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Original Article

Post-operative Hypocalcaemia Following Open Thyroidectomy for Benign Multinodular Goiters Using FOCUS Harmonic Scalpel Versus Conventional Suture Ligation Technique for Hemostasis: a Prospective, Single-blind, Randomized Controlled Trial

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ABSTRACT

Purpose: Vessel hemostasis during thyroidectomy reduces the risk of post-operative hypocalcaemia and is achieved using several techniques. The aim of this study was to compare the occurrence of hypocalcaemia 24-48 hours following total thyroidectomy using FOCUS harmonic scalpel (HS) versus conventional suture ligation (CSL).
Methods: A prospective, single-blind, randomized trial in which 76 patients with benign multinodular goiters were randomized into two groups to receive total thyroidectomy using HS (n=38) or CSL (n=38) techniques. Patients were monitored for hypocalcaemia at 24 and 48 hours post- thyroidectomy and their length of postoperative hospital stay was recorded. Statistical analysis was performed using Student's t-test using SPSS to detect significant differences between groups.
Results: The incidence of post-operative hypocalcaemia was 15.79% in the HS group, and 36.84%, in the CSL group (p =0.033). The number of in situ parathyroid glands was significantly associated with hypocalcaemia in the CSL group (P=0.019), but not in the HS group (P=0.372). Length of hospital stay was 2.63±0.85 in the CSL group and 1.37±0.67 days in the HS group (P<0.001).
Conclusion: Compared to conventional hemostasis, FOCUS HS reduces the overall risk of hypocalcaemia during thyroidectomy for benign thyroid disease. The conventional suture ligation technique should be replaced with FOCUS HS technique for thyroidectomy.

Keywords: Goiters; Thyroidectomy; Hypocalcemia; Parathyroid glands; Hemostasis; Scalpel; Suture; Ligation

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

INTRODUCTION

Modern thyroid surgery techniques were developed between 1873 and 1883 by Theodor Kocher and Theodor Billroth. By mid-20th century, the standards for efficient and safe thyroid surgery which guide modern thyroid surgery had been established (1-3) and set forth three basic procedures: identification of vessels and ligation, identification of recurrent laryngeal nerves (RLNs), and conservation of parathyroid glands (PGs). The basic technique for thyroid surgery remains largely unchanged, except for major innovations of coagulation and vascular section. The current approach now addresses the inherent risks associated with the vascularity of the thyroid gland and the relatively small operative field. Disruption of the blood vessels can result in excessive perioperative and prolonged post-operative bleeding and unstable hemostasis (1,4). Perioperative bleeding is associated with an obscure operative field, which makes it challenging to perform safe conservative dissection of the RLNs and PGs. Injury to RLNs, which provide motor innervation to the intrinsic muscles of the larynx, can lead to unilateral vocal cord paralysis characterized by inadequate coughing, inability to clear secretions, and aspiration in the postoperative setting (4) and may cause life-threatening airway obstruction.(3) Inadvertent damage or removal of the PGs during thyroid surgery can result in acute and chronic parathyroid insufficiency syndromes, especially postoperative hypocalcaemia, protracted hypoparathyroidism, and permanent hypoparathyroidism (5,6).

Post-operative hypocalcaemia is clinically defined as a serum calcium of less than 8 mg/dL (80%) in post-operative patients with permanent hypoparathyroidism (5,7,8). Untreated post-operative hypocalcaemia can result in renal and neurological dysfunction (2,9), with clinical manifestations ranging from mild (numbness and tingling in the arms or hands and around the mouth) to severe (severe muscle cramping of the entire body and sometimes convulsions). Therefore, monitoring post-thyroidectomy hypocalcaemia is important because its symptoms can necessitate lifelong medication, and increase clinical visits, and increase healthcare costs which impact quality of life. Post-thyroidectomy hypocalcaemia is clinically managed by administration of daily high-dose calcium and/or active vitamin D supplementation therapy before discharge (6,7). However, despite pharmacological intervention, 45% of patients still experience some hypocalcaemia symptoms which negatively impact on quality of life.

Effective vessel hemostasis during thyroidectomy is the key to intra-operative prevention of post-thyroidectomy hypocalcaemia and hypoparathyroidism (5,10). Conventional techniques, such as LigaSure and clamp-and-tie techniques, have been demonstrated to have comparable efficacy and safety for achieving hemostasis in total thyroidectomy (11). The Harmonic scalpel (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) revolutionized the thyroidectomy nearly 2 decades ago when it was introduced and remains a benchmark device. Using mechanical vibrations at a frequency of 55.5 kHz, the Harmonic scalpel has the ability to simultaneously, cut and coagulate target tissue (12), diminishing blood loss and shortening operative time (13). Other advantages of this technique over the traditional electrocautery technique are that it causes minimal thermal injury to the lateral tissue, does not cause neuromuscular stimulation, and does not transmit electrical energy to or through the patient (14,15). Conventional techniques for securing hemostasis include the tying of knots, the use of resorbable ligatures, vicryl 3-0/4-0, stitches, monopolar or bipolar electrocautery, and bipolar diathermy (1). The efficacy and safety of the harmonic scalpel (HS) versus conventional hemostasis (CH) in thyroid surgery has been evaluated in several randomized

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clinical trials. Compared to CH, HS was shown to reduce operative duration, blood drainage volume, postoperative pain and transient hypocalcaemia (1). Two meta-analysis of randomized clinical trials (16,17) demonstrated efficacy and safety profiles significantly favoring HS groups over CH groups, with respect to lower occurrence of hypocalcaemia and shortened operative time. However, the two meta-analyses were based on mixed populations of thyroidectomy patients with benign and malignant thyroid disease, with no attempt to perform a subgroup analysis. As such, the evidence cannot be generalized to a homogeneous population of either benign or malignant thyroid disease.

There is a saturation of evidence verifying the superior safety and efficacy profile of HS over CH with respect to post-operative complications, especially postoperative hypocalcaemia. Hoverer, most trials only assessed hypocalcaemia up to 24 hours following thyroidectomy (6,16,17); yet it can occur from 24–48 hours post-thyroidectomy (18). In addition, visual identification of all 4 (or 3 or 4) PGs for preservation during thyroidectomy has traditionally been advocated by surgeons to lower the risk of hypocalcaemia and inadvertent parathyroidectomy following thyroidectomy (10,16). However, no previous trial has investigated whether the HS technique reduces the risk of hypocalcaemia associated with the identification of in situ PGs during total thyroidectomy. The present prospective, single-blind, randomized controlled trial evaluated the comparative incidence of hypocalcaemia 24–48 hours following total thyroidectomy using HS versus conventional suture ligation (CSL) in patients with benign multinodular goiters. Given the increased postoperative blood drainage volumes by CSL technique; the aim of the present study was based on three hypotheses: First, the incidence of postoperative hypocalcaemia would be lower in the HS group than CSL group. Second, the length of hospital stay would be shorter in the HS group than CSL group. Last, the risk of hypocalcaemia associated with identification of a greater number (3 to 4) of in situ PGs would be lower in the HS group than CSL group.

METHODS

1. Study design and setting

This prospective, single-blind, randomized controlled trial study was conducted at a teaching hospital, in the Department of General Surgery, in a Jinnah Postgraduate Medical Centre, Karachi, Pakistan. The study was conducted between July 1, 2015 and July 30, 2016, according to the institution's ethical guidelines (approval No. 31673).

2. Patients

Consecutive patients with benign multinodular goiters scheduled to undergo elective total thyroidectomy, performed by a single surgeon, were evaluated for inclusion in the study.

Inclusion criteria

Inclusion criteria included indication for total thyroidectomy for benign multinodular goiters, total euthyroid patients, aged 18–40 years, consented to participate in the study by signing an informed consent form.

Patients exclusion criteria

Exclusion criteria included diagnosis with cervicomediastinal goiters or no indication for total thyroidectomy, evidence of concomitant parathyroid disorders, previous history of

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medical irradiation, indication for total thyroidectomy requiring dissension of lymph node block (indicated in patients with malignant invasive cancer), previous neck surgery.

3. Sample size calculation

A homogenous sample size of 76 was determined to be statistically sufficient for the study, using a sample proportion of 14% (based on the 14% global incidence rate of hypocalcaemia) and a 7% bond of error at a 95% confidence level (19). It was further determined that the calculated sample size would have a sufficient statistical power to detect significant differences between groups at an alpha level of 0.05 (20).

A total of 98 consecutive patients were screened for eligibility and 76 met the inclusion criteria. The patients were admitted to the hospital from the outpatient department for clinical and pre-surgical evaluation. Using computer generated sequence numbers, the patients were randomized into 2 surgical groups to receive total thyroidectomy by either CSL (n=38) or HS (n=38) techniques. Preoperatively, patients were evaluated both clinically and biochemically. After anesthesia assessment, patients gave written/signed informed consent before final inclusion into the study. All surgical procedures were carried out under general anesthesia with endotracheal intubation, performed by a senior consultant with at least 5 years post fellowship experience.

4. Surgical intervention

Open thyroid surgery was performed as previously described by Anandaravi et al. (4). Relatively large goiters warranted division of the strap muscles and reflected laterally. In all cases the strap muscles were reflected laterally. The thyroid gland lobe was dissected away from the strap muscles; where the middle, superior and inferior thyroid vessels were identified and subsequently ligated with Vicryl 2-0 polyglactin sutures (CSL technique) or coagulated and divided using HS technique with the ultrasonically activated HARMONIC FOCUS© scalpel (Ethicon Endo-Surgery, Inc.). Ultrasonography with in the harmonic frequency range was used to dissect the target tissue throughout the thyroidectomy procedure and achieved coagulation, cutting, and cavitation synergistically.

5. Outcome assessment and follow-up

The primary outcome measured was post-operative hypocalcaemia. Serum calcium levels were assessed at 24 and 48 hours post-operatively. Serum calcium levels <8 mg/dL observed in at least 2 consecutive tests were considered positive for hypocalcaemia. Patients with hypocalcaemia on discharge were monitored for 6 months post-operatively by outpatient consultation or telephone. The secondary outcomes measured were the length of hospital stay following total thyroidectomy and the association between parathyroid identification and hypocalcaemia.

6. Data collection and statistical analysis

Clinical data was collected by a primary researcher at the institution. The researcher was blinded to the study in order to reduce detection bias due to outcome assessor bias. Collected data were processed and analyzed using Statistical Program for Social Sciences (SPSS), version 11; unpaired t-test and Fischer's exact test. Age was presented as mean and standard deviation (SD), while gender and hypocalcaemia was presented by frequency and percentage. Probable effect modifiers were controlled by stratification of age and gender. Between-group effects of these modifier on outcome variables were evaluated using χ^2 test. P values of <0.05 were considered statistically significant.

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RESULTS

The progress of enrolment, intervention allocation, follow-up, and data analysis is presented using the latest version (2010) of CONsolidated Standards of Reporting Trials (CONSORT) Flow Diagram (**Fig. 1**) (21). The CONSORT tool was used to report attrition bias. Finally, 76 total thyroidectomy patients met the inclusion criteria, and were randomized into 2 groups according to surgical technique: CSL group (n=38) and HS group (n=38). All 76 patients received the intervention in their respective groups as originally randomized. However, post-operatively, 2 patients from the HS group and 1 patient from the CSL group were lost to follow-up and excluded from analysis.

1. Baseline characteristics

Baseline characteristics of the 2 groups are summarized in **Table 1**. There were significantly more female than male patients in both groups (P=0.033). However, the gender ratio was comparable between the groups with male to female ratio being 1:1.92 in the CSL group, and 1:2.16 in the HS group. A slight majority of patients (52.63%) were aged between 18 and 33 years, and the remaining 47.37% were aged between 34 to 40 years in both surgical groups. The deference was not significant (P>0.999), thus the age composition was comparable between the 2 surgical groups. There was no significant age difference between the mean age of patients in the groups (P=0.577). All surgical cases were benign thyroids disease (multi nodular goiters) in both groups.

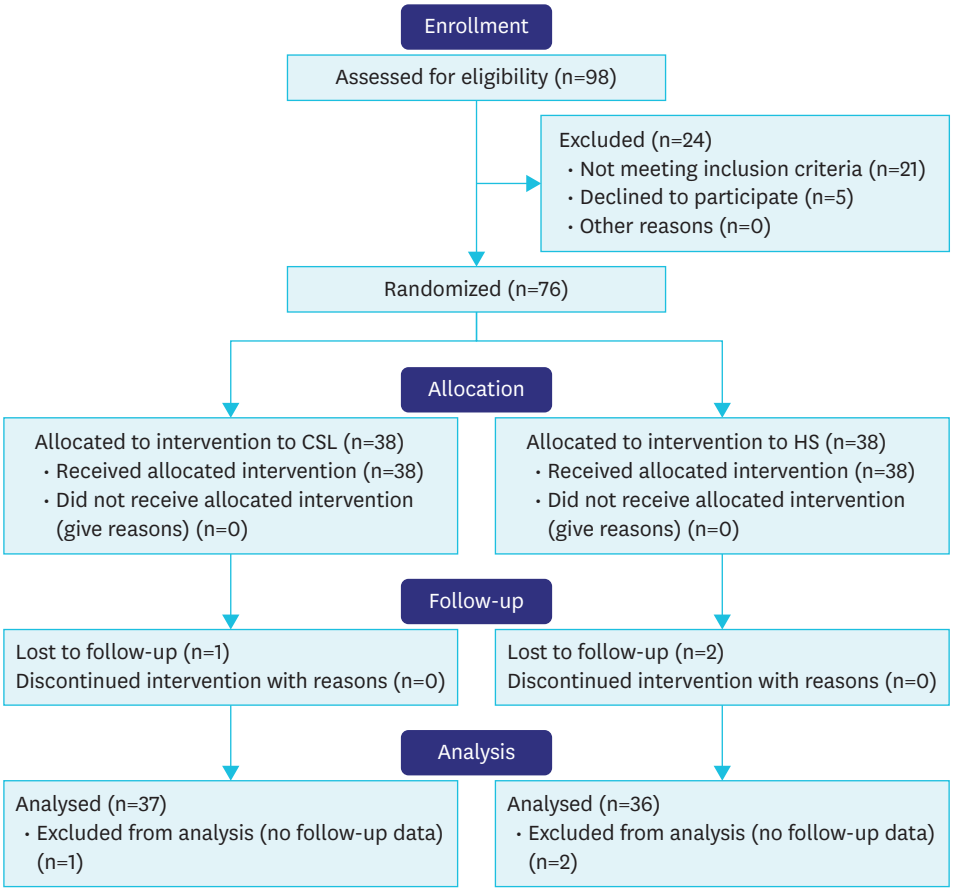

Fig. 1. CONSORT Flow Diagram for enrollment, allocation, follow-up, and analysis of patient participants.
CONSORT = CONsolidated Standards of Reporting Trials; CSL = conventional suture ligation; HS = harmonic scalpel.

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Table 1. Baseline and pre-operative characteristics of the included patients

Baseline characteristic	CSL (n=38)	HS (n=38)	P value†
Gender			0.033*
Male	13 (34.21)	12 (31.58)	
Female	25 (65.79)	26 (68.42)	
Age (yr)			
Mean±SD	31.92±6.48	32.71±5.78	0.577
18–33	20 (52.63)	20 (52.63)	>0.999
34–40	18 (47.37)	18 (47.37)	
Diagnosis			>0.999
Multinodular goitre	38 (100)	38 (100)	

Values are presented as number (%).
CSL = conventional suture ligation; HS = harmonic scalpel; SD = standard deviation; ANOVA = analysis of variance.
*Statistically significant at 5% level of significance; †P values are based on χ^2 test for proportions and ANOVA for mean.

Table 2. Post-operative hypocalcaemia and length of hospital stay by surgical technique

Post-operative hypocalcaemia by surgical technique	CSL (n=38)	HS (n=38)	P value†
Calcium (mg/dL)			
At 24 hr	8.00±1.05	8.56±0.96	0.018*
At 48 hr	8.28±1.04	8.09±1.03	0.013*
Post-operative hypocalcaemia			0.033*
Yes	14 (36.84)	6 (15.79)	
No	24 (63.16)	32 (84.21)	
Length of stay (day)	2.63±0.85	1.37±0.67	<0.001*

Values are presented as mean±SD or number (%).
CSL = conventional suture ligation; HS = harmonic scalpel
*Statistically significant at 5% level of significance. P values are based on χ^2 test for proportions and ANOVA for mean.

2. Post-operative hypocalcaemia

All patients were evaluated for post-operative hypocalcaemia at 24 and 48 hours post thyroidectomy, and the length of hospital stay (days) following thyroidectomy was recorded (**Table 2**). Twenty-four hours post- thyroidectomy, the mean serum calcium level was significantly higher (P=0.018) in the HS group (8.56±0.96 mg/day) than in the CSL group (8.00±1.05 mg/day). However, at 48 hours post-thyroidectomy, the mean serum calcium level was significantly higher (P=0.013) in the CSL group (8.28±1.04) than in the HS group (8.09±1.03). When the criteria for the presence of post-operative hypocalcaemia was applied, only 15.79% of surgical patients in the HS group tested positive for hypocalcaemia compared to 36.84% in the CSL group (P=0.033). The length of hospital stay was significantly shorter (P<0.001) in the HS group (1.37±0.67 days) than in the CSL group (2.63±0.85 days).

3. Hypocalcaemia risk and parathyroid safety

The association between parathyroid identification and the risk of post-operative hypocalcaemia was compared between the 2 surgical groups (**Table 3**). In the CSL group, identification of PGs was significantly associated with hypocalcaemia compared to when PGs were not identified (P=0.019). A similar association was observed in the HS group, though not statistically significant (P=0.372). Univariate analysis showed no association of

Table 3. Association of parathyroid identification with post-operative hypocalcaemia in both techniques

Method	Hypocalcaemia	Parathyroid not identified	Parathyroid identified	Fisher's exact test P value
CSL	Yes	6 (75)	8 (26.67)	0.019*
	No	2 (25)	22 (73.33)	
HS	Yes	2 (25)	4 (13.33)	0.372
	No	6 (75)	26 (86.67)	

CSL = conventional suture ligation; HS = harmonic scalpel.
*Statistically significant at 5% level of significance.

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Table 4. Association of gender with post-operative hypocalcaemia in both techniques

Method	Hypocalcaemia	Male	Female	Fisher's exact test P value
CSL	Yes	65 (38.46)	9 (36)	0.577
	No	8 (61.54)	16 (64)	
HS	Yes	1 (8.33)	5 (19.23)	0.369
	No	11 (91.67)	21 (80.77)	

CSL = conventional suture ligation; HS = harmonic scalpel.

Table 5. Association of age group with post-operative hypocalcaemia in both techniques

Method	Hypocalcaemia	18–33 yr	34–40 yr	Fisher's exact test P value
CSL	Yes	8 (40)	6 (33.33)	0.465
	No	12 (60)	12 (66.67)	
HS	Yes	2 (10)	4 (22.22)	0.279
	No	18 (90)	14 (77.78)	

CSL = conventional suture ligation; HS = harmonic scalpel.

gender and age with post-thyroidectomy hypocalcaemia in either technique (**Tables 4** and **5**). Therefore, no further multivariate adjustment was required.

DISCUSSION

Thyroidectomy is a high-risk surgical intervention for both benign and malignant thyroid disease with notable surgical challenges (22). Surgical removal of the total thyroid gland, which is highly-vascularized, potentiates the risk of subtle damage to the neighboring blood vessels that supply concealed PGs which increases the risk of hypoparathyroidism, and post-operative hypocalcaemia (4,22). There is strong evidence that achieving effective hemostasis is a critical surgical step for a successful total thyroidectomy for the management of both benign and malignant thyroid disease (4,5) The present prospective, single-blind, randomized controlled trial evaluated the efficacy and safety of the FOCUS harmonic scalpel versus the conventional suture ligation techniques for achieving homeostasis, during total thyroidectomy for benign multinodular goiters.

The main objective was to evaluate whether monitoring of mean serum calcium and symptomatic hypocalcaemia from 24–48 hours following total thyroidectomy using HS technique would still yield lower incidences of postoperative hypocalcaemia than the conventional suture ligation technique. First, consistent with a previous prospective randomized study (4), findings from the present study demonstrated a significantly lower incidence of postoperative transient hypocalcaemia in the HS group than the CSL group. In the present study, the mean serum calcium was significantly lower in the CSL group than in the HS group (P=0.018) 24 hours post-operatively. This indicated a higher risk of hypocalcaemia in the CSL group than the HS group. However, the mean serum calcium levels were inverted by 48 hours post-operatively and were significantly lower in the HS group than in the CSL group indicating an increased risk of hypocalcaemia in the HS group (P=0.033). By this account, it appears that postoperative transient hypocalcaemia is unpredictable within 24-hours post-thyroidectomy, and may therefore misrepresent the actual risk of symptomatic post-thyroidectomy hypocalcaemia. Findings from a prospective trial by Anandaravi et al. (4) lack external validity as it enrolled a mixed population of patients with malignant and benign thyroid disease treated with near total thyroidectomy or total thyroidectomy.

Surprisingly, regardless of the postoperative transient hypocalcaemia, the present study demonstrated a significantly lower incidence of symptomatic hypocalcaemia in the HS

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group (15.79%) than in the CSL group (36.84%) 24–48 hours post-operatively (P=0.033). These incidences are consistent with those reported in a prospective randomized study (1) which enrolled patients who underwent neck dissection for head and neck cancer. The study demonstrated symptomatic hypocalcaemia incidence rates during the first 24 hours after surgery of 14% and 42% in HS and CH groups, respectively. In a study by Ferri et al. (1) a higher incidence of postoperative hypocalcemia in the CH group may be attributed to the use of mixed conventional hemostasis techniques which included tying and knots, resorbable ligature, and bipolar diathermy. In the present trial, suture ligation technique was selected as the only conventional technique because the technique appears to present a hypocalcaemia incidence rate that is comparable to conventional techniques in general. The findings of the current study are consistent with the literature (1,4) which demonstrates that HS is associated with a lower incidence of symptomatic hypocalcaemia without necessarily reducing postoperative transient hypocalcaemia. As described in a recent systematic review and meta-analysis study (16), most studies that evaluated post-operative hypocalcaemia following thyroidectomy were based on the standard care, which monitors patients for up to 24 hours post-operatively. This study demonstrates that low serum calcium levels at 24 hours post-operatively could merely be an indication of postoperative transient hypocalcaemia which may or may not progress to symptomatic hypocalcaemia (4). This study demonstrates that monitoring patients' serum calcium for up to 48 hours post-thyroidectomy should be embraced in clinical practice to prevent overlooking cases of symptomatic hypocalcaemia after discharge.

The length of post-operative hospital stay is one indicator of whether a thyroidectomy is successful. Consistent with the hypothesis guiding this clinical question, this study demonstrated that HS technique significantly shortened the length of hospital stay (1.37 days) to half that of CSL (P<0.001). While low serum calcium may be evident 48 hours post-operatively, most postoperative transient hypocalcaemia in the HS group resolved steadily. These findings indicate that the HS approach reduced the incidence of symptomatic hypocalcaemia (4). The pitfall of a shortened length of hospital stay in the HS group was that there was the possibility of overlooking cases of symptomatic hypocalcaemia which may have developed later than 1.37 days, but within 48 hours post-thyroidectomy (18). This was evidenced by a significantly lower calcium level in the HS group than in the CSL group 48 hours post-thyroidectomy (8.09±1.03 vs. 8.28±1.04; P=0.013). Cases of overlooked symptomatic hypocalcaemia could have been minimized if asymptomatic patients discharged before 48 hours post-thyroidectomy were followed-up for a further 48 hours following discharge. The finding of the current study confirms that the 24–48 hours window in the definition for postoperative hypocalcaemia should be strictly observed. Indeed, a previous study by Chindavijak (23) was cautious about the time window for postoperative hypocalcaemia as calcium levels were measured at 24 and 72 hours after surgery. According to Sperlongano et al. (24), to reduce cases of missed hypocalcaemia, the observation period for patients who undergo total thyroidectomy should be at least 72 hours. However, the finding from the present study is generally consistent with a previous prospective randomized study (1) which also demonstrated that HS is a reliable and safe hemostasis technique for reducing intraoperative hemorrhage as well as operative time in patients undergoing neck dissection for head and neck cancer.

Visual identification of all four (or 3–4) in situ PGs for preservation during total thyroidectomy has traditionally been advocated by surgeons to lower the risk of hypoparathyroidism and hypocalcaemia (5,10). However, this approach may not guarantee

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safety in thyroidectomy as it potentiates the risk of subtle damage to the neighboring blood vessels supplying the PGs. This is could pose a risk for hypoparathyroidism including post-operative hypocalcaemia (5). Therefore, the present study tested the hypothesis that HS reduces the risk of hypocalcaemia associated with identification of a greater number (3–4) of in situ PGs. As at the time of conducting this trial, no study evaluating the efficacy and safety of HS technique assessed this risk. In the present study, the association between parathyroid identification and postoperative hypocalcaemia for HS and CSL groups was assessed using the Fisher exact test. It was demonstrated that identification of a greater number of in situ PGs was associated with hypocalcaemia in the CSL group (P=0.019) but not the HS group (P=0.372). By contrast, findings from a previous prospective study (10), and a retrospective study (25) demonstrated that selective identification of fewer in situ PGs (0–2) for preservation during total thyroidectomy was associated with a significantly reduced incidence of post-operative hypocalcaemia and permanent hypoparathyroidism compared to routine identification of 3–4 PGs. This indicates that routine identification of all 4 PGs is not necessary, while a selective approach to preservation of PGs could allow minimal damage to blood vessels (10). In the present study, the risk of post-operative hypocalcaemia was significantly higher in the CSL group (P=0.019) than in the HS group (P=0.372). This indicates that HS may reduce the risk of inadvertently damaging blood vessels when identifying in situ PGs for preservation during total thyroidectomy.

CONCLUSION

The novel FOCUS HS technique is effective for achieving adequate hemostasis during total thyroidectomy. It reduces the risk of symptomatic hypocalcaemia without reducing the risk of transient hypocalcaemia. One or two selectively identified in situ PGs can be safely preserved during total thyroidectomy using the HS technique which reduced the risk of hypoparathyroidism and hypocalcaemia. This technique also reduces the length of post-thyroidectomy hospital stay. Therefore, the Focus harmonic scalpel is currently a more reliable and safe instrument compared to conventional suture ligation for performing total thyroidectomy in cohort of benign and malignant goiters.

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