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ORIGINAL ARTICLE

Safety and Cost Efficiency in Thyroid Surgery

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ABSTRACT

Aim: Recent developments in technology aim to reduce operative time and improve safety, albeit at significant cost. Thyroidectomy is a common procedure worldwide and an assessment of costefficiency is important.

Materials and methods: An audit of prospectively collected data on all thyroidectomies performed by a single endocrine surgeon at two private hospitals from 2009 to 2013. The technique was a conventional open dissection emphasizing capsular dissection with ligature and ligaclip and without intraoperative nerve monitoring (IONM). The operative duration was compared to those reported in literature with the use of vessel sealing devices (VSDs). Estimated time-dependent operating theater cost was used to determine the amount of time saving required by VSDs to match the costefficiency of our technique.

Results: There were 503 thyroidectomies with the expected mix of pathologies. There were zero permanent recurrent laryngeal nerve injuries (0.5% temporary, 746 nerves at risk), 0.6% permanent hypoparathyroidism (19.5% temporary, 308 completion and total thyroidectomies) and 0.6% hematoma. These outcomes compare favorably with published best practice. The median skin to skin operating time was 59 minutes for total and 35 minutes for hemithyroidectomies which are shorter than those reported with VSDs. The minimum time reduction required by VSDs to match the costefficiency of our technique was 27 minutes for hemithyroidectomy and 15 minutes for total thyroidectomy, which are longer than those reported in the literature.

Conclusion: Despite the current popularity of VSDs and the promotion of IONM, their routine use may not be justified. Technique is more important than technology.

Keywords: Thyroidectomy, Technique, Safety, Cost, Efficiency, Operative time.

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INTRODUCTION

Thyroidectomy is the most commonly performed endocrine surgical procedure.

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This applies worldwide where there are important issues to be considered involving equity of access, availability of surgeons, affordability of equipment, and the safety and quality of surgery and devices.

The open method of capsular dissection has been established as safe and effective.[1,2] In the past decade, variations have been introduced including minimally invasive approaches, either open or endoscopic/videoscopic/robotic. Vessel seating devices (VSDs), such as Ligasure Precise (Covidien, Boulder, CO, USA) and Harmonic scalpel (Harmonic Focus, Johnson and Johnson, Ethicon Endo-surgery, Cincinnati, OH, USA) have been introduced and promoted as saving operating time. They may be used to either replace or complement conventional clip and tie techniques. Intraoperative nerve monitoring (IONM) has also been promoted as improving the safety of the operation, although the evidence for this is lacking. These innovations are associated with significantly increased cost and their true costefficiency remains to be established.

Our approach has been to refine the open capsular dissection technique using the smallest incision that will allow adequate safe exposure and to employ the automatic small titanium Ligaclip applier (MSM20, Ethicon Inc, Somerville, NJ, USA) as a time saving device. The senior author believed that his operating times and complications were unlikely to be improved by adding VSDs or IONM, so commenced a prospective study to test the hypothesis that a conventional capsular dissection technique with relatively low cost and widely available instrumentation by an experienced surgeon would be equal to or better than reported experience with the VSDs or IONM. We focussed particularly on the time taken to complete the surgery and complications and assessing the costefficiency of our relatively conventional surgery compared to the newer devices.

MATERIALS AND METHODS

An analysis was performed on prospectively collected data on all patients undergoing total or hemithyroidectomy during the 4½ years from June 2009 to December 2013. The data were independently verified by the primary author who worked as the Ramsay Breast and Endocrine Surgical Fellow during 2013. All cases were performed by a single specialist endocrine surgeon in two private centers. The technique was a conventional open approach

using the capsular dissection method.[1-3] The dissection was performed in a bloodless field with suction only very rarely being employed. No vessel sealing system was used and all vessels were secured according to size by either ligature, Ligaclip or diathermy. Emphasis was placed on retraction and counter traction to expose and develop tissue planes by blunt dissection. The thyroid lobe was delivered as early as possible to achieve visualization of the important structures posterior to the thyroid. Parathyroid glands were identified and gently separated from the thyroid with their blood supply intact. External laryngeal nerves (ELN) were looked for but not sought beyond the usual field of dissection if it was certain they were being avoided. Recurrent laryngeal nerves (RLN) were encountered relatively late in the mobilization in the region of the ligament of Berry. No IONM device was used.

All patients underwent preoperative vocal cord examination with fiber-optic laryngoscopy. Postoperative laryngoscopy was not repeated in patients who had a completely normal voice but was performed liberally in any patient with voice change. Patients who had a total thyroidectomy or reoperation had serum calcium and parathyroid hormone (PTH) measured on at least the first two postoperative days.

The database consisted of pre-, intra- and postoperative variables. Preoperative variables included indications for surgery, primary *vs* reoperation or early completion thyroidectomy (for those with diagnosis of cancer in the contralateral lobe) and ultrasound measurement of the largest nodule.

Intraoperative variables included extent of surgery (hemi *vs* total, concurrent central or comprehensive nodal clearance), duration (time in minutes from skin incision to completion of skin closure), number of Ligaclip cartridges used, identification of ELNs and RLNs and their anatomical variations, number of parathyroid glands identified and reimplanted, subjectively perceived difficulty by the surgeon (extensive adhesions, difficult access or severe thyroiditis), use of drains and method of closure.

Postoperative variables included histopathological diagnosis, thyroid volume (calculated from multiplication of length, width and height in centimeters by modified coefficient 0.479),[4] type, focality and the size of the largest cancer, size of the largest nodule and the number of parathyroid glands identified with the specimen.

Postoperative complications recorded were temporary or permanent paralysis of vocal cords, temporary or permanent hypoparathyroidism and postoperative hemorrhage. All vocal cord paralyses and their recovery were confirmed with postoperative fiber-optic laryngoscopy. Hypoparathyroidism was defined as corrected calcium below 2 mmol/l and/or PTH undetectable after surgery; temporary less than 6 months and permanent longer than 6 months. Any patients with even subtle voice change postoperatively was examined by laryngoscopy. Vocal cord paralysis was defined as temporary only if both the symptoms and fiber-optic visualization of cord paralysis had completely resolved within 6 months. Postoperative hemorrhage was defined as that needing to return to the operating theater.

A multivariate logistic regression analysis was performed using duration of surgery as the primary endpoint against the above-mentioned pre/intra/post operative variables. The mean operative duration was also compared to those reported in literature with the use of VSDs.

For costefficiency analysis, the time-dependent cost of operating theater utilization at the two private centers was calculated. This was derived by dividing the total annual time-dependent staffing cost of scrub and scout nurses, orderlies and clerks by the total annual operating time, defined by time taken from start to closure of incision. Surgeon and anesthetist costs were excluded as they are reimbursed per case rather than per unit time in the private healthcare setting. This time-dependent theater utilization cost was used to compare the difference in cost of Ligaclips used in our technique *vs* VSD utilization cost to find out how much time would need to be saved using VSDs to counter the gap in cost and render it truly costefficient.

RESULTS

A total of 503 cases were performed in the 4½ years period. The mean age was 52 years, with a female to male ratio of 3.7 to 1. Multinodular goiter comprised the majority (186) of indications for surgery with 42 of them being retrosternal, followed by cancer (64), hyperthyroidism (53), suspicious or large solitary nodule on ultrasound and atypical FNA (200). The cases included 46 reoperations and 26 early completion thyroidectomies. One full median sternotomy was required for a large recurrent intrathoracic goiter. Ultrasound measurement of the largest nodules averaged 31 mm (32 median). The volume of the largest gland was 480 ml.

There were 260 hemithyroidectomies (52%) and 243 total thyroidectomies (48%). The skin to skin operating time (duration) for hemithyroidectomies was median 35 minutes, mean 38 minutes with the majority lasting between 31 and 45 minutes (Fig. 1). Hemithyroidectomies were completed in less than 45 minutes in 82% of cases. Total thyroidectomy time was median 59 minutes, mean 66 minutes, with 55% completed in less than 60 minutes. A total of 268 Ligaclip cartridges were used

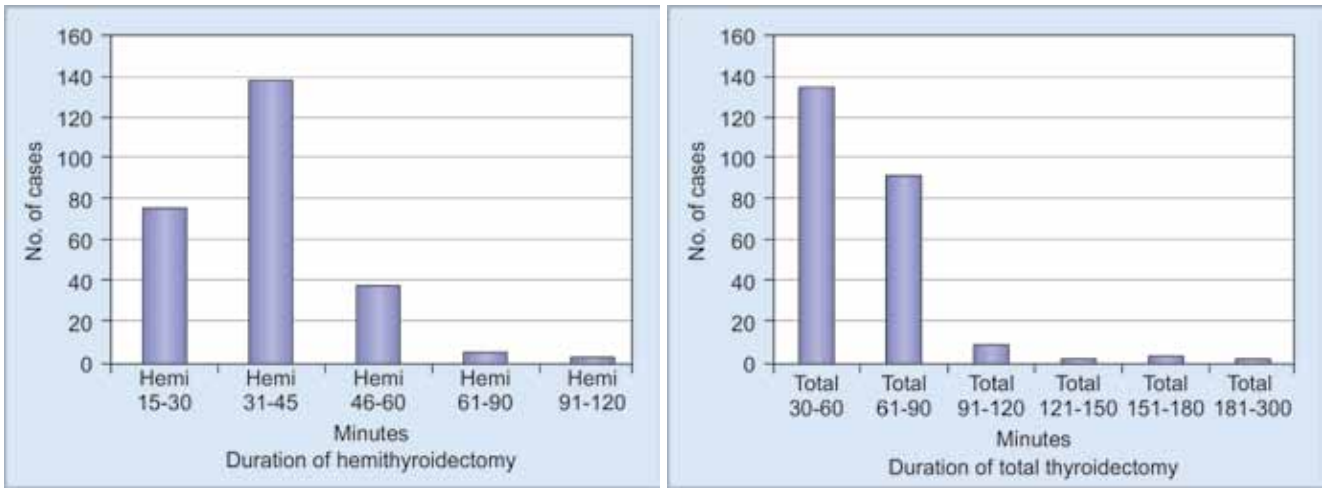

Fig. 1: Duration of thyroidectomy

in 260 hemithyroidectomies and 370 Ligaclip cartridges in 243 total thyroidectomies.

Out of 56 ELNs identified, type 2b (38.68%) was the most common followed by 2a (14.25%) and 1 (4.7%). Seven hundred and twenty six RLNs were identified (253 out of 260 for hemi, 473 out of 486 for total). Eighty-four (11.6%) were branched and 2 (0.3%) were nonrecurrent. There was 1 case of trifurcated RLN. Thirty-one unilateral and 27 bilateral central neck dissections and 3 unilateral and 3 bilateral comprehensive neck dissections were performed. There were 82 (16.3%) cases which were perceived to be 'difficult' by the surgeon.

A total of 342 and 673 parathyroid glands were identified in hemi and total thyroidectomy group, with 17 and 38 reimplanted in the respective groups. Sixty-seven and 183 drains were inserted in hemi and total thyroidectomies. Skin clips were used in 436 and absorbable suture in 67 cases.

In accordance with the indications for surgery, MNG was also the most common histopathological diagnosis, followed by cancer, hyperplastic nodule, Graves' disease, thyroiditis, follicular nodule and Hurthle cell adenoma (Table 1). Fifty-five of 164 diagnoses of cancer were incidental findings, with the majority (47) being sub-centimeter lesions. Papillary carcinoma was the most common type, followed by Hurthle cell and follicular carcinoma. There was one case each of medullary and anaplastic carcinoma.

There were 4 RLN palsies and all were temporary (Table 2). The cases consisted of two reoperative hemithyroidectomies, one completion hemithyroidectomy, and 1 total thyroidectomy. The cases included a 170 ml recurrent retrosternal goiter after previous total thyroidectomy that was deemed 'difficult' by the surgeon and another had marked thyroiditis.

There were total of 62 postoperative hypoparathyroidism including two permanent. As expected, the majority were related to total thyroidectomy. Six cases of hypoparathyroidism in the hemithyroidectomy group all resulted from reoperative surgery and one of these was permanent despite reimplantation of one gland.

Table 1: Postoperative pathological analysis of glands

Pathology	MNG	148	
	Graves' disease	36	
	Follicular nodule	35	
	Cancer	164 (55 incidental with 8 of them 10 mm or greater)	Papillary 141 Follicular 9 Hurthle cell 12 Medullary 1 Anaplastic 1
	Hyperplastic nodule	86	
	Thyroiditis	35	
	Hurthle cell adenoma	13	
Volume of gland (ml)	Hemithyroidectomy	26.77 ± 18.81; 26.7 median	
	Total thyroidectomy	53.96 ± 112.43; 99.5 median	

Table 2: Complications

Complications	Hematoma		3 (0.6%)
	RLN palsy (temporary)		4 (0.5%)
	RLN palsy (permanent)		0
	Hypoparathyroidism (temporary)	Hemithyroidectomy	5 (7.7%) (all reoperations)
		Total thyroidectomy	55 (22.6%) (1 reoperation)
	Hypoparathyroidism (permanent)	Hemithyroidectomy	1 (1.5%) (completion)
		Total	1 (0.4%)

*RLN palsy percentage has been calculated in terms of number of nerves at risk (i.e. total of 746 nerves at risk); †Rate of hypoparathyroidism in hemithyroidectomy group was calculated using a denominator 65, the total number of reoperative or completion hemithyroidectomies

The other permanent hypoparathyroidism followed total thyroidectomy for a large multinodular goiter with two completely intrathyroidal inferior parathyroid glands removed with the specimen.

Multivariate analysis using the skin to skin time (duration) of surgery as the primary endpoint was performed against all pre/intra/postoperative variables collected. In the hemithyroidectomy group, a significant association was observed with perceived difficulty [p <0.001, 90% CI (3.68, 31.74)] and insertion of a drain [p <0.001, 90% CI (5.54, 37.19)]. In total thyroidectomy group, significant associations were observed with age <50 [p = 0.007, 90% CI (0.13, 0.72)], male gender [p = 0.04, 90% CI (1.05, 6.90)], Graves' disease [p = 0.04, 90% CI (1.12, 53.69)], volume of the gland [p = 0.03, 90% CI (1.00, 1.03)], and concurrent central neck dissection [p = 0.003, 90% CI (2.80, 159.93)] and insertion of a drain [p <0.001, 90% CI (2.15, 15.94)].

The costefficiency comparison is presented in Table 3. The difference in cost of our technique aided by Ligaclips *vs* using Ligasure was $267 for hemithyroidectomy and $150 for total thyroidectomy. The time-dependent operating theater costs at the two private hospitals were estimated at A$7.90 per minute at one and A$9.08 at the other using calculations outlined in the method. Using a theoretical estimated theater cost of A$10 per minute, time reduction required to offset the extra cost of Ligasure was 26.7 for hemithyroidectomy and 15 minutes for total thyroidectomy.

Table 3: Cost efficiency analysis of our technique *vs* utilization of Ligasure

	Hemithyroidectomy (n = 260)	*Total thyroidectomy (n = 243)*
Duration (minutes)	38 ± 1.4; 35 median	66 ± 25; 59 median
Number of Ligaclip cartridges used ($250/cartridge)	268 (average 1.03/case = $258/case)	364 (average 1.5/case = $375/case)
Extra cost, if using Ligasure ($525/handle)	$525 – $258 = $267	$525 – 375 = $150
Time reduction required to offset extra cost, if using Ligasure	267 ÷ 10* = 26.7 minutes	150 ÷ 10* = 15 minutes
Reported time savings with Ligasure (vs conventional technique) in literature	5.6, 12.6, 14.3, 15 minutes	

*Time-dependent operating theater running costs at A$10 per minute

Table 4: Comparison of mean operative duration for total thyroidectomy in literature

	Conventional	*Ligasure**	*Time saving*
Kiriakopoulos et al	89 minutes (n = 40)	84 minutes (n = 40)	5 minutes
Cipolla et al	110 minutes (n = 52)	104 minutes (n = 53)	6 minutes
Kilic et al	68.25 minutes (n = 20)	55.65 minutes (n = 20)	12.6 minutes
Manouras et al	101.6 minutes (n = 90)	87.3 minutes (n = 94)	14.3 minutes
Chang et al	86 minutes (n = 772)	71 minutes (n = 1163)	15 minutes
Average duration and time saving	90.97 minutes	80.39 minutes	10.58 minutes

*Study by Chang et al included 50% ligasure and 50% harmonic scalpel usage

DISCUSSION

In the past decade, there have been some technical variations introduced in thyroid surgery.

Among these are minimally invasive approaches that may be open or endoscopic, VSDs, such as Ligasure and Harmonic shears and intraoperative nerve monitoring. These all come with significant additional cost compared to traditional methods. If their routine use is to be accepted, it is imperative that this cost is justified by either a reduction in complications (safety) or a reduction in operative time (costefficiency).

The accepted clinical indicators for the outcomes of thyroid surgery are postoperative hemorrhage, RLN injury (temporary and permanent) and hypoparathyroidism (temporary and permanent). The outcomes of these parameters in our series using conventional approach are better than most recently published data. The patient population and pathologies was similar to the expected case mix[1] so patient and thyroid pathology variations are unlikely to have influenced the results. Surgeon experience is probably more relevant.

The UK BAETS 4th national audit in 2012 of 18,904 patients reported 27.4% overall rate of hypocalcemia after first time total thyroidectomy.[5] A multicenter Italian study showed 17.64% rate of temporary and 1.51% permanent hypocalcemia.[6] Watkinson et al reported the rate of temporary and permanent hypocalcemia at 21 and 3% respectively.[7] Variation in results may be partly explained by differences in definitions.[8] Nevertheless, our rate of 19.5% temporary and 0.6% permanent hypoparathyroidism are comparable to the literature.

Recent literature also reports temporary RLN palsy rates at 1.4 to 3.2% and permanent palsy at 0.3 to 1.4%.[7,9] Intraoperative nerve monitoring has been adopted by some thyroid surgeons, particularly those with developing experience. It has been advocated that it should be used routinely in order to assist in interpretation of signals in more difficult cases, such as in reoperations. However, despite widespread interest and now large experience, there is no evidence of benefit. A meta-analysis of multiple large published studies involving 64,699 nerves at risk showed no benefit for IONM. The rate of temporary

RLN palsy was 2.74% when IONM was used compared to 2.49% when only visual identification was employed. The rate of permanent RLN palsy was 0.75% when IONM was used and 0.58% when only visual identification was employed.[10] The cost for the special endotracheal tube, associated electrodes and probe exceeds A$770. Our experience of zero permanent RLN in 746 nerves at risk clearly could not be improved by IONM and routine IONM is therefore not a requirement for safe thyroid surgery. It follows that an expert thyroid surgeon, or a trainee operating under the supervision of an experienced thyroid surgeon, as we have previously reported, may achieve good results without routine use of IONM.[1]

There have been many publications that have addressed the safety of VSDs with no differences in complications compared to the conventional clip and tie technique.[11,12] Therefore, if safety outcomes are comparable, the extra cost needs to be justified by reduced operating time and/or other cost savings. The minimum time reduction by VSDs to establish costefficiency against our technique was calculated by dividing the difference in device cost between Ligaclips and Ligasure by the cost of running an operating theater per unit time at the two centers. Calculating the cost of operating theater utilization is an extremely complex and contentious issue as evidenced in the literature.[13] Because, the aim was to compare the difference in operative duration using different devices, however, only the time-dependent costs needed to be considered in our analysis. Our estimated theater cost of A$7.90 and A$9.08 per minute at the two private centers were slightly lower than the figures quoted in previous studies. A study in Sydney, Australia estimated A$12.80[14] while in France it was US$13.33.[15] Neither of the two studies however included a detailed methodology of how the costing analysis was derived. Nevertheless, we wanted to make our analysis as practical and closely aligned with the current literature as possible, hence using a higher than calculated average cost at A$10 per minute. This would have had no undesirable effect on our analysis as using a higher theater cost in the calculation would naturally yield less time reduction necessary for Ligasure to be costefficient. Even using this higher figure in our calculation, the minimum time reduction required by use of Ligasure to be equally costefficient to our technique was 27 minutes for hemithyroidectomy and 15 minutes for total thyroidectomy, which are mostly longer than the reported time savings of 5, 6, 12.6, 14.3, and 15 minutes in the literature.[11,14,16-18] The study that found 15 minute reduction for total thyroidectomies also included a significant proportion of operations utilizing harmonic scalpel with its inherent higher cost.[14] Further exacerbating the cost strain by VSD utilization is that many surgeons would employ Ligaclips in addition to the VSD, especially in close proximity to the RLN, nullifying any costefficiency benefit afforded by VSDs. The cost of Ligasure generators were not included in the calculations either, which if included would naturally drive up the necessary time reduction required by VSDs. Furthermore, our mean operating times of 38 (35 median) minutes for hemithyroidectomy and 66 (59 median) minutes for total thyroidectomy are already shorter than the average of mean operating durations published for VSDs (80.39 minutes) in the above series.[11,14,16-18] The reported mean operative duration and time savings with Ligasure are summarized in Table 4.

It is reasonable to consider whether VSDs are really necessary. We estimate that the time saving when using an automatic Ligaclip applier is approximately 5 to 10 minutes. Using only ligatures and diathermy without Ligaclip, it should still be possible to operate safely and cost effectively. Many hospitals and heath systems worldwide will not be able to afford these devices. We contend that the safety and efficiency of the operation are more dependent on the technique and skill of the surgical dissection rather than on the use of special devices. We recognize that some surgeons are already using VSDs and it may be a costeffective consideration in total thyroidectomy where our data have shown that longer operating time may be predicted (age under 50, male patients, Graves' disease, large volume thyroid glands or when concurrent lymph node dissection is planned).

This study did not compare the surgeon's technique with another using VSDs. However, it would not have been possible to demonstrate that the vessel sealing technique nor any other technique would have been safer, with our zero permanent RLN palsy rate. Furthermore, the operating times were already comparably shorter than published durations with the use of VSDs. In our hands, VSDs would not have improved safety or efficiency and we therefore suggest that the costefficiency of these devices is reassessed. An open capsular dissection technique using conventional ligatures, diathermy and Ligaclips remains an appropriate method of thyroid surgery.

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