

Intrapersonal randomized controlled trial comparing bipolar Scissors and conventional cold tonsillectomy

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Abstract

Objective: To evaluate bipolar scissors tonsillectomy by comparing it with traditional cold dissection tonsillectomy in the same patients, utilising one technique on either side.

Study design: Randomized controlled trial.

Setting: ENT Daycare unit of the Karolinska University Hospital at Danderyd Hospital, Stockholm.

Patients: Fifty patients of which 49 were eligible (M/F 20/29), mean age 14.3 (4-41) years and included in the study. Thirty-one patients were operated due to upper airway obstruction and 18 for chronic tonsillitis. **OUTCOME MEASURES:** (1) Intraoperative bleeding, (2) operative time, (3) postoperative pain, and (4) complication rates, including primary and secondary hemorrhage.

Methods: Cold technique; cold scissors, Henke tonsil elevator, bipolar diathermy. Hot technique; bipolar scissors (Ethicon, set on 20 W), bipolar diathermy if needed. Each side was completed separately. Blood loss and total operative time on each side were registered. Pain was

evaluated daily on a visual-analogue scale, VAS (0-100 mm) in patients from 10 years of age.

Results: Mean operative time for the conventional cold technique was 11.6 SD +/- 8.5 (range 1.0-55 min) and for the hot technique 3.1 SD +/- 3.1 min (range 0.5-8.5 min) (Wilcoxon-test $p < 0.001$). The corresponding median values were 3 and 1.9 min respectively. The mean blood loss was 43.2 SD +/- 41.7 ml (range 7-225 ml) vs 3.0 SD +/- 4.7 ml (range 0-25 ml) (Wilcoxon-test $p < 0.001$). The corresponding median values were 30 and 1 ml, respectively. No early or late haemorrhages requiring surgical intervention occurred. There was no difference in pain.

Conclusions: Tonsillectomy with bipolar scissors was mean 4 (median 3) times faster and the blood loss mean 14 (median 30) times less than on the side operated with the conventional cold technique, whereas no difference in morbidity was found.

Parts of the study were presented at the 7th. World Congress on Sleep Apnea in Helsinki, Finland in 2003 (abstract 047)

Keywords: Tonsillectomy; Bipolar scissors; Pain; Bipolar diathermy; Henke; "Hot technique"; "Cold technique"; Intrapersonal.

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Introduction

The first known tonsillectomy was performed by Celsus 2000 years ago using blunt digital dissection [1]. Snaring and "giljotining" the tonsils (i.e. tonsillotomy) was introduced in the 19th century and the use of elevators at the turn of that century. Only 50 years ago patients were often operated on in a sitting position under local anaesthesia.

The more common use of general anaesthesia with intubated patients made it possible to perform complete tonsillectomies with the patients in a supine position, which was more convenient for both the patient and the surgeon. The standard technique is still cold steel dissection but hot techniques have evolved during the last 40 years like monopolar and bipolar diathermy, laser and more recently also the ultrasonic scalpel and coblation. The refinements of surgical and anaesthetic techniques have made it possible to treat patients on a day-care basis [2]. In our ENT day-care centre, day-care tonsillectomies have been performed since 1996. Previous investigations indicate that tonsillectomy performed in day surgery may be considered cost effective and safe [3, 4].

Conventional tonsillectomy is performed with cold scissors and a tonsil elevator. Earlier, bleeding was stopped by ligatures or vessel strangulation by deep sutures in the tonsillar bed. The latter measure infrequently caused life threatening injury to the branches of the external carotid artery [5]. These procedures have therefore been replaced by monopolar or bipolar diathermy.

Bipolar scissors technically combine bipolar diathermy with the scissors. They are thereby replacing the tonsil elevator, scissors and

usually the bipolar diathermy. There are indications that the bipolar scissors allow faster intervention than the conventional cold steel techniques [6, 7].

In the present trial the patients were subjected to a hot or a cold technique on either side, in a randomised and single blinded manner. The outcomes were the operative time at the table, per-operative blood loss, post-operative pain and complications related to each technique.

Material and methods

Patients

Fifty consecutive patients booked for day-care surgery (ASA I) were, after informed consent, subjected to bilateral tonsillectomy (TE) in a randomised controlled trial using bipolar scissors on one side and the conventional cold technique on the other side. Patients with a history of quinsy were excluded. One male did not disclose his history of quinsy until after surgery and was then excluded from the study. Forty nine patients (M/F 20/29), mean age 14.3 (4-41) years could be included. Thirty-two of these patients were operated due to upper airway obstruction and 17 were operated due to chronic tonsillitis.

Surgery

The patients left sides were randomised either to conventional cold tonsillectomy or to the hot technique with bipolar scissors immediately prior to surgery in the operating theatre. The right side automatically fell into the other group. Surgery was performed

by the two senior consultants (POH/LF) on one side at a time and considered finished when full haemostasis was achieved, always beginning with the left side.

The conventional cold technique used cold Metzembaum scissors and a Henke tonsil elevator (Fig 1). Bleeding was stopped with compression and/or bipolar diathermy. The hot technique used Power-Star bipolar scissors (Ethicon) set on 20W (Fig.1). They consist of a pair of modified 18 cm Metzembaum scissors where the cutting blades have a partial ceramic isolation in order to act as electrodes in the bipolar instrument (7). Vessel bleeding was usually stopped by the bipolar scissors but if necessary with the more effective bipolar diathermy forceps.



Figure 1 Bipolar scissors vs Henke tonsil elevator.

Parameters

Registered operation time comprised the time for elevation and haemostasis for each side using a chronograph. Per-operative bleeding from each side was simultaneously measured. Primary haemorrhage was defined as haemorrhage occurring within the first 24 h after the operation and secondary haemorrhage occurring between 24h and 28 days. Pain was self reported on a visual-analogue scale (VAS 0–100 mm) at noon every day on patients from 10 years of age. Maximum pain in millimeters and total pain duration in days were registered.

Post-operative analgesia

All patients were injected with local analgesia in the tonsillar bed using 5 ml of bupivacaine hydrochlor. (2.5 mg/ml) in children and 5 ml of bupivacaine hydrochlor. (5 mg/ml) in adults (> 50 kg), respectively. No epinephrine was used during the study. The patients were treated with morphine (0.1 mg/kg) i.v during the first 2 h at the hospital. At home the smallest children < 40 kg were given Citodon minor® suppositories (paracetamol 350 mg + codeine 15 mg) 4 times daily whereas children > 40 kg and < 50 kg were given suppositories diclofenac 25 mg 3 times daily and paracetamol 4 times daily. Adults were given Citodon® (paracetamol 500 mg + codeine 30 mg) 4 times daily and diclofenac 50 mg 3 times daily.

Statistics

Data are given as median, mean, standard deviation SD, or min-max range, or the combination of these. Wilcoxon test was used

to compare the mean values for pain, bleeding and time for the total surgical procedure. X2 -test was used for comparison of rate of complications. Statistically significant difference was defined as $p < 0.05$. The estimation of the required sample size obtaining 80% power and α 0.05 for the main outcomes operation time, per-operative bleeding and pain on VAS was performed from a pilot study including 10 patients. The required sample size was 6, 10 and 47 respectively. The sample size for post-operative bleeding could not be calculated.

The study was approved by the local Ethical Committee at the Karolinska Institutet, Stockholm (D-nr 03-238)

Results

Total surgical time

Mean surgical time was more than 3 times longer for the conventional cold technique compared to the hot technique; 11,6 SD +/- 8.5 min (range 1 - 55 min) vs 3,1 SD +/- 1.9 min (range 0.5 - 8.5 min) ($p < 0.001$) (Fig. 2). The corresponding median values were 10.0 vs 3.0 min.

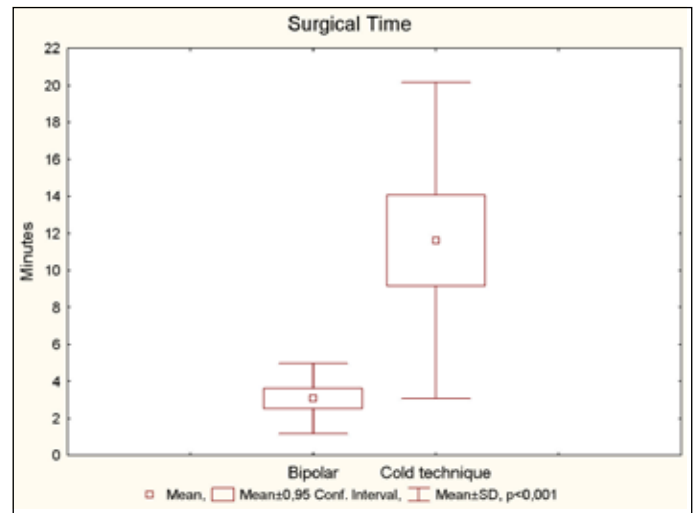


Figure 2.

Blood loss

Mean blood loss was 14 times greater for the conventional cold technique compared to the hot technique; 43.2 SD +/- 41.7 ml (range 7 - 225 ml) vs 3.0 SD +/- 4.7 ml (range 0 - 25 ml) ($p < 0.001$) (Fig. 3). The corresponding median values were 30 vs 1ml.

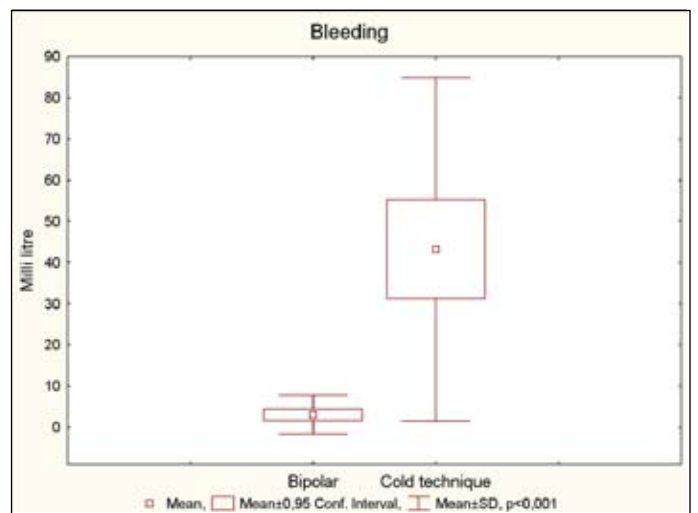


Figure 3.

Pain

Only 18/26 (69%) patients aged 10 years or more completed the VAS procedure.

Maximal pain

Mean VAS value for the conventional cold technique was 52.4 SD +/- 26.7 mm (range 11–97 mm) vs 52.0 SD +/- 27.4 mm (range 8–97 mm) for the hot technique (Fig.4).

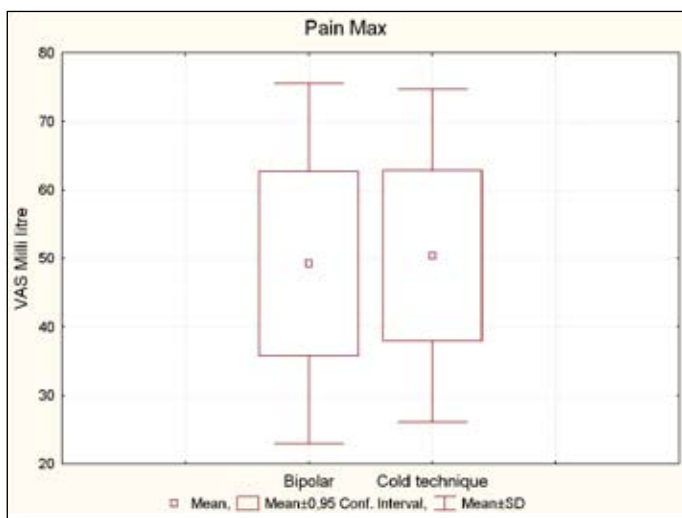


Figure 4.

Pain Duration

Mean pain duration for the conventional cold technique was 9.1 SD +/- 2.3 days (range 6–14 days) and 9.4 SD +/- 2.3 days (range 6–14 days) for the hot technique (Fig. 5).

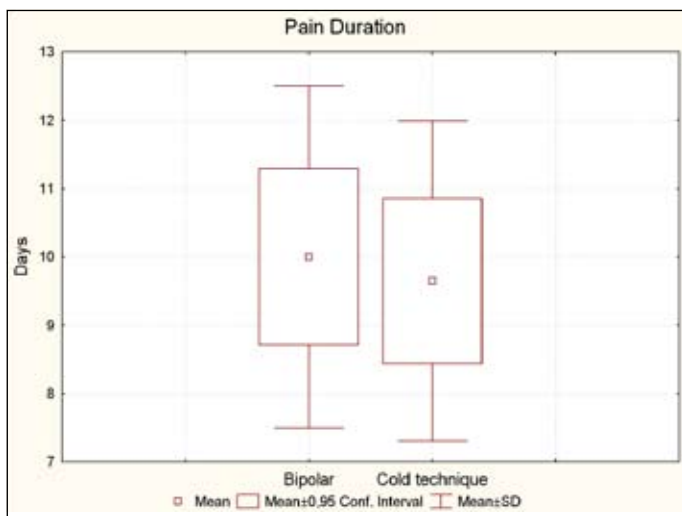


Figure 5.

Early and late complications

No primary haemorrhage occurred. No accidental burn from the use of the bipolar scissors was seen. Transient small conservatively treated secondary haemorrhages were reported by 5 patients after 3–5 days; two patients bleeding on the “cold” side and three patients from the “hot” side (ns). No surgical intervention was required. One patient was treated for a general throat infection. No post-operative taste disturbance was reported.

Discussion

In the present randomised controlled trial a hot and a cold technique were employed for tonsillectomy in a novel way. Both techniques were utilized simultaneously in the same subjects for a more

precise comparison of per-operative blood loss, surgical time and postoperative pain.

Surgical time was much in favour of the hot technique (Fig. 2). This may not only shorten the time under general anaesthesia but also increase the turnover in the operating theatre. It may facilitate the waiting list being shortened and be more cost effective for healthcare providers.

The difference in blood loss between the two methods used was significant (Fig.3). This might be of importance especially in small children susceptible to blood loss and for patients with haemostatic disturbances. The five patients with substantial bleeding (>100 ml) on the conventionally operated side altogether had a mean blood loss of only 3.5 ml on the side operated on with bipolar scissors. Only plain bupivacaine hydrochlor. was injected in the tonsillar bed during the comparative study to minimize external impact on the results and to minimize the risk of late per-operative haemorrhage. The use of epinephrine in the local anaesthesia would probably have decreased the per-operative bleeding even more, at least on the conventionally operated side [8].

A number of life threatening or lethal injuries have been reported after tonsillectomy [5, 9]. The lingual, facial and internal maxillary arteries are the main suppliers of the tonsillar region. There may even exist some collaterals between these branches from the external carotid artery to the internal carotid artery. The lingual and the facial arteries often pass in the close vicinity of the inferior tonsillar bed, and are at special risk of being traumatized by deep sutures. Pulsations in the inferior tonsillar bed may be caused by a tortuous internal carotid artery or by aberrant lingual and/or facial arteries [5]. The glossopharyngeal nerve passes external to the superior pharyngeal constrictor to which the tonsillar bed may be attached after peritonsillitis. The lingual branch of the nerve passes between the superior and middle pharyngeal constrictors close to the inferior tonsillar bed. Nerve injury causes taste disturbances [10].

By using the bipolar scissors it is possible to elevate the tonsils with minimal bleeding and thus to perform the operation with better visual control as compared to traditional cold techniques. Furthermore, diathermy usually makes the blind and dangerous deep strangulating sutures superfluous. A small number of transient post-operative haemorrhages occurred in both groups, none needing any surgical intervention. No taste disturbances were reported.

Pain assessment was performed with a VAS-scale suitable for adolescents and adults but not for small children. Still it is difficult to compare VAS interpersonally as it may depend on the individual pain references and the mood, but it might be feasible for intrapersonal evaluation. For small children secondary assessment of eating and behaviour is usually performed but it was not possible with the current method. Two thirds completed and returned the VAS formulas. No significant differences were registered for maximal pain and pain duration between the bipolar and cold techniques as previously indicated by others [11, 12].

Patel et al [13] found that tonsillectomy with bipolar scissors did not cause more postoperative pain or post-operative haemorrhage than when operating with the bipolar forceps. The latter was not infrequently used in the present study to stop bleeding, even when cold instruments were used, in accordance with the present tradition at the department to shorten operative time and blood loss. This may, however, have contributed to the similarity in the pain experienced by the two groups.

The main purpose of the present randomised controlled study was to detect if the bipolar scissors have per-operative advantages compared to traditional cold technique for tonsillectomy. We found that the

bipolar scissors significantly decreased surgical time and blood loss. No difference in complication rate was seen in this limited sample, but the conclusion of the British National Prospective Tonsillectomy Audit, when comparing postoperative haemorrhage after hot and cold techniques in thousands of patients was that hot techniques like diathermy and coblation still lead to an increased risk of post-operative bleeding [14]. If these haemorrhages will be found less harmful than those after cold techniques with suture ligatures the hot techniques most likely will dominate still in the future.

Conclusions

Bipolar scissors significantly reduced the operating time and the per-operative blood loss without increasing the post-operative morbidity when compared to conventional cold tonsillectomy in a limited sample of patients. Acknowledgements to Björn Strander for data collection and to Mikael Eriksson for valuable statistical support.

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