Prospective comparative study of pulsed-electron avalanche knife (PEAK) and bipolar radiofrequency ablation (coblation) pediatric tonsillectomy and adenoidectomy

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Purpose: To compare post-operative pain severity, analgesic intake, and complications in children undergoing tonsillectomy and adenoidectomy with bipolar radiofrequency ablation (Coblation) vs. pulsed-electron avalanche knife (PEAK) technology.

Materials and methods: This was a prospective, non-randomized, non-blinded comparative cohort study in a private practice setting with three fellowship-trained pediatric otolaryngologists. Patients aged 3 to 12 years undergoing tonsillectomy and adenoidectomy were assigned to surgery with either bipolar radiofrequency ablation or pulsed electron avalanche knife instrumentation. Daily telephone contact for the first 14 post-operative days obtained the following data: validated proxy pain scale scores, number of post-operative analgesic medication doses consumed, and occurrence and severity of post-operative hemorrhage.

Results: One-hundred adenotonsillectomy subjects were enrolled (50 bipolar radiofrequency ablation, 50 pulsed-electron avalanche knife). There were no clinically relevant differences in post-operative pain scores between the two surgical groups on all post-operative days. Total doses of non-narcotic and narcotic analgesics were similar between the groups, with the exception of less acetaminophen doses being consumed in pulsed-electron avalanche knife patients on post-operative days 9, 10, and 12. Post-operative hemorrhage episodes resulting in re-operation and/or hospitalization were equivalent between the two groups. However, bipolar radiofrequency ablation patients were 2.33 times more likely to experience minor bleeding events at home (that did not require medical intervention).

Conclusion: Pulsed-electron avalanche knife surgery was found to be an adequate technique for pediatric adenotonsillectomy, with similar amounts of post-operative pain and clinically relevant hemorrhage when compared to bipolar radiofrequency ablation.

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1. Introduction

Pediatric tonsillectomy is a commonly-performed surgical procedure, with an estimated 530,000 cases performed annually in the United States [1]. The most common pediatric indication is sleep disordered breathing and obstructive sleep apnea, followed by recurrent and/or chronic tonsillitis [2]. The morbidity associated with tonsillectomy is not negligible. Post-operative pain can be severe and lead to dehydration and hospitalization and use of narcotics, while post-operative hemorrhage can lead to a return trip to the operating room and can be life-threatening. Between 2.7% and 15.9% of all tonsillectomy patients experience hemorrhage during surgical recovery, with a re-operation rate of 2% [3]. The generally accepted recovery period after tonsillectomy is 14 days [2].

The goal of any technique is to reduce the two most important post-tonsillectomy risks: pain and hemorrhage. A variety of surgical instruments are available for performance of tonsillectomy, with no consensus regarding which instrument is optimal at reducing these risks.

1.1. Traditional tonsillectomy techniques

Traditional tonsillectomy techniques using “cold” steel (e.g. scalpel, snare, guillotine) are infrequently used in the United States due to a high rate of intra-operative blood loss [4]. Monopolar electrosurgical devices supplanted “cold” techniques, resulting in decreased intra-operative blood loss [4]; however, there are clinicians who feel these devices might lead to increased post-operative pain due to the high level of continuous energy utilized.

1.2. Bipolar radiofrequency ablation

Bipolar radiofrequency ablation (Coblation, Arthrocare, Inc., Austin, TX) is a form of high-frequency electrosurgery in which radiofrequency energy passes through a conductive medium between two active electrodes, producing a plasma field. The resultant charge-carrying ions have sufficient energy to break organic molecular bonds resulting in disintegration of tissue. The bipolar probe or wand is used to accurately remove tonsil and adenoid tissue, with less heat generation (40–60 °C) than traditional monopolar electrosurgical devices and minimal damage to surrounding structures [4]. Although this advanced technology is purported to lead to a less painful recovery, a Cochrane review on this subject concluded that current evidence supporting the benefits of bipolar radiofrequency ablation over other techniques is lacking [2].

1.3. Pulsed-electron avalanche knife

The pulsed-electron avalanche knife (PEAK) PlasmaBlade device (Medtronic Inc., Minneapolis, MN) is a soft tissue dissection instrument that uses very brief, high-frequency pulses of radiofrequency (RF) energy to induce electrical plasma along the edge of a thin (12.5 um), 99.5% insulated electrode [4,5]. Due to the low duty cycle from RF pulsing and proprietary thermal protection shield (TPS) insulation technology, the device uses less total energy and, like bipolar radiofrequency ablation, operates at significantly lower temperatures (40–170 °C) than traditional electrocautery (200–350 °C), presumably allowing dissection of tonsil and adenoid tissue and hemostatic control with less collateral damage than traditional electrocautery [4,5].

1.4. Purpose of present study

The purpose of the present study was to compare post-operative pain and complications in children undergoing adenotonsillectomy with bipolar radiofrequency ablation vs. pulsed-electron avalanche knife technology. The primary null hypothesis was that adenotonsillectomy would be equally painful with pulsed-electron avalanche knife vs. bipolar radiofrequency ablation. The study also was designed to compare pulsed-electron avalanche knife surgery vs. bipolar radiofrequency ablation with respect to 1) number of post-operative analgesic medication doses (narcotic and non-narcotic), and 2) post-operative hemorrhage rate. The type, frequency and the amount of analgesic medication taken by each patient also served as an indirect indication of the amount post-operative pain they experienced.

2. Materials and methods

A prospective, non-randomized, non-blinded comparative cohort study was designed. Patients were enrolled from July 2013 through August 2014. IRB approval was obtained (Sterling IRB ID: 4286-001). Inclusion criteria were children between the ages of 3 to 12 years undergoing outpatient adenotonsillectomy for either sleep disordered breathing or recurrent tonsillitis. Tympanostomy tube placement was the only allowable concurrent procedure. Children were excluded from enrollment if there was an underlying syndrome, craniofacial abnormality, or bleeding disorder. Disallowable surgical indications were history of peritonsillar abscess or surgery performed to rule out malignancy. Informed consent was obtained from parents or legal guardians for all subjects.

2.1. Enrollment mechanism

Children were consecutively enrolled until the quota for the study was reached. Two experimental arms were utilized: pulsed-electron avalanche knife adenotonsillectomy and bipolar radiofrequency ablation adenotonsillectomy. The study included 100 total subjects (50 in each arm). The first 25 patients enrolled were assigned to undergo bipolar radiofrequency ablation; the second group of 25 patients was assigned to undergo pulsed-electron avalanche knife surgery; the third group of 25 patients was assigned to undergo bipolar radiofrequency ablation; the fourth and final group of 25 patients was assigned to undergo pulsed-electron avalanche knife surgery.

2.2. Surgical procedure techniques

All procedures were performed in the outpatient surgical center affiliated with the Center for Pediatric ENT – Head and Neck Surgery, and all procedures were performed by one of...
three senior fellowship-trained pediatric otolaryngologists (ZS, DJK, DLM). All three surgeons performed both techniques; the decision of which technique to use was pre-determined based on the assignment scheme (see description in previous paragraph). In this practice, bipolar radiofrequency ablation had been performed for many years as the primary mechanism of adenotonsillectomy. In an attempt to minimize “learning curve” bias, each surgeon performed as many pulsed-electron avalanche knife adenotonsillectomies as possible in the 6 months prior to initiation of the study (over 20 cases for each surgeon). General anesthesia with orotracheal intubation was identical for all patients. All tonsillectomies were extra-capsular. As per American Academy of Otolaryngology tonsillectomy guidelines [6], no perioperative antibiotics were given, no local anesthetic infiltration was used, and every patient received a single IV dose of dexamethasone during surgery [6].

Bipolar radiofrequency ablation procedures were performed with the Precise XP wand (Arthotec Corp., Sunnyvale, CA), using a ablation setting of 6 or 7 and a coagulation setting of 3 to 5 for tonsillectomy and an ablation setting of 9 and a coagulation setting of 5 for adenoidectomy. PEAK procedures were performed with the PlasmaBlade TnA device (Medtronic Inc., Minneapolis, MN) on a coagulation setting of 4 for tonsillectomy and 8 for adenoidectomy (coagulation was used for dissection and hemostasis). Patients were discharged home the same day as the surgery, and were encouraged to use over-the-counter ibuprofen every 6 h as-needed, acetaminophen every 4 h as-needed, and were given a prescription for acetaminophen and hydrocodone, dosed based upon weight, to be used as-needed for severe pain unresponsive to over-the-counter analgesics.

2.3. Data collection

One of two trained operating room registered nurses collected subject data prior to same-day discharge (day #0), and then made daily telephone calls to parents or legal guardians from post-operative day #1 through post-operative day #14. One nurse was required to contact the assigned patient’s parents or legal guardians throughout the entire 14-day postoperative period. Parents or legal guardians were specifically asked the following items: 1) to quantify maximal pain that day per a validated 11-point proxy-evaluated pediatric pain scale (0 = no pain, 10 = intense pain) (Children’s and Infants’ Postoperative Pain Scale, CHIPPS) [7]; 2) whether or not any doses of narcotic and non-narcotic medication were needed that day, and the number of doses; 3) whether or not there was any bleeding that day, and how it was managed (e.g. conservatively at home; in the ENT’s office; in the emergency room; in the hospital overnight with observation; or in the operating room). Primary bleeding was defined as bleeding on the day of surgery, and secondary bleeding as hemorrhage that began on post-operative day #1 or later.

2.4. Statistical analysis

One goal of the study was to compare the amount of post-operative pain between pulsed-electron avalanche knife surgery and bipolar radiofrequency ablation. The null hypothesis was that the two population means would be equal. A mean difference of 3 points on the pain scale was considered to be clinically relevant, since the pain scale we utilized has shown that scores between 0 and 3 are obtained in pain-free post-operative situations, whereas scores of 4 or higher are obtained in painful post-operative situations [7]. Prior research has shown that the CHIPPS score was 3.0 in pain-free post-surgical pediatric situations, vs. 5.7 in painful situations (e.g. difference of 2.7 points) [7]. This effect was selected as the smallest difference that would be important to detect, in that any smaller effect would likely not be of clinical or substantive significance. The criterion for significance was determined by a two-tailed t-test with significance (alpha) of 0.05. With a proposed sample size of 45 subjects in each group, the study was calculated to have a power of 80.4% to yield a statistically significant result. (We were planning to recruit 100 subjects, but prepared our power analysis for 90 subjects, assuming a potential 10% drop-out rate.)

Another goal of the study was to estimate the mean difference between the two populations. On average, a study of this design would enable us to report the mean difference in pain scale scores with a precision (95.0% confidence level) of plus/minus 2.09 points. For example, an observed difference of -3.0 would be reported with a 95.0% confidence interval of 0.91 to 5.09. The precision estimated here is the median precision and will vary as a function of standard deviation. Median pain scores between the two study populations were compared with a two-sample Wilcoxon rank-sum (Mann-Whitney U) test.

3. Results

3.1. Demographic and descriptive data

A total of 100 consecutive children aged 3 to 12 years were enrolled in the study. Fifty subjects underwent adenotonsillectomy using bipolar radiofrequency ablation, and 50 subjects using the pulsed-electron avalanche knife. The bipolar radiofrequency ablation subjects were older, with a mean age of 7.1 years, compared to the pulsed-electron avalanche knife subjects, who had a mean age of 6.0 years (p < 0.05). The male:female ratio was 26:24 in the bipolar radiofrequency ablation group and 23:27 in the pulsed-electron avalanche knife group. Sleep disordered breathing was the primary indication for surgery in 80% of the bipolar radiofrequency ablation subjects and 76% of the pulsed-electron avalanche knife subjects (no significant difference). A pre-operative history of recurrent tonsillitis was present in 23 subjects in the bipolar radiofrequency ablation group and 23 subjects in the pulsed-electron avalanche knife group. Concurrent bilateral tympanostomy tube placement was performed at the time of adenotonsillectomy for 2 subjects in the bipolar radiofrequency ablation group and 2 patients in the pulsed-electron avalanche knife group. No other concurrent surgeries were performed. Mean duration of surgery (from the time the mouth retractor was placed to the time it was removed) was 16.2 min in the bipolar radiofrequency group and 17.0 in the pulsed-electron avalanche knife group; this difference was not statistically significant (unpaired t-test). Estimated intra-
operative blood loss was measured at 10 mL or less in all cases in both groups.

Each patient was followed for 14 days postoperatively for a total of 15 days per patient. Out of the total 1500 potential patient-days, 1485 total patient-days were recorded via direct telephone contact with each patient caregiver by a trained registered operating room nurse, representing a capture rate of 99%.

3.2. Pain score comparisons

Fig. 1 shows the mean VAS pain scale scores for each treatment group stratified by post-operative day. Both groups experienced the worst pain on the second post-operative day. The two groups demonstrated statistically equivalent pain scores for the first 6 days following the operation, and for the last 5 days of the 14-day follow-up period. From post-operative days #7–9, the difference in median pain scores was statistically different between the two groups (with lower scores in the pulsed-electron avalanche knife group), but these differences were not expected to be clinically significant, since the largest difference between groups on any of these days was 2 points (day #7), which did not reach the difference of 3 that has previously shown to be clinically significant [7]. Also, on post-operative days #8–14, none of the median pain scores in either group were higher than 2, and prior research has shown that scores of 3 or less are not associated with clinically painful situations [7].

3.3. Analgesic medication dose comparisons

Over the 15-day study, there was no difference in the total number of doses of acetaminophen, ibuprofen, or narcotic pain medication taken in the bipolar radiofrequency ablation vs. the pulsed-electron avalanche knife group (see Fig. 2). The highest number of narcotic doses given was on post-operative day 2 for the bipolar radiofrequency ablation group, and on the day of surgery for the pulsed-electron avalanche knife group. The highest number of ibuprofen doses given was on post-operative day 1 for the bipolar radiofrequency ablation group, and on post-operative day 2 for the pulsed-electron avalanche knife group. When comparing analgesic dosages on a day-to-day basis, the pulsed-electron avalanche knife group consumed significantly less total doses of acetaminophen on post-operative days 9, 10, and 12. There were no other significant daily differences between the two study groups with respect to acetaminophen, ibuprofen, or narcotic doses taken.

3.4. Bleeding comparisons

There were no cases of primary bleeding in either group. The number of subjects who underwent hospitalization for post-operative hemorrhage was not significantly different between the two study groups. There were 5 subjects in the bipolar radiofrequency ablation group (10%) who underwent hospitalization due to secondary hemorrhage, of which 1 required surgical intervention. There were 2 participants in the pulsed-electron avalanche knife group (4%) who underwent hospitalization due to secondary hemorrhage, of which 1 required surgical intervention.

All parents or legal guardians were asked on each day of the study if they noticed any bleeding whatsoever from the patient, including blood-tinged saliva which otherwise would have not been significant enough to alert the surgeon or seek medical attention. These minor bleeding episodes at home were noted in 21 of the bipolar radiofrequency ablation subjects and 9 of the pulsed-electron avalanche knife subjects (p = 0.0156, Fisher’s exact test). Subjects in the bipolar radiofrequency ablation group were 2.33 times more likely to experience minor bleeding events (that did not result in hospitalization or surgery) than subjects in the pulsed-electron avalanche knife group (95% CI: 1.19–4.58). In the bipolar radiofrequency ablation group, one subject experienced two such episodes and another experienced three such episodes. All other cases in both groups experienced only a single episode. The episodes in the coblation group were distributed bimodally, mostly occurring either in the first few days after surgery or a week later, with the highest incidence on post-operative day 7. The episodes in the pulsed-electron avalanche knife group occurred mostly within the first few days after surgery, with no reported episodes beyond post-operative day 6.

4. Discussion

4.1. Discussion of different technologies

The concept behind both bipolar radiofrequency ablation and pulsed-electron avalanche knife technologies for adenotonsillectomy is to use radiofrequency energy to remove tissue at lower temperatures than traditional electrosurgical devices. This technology still allows for control of intra-operative bleeding, but decreases the depth of collateral

Fig. 1 – Mean pain scores for bipolar radiofrequency ablation vs. pulsed-electron avalanche knife adenotonsillectomy patients on each post-operative day. There were statistically different median pain scores on days 7 to 9 (scores were lower in the pulsed-electron avalanche knife group), but a clinically meaningful difference of 3 or more points was not reached.
tissue damage and potentially decreases post-operative complications such as pain.

Bipolar radiofrequency ablation, the older and more established of the two techniques, is a form of high-frequency electrosurgery, delivered by a disposable bipolar wand (ArthroCare Corp. Sunnyvale, CA). Alternating current passes between electrodes on the device tip, and the physical space between the electrodes is bridged with a conductive medium, most often isotonic saline. The electrical current dissociates the medium into free ions which subsequently destroy intercellular bonds, resulting in tissue dissociation. This reaction is achieved at temperatures of 40–60 °C with minimal collateral thermal tissue damage, and the cool, irrigating isotonic saline also helps to limit the amount of heat delivered to surrounding structures [8]. By comparison, traditional electrosurgical devices typically deliver energy at 250–350°C [9].

The pulsed-electron avalanche knife (PEAK) PlasmaBlade (Medtronic, Inc., Minneapolis, MN) is a more recently-developed disposable monopolar electrosurgical device that provides plasma mediated electroconduction via a probe tip that has a similar shape to a scalpel, allowing precise dissection of tissue with control of bleeding similar to traditional electrocautery. Similar to coblation, the instrument causes less collateral damage than traditional electrocautery due to its lower operating temperature (40–170 °C), as well as due to the pulsed nature of the delivered energy [4]. The instrument has been shown to reduce thermal injury depth, inflammatory response, and scar width compared with standard electrosurgery on human abdominal skin [5].

4.2. Bipolar radiofrequency ablation

A Cochrane review of bipolar radiofrequency ablation tonsillectomy attempted to compare the post-operative morbidity associated with bipolar radiofrequency ablation to other techniques [2]. There were no pulsed-electron avalanche knife studies included in the review. Only 9 studies were deemed of sufficient quality to include in the analysis, and most of these were still considered methodologically flawed. Most studies showed equivalent post-operative pain between bipolar radiofrequency ablation tonsillectomy vs. other techniques, as well as equivalent primary and secondary rates of hemorrhage [2]. Based on all the data in the review, it was concluded that it is still unclear whether or not bipolar radiofrequency ablation offers any advantage over more traditional methods [2]. However, in a recent prospective, randomized study comparing bipolar radiofrequency ablation tonsillectomy to cold steel dissection in children, significantly more post-operative pain was present (using a validated pain scale) in the cold steel group (assessed at 6 h and 4 days post-operatively), and there was significantly more intra-operative blood loss and longer average operative times [10].

Regarding tonsillectomy-related hemorrhage, a large review has shown that in children undergoing bipolar radiofrequency ablation tonsillectomy, the rate of secondary hemorrhage is 2.3% to 4.6%, although the definition of secondary hemorrhage only included cases that returned to the operating room in some of the included series [11,12]. The rate in our series was higher than we would have expected (10%), most likely due to small sample size. In the current study, more bipolar radiofrequency ablation patients (n = 5) were hospitalized for hemorrhage than pulsed-electron avalanche knife subjects (n = 2), but this difference was not statistically significant. However, when considering all cases of reported bleeding, bipolar radiofrequency ablation subjects were 2.33 times more likely to experience minor bleeding events when compared to subjects in the pulsed-electron avalanche knife group. The clinical significance of this difference is not clear, as most of these reported bleeding episodes were minor (e.g. blood-tinged saliva) that likely would not have been brought to medical attention had a study with daily phone calls not been performed.

4.3. Pulsed-electron avalanche knife

There is currently not much data in the literature available to assess the clinical outcomes of patients undergoing pulsed-electron avalanche knife adenotonsillectomy. In one recent retrospective cohort study, children undergoing adenotonsillectomy with traditional monopolar electrosurgery, bipolar radiofrequency ablation, and pulsed-electron avalanche knife PlasmaBlade techniques were compared regarding post-operative hemorrhage rate. Total post-operative bleeding rates were 0.3% for monopolar diathermy, 1.1% for bipolar radiofrequency ablation, and 0.6% for pulsed-electron avalanche knife surgery; these differences were not statistically significant, with no differences in rates of primary vs. secondary bleeding between techniques [4]. In the current study, we found that pediatric patients undergoing pulsed-electron avalanche knife adenotonsillectomy had similar pain scores throughout the 14-day recovery period. Although median pain scores in the pulsed-electron avalanche knife group on post-operative days #7–9 were significantly lower statistically, these differences were not clinically significant, since most scores in both groups on these days were below 4, and prior research has shown that only a score of 4 or higher is associated with painful post-operative situations [7]. The current study did demonstrate that fewer doses of acetaminophen were taken on post-
operative days 8, 10, and 12 in the pulsed-electron avalanche plasma knife group.

4.4. **Features of the present study**

Although this study did not use a true randomization scheme, it was structured such that a pre-determined number of consecutive subjects would be enrolled into each of the study groups, in groups of 25 subjects at a time per group. It seems unlikely that such a structure would introduce any significant bias, but bias could arise from both the surgical team and the patient's caregivers being un-blinded as to which technique was used. Other drawbacks of the current study may be the proxy nature of the pain scores (which could have introduced parent or parent/legal guardian bias); the fact that pain assessment was performed via telephone encounter (without office visits with direct observational physician evaluation of pain); and the relatively small study size (100 subjects). Also, the cohorts were not entirely identical, with bipolar radiofrequency ablation subjects being older (mean age 7.1 years) than pulsed-electron avalanche knife patients (mean age 6.0 years). Despite these weaknesses, it seems reasonable to conclude that pulsed-electron avalanche knife adenotonsillectomy in children has at least been shown to be feasible as a technique, and certainly comparable in outcomes to bipolar radiofrequency ablation, with some suggestion in this study that there may be an advantage regarding post-operative pain and hemorrhage. Future studies should explore this topic further and determine if these findings are reproducible.

5. **Conclusions**

Pulsed-electron avalanche knife surgery was found to be a technique that was similar in adequacy to bipolar radiofrequency ablation for pediatric adenotonsillectomy. In this study comparing the two techniques, there were similar degrees of post-operative pain and analgesic consumption reported between the 2 study groups. There were also similar numbers of clinically significant post-tonsillectomy hemorrhage between the two groups. The overall rate of secondary bleeding was higher in bipolar radiofrequency ablation group, but most of these episodes were minor and did not require medical attention. Future studies are needed to further elucidate the potential benefits of pulsed-electron avalanche knife adenotonsillectomy in children.

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