International Journal of Pediatric Otorhinolaryngology (2004) 68, 1519–1523

ELSEVIER

International Journal of Pediatric Otorhinolaryngology

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Safety of electronic molecular resonance adenoidectomy

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Received 5 April 2004; received in revised form 9 July 2004; accepted 14 July 2004

KEYWORDS
Adenoidectomy;
Adenoidectomy complications;
Hemorrage;
Postoperative pain;
Radiosurgery

Summary Adenoidectomy is one of the most frequent operations in children. In order to reduce hospital stay costs, today, this procedure is performed as day surgery. Even though adenoidectomy is not considered risky, some minor complications may occur, the most important being bleeding (0.5–8% incidence). The surgical technique used can influence considerably postoperative pain and time to recovery. This aspect is essential in the management of day surgery patients, for whom the need of safe and rapid manoeuvers associated with early recovery determines the choice of the surgical procedure.

Recently, we developed a surgical technique based on the use of an electronic molecular resonance tool associated with bendable suction electrocautery.

This study was carried out on 600 patients, divided into two groups, the first undergoing ablation using the molecular resonance tool and the second undergoing curette adenoidectomy. The two groups were homogeneous for age, sex, surgical indications, and grade of adenoid hypertrophy. The following parameters were considered: duration of surgery, importance of intraoperative bleeding, time to cicatrization, incidence of bleeding complications.

Duration of surgery and intra- and postoperative bleeding were much lower in the first group than in the group undergoing traditional adenoidectomy. In addition, rhinopharyngeal complete cicatrization, defined as absolute absence of pseudomembrane, was much quicker in the first group, as assessed by postoperative endoscopy.

Another major advantage offered by the molecular resonance tool is the accuracy of surgery performed under visual control in a practically bloodless field.

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0165-5876/$ – see front matter
doi:10.1016/j.ijporl.2004.07.013

To sum up, this method, thanks to its technical features and safety, is particularly indicated in children and in patients with coagulation disorders.

1. Introduction

Adenoidectomy (alone or in association with tonsillectomy) is one of the oldest and most frequent surgical operations in children [1–6]. In the USA, these surgical procedures have been considered for several years in the policy of reduction of health care costs. The need to rationalize health care expenditure is strongly felt also in the Italian national health care system; for this reason, tonsillectomy and/or adenoidectomy is performed as day surgery also in Italy now [3].

Even though these surgical procedures are not considered risky, they can present severe and even fatal surgical and anesthesiologic complications [6–9].

Of particular interest in paediatric adenoidectomy is perioperative blood loss because of the small total circulating volume in younger children [10]. Actually, bleeding is the most important minor complication, which, if very intense or inadequately treated, can determine airway obstruction or shock [10–13]. The incidence of postoperative bleeding reported in the literature ranges from 0.5 to 8% [8–14].

In addition, the technique used for adenoidectomy influences postoperative pain and time taken to resume a normal diet, and it is therefore important for a rapid recovery [15–17]. This aspect is now particularly topical in Italy as the interest in day case surgery is growing and quick, and safe techniques with a short recovery time are favoured. Numerous instruments have been designed for adenoidectomy: in the past 10 years, curette adenoidectomy and desiccation by suction electrocautery was the most common technique [15]. Heras and Koltai [18] subsequentely performed this operation using a modified powered instrumentation for sinus surgery.

Recently, we developed a technique using an electronic molecular resonance tool (Vesalius, Telea Elettronica Biomedica) for adenoidectomy with bendable suction electrocautery.

Vesalius is an electronic tool, which performs cuts and coagulation by generating alternate current with series of high-frequency waves characterized by a major 4 MHz wave and subsequent 8, 12, and 16 MHz waves with decreasing amplitude and increasing frequency. Energy quanta are thus obtained, calibrated for human tissue and allowing tissue cutting not by thermal vaporisation as when using traditional electrocautery knife and laser, but by breaking cell molecular bindings [19,20]. Coagulation is obtained through a process of proteic fibrinogen denaturation able to trigger coagulation physiologic cascade without the need of creating a necrotic plug as in warm techniques. As a result, a cold cut (<50 °C) is obtained, and cut edge tissues do not undergo thermal damage and therefore do not present any slough [21].

This study was undertaken to demonstrate that electronic molecular resonance adenoidectomy (EMRA) is a safe and effective procedure. The surgical method of EMRA is described; advantages and disadvantages are outlined and compared with curette adenoidectomy.

2. Materials and methods

Our series included 600 consecutive patients aged 2–10 years, admitted to the Department of Otolaryngology of the Giannina Gaslini Institute from September 1, 2002 to December 30, 2003, to undergo adenoidectomy and/or adenotonsillectomy. The indications for adenoidectomy included signs and symptoms of subcontinuous nasal obstruction as nasal dyspnea, noisy nocturnal breathing, posterior rhinophonia, frequent otitis media, conductive hearing loss. Tonsillectomy was performed in patients with history of relapsing tonsillitis, mechanical dysphagia, or clinical evidence of focal disease.

All patients were given informed consent and enrolled in the study voluntarily. The study was approved by the Institutional Review Board (IRB) of this institution. Patients could withdraw from the study at any time.

All the patients underwent laboratory tests, including blood test, prothrombin and thromboplastin time, and fibrinogen assay.

After obtaining a complete anaesthesiologic and ENT evaluation, the study patients were examined with flexible nasopharyngoscope to measure the size of the adenoid pad.

The grade of adenoid hypertrophy was measured as described by Clemens [15].

The grading scale was based on the proportion of the choana obstructed by the adenoid pad:

- Grade I: adenoid tissue filling 1/3 of the vertical portion of the choana;
- Grade II: adenoid tissue filling from 1/3 to 2/3 of the choana;

- Grade III: from 2/3 to nearly complete obstruction of the choana;
- Grade IV: complete choanal obstruction.

Children were randomized into two surgical groups:

- Group A (electronic molecular resonance adenoidectomy, EMRA).
- Group B (curette adenoidectomy).

All the interventions were performed under general endotracheal anaesthesia.

About 20 min before surgery, the patients received a premedication with a mixture of atropine sulfate 0.01 mg/kg and flunitrazepam 30–50 mcg/kg.

Intravenous induction of general anesthesia included administration of thiopentone sodium 5 mg/kg, followed by atracurium 0.1 mg/kg and subsequent intubation with cuffed endotracheal tube. The patients were ventilated using IPPV until spontaneous respiration. Anesthesia was maintained with propofol 8–9 mg/kg/h and a 50% O_2–air gaseous mixture. Analgesia was also obtained with fentanyl 1–2 mcg/kg. During surgery, the patients were hydrated with venous perfusion of 5% glucose solution.

The child was positioned on a shoulder roll, a Crowe-Davis mouth prop was inserted and suspended from a Mayo stand. The palate and the lateral nasopharyngeal walls were palpated to ensure the absence of submucous clefting of the palate and pulsation. A catheter was introduced transnasally and used for retraction of the soft palate. An adequately sized mirror was used to visualize the nasopharynx and to guide surgical dissection. The disposable suction electrocautery was shaped into the curvature necessary for the adenoidectomy.

The molecular resonance electrocautery was set at 40–60 watts on spray: fulgurate mode, during the dissection phase, and coagulate mode in case of intraoperative bleeding.

Starting from the superior nasopharynx, suction electrocautery was applied until the obstructing adenoid was removed. In order to prevent cicatricial stenosis, care was taken around the eustachian tube orifice.

Intraoperative bleeding during curette dissection was controlled by electrocoagulation of open vessels using protected aspirator during the hemostatic control phase of the operation. The electrocautery unit (Martin ME 401) was set on spray, coagulate mode, at 40–60 watts. Children weighing less then 15 kg required 40 watts, while children more than 40 kg could benefit from 60 watts. Smoke was removed by suction.

Length of adenoidectomy and blood loss were recorded.

In order to relieve postoperative pain, control rising temperature and favour fluid intake, all the children received rectally a mixture of acetaminophen, codeine, and caffeine. Temperature was considered as pathologic if exceeding 38° [12,21]. The cases of repeated vomiting (more than three episodes in 4 h) were controlled by i.v. administration of ondasetron hydrochloride and possible parenteral rehydration.

The patients were then evaluated 10 days postoperatively. Videonasopharyngoscopy was performed to verify any residual adenoid pad and cicatrization rate.

Postoperative bleeding was classified as follows:

- early bleeding: within 4 h from operation;
- primary bleeding: within the first 24 h;
- late bleeding: after 24 h.

The importance of each bleeding episode was defined according to a 1st to 3rd degree scale:

- 1st degree: bleeding stopping spontaneously;
- 2nd degree: bleeding easily controlled with drugs or with manoeuvres not requiring anesthesia;
- 3rd degree: bleeding requiring the patient to return back into the operating room and to undergo general anesthesia.

Data are described as mean and standard deviation (S.D.) for continuous variables, and as absolute and relative frequencies for categorical variables.

The nonparametric Mann–Whitney *U*-test was used to compare the two groups for blood loss (cc) and length of operation (min), and the Chi square or Fisher's exact tests for categorical variables were used to measure differences between the two groups for postoperative bleeding and complete cicatrization. *P*-value <0.05 was considered as significant. All the statistical tests were two-tailed. Statistical analysis was performed using SPSS for Windows (SPSS Inc, Chicago, Illinois).

3. Results

Five hundred and ninety children, namely 296 in EMRA group (Group A) and 294 in curette group (Group B), completed the study. Four patients in Group A and six in Group B were lost at follow-up and were excluded from our results (Table 1).

Table 1 Comparison of electronic molecular resonance adenoidectomy versus curette adenoidectomy

	EMRA (N = 296) ($X \pm$ S.D.)	Curette (N = 294) ($X \pm$ S.D.)		
Age (years)	4.5 ± 2.4	4.9 ± 3.1		
Grade of adenoid hypertrophy	3.2 ± 0.6	3.0 ± 0.6		
Length of operation (min)	5 ± 2*	12 ± 4		
Blood loss (cc)	1.2 ± 0.6*	25 ± 9		
	N	%	*N*	%
Postoperative bleeding	1	0.34	4	1.36
Complete cicatrization	138/150	92*	68/150	45.3

* $P \leq 0.0001$.

Age ranged from 2 to 10 years with a mean of 4.5 years ± 2.4 in Group A and 4.9 years ± 3.1 in Group B. The two groups were homogeneous for sex, age, weight, grade of adenoid hypertrophy, and concomitant procedures.

Mean length of surgery was much lower in Group A. This difference was statistically significant: 5 min ± 2 for EMRA technique and 12 min ± 4 for curette procedure ($P \leq 0.0001$).

Average blood loss was 1.2 cc ± 0.6 in Group A and 25 cc ± 9 in Group B ($P \leq 0.0001$).

The only postoperative complication was bleeding. Among the 296 patients in Group A (EMRA), there was one case (0.34%) of postoperative bleeding from the rhinopharynx. It started in the first 4 h from operation (early bleeding) and stopped spontaneously (1st degree). Among the 294 children in Group B (curette), postoperative bleeding occurred in four cases (1.36%). Three cases had early bleeding (two cases 3rd degree and one case 1st degree), while one case required readmission after 7 days from operation for late bleeding (1st degree).

There were no cases with unusual problems.

In order to evaluate the effectiveness of surgery and the rapidity of cicatrization, 150 patients of Group A and 150 of Group B underwent postoperative videopharyngoscopy. No significant residual adenoid tissue was observed.

The absence of pseudomembranes was the criterion used to define as complete the process of cicatrization. Ten days after surgery, this criterion was met by 138 patients (92%) of Group A and 68 (45.3%) of Group B ($P \leq 0.0001$).

4. Discussion

Adenoidectomy is one of the most frequent surgical operations in children. In order to rationalize health care expenditure, this procedure is now performed as day surgery. Even though adenoidectomy is not considered risky, it can present surgical complications; of particular interest in the child is postoperative bleeding. Many different instruments and techniques have been proposed to perform a quick and safe surgery with a short recovery. We analyzed the technique of ablation of the adenoid tissue by electronic molecular resonance tool for adenoidectomy with a bendable suction electrocautery, and compared it with the curette technique.

The two study groups were well matched for age, sex, weight, indications, and grade of adenoid hypertrophy.

In this study, we found that the average operation time was considerably shorter using the electronic molecular resonance tool, with a statistically significant difference.

These data suggest the possibility of a better use of resources in the operating room as well as optimization of costs.

Intraoperative blood loss was about 25 cc in Group B and almost absent in Group A. Since no child in either group had an important blood loss, the clinical significance of this result is debatable. However, an important advantage of EMRA over curette adenoidectomy is precise removal of adenoid tissue guided by the nasopharyngeal mirror in a practically bloodless field. In fact, adenoids obstructing the choana and surrounding the eustachian tube orifice can be accurately removed – thanks to clear visualization, proceeding from the higher portion of the nasopharynx toward the lower edge of the adenoid pad without bleeding. The use of EMRA makes it possible to control the depth and location of the resection and thus to limit blood loss.

Especially in older children, the best technique for a complete removal of adenoid tissue extending from the nasopharynx intranasally is the transanasal use of the bendable tool with mirror control of the resection.

Both EMRA and curette procedures equally provide adequate removal of adenoid tissue. Our study shows that EMRA is safer than curette adenoidectomy. Actually, in Group B, there was a much higher incidence of postoperative bleedings; the impor-

tance of bleeding as postoperative complication suggests to further investigate safer alternatives to traditional techniques.

Of clinical importance is the earlier cicatrization observed in the EMRA group, with a double incidence of recovery at 10 days from surgery with respect to patients receiving traditional surgery. This result can be ascribed to the peculiar action mechanism of the molecular resonance tool, which cuts tissues by breaking intercellular molecular bindings and obtains coagulation through intravasal proteic fibrinogen denaturation. These features allow a cold action (<50 °C) and cut edge tissues do not undergo thermal injury and therefore do not present any eschar.

The almost complete absence of intra- and postoperative bleeding and the reduced aggressiveness make the EMRA technique very appropriate in children and in subjects with coagulation disorders.

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