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COMPARISON OF POST OPERATIVE HYPOCALCEMIA BETWEEN LIGASURE® AND CLAMP-AND-TIE HEMOSTATIC TECHNIQUE IN TOTAL THYROIDECTOMIES

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Abstract

Background: *Thyroid disorders are among the most common endocrine conditions worldwide, with a significant prevalence in Pakistan. Thyroidectomy, a frequently performed surgical procedure, requires meticulous hemostasis due to the gland's rich vascular supply and proximity to critical structures. This randomized study compares the incidence of post-operative hypocalcemia in total thyroidectomy patients undergoing the LigaSure technique versus the conventional clamp-and-tie method.*

Materials and Methods: *This randomized controlled trial compared the LigaSure technique with the conventional clamp-and-tie method in total thyroidectomy patients to assess postoperative hypocalcemia. Conducted at the Federal Government Polyclinic Hospital, Islamabad, from January to December 2024, 100 patients were enrolled and randomly assigned to either technique. Surgical outcomes, including operative time and calcium levels, were analyzed using SPSS version 23.0, with statistical significance set at $p \leq 0.05$.*

Results: *This study included 100 total thyroidectomy patients, with 50 in the Conventional Clamp-and-Tie group and 50 in the LigaSure group. The LigaSure technique significantly reduced operative time ($p < 0.001$) and postoperative hypocalcemia incidence ($p = 0.038$). Binary logistic regression confirmed a lower risk of hypocalcemia with LigaSure (OR 3.173, $p = 0.048$), independent of other factors.*

Conclusion: *The LigaSure vessel-sealing system significantly reduces operative time and postoperative hypocalcemia compared to the conventional clamp-and-tie technique in total thyroidectomy, demonstrating its superiority in surgical outcomes.*

INTRODUCTION

Thyroid issues are among the most prevalent endocrine disorders worldwide.[1] In Pakistan, where around 20 million people reside in areas with a high incidence of such problems, the risk of developing thyroid disorders is particularly high. According to the American Thyroid Association, approximately 150,000 individuals in the United States undergo

thyroidectomy each year for benign or malignant conditions.[2,3]

Thyroidectomy is a frequently performed surgical procedure in the field of head and neck surgery worldwide. Given the thyroid gland's abundant arterial and venous supply, as well as its proximity to critical structures such as the carotid artery, jugular vein, and recurrent laryngeal nerve (RLN), achieving prompt and effective hemostasis during thyroid surgery is of utmost importance.[4,5]Achieving effective hemostasis during thyroid surgery is essential in preventing both intraoperative and post-operative blood loss.[6] Intraoperative bleeding can obscure the surgical field and increase the likelihood of damaging delicate structures such as the recurrent laryngeal nerve (RLN) and parathyroid glands, leading to complications such as RLN palsy and hypocalcemia. The most severe complication associated with thyroidectomy is post-operative hemorrhage, which can be life-threatening due to the potential for airway obstruction.[7,8] The literature reports complication rates ranging from 50% to 80%, with a fatality rate of up to 20%.[9]

In the early 1900s, Kocher introduced a novel technique for achieving hemostasis during surgery involving the use of suture ligation to clamp and tie off blood vessels.[2] However, this approach can be time-consuming and requires significant skill to apply sutures accurately. In recent decades, a range of advanced energizing devices for vessel ligation have been developed. One such device is LigaSure® (Covidien, Boulder, CO, USA), which utilizes energy-based technology to rapidly seal vessels up to 7 mm in diameter, allowing for efficient dissection, ligation, and cutting.[10]

This randomized study seeks to address a gap in the existing literature by comparing the incidence of post-operative hypocalcemia in total thyroidectomy patients undergoing two distinct surgical techniques: the LigaSure method and the conventional clamp and tie technique. The study's findings will provide valuable insights into the efficacy of these two methods in reducing the incidence of post-operative hypocalcemia. This information may be used to inform clinical practice and potentially enhance patient outcomes.

MATERIALS AND METHODS:

This randomized controlled trial was conducted in the Department of General Surgery at the Federal Government Polyclinic Hospital, Islamabad, from January 2024 to December 2024 following the approval from the institutional ethical committee. A total of 100 patients were included in the study. The sample size was determined using the WHO-recommended sample size calculator. A non-probability consecutive sampling technique was used for patient selection. Patients aged 15 to 65 years, diagnosed with multinodular goiter, retrosternal goiter, thyroid cancer, or other indications for total thyroidectomy, were included in the study. Patients with a history of previous neck surgery, requiring a repeat thyroidectomy, those taking calcium supplements with underlying parathyroid disease, and those with contraindications for general anesthesia were excluded.

Patients meeting the inclusion criteria were enrolled, and informed consent was obtained. Demographic information, including name, age, gender, BMI and address, was recorded while ensuring confidentiality. The participants were then randomly allocated into two groups: Group A, undergoing the clamp-and-tie technique, and Group B, undergoing the LigaSure technique. A comprehensive preoperative evaluation, including history-taking, physical examination, laboratory investigations such as thyroid profile and serum calcium concentration measurements, and neck ultrasonography, was performed. Fine needle aspiration cytology (FNAC) was conducted if indicated. All patients were medically optimized to achieve a euthyroid state before surgery.

The surgical procedure was carried out by the same surgical team using a standardized approach to thyroid gland dissection. This involved dissection of the superior thyroid pole, followed by the lateral thyroid lobe, with meticulous care to preserve the blood supply to the parathyroid glands and identify and protect the recurrent laryngeal nerves. In Group A, the clamp-and-tie technique was employed, where branches of major vessels were ligated using Vicryl 2.0 sutures as distally as possible. In Group B, LigaSure was utilized along the thyroid capsule at the distal ends of vessel branches to achieve hemostasis without requiring suture ligation. A single Redivac suction drain was placed in all patients postoperatively and

was removed once the drain output was less than 20 mL in 24 hours. The perioperative management remained identical for both groups, except for the hemostatic technique used. Data collection included the duration of surgery in minutes and preoperative and postoperative calcium levels, all of which were recorded in a structured proforma.

Statistical analysis was performed using SPSS version 23.0. Quantitative variables, including patient age, surgery duration, and serum calcium concentrations, were expressed as mean ± standard deviation. The independent t-test was applied to compare the means of these variables, and the Shapiro-Wilk test was used to assess the normality of data distribution. A binary logistic regression was applied for predicting hypocalcemia. A p-value of ≤0.05 was considered statistically significant, and all statistical tests were conducted with a 95% confidence level.

RESULTS:

A total of 100 patients who underwent total thyroidectomy were included in this study, with 50 patients assigned to the Conventional Clamp-and-Tie group and 50 to the Ligasure group. The mean age of patients in the Conventional group was 49.88 ± 6.78 years, while in the Ligasure group, it was 54.90 ± 6.21 years. Gender distribution was similar between groups, with males comprising 4% in the Conventional group and 8% in the Ligasure group. The mean BMI was 23.78 ± 2.98 kg/m² in the Conventional group compared to 22.26 ± 2.95 kg/m² in the Ligasure group. Preoperative calcium levels were slightly lower in the Conventional group (9.20 ± 0.55 mg/dL) compared to the Ligasure group (9.60 ± 0.64 mg/dL). A detailed comparison of patient characteristics is presented in Table 1.

Table 1: Comparison of Baseline Characteristics

Variables	Group A Conventional Group (n=50) (Mean ± SD or n, %)	Group B Ligasure Group (n=50) (Mean ± SD or n, %)
Age (years)	49.88 ± 6.78	54.90 ± 6.21
Gender (male/female)	2 (4%) / 48 (96%)	4 (8%) / 46 (92%)
BMI (kg/m²)	23.78 ± 2.98	22.26 ± 2.95
Preoperative calcium (mg/dl)	9.20 ± 0.55	9.60 ± 0.64

Operative time was significantly longer in the Conventional group, with a mean duration of 138.18 ± 28.32 minutes compared to 93.28 ± 16.13 minutes in the Ligasure group ($p < 0.001$). Postoperative calcium levels were significantly lower in the Conventional group (8.050 ± 0.7565 mg/dL) compared to the Ligasure group (8.794 ± 0.7818 mg/dL, $p < 0.001$), as shown in Table 2.

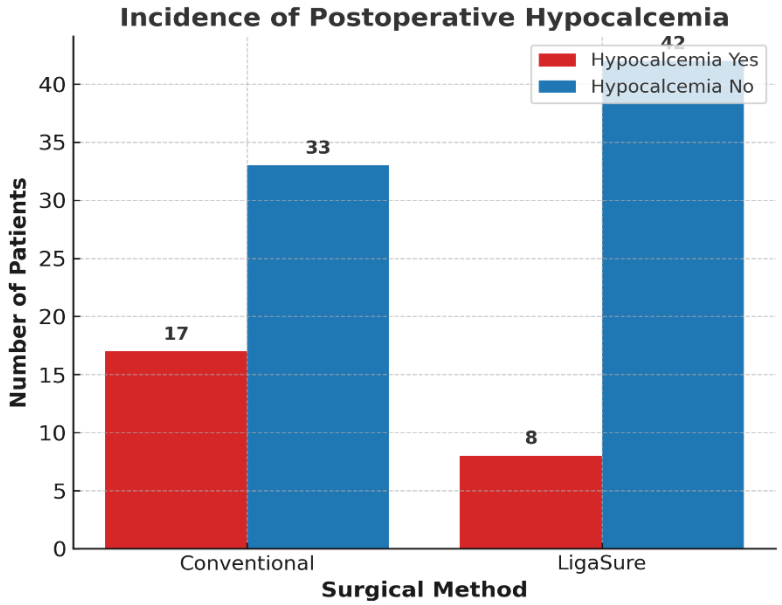
Table 2: Operative Time and Postoperative Calcium Levels

Variables	Group A Conventional Group (Mean ± SD)	Group B Ligasure Group (Mean ± SD)	p-value*
Operative Time (minutes)	138.18 ± 28.32	93.28 ± 16.13	0.000
Postoperative Calcium (mg/dL)	8.050 ± 0.7565	8.794 ± 0.7818	0.000

* $p \leq 0.05$ was considered significant. Calculated by independent t test.

The incidence of postoperative hypocalcemia was significantly higher in the Conventional group, with 17 patients (34%) affected, compared to 8 patients (16%) in the Ligasure group ($p = 0.038$) as shown in figure 1.

Figure 1: Incidence of Postoperative Hypocalcemia in Conventional vs. LigaSure Groups



Chi-square analysis confirmed a statistically significant association between the surgical method and hypocalcemia, as summarized in Table 3.

Table 3: Analysis of Postoperative Hypocalcemia

Group	Hypocalcemia		p-value*
	Yes (n, %)	No (n, %)	
Conventional	17 (34%)	33 (66%)	0.038
Ligasure	8 (16%)	42 (84%)	

*p ≤ 0.05 was considered significant. Calculated by chi-square test.

Binary logistic regression analysis demonstrated that the Ligasure technique was associated with a significantly lower risk of postoperative hypocalcemia, with an odds ratio (OR) of 3.173 (95% CI: 1.005–10.024, p = 0.048), independent of age, BMI, and preoperative calcium levels. None of these additional variables were significant predictors of postoperative hypocalcemia as shown in table 4.

Table 4: Binary Logistic Regression for Predicting Hypocalcemia

Variable	SE	p-value	OR (Odds Ratio)	95% CI for OR
Surgical Method (Ligasure vs. Conventional)	0.583	0.048	3.173	(1.005 - 10.024)
Age	0.037	0.553	0.978	(0.911 - 1.049)
BMI	0.081	0.896	1.011	(0.862 - 1.186)
Preoperative Calcium	0.417	0.856	0.927	(0.412 - 2.086)

DISCUSSION:

Thyroidectomy remains one of the most frequently performed surgical procedures in regions with a high prevalence of goiter.[11] The primary objective of surgical intervention for thyroid disorders is to achieve complete disease resolution while minimizing postoperative complications.[12,13] Over time, traditional thyroidectomy techniques have evolved with the introduction of advanced hemostatic technologies, such as the LigaSure diathermy system. Total thyroidectomy is a technically demanding procedure requiring meticulous surgical precision to

prevent injury to adjacent anatomical structures and reduce the risk of postoperative complications.[14] Optimal surgical outcomes depend not only on anatomical expertise but also on the selection of appropriate surgical instruments. Comparing a conventional, time-tested technique with a newer, advanced device is essential to determine the most effective and safe approach.[15]

In the present study, the mean age of patients in the Conventional Clamp-and-Tie group was 49.88 ± 6.78 years, whereas in the LigaSure group, it was 54.90 ± 6.21 years. Gender distribution was similar between the groups. The mean BMI was 23.78 ± 2.98 kg/m² in the Conventional group and 22.26 ± 2.95 kg/m² in the LigaSure group. These findings align with previous studies, such as those by AlJuraibi et al. and Ciftci, which reported no significant differences in baseline demographic characteristics between study groups.[14,16]

Operative time was significantly longer in the Conventional group, with a mean duration of 138.18 ± 28.32 minutes compared to 93.28 ± 16.13 minutes in the LigaSure group ($p < 0.001$). This observation is consistent with findings from AlJuraibi et al., who reported a significantly shorter operative duration in the LigaSure group (115.54 ± 15.35 minutes) compared to the suture-ligation group (127.1 ± 7.95 minutes; $p < 0.0001$).[16] Similarly, Bibi et al. demonstrated a significant reduction in operative time with LigaSure (73.15 ± 9 minutes) compared to conventional techniques (87.35 ± 7.02 minutes; $p \leq 0.001$).[17] These findings highlight the efficiency of LigaSure in reducing intraoperative time, which may contribute to decreased anesthesia exposure and improved postoperative recovery.

Postoperative calcium levels were significantly lower in the Conventional group compared to the LigaSure group ($p < 0.001$). This finding supports the notion that the LigaSure technique may reduce the extent of parathyroid gland manipulation, thereby preserving calcium homeostasis. However, previous studies have shown variable results regarding postoperative calcium levels. Chavez et al. reported no statistically significant difference in postoperative calcium levels between groups (Clamp: 8.49 ± 0.69 mg/dL, LigaSure: 8.70 ± 0.62 mg/dL; $p = 0.3$).[8] Similarly, Coiro et al. found no significant differences, although mean values were consistently lower in the Conventional group.[15]

The incidence of postoperative hypocalcemia was significantly higher in the Conventional group compared to the LigaSure group ($p = 0.038$). These findings are in accordance with those of Liu et al., who reported a lower incidence of postoperative hypocalcemia in the LigaSure group (20.1%) compared to the Clamp-and-Tie group (30.0%; $p = 0.0032$).[18] Bhittani et al. also reported a statistically significant difference, with transient hypocalcemia occurring in 6.8% of patients in the LigaSure group versus 2.9% in the conventional group ($p < 0.05$).[19] In contrast, Mosalam et al. found no significant difference in transient hypocalcemia rates between groups (30% in the Conventional group vs. 20% in the LigaSure group; $p = 0.257$).[20] Moreover, Malik et al. similarly demonstrated a significantly higher rate of hypocalcemia in the LigaSure group (54%) compared to the Clamp-and-Tie group (38%; $p = 0.02$).[21] These discrepancies may be attributed to differences in surgical technique, patient selection, and perioperative management protocols across studies.

Overall, the results of our study support the use of LigaSure in total thyroidectomy as an effective alternative to the conventional Clamp-and-Tie method, offering advantages in terms of reduced operative time, improved postoperative calcium levels, and a lower incidence of postoperative hypocalcemia. However, given the variability in findings across studies, further large-scale, multicenter trials are warranted to establish definitive conclusions regarding its superiority in thyroid surgery.

This study is limited by its relatively small sample size and further large-scale, multicenter studies with extended follow-up periods are necessary to confirm these findings and evaluate long-term outcomes.

CONCLUSION:

This study demonstrates that the LigaSure vessel-sealing system is associated with a significantly lower incidence of postoperative hypocalcemia and shorter operative time compared to the conventional clamp and-tie technique in total thyroidectomy. The use of LigaSure depicted superior results as compared to the conventional clamp and tie technique in total thyroidectomy.

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