Thermal sealing systems with and without tissue divider for total thyroidectomy

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Key words
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Abstract
Background: Sutureless thyroid surgery utilizing thermal sealing is now well established. However, incremental advances in technology still require formal clinical evaluation in order to ensure that added technology does not compromise safety. In this study, we compared a new thermal sealing device incorporating a tissue divider (LigaSure Small Jaw) with the device we have previously reported for use in total thyroidectomy (LigaSure Precise).

Methods: A cohort study was undertaken of 872 total thyroidectomies over a 2-year period. Patients were selected for each group on the basis of device availability within four institutions and outcomes were obtained from a prospectively maintained database.

Results: Small Jaw was used in 399 cases and Precise in 473. No significant differences between patient demographics (sex, age), operation indication or pathology were found. Significantly more Small Jaw operations were performed in private versus public hospitals ($P < 0.01$). Regarding outcomes, there was no significant difference in the incidence of any complication (haematoma, temporary/permanent hypoparathyroidism or temporary/permanent recurrent laryngeal nerve injury). In a subgroup analysis of operations performed in the public hospital system, Small Jaw was found to be significantly faster (mean operative time: 79 versus 103 min) (95% CI 74–84 and 96–110 min) ($P < 0.01$).

Conclusion: The incorporation of a tissue divider into thermal sealing devices is efficacious and safe, with no compromise in clinical outcome, while providing the added benefit of a significant reduction in operative times.

Introduction

Sutureless thyroid surgery utilizing vessel sealing technology is well established and has been shown to achieve similar outcomes compared with conventional (clamp/clip and tie) thyroidectomy with the benefit of reduced operative times.$^1$–$^4$ Sutureless surgical technologies include electrothermal vessels sealing devices such as the LigaSure system and ultrasonic mechanical energy sealing devices such as the Harmonic Scalpel. A potential disadvantage of the electrothermal systems has been the lack of a tissue divider. This compares to the Harmonic Scalpel, which is able to both seal and separate tissue, reducing the number of surgical steps and operative time.$^5$–$^8$ This disadvantage has been addressed by the development of the LigaSure Small Jaw hand piece (Small Jaw) that includes thermal sealing with a tissue divider. The aim of this study was to compare the use of this new device with the LigaSure Precise hand piece (Precise), which has previously been extensively investigated for use in total thyroidectomy.$^3$
were selected for each group on the basis of device availability over a 2-year period. Total thyroidectomy was performed in a standardized way which has been previously described. Serum parathyroid hormone levels were measured at 1–4 h following surgery and corrected calcium levels obtained routinely at 24 h, 2 weeks and 3 months following surgery. Patients were discharged with oral calcium supplementation that was reduced according to an established protocol. Post-operative haemorrhage was defined as a haematoma that required wound re-exploration. Post-operatively, patients with a serum calcium level less than 2.0 mmol/L were classified as having permanent hypoparathyroidism. Patients with undetectable serum parathyroid hormone levels or inappropriately low levels requiring ongoing calcium or vitamin D replacement after 6 months were classified as having permanent hypoparathyroidism. Patients with a vocal cord palsy that persisted at 6-month follow-up were classified as having a permanent recurrent laryngeal nerve injury. Operative time was measured from the start of anaesthesia to its completion as recorded in the operative report.

Operative theatre running cost per hour was obtained from the hospital finance department for the Northern Sydney Central Coast Area Health Service. Costs for one surgeon, one surgical registrar, one anaesthetist, one anaesthetic registrar and nursing staff were calculated.

**Sample size estimation**

Assuming a difference of 1% in the complication rate between each group, with 80% power and a 5% significance level, each group would need a minimum of 393 cases.

**Statistical analysis**

Data were analysed using SPSS Statistics, release 21 (IBM Corp, Armonk, NY, USA). Categorical variables were compared using Fisher’s exact test. Continuous variables were compared using Student’s t-test. Statistical significance was set at \( P < 0.05 \).

**Results**

Between July 2010 and July 2012, 872 consecutive patients underwent total thyroidectomies at four institutions that form part of the University of Sydney Endocrine Surgical Unit. A total of 399 thyroidectomies were performed using the Small Jaw and 473 performed using the Precise device. The Small Jaw device had been introduced to three (one public and two private hospitals) of the four institutions during this time. The different availability being due to each hospital’s contractual arrangement with the supplying company. Patient demographics and indication for surgery were similar between the two groups (Table 1), although significantly more Small Jaw operations were performed in the private hospital setting. There was no significant difference in the histopathology diagnosis of the resected specimens (Table 2).

<table>
<thead>
<tr>
<th>Table 1 Patient demographics and indication for surgery</th>
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<tr>
<td>Demographics (%)</td>
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<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Mean age (years)</td>
</tr>
<tr>
<td>Public hospital admission:</td>
</tr>
<tr>
<td>Indication for surgery (%)</td>
</tr>
<tr>
<td>Risk of malignancy</td>
</tr>
<tr>
<td>Sub-sternal goitre</td>
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<tr>
<td>Thyrotoxicosis</td>
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<tr>
<td>Other</td>
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MNG, multi-nodular goitre.

<table>
<thead>
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<th>Table 2 Post-operative complications</th>
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<tbody>
<tr>
<td>Complication (%)</td>
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<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Haematoma</td>
</tr>
<tr>
<td>Temporary</td>
</tr>
<tr>
<td>Permanent</td>
</tr>
<tr>
<td>Permanent RLN palsy</td>
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RLN, recurrent laryngeal nerve.

There was no significant difference in rates of any complication – haematoma, temporary/permanent hypoparathyroidism or temporary/permanent recurrent laryngeal nerve palsy between the two groups (Table 3). No deaths were reported in the series. There was a higher number of permanent recurrent laryngeal nerve palsies seen in the Precise group, which included one patient in which the recurrent laryngeal nerve had been intentionally resected as it had been invaded by tumour.

A subgroup analysis of operative time was undertaken for patients undergoing surgery in the public hospital setting. For this analysis, there was also no significant difference between each group for demographics or surgery indication. Operations performed with the Small Jaw device were found to be significantly faster (mean operative time: 79 min, 95% CI 74–84 min) than the Precise (103 min, 95% CI 96–110 min) \( P < 0.01 \).

Recommended retail prices for the devices for New South Wales public hospitals were obtained from the manufacturer, with the Small Jaw device costing AUD$14 more than the Precise. Public hospital operative running costs were calculated at AUD$768/h. Applying a mean time saved for 24 min with the Small Jaw against its increased cost could lead to a saving of AUD$293.20 per case.

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Thyroidectomy and thermal sealing systems

Discussion

This is the first study to compare total thyroidectomy using the newer LigaSure Small Jaw with the Precise. The Small Jaw has been approved by the U.S. Food and Drug Administration for thyroid surgery and a recent randomized controlled trial has supported its safety to be equivalent to the Harmonic Scalpel. With the advent of new technologies, it is important to continually evaluate their impact on surgical outcomes and compare new technology outcomes with the established technology, in this case the LigaSure Precise.

This study showed no significant difference in its primary outcomes: complications of thyroidectomy using the Small Jaw or Precise devices. The two cohorts showed no significant difference in age, sex, indication for surgery or thyroid pathology.

Because of the potential for confounding due to the difference in public hospital admission rate between the two groups, it was decided to perform operative time analysis only on patients treated in the public hospital setting. This subgroup analysis showed a significant amount of operative time saved when using the Small Jaw with a potential considerable cost saving. This operative time saving of the Small Jaw over the Precise has obvious benefits to patients due to reduced anaesthetic times as well as improving operating room efficiency. A weakness of this study is the non-randomized nature of the selection of the thermal sealing system with device availability depending on supply arrangements. Further selection bias is possible due to the primary surgeon experience between the public and private hospital settings; however, the same surgical team was involved in all operations with the role of primary surgeon varying depending on the location of the surgery and the individual case details.

Both the Small Jaw and the Precise use the same electrothermal bipolar tissue sealing system; however, there are a number of differences in the hand pieces. The Precise hand piece is 16.5 cm long with a jaw angle of 15° and allows for a 15.5-mm seal and is activated by a foot pedal. The Small Jaw is 18.8 cm long with a jaw angle of 28°, allowing for a 16.5-mm seal length and can be foot or hand activated. This longer seal length of the Small Jaw, along with its hand activation, may also contribute to a shorter operative time.

Electrothermal bipolar systems work by grasping tissue and creating an electromagnetic wave. This wave is dissipated as heat in the tissue, leading to vessel coagulation. The LigaSure with the ForceTriad generator system modifies this system by applying higher currents across larger surface areas in combination with a cooldown period that allows reforming of seals, reducing thermal spread and allowing the sealing of larger vessels up to 7 mm in diameter. The Harmonic Scalpel uses high-frequency ultrasonic mechanical energy to coagulate and separate tissue.

The potential disadvantage for both of these systems is due to the possibility of thermal spread to surrounding tissue. Thermal spread is critical in thyroid surgery due to the close anatomical proximity of the recurrent laryngeal nerve and parathyroid glands. Experimental animal evidence suggests ultrasonic dissection produces a higher tissue temperature during sealing compared with electronic bipolar vessel sealing which could translate into greater thermal injury. This animal evidence has not been found to be clinically apparent with no consistent difference between hypoparathyroidism and recurrent nerve injury with the use of either vessel sealing system. With both systems, the defined clinical margin of thermal spread remains controversial and thermal spread must be considered when operating in proximity to the recurrent laryngeal nerve and parathyroid glands with 3 mm being suggested as a minimum distance of safety.

Conclusion

The Small Jaw with the incorporation of a tissue divider into a thermal vessel sealing system is efficacious and safe with no compromise in clinical outcomes and the benefit of a significant reduction in operative time. The results of this series support the use of the LigaSure Small Jaw over the Precise for thyroid surgery.

References


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