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Study Protocol/Synopsis

A Comparative Analysis of Hypocalcemia Incidence in Patients Undergoing Thyroidectomy: Ligasure vs Conventional Ligation of vessels by knot tying.

NCT Number: NCT06716632

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Introduction:

Thyroidectomy is surgical removal of all or part of the thyroid gland, which is located in the front of the neck. Depending on how much thyroid tissue is removed, thyroidectomy could be classified into Total thyroidectomy, subtotal thyroidectomy, near total thyroidectomy and lobectomy.

In total thyroidectomy, the entire thyroid gland is removed. In thyroid lobectomy, one lobe of the thyroid gland is removed. In Thyroid lobectomy with isthmectomy, thyroid lobe along with the isthmus is removed. In Subtotal thyroidectomy, a small portion of the thyroid gland is left during the surgery. This portion is near the trachea, parathyroid glands and the recurrent laryngeal nerve. Indications for thyroidectomy are thyroid cancer, MNG, solitary thyroid nodule.

Complications of thyroidectomy include hoarseness or change in voice (33.3%), damage to parathyroid glands causing hypocalcaemia (54.4%), wound infection (3.4%), dysphagia (32.8%). Several risk factors may contribute to the occurrence of post-thyroidectomy complications, including age, gender, enlarged gland size, type of thyroid disease, presence of fibrosis and inflammation, extent of thyroidectomy, and lymph node dissection. Among these complications, hypocalcaemia and recurrent laryngeal nerve injury are the most frequently observed[1,2].

The superior and inferior parathyroid glands, located near the thyroid gland, play a vital role in calcium homeostasis by producing parathyroid hormone (PTH), which regulates calcium levels in the bloodstream.

Hypocalcemia, characterized by low serum calcium levels. It is a frequent and significant complication of thyroidectomy due to damage, ischemia, or removal of one or more of the parathyroid glands during surgery. It can be categorized into two main types, transient hypocalcemia and permanent hypocalcemia. The primary difference between these two types lies in the duration. Transient hypocalcemia lasts for 3 months after surgery, while permanent hypocalcemia persists for 3 months or longer after surgery[3].

To minimize the risk of parathyroid gland damage, various surgical techniques have been developed, including the utilization of energy-based devices such as Ligasure. Ligasure has gained popularity in thyroidectomy procedures due to its potential advantages in terms of precision, hemostasis, and reduced operative time.

Ligasure is a bipolar vascular sealing system utilized to achieve effective control of bleeding and create a bloodless surgical environment. It operates by utilizing an electrical current within the frequency range of 2-4 MHz It induces denaturation of collagen and elastin within the vessels and surrounding tissues. The localized tissue temperatures typically range between 60-100°C, facilitating the fusion of collagen and elastin in the vessel walls. This fusion process creates a durable sealed zone without any carbonization and enables hemostasis in vessels with diameters of up to 7 mm[4,5].

Conventional methods of vessel ligation, which involve the use of ties and suture ligatures, have long been employed in most medical centers. While these techniques effectively control bleeding from vessels, they are time-consuming and carry the risk of harming adjacent structures like the recurrent and superior laryngeal nerves. In light of the growing demand for time-saving procedures, particularly in high-volume operating theaters where efficient patient turnover is essential, there is a growing interest in devices or techniques that minimize the reliance on conventional knot-tying or suture ligation for achieving hemostasis. This is particularly important to optimize anesthesia time and improve overall efficiency[6].

According to a recent study, hypocalcemia occurred in 6.7% of individuals who underwent surgery using the Liga Sure method[7]. In a separate study, 32.4% of patients who had surgery utilizing the traditional knot tying technique experienced hypocalcemia[8].
However, despite the increasing use of Ligasure and other energy devices, there is a paucity of research comparing their efficacy in preventing hypocalcemia after thyroidectomy. Therefore, this study aims to address the existing gap in knowledge by conducting a comprehensive comparison of the incidence of hypocalcemia in patients undergoing thyroidectomy using Ligasure versus the conventional artery forceps/knot tying technique.

Objective:

This study aims to address the existing gap in knowledge by conducting a comprehensive comparison of the incidence of hypocalcemia in patients undergoing thyroidectomy using Ligasure versus conventional ligation of vessels by knot tying. Additionally, secondary outcomes such as operative time, intraoperative bleeding, length of hospital stay, and postoperative complications will be assessed to provide a holistic understanding of the two surgical approaches.

Hypothesis:

The incidence of hypocalcemia in patients undergoing thyroidectomy using Ligasure is less versus conventional ligation of vessels by knot tying.

Operational definition:

1)Hypocalcemia: Patients having calcium level below 8.0 mg/dL will be labelled as hypocalcemia.

Material and methods:

1)Study design:

Randomized control trial

2)Study setting:

Surgical unit I Gulab Devi hospital, Lahore

3)Duration of study:

6 months after approval of study.

4)Sample size:

Sample size will be 76 patients (38 in each group) calculated by WHO calculator, with confidence interval of 95% and margin of error 5%, power of test at 90% taking 6.7 % in Liga Sure[7] vs 32.4% in conventional knot tying technique[8].

5)Sampling technique:

Non-probability purposive sampling for including patients in study and random allocation for grouping of patients using lottery method.

6)Sample Selection:

Inclusion criteria:

1) Patients from both genders.
2) Age between 20 years to 50 years.
3) Patients undergoing Total thyroidectomy for benign thyroid disease.

Exclusion criteria:

1) Patients having pre-operative hypocalcaemia.
2) Patients having malignant thyroid disease.
3)Patients having recurrent thyroid disease.
4)Patients having lobectomy + isthmectomy.
5)Patients having pro-operative calcium supplements.

Data collection procedure:

After approval from hospital ethical committee,76 patients (38 in each case) will be enrolled presenting in department of Surgery, Gulab Devi Hospital, Lahore for total thyroidectomy. Informed consent will be taken from each patient. Demographic information including age and address will be noted. Patients will be divided into two groups by using lottery method.

Group A will be managed with Ligasure and group B will be managed with conventional ligation of vessels by knot tying. All the patients will be subjected to their treatment according to their respective groups by single experienced surgeon having minimum experience of five years. Calcium levels will be taken pre operatively, 24 and 48 hours postoperatively. All the data will be collected in a pre-designed proforma. All information regarding patients will be kept confidential and bias will be addressed by single blind data collection procedure.

Data Analysis:

Statistical analysis will be done using Statistical Package for Social Sciences (SPSS) version 24. Mean and standard deviation was calculated for all quantitative variables like age, BMI, serum calcium level. Qualitative data like gender, presence of hypocalcemia will be presented as frequencies and percentages. Chi square test will be applied to compare two treatments effectiveness by taking P value 0.05 as significant.

References:

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Questionnaire

1)Demographic Information:
a. Name: _____
b. Age: _____ years
c. Gender: Male / Female
d. Address: _____
e. Occupation: _____

2)Pre-operative diagnosis: _____

3)Type of surgery:
a. Total thyroidectomy ☐

4)Surgery done by:
a. Professor ☐
b. Associate Professor ☐
c. Assistant Professor ☐
d. Senior Registrar ☐

5)Symptoms of hypocalcaemia:

	Pre-operatively		Post operatively	
a. Tingling:	☐ Yes	☐ No	☐ Yes	☐ No
b. Muscle spasms:	☐ Yes	☐ No	☐ Yes	☐ No
c. Seizures:	☐ Yes	☐ No	☐ Yes	☐ No
d. Paraesthesia/Numbness:	☐ Yes	☐ No	☐ Yes	☐ No
e. Laryngospasm:	☐ Yes	☐ No	☐ Yes	☐ No
f. Tetany:	☐ Yes	☐ No	☐ Yes	☐ No
g. Chvostek's sign:	☐ Yes	☐ No	☐ Yes	☐ No
h. Trousseau's sign:	☐ Yes	☐ No	☐ Yes	☐ No

6)Treatment Allocation:
a. Group A: Ligasure
b. Group B: Conventional ligation technique

7)Surgical Outcomes:
a. Operative Time: _____ minutes
b. Intraoperative Bleeding (Estimated amounts_ _____
c. per-operative parathyroid identified: ☐ Yes ☐ No How many: _____
d. Length of Hospital Stay: _____ days
e. Postoperative Complications: None / Infection / Hoarseness / Other (Please specify: _____)
f. Drain output :1st day_____,2nd day_____,3rd day_____.

8)Hypocalcaemia Assessment:
a. Preoperative Calcium Level: _____ mg/dL
b. Calcium Level at 24 Hours Postoperatively: _____ mg/dL
c. Calcium Level at 48 Hours Postoperatively: _____ mg/dL

9)Histology of Specimen: _____

10)Hypocalcaemia Management:
a. Injection Ca gluconate ☐
b. Tab Qalsan D ☐
c. Tab one Alpha ☐
d. Others ☐