



Outcomes of Partial Intracapsular Bizact™ Versus Bipolar Electrocautery Tonsillectomy in Pediatric Patients: A Prospective Analysis

Pediyatrik Hastalarda Parsiyel İntrakapsüler Bizact™ ve Bipolar Elektrokoter Tonsillektominin Sonuçları: Prospektif Bir Değerlendirme

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Outcomes of Partial Intracapsular Bizact™ Versus Bipolar Electrocautery Tonsillectomy in Pediatric Patients: A Prospective Analysis

ABSTRACT

Objective: : This study aimed to compare the intraoperative and postoperative outcomes of Partial Intracapsular Bizact™ Tonsillectomy (PIBT) and Bipolar Electrocautery Tonsillectomy (BET) in pediatric patients.

Material and Method: We conducted a single-center, prospective, randomized study involving 260 pediatric patients who underwent tonsillectomy under general anesthesia. Patients were randomly assigned to either the PIBT group or the BET group. Demographic and clinical data were collected, and the measured outcomes included operation time, intraoperative bleeding, postoperative pain scores, time to resume a normal diet, and the incidence of secondary bleeding.

Results: The mean age of patients was similar between the PIBT and BET groups. The PIBT group demonstrated a significantly shorter operation time (11 ± 3.3 minutes) compared to the BET group (18 ± 3.7 minutes, $p<0.05$). Intraoperative bleeding was significantly lower in the PIBT group (PIBT: 11 ± 2.7 ml; ET: 13 ± 2.3 ml, $p<0.05$). Postoperative pain scores were significantly lower in the PIBT group on days 3 and 7. Patients in the PIBT group resumed a normal diet significantly earlier (7.3 ± 1.5 days) than those in the BET group. The incidence of secondary bleeding was slightly lower in the PIBT group (3.6%) compared to the BET group (4.7%).

Conclusion: Partial Intracapsular Bizact™ Tonsillectomy offers significant advantages over electrocautery tonsillectomy, including shorter operation time, reduced intraoperative blood loss, decreased postoperative pain, and a faster return to a normal diet. These findings suggest that PIBT may be a preferred technique for pediatric tonsillectomy.

Keywords: Bizact™, intraoperative bleeding, postoperative pain, tonsillectomy.

ÖZET

Amaç: Bu çalışmanın amacı, pediatrik hastalarda Parsiyel Intrakapsüler Bizact™ Tonsillektomi (PIBT) ve Bipolar Elektrokoter Tonsillektomi (BET) tekniklerinin intraoperatif ve postoperatif sonuçlarını karşılaştırmaktır.

Gereç ve Yöntem: Genel anestezi altında tonsillektomi yapılan 260 pediatrik hasta dahil edildi. Tek merkezli, prospektif ve randomize bir çalışma gerçekleştirildi. Hastalar rastgele olarak PIBT grubuna veya BET grubuna atandı. Demografik ve klinik veriler toplandı; değerlendirme ölçütleri arasında ameliyat süresi, intraoperatif kanama, postoperatif ağrı skorları, normal diyetle dönüş süresi ve sekonder kanama insidansı yer almaktaydı.

Bulgular: Hastaların yaş ortalaması PIBT ve BET grupları arasında benzerdi. PIBT grubunda ameliyat süresi ($11 \pm 3,3$ dakika), BET grubuna göre anlamlı olarak daha kısaydı ($18 \pm 3,7$ dakika, $p<0,05$). İntraoperatif kanama miktarı PIBT grubunda diğer guruba göre azdı. (PIBT: $11 \pm 2,7$ ml; BET: $13 \pm 2,3$ ml, $p<0,05$). PIBT grubunda postoperatif ağrı skorları 3. ve 7. günlerde anlamlı derecede düşüktü. PIBT grubundaki hastalar, BET grubuna kıyasla normal diyetle daha erken döndü ($7,3 \pm 1,5$ gün). İkincil kanama insidansı PIBT grubunda (%3,6) BET grubuna (%4,7) göre istatistiksel anlamlı olmasa da düşük olarak gözlemlendi.

Sonuç: Parsiyel İntrakapsüler Bizact™ Tonsillektomi, elektrokoter tonsillektomiye kıyasla daha kısa ameliyat süresi, azalmış intraoperatif kanama, düşük postoperatif ağrı ve normal diyetle erken dönüş gibi önemli avantajlar sunmaktadır. Bu bulgular, PIBT'nin pediatrik tonsillektomide tercih edilen bir teknik olabileceğini göstermektedir.

Anahtar Sözcükler: Bizact™, intraoperatif kanama, postoperatif ağrı, tonsillektomi.

Introduction

Tonsillar hypertrophy and recurrent tonsillitis are common childhood conditions that significantly impact a child's quality of life. Tonsillectomy, either alone or in combination with adenoidectomy, is a commonly performed surgery in ENT practice for these reasons (1).

Conventional tonsillectomy is a well-known and widely performed technique. However, new surgical techniques such as monopolar or bipolar electrocautery, cryosurgery, laser, and coblation tonsillectomy have also been described. Despite the availability of these new techniques, there is no standardized optimal technique or device (2).

Several different surgical techniques have been described in the literature, particularly concerning the risk of postoperative pain and bleeding. Therefore, the optimal tonsillectomy technique should ensure fast recovery, acceptable levels of pain, and a low complication risk (3).

One of the new tonsillectomy devices, Bizact™, produced by Medtronic (Minneapolis, MN, USA), has been frequently used in recent times. Previous studies have reported its advantages, such as reduced bleeding and tissue damage (4).

In our study, we used Bizact™ devices in one of the groups during the operation. We aimed to compare the intraoperative and postoperative parameters of Partial Intracapsular Bizact™ Tonsillectomy (PIBT) and Bipolar Electrocautery Tonsillectomy (BET).

Material and Method

Study Design

We conducted a single-center prospective randomized study at the Ear, Nose, and Throat (ENT) Department of Medipol University, Istanbul, Türkiye. The study included 260 pediatric patients who underwent tonsillectomy under general anesthesia between March 1st, 2020, and November 1st, 2022. The study was designed as a single-blind prospective study.

Patient Selection

Patient selection was based on history and physical examination results obtained from the children's families. Preoperative data, including age, gender, vital signs, tonsil size, tonsillectomy indication, and medical history, were documented. Children aged 4

to 8 with a history of recurrent tonsillitis or symptoms of upper airway obstruction, such as open-mouth breathing during sleep, snoring, and sleep apnea, were included. Patients with systemic diseases such as coagulopathies, craniofacial disorders, or genetic variants were excluded. Physical examination included evaluating tonsil hypertrophy using the Brodsky grading system (Grade 1-4) (5).

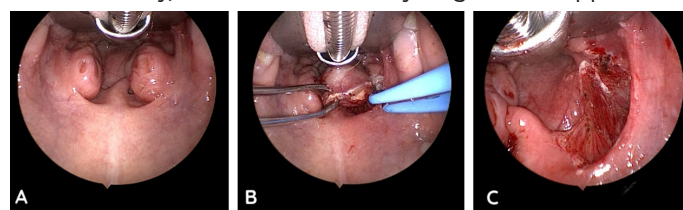
The surgical technique, intraoperative, and postoperative medications used for general anesthesia were standardized across all patients. Patients were randomly divided into two groups: those who underwent Bipolar Electrocautery Tonsillectomy (BET) and those who underwent Partial Intracapsular Bizact™ Tonsillectomy (PIBT). Families unaware of the surgical technique recorded pain scores, daily activities, and diet for 7 days.

Surgical Technique

All surgeries were performed by a single operator who holds a proficiency certificate. The operation began after placing the mouth gag and was recorded until the mouth gag was removed. Preoperative preparation and anesthesia processes were not included in the operation time.

In the BET group, bipolar electrocautery (Valleylab Force 2 ESU, USA) was utilized for both dissection and cauterization, with the device set at a power level of 35 watts. During the procedure, the tonsil was grasped with one hand while electrocautery was used with the other hand to dissect and excise the tonsil tissue along with its capsule. Hemostasis was then ensured in the surgical field (Figure 1).

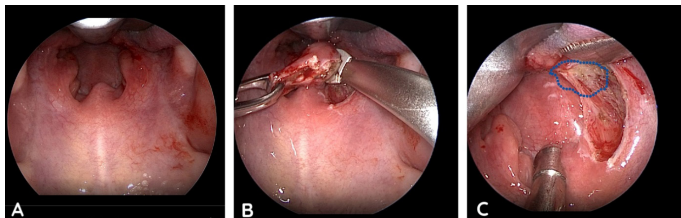
Figure 1. A- Preoperative endoscopic examination reveals bilateral tonsils, B- The tonsil was grasped and retracted from the tonsillar fossa, followed by the dissection using bipolar electrocautery, C- Post-tonsillectomy surgical field appearance



In the PIBT group, the Bizact™ device (Medtronic, Minneapolis, MN, USA) was utilized for surgical dissection, incision, and hemostasis. Dissection was performed using an extracapsular approach for the

superior and middle poles of the tonsil. For the inferior pole, the dissection continued in an intracapsular plane, ensuring the complete excision of the tonsillar tissue. Great care was taken to ensure that no visible residual tonsil tissue was left. In both inferior tonsillar fossae, the white capsule was observed to be intact (Figure II).

Figure II. A- Preoperative endoscopic examination reveals bilateral tonsils, B- Extracapsular dissection of the tonsil tissue using the Bizact™ device at the superior and middle poles, followed by transitioning to an intracapsular dissection plane at the inferior pole, C- Post-tonsillectomy appearance of the surgical field, showing the preserved tonsil capsule at the marked area on the inferior pole.



Intraoperative bleeding during tonsillectomy was quantified using a vacuum aspirator bottle that collected all blood and fluids. The total volume of bleeding was calculated by subtracting the volume of irrigation fluid administered from the total volume of fluid collected in the aspirator container at the end of the procedure.

Postoperative Period

All patients were monitored in the hospital for one day after the surgery. A single dose of intravenous cefazolin sodium was administered at a dosage of 30 mg/kg. All children received regular oral non-steroidal anti-inflammatory drugs (5 mg/kg-100 mg ibuprofen and 1 mg chlorpheniramine maleate) every 6 hours to relieve postoperative pain. Oral amoxicillin-clavulanate was prescribed at a dose of 50 mg/kg and continued for seven days postoperatively. Patients were discharged on the first day postoperatively. All patients were provided with a one-week dietary plan. They were instructed to follow a liquid-based diet for the first three days, transitioning to soft solid foods for the following four days.

Upon discharge, families were provided with instructions on postoperative pain management and

oral intake, along with detailed guidance on completing notes. All patients were seen and examined on the 7th day postoperatively. Postoperative pain was assessed using the Wong-Baker FACES® Pain Rating Scale on postoperative days 1, 3, and 7. Early (within 24 hours post-operation) (6) and late postoperative complications, such as bleeding, infection, difficulty in oral feeding, rehospitalization, or reoperation, were recorded. All patients were followed up for an average of two years postoperatively.

Ethics Statement and Statistical Analysis

Ethics approval was obtained from the Institutional Ethics Committee of Our University before the study commenced, in accordance with the Helsinki Declaration (Date: 03/06/2020; Decision No: E-10840098-202.3.02-3329). Detailed information about the surgical procedure and postoperative care was provided to the families, and informed consent forms were obtained from the parents. Statistical analyses were performed using SPSS software (version 20.0; IBM, Armonk, NY). Mann-Whitney U-test and independent t-test were used for between-group evaluation of quantitative data. The chi-square test was used to compare qualitative data. A *p-value* of less than 0.05 was considered significant.

Results

The mean age of the 150 patients in the BET group was 4.5 ± 2.6 years. According to gender distribution, 78 of these patients were male and 72 were female. Among them, 26 patients were diagnosed with recurrent tonsillitis, 69 with tonsil hypertrophy, and 55 with both conditions. Both tonsillectomy and adenoidectomy were performed on 98 patients, while only tonsillectomy was performed on 52 patients. The mean age of the 110 patients in the PIBT group was 4.2 ± 2.3 years. According to gender distribution, 59 were male and 51 were female. In this group, 12 patients were diagnosed with recurrent tonsillitis, 55 with tonsil hypertrophy, and 43 with both conditions. Both adenoidectomy and tonsillectomy were performed on 76 patients, while only tonsillectomy was performed on 34 patients.

The demographic and clinical characteristics of the patients were compared in Table I. There was no statistical difference in the mean age and gender distribution between the two groups.

Table I. Demographic and Clinical Characteristics of Each Group of Patients

	BET n=150	PIBT n=110	p value*
Sex,n(%)			
Male	78(52)	59(53.6)	0.415
Female	72(48)	51(46.4)	
Age,years			
Mean ± SD	4.5±2.6	4.2±2.3	0.335
Indications for tonsillectomy,n			
Tonsillar hypertrophy	69	55	0.295
Hypertrophy and Recurrent tonsillitis	55	43	
Recurrent tonsillitis	26	12	
Surgical preformed,n			
Tonsillectomy+Adenoidectomy	98	76	0.452
Tonsillectomy only	52	34	

BET=Bipolar Electrocautery Tonsillectomy;PIBT= Partial Intracapsular Bizact™ Tonsillectomy;SD=Standart deviation

* P-values were derived using the Chi-square test, as deemed appropriate for the data type and distribution.

The operation time was 18 ± 3.7 minutes in the BET group and 11 ± 3.3 minutes in the PIBT group. The operation time was shorter in the Bizact™ tonsillectomy group, and this difference was statistically significant ($p < 0.05$).

Intraoperative blood loss was also significantly lower in the PIBT group (11 ± 2.7 ml) compared to the BET group (13 ± 2.3 ml, $p = 0.004$).

Postoperative pain scores were compared in both groups. The average pain scores on days 3 and 7 were significantly lower in the PIBT group (Figure III). Additionally, in the PIBT group, the average time to return to a normal diet was 7.3 ± 1.5 days. This duration was found to be significantly shorter compared to the BET group (Table II).

Figure III. Comparison of postoperative visual analog scale (VAS) pain scores between the two groups. P-values at postoperative day (POD) 1, 3, and 7 are 0.31, 0.03, and 0.05 each. BET=Bipolar Electrocautery Tonsillectomy;PIBT= Partial Intracapsular Bizact™ Tonsillectomy;SD=Standart Deviation

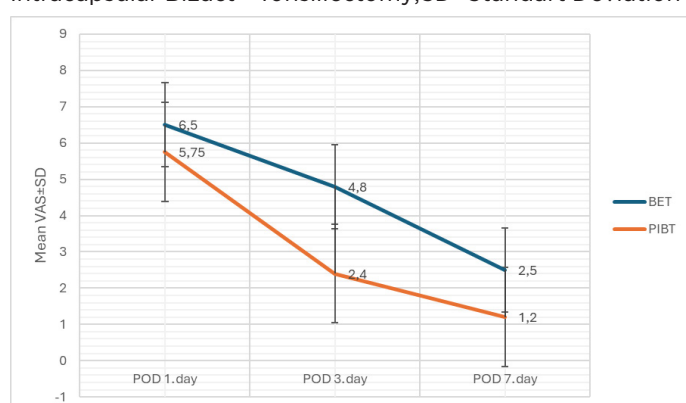


Table II. Comparison of the Intraoperative and Postoperative Parameters of Each Group of Patients

	BET n=150	PIBT n=110	p value*
Mean operative time, minutes(±SD)	18 ±3.7	11 ±3.3	<0.001
Intra-operative blood loss, ml (± SD)	13 ±2.3	11 ±2.7	0.004
PPS mean (± SD)			
1.day	6.5 ±1.5	5.75±1.4	0.046
3.day	4.8±1.2	2.4±1.1	<0.001
7.day	2.9±1.5	1.2±0.4	<0.001
Day to normal diet mean (± SD)	9.7±2.4	7.3±1.5	<0.001

BET=Bipolar Electrocautery Tonsillectomy; PIBT= Partial Intracapsular Bizact™ Tonsillectomy;SD=Standart deviation; PPS=Postoperative pain score.

*- independent samples t-test

Post-tonsillectomy secondary hemorrhage was graded according to the Stammberger classification (7). Postoperative secondary hemorrhage was observed in 7 (4.7%) patients in the BET group and 4 (3.6%) patients in the PIBT group. In the BET group, one patient underwent bleeding control under general anesthesia on the 7th day due to active bleeding. The days, sites, and severity of bleeding in both groups are recorded in Table III. There was no significant difference in bleeding rates between the two groups. In both groups, no recurrent tonsillitis or regrowth of tonsil tissue was observed during the 2-year follow-up period.

Table III. Comparison of Secondary Hemorrhage Data According to Group

	BET n=7(4.7%)	PIBT n=4(3.6%)
Day of POB, n		
<1	1	0
1-3	1	2
4-6	3	1
>7	2	1
POB site,n		
Superior pole	2	1
Middle pole	2	1
Inferior pole	3	2
POB severity*, n		
Grade A1	2	2
Grade A2	2	1
Grade B1	1	1
Grade B2	1	0
Grade C	1	0

BET=Bipolar Electrocautery Tonsillectomy;PIBT= Partial Intracapsular Bizact™ Tonsillectomy;POB=Post-Operative Bleeding,

*Severity of bleeding according to the Stammberger classification system.

Discussion

Postoperative pain management following tonsillectomy can be challenging and frequently insufficient. Pediatric patients often experience prolonged painful recoveries with symptoms such

as odynophagia, otalgia, dehydration, and poor oral intake, which significantly impact both the patients and their caregivers (8).

The use of the Wong-Baker FACES® scale for postoperative pain assessment has certain limitations, particularly within the pediatric population, due to subjectivity and communication challenges. Children's inability to accurately express pain or the potential biases in parental observations necessitate caution when interpreting the data (9). To mitigate this limitation, parents were thoroughly educated about pain scoring, and assessments were conducted under the supervision of a nurse on postoperative day 1. In our study, pain scores were significantly lower in the PIBT group on the 3rd and 7th days. Additionally, the shorter time required to resume a normal diet in this group (7.3 ± 1.5 days) can be considered a concrete indicator supporting the reduction in pain scores. New surgical techniques and instruments aim to reduce morbidity and enable patients to return to their normal lives quickly. The extent and depth of dissection during tonsillectomy, along with tissue damage and necrosis, can increase postoperative pain, infection, and bleeding risk (10,11).

One such technique is intracapsular tonsillectomy, which has gained popularity in recent years. This technique is particularly common in cases involving obstructive symptoms and offers advantages over classical extracapsular tonsillectomy, such as faster postoperative recovery and reduced pain. However, there is a risk that residual tonsil tissue may cause recurrent tonsillitis in the long term following intracapsular tonsillectomy (12,13). In our study, patients were followed up for an average of 2 years postoperatively. No residual or recurrent tonsil tissue was observed in either group.

Koltai and colleagues observed a reduction in postoperative morbidity with intracapsular tonsillectomy in cases of hypertrophic tonsils. They attributed this to the small diameter of vessels in the intracapsular area, suggesting that the preserved tonsil capsule acts as a biological dressing (14). In our study, the PIBT group had the inferior tonsillar capsule left intact, and it was observed that patients in this group were able to resume a normal diet in a shorter period.

Bipolar electrocautery tonsillectomy is commonly

used for its ease of use and reduced intraoperative bleeding. However, a study comparing blunt dissection and bipolar electrocautery dissection found that the latter group experienced increased postoperative pain and delayed oral intake resumption, possibly due to thermal tissue damage from frequent cauterization (15,16). Our study found significant difference in intraoperative bleeding between the BET and PIBT groups. Higher pain scores were observed in the BET group on days 3 and 6. This outcome is attributed to dermal tissue damage caused by extracapsular dissection and cauterization.

Coblation tonsillectomy has emerged as an alternative with advantages such as less pain and shorter operation time due to its low-temperature coagulation that minimizes tissue damage. However, it has a higher risk of secondary bleeding compared to conventional tonsillectomy (17).

A study by Lowe D. et al. found that tonsillectomies performed with diathermy (an electric cutting tool) for removal and bleeding control had higher rates of bleeding compared to those using traditional cold steel instruments and ties to stop bleeding (18). The secondary hemorrhage rates in both of our groups were observed to be consistent with the data reported in the literature.

Preserving the tonsil capsule in the inferior pole during tonsillectomy, as described in the Tonsillectomy with Inferior Pole Capsule Preservation technique, has been shown to reduce postoperative pain and bleeding risk. This is due to the short distance between the tonsil capsule and the superior pharyngeal constrictor muscle, as well as the presence of important vessels supplying the tonsil in this area (19,20). In our study, there was no statistically significant difference in the risk of postoperative bleeding in the group where the tonsil capsule was preserved at the inferior pole. In a retrospective study conducted by Falz H and colleagues, the intraoperative and postoperative parameters of BiZact™ tonsillectomy were compared with cold steel dissection with bipolar hemostasis in adults. The study found that BiZact™ tonsillectomy offers advantages such as shorter operative time and reduced intraoperative bleeding. However, there was no significant difference in terms of post-hemorrhagic bleeding and pain between the two techniques (21).

The Ligasure group, which included BiZact tonsillectomy, performed simultaneous dissection and hemostasis. This technique offers advantages such as a clear surgical field and a shorter operation time, ultimately reducing patients' exposure to anesthesia (22). Our finding of a shorter operation time is consistent with the literature.

In a study conducted by Mao et al., the primary bleeding rate among 1,717 patients who underwent BiZact™ tonsillectomy was reported to be low. The secondary bleeding rate of 5.9% was found to be comparable to other techniques (23). In our series, the PIBT group demonstrated a secondary bleeding rate of 3.6%. When compared to the rates reported in the literature, this lower bleeding rate can be attributed to the intracapsular dissection performed at the inferior tonsillar pole.

A systematic review and meta-analysis evaluated the intraoperative outcomes and morbidity associated with BiZact™ tonsillectomy. A total of 12 studies involving 1,452 patients were analyzed, revealing that BiZact™ resulted in less intraoperative bleeding, lower postoperative pain scores, and shorter recovery times compared to traditional techniques, including bipolar electrocautery, coblation, and cold dissection (24). In our study, intraoperative blood loss was significantly lower in the PIBT group. This finding can be attributed to the design of the BiZact™ device, which allows simultaneous dissection and hemostasis. Additionally, the low tissue temperature during hemostasis minimizes tissue necrosis at the surgical site, thereby reducing postoperative pain and promoting a faster return to a normal diet. Tierney et al. conducted a randomized controlled trial comparing the outcomes of extracapsular tonsillectomy performed using Coblation and BiZact™ in adult patients. Although the rates of secondary bleeding were similar between the two techniques, BiZact™ demonstrated superior results in terms of shorter operative time and reduced postoperative pain. The study concluded that BiZact™ is an effective and safe alternative for adult tonsillectomy (25).

Another study compared the intraoperative and postoperative outcomes of BiZact™ and Bipolar Electrocautery Tonsillectomy techniques in pediatric patients. Tonsillectomy performed with BiZact™ was associated with a shorter operative time,

reduced bleeding (16 ml), lower postoperative pain, and faster recovery compared to the bipolar electrocautery technique (26). In contrast to our study, the intraoperative blood loss was lower (11 ml) in our PIBT group. Although the irrigation fluid used was included in the calculation of blood loss, the influence of bodily fluids should also be taken into account. Furthermore, in our PIBT group, intracapsular dissection at the inferior pole may have contributed to reduced intraoperative bleeding compared to total extracapsular dissection.

In the PIBT group, we hypothesized that intracapsular dissection at the inferior pole of the tonsil would reduce postoperative pain and secondary bleeding rates. Comparing this technique with the other group, it is too early to conclude whether the quicker return to normal activities and significantly lower postoperative pain are attributable to this specific technique or to BiZact™ tonsillectomy itself. Future studies comparing intracapsular and extracapsular BiZact™ tonsillectomy outcomes will be necessary to address this question.

Despite its single-center nature, limited case number, and lack of long-term follow-up, our study prospectively evaluated two different groups, providing unique insights. Future research should aim for an adequate number of patients and a double-blind, randomized prospective design comparing different techniques.

Conclusion

Partial Intracapsular Bizact™ Tonsillectomy (PIBT) demonstrates significant clinical advantages over bipolar electrocautery tonsillectomy (BET) in pediatric patients. The PIBT technique achieved a shorter operative time, reduced intraoperative blood loss, and lower postoperative pain scores. These findings position PIBT as a preferred surgical approach for pediatric tonsillectomy, balancing efficacy, safety, and enhanced patient outcomes.

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