

Original Research Article

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Harmonic scalpel thyroidectomy versus conventional haemostasis thyroidectomy

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ABSTRACT

Background: As there is paucity of data on harmonic scalpel thyroidectomy from Jammu and Kashmir belt. So, we conducted this study to bridge this gap and also to create awareness about the use of harmonic scalpel. Thyroidectomy has become one of the most common and frequent surgery. Hemostasis in thyroid surgery is of utmost importance for a successful surgery. Our aim was to compare operative factors, postoperative outcomes of thyroidectomy using the Harmonic Scalpel (HS) and Conventional Haemostasis (CH).

Methods: In this randomized control trial study, 100 patients who underwent thyroidectomy were enrolled and randomly divided in two groups- HS group and CH group. The inclusion criteria were age>18years, acceptance to participate in the study (signed informed consent form) and scheduled total thyroidectomy. The groups were compared with regards to age, gender, operative time, post-operative drainage volume, postoperative pain, and hospital stay.

Results: The mean age in years was 39.8 years for HS group and 43.8 years for CH group with female preponderance. There was a significant difference with regards to operative time, post-operative drainage volume, postoperative pain, and hospital stay ($p<0.001$). Harmonic Scalpel shortens the operative time. And there was less post-operative drainage volume and postoperative pain in HS group. Hospital stay was also less as compared to CH group.

Conclusions: HS is superior than CH thyroidectomy and is considered as a safe and better tool in thyroidectomy.

Keywords: Conventional, Harmonic, Thyroidectomy

INTRODUCTION

Thyroidectomy has become one of the most common and frequent surgery and bilateral total thyroidectomy is performed in majority of cases. Between 1873 and 1883, Kocher and Billroth, pioneer of thyroidectomy, developed standardized thyroid surgery.¹ Basic surgical instruments are not substantially altered. The main innovations are new methods of coagulation and vascular

incision. A technical advance in the early 1990s was the development of an ultrasound-activated device that includes scissors and a scalpel, allowing the surgeon to simultaneously cut tissue and control blood loss.² The Harmonic Scalpel (HS) uses high-frequency mechanical energy to simultaneously cut and coagulate tissues and blood vessels without the need to tie knots.³ During thyroidectomy, bleeding can obscure the surgical site, making it difficult to dissect the recurrent laryngeal nerve

and parathyroid glands. Effective vascular hemostasis can be achieved using traditional clamping and tightening techniques. Newer techniques of vessel haemostasis via coagulation are thought to be more rapid while achieving the same effectiveness.⁴ Apart from thyroid surgery, the use of HS reduce surgery time, complications and bleeding in abdominal, thoracic and parotid surgery.⁵ This study was designed to evaluate the efficacy and safety of HS use compared with conventional haemostasis (CH) in thyroidectomy. The objectives of this study were to assess the operative time, postoperative pain, post operative drainage volume in thyroid surgery and hospital stay in HS and CH thyroidectomy.

METHODS

This randomized control trial study was conducted between October 2018 and October 2020 in Department of Otorhinolaryngology. In this time period, 108 patients came for thyroidectomy. Out of which 100 patients willingly consented for their participation in the study. So, excluding the 8 patients, our total sample size was 100 patients. They were enrolled in the study and thyroidectomy was performed by the same team of Otorhinolaryngologist. Patients were randomly assigned to either the HS thyroidectomy group or the CH thyroidectomy group. The protocol of this study have been submitted and approved by the ethical committee of our Institution.

All patients were blinded to the surgical technique used and signed an informed consent before enrollment in the study. The inclusion criteria were age >18 years, acceptance to participate in the study (signed informed consent form) and scheduled total thyroidectomy. The exclusion criteria were age <18 years, coagulation disorders, previous neck surgery, history of neck irradiation, total thyroidectomy with need of lymph node block dissection, concomitant parathyroid disorders, pregnancy, cervicomedastinal goiters.

A specific questionnaire regarding demographic and preoperative clinical characteristics was assessed before surgery. Patients were randomly assigned to HS group or CH group. All the patients were blinded about the technique used for hemostasis. The medical staff was responsible for the collection of the clinical data, including preoperative diagnosis, operative time (from skin incision to skin closure), operative procedure,

postoperative complications and hospital stay. Laryngoscopy to check vocal cord motility was performed preoperatively only in symptomatic patients and postoperatively in all the patients.

Thyroidectomy was performed under general anesthesia and with endotracheal intubation in all cases. A complete preoperative assessment was obtained for all patients. All patients were positioned and draped in the conventional manner. A 4 to 6 cm low collar incision was made over the level of the thyroid isthmus. Subplatysmal flaps were developed and the strap muscles were separated in the midline and laterally reflected. The inferior, middle, and superior thyroid vessels were then divided either with the help of Harmonic Scalpel or with conventional clamp and tie technique. The thyroid lobe was then medially rotated, and the vessels in the ligament of Berry, with recurrent laryngeal nerve under direct vision, were clamped and tied in both groups. The same steps were repeated for removal of the contralateral lobe. Finally, the wound was irrigated and closed using interrupted 3-0 polyglaclin sutures to approximate the strap muscles and the platysmal layer. Lastly, the skin was closed.

Outcomes of the study included operative time, post operative drainage volume during the first 24 hours after surgery, postoperative pain, hospital stay. Suction drainage was used to evaluate the overall amount of blood loss after the procedure. Patients were given acetaminophen, every 8 hourly, for the first 24 hours after surgery. Pain assessment was analyzed via visual analogic scale (VAS). The VAS consisted of a printed 10 cm horizontal line anchored by the descriptors "no pain" (minimum, on the left end of the scale) and "worst pain imaginable" (maximum, on the right end). Patients used the VAS to assess their level of pain when they started deglutition and early feeding 24 and 48 hours after the operation. Grading of pain was done at 24 and 48 hours after surgery. Data were analyzed with the use of the SPSS software with the help of Student's t-test. The results were expressed as mean \pm SD. The level of statistical significance was set at a P value of less than 0.05.

RESULTS

In demographic characteristics of the patients, we found that mean age in years was 39.8 years for HS group and 43.8 years for CH group.

Table 1: Comparison of HS and CH group.

Variables	HS group (n=50)	CH group (n=50)	P-value
Age in years	39.8	43.8	
Gender (Male/Female)	20/30	23/27	
Operative time in min (mean\pmSD) (range)	46.9 \pm 9.3	66.5 \pm 8.5	<0.001
Postoperative drainage at 24 hour in ml (mean\pmSD)	27.4 \pm 2.8	58.9 \pm 5.2	<0.001
Hospital stay in days (mean\pmSD)	2.0 \pm 0.4	4.7 \pm 1.9	>0.001
Postop pain VAS at 24 hour	2.09 \pm 0.07	4.92 \pm 1.03	<0.001
Postop pain VAS at 48 hour	1.09 \pm 0.55	2.99 \pm 1.02	<0.001

The range of age in HS group is (25-69) year and in CH group is (27-81) year. Male to female ratio in HS group is 20/30 and in CH group is 23/27.

The operative time was significantly less in the HS group (46.9 ± 9.3 minutes) compared with the CH group (66.5 ± 8.5 minutes; $p < 0.001$). The post-operative drainage was lower in HS (27.4 ± 2.8 ml) than in CH (58.9 ± 5.2) ($p < 0.001$). Hospital stay significantly less in HS group (2.0 ± 0.4 days) compared to CH group (4.7 ± 1.9 days). According to the VAS scores, patients of the HS group experienced significantly less postoperative pain compared with patients of the CH group. The difference in VAS scores between the HS and CH groups were statistically significant at 24 and 48 hours ($p < 0.001$) (Table 1).

DISCUSSION

The thyroid gland has a branched vascular network, therefore it is very important to achieve good hemostasis to avoid postoperative bleeding, which is potential cause of asphyxia and death of the patient.⁶ Total thyroidectomy requires thorough dissection, safe anatomical exposure and effective hemostasis. It is a treatment choice for many thyroid diseases. This operation is performed often without mortality and low morbidity.

Total thyroidectomy requires extensive clamp-and-tie maneuvers for small vessels of the thyroid gland, the use of conventional technique takes time. Other common tools like diathermy are also available for thyroid surgery, but they are unsafe with total thyroidectomy due to the risk damage to adjacent structures from lateral thermal spread.

The harmonic scalpel is the first device specially designed for every procedure that requires careful dissection and effective hemostasis are paramount importance, especially in a narrow operating field as in thyroid surgery. Primary application for HS in otolaryngological literature is its use for tonsillectomy and thyroidectomy. It uses high frequency mechanical energy to cut and coagulate tissues at the same time. The HS denatures protein using ultrasonic vibration to transfer mechanical energy sufficient to break tertiary hydrogen bonds.⁷ Its specifications permit the safe ligation of vessels less than 3 mm in diameter. However, it can also be used for larger vessels such as the superior thyroid artery.⁸

Unlike variable results described with use of HS in tonsillectomy, literature is consistent on the benefits of a harmonic scalpel in the thyroid gland operation. During thyroidectomy, dissection, ligation, and separation from the main vessels of the thyroid gland take a long time. In our study, the operative time in HS group was 46.9 ± 9.3 minutes whereas in CH group it was 66.5 ± 8.5 minutes

which shows that HS thyroidectomy shortens the operative time. This was similar to Miccoli et al who observed that the mean operative time was significantly reduced in the HS total thyroidectomy (HS versus CH= 53.8 ± 16.3 versus 90.6 ± 22.1 min) and the study of Ortega et al in which the average operative time was significantly shorter in the HS group (44.9 ± 8.3 minutes) as compared with the CH group (69.5 ± 10.7 minutes).^{9,10} We also found that the amount of postoperative drainage in patients treated with HS was reduced as compared to CH group (27.4 ± 2.8 ml versus 58.9 ± 5.2 ml respectively). The less drainage volume also helps in preventing the postoperative surgical site infections. This finding was similar to Ferri et al who also observed that the total drainage fluid volume was lower in HS than in CH (37.4 ± 2.4 versus 56.1 ± 4.2 , respectively).¹¹

We assessed the postoperative pain also and found that at 24 and 48 hour, patients of the HS group experienced significantly less postoperative pain as compared with CH group. The VAS score at 24 hour for HS and CH group was 2.09 ± 0.07 and 4.92 ± 1.03 respectively and at 48 hours was 1.09 ± 0.55 and 2.99 ± 1.02 respectively. The difference in VAS scores between the HS and CH groups were statistically significant at 24 and 48 hours ($p < 0.001$). This finding was consistent with Ferri et al who also observed the similar finding in their study, VAS score at 24 hour was 3.89 ± 1.07 and 5.82 ± 1.43 respectively whereas VAS score at 48 hour was 1.99 ± 0.97 and 3.69 ± 1.36 respectively.¹¹ Less pain in HS group may be due to less tissue injury, with no neuromuscular stimulation. The post-operative hospital stay was also decreased in HS group (2.0 ± 0.4 days) as compared to CH group (4.7 ± 1.9 days). Duan et al also observed that mean post-operative hospital stay in HS group was significantly lower than CH group (2.6 ± 0.9 days versus 2.9 ± 1.0 days).¹² The benefits seen with the Harmonic Scalpel thyroidectomy were shorter operative time and hospital stay, in addition to less post operative drainage and post-operative pain.

Limitations

The cohort of our study was small, so there is a need of randomized trial of larger cohort. A drawback of HS is that it is expensive. However we have not analysed this in the present study. More detailed studies have to be planned in order to analyze the cost-effectiveness of HS.

CONCLUSION

As there is paucity of data on comparative study between harmonic and conventional thyroidectomy from Jammu and Kashmir belt. So, to bridge this gap we conducted the study and tried to bring awareness about harmonic scalpel thyroidectomy which all Otorhinolaryngologist should keep in mind. This study tells about the benefits offered by Harmonic Scalpel use in thyroidectomy. According to our results, the Harmonic Scalpel shortens the operative

time, post-operative drainage, hospital stay and post-operative pain. It is considered to be superior then CH thyroidectomy technique. Hence, HS thyroidectomy is supposed to be more reliable and safe instrument as compared to CH thyroidectomy.

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