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Thermal Welding Versus Cold Dissection Tonsillectomy: A Prospective, Randomized, Single-Blind Study in Adult Patients

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Objectives: We performed a single-blind, prospective, randomized, controlled clinical study to compare the rates of postoperative morbidity in adults undergoing thermal welding tonsillectomy versus cold dissection tonsillectomy.

Methods: Thirty-two adults with recurrent tonsillitis who were scheduled for elective tonsillectomy were randomized to either thermal welding or cold dissection tonsillectomy groups. The main outcome measures included intraoperative blood loss, intensity of postoperative pain expressed on a 10-cm visual analog scale (with 0 representing no pain and 10 representing the worst possible pain), day of cessation of significant pain (ie, a pain score of at least 7), and presence of postoperative hemorrhage estimated on a 3-point scale (with 0 representing no bleeding, 1 representing minor bleeding, and 2 representing major bleeding). Additional outcome measures included total analgesic requirements, last day of receipt of analgesics, presence of nausea and/or vomiting, and wound healing after 10 days of surgery.

Results: The rate of intraoperative blood loss was significantly lower in the thermal welding group ($p < .0001$). Patients who had thermal welding tonsillectomy also showed a general trend toward lower pain scores, and this difference was statistically significant from the first to the fourth postoperative days ($p < .05$). Cessation of significant pain also occurred 3 days earlier in this group ($p < .05$). No significant difference was observed regarding pain medication, nausea and/or vomiting, postoperative hemorrhage, or wound healing.

Conclusions: Thermal welding tonsillectomy is a relatively safe and reliable method with significantly less postoperative morbidity than cold dissection tonsillectomy.

Key Words: adult, morbidity, pain, thermal sealing, thermal welding, tonsillectomy.

INTRODUCTION

Tonsillectomy is one of the oldest and most common surgical procedures performed worldwide. However, the morbidity of this procedure (mainly hemorrhage and postoperative pain) remains high, and a variety of techniques have evolved over the years with the hope of decreasing it. Described techniques include cold dissection, monopolar and bipolar diathermy dissection, bipolar scissors dissection, laser tonsillectomy, cryosurgery, ultrasonic removal, microdebrider, coblation, and, now, thermal welding (TW) technology.[1] All of these techniques have advantages and disadvantages, and the minimally painful, maximally safe and effective tonsillectomy technique still remains elusive despite decades of investigation.

The Thermal Welding System (Starion Instruments Corp, Sunnyvale, California) is a new surgical device that uses direct heat and pressure as a means of coagulating and cutting soft tissue. The application of thermal energy sequentially denatures, bonds, and cuts protein-based tissue structures. This process is referred to as TW.[2] The system consists of a power supply unit, cautery forceps, and a foot switch. It has been widely used in many fields of surgery for both open and laparoscopic procedures. The Starion cautery forceps, specially designed for tonsillectomy procedures, have a Nichrome heating element at the tip with a insulating layer that isolates the heating effect of the wire from the rest of the instrument. Closing the forceps' jaws presses the thermal element against a silicone "boot" and facilitates the development of a graded thermal profile: a narrow high-temperature (300°C to 400°C) cutting zone (direct vaporization with very little charring) surrounded by a lower-temperature coagulating zone (60°C to 100°C) that is in the ideal temperature range to coagulate and seal tissues by means of protein denaturation. Furthermore, the silicone "boot" exerts pressure or crimps the vessel walls together in the lower-temperature coagulation zone, producing a strong seal on the ends of the cut vessel. Thus, a hemostatic surgical field is provided with minimal collateral thermal damage to the surrounding tissue.[2] This reaction is described as less traumatic to

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TABLE 1. ANESTHETIC PROTOCOL

Induction with intravenous propofol 2.5 mg/kg and rocuronium bromide 0.8 mg/kg
Maintenance with nitrous oxide and sevoflurane
Analgesia: intravenous fentanyl citrate 3 μg/kg at induction
Antiemetic: ondansetron hydrochloride dihydrate 4 mg/kg

adjacent tissues and by this means is hypothesized to cause less postoperative pain.

The aim of this prospective randomized study was to evaluate whether in adults, the TW tonsillectomy results in decreased postoperative morbidity when compared with the cold dissection tonsillectomy, the most frequently used technique in Greece and in many other countries. To our knowledge this is the first single-blind, prospective, randomized controlled study evaluating the efficacy and safety of TW tonsillectomy versus the cold dissection technique in adults.

MATERIALS AND METHODS

Thirty-two adults with recurrent tonsillitis who were scheduled for elective tonsillectomy were randomized to tonsillectomy with the TW technique or the cold dissection technique. The randomization was performed by the use of a random number generator (Excel, Microsoft Corp, Redmond, Washington), and patients were not informed which technique was used to remove their tonsils. Exclusion criteria included a history of tonsillitis within 2 weeks, hemorrhagic diathesis, and an asymmetric tonsil appearance. The research protocol was approved by the hospital review board, and informed consent was obtained from all patients.

All participants were anesthetized by a standard protocol, which included the same airway management and intraoperative analgesia (Table 1).

The surgical technique of TW tonsillectomy was based on dissection of the tonsil in the relatively bloodless tonsillar-muscular plane with the Bayonet UltraSlim Forceps (110-005D). These are single-use, foot switch–activated, handheld surgical forceps that are relatively easy to handle without special training. The patient position was the usual tonsillectomy orientation (supine with shoulder roll, neck extension, and head support). The mouth was held open with a Boyle-Davis gag (B. Braun Medical Ltd, Sheffield, England) held by Draffin rods. After retraction of the tonsil medially with Dennis-Brown forceps (B. Braun Medical Ltd), the mucosa of the anterior tonsillar pillar was coagulated with the TW forceps on the "1" setting of the power supply unit and was divided afterward with the same forceps on the "8" setting of the power supply unit.

The underlying fascial plane was exposed to facilitate the dissection of the tonsil from the surrounding soft tissues toward the inferior pole. Any visible blood vessels were grasped with the tips of the TW forceps and sealed on a power setting of "1." The inferior pole was then coagulated and divided, and the tonsil specimen was removed. After complete removal of both tonsils, the tonsil fossae were thoroughly inspected for any evidence of bleeding, and if necessary, the coagulation mode was further used. The cold dissection tonsillectomy was performed in the standard way, and bleeding was controlled by tampon and ligation, without any type of diathermy. Intraoperative blood loss was estimated by measuring the amount in the suction bottle as well as by weighing the cotton pledgets before and after the procedure.

The patients were discharged the day after surgery with an acetaminophen (paracetamol) prescription for pain control (1,000 mg orally every 8 hours on the first postoperative day and thereafter as needed). All of them received a follow-up chart on which they were instructed to record daily for the next 10 days the intensity of the postoperative pain, the total analgesic requirements, the last day of taking analgesics, and any other adverse events during recovery such as nausea and/or vomiting or hemorrhage. A visual analog scale (VAS) was used to quantify patients' initial postoperative pain and to follow the changes in pain over time. The VAS is a 10-cm line with the end points labeled "no pain" (0) and "worst possible pain" (10), and the patient marks the line at the distance corresponding to the intensity of the present pain.[3] The VAS is a methodologically sound instrument for quantitative assessment of postoperative pain and for detecting clinically important changes in such pain.[4] The degree of postoperative hemorrhage was estimated on a 3-point scale (with 0 representing no bleeding at all, 1 representing minor bleeding requiring medical attention, intravenous fluids, or suction of the clot, and 2 representing major bleeding requiring reoperation or blood transfusion). All patients were also examined on the 10th postoperative day by the operating surgeon, and an estimation of healing within the tonsillar fossa was recorded by calculation of the amount of remucosalization. A fully healed fossa was defined as one that was 100% remucosalized.

All patients' data, including demographic characteristics (age, gender) and outcome measures (main outcome measures, including intraoperative blood loss, intensity of postoperative pain, day of cessation of significant pain [pain score 7 or more], and presence of postoperative hemorrhage; and minor outcome measures, including total analgesic re-

TABLE 2. PAIN LEVELS ON VISUAL ANALOG SCALE

	Cold Dissection Group (n = 16)		*Thermal Welding Group (n = 16)*					
	Mean	*SD*	*Mean*	*SD*	*Student's t-Test*	*p†*	*95% CI*	*rpb*
Day 0	7.343	2.36	6.093	2.14	1.566	.128	–0.38 to 2.88	.273
Day 1	8.375	1.58	6.031	2.41	3.248	.003	0.87 to 3.82	.510
Day 2	7.562	2.18	5.812	2.22	2.241	.033	0.16 to 3.34	.378
Day 3	7.312	1.92	5.593	2.27	2.308	.028	0.20 to 3.24	.388
Day 4	6.531	2.40	4.875	1.70	2.246	.032	–0.15 to 3.16	.379
Day 5	5.843	2.69	4.500	1.89	1.631	.113	–0.34 to 3.03	.285
Day 6	5.218	2.61	3.875	2.06	1.615	.117	–0.36 to 3.04	.282
Day 7	4.656	2.42	3.218	2.31	1.714	.097	–0.28 to 3.15	.298
Day 8	4.406	2.44	2.750	2.23	2.000	.055	–0.035 to 3.35	.342
Day 9	3.500	2.36	1.937	2.17	1.945	.061	–0.078 to 3.20	.334
Day 10	2.125	2.21	1.125	1.85	1.383	.177	–0.48 to 2.48	.244
Day of cessation of significant pain	5.437	3.59	2.185	2.73	2.876	.007	0.94 to 5.56	.464

*Student's *t*-test for independent groups.

†Two-tailed p values (degrees of freedom = 30).

quirements, last day of taking analgesics, presence of nausea and/or vomiting, and wound healing), were entered in a database and analyzed with Microsoft Excel and SPSS for Windows (SPSS, Inc, Chicago, Illinois). The differences between the two groups concerning continuous, ordinal variables such as age, intraoperative blood loss, pain scores, day of cessation of significant pain, total analgesic requirements, and last day of taking analgesics were analyzed with the 2-tailed Student's *t*-test for independent groups, and the severity of postoperative hemorrhage was assessed with the Mann-Whitney U-test. Fisher's exact test was applied to analyze the differences between the groups for frequency data that included small numbers (<5), such as gender, presence of postoperative nausea and/or vomiting, and tonsillar fossa healing. A confidence interval of 95% was used, and statistical significance was accepted for p values of less than .05. The study was powered around the VAS pain score. Assuming a power of the study of 80% (p = .05) and a difference between the two groups of 3 on the visual analog pain scores (SD of 3), the total sample size would need to be 30.[5] Furthermore, the strength of relationships between the group status and the remaining outcome measures (other than the pain scores) was assessed by calculating the point biserial correlation coefficient (rpb) when Student's *t*-test was used or calculating the phi coefficient when Fisher's exact test and Cohen's criteria were used.[6]

RESULTS

Demographics. Sixteen patients were included in each group (cold dissection, TW), and no patient was lost to follow-up. No significant differences were found in any of the demographic characteristics (age and gender) between the patients of the two groups. In the cold dissection and TW groups, 13 of 16 (81.25%) and 11 of 16 (68.75%) patients were female, respectively (χ^2 = .667; p = .685; 95% confidence interval [CI], 0.678 to 0.696; phi = .14). The mean ages for the cold dissection and TW groups were 25.56 ± 5.10 years and 27.19 ± 8.28 years, respectively (*t*[*df* 30] = –0.668; p = .509; 95% CI, –6.59 to 3.34; rpb = .121).

Intraoperative Blood Loss. With the TW technique, essentially no intraoperative bleeding was observed. In the rare instances in which it was required, the use of the coagulation setting ("1") was extremely effective at achieving hemostasis. The mean intraoperative blood loss in the cold dissection group (158.44 ± 30.40 mL) was statistically very significantly higher than the mean blood loss in the TW group (9.40 ± 5.20 mL; *t*[*df* 30] = 18.573; p < .0001; 95% CI, 132.28 to 165.78; rpb = . 96).

Postoperative Pain. The perception of pain decreased over time in both groups. The mean ratings of pain perception by technique are shown in Table 2 and are graphically displayed in Fig 1. Patients treated with the TW technique showed a general trend toward lower pain scores than those treated with cold dissection, and this difference was statistically significant from the first to fourth postoperative days (Table 2). As shown in Table 2 and in Fig 1, the daily pain scores over the entire 10-day postoperative period were consistently lower in the TW group than in the cold dissection group. Furthermore, when we compare pain scores a day at a time, significantly less pain with TW was seen from the first to fourth postoperative days. Beyond that, the pain was consistently less in the TW group, but the difference was small and not significant. Further-

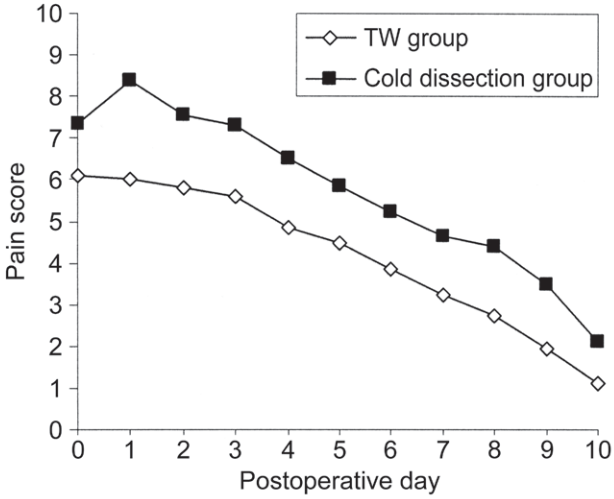

Fig 1. Mean posttonsillectomy pain scores. TW — thermal welding.

more, the cessation of significant pain (pain score of 7 or higher) occurred 3 days earlier in the TW group than in the cold dissection group (Table 2).

Analgesic use was higher in the cold dissection group, and the mean numbers of acetaminophen doses in the cold dissection and TW groups were 6.88 ± 5.63 and 4.38 ± 4.29, respectively. However, this difference did not reach statistical significance ($t[df\ 30] = 1.413$; $p = .168$; 95% CI, –1.11 to 6.11; $r_{pb} = .249$). In addition, no significant difference was observed between the two groups in the day of the last analgesic dose, although it was earlier in the TW group (cold dissection group, 5.50 ± 3.35 days, versus TW group, 3.50 ± 3.01 days; $t[df\ 30] = 1.777$; $p = .086$; 95% CI, –0.30 to 4.30; $r_{pb} = .308$).

Postoperative Nausea and/or Vomiting. Dehydration did not occur, and no patient required hospitalization or intravenous fluids for more than 24 hours. Few patients experienced nausea and/or vomiting after operation (mainly during the first postoperative day; Fig 2). No significant difference was found in the incidence of these symptoms between the two patient groups ($\chi^2 = 0.183$; $p = 1.000$; 95% CI, 0.100 to 1.00; phi = .076).

Postoperative Hemorrhage. Three patients (18.75%) in the cold dissection group experienced postoperative hemorrhage. Two of them were returned to the operating room on the day of surgery to stop a primary bleeding (ligation), and the third patient was readmitted on postoperative day 7 and was treated successfully with silver nitrate application. With the TW technique, no bleeding at all was observed after operation. Although the hemorrhage rate was greater for classic tonsillectomy, the difference did not reach statistical significance ($U[df\ 30] = 97.5$; $p = .083$; 95% CI, 0.220 to 0.236).

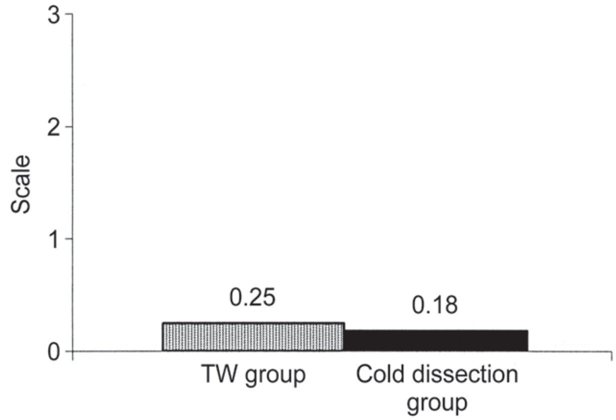

Fig 2. Postoperative incidence of nausea and/or vomiting.

Tonsillar Fossa Healing. On the 10th postoperative day, 3 patients (18.75%) in the TW group had fully healed tonsillar fossae, whereas none of the patients in the cold dissection group had fully healed fossae. Although healing was quicker in the TW group, the difference was not significant ($\chi^2 = 3.31$; $p = .226$; 95% CI, 0.217 to 0.233; phi = .322).

DISCUSSION

Despite advances in surgical and anesthetic techniques, postoperative morbidity after tonsillectomy still remains a significant problem. The resulting morbidity includes intraoperative blood loss, primary and secondary hemorrhage, and postoperative pain and dehydration.[7,8] Reduction in those parameters accelerates patient recovery time, improves patient satisfaction, and decreases hospitalization and readmission rates with clear social and economic implications.

In our study, intraoperative bleeding was significantly lower with the TW technique. Although the difference in blood loss between the two techniques was statistically significant, both values are clinically acceptable. Intraoperative blood loss during tonsillectomy with cold instruments has been estimated at 80 to 90 mL per tonsil, which is in accordance with our intraoperative blood loss (158.44 ± 30.4 mL).[9,10] The TW technique can be accomplished in a virtually bloodless manner.[2] One of the advantages of this technique is its ability to be used not only for cutting but also for coagulation and dissection, eliminating the need to frequently change instruments or use coagulating-sealing technologies in order to stop bleeding.

Posttonsillectomy hemorrhage rates depend on the technique used and vary from 1% to 6% in patients who do not receive nonsteroidal anti-inflammatory agents (cold dissection, 1.3%; cold dissection and diathermy, 2.9%; bipolar diathermy, 3.9%;

monopolar diathermy, 6.1%; and coblation, 4.4%).[11] In our study, 2 patients in the cold dissection group experienced primary hemorrhage that required a return to the operating room. However, both of them had a history of peritonsillar abscess, which increases the likelihood of bleeding. In the medical literature, posttonsillectomy hemorrhage rates usually refer to patients without such a history; this difference explains our relatively higher incidence of postoperative bleeding.

During tonsillectomy, surrounding tissue undergoes mechanical or thermal damage that results in severe pain due to inflammation, spasm of the exposed pharyngeal muscles, and nerve irritation (glossopharyngeal and/or vagus).[8] The cold dissection technique often results in an increased requirement for postoperative pain medication, and a significant number of patients require an overnight stay at the hospital for pain control and hydration. Frequently, this postoperative pain and dehydration necessitates that patients be readmitted. The TW technique is both relatively simple and quick (approximately 6 to 8 minutes per side), and the amount of collateral thermal damage is minimal and significantly less than with monopolar or bipolar electrocautery.[2] For this reason, the TW technique is considered less traumatic to adjacent tissues, so it may be associated clinically with less pain and faster recovery. In the present study, although we did not have any readmissions for pain control or dehydration, the pain levels were still significant, especially with the cold dissection technique. The maximum pain scores were observed on the first postoperative day for both groups. From a quantitative standpoint (as shown in Table 2 and Fig 1), TW showed the greatest improvement in pain over cold dissection on the first postoperative day: a difference of 2.3 points on the 10-point scale. For the next 3 days (days 2, 3, and 4), we observed approximately a 1.7-point difference in pain between TW and cold dissection. Beyond the fourth postoperative day, the difference was still at least 1 point (ranging from 1.6 on the 8th postoperative day to 1.0 on the 10th postoperative day), although the difference was not statistically significant. On the day of surgery, pain scores were not significantly different between the two groups, probably because of the maximal doses of acetaminophen being administered to the majority of patients in both groups. In addition, the cessation of significant pain occurred 3 days earlier in the TW group than in the cold dissection group.

The healing time with the TW technology should be faster than with the cold dissection technique. However, in our study, although the amount of remucosalization of the tonsillar fossae was greater in the TW group, our data do not support the theory that TW results in significantly faster healing compared with the cold dissection technique.

Our study was powered around the VAS pain scores. The VAS is a valid and reliable measure of postoperative pain intensity in young people.[4] Calculations were performed by use of a change in VAS mean values of 3 cm with an SD of 3 cm, because such changes in VAS have been associated with a patient assessment of clinical significance.[12] Patients with pain in the upper third of the VAS had been proved to experience a minimal clinically significant change in pain with a greater difference in VAS scores than those patients with pain within the lower third of the VAS. Indeed, patients in the upper cohort (VAS score of 6.7 cm or higher) had clinically significant pain relief with mean VAS changes of 2.8 ± 2.1 cm. Smaller changes in VAS scores, although of possible statistical significance, are of questionable clinical significance and should be cautiously used in clinical studies. In this setting, the power of our study was 0.82 (higher than the conventional standard of 0.80) with a sufficient sample size of 16 subjects per group.

The efficacy and safety of TW tonsillectomy have also been evaluated in 2 other studies.[13,14] In the first one, both children and adults were included, and the study was uncontrolled, with the report describing mainly the operating technique. The outcome measures included only hemorrhage rates and return to a normal diet, and no statistics were provided.[13] The second study was a prospective one, comparing the TW tonsillectomy with the bipolar electrocautery technique, and although power analysis is not provided, the sample size is probably sufficient.[14] The postoperative morbidity after TW tonsillectomy was less, but the pain scores recorded in their TW group were surprisingly high (compared to our study), and this difference cannot be explained, especially taking into consideration the similar age ranges in both studies. To our knowledge, ours is the first single-blind, prospective controlled study comparing the TW technique with the classic cold dissection technique. Rigorous trials in pediatric patients are also missing, and we are currently investigating postoperative morbidity after TW tonsillectomy in children.

Another important advantage of the TW tonsillectomy is that the dissection forceps used are easy to handle without the need for special training. Moreover, they are disposable, also removing the risk of transmission of variant Creutzfeld-Jakob disease that exists with reusable instruments.[15] Tonsillectomies are predominately performed in children, so the potential impact of iatrogenic transmission of disease with a possible incubation period of several decades is obvious. The cost of TW should also be considered. The disposable dissection forceps used in TW have an approximate cost of €250 or $340. The Starion sales policy is to loan the TW controller unit at no charge as long as dissection forceps are ordered on a regular basis.

Our results provide evidence that patients treated with the TW tonsillectomy may experience improved quality of recovery. If the recovery time could be reduced by 10% or 20%, then the annual savings in lost worker productivity would be substantial, and the higher per-patient expense for the forceps would seem justified. Further studies are needed to investigate whether the reduced pain of the TW technique results in reduced convalescent time and in cost savings from decreased pain medications or earlier return to work.

CONCLUSIONS

Improvements in tonsillectomy technique are defined by reduction of postoperative pain, low rates of perioperative or postoperative hemorrhage, and early return to normal activities. Thermal welding tonsillectomy is a new innovation that appears to provide a valuable addition to our surgical armamentarium for reducing the postoperative morbidity that is usually experienced after total tonsillectomy.

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