Differences in Surgical Outcome in Near Total Thyroidectomy for Benign Nodular Goiter: A Comparison of LigaSure Vessel Sealer versus Conventional Clamp Knot Tie Technique

Shiraz Shaikh†*, Champa Sushel†, Ahsan Ali Laghari†, Qamber Ali Laghari†, Zameer Hussain Laghari† and Aisha Memon†

†Department of Surgery, Liaquat University of Medical and Health Sciences (LUMHS), Jamshoro, Sindh, Pakistan.

Authors’ contributions

This work was carried out in collaboration among all authors. Author SS designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors CS, AAL, QAL managed the analyses of the study. Authors ZHL, AM managed the literature searches. All authors read and approved the final manuscript.

ABSTRACT

Objective: To compare the efficacy of LigaSure Vessel Sealer in Near Total Thyroidectomy versus Conventional Clamp Knot Tie Technique in terms of bleeding, operative time and postoperative drainage.

Methodology: This comparative cross sectional study was conducted at Department of Surgery, Liaquat University of Medical and Health Sciences, Jamshoro. Study duration was one year from November 2019 to October 2020. All patients of any age with benign multinodular goiter and either of gender were included. The study subjects were grouped into two categories by randomization (odd / even). The odd numbers were given to patients operated for ligasure and even numbers were given to patients operated with conventional clamp knot tie technique. Outcomes were observed with respect to post-operative calcium level, intra-operative bleeding, operative time, post-operative pain & post-operative hospital stay. All the data was recorded via study proforma.
INTRODUCTION
Multinodular goitre is a thyroid pathology that is encountered most frequently, for which; surgical intervention remains the most effective therapeutic choice [1-4]. The thyroid gland is among the largest blood supplying sources of any organ, with multiple blood vessels as well as plexuses accessing its parenchyma; and thyroid surgery encompasses the thyroid gland’s meticulous devascularization. Before the gland’s excision, hemostasis is essential for controlling and dividing different vessels [5-6]. At most facilities, standardized vessel ligation with suture ligatures and ties has become the standard procedure. However, despite being an extremely effective method for controlling vessel bleeding, it takes too much time. Time-saving surgical interventions are becoming highly important, particularly in high-volume operation theatres where patient frequency is high and anaesthesia time is limited. As a result, devices or approaches that eliminate the necessity for standard suture ligation or knot-tying for haemostasis are being pursued [7]. LigaSure is a vascular sealing bipolar system that induces fusion of elastin and collagen in vessels as well as underlying tissues, allowing for vascular hemostasis around 7 mm and greatly reduces procedure time [8,9,10]. It has been proposed as a substitute to the traditional knotting procedure and has been successfully used for surgical procedure of thyroid [1,11,12].

Thyroidectomy can be a complicated procedure because of the unnecessary vascularization of thyroid, and bleeding control can be difficult. Despite the fact that a “clamp, tying thread knot” procedure along with bipolar electro-cauterization method has now become the benchmark, multiple knots can prolong the procedure. The LigaSure system has been successfully used in surgical procedure of thyroid as a substitute to the traditional knotting technique. However this study has been conducted to contrast the effectiveness of LigaSure Vessel Sealer in Near Total Thyroidectomy versus Conventional Clamp Knot Tie Technique with respect to bleeding, operative time & postoperative drainage.

MATERIALS AND METHODS
This comparative cross sectional study was conducted at Department of Surgery, Liaquat University of Medical and Health Sciences, Jamshoro. Study duration was one year from November 2019 to October 2020. All the patients with all age groups, with benign multinodular goiter and either of gender were included. All the patients those who were not willing to participate in study, patients with solitary thyroid nodule, patients with malignant thyroid disease, patients with retrosternal extension of thyroid and patients with co-morbidities and unfit for anaesthesia were excluded. The study subjects were grouped into two categories by randomization (odd / even). The odd numbers were given to patients operated for ligasure and even numbers were given to patients operated with conventional clamp knot tie technique. The Ligasure system of vessel-sealing appears to be the best system for thyroid surgery as it combines excellent localized coagulation with a collateral thermal spread as low as 2 mm, allowing for quick bloodless incision with least collateral damage.[13] However, both of the thyroid lobes are removed in a near-total thyroidectomy, with the exception of a minimal amount of thyroid tissues (on one side or both) near the superior parathyroid gland and the entry point of recurrent laryngeal nerve. Both surgical techniques in all cases were performed by same surgeon and his team. Near total thyroidectomy been performed in all cases, so usually parathyroid glands along with normal rim of thyroid gland has been preserved. Outcomes were observed in terms post-operative...
calcium level, bleeding, operative time, post-operative pain and post-operative Hospital stays. The record sheet and proforma of the patients includes: age, operative details, postoperative drainage, hospital stay and follow-up. Data was analyzed by using SPSS version 20.

3. RESULTS

Total 55 patients were observed; 24 in clamp knot tie technique group and 31 in ligasure technique group. Mean age of study subjects was 33.25±10.60 years in clamp knot tie procedure group and 35.16±7.96 years in ligasure technique group without significant difference (p=0.448). Almost all study subjects were females in clamp knot tie procedure group; however, there was only one male patient. Table 1.

Averages of pre and post-operative calcium levels were statistically insignificant among both groups (p=0.358 and 0.163). However, loss of blood, hospital stay, post-operative pain and operative duration were significantly greater in Clamp knot procedure group in comparison to ligasure technique group (p<0.001). However no any complications related to EBSLN or RLN in these cases has been observed or seen in either group participants. Table 2.

4. DISCUSSION

In regions with low iodine levels in the drinking water, nodular goiters are common as well as endemic, and the majority of nodules remain benign. Thyroid surgery has become safer as surgical procedures have improved and our comprehension of thyroid pathology has improved. However, in ligasure vessel sealer in near total thyroidectomy in comparison with conventional clamp knot tie technique for benign nodular goiter, the ligasure vessel sealer observed to be effective in terms of loss of blood, hospital stay, post-operative pain and operative duration. Similarly Khafagy AH et al [10] also observed that ligasure hemostasis enhanced surgical outcomes by reducing the duration of surgical procedure, wound drainage and hospitalization in total thyroidectomy. Furthermore, ligasure use substantially decreased wound pain levels and demands for emergency analgesia.[10] Consistently, Saint Marc O et al also observed that ligation is just as secure and reliable as clamp-&-tie procedure for homeostasis and vessel differentiation, with statistically significant reduction (however minor) in mean duration of surgical procedure. Due to this small reduction in the duration of surgical procedure, LigaSure will enable more patients to undertake total thyroidectomy annually, helping to offset the higher expenditure [8] In this study, no mortality was seen and these findings were in agreement with Saint Marc O et al [8] as they did not report mortality at all. In another study, Tamer Yet al [5] reported that the ligasure procedure group experienced shorter period of surgery, lesser blood loss during surgical procedure, lesser pain following surgical procedure, and a quicker return to routine work.

In this study post-operative average calcium was statistically insignificant among both study groups (p=0.163). Similarly Saint Marc O et al [8] reported that the pre-operative and post-operative serum calcium level was not different statistically among two study groups and in the subset of patients undergoing parathyroid gland auto-transplantation.

In this study, there was significantly greater mean operative time as 113.62±11.50 minutes in clamp knot tie technique group as compared to ligasure technique group as 85.90±15.40 minutes; (p=0.0001) and these findings were similar to the study of Saint Marc O et al [7] as they reported 41.5±11.2 minutes of mean operative time in CT group (P<0.001). On the other hand, Al Juraibi W et al [14] reported that the mean duration of surgical procedure, was 115.54±15.35 minutes in ligasure group and 127.1±7.95 minutes in suture-ligation group and this variance is thought to be statistically highly significant. Schiphorstet al [15] documented that mean duration of surgical procedure in ligasure group was significantly shorter; with insignificant differences seen in complications. In this study, mean age was 33.25±10.60 years in clamp knot procedure group and 35.16±7.96 years in ligasure technique group; without significant difference (p=0.448). Similarly, AlJuraibi W et al [14] also found 42.25± 9.5 years of mean age in group A patients and 40.19±9.6 years of mean age in group B patients; with insignificant variance. Thyroid surgery is a delicate procedure that necessitates careful tissue manipulation and anamolization.[5] We could use the LigaSure generator with the small thyroid vessels since there were different hand pieces sizes available.[5] In LigaSure group, statistically significant decrease in blood loss was seen during surgical procedure.[5]
**Table 1. Descriptive statistics regarding age and gender n=55**

| Variables   | Type of Operation | p-value |
|-------------|-------------------|---------|
|             | Clamp knot the technique | ligasure technique |         |
| Age         | Mean+SD           |         |
|             | 33.25±10.60 years | 35.16±7.96 years | 0.448   |
| Gender      | Males             |         |
|             | 01(4.2%)          | 00      | 0.251   |
|             | Females           | 23(95.8%) | 31(100.0%) |

**Table 2. Comparison of surgical outcome in both study groups n=55**

| Types of operations | N   | Mean+Std. Deviation | p-value |
|---------------------|-----|---------------------|---------|
| Pre-operative       |     |                     |         |
| calcium             | Clamp knot the technique | 24   | 9.76±0.60 | 0.358 |
| post-operative      | Ligasure technique    | 31   | 9.61±0.58 |       |
| calcium             | Clamp knot the technique | 24   | 8.87±1.14 | 0.163 |
| post-operative      | Ligasure technique    | 31   | 9.28±0.63 |       |
| Loss of blood       | Clamp knot the technique | 24   | 128.75±11.34 | 0.0001 |
| post-operative      | Ligasure technique    | 31   | 75.16±16.45 |       |
| Post-operative drain| Clamp knot the technique | 24   | 142.29±36.69 | 0.0001 |
| post-operative      | Ligasure technique    | 31   | 49.51±33.62 |       |
| Hospital stay       | Clamp knot the technique | 24   | 3.29±1.08 | 0.0001 |
| VAS Pain score      | Ligasure technique    | 31   | 1.58±0.71 |       |
| Operative time      | Clamp knot the technique | 24   | 113.62±11.50 | 0.0001 |
| post-operative      | Ligasure technique    | 31   | 85.90±15.40 |       |

5. CONCLUSION

As per conclusion the LigaSure Vessel Sealer is a feasible and reliable surgical technique and significantly more effective as compared to conventional Clamp Knot Tie Technique in terms of post-operative bleeding, operative time, post-operative pain and post-operative hospital stay. However, calcium level was statistically insignificant. Due to small sample size and single unit of this study, it is recommended that the large scale and multicenter studies should be conducted on this subject.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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