

Is an Energy-Based Vessel Sealing Device more Effective Than the Conventional Clamping and Knot Tying Technique in Thyroid Surgery? A Quasi-Experimental Study

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ABSTRACT

Objective: To evaluate the effectiveness of the energy-based vessel-sealing device versus the conventional clamping and knot tying technique in thyroid surgery by comparing postoperative complications, operative time and hospital stay.

Study Design: Quasi-experimental study.

Place and Duration of Study: Pak Emirates Military Hospital Rawalpindi, Royal Free Hospital London and South mead Hospital Bristol between Jan 2016 to Jan 2020.

Methodology: A total of 100 patients that underwent total thyroidectomy were included in the study. Half of these patients having thyroid surgery with energy-based vessel sealing devices were allotted into group-1. While, the other half with conventional clamping and knot tying technique were included in group-2. The demographical characteristics and surgical outcomes of both the groups were compared using statistical analysis.

Results: There were 93 females and 7 male patients. The mean age was 44.6 ± 17.33 years. The mean duration of surgery was significantly shorter in group-1 than group-2 (p -value = 0.001). There was no statistical difference in clinical hypo calcemia, recurrent laryngeal nerve injury, and hospital stay. However, more patients 27 (54%) in group-1 had laboratory hypo calcemia, compared to 19 (38%) group-2, (p -value = 0.02).

Conclusion: Thyroid surgery by an energy-based vessel-sealing device is an effective technique as it reduces the operative time; however, higher laboratory hypo calcemia levels were observed.

Keywords: Complications, Conventional clamping and knot tying technique, Energy-based vessel sealing system, Ligasure, Thyroid surgery.

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INTRODUCTION

Thyroid dysfunction requiring surgery is the commonest endocrine procedure performed. According to the BAETS (British Association of endo-crine and thyroid surgeons) and National Database of Endocrine and Thyroid Procedures, in the UK, around 7,000 Thyroid surgeries were performed in 2017.^{1,2,3} Due to financial restraints and the increasing patient load on the health systems worldwide, there is a drive for adapting practices that warrant the unit's high efficiency. The rapid turnover of patients is encouraged to optimise theatre space. Time-saving procedures are favoured by the theatre managers in high-volume centres.^{4,5}

Ligasure small jaw is one such device (Figure), which is the bipolar energy-based vascular sealing system that produces a reliable autologous seal in the tissues up to 7 mm in diameter with reduced lateral thermal spread.^{6,7} This device has been used effectively

by both open and laparoscopic approaches in other surgical specialities and reduced operative time, blood loss, injury to surrounding structures, and hospital stay. To introduce any intervention in practice, it is mandatory to establish that the new technique is time-saving yields similar benefits with the same or less complication rate compared to the conventional technique.⁸ In medical literature, most of the studies comparing thyroid surgery with energy-based vessel sealing (EBVS) device and conventional clamping and knot tying (CCKT) technique have conflicting results.⁹



Figure: Energy-based vessel sealing device.

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Considering the persevering need for a rapid and safe surgical technique for thyroid surgery and lack of consensus in practice due to conflicting results involving this device, this study was aimed to evaluate the effectiveness of the EBVS device in thyroid surgery as compared to the CCKT technique in terms of operative time, postoperative complications and hospital stay.

METHODOLOGY

This quasi-experimental study was conducted at the Pak Emirates Military Hospital Rawalpindi (PEMH), Royal free hospital London and South mead Hospital Bristol. It was carried out over 48 months, from Jan 2016 to Jan 2020. Ethical approval (No: 17/18-596) was obtained from the Research and Development (R&D) department of the Royal Free hospital, where data compilation and analysis was undertaken. The sample size of 100 patients was appraised, keeping in context other contemporary studies.¹⁰

Inclusion Criteria: Patients above the age of 15 years undergoing total thyroidectomy by either of the two techniques were included in the study. The indication for total thyroidectomy was thyroid carcinoma and symptomatic benign disease.

Exclusion Criteria: The patients with complicated procedures carrying high risk like recurrent surgery, thyroid carcinoma with extra-thyroidal extension, previous irradiation, and extensive lateral compartment lymph node clearance were excluded.

The patients underwent similar diagnostic work-up and clinical optimisation. After informed written consent, total thyroidectomy was performed by either of the two techniques by the same surgical team. Recurrent laryngeal nerve (RLN) was identified in all the cases. Half of these patients having thyroid surgery with EBVS device were allotted in the group-1, while the other half with CCKT technique were included in the group-2.

The post-operative complications were RLN injury and hypocalcemia. RLN injury is defined as the presence of hoarseness or shortness of breath after thyroid surgery due to transient or permanent injury to the nerve. It is confirmed by the vocal cord paralysis visualised by indirect laryn gscopy.¹¹ Hypocalcemia occurs due to the devascularisation of parathyroid glands during thyroid surgery and is defined as the drop in calcium levels (less than 2.1 mmol) measured 24 hours after the procedure or earlier if the patient exhibits symptoms.¹² Clinical hypocalcemia is defined as the patient showing symptoms of hypocalcemia (i.e.

circumoral numbness, paresthesia, muscle spasms, cramps, tetany) along with decreased calcium levels on blood reports. Laboratory hypocalcemia is defined as the asymptomatic decrease in the calcium levels on blood reports. Operative time was calculated from the beginning of the surgery with the skin incision till the completion with skin closure.¹³ The hospital stay was defined as the number of nights the patient stayed in the hospital after the procedure.¹⁴

The data, including the demographical characteristics and surgical outcomes of both groups, were collected and saved in a password-protected drive to ensure the confidentiality of the patients. The participants’ demographical characteristics included age, gender, ethnicity, and indication for surgery. The surgical outcomes were post-operative complications, operative time, and hospital stay. Statistical Package for Social Sciences (SPSS) version 21.0 was used for the data analysis. Quantitative variables were summarized as mean ± SD and qualitative variables were summarized as frequency and percentages. The percentages of the surgical outcomes in both groups were also compared in tabular form to assess if the EBVS device made any substantial change in the outcome. The *p*-value of ≤0.05 was considered statistically significant.

RESULTS

One hundred patients undergoing total thyroidectomy included in the study had 44.6 ± 17.33 years. There were seven males and 93 female patients. Table-I showed the demographic characteristics of the sample population.

Table-I: Demographical characteristics of both the groups.

Number of Patients	Gender		Mean Age (years)
	Male	Female	
Total: 100	7 (7%)	93 (93%)	44.6 (± 17.33)
Group-1: 50 (Energy-Based Vessel Sealing Device)	4 (8%)	46 (92%)	42.71 (± 14.44)
Group-2: 50 (Conventional Clamping and Knot Tying Technique)	3 (6%)	47 (94%)	45.10 (± 15.99)

Table-II enumerated the common indications of total thyroidectomy in our study. The commonest indication encountered was toxic multi nodular goitre and thyroid carcinoma.

Table-II: Indications for Total thyroidectomy.

Indications for Total Thyroidectomy		
Malignant	Thyroid Carcinoma	33
	Toxic Multinodular Goitre	39
Benign	Symptomatic Multinodular Goitre	11
	Graves’ disease	13
	Hashimoto’s thyroiditis	4

Table-III elaborated the comparison of the surgical outcomes in both groups. There was no significant difference in the RLN injury, group-1 recorded two cases, while group-2 recorded one case (p -value=0.177). The RLN injury was transient as the symptoms of all three patients resolved spontaneously after three months.

Table-III: Comparison of surgical outcomes in both groups.

Surgical Outcomes	Group-1(n = 50) (Energy-Based Vessel Sealing Device)	Group-2 (n = 50) (Conventional Clamping and Knot Tying Technique)	p -value	Relative Risk/ Risk-Ratio
Recurrent Laryngeal Nerve Injury	2 (4%)	1 (2%)	0.177	2
Laboratory Hypocalcemia	27 (54%)	19 (38%)	0.02	1.42
Clinical Hypocalcemia	12 (23%)	09 (18%)	0.06	1.2
Operative Time (min)	79.21 (\pm 29.12)	107.53 (\pm 32.41)	0.001	NA
Hospital stay (days)	1.93	2.55	0.09	NA

Laboratory hypocalcemia measured on the first postoperative day was significantly higher in group-1 (27 patients, 54%) as compared to group-2 (19 patients, 38%) (p -value = 0.02, risk ratio=1.42). However, no significant difference was noted in the clinical hypocalcemia measured on the first postoperative day (p -value=0.06). In Group-1,¹² patients complained of numbness and tingling in the perioral area, fingers, or toes compared to nine in group-2. All the patients with laboratory and clinical hypocalcemia were treated with calcium supplementation.

There was a significant reduction in the operative time in group- 1 (79.21 \pm 29.12 mins) compared to group-2 (107.53 \pm 32.41 mins), (p -value = 0.001). There was no difference in the hospital stay of patients in both groups (p -value=0.09). No wound infection or secondary haemorrhage was noted in any patient. Two patients presented later with seroma that was aspirated in the outpatient clinic.

DISCUSSION

In our study, the patients undergoing thyroid surgery by EBVS device had a significantly reduced operative time while the laboratory hypocalcemia rates were higher. The RLN injury, clinical hypocalcemia, and hospital stay were comparable to the CCKT technique.

The recent advances in medical technology have led to the introduction of new devices that may potentially improve thyroid surgery outcomes patient safety.^{15,16} Despite research conducted evaluating these devices compared with the conventional technique in thyroid surgery, there is still no consensus. The main reason for this is the conflicting results of the earlier research conducted in the same area. This study descri-

bed the four-year experience of the same surgical team at three different surgical units, evaluating the EBVS device in thyroid surgery by comparing its surgical outcomes with that of the widely accepted CCKT technique. The results of this study were interpreted in the context of previous differing findings in the medical literature on a similar topic.

The surgical techniques that reduce the operative time are paramount for the proficiency of the health-care systems as they decrease the financial burden and complication rates.¹³ Kilic *et al*,¹⁷ and Marrazzo *et al*,⁸ conducted randomised control trials comparing the EBVS device with the CCKT technique. Although both studies were inadequately powered and required a further explanation of their methodology, they reported a decrease in the operative time with the device. On the contrary, Marc *et al*,¹⁸ and Singh *et al*.² conducted prospective randomised studies with improved sample size and reported no reduction in the operative time with the device. In our study, we recorded a significant reduction in the operative time with the EBVS device. It is possible that the earlier studies reporting no reduction in the operative time were conducted during the early part of the surgeon's learning curve with the device.

The commonest surgical complications of thyroid surgery are hypocalcemia and RLN injury, which occurs due to damage to the delicate neck structures around the thyroid gland.¹⁹ In the literature, laboratory hypocalcemia is described in 40-60% of the thyroid surgery patients,²⁰ while the incidence of clinical hypocalcemia is 20-36%.^{21,22} Our study observed an overall laboratory and clinical hypocalcemia of 46% and 21%, respectively. Similarly, RLN injury is reported in 1-4.5% of thyroid surgery patients even with intraoperative nerve monitoring.^{22,23} We observed RLN injury in 3% of the patient population. The results of our study are in line with the previous literature.

Pergel *et al*,¹⁹ conducted a prospective observational study including 456 patients undergoing thyroid surgery in two years and reported an increase in the

postoperative complications with the EBVS device. On the contrary, Bircan *et al*,²⁴ conducted a prospective randomised controlled study recruiting 54 participants over four months in Turkey and reported a decrease in the complication rate with the EBVS device. Arowolo *et al*,²⁵ conducted a quasi-experimental study including 60 patients comparing the two techniques in thyroid surgery. They concluded that there was no difference in the complication rates. The results of our study also concluded no difference in the complication rates between the two techniques. However, we observed higher laboratory hypocalcemia rates with the EBVS device due to the device's lateral thermal spread.

A multicentre randomised controlled trial is warranted in this area to further elaborate and standardise the results. The advantage of this study was its applicability as it included the general hospital settings and patient thyroid population.

Thyroid surgery with the EBVS device is an effective technique as it reduces the operative time with comparable results to the CCKT technique. However, we recommend its cautious use in the vicinity of parathyroid glands and tracheoesophageal grooves due to the lateral thermal spread.

STUDY LIMITATIONS

The methodological quality and the resultant level of evidence would have increased with the inclusion of double-blinding and randomisation. Secondly, since the same surgical team operated on all the patients in the study, the results might be influenced by personal experience.

CONCLUSION

Thyroid surgery by an energy-based vessel-sealing device is an effective technique as it reduces the operative time; however, higher laboratory hypo calcemia levels were observed.

Conflict of Interest: None.

Authors' Contribution

SM: Data collection, data analysis, write up, TI; JM; NI; Write up.

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