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Original Research Article

Prospective study on the outcomes of harmonic scalpel assisted thyroidectomy in a tertiary care centre in South Kerala

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ABSTRACT

Background: To estimate the outcomes of thyroidectomy using harmonic scalpel in terms of intra-operative and post-operative blood loss, operating time, incidence of post-operative hypocalcaemia, incidence of recurrent laryngeal nerve and superior laryngeal nerve palsy and post-operative pain.
Methods: The patients are selected consecutively as and when they were presented during the study period. The study involved 23 patients out of which 17 underwent total thyroidectomy and 6 underwent hemithyroidectomy, all using harmonic scalpel. A complete history, physical examination and appropriate investigations were done to arrive at the correct diagnosis. Surgery was done and all the parameters were accurately assessed.
Results: The mean intra-operative and post-operative blood loss in thyroidectomy by harmonic scalpel was 92.2 ml and 20.6 ml respectively. The mean operative time for thyroidectomy using harmonic scalpel was 58.2 minutes that includes 38 minutes for hemi thyroidectomy and 65.3 minutes for total thyroidectomy. Out of 23 patients, only 1 patient (4.3%) had transient hypocalcaemia in the post operative period. Three patients (13%) had transient unilateral recurrent laryngeal nerve palsy and none had superior laryngeal nerve palsy. The pain assessment by visual analog scale (VAS) score at 24 hours and 48 hours after harmonic scalpel assisted thyroidectomy were 3.87±0.97 and 2.35±1.30 respectively.
Conclusions: Harmonic scalpel gives effective and reliable hemostasis, shortens the operative time, reduces the complications and improved pain control and hence may be considered as an effective tool in thyroidectomy.

Keywords: Total thyroidectomy, Hemi thyroidectomy, Harmonic scalpel, Post-operative blood loss, Post-operative pain

INTRODUCTION

History of thyroid surgery dates back to 952 AD when Albucasis documented his experience of removal of a large goiter.[1] At that time the outcomes were poor and surgeons refused to perform this surgery because of the complications

The high mortality due to the surgery at that time was mainly due to hemorrhage. Because of the significant vascularity of the thyroid gland and the relatively small operative field, meticulous hemostasis has been an important prerequisite for a successful outcome in thyroid surgery.[2] The mainstay for achieving hemostasis in thyroidectomy has been tying, clipping of blood vessels and electro coagulation, all effective but have their limitations.[3] While suture ligation is a time-consuming procedure and carries the risk of knot slipping; electrocautery on the other hand is an unattractive alternative because it implies the potential risk of injuring surrounding tissues from dispersion of heat.[4]

Now a days with major advent of energy devices like ultrasonic coagulation (Harmonic scalpel) for cutting and

hemostasis introduces new methods of vessel ligation and division without increasing the risk of postoperative complications. Harmonic scalpel was introduced in the early 90's.[5] It is used to simultaneously cut and cauterize tissues using high frequency (55000Hz) ultrasonic energy transmitted between the instrument blades.[6] This vibration breaks hydrogen bonds within the tissue. This takes place at a relatively low temperature (80° C) causing less thermal damage.[6] Since the tissue fluid does not boil at this temperature, the proteoglycans and collagen fibers in the tissue undergo denaturation and mix with intracellular and interstitial fluids to form a glue-like substance or coagulum.[7]

The proposed advantages of using harmonic scalpel over traditional methods like tying, clipping and electrocautery include less lateral thermal tissue damage, less nerve injuries and avoidance of transmission of electrical energy through the patient.[3] Thus, use of harmonic scalpel can reduce bleeding, thus obtaining a good operating field, minimizing the injury to surrounding structures like laryngeal nerves and parathyroid glands. So, the purpose of the study is to measure the outcomes of Harmonic scalpel assisted thyroidectomy in terms of various intra operative and post operative parameters.

METHODS

Type of study and source of data

A prospective study was conducted for a period of one and a half years from January 2018 to estimate the outcomes of thyroidectomy using harmonic scalpel in terms of the intra operative and post operative blood loss, operative time, incidence of postoperative hypocalcemia, incidence of recurrent and superior laryngeal nerve palsies, postoperative pain in the department of ear, nose and throat (ENT), Pushpagiri Institute of Medical Sciences and Research Centre, Thiruvalla, Kerala.

Inclusion criteria

Patients with age >18 years of both sexes, and patients with benign thyroid swellings requiring near total/total/hemi thyroidectomy as per American Thyroid Association (ATA) guidelines, 2015 were included.

Exclusion criteria

Patients with age <18 years, malignancy, bleeding disorders, previous neck irradiation, previous thyroid surgeries, neck dissections, and endoscopic thyroidectomy were excluded.

Method of data collection

The patients are selected consecutively as and when they were presented during the study period of one and a half years from January 2018 in the department of ENT, Pushpagiri Institute of Medical Sciences and Research Centre, Thiruvalla, Kerala considering the inclusion and exclusion criteria. The study involved 23 patients out of which 17 underwent total thyroidectomy and 6 underwent hemithyroidectomy, all using harmonic scalpel. A complete history, ENT examination and appropriate investigations were done to arrive at the correct diagnosis.

Routine blood investigations including haemoglobin, total count, differential count, platelet count, erythrocyte sedimentation rate (ESR), urea, creatinine, coagulation profile like bleeding time (BT), clotting time (CT), prothrombin time (PT), partial thromboplastin time (aPTT), international normalized ratio (INR), blood grouping, Rh, serology like human immune-deficiency virus (HIV), hepatitis B surface antigen (HBsAg), and hepatitis C virus (HCV) were done.

Special blood investigations include thyroid function test (TFT), serum calcium (Ca) (preoperative and postoperative), and serum PTH (in patients with hypocalcemia after total or near total thyroidectomy).

Other investigations include: videolaryngoscopy (preoperative and postoperative) to assess vocal cord function, fine needle aspiration cytology (FNAC), ultrasonography (USG) thyroid, chest X-ray, electrocardiography (ECG), and surgery.

During admission day, all the patients were taught how to fill the post operative pain score form. Pre operatively single dose of amoxicillin clavulanic acid or ceftriaxone injection was given for all the patients. All surgeries were done using harmonic scalpel (FOCUS Harmonic scalpel) under general anesthesia with endotracheal intubation (Figure 1). We used bipolar cautery to achieve hemostasis at the entry point of RLN into the larynx, since harmonic scalpel tip was relatively bulky.

Figure 1: Focus Harmonic scalpel.

Blood volume

Intra operative blood loss was measured by weighing the swab before and after thyroidectomy and by measuring the amount in suction bottle after deducting the saline used for surgery. Post operative blood loss was calculated by drain volume up to 24 hours after surgery.

Operative time

Operating time was calculated in minutes from the time of dissection of strap muscles up to approximation of strap muscles.

Hypocalcemia

Incidence of hypocalcemia was assessed by estimating serum calcium and serum PTH, 6 hours postoperatively in patients with total/near total thyroidectomy. Patients with hypocalcemia were followed up for a period of 6 months.

Nerve palsies

Post operative nerve palsies were assessed by video laryngoscopy on post-operative day 1. Patients with recurrent and superior laryngeal nerve palsies were followed up for a period of 6 months.

Post operative pain

Post operative pain outcome estimated for a period of one week after surgery was obtained according to patient responses to visual analogue scale (VAS) (Figure 2). 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 "unbearable pain" (maximum, on the right end).

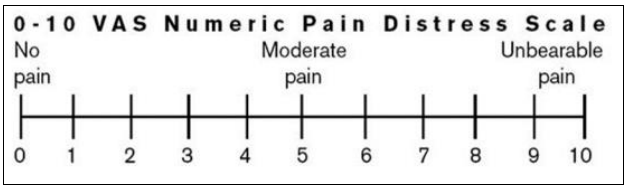

Figure 2: Visual analogue scale.

Post-operative care

Post-operatively all the patients are treated with antibiotics, analgesics and other supportive measures. All the patients were followed up for 7 days after surgery. Patients were all seen in the outpatient department on the 7th post-operative day and examination of the wound and videolaryngoscopic examination for assessment of vocal cord function were carried out.

Statistical analysis

The data was entered into Microsoft excel data sheet and was analyzed using statistical package for the social sciences (SPSS), version 20.0. Categorical and quantitative variables were expressed as frequency (percentage) and mean±SD respectively. Mann-Whitney U Test and Fisher's exact test were used to compare quantitative and categorical parameters between groups. For all statistical interpretations, $p<0.05$ was considered the threshold for statistical significance.

RESULTS

A total of 23 cases underwent thyroidectomy (hemi and total) using harmonic scalpel. All the patients were available for regular post operative follow up.

The data were analyzed under the following headings: patient factors and results.

Patient factors

Age

From the Table 1 it was clear that all of the patients were adults and the mean age was 50.3±11.7 years.

Table 1: Percentage distribution of the sample according to age.

Age (in years)	Count	Percentage
31-40	6	26.1
41-50	6	26.1
51-60	5	21.7
>60	6	26.1
Mean±SD	50.3±11.7	

Sex

Out of the 23 cases, 19 (82.6%) were females and 4 (17.4%) were males.

Type of surgery

73.9% underwent total thyroidectomy and 26.1% underwent hemi thyroidectomy.

Outcomes of thyroidectomy using harmonic scalpel.

Blood loss

Table 2 shows the estimated intra operative and post operative blood loss in thyroidectomy using harmonic scalpel. The range of intraoperative blood loss was from 7 ml to 300 ml with an average of 92.2 ml (SD ±79.9) whereas, the post operative blood loss was from 6 ml to 68 ml with a mean of 20.6 ml (SD ±13.9).

Table 2: Descriptive statistics for blood volume.

Parameters	Intra-operative (in ml)	Post-operative (in ml)
Mean	92.2	20.6
SD	79.9	13.9
Q1	34.0	10.0
Median	55.0	19.0
Q3	135.0	23.0
Minimum	7.0	6.0
Maximum	300.0	68.0

Operative time

The operative time ranges from 20 minutes to 150 minutes with a mean of 58.2 minutes (SD ± 30.8) (Table 3).

Table 3: Descriptive statistics for operative time.

Parameters	Operative time
Mean	58.2
SD	30.8
Q1	33.0
Median	60.0
Q3	70.0
Minimum	20.0
Maximum	150.0

Hypocalcaemia and nerve palsies

In the present study 4.3% of patients developed post operative hypocalcemia and 13% developed post operative nerve palsies (Table 4).

Post-operative pain

There was an average pain score of 4.91 on post op day 0, 3.87 on day I, 2.35 on day II, 1.26 on day III, and was gradually reducing to 0.013 on day VI. all the patients experienced moderate pain on the day of surgery (100%), 65.2% experienced moderate pain on day 2 and 17.4% on day 2. None of the patients experienced moderate pain after day 2 (Table 5).

Table 4: Percentage distribution of the incidence of hypocalcemia and nerve palsy.

Parameters	Count	Percent
Incidence of hypocalcemia	1	4.3
Incidence of nerve palsy	3	13.0

Table 5: Descriptive statistics for post operative pain score (VAS).

Day	Mean	SD	Median
Day 0	4.91	0.73	5
Day 1	3.87	0.97	4
Day 2	2.35	1.30	3
Day 3	1.26	1.14	1
Day 4	0.65	0.83	0
Day 5	0.30	0.56	0
Day 6	0.13	0.34	0

From the Table 6, it is clear that 34.8% experienced mild pain on day 1, 69.6% on day 2, 65.2% on day 3, 43.5% on day 4, 26.1% on day 5 and 13% on the day 6. No pain was experienced by 13% of the population on day 2, 34.8% on day 3, 56.5% on day 4, 73.9% on day 5 and 87% on day 6. None of the patients experienced severe pain (VAS pain score 7-10) on any of the day. This shows that the severity of the pain was gradually decreasing from day 1 to day 6.

Table 6: Distribution of post operative pain based on VAS scores.

Pain	No pain (0)		Mild pain (1-3)		Moderate pain (4-6)	
	Count	Percent	Count	Percent	Count	Percent
Day 0	0	0.0	0	0.0	23	100.0
Day 1	0	0.0	8	34.8	15	65.2
Day 2	3	13.0	16	69.6	4	17.4
Day 3	8	34.8	15	65.2	0	0.0
Day 4	13	56.5	10	43.5	0	0.0
Day 5	17	73.9	6	26.1	0	0.0
Day 6	20	87.0	3	13.0	0	0.0

DISCUSSION

The meticulous hemostasis is of crucial importance for successful outcomes in thyroidectomy as it prevents intra operative and post operative complications, and improves the quality and shortens the hospital stay. Hemostasis can be performed by classic suture ligation with knot and tie maneuvers or by electrocoagulation. Suture ligation is effective, but time-consuming procedure and carries the risk of knot slipping while electrocautery on is an unattractive alternative because it implies the potential risk of injuring surrounding tissues from dispersion of heat.[8]

Bearing this in mind, newer techniques to achieve a safer and faster hemostasis with less thermal spread to reduce both operating time and complications have been researched and developed. As an alternative to conventional hemostatic technique, the harmonic scalpel was developed in the early 1990s. It allows simultaneous cutting and coagulation of blood vessels by using mechanical vibration resulting in protein denaturation to form a coagulum, which seals the vessels and assures hemostasis at low temperatures.[4] In the present study, we prospectively evaluate the possible advantages and disadvantages of the Harmonic scalpel (FOCUS) assisted thyroidectomy.

In a study by Soroush et al in 2013 the mean of operation time in harmonic scalpel (HS) assisted thyroidectomy was 60.00±9.20 minutes.[9] Mourad et al in 2011 concluded that operative time was 57±13 minutes in total thyroidectomy using harmonic scalpel.[10] Bove et al in 2012 observed that the operative time was 62.7±14.1 minutes.[11] Pons et al in a comparison study reported mean operative time for total thyroidectomy in HS group was 114±9 minutes.[12] Anandaravi et al in a prospective randomized study revealed that the mean operative time for hemithyroidectomy and near total thyroidectomy were 53.40±9.07 minutes and 67.21±10.36 respectively using harmonic scalpel.[13]

In the present study, the mean operative time for thyroidectomy using harmonic scalpel was 58.2 minutes that includes 38 minutes for hemi thyroidectomy and 65.3 minutes for total thyroidectomy which was found to be comparable to the previous studies.[9,10,11,13]

Cannizzaro et al reported the post operative blood loss in total thyroidectomy using harmonic scalpel as 68.72±40.86 ml.[14] Konturek et al in 2012 stated that post operative blood loss in harmonic scalpel assisted thyroidectomies was 29.9±9.8 ml.[15] Deffechereux et al observed that intraoperative blood loss in total thyroidectomy by harmonic dissection was 74.5±50 ml.[16] In our study mean intraoperative and post operative blood loss in thyroidectomy by harmonic scalpel was 92.2 ml and 20.6 ml respectively.

Yener et al observed that no one (0%) in the harmonic scalpel group sustained postoperative hypocalcemia.[3] In a prospective randomized study by Anandaravi et al in 2017, out of 19 patients, 1 patient (5.2%) had transient hypocalcemia.[13] Melck et al concluded a lower rate of transient hypocalcemia with the use of the HS (RR=0.69, 95% CI =0 .51, 0.92).[17] In our study, out of 23 patients, only 1 patient (4.3%) had transient hypocalcemia in the post operative period requiring calcium supplementation. The exact reason for the single case of transient hypocalcemia we observed is not clear. We attributed this to the probable lateral thermal damage by the harmonic scalpel and transient ischemia to the parathyroid glands. Barczynski et al performed blunt dissection with the harmonic scalpel, 5 mm away from the gland, which was twice the reported safe distance.[18]

Miccoli et al in 2006 observed that there is no occurrence of recurrent laryngeal nerve palsies in patients undergoing thyroidectomy by harmonic scalpel.[19] In a study by Ferri et al in 2011, none of the patients of harmonic scalpel group had recurrent laryngeal nerve palsies.[20] Ciftci et al in 2016 reported transient recurrent laryngeal nerve palsy in 4% of the patients who underwent thyroidectomy by harmonic scalpel and no permanent nerve palsy. Sultan et al in 2018 observed that 5% of patients in HS group sustained unilateral recurrent laryngeal nerve palsy which was not statistically significant.[21] In a prospective randomized study by Anandaravi et al in 2017, 2 out of 19 patients (10.5%) had transient recurrent laryngeal nerve palsy in HS group. Arslan et al reported the external branch of the superior laryngeal nerve and recurrent laryngeal nerve palsy were noted in three (3%) and two (2%) patients out of 101 patients in the HS group.[22] In the present study of harmonic scalpel assisted thyroidectomy, 3 patients (13%) had transient unilateral recurrent laryngeal nerve palsy and none had superior laryngeal nerve palsy. All the three patients recovered from palsy by 1 week, 3 weeks and 1 month respectively. Thermal injury of the HS is a potential cause of RLN injury. According to the reports of Owaki et al temporary RLN paralysis after thyroidectomy may be related to the thermal injury caused by the harmonic scalpel.[23]

Postoperative pain assessment was analyzed according to patient responses to a 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). Ferri et al observed pain scores (VAS scores) for the patients who underwent thyroidectomy by harmonic scalpel dissection at 24 hours and 48 hours postoperatively were 3.89±1.07 and 1.99±0.97 respectively.[20] Miccoli et al reported that VAS scores at 24 hours and 48 hours after surgery were 3.90±1.74 and 2.27±1.47 respectively in HS group.[19] Askar et al found that VAS in the HS group at 24 hours and 1 week postoperatively were 2.57±1.32 and 0.75±1.16 respectively.[24] These results may be attributed to shorter operative time, lesser traction on the neck muscles, minimal thermal injury.

In our study, the pain assessment by VAS score at 24 hours and 48 hours after harmonic scalpel assisted thyroidectomy were 3.87±0.97 and 2.35±1.30 respectively which were consistent with the previous studies cited above.

Limitations

The sample size was small and there were no control groups.

CONCLUSION

Harmonic scalpel gives effective and reliable hemostasis, shortens the operative time, reduces the complications and improves pain control. The major disadvantages of harmonic scalpel were its cost, skill required to overcome the learning curve although it was relatively short. Since the time spent in the operating room is expensive, this would counterbalance the cost of the HS hand piece and eventually result in an overall cost saving. Another disadvantage was that we could use only bipolar cautery to control the bleeding of terminal branches of inferior thyroid artery at the entry point of RLN into the larynx, since harmonic scalpel tip was relatively bulky. The shorter operative time implies the possibility to treat more patients in the same operative sessions. Other disadvantages are, the thermal injury to the surrounding tissues and instrument fractures due to the heat generated

by the device. Harmonic scalpel can be considered as one of the effective tools for performing thyroidectomy.

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