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Comparative Study of Early Postoperative Complications Between Vessel Sealing System Device and Conventional Suture Ligation in Total Thyroidectomy

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Abstract: Background: The imperative to ensure the safety of thyroid surgery and to reduce its adverse effects motivates surgeons to explore novel technologies. The vessel sealing system device (VSSD) (Ethicon Endosurgery) was introduced into the surgeon's armamentarium almost two decades ago. The objective of this study was to compare the incidence of early postoperative complications (including bleeding, hypocalcaemia, recurrent laryngeal nerve injury, and operative time) between conventional suture ligation and the sealing vessel device in a cohort of approximately 126 cases at Baghdad Teaching Hospital/Medical City. Patients and Methods: A prospective cohort study was conducted on patients who underwent total thyroidectomy by two techniques (conventional suture ligation and the vessel sealing system device) at Baghdad Teaching Hospital and Medical City. The study aimed to compare the incidence of early postoperative complications, including hypocalcaemia, bleeding, and recurrent laryngeal nerve injury, between the two techniques. The results demonstrated that the vessel sealing system significantly reduced the operative time, postoperative hypocalcaemia, and bleeding. Additionally, the risk of recurrent laryngeal nerve injury was reduced, although this was not statistically significant in comparison with conventional suture ligation. In conclusion, the vessel sealing system is a reliable and safe tool for reducing operative time and postoperative hypocalcaemia and bleeding.

Keywords: Vessel sealing system device, Conventional method, Postoperative complications of thyroidectomy.

Introduction

The history of thyroid surgery is both interesting and illustrative where the aspirations of a thyroid surgeon have undergone a transformation over time. The earliest documented instance of thyroid surgery can be traced back to 952 AD when Albucasis (Alzahrawi) performed the procedure for the first time. Subsequently, the trajectory of this surgical procedure has experienced periods of both advancement and regression. "There have been several developments in the technical aspects of thyroid surgery since the surgical approach described by Kocher over a century ago (2)".

Given that total thyroidectomy is the most common operation in the field of endocrine gland surgery and the most convenient therapeutic choice in the treatment of many thyroid disorders through surgical intervention (3, 4), there is a clear imperative for surgeons to ensure the safety of thyroid surgery and to minimise its potential complications. This has led to a search for new technologies. The harmonic

scalpel (Ethicon Endosurgery) was introduced into the surgeon's armamentarium almost two decades ago.

The device employs mechanical vibrations at 55.5 kHz, enabling the cutting and coagulation of tissue in a simultaneous manner. The harmonic scalpel is a surgical instrument that is used to simultaneously cut and cauterise tissue. The Harmonic Scalpel employs ultrasonic energy in a unique manner, whereby ultrasonic energy is converted to mechanical energy at the active blade (5,6,7). The primary mechanism is the active blade, which generates a high-grade frictional force, while the inactive upper arm holds the tissue in apposition. The key advantages of this technology include precise dissection, reliable hemostasis, and minimal lateral thermal spread. The charring process primarily involves applying pressure and then sealing with a denatured protein coagulum, while ultrasonic vibration denatures hydrogen bonds to perform vessel coagulation (8,9,10).

The thyroid gland is susceptible to injury due to its rich vascularity and the limited surgical field available during thyroidectomy. Meticulous hemostasis is, therefore, a crucial aspect of successful thyroid surgery. The potential for bleeding to cause life-threatening airway obstruction must be considered. During thyroidectomy, the potential for bleeding to obscure the operative field increases the risk of unsafe dissection of the recurrent laryngeal nerve (RLN) and parathyroid glands (11). The aetiology of post thyroidectomy haemorrhage has been described as a result of a number of factors, including slippage of the ligature on major vessels, reopening of the veins that have been cauterised, retching and bucking of the patient during recovery, a Valsava manoeuvre, and increased blood pressure.

Furthermore, oozing from the incision site on the thyroid gland may also occur. One of the primary complications of thyroid surgery is vocal cord paresis or paralysis due to iatrogenic injury of the recurrent laryngeal nerve (RLNI) (12,13). The most common and frequently problematic long-term consequence of aggressive thyroid surgery is postsurgical hypoparathyroidism. This may result from injury to the parathyroid glands or their blood supply or from inadvertent resection of parathyroid tissue. This potentially severe complication of endocrine surgery presents with a broad range of signs and symptoms that may be either transient or permanent. The aim of this study was to compare the incidence of early postoperative complications (bleeding, hypocalcaemia, nerve injury, and operative time) between conventional suture ligation and the harmonic scalpel.

Material and method

The study population comprised patients, and the methodology employed was as follows:

The study was a prospective observational cohort study conducted on patients admitted to the surgical wards of Baghdad Teaching Hospital/Medical City between 1 January 2016 and 1 October 2017. The study cohort comprised 126 patients aged 18 years and over with a diagnosis of multinodular goitre who required a total thyroidectomy. The incidence of postoperative complications was monitored until the six-month follow-up point.

Patients were excluded from the study if they met any of the following criteria:

1. Preoperative hypocalcaemia and hypercalcaemia.
2. Goitre is situated in the retrosternal region.
3. Previous surgical intervention for a goitre.
4. Previous irradiation of the neck.
5. Coagulopathy.
6. Thyroidectomy, either partial or total removal of one lobe of the thyroid gland.
7. Graves' disease.
8. Preoperative diagnosis of malignant thyroid disease.

9. Previous history of recurrent laryngeal nerve immobility.

Preoperative preparation of patients:

First, all patients' thyroid function tests should be within normal limits. Then, an ultrasound of the neck should be performed, followed by FNA aspiration of the mass to diagnose the presence of malignant cells. Additionally, serum calcium levels should be monitored, and an indirect laryngoscope or endoscope should be used to visualize the vocal cords. Second, other investigations that are important for the operation should be conducted in accordance with the hospital policy.

Post-Procedure:

The patients were observed postoperatively for early postoperative complications (till 6 months):

a) Intraoperative time from dissection of thyroid capsule till remove it.

b) Post-operative complication of hypocalcaemia.

c) Post-operative complication of bleeding more than 100ml or less than 100ml per drain in 48 hours. D- Recurrent laryngeal nerve injury, including stridor and hoarse voice and, was confirmed by indirect laryngoscope. Post-operative discharge: Before discharge, patients should be instructed on proper incision care as well as given information on signs of hypocalcaemia (numbness or 11 tingling of the digits or perioral area). Additionally, they should be made aware of neck hematoma as a possible complication and the signs to observe. Statistical analysis: Statistical analysis was done by SPSS version 19.

Results Table (1): Mean age in harmonic vs conventional group patients.

operative technique	Mean	N	Std. Deviation
suture ligation	41.73	74	12.235
harmonic scalpel	42.92	52	13.631
Total	42.22	126	12.790

P value=0.652

Table (2): Operative time of harmonic and conventional methods.

		operative technique		Total
		suture ligation	harmonic scalpel	
Operative time	60-79min	45 35.7%	44 34.9%	89
	80-99min	22 17.5%	8 6.5%	30
	>100min	7 5.4%	0	7
Total		74	52	126

(P<0.001)

Table (3): Post-operative hypocalcaemia in harmonic and conventional methods.

			s. calcium		Total
			normal	hypocalcaemia	
operative technique	suture ligation	Count	45	29	74
		% within operative technique	60.8%	39.2%	
	harmonic scalpel	Count	41	11	52
		% within operative technique	78.8%	21.2%	
Total		Count	86	40	126
		% within the operative technique	68.3%	31.7%	100.0%

P<0.001

Post-operative bleeding, in conventional method (89.2%) bleeding less than 100ml/48hr, while (10.8%) there were bleeding more than 100ml/48hr of total cases (74 cases), and in harmonic method (98.1%) bleeding less than 100ml/48hr, while (1.9%) there were bleeding more than 100ml/48hr of total cases (52 cases). As in Table (4)

Table (4): Post-operative bleeding in both groups.

v			post-operative bleeding		Total
			Less than 100ml	More than 100ml	
operative technique	suture ligation	Count	66	8	74
		% within the operative technique	89.2%	10.8%	
	harmonic scalpel	Count	51	1	52
		% within the operative technique	98.1%	1.9%	
Total		Count	117	9	126
		% within the operative technique	92.9%	7.1%	100.0%

P value= 0.03

Table (5): Number and percentage of patients with unilateral and bilateral RLN injury in both groups.

			operative technique		Total
			suture ligation	harmonic scalpel	
RLN injury	unilateral	Count	3	1	4
		% within operative technique	4.1%	1.9%	3.2%
	bilateral	Count	1	0	1
		% within operative technique	1.4%	.0%	.8%
	intact bilaterally	Count	70	51	121
		% within operative technique	94.6%	98.1%	96.0%

Total		Count	74	52	126
		% within the operative technique	100.0%	100.0%	100.0%

P>0.005

Discussion

The results of the operative time for the harmonic and conventional methods demonstrated a statistically significant difference (p-value = 0.001), a finding that has also been reported by Emanuele F. et al. (14). The average operative time was significantly shorter in the harmonic group (44.9 ± 8.3 minutes) compared to the conventional group (69.5 ± 10.7 minutes). The conventional group exhibited a significantly longer operative time (69.5 ± 10.7 minutes; $p < 0.001$) compared to the harmonic group. The ease of handling, cutting, and coagulation of the harmonic scalpel allows for simultaneous actions, whereas the conventional method requires additional time for vessel ligation and major thyroid vessel division. This study demonstrates that it is feasible to reduce the operative time by utilising a harmonic scalpel.

The incidence of postoperative hypocalcaemia in the harmonic technique was 21.2%, while in the conventional technique, it was 39.2%. These figures demonstrate that hypocalcaemia occurs significantly less frequently in the harmonic technique than in the conventional technique (p-value <0.001). This finding is corroborated by the results of other researchers, such as Oktay et al. (15), who observed that postoperative transient hypocalcaemia occurred more frequently in the conventional group than in the harmonic group. The observed difference was statistically significant (48% in the conventional group and 16% in the harmonic group, $P < 0.01$), as also reported by Hang et al. (19,16), who found that a comparison between conventional techniques in total thyroidectomy and the harmonic resulted in a statistically significant decrease in transient hypocalcaemia with a relative risk of 0.60 (95% confidence interval), $P < 0.001$. The occurrence of hypocalcaemia was more prevalent in the conventional method due to the extensive manipulation of the gland, which resulted in parathyroid ischaemia and the cessation of the blood supply to the parathyroid gland. The incidence of transient hypocalcaemia varies in the literature, with figures ranging from 5 to 50%. However, the rate of permanent hypocalcaemia secondary to hypoparathyroidism (lasting more than six months) is between 0.5 and 2%. The harmonic technique demonstrated a postoperative bleeding rate of 1.9%, with instances of bleeding exceeding 100ml/48hr observed in 1.9% of cases.

Conversely, 98.1% of cases exhibited bleeding volumes below 100ml/48hr, with the majority of these instances occurring in the absence of suction drains. In the conventional technique, 10.8% of cases exhibited bleeding in excess of 100ml/48hr in the suction drain, while 89.2% demonstrated bleeding of no more than 100ml/48hr in the suction drain. A statistically significant difference was identified ($p=0.032$). The amount of postoperative bleeding estimated by suction drain over a 48-hour period was also found to be significantly different between the harmonic and conventional methods in the aforementioned studies; the harmonic method resulted in an average blood loss of 128 mL, while the conventional method resulted in an average blood loss of 268 mL. The observed difference was not statistically significant ($P = 0.16$), likely due to the high degree of variation in the amount of bleeding caused by the tendency of some patients with toxic goitre to bleed considerably. (Eforeman et al.) (16) observed that the total volume of drainage fluid during the 48-hour period was significantly higher in the conventional method (237ml) compared to the harmonic method (356ml) (p-value <0.001). Postoperative bleeding was more prevalent in the conventional method than in the harmonic method. This was attributed to factors such as slipped ligatures, unsecured tied vessels, and excessive manipulation of the gland, which resulted in oozing blood from the surrounding tissue. It should be noted, however, that all patients in this study underwent a total thyroidectomy and that a more extensive thyroid resection is likely to increase the risk of postoperative bleeding.

There was no significant difference between the two methods in terms of the incidence of unilateral recurrent laryngeal nerve injury, with one case occurring in the harmonic method and three cases occurring in the conventional method. However, there was one case of bilateral recurrent laryngeal

nerve injury reported in the conventional method, which necessitated tracheostomy. The statistical analysis revealed no significant difference between the two methods (p-value > 0.005). Injury to the recurrent laryngeal nerve (RLN) can result in vocal fold paralysis. Studies have demonstrated that the identification of the RLN is associated with a reduction in the incidence of injury (Donnellan KA et al., 2022).

The following conclusions may be drawn from the evidence presented:

- The Utilisation of the harmonic method in thyroidectomy has been demonstrated to result in a notable reduction in the overall operative time.
- The harmonic method in thyroidectomy has been demonstrated to reduce the incidence of postoperative hypocalcaemia and bleeding when compared with the conventional method.
- The incidence of recurrent laryngeal nerve injury is reduced in the harmonic method, although this is not a statistically significant finding.

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