



Harmonic Scalpel is more Secure than Conventional Methods in Total Thyroidectomy: A Randomized Clinical Trial

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ABSTRACT

Background: Traditional haemostatic techniques in total thyroidectomy may cause some damages to surrounding tissues. It is believed that these damages can be reduced using ultrasonic dissector devices like Harmonic Scalpel (HS).

Objective: In this study, we investigated the efficacy of ultrasonic dissectors (HS) versus conventional techniques (Clamp and Tie).

Patients and Methods: A single blinded randomized clinical trial was performed at a referral educational center. Sixty eight eligible participants were enrolled and assigned to conventional group (operated with Clamp and Tie technique) and HS group (operated with Harmonic Scalpel). The following items were recorded in both groups: haemostatic technique, operative blood loss, duration of surgery, length of hospital stay, pathology, thyroid weight, postoperative recurrent laryngeal nerve injury, change in calcemia, pain, drainage volume and hematoma formation.

Results: The results demonstrated that application of HS in thyroidectomy significantly reduces operating time ($P \leq 0.0001$) and Intra operative bleeding ($P \leq 0.0001$). Postoperative drainage ($P \leq 0.0001$), pain ($P \leq 0.0001$), hypocalcemia ($P \leq 0.0001$), and length of hospitalization ($P \leq 0.0001$) were significantly lower in HS group. Voice score was significantly lower in HS group ($P \leq 0.0001$).

Conclusions: HS in total thyroidectomy, reduces operating time, blood loss, postoperative pain, drainage volume, voice changes, and postoperative hypocalcemia, compared to conventional techniques.

Keywords: Hemorrhage; Pain, Postoperative; Thyroidectomy; Ultrasonics

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Traditional haemostatic techniques in total thyroidectomy may cause some damages to surrounding tissues. The Harmonic Scalpel (HS) cuts and coagulates simultaneously using mechanical vibration. HS in total thyroidectomy reduces intra and postoperative complications and also HS, compared to the conventional technique is a trustworthy haemostatic technique which reduces operating time, blood loss in patients undergoing total thyroidectomy.

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1. Background

Conventional haemostatic techniques in thyroidectomy include clip and tie, suture ligation, electrocoagulation, and other devices. These techniques may have some damages to surrounding tissues, including heat, pressure, or instrumentation. Various devices were introduced in order to do a safe section and haemostasis of thyroidal vessels (LigaSure and ultrasonic dissector). Published experiences suggest that ultrasonic dissector devices are effective to reduce operating time (1-3) and blood loss during the operation (4-6) compared to traditional devices (conventional technique). Ultrasonic dissector devices reduce the length of hospitalization (7) and postoperative hypocalcemia, too (8, 9). There are some studies which suggest that the blood loss during the operation is the same in both techniques (2). On the other hands, in some studies, postoperative complication includes transient hypocalcemia and transient laryngeal nerve palsy were more frequent in ultrasonic techniques than in traditional ones (10). Electrocoagulation done to control bleeding has the potential risk of injuring the surrounding tissues from lateral dispersion of heat. The Harmonic Scalpel (HS) cuts and coagulates simultaneously using mechanical vibration rather than high temperatures. HS technique employs ultrasonic technology to cut and coagulate tissues at lower temperatures rather than those associated with electrocautery and lasers.

2. Objectives

In this study, we evaluated the benefits of HS versus conventional technique (Clamp and Tie) in total thyroidectomy.

3. Patients and Methods

A single blinded randomized clinical trial was performed at a referral general hospital of Tehran University of Medical Sciences, Tehran, Iran. The local ethics review committee of Tehran University of Medical Sciences approved the

study protocol. All participants gave written informed consent before operation. During a year, 68 patients who underwent total thyroidectomy were assigned for this study. Thirty three subjects were assigned as HS group and 35 ones as conventional group randomly. Inclusion criteria included age of over 18 years, proved indication of total thyroidectomy and euthyroid state. Subjects which had large goiter, hyperthyroidism, non-differentiated thyroid carcinoma, locally invasive carcinoma, need to neck dissection, history of surgery, radiotherapy or I-131 therapy, coagulopathies, vocal cord dysfunction, and ligation need during surgery due to severe bleeding, were excluded from this study. Subjects enrolled in conventional group operated with Clamp and Tie and HS group operated with ultrasonic dissectors. All surgeries were performed or supervised by two experienced endocrine surgeons. The followings were recorded in two groups, duration of surgery, pathology, thyroid weight, operative blood loss, length of hospitalization, post-operative recurrent laryngeal nerve injury, change in calcemia, pain, drainage volume and hematoma formation. The Statistical Package of Social Science version 16.0 (SPSS, Chicago, Illinois, USA) was used for data analysis. Statistical significance was noted for p value of ≤ 0.01 . Mann-Whitney and Chi-Square tests were used for non-parametric quantitative variables and qualitative variables, respectively. Data are expressed as mean \pm SD.

4. Results

Mean age of 68 subjects was 41 ± 14.1 years; Mean age was 38.7 ± 13.5 years for HS group and 43.2 ± 14.5 years for conventional group. There was no significant difference between the age of two groups ($P = 0.19$). Thirty three (48.52%) of subjects were male and 35 (51.47%) were female. HS group contained 17 males and 16 females and conventional group included 16 males and 19 females. There was no significant difference between the gender of two groups ($P = 0.80$). Other characteristics of subjects before operation were shown in Table 1.

Table 1. Characteristics of Harmonic Scalpel (HS) and Conventional Groups Before the Operation

Before Operation Findings	HS Group	Conventional Group	Total	P value
Age, y	38.7 ± 13.5	43.2 ± 14.5	41 ± 14.1	0.19
Sex, %				
Female	17 (51.52)	16 (45.7)	33 (48.53)	0.80
Male	16 (48.48)	19 (54.28)	35 (51.47)	
FNA, %				
Benign	18 (54.46)	17 (48.6)	35 (57.35)	
Malignant	9 (27.28)	14 (40.00)	23 (33.82)	0.45
Suspicious	6 (18.26)	4 (11.40)	10 (8.82)	
Nodule, %				
Solitary	15 (45.5)	18 (51.40)	33 (48.52)	
Multiple	18 (54.5)	17 (48.6)	35 (51.47)	

Intra operation findings and thyroidectomy tissue specifications were shown in Table 2. The mean of operation time in HS and conventional group was 60.00 ± 9.20 and 121.91 ± 30.90 minutes respectively. The mean of blood loss in HS and conventional groups was 24.54 ± 6.04 and 110.58 ± 19.68 milliliter respectively. HS significantly reduced the operation time ($P < 0.0001$) and the blood loss ($P < 0.0001$), compared to Conventional techniques. There were no significant differences in thyroid weight ($P = 0.16$) and frozen findings for malignancy between the two groups ($P = 0.23$). Post operation characteristics of HS and conventional groups were shown in Table 3. No laryngeal nerve damage was occurred during the operation. Postoperative

drainage volume ($P < 0.0001$), pain severity ($P < 0.0001$), and length of hospital stay ($P < 0.0001$) were significantly lower in HS group. Pain severity between conventional and HS groups, after 24 hours (A) and 48 hours (B) of operation were illustrated in Figure 1. Postoperative hypocalcemia were lower in HS group significantly ($P < 0.0001$). Mean values for serum calcium concentrations after 24 hours, 48 hours, and a week after the operation were shown in Figure 2 A. Voice score was not different before the operation ($P = 0.47$) but it was significantly lower in HS group after the operation ($P < 0.0001$). Mean values for voice score before and after the operation in two groups were shown in Figure 2 B.

Table 2. Intra Operation Characteristics of Harmonic Scalpel (HS) and Conventional Groups

Intra Operation Findings	HS Group	Conventional Group	Total	P value
Time, min	60.00 ± 9.20	121.91 ± 30.90	91.41 ± 38.62	$< 0.0001^a$
Blood loss, ml	24.54 ± 6.04	110.58 ± 19.68	68.20 ± 45.71	< 0.0001
Thyroid weight, gr	283.93 ± 85.47	315.25 ± 76.87	300.05 ± 82.08	0.16
Frozen, %				
Benign	22 (66.7)	17 (48.6)	39 (57.35)	
Malignant	9 (27.3)	16 (45.7)	25 (36.76)	
Suspicious	2 (6.1)	2 (5.7)	4 (5.88)	

^a $P < 0.01$ is considered significant

Table 3. Post Operation Characteristics of Harmonic Scalpel (HS) and Conventional Groups

Post Operation Findings	Time	HS Group	Conventional Group	Total	P value
Drainage, ml	1st 24 hours	33.43 ± 8.17	77.28 ± 19.49	56.34 ± 26.72	$< 0.0001^a$
	2nd 24 hours	10.31 ± 5.22	37.28 ± 9.87	24.40 ± 15.72	< 0.0001
Serum Calcium, mg	1st 24 hours	9.26 ± 0.45	7.96 ± 0.62	8.59 ± 0.85	< 0.0001
	2nd 24 hours	9.40 ± 0.38	8.46 ± 0.61	8.91 ± 0.69	< 0.0001
	Seventh day	9.72 ± 0.32	9.10 ± 0.55	9.40 ± 0.55	< 0.0001
Voice score	One day before operation	2.87 ± 0.92	3.08 ± 1.44	2.98 ± 1.21	0.47
	1st 24 hours	5.33 ± 1.13	10.71 ± 2.26	8.10 ± 3.25	< 0.0001
	Seventh day	3.54 ± 1.00	6.08 ± 1.50	4.85 ± 1.80	< 0.0001
Hospitalization (day)		1.15 ± 0.36	2.54 ± 0.56	1.88 ± 0.84	< 0.0001

^a $P < 0.01$ is considered significant

5. Discussion

Many studies demonstrated the reduction of operation time by HS in total thyroidectomy (4, 5, 11-14) but in 2010, in a systematic review, there was no significant difference for hemi-thyroidectomy (15). In our study, the operation time in HS was half compared to the conventional technique. Blood loss in most studies was significantly lower in HS group (4, 14, 16-18). In some studies, there were no significant differences (2). In our study, blood loss was significantly lower in HS group rather than conventional

group. In some studies, postoperative complications including transient hypocalcemia and transient laryngeal nerve palsy were more frequent in ultrasonic techniques rather than traditional ones (10) like our study. Our study revealed higher serum calcium concentrations in all 24 hours, 48 hours, and a week after the operation in HS group, which was significant compared to the conventional group (Figure 2 A). Our study confirmed lower pain severity in HS group rather than conventional group especially in the first and second 24 hours after the operation similar to some previous studies (4, 9). Postoperative

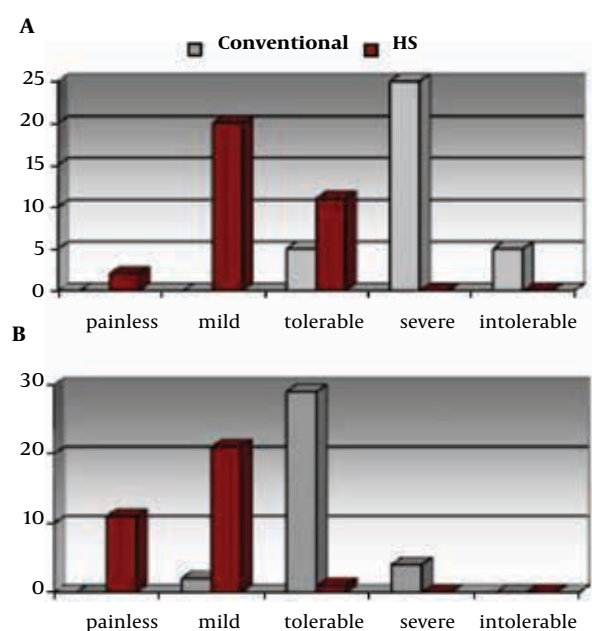


Figure 1. Pain severity Between Conventional and HS Groups 24 Hours (A) and 48 Hours (B) After the Operation

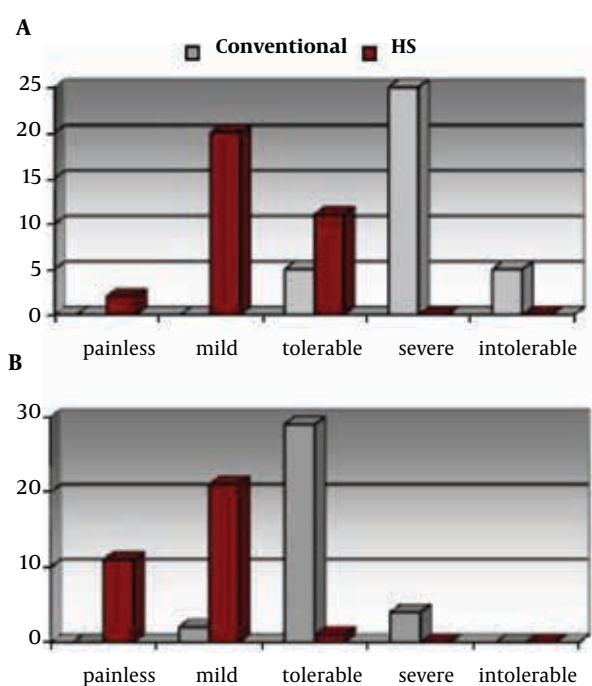


Figure 2. A) Mean Values for Serum Calcium Concentrations after 24 Hours, 48 Hours, And A Week After the Operation, B) Mean Values for Voice Score Before and After the Operation in two Groups

drainage volume was lower in HS group like other studies (18). A meta-analysis in 2010 was done on 12 prospective

randomized controlled relevant studies (19). This study certainly validates the feasibility of using the HS at the authors' center, but Ecker and et al. mentioned that lack of compromising on safety or costs-consistently shown over a wide range of studies-underpins harmonic scalpel's usefulness. Although we did not compare the costs between two groups, but it seems that HS is more cost-benefit compared to conventional technique in case of reducing operation time like other studies (9, 13, 16) and reducing length of hospitalization like the same as Papavramidis et al. study results (7). We concluded that HS, is a trustworthy haemostatic technique which reduces intra and postoperative complications and also can shorten the operation time compared to conventional technique.

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Authors' Contribution

The Corresponding author of this manuscript is Shirzad Nasiri and contribution of the authors as mentioned below with their responsibility in the research: Ahmad Reza Soroush: Conception and Design, Collection of data, Critical Revision of the Article and Administrative Technical Scientifically Revision of the Article. Elham Poubakhtyaran: Conception and Design, Obtaining Funding and Data Interpretation and Writing the Article Somayyeh Allame: assembly of data, Clinical Analysis Mohammad Mahdi Zamani: Literature Search, Clinical Analysis and Scientifically Revision of the Article Mehrnoosh Etemadi: Literature Search and Conception and Design Shirzad Nasiri: Conception and Design, Data Collection and Data Analysis, Critical Revision of the Article

Financial Disclosure

We have no financial interests related to the material in the manuscript

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