

Tonsillectomy Performed by Ultrasonic Harmonic Scalpel is Associated With Lower Postoperative Pain as Compared With Conventional Blunt Dissection Method

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ABSTRACT

Aims: To compare the mean intensity of post-operative pain in Harmonic scalpel tonsillectomy and conventional blunt dissection method in pediatric age group. **Patients and Methods:** It was randomized control trial with non-probability, consecutive sampling done in the ENT Department, Shaikh Zayed Hospital, Lahore. The study was conducted. from 01-03-2012 to 31-08-2013. **Results:** In 81 out of 162 patients, tonsillectomy was performed by Harmonic scalpel and they were labeled as Group-A. While in remaining 81 patients, labeled as Group-B, tonsillectomy was performed by conventional blunt dissection method. The post operative pain was significantly less in Group-A on day 1, 2, 3 & 5 with P-value <0.001. While on day seven although the pain is less in Group-A but it is not statistically significant. **Conclusions:** Tonsillectomy performed by ultrasonic harmonic scalpel is associated with lower postoperative pain as compared with conventional blunt dissection method. Thus, we believe that the use of this new technique for tonsillectomy may result in additional benefit to the patients.

Key Words: Palatine tonsil, Tonsillectomy, Postoperative pain, harmonic scalpel.

INTRODUCTION

Palatine tonsils are secondary lymphoid organs located at the junction of oral cavity with the oropharynx.¹ Most widely accepted indications include; recurrent tonsillitis, obstructive sleep apnea; peritonsillar abscess; malignancy or suspected malignancy and tonsillitis that has caused febrile seizures.²⁻⁶ Tonsillectomy is a surgical procedure that removes the tonsil including its capsule.⁷ Until the late 1960s; Surgeons used to perform tonsillectomies by conventional dissection method.² Since then, several techniques for tonsillectomy have been described including laser, Monopolar Radiofrequency ablation, Microdebrider, Liga-sure vessel sealing system, Bipolar

Radiofrequency ablation (Coblation) and ultrasonic harmonic scalpel dissection.^{7,8} Despite the advances in technologies two areas of concern-postoperative hemorrhage and postoperative pain-remain a great challenge for the surgeon.² So far no definite consensus has been reached regarding the optimal technique with the lowest morbidity rates.¹

Certainly otolaryngologists would like to investigate the feasibility of any new instrumentation that would decrease the morbidity of tonsillectomy both in adults as well as pediatric age group. Only a few international studies have been done comparing these two techniques with each other.⁸ Local study is also available comparing these two techniques in adults.² In pediatric age group no local study, comparing the harmonic

scalpel tonsillectomy with conventional blunt dissection tonsillectomy has been found in the literature.

The Ultrasonic Harmonic Scalpel (Ethicon Endo-Surgery Inc, Cincinnati, Ohio), has been used in a variety of surgical procedures primarily, intra-abdominal, intra-thoracic and Gynecologic².

Harmonic scalpel uses ultrasonic energy to vibrate blade at 55 kHz, providing both cutting and coagulation of the tissues simultaneously.⁸ This vibration transfers energy to the tissue and causes superficial denaturation and coagulation of protein by heating the tissue. Temperature of the surrounding tissue reaches to a maximum of 80°C.³ The manufacturer claims precise cutting and minimal thermal damage with this procedure.⁸

Harmonic Scalpel is also being used in otorhinolaryngology for performing tonsillectomy for about last one decade.^{2,8} Various studies have been conducted to compare harmonic scalpel tonsillectomy with the conventional methods and these studies show variable results.⁹⁻¹³

In 2007, Lachanas et al compared harmonic scalpel tonsillectomy with conventional dissection (cold knife dissection) and liga-sure vessel sealing method. This study shows that mean intensity of post operative pain was less in harmonic scalpel group as compared with two other groups in which tonsillectomies were performed by conventional dissection (cold knife dissection) and liga-sure vessel sealing method.⁹ In this study mean pain score in patients with harmonic scalpel tonsillectomy was 3.64 with a standard deviation of 1.32, on the other hand patients who underwent conventional dissection (cold knife) showed mean pain score of 6.03 with standard deviation of 0.88.⁹

Yet in another study, carried out by Oko MO et al,¹⁰ pain was significantly greater in ultrasonic group as compared with conventional blunt dissection method.¹⁰

The Rationale of conducting this study is to practically establish whether or not this new technique of tonsillectomy has any added benefit in decreasing the intensity of postoperative pain as compared with conventional blunt dissection method. No local study has been conducted to compare these two techniques with each other in pediatric age group.

MATERIALS AND METHODS

This study was carried out at the Department of ENT Shaikh Zayed Hospital, Lahore. The duration of the study was six months *i.e.* from 01-03-2013 to 31-08-2013. Sample size of 162 cases (81 in each Group) was calculated with 95% confidence level, 80% Power of test and taking expected mean \pm Standard Deviation of mean pain score in both groups (*i.e.* 1.7111 with standard deviation of 0.75 in harmonic scalpel and 1.3333 with standard deviation of 0.75 in conventional blunt dissection group). It was calculated by using software Open EPI Version 2.3. 162 cases were enrolled by Non-Probability, Consecutive Sampling and was a Randomized control trial.

Patients between 5-13 years of age of both genders with history of Recurrent Episodes of Tonsillitis at least for the last one year, and on examination having bilateral enlarged tonsils And having no history of fever or sore throat in the last 4 weeks were included in this study.

Those patients whom parents or guardians were unable to give consent, any patient who had difficulty in communicating his/her pain levels, patients with history of bleeding disorders or showing INR of 1.5 or more and patients who had enlarged adenoids and required adeno-tonsillectomy were excluded from this study.

Data collection and procedure

Study was carried out in 162 patients. They were registered from Indoor. Approval of this study has was taken from hospital regarding ethical issues. Fitness for General anesthesia was obtained from anesthesia department. The parents/ guardians of the children (patients) were explained about the purpose, procedure, risks and the benefits of surgery and informed written consent was taken for the study from parents/guardians. They were also explained that all the information taken would be kept confidential.

The patients were divided into two groups. *i.e.* Group-A & Group-B. There were 81 patients in each group. These groups were randomized by using random numbers table. In Group-A tonsillectomy was performed with Harmonic Scalpel, while in Group B, Tonsillectomy was performed by

conventional Blunt Dissection method.

Outcome variables in this study were Intensity of Post-operative pain, age and gender.

The harmonic scalpel was used by setting at power of 2. Conventional blunt dissection tonsillectomy was done by using sharp and blunt dissection by using knife and tonsillar dissector. Hemostasis was secured by silk ligation and bipolar electrocautery (set at 15 watts). All of these tonsillectomies were done by consultants to avoid the expertise related bias. Post operatively injection Diclofenac Sodium 3mg/kg/day was given intramuscularly on the day of surgery for pain control. Then from first post-operative day onward syrup Ibuprofen (5mg/kg / 6 hourly) was given for pain control. These methods were then compared by measuring mean intensity of post-operative pain. Intensity of pain was recorded by Faces pain scale-Revised on post-operative day 1, 2, 3, 5, 7 and overall average pain score was calculated for each patient. All outcome variables, including intensity of post-operative pain, were recorded on a specially designed Performa.

Data analysis

The collected data was analyzed statistically by using SPSS version 10. Quantitative variables like post-operative pain and age were presented in form of mean ± S.D.

Qualitative variables like gender were presented in form of frequency and percentage. Stratification with respect to age and gender was done. Post-stratification T-test was used as test of significance. P-value ≤ 0.05 was taken as significant.

RESULTS

Total one hundred & sixty two (162) patients were included in the study, 81 patients underwent tonsillectomy by harmonic scalpel and in remaining 81 patients tonsillectomy was performed by conventional blunt dissection method.

The age range of patients was 5-13 years. The mean & standard deviation were 8.22±2.67 in group A and 8.52±2.33 in group B. A major proportion of the patients were between 5-9 years of age. There were 55 (68%) of patients between 5-9 years of age in group A and 54 patients (67%) in group B. While,

26 (32%) patients in group A between 10-13 years of age and 27 (33%) patients in group B between 10-13 year of age (Table 1)

Out of total 162 patients, 40 (49%) in group A and 39 (48%) patients in group B were male. While, 41 (51%) patients in group A and 42 (52%) patients in group B were females. Male to female ratio were 1:1.02 and 1:1.07 in Group A & Group B respectively (Table 2).

Table 1: Age distribution of patients (n=162)

Age (Years)	Group A		Group B	
	Harmonic scalpel (n=81)		Blunt dissection (n=81)	
	No.	%	No.	%
5 – 9	55	68.0	54	67.0
10 – 13	26	32.0	27	33.0
Mean±SD	8.22±2.67		8.52±2.33	

Table 2: Sex distribution of patients (n=162)

Sex	Group A		Group B	
	Harmonic scalpel (n=81)		Blunt dissection (n=81)	
	No.	%	No.	%
Male	40	49.0	39	48.0
Female	41	51.0	42	52.0
M:F ratio	1:1.02		1:1.07	

Table 3 shows the comparison of mean postoperative pain scores in both groups. It shows that mean postoperative pain in Group A is significantly less than group B on day 1, 2, 3 & 5. While on day 7 although the pain is less in Group A but it's not statistically significant. The overall postoperative pain score in Group A is 3.33 with standard deviation (SD) of ±0.64, while in Group B, it is 3.84 with standard deviation of ±0.53, showing that mean postoperative pain was less in group A. It is also statistically significant with P-value of <0.001 (Table 3)

Age stratification of pain in both groups was done. The results show that mean pain score of patients between 5-9 years is 3.34±0.64 in Group a, while 3.80±0.52 in Group B. Similarly mean pain score of patients between the age of 10-13 years, is 3.30±0.65 in Group A, while it is 3.94±0.54 in Group B This shows that in Harmonic scalpel

group, mean post operative pain is slightly more in younger children. On the other hand, in blunt dissection group the mean postoperative pain is relatively less in younger children (Table 4).

Table 3: Comparison of mean pain score in both groups during the postoperative period.

Days	Group A (n=81)	Group B (n=81)	P value
1	5.81±1.14	6.63±0.88	<0.001
2	4.81±0.88	5.27±0.72	<0.001
3	3.04±0.90	3.84±0.91	<0.001
5	2.01±0.71	2.41±0.71	<0.001
7	1.00±0.70	1.07±0.77	0.525
Overall M±SD	3.33±0.64	3.84±0.53	<0.001

Table 4: Age stratification of pain in both groups

Days	Group A (Years)		Group B (Years)	
	5-9	10-13	5-9	10-13
1	5.89±1.11	5.65±1.19	6.65±0.89	6.59±0.88
2	4.85±0.87	4.73±0.91	5.24±0.67	5.33±0.83
3	3.02±0.93	3.08±0.84	3.76±0.84	4.00±1.03
5	2.00±0.72	2.04±0.72	2.33±0.67	2.56±0.57
7	0.98±0.70	1.04±0.72	1.00±0.80	1.22±0.69
Overall (M±SD)	3.34±0.64	3.30±0.65	3.80±0.52	3.94±0.54

Table 5 shows Gender stratification of pain in both groups. It shows that mean pain score in male patients 3.42±0.62 in Group A, while it is 4.07±0.34 in Group B. Similarly, mean pain score in female patients 3.25±0.65 in Group A, while it is 3.63±0.58 in Group B (Table 5). This shows that mean postoperative pain score in male patients is slightly more than females in both groups.

Table 5: Gender stratification of pain in both groups

Sex	Group A		Group B	
	Male	Female	Male	Female
1	5.95±1.30	5.68±0.96	6.79±0.73	6.48±0.99
2	5.12±0.88	4.51±0.77	5.54±0.68	5.02±0.68
3	2.88±1.06	3.20±0.67	4.15±0.74	3.55±0.96
5	2.02±0.57	2.00±0.83	2.69±0.46	2.14±0.68
7	1.15±0.70	0.85±0.69	1.18±0.60	0.98±0.89
Overall (M±SD)	3.42±0.62	3.25±0.65	4.07±0.34	3.63±0.58

DISCUSSION

Otolaryngologists utilize every effort to make benefit from any instrumentation that would decrease the morbidity of tonsillectomy and increase its safety. The ideal tonsillectomy should be fast, painless, bloodless and associated with rapid and smooth recovery from the surgery.

The Harmonic Scalpel (HS) uses ultrasonic technology to cut and coagulate tissues with minimal tissue damage. The device has two cutting mechanisms. The most important is a sharp blade vibrating at a frequency of 55.5 kHz. The other results from the rapid forward-and-backward motion of the cutting tip in contact with the tissue, which increases and decreases internal tissue pressures, thereby leading to cavitation fragmentation and separation of tissue planes. Coagulation occurs when mechanical energy is transferred to the tissues, breaking tertiary hydrogen bonds to denature protein, and through generation of heat from internal tissue friction caused by the high-frequency vibration. With electrocautery or lasers, cutting and coagulation take place when the temperature of cells is sufficiently high for gas pressure to explode them (typically, 150-400°C). With the HS, the temperature caused by the friction is much lower (typically, 50-100°C). The Harmonic Scalpel has been used for more than 10 years in procedures other than tonsillectomy. The HS has been used clinically for tonsillectomy in adults and children, with favorable results regarding hemostasis, operative time, and postoperative pain.¹⁴⁻¹⁶

Our study has shown that ultrasonic Harmonic scalpel tonsillectomy, when compared with conventional blunt dissection tonsillectomy, causes statistically significant less post operative pain on postoperative days 1, 2, 3 and 5. The pain on postoperative day 7 was also less in Harmonic scalpel group but the difference was not statistically significant. Similarly the overall mean postoperative pain was also less in Harmonic scalpel group and it is statistically significant as well. The technique of blunt dissection tonsillectomy with bipolar diathermy for hemostasis was used as our control group as this is the routine method of tonsillectomy in our department. This method is a well-established technique and has been shown to be less painful

than monopolar electrocautery technique.¹⁷

When we search the literature, we find that eleven studies comparing blunt dissection tonsillectomy with ultrasonic scalpel tonsillectomy examining postoperative pain, have recently been published.^{9-13,18}

Four of these trials did not demonstrate any significant difference in postoperative pain when comparing these 2 techniques.¹³ Five out of these eleven studies have demonstrated that there is a significant difference in postoperative pain. These studies have shown that the post operative pain is significantly less in patients who have underwent tonsillectomy by the ultrasonic scalpel, as compared with conventional blunt dissection tonsillectomy.¹⁶

These studies have shown that the postoperative pain is significantly less in the patients who have underwent tonsillectomy with conventional blunt dissection method, as compared with the ultrasonic harmonic slapel.¹⁰⁻¹²

CONCLUSION

It is concluded from this study that tonsillectomies performed by ultrasonic harmonic scalpel are associated with lower postoperative pain as compared with conventional blunt dissection method. Thus, we believe that the use of this new technique for tonsillectomy may result in additional benefit to the patients.

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