



ORIGINAL ARTICLE

Ligasure versus harmonic scalpel tonsillectomy.

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ABSTRACT... Objective: To determine whether harmonic scalpel has any advantage over Ligasure tonsillectomy or not in terms of blood loss, duration of surgery, pain scores and slough separation time. **Study Design:** Double Blind Cross Sectional study. **Setting:** Faisalabad Medical University and Affiliated Institutions. **Period:** January to June 2022. **Material & Methods:** Seventy patients in total were selected and divided by Random sampling into two groups to be operated either with Ligasure or Harmonic Scalpel. The difference between the two groups was assessed in terms of pain scores, slough separation time, duration of surgery and blood loss between the two groups. **Results:** Patients results showed statistical significant difference in the two groups in terms of slough separation time and pain scores but there was no significant difference in terms of blood loss and duration of surgery. **Conclusion:** Harmonic scalpel does have an advantage over Ligasure tonsillectomy as far as early healing is concerned and thus certainly helps in reducing the morbidity of the patients.

Key words: Harmonic Scalpel, Ligasure, Pain Scores, Slough Separation Time, Tonsillectomy.

INTRODUCTION

Not only conventional tonsillectomy but also diathermy tonsillectomies are fast losing their popularity among ENT surgeons all over the world. Despite the fact that number of tonsillectomies are declining¹ in the first world it is still one of the most commonly performed surgical procedure in the third world countries including Pakistan. Evolution of tonsillectomy has seen many modifications and advancements especially during 20th century. It has come a long way from crude dissection methods to recently introduced Harmonic and Enseal technology. Ligasure consoles are easily and commonly available and are being used by various surgical specialties in almost all teaching hospitals of Pakistan for the last many years. In big teaching institutions of Pakistan Harmonic scalpel is fast gaining popularity among surgeons of all specialties because of its ultrasonic nature and considerably less effect on surrounding tissues.² It is already in use for bariatric, colorectal and gynecologic procedures. It cuts and

coagulates simultaneously at lower temperature than diathermy and lasers. There are number of studies on cold steel dissection and diathermy tonsillectomies in Pakistan³⁻⁵ and Internationally.^{6,7}

Harmonic scalpel tonsillectomies are also being performed routinely in tertiary care hospitals.^{8,9} Although a number of studies are available on Ligasure vessel sealing system and other techniques of tonsillectomies but no comparative study has ever been conducted between Ligasure and Harmonic tonsillectomy to date in any hospital of Pakistan as per records obtained from multiple search engines including pubmed, pakmedinet and Cochrane database. It may either be due to the cost of equipment or lack of surgical expertise. Due to fast changing disease scenario in recent times considerable resources are now being allocated for health sector. I am undertaking this study to prove its effectiveness in reducing the morbidity of the patients. Aim/objective/purpose: To determine whether

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Ligasure vessel sealing system and Harmonic scalpel technology has any advantage over one another or not. Rationale: To see whether the use of Harmonic scalpel can reduce the morbidity of the patients or not.

MATERIAL & METHODS

A cross sectional study of six months duration was conducted from January to June 2022 at Department of Otorhinolaryngology, Faisalabad Medical University, Faisalabad and its affiliated hospitals. Seventy patients belonging mostly to lower class and lower middle class between 7-15 years of age both males and females having history of five episodes of acute tonsillitis per year for at least last one year, three episodes of acute tonsillitis with acute otitis media or mesenteric adenitis or loss of seven school days per month for the last six months were included in the study.

All the patients were interviewed in detail and complete ENT examination was done. Exclusion criteria was Peritonsillar abscess, blood dyscrasias, concomitant adenoidal hypertrophy, DNS or nasal poly, known case of allergies, asthma, obstructive sleep apnea, obesity and anemia. The intervention technique and study variables were such that no special informed consent was needed albeit explanation of operative technique in each case. Seventy patients were randomized into two groups depending upon the day of surgery whether operated on Tuesday, Wednesday or Friday, Saturday. Both surgeon and anesthetist were unaware of the study design/existence. All the surgeries were done by consultant surgeon. Duration of surgery was calculated from the time when anterior pillar parallel incision is given to the time of removal of mouth gag. Time was rounded to nearest whole number depending upon whether it is above or below 30 seconds. Blood loss was calculated by measuring the fluid in the suction bottle. Pain scores were calculated on 5th and 10th day postoperatively on Numeric pain scale of 0-10 where 0 means no pain, 1-3 mild pain, 4-6 moderate pain and 7-10 represents severe pain.

0-10 NUMERIC PAIN RATING SCALE



Slough separation time (recovery time, healing ranging to no slough) was calculated by serial direct examination of the patient's throat in ENT OPD till the time complete epithelialization of the tonsillar fossae happen as well as photographic evidence sent daily by the patient and counting start by taking the 1st postoperative day as day one. All the patients were given amoxicillin and paracetamol for 14 days after tonsillectomy. The article was duly reviewed and approved by Ethical Review Committee of PHRC (Pakistan Health Research Council) (48.ERC/FMU/2021-22/265).

Operative Procedure

Anterior pillar parallel incision from superior to inferior pole with either Ligasure or harmonic scalpel. Dissection either with Ligasure or harmonic scalpel was carried out in loose areolar tissue plane up to tonsillogingual sulcus.

Statistical Analysis

Data analysis was performed using a commercial statistics program (Statistical Package for Social Sciences) computer program (SPSS, Version 26, Chicago IL). t-test was used for quantitative variables and chi-square was used for qualitative variables.

RESULTS

Seventy patients fulfilling the above criteria were operated for chronic tonsillitis. In group I 37.14 % were females and 62.85 % males while in group II 42.85 % were females and 57.1 % males. All of them were between 7- 15 years of age. Mean age of presentation was 9.4 years in Group I and 10.2 years in Group II. All of them belonged to lower and lower middle class socioeconomic status. 77.14 % belonged to lower class and 22.85 % belonged to lower middle class. In Group I 48.57 % had history of recurrent fever, 71.42 % had recurrent sore throats, 14.28 % had odynophagia, 17.14 % had otitis media and 8.57

% had mesenteric adenitis. In Group II 60 % had history of recurrent fever, 60 % had recurrent sore throats, 28.57 % had odynophagia, 17.14 % had otitis media and 11.42 % had mesenteric adenitis.

Mean duration of presenting complaints was 15.02 months in Group I and 14.42 months in Group II. On full ENT examination 68.57 % and 65.71 % had hypertrophic tonsils and 31.42 % and 34.28 % had atrophic tonsils in Group I and II respectively. Patients were randomized into two groups depending upon on the day of surgery whether operated on Tuesday, Wednesday or Friday, Saturday. Both surgeon and anesthetist were unaware of the study design/existence. In Group I Ligasure was used for tonsillectomy and in Group II Harmonic scalpel was used. Results for blood loss and duration of surgery were recorded on the day of surgery.

Mean blood loss in Group I was 0.17 ml and in Group II it was 0.22 ml. Mean time of surgery in Group I was 4.02 minutes and 3.77 minutes in Group II. Slough separation time in Group I was 16.08 days and in Group II was 12.68 days. Mean Pain Scores were 5.22 cm and 5.57 cm in Group I on day 5 and 10 respectively and were 3.74 cm and 3.11 cm in Group II on day 5 and 10 respectively. A significant difference at $P < 0.05$ and C.I 95% was thus observed between the two groups in terms of slough separation time ($P < .00001$) and pain scores on day 5 ($P < 0.00116$) and 10 ($P < 0.00001$) but the difference was not significant at $P < 0.05$ in terms of blood loss (P is 0.53488) and duration of surgery (P is .20294).

DISCUSSION

Although the use of Ligasure and Harmonic scalpel is well established in general, bariatric and gynecological procedures but recently its role in ENT surgery is fast gaining popularity. Most common complaints encountered in post tonsillectomy days are usually pain, bleeding and wound healing issues. Various new tonsillectomy techniques are being employed to minimize these problems. To improve surgical outcomes with efficient dissection, ligation and hemostasis has resulted in development of innovative surgical gadgets recently. Ligasure, Harmonic scalpel and

Enseal systems are few examples.

In this study we have compared Harmonic scalpel and Ligasure in tonsillectomy. Rationale behind using Ligasure and Harmonic scalpel for tonsillectomy is their easy availability in our hospital. Despite easy availability their use in ENT is not yet widely accepted and done. Although a number of studies have already been done on cold steel dissection method, diathermy, Ligasure, coblation and harmonic scalpel tonsillectomy but a very few comparative studies are available in literature about Ligasure versus harmonic scalpel tonsillectomy.

Harmonic scalpel cuts and coagulates simultaneously. Ultrasonic energy is converted to mechanical movement of 55.5 kHz frequency (vibration of 55500 per second) at the active blade. The pressure by the blade collapses the blood vessels and the vibrating mechanically energy then forms a sticky coagulam that results in hemostatic seal. The HS controls bleeding by coaptive coagulation at low temperatures ranging from 50-100° C.¹⁰ It has built in feedback control. HS can safely dissect and coagulate areteries of 2 mm and veins of 3 mm diameter.^{11,12}

Ligasure is a bipolar vascular sealing system with integrated active feedback control. Tissue grasping senses density that results in optimal delivery of electrical energy. This energy denatures collagen and elastin within vessel wall and surrounding connective tissue thus resulting in hemostatic seal. LVSS has approval from US Food and Drug Administration for sealing vessels up to 7 mm in diameter.^{13,14} We used LS1200 Ligasure precise handpiece. It is a 16.5 cm long 15° jaw angle instrument. Its electrode has a length of 20 mm and the seal width is 1-3 mm.

Both Ligasure and Harmonic scalpel developer claim precise dissection, excellent hemostasis and less lateral damage as their attributes. The variables used in this study are so selected that careful comparative assessment of these attributes can be done not only subjectively but also objectively and as such accurate effectiveness of the two techniques can be measured.

LS1200 Ligasure precise handpiece 16.5 cm long 15° jaw angle instrument was used in Group I for easy maneuverability and access. In Group II Harmonic scalpel (gun type) having 14 cm length, 110 grams weight and a rotation of 360° was used. To avoid selection bias patients were randomized into two groups on the basis of day of surgery whether operated on Tuesday, Wednesday or Friday, Saturday. To avoid observer bias both surgeon and anesthetist were not aware of the study existence. Our study showed no significant difference at $P < 0.05$ in terms of blood loss (P is 0.53488) and duration of surgery (P is .20294). This finding is totally in agreement with a previous finding¹⁵ in terms of operation time but as far as blood loss is concerned results are different. Vassilios A Lachanas et al¹⁵ reported significant less blood loss in case of Ligasure technique as compared to Harmonic scalpel. Not even a single patient from two groups suffered more than 1ml blood loss in our study. Willging and Wiatrak² reported a mean operative time of 8.42 minutes with Harmonic scalpel which is grossly different from our finding that is 3.77 minutes. Mean operative time in a study by Vassilios A Lachanas et al¹⁶ was 16 minutes with ligasure vessel sealing system. This also differs markedly from our finding that is 4.02 minutes. As far as postoperative pain is concerned results are similar to Vassilios A Lachanas et al. However, pain scores are calculated on different time intervals in their study than ours. Moreover pain scores in both the groups were not statistically significant when intra group analysis of day 5 and day 10 pain scores was done.

Different Visual analogue scales and methods have been used in literature¹⁷⁻²⁰ to evaluate and measure exact time of separation of slough (tonsillar fossa wound healing). We have used a modification and a combination^{17,19} of these visual analogue scales. It was calculated by serial direct clinical examination of the patient's throat in ENT OPD till the time complete epithelialization of the tonsillar fossae happen as well as digital photographic evidence sent daily by the patient and counting start by taking the 1st postoperative day as day one. Although a number of comparative

studies of different methods of tonsillectomy are present in literature but one striking finding was that there were very few comparative studies of harmonic scalpel and Ligasure tonsillectomy and although harmonic scalpel showed²¹ promising results in terms of early healing of tonsillar fossae but its comparison with Ligasure has never been studied in terms of slough separation time.

CONCLUSION

We consider HS tonsillectomy much safer and better than diathermy tonsillectomy. Our study showed a significant difference in postoperative morbidity that is slough separation time and pain scores. Intraoperative measuring variables, operation time and blood loss, however showed no difference. In both techniques disposable hand pieces ensures excellent sterilization. A lot more comparative studies of these two techniques with much bigger sample size are needed to come to a final conclusion. Post tonsillectomy wound healing requires more research. Moreover, further comparative study of Harmonic scalpel tonsillectomy with other modern gadgets like Enseal system must be pursued to seek ways to reduce post-operative morbidity in tonsillectomy.






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2	M. Asfand Rafiq Gill	Drafting, Proof reading.	
3	Shaukat Javed	Medical fitness of patients.	
4	Asma Hussain	Literature search.	
5	Muhammad Khalil	Literature search.	
6	Muhammad Shoaib Farooq ⁶	Literature search.	