Austin Journal of Surgery

Open Access

Austin Publishing Group

Special Article: Tonsillectomy

Comparison of Bizact™ Low Temperature Dissecting Device with Bipolar Diathermic Scissors for Tonsillectomy in Adult Patients

Dag Manhein[1]; Johan Raeder[1,2*]

[1]Bogstadveien ENT Clinic, Oslo, Norway

[2]Medical Faculty, University of Oslo, Oslo, Norway

***Corresponding author: Johan Raeder**

Gulleraasveien 30B, 0779 Oslo, Norway

Email: johan.rader@medisin.uio.no

Received: March 28, 2023

Accepted: May 03, 2023

Published: May 10, 2023

Introduction

Tonsillectomy is one of the most frequent surgical procedures done worldwide. While the surgical procedure may take less than 10 minutes, there is a significant related morbidity due to per- and post-operative bleeding, post-operative pain and delayed return to normal activity and diet [1]. There is no consensus on the optimal method and device for surgery; use of cold dissection or coblation or diathermia scissors, with electro-cautery as needed; are advocated by different authors. The BIZact ™ vessel seal instrument (Medtronic, Mansfield, MA, USA) is a new technology with continuous measurements of tissue impedance, in order to deliver minimally bipolar energy for dissection and vessel sealing, with minimal thermal damage of remaining tissue [2].

The purpose of the present prospective, partly double-blinded study, was to evaluate the usefulness of BIZact for surgery in a population of adult tonsillectomy patients, in terms of: safety, bleeding, perioperative easiness and time consume, as well as postoperative parameters such as pain, resumption of oral intake, bleeding and overall satisfaction.

Materials and Methods

Approvals, Study Population and Study Design

The study was planned with a prospective, randomized, parallel group design with single blinded data collection per-operatively and double-blinded collection post-operatively.

The study was registered with Clinical Trials (clinicaltrials.gov, identifier: NCT0385279) and approval was granted by the South-East Norway regional ethics committee (helseforskning.etikkom.no, ref: 2018/750).

Written informed consent was obtained from adult patients above 18 years of age, ASA class I or II, scheduled for elective day-case tonsillectomy. The patients had to be fluent in Norwegian language.

Randomization

When the patient was included for the study and after induction of general anaesthesia, an opaque envelope was opened with the name of the instrument to be used written inside. The envelopes were prepared well in advance of the study from a code of random numbers designating the patient to either “New” (N) (i.e. BIZact) or “Control” (C) method in a random way.

Anaesthetic and Surgical Method

The anaesthetic method was strictly standardized with no premedication before start of anaesthesia which was with intravenous bolus injection of propofol 2mg/kg and remifentanil 3 micro/kg and then mask with oxygen ventilation for 2 min upon apnoe. The trachea and vocal cord area was sprayed with 1mg/kg lidocaine in solution, then 1 min further mask ventilation and subsequent endotracheal intubation with a cuffed oral tube, without the use of neuromuscular blocking agents. Paracetamol 1g, parecoxib 40mg and dexamethasone 8mg was given IV for pain and nausea prophylaxis. The patients were normo-ventilated with 33% oxygen in nitrous oxide, and anaesthesia was supplemented with IV increments of remifentanil 0.5

Citation: Manhein D, Raeder J. Comparison of Bizact™ Low Temperature Dissecting Device with Bipolar Diathermic Scissors for Tonsillectomy in Adult Patients. Austin J Surg. 2023; 10(2): 1300.

microg/kg and eventually propofol 0.3mg/kg as needed. By the end of surgery nitrous oxide was terminated, and patients were allowed to retrieve spontaneous ventilation with extubation (defined as end of anaesthesia) upon movement or coughing.

Apart from the difference in surgical instruments, the surgical procedure was standardized and started by application of Boyle Davies gag and infiltration of the upper and lower tonsil poles by 0.5ml of lidocaine 20mg/ml with epinephrine 12.5microg/ml at each site. Mucus was cleaned with suction device and any bleeding was dried by minor compresses during surgery. In Group C a conventional non-disposable diathermic scissor (Valeylab, Boulder, CO, USA) was used for complete resection of both tonsils, in Group N the disposable BIZact™ vessel seal instrument was used. After resection of the tonsils, the wound area was cleaned with minor compresses, and bipolar diathermia forceps (Valleylab, Boulder, CO, USA). When both wound areas appeared dry and without any bleeding for 1-2 min inspection, the gag was removed and surgery ended.

Postoperatively the patients were observed in lateral supine position in a designated recovery area, observed by a trained recovery nurse not knowing the method of surgery. If the patient reported pain or nausea, this was treated with fentanyl 0.5microg/kg, eventually repeated, and ondansetron 4mg IV, respectively. After 45 min the patients were tested every 5-10 min for discharge readiness, and then eventually discharged soon after upon resolution of practical issues and logistics. The patients had to be escorted home with a responsible adult, staying with them until next day, and had to be within 1h reach of the unit until the late afternoon, then within 1h reach of a ENT hospital department for the next two weeks. The patients were instructed to use oral paracetamol bid 4 for as long as they felt any need of analgesics, supplementing with oral diclofenac bid 3 for 5-7 days as needed. In case of strong pain they were instructed to replace paracetamol tablets with paracetamol+codeine combination tablets. The patients had full access to the Clinic's telephone during day-time hours and to the surgeon on a 24/7 basis during the two weeks of postoperative observation. In case of bleeding, the patients were instructed to go to the nearest ENT hospital department, bringing with them a pre-written requisition for admittance 24/7.

All patients had a call with an interview from the clinic the day after surgery, and a control with the surgeon after two weeks, bringing with them a diary of daily pain scores (0-10, 10=extreme pain), analgesic use, any bleeding or other side-effects.

Study End-Points

The primary outcome for the study was postoperative pain during two weeks postoperative observation, whereas secondary outcomes were bleeding during the same time-frame, as well as duration and easiness of surgery.

Statistical Analyses

The data was processed in SPSS version 10 (SPSS inc, Chicago, MI, USA). The groups were compared with Student's t-test for normally distributed data, and with Mann-Whitney (MW) test for non-normally distributed, ranked data. A p-value of less than 0.05 was considered statistically significant. The data set was finished and closed before the randomization code was broken, and the patients were then grouped into the two study groups for analyses.

The number of postoperative days in daily need of analgesic medication was used as an endpoint for power calculation. From our own data on file with diathermia scissors, this was expected to be mean 12±2 days (mean±SD). As we regarded a reduction in 25% of this number to be clinically significant, the study needed a minimum of 2x23 patients with a alpha of 0.05 and beta of 0.8.

Ethical Considerations

The study of the control group may be considered as an observational study of established everyday routines in a patient population due for planned surgery. As to the BIZact™ device, this has been e-market and approved for clinical use in Norway, and some few international reports have been promising [2-7]. Also, our own experience in a series of pilot patients had been promising and uneventful. The patients were fully informed of all risks, including severe bleeding, and we have a tested logistic system for transfer to nearby University Clinic in case of severe peri-operative bleeding. Patients who refused to participate in the study were subjected to the scissor method of the control group, and were otherwise treated similarly as the study patients.

Results

Patient Characteristics

In the study period from Nov 30th-2018 to Dec 8th 2020 a total of 23 patient lists were available for inclusion of patients. In total 71 tonsillectomy patients fulfilled the inclusion criteria and were asked to participate, of whom 65 accepted and were completed for the perioperative data set collection. A total of 12 patients were lost for follow-up on the day after surgery, and 11 were lost for follow-up after 2 weeks. The demographic data and per-operative drug consumption data were similar between the two groups (Table 1) as were risk factors of postoperative nausea and pain.

Table 1: Demographic data.

		Group New (n=34)	Group Control(n=31)
Age (yr)	(mean(SD))	25(4.9)	26(5.2)
Gender, % female		79%	66%
Weight (kg)	(mean(SD))	68(11)	68(11)
Height (cm)	(mean(SD))	170(7.6)	171(9,9)
Indication, n(%)	repeat infection	14(42%)	17(59%)
	bad smell	7(21%)	1(3%)
	big size, snoring	2(6%)	1(3%)
	infect+smell	6(18%)	6(21%)
	infect+snore	4(12%)	4(14%9
ASA Group	1	24(75%)	21(71%)
	2	8(25%)	3(10%)
Preop pain, n(%)=yes		6(18%)	9(30%)
Preop painkiller, n(%)=yes		2(6%)	3(10%)
Preop anxiety, n(%)=yes		4(12%)	3(10%)
Preop depression, n(%)=yes		2(6%)	3(10%)
Peop pessimist, n(%)=yes		4(12%)	2(7%)
University education, n(%)=yes		18(53%)	14(45%)
Daily smoking, n(%)=yes		0	2(7%)
Strong travel sickness, n(%)=yes		3(9%)	6(20%)
Previous PONV, n(%)=yes		0	0

Per- and Postoperative Results

Per-operatively Group N proved significantly better in terms of shorter duration of surgery (11 vs 17 min), shorter duration of anaesthesia (17 vs 22 min), less blood-loss and less surgical challenges (Table 2).

During the recovery stay in the clinic of mean 82 min (both groups pooled), the total dose of rescue analgesic fentanyl for pain was significantly higher in Group N (mean 30 vs 12 microg) (Table 3). The incidence of nausea or vomiting was similar (21% vs 19%, Group N and C respectively) and pain at discharge was similar (mean NRS=4.0 vs 3.3, Group N and C respectively) (Table 3).

In the data set from the day after surgery (Table 4) and two weeks after surgery (Table 5), there were no significant differences between the groups in pain, analgesic consumption, activity level (day 1), overall satisfaction, bleeding or other side-effects. A minor significant difference was noted (p=0.014) in time to first consumption of food, 8.7hr vs 4.8hr (mean value, Group N vs Group C, respectively). In the patients with a complete drug diary (n=44), 28 was still using regular paracetamol or diclofenac at day 14, whereas 16 had stopped with their pain medication, at median day 12, no difference between the groups (n=9 in Group N, n=7 in Group C).

Only two episodes (4%) of minor bleeding (one patient in each group) was noted during the first 24 hours, whereas 7 patients (11%), 4 in Group N and 3 in Group C were submitted to hospital during the 2 weeks observation period for bleeding, only one was re-operated.

Table 2: Per-operative data.

		Group New (n=34)	Group Control(n=31)
Duration of anaesthesia(min) (mean(SD))		17.2(4.0)	22.2(6.1)*
Duration of surgery (min)(mean(SD))		11.4(2.8)	17.2(4.6)*
Anaestesia drugs, total(mg)	Propofol	180(21)	180(15)
(mean(SD))	Fentanyl	0.096(0.014)	0.096(0.0093)
	Remifentanil	0.253(0.345)	0.193(0.024)
Blood-loss(n(%))	0	17(52%)	8(28%)**
n of red, minor compresses	0-1	12(36%)	12(41%)
	2-4	3(9%)	6(21%)
	5-9	1(3%)	2(7%)
	>9	0	1(3.5%)
Surgical difficulty	easy	10(45%)	3(12%)***
	easy-medium	4(18%)	5(20%)
	medium	7(32%)	13(50%)
	medium-difficult	1(4.5%)	2(7.7%)
	difficult	0	3(12%)

*p<0.001(Student's t-test)
**p=0.015(MW test)
**p< 0.005

Table 3: Postoperative data - in unit.

(mean(SD))	Group New (n=34)	Group Control(n=31)
First analgesic, min	18.1(16)	16.6(9.7)
Total, fentanyl postop(mikrog)	29.9(29.9)	12.1(19.4) *
PONV recovery, n=yes(%)	7(21%)	6(19%)
Discharge ready(min)	75.9(19.1)	71.6(4.71)
Discharge time(min)	86.0(16.8)	78.1(23.7)
Pain at discharge(0-10)	3.98(2.27)	3.32(1.97)

Table 4: Postoperatively Day after interview.

(mean(SD)) or n(%)		Group New (n=30)	Group Control(n=23)
Pain at interview(0-10)		4.27(2.23)	3.43(1.65)
Average pain, since disch		4.59(2.00)	3.76(1.38)
Worst pain, since disch		6.26(2.04)	5.57(1.40)
Analgesic use	Paracetamol(g)	3.02(1.71)	2.84(1.95)
	Diklofenac(mg)	145(67.3)	107(65.8)*
	Codeine, n(%)	8(29%)	11(52%)
First drinking, hr		3.10(2.65)	2.65(1.80)
First eating, hr		8.67(6.75)	4.76(1.80)
	median(hr)	6	2**
Amount of sleep	less	15(50%)	13(57%)
	normal	12(40%)	7(30%)
	more	3(10%)	3(13%)
Pain, disturbing sleep, n(%)=yes		9(35%)	8(36%)
Activity, day 1	in bed	1(3%)	0
	mostly bed/sofa	9(30%)	9(39%)
	50% bed/sofa	5(17%)	2(10%)
	mostly sitting	8(27%)	9(39%)
	mostly normal	4(14%)	2(10%)
	all normal	0	1(4%)
Bleeding, n=yes		1(3%)	1(4%)

*p=0.04(M-W test)
**p=0.014(M-W test)

Table 5: Postoperatively - Consultation 2 weeks.

		Group New (n=28)	Group Control(n=26)
Number of days with regular analgesic consumption	(median)	12	12
Pain at control(0-10)(mean(SD))		0.625(0.95)	0.884(1.10)
	no pain(n)=yes(%)	17 (61%)	14(53%)
Pain average, 0-2 weeks(mean(SD))		4.20(1.98)	3.76(1.56)
Pain, worst, 0-2 weeks		8.61(1.20)	8.46(1.36)
Maximum pain at day(0-14)		5.48(1,13)	5.65(0.94)
	median	5	6
Analgesic, total dose post discharge			
	Paracetamol(g)	21.2(12.8)	19.7(13.0)
	Diclofenac(g)	1.61(0.65)	1.86(0.57)
	Codeine(g)	0.93(0.49)	0.82(0.49)
Bleeding, n	none	21(75%)	19(73%)
(n(%)	1 episode	2	3
	more than 1 episode	0	0
	to hospital(no surgery)	4	2
	re-operation	0	1
Side-effects	Nausea	1	4
	Gastritis	1	1
	Shivering	1	0
	Diarea	1	0
Overall satisfaction	Very high	12(44%)	8(35%
(n(%)	High	15(56%)	15(65%)
	Medium	0	0
	Less than medium	0	0
	Bad	0	0

Discussion

The study shows a benefit of the BIZact (New) method in terms of a 6 min reduction (35%) in time for surgery, in perceived impression of more ease of surgery and less per-operative blood-loss, which in 88% of cases were close to zero. The BIZact patients had a higher need of immediate post-operative analgesics and took longer to start food consumption, but time to discharge readiness and other postoperative parameters were similar for two weeks in the two groups.

No serious complications were reported in this study series of 65 patients, but the pain ratings were generally high in these adult patients, with a maximum at day 5-6 and still use of painkillers in a majority at day 14 after the procedure. A 0-2 week bleeding rate of 11%, with only one case in need of re-operation, is considered low in an adult tonsillectomy population.

The ratings of "surgical difficulty" was rated by the surgeon as a subjective non-blinded opinion on global impression, which came out as a composite of anatomical difficulties (i.e. adhesions, previous abscess, invasive growth etc) and the ease of use of the surgical instrument for the purpose. As we consider the randomisation to distribute anatomical differences equally between the groups (also supported by demographic data in the two groups), it is fair to conclude that the lower rating of surgical difficulties in the N group was due to characteristics of the instrument, although the surgeon was not blinded. This is in agreement with the study of Dulku and co-workers, who reported the BIZact to be easy to learn to use adequately in residents [6]. Shorter per-operative time-consume with BIZact is also reported in a study of Krishnan and coworkers [4], with a mean duration of surgery of only 5.6 min. Their study is, to our knowledge, the only one before our report to provide clinical results of BIZact in adults. They confirm the safety data from our study, with only 4.3% postoperative bleeding in their study, compared to 1 patient (4%) in our study.

The high rate of overall satisfaction, high or very high in 90% of the patients in both our groups, may be a composite result on being pleased by having solved a health problem as well as the experience of postoperative pain as expected, and no serious problems encountered.

The strengths of the study include a highly standardized team with the same surgeon, anaesthesiologist and surgical assistant for all cases. All aspects of peri-operative care, except for method of surgery, were highly standardized and optimized, such as: shortlasting anaesthesia, adequate pain prophylaxis and nausea prophylaxis. The data collection after end of surgery was double-blinded. Only 6 patients refused to participate in the study and only 11 patients (17%) did not show up for two weeks follow-up, making the data representative for our mixed, adult patient population. As there were no strong non-significant trends of differences between the groups, we also consider the number of patients appropriate for revealing important clinical differences, although a very much higher number of patients will be needed for adequate evaluation of safety in terms of rare and serious complications.

We did not perform any health economic calculations in our study, but there is a potential of allowing for longer surgical lists with the BIZact device, as duration of surgery is 35% reduced, without any longer stay in the recovery. This should be balanced with the extra costs of the disposable, single use BIZact device, as opposed to the re-usable diathermic scissors.

The limitations include a prolonged period- with a break- to complete the study, due to the Covid situation which resulted in close-down of elective surgery for prolonged periods in 2020 and 2021. Also, in other periods the program was slowed down (i.e. less patients per list) due to Covid regulations. However, during the study period there was no change in any routines, personnel or general handling of the patients. Due to logistics, a maximum of 4-6 patients were possible to handle for the project from an individual surgical list, consisting of a maximum of 10 patients due for tonsillectomy. Usually, about half the lists were not fulfilling the inclusion criteria (i.e. too young, not speaking Norwegian, mixed type of surgery (adenoids, tympanotomy)). In addition, some were not asked to participate due to logistic limitations.

The surgeon and anaesthesiologist were not blinded for the procedure and the registration of per-operative data, which is difficult to do, as the surgeon will always know what instrument he/she is using. Also, a higher number of patients and even better follow-up rate at day one and two weeks would have been beneficial. The primary endpoint used for power calculation of mean 12 days of analgesic use turned out to be non-optimal, as more than half of the patients were using painkillers at end of the data collection at day 14.

Clinical Implications

The choice of routine method for tonsillectomy, choice of either BIZact of diathermic scissors, may be an issue based on minor clinical differences as well as considerations on logistiscs and overall cost-efficacy.

Conclusions

The BIZact device came out with shorter time and more easy of surgery, while immediate pain after surgery were stronger, without delaying discharge. Otherwise, pain and postoperative characteristics were similar as after diathermic scissors in the postoperative 2 weeks period. The incidence of bleeding was low with both devices.

Author Statements

Disclosure Statement

Apart from funding (see below) there is no conflict of interests to be declared from the authors.

Funding

The study was supported with a non-restricted grant and free supply of BIZact device for the study from Medtronic, Germany.

Medtronic had no role in protocol setup, data collection, data management, results workout or writing of the manuscript, but were allowed to make statements (without decisions), on the protocol in advance and the manuscript, before submission.

References

1. Aldamluji N, Burgess A, Pogatzki-Zahn E, Raeder J, Beloeil H, et al. PROSPECT guideline for tonsillectomy: systematic review and procedure-specific postoperative pain management recommendations. Anaesthesia. 2021; 76: 947-61.

2. Housley DM, Imrie J, Low C. Clinical utility of local over general anesthetic tonsillectomy using the BiZact device. Am J Otolaryngol. 2022; 43: 103547.

3. Ni G, McAuliffe D, Sethi HK, Patel P, Terk A, et al. A single center retrospective comparison of post-tonsillectomy hemorrhage between BiZact and Coblator. Int J Pediatr Otorhinolaryngol. 2022; 158: 111165.

4. Krishnan G, Stepan L, Du C, Padhye V, Bassiouni A, et al. Tonsillectomy using the BiZact: A pilot study in 186 children and adults. Clin Otolaryngol. 2019; 44: 392-6.

5. Stepan L, Huang L, Huynh J, Xie P, Woods CM, et al. Health Related Quality of Life T-14 Outcomes for Pediatric Bizact Tonsillectomy. Medicina (Kaunas). 2021; 57: 480.

6. Dulku K, Toll E, Kwun J, van der Meer G. The learning curve of BiZact tonsillectomy. Int J Pediatr Otorhinolaryngol. 2022; 158: 111155.

7. Salley JR, Johnson R, Mitchell RB, Shah G, Coffey AR. Comparison of outcomes between thermal welding forceps, controlled ablation and monopolar electrosurgery for tonsillectomy in children. Int J Pediatr Otorhinolaryngol. 2022; 152: 110941.