LARYNGOLOGY

Tissue welding tonsillectomy provides an enhanced recovery compared to that after monopolar electrocautery technique in adults: a prospective randomized clinical trial

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Abstract We have compared tonsillectomy (TE) with tissue welding (TW) technology using a specially designed forceps versus conventional monopolar electrocautery to evaluate whether this new technology may improve recovery after TE. This was a single-blind, randomized clinical trial with two parallel groups. Sixty healthy adult day-surgery patients were allocated into the TW-TE group ($n = 31$) and the monopolar electrocautery-TE group ($n = 29$). We recorded intraoperative events and short- and long-term recovery for 2 weeks postoperatively. The patients and study nurses evaluating patients during recovery were blinded to the operation method used. All patients in the TW-TE group completed the study as per protocol, but in the monopolar electrocautery-TE group, there was one drop-out in the hospital and another after discharge. There was no difference in the perioperative parameters and early recovery between the two groups. After discharge, recovery was significantly faster in the TW group than in the monopolar group: (1) the duration of postoperative pain was 2 days shorter, and (2) activities of normal daily living were less affected, and (3) the need for hospital contacts after discharge, and (4) the incidence of postoperative bleeding was less in the TW group than that in the monopolar group. No patients in the TW group developed secondary bleeding versus three patients in the monopolar group requiring electrocautery to control

bleeding. In conclusion; our results indicate that, TW technique may provide reduced pain, faster recovery, and fewer complications compared to electrocautery TE.

Introduction

Tonsillectomy (TE) is one of the most common surgical procedures; in Finland with a population of 5,000,000 about 14,000 TE and in the United States 300,000 TE are performed each year [1]. TE causes significant morbidity, with severe postoperative pain often lasting up to 10–14 days, and some patients may require sick leave up to 3 weeks [2]. In order to reduce morbidity and enhance recovery after TE, several techniques have been developed [3]. It is supposed that, cold dissection and radiofrequency may provide a more rapid recovery than electrocautery [4, 5]. However, none of the commonly used techniques has been shown to be superior, and thus, there is still an obvious need for a rapid and safe method for TE [5].

Tissue welding (TW) is a new technique for tissue dissection first introduced in gastrointestinal surgery [6]. The need to dissect the gut with minimal tissue damage to gain rapid and safe healing led to the introduction of TW. Recently, TW technology (with a low voltage direct current power device (UPS) and specially designed forceps (ENTceps); Starion Instruments Corp., Sunnyvale, USA) has been applied to TE [7–9]. The principle of TW is simple. The procedure is based on a controlled direct current heating of a 0.4 mm metal wire embedded in the tip of surgical forceps. The other tip of the forceps consists of

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silicone isolation, which works as a counterpart to forceps compression. The heating and welding effect are limited to a narrow area of 0.4 mm. This is enough to seal most vessels in the tonsillar capsule. The same wire gives a short high thermal cutting effect in the second phase, which dissects tissue. The procedure is performed in two phases. The first one is TW, which seals the blood vessels, and the second phase is a short cutting action, which dissects tissue. The result is, as a rule, a clean dissection surface with minimal thermal damage without bleeding or charring. Some large arteries require additional hemostasis either with the same forceps or separate bipolar electrocautery forceps.

The TW technique is reported to reduce postoperative pain and bleeding after TE, and thus, enhance patients' recovery [7–9]. To evaluate this hypothesis, we conducted a single-blinded controlled clinical trial comparing this novel method, TW-TE, with the present standard in our clinic, monopolar electrosurgery-TE, in adult patients scheduled for day surgery.

Materials and methods

This prospective, randomized, single-blinded clinical study with two parallel groups was approved by the ethics committee of Päijät-Häme Central Hospital, Lahti, Finland. All patients were informed and provided written consent according to the principles presented in the Declaration of Helsinki. In our clinic, we have an established clinical study experience with postoperative recovery and pain control studies after TE [10].

We enrolled 60 otherwise healthy, American Society of Anesthesiologists physical status group 1 or 2 consecutive adult day-surgery patients. Patients were randomly allocated into the TW group ($n = 31$) and the monopolar group ($n = 29$). We excluded patients with acute infection, age under 16 or over 65 years, bronchial asthma, cardiopulmonary disease, kidney or liver dysfunction, or bleeding disorder.

Patients' were allocated by computer and the sealed opaque envelope method was used to ensure blinding. Patients in the TW group had their tonsils removed with ENTceps with UPS. In the monopolar group, a conventional monopolar electrocautery was used. Three surgeons with an extensive previous experience using an electrodissection technique and 5–10 cases with TW-TE performed the operations. The patients and study nurses recording the outcome were blinded to the patients allocation and the surgical method used.

In the TW group, the Starion ENTceps and UPS were used with power setting 3. In the first phase of the procedure, hemostasis was performed with the left pedal for 5 s

followed by rapid dissection with the right pedal. Hemostasis was completed with bipolar cautery and/or gauze compression as necessary. In the monopolar group, a standard monopolar electrocautery extracapsular surgical technique was used with a 50 W power (Erbotom 450, Erbe Elektromedizin, Tübingen, Germany). This technique uses intense local heat to destroy tissue and cause "obliterative coagulation". The device used for dissection was also used for control of bleeding with gauze compression as necessary.

All patients received standard postoperative pain treatment. Ketoprofen (Ketorin, OrionPharma, Espoo, Finland), a non-steroidal anti-inflammatory analgesic, was given for background analgesia. The first dose of ketoprofen 1 mg kg^{-1} i.v. was given after surgery, and after that, patients were prescribed 100 mg ketoprofen capsules TID for the first five postoperative days, and to be used as needed after postoperative day 5. For rescue analgesia in the hospital, patients were given oxycodone 2 mg i.v. (Oxanest, Leiras, Turku, Finland) if numeric rating pain score (NRPS) at rest was >3/10 and/or dynamic pain during swallowing >5/10. The oxycodone dose was repeated at 15 min intervals until pain had diminished to slight (NRPS at rest ≤3/10 and during swallowing ≤5/10). All doses of rescue analgesics were recorded. No other analgesic medication than fentanyl 2 µg kg^{-1} during anesthesia, ketoprofen 1 mg kg^{-1} i.v. after surgery, and oxycodone for rescue analgesia as required were permitted during the hospital stay. At discharge, the patients were prescribed paracetamol–codeine tablets (500 mg paracetamol–30 mg codeine per tablet; Panacod, sanofi-aventis, Solna, Sweden) to be taken in adjunct with ketoprofen, when required at a maximum of eight tablets in 24 h. Patients were discharged within 10 h after surgery, when they had no pain or slight pain, were able to tolerate clear fluids and soft food, had no bleeding or vomiting, and had no or mild nausea.

The baseline data, perioperative data, and patients recovery at hospital were recorded on standardized forms. The baseline data were recorded during the preoperative visit, and the patients were instructed in the use of pain scale and completion of the follow-up forms. For the surgery, the duration of anesthesia and surgery, and the estimated blood loss were recorded. At the PACU pain at rest, and during swallowing was expressed on an 11-point NRPS with 0 being no pain and 10 being the most possible pain. All doses of rescue analgesic and adverse events, and time to discharge were also recorded.

The patients' recovery after discharge was recorded by the Wisconsin Brief Pain Questionnaire [11]. Eight of these were filled out by the patients at the first eight postoperative mornings and ninth of which was filled by a study nurse during a phone interview at 2 weeks after surgery.

The emphasis of the questions was on pain duration and severity, recovery of activities of normal daily living, and patient satisfaction with the analgesic treatment. Pain was assessed on an 11-point NRPS. The pain interference with normal activities of daily living (drinking, eating, speech, sleep, general activity, mood, relation with other people) was assessed on an 11-point NRS (0 = does not interfere, 10 = total interference). The use of analgesics was reported. All adverse events as well as satisfaction with pain medication were also recorded for each patient.

The primary outcome measure was cessation of dynamic pain during swallowing. The secondary outcome measures were the number of oxycodone doses during the first 4 h after surgery, need for analgesics after discharge, interface of the pain with the activities of daily living, recovery of daily functions, and the incidence of postoperative hemorrhage, and other adverse effects.

Statistics

The sample size calculation was based on our results in adults with monopolar electrocautery-TE. In that study, the mean of pain cessation was 11 days and the standard deviation (SD) 2 days [2]. In order to detect a difference of 2 days in the cessation of significant pain between the two groups at a two-sided significance level of 0.05 with 0.9 study power, 24 patients for both groups should have been enrolled.

Patient characteristics and variables were stored and analyzed with the Statistical Package for Social Sciences (SPSS software version 16.0 for Windows, SPSS Inc., Chicago, USA). Differences according to treatment assignment for categorical variables were assessed with the Pearson χ^2-test and for the continuous and nominal variables with the Mann–Whitney U test, as appropriate. Differences were regarded as statistically significant, if the two-sided P-value was less than 0.05. Data are expressed as number of cases or mean with SD. For main outcome measures, 95% confidence intervals (CI) were calculated.

Results

There were no significant differences in patients' baseline characteristics or surgical data between the two groups (Table 1). There was one drop-out in the monopolar group in hospital and one patient could not be contacted after discharge, but no protocol deviations likely to affect the outcome were noted, thus, leaving 28 patients in the monopolar group for the analysis of early recovery in hospital and 27 patients with data after discharge. There were no drop outs or protocol deviations likely to affect the outcome among the 31 patients in the TW group.

Table 1 Patient baseline characteristics and surgical data

Variable	Monopolar group ($n = 29$)	TW group ($n = 31$)
Gender: men/women	12/17	14/17
ASA I/II	23/6	25/6
Age (years)	28 (11)	26 (8)
Height (cm)	169 (9)	171 (8)
Weight (kg)	74 (22)	73 (17)
Operative diagnosis		
Chronic-recurrent tonsillitis	26	26
Hypertrophia tonsillae	2	1
Status post peritonsillar abscessus	1	4
Operation duration (min)	13 (4)	15 (5)
Surgical blood loss (ml)	11 (14)	18 (36)

Values are mean (SD) or number of cases. *ASA* American Society of Anesthesiologists' Physical Status

Recovery in the hospital

There was no difference between the two groups during early recovery. A total of 27/31 patients in the TW group and 22/28 patients in the monopolar group ($P = 0.26$) required rescue analgesia during the first 4 h postoperatively. The mean (SD) number of oxycodone doses was 2.1 (1.2) in the TW group and 2.1 (1.0) in the monopolar group ($P = 0.83$). Time to the first dose of rescue analgesia was 59 (44) min in the TW group and 49 (43) min in the monopolar group ($P = 0.45$). The pain score at rest, 2.3 (1.9), was significantly higher in the TW group at 2 h after the surgery than that in the monopolar group 1.1 (1.3) (mean difference 1.1, 95% CI of the difference 0.3–2.0, $P = 0.012$). There was no difference between the groups in dynamic pain during the PACU stay.

No cases of primary hemorrhage occurred. In the TW group, five patients developed five non-serious adverse events: nausea and vomiting ($n = 4$) and somnolence ($n = 1$). In the monopolar group, eight patients experienced nine non-serious adverse events: vomiting ($n = 7$), shivering ($n = 1$), and itching ($n = 1$).

Recovery after discharge

There was a significant difference between the two groups in the primary outcome variable. The cessation of dynamic pain during swallowing occurred 2 days (95% CI 0.1–3.6 days) earlier in the TW group than that in the monopolar group ($P = 0.037$). In the TW group, recovery after discharge was significantly shorter, less pain was reported, interference with daily activities was significantly less, and patients' satisfaction was significantly higher compared to the monopolar group (see Fig. 1a, b; Tables 2, 3).
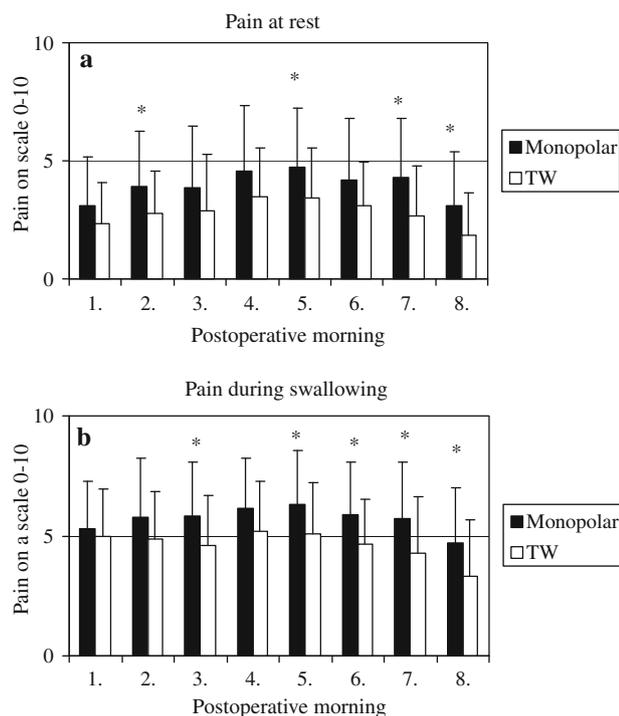
Fig. 1 **a** Pain at rest in the first eight postoperative mornings. Data are mean and SD. *P < 0.05. **b** Pain during swallowing in the first eight postoperative mornings. Data are mean and SD. *P < 0.05

Table 2 Pain interference with daily activities during the first week on an 11-point numeric rating scale

Variable	Monopolar group ($n = 29$)	TW group ($n = 31$)	P-value
Daily activities in general	4.0 (3.1) [4]	2.8 (2.8) [2]	0.11
General activity	4.0 (3.4) [4]	2.0 (2.2) [2]	0.054
Mood	4.0 (3.4) [3]	2.0 (2.2) [1]	0.009
Relations with other people	4.0 (3.4) [3]	2.6 (2.6) [2]	0.07
Drinking	3.2 (2.7) [3]	2.4 (2.3) [2]	0.2
Eating	4.4 (2.7) [5]	3.3 (2.6) [2]	0.1
Speaking	3.4 (2.8) [3]	2.5 (2.4) [2]	0.18
Sleeping	3.0 (2.8) [3]	1.3 (1.9) [1]	0.07

(0 = does not interfere, 10 = total interference). Values are mean (SD) and [median] of the first eight postoperative morning assessments

Table 3 Cessation of pain and recovery of daily activities after tonsillectomy in the two study groups

Variable	Monopolar group ($n = 27$)	TW group ($n = 31$)	P-value
Cessation of pain			
At rest	8.3 (3.6) [9]	7.4 (3.5) [7]	0.32
During swallowing	12.0 (3.4) [14]	10.2 (3.3) [10]	0.037
During speaking	7.3 (4.8) [7]	5.7 (3.8) [7]	0.024
During sleep	7.4 (3.8) [8]	4.4 (3.5) [5]	0.013
Recovery of daily functions			
Drinking	8.2 (3.8) [7]	6.6 (3.7) [7]	0.1
Eating	10.8 (3.7) [10]	9.6 (3.9) [10]	0.24
Sleeping	8.3 (4.4) [8]	5.8 (4.0) [6]	0.03
Normal activities	13.1 (4.5) [14]	11.6 (3.6) [14]	0.19

Values are mean (SD) and [median] on days

At 2 weeks, one patient in the TW group reported mild pain at rest versus four patients in monopolar group ($P = 0.12$). During swallowing, 5/31 patients in the TW group had pain versus 12/27 patients with in the monopolar group ($P = 0.01$). At 2 weeks, 5/31 patients in the TW group versus 12/27 patients in the monopolar group ($P = 0.018$) reported that postoperative pain continued to interfere with activities of normal daily living. The most commonly affected function was eating in the TW group ($n = 4$) and in the monopolar group ($n = 11$), respectively. The mean satisfaction with pain management on the 11-point NRS (0 = total satisfied, 10 = total dissatisfied) was better in the TW group at 1 week (1.5 (1.6)) and at 2 weeks (1.3 (1.7)) compared to that in the monopolar group (3.0 (2.7) at 1 week ($P = 0.01$) and 2.3 (2.2) at 2 weeks ($P = 0.064$).

There was no difference between the two groups in the need for analgesics during the first two postoperative weeks. The mean number of ketoprofen capsules was 23 (7) doses in the TW group and 23 (8) doses in the monopolar group, and the mean of paracetamol–codeine tablets was 32 (12) in the TW group and 38 (21) doses in the monopolar group ($P = 0.18$), respectively.

No serious or unexpected adverse events occurred. A total of 26/31 patients in the TW group developed 51 adverse effects versus 23/27 patients in the monopolar group with 66 adverse effects. The most common adverse effects were constipation ($n = 28$), tiredness ($n = 24$), nausea ($n = 15$), and abdominal pain ($n = 9$). The only significant difference between the groups was noted in the incidence of vomiting: in the TW group 1 patient vomited versus 11 patients with vomiting in the monopolar group ($P = 0.025$).

None in the TW group versus three patients in the monopolar group ($P = 0.086$) developed secondary hemorrhage after discharge requiring electrocautery to stop the bleeding; however, no blood products were required. Two patients in the TW group versus seven patients in the monopolar group ($P = 0.048$) contacted the hospital after the discharge.

Discussion

Karatzias and co-workers [12] introduced TW-TE in 2005 showing that the technique is quick to perform and that

postoperative recovery after TW-TE is straightforward. Since then the technique has been applied with high success both in retrospective case series [13] and in prospective clinical trials in adults [14], and recently also in children [15]. In consistent with previous reports [7–9, 14] our results indicate also that the use of TW forceps technology may improve patient outcome after TE. There were no differences between the two groups in the intraoperative course or early recovery during the first hours after surgery. On the contrary, after discharge, recovery was significantly shorter in the TW-TE up to the eighth postoperative day. Sleeping, the function patients are most often worried about, was significantly easier on all postoperative nights in patients with TW-TE. The recovery of other parameters was also in favor of the TW technique as late as the sixth postoperative day. This finding is important because it indicates that patients treated with TW-TE would probably require shorter sick leave after surgery than after electrocautery TE, and may thus return to work few days earlier. Moreover, better quality of life during the recovery improves the likelihood of returning to normal functioning after sick leave.

One of the main concerns in patients with TE is the risk of hemorrhages. The TW technique may result in fewer bleeding complications than classical TE techniques. In the TW group, no cases of hemorrhages occurred, but in the monopolar group, three patients developed late hemorrhage. Large-scale confirmatory studies are needed to confirm the superior safety of the TW technique noted in the present study and in previous reports [7–9, 12–15].

In a subjective assessment, all surgeons clearly felt that the operation was easier to perform with the TW technique because of reduced intraoperative bleeding. With the TW technique, the tonsillar fossa also shows a clean surface during the operation, which probably helps to achieve gentle tissue preparation. TW uses the simultaneous application of heat and pressure to cut, and coagulate tissue. The effect produced on a vessel by the ENTceps is to cut cleanly, while producing a coagulated (sealed) zone at the ends of the vessel on either side of the cut. The overall procedure time was between 10 and 20 min with both techniques and experienced surgeons did not gain in this respect. However, this time was 10 min shorter than 20–30 min reported by others [7, 12].

From the patient's perspective, the main concern after TE is postoperative pain. Most patients with classical TE techniques have significant pain and, thus, should be provided and prescribed sufficient pain medication and given proper counseling for pain management after discharge to allow a smooth recovery [10]. In the present study, patients were given a low dose of fentanyl during anesthesia. After surgery, they were given a NSAID (ketoprofen) on a regular basis for the first five postoperative days and as needed after 5 days. For rescue analgesia in the hospital, patients

were given oxycodone; after discharge, paracetamol–codeine was used. This multi-modal pain management approach resulted in satisfactory pain relief in both groups. The recovery in the present study was significantly enhanced compared to that, when only paracetamol 1 g three times daily, and only for the two-first postoperative days was allowed for patients with TW-TE [7]. In the Karatzias study [7], all patients had significant pain for the first week after surgery, pain scores >6/10 for the entire first week and up to >9/10 on the first two postoperative days. Thus, we cannot agree with the Karatzias conclusion that the postoperative pain in their series was minimal: pain scores of 7–9/10 indicate severe pain.

According to previous results [2], pain after electrocautery-TE is the most on the fourth and the fifth postoperative day, and most patients had significant pain, i.e., pain at rest more than 3/10 and dynamic pain during swallowing more than 5/10. In contrast to patients treated with electrocautery-TE in the present study and the results reported by others in patients with TW-TE [7, 8], most patients in the TW group reported sufficient pain relief with the multimodal analgesia provided. Although the recovery was less painful after TW-TE than that after electrocautery after discharge, the use of analgesics did not differ between the two groups: the total number of ketoprofen and paracetamol–codeine tablets was 54 tablets in the TW group and 63 tablets in the monopolar group. Stavroulaki [8] had a more conservative approach to pain management. Only three doses of paracetamol 1 g were provided for the first 24 h and after that, paracetamol was used as needed. Patient counseling seems to have been unsuccessful because the total consumption of paracetamol tablets was only seven tablets in the patients with cold dissection-TE and just four doses with TW-TE, i.e., only one-tenth of that in the present study. Similar to the study by Karatzias [7], the patients in the Stavroulaki trial [8] seem to have suffered unnecessarily severe pain after TW-TE, and the criteria for sufficient pain relief, i.e., pain score less than 7/10, is significantly higher that that in our institutions and in most other ENT units. In general, the quality criterion for the successful pain management is that, patients should not have more than slight pain at rest, i.e., 3/10 or less, and rescue analgesia should be provided, if the dynamic pain score is 6/10 or higher.

Conclusion

The novel TW technique seems to provide an earlier return to normal activities and a less affected sleep pattern than that after electrocautery-TE. If it is confirmed in large studies that the TW technique is associated with fewer bleeding complications after surgery, this technique could be considered as a significant innovation in the field of

ENT surgery and applied for other patient groups [16], and for other types of ENT surgery [17].

Conflict of interest statement The authors declare that they have no conflict of interest.

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