Original Article The comparison of the harmonic focus shears device with conventional clamp binding in total thyroidectomy

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Abstract: Aim: Harmonic Focus (HF) is an ultrasonic device developed most recently for thyroid surgery. The aim of this study was to compare the surgical completeness and outcome of total thyroidectomy in two patient groups. One group was treated by HF and one by Conventional Dissection (CD). Methods: Total thyroidectomy was performed in 38 patients with CD, and in 38 patients with HF. Results: When compared to conventional haemostasis, a reduction was observed in the duration of surgery in the HF group, and the amount of blood loss was reduced by 29%, and 46%, respectively. The number of intraoperative device changes was decreased by 70%. The utilisation of special materials to obtain haemostasis was also significantly decreased. HF was found to be as safe as the conventional haemostasis technique. Conclusions: Our study has demonstrated the beneficial effects and relative safety of HF in thyroid surgery. Further studies are needed about the financial benefits provided by reductions in human resources, and in materials employed for haemostasis.

Keywords: Total thyroidectomy, harmonic focus shears, ultrasonic dissection

Introduction

Thyroid surgery has benefited from a substantial number of inventions in the last two decades, such as endoscopical and video-assisted approaches, anaesthetic care, intraoperative nerve monitoring [1-5] and new haemostatic devices. The surgical principles previously developed by pioneering surgeons, on the other hand, are still strictly followed. The aforecited principles are firm exposure of the thyroid gland, complete identification of the nerves and the parathyroid glands, and flawless haemostasis.

The combination of established principles and novel techniques has made it possible for minimally invasive thyroid surgery to be performed. Furthermore, other advantages such as better cosmetic results, decrease in duration of surgery, better post-operative comfort, decrease in morbidity rates, and reduction of in-hospital stays have been achieved. In thyroid surgery, haemostasis can be achieved by mechanical approaches such as knotting, use of clips, conventional monopolar or bipolar cautery-systemsourced energy, an electrothermal bipolar sealing system (Ligasure, Tyco Healthcare, Gosport, UK) and use of an ultrasonic device (Harmonic, Ethicon Endo-surgery, Guaynabo, PR, USA).

The high-frequency energy released from the blades of the ultrasonic devices produces coagulation, and thereby permits the dissection of blood vessels and tissues. There are many prospective randomised studies showing the use of ultrasonic devices in conventional open or video-assisted thyroidectomies, and also in lymph node dissection [6, 18].

The curved Harmonic Focus (HF) shears are ergonomically designed for open thyroidectomy. They simplify dissection, coagulation, and cutting. They also provide advantages in thyroid surgery in comparison to older devices (Harmonic HS002, Harmonic HC145, and Harmonic CS-14C) due to the hand probe, hand-activated trigger system, and versatility. This device, designed for fine dissection, provides significant improvement in ergonomy. The aim of this study was to retrospectively evaluate and compare the efficacy and safety of HF in total thyroidectomy with conventional dissection (CD) (clamp and knot tying).

	HF group n=38	CD group n=38	P value
Age, y-year (mean ± SD)	49±14	46±13	.68*
Male, n (%)	12 (31.5)	12 (31.5)	
Pathology n (%)			
Colloid goitre	29 (76.3)	32 (84.2)	.45\$
Thyroiditis	7 (18.4)	5 (13.1)	.44\$\$
Cancer	8 (21.0)	8 (21.0)	
Hyperthyroidism	1 (2.6)	0	
Thyroid gland weight, g (mean, minimum, maximum)	33.6 (9-171)	33.6 (6-91)	.73*
Duration of Surgery, minutes	58±14	81±13	<0.001*
Duration of Surgery Adjusted According To Weight of Thyroid Gland	1.88±1.04	2.75±2.17	<0.03*
Bleeding, g (gram)	29±31	53±30	<0.001*
Bleeding Adjusted According To Weight of Thyroid Gland	.78±.74	1.51±.89	<0.001*
Number of Change of Apparatus, n	72±29	224±59	<0.001*
Change of Apparatus Adjusted According To Weight of Thyroid Gland	2.31±1.62	7.59±6.41	<0.001*

Table 1. Demographical parameters and intraoperative parameters of the patients in the harmonic focus and the conventional dissection groups

SD: Standard Deviation, HF: Harmonic Focus, CD: Conventional Dissection; *Mann-Whitney U test; *Fisher test; *Chi square test; The units of measurements for the duration of surgery, bleeding, and the number of times devices were changed-all adjusted according to the weight of the thyroid gland-have been demonstrated as minutes, grams, and number counts, respectively.

Patients and methods

Between March and November 2011, 76 adult patients who were assumed to have benign lesions with a diagnosis of multinodular goitre were evaluated in our hospital. The same surgeon, saw them, and all were considered eligible for total thyroidectomy. The patients were compared into two groups with regard to haemostasis technique: CD (n=38) or HF (n=38). In the CD group, the materials used were: Vicrly, Ligapak 3-0 (Johnson & Johnson Intl, Sint-Stevens-Woluwe, Belgium), suture materials: Vicrly SH-I plus, (Johnson & Johnson), titanium haemostatic clips, a SLS-Clip (Vitalitec Intl Inc, Plymouth, MA), and a monopolar electrical cauter.

In the HF group, the haemostasis was obtained with the ultrasonic scissors, but if considered necessary, conventional materials were also used intraoperatively in regions near the recurrent laryngeal nerve (RLN), and parathyroid glands. The use of the monopolar electrical cauter was avoided in all of these cases. The exclusion criteria were previous surgical operations performed on the neck region or a preoperative diagnosis of thyroid malignancy. All surgical procedures were performed by the same surgeon with the assistance of two nurses. In the HF group, the only device utilised was ultrasonic scissors, except for devices used to protect the parathyroid glands and RLN. Gender, age, the final pathological reports according to our pathologist's assessment, and the weight of the excised gland were assessed. The duration of surgery, amount of blood loss, the number of times devices were changed, including the number of times HF was given to the surgeon's hand, the requirement for titanium haemostatic clips including use of haemostatic sponges, and the utilisation of special materials for tying and suturing were evaluated intraoperatively. The blood loss was measured by the weight increase of the blood-stained gauzes. The nurse marked an X on the device table whenever she was requested to give any device or materials to the surgeon. These parameters were adjusted according to the gland weight (in grams) in order to prevent the possible bias of gland size. The first-day drainage volume determined in ml, the first-day calcium level, the need for in-hospital stay for more than one night, development of haematoma, permanent hypocalcaemia and/or permanent palsy of RLN are assessed. All patients underwent laryngoscopy, both preoperatively and on the first day after surgery, by an ENT specialist, who was independent of the study, for evaluation of the vocal cords. These evaluations were repeated on the 10th day, and again at the sixth month after surgery. Any continuing need or complication (i.e., calcium replacement or RLN palsy) after the sixth month of surgery was considered permanent.

in the conventional dissection group				
	HF Group n=38	CD Group n=38	P value	
1st day drainage, mL	35±15	39±25	0.88*	
1st day hypocalcaemia, mmol/L	2.06±.16	2.03±.13	0.46*	
In-hospital stay >1 night (n, %)	5 (13.1%)	9 (23.6)	0.23\$	
Hematoma	1	1		
Temporary hypocalcaemia	3	3		
Permanent hypocalcaemia	0	0		
Temporary paralysis of RLN	0	1		
Permanent paralysis of RLN	0	0		
For tying knots	1 (0-1)	3 (2-4)	<0.001*	
Suture materials	4 (3-6)	8 (5-12)	<0.001*	
Haemostatic clips	8 (1-16)	15 (5-31)	<0.001*	
Haemostatic sponges, n (%)	3 (7.8)	11 (28.9)	0.02 ^{\$\$}	
UE: Harmonia Facua, CD: Conventional dispection, DLN: Desurrent				

Table 2. Post-operative course and specific materialsrequired intraoperatively in the harmonic focus group andin the conventional dissection group

HF: Harmonic Focus, CD: Conventional dissection, RLN: Recurrent Laryngeal Nerve; The results have been shown as mean and ranges.

*Mann-Whitney U test; *Fisher exact test; **Chi square test.

Statistical analysis

All data were expressed as mean ± standard deviation, proportions, or numbers. The data were analysed using SPSS release for Windows 15.0 (SPSS Inc, Chicago, IL, USA). Statistical differences between the two groups were assessed by the Student's t-test or the Mann-Whitney test for continuous variables, depending on distribution. Inter-arm comparisons of categorical variables were performed using the chi-square test. The dual variables were compared using the Fisher exact test and the chisquare test. Multivariate analysis was used to compare outcomes of harmonic focus use, age, gender, thyroid gland weight, pathological findings, materials for knotting, use of suture materials and clips, utilization of haemostatic sponges and changes of devices.

Results

A total of 24 men (12 in each group), and 52 women were included. The mean age was 49 ± 14 in the HF group and 46 ± 13 in the CD group. The final pathological and intraoperative findings have been summarized in **Table 1**.

The mean duration of surgery was significantly shorter in the HF group compared to the CD group. The weight-adjusted duration was also significantly shorter in the HF group. Intraoperative bleeding (also weight-adjusted) was significantly less in the HF group compared to the CD group. The number of times devices were changed was prominently higher in the CD group. Similarly, the number of times devices were changed, adjusted for the weight of the thyroid gland, was also markedly higher in the CD group.

The specific materials required during surgery and postoperative findings have been summarized in **Table 2**. The number of materials utilised for knot tying, and suturing was lower in the HF group. The utilisation frequency of the intraoperative haemostatic clips was higher in the CD group compared to the HF group. The need to use haemostatic sponges was significantly higher in the CD group.

No significant differences were observed between the two groups with regard to the postoperative first-day drainage, the

first-day calcium levels, and the need of in-hospital stays of more than one night. No mortality was observed in either group.

Multivariant analysis

In the whole study population, the joint variables used to determine the intraoperative bleeding and the duration of surgery were: the use of harmonic focus, age, gender, weight of the thyroid gland, pathological findings, materials for knotting, use of suture materials and clips, utilisation of haemostatic sponges, and changes of devices. In the multivariate analysis, the thyroid gland weight and the materials used for knotting emerged as significant independent variables influencing the duration of the operation.

When the durations of surgery adjusted for the weight of the thyroid gland were considered, the use of HF and the number of changed devices were found to be significant independent variables, explaining 90% percent of the variability in the patient series (**Table 3**). When the bleeding amount was adjusted according to the weight of the thyroid gland, and the number of changed devices were found to be associated with blood loss. These parameters explain 45 percent of the variability of the intraoperative bleeding in the whole patient series.

Table 3. Factors determining the duration of operation among the whole patient series with total
thyroidectomy

	Independent Variables	b	SE (b)	P *
Duration of Operation	Weight of Thyroid Gland	0.12	0.05	0.02
	Materials for Tying Knots	3.99	1.78	0.04
	Model r ² =.65			
Duration of Operation Adjusted According to Weight of Thyroid Gland	Harmonic Focus Utilisation	0.97	0.17	<0.001
	Changes of Devices	0.34	0.03	<0.001
	Model r ² =0.91			
Bleeding	Thyroid Weight	0.40	0.08	<0.001
	Changes in Device Utilisation	0.18	0.02	<0.001
	Model r ² =.44			
Bleeding Adjusted According to Weight of Thyroid Gland	Changes in Device Utilisation	0.08	0.01	<0.001
	Model r ²			

The duration of surgery and the duration of surgery adjusted according to the weight of the thyroid gland were both demonstrated in minutes. The extent of bleeding and the bleeding adjusted to the gram weight of thyroid was demonstrated in grams. The tested independent variables were as follows: weight of thyroid gland, utilisation of the Harmonic Focus device, gender, pathological findings, materials were used for knot tying, suture and clips, number of changes in device utilisation, and use of haemostatic sponges. b=calculated regression coefficient, SE (b)=standard error in the calculated coefficient, P*=partial P value.

Discussion

HF is an ultrasonic device developed most recently for thyroid surgery. It provides significant benefits with its versatility, manually activated trigger system, hand probe, and weight. HF, having superior features in comparison to its preceding devices such as Harmonic HS002, Harmonic HC145 and Harmonic CS-14C, is aimed at achieving precise dissection to increase surgical efficiency, for tissue-clutching, for coagulation, and lastly, for cutting without the need for many other surgical devices and materials. Our study clearly demonstrates the advantages of HF in total thyroidectomy with regard to shortened surgery duration, decreased intraoperative bleeding, decreased materials requirements, and decreased number of device changes to obtain haemostasis without causing increased morbidity.

Concordant with previous studies on ultrasonic energy devices (**Table 4**), a relative decrease in surgery duration at a rate of 29 percent was observed in our study. This decrease has been reported to occur at a rate between 15 and 30 percent in the current literature, and it becomes more prominent if the surgical procedure is prolonged and sophisticated [10, 15]. In a prospective randomised study, thyroid lobectomy combined with ultrasonic dissection was compared with single lobectomy; and no influence was observed with regard to the influence of single lobectomy on the duration of surgery [19].

Such conditions as thyroid gland volume and weight, hyperthyroidism, and thyroiditis could possibly produce complications affecting the duration of surgery. Therefore, we adjusted the duration of surgery according to the weight of the excised thyroid gland. With this adjustment, we observed a 32 percent decrease in duration of surgery. With stepwise multiple regression analysis, the excised gland weight, and the required materials for knot tying emerged as the two most independent variables. Moreover, when the use of Harmonic Focus, number of times devices were changed, and adjusted surgery duration were considered, negative and positive slope effects were significantly observed. The obtained models explain 66 percent and 90 percent of variability in the duration of surgery, and in the weight-adjusted duration of surgery, respectively.

Since the thyroid gland is intensely vascularised, haemostasis remains an important issue in thyroid surgery. In our current study, a relative reduction of 46 percent was observed in the blood loss in the HF group. In previous studies, which compared the HF with older ultrasonic devices, varying relative reductions in the intraoperative bleeding were reported, ranging from 13 percent [15] to 61 percent [13].

Total thyroidectomy

Study (Authors)	Type of Thyroid Surgery	Conventional or Video- Assisted Surgery	Utilised Device	Number of Patients	Findings Related to the Use of Ultrasonic Device
Lombardi et al. 2008	Total	Conventional	Ultracision CS-14C	200	Reductions in duration of surgery, employed drugs, and personnel
Barczynski et al. 2008	Partial	Video-assisted	Harmonic Scalpel	76	Reductions in duration of surgery, bleeding and scar formation, increased costs
Yıldırım et al. 2008	Total	Conventional	Ultracision CS-14C	104	Reductions in use of materials, bleeding and in duration of surgery
Hallgrimsson et al. 2008	Total Grave's disease	Conventional	Harmonic Scalpel	51	Reduction in duration of surgery
Sartori et al. 2008	Total	Conventional	Ligasure/Harmonic	150	Reduction in duration of surgery
Papavramidis et al. 2010	Total	Conventional	Harmonic Focus	90	Reductions in duration of surgery, pain, in-hospital stay and in difficulty
Mourad et al. 2011	Total	Conventional	Harmonic Focus	68	Reductions in duration of surgery and in utilisation of devices
Bove at al. 2012	Total	Conventional	Ligasure/Harmonic Focus	240	Reduction in duration of surgery
Current Study	Total	Conventional	Harmonic Focus	76	Reductions in duration of surgery, bleeding and changes of devices

Table 4. An overview of the published randomised studies

The advantage of HF may be associated with the fact that its ultrasonic device is effective on both sides of the active blade. Therefore, it not only cuts the vessels at the thyroidectomy bed, but also closes and cuts the vessels in the surrounding tissues. We demonstrated that bleeding risk was directly linked to the excised gland weight and the number of times devices were changed. This risk was also directly linked to the complexity of the surgical procedure, which was decreased with the use of the HF.

There is also an assumption that ultrasonic procedures can provide benefits in terms of cost effectiveness, albeit with discrepancy. Our study provides some clues indicating that the HF is cost-effective, although it was not planned for such an analysis. It is certain that the use of an ultrasonic device is more costly than the absorbable suture materials, and clips. However, when the cost is re-evaluated and adjusted according to the occupation of the surgical room, some studies comparing the old ultrasonic devices with the conventional haemostasis methods have shown minimal cost increases [13], or no difference at all [12, 15].

In one study, overall cost, including drugs, the duration of stay in the surgical room, single-use materials, and the duration of the in-hospital stay was found to be significantly lower per patient in the Harmonic CS-14C group in comparison to the control group [8]. Furthermore, ultrasonic devices can be used efficiently and safely in many patients. This may also beneficially affect the cost/effect ratio as shown in two studies cited above performed with the Harmonic HS002 [7] and Harmonic CS-14C [14] devices.

Overall, our current study has also demonstrated that the number of device changes was decreased by 70 percent with the use of HF. All procedures in this study were performed by one surgeon, and two nurses (a total of three persons). The reduced number of device changes also indicated the possibility that such operations could be performed by two persons only. Reducing the work load in such a manner cou-Id anticipate reductions in human resources, which would theoretically lead to reductions in general costs. Further studies are needed to assess whether the HF use mediated reductions in the duration of surgery and whether the use of fewer human resources could lead to reductions in general costs.

Parallel to the previously reported data [8-17], our current results did not show any negative effects of HF use with regard to permanent hypocalcaemia or vocal cord dysfunction. In two different prospective randomised studies utilising Harmonic HS002 and Harmonic CS-14C, it was shown that temporary postoperative hypocalcaemia was lower in patients who had been operated upon with these devices. In a recent prospective randomised threearmed study, Ligasure and Ultracision were compared with conventional dissection. In this study, it was demonstrated that temporary hypocalcaemia was more often observed in patients who had been operated upon with these two energy-activity devices in comparison to those who had been operated upon with conventional haemostasis [16].

In thyroidectomy, the effects of the employed haemostasis methods on the length of in-hospital stay have not yet been clarified [8, 11-14]. In one of the published studies, a reduction of in-hospital stay was demonstrated in patients who had undergone the Ultracision procedure. Our current clinical strategy is to discharge all patients on the first post-operative day independent of the applied surgical procedure, unless there are accompanying comorbidities or poor prognosis conditions such as serious surgical complications, Type 1 diabetes, or geriatric or physically-handicapped patients.

The controversies regarding post-operative pain are still unresolved. In one study, no effect of the haemostasis technique on post-operative pain was determined [11], whereas in another study, a lower analgaesic consumption was found in patients who had been operated upon with Harmonic HS002 in comparison to the control group [7]. Parallel to this finding, other researchers have reported that by using Harmonic scissors, the post-operative pain was decreased, determined by the visual analogue scale scores in patients [10-21]. Nonetheless, the mechanisms regarding the beneficial effects of haemostatic techniques on the pain are still not illuminated, since many factors such as neck extension, endotracheal intubation, and surgical wound influence the pain. Thus, further research is necessary.

In conclusion, the benefits and relative safety of this novel ultrasonic device have been supported by our randomised study, which has compared the HF scissors with the conventional clamp and tying techniques. The cost is still an issue of debate, and further studies are needed to show its relevance with regard to the surgery duration, the use of conventional materials for haemostasis, and reductions in human resources.

Disclosure of conflict of interest

None.

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