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Original Research Article

Comparative study of sutureless thyroidectomy using harmonic scalpel versus vessel ligation thyroidectomy

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ABSTRACT

Background: Hemostasis is crucial for thyroidectomy surgery. Traditional methods used for hemostasis like suture ligation has a risk of knot slipping hence new methods of ligation became need of the hour. Harmonic scalpel is one such newer method of vessel ligation providing faster and precise ligation of vessels. The objective was to compare effectiveness of sutureless technique using harmonic scalpel in thyroid surgery with conventional suture ligation technique.
Methods: The 50 patients undergoing thyroid surgery were divided into two groups of 25 each. Group A underwent thyroid surgery using conventional suture ligation and group B underwent thyroid surgery using harmonic scalpel.
Results: Our results showed that in group B, none of the patients had change of voice and only 1 had transient hypocalcemia while 2 in group A had recurrent laryngeal paresis and 4 had transient hypocalcemia (not statistically significant). The average blood loss was less in group B as compared to group A (p=0.014), as was the post op drain collection 12.60 ml (p=0.034) as compared to 17.80 ml in group A, and the operative time 34.60 minutes (p=0.00) as compared to 45.44 minutes in group A. The overall cost was thus conspicuously reduced as compared to group A.
Conclusion: Sutureless thyroidectomy using harmonic scalpel is safe, fast and cost-effective technique to perform thyroidectomies.

Keywords: Hemostasis, Recurrent laryngeal nerve, Thyroidectomy, Sutureless thyroidectomy, Ultrasonic device

INTRODUCTION

In India, it is estimated that 54 million people are suffering from goiter.[1] The incidence is higher in the sub-Himalayan belt and therefore, thyroid surgery for multinodular goiter is inevitable. Post-op morbidity in thyroid surgery can lead to compromised quality of life as the complications range from hematoma, and wound infection to dysphonia and dysphagia due to recurrent and superior laryngeal nerve palsies respectively.[2] Therefore, achieving hemostasis is one of the key steps in thyroid surgery as it helps to provide a dry surgical field, saves time, and avoids post-operative complications. Hemostasis achieved by traditional methods such as tie and clamp, is time-consuming and has a risk of knot slipping. On the other hand, cautery has a risk of injuring surrounding structures due to thermal injury.[3-5]

As compared to other hemostatic devices harmonic scalpel has the least thermal spread and smoke production. The device uses ultrasound waves of high frequency (55 kHz) that can cut vessels of diameter up to 5 mm. The harmonic scalpel has two blades the active blade of the instrument vibrates longitudinally against an

inactive blade over an excursion of 50-100 micrometers.[6] Its main advantages are precise dissection; exceptional hemostasis and less lateral thermal spread. It mainly works by applying pressure and then sealing with a denatured protein coagulum while applying ultrasonic vibration to denature hydrogen bonds thus performing vessel coagulation due to tamponade and coaptation.[7]

In the present study, we aim to compare the effectiveness of the sutureless technique using harmonic scalpel in thyroid surgery with conventional suture ligation.

METHODS

A prospective, randomized, comparative study was conducted in the department of otorhinolaryngology, Shri Mahant Indiresh hospital, Dehradun in which 50 patients who underwent thyroid surgery for various benign and malignant thyroid diseases and who fulfilled the various inclusion and exclusion criteria were included. This study was conducted from January 2020 to June 2021.

This study was permitted and approved by the institutional ethical committee. The patients were divided into two groups of 25 each randomly with the help of random number tables. Group A underwent thyroid surgery using conventional suture ligation and group B underwent thyroid surgery using harmonic scalpel.

The sample size was calculated as follows:

$n=(\sigma 1^2 + \sigma 2^2)\ (Z\alpha + Z\beta)^2/(\ m1\text{-}m2)^2$

Where,

Zα=Value of standard normal variate corresponding to α level of significance (1.96)

Zβ=The standard normal deviate for desired power (0.842)

m=Average

σ=Standard deviation

Assumptions

From the study conducted by Cannizzaro et al using operative time, mean group (m1)=79.6, mean group (m2)=110, standard deviation group (σ1)=21.88, standard deviation (σ2)=25.80. With the above assumptions the sample size for a 95% confidence level and 80% power works out of 22 in each group.[8] This number has been increased to 25 per group (a total of 50) to allow for a predicted dropout from treatment.

Inclusion criteria

All patients with benign or malignant thyroid disease undergoing thyroidectomy, euthyroid state, age <70 years and all patients who willingly agreed to take part in the study and for follow-up were included in study.

Exclusion criteria

Patients with age >70 years, recurrent goiter, previous neck irradiation, previous radio-iodine ablation and hypothyroidism or hyperthyroidism were excluded.

All the cases were subjected to a detailed clinical work-up. Relevant history and detailed examination were recorded in a proforma for this study (Figure 1). All the patients underwent routine blood tests along with chest X-ray, an X-ray neck lateral view, electrocardiography, thyroid function tests, ultrasonography neck, fine needle aspiration cytology of thyroid swelling, and Contrast-enhanced CT scan of the neck. Pre-operative vocal cord mobility was checked and documented. Analysis was done using SPSS version 24 and interpreted with the help of suitable statistical tests such as the student t test after tabulation of findings.

Figure 1 (a-c): Pre-operative frontal view of a patient depicting a thyroid swelling (bold white arrow), pre-operative lateral view of the patient and marking of Kocher's incision (white arrow).

Informed written consent was taken from patients undergoing thyroidectomy. Time was recorded at the start and end of surgery. Start time was taken as the time when skin incision was given and end time was taken when the patient was handed to the anesthetist. Hemithyroidectomy and total thyroidectomy were done as per the standard protocol except that in group A, the vessels and pedicles were ligated while in group B, they were cut and coagulated with harmonic scalpel (Figure 2). The power setting used in harmonic was kept at level 3 and the vessels were coagulated with an application time of 4 to 5 seconds. Central compartment neck dissection was done whenever necessary. After completion of surgery, the specimen was sent for histopathological examination and the thyroid bed was inspected for any bleeding. The anesthetist was requested to do a Valsalva maneuver and any bleeding point was again secured. Cavity was washed with betadine and saline. negative suction drain (Romovac™ FG14 vacuum drain) was inserted and secured. Incision was closed in layers.

Blood loss was documented in each surgery by counting the number of gauzes used as well as the amount collected in the suction machine. Postoperatively patient

was put on intravenous antibiotics and analgesics in both groups. Postoperative drain collection was documented in each case and the drain was emptied at 8 am daily. The drain was removed when the collection was <20 ml post-operative laryngoscopy was done on day 2 following surgery.

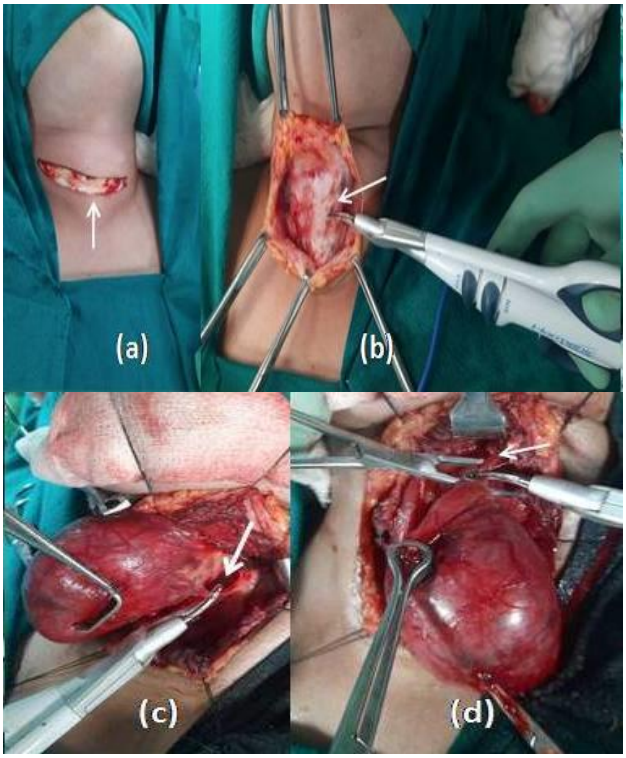

Figure 2 (a-d): Picture illustrating Kocher's incision (white arrow), simultaneous cutting and coagulation of anterior jugular vein using harmonic scalpel (white arrow), middle thyroid vein being cut and coagulated simultaneously using harmonic scalpel (white arrow) and picture exhibits superior pedicle being cut and coagulated using harmonic scalpel (white arrow).

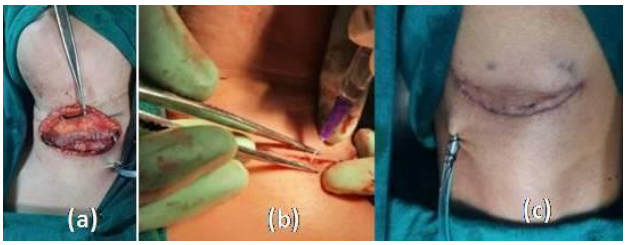

Figure 3 (a-c): Picture exhibits suturing of the wound in layers, skin closure using tissue glue and final sutureless skin closure of the wound.

Postoperative serum calcium levels were done after 48 hours of surgery in all cases of total thyroidectomy. In cases with hypocalcemia oral or injectable calcium supplements were started and daily monitoring of serum calcium levels was done. All the complications were looked for and meticulously documented. Hospital stay was documented from the day of admission to the day of discharge. The cost was calculated by adding the cost of surgery, anesthesia charges, suture charges, bed charges, nursing care charges, and charges for doctor visits.

Dressing was done every alternate day. Suture removal was done on day 7 in all cases where sutures were applied. Discharge was done following the type of thyroidectomy and post-operative serum calcium levels. Hemithyroidectomy patients of group A were discharged on 4th day following surgery whereas those in group B were discharged 48 hours following surgery after the first dressing change.

In cases requiring total thyroidectomy, in both the groups patients were discharged on the 6th day following surgery. In these cases, extra days of stay were to monitor serum calcium levels. Thyroid function tests were done 7 days following surgery in all cases of total thyroidectomy. In cases where histopathology showed benign disease, oral thyroid supplements were started; whereas in malignancy cases, the patients were kept in a hypothyroid state and were referred to the nuclear medicine department for post-operative radio-active iodine screening. Regular follow up of patients were done on subsequent visits.

RESULTS

In the present study, 44 female and 6 male patients underwent thyroid surgeries. The mean age in group A was 37.56 (±12.95) and in group B was 36.24 (±13.12).

In this study, 4 patients out of 50 had transient hypocalcemia, and 2 out of 50 had recurrent laryngeal nerve paresis. Concerning the distribution of post-op complications in the different study groups, in the suture ligation technique, 2 patients developed recurrent laryngeal nerve paresis. Of these, one case was of follicular thyroid neoplasm and the other was of papillary carcinoma that underwent total thyroidectomy with neck dissection. The 3 patients in group A that had transient hypocalcemia were those who underwent total thyroidectomy with neck dissection for carcinoma. In group B, none had recurrent laryngeal nerve palsies while 1 had transient hypocalcemia who underwent total thyroidectomy with neck dissection for papillary carcinoma (Table 1).

Table 2 shows that in group A, the average hospital stay was 6.08 (±1.93) days while in group B patients the average hospital stay was 4.04 (±2.28) days. It was observed through this study that there was a significant difference between hospital stays of 2 groups ($p<0.05$).

Table 3 shows that there was a statistically significant reduction in blood loss in the harmonic group ($p=0.014$).

In this study, we observed that in group A, post-operative drain collection was significantly more than in group B. In group A, the mean of post-op drain collection was 17.80 (±8.79) ml while in group B it was 12.60 (±8.05) ml (Table 4).

Table 1: The distribution of patients according to post-operative complications.

Post-op complications	Method				Total cases	Chi-square value	P value
	Suture ligation		Harmonic				
	N	%	N	%			
Nil	21	84	23	92	44	3.364	0.186
RLN paresis	2	8	0	0	2	2.083	0.490
Transient hypocalcemia	3	12	1	4	4	1.087	0.609
Total	25	100	25	100	50		

Table 2: Distribution of patients according to duration of hospital stay.

Variables	Suture ligation		Harmonic		T value	P value
	Mean	±SD	Mean	±SD		
Duration of stay (days)	6.08	±1.93	4.04	±2.28	3.409	0.001

Table 3: Distribution of cases according to blood loss.

Variables	Suture ligation		Harmonic		T value	P value
	Mean	±SD	Mean	±SD		
Blood loss (in ml)	64.20	±32.36	44.00	±22.55	2.561	0.014

Table 4: Post-operative drain collection in the study population.

Variables	Suture ligation		Harmonic		T value	P value
	Mean	±SD	Mean	±SD		
Post operative drain collection (ml)	17.80	±8.79	12.60	±8.05	2.181	0.034

Table 5: Distribution according to the operative time.

Variables	Suture ligation		Harmonic		T value	P value
	Mean	±SD	Mean	±SD		
Operative time taken (minutes)	45.44	±9.74	34.60	±10.04	3.875	0.000

The mean operative time in group B was 34.60 (±10.04) minutes which was significantly less than the mean operative time i.e. 45.44 (±9.74) in group A. The mean difference being 10.84 minutes (Table 5).

In our study, we observed that the additional money spent by the patient on thyroidectomies (excluding the cost of surgery) using harmonic (Rs. 7522/-) was less than the money spent on thyroidectomies by suture ligation technique (Rs. 12,159/-). The Harmonic use is calculated as Rs 500/- per surgery (one-time charge).

DISCUSSION

A total of 50 patients were included to compare the effectiveness of the sutureless technique using a harmonic scalpel in thyroid surgery with the conventional suture ligation technique.

In our study, we found that 44 females (88%) and 6 males (12%) patients underwent thyroid surgeries. This is in keeping with the known literature where females are found to have a preponderance of thyroid diseases as also stated by Kadhim et al (75% females, 25% males); Ruggiero et al (65% females, 35% males); and Bove et al (74% females, 26% males).[9-11]

Reduced thermal spread of harmonic has aided in the preservation of recurrent laryngeal nerve. Also, it avoids neuro-muscular stimulation and electrical conductance through the tissues.[12] We found that 2 (8%) out of 25 patients who underwent thyroid surgery using the conventional technique developed recurrent laryngeal nerve paresis while there was no patient (0%) that developed paresis using a harmonic scalpel. The patients in group A who developed RLN paresis eventually recovered. It was seen that 11.45%, 2.55%, and 3.84% of patients who had undergone thyroid surgery by conventional technique had post-operative recurrent laryngeal nerve damage, while only 5.3%, 2.64% and 0% of patients who underwent sutureless thyroidectomy had post-operative laryngeal nerve damage in studies conducted by Sista et al, Calo et al and Khadim et al respectively.[9,13,14] There were no patients with permanent recurrent laryngeal nerve palsy in our study (defined as persistent palsy after 6 months). Also, there were no

patients with temporary/permanent recurrent laryngeal nerve injury in harmonic scalpel group.

In our study, we found that 4 out of 50 patients had transient hypocalcemia: 3 in patients that underwent suture ligation thyroidectomy while in 1 that underwent thyroidectomy using harmonic scalpel. All the patients with hypocalcemia were given injectable/ oral calcium supplements with daily monitoring of serum calcium levels, and the signs of hypocalcemia were looked for. All the patients recovered within 6 days of surgery. This was attributed to transient ischemia of parathyroid glands leading to hypocalcemia.[15] Zanghi et al had comparable results with our study, where 11 cases out of 83 had temporary hypocalcemia that underwent thyroidectomy, 5 in the harmonic group and 6 in the conventional group.[16] Similarly, Giovani et al in his study documented that 38 out of 200 patients (19%) had transient hypocalcemia; 20 and 18 in the conventional and harmonic groups respectively.[17] There was no statistical significance between the two groups in both these studies. On the other hand, in a study conducted by Ferri et al, transient hypocalcemia was significantly higher in the conventional hemostasis group (21 out of 50) than in the harmonic scalpel group (7 out of 50) ($p<0.01$).[18] The lower rate of hypocalcemia is achieved by a better view of the operative field and thus better preservation of blood supply of parathyroid glands.

Regarding the intraoperative blood loss, we observed that in the patients that underwent total thyroidectomy using a harmonic scalpel, the mean blood loss was 62.27 (±15.23) ml which was significantly ($p<0.05$) less than in patients that underwent total thyroidectomy using suture ligation technique where the mean intra-operative blood loss was 90.38 (±12.33) ml. While in cases of Hemithyroidectomy, the mean blood loss was 35.83 (±20.76) ml via suture ligation technique whereas by harmonic scalpel total blood loss was 29.64 (±15.99) ml. Basoglu et al documented in their study that the amount of blood loss was significantly lower ($p<0.01$) using Harmonic (82±67 ml) than conventional thyroidectomies (142±87 ml).[15] Similar results were obtained in the meta-analysis by Revelli et al and Zanghi et al ($p<0.05$).[16,19]

In the present study, as regards post-operative drain collection, in group A, it was significantly more than in group B. The mean post-operative drain collection in group A 17.80 (±8.79) ml while in group B it was 12.60 (±8.05) ml ($p=0.034$). Ferri et al reported that post-operative drainage at 24 hours was 37.4±2.4 in the harmonic group whereas, in conventional It was 56.1±4.2 ml which was statistically significant ($p<0.001$).[18] Revelli et al in their meta-analysis also documented a significant reduction in post-op drainage volume in harmonic scalpel group.[19]

In our study, the suture line was healthy in all patients and there was no wound dehiscence or post-operative surgical site infection in any patient.

The average time taken in group B in hemithyroidectomy was 28.43 (±8.58) minutes which was significantly less than the mean operative time i.e. 37.08 (±5.78) in group A. The mean difference was 8.65 minutes. In cases of total thyroidectomy, the mean operative time in group B was 42.45 (±4.99) minutes which was significantly less than group A where it was 53.15 (±5.00). The mean difference was 10.7 minutes. It was documented by Ruggerio et al that the time was 65±16 min in the harmonic group and 75±11 mini ligasure.[10] Foreman et al also documented that the operations were quicker with a harmonic scalpel.[6] Ferri et al found that operative time in the harmonic group was only 44.9 mins (±8.3) while it was 69.5 (±10.7) in the conventional group.[18] Cannizzaro et al reported that the surgical time in the harmonic group was 79.36±21.88 minutes vs. the conventional group, where it was 110±25.80 minutes ($p<0.00001$).[8] A shorter operative time translates to a shorter duration of anesthesia and faster post-operative recovery time.[20]

Concerning the duration of hospital stay, the average hospital stay was 6.08 (±1.93) days in the conventional suture ligation group while in the harmonic scalpel group, it was 4.04 (±2.28) days which was statistically significant. This is a reflection of lesser dissection, lesser tissue injury as well as lesser surgical time. However, Ruggiero et al comparing harmonic with ligature found the duration of hospital stay was 2 to 3 days (statistically insignificant).[10] Cannizzaro et al documented the length of hospital stay was shorter in the harmonic group (1.93±0.496 days) than in the conventional group (2.75±0.739) ($p<0.00001$).[8] Ecker et al in their meta-analysis measured the length of stay and documented a mean difference of 0.13 days in favor of the harmonic scalpel which is in keeping with this study.[20]

Comparing the cost, in our study, we excluded the cost of surgery as it was the same in both the groups, we observed that the additional money spent by the patient in thyroidectomies using harmonic (Rs. 7522/-) was less than the money spent in thyroidectomies by suture ligation technique (Rs. 12,159/-) resulting in a reduction by 38.1%. Harmonic scalpel can reduce costs associated with anesthesia, pain medication, and hospital stay and eliminate the cost of clips and suture ligation; hence decreasing the overall hospital costs.[21-23] Yildirim et al conducted a study on the use of a harmonic scalpel and reported that the use of a harmonic reduces the cost of surgery by 15 times.[24] This is a major advantage in a developing country like ours where affordability is always a concern.

It has been postulated that harmonic scalpel operates at <100°C, but when used at higher power settings (level 4 or level 5) or when the application time is prolonged >10 seconds, the temperature may be higher.[10,25] Thus, it needs to be used at level 3. Some authors have raised concerns regarding the diameter of vessels that can be ligated using harmonic. However, we faced no such concern and there was no evidence of bleeding from any

vessel post coagulation by harmonic. The thin and curved tip of the harmonic was advantageous in neck surgery where the space is limited which gives it an advantage over the newly developed thunder beat.

Limitations

The relatively short duration of the study may be cited as a limitation of our study. Additionally, when comparing costs, we only calculated the cost to the patient and did not account for the institute's expense in purchasing the harmonic scalpel.

CONCLUSION

Thyroidectomy using a harmonic scalpel is better and more cost-effective as compared to conventional ligation, although the importance of learning to ligate vessels using knot and tie should not be overlooked. As the way with technology goes, newer devices are being developed recently and constant upgradation is the norm

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