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Original Article

Incidence of Recurrent Laryngeal Nerve Injury While Using LigaSure in Total Thyroidectomy as Compared to Conventional Knot Tying

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ABSTRACT

Recurrent laryngeal nerve (RLN) injury is a recognized complication of thyroid surgery. Although LigaSure enables faster vessel sealing, concerns remain about thermal injury to the RLN. As local randomized evidence is limited, this trial compared LigaSure with conventional knot tying to assess the risk of RLN injury. **Objective:** To compare the incidence of recurrent laryngeal nerve (RLN) injury between LigaSure and conventional knot tying in patients undergoing total thyroidectomy. **Methods:** This randomized controlled trial was conducted at Gulab Devi Hospital, Lahore, from July 2025 to March 2026, including 120 patients undergoing total thyroidectomy who were consecutively enrolled and randomly allocated, with allocation concealment, to Group A (conventional knot tying, n=60) or Group B (LigaSure, n=60). RLN injury was assessed postoperatively by clinical examination and laryngoscopy over 6 months of follow-up. Fisher's Exact Test was used for comparison, with statistical significance defined as $p<0.05$. **Results:** The mean age was 36.29 ± 7.63 years, and 75% of patients were female. Multinodular goitre was the most common indication (60%). RLN injury occurred in 1 patient (1.7%) in the conventional group, and 2 patients (3.3%) in the LigaSure group; the overall rate was 2.5%. All injuries were unilateral and temporary, resolving within follow-up, and the difference between groups was not statistically significant ($p=1.000$). The risk ratio for RLN injury (LigaSure vs conventional) was 2.0 (95% CI 0.2–21.5). **Conclusions:** Only three RLN injury events occurred, with no significant difference between LigaSure and conventional knot tying during total thyroidectomy.

INTRODUCTION

The thyroid gland is an endocrine gland located at the lower anterior neck, near the larynx, trachea, oesophagus, and major neurovascular structures [1]. Thyroid surgery requires careful dissection and maintains close hemostasis due to the abundant blood supply and close anatomical proximity to vital nerves. Total thyroidectomy is mainly done for conditions like multinodular goitre, Graves' disease, and thyroid malignancy [2, 3]. Although it is performed routinely, it presents certain risks, the most notable being injury to the recurrent laryngeal nerve (RLN) and postoperative hypocalcaemia [4, 5]. One of the branches of the vagus nerve is the recurrent laryngeal nerve, which runs through the tracheoesophageal groove and is in close anatomical relation with the inferior thyroid artery and enters the larynx. This anatomical proximity makes the nerve particularly vulnerable, especially when thyroid vessels are ligated and divided. Damage to the RLN may lead to hoarseness of voice, a paralyzed vocal cord, aspiration and, in bilateral injuries, airway obstruction, which is life-threatening [6, 7]. Even a temporary nerve injury can significantly reduce a patient's quality of life, pressing the importance of preventing it as a central goal of

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thyroid surgery. Postoperative hypocalcaemia results from inadvertent injury to or devascularization of the parathyroid glands during dissection. The standard method of vessel control has traditionally been manual knot-tying with suture ligation, commonly combined with bipolar cautery [8, 9]. Energy-based vessel-sealing devices, such as LigaSure, have been introduced in recent years. LigaSure is a bipolar electrosurgical system that closes vessels with a maximum diameter of 7mm by denaturing collagen and elastin in the vessel wall, providing fast and adequate hemostasis with minimal lateral thermal dispersion [9-11]. However, concerns have been raised about thermal damage to the surrounding structures, especially the recurrent laryngeal nerve. Experimental data suggest LigaSure produces a lateral thermal spread of only about 1–2 mm, which is generally regarded as a safe margin from the nerve [5].

The rationale for the current research is to provide a focused comparison between the LigaSure vessel-sealing system and the traditional knot-tying system in total thyroidectomy, particularly regarding the incidence of RLN injury. Since the vital nerves are close to the thyroid vessels, it is necessary to determine whether newer energy-based devices are as effective as traditional ones. Production of local evidence for this comparison will optimize patient safety and outcomes in thyroid surgery by informing surgical decision-making. Local randomized evidence comparing these techniques remains scarce; therefore, this study aimed to compare the incidence of recurrent laryngeal nerve injury between LigaSure and conventional knot-tying during total thyroidectomy.

METHODS

This randomized controlled trial was conducted at Surgical Unit 1 of the Gulab Devi Hospital, Lahore, between July 2025 and March 2026, following approval from the Ethical Committee (reference no. AAMC/IRB/EA-24/2025, dated 7th July 2025) and CPSP Approval No: CPSP/REU/SGR-2021-061-13417, dated 30th March 2025. The trial is registered at ClinicalTrials.gov under reference NCT07522983. Sample size was calculated using the standard two-proportion formula: n per group = $[(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \{p_1(1 - p_1) + p_2(1 - p_2)\}] / (p_1 - p_2)^2$, where $\alpha = 0.05$ (two-sided), power = 80% ($\beta = 0.20$), $Z_{1-\alpha/2} = 1.96$, $Z_{1-\beta} = 0.8416$, and the expected incidence of RLN injury was taken as $p_1 = 16.3\%$ for LigaSure and $p_2 = 0.3\%$ for conventional vessel ligation based on Pacilli *et al.* [5]; this yielded approximately 43 patients per group (86 total), and after allowing for 20% attrition, 43 / 0.80 ≈ 54 patients per group were required, so 60 patients per group (120 total) were enrolled to ensure adequate power and permit possible loss to follow-up; however, because the observed event rates were much lower (1.7% vs 3.3%), the study was underpowered to detect smaller but clinically relevant differences, as acknowledged in the limitations. Adults aged between 18 and 60 years of either gender who were undergoing a total thyroidectomy surgery, with normal pre-operative results on indirect laryngoscopy, and no history of prior hoarseness were included. Patients who needed to undergo reoperation (even parathyroidectomy), patients who had undergone concurrent cervical lymphadenectomy/neck irradiation, and patients with a previous history of surgery on the neck or irradiation of the neck were excluded. This study shows the CONSORT flow diagram (Figure 1).

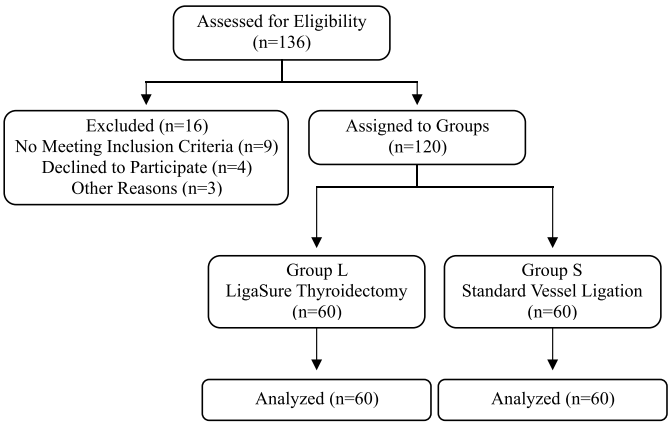


Figure 1: CONSORT Flow Diagram

Informed written consent was obtained from all subjects by the researcher before enrolment. Treatment groups were assigned randomly using computer-generated randomization. Group A included patients who had undergone total thyroidectomy and had conventional knot-tying used to achieve hemostasis and seal the vessels. Group B included patients who had undergone the same procedure but used LigaSure to seal vessels. Patients were closely observed by the investigators for clinical signs of RLN injury and for postoperative vocal changes (hoarseness, breathlessness, or vocal fatigue) during hospitalization, as defined by postoperative vocal changes diagnosed during inpatient care and verified by indirect laryngoscopy. Allocation used a computer-generated random sequence concealed in sequentially numbered, opaque, sealed envelopes opened only after enrolment, resulting in a balanced 1:1 allocation. LigaSure sealing was performed using the LigaSure Small Jaw device (LF1212, Medtronic/Covidien, USA) with the manufacturer's preset energy algorithm, maintaining a safety distance of 2–3 mm from the recurrent laryngeal nerve. In every case, the recurrent laryngeal nerve was routinely identified visually and preserved before vessel sealing or ligation. Laryngeal assessment used an indirect mirror and flexible fibre-optic laryngoscopy performed by an otolaryngologist on the first postoperative day and at discharge, with review at 6 weeks

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and 6 months for any persistent deficit. Temporary RLN injury was defined as recovery of vocal-cord function within 6 months, and permanent injury as a deficit persisting beyond 6 months.

SPSS version 27.0 was used to analyze data. The Shapiro-Wilk test was applied to assess the normality of the numerical data. Age (W = 0.981, p=0.080) and BMI (W = 0.994, p=0.861) were approximately normally distributed. The chi-square test / Fisher's exact test was used to assess the incidence of RLN injury between the two groups. Statistical significance was evaluated using a p-value of <0.050. The Fisher-Freeman-Halton exact test was used to compare RLN injury across the three surgical indications.

RESULTS

The mean (SD) age of the 120 patients was 36.29 (7.63) years, with a range of 20 to 52 years. The mean body mass index (BMI) was 23.74 ± 2.66 kg/m^2. A total of 90 (75.0%) patients were females, and 30 (25.0%) were males. Multinodular goitre was the most frequent indication for total thyroidectomy, reported in 72 (60%) of cases; Graves' disease, in 30 (25%); and solitary thyroid nodule, in 18 (15%). Total thyroidectomy was undertaken for solitary thyroid nodules only when cytology was indeterminate or suspicious (Bethesda III–V) or when compressive symptoms warranted complete excision. Final histopathology confirmed benign disease in all 120 patients; no malignancy was identified, and no patient was excluded from the analysis on histological grounds (Table 1).

Table 1: Baseline Characteristics of Patients

Variables	Conventional (n = 60)	LigaSure (n = 60)	Total (n = 120)
Age (years), Mean ± SD	35.20 ± 7.14	37.38 ± 8.01	36.29 ± 7.63
BMI (kg/m^2), Mean ± SD	24.00 ± 2.92	23.48 ± 2.36	23.74 ± 2.66
Gender, n (%)			
Female	43 (71.67%)	47 (78.33%)	90 (75.0%)
Male	17 (28.33%)	13 (21.67%)	30 (25.0%)
Surgical Indication, n (%)			
Multinodular Goitre	38 (63.3%)	34 (56.7%)	72 (60.0%)
Graves' Disease	12 (20.0%)	18 (30.0%)	30 (25.0%)
Solitary Thyroid Nodule	10 (16.7%)	8 (13.3%)	18 (15.0%)
Final Histopathology, n (%)			
Benign	60 (100%)	60 (100%)	120 (100%)
Malignant	0 (0%)	0 (0%)	0 (0%)

This study shows the distribution of recurrent laryngeal nerve injuries by surgical technique. In general, 3 out of 120 patients (2.5%) had RLN injury. One (1.7%) patient in the traditional knot-tying group and two (3.3%) patients in the LigaSure group had RLN injury. The injuries were all unilateral and temporary (one on the right side and two on the left side), and there was no bilateral RLN injury. Fisher's Exact Test was used to compare the rates of RLN injury in conventional knot tying and LigaSure, and the p-value was 1.000. Postoperative hoarseness was observed in all patients who had RLN injury. In all three cases, indirect laryngoscopy showed a paramedian (paralyzed) vocal cord. None of the patients had stridor or had to be intubated. All three injuries were temporary, with vocal cord function recovering within the 6-month follow-up period; none were classified as permanent. The risk ratio for RLN injury (LigaSure vs conventional) was 2.0 (95% CI 0.2–21.5). All three injuries occurred in patients operated for multinodular goitre (3/72, 4.2%); no injury occurred in Graves' disease (0/30) or solitary thyroid nodule (0/18), and the difference across indications was not significant (Fisher-Freeman-Halton exact test, p=0.727). Within the multinodular goitre group, injury was recorded in 1 of 38 patients (2.6%) after conventional knot tying and in 2 of 34 patients (5.9%) after LigaSure (p=0.599) (Table 2).

Table 2: Incidence of Recurrent Laryngeal Nerve (RLN) Injury by Surgical Group

Outcomes	Conventional (n=60), n (%)	LigaSure (n=60), n (%)	Total (n= 120), n (%)	p-value
RLN Injury – Yes	1 (1.7%)	2 (3.3%)	3 (2.5%)	1.000
RLN Injury – No	59 (98.3%)	58 (96.7%)	117 (97.5%)	
Side of Injury – Right	1 (1.7%)	0 (0.0%)	1 (0.8%)	0.496
Side of Injury – Left	0 (0.0%)	2 (3.3%)	2 (1.7%)	
Bilateral Injury	None	None	None	

All RLN injuries were temporary and unilateral, resolving within the 6-month follow-up; none were permanent)

This results in a stratified analysis of RLN injury by age, gender, and BMI. In female patients, RLN injury occurred in 1 of 43 patients (2.32% of females in that group) with conventional knot tying and in 2 of 47 patients (4.25% of females in that group) with LigaSure. Male patients had no RLN injury. Patients were aged 18-30 years (0/18 in conventional knot tying vs 1/11 in LigaSure) and 31-45 years (1/38 vs 1/41). There was no RLN injury among patients aged 46-60 years. BMI stratification indicated that the normal-weight group (0/38 in conventional knot tying vs 1/43 in LigaSure) and the overweight group (1/19 vs 1/17) had injuries. There were no injuries in patients with underweight and obesity. Because only three events occurred, this stratified analysis is exploratory, and BMI was not an independent risk factor for RLN injury (Table 3).

Table 3: Post-Stratification Analysis of RLN Injury by Age Category, Gender, and BMI Category Using Fisher's Exact Test

Stratifying Variables	N	Conventional – Injury, n (%)	LigaSure – Injury, n (%)	p-value
Age Category				
18–30 Years	29	0/18 (0.0%)	1/11 (9.1%)	0.379
31–45 Years	79	1/38 (2.6%)	1/41 (2.4%)	1.000
46–60 Years	12	0/4 (0.0%)	0/8 (0.0%)	1.000
Gender				
Female	90	1/43 (2.32%)	2/47 (4.25%)	0.61
Male	30	0/17 (0.0%)	0/13 (0.0%)	1.000

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BMI Category				
Underweight (<18.5)	2	0/2 (0.0%)	0/0 (N/A)	1.000
Normal Weight (18.5–24.9)	81	0/38 (0.0%)	1/43 (2.3%)	1.000
Overweight (25.0–29.9)	36	1/19 (5.3%)	1/17 (5.9%)	1.000
Obese (≥30.0)	1	0/1 (0.0%)	0/0 (N/A)	1.000

DISCUSSION

This study compared recurrent laryngeal nerve (RLN) injuries between LigaSure and standard knot-tying in 120 patients undergoing total thyroidectomy. The total RLN injury rate was 2.5% (1.7% with conventional and 3.3% with LigaSure). This difference was not significant (p=1.000). The injuries were all unilateral, and none of the patients had bilateral nerve damage, stridor, or intubation. These results are within the range of incidences reported in the literature, typically 1-7%, depending on the clinical setting and surgical factors [12, 13]. Al-Hakami and Al Garni conducted a retrospective study of 1,368 thyroidectomy patients and found that the overall RLN injury rate was 3.4%, with presentations ranging from airway obstruction to hoarseness, depending on the side and extent of injury [12]. The finding of no significant differences in RLN injury rates between the two techniques is strongly supported by current evidence on energy-based devices. In their systematic review of 43 studies (17,953 patients), Spartalis *et al.* found that 40 studies reported no significant difference in the incidence of RLN palsy between energy-based and conventional hemostatic methods [14]. Two studies in that review favored LigaSure and Harmonic Scalpel, while one favored conventional hemostasis, so the pooled evidence points to no consistent difference. In their study, which used data on 13,961 thyroidectomy cases in the National Surgical Quality Improvement Program (NSQIP) database, Best e*t al.* did not observe any notable difference in the postoperative RLN injury between alternate cautery sources, such as LigaSure and traditional cautery, which led them to the conclusion that the risk of RLN injury cannot be considered the determining factor when choosing a hemostatic device [8]. In their comparative thyroidectomy studies, El Hoseiny *et al.* and Cheema *et al.* also did not find any significant increase in RLN injury by LigaSure [3, 15]. One theoretical concern with energy-based vessel-sealing devices is the potential for lateral thermal diffusion during vessel sealing, which may harm nearby structures, such as the RLN. LigaSure uses bipolar electrical energy to induce hemostasis by denaturing collagen and elastin in the vessel walls. Unwanted contact between the device and the nerve during activation can transfer heat to surrounding tissue, resulting in thermal damage [5]. Farid *et al.* characterized LigaSure Small Jaw as a bipolar diathermy tool specifically used to cut vessels with minimal heat transfer to surrounding tissue, and their comparative study indicated acceptable RLN results with the tool [9]. A study by Kadhim and Ibrahim, analyzing the records of 81 patients who underwent total thyroidectomy, found that the device did not increase the risk of RLN injury compared with suture ligation, provided that proper dissection principles were observed [16]. The beneficial impact of LigaSure on hemostasis during surgery and on procedural efficiency is among the most well-known benefits compared with traditional methods. In a prospective controlled study conducted on 104 patients, Habash *et al.* found significantly less intraoperative blood loss (49.64 ± 19.24 ml vs. 74.42 ± 20.72 ml; p=0.000), less postoperative blood loss (p<0.001), and fewer days in the hospital (1.19 ± 0.47 days vs. 1.52 ± 0.852 days; p=0.018) [11]. In a register-based study of 3,346 thyroidectomies, Grøndal *et al.* reported only small reductions in operating time and intraoperative blood loss with the LigaSure Small Jaw, together with a lower rate of postoperative haemorrhage, compared with the conventional technique [17]. In a randomized controlled study, Hameed *et al.* demonstrated better bleeding control and lower complication rates with LigaSure than with conventional vessel ligation [18]. Across these reports, the operative benefit of LigaSure is consistent in direction but modest and variable in size. The current study, however, did not measure blood loss and hospital stay. The contribution of surgical methods to the prevention of RLN injury is clearly established and applies to both traditional and energy-based methods. Liang and Scharpf concluded that exposing the nerve through careful dissection remains the safest way to lower the risk of injury, with intraoperative neuromonitoring used as an adjunct [19]. Głód *et al.* in an analysis of 1,500 nerves at risk, reported that goitre volume, retrosternal extension, malignancy, male sex and repeat surgery, together with the operating surgeon's experience, were significant determinants of postoperative vocal cord paralysis [20]. The current study included a single surgical team performing all procedures under the guidance of two experienced surgeons, which may have contributed to the low and similar RLN injury rates in both groups. In all cases, routine visual identification of the RLN was performed, which is the most important and most credible protective measure against iatrogenic nerve damage during thyroidectomy. RLN injury is multifactorial. Gland size, the underlying disease, extent of resection, anatomical variation of the nerve, traction, thermal spread, and the surgeon's experience all contribute, so the sealing device is only one of several factors that determine the risk. The established epidemiology of thyroid disease and the most frequent surgical indications of this disease are demonstrated by the female predominance (75%) and high proportion of multinodular goitre in our study (60%). The three RLN injuries in the study were all unilateral, and none

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of the patient's required intubation or emergency airway management, indicating that both methods have a clinically acceptable risk of nerve injury in the context of routine total thyroidectomy. All three injuries were temporary and recovered fully, a pattern consistent with neurapraxia rather than structural nerve damage. Obata et al. reported that transient vocal cord paralysis after thyroid surgery recovered at a mean of 2.8 months after minor nerve injury and 4.5 months after major nerve injury, a course similar to that seen in the current patients [21]. In this trial, the RLN injury rate with LigaSure was not significantly different from conventional knot tying, but with only three events, the result is inconclusive rather than evidence of equal safety.

There are certain limitations of the study. The sample size was calculated using a two-proportion formula, assuming a large between-group difference in RLN injury rates. Given the low overall incidence, the study may be underpowered to detect smaller, more clinically realistic differences. The observed rates (1.7% vs 3.3%) were far lower than the assumed values. The wide confidence interval around the risk ratio (2.0, 95% CI 0.2–21.5) reflects this imprecision and the study's limited power to detect a true between-group difference. Follow-up extended to 6 months postoperatively; nonetheless, late or subclinical RLN dysfunction beyond this period might not have been captured. Intraoperative neuromonitoring was not used, which may have reduced the method's sensitivity in identifying subclinical nerve dysfunction. Patient- and surgeon-related risk factors were not assessed. Factors such as goitre size, retrosternal extension, thyroiditis, malignancy, and nerve anatomy were not recorded, and all surgeries were performed by a single experienced team at one centre, limiting adjustment for these variables and the generalizability of the findings. To provide more definite evidence, larger trials that include intraoperative neuromonitoring and more postoperative follow-up are required. Future adequately powered multicenter randomized trials with standardized intraoperative neuromonitoring and at least 6–12 months of follow-up are recommended.

CONCLUSIONS

LigaSure showed no significant difference in recurrent laryngeal nerve injury compared with conventional knot tying during total thyroidectomy, with only three unilateral, temporary injuries observed. However, the small number of events limited the study's power to demonstrate equivalent safety, and other perioperative outcomes were not assessed. Larger, adequately powered studies with longer follow-up are needed to confirm these findings.

Authors' Contribution

Conceptualization: MWZB
Methodology: MWZB, UAR, MM
Formal analysis: MS, MM
Writing and Drafting: MWZB, UAR, MS, MA, MM
Review and Editing: MWZB, UAR, MS, MA, MM

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

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