative bleeding.

Complications

No significant difference in the occurrence of complications between the groups was seen ($p = 0.385$, Fisher's exact test). Three secondary hemorrhages (6.5%) were seen at, respectively, 3, 5, and 7 days post-operatively in the TE group. A severe intake problem (2.2%) was noted to be the reason for re-admission after discharge in one patient who underwent TE. Hemorrhages were managed with bipolar coagulation at the OR in two patients. Other complications after TE included four post-operative infections (8.7%), which were successfully managed with oral antibiotics. In the TO group two patients (4.1%) presented oozing after 6 and 7 days, respectively. Two patients developed an infection (4.1%). All four patients were successfully treated at the outpatient department. No re-admission was required in TO patients.

Patient Recovery Rate (Figure 4)

After 4.8 days (95% CI = 3.6–5.9, SD = 3.0) patients could resume their daily activities or work in the TO group compared to 10.6 days (95% CI = 9.3–11.9, SD = 4.3) after TE ($p < 0.001$, Unpaired t-test). The subjective feeling of complete recovery was 9.6 days (95% CI = 8.2–11.0, SD = 3.7) in TO and 14.7 days (95% CI = 13.2–16.3, SD = 4.9) after TE ($p < 0.001$, Unpaired t-test).

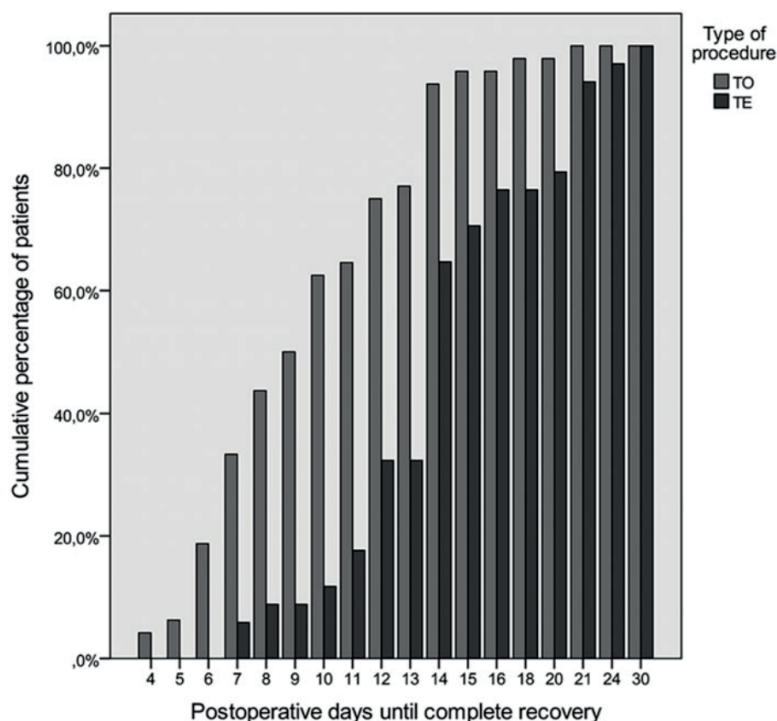


FIGURE 4. DIAGRAM SHOWING THE AMOUNT OF POST-OPERATIVE DAYS AND THE CUMULATIVE PERCENTAGE FOR SUBJECTIVE FEELING OF COMPLETE RECOVERY. TE = TONSILLECTOMY; TO = TONSILLOTOMY;

Satisfaction

After 2 weeks patients were asked to score their feeling of satisfaction about the procedure on a Visual Analogue Scale (VAS), ranging from complete dissatisfaction to high satisfaction (0–10). TO patients scored 8.3 (range = 7–10) and TE patients scored 8.3 (range = 5–10) ($p = \text{NS}$). In 93.6%, patients would recommend the procedure to others after TO, as compared to 73.5% after TE ($p = 0.002$). Only 57.1% would undergo the procedure again after TE vs 86.8% after TO ($p = 0.004$).

Success after Procedure (Figure 5)

One year after a first TO procedure, 29 patients (72.5%) were free of their initial complaint compared to 35 patients (97.2%) after TE ($p < 0.001$, Fisher's exact test). A flowchart of treatment courses is shown in Figure 5. Two TO patients with a high peri-operative risk of incomplete cryptolysis, caused by extreme anxiousness, were excluded from this analysis. Eleven TO patients were not free of their complaints. One TE patient suffered from persistent oropharyngeal pain. Both groups were highly satisfied, with a mean of

8.2 (range = 6–10) in TE patients and 8.0 (range = 0–10) in TO patients (NS, Unpaired t-test). After TO 90% would undergo surgery again, in contrast to 27.8% patients after TE (Odds = 27.2).

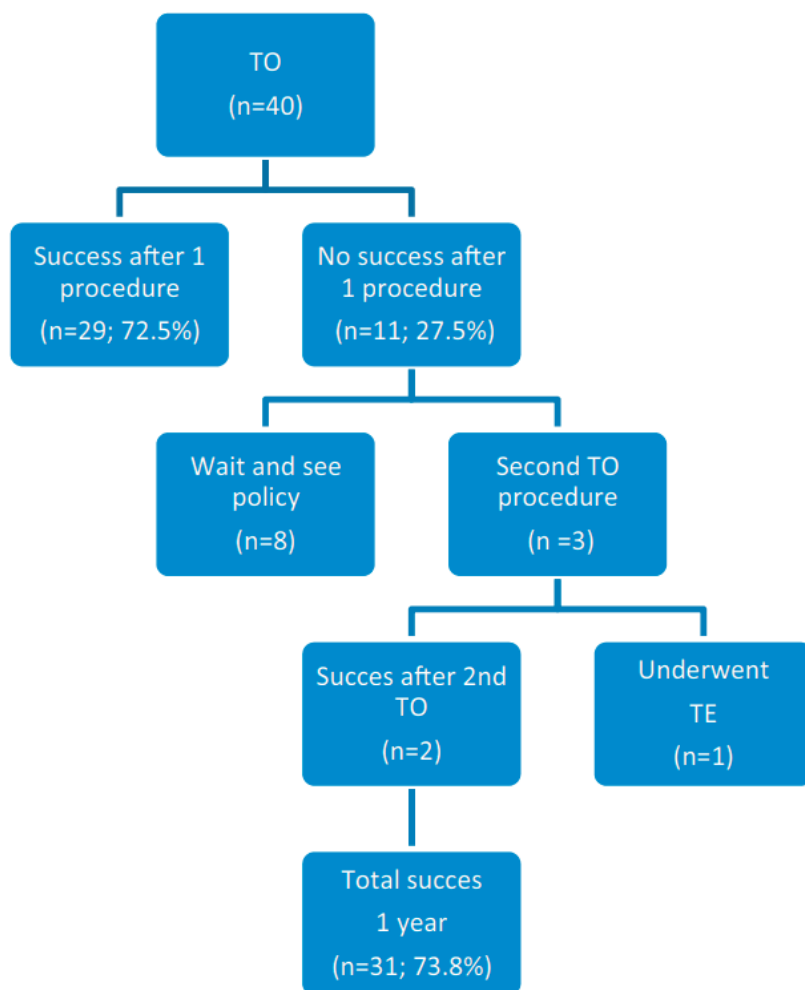


FIGURE 5. FLOWCHART OF COMPLAINTS AND TREATMENT COURSE AFTER TONSILLOTOMY (TO).

Best- and Worst-Case Outcome Analysis (Table 2)

The upper (best case) and lower (worst case) boundaries of the success rates in both groups were established by making missing values positive or negative. In TE patients an interval of 80.7–97.8% for success rate was observed, in comparison to 50.9–76.1%

in TO patients. In both scenarios TE patients had significantly more relief of symptoms. A cross-over analysis was also performed, comparing a best-case scenario in one treatment group with a worst-case scenario in the other treatment group.

TABLE 2. BEST- AND WORST CASE SCENARIO ANALYSIS FOR SUCCESS RATE OF TE AND TO

Scenario	TE (n=46)	TO (n=59)	Level of significance
Best case scenario	97.8%	80.7%	p = 0.011
Worst case scenario	76.1%	50.9%	p = 0.014
Cross-over I ^a	76.1%	80.7%	NS
Cross-over II ^b	97.8%	50.9%	p < 0.000

^a Cross-over scenario I = best case in TO vs worst case in TE.

^b Cross-over scenario II = best case in TE vs worst case in TO.

DISCUSSION

To our best knowledge, no studies in adults comparing TE with CO₂-laser TO have been performed. Studies that have been published focus on children (mainly for treatment of OSAS) or compare TE with other tonsillotomy procedures (e.g. microdebrider; coblation; radiofrequency ablation)⁶⁻⁸. In some countries TO is widely accepted as an alternative for TE and over the last decades a shift towards this technique is noticeable. Recently, even new recommendations were made for tonsil surgery in children in Austria by the Austrian Society of Otorhinolaryngology, aiming to restrict TE to severe cases and to treat all children below the age of 6 years with TO. This new recommendation was preceded by the death of at least five children after post-tonsillectomy hemorrhage in Austrian hospitals in 2006 and 2007.⁹

The CO₂-laser used for TO in this study and the preceding pilot study by Datema et al.³ was chosen, because it was investigated to have potential direct advantages as compared to the dissection technique.¹⁰ Also, no surgical technique has proven superiority in performing partial tonsil resection.¹¹ The ENT-department of the HagaZiekenhuis decided in 2011 to start a prospective randomized controlled trial, the SMOKE study, to determine the place of TO in tonsil surgery. This study had to be stopped in 2012 due to a lack of patient willingness to participate in randomization. The reason for the impossibility of convincing patients was as follows; our ENT-department located in the HagaZiekenhuis is the only centre in the Netherlands performing TO and, as a result, many patients presenting with tonsil-related complaints are specifically re-directed to our clinic to discuss this laser procedure. A classical TE can be performed in any hospital

in the country. For this reason, the design of the study was changed into a prospective comparative setting.

The initial 193 patients diagnosed with any 'adenoid and tonsillar disorder' during the study period were all patients that were first treated suitably by their general practitioner. In the Dutch national healthcare system patients are referred to the medical specialist in case of major complaints and to discuss surgical options. From this point of view, 114 patients that underwent surgery is within expectations. More females than males undergoing tonsil surgery, which was demonstrated in this study, is in accordance with our National registration centre (CBS).

Less risk of post-operative re-bleeding is observed after TO.^{6,12,13} The general reduction in post-operative morbidity in TO patients can be explained by the restricted vaporization of lymphoid tissue and avoidance to damage the tonsillar capsule. All large vessels are packed in the capsule and bottom of the crypts, with only smaller vessels radiating into the lymphoid tissue. This explains why intraoperative bleeding and major post-operative bleeding was not seen during and after TO in this study. Acevedo et al.⁸ also support our results by demonstrating a statistically significant lower risk ratio (0.29) of post-operative hemorrhage after TO in comparison to TE, however no differences were seen between intra-operative bleeding. This possibly reflects differences between surgical instrumentation used to perform TO.

Few studies have looked specifically at patients regaining normal activities in the post-operative period comparing TO and TE.⁶ However, the study of Ericsson and Hultcrantz supports our findings.⁷ Good short- and long-term patient satisfaction after TO procedures is already demonstrated by Krespi et al.^{14,15} and Wireklint and Ericsson¹⁶, and these findings are consistent with this study's findings regarding patients prompt resumption of daily activities and self-reported overall high satisfaction. It is surprising though that, after 1-year follow-up, patients were equally satisfied. This suggests that patients with (minor) persisting tonsil related complaints after one or more laser treatments take this for granted.

In 35% of TE patients any physician was contacted with questions regarding discomfort, which was pain mostly. This implies uncertainty about expected symptoms and signs after surgery. TE patients should perhaps be prescribed stronger analgesics (opiates) post-operatively and should be advised to use a strict analgesics regimen.

The shorter period of post-operative pain and earlier return to daily activities after TO yields a potential socioeconomic gain. Also, TO does not require general anesthesia or

hospitalization and this can substantially reduce medical costs. On the other hand, the special equipment purchased for performing TO is currently an investment of at least €60.000 (2014). A proper cost analysis was not conducted alongside this study. In future studies a cost-effectiveness analysis evaluating the socioeconomic costs would be of high value.

Independently of the reduction regarding initial symptoms in the TE patients that were lost to follow-up, effectiveness of surgery after 1 year of follow-up was still equal or better compared to that in TO patients. Opponents of partial tonsillectomy procedures argue the issue of considerable risk of tonsillar regrowth. After TE, success rates of 90%^{17,18} compared to 70–93% for TO have been reported.^{6,14,19–21} Re-growth of tonsillar tissue has a broad range of 0–26%⁶ after TO and few studies report secondary surgery rates in adults.⁸ This lack of data highlights the need for more research on this specific topic. The majority of TO patients who were still not free of symptoms in this study chose a wait-and-see policy, while only 7.5% of the total patient group needed revision TO. These results differ from the previously published results by Datema et al.³, in which 20–25% of patients underwent a second laser session. Krespi and Kizhner¹⁴ describes a second laser session of 16% in 500 reviewed patients with follow-up rates between 1–8 years. This difference in outcomes could reflect an improved TO technique over the years, resulting in less severe complaints after one laser session which could warrant a conservative policy. Another possible factor of influence is the power setting of the laser, which is currently 25 W instead of 18 W, possibly resulting in a more extensive evaporation.¹⁵

Limitations of the Study

The main limitations of this study are the non-randomized setting and the incomplete follow-up. As a result the current study is prone to bias. The patient group could be biased by highly motivated patients to experience success, after being re-directed especially to our hospital for an intake visit to determine laser TO a suitable treatment option for their complaints. Also, the baseline characteristics for TE and TO patients differed significantly with respect to age, tonsil size, and indication for surgery. First, this difference possibly reflects a surgeons' preference for TE in larger tonsil sizes, considering the higher risk for a second laser session or TE.³ Second, it is well known that older patients experience more pain after TE⁷, which could have been a reason older patients preferred TO. Third, guidelines almost exclusively include recurrent tonsillitis (with a lot of morbidity) as an indication for surgery. Finkelstein et al.²¹ and Krespi and Kizhner demonstrated TO a good solution for foetid chronic tonsillitis caused by tonsilloliths.¹⁴ As a result of this finding, tonsillolithiasis was treated predominantly by TO. We, however, believe the study population to be representative for the general patient population presenting with tonsillar problems, because the majority of patients were already indicated for surgery

by other ENT-specialists. Most patients chose to be re-directed to our ENT-department for discussing laser treatment. The best- and worst-case analyses are for the reader to interpret. We believe the patient group that could be followed to be representative for the entire study population as the dropout rate is equal in both groups.

Another point that warrants discussion is the time range of follow-up. The conducted 1-year follow-up could be a relatively short period to assess success rates. Windfuhr and Werner showed recurrence of symptoms to be predominantly after 1 year of follow-up.¹⁹ This stresses the need for an extended follow-up period to establish long-term treatment effects with more certainty. It is also recommended to make a strict pre-operative patient selection, because not every patient is suitable to undergo TO.

CONCLUSION

Total resolution of complaints after CO₂-laser tonsillotomy is 72.5% after one laser session. In another 20% of patients a significant improvement is noticed, with only minor complaints left. No adequate improvement of complaints is seen in 7.5% of patients and a second laser session or tonsillectomy is needed. When indicating a patient for tonsil surgery this has to be kept in mind. The success rate of cold dissection tonsillectomy in this study is 97.2%. Tonsillotomy is associated with a significant shorter time to resumption of normal activities and comes with less post-operative pain compared to dissection tonsillectomy. Both types of surgery bring high overall satisfaction in the short-term as well as after 1 year of follow-up. We advise a strict patient selection before TO is performed: our study group exists mainly of patients suffering from chronic recurrent tonsillitis or tonsilloliths with a tonsil size I or II according to the Friedman classification. Long-term follow-up studies should be conducted for further evaluation of the clinical value of CO₂-lasertonsillotomy for tonsil related complaints.

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DISCLOSURE STATEMENT

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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APPENDIX: QUESTIONNAIRE USED FOR FOLLOW-UP AFTER TONSIL SURGERY

Questions for 2-Week Follow-Up:

1. Do you work in an environment with children?
2. How intense was your pain?*
3. How many days did you use analgesic drugs?
4. Describe the type(s) of oral analgesics used.
5. After how many days was it possible to resume daily activities?
6. After how many days did you feel completely recovered?
7. Did you visit a GP with complaints related to surgery?
8. If yes, what were your complaints, and was any action needed?
9. Did you visit the First Aid department with complaints related to surgery?
10. If yes, what were your complaints, and was any action needed?
11. Did you receive antibiotics due to a post-operative infection?
12. Would you undergo the same operation again?
13. How satisfied are you in terms of recovery and pain post-operatively?*

*Questions 2 and 13 were based on a Visual Analogue Scale, ranging from 0–10.

Questions for 6-Month and 1-Year Follow-Up:

1. Are you free of the initial complaints?
2. If not, what are your current complaints?
3. For those who had tonsillotomy: how many laser sessions did you have?
4. For those who had tonsillotomy: did you subsequently undergo a tonsillectomy?
5. Would you undergo the same surgery again?
6. How satisfied are you in terms of relief of symptoms?*

*Question 6 was based on a Visual Analogue Scale, ranging from 0–10.