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### Özet

**Amaç:** Bu klinik çalışmanın amacı, Harmonik Scalpel (HS) ile yapılan sütürsüz tiroidektomileri konvansiyonel tiroidektomilerle evrensel parametreler açısından karşılaştırmaktır. **Gereç ve Yöntem:** Bu prospektif randomize çalışmada total tiroidektomi uygulanan 929 hasta üzerinde yapıldı. Hastalar randomize olarak 2 gruba ayrıldı. Grup I 461 hasta içeriyordu ve bu hastalara harmonik scalpel ile total tiroidektomi uygulandı. Grup II ise 468 hastadan oluşuyordu ve onlarda konvansiyonel tiroidektomi uygulandı. **Bulgular:** Operasyon süresi Grup I'e göre Grup II ( $49 \pm 11$  min) ( $32 \pm 8$  dk) anlamlı olarak daha uzundu. Ortalama kan kaybı hastalarda her iki grupta da anlamlı değildi. Tiroid boyutunda istatistiksel olarak anlamlı bir fark yoktu. Geçici / kalıcı hipokalsemi oranları karşılaştırıldığında, iki grup benzerdi. Kalıcı RLN felci açısından istatistiksel olarak anlamlı fark yoktu Grup I'de beş hastada görüldü. Ameliyat sonrası kanama, enfeksiyon oranları, hastanede kalış süresi iki grup arasında farklı değildi. **Tartışma:** Sonuç olarak, tiroid cerrahisinde HS kullanımı, geleneksel yöntemlere göre ameliyat süresini kısaltmaktadır. Ameliyat sonrası komplikasyonlar arasında hiçbir fark yoktur. HS tiroid cerrahisinde etkili, uygun ve güvenilir bir yöntemdir.

### Anahtar Kelimeler

Tiroid Cerrahisi; Harmonik Scalpel; Total Tiroidektomi

### Abstract

**Aim:** Our purpose, Harmonic Scalpel (HS) and Conventional thyroidectomy in this clinical study was to compare in terms of universal parameters. **Material and Method:** This prospective randomized trial study was performed on these 929 consecutive patients given total thyroidectomy. Patients were randomly assigned to either the Focus group (in which the operation was performed entirely using the Harmonic Focus and no other hemostatic tool; 468 patients) or the classic group (in which the operation was performed using conventional clamp-and-tie technique and mono-polar electric scalpel; 461 patients). **Results:** The operation time was significantly longer in Group II ( $49 \pm 11$  min.) than Group I ( $32 \pm 8$  min). The mean blood loss was not significantly in patients both groups. There was no statistically significant difference in specimen size. The two groups were similar when transient/permanent hypocalcaemia rates were compared. Permanent RLN palsy was seen in five patient in Group I. There was no statistically significant difference in drain usege. Postoperative bleeding, seroma, infection rates, hospitalisation time were not different between the two groups. **Discussion:** In conclusion, usage of the UHS in thyroid surgery decreases operation time when it is compared to conventional methods. On the other hand there is no difference in postoperative complications. The UHS is an effective, reliable and feasible technique in thyroid surgery.

### Keywords

Thyroid Surgery; Harmonic Focus; Total Thyroidectomy

## Introduction

The technique of total thyroidectomy has been well described and involves capsular dissection of the thyroid gland, encountering the recurrent laryngeal nerve in the region of the ligament of Berry and preservation or autotransplantation of the parathyroid glands [1,2]. The most recent development in thyroid surgery is the use of vessel sealing technology as an alternative to traditional ligatures and titanium clips [3]. Two devices designed specifically for thyroid surgery are available; the Harmonic Scalpel FOCUS (Johnson & Johnson, Ethicon Endo-Surgery, Cincinnati, OH, USA) and the Ligasure Precise (Covidien, Boulder, CO, USA). The Harmonic Scalpel FOCUS has an active blade that oscillates at 55 kHz, simultaneously sealing and cutting tissue. This vibration denatures hydrogen bonds, leading to formation of a protein coagulum [5,6]. Thermal spread from either instrument is reported to be 0.5–2 mm and is related to vessel size and hence the corresponding energy required for proper vessel sealing. The coagulation of smaller vessels is associated with lower thermal spread [4,5]. The aim of this prospective study was to compare the usage of the ultrasonic harmonic scalpel (UHS) with conventional procedures, in total thyroidectomies, for operation time, blood loss, usage of drain, length of hospitalisation and complications.

## Material and Method

### Study Design

The study involved 115 men and 814 women from January 2007 to July 2012. 929 patients underwent total thyroidectomy in the General Surgery Department of Bartın State Hospital. These patients thought to be benign in the preoperative period. (After the pathological examination of 32 patients were found to be malignant). Approval was obtained from the ethical committee of the hospital before initiating the study and informed consent was obtained from the patients. All patients were blinded to the surgical technique used and signed an informed written consent before enrollment to the trial. This prospective randomized trial study was performed on these 929 consecutive patients total thyroidectomy. Patients were randomly assigned to either the Focus group (in which the operation was performed entirely using the Harmonic Focus and no other hemostatic tool; 468 patients) or the classic group (in which the operation was performed using conventional clamp-and-tie technique and mono-polar electric scalpel; 461 patients). The method of randomization was performed by drawing lots. The patients all underwent similar treatment following the same protocol, except for the Harmonic Focus used. Total thyroidectomy were performed by the same experienced thyroid surgical team (four adept surgeons) in all cases. This team was stable during the study period. The two groups did not display statistically significant differences in terms of age, gender, BMI, and pathology classification. A complete preoperative assessment (serum thyrotropin levels, parathyroid hormone, serum Ca and P, nodule size by ultrasonography) was obtained in all patients. Preoperative laryngeal nerve status was determined by indirect laryngoscopy, performed by the same otolaryngologist from the Department of Otolaryngology.

## Surgical Technique

Four adept surgeons can use both techniques. Total thyroidectomy was performed in all patients. Under general anesthesia and with endotracheal intubation, the patients were placed on the operating table in the supine position with the neck extended. A 5 cm low-collar incision was made above the sternal notch. After skin incision with the conventional scalpel, flaps were raised using the mono-polar electric scalpel. In the Focus group, we used the Harmonic Focus for vascular control of the thyroid gland (Harmonic Focus, Ethicon Endo-Surgery, Inc, Cincinnati, OH). For better hemostasis, the middle vein, the superior and inferior thyroidal arteries and veins were controlled using. Other small vessels and surrounding connective tissues were controlled using easy cutting. For patients in the classic group, mono-polar electric scalpel was used to control the small vessels of the gland and conventional “clip, cut and tie” routines were adapted for the superior and inferior thyroidal arteries, as well as the superior, middle and inferior veins. Total thyroidectomy was first performed. In all patients, we identified recurrent laryngeal nerve routinely. The parathyroid glands were identified macroscopically, and a meticulous dissection from the thyroid gland was performed. Every effort was made to identify and preserve all parathyroid glands. Parathyroid glands were transplanted in the sternocleidomastoid muscle, if the blood supply to the glands was compromised. Hypocalcemia not developed in these patients. Outcomes of the study included operating time, fluid content in the suction balloon (drainage volume), and incidence of complications (rate of hypocalcemia and laryngeal nerve injury). The operative time was measured from initiation of the incision to conclusion of the skin closure. We placed a vacuum drain where large dead spaces remained after thyroidectomy or in cases where we were unsure of haemostasis. The drainage was measured and the drain was removed on postoperative day 1. Serum calcium, phosphate and total protein levels were recorded preoperatively. Vocal cord mobilities of all patients were evaluated laryngoscopically. Operation time, blood loss, intraoperative complications, weight of the specimen and necessity of drain was noted. Blood loss was calculated from the increase in weight of the blooded gauzes. Postoperative seroma, bleeding, infection, transient or permanent hypocalcaemia, permanent RLN palsy and length of hospitalisation were recorded.

### Statistical Analysis

Statistical analysis of the differences between groups was performed using the 2-sample t test and  $\chi^2$  test. Statistical analysis was made by SPSS 13.  $P < 0.05$  was considered statistically significant.

Operating time was significantly shorter in Focus group ( $P < 0.05$ ) by allowing a one third time saving vs classic hemostasis. Postoperative transient biochemical hypoparathyroidism occurred less frequently Focus group (43 patients) than in the classic group (48 patients) but no obvious distinction. 9 patient injury to recurrent laryngeal nerve occurred. (Both group) 5 patient (in Focus group) presented permanent recurrent laryngeal nerve paralysis. Intraoperative bleeding was not significant in any patient, and no neck hematoma, seroma, wound infection, or postoperative bleeding was observed. There were neither blood transfusions nor postoperative definitive sequelae. The mean postoperative hospital stay was no statistically difference ( $P > 0.05$ ).

## Results

The results of our study are shown in Table 1. We did not find any difference between the two groups in pre-operative demographic and laryngoscopic data and both groups had a similar mean age. The operation time was significantly longer in Group II (49±11 min. ) than Group I (32±8 min). The mean blood loss was not significantly in patients both groups. There was no statistically significant difference in specimen size (Table 1). The two groups were similar when transient/permanent hypocalcaemia rates were compared. The mean transient hypocalcaemia rate % 0.9 of Group I, was similar to the in % 1 Group II. Permanent hypocalcaemia rate was in Group I and in Group II. Permanent RLN palsy was seen in only one patient in Group I. There was no statistically significant difference in drain use (Table 1). The two groups were similar when transient/permanent hypocalcaemia rates were compared.. Postoperative bleeding, seroma, infection rates, hospitalisation time were not different between the two groups. Among all of the cases, no death was seen.

Table 1. The results of our study

Parameters	Group 1 (Focus G)	Group 2 (Knot G)	p
Average age	47.61±13.68	48.41±12.98	p>0.005
Mean operative time (dk)	32±8	49±11	p<0.005
Specimen weight (cm)	4.2±2.1	4.4±2.3	p>0.005
Mean blood loss (ml)	51.21±12.1	56.12±17.4	p>0.005
DOHD	1.32±0.67	1.23±0.67	p>0.005
Drain use	91/377	73/388	p>0.005
Transient hypocalcaemia n	43/468	48/461	p>0.005
Permanent hypocalcaemia n	4/468	3/461	p>0.005
Permanent RLN palsy n (%)	5/468	4/461	p>0.005

DOHD: Duration of hospitalization, days

## Discussion

The thyroid has a rich blood supply, haemostasis is very important thyroid surgery. Electrocautery used in conventional techniques may harm the surrounding vital tissues due to high rates of lateral tissue damage. Also, the patient is subjected to electricity when electrocoagulation is used. On the other hand, UHS allows haemostasis to occur in low temperatures, lateral tissue damage is less, and electricity is not used. The main advantage of using the UHS in thyroid surgery is the reduction in operation time. In conventional methods, dissection, tying and cutting the vessels takes time. The UHS allows simultaneous dissection, cutting and coagulation so the operation time is shorter. The studies published by Siperstein et al.<sup>11</sup> (29 minutes), Voutilainen et al.<sup>8</sup> (35 minutes) and Defechereux et al.<sup>9</sup> (26 minutes) show that the operation time shortens with the UHS. In our study, we observed a significant reduction in operation time by 32±8.

Blood loss is minimal when thyroidectomy is performed by experienced surgeons. We calculated blood loss from the increase in weight of the blooded gauzes. Some authors have reported that the amount of bleeding did not differ between the two methods [7,12,13]. Also Defechereux et al.<sup>5</sup> reported a reduction in intra-operative bleeding. Drains were used in operations where large dead space remained after thyroidectomy or when the surgeon had concerns about haemostasis. Bleeding was less and so the space was drier in the UHS group, therefore drain usage was significantly less in the UHS group. The major local complications of thyroidectomy are RLN palsy and hypocalcaemia. The permanent RLN paralysis range is 0%–14% in various studies. In experienced hands the rate of this complication is lower than 2% [10]. In line with previous studies, the use of a UHS did not increase the RLN palsy risk in our study [7,10,12]. The rate of transient hypocalcaemia has been reported as %5–%15 and permanent hypocalcaemia rates have been reported as %5 in total thyroidectomies [12]. The rates of transient and permanent hypocalcaemia were 9.1% and 0.8%, respectively, in our UHS group.

## Conclusion

In conclusion, usage of the UHS in thyroid surgery decreases operation time when it is compared to conventional methods. On the other hand there is no difference in postoperative complications. The UHS is an effective, reliable and feasible technique in thyroid surgery.

## Competing interests

The authors declare that they have no competing interests.

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