ORIGINAL ARTICLE

COMPARISON OF THE EFFECTS OF FOCUS HARMONIC SCALPEL AND CONVENTIONAL HAEMOSTASIS ON PARATHYROID FUNCTION IN THYROID SURGERY

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Background: Protection of parathyroid is very important in thyroid surgery. Our aim was to compare the effect of Focus Harmonic Scalpel and Conventional Haemostasis on parathyroid function in thyroid surgery. **Methods:** To analyse the clinical data of patients in our hospital from November 2011–December 2015 retrospectively. Operations have been performed with Focus Harmonic Scalpel in thyroid surgery since May 2013. Seventy-four patients with nodular goitre constituted Harmonic Scalpel group and Conventional Haemostasis group, and so did 139 patients with thyroid papillary carcinoma. Clinical data were compared such as age, gender, thyroid volume, operation procedure, preoperative parathyroid hormone and serum calcium concentration between the two groups. The differences between the two groups were observed in serum calcium concentration, parathyroid hormone concentration, incidence of transient hypocalcaemia and hypoparathyroidism after operation. **Results:** The preoperative data showed no significant difference between Harmonic Scalpel group and Conventional Haemostasis group. No significant difference existed in postoperative clinic data at six a.m. the first day after operation between the two groups for patients with nodular goitre. The incidence of transient hypoparathyroidism and hypocalcaemia in Harmonic Scalpel group were less than that in Conventional Haemostasis group in thyroid surgery. Significant differences existed in the mean of serum calcium concentration and incidence of transient hypocalcaemia between the two groups for thyroid papillary carcinoma statistically. **Conclusions:** Focus Harmonic Scalpel has certain advantages than conventional Haemostasis in protecting parathyroid glands, reducing the incidence of transient hypoparathyroidism and hypocalcaemia in thyroid surgery, especially for patients with thyroid cancer.

Keywords: Thyroidectomy; Focus Harmonic Scalpel; Hypoparathyroidism; Hypocalcaemia

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INTRODUCTION

Protection of parathyroid is very important in thyroid surgery; otherwise it is very easy to cause transient or permanent hypoparathyroidism. Permanent hypoparathyroidism may have a serious impact on patients' lives. Coimbra C *et al*[1] found that the incidence of permanent hypoparathyroidism were 5% following thyroidectomy. Thyroid surgeons are always thinking about how to reduce the incidence of postoperative parathyroid injury. Focus Harmonic Scalpel, a new generation of thyroid surgical instruments, which is different from traditional electric knife, brings innovation to thyroid surgery. The high-frequency ultrasonic energy of the Ultrasonic scalpel can cut off blood vessels and tissues effectively.[2]

A meta-analysis has shown that total thyroidectomy with Focus Harmonic Scalpel can significantly reduce the operation and hospitalization time, transient hypocalcaemia and postoperative pain.[3] Other studies suggest that the use of the Harmonic FOCUS in thyroid surgery did not change the incidence of postoperative hypocalcemia.[4,5]

This study retrospectively analysed the clinical data of Focus Harmonic Scalpel (HS) and Conventional Haemostasis (CH) in thyroid surgery from November 2011 to December 2015, and evaluated their influence on parathyroid function in thyroid surgery.

MATERIAL AND METHODS

We analysed clinical data of 213 patients in our hospital from November 2011 to December 2015 retrospectively. Operations have been performed with Focus Harmonic Scalpel in thyroid surgery since May 2013. Seventy four patients with nodular goitre (NG) comprised HS group (n=41) and CH group (n=33). One hundred and thirtyinine patients with thyroid papillary carcinoma (PTC) were divided into HS group (n=71) and CH group (n=68). The protocol of this study excluded previous neck surgery, age <18 years, irradiation, concomitant parathyroid disorders, and abnormal blood calcium concentration.

All operations were performed by the fixed surgery expert team. The two groups of patients compared underwent the same operation procedure. Patients with nodular goitre was treated with near total thyroidectomy (NTT). Patients with thyroid papillary carcinoma underwent total thyroidectomy (TT) plus unilateral central compartment node dissection (UCCND) or bilateral central compartment node

dissection (BCCND). When the thyroid gland was exposed, the thyroid vessels of patients in HS group were cut by Focus Harmonic Scalpel (Ethicon Endo-Surgery, Inc, USA), and the thyroid vessels in CH group were ligated by Conventional Haemostasis during operation.

Preoperative examination included thyroid ultrasound, parathyroid hormone (PTH) and serum calcium concentration. Serum calcium and PTH concentration were monitored at six a.m. on the first day after surgery. Serum calcium level below 2.0mmol/L was regarded as hypocalcaemia and hypoparathyroidism was defined as PTH levels below 1.6 pmol/L. Patients with hand-feet numbness were administrated oral calcium and vitamin D, or intravenous calcium gluconate.

Clinical data were compared such as age, gender, thyroid volume, operation procedure, preoperative parathyroid hormone and serum calcium concentration between the two groups. When there was no statistically significant difference in the preoperative observation data between the two groups, the differences were observed in serum calcium concentration, parathyroid hormone concentration, incidence of transient hypocalcaemia and hypoparathyroidism after operation between them.

SPSS software (Version19.0) analysed the study data and Student's t test and $\chi 2$ test were for statistical analysis. The *p*-value of less than 0.05 was set the level of statistical significance.

RESULTS

Comparison of preoperative clinical data between HS group and CH group. There were no significant differences in statistical information of patients' age, gender, thyroid volume, operation procedure, preoperative parathyroid hormone and serum calcium concentration between HS group and CH group for patients with nodular goitre (Table-1), and so were between HS group and CH group for patients with thyroid papillary carcinoma (Table-2).

Comparison of serum calcium concentration and PTH at six a.m. on the first day after surgery between HS group and CH group.

Significant difference existed in the mean of blood calcium concentration between the HS group and CH group at six a.m. on the first day after surgery for patients with thyroid papillary carcinoma statistically, but the mean of parathyroid hormone concentration showed no significant difference (Table-3).

For patients with nodular goitre, no significant difference existed in the mean of blood calcium concentration and parathyroid hormone concentration between the HS group and CH group at six a.m. on the first day after surgery (Table-4).

Comparison of the incidence of postoperative transient hypoparathyroidism and hypocalcaemia on the first day after surgery between HS group and CH group.

The incidence of transient hypoparathyroidism and hypocalcaemia in Harmonic Scalpel group were less than that in Conventional Haemostasis group in thyroid surgery. The incidence of hypoparathyroidism showed no significant difference between HS group and CH group statistically for patients with thyroid papillary carcinoma. But the incidence of hypocalcaemia were 45.1%, 73.5% respectively in HS group and CH group, and significant difference existed between HS group and CH group statistically (Table-3). For patients with nodular goitre, the incidence of hypoparathyroidism and hypocalcaemia showed no significant difference between the HS group and CH group on the first day after surgery statistically. (Table-4).

Table-1: Pre-operative demographic characteristics of patients with nodular goitre

Study	HS group (n=41)	CH group (n=33)	*p*-value
Age, mean (SD),y	58.07 (9.53)	58.97 (8.44)	.897
Sex (M/F)	7/34	5/28	.827
Thyroid volume, mean (SD), mL	62.82 (45.17)	48.18 (32.81)	.124
PTH, mean (SD), pmol/L	5.25 (1.21)	4.94 (1.00)	.244
Calcium, mean (SD), mmol/L	2.28 (0.09)	2.28 (0.11)	.867

F: female; M: male, SD: stand deviation; PTH: parathyroid hormone; HS: Focus Harmonic Scalpel; CH: Conventional Haemostasis; Calcium: serum calcium concentration

Table-2: Pre-operative demographic characteristics of patients with thyroid papillary carcinoma

Study	HS group (n=71)	CH group (n=68)	*p*-value
age, mean (SD), y	47.7 (11.4)	47.1 (10.56)	.755
Sex (M/F)	9/62	12/56	.417
Thyroid volume, mean (SD), mL	16.2 (10.3)	15.7 (10.6)	.750
PTH, mean (SD), pmol/L	4.93 (1.81)	5.11 (1.36)	.512
Calcium, mean (SD), mmol/L	2.31 (0.11)	2.30 (0.07)	.480
Operation procedure TT+UCCND (%) TT+BCCND (%)	 32 (45.1%) 39(54.9%)	 35 (51.5%) 33 (48.5%)	.450

F: female; M: male; SD: stand deviation; PTH: parathyroid hormone; HS: Focus Harmonic Scalpel; CH: Conventional Haemostasis; Calcium: serum calcium concentration; TT: total thyroidectomy; UCCND: unilateral central compartment node dissection; BCCND: bilateral central compartment node dissection

Table-3：postoperative data in HS and CH groups of patients with thyroid papillary carcinoma

Study	HS group (n=71)	CH group (n=68)	*p*-value
Parathyroid hormone, mean (SD), pmol/L	1.88 (1.35)	2.04 (1.56)	.517
Serum calcium, mean (SD), mmol/L	2.03 (0.13)	1.91 (0.15)	.000
Transient hypoparathyroidism (%)	37 (52.1%)	39 (57.4%)	.535
Transient hypocalcaemia (%)	32 (45.1%)	50 (73.5%)	.000

SD: stand deviation; HS: Focus Harmonic Scalpel; CH: Conventional Haemostasis

Table-4：Post-operative data in HS and CH groups of patients with nodular goitre

Study	HS group (n=41)	CH group (n=33)	*p*-value
Parathyroid hormone, mean (SD), pmol/L	3.25 (2.00)	2.80 (1.98)	.343
Serum calcium mean (SD), mmol/L	2.06 (0.17)	2.04 (0.20)	.051
Transient hypoparathyroidism (%)	12 (29.3%)	12 (36.4%)	.069
Transient hypocalcaemia (%)	14 (34.1%)	16 (48.5%)	.211

SD: standard deviation; HS: Focus Harmonic Scalpel; CH: Conventional Haemostasis

DISCUSSION

Because of the special design of Focus Harmonic Scalpel, it can partly replace the function of vascular clamp in the operation.[6] Surgeon use Focus Harmonic Scalpel to coagulate the blood vessels of thyroid simultaneously. The new generation of Focus Harmonic Scalpel permit the safe coagulation of vessels up to 5mm in diameter.[7] Compared with conventional haemostasis, surgical wound has less bleeding and surgical field of vision is clearer. And parathyroid was more easily recognizable during surgery. In addition, Focus Harmonic Scalpel has the protection side to avoid the heat damage to the surrounding tissue. Therefore, compared with traditional electric knife, the use of Focus Harmonic Scalpel has obvious advantages and might reduce the surgical risk in thyroid surgery.

During the separation of parathyroid with Conventional Haemostasis，it is necessary to separate, clamp and cut off the upper pole of thyroid. Separation from rectangular pliers might result in parathyroid injury and loss of in situ protection of parathyroid. Conventional haemostasis often leads to the traction and bleeding of parathyroid glands in the separation of parathyroid glands. Bandi G *et al*[8] consider that heat transmission from Conventional Haemostasis can damage the surrounding tissue. Therefore, Conventional Haemostasis has its limitations in situ protection of the parathyroid gland.

Focus Harmonic Scalpel can directly cut off the upper pole blood, and reduce the incidence of parathyroid injury. During separation of the attachment between parathyroid and thyroid, Focus Harmonic Scalpel can resect it directly without clamp and ligation, which reduce the incidence of parathyroid injury further. Clinical experience suggests that Focus Harmonic Scalpel can reduce the direct damage caused by the separation of parathyroid. In addition, thermal radiation from Focus Harmonic Scalpel is only limited to 0–2mm beyond the cut tissue. Because of less thermal damage, Focus Harmonic Scalpel might decrease the incidence of parathyroid vascular injury. [9]

On the first day after surgery, the incidence of hypoparathyroidism in HS group was less than that in CH group for the patients with nodular goitre and thyroid papillary carcinoma, as can be seen from table 3 and table 4.Yano Y [10] held the same views through research. Pelizzo MR[11] reported that the incidence of transient hypoparathyroidism was 45.2–48% after total thyroidectomy with Focus Harmonic Scalpel, less than 51.7–54.26% with Conventional Haemostasis. These show that Focus Harmonic Scalpel might protect the parathyroid gland better and reduce the incidence of hypoparathyroidism.

For patients with nodular goitre, the incidence of hypocalcaemia in HS group was also less than that in CH group on the first day after operation. The incidence of hypocalcaemia in CH group was significantly more than that in HS group on the first day after operation for patients with thyroid papillary carcinoma, which is consistent with the reports of Duan YF and Grodski S.[12,13] The serum calcium concentration in Focus Harmonic Scalpel group was significantly more than that in Conventional Haemostasis group the first day after operation in patients with thyroid papillary carcinoma statistically. These indicate that Focus Harmonic Scalpel has certain advantages for conventional haemostasis in protecting parathyroid glands, especially for patients with thyroid papillary carcinoma who undergo central compartment node dissection.

Undeniably, the thermal damage fromFocus Harmonic Scalpel can also produce certain effect on blood vessels around parathyroid gland. There is a lack of long-term and extensive clinical follow-up data for this study. Relevant study suggests that the use of ultrasonic knife is only a protective factor for recurrent laryngeal nerve paralysesin thyroid surgery.[14]

In short, Focus Harmonic Scalpel is a safe and convenient tool for patients undergoing thyroidectomy. Compared with conventional Haemostasis techniques, it reduces operative times, and shortens the incision of the neck in thyroidectomy.[15] In thyroid surgery, Focus Harmonic Scalpel has certain advantages in protecting parathyroid glands, reducing the incidence of transient hypocalcaemia, especially for patients with thyroid carcinoma. However, it is more important for in situ protection of parathyroid to prevent hypoparathyroidism in total thyroidectomy.[16] If necessary, parathyroid auto transplantation seems to

reduce the risk of permanent hypoparathyroidism.[17]

CONCLUSIONS

Focus Harmonic Scalpel has certain advantages than Conventional Haemostasis in protecting parathyroid glands, reducing the incidence of transient hypoparathyroidism and hypocalcaemia in thyroid surgery, especially for patients with thyroid carcinoma.

AUTHORS' CONTRIBUTION

SQX: Data management, manuscript writing, final editing. YM, HWS, JFC: Data management, manuscript writing. YXZ: Data analysis, final editing.

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