

Ultrasound-guided radiofrequency submucosal tongue-base excision for sleep apnoea: a preliminary report¹

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Surgery for sleep apnoea is challenging, particularly in patients with macroglossia. This has led us to develop a new procedure for reduction of the tongue base with low morbidity. Two types of bipolar radiofrequency probe were used via a percutaneous approach under an aseptic technique and general anaesthesia on 15 consecutive patients with retropalatal and retrolingual collapse. The lingual neurovascular bundles and probe were simultaneously identified with intraoperative real-time ultrasound to prevent neurovascular damage, and five patients had additional tongue mucosal suture advancement. All patients had previous or concurrent palatal surgery. The increase in cephalometric (retrolingual) posterior airspace (PAS) was 4 mm with a Spinevac wand and mucosal suture advancement, which is comparable to current-staged monopolar radiofrequency protocols requiring treatment for up to 6 months. Overall, 40% polysomnographic success was achieved, but it was 80% when additional phase 1 procedures were used. Morbidity was minimal with careful adherence to the perioperative care protocol.

Keywords *obstructive sleep apnoea radiofrequency treatment surgery*

For adult obstructive sleep apnoea syndrome (OSAS), nasal continuous airway pressure (nCPAP) or oral appliances are the most common therapies. Surgical approaches for OSAS usually involve site-specific upper airway procedures. Uvulopalatopharyngoplasty (UPP) has only a 5% success rate in controlling OSAS when tongue-base obstruction, in addition to retropalatal obstruction, exists.¹ Retrolingual segment obstruction, as measured by overnight manometry, occurs in ≈ 50% of the OSAS patients during non rapid eye movement (NREM) sleep; however, this rises to around 80% in rapid eye movement (REM) sleep.² Current low-morbidity (phase 1) surgery popularized by Riley *et al.*³ for the retrolingual segment relies primarily on increasing tension on the tongue/pharynx with a genioglossus advancement and/or

hyoid suspension (although hyoid suspension may also increase retrolingual airspace).

Creating a larger retrolingual airway with endoscopic/open tongue-base reduction or maxillomandibular advancement is a more morbid surgery, and is generally reserved for failure of the phase 1 protocol.³ Powell *et al.*⁴ have recently introduced monopolar radiofrequency technology for tongue volume reduction with low morbidity (therefore phase 1), but requiring multiple treatment sessions (mean 5.5). Our technique involves haemostatic submucosal resection of tongue bulk to achieve a maximal single-stage reduction under ultrasound guidance.

Patients and methods

Fifteen adult patients with OSAS and a respiratory disturbance index greater than 20 were selected for treatment. They had all been intolerant of nCPAP, and had refused, or had been intolerant of, a mandibular advancement device. Three patients had a previous unsuccessful UPP, one of whom also

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had a previous genioglossus advancement (patient 4), but otherwise the group was previously surgically untreated. All patients had macroglossia as defined by posterior airway space (PAS) of ≤ 10 mm, without retrognathia sella-nasion-supramentale (SNB) $\geq 76^\circ$, based on previously defined normal values.⁵ The PAS was calculated as the narrowest distance from the tongue base to the posterior pharyngeal wall, parallel to the Frankfurt horizontal plane. The presence of retrolingual collapse (with or without retropalatal collapse) was confirmed preoperatively with propofol sedation nasendoscopy.⁶

Ethical approval was given by the appropriate medical advisory committee. Informed consent was obtained from all the patients. All the patients were offered standard surgical treatment, modelled on the Stanford phased protocol, as an alternative.³

Following induction of anaesthesia, the airway was secured with nasotracheal intubation. Dexamethasone (8 mg) and cephalothin (1 g) were administered intravenously. An aseptic technique was used with a suprahyoid stab incision. A bipolar radiofrequency probe was passed into the neck in the midline, while the surgeon's non-dominant hand palpated the tongue-base mucosa intraorally. Initially, a Reflex 55TM wand was used in six patients, then the SpinevacTM wand was used in the remainder of the patients (ENTec division of ArthroCare Corp, Sunnyvale, CA, USA). Real-time ultrasound was used throughout the procedure with a Philips (ATL) HDI 5000 SonoCT system and L 12-5 broadband linear array transducer in a sterile cover (Philips Medical Systems, DA Best, the Netherlands). A dedicated sonographer was used to simultaneously identify the radiofrequency probe and lingual neurovascular bundles (hypoglossal nerve and lingual artery) in the tongue, allowing a minimum of 5-mm clearance between the tip of the probe and the bundles at all times. Progressive haemostatic submucosal resection of the tongue-base musculature proceeded from valleculae to foramen caecum on power setting five, with the depth of treatment gauged by intraoral palpation through intact tongue mucosa and ultrasound guidance. The midline was initially treated, with dissection carried laterally between the mucosa and the neurovascular bundles. Occasional intraoperative bleeding occurred, which was easily managed by ultrasound-guided aspiration of blood and bimanual pressure.

All but the first three patients were left nasotracheally intubated for several hours postoperatively to ensure that no tongue haematoma or significant oedema had occurred, and were then extubated. Intra-arterial blood pressure monitoring was routinely carried out, and mean arterial pressure was maintained below 100 mmHg with intravenous antihypertensives. Concurrent radiofrequency assisted or classical UPP was performed for patients with co-existing retropalatal collapse. The last five patients had concurrent palatal advancement, hyoid suspension (five patients), with or without genioglossus advancement (two patients) being performed. The

tongue-base mucosa was advanced anteriorly into the defect in the tongue-base musculature with a transmucosal suture (patient 9) or extramucosal suture (patients 10, 11, 14 and 15). Extramucosal suturing utilized an endostitchTM 10-mm disposable suturing device and 0 polysorb suture (Autosuture, CT, USA), inserted after tract dilation, and a glove change prior to tying the knots. Repeat polysomnography and lateral cephalometry were obtained 3 months postoperatively.

Results

The patients were generally obese with a mean body mass index (BMI) of 30.6 (± 3.7), range 26–37. The mean sella-nasion-subspinale (SNA) was 83.9° ($\pm 3.7^\circ$), mean SNB was 83.3° ($\pm 5.0^\circ$) and mean PAS was 6.8 mm (± 2.0 mm). A cephalostat on the first postoperative morning confirmed that the only patient with a decrease in PAS in the early postoperative period was the one with a reactive haematoma. Cephalometry was compared preoperatively to 3 months postoperatively using previously described methods.⁵ Initially, the Reflex 55TM probe was used in 10 treatment sessions to six patients, and the mean increase in PAS was 1 mm per treatment. The SpinevacTM probe was used only once on all other patients, and yielded an increase of 2.5 mm when used alone (in two patients), or 4 mm when used with mucosal suture advancement (two patients). Following review of the initial 10 cases, the subsequent 5 cases had additional hyoid suspension and palatal advancement, with 2 cases also having a genioglossus advancement (patients 13 and 15). Increases in PAS in these cases (patients 11–15) were therefore difficult to attribute solely to the tongue-base reduction component and, for this reason, they are not reported.

Polysomnography was compared preoperatively to 3 months postoperatively (Table 1). The Stanford criteria for success (respiratory disturbance index (RDI) < 20 and RDI reduced by $> 50\%$) was overall met in 40% of the cases. Additional procedures were performed on the last five patients, which increased the success rate from 20% (2 of the first 10 patients) to 80% (4 of the last 5 patients). Overall, RDI fell from a mean of 45.7 (± 27.8) to 29.0 (± 23.8). The responders' RDI fell from mean 50.6 (± 36.3) to 9.5 (± 5.9). The mean RDI of the failures was 42.5 (± 22.2) preoperatively, compared with 42.0 (± 22.3) postoperatively. A Mann-Whitney *U*-test was performed on mean BMI before and after surgery in the responder and non-responder groups. This was not statistically significant ($P = 0.211$), therefore change in weight was not considered to be a factor in polysomnographic outcome in these patients. Similar proportions of the sleep studies were spent in the supine *versus* lateral positions in the pre- and postoperative studies, except for patients 3 and 4, who spent the entire postoperative study in the supine position. When comparing the supine and the lateral data separately before and after surgery, the apparent worsening of these

Table 1. Polysomnographic and cephalometric results

Patient	Operation	Before treatment					After treatment				
		RDI (%)	Lsat (%)	ESS	BMI (mm)	PAS (mm)	RDI (%)	Lsat (%)	ESS	BMI (kg/m ²)	PAS (mm)
1	1xR55	20	89	10	33	6	5.3	84	9	34.3	7
2	1xR55	25	78	4	30.8	4	3.8	90	3	29.8	6
3	2xR55	34	87	16	31	9	5.3	89	11	29.3	10
4	2xR55	69	85	6	28.7	5	8.7	79	3	30.4	8
5	1xR55	28.5	89	7	26	7	27.9	87	12	26	7
6	3xR55	28	87	17	28.3	9	2.2	87	10	28.7	12
7	SV	43	76	6	29.6	6	4.4	79	6	29.3	9
8	SV	14.8	89	7	32	7	13.8	91	7	33.6	9
9	SV/sut	69	84	16	36.8	10	5.6	82	11	36.8	15
10	SV/sut	23	75	19	31.6	4	27.5	75	7	33.2	7
11	Multi	47	87	18	30.3	5	1.1	90	8	29.1	N/A
12	Multi	74.3	76	20	29.0	10	5.6	92	1	28.4	N/A
13	Multi	72.9	78	5	31.2	7	4.6	72	3	32.3	N/A
14	Multi	112.2	73	10	29.4	8	19.4	81	3	26.7	N/A
15	Multi	25.2	82.4	15	19.5	5	1.2	86	5	21.1	N/A
Mean		45.7	82.4	11.7	29.8	6.8	29.0	84.3	6.5	29.9	9.1
SD		(27.8)	(5.8)	(5.7)	(3.7)	(2.0)	(23.8)	(6.1)	(3.5)	(3.8)	(2.6)

R55 = Reflex 55 wand; SV = Spinevac wand; SV/sut = Spinevac wand and mucosal suture advancement; multi = spinevac (patients 11–15) with or without suture advancement (patients 11, 14 and 15) with hyoid suspension, UPP, palatal advancement (patients 11–15) with or without genioglossus advancement (patients 13 and 15); RDI = respiratory disturbance index; Lsat = nadir oxygen saturation; ESS = Epworth sleepiness scale; BMI = body mass index; PAS = posterior airway space.

patients' sleep apnoea was in fact because of more supine sleep; thus, no patients were made worse by the surgery. The preoperative sedation videonasendoscopies were analysed retrospectively for any differences between responders and non-responders (see below).

In patients having radiofrequency tongue-base reduction with or without radiofrequency palatoplasty, pain was sufficient to require morphine to be given to some patients on the day of surgery; however, analgesia requirements after the first 12 h were usually limited to paracetamol, with occasional use of oxycodone.

Significant complications were seen in three patients. One reactive tongue haematoma requiring emergency tracheotomy and drainage was seen as a result of uncontrolled postoperative hypertension. One temporary hypoglossal nerve neuropraxia occurred, which resolved over 3 months, and one wound infection was seen. This discharged through the puncture site and responded to antibiotics without significant tongue swelling, thus avoiding any need for tracheotomy or formal incision and drainage. No long-term adverse sequelae were seen.

Discussion

Endoscopic CO₂ laser or open excision of the midline with extension to the lateral thirds of the tongue base has yielded around 80% success in the treatment of severe OSAS and macroglossia, when combined with UPP.^{7,8} The high morbidity of these procedures has limited their popularity. Monopolar radiofrequency tongue volume reduction with a mean of 5.5

treatments achieves a reduction in total tongue volume of 17%, although the percentage reduction of the tissue treated remains uncertain.⁴ The mechanisms of volume reduction are coagulative necrosis and subsequent scar contraction, which have been clearly demonstrated in preliminary animal work by the same group.⁹ The bipolar radiofrequency probe used in this series has a dual action of immediate liquification of tissues at the tip of the probe from a plasma spray (coblation) and additional surrounding coagulative necrosis (for haemostasis) with delayed volume reduction of this tissue, secondary to scar contraction. The SpinevacTM wand is more efficient at immediate tissue removal than the Reflex 55TM wand. The immediate space created helped to offset the oedema from tissue damage, and therefore increase the volume of tissue which could be safely treated in one procedure. The single dose of steroid on induction also helped in this regard.

The technique of Powell and co-workers⁹ is largely restricted to the middle-third of the tongue base as a result of the location of the neurovascular bundle entering the tongue base laterally. Localization of this structure (which has a variable position) by ultrasound enabled more extensive dissection laterally with minimal risk of neurovascular damage, and without the morbidity of dissecting and rerouting these structures, as has been advocated by some.⁸

The improved reduction per treatment of the Spinevac wand demonstrated is because of more aggressive tissue removal. Maximization of the effect of tissue reduction on PAS was achieved with suture advancement of the mucosa anteriorly, rather than allowing both lateral and anteroposterior contrac-

tion into the defect. This strategy yielded an increase in PAS, similar to Powell *et al.*'s⁴ monopolar radiofrequency protocol (increase of 3.7 mm in 5.5 treatments) and to the results of more morbid open single-stage tongue-base reduction surgery.⁸

The effects of the intervention on sleep-disordered breathing were modest. The first 10 patients had radiofrequency tongue reduction as the only tongue-base treatment, and their preoperative sedation videonasendoscopies were reviewed retrospectively. One patient had a markedly posteriorly tilted epiglottis, which still caused obstruction, despite good tongue shrinkage (patient 7). He was salvaged with a second-stage hyoid suspension (RDI 43 reduced to 11), but was reported as a failure in this paper. Two patients had poor volume reduction, both of whom were treated with the Reflex 55 probe (patients 3 and 5). There was a greater tendency towards lateral wall collapse in all the other failures, both in the retropalatal and in the retrolingual segments. In particular, if jaw advancement under sedation nasendoscopy failed to overcome lateral wall retrolingual collapse, despite a significant increase in anteroposterior retrolingual space, then cure with tongue volume reduction with or without palatoplasty alone was very unlikely. In these patients, therefore, we concluded that additional procedures aimed at decreasing collapsibility of the lateral wall were likely to be needed for satisfactory sleep apnoea control. These are palatal advancement (utilizing the pulley effect of tensor palati around the hook of hamulus) and hyoid suspension with preservation of stylohyoid ligaments to tension the stylohyoid muscles. Additional procedures were performed on the later patients in the series with good results. The addition of palatal advancement to UPP (as used in the last five patients) has been shown to be more effective than UPP alone at this level by increasing retropalatal area both in anteroposterior and in lateral dimensions, and producing a large fall in segmental closing pressure.^{10,11} We found no significant increase in morbidity by adding palatal advancement to a traditional UPP and, in particular, no patients had velopharyngeal incompetence.

All other tongue-base reduction series in the literature include at least some cases with additional tongue-base or epiglottic procedures. Chabolle *et al.*'s⁸ open tongue-base reduction includes a hyoepiglottoplasty routinely. Although not specifically stated, it is likely that many, if not all, of Powell *et al.*'s^{3,4} series of radiofrequency tongue-base reduction had previous genirotuberle advancement and hyoid suspension as per their phase 1 protocol. Woodson and Fujita's⁷ lingualplasty includes partial epiglottectomy in some patients. It is therefore difficult to assess the efficacy of tongue-base reduction alone from the literature. We admit that good results seen in the last five patients may have largely been as a result of the additional procedures, but our experience has previously been that patients with sleep apnoea and macroglossia are particularly difficult to cure with standard phase 1 tech-

niques unless an adequate retrolingual airspace volume is obtained. Therefore, we feel that whilst radiofrequency submucosal tongue-base excision is relatively ineffective as a sole tongue-base treatment, it is a valuable adjunct to other phase 1 procedures for the subset of sleep apnoeic patients with macroglossia.

The morbidity of the procedure was low. Most patients having tongue-base reduction and radiofrequency-assisted palatoplasty alone were discharged the following day, requiring paracetamol, with some using small amounts of oxycodone for analgesia. Several serious complications occurred. One patient rapidly developed a tongue-base haematoma around 30 min postoperatively in the context of uncontrolled hypertension. He required an emergency tracheotomy under local anaesthetic and drainage procedure. He was subsequently decanulated on day 7 postoperatively, without any long-term sequelae. In a large series from the Stanford group, 70% of the patients with sleep apnoea undergoing upper airway surgery required intravenous postoperative antihypertensive treatment.¹² Our patients typically had labile blood pressure intraoperatively and particularly in the first 1–2 h postoperatively. Unlike the monopolar radiofrequency technique, our technique produces a cavity in the tongue musculature with raw surfaces, which, despite the coagulating effect of the probe on the surface, is susceptible to bleeding in the face of hypertension. Ensuring that postoperative mean arterial pressure was kept below 100 mmHg, it protected all subsequent patients against reactive tongue bleeding. One wound infection was seen in the only patient to have trans-mucosal suture advancement of the tongue mucosa, which settled on antibiotics and probing of the suprahyoid incision. The extramucosal suture technique avoids salivary contamination, and there have been no more instances of wound infection. One case of temporary hypoglossal neuropraxia occurred when the probe inadvertently passed within 3 mm of the hypoglossal nerve. This resolved completely over several months. High-quality ultrasound, precise communication between the sonographer and the surgeon and careful dissection are needed to avoid this complication.

Conclusion

The spinevac and suture technique achieve tongue volume reduction in one procedure, which is comparable to current-staged monopolar radiofrequency treatment protocols requiring up to 6 months, to higher morbidity alternatives of open tongue base, or to the endoscopic CO₂ laser tongue-base excision. Polysomnographic outcome is dependent on patient selection and is improved by additional phase 1 procedures. These results are only applicable to OSAS patients with retrolingual collapse and large tongues, and should not be extrapolated to those with skeletal deficiency or retrolingual hypotonia without macroglossia.

A larger series is required to confirm these initial results, and work is ongoing to prospectively study the efficacy of the spinevac and suture techniques in patients with macroglossia, who have previously had other sites of collapse stabilized. The technique is safe as long as careful adherence to the perioperative care protocol is observed. Avoidance of postoperative oedema and hypertension is stressed. Morbidity is minimal.

References

- 1 SHER A.E., SCHECHTMAN K.B. & PICCIRILLO J.F. (1996) An American Sleep Disorders Association review. The efficacy of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep* **19**, 156–177
- 2 SHEPARD J.W. & THAWLEY S.E. (1990) Localization of upper airway collapse during sleep in patients with obstructive sleep apnea. *Am. Rev. Respir. Dis.* **141**, 1350–1355
- 3 RILEY R.W., POWELL N.B. & GUILLEMINAULT C. (1993) Obstructive sleep apnea syndrome: a review of 306 consecutively treated surgical patients. *Otolaryngol. Head Neck Surg.* **108**, 117–125
- 4 POWELL N.B., RILEY R.W. & GUILLEMINAULT C. (1999) Radiofrequency tongue-base reduction in sleep-disordered breathing: a pilot study. *Otolaryngol. Head Neck Surg.* **120**, 656–664
- 5 DEBERRY-BOROWIECKI B., KUKWA A. & BLANKS R.H.I. (1988) Cephalometric analysis for diagnosis and treatment of obstructive sleep apnea. *Laryngoscope* **98**, 226–234
- 6 ROBLIN G., RHYS WILLIAMS A. & WHITTET H. (2001) Target-controlled infusion in sleep endoscopy. *Laryngoscope* **111**, 175–176
- 7 WOODSON B.T. & FUJITA S. (1992) Clinical experience with lingualplasty as part of the treatment of severe obstructive sleep apnea. *Otolaryngol. Head Neck Surg.* **107**, 40–48
- 8 CHABOLLE F., WAGNER I., BLUMEN M.B. *et al.* (1999) Tongue-base reduction with hyoepiglottomy: a treatment for severe obstructive sleep apnea. *Laryngoscope* **109**, 1273–1280
- 9 POWELL N.B., RILEY R.W., TROELL R.J. *et al.* (1997) Radiofrequency volumetric reduction of the tongue. A porcine pilot study for the treatment of obstructive sleep apnea syndrome. *Chest* **111**, 1348–1355
- 10 WOODSON B.T. (1997) Retropalatal airway characteristics in uvulopalatopharyngoplasty compared with transpalatal advancement pharyngoplasty. *Laryngoscope* **107**, 735–740
- 11 WOODSON B.T. (1999) Acute effects of palatopharyngoplasty on airway collapsibility. *Otolaryngol. Head Neck Surg.* **121**, 82–86
- 12 RILEY R.W., POWELL N.B., GUILLEMINAULT C. *et al.* (1997) Obstructive sleep apnea surgery: risk management and complications. *Otolaryngol. Head Neck Surg.* **117**, 648–652

Randomized-controlled study comparing post-operative pain between coblation palatoplasty and laser palatoplasty¹

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Objectives: This study aimed to evaluate differences in post-operative pain comparing KTP laser-assisted uvulopalatoplasty without tonsillectomy (LAUP) with a new described surgical method: coblation uvulopalatoplasty with tonsillectomy (CP). We also evaluate the impact of each surgical technique in reduction of snoring loudness.

Material and methods: Single blind randomized-controlled trial. From a population of 41 consecutive patients on the waiting list for uvulopalatoplasty for simple snoring, the study group was reduced to 17 CP and 13 LAUP. Post-operative pain and reduction of snoring loudness were recorded using visual analogue scales (VAS) during the first 15 post-operative days. Post-operative snoring loudness was documented for 1-year period.

Results: Both groups had similar post-operative pain during the first seven post-operative days. A statistically significant reduction in post-operative pain was observed in

the CP group after day 8, and maintained until the end of the study. Reduction of snoring loudness was significant in both groups, but no differences were observed between them.

Discussion: Coblation uvulopalatoplasty compared with LAUP demonstrates a reduction in post-operative pain, significant after the first post-operative week. The collateral thermal injury caused by laser is responsible for the slow-healing rate and maintained post-operative pain. Coblation dissociates tissue at lower temperatures with minimal collateral thermal injury and consequently faster and less painful recovery. Both surgical procedures have significant and similar reduction in snoring loudness.

Conclusions: Both methods are adequate treatment options for snoring. The less painful recovery in CP promotes this surgical technique as our preferred choice for palate surgery.

Ikematsu in 1952 described the principles of uvulopalatopharyngoplasty (UPPP or U3P),¹ but the procedure was not popularized until 1981 when Fujita² re-introduced UPPP in North America, changing the perception of snoring from a social nuisance to a potentially curable condition. The initial euphoria of surgical treatment for snoring and obstructive sleep apnoea was subdued over the coming years, by the post-operative morbidity, high rate of complications and progressive deterioration in the long-term results.³

Palatoplasty surgery is associated with high post-operative morbidity in terms of severe post-operative pain and associated odynophagia.^{4,5} UPPP has also a high inci-

dence of complications, including: reactionary and delayed haemorrhage, infection, nasal regurgitation and velopalatine insufficiency.^{1,4–6} The severity of early post-operative discomfort, the high prevalence of complications and the discouraging long-term results has dissuaded some surgeons from using these mutilating surgical methods and prompted the search for less aggressive and more tolerable therapeutic options.¹

In 1990, Kamami⁷ proposed a laser-assisted uvulopalatoplasty (LAUP) as a more accurate and tolerated surgical modification of UPPP, with similar long-term surgical results.⁵ Minor variations by Coleman^{5,8} in 1993 allowed laser-palatal surgery to be performed under sedation or local analgesia, as a staged procedure in an outpatient setting.^{1,5,6}

Laser produces pyrolysis and tissue vaporization by heating the target tissue to a temperature up to 750–900°C with consequent considerable collateral thermal tissue damage.^{1,9} In the oral cavity/oropharynx, the potassium titanyl-phosphate crystal laser (KTP laser) is the laser of choice. It produces a green visible beam that can

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be transmitted down an optical fibre and coupled to a free handle appliance to be manoeuvred in this complex anatomical space.¹

A recently introduced surgical instrument for tissue dissection is coblation or electro-dissociation.^{10–12} By coblation, a medium rich in sodium is dissociated into free ions, which are responsible for the destruction of intercellular bonds, resulting in tissue dissociation.^{11–13} This reaction is achieved at temperatures between 60 and 70°C with minimal collateral thermal tissue damage.^{10,11,14}

The advantage of coblation when compared with surgical methods producing extreme temperatures and extensive collateral thermal tissue damage (such as diathermy or laser)⁹ is faster tissue healing^{1,10,13,14} and consequently decreased post-operative pain.^{12,13} This hypothesis has been demonstrated in diverse medical publications evaluating the post-operative pain and complication rates between coblation and diathermy tonsillectomy.^{11–13}

Objectives

Using the theory of direct relation between thermal tissue damage and maintained post-operative pain,^{9,11–13} we have proposed a study aimed at comparing post-operative pain between coblation-assisted uvulopalatoplasty with tonsillectomy (CP) and our departmental standard palatoplasty technique: KTP LAUP. Simultaneously, we aim to evaluate the impact of these techniques in the reduction of snoring loudness.

Materials and methods

Participants/recruitment

This single blind randomized trial was granted ethical approval in December 2002. The study period extended from December 2002 to September 2003 and included all patients on the waiting list for uvulopalatoplasty for simple snoring in Blackpool Victoria Hospital, which was compliant with our inclusion criteria. The patients were contacted by post in October 2004 to obtain information regarding the post-operative snoring loudness.

The inclusion criteria for this study were: simple snoring [excluding obstructive sleep apnoea syndrome (OSAS)], age over 18 years, ability to understand and consent to the study, no cardio-vascular or chronic respiratory disease, no diabetes, no haematological disorders or coagulopathies, no neurological disorders, no regular use of analgesia and no concomitant surgery (only UPPP).

Obstructive sleep apnoea syndrome was excluded by medical history, clinical examination and Epworth's score

index <12. Patient with suspected OSAS were investigated with polysomnography, including respiratory disturbance index (RDI) and apnoea/hypopnoea index.

Randomization/blinding

The study population consisted in the entire group of patients undergoing uvulopalatoplasty during the study period. They were selected, recruited, instructed and consented in the pre-operative period. No further contact between patient and researcher was allowed until the completion of the study. The randomization was predetermined by computer random-generated number (STATSDIRECT[®]; statistics package). The allocation sequence was kept in theatre in individual, numbered, opaque, concealed envelopes and only revealed to the surgeon and theatre staff when the patient was called from theatre.

Interventions

All surgery was carried out under general anaesthesia. In the CP group, the surgical procedure was performed under microscopic vision using an ArthroCare Evac[™] 70 ArthroWand[®] (ArthroCare Corp., Sunnyvale, CA, USA). In the CP group, we performed a routine coblation tonsillectomy using settings 6, and trimming of the soft palate/uvula and triangular submucosal resection of the soft palate using settings 7–8. In the LAUP group, we limited the surgical procedure to an excision of the soft palate/uvula and triangular submucosal resection of the soft palate, without tonsillectomy. We used a KTP/532[™] laser (Laserscope[®]; San Diego, CA, USA) with a delivered energy of 12 W in a continuous exposure mode.

All patients were discharged the day after surgery with an analgesic regimen consisting of two tablets of co-codamol[®] (paracetamol 500 mg and codeine phosphate 30 mg) every 4 h as required, and ibuprofen 400 mg every 8 h as required. The patients were followed up in the ENT clinic 2 weeks after surgery. Subjects were withdrawn from the study if during the study period further medication was introduced to reduce the throat discomfort (increase analgesic regimen) or to treat a possible oropharyngeal infection (antibiotic).

Outcomes

The main outcome parameter to compare both surgical procedures was the subjective pain level recorded by the patient. Secondary outcome parameters were the total doses of analgesia used and the subjective snoring level recorded by the patient's partner. Pain and snoring were

evaluated using visual analogue scales (VAS) of 100 mm. The pain level was recorded daily for the first two post-operative weeks in conjunction with the daily requirements of analgesia. Snoring levels were recorded by two separate questionnaires. The first questionnaire contrasted pre-operative snoring with the snoring at one and two post-operative weeks. The second questionnaire contrasted pre-operative snoring with the snoring at 1 month and 1 year after surgery.

We discarded the use of objective snoring measurement methods based on sleeping patents and sound recording,⁴ because of poor correlation reported between those objective indices and the subjective disturbances produced by snoring.^{3,5} Because it is usually the patient partner's perception of snoring that motivates the patient to seek treatment, we felt that the subjective measurement of the surgical outcome by the patient's partner has the most significant clinical relevance³. Therefore, we have used patient partner's snoring perception, measured with VASs.

Sample size

The study was designed to compare post-operative pain between groups. We considered clinically significant, a difference in the visual-analogue scales of 2.5 cm, with an estimated SD of 2 cm. For an 80% power with $P < 0.05$, 12 patients per group were adequate. We estimated a dropout rate of 20% because of follow-up problems and withdrawal because of the introduction of new medication. The final estimated sample was two arms of 20 patients. It was our initial intention to evaluate differences in snoring loudness between groups, but two arms of 75–120 patients would be needed to evaluate differences of 2.5 cm, with an estimated SD of 4–4.5 cm. A sample size of 200 patients was unrealistic for the recruitment capacity of our department.

Statistical method

The results were analysed using STATSDIRECT[®] statistics package, version 2.2.3. Non-parametrical tests for the median were analysed statistically using the Mann–Whitney *U*-test. Indication of statistical differences between groups was determined as $P < 0.05$.

Results

Participant flow/adverse events

From a total of 44 patient undergoing palatoplasty during the study period, the study group was reduced to 41

patients because one patient did not satisfy the inclusion criteria (diabetic) and two patients refuse to participate. The initial study population was of 41 patients: 23 underwent CP and 18 LAUP. The CP sample was reduced from 23 to 17, because three patients failed to return the questionnaire, two were re-admitted for post-operative bleeding (antibiotics and analgesia were introduced) and one patient developed a post-operative infection (antibiotics were introduced). In a similar manner, the LAUP population was reduced from 18 to 13, because three patients failed to return the questionnaire, one had encountered post-operative bleeding and one developed an infection.

Baseline data

The study population consisted of 17 patients in the CP group, 13 males and four females with an age group ranging from 29 to 67 years. The LAUP group consisted of 13 patients, nine males and four females, with ages ranging from 26 to 60 years.

Outcomes and estimation

The post-operative pain was analysed in three ways. Firstly, we compared the overall post-operative pain between both groups during the 2-week study period. Trying to evaluate the pace of tissue healing, we divided the study period into weeks. We consider that the first week or early post-operative pain represents the surgical tissue damage,^{9,10,13,14} and the second week or late post-operative pain represents healing differences secondary to thermal tissue damage.^{9,10,13,14} The median overall pain was significantly less in the CP group (median: 57.29) compared with the laser group (median: 79.85), with a $P = 0.0116$ (CI: 42.94–4.45). The early post-operative pain (first week) was less in the coblation group (median: 35.98) compared with the laser group (median: 40.68), but was not statistically significant ($P = 0.457$, CI: 11.82 to –5.99). On the second post-operative week, the pain in the coblation group (median: 18.18) was significantly less compared with the laser group (median: 44) with a $P = 0.0039$ (CI: 32.52–5.61) (Fig. 1) (Table 1).

The use of analgesia was recorded as total number of doses per day. As expected, the results correlated with the patient's pain scores, but the differences were not statistically significant. For the whole study period, the CP group used less analgesia (median: 2.8) than the LAUP group (median: 4) but was non-significant ($P = 0.37$). During the first week, both groups consumed similar doses of analgesia (CAUP median: 4.29, LAUP median: 4.14, $P = 0.48$). During the second week, there was a non-significant reduction of the use of analgesia in the

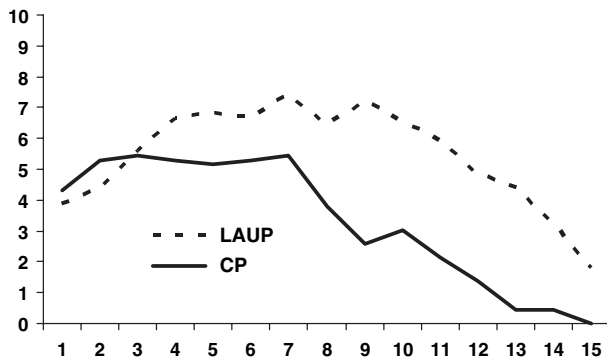


Fig. 1. Median post-operative pain comparing coblation uvulopalatoplasty with tonsillectomy (CP) and laser-assisted uvulopalatoplasty without tonsillectomy (LAUP) in the first 15 post-operative days.

CAUP group (CAUP median: 1.5, LAUP median: 2.88, $P = 0.25$).

Information regarding snoring loudness was obtained by two separate questionnaires. The first questionnaire was used to evaluate differences in the early post-operative period (2 weeks after surgery) and the second questionnaire to evaluate the late or maintained snoring control (1 year after surgery). The median results of those questionnaires are summarized in Table 2.

With our sample power, the only valid conclusions were on the individual impact of each technique in the snoring loudness. The CP group had a significantly earlier reduction of snoring loudness the first week after surgery

Table 2. Median (and quartiles) snoring level comparing CAP and LAUP in the early (2 weeks) and late (1 year) questionnaire

		CP		LAUP	
		Median	Quartiles	Median	Quartiles
Early results	Pre-operative	7.1	6.59–7.39	7	6.0–7.65
	1 week	3.57	1.19–4.63	3.75	2.40–6.55
	2 weeks	0.97	0.69–2.10	1.35	0.88–2.10
Late results	Pre-operative	8.64	8.37–9.24	8.53	7.83–9.24
	1 month	4.02	1.30–5.38	6.14	3.83–6.86
	1 year	4.02	0.43–6.68	2.77	1.63–3.95

($P < 0.0001$, CI: 2.15–5.1), which continued during the second week ($P = 0.0295$, CI: 0.15–3.45). In the 1-year snoring questionnaire, the CP group had a post-operative reduction of the snoring for the first month ($P = 0.0002$, CI: 2.5–7.55), but it reached a plateau and was maintained until the end of the year ($P = 0.91$, CI: 3.75 to –2.93). In the LAUP group, the early post-operative snoring questionnaire showed similar results to that of the CP group. A significant reduction of the snoring level occurred the first week after surgery ($P = 0.0149$, CI: 0.35–4.5), which continued for the second week ($P = 0.007$, CI: 0.5–4.95). The 1-year questionnaire of the LAUP group showed an early significant post-operative reduction of the snoring during the first months ($P < 0.0001$, CI: 1.31–4.51), but in this group the reduction of snoring continues during the 1-year period ($P = 0.0201$, CI: 0.38–4.73) (Fig. 2).

Table 1. Daily results and statistic analysis (Mann–Whitney U -Test) comparing post-operative pain between coblation palatoplasty (CP) and laser-assisted palatoplasty (LAUP)

Day	Coblation palatoplasty			Laser-assisted palatoplasty			P -value	CI		
	Mean \pm SD	Median–Quartiles–Range		Mean \pm SD	Median–Quartiles–Range					
1	4.60 \pm 1.98	4.32	3.4–5	1.21–9.7	4.92 \pm 2.33	3.86	3.2–6.6	2.7–9.1	0.860	–1.97 to 1.36
2	5.47 \pm 1.4	5.30	4.8–6	2.9–8.1	5.31 \pm 2.13	4.39	3.6–7.3	3–9.2	0.438	–1.21 to 1.67
3	5.60 \pm 1.8	5.45	4.4–6.7	3–9.5	5.87 \pm 1.78	5.61	4.7–7	3.3–8.9	0.672	–1.75 to 1.07
4	5.57 \pm 1.8	5.30	4–7	3–8.6	6.35 \pm 2	6.67	5.2–7.7	3.1–9.1	0.295	–2.5 to 0.88
5	5.87 \pm 2.3	5.15	3.9–8	2.8–9.47	6.46 \pm 1.91	6.82	4.8–8	3.2–8.9	0.556	–2.65 to 0.99
6	5.68 \pm 2.3	5.30	4.1–7	2.3–9.5	6.56 \pm 1.97	6.67	5.2–7.9	3.5–8.9	0.379	–2.58 to 0.76
7	5.34 \pm 2	5.45	3.5–7	1.9–8.3	6.59 \pm 2.16	7.42	5.2–8.5	2.8–9.1	0.088	–3.04 to 0.31
8	4.45 \pm 2.4	3.79	2.7–7	1.1–8.3	6.55 \pm 2.11	6.44	5.8–8.5	2.7–8.9	0.024	4.24–0.45
9	3.63 \pm 2.3	2.58	2–5.5	0.8–7.4	6.52 \pm 2.56	7.2	5.6–8.3	1.7–9.7	0.005	4.94–0.92
10	3.02 \pm 2.1	3.03	1.1–4.3	0.3–7	6.26 \pm 2.6	6.55	5.4–7.9	1.5–9.8	0.001	5.23–1.22
11	2.58 \pm 1.9	2.12	0.9–3.9	0.2–5.5	5.54 \pm 2.62	5.91	4.5–6.8	1.1–9.8	0.001	5–0.91
12	2.13 \pm 1.8	1.36	0.6–3.9	0.9–5.3	4.7 \pm 2.64	4.85	3.3–6.7	0.6–9.4	0.004	4.32–0.61
13	1.31 \pm 1.6	0.45	0.2–2	0–5.2	3.82 \pm 2.58	4.39	1.8–4.8	0.3–8.6	0.002	4.33–0.68
14	1.21 \pm 1.6	0.45	0–1.7	0–5.9	2.97 \pm 3.24	3.24	0.8–4.4	0–7.7	0.045	3.64–0
15	0.78 \pm 1.5	0	0–0.6	0–5.9	2.32 \pm 2.2	2.2	0.5–4.2	0–7	0.024	3.03–0

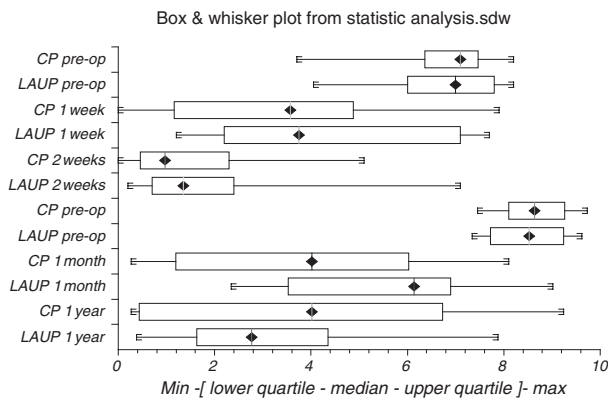


Fig. 2. Box & whisker snoring graphic comparing CP and LAUP. Median, quartiles and range. Two weeks questionnaire in the top (pre-op, 1 week, 2 weeks). One year questionnaire in the bottom (pre-op, 1 month, 1 year).

Considering the effect of our sample restrictions and possible inaccuracies on the results, a second analysis was performed contrasting differences in the snoring loudness between both methods. In the early questionnaires, both surgical techniques started from similar pre-operative snoring levels ($P = 0.95$, CI: 1.1 to -0.8). The reduction of the snoring levels in the two groups was not statistically different for the first week ($P = 0.32$, CI: 1.15 to -3.15) or second week ($P = 0.503$, CI: 0.65–1.1). In the 1-year questionnaire, both surgical techniques had similar pre-operative snoring levels ($P = 0.641$, CI: 1.03 to -0.6), both had similar reduction of snoring for the first month ($P = 0.168$, CI: 0.93 to -4.46), but at the end of the year, the LAUP group had a slightly more reduced final snoring level, which was not statistically significantly different ($P = 0.985$, CI: 4.29 to -2.34) (Fig. 2).

Discussion

In this randomized-controlled study, we are not only comparing two different surgical devices to perform palate surgery, but also take into consideration some variations in the surgical technique. In the CP group, we have included tonsillectomy in the surgical resection, which was omitted in the LAUP group. The addition of tonsillectomy to palatoplasty has been reported to produce a better reduction of snoring and OSAS.¹⁰ Therefore, the more mutilating approach used in the CP group would pre-suppose a more painful post-operative recovery but better long-term snoring control.

Various authors have suggested that the early post-operative pain in surgery is mainly because of the direct surgical injury to tissues as mucosa, skin and muscle.¹ In the specific case of palate surgery, the palate/pharyngeal

mucosa has profuse tactile and pain innervations and consequently is prone to considerable discomfort.⁹ Because tonsillectomy results in damage to the oropharyngeal mucosa, we pre-supposed that the dissection of the tonsil in the CP group would be associated with more early post-operative discomfort. This has been disproved in our results, in which the CP group had non-significantly lower pain scores in the first post-operative week and significantly less overall post-operative pain. It can be hypothesized that despite the CP group having more extensive mucosal resection, than in the LAUP group, the degree of mucosal and muscular damage was more severe in the LAUP group as a consequence of the thermal tissue injury inflicted.^{10,11,14}

Late post-operative pain is thought to be related to the pace of tissue healing.¹ The substantial thermal tissue injury caused by laser delayed healing in the palate^{1,10,13,14} and maintained the discomfort in the LAUP group.⁹ This supposition was confirmed by our results, showing a significant maintained late post-operative pain in the LAUP group until the end of the second week. The same conclusions have been found in studies comparing tonsillectomies performed by coblation and tonsillectomies performed by surgical devices producing thermal tissue injury (diathermy).^{11–13}

Both surgical techniques proved to be an adequate option in the treatment of snoring. Both techniques produced a similar early post-operative reduction of snoring, which was maintained for the whole study year in both groups. As mentioned, the more mutilating surgery used in the CP group was justified by an expected greater decrease of the snoring loudness. The results dispute our expectations, as the LAUP group had better long-term results compared with the CP. A possible explanation could be that the thermal injury inflicted by the laser has increased the scarring and tightened the soft palate^{9,14} with the consequent decrease of palate mobility and reduction of snoring level. These results may question the contribution of tonsillectomy in the long-term control of snoring.

The rate of complication in this study was high, as is described in previous literature⁴, but similar in both groups. We cannot comment about complication rates because the power of the study sample is insufficient to reach conclusions.

Conclusion

Generalizability/overall evidence

Post-operative pain in is legendary and still considered a major contributory factor in the morbidity of this type of surgery, and one of the more important reasons that

discourage the patient and surgeons from undertaking UPPP.³ CP is associated with less post-operative pain than LAUP, during the whole 2 weeks post-operative study period although the differences are only statistically significant during the second week.

Reduction of loudness of snoring is significant in both groups, and therefore both surgical procedures can be considered valid options in the treatment of snoring. The addition of tonsillectomy in the CP group did not improve the final snoring level. Therefore, more extensive studies will be necessary comparing CP with and without tonsillectomy, to evaluate the impact of tonsillectomy on snoring loudness.

One of the limitations of the study is the restricted 1-year follow-up. Because of the described discouraging long-term UPPP results,³ we considered it necessary to extend the follow-up period to at least 5 years, to evaluate the long-term results.

The significant differences in post-operative pain with similar reduction of snoring level have promoted CP over LAUP as our preferred surgical option in the treatment of snoring.

Conflict of interest

None declared.

References

- 1 Ducic Y., Marsan J., Olberg B. *et al.* (1996). Comparison of laser-assisted uvulopalatoplasty to electrocautery-assisted uvulopalatoplasty: a clinical and pathologic correlation in an animal model. *J. Otorhinolaryngol.* **25**, 234–238
- 2 Fujita S., Conway W., Zorick F., *et al.* (1981). Surgical correction of anatomical abnormalities of obstructive sleep apnea syndrome: uvulopalatopharyngoplasty. *Otolaryngol. Head Neck Surg.* **89**, 923–934
- 3 Hicklin L.A., Tostevin P. & Dasan S. (2000). Retrospective survey of long-term results and patient satisfaction with uvulopalatopharyngoplasty for snoring. *J. Laryngol. Otol.* **114**, 675–681
- 4 Osman E.Z., Osborne J.E., Hill P.D. *et al.* (2000). Uvulopalatopharyngoplasty versus laser assisted uvulopalatoplasty for the treatment of snoring: an objective randomised clinical trial. *Clin. Otolaryngol.* **25**, 305–310
- 5 Maw J. & Marsan J. (1997). Uvulopalatoplasty versus Laser-Assisted Uvulopalatopharyngoplasty in the treatment of Snoring. *J. Otolaryngol.* **26**, 232–235
- 6 Schiebert L.L., Zeiler J.E., Bandaruk L.R. *et al.* (1997). Laser-assisted uvulopalatoplasty: evaluation of postoperative discomfort and the effectiveness of this procedure. *Lasers Surg. Med.* **20**, 157–163
- 7 Kamami Y.V. (1990). Laser CO₂ for snoring. Preliminary results. *Acta Oto. Rhino. Laryngol. Bel.* **44**, 451–456
- 8 Coleman J.A. (1993). *Laser-Assisted Uvula-Palatoplasty, A new Procedure for Snoring*. Instructional Course, Department of Otolaryngology, Vanderbilt University Medical Center. April 13
- 9 Rombaux P., Hamoir M., Bertrand B. *et al.* (2003). Postoperative pain and side effects after uvulopalatopharyngoplasty, laser-assisted uvulopalatoplasty, and radiofrequency tissue volume reduction in primary snoring. *Laryngoscope* **113**, 2169–2173
- 10 Kern R.C., Kutler D.I., Reid K.J. *et al.* (2003). Laser assisted Uvulopalatoplasty and Tonsillectomy for the Management of Obstructive Sleep Apnoea Syndrome. *Laryngoscope* **113**, 1175–1181
- 11 Belloso A., Chidambaram A., Morar P. *et al.* (2003). Coblation tonsillectomy versus dissection tonsillectomy: postoperative hemorrhage. *Laryngoscope* **113**, 2010–2013
- 12 Timms M.S. & Temple R.H. (2002). Coblation tonsillectomy: a double blind randomised controlled study. *J. Laryngol. Otol.* **116**, 450–452
- 13 Temple R.H. & Timms M.S. (2001). Paediatric coblation tonsillectomy. *Int. J. Paediatr. Otorhinolaryngol.* **61**, 195–198
- 14 Chinpaioj S., Feldman M.D., Saunders J.C. *et al.* (2001). A comparison of monopolar electrosurgery to a new multipolar electrosurgical system in a rat model. *Laryngoscope* **111**, 213–217

How we do it: Coblation tonsillectomy complication rates from a single ENT department compared with the National Prospective Tonsillectomy Audit

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Keypoints

- Coblation tonsillectomy is a relatively new technique, the results of which need auditing within practising units, to justify its continued usage.
- The National Prospective Tonsillectomy Audit provides an excellent source of data for individual units to compare their results to.
- This retrospective audit of 391 coblation tonsillectomies shows that our units haemorrhage and return to theatre rates are similar to the National rates for cold steel & ties data.
- Resolution of training issues and patient selection may lead to increased use of this technique.

Recent statistics from the National Prospective Tonsillectomy Audit (NPTA) indicate that tonsillectomy using the coblation technique carries a higher complication rate than by the cold steel technique.¹ At Northampton General Hospital (NGH), coblation has been used as a technique for tonsillectomy for over 2 years, by a number of the consultant surgeons who have embraced it as a preferred technique. Instinct and regular departmental morbidity and mortality meetings tells us that we are not experiencing a higher complication rate than for other techniques, so this audit was conducted to formally analyse our departments complications and to draw comparison with the NPTAs figures.

Coblation is a relatively novel technique for an ancient operation: it makes use of a radiofrequency electrical current through a sodium chloride solution to cause cell lysis (ablate). The theoretical advantages of this are to remove the tonsils with a lower maximum heat (60°), and hence less energy, than that caused by bipolar diathermy. This might allow for less 'collateral damage', fewer complications and a more comfortable post-operative recovery. The coagulation setting arrests any bleeding the moment it is seen, which should be an advantage over cold-steel dissection in which there is some inevitable delay. This allows for lower intra-operative blood loss, an issue particularly important in children, although concern exists

regarding a possible subsequent higher incidence of secondary haemorrhage if the instrument is over-used.

Methods

All coblation tonsillectomies undertaken between April 2003 to May 2005 in NGH and the local private hospital (The Three Shires) were included. A proportion of these patients were therefore also included in the NPTA (July 2003–September 2004). Patients were selected for tonsillectomy for the indications of recurrent tonsillitis [using in general the Scottish Intercollegiate Guidelines Network (SIGN) criteria], peritonsillar abscess and obstructive sleep apnoea. The method of dissection to be used did not influence this decision.

Tonsillectomies were performed with the ArthroCare PlasmaWand (Arthrocare ENT, Sunnyvale, CA, USA). This period covered the initiation of the technique within the unit as well as its rising popularity and increased employment. A total of 14 surgeons (five Consultants, eight Specialist Registrars, one Associate Specialist) were involved. The consultants involved used coblation exclusively and so did not select their patients specifically for the technique. Use of coblation by SpRs was determined by their supervising consultant after a period of assessment. Again, patients were not specifically selected. There were no exclusion criteria. In no cases did the dissection start with coblation and revert to another technique.

The hospital computer-based patient record system was used to identify any patients who had a delayed discharge

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(>1 night stay) or were readmitted via A&E or their General Practitioner. The notes of these patients were then studied. Complications were considered as primary haemorrhage (any bleeding that lead to delayed discharge, blood transfusion or return to theatre during initial stay), secondary haemorrhage (any bleeding that led to readmission to hospital within 28 days post-operatively), return to theatre, delayed discharge (because of pain, vomiting, etc) and readmission for pain.

Statistical analysis was made between this audits data and that from the NPTA, using Chi-squared tests.

Results

During the study period 391 coblation tonsillectomies were performed. 58.3% of the patients were female and 41.7% were male. The age range was 2–89 years with a median of 44 years. This is very similar to the NPTA sample which studied 1565 coblation patients (5% of the total number studied): 60.1% female and 39.2% male and to all NPTA techniques combined [Table 1].

The tonsillectomies were performed by consultants (68.0%), SpRs (24.1%) and Associate Specialists (1.5%).

The primary haemorrhage rate was 1.0%, secondary rate 1.5% with an overall haemorrhage rate of 2.6%. All primary haemorrhages returned to theatre (a rate of 1.0%) whilst none of the secondary haemorrhages did. None of the secondary haemorrhages were found to be actively bleeding on admission to hospital. They were treated with 24 hours of intravenous antibiotics and sub-

sequently discharged on oral antibiotics. There was a delayed discharge rate of 0.5% and a readmission for pain rate of 0.5%.

Discussion

The NPTA has provided an excellent source of data and whilst it did not go so far as to give specific recommendations for dissection technique in tonsillectomy, the figures for cold steel dissection and ties/packs came out most favourably. This method is looking to be the gold standard against which others are compared.

Table 2 compares our data with the NPTA coblation data. Our secondary haemorrhage rate is 1.5% compared with 3.6% in the NPTA, a difference that is statistically significant [difference 2.1% (95% CI: 0.6–3.6) $P < 0.05$]. Our figures for primary haemorrhage and return to theatre for both primary and secondary bleeds are statistically the same. Comparison with the NPTA cold steel dissection and ties/packs [Table 3] shows that rates for haemorrhage and return to theatre are not statistically different. Our coblation data does not come out worse than the best of the NPTA.

With regard to secondary haemorrhage rates, our research showed that none returned to theatre nor presented with active bleeding. Inclusion criteria for secondary haemorrhage must vary widely between units and individuals. What one person sends home and so does not include in their complications data, another might admit. Non-ENT Senior House Officer cover out-of-hours exacerbates this problem. Secondary haemorrhage figures are the hardest to be certain of regardless of technique, with too much potential for reporting bias. A recent Editorial in *Clinical Otolaryngology* also suggested that it is the return to theatre rate that is most important.²

All of our primary haemorrhages returned to theatre. In total there were four primary haemorrhages, two of which were carried out during particular surgeon's first seven cases, or within a possible 'training period' of the coblator technique. Any new procedure has a learning curve, the number required to acquire the new

Table 1. Age-sex distribution for current audit compared with the National Prospective Tonsillectomy Audit (NPTA)

Age (years)	% Current audit		% NPTA (all methods)	
	Male	Female	Male	Female
<5	25	24	23	10
5–16	41	37	49	46
>16	34	39	28	43

Table 2. Comparison of current audit with the National Prospective Tonsillectomy Audit (NPTA) coblation data

Outcome	% in current audit (n= 391)	% in NPTA (n= 1565)	Difference	95% CI	P value*
Primary haemorrhage	1.0 (4/391)	1.0 (15/1565)	0	–1.2 to 1.0	0.91
Secondary haemorrhage	1.5 (6/391)	3.6 (57/1565)	2.1	0.6 to 3.6	0.04
Primary return to theatre	1.0 (4/391)	1.1 (17/1565)	0.1	–1.1 to 1.2	0.91
Secondary return to theatre	0.0 (0/391)	0.7 (11/1565)	0.7	0.3 to 1.1	0.10
Overall haemorrhage	2.6 (10/391)	4.6 (72/1565)	2.0	0.2 to 3.9	0.07

*Chi-squared test.

Table 3. Comparison of current audit with the National Prospective Tonsillectomy Audit (NPTA) cold steel & ties/packs data

Outcome	% in current audit (n= 391)	% in NPTA (n= 4285)	Difference	95% CI	P value*
Primary haemorrhage	1.0 (4/391)	0.8 (34/4285)	-0.2	-1.3 to 0.8	0.63
Secondary haemorrhage	1.5 (6/391)	1.0 (43/4285)	-0.5	-1.8 to 0.7	0.32
Primary return to theatre	1.0 (4/391)	0.6 (26/4285)	-0.4	-1.4 to 0.6	0.32
Secondary return to theatre	0.0 (0/391)	0.2 (8/4285)	0.2	0.1 to 0.3	0.39
Overall haemorrhage	2.6 (10/391)	1.7 (73/4285)	-0.9	-2.5 to 0.8	0.22

*Chi-squared test.

technique varying amongst individuals, but a figure of 15 was considered appropriate in Philpott's study³ in which the data from each surgeon's first 15 coblation cases was excluded from the analysis. Timms (one of the most experienced coblation operators in the country) and the manufacturers, recommend 20 paediatric tonsillectomies should be undertaken before performing more difficult adult tonsillectomies.⁴ The NPTA may have included the initial 15 or so coblation tonsillectomies for a number of surgeons in which a higher yield of complications could be expected. The inclusion of these figures in the NPTA is quite correct and may help give a more accurate picture of haemorrhage rates in practice than if they were excluded. However, it may help explain the difference between our figures and those of the NPTA and again highlights the need for individual units to audit their own results.

Of our two remaining primary haemorrhages, one had anaesthetic complications, requiring them to have opiate reversal and so wake in pain and distress. The patient was then given a dose of Ketorolac, now non-formulary and a known potent anti-platelet agent. We cannot exclude this case from our analysis, but can recognize that the complication was likely independent of the dissection technique. National audits can help guide our practice, but they intrinsically generalize and potentially over-simplify their conclusions. By looking at our units personal experience in detail, we can reassure ourselves that acceptable complication rates are being achieved with this novel technique.

In selecting a technique for use in the National Health Service, cost effectiveness must be considered. Data from the NPTA suggests that patients are more likely to have day case surgery when coblation tonsillectomy has been performed (up to 40% of cases) compared with any other technique (cold steel rate 7%, bipolar dissection rate 19%).⁵ This would counter the cost incurred in the instruments by saving the cost of an overnight hospital stay. This in itself is not sufficient evidence that coblation is a more suitable tool in day-case tonsillectomy as there are too many potential confounding factors, but it does

highlight a further avenue for research. With fears regarding the spread of prion diseases such as new variant Creutzfeld-Jacob disease, one must also consider the merits of entirely disposable instruments in surgery.

Analysing the benefits of coblation with respect to age may prove to be most interesting. Children's tonsils are generally smaller. One suspects they are also less fibrotic than adult tonsils because of less infection exposure. This certainly seems the case when 'normal' tonsils are removed for sleep apnoea. Anecdotally it is on children that the technique seems most favourable, resulting in minimal blood loss in the age group for whom this is most significant. Concern has been raised that overuse of the instrument to control bleeding may result in an increased risk of later secondary haemorrhage, although this was not evident from our results. We feel that the bleeding is controlled quicker and more accurately as both the dissecting and coagulating instrument are one in the same.

The coblation technique is still relatively new and has yet to be fully discovered. Surgical innovation should be encouraged but also carefully scrutinized. It is one way that our profession moves forward. It should be remembered that most techniques and procedures that we take as 'gold standard' were not introduced on the basis of clinical trials or evidence-based medicine. Their apparent advantage over newer techniques might be simply down to a numbers game. The problem with most research regarding coblation tonsillectomy is the small numbers studied and so questionable significance of the findings. Reporting early experience with a new technique is helpful, but to assess the true benefit requires the analysis of larger numbers. Many fewer coblation tonsillectomies were analysed in the NPTA compared with cold steel, so the figures are more easily affected by what may be a few rogue cases. If complication rates are higher during the learning period, then we need to address how to better train surgeons to the new technique, rather than simply abandoning it. By exploring issues surrounding training and patient selection, the technique may be used to a greater extent and with better results.

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Conflict of interest

None declared.

References

- 1 Clinical Effectiveness Unit, Royal College, of Surgeons, of England (2005) National Prospective Tonsillectomy Audit. Report of an Audit in England and Northern Ireland between July 2003 and September 2004. Available at: <http://www.rcseng.ac.uk/services/publications/publications/pdf/ta-finalreport.pdf>
- 2 Browning G.G. (2005) What is in this issue; tonsillectomy haemorrhage. *Clin. Otolaryngol.* **30**, 301–302
- 3 Philpott C.M., Wild D.C., Mehta D. *et al.* (2005) A double-blinded randomized controlled trial of coblation versus conventional dissection tonsillectomy on post-operative symptoms. *Clin. Otolaryngol.* **30**, 143–148
- 4 Rachmanidou A., Robb P.J. & Timms M. (2005) Correspondence to 'A double-blinded randomized controlled trial of coblation versus conventional dissection tonsillectomy on post-operative symptoms'. *Clin. Otolaryngol.* **30**, 477–478
- 5 Brown P. (2005) Audit update from ENT-UK: ripples from the tonsillectomy audit. *The BAO-HNS newsletter* **15**, 6