

## COMPARISON BETWEEN TOTAL THYROIDECTOMY WITH LIGASURE SMALL JAW DEVICE VERSUS CONVENTIONAL VASCULAR LIGATURE TECHNIQUE

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### ABSTRACT

**Objective:** To compare total thyroidectomy with LigaSure small jaw device with conventional vascular ligature technique in terms of mean operation time and intra-operative and postoperative blood loss.

**Study Design:** Randomized controlled trial.

**Place and Duration of Study:** Department of General Surgery, Military Hospital Rawalpindi from, Jun 2017 to Feb 2018.

**Material and Methods:** A total of 70 patients (35 in each group) diagnosed with benign multinodular goiter meeting the inclusion and exclusion criteria were included in the study. Patients with malignancy of thyroid, redo surgery and coagulopathies were excluded. Group A patients underwent total thyroidectomy with the LigaSure small jaw device while group B patients were operated by the conventional technique. Mean operative time, intraoperative and postoperative blood loss of all patients was documented. Data was analyzed by SPSS 23.0. A  $p$ -value  $\leq 0.05$  was taken as significant.

**Results:** Mean operative time in group-A was  $63.73 \pm 3.67$  minutes while in group-B it was  $96.53 \pm 7.96$  minutes ( $p=0.000$ ). Mean intra-operative blood loss was calculated as  $42.13 \pm 3.15$  mL in group-A and  $73.50 \pm 3.66$  mL in group-B ( $p=0.000$ ). The mean post-operative blood loss was calculated to be  $53.80 \pm 3.17$  mL in group-A and  $63.80 \pm 3.31$  mL in group-B ( $p=0.000$ ).

**Conclusion:** Total thyroidectomy with LigaSure small jaw device is significantly better when compared with conventional vascular ligature technique in terms of mean operation time, intra-operative and postoperative blood loss.

**Keywords:** Intraoperative, Operative time, Postoperative blood loss, Thyroidectomy.

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### INTRODUCTION

The earliest account of thyroid surgery was described by Roger Frugardi of Salerno in the year 1170 AD<sup>1</sup>. Thyroidectomy was first performed by Theodore Kocher in 1872. His pioneering work along with the work of Billroth ultimately led to the standardization of the surgical technique which is still being practiced with few modifications<sup>2</sup>. Continuous development in surgical techniques with better understanding of thyroid pathology have increased the safety of thyroid surgery. The thyroid gland has a rich blood supply hence in thyroid surgery dissection in planes followed by prompt and effective hemostasis is of crucial

importance to avoid intra-operative and post-operative blood loss and to curtail the post-operative complications<sup>3,4</sup>.

Total thyroidectomy has now become the preferred option for all patients presenting with bilateral benign multinodular goiter<sup>5</sup>, Graves' disease<sup>6</sup> and most patients with thyroid cancer<sup>7</sup>. Total thyroidectomy procedures are now being increasingly employed to treat bilateral benign thyroid disease with the same safety profile as the sub total or near total thyroidectomy procedures, which are more conservative but are associated with significantly higher recurrence rates<sup>8</sup>.

Recently new techniques have been introduced in performing thyroidectomy by using sealing, ligation, section and dissection devices, such as LigaSure Small Jaw and ultrasonic dissector like Harmonic scalpel. Numerous studies

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have demonstrated the effectiveness of LigaSure Small Jaw device in terms of reducing the operative time, intra-operative and post-operative blood loss. Time saving surgical techniques are being increasingly employed these days due to high turnover rate of patients and for requiring less anesthesia time<sup>9</sup>.

The objectives of this study were to compare the conventional suture ligation technique with the newer LigaSure vessel sealing system in terms of operative time and blood loss during and after surgery. The rationale of this study was that there is no previous study till date focusing on the comparison of total thyroidectomy with LigaSure small jaw device versus the conventional vascular ligature method in Pakistan. Thus the results of this study will provide local evidence that will help adopt the better technique with less operation time and reduction in the both intra-operative and post-operative blood loss eventually leading to early recovery, reduced complication rate and reduced hospital stay for the patients.

## MATERIAL AND METHODS

We conducted a randomized controlled trial from Jun 2017 to Feb 2018 in the department of Surgery, Pak Emirates Military Hospital Rawalpindi on patients undergoing total thyroidectomy for benign multinodular goiter who fulfilled the sample selection criteria after approval from ethical review committee of Pak Emirates Military Hospital, Rawalpindi. A written informed consent was taken from every patient included in the study. The sample size was calculated by using the WHO sample size calculator with Power of test  $(1-\beta)=80\%$ , Level of significance  $(\alpha)=5\%$ , population SD  $(\sigma)=22.855$ , population variance  $(\sigma^2)=522.351$ , test value of population mean=60.2 minutes and anticipated population mean=73.9 minutes (operation time)<sup>10</sup>. The sample size was calculated to be 35+35=70 patients. The sampling technique was non-probability consecutive sampling.

The inclusion criteria included Euthyroid patients of both genders with benign multi-

nodular goiter undergoing total thyroidectomy. Patients between 15-70 years of age and ASA grades I, II and III were included in the study. The exclusion criteria included patients with thyroid malignancies, congenital anomalies of neck, ASA class IV & V, ischemic heart disease, redo surgery and coagulopathies. Patients were randomly divided by lottery method into two equal groups (group 1 and 2) consisting of 35 patients each. Group 1 patients underwent total thyroidectomy with LigaSure small jaw device while patients in group 2 underwent total thyroidectomy by the conventional vascular ligature method.

In group 1, LigaSure small jaw device was used to perform the total thyroidectomy without the use of any suture material to secure superior pole of thyroid gland or ligation of inferior thyroid artery. While in group 2, superior pole of thyroid gland was ligated by using Vicryl 1/0 suture and inferior thyroid artery was ligated using the Vicryl 2/0 suture. After removal of thyroid gland, a single Redivac suction drain was placed in all patients which was removed if the drain output was less than 20 mL in 24 hours. Operative time of all patients was recorded from the time of skin incision to the application of last stitch in minutes.

Intra-operative blood loss was determined by calculating the increase in weight of the swabs/gauzes used during the surgery with each gram taken as equal to one milliliter of blood (i.e. 1g = 1ml). The blood collecting in drain bottle by suction was also added to the final blood loss measured from soaked gauzes. Postoperative blood loss was determined by the amount of drain output after the surgery till removal of drain. All patients were given due respect and their comfort was taken care of during the study. The exclusion criteria will be strictly followed to control confounders and bias in the study.

Data was entered in and analyzed by using SPSS version 23.0. Mean and standard deviation was calculated for quantitative variables like age, BMI, operation time, intra-operative and post-

operative blood loss. Qualitative variable i.e. Gender was recorded in terms of frequency percentage. Chi square test was applied for qualitative variables. Independent sample t-test was applied for quantitative variables. A *p*-value of  $\leq 0.05$  was considered as significant.

## RESULTS

The total number of patients included in the study was 70 ( $n=70$ ) which were divided into two equal groups (35 patients each). The patients included 66 females (94.29%) and 4 males (5.71%). Female to male ratio in the study sample was 16.5:1. The mean  $\pm$  SD age of patients was calculated as  $36.9 \pm 8.82$  years in group-A and  $38.97 \pm 9.09$  years in group-B. Mean BMI of the patients was recorded as  $28.2 \pm 2.98$  Kg/m<sup>2</sup> in

required reoperation while none of the patients undergoing total thyroidectomy with LigaSure small jaw device developed hematoma formation. The difference between the two groups was statistically insignificant ( $p=0.314$ ). None of the patients in both the groups developed surgical site infection.

The results have been summarized as shown in table.

## DISCUSSION

Our study included 66 female patients (94.3%) and only 4 male patients (5.7%). This was because of the fact that our clientele at Pak Emirates Military Hospital mainly consists of families of soldiers of Pakistan Army. The overall mean age of patients included in the study

**Table: Summary of results.**

|                                | Group A (n=35)         | Group B (n=35)          | <i>p</i> -value |
|--------------------------------|------------------------|-------------------------|-----------------|
| Gender (M:F)                   | 2 (5.71%): 33 (94.29%) | 2 (5.71%) : 33 (94.29%) | 1.000           |
| Age (years)                    | $36.9 \pm 8.82$        | $38.97 \pm 9.09$        | 0.471           |
| BMI (Kg/m <sup>2</sup> )       | $28.2 \pm 2.98$        | $27.8 \pm 3.07$         | 0.477           |
| Operation time (minutes)       | $63.73 \pm 3.67$       | $96.53 \pm 7.96$        | 0.001           |
| Intraoperative blood loss (ml) | $42.13 \pm 3.15$       | $73.50 \pm 3.66$        | 0.001           |
| Postoperative blood loss (ml)  | $53.80 \pm 3.17$       | $63.80 \pm 3.31$        | 0.001           |
| Hematoma formation             | 0 (0.00%)              | 1 (2.86%)               | 0.314           |
| Surgical site Infection        | 0 (0.00%)              | 0 (0.00%)               | 1.000           |

group-A and it was  $27.8 \pm 3.07$  Kg/m<sup>2</sup> in group-B.

In group A, the mean operative time was  $63.73 \pm 3.67$  minutes while in group B, the mean operative time was found to be  $96.53 \pm 7.96$  minutes. The difference in the mean operation time between the two groups was statistically significant ( $p=0.001$ ). Mean intra-operative blood loss was calculated as  $42.13 \pm 3.15$  mL in group-A and  $73.50 \pm 3.66$  mL in group-B. The difference between the two groups was statistically significant ( $p=0.001$ ). Similarly the post-operative blood loss between the two groups was also found to be statistically significant ( $p=0.001$ ). The mean post-operative blood loss was calculated to be  $53.80 \pm 3.17$  mL in group-A and  $63.80 \pm 3.31$  mL in group-B patients respectively. There was one case of hematoma formation in the conventional vascular ligature group (2.86%) that

revealed that most patients present in the fourth decade of life. The mean age of patients was found to be  $37.94 \pm 8.96$  years. However a study by Baloch *et al* from Karachi reported a mean age of  $42.38 \pm 17.39$  years for patients undergoing open thyroidectomy for benign multinodular goiter<sup>2</sup>. On the contrary, a study from Iraq by Al-Aubaidi *et al* revealed that the mean age of patients undergoing total thyroidectomy was  $48 \pm 11$  years<sup>11</sup>.

Our study reported a statistically significant difference in the mean operation time between the LigaSure small jaw group and conventional vascular ligature group ( $p=0.001$ ). The mean operative time in LigaSure small jaw group was  $63.73 \pm 3.67$  minutes while in the conventional vascular ligature group, the mean operation time was  $96.53 \pm 7.96$  minutes. The results of our study

are comparable to the study by Hirunwiwatkul *et al* in 2013 who reported an operative time of  $62.4 \pm 15.9$  minutes in LigaSure group versus  $83.3 \pm 16.1$  minutes with conventional method with a statistically significant difference ( $p < 0.001$ )<sup>12</sup>. Similarly Molnar *et al* reported a reduction in operative time from  $80 \pm 12.4$  minutes when thyroidectomy was performed with the help of LigaSure Small Jaw versus an operative time of  $106 \pm 23.5$  minutes for conventional thyroidectomy ( $p = 0.006$ )<sup>3</sup>. A meta-analysis by Zhang *et al* also reported significant reduction in operative time in Ligasure group versus conventional suture ligation method ( $p < 0.00001$ )<sup>13</sup>. Studies have reported mean operative times ranging from 58 minutes to 115.54 minutes for total thyroidectomy with LigaSure small jaw device<sup>11,14</sup> and mean operative times between 75 to 153.45 minutes for conventional vascular ligature technique<sup>11,15</sup>.

Because of its rich vascular supply, hemostasis during thyroid surgery is of utmost importance<sup>16</sup>. In our study, the intraoperative blood loss was  $42.13 \pm 3.15$  ml in LigaSure small jaw group versus  $73.50 \pm 3.66$  ml in conventional technique group which was statistically significant ( $p = 0.000$ ). This finding of our study is in agreement with the study by Hirunwiwatkul *et al* who reported an intraoperative blood loss of  $40.5 \pm 19.1$  ml with LigaSure versus  $63.3 \pm 22.4$  ml with conventional vascular ligature group respectively. The difference was reported to be statistically significant ( $p = 0.001$ )<sup>12</sup>. Similarly Coiro *et al* from Italy reported a significant reduction in intraoperative blood loss with LigaSure small jaw device ( $p = 0.002$ )<sup>10</sup>. On the contrary, Petrakis *et al* reported that there was no significant difference in the intraoperative blood loss between the two groups ( $p > 0.05$ ). The intraoperative blood loss being  $71 \pm 32$  ml in LigaSure group versus  $76 \pm 37$  ml in conventional group respectively<sup>17</sup>.

The mean postoperative blood loss was also found to be significantly reduced in Ligasure group ( $53.80 \pm 3.17$  ml) versus conventional method ( $63.80 \pm 3.31$  ml) with  $p = 0.000$ . Al Juraibi *et al* also reported similar post-operative blood

loss of  $54.16 \pm 9.21$  ml with LigaSure versus  $66.28 \pm 8.99$  ml with conventional suture ligation technique respectively ( $p < 0.0001$ )<sup>13</sup>. On the contrary, the study by Coiro *et al* reported non-significant post-operative blood loss amongst the two groups ( $p = 0.105$ ). The post-operative blood was  $39.80 \pm 20.50$  ml in LigaSure small jaw group versus  $45.37 \pm 21.37$  ml in conventional technique group<sup>10</sup>. Zhang *et al* in their meta-analysis also reported that the difference in post-operative blood loss between the two groups was found to be statistically significant ( $p = 0.03$ )<sup>13</sup>.

Postoperative hematoma formation after total thyroidectomy can be potentially life threatening due to airway obstruction. Therefore meticulous dissection with careful hemostasis is of utmost importance in these patients<sup>18</sup>. In our study there was only one case of post-operative hematoma formation in the conventional vascular ligation group (2.86%), while none of the patients in the LigaSure group developed hematoma formation ( $p = 0.314$ ). In a study by Khafagy *et al*, hematoma formation occurred in 1 out of 15 patients (6.7%) in conventional group versus none in the LigaSure small jaw group ( $p = 0.098$ )<sup>4</sup>. Similarly the meta-analysis by Zhang *et al* did not report statistically significant difference in hematoma formation between the two groups respectively ( $p = 0.94$ )<sup>13</sup>.

Thyroidectomy with LigaSure small jaw device was reported to be a safe procedure in the hands of young surgeons and trainees without increase in the number of complications<sup>19</sup>. LigaSure small jaw has also been reported to cause reduced thermal damage as compared to other energy based devices like Harmonic focus. LigaSure operates at a temperature of  $< 80^\circ\text{C}$  and quickly cools to  $< 60^\circ\text{C}$  within 1 second<sup>20</sup>. Thus, Total thyroidectomy with LigaSure small jaw device promises to be a safe, effective and quick alternative to the commonly practiced conventional clamp tie or suture ligation group. The limitations of our study are that it comprised mainly of female patients. Since this is the first study on comparison of total thyroidectomy with LigaSure small jaw device versus conventional

method for benign multinodular goiter in the country, further research is required on the topic with bigger sample size with study of short term and long term complications and the cost difference analysis between the two groups.

## CONCLUSION

Total thyroidectomy with LigaSure small jaw device is significantly better when compared with conventional vascular ligature technique in terms of mean operation time, intra-operative and postoperative blood loss.

## CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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