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Randomized controlled trial comparing argon plasma coagulation tonsillectomy with conventional techniques

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Abstract

Argon plasma coagulation (APC) is based on the principle of ionized argon creating a conductive plasma between an activating electrode and a tissue surface. To date, its use in tonsillectomy has not been extensively examined. The purpose of this randomized controlled trial was to assess the clinical efficacy of APC as a tool for this common surgical procedure. Forty patients were randomized into two groups – treatment A (conventional tonsillectomy, n = 20) and treatment B (APC tonsillectomy, n = 20). Trial endpoints included a) operative time, b) intra-operative blood loss, and c) objective assessment of post-operative pain, by completion of a visual analogue pain score chart, over a two-week period. Thirty-one patients were available for analysis. There was a statistically significant reduction in the intra-operative blood loss with treatment B ($p = 0.02$). There was no statistical difference between both groups for the other outcome measures. First clinical experience with this treatment modality shows that it is an attractive alternative to conventional tonsillectomy and may offer possible benefits.

Key words: Tonsillectomy; Argon Coagulation; Treatment Outcome

Introduction

Tonsillectomy is a common surgical procedure associated with significant post-operative morbidity and general fiscal considerations. The tonsillectomy rate, for adults in the UK, is in the order of 0.8/1000 population[1] and the annual US expenditure on tonsillectomy and adenoidectomy is in the region of half a billion dollars.[2,3] Numerous studies have endeavoured to determine the effect of different operative techniques,[4–6] and the use of various pharmacological agents[7–9] on parameters such as operative time, intra-operative blood loss and subsequent patient morbidity. Yet, the comparative results between different modalities, such as sharp dissection and ligation, snare tonsillectomy, electro-dissection and laser tonsillectomy, have proven to be somewhat equivocal and inconclusive.

Argon plasma coagulation (APC) has been common-place in the disciplines of general surgery, gynaecology and laparoscopy[10–12] for more than a decade. It has been utilized for tissue resection, tissue devitalization and haemostasis. This non-contact electrosurgical technique applies high frequency current, through ionized electrically-conductive argon gas, to a target surface. Uniform zones of desiccation and coagulation (1–2 mm) are created because the potency of the conductive jet of ionized argon ('the argon plasma beam') is directly related/proportional to the electrical conductivity of the tissue. This ensures that bleeding tissue is preferentially treated.[13] Claims for improved healing, shortened operative time, better intra-operative visibility and less bleeding have also been made.[14] Unlike laser technology, additional safety protocols are unnecessary for patients and operating theatre personnel. Theoretically, argon plasma coagulation would appear to be the ideal choice for the surgical excision of lymphoid tissue, such as tonsils.

Surprisingly, to date, only one study has appeared in the English literature attempting to substantiate the possible advantages of APC tonsillectomy.[15] Yet it has been used to manage such diverse ENT pathologies as recurrent respiratory papillomatosis, hypertrophic nasal turbinates and hereditary haemorrhagic telangiectasia.[16–18] The purpose of this randomized controlled trial was to describe the usability of APC and to ascertain if its use was warranted for tonsillectomy.

Methods

Forty patients were enrolled in the study, which was conducted in the Eye and Ear Hospital, Dublin in

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the latter months of 2000. Inclusion criteria were elective tonsillectomy and age over 15 years. Paediatric tonsillectomy was considered to be a quick bloodless operation, in comparison to its adult equivalent, and therefore was excluded from this systematic technique analysis. The study was approved by the hospital's ethical review board. The paper design was prospective and the patients were randomized into one of two groups – treatment A conventional tonsillectomy and treatment B – argon plasma coagulation (APC) tonsillectomy. Conventional tonsillectomy was either bipolar diathermy extracapsular dissection or cold dissection. For this part of the study, there were two operators. All APC tonsillectomies were performed by a single operator.

The APC tonsillectomy raspatory® is composed of a handle and a detachable tip. The tip of the raspatory® has teeth at its distal end, whose purpose is to abrade peritonsillar tissue from the tonsil capsule during tonsillectomy. A suction port for blood and an outlet for the argon plasma beam are also part of this chromic tip.

APC tonsillectomy was performed in a standard manner. The upper role of the tonsil was subluxed in a medial direction and the overlying mucosa was sharply incised with scissors. The APC raspatory® was used to abrade the tonsil off its capsule and the brightly shining argon plasma beam (directed under visual control) secured haemostasis. Care was taken to avoid muscle coagulation and neither bismuth subgallate nor conventional diathermy were used in this arm of the study.

Outcome measures determined in the study included the following:

(1) operative time – recorded from the time of insertion of the Boyle-Davis gag to its final withdrawal,
(2) intra-operative blood loss – calculated from suction and swabs used during tonsillectomy, and
(3) objective pain scores – by use of a standard visual pain analogue score chart.

Patients were instructed to mark, at the same time daily over a two-week post-operative period, along an unmarked 10 cm line where they felt their pain lay (0 = little or no pain and, 10 = unbearable pain). The visual analogue score has been firmly established as a reliable method for the objective reporting and evaluation of pain.[19]

Anaesthetic technique and post-operative analgesia regimes and discharge protocols were standardized for all patients. In brief, following a pre-medication of diazepam 10 mg, induction was with intravenous propofol or inhalation sevoflurane and a non-depolarizing neuromuscular blocker. Maintenance of anaesthesia was with sevoflurane and all patients received intra-operative morphine 0.1 mg/kg intravenously. Post-operative analgesia consisted of paracetamol and codeine phosphate formulations prescribed in mg/kg doses according to the British National Formulary 2000 edition. Patients were discharged home on the second post-operative day. Follow-up was facilitated by patient review at two weeks post-discharge. Failure to attend prompted the mailing of a letter to request the return of the pain score chart. Patients were discarded from the study if they did not complete and return their visual analogue scores.

The results were collated and the two groups compared. The unpaired Student's *t*-test was used to calculate any statistically significant difference in intra-operative blood loss between the two groups. The Wilcoxon rank sum test was employed to statistically compare operative times and pain scores.

Results

Data from 31 patients (77.5 per cent of those originally enrolled in the study) was available for analysis – 14 patients from treatment A and 17 patients from treatment B. Of the conventional tonsillectomy group, four of 14 patients were treated with bipolar extracapsular diathermy, while the remaining 10 patients underwent cold dissection. The mean age of the overall cohort was 24.7 years (range 16–35 years) with similar distribution of age and sex in both arms of the trial. Numerical analysis of the outcome measures is summarized in Tables I and II. Because our sample size was less than 2000, the Shapiro-Wilk test was used to test for normality and so determine the most appropriate comparative statistical test for each of the trial end-points.[20]

Intra-operative blood loss between the two groups was compared with an unpaired Student's *t*-test. The intensity of bleeding was significantly reduced in the APC tonsillectomy group ($p = 0.02$, 95 per cent CI of difference of means 9–94.9). Both arms of the study experienced a single secondary haemorrhage, that was managed conservatively. There were no primary bleeds in either group. Our subjective impression of quicker operative times with APC tonsillectomy was not proven when both groups were compared by the

TABLE I
TREATMENT A/CONVENTIONAL TONSILLECTOMY (N = 14)

	Blood (mls)	Time (mins)	Day 2 Pain score	Day 5 Pain score	Day 8 Pain score	Day 11 Pain score	Day 14 Pain score
Mean	107.57	24.64	5.29	5.43	4.57	3.14	1.57
STD dev	68.18	6.01	2.13	2.24	1.83	2.82	1.99
Median	95	24	6	5	5	2.5	1
Range	20–250	15–40	2–8	1–10	1–7	0–9	0–6

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TABLE II
TREATMENT B/APC TONSILLECTOMY (N = 17)

	Blood (mls)	Time (mins)	Day 2 Pain score	Day 5 Pain score	Day 8 Pain score	Day 11 Pain score	Day 14 Pain score
Mean	55.71	20.18	6.01	6	4.41	2.59	1.18
STD dev	39.27	7.27	2.01	2.18	2.53	2.48	2.12
Median	52	18	6	7	4	2	0
Range	3–153	10–31	2–8	1–8	0–9	0–9	0–7

Wilcoxon rank sum test. A statistical difference favouring either arm of the study could not be demonstrated. Figure 1 highlights visual analogue scores with APC and conventional tonsillectomy groups. Both treatments have similar trends regarding pain scores and statistically there was no difference between the two groups.

Discussion

In an era of cost containment and 'managed' health economics, cost-effectiveness is a prime issue when different technology and instruments are introduced to a familiar procedure. Given the frequency of tonsillectomy, it is not surprising that the literature is replete with different modalities reporting various improvements over older techniques.[4–6,21] Against this background, our systematic analysis concentrated on APC usability and potential patient/clinical benefits. Because of cohort size, we concentrated on the three aforementioned outcome measures and did not look at the confounding effects of such variables as age, sex of the patient or previous quinsy.

Previous studies have suggested that electrocautery tonsillectomy is associated with increased pain and delayed healing in comparison with other techniques.[22] This certainly was not our experience with APC tonsillectomy. Although a slightly higher pain profile for APC tonsillectomy at day five is in agreement with other publications on electrodissection tonsillectomy,[4] overall, there was no statistical difference between pain profiles in either arm of the study. Because of the individualized tolerance and subjectivity of pain, an objective comparison between patients was difficult. Our decision to adopt a standardized analgesia protocol for all patients goes some way towards addressing this problem. Granulation tissue was more commonly seen in the tonsillar fossae of the APC tonsillectomy group at the two week post-operative follow-up. This is a common feature of electrodissection and is not representative of delayed healing.

Although a statistical difference in operative time could not be shown between the two treatments in this study, we believe a real time benefit may be evident when APC is used to perform tonsillectomy on patients who have experienced previous quinsy.

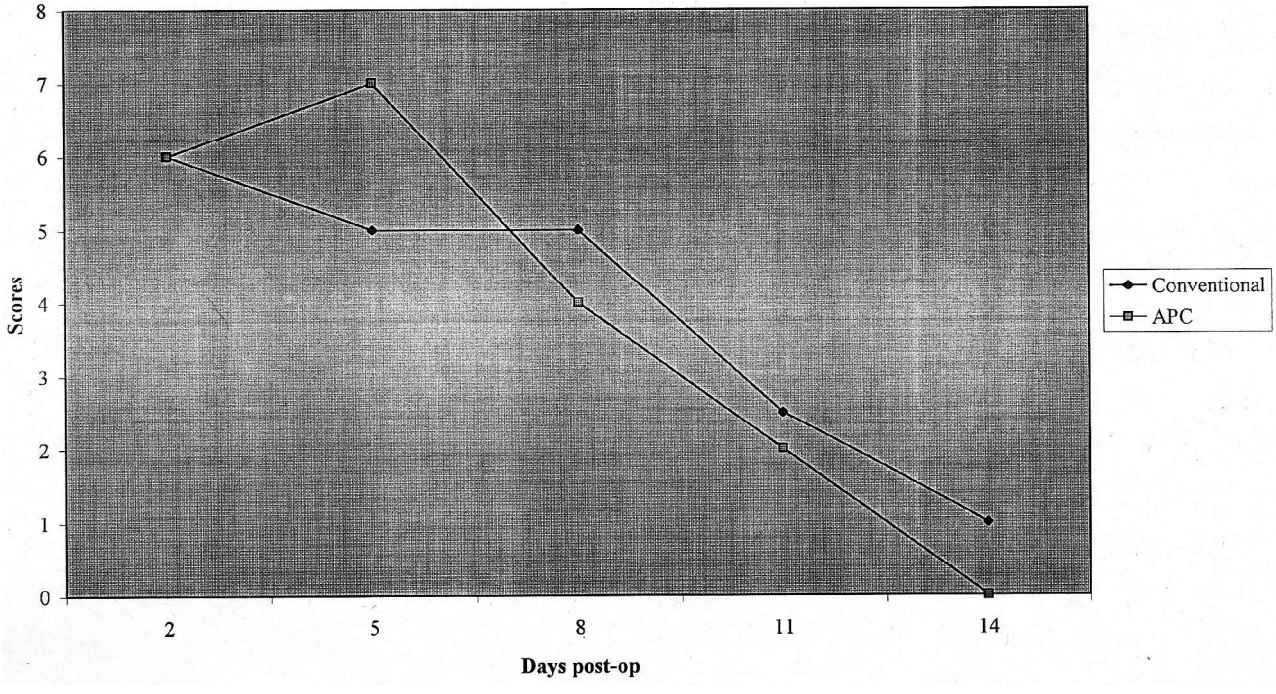


FIG. 1
Median pain scores.

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In such cases (three patients in our series – one in the controlled group and two in the APC tonsillectomy group), dissection planes and fibrous tissue are problematic and an integrated haemostasis/dissection instrument, such as APC, may be of significant advantage in this setting. More formal studies are required to address this issue. As with all new treatment modalities, there is an inherent brief learning curve but we counteracted this by ensuring that this was confined to one operator. There was compelling evidence for a significant reduction in the frequency and intensity of intra-operative blood loss. This was probably attributable to the 'user friendly' nature of APC and the one step procedure for haemostasis and dissection. Unnecessary tissue traction and muscle tearing will also have contributed to this reduction in blood loss.

In conclusion, we would advocate the use of APC in adult tonsillectomy and especially when the patient has experienced previous quinsy. Although, we could only demonstrate real benefit in the outcome measure of intra-operative blood loss, we believe that the aforementioned advantages of APC are of benefit to the patient.

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