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SAFETY OF LIGASURE IN THYROIDECTOMY IN COMPARISON WITH CONVENTIONAL SUTURE TIE TECHNIQUE

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Abstract

Objectives: *To compare the outcomes of LigaSure versus suture tying in patients undergoing total thyroidectomy.*

Study Design: *Comparative observational study.*

Place and Duration of Study: *"Combined Military Hospital, Lahore from January to July 2024".*

Methodology: *Ninety six patients who underwent total thyroidectomy were divided into LigaSure group and Suture tie group. Outcomes were assessed and compared between groups. SPSS version 20 was used for statistical analysis.*

Results: *Mean age of the patients was 31.72 ± 11.11 years. There were 26 (27.08%) male and 70 (72.92%) female patients. Mean operation time, blood loss during surgery, drain output, drain duration and hospitalization length were significantly shorter in LigaSure group ($p < 0.001$). There was no statistically significant difference between LigaSure and Suture tie group in terms of frequency of complications ($p > 0.05$).*

Conclusion: *Better outcomes are achieved after thyroidectomy with use of LigaSure as compared to traditionally used suture tying technique.*

INTRODUCTION

Thyroidectomy, a surgical procedure for the removal of all or part of the thyroid gland, remains a cornerstone in the management of various thyroid pathologies, including malignancies, multi-nodular goiters and Graves' disease. [1, 2] This procedure can be categorized into total, near-total, subtotal and hemithyroidectomy, depending on the extent of gland removal. Recent advancements in thyroidectomy have emphasized minimally invasive techniques, such as endoscopic and robotic-assisted approaches, which have gained popularity due to reduced postoperative pain, quicker recovery times, and improved cosmetic outcomes. [3] Despite the benefits of thyroidectomy, the choice of surgical technique and extent of resection is controversial and must be individualized, taking into account patient factors such as age, comorbidities and the nature of the thyroid pathology. [4]

Despite the advancements in the surgical approach, a significant consideration in thyroidectomy is the risk of complications which may include transient decrease in the blood calcium levels (hypocalcemia), hoarseness of voice and dysphonia secondary to recurrent laryngeal nerve injury, intra-operative hemorrhage and wound infections. [5, 6] Hypocalcemia primarily occurs either due to iatrogenic damage to the parathyroid glands or secondary to devascularization of the respective gland due to intraoperative hemorrhage. [7] In addition, loss of excessive amount of blood during the surgery can also put a patient's life at risk and adversely impacts the surgical outcome. [8] It is therefore important to take intraoperative measures to reduce the possibility of these complications.

One such method is to adopt better methods to maintain hemostasis since reduction in loss of blood can not only improve operative outcomes but also the frequency of complications. [9] Two such methods of hemostasis are "LigaSure" and "conventional suture tying", however, when it comes to comparison of these two techniques, not much data is available focused on local population and previous studies also exhibit a certain degree of variability. Therefore, to address this research question, present study was conducted with the aim to compare the outcomes of "LigaSure" versus "conventional suture tie" technique in patients undergoing thyroidectomy.

METHODOLOGY

This comparative observational study was conducted at "Combined Military Hospital, Lahore from January to July 2024" after taking approval from institutional ethical review board (IERB #: _____) and obtaining written informed consent from the patients. Sample size was calculated by WHO calculator using following formula:

For calculating appropriate sample size following parameters were used; level of significance at 5%, power at 80%, anticipated mean post-operative calcium levels in "LigaSure group" at 8.62 ± 2.1mg/dl [10] and anticipated mean post-operative calcium levels in "suture tie group" at 7.55 ± 1.6. [10] Calculation gave a sample size of 96 (48 in each group) which was selected using non-probability consecutive sampling technique.

$$n = \frac{2\sigma^2(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

Inclusion criteria: Adult male and female patients aged above 18 years who underwent total thyroidectomy due to any indication were included in the study.

Exclusion criteria: Patients with thyroid malignancy, previous history of thyroid surgery, coagulopathy, radiotherapy to thyroid gland, severe comorbid conditions (like uncontrolled diabetes, hypertension, malignancy, renal failure, liver cirrhosis, uncontrolled asthma, decompensated COPD and heart disease) and recurrent goiter were excluded from the study.

Prior to surgery, small paper sheets were taken on which name of either of the hemostasis and dissection technique was written in equal numbers i.e., "LigaSure" or "suture tie", and were placed in a pot. Just before washing up, while keeping patient blind to the process, a slip was taken out by the operating surgeon and the respective technique was decided to be used during the surgery. Based on this patients were placed in "LigaSure group" or "Suture tie group". Baseline characteristics of all the patients including age, gender, BMI and indication of thyroidectomy were documented. In alignment with the standard protocol at CMH, Lahore, all patients had preoperative evaluations, encompassing essential laboratory examinations including complete blood count, renal and hepatic function tests, and coagulation profile assessment. Furthermore, an electrocardiogram and a chest radiograph were conducted. Patients were thereafter given a detailed explanation of the surgical procedure as well as purpose of research.

The procedures were performed with the patient under general anesthesia, delivered and overseen by a consultant anesthesiologist with at least four years of experience. All procedures were performed by a singular surgical team, directed by a highly experienced senior surgeon with over eight years of competence and executed uniformly to mitigate any impact on the outcome. Standard surgical protocols of thyroidectomy were followed in all the patients. The only difference was of hemostasis and dissection technique. In "LigaSure group" (n = 48), this was performed using "LigaSure" while in "Suture tie

group (n = 48)", this was performed using conventional technique of tying suture.

Intra-operative parameters including operative time and blood loss (by sponge weighing technique) was documented. Post-surgery, a closed suction drain was placed at the surgical site and the neck wound was sutured using a standard two-layer technique. The patient was subsequently transferred to the surgical intensive care ward, where drain output monitoring was conducted, and all patients received an identical post- operative care package in accordance with hospital procedure to mitigate any impact on outcomes. Drain was kept in place till the drain output reduced to < 1ml/h/24 hours. Total drain output and duration of drain was documented. Once drain was removed, patient was discharged to home and length of hospitalization was documented. During hospitalization, patients were assessed for presence of any surgical complication and occurrence of any complication was documented and managed as per standard protocols.

Statistical analysis of the collected data was performed using Statistical Package for Social Sciences (SPSS) software version 20. Shapiro-Wilk test was utilized to ascertain data normality. All quantitative variables were normally distributed and were represented using mean ± standard deviation (SD). Qualitative data was represented using frequency and percentage. To compare quantitative outcome variables, Student t-test was used while for comparing qualitative variables, Chi-square test was used. A p-value of ≤ 0.05 will be taken as statistically significant.

RESULTS

Mean age of the patients was 31.72 ± 11.11 years. There were 26 (27.08%) male and 70 (72.92%) female patients. Mean BMI was 26.06 ± 5.27 kg/m2. Most common indication for thyroidectomy was Graves disease 55 (57.29%) followed by multi-nodular goiter 33 (34.38%), hot nodule 4 (4.17%) and retrosternal goiter 4 (4.17%). Comparison of baseline characteristics of the patients between groups is given below in Table-I:

Table-I: Comparison of baseline characteristics of the patients between groups (n = 96)

Parameter	LigaSure Group (n = 48)	Suture tie Group (n = 48)	p-value
Mean age	31.52 ±11.63 years	31.93 ± 10.67 years	0.855
Gender			
Male	15 (31.25%)	11 (22.92%)	0.358
Female	33 (68.75%)	37 (77.08%)	
Mean BMI	26.99 ± 5.54 kg/m2	25.12 ± 4.85 kg/m2	0.081
Thyroidectomy indication			
Graves disease	28 (58.33%)	27 (56.25%)	
Multi-nodular goiter	16 (33.33%)	17 (35.41%)	0.562
Hot nodule	3 (6.26%)	1 (2.08%)	
Retrosternal goiter	1 (2.08%)	3 (6.26%)	

Mean operation time in "LigaSure group" was 96.45 ± 5.37 minutes while in "Suture tie group" it was 116.95 ± 10.52 minutes (p < 0.001). Mean blood loss during surgery in "LigaSure group" was 57.89 ± 12.22 ml while in "Suture tie group" it was 118.43 ± 14.52 ml (p < 0.001). Mean drain output in "LigaSure group" was 42.41 ± 8.44 ml while in "Suture tie group" it was 68.87 ± 8.74 ml (p < 0.001). Mean drain duration in "LigaSure group" was 2.16 ± 0.55 days while in "Suture tie group" it was 3.97 ± 0.81 days (p < 0.001). Mean hospitalization length in "LigaSure group" was 2.95 ± 0.71 days while in "Suture tie group" it was 4.58 ± 0.91 days (p < 0.001). Comparison of these intra- and immediate post-operative outcomes between groups is given below in Table-II:

Table-II: Comparison of intra- and immediate post-operative outcomes between groups (n = 96)

Parameter	LigaSure Group (n = 48)	Suture tie Group (n = 48)	p-value
Mean operation time	96.45 ± 5.37 minutes	116.95 ± 10.52 minutes	< 0.001
Mean blood loss	57.89 ± 12.22 ml	118.43 ± 14.52 ml	< 0.001
Mean drain output	42.41 ± 8.44 ml	68.87 ± 8.74 ml	< 0.001
Mean drain duration	2.16 ± 0.55 days	3.97 ± 0.81 days	< 0.001
Mean hospitalization length	2.95 ± 0.71 days	4.58 ± 0.91 days	< 0.001

In terms of frequency of post-operative complications, in "Ligasure group" (n = 48), hematoma occurred in 0 (0.00%), transient hypocalcemia in 3 (6.25%), transient palsy of recurrent laryngeal nerve in 7 (14.58%) and wound infection in 2 (4.17%) patients while in "Suture tie group" (n = 48), hematoma occurred in 2 (4.17%); (p = 0.153), transient hypocalcemia in 2 (4.17%); (p = 0.646), transient palsy of recurrent laryngeal nerve in 2 (4.17%); (p = 0.080) and wound infection in 3 (6.25%) patients (p = 0.646). Comparison of post-operative complications between groups is given below in Table-III:

Table-III: Comparison of post-operative complications between groups (n = 96)

Outcome	LigaSure Group (n = 48)	Suture tie Group (n = 48)	p-value
Hematoma	0 (0.00%)	2 (4.17%)	0.153
Transient hypocalcemia	3 (6.25%)	2 (4.17%)	0.646
Transient palsy of recurrent laryngeal nerve	7 (14.58%)	2 (4.17%)	0.080
Wound infection	2 (4.17%)	3 (6.25%)	0.646

DISCUSSION

Hyper-functioning of thyroid gland poses various adverse effects on different organ system of the body, particularly the heart, for which it is essential to effectively manage the hormone levels to avoid complication related to these adverse effects. [11, 12] Primary management of overactive thyroid involves medical intervention through drugs that reduce either production or the activation of thyroid hormone. [13, 14] However, in certain cases, surgical removal of thyroid gland is warranted for its effective management. [15] Present study focused on an important aspect of this surgical procedure which is comparison of the outcomes of "LigaSure" versus "Suture tying" in patients undergoing total thyroidectomy.

In present study, most patient who underwent thyroidectomy due to any pathological condition of thyroid gland were females which can be explained by the general trend of female predominance for having thyroidal illness. [16, 17] In terms of intra-operative parameters, it was observed that use of "LigaSure" significantly reduced not only the operation time (p < 0.001) but also the total volume of blood being lost during the surgery (p < 0.001). These finding were in coherence with the results being reported by Ahmed et al. [18] and Youssef et al. [19] both of which reported a statistically significant reduction in the time of surgery as well as volume of blood being lost during surgery. Contrary to this, Ramouz et al. [20] reported significantly lesser blood loss with "conventional suture tying" as compared to "LigaSure" (p = 0.04) which was opposite to the findings of present study.

In terms of outcomes related to immediate post-operative care, it was observed that use of "LigaSure" significantly reduced both the total output being collected in the drain (p < 0.001) but also helped in significantly reducing the duration for which it was necessary to keep the drain in place after surgery (p < 0.001). Both Bhettani et al. [10] and Ahmed et al. [18] reported findings similar to the results of present study in this regard. Similarly, the hospitalization length was also significantly shortened by the use of "LigaSure" during thyroidectomy (p < 0.001) which can be explained by earlier removal of drain with its use which is a major reason for stay at the hospital after the surgery.

In terms of complications, it was observed that there was no major impact of the use of "LigaSure" as compared to "conventional suture tying" on the frequency of various thyroidectomy related complications including hematoma (p = 0.153), transient hypocalcemia (p = 0.646), transient palsy of recurrent laryngeal nerve (p = 0.080) and wound infection (p = 0.646). As compare to this, Bhettani et al. [10] reported that "LigaSure" was associated with significantly less frequency of transient hypocalcemia as compared to "suture tie" while in case of other complication there was no significant difference between these two techniques. Similarly, Liu et al. [21] also reported that both hematoma and transient hypocalcemia frequency was significantly lowered by the use of "LigaSure" as compared to conventional techniques which was not congruent with the findings of present study. Contrary to most studies and the present research, Ramouz et al. [20] reported that the frequency of transient hypocalcemia was significantly higher in "LigaSure grouo" as compared to "suture tie technique".

Results of present study strongly favor the preferential use of "LigaSure" as a mean of performing dissection and maintain hemostasis during thyroidectomy over conventionally used techniques since it not only reduces the operative time and hospitalization length but also is quite safe in terms of complication rates. Limitations of present study include limited sample size, non-inclusion of malignancy cases and shorter follow up period.

CONCLUSION

In conclusion, LigaSure provides significantly better outcomes as compared to conventional suture tie technique in patients undergoing thyroidectomy.

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CONFLICT OF INTEREST

None.

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