Comparison of outcome of conventional suture ligation versus Ligasure vessel sealing in patients undergoing total thyroidectomy for multinodular goiter.

Ahmed Raza Hameed¹, Ahmed Siddique Ammar², Mishal Saleem³, Hamza Naem⁴, Umar Hameed⁵, Shehr Bano Khattak⁶, Ameer Afzal⁷, Syed Asghar Naqi⁸

ABSTRACT... Objective: To compare the results of Ligasure versus conventional suture ligation for thyroidectomy for multinodular goiter in terms of mean operative time and post-operative drain output volume. Study Design: Comparative Prospective study. Setting: Department of General Surgery, Mayo Hospital Lahore. Period: 1st April 2020 to 31st March 2021. Material & Methods: After approval from the Institutional review board of King Edward medical university, a sample of 140 patients was obtained. Patients were divided into 2 groups, Group A and Group B. Group A patients underwent total thyroidectomy with Ligasure vessel sealing while Group B patients underwent total thyroidectomy with conventional suture ligation. Operative time and post-operative drain volume were measured and documented. The P-value of ≤ 0.05 was considered significant. Results: The average age of the patients was 36.04 ± 9.78 years with minimum and maximum ages being 18 & 61 years respectively. The mean surgery time was 137.80 ± 26.21 minutes in group A while in group B the mean surgery time of the patients was 164.91 ± 31.94 minutes (P-value= <0.001). The mean post-op drain volume in group A was 91.28 ± 7.82 ml, almost similar to group B patients i.e 70.28 ± 4.33 ml (P-value=0.14). Conclusion: Ligasure vessel sealing is significantly better than conventional suture ligation in terms of mean surgery duration but there is no difference in post-operative drain volume in both groups.

Key words: Bleeding, Ligasure, Post-operative, Surgery, Suture, Thyroidectomy.

INTRODUCCIÓN
A diffuse or nodular goiter is an enlargement of the thyroid gland. Iodine deficiency is the most typical cause of goitre in the world. Up to 200 million people who consume an iodine-deficient diet are thought to have goiter.¹ The majority of goiters are benign and just cosmetically disfiguring. Compression of nearby structures, thyroid cancer, hyperthyroidism, or hypothyroidism can all cause morbidity or fatality. 4:1 is the female to male ratio. When people get older, goiters become less common.²

The thyroid gland illnesses that are most prevalent are multinodular goitre (MNG) and thyroid cancer. MNG is caused by the genetic variability of follicular cells and the apparent acquisition of new, inheritable cellular properties. The percentage of MNGs that meet the criteria for malignant transformation ranges from 4 to 17 %.³

Patients with bothersome thyroid masses or goiters may also be a good candidate for thyroidectomy in addition to malignancies. Individuals who experience compressive symptoms from a big goitre, such as dysphagia, dyspnea, shortness of breath, and/or hoarseness, should have a thyroidectomy.⁴ Both thyroidectomy surgical technique and supporting technology kept improving. Recent developments include a number of novel tools (i.e., harmonic technology) and procedures, such as robot- and video-assisted thyroidectomy.⁵ Because the thyroid gland is removed in a wider...
area during a whole thyroidectomy than during a partial thyroidectomy, postoperative problems such as hematoma formation and others have been reported slightly more frequently.\(^6\)

When tying off the numerous vessels to remove the gland, hemostasis is absolutely necessary. The suturing technique is one of the most efficient and classical way to achieve hemostasis. To reduce the possibility of hemorrhage during the procedure, other diathermy techniques have also been developed recently.\(^7\) The revolutionary electrothermal bipolar tissue sealing device (Ligasure) has also been used in a variety of surgical specialties. The Ligasure device needs high current, low voltage bipolar radiofrequency energy in addition to a feedback-controlled response mechanism that automatically provides and interrupts the power depending on the make-up and impedance of the tissue in the space between the instrument’s jaws.\(^8\)

In a study done by Prakash O et al, showed that the mean time of surgery is almost same in Ligasure group and conventional suture-ligation group (44.3 minutes verses 48.1 minutes value= 0.65),\(^9\) while another study done by Spartalis et al showed significant less operating time in Ligasure group is 63.73 ± 3.67 minutes while in suture group was 96.53 ± 7.96 minutes (p= <0.05).\(^10\)

In this study we are going to compare the mean operating time of total thyroidectomy for MNG and total post operative drain output in patients operated with Ligasure vessel sealing device and with conventional suturing techniques.

**MATERIAL & METHODS**

It was a comparative study conducted at Department of General Surgery, Mayo Hospital Lahore. The duration of the study was one year from 1\(^{st}\) April 2020 to 31\(^{st}\) march 2021. Sample size of 140 patients (70 patients in each group) was estimated by using 5% level of significance, 90% power of test with expected mean value Ligasure sealing as 115.54 ± 15.35 minutes and conventional suture ligation as 127.1 ± 7.95 minutes.\(^11\) The formula used was 

\[
n = \frac{Z^2 \times (1 - \alpha/2) \times (P_1 (1 - P_1) + P_2 (1 - P_2))}{d^2}
\]

Where 

\[
Z = \text{confidence level 90%} = 1.6, \quad P_1 = \text{population proportion 1} = 115.54 \pm 15.35 \text{ minutes and } P_2 = \text{population proportion 2} = 127.1 \pm 7.95 \text{ minutes and } d = \text{absolute precision} = 5.
\]

After approval from the Institutional review board of King Edward Medical University (528/ RC/KEMU), the sample was raised using non-convenience probability sampling from among those admitted through the surgical outpatient department (OPD) of MAYO Hospital Lahore. Inclusion criteria include all the patients with age more than 18 years and diagnosed as case of multinodular goiter on ultrasound neck and thyroid scan with euthyroid status. All those patients were excluded from the study who had single thyroid nodule or with enlarged neck lymph nodes or patients unfit for general anesthesia. Informed consent of patients was obtained from all the included patients for this study. Basic demographic information of each patient (name, age, sex) was noted. Patients were divided into 2 groups, Group A and Group B by using lottery method. Group A patients were undergoing total thyroidectomy with Ligasure vessel sealing, while Group B patients was undergoing total thyroidectomy with conventional suture ligation. All thyroidectomies were done by consultant surgeons who had experience of more than 7 years doing thyroidectomies.

After intubation, patients were placed in reverse Trendelenburg posture. Kocher's neck incision was made extending from one sternocleidomastoid muscle to other. Upper and lower flaps were elevated up to thyroid notch and sternal notch. Underlying fascia was dissected vertically in center. Strap muscles were divided vertically in the center using diathermy and retracted outward on both sides. The middle thyroid vein was dissected and ligated using conventional suture ligation in Group B and with Ligasure in Group A. The upper pole was dissected and ligated using conventional suture ligation in Group B and with Ligasure in Group A with careful dissection to prevent the damage of superior laryngeal nerve. The lateral parts were ligated and dissected in the same manner. The Recurrent laryngeal nerve (RLN) was identified and saved. Parathyroid
glands were pinpointed and saved before ligating the vessels. The lower pole was dissected and ligated with conventional suture ligation in group B and Ligasure in Group A. Same procedure was performed to the other lobe. A single Suction drain of 18 French was placed in every surgery. Strap muscles, deep fascia and platysma were stitches with polyglactin 910 2/0. Skin was approximated with polypropylene 5/0.

The outcomes parameters were measured by post-graduate residents who were blinded about group allocation. Intra surgery time was measured in terms of minutes from skin incision till skin closure. Drain volume after surgery was measured and drain was removed when volume below 30ml in 24 hours. Patients were discharged from hospital when hemodynamically stable and drain was removed. All the data was entered and processed by using SPSS 26. Quantitative variables like age, intra-operative time, post-operative drainage, mean hospital stay and pain score was described by using Mean ± S.D. Gender and transient hypocalcemia was described by using frequencies and percentages. Comparison of two groups Ligasure vessel sealing and conventional suture ligation apply independent sample t-test. A p-value of ≤ 0.05 was considered significant.

RESULTS
The total sample size was 140 patients. The average age of the patients was 36.04 ± 9.78 years with minimum and maximum ages were 18 & 61 year respectively. In group A the average age of the patients was 37.17 ± 11.92 years while in group B the average age of the patients was 34.91 ± 9.55 years. In our study 126 (90%) patients were females and 14 (10%) patients were male. Female to male ratio of the patients was 9:1. In group A, 10 (7.14%) patients were male whereas in group B, 4 (2.85%) patients were male. Similarly in group A, 60 (42.8%) patients were females and in group B, 66 (47.14%) patients were females.

In group A the mean surgery time was 137.80 ± 26.21 minutes while in group B the mean surgery time of the patients was 164.91 ± 31.94 minutes. Statistically there is significantly less intra-operative time was found in group A as compared to group B. P-value= <0.001 (Table-I).

In group A the mean post-op drain volume of the patients was 91.28 ± 7.82 ml while in group B the mean intra-operative drain volume of the patients was 70.28 ± 4.33 ml. Statistically there is insignificantly difference was found between the post-op drain volume of both study groups. P-value=0.143 (Table-I).

DISCUSSION
Total thyroidectomy is now the recommended treatment option for all patients with benign MNG on both sides, Graves’ illness, and many thyroid cancer patients. Modern advancements in thyroidectomy procedures have included the use of ultrasonic dissectors such the Harmonic scalpel as well as sealing, ligation, sectioning, and dissection tools like Ligasure Small Jaw. Ligasure Small Jaw has proven to be beneficial by decreasing the amount of time needed for surgery, as well as bleeding afterward. Time-saving surgical techniques are growing in popularity these days because of the rising patient turnover rate and the requirement for less anesthesia duration.

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<tr>
<th>Variables</th>
<th>Study Groups</th>
<th>P-Value</th>
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<tr>
<td></td>
<td>A (Ligasure Sealing Device)</td>
<td>B (Conventional Suturing Technique)</td>
</tr>
<tr>
<td>Intra-operative time (minutes)</td>
<td>N 70</td>
<td>70</td>
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<tr>
<td></td>
<td>Mean 137.80</td>
<td>164.91</td>
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<td></td>
<td>Std. Deviation 26.21</td>
<td>31.94</td>
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<tr>
<td>Post-op Drain Volume (ml)</td>
<td>N 70</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>Mean 91.28</td>
<td>70.28</td>
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<tr>
<td></td>
<td>Std. Deviation 7.82</td>
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Table-I. Comparison of intraoperative time (minute) and post-op drain volume (ml) in both study groups
The mean age of all the sample in our study was 36.04 ± 9.78 years. The average age in the ligasure vascular sealing group was 37.17±11.92 years, while the average age in the conventional technique group was 34.91±9.55 years. In a study conducted by Mund et al, the mean standard deviation age of patients was calculated to be 39.9 ± 11.82 years in group-A and 36.97 ± 9.09 years in group-B.15 Hegab et al found that patients receiving open thyroidectomy for benign multinodular goitre had an average age of 42.38 ± 17.39 years.16 Habash et al found no statistical significance between the two groups in terms of age, gender, or BMI, as well as no surgical mortality.17

In our study 126 (90 %) patients were females and 14 (10 %) patients were male. In ligasure vessel sealing group 10 (7.14 %) patients were male whereas in conventional method group 4 (2.85 %) patients were male. Similarly, in the ligasure vascular sealing group, 60 patients (42.8 %) were females, while in the conventional technique group, 66 patients (47.1 %) were females (p-value=0.428). According to a study by Finnerty et al, there were 98 female patients (89.09 %) and only 12 male patients (10.9 %).18 The female to male ratio was 16.5:1. 5.71 % of patients in group A were male, while 94.29 % were female. Similarly, 5.71 % of patients in group B were men, while 94.29 % were females. Two other studies done by Sarda et al and Mehra et al also showed similar patient’s demography (age, female/male ratio) and thyroid pathology.6,19

In our study ligasure vessel sealing group the mean intra-op time was 137.80 ± 26.21 minutes whereas in conventional method group the mean intra-operative duration of the patients was 164.91 ± 31.94 minutes (P-value < 0.001). A study done by Elhady et al reported that in the average surgery duration was 63.73 ± 3.67 minutes in Ligasure group, while in conventional suturing group, the average surgery duration was 96.53 ± 7.96 minutes. The difference between the two groups in mean operation time was statistically significant (P = 0.001).20 Rashid et al observed a substantial reduction in operational time in the Ligasure group compared to the traditional suture ligation procedure (P < 0.001) in a meta-analysis.8

The results of our study are similar to those of Davies et al. which showed that the surgery duration was 62.4 ± 15.9 minutes in the Ligasure group against 83.3 ± 16.1 minutes in the conventional approach, with a statistically significant difference (P < 0.001).21 Similarly, Akram et al found that when thyroidectomy was conducted using Ligasure Small Jaw, the operational duration was reduced from 106 ± 23.5 minutes to 80 ± 12.4 minutes (P=0.006), compared to 106 ± 23.5 minutes for traditional suturing thyroidectomy.22 Different other studies also have indicated mean operating times for complete thyroidectomy with Ligasure group ranging from 58 minutes to 115.54 minutes, and mean operative durations for conventional vascular ligation approach ranging from 75 to 153.45 minutes.3,4

Ozben et al concluded in their study that Ligasure vessel ligation is a safe approach for thyroid surgery with few problems, similar to our findings. Ligasure enables a much shorter surgery duration for all forms of thyroidectomy. When compared to the suture ligation group, the Ligasure group average surgery duration for thyroidectomy and total thyroidectomy was considerably shorter.13 Metere et al on the other hand, found no decrease in surgery duration time for patients who had total thyroidectomy using the Ligasure.23

Alsaleh et al found no significance in hemorrhage during surgery between the two groups (p 0.05), which is similar to our findings. The post operative drain output in the Ligasure group was 71 ± 32 ml versus 76 ± 37 ml in the traditional suturing group.24 Chen et al also found no significant difference in post-operative hemorrhage between the two groups (P = 0.105). The post-operative hemorrhage in the Ligasure small jaw group was 39.80 ± 20.50 ml against 45.37±21.37 ml in the conventional method group.25 In terms of blood loss Habash et al showed contrary findings to our study. Hemorrhage during surgery was assessed to be 42.13 ± 3.15 ml in Ligasure group and 73.50 ± 3.66 ml in conventional suturing group. There
was a statistically significant difference between the two groups (p=0.001).17

There is certain limitation to this study. First it is single center study with relatively small sample size. More multicenter studies with significant sample size are needed to ascertain a broader picture of less intraoperative time of total thyroidectomy. Secondly the technique of total thyroidectomy is operative dependent and new approaches are inventing which also affects the operative time regardless which ligation method is used during the surgery. Thirdly the study included total thyroidectomy for multinodular goiter only. More studies with use of Ligasure in thyroidectomy done for malignant thyroid surgeries are needed.

CONCLUSION
This study concluded that Ligasure vessel sealing is significantly better than conventional suture ligation in patients with MNG undergoing total thyroidectomy in terms of mean operative time but in terms of mean post-operative drain output there is no statistically difference.

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REFERENCES


### AUTHORSHIP AND CONTRIBUTION DECLARATION

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<th>No.</th>
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