ORIGINAL ARTICLE

A COMPARATIVE STUDY OF FOCUS HARMONIC SCALPEL VERSUS CONVENTIONAL VASCULAR LIGATURE TECHNIQUE IN PATIENTS UNDERGOING TOTAL THYROIDECTOMY

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Background: Thyroid surgery is one of most commonly employed procedures by the surgeons. Evolution of the technique was based on different techniques employed during the dissection of the thyroid tissue, control of bleeding to ensure hemostasis and nerve monitoring with the aim to decrease the complications during the intraoperative and the post operative period. Objective was to compare total thyroidectomy with FOCUS Harmonic scalpel with conventional vascular ligature technique in patients undergoing total thyroidectomy. It was a randomized controlled Trial conducted at the CMH Bahawalpur from 1st July to 31st Dec 2022 (6 Months). **Methods:** A total number of 78 patients who were planned for total thyroidectomy were included in the trial. Employing a non-probability consecutive sampling technique via lottery method 39 patients were assigned to either of the 02 groups, i.e., Group A (harmonic scalpel technique) and Group B (conventional vascular ligature technique). Recorded variables included mean operative time, intraoperative and postoperative blood loss. Demographic characteristics and ASA grade were recorded for each patient. **Results:** Mean age of the patients in Group A was 44.05±6.37 years while 44.79±7.62 years in Group B. Male to female ratio was 1:2 among the total participants with 26 (33.3%) males and 52 (66.7%) females however male participants in both groups were 11 (28.2%) versus 15 (38.5%) and females were 28 (71.8%) versus 24 (61.5%) respectively. Harmonic scalpel technique showed significant results in terms of mean operative time, intraoperative and post operative blood loss as compared to conventional vessel ligature technique with a $p<0.05$. **Conclusion:** In terms of mean operative time, intraoperative and postoperative blood loss Harmonic scalpel technique is superior to conventional vascular ligature technique for total thyroidectomy.

Keywords: Harmonic; Ligature; Thyroidectomy; Vascular

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INTRODUCTION

Thyroid surgery is one of most commonly employed procedures by the surgeons. Evolution of the technique was based on different techniques employed during the dissection of the thyroid tissue, control of bleeding to ensure hemostasis and nerve monitoring with the aim to decrease the complications during the intraoperative and the post operative period. The exemplary work done by Kocher and others during the 19th century in the field cannot be negated.[1,2]

Subtotal thyroidectomies lead to a greater rate of recurrence and redo surgeries are often required by such patients however total thyroidectomy is a gold standard procedure which can be applied to as an effective surgical treatment in patients with multinodular toxic goiter or patients with benign multinodular goiter. In our country the turn out of the patients is enormous and the time management along with the safety of the patient is the most important component from surgical point of view. Procedure that is least invasive with better outcomes and lesser complications is the need of the day.[3]

A variety of techniques are in practice and under consideration aiming the safety of the patient's undergoing thyroidectomy. This includes assessment of the risk of difficult thyroidectomy in patients and better monitoring standards in the intraoperative period like nerve monitoring and employing total intravenous anesthesia for thyroidectomies to assess the nerve function and prevent any damage to the surrounding nerves.[4,5]

Complications like bleeding, airway complications and nerve injuries were commonly seen during and after thyroid surgeries leading to a high rate of morbidity and mortality. In the 21st century the use of harmonic devices produced better results by producing a bloodless field and decreasing the operative time in patients undergoing thyroidectomy as compared to the usual suturing technique employed.[6,7]

The conventional technique of suturing poses a risk of bleed as the knot can slip and result in bleeding as compared to ligasure or harmonic devices which coagulate the bleeding vessels and the surrounding tissues. These devices take a shorter time to achieve the control of bleed with lesser chances of bleed from the same site with a greater reliability. Chances of postoperative bleeding is further reduced with ligature or harmonic devices as compared to conventional technique of applying suture.[8,9]

This study was aimed at comparing the use of harmonic devices versus conventional suturing technique[10] in reducing the operative time and reduction of blood loss in the intraoperative and postoperative period.

MATERIAL AND METHODS

This Randomized control trial was carried out at CMH Bahawalpur for a period of 06 months from 1st July to 31st Dec 2022 after obtaining approval from ethical committee of the hospital.

A study revealed that post operative blood loss in patients after thyroidectomy using FOCUS Harmonic scalpel was 97.38 ml[11] as compared 68.72 ml[11] when conventional vascular ligature technique was employed to patients undergoing total thyroidectomy. Sample size calculation was performed by using WHO sample size calculator. Using a 5% level of significance with a 90% power of test, the total sample size calculated was 78. Employing a non-probability consecutive sampling method 39 patients were assigned to either of the 02 groups i.e Group A (harmonic scalpel technique) and Group B (conventional vascular ligature technique).

The study included patients of either gender aged between 15 and 60 years who were classified as American Society of Anesthesiologists (ASA) grade I or II, were euthyroid, and diagnosed with benign multinodular goiter. Patients were excluded if they had multinodular toxic goiter, a history of recurrent goiter, coagulopathy, malignancy, ischemic heart disease, or if they were classified as ASA grade III or higher.

After obtaining a detailed history and performing examination patients underwent ultrasonography of neck region followed by fine needle aspiration cytology. Laboratory investigations were performed including baseline and thyroid function tests. Patients diagnosed with benign multinodular goiter with euthyroid status indicated by thyroid function tests were included in the research after their approval.

After obtaining fitness from a classified anesthetist at pre anesthesia clinic patients were prepared to undergo procedure under general anesthesia. As per the institutional protocol patients were prepared a day before surgery and shifted to operation theatre on the day of surgery. Under general anesthesia surgical procedure was performed employing FOCUS harmonic scalpel for dissection of thyroid and control of bleed in Group A while conventional ligature of the vessels of superior pole was done by using Vicryl suture 1/0 and inferior thyroidal artery by vicryl 2/0 in participants of Group B. Recorded variables included the demographic characteristics of each participant, operative time, bleeding in the intraoperative and the post operative period. For assessment of intraoperative bleed surgical gauzes were weighed before and after the procedure and each gram increase in weight was taken as one ml of blood loss. Suction bottle readings were also added to the total blood loss.

Group A patients underwent total thyroidectomy with FOCUS Harmonic scalpel while group B patients underwent total thyroidectomy by the conventional vascular ligature technique. All the operations were performed by the same surgical team headed by my supervisor. In Group A, dissection of thyroid tissue was done by harmonic scalpel including the coagulation of the blood supply of thyroid gland. While in Group B, superior pole was ligated by Vicryl 1/0 and inferior thyroid artery by Vicryl 2/0 respectively. Operative time of all the patients was recorded from the time of incision till the application of last stitch. Drains placed during the procedure were used to measure the loss of blood in post operative period assessed from the total blood obtained in the bottles attached to the drain till the drain was removed.

Data obtained from the participants was analyzed using statistical package for the social sciences software version 23. Analysis for qualitative and quantitative variables was done using chi square test and independent t test respectively. The p-value was considered significant if it was ≤0.05.

RESULTS

Using lottery method 78 patients were equally divided into two groups, i.e., Group A and Group B. Mean age of the patients in Group A was 44.05±6.37 years while 44.79±7.62 years in Group B. Male to female ratio was 1: 2 among the total participants with 26 (33.3%) males and 52 (66.7%) females. ASA and gender distribution are shown in Table-1. Operative time in Group A was 52.05±3.83 mins which was significantly lower as compared to Group B with operative time of 72.54±4.35 mins with a *p*-value of 0.00. Intraoperative and post operative blood loss in Group A was significantly lesser as compared to Group B. Age distribution and mean operative time are shown in Table-2. Intraoperative blood loss and post operative blood loss also revealed significant results with lesser blood loss in Group A as compared to Group B as shown in Table-3.

Table-1: ASA and Gender distribution

ASA grade & Gender	Group A (n = 39) n(%)	Group B (n=39) n(%)	*p*-value
ASA I	08 (20.5%)	14 (35.9%%)	
ASA II	31 (79.5%)	25 (64.1%)	0.131
Males	11 (28.2%)	15 (38.5%)	
Females	28 (71.8%)	24 (61.5%)	0.337

Table-2: Age and mean operative time among groups

Groups	Group A (n=39) Mean±S.D	Group B (n=39) Mean±S.D	*p*-value
Age in years	44.05±6.37	44.79±7.62	0.471
Mean operative Time in minutes	52.05±3.83	72.54±4.35	**0.000**

Table-3: Intraoperative and post-operative blood loss

Groups	Group A (n = 39) Mean±S.D	Group B (n = 39) Mean±S.D	*p*-value
Intraoperative blood loss in ml	47.10±4.35	91.21±6.16	**0.000**
Post operative blood loss in ml	53.74±4.17	115.95±9.31	**0.000**

DISCUSSION

The randomized control trial underwent to compare the effectivity of use of harmonic devices with conventional suturing in total thyroidectomies. Results revealed that the operative time (52.05±3.83 mins vs 72.54±4.35) was significantly reduced when harmonic scalpel was used for securing bleeding points during surgical procedure. The mean blood loss intraoperatively (91.21±6.16 vs 47.10±4.35) and post operatively (115.95±9.31 vs 53.74±4.17) recorded in milliliters was also reduced signifying an effective and reliable control of bleeding with harmonic scalpel device as compared to conventional suturing.

Another study with similar results showed that the mean operative time and mean blood loss was reduced significantly in patients undergoing total thyroidectomy when harmonic scalpel device was used as compared to conventional suturing technique.[11]

Thyroid surgery becomes inevitable in some patients with thyroid pathologies and the invasive nature of the surgery makes the patients prone to complications in the intraoperative and post operative period out of which bleeding is the most serious complications. Males with toxic multinodular goiters undergoing total thyroidectomy are at a higher risk of bleeding perioperatively. The usual source of bleeding may be the tissues surrounding or the subcutaneous regions which can lead to grave consequences and requirement of patient care in the intensive care units. Different modalities have been in practice to decrease the risk of bleeding including the use of coagulation devices as opposed to conventional suturing with fruitful results in minimizing the morbidity and mortality.[12,13]

Harmonic scalpel devices have been effectively in use in multiple surgical procedure, and it has shown to reduce the operative time by 30 mins as opposed to conventional suturing and applying knots in thoracic surgeries. This device helps to coagulate the bleeding structures hence reducing the bleed effectively and reliably to approximately 200 ml less as compared to when the conventional technique is employed.[14]

Similar to our study another trial showed that conventional suturing technique when used in patients undergoing thyroidectomy had a total blood loss of 89.45±23.21ml in drains postoperatively as compared to a total blood loss of 48.82±16.56 ml when harmonic scalpel was used. This trial also revealed significant reduction in the mean operative time from 128.62 ± 11.76 mins to 104.19±13.67 mins when harmonic device was used for control of bleed as compared to conventional suturing of the bleeding sites.[15]

Thyroid surgeries require meticulous control of bleeding during surgery to decrease the post operative bleeding complications.[16] A new technique of using harmonic knife in resection of thyroid gland by surgeons revealed that the time to complete procedure was shorter with lesser bleed in the operative and post operative period as compared to conventional technique of thyroidectomy. This trial also showed that the episodes of hypocalcemia were significantly reduced when harmonic knife was used as compared to conventional technique of thyroidectomies.[17]

Different energy-based devices have been used to control the bleeding during thyroidectomies and the comparison of these devices revealed the superiority of such devices in reduction of operative time, hospital stay and bleeding in the perioperative period as compared to conventional techniques. These energy devices included ligature, harmonic scalpel and electrotome.[18]

Patients undergoing thyroidectomies are prone to bleeding, nerve injuries and airway complications which increases the requirement of redo procedures.[19] The expertise of the surgeon in identifying the patients at risk play a primary role in reducing the critical events. Use of devices that are reliable and effective in reducing the time interval and loss of blood can help in decreasing the complications.[20] This will further reduce the patient load on the intensive care units particularly and will help to reduce the post operative hospital stay thus reduction in the chances of hospital acquired infections.[21]

The use of different modalities with the aim to reduce the perioperative complications[22] in patients undergoing thyroidectomy are in practice. Our study proves the effective and reliable role of the use of harmonic scalpel device by decreasing the complications and reducing the operative time as compared to the

conventional technique of suturing as seen in multiple previous trials.

CONCLUSION

In terms of mean operative time, intraoperative and postoperative blood loss Harmonic scalpel technique is superior to conventional vascular ligature technique for total thyroidectomy.

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Limitations of the Study: None

Conflict of Interest: None

AUTHORS' CONTRIBUTION

IUKB: literature search, conceptualization of study design, data collection, data analysis, data interpretation, write-up. MSA: Conceptualization of study design, data collection, data analysis. NB: Literature search. RH, KS, FG: Data analysis, write-up.

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