Original Article

Conventional Cold steel and Modern technique BiZact LigaSure for tonsillectomy: A comparative analysis

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Abstract

Objective: The definitive treatment of tonsilitis is surgical resection of inflamed tonsils. Various surgical techniques have been implicated to refine preoperative and post-operative care of the patients. One such innovation is the use of BiZact LigaSure for tonsillectomy. The study compares the conventional cold steel method and the modern technique BiZact LigaSure for tonsillectomy.

Materials & Methods: A comparative study was designed using a non-probability purposive sampling technique at Aziz Fatimah Hospital, Faisalabad. One hundred participants were enrolled and divided into two groups (50 each). One group underwent BiZact LigaSure tonsillectomy and participants of the other group were treated with the conventional cold steel method. Per-operative (Blood loss, Operative time) and post-operative variables (Pain) were assessed using an independent t-test.

Results: The blood loss calculated in Group A patients who underwent BiZact LigaSure tonsillectomy was 0.39 0.15 and in Group B, 15.9 2.65. The mean operative time assessed in groups A and B was calculated as 4.26 0.66 and 32.38 5.56 respectively. Both of these variables were recorded as highly significant as the P value = 0.000. The pain was assessed using the (Visual analogue Scale) VAS pain scale. The post-operative pain variable was also recorded as a highly significant variable.

Conclusion: BiZact ligaSure tonsillectomy procedure is a more effective and safe procedure than the conventional cold steel method as this significantly reduces the blood loss during surgeries, operative time and minimizes post-operative pain.

Keywords: BiZact ligature, cold steel, tonsillectomy.

Introduction

The inflammation of the tonsils is known as tonsillitis. Tonsillitis is common among every age group and either gender. Surgical resection remains the only best option for treating recurrent inflamed tonsils. Tonsillectomy comprises a major bulk of operations undergoing in otorhinolaryngology throughout the world.¹ Tonsillectomy dates back 3000 years, referred to in Indian medicine. However, much literature evidence is the testaments for the radical change surgical procedure to remove chronically inflamed tonsils.² From the past few decades, surgical approaches and procedures have taken a dynamic shift minimizing the risk of primary hemorrhage, postoperative complications, pain, and hemorrhage. The paramount to improving these parameters has led the surgeons to devise modern surgical techniques that minimize the risks involved and are cost-effective.³ Tonsillectomy carries a significant risk of morbidity and complications. The surgeons and investigators are now more inclined toward modern techniques than the old conventional cold steel method due to the advent of various new techniques that pose a lesser risk of morbidity and complications. Over the past few years, various techniques have been developed to achieve the ideal aim of rapid, bloodless surgical procedures and uneventful recoveries, such as bipolar electrocautery, thermal welding, cold steel method, and ultrasonic dissector coagulator.4

of the latest interventions devised One for tonsillectomy is the use of the BiZact LigaSure device. The BiZact LigaSure device provides a 12 cm shaft for safe access and handling. The shape of the instrument is designed to keep a picture of the tonsillar bed in mind. This ergonomic device provides intuitive controls to seal and divide the tissue and vessels up to 3mm in diameter. Literature evidence advocates the efficacy and minimal surgical risks of BiZact ligaSure.⁵ Our study aims to evaluate the intra-operative variables such as surgical time, blood loss, and postoperative variables such as pain using the visual analogue pain scale and compare it with the conventional cold steel method.

Ethical Considerations: The institutional ethical committee approved the study of Aziz Fatimah Medical and Dental College, Faisalabad, under ethical certificate number IEC/34-20.

Materials and Methods

A comparative study was conducted in Aziz Fatimah Trust Hospital, Faisalabad, at the department of Otorhinolaryngology from March 3, 2020, to June 26, 2021. A non-probability purposive sampling technique was implied, and after taking informed consent from the patients between the ages of 6 to 55 years of either gender presented with inflamed tonsils undergoing tonsillectomy were included in the study. Patients with uncontrolled diabetes, hypertension, anemia, undergoing acute infection. and emergency tonsillectomies were excluded from the study. The sample size was calculated by taking a reference from the study conducted by Ali, et al conducted at Faisalabad Medical University, Faisalabad.⁴

One hundred patients were enrolled and divided randomly into two groups using random numbers in two equal groups of 50 labeled as A and B. Group A comprised 50 patients operated by the BiZact LigaSure method, and group B underwent the conventional cold steel method. Patients of either group were enrolled in groups randomly. Patients were admitted for tonsillectomy one day before the surgery. A complete preoperative investigation package including, bleeding profile, complete blood count, X-ray chest, and Electrocardiography (ECG) in patients above forty years was done on all patients before surgery. Oral intake was stopped 8 hours before the surgery and all the participants were given a broad-spectrum antibiotic, ceftriaxone 1 gram twice before the surgery. Operative time and Blood loss were measured in minutes and milliliters, respectively. Blood loss was estimated using the calorimetric method. Cotton and ribbon gauze of the same size and weight were used during each surgery. The suction bottle and rubber tube were cleaned and emptied with a measured amount of saline and were used for intermittent suctioning to avoid blockage. In group A, patients undergoing Bizact LigaSure tonsillectomy noted immediate coagulation, while in group B hemostasis was achieved by ligature and local pressure.

The pain assessment was done using the Visual Analog Score (1= No pain, 4-6= Moderate Pain, 10= worst pain). Before the surgical procedure, a visual analog pain scale was demonstrated to the patient. The post-operative antibiotic cover was given to avoid any sort of secondary bacterial infection.

The first pain assessment was taken immediately after 6 hours of the surgery and the patients were instructed to maintain a follow-up by visiting the hospital on the 3rd and 7th day after surgery.

The data collected was analyzed in SPSS 20 using an independent t-test. Age and Gender distribution between the two groups were represented in percentages and frequencies. The comparison of per-operative variables such as blood loss and operation time was analyzed and represented in the form of and P-value. The pain was assessed using the VAS pain scale and the data analyzed was represented in. The P-value of 0.005 was considered significant and 0.000 was highly significant.

Results

Our study comprised 100 patients ranging from 6 years to 55 years. Table 1 depicts the percentage and means & standard deviation among the two groups. Age and gender distribution in group A depicts 34 (68%) participants between the age range of 6-21 years, 12 (24%), and 4 (8%) between 22-38 years and 39-55 years respectively. Group B comprised 37 participants in the range of 6-21 years. Mean and Standard deviation was calculated between two groups stated as two different identities.

Table 1: Age and Gender Distribution betweenGroup A and B

Age	Group A		Group B	
group	(n=50)		(n=50)	
(Years)				
	No. of	Percent	No. of	Percent
	Patients	age	Patients	age
6-21	34	68%	37	74%
22-38	12	24%	7	14%
39-55	4	8%	6	12%
Total	50	100%	50	100%
Gender				
Male	24	48%	21	42%
Female	26	52%	29	58%
Total	50	100%	50	100%

The two groups evaluated per-operative variables such as blood loss (ml) and surgery time (minutes). Group A recorded a blood loss of 0.39 ± 0.15 , while Group B recorded a response of 15.9 ± 2.65 and a P-value=0.000. The mean operative time recorded for group A was 4.26 ± 0.66 and group B 32.38 ± 5.56 . The analyzed P-value was 0.000.

Table 2: Comparison of Per-operative variables ingroup A and group B

Variables	Group A $(n=50)$	Group B (n=50)	P-value
Blood loss (ml) Operative time (minutes)	Mean \pm SD 0.39 \pm 0.15 4.26 \pm 0.66	15.9 ± 2.65 32.38 ± 5.56	0.000 0.000

Table 3 depicts the postoperative pain assessment by two different surgical approaches for tonsillectomy. Pain assessment was carried out using the visual analog score on Days 1, 3, and 7.

Table 3: Comparison of pain assessment on days 1, 3, and 7 using Visual Analogue Pain Scale

	0	0	
Pain as	Group A	Group B	P-value
VAS	(n=50)	(n=50)	
	Mean \pm SD		
Pain on	6.32 ± 0.89	7.86 ± 1.03	0.015
Day 1			
Pain on	5.20 ± 1.06	5.76 ± 1.45	0.000
Day 3			
Pain on	4.34 ± 1.22	3.80 ± 0.83	0.000
Day 7			

Discussion

One of the most commonly performed surgical operations in the otorhinolaryngology department across the globe is tonsillectomy. With an extensive history of surgical approaches and major bulk surgeons have changed the course of surgical approach devising new strategies and procedures to minimize the risks of morbidity and mortality.⁶ The surgeons have evolved various advances in the technology and instrumentation for tonsillectomy and homeostasis. The surgeon's perception concerning less operative time, minimum per-operative and post-operative bleeding, and increased recovery time towards a specific surgical technique influences his choice to advocate and treat the patients via that procedure.⁷

The present study focuses to compare the efficacy of BiZact LigaSure tonsillectomy with the conventional cold steel method. BiZact LigaSure is a bipolar current-carrying device that seals the vessels simultaneously. The device measures the tissue impedance and supplies the controlled energy.⁸

In our study, the patients were divided into two groups. Group A underwent BiZact LigaSure tonsillectomy while Group B with conventional cold steel method. Intra-operative parameters were compared in both groups. In Group A, Blood loss and Operative time were measured at 0.39 ± 0.15 ml and 4.26 ± 0.66 minutes respectively as compared to the blood loss of 15.9 ± 2.65 ml and operative time of 32.38 ± 5.56 minutes in Group B patients. Both the parameters were found to be highly significant statistically with a P-value of 0.000. Similar results were found in the study conducted by Adeel Niaz et al. and Muhammad Ali et al. in Allied hospital Faisalabad and Combined military hospital Kharian and Lahore.^{4,9}

Another study by Lucy Huang et al. states the efficacy of BiZact LigaSure with a blood loss average of 2.7 ml and operative time of approximately 4 minutes similar to our study. Moreover, the study also focuses on the parental perception of the child's quality of life.¹⁰ Literature evidence by Giri Krishnan et al. also reported a mean surgical time of 5 minutes and a blood loss of fewer than 1 ml observed in the majority of the cases.¹¹ All these results indicate the intraoperative efficacy of using these modern techniques such as BiZact LigaSure as compared to the conventional cold steel method.

One of the most important post-operative parameters is the assessment of pain during the recovery phase. The majority of patients seeking medical care after tonsillectomy were due to pain. In the present study, the pain was assessed using the Visual Analog Score for the pain scale. According to our study, the Assessment of pain on Day 1 in Group A patients was 6.32 0.89, 7.86 1.03 in Group B patients, and P-Value= 0.015. Significant statistical difference was found on Day 3 and Day 7 having a P-value=0.000.

Muhammad Ali et al. also document significant values of the pain assessed using the VAS scale.⁴ Similar results were stated by the systematic review conducted by Robert et al. The main reason for this difference in pain score is that more thermal damage was caused during the bipolar diathermy dissection procedure.¹² A study carried out by Pang et al. reported a minimum blood loss of 10 ml during bipolar electrothermy advocating the efficacy of the surgical intervention.

Conclusion

Tonsillectomies done by biZact LigaSure were effective and rapid surgical procedures with an added

advantage of less operative time, and minimum blood loss during the surgery as compared to the cold steel dissection method. Post-operative pain was also recorded as a significant variable for BiZact LigaSure.

References

1. Bohr C, Shermetaro C. Tonsillectomy and Adenoidectomy. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. PMID: 30725627.

2. Verma, R., Verma, R. R., & Verma, R. R. (2017). Tonsillectomy-Comparative Study of Various Techniques and Changing Trend. Indian journal of otolaryngology and head and neck surgery: official publication of the Association of Otolaryngologists of India, 69(4), 549–558. DOI: https://doi.org/10.1007/s12070-017-1190-6

3. Besser G, Grasl S, Meyer EL, Schnoell J, Bartosik TJ, Brkic FF, Heiduschka G. A novel electrosurgical divider: Performance in a self-controlled tonsillectomy study. Eur Arch Otorhinolaryngology. 2021. doi:10.1007/s00405-021-07008-9. Epub ahead of print. PMID: 34338876.

4. Mofatteh, M. R., Salehi, F., Hosseini, M., Hassanzadeh-Taheri, M., Meghdadi, S., & Hassanzadeh-Taheri, M. (2019). Postoperative Outcomes in Cold Dissection Versus Bipolar Electrocautery Tonsillectomy: A Randomized Double-Blind Controlled Study. Indian journal of otolaryngology and head and neck surgery: official publication of the Association of Otolaryngologists of India, 71(Suppl 1), 182–187. DOI: https://doi.org/10.1007/s12070-017-1204-4

5. BiZact[™] Tonsillectomy Device [instructions for use]. Boulder, CO: Medtronic; 2017. [Internet, Accessed on September 22, 2021]

6. Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States. Natl Health Stat Report. 2008. 28;(11):1-25. PMID: 19294964.

7. Krishna P, LaPage MJ, Hughes LF, Lin SY. Current practice patterns in tonsillectomy and perioperative care. International Journal of Pediatric Otorhinolaryngology. 2004 Jun;68(6):779-84. DOI: 10.1016/j.ijporl.2004.01.010. PMID: 15126019.

8. Çelikoyar, M. M. (2020). Tonsillectomy with BiZact: Impressions from four cases. Praxis of Otorhinolaryngology, 8(1), 51–55. DOI: https://doi.org/10.5606/kbbu.2020.52714

9. Niaz, A., Saeed, M., & Hyder, H. (2020). Comparison of Bipolar Diathermy Tonsillectomy Versus Cold Steel Dissection Tonsillectomy. Annals of Punjab Medical College, 14(2), 102-105. DOI: https://doi.org/10.29054/apmc/2020.802

10. Huang, L., Stepan, L., Woods, C. M., Huynh, J., & Ooi, E. H. (2018). Surgery and Medicine. 3. DOI: https://doi.org/10.29011/2575-9760.C1.006

11. Krishnan G, Stepan L, Du C, Padhye V, Bassiouni A, Dharmawardana N, Ooi EH, Krishnan S. Tonsillectomy using the BiZact: A pilot study in 186 children and adults. Clinical Otolaryngology. 2019. 44(3):392-396. DOI: 10.1111/coa.13273. Epub 2019 Feb 4. PMID: 30576062.

12. Leinbach RF, Markwell SJ, Colliver JA, Lin SY. Hot versus cold tonsillectomy: a systematic review of the literature. Otolaryngol Head Neck Surgery. 2003 Oct;129(4):360-4. DOI: 10.1016/s0194-5998(03)00729-0. PMID: 14574289.

13. Pang YT, el-Hakim H, Rothera MP. Bipolar diathermy tonsillectomy. Clinical Otolaryngology Allied Science. 1994 Aug;19(4):355-7. DOI: 10.1111/j.1365-2273.1994.tb01247.x. PMID: 7994897.