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Comparison of Bizact™ and Bipolar Tonsillectomy in Pediatric Patients

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Abstract **Original Research Article**

Background: The aim of this study is to compare the effects of Bizact™ and bipolar electrocautery on peroperative and postoperative bleeding, pain, operation time in pediatric patients. ***Methods:*** One Hundred and twenty eight (128) pediatric patients who underwent tonsillectomy were included in this prospective study. The patients were operated with indications of recurrent tonsillitis, chronic tonsillitis and obstructive sleep apnea syndrome (OSAS). Patients with a history of bleeding diathesis and peritonsillar abscess were excluded from the study. ***Results:*** While the mean peroperative bleeding amount measured in the Bizact™ tonsillectomy group was 16 ml, the mean amount of bleeding in the bipolar cautery group was 65 ml. When the mean operation times were compared, the mean operation time in the Bizact™ group was 15 minutes, and it was significantly lower than in the bipolar cautery group, which was 22 minutes. Patients' postoperative pain scores and return to normal diet were also significantly lower in the Bizact™ group than in the bipolar cautery group. Pain scores of the patients on postoperative 1st, 3rd and 5th days were significantly lower in the Bizact™ tonsillectomy group than in the bipolar cautery group. While bleeding occurred on the 4th day in 1 patient in the bipolar cautery group, no postoperative bleeding was observed in the Bizact™ group. ***Conclusion*:** Bizact™ tonsillectomy provides safe peroperative and postoperative bleeding control, less pain, and an earlier return to normal diet and social life.

Keywords: Bizact™, pediatric patients, chronic tonsillitis, peroperative bleeding.

INTRODUCTION

Tonsillectomy, first described by Celsus in the 1st century BC, is one of the most performed operations in ENT practice today [1]. A wide range of surgical techniques and surgical tools such as blunt dissection, electrocautery, monopolar and bipolar cauterization, cryosurgery, laser surgery, thermal welding, coblator, radiofrequency and ligasure devices to reduce complications over the years, increase patient comfort and enable patients to return to social life earlier (Younis RT, Lazar H, Prokopakis EP, Karatzias GT, Lachanas VA). While tonsillectomy with bipolar cautery has a long history and widespread use, the Bizact™ device (Medtronic, Minneapolis, MN, USA) is a vessel sealing and incision device that has become more popular and common in recent years and its use in head and neck surgery operations is increasing day by day. Bipolar cauterization is frequently used in tonsillectomy operations because it provides vascular coagulation together with dissection [2]. Ligasure, which we frequently use in head and neck surgery operations in our clinic, has been shown to be very effective and safe in studies [3, 4]. In addition, in clinical studies, it is stated that Ligasure is very safe and effective in tonsillectomy operations, as well as providing adequate hemostasis and minimizing postoperative pain [4]. In this study, we compared bipolar cauterization tonsillectomy and Bizact™ tonsillectomy in pediatric patients in terms of peroperative bleeding, operation time, postoperative pain and bleeding. According to our literature review, our study is the first in the literature to compare Bizact™ device with bipolar cautery in pediatric population.

MATERIALS AND METHODS

One Hundred and twenty eight (128) pediatric patients who underwent tonsillectomy between September 2018 and June 2022 were included in the study. The patients were operated with indications of chronic tonsillitis, recurrent tonsillitis or obstructive sleep apnea (Table 1). Approval for the study was obtained from the Ethics Committee of Fırat University. Patients' parents were informed about the study and their written consent was obtained. The study was

conducted in accordance with the Declaration of Helsinki.

The patients were divided into two groups according to the surgical method used:

Group I: It consisted of 64 patients (30 boys, 34 girls) aged between 5 and 14 (mean age 8.2), who underwent tonsillectomy with bipolar cautery.

Group II: It consisted of 64 patients who underwent tonsillectomy with Bizact™. The age range of the patients, 31 of whom were boys and 33 were girls, ranged from 4 to 15, with a mean age of 7.6 years.

Table 1: Demographic Information and Indication Distribution of the Patients

Demographic Data of Patients	Group I (n=64)	Group II (n=64)
Boy: Girl (number)	30:34	31:33
Age Range (years)	5-14	4-15
Average Age (years)	8.2	7.6
Indications		
Recurrent Tonsillitis	39	40
Obstructive Causes	25	24

Surgical Technique

Preoperative hemogram, prothrombin/partial thromboplastin values of the patients were measured. Patients with a history of peritonsillar abscess and bleeding diathesis were excluded from the study. All patients were operated under general anesthesia by two senior surgeons. In Group I patients, a pillar incision was made first, the tonsil was dissected by reaching the tonsil capsule through the incision, and then bipolar cauterization was applied at 30 Watts and tonsillectomy was performed by dissecting from the tonsil capsule. Medtronic Bizact™ tonsillectomy device was used for the LT group (LVSS) (Valleylab, Boulder, CO) (Photo 1).

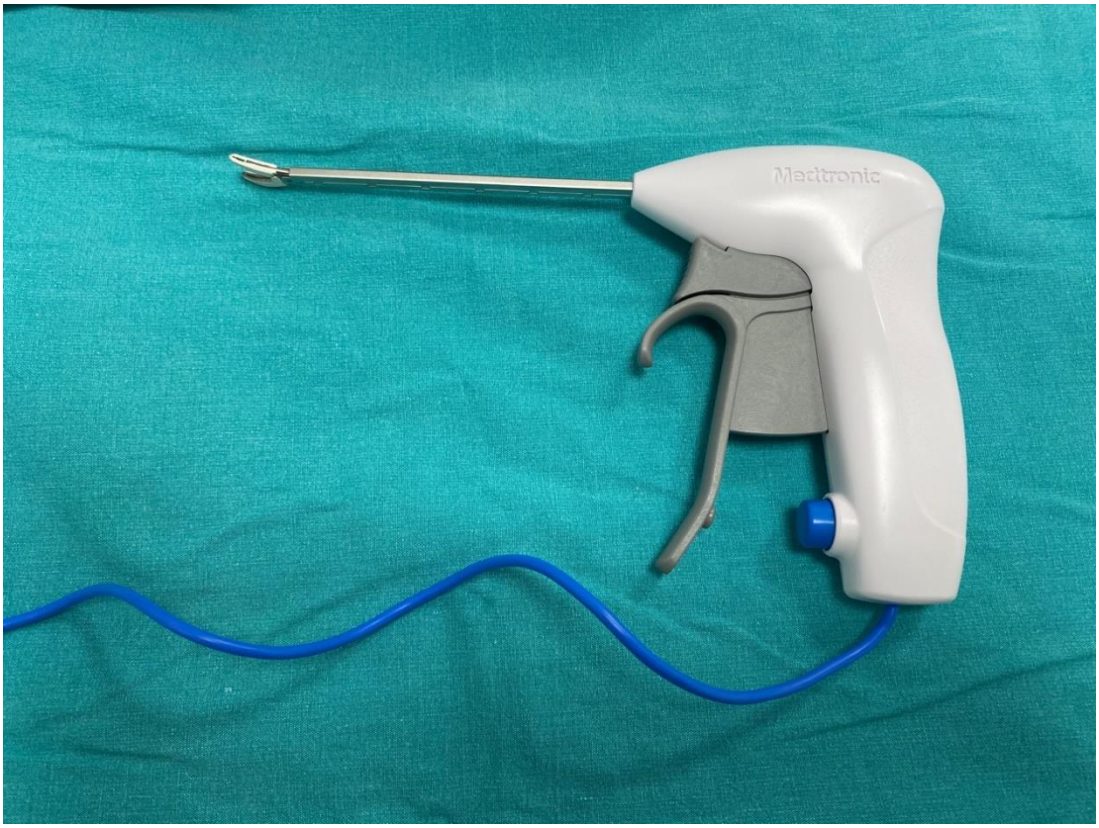

Photo 1: Bizact™ Tonsillectomy Device

This instrument was used to simultaneously perform both hemostasis and dissection. After holding the tonsil with an Allis clamp and pulling it medially, the anterior tonsillar plica was gently sealed with the Bizact™ device and then dissected without any mucosal incision. It was dissected from the tonsillar capsule and advanced to the lower pole, and finally the lower pole was cauterized with the same probe and removed (Video 1). The bleeding that occurred during the operation was calculated by looking at the amount of

blood in the aspiration tube, and for the duration of the operation; it was calculated as the time between the pillar incision in the bipolar cautery group, from the time of the first sealing in the Bizact™ tonsillectomy group, when both tonsils were removed and the bleeding control ended (Table 2).

All patients were followed up in the hospital on the night of the operation and oral suspension antibiotics (amoxicillin/clavulanate) and paracetamol were started. A visual analog scale was used for postoperative pain, and the patients were contacted and their pain scores were recorded on the postoperative 1st, 3rd, 5th, 7th and 10th days (range 0-10, 0= no pain, 10= excruciating pain) (Table 3). The patients were followed for three weeks postoperatively. Patient information including operation times, amount of peroperative bleeding, postoperative pain scores and complications were recorded.

Statistical analysis

Chi-square test was used to compare categorical variables between groups. Two-way analysis of variance (ANOVA) was used to compare pain scores between groups. P values less than 0.05 were considered statistically significant. IBM SPSS version 24.0 was used for calculations (IBM Corp. Armonk, NY, USA).

RESULTS

When the operative times were compared, the mean operation time was 22±1.58 min (16-29 min) in the bipolar cautery group and 15 ± 1.22 min (9-23 min) in the Bizact™ tonsillectomy group. The difference between the groups was statistically significant (P<0.001). Considering the amount of peroperative bleeding, the mean amount of bleeding was 16 ml (0-20) in the Bizact™ tonsillectomy group and 65 ml (35-175 ml) in the bipolar cautery group. This difference was also statistically significant (Table 2). When postoperative pain scores were evaluated, the mean pain score was 8.45± 1.41 (between 5-10) in the bipolar cautery group on the postoperative 1st day, 5.96 ± 0.90 (between 4-8) in the Bizact™ tonsillectomy group, and 5.96 ± 0.90 (between 4-8) in the postoperative 3rd day, 7.15 ± 1.38 (range 5-9) in the bipolar cautery group, 5.04 ± 1.09 (range 3-7) in the Bizact™ tonsillectomy group, 5.84 ± 0.87 (range 3- 6) in the bipolar cautery group at postoperative 5th day, 3.96 ± 0.86 (range 3-5) in the Bizact™ tonsillectomy group. When the results were compared, the difference between the bipolar cautery and Bizact™ tonsillectomy groups in pain scores on the 1st, 3rd and 5th days was statistically significant (p<0.05). Pain scores on the 7th day were 4.284 ± 0.76 (between 3-6) in the bipolar cautery group, 3.68 ± 0.81 (between 2-5) in the Bizact™ tonsillectomy group. Pain scores on the 10th day were 3.44 ± 0.84 (range 2-5) in the bipolar cautery group and 2.86 ± 0.706 (range 2-4) in the Bizact™ tonsillectomy group. Although the mean pain scores in the Bizact™ tonsillectomy group were lower on the 7th and 10th days than in the bipolar cautery group, the difference was not statistically significant (Table 3).

Table 2: The amount of preoperative bleeding and operation times of the groups

	Group I	Group II
Average Operation Time (min)	22±1.58	15 ± 1.22
Amount of Peroperative Bleeding (ml)	16	65

Table 3: Postoperative pain scores of the patients

	Bipolar Tonsillectomy Group	Bizact™Tonsillectomy Group	P value*
Postop. day 1	8.45±1.41	5.96 ± 0.90	**0.01**
Postop. day 3	7.15 ± 1.38	5.04 ± 1.09	**0.03**
Postop. day 5	5.84 ± 0.87	3.96 ± 0.86	**0.03**
Postop. day 7	4.284 ± 0.76	3.68 ± 0.81	0.35
Postop. day 10	3.44 ± 0.84	2.86 ± 0.706	0.47

*Chi-square test

DISCUSSION

Tonsillectomy complications are; complications related to anesthesia, drug reactions, carotid artery injury, tonsillectomy infection, dehydration and bleeding [3-5]. The most important and most common of these complications is postoperative bleeding, which is divided into two. Bleeding within the first 24 hours is classified as primary bleeding, and bleeding after 24 hours is classified as secondary bleeding. While the main cause of primary bleeding is the surgical technique used, the main causes of secondary bleeding are consumption of hard food, tonsillar bed infection, NSAID use or idiopathic [6-10]. The Ligasure vessel sealing device is a new bipolar sealing device with active feedback control. The device consists of an energy source and a hand probe that provides incision. When the tissue to be sealed is placed between the clamp and compressed, the device detects the response and produces the most appropriate current according to the density of the tissue compressed between the clamp. This energy denatures the collagen and elastin in the vessels and surrounding tissue, when the device senses that the sealing process is complete, it automatically cuts off the current, gives an audible

warning, and the surgeon cuts the tissue with the help of micro scissors in the probe [3-7].

The FDA states that the Ligasure sealing device can securely seal vessels up to 7 mm in diameter, and it has been confirmed that sealing in this way can control bleeding even against elevations of up to three times the normal systolic blood pressure [7-9]. Shows that it provides equal bleeding control with ligation and clips, and better bleeding control than ultrasonic and bipolar coagulation devices [10, 11]. In our study, while the mean amount of perioperative bleeding was 65 ml in the bipolar cautery group, it was 16 ml in the Bizact™ group, and this difference was statistically significant. While no early postoperative bleeding was observed in both groups, bleeding occurred from the left lower pole of the tonsil in the bipolar cautery group on the 4th day and bleeding control was needed in general anesthesia, while no primary or secondary bleeding was observed in the Bizact™ tonsillectomy group. Vassilios *et al*., [12] in a study they conducted on adults in 2005, compared ligasure with bipolar cautery. As a result of the study, they reported that there was no detectable bleeding preoperatively in the ligasure group, and that there was an average of 125 ml bleeding in the bipolar cautery group. Our study, which is similar to this study, showed that Bizact™ significantly reduced intraoperative bleeding. Again in their study, they found that the duration of surgery in the Ligasure group was significantly lower than in the bipolar cautery group. In our study, the mean operation time was 22±1.58 minutes (16-25 minutes) in the bipolar cautery group and 15± 1.22 minutes (14-25 minutes) in the ligasure group, and this difference was statistically significant in our study as well. The probable reason for this difference is that Ligasure significantly reduces the operation time because it seals the vascular structures before dissection and allows the tissue to be cut afterward, and therefore bleeding control is not required. In many studies, it has been reported that the Ligasure vessel sealing device shortens the operation time [12-16]. In the study of Vassilios et al., the pain scores on postoperative 1st, 3rd, 5th, 7th, 10th,14th days were compared with the pain scores on the 5th day and they stated that the pain scores in the ligasure group were statistically significant compared to the bipolar cautery group on all days except the 5th day. In our study, the pain scores on postoperative 1st, 3rd, 5th, 7th, 10th days were compared, and although the pain scores were found to be lower in the Bizact™ tonsillectomy group on all days, in postoperative 1st, 3rd, 5th days, differences in days were statistically significant. Bizact™ device provides energy transmission in a controlled manner according to the density of the tissue taken between the clamp. As a result, there is a more limited energy flow, thus causing less thermal radiation and damage to the surrounding tissues, which reduces postoperative pain [14-17]. Histological studies have reported that there is a thermal spread between 1.5 mm and 3.3 mm after dissection with Ligasure sealing [18-21].

In our study, mild edema developed in the tonsillar bed in 6 patients in the Bizact™ group, and this edema completely regressed after 24 hours without the need for any intervention. The low thermal effect ensures that tissue damage is less, which means that postoperative pain, which is a very important cause of discomfort in patients undergoing tonsillectomy, is significantly lower. Postoperative pain also limits oral intake. Leaper *et al*., [22] reported in their study that electrodissection or bipolar coagulation increased postoperative pain. The use of Bizact™ in the early postoperative period causes less pain and the patient can be fed orally with a suitable diet. Thus, the chronic cycle is quickly broken. Since patients with severe pain refuse to feed, the pain decreases later, which prolongs the healing process. This delays the patients' return to social life after surgery. In addition, low oral intake increases the risk of dehydration in children. Bizact™ tonsillectomy in children not only provides effective and safe hemorrhage control, but also shortens the operation time and thus reduces the analgesic drug exposure of the pediatric patients.

No special training is required for the use of the Bizact™ device, which is used in many ENT clinics, especially in head and neck surgery ligasure is used widely; however, it is difficult to use in pediatric patients because the surgical field is narrower than adults. Dulku *et al*., [23] showed that Bizact tonsillectomy is safe and easier than traditional tonsillectomy. Bizact™ device is specially designed for tonsillectomy make this system easier to use. However, the fact that the probes are designed for single use increases the cost. Although it has been reported that the probes will be reused in some studies, it is reported that the use of reuseable instruments in tonsillectomy carries a risk of Creutzfeldt-Jakob contamination at a ratio of 1/5000 [16]; therefore, reuse of the probe is risky.

Our clinical experience shows that operation times are shorter and intraoperative and postoperative bleeding is less in pediatric patients who were operated on with the Bizact™ tonsillectomy device. In addition, since they have less postoperative pain, they do not experience oral feeding problems.

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