ARAŞTIRMA MAKALESİ / *RESEARCH ARTICLE*

Comparison of Starion Vessel Sealing System with Conventional Technique and Harmonic Focus Ultrasonic Scalpel in Total Thyroidectom

Total Tiroidektomide Starion Damar Mühürleme Sisteminin Konvansiyonel Teknik ve Harmonik Odaklı Ultrasonik Cihaz ile Karşılaştırılması

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ABSTRACT

Aim: *This study compares the use of Starion Tissue Welding SystemTM (STWS) in patients who underwent total thyroidectomy due to Multinodular Goiter (MNG) with the conventional technique and Harmonic Focus Ultrasonic ScalpelTM (HFUS) in terms of operation time, bleeding during and after the operation, and complications.*

Materials and Methods: *Between June 2013 and August 2014, 60 patients who underwent a total thyroidectomy due to MNG were retrospectively analyzed. The patients were divided into three groups according to the surgical method. Each group consisted of 20 patients. In the operations, ligation/coagulation and cutting procedures were performed to middle thyroid veins, upper and lower pole arteries/veins of the thyroid gland using conventional clamp and-tie technique in Group-A, STWS in Group-B, and HFUS in Group-C. Groups were compared regarding the operation time, the amount of bleeding during and after the operation, and the complications encountered.*

Results: *Operation times were established as 63.25±28.66 minutes in Group-A, 42.60±20.14 minutes in Group-B, and 49.60±9.17 minutes in Group-C ($p<0.05$). Perioperative bleeding was 93.50±56.05 ml in Group-A, 25.60±15.21 ml in Group-B, and 62.50±23.31 ml in Group-C ($p<0.05$). Postoperative blood drainage was 124.50±153.09 ml, 8.75±11.68 ml, and 35.75±25.91 ml, respectively ($p<0.05$). Regarding hemostasis, while two patients in Group-A required hemostasis within the first 24 hours, there was no need for hemostasis in Group-B and Group-C ($p=0.12$). The blood calcium levels measured on the first postoperative day were found to be 8.39±0.56 mg/dl in Group-A, 8.34±1.14 mg/dl in Group-B, 8.37±0.78 mg/dl in Group-C ($p=0.86$). Blood parathormone levels measured on the first postoperative day were 52.72±35.85 pg/dl, 34.77±20.0 pg/dl, and 56.41±36.56 pg/dl, respectively ($p=0.09$).*

Conclusion: *STWS can be used safely in thyroid surgery because it reduces bleeding during and after surgery, shortens the operation time, and has low complication rates.*

Key words: *thyroidectomy; tissue welding system; ultrasonic device; clamp and tie*

ÖZET

Amaç: *Bu çalışmada Multinodüler Guatr (MNG) nedeniyle total tiroidektomi yapılan hastalarda Starion Tissue Welding SystemTM (STWS) kullanımının, konvansiyonel teknik ve Harmonik Odaklı Ultrasonik ScalpelTM (HFUS) kullanımı ile operasyon süresi, ameliyat sırasında ve sonrasındaki kanama miktarı ile ameliyat sonrası komplikasyonlar açısından karşılaştırılması amaçlanmaktadır.*

Materyal ve Metot: *Haziran 2013 ile Ağustos 2014 tarihleri arasında MNG nedeniyle total tiroidektomi yapılan 60 hasta retrospektif olarak incelendi. Hastalar uygulanan cerrahi yönteme göre üç gruba ayrıldı. Her grup 20 hastadan oluşuyordu. Operasyonlarda Grup-A'da konvansiyonel klemp bağlama tekniği, Grup-B'de STWS, Grup-C'de HFUS kullanılarak orta tiroid damarlarına, tiroid bezinin üst ve alt kutup arterlerine/venlerine ligasyon/koagülasyon ve kesme işlemleri uygulandı. Gruplar operasyon süresi, operasyon sırasında ve sonrasında kanama miktarı ve karşılaşılan komplikasyonlar açısından karşılaştırıldı.*

Bulgular: *Operasyon süreleri Grup-A'da 63,25±28,66 dakika, Grup-B'de 42,60±20,14 dakika, Grup-C'de 49,60±9,17 dakika olarak belirlendi ($p<0,05$). Perioperatif kanama Grup-A'da 93,50±56,05 ml, Grup-B'de 25,60±15,21 ml, Grup-C'de 62,50±23,31 ml idi ($p<0,05$). Ameliyat sonrası kan drenajı sırasıyla 124,50±153,09 ml, 8,75±11,68 ml ve 35,75±25,91 ml idi ($p<0,05$). Hemostaz açısından Grup-A'daki iki hastada ilk 24 saat içinde hemostaz ihtiyacı duyulurken, Grup-B ve Grup-C'de hemostaz ihtiyacı olmadı ($p=0,12$). Ameliyat sonrası 1. günde ölçülen kan kalsiyum düzeyleri Grup-A'da 8,39±0,56 mg/dl, Grup-B'de 8,34±1,14 mg/dl, Grup-C'de 8,37±0,78 mg/dl olarak tespit edildi ($p=0,86$). Ameliyat sonrası 1. Günde ölçülen kan parathormon düzeyi sırasıyla 52,72±35,85 pg/dl, 34,77±20,0 pg/dl ve 56,41±36,56 pg/dl idi ($p=0,09$).*

Sonuç: *Tiroid cerrahisinde STWS, ameliyat sırasında ve sonrasında kanama miktarının azalması, ameliyat süresinin kısalması ve komplikasyon oranlarının düşük olması nedeniyle güvenle kullanılabilir.*

Anahtar kelimeler: *tiroidektomi; doku mühürleme sistemi; ultrasonik cihaz; klemp-bağlama*

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Geliş/Received: *25.02.2024* • ***Kabul/Accepted:*** *20.10.2024*

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Introduction

Thyroidectomy has been performed quite frequently since the day it was defined. The frequency of thyroidectomy operations is higher in endemic areas for thyroid gland diseases, especially in the Black Sea Region of Türkiye. The morbidity of thyroid surgeries is very low, and the possibility of mortality is rare. Complications such as Recurrent Laryngeal Nerve (RLN), Superior Laryngeal Nerve (SLN), and parathyroid gland damage that may occur during thyroid surgeries can adversely affect the patient's life. Due to the high rates of bleeding, infection, and sepsis, as well as the morbidity and mortality rates of around 40%, this type of surgery was only frequently performed in general surgery clinics at the time of Theodore Kocher. Towards the end of the nineteenth century, innovative surgical techniques developed with Kocher's introduction of antisepsis, enucleation, and ligation techniques. With the standardization of vascular control in thyroid surgery, a significant reduction in mortality has been achieved. The importance of demonstrating the vascular structures and visualizing the anatomical structures has been understood by surgical standardization[1].

Hemostasis is conventionally achieved in thyroid surgery with clamps and sutures, tissue adhesives, or hemostatic clips. However, energy-based surgical instruments (ESIs), which started to be used in the 2000 s, coagulate vascular structures and can cut simultaneously. Coagulated vascular structures can be safely coagulated and cut without ligation. Although ESIs in use are unsuitable for large-scale arteries and veins, they can coagulate all arteries and veins encountered in thyroid surgery. In thyroid surgery, it has been shown that they shorten the operation time and reduce the risks and complications of surgery[2–4]. Hemostasis can be achieved in thyroidectomy operations with Harmonic Focus Ultrasonic Scalpel™ (Ethicon Inc., Cincinnati, OH, USA) (HFUS) and the bipolar vessel ligation system: LigaSure™ (Valleylab, Boulder, Colo, USA) (Ligasure), which have been used recently. Even minor bleeding during thyroid surgery can obscure the visualization of structures such as the RLN and parathyroid glands and cause damage to them. Therefore, performing thyroid surgery in a bloodless environment is very important. ESIs such as HFUS and Ligasure are successful in hemostasis; they reduce the amount of bleeding during the operation and the risk of hematoma that may develop in the postoperative period. They significantly reduce the operation time and the hospitalization in the postoperative period. They allow the thyroidectomy incision to be made smaller. They can also be used in endoscopic thyroidectomy[3,5].

The study, which compared the use of traditional surgical techniques with HFUS, reported that the use of HFUS shortens the operation time by 15–20% and is cost-effective compared to the traditional surgical technique. Although the costs of ESIs are high, they have reported that the increased cost due to the use of ESIs is balanced due to the shortened time of surgery and hospitalization[6]. ESIs work by producing various types of energy; they have coagulation and cutting abilities (e.g., ultrasound, radiofrequency, tissue welding). Starion Tissue Welding System™ (Starion Instruments, Sunnyvale, CA, USA) (STWS) produces less smoke when coagulating the tissue and has been used safely and effectively for hemorrhoidectomy in clinical practice. The safety and effectiveness of STWS in total thyroidectomy operations were studied in 2010 for Total Thyroidectomy (TT) operations. Starion Tissue Welding System™ was used for the first time and compared to the conventional surgical method for TT. It has been demonstrated that STWS can easily perform the sealing and cutting process, shorten the operation time, be used for open and minimally invasive video-assisted thyroidectomy, provide faster recovery, and be used safely regarding complications[7].

In our clinic, located in an endemic region for thyroid diseases, various ESIs or traditional methods were used in TT surgeries, depending on the financial means provided by the patients and their health insurance. In our study, we aimed to compare the results of using three different methods, STWS, clamp-and-tie technique, and HFUS, in terms of the operation time, the amount of bleeding during and after the operation, and the complications that developed.

Materials and Methods

Patients who underwent TT surgery in the General Surgery Clinic of Karabuk University Medical Faculty Hospital between June 2013 and August 2014 were included in the study. Patients with a histopathological diagnosis of malignant, toxic multinodular goiter and giant goiter who had undergone unilateral surgery, secondary surgery, and additional neck dissection were determined as exclusion criteria, and only Benign Multinodular Goiter (BMNG) patients (n=60) were retrospectively analyzed and included in the study. All of the patients were female patients. The patients

were divided into three groups according to the ESIs and clamp-and-tie techniques used in the surgery. Each group consisted of 20 patients. The same surgical team performed all operations. Ligation/coagulation and cutting procedures were performed using the clamp-and-tie technique (n=20) in Group-A, STWS (n=20) in Group-B, and HFUS (n=20) in Group-C. The patients were evaluated by examining the records of the operation time, the amount of bleeding during the operation, and the clinical findings of serum calcium, parathormone values, hoarseness, and hypocalcemia in terms of early RLN and parathyroid gland damage within the first 24 hours after the operation. Aspirative drainage amounts and re-hemostasis needs were examined in the postoperative period. By establishing these criteria, three groups were compared.

All patients were operated under general anesthesia with endotracheal intubation. A standard Kocher's Necklace Incision of 5–6 cm in length was made in all patients, and a TT operation was performed. In the operations performed, the skin, subcutaneous tissue, and platysma were passed using a scalpel and monopolar electrocautery. In each group, the midline was dissected with monopolar electrocautery. After the thyroid tissue is exposed, the middle thyroid veins, upper and lower pole arteries/veins of the thyroid gland were ligated/sealed and cut using the conventional clamp-and-tie technique in Group-A, STWS in Group-B, and HFUS in Group-C. Berry's ligament, which is in close anatomical proximity to the RLN, was separated from the surrounding tissues by dissecting using a dissector and ligatures in Group-A, using dissector and group-specific ESIs in the other two groups. An aspirative drain was placed in the thyroid lodge after bleeding control as a standard in each operation. The amount of bleeding during the operation was measured. Blood calcium and parathormone levels were measured on the first postoperative day. The amount of bleeding in the drain was recorded 24 hours after the operation, and the drain was removed. The patients were evaluated by physical examination and checked for Chvostek's or Trousseau's signs and dysphonia.

Statistical Analysis

Analyzes were performed using IBM Statistical Package for Social Sciences (SPSS) program version 10 (IBM, Inc. Chicago, IL, USA). In comparisons between groups, the test of differences between two independent groups was used to compare parametric data, and the chi-square test was used to compare non-parametric data. Statistically ($p<0.05$) values were considered significant.

Results

The mean age of Group-A was 52.85±12.12 years, Group-B was 52.75±13.09 years, and Group-C was 51.0±12.94 years. There was no statistically significant difference between the groups regarding mean age ($p=0.78$). The diameter of the largest nodule in the thyroid gland is 3.07±1.34 millimeters (mm) in Group-A, 3.1±1.42 mm in Group-B, and 2.95±1.3 mm in Group-C. Other nodule numbers and sizes were not taken into account. No statistically significant difference was found between the groups ($p>0.05$) (Table 1). When the mean operation times were evaluated, it was found that Group-A was 63.25±28.66 minutes (min), Group-B was 42.60±20.14 minutes, and Group-C was 49.60±9.17 minutes. A statistically significant difference was found between the mean operation times ($p<0.05$). When the groups were compared among themselves, it was observed that the shortest time was obtained in the STWS group ($p<0.017$) (Table 1). In terms of perioperative and postoperative bleeding, the amount of perioperative bleeding was 93.50±56.05 milliliter (ml) in Group-A, 25.60±15.21 ml in Group-B, 62.50±23.31 ml in Group-C ($p<0.05$). In contrast, postoperative bleeding was 124.50±153.09 ml, 8.75±11.68 ml, and 35.75±25.91 ml, respectively. A statistically significant difference was found between the groups ($p<0.05$). When the groups were compared, it was observed that the least amount of bleeding was observed in the STWS group ($p<0.017$) (Table 1) (Tables 2a and 2b). Regarding hemostasis, while two patients in Group-A required hemostasis within the first 24 hours, hemostasis was not needed in Group-B and C. However, no statistically significant difference was found between the groups ($p=0.12$) (Table 3). When evaluated in terms of blood calcium and parathormone results measured on the first postoperative day, calcium values were 8.39±0.56 milligrams/deciliter (mg/dl) in Group-A, 8.34±1.14 mg/dl in Group-B and 8.37±0.78 mg/dl in Group-C ($p=0.86$). Parathormone levels were found to be 52.72±35.85 picograms/deciliter (pg/dl), 34.77±20.0 pg/dl, and 56.41±36.56 pg/dl, respectively ($p=0.09$). There was no statistically significant difference in both parameters ($p>0.05$) (Table 1).

Table 1. *Results of patients who underwent bilateral total thyroidectomy*

	Device	Number	Average	Standard deviation	P value
Age (years)	Classic	20	52.85	12.12	0.78
	Thermal welding	20	52.75	13.09	
	Harmonic	20	51.00	12.94	
Operation time (minute)	Classic	20	63.25	28.66	<0.05
	Thermal welding	20	42.60	20.14	
	Harmonic	20	49.60	9.17	
Nodule diameter (millimeter)	Classic	20	3.07	1.34	>0.05
	Thermal welding	20	3.1	1.42	
	Harmonic	20	2.95	1.36	
Peroperative bleeding (milliliter)	Classic	20	93.50	56.05	<0.05
	Thermal welding	20	25.60	15.21	
	Harmonic	20	62.50	23.31	
Postoperative bleeding (milliliter)	Classic	20	124.50	153.09	<0.05
	Thermal welding	20	8.75	11.68	
	Harmonic	20	35.75	25.91	
Calcium (milligram per deciliter)	Classic	20	8.39	0.56	0.86
	Thermal welding	20	8.34	1.14	
	Harmonic	20	8.37	0.78	
Parathormon levels (picogram per decilitre)	Classic	20	52.72	35.85	0.09
	Thermal welding	20	34.77	20.0	
	Harmonic	20	56.41	36.56	

Table 2a. *Evaluation of the conventional method and the HFUS system among themselves*

	Device	P value	Bonferroni ratio
Operation time (minute)	Classic	0.16	p>0.017
	Harmonic		
Perioperative bleeding (milliliter)	Classic	0.42	p>0.017
	Harmonic		
Postoperative bleeding (milliliter)	Classic	0.26	
	Harmonic		

Table 2b. *Evaluation of HFUS system and STWS among themselves*

	Device	P value	Bonferroni ratio
Operation time (min)	Thermal welding	0.002	p<0.017
	Harmonic		
Perioperative bleeding (ml)	Thermal welding	0.001	p<0.017
	Harmonic		
Postoperative bleeding (ml)	Thermal welding	0.002	
	Harmonic		

Table 3. *Evaluation for complications (p>0.05)*

	Device	Number	Present	%	p-value
Hoarseness	Classic	20	0	0	p=0.59
	Thermal welding	20	1	5	
	Harmonic	20	1	5	
Hemostasis	Classic	20	2	10	p=0.12
	Thermal welding	20	0	0	
	Harmonic	20	0	0	

In terms of complications, transient hoarseness was not observed in Group-A but in one patient each in Group-B and C. These patients were evaluated with laryngoscopy when dysphonia was detected and unilateral partial paralysis was detected. These two patients were followed up clinically and by laryngoscopy, and it was found that dysphonia was resolved in less than 6 months of their follow-up. Permanent hoarseness did not develop in any patient. No clinical evidence of SLN injury or wound infection was found in any group. No statistically significant difference was found in complications (p=0.59) (Table 3).

Discussion

Total thyroidectomy is the most frequently performed surgery in the field of endocrine surgery. Thyroid surgeries are performed more frequently, especially in endemic regions such as our country. The morbidity after TT surgery is quite low, and mortality is not predicted under normal circumstances[8]. Thyroid tissue is a very rich blood supply organ and is prone to bleeding during surgery. To avoid complications of thyroidectomy operations, anatomical formations must be seen clearly. For this purpose, the fact that the operation area is quite dry and bloodless will facilitate visualization. The upper and lower pole vessels can be dissected, ligated, and cut to prevent bleeding during surgery. Traditionally, sutures and clips can be used for this, but ligatures and clips can slip out of place and cause bleeding. Using ESIs reduces this possibility and does not leave foreign objects, such as ligatures and clips, in the surgical field. There is a concern for thermal damage in these devices, especially in dissections performed close to the nerves, but studies show that the devices can be used safely without causing thermal damage[7,9]. One of the important complications that can be fatal after thyroidectomy is bleeding. Although the bleeding rate after thyroidectomy performed by experienced surgeons is reported to be approximately 1%, there are also publications reporting a bleeding rate of over 4%[10–12].

While most of the bleeding occurs in the first 6 hours after thyroidectomy, only 10% may occur after 24 hours. Bleeding after 7 days has also been reported in the literature in a few cases. It is important whether the bleeding is life-threatening or not. The majority of early bleeding is life-threatening and requires immediate surgical intervention. Bleeding occurring in the late period may not always be life-threatening and can be followed conservatively[13,14]. Hemostasis is, therefore, very important. As conventional methods of hemostasis, suturing and electrocautery are common. However, high lateral tissue damage due to electrocautery use may also cause damage to the surrounding vital tissues. In addition, burns may occur due to the patient's exposure to electricity. Recently, it has been shown that ESIs can be used safely in open and endoscopic thyroid surgery. The fact that hemostasis is one of the most important parts of the operation in thyroid surgery and that hemostasis is a time-consuming procedure has increased the use of ESIs in thyroid surgery[9,15].

A study used STWS for TT operations and compared it with the conventional method. In the study, it has been detected that using STWS shortens the operation time and provides a faster recovery opportunity by reducing the possibility of hypocalcemia in the postoperative period. However, to show the extent of the thermal damage in the surrounding tissue, they examined the part of the superior thyroid artery sealed with STWS and the surrounding tissue histopathologically by staining with hematoxylin and eosin, and they detected collateral damage of no more than 0.5 mm in the surrounding tissue. This shows that minimal thermal damage occurs and can be used safely[7].

Harmonic Focus Ultrasonic Scalpel™ often cuts with 55,500 Hz vibration. During this vibration, microlevel heat is generated and causes the denaturation of proteins. In the veins, both the closing and cutting process takes place. The heat generated is less than 60°C, and it is stated that the thermal heat damage is less than 1.5 mm. Starion Tissue Welding System™ is a simple resistive heater wire powered by low voltage direct current. The STWS is not a bipolar device, as no electrical current flows through the tissue between the tips of the STWS forceps. The active part of the device is the heating element, which consists of nickel chrome resistance and a thermally insulated back part. This layer prevents the heating effect of the nickel chrome wire from spreading to other parts of the device. Coagulation and cutting co-occur. The device closes both ends of a cut vessel. Due to the heat conduction in the nickel chrome wire, the cut area is larger than the diameter of the wire. The heat in the tissue is sufficient to cut the tissue by direct vaporization. This temperature varies between 300–400°C. Moving away from the wire's center, the temperature drops to 100°C, which is the ideal value for coagulating and bonding the tissues with protein denaturation[16].

In a study in which they compared the use of HFUS and conventional techniques in TTs for thyroid cancer and Basedow's disease, the average bleeding amount during the operation was 40 ml in the HFUS group. In comparison, it was 125 ml in the conventional method group, and the postoperative drainage amount was 120 ml and 175.5 ml, respectively. The study showed that using HFUS resulted in a statistically significant reduction in bleeding and total drainage during surgery[17]. In another study, in which they compared TT surgeries performed using HFUS and LigaSure and their results, it was found that both ESIs provided effective and safe dissection of all vessels and tissues. There was no significant difference in postoperative morbidity[18].

Many studies have stated that there is less bleeding in the use of HFUS and LigaSure compared to conventional methods. However, more studies need to be done on using STWS in thyroid surgery. In our study, hemostasis was required in patients who used the conventional method. The least amount of bleeding is in the thermal welding system. For this reason, we see that STWS can be used in thyroid surgery without the need to suture the upper and lower pole arteries/veins, and it is very effective in reducing the amount of bleeding and total drainage.

Compared to the conventional technique, the most important advantage of using HFUS is shortening the operation time. It has been revealed that an average reduction of 35.8 minutes in TT operations performed by an experienced surgeon using HFUS compared to TT surgeries performed with conventional technique[19]. Another study reported a time saving of 40 minutes for bilateral total thyroidectomy and 30 minutes for lobectomy[3]. However, using HS reduces the operation time by 18% on average[20]. In our study, the shortest operation times were obtained with STWS compared to the conventional method and the use of HFUS. This result is due to the shorter waiting time of the system during coagulation and cutting. Other advantages of using STWS are that it causes 5 mm or less thermal damage to the surrounding tissue and no vibration in contact with metallic surgical instruments. In addition, the device's ergonomics provide a more comfortable and controlled use[7].

As a result of the dissection performed during thyroidectomy operations, the blood supply to the parathyroid glands is often temporarily impaired. When operations performed due to MNG or thyroid cancer are compared, hypocalcemia is more common in operations performed due to cancer. When total thyroidectomy and thyroid lobectomy operations are compared, the probability of developing hypocalcemia is lower in lobectomies[21]. Nowadays, total thyroidectomy is replaced by thyroid lobectomy in selected cases of thyroid cancer. After this type of limited surgery, the probability of developing hypocalcemia decreases, and hospital stays also shorten. Therefore, when comparing the energy devices used in thyroidectomy operations in terms of hypocalcemia, it is important whether the surgery is performed for benign or malignant reasons[22].

Conclusion

In our study, it is notable that using STWS in TT surgeries reduces the amount of bleeding during and after the surgery, shortens the operation time, and has low complication rates. The shortening of the operation time when STWS is used is due to the ability of the STWS device to perform both cutting and coagulation simultaneously. The fact that blood Ca and Parathormone values measured postoperatively are not low indicates that using STWS is safe regarding parathyroid damage that may occur during surgery. In our study, dissection around the Berry Ligament was performed with STWS and HFUS. No permanent nerve damage was observed, indicating that dissecting around the nerve tissue with ESIs is safe. In addition, when compared to other ESIs, STWS is a simpler and more practical system that can work with a universal power supply. We believe that STWS, like other ESIs, is a safe alternative for TT surgeries.

Statement of Ethics

The approval for this study was obtained from Istanbul Okan University, Ethics Committee, dated October 18, 2023, and numbered 169/32.

Conflict of Interest Statement

The authors declare that they have no conflicts of interest.

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