

Traditional Tonsillectomy Compared With Bipolar Radiofrequency Thermal Ablation Tonsillectomy in Adults

A Pilot Study

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Objectives: To assess the morbidity and efficacy of bipolar radiofrequency thermal ablation tonsillectomy and compare it with traditional cold dissection tonsillectomy with diathermy hemostasis.

Design: Prospective, randomized, single-blinded, controlled clinical study.

Setting: Helsinki University Central Hospital, Department of Otorhinolaryngology–Head & Neck Surgery, Helsinki, Finland.

Patients: Forty healthy volunteer patients aged 18 to 65 years admitted for elective tonsillectomy with recurrent or chronic tonsillitis, obstructive tonsillar hypertrophy, or history of quinsy. Two patients were excluded from the study and 1 patient cancelled the operation.

Interventions: Nineteen patients underwent a traditional cold dissection tonsillectomy with diathermy hemostasis, and 18 patients underwent a bipolar radiofrequency thermal ablation tonsillectomy. There was no intergroup difference in age, sex, weight, and indications for tonsillectomy. The subjects were not informed of the type of procedure

until the telephone interview 3 weeks after the operation.

Main Outcome Measures: Operating time and intraoperative blood loss; need for anesthetics during the operation; different recovery indicators in the recovery room (ie, duration and medications administered), surgical ward (ie, medications administered, use of corticosteroids, general condition, and status of the uvula on the first postoperative day), and in the 2 weeks following surgery (ie, visual analog scale scores on 6 symptoms, medications needed, the day patients returned to work, use of antibiotics, and retreatment acceptance); and complications and certain laboratory parameters.

Results: There was a statistically significant but clinically insignificant difference in operating time and intraoperative blood loss in favor of the traditional tonsillectomy group. The other outcome measures showed no statistically significant differences.

Conclusion: Bipolar radiofrequency thermal ablation and traditional tonsillectomy were associated with similar postoperative morbidity.

Arch Otolaryngol Head Neck Surg. 2001;127:1106-1112

TONSILLECTOMY is one of the most common surgical procedures performed worldwide. Over the years, various techniques and instruments have evolved to accomplish this operation and have a long history; in fact, the first description of tonsillary removal as a medical procedure is from the first century AD.¹

There is still controversy over which is the optimal technique of tonsillectomy with the lowest morbidity rates. The described techniques are blunt dissection, guillotine excision, cryosurgery, monopolar and bipolar diathermy dissection, suction diathermy dissection, bipolar scissor dissection, microscopic bipolar diathermy dissection, ultrasonic removal, and laser dissection.²⁻¹⁰ A few centers perform guillotine excisions, and tonsillotomies are also performed for certain indications.¹¹

All the techniques have certain advantages and disadvantages. Any improvement of this procedure should decrease operating time, blood loss, postoperative hemorrhage, and particularly the postoperative morbidity. With the growing interest in day-case surgery, quick techniques with rapid recovery are favored.

Unlike most operative procedures, which are closed primarily, tonsillectomy produces an open wound that heals by secondary intention. The major postoperative morbidity problems are pain and delayed hemorrhage. The pain is the result of disruption of mucosa and glossopharyngeal and/or vagal nerve fibers followed by inflammation and spasm of the pharyngeal muscles that leads to ischemia and a protracted cycle of pain; it does not completely subside until the muscle becomes covered with mucosa 14 to 21 days after sur-

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PATIENTS, MATERIALS, AND METHODS

This study was prospective, randomized, and single blinded. The study protocol was reviewed and approved by the research ethical committee of the Department of Otorhinolaryngology–Head & Neck Surgery, Helsinki University Central Hospital, Helsinki, Finland. Written informed consent was obtained from all patients. Forty patients aged 18 to 65 years admitted for elective tonsillectomy at the ENT unit of Helsinki University Central Hospital entered the study. The indications for tonsillectomy were recurrent infections, chronic infection, airway obstruction, or history of quinsy. Exclusion criteria included patients with bleeding disorders and any significant chronic illness that would interfere with expected recovery. The electrosurgery system was also contraindicated in patients with pacemakers or other electronic device implants. Each patient was randomly assigned to either the TEtrad or TErfta group by the surgeon's (L.B.) picking a card from a pack of cards. None of the nursing staff taking care of the patient was aware of the group in which the patient was randomized, and the subjects were not informed of the type of procedure until the telephone interview 3 weeks after the operation. The first author (L.B.) did all the procedures, and the same anesthesiologist (M.P.) administered the anesthesia.

A standardized anesthetic technique was used in all patients. The preoperative inquiry was based on a questionnaire completed by the patient. Premedication, if requested by the patient, consisted of 10 mg of oral diazepam. After 2 µg/kg of intravenous fentanyl citrate was administered, anesthesia was induced with an injection of 10 mg/kg of propofol, and 3% isoflurane in oxygen was administered by endotracheal intubation without neuromuscular block. Prior to the start of the tonsillectomy, an additional dose of 1 µg/kg of fentanyl citrate was administered. Anesthesia was maintained with 65% nitrous oxide in oxygen and isoflurane in necessary concentrations (1–2 minimum alveolar concentration). An additional dose of

fentanyl was given, if necessary, according to autonomous nervous system signs (eg, a sudden increase in heart rate or blood pressure and reduction of the plethysmographic pulse amplitude). In the recovery room, 0.05 mg/kg of intravenous oxycodone was administered to relieve immediate postoperative pain, and a dose of 0.1 mg/kg of intramuscular oxycodone was allowed in the surgical ward for intractable pain. The numbers of required analgesic doses were used to differentiate the patients between the groups.

The patients were prepared in accordance with our standardized guidelines for tonsillectomy in both groups. Routine prophylactic antibiotic agents were not prescribed. Traditional tonsillectomy was initiated by an incision overlaying the superior pole of the tonsil. The dissection proceeded along the tonsillar fossa in the peritonsillar plane keeping as close to the tonsil capsule as possible. Hemostasis was achieved by the application of pressure with packs, and persistent bleeding was controlled by a bipolar diathermy coagulation of vessels. The bipolar ENTec Coblator Plasma Surgery System and ENTec Plasma Scalpel wand (ArthroCare Corporation) were used in the TErfta technique. The wand comprises 5 active electrodes located at the distal end of the tip with the exposed portion of the shaft acting as the return electrode just proximal to the active electrodes. Cooled saline was connected to the wand and set to a flow rate of 1 to 3 drops per second through the saline delivery channel. A different suction line was used. The power was set to levels 5 to 7 (192–260 Vrms) during the ablation, and in case of bleeding the coagulation mode was applied. The Coblation tonsillectomy proceeded slowly along the capsular plane. If there was more bleeding or if the wand did not seal the vessel within 5 seconds, the point diathermy coagulation was applied. In both groups, the tonsillar beds were irrigated with water to localize smaller bleeding vessels.

The time taken to perform the operation was measured from the first incision to the removal of the mouth gag. The intraoperative blood loss was measured by volume of suction aspirate. The need for anesthetics during the operation, the time spent in the recovery room, and the need for pain medications in the recovery room were recorded.

Continued on next page

gery. The postoperative delayed hemorrhage is due to secondary infection of the tonsillar fossa resulting in disruption of vessels and bleeding.¹²

Monopolar radiofrequency thermal ablation (RFTA) of soft tissues has been studied extensively by specialists in cardiology,¹³ neurosurgery,¹⁴ urology,¹⁵ and oncology.¹⁶ It has demonstrated acceptable efficacy, safety, and reproducibility of treatment results. A precise controllable lesion characterizes the RFTA method. The coagulation necrosis effect of monopolar radiofrequency energy is also effective, safe, and associated with low morbidity in treatments of the soft palate,¹⁷ nasal turbinates,¹⁸ and the tongue base.¹⁹

The bipolar ENTec Coblator Plasma Surgery System (ArthroCare Corporation, Sunnyvale, Calif) functions with a voltage range of 96– to 312–voltage root-mean-square value (Vrms) at 100 kHz. The molecular disintegration achieved by the gentle heating of tissue breaks molecular bonds with improved precision and control at a low temperature of 60°C to 100°C, with minimal thermal damage to the surrounding tissue while simultaneously coagulating blood vessels.

The ENTec Coblator Plasma Surgery System has a Food and Drug Administration approval for “ablation and coagulation of soft tissue in ENT [ear, nose, and throat] surgery including head, neck, oral and sinus surgery.”²⁰ One of the suggested applications is for the entire removal of the tonsil (tonsillectomy) with the bipolar radiofrequency equipment. This differs from Coblation (cold + ablation) (ArthroCare Corporation) of the tonsils or Coblation tonsillotomy, which leaves the tonsillar capsule intact.

Our aim was to assess the morbidity and efficacy of bipolar RFTA (Coblation) tonsillectomy (TErfta) and compare it with traditional tonsillectomy (TEtrad) in subjects scheduled for elective tonsillectomy. For this purpose we evaluated several specific recovery rate indicators related to the procedure.

RESULTS

Forty patients entered the study; 2 were subsequently excluded: 1 developed severe postoperative pneumonia,

In the surgical ward we registered the need for treatment with pain medications and corticosteroids during the first postoperative day and recovery status the morning after surgery, including patients' general condition as graded 1 to 4 (grade 1, no problems; grade 2, a minor problem with pain, nausea, or difficulty swallowing, but normal hospital discharge; grade 3, left the hospital in the evening of the postoperative day because of pain, nausea, or difficulty swallowing; and grade 4, stayed in the hospital an additional day because of pain, nausea, or difficulty swallowing) and the swelling of uvula as graded 1 to 3 (grade 1, no swelling; grade 2, the tip of the uvula is swollen but not lying on the tongue base; and grade 3, the tip of the uvula is swollen and lying on the tongue base).

We measured C-reactive protein values, leukocyte counts, and erythrocyte sedimentation rates before surgery and 1 day and 2 weeks postsurgery to evaluate the inflammatory host response induced by the procedure.

The use of a visual analog scale (VAS) has been firmly suggested as a reliable method for reporting pain and other symptoms.²¹ Patients were asked to grade their symptoms with a VAS and to start the recording on the evening after surgery. They drew a vertical line crossing a 100-mm line where 0 indicated no symptoms and 100, very intense symptoms. The symptoms evaluated were pain, a swelling sensation of the soft palate, difficulty drinking, difficulty eating, difficulty opening the mouth, and difficulty speaking. On discharge, all patients were given a questionnaire to be completed during the next 2 weeks; they were also asked to keep a diary of the doses and frequency of pain medication use.

The patients were prescribed analgesia as required (100 mg of ketoprofen and a combination of 500 mg of acetaminophen and 30 mg of codeine phosphate). In the analysis of the amount of pain medications used, we converted the milligrams into doses related to the maximum amount of the medication recommended per day (for ketoprofen at 300 mg/d, 1 dose=100 mg; ibuprofen at 3200 mg/d, 1 dose=800 mg; acetosalicylic acid at 3000 mg/d, 1 dose=1000 mg; combination of 500 mg of acetaminophen and 30 mg of codeine phosphate in 8 tablets/d, 1 dose=1 tablet; and

tramadol hydrochloride in 8 tablets/d, 1 dose=1 tablet). The total number of doses taken by group A (those treated with ketoprofen, ibuprofen, and acetosalicylic acid) and group B (those treated with acetaminophen-codeine and tramadol) were calculated in 3 different periods: 3 days, 7 days, and 2 weeks.

Three weeks after surgery, the first author (L.B.) conducted a telephone interview with each patient. All the bleeding episodes were evaluated according to the following: (1) by report only; (2) witnessed (patients were observed and treated conservatively); (3) treated with local care; and (4) controlled in the operating room. Primary bleeding occurred during and secondary bleeding after the first 24 hours postoperatively. We also asked about any eventual antibiotic requirement, the day each patient returned to work, and each patient's retreatment acceptance.

We chose a clinically significant difference of 20 mm on the VAS, which is considered reasonable. A sample size of 15 patients per group was calculated to reveal a clinically significant difference of 20 mm on the VAS with a probability of 80% in our power calculations.

The Friedman test was used to determine whether changes from the baseline to the final measurements in the laboratory parameters were significant. Pairwise multiple comparison procedures with the Dunnett method were performed if the change was significant. Nonrepeated, nonparametric data were compared using the Mann-Whitney test (MWT). For the VAS scores, area under the curve (AUC) values were calculated from the time points of postoperative days 1 through 14 to evaluate the total discomfort of the 14 postoperative days. Day-by-day calculations were made using the MWT. A learning curve of the new TERfta method was drawn to evaluate the influence of experience on operating time and intraoperative blood loss. Correlations were calculated using nonparametric Spearman rank correlation.

Results are expressed as medians and range, and they were generated using a computerized statistical package (SPSS version 9.0 and Sigma Stat version 3.0; SPSS Inc, Chicago, Ill). We considered $P < .05$ to be statistically significant.

which influenced her recovery rates significantly (TERfta group); the other had only the right tonsil removed because the left one had been removed previously (TEtrad group). One patient cancelled the operation (TERfta group). Thus, 37 patients were available for the analysis, 19 in the TEtrad group and 18 in the TERfta group. Thirty-six patients completed the VAS analyses and the analgesic consumption questionnaires.

The groups were similar for the demographic and clinical parameters of interest. No intergroup difference was noted in age ($P = .39$), sex ($P = .71$), weight ($P = .48$), and indications for tonsillectomy ($P = .21$) (MWT, **Table**). There was a statistically significant difference in operating time and intraoperative blood loss in favor of the TEtrad group (**Figure 1**).

The study groups differed neither in the need for additional intraoperative fentanyl doses nor in the need for postoperative oxycodone doses. The median dose of intravenous oxycodone in the recovery room was 4 mg (range, 0-16 mg) for the TEtrad group vs 7 mg (range, 0-12 mg) for the TERfta group ($P = .39$, MWT). For intramuscular oxycodone in the surgical ward, the median dose was

7 mg (range, 0-21 mg) for the TEtrad group vs 0 mg (range, 0-16 mg) for the TERfta group ($P = .99$, MWT). To achieve hemostasis, the vessels of the upper and lower part of the tonsillary bed were more or less coagulated by bipolar diathermy in the TERfta group.

The median time spent in the recovery room was 85 minutes (range, 60-185 minutes) for the TEtrad group vs 82.5 minutes (range, 60-210 minutes) for the TERfta group ($P = .95$, MWT) and the use of pain medications in the surgical ward showed no statistically significant difference: the median dose of ketoprofen was 250 mg (range, 0-300 mg) for the TEtrad group vs 200 mg (range, 0-200 mg) for the TERfta group ($P = .23$, MWT), and for the combination of acetaminophen (500 mg) and codeine phosphate (30 mg), the median dose was 3 tablets (range, 1-6 tablets) for the TEtrad group vs 2 tablets (range, 1-5 tablets) for the TERfta group ($P = .73$, MWT). Two patients in both treatment groups needed therapy with corticosteroids during the first 24 hours because of an extreme swelling sensation of the soft palate and an edematous uvula found in the clinical examination ($P = .99$, MWT). There were no statistically significant dif-

Demographic Data of the TEtrad and TErfta Groups*

	TEtrad	TErfta
Median (range) age, y	31.0 (20-50)	29.5 (19-63)
Sex, M/F	7/12	8/10
Median (range) weight, kg	69 (52-116)	74 (54-113)
Chronic and/or recurrent tonsillitis	14	14
History of quinsy	5	4

*TEtrad indicates traditional tonsillectomy; TErfta, bipolar radiofrequency thermal ablation (Coblation [Arthrocare Corporation, Sunnyvale, Calif]) tonsillectomy. Unless otherwise indicated, data are number of patients.

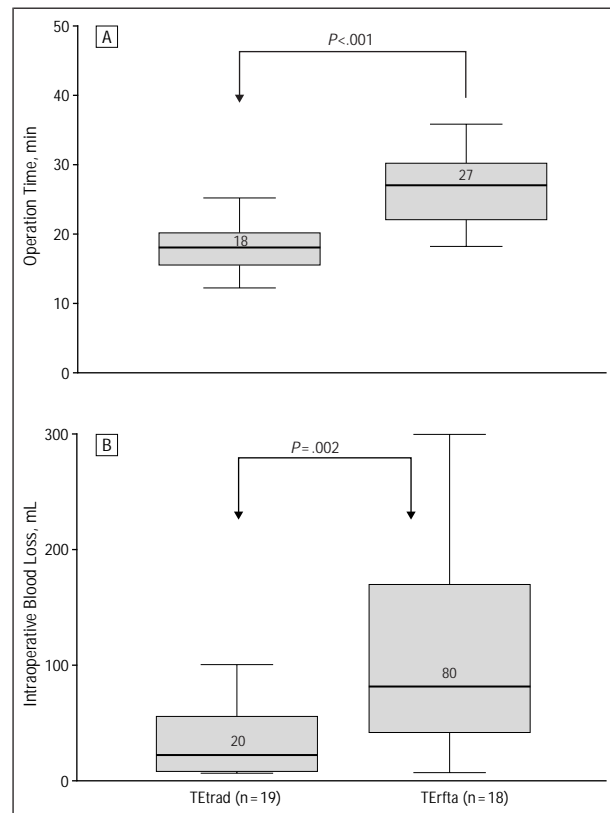


Figure 1. The operation time (A) and intraoperative blood loss (B) during elective tonsillectomy with traditional tonsillectomy (TEtrad) and bipolar radiofrequency thermal ablation (Coblation) tonsillectomy (TErfta) techniques presented as a box plot. There was a statistically significant but clinically insignificant difference between the groups (Mann-Whitney test). The black line indicates median value; the shaded boxes, interquartile range (25% and 75% percentiles); and error bars, range.

ferences between the groups in the occurrence and management of primary and secondary bleeding ($P = .56$ and $.82$, respectively, MWT). In 2 (5%) of 37 patients the hemostasis was performed in the operating room, and in 7 (19%) of 37 patients the bleeding was managed locally (**Figure 2**). Regarding the general condition of the patients and the swelling of the uvula the morning after surgery, the use of antibiotics and the patients' retreatment acceptance showed no statistically significant differences (**Figure 3**). The patients in both groups returned to work in a median time of 14 days (range, 14-27 days [TEtrad group] vs 14-21 days [TErfta group]; $P = .92$, MWT).

The VAS questionnaires on the different symptoms showed no statistically significant differences either in

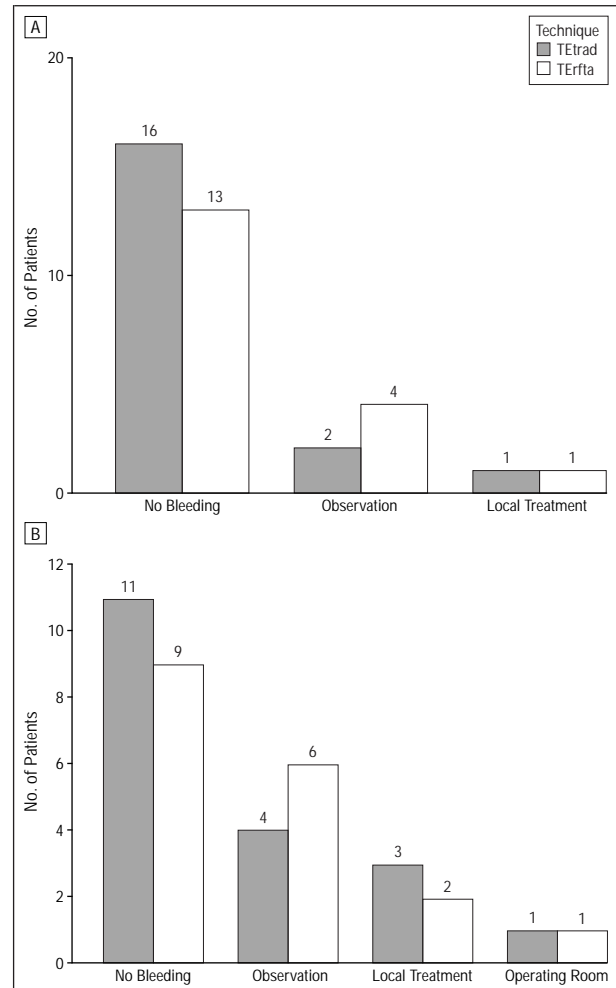


Figure 2. The occurrence and management technique of primary (A) and secondary (B) bleeding after elective tonsillectomy with the traditional tonsillectomy (TEtrad) and bipolar radiofrequency thermal ablation (Coblation) tonsillectomy (TErfta) techniques. Primary bleeding occurred during and secondary bleeding after the first 24 hours postoperatively.

the day-by-day analysis ($P > .05$, MWT) or in the whole postoperative period analysis ($P > .05$ for AUC, MWT; **Figure 4**). The use of pain medications during the postoperative periods of 3 days, 7 days, and 2 weeks did not show statistically significant differences between the groups ($P > .05$, MWT; **Figure 5**).

The laboratory parameters showed a statistically significant change from the baseline to the final measurements, suggesting that an inflammatory host response is induced by the procedure ($P < .001$, Friedman test). According to the pairwise multiple comparison procedures with the Dunnnett method, the change in the erythrocyte sedimentation rate was statistically significant on the first postoperative day and 2 weeks after the operation with both techniques. A statistically significant change occurred in C-reactive protein values for both techniques in the first postoperative day, but in the TErfta group this statistically significant change also occurred 2 weeks postsurgery. Thus, the only difference between the groups was a statistically significant C-reactive protein value change in the TErfta group but not in the TEtrad group (**Figure 6**).

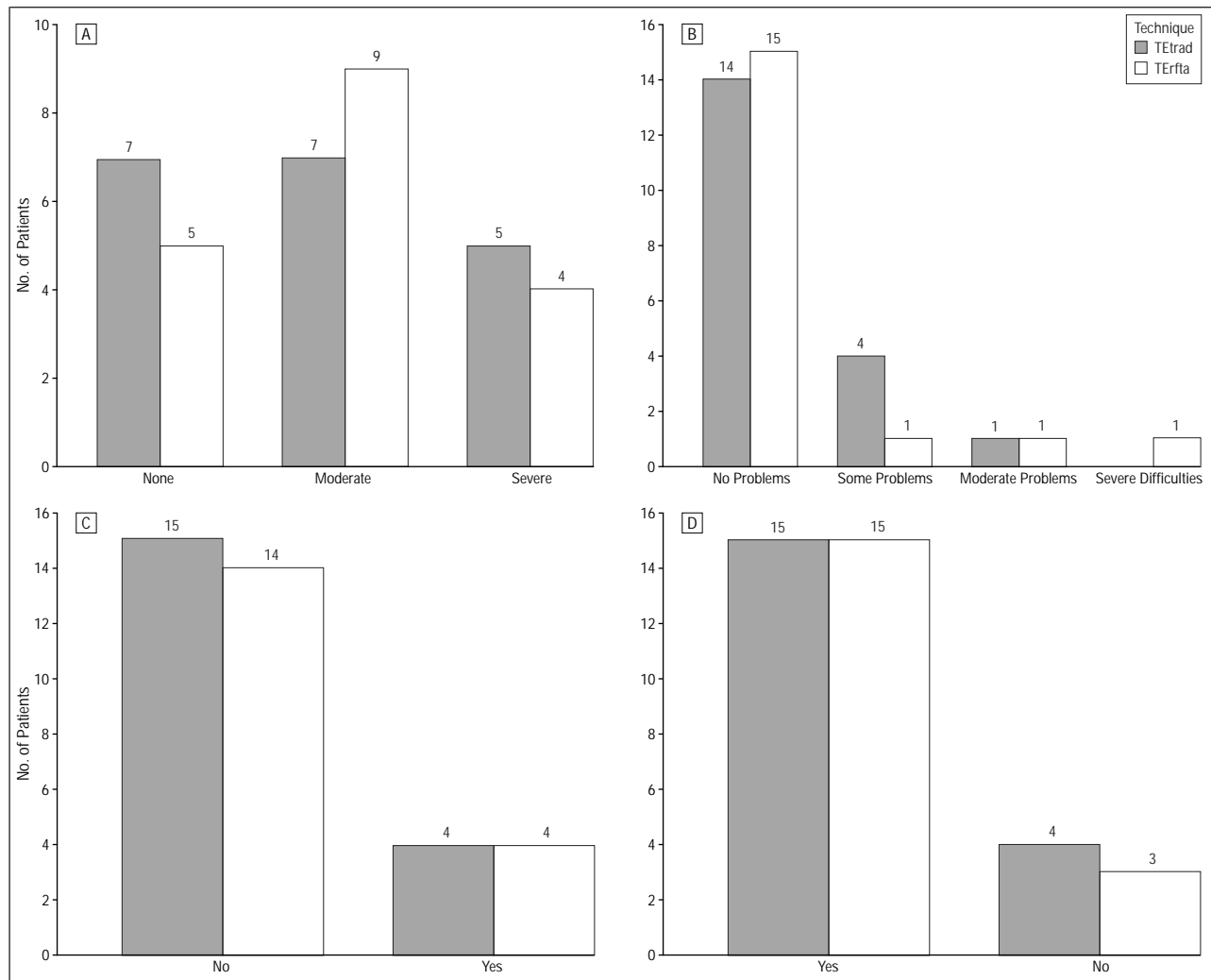


Figure 3. The 2 operative techniques, traditional tonsillectomy (TETrad) and bipolar radiofrequency thermal ablation (Coblation) tonsillectomy (TErfta), compared in relation to 3 recovery parameters (A, uvula swelling; B, general condition; and C, need for antibiotics) following tonsillectomy and the retreatment acceptance (D).

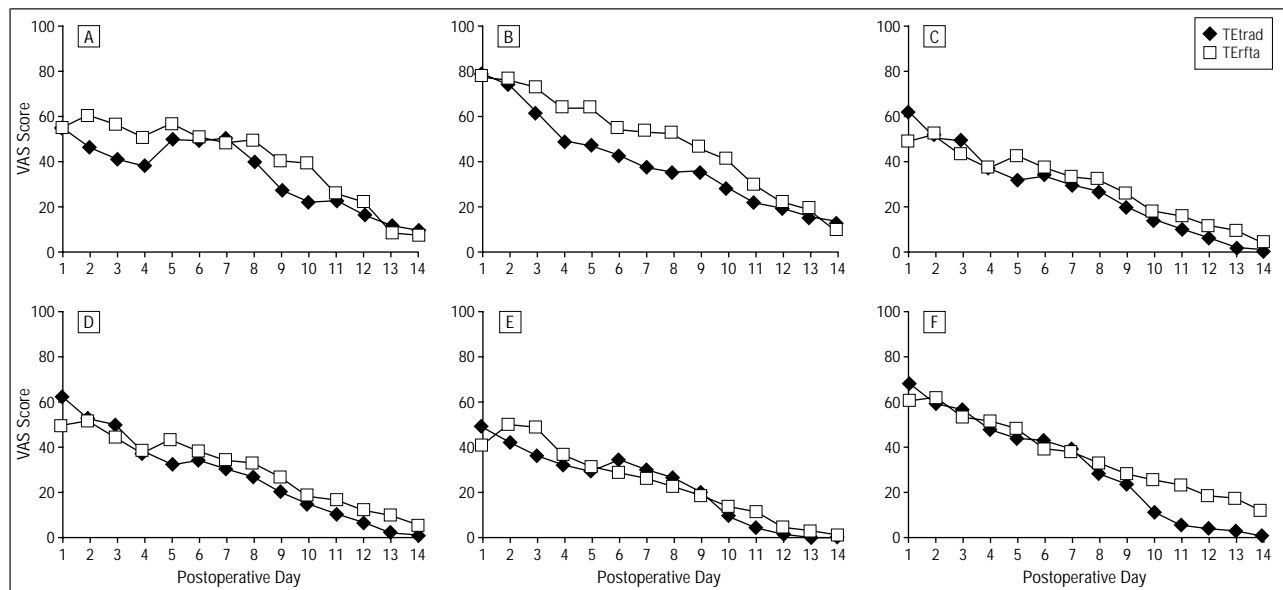


Figure 4. The visual analog scale (VAS) scores obtained daily for 2 weeks on different symptoms (A, pain; B, swelling sensation; C, difficulty drinking; D, difficulty eating; E, difficult opening the mouth; and F, difficulty speaking) following elective tonsillectomy with the traditional tonsillectomy (TETrad) and bipolar radiofrequency thermal ablation (Coblation) tonsillectomy (TErfta) techniques. The data points represent the median value for the group on each day.

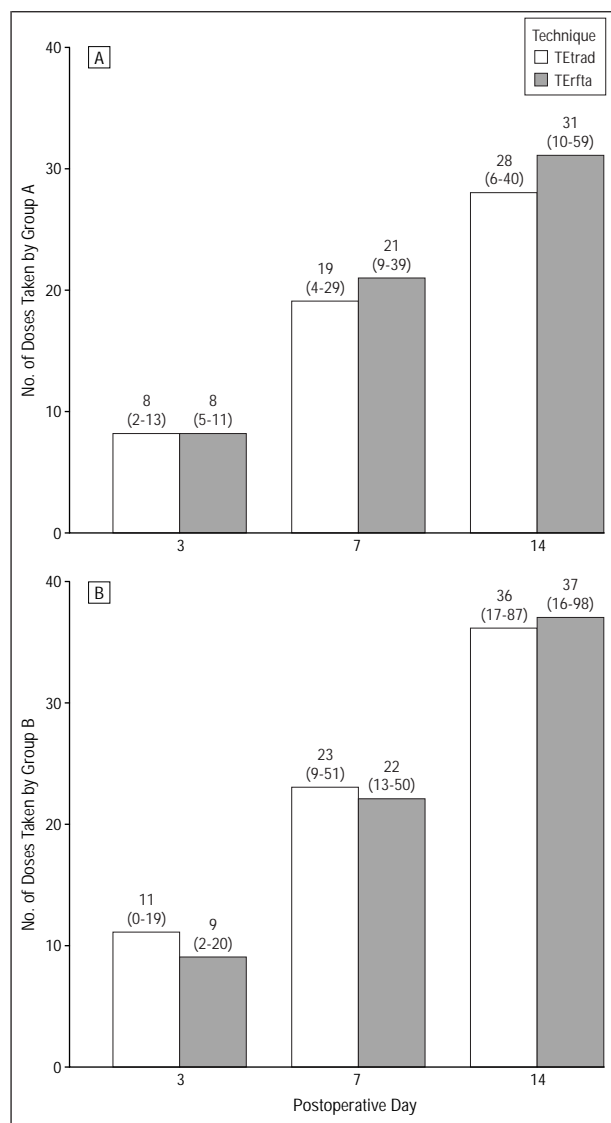


Figure 5. The median (range) number of doses of pain medication taken by group A (A, those treated with ketoprofen, ibuprofen, and acetosalicylic acid) and group B (B, those treated with acetaminophen–codeine phosphate and tramadol hydrochloride) following elective tonsillectomy with the traditional tonsillectomy (TETrad) and bipolar radiofrequency thermal ablation (Coblation) tonsillectomy (TERfta) techniques measured at 3 different times. There were no statistically significant differences between the groups (Mann-Whitney test).

The variations on the learning curves in the TERfta group on operating time and intraoperative blood loss diminished, but they showed no statistically significant correlations with the number of procedures performed: nonparametric Spearman rank correlation for number vs operating time was $r=0.185$ ($P=.46$) and for number vs intraoperative bleeding, $r=-0.099$ ($P=.70$; **Figure 7**).

COMMENT

The reduction of posttonsillectomy morbidity is important, not only for patient comfort, but also because reducing pain improves oral intake, reducing the risk of dehydration, infection, and postsurgery hemorrhage. Electrosurgical instruments and lasers all achieve cutting and simultaneous

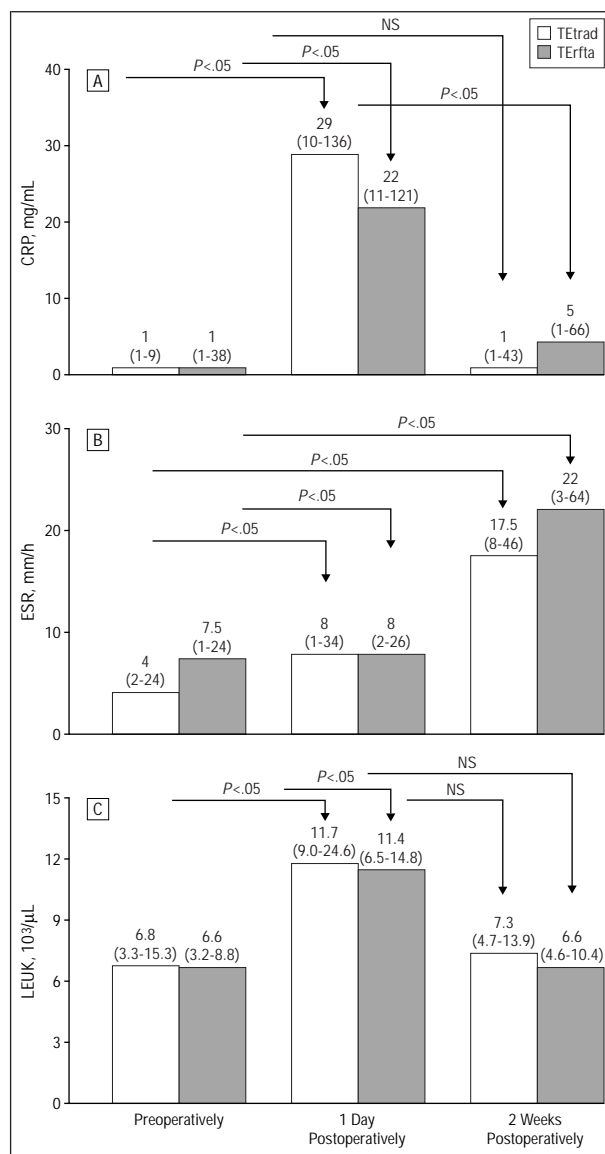


Figure 6. Median (range) for C-reactive protein (CRP) values, A; leukocyte count (LEUK), B; and erythrocyte sedimentation rate (ESR), C before surgery, 1 day after surgery, and 2 weeks after surgery. NS indicates not significant (P value calculations performed with a pairwise multiple comparison procedure with the Dunnett method).

hemostasis by sealing the blood vessel lumina by virtue of tissue heating. Several studies support the hypothesis that the extent of diathermy used in tonsillectomy has a direct influence on the delayed postoperative morbidity and healing of the mucosal wounds.²² The degree of pain must be related to the degree of soft tissue damage.

Radiofrequency current applied to surgical tools was used to generate a plasma field to remove tissue volume without heat as the primary means. This technology (Coblation) is fundamentally different from electrocautery and monopolar thermal radiofrequency ablation. Bipolar administration of radiofrequency current results in less electricity being leaked to distant tissues, theoretically decreasing the morbidity following tonsillectomy.

Questionnaires were used extensively in this investigation to gather data on the subjective variables such as pain, swelling sensation of the soft palate, swallow-

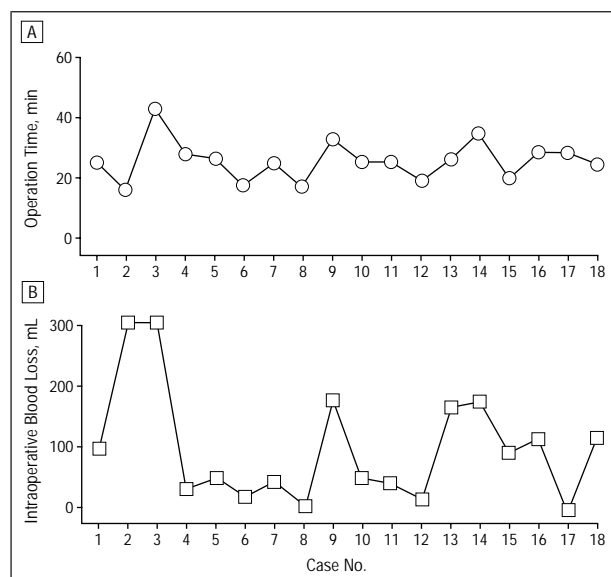


Figure 7. Effects of learning curves of the new bipolar radiofrequency thermal ablation tonsillectomy (n=18) on operating time (A) and intraoperative blood loss (B).

ing problems, and difficulties opening the mouth and speaking. Pain is moderate or intense after tonsillectomy and requires treatment with pain medication for up to 2 weeks, even if laser equipment is used.

Our aim was to evaluate several different postoperative symptoms in our VAS questionnaires, and we thought that it would be difficult to evaluate differences between sides. Therefore we chose to randomize the patients into 2 treatment groups.

Our study did not show a statistically significant difference in postoperative morbidity between the 2 techniques, TEtrad and TERfta. Differences in intraoperative blood loss and operating time were statistically significant but clinically insignificant in otherwise healthy adults (median time, 18 minutes for the TEtrad group [range, 12-33 minutes] and 27 minutes for the TERfta group [range, 18-43 minutes]; median blood loss, 20 mL for the TEtrad group [range, 5-100 mL] and 80 mL for the TERfta group [range, 5-300 mL]).

Although there were no statistically significant differences between the groups in the occurrences of primary and secondary bleeding, their frequencies were higher than usual in our practice. This might have been a function of the study setting (ie, the patients were advised to contact the ENT ward immediately when there were signs of bleeding) or chance.

During the operation, the need for diathermy was common in the TERfta group, indicating there might be deeper thermal damage to the surrounding tissue. Thus, both groups sustained the same thermal injury at least in portions of the tonsillar beds, and the possible benefit of TERfta was eliminated by the use of cautery. This can affect the postoperative morbidity in a significant manner. In 1 patient in the TERfta group, the peritonsillar plane was partly obliterated by scar tissue, and sharp scissor removal was therefore required. When learning a new technique, these procedural flaws may be corrected; however, this was not shown in this pilot study

with small groups. Apparently the Coblation technique does not positively affect the factors that cause postoperative pain. The laboratory parameters showed minor differences in the inflammatory host response in favor of the TEtrad group, but its clinical significance cannot be evaluated in this study.

CONCLUSIONS

Patients with elective TERfta did not show any significant advantages compared with the traditional technique in this study. Both techniques were safe and resulted in similar postoperative morbidity. The controversy is not resolved over which tonsillectomy technique is preferable and which has the lowest morbidity rates.

Accepted for publication March 27, 2001.

This study was supported by the Helsinki University Central Hospital Funds.

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