

Total Tiroidektomi Sırasında Enerji Bazlı Damar Mühürleme Cihazlarının Etkinliği: Karşılaştırmalı Tek Merkez Çalışması

The Efficacy of Energy Based Vessel Sealer Devices During Total Thyroidectomy: A Comparative Single Institution Study

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ÖZ

GİRİŞ ve AMAÇ: Son yıllarda tiroid ameliyatlarında LigaSure® (LS) ve Harmonic Scapel® (HS) kullanımı cerrahlar arasında popüler hale gelmiştir. Bu yeni teknolojinin, geleneksel bağlama yöntemi ile karşılaştırılması, kapsamlı bir şekilde incelenmiştir. Bu çalışmada, bölümümüzün 'de LS ve HS kullanarak yapılan tiroidektomi sonuçlarının güncel literatür eşliğinde tartışılması amaçlanmıştır.

YÖNTEM ve GEREÇLER: Ocak 2013-Ekim 2017 tarihleri arasında bölümümüzde primer total tiroidektomi uygulanan 224 hastanın dosyaları bu çalışma için gözden geçirildi. Demografik özellikleri, operasyon süresi, patolojik değişkenler, hastanede yatış süresi ve komplikasyon oranları retrospektif olarak incelendi.

BULGULAR: Yüz kırk dokuz hasta LS, 75 hasta ise HS kullanılarak ameliyat edildi. Otuz sekiz hasta erkek, 186 hasta kadındı. LS grubundaki hastalar HS grubundan daha yaşlıydı ($p < 0.05$). Komorbidite oranları, hastalık özellikleri, operasyon süresi, patolojik analiz sonuçları ve rekürren laringeal sinir hasarı açısından LS ve HS grupları arasında istatistiksel anlamlı fark yoktu. Postoperatif kanama, ses kısıklığı, hipokalsemi, postoperatif serum kalsiyum düzeyi, postoperatif parathormon düzeyleri ve hastanede yatış süresi açısından da LS ve HS grupları arasında istatistiksel fark yoktu. Fakat LS grubunda dren HS grubundan daha uzun sürede çekildi ($p < 0.05$).

TARTIŞMA ve SONUÇ: Total tiroidektomi sırasında her iki cihaz etkili ve güvenli olduğu görüldü. LS grubundaki hastaların dren drenaj oranları anlamlı yüksek bulundu.

Anahtar Kelimeler: total tiroidektomi, enerji bazlı damar mühürleyiciler, rekürren sinir

ABSTRACT

INTRODUCTION: Nowadays, LigaSure® (LS) and Harmonic Scapel® (HS) have been popularized among surgeons during thyroid operations. The comparison of this new technology with conventional ligature have been extensively studied. The aimed of this study was to discuss the results of thyroidectomies with LS or HS in the context of the literature.

METHODS: Between January 2013 and October 2017, 224 patients who underwent total thyroidectomy in our department were evaluated for this study. The demographic characteristics, duration of operations, pathologic variables, duration of hospitalization and complication rates were retrospectively analyzed.

RESULTS: Hundred and forty-nine patients were operated with LS and 75 patients were operated with HS. Thirty-eight patients were male, and 186 patients were female. Patients in the LS group were older than the HS group ($p < 0.05$). There was no statistically significant difference between LS and HS groups in terms of comorbidity rates, disease characteristics, operative time, pathology results and recurrent laryngeal nerve injury rate. Postoperative bleeding, hoarseness rate, hypocalcemia, postoperative serum calcium level and postoperative parathormone levels and length of hospital stay were also similar among LS and HS groups. The drain removal time for LS group was longer than HS group ($p < 0.05$).

DISCUSSION and CONCLUSION: Both devices were found to be safe and effective during total thyroidectomy. Although the drainage rate of the patients in the LS group was found to be significantly higher. But it was not a statistically significant difference.

Keywords: total thyroidectomy, energy based vessel sealers, recurrent nerve

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INTRODUCTION

The first records of thyroidectomy dates back to 12th century, however due to high morbidity and mortality thyroid surgery was not routinely performed until 1800s (1). With advances in antisepsis and anesthesia techniques in the 19th century, Theodor Billroth reported an 8% mortality rate after thyroid surgery (2). It is now the standard of care for many thyroid diseases and mortality or major disability is extremely low (3).

Thyroid is a well vascularized gland and hemostasis is one of the most important limiting factors in the morbidity and mortality of thyroid surgery [4]. Other postoperative morbidity sources include dysphonia and dysphagia due to recurrent and/or superior laryngeal nerve injury, parathyroid ischemia or unwanted withdrawal, postoperative bleeding, wound infection and postoperative pain due to hypocalcemia (4,5). The incidence of recurrent laryngeal nerve injury and hypoparathyroidism in total thyroidectomy cases performed by experienced neck surgeons in different thyroid surgical centers has been reported between 2% -3% (6,7). However persistent recurrent nerve palsy and hypocalcemia have been reported to be less than 1% (8,9).

In recent years, new vessel sealing systems have been applied to thyroid surgery, including electrothermal bipolar-activated devices such as LigaSure® (LS) or Harmonic Focus® devices (HS). The aim of these devices were to reduce blood loss, surgical time and shorten skin incision length (3). The aim of this study is to discuss the results of thyroidectomy performed with LS and HS by two surgeons in the context of current literature.

METHODS

Between January 2013 and October 2017, 267 thyroid operations were performed by two surgeons in our department. Only primary total thyroidectomy cases were included in the present study and 43 patients were excluded because total thyroidectomy was not performed, who were operated for recurrent multinodular goiter or solitary toxic nodules. A total of 224 patients were analyzed retrospectively and divided into two groups; LS (n=149, 66.5%) and HS (n=75, 33.5%). Demographic characteristics of cases, operative time, and length of hospitalization, preoperative

diagnosis, hematoma formation, hypocalcemia rate, and pathological diagnosis have been evaluated for the study.

Statistical Analysis

Continuous variables are expressed in mean and standard deviation and median and range according to normal distribution. Student t Test and Mann Whitney U test have been used to determine the relationship between dependent and independent variables. Any p value less than 0.05 was considered as statistically significant. All statistical analyses were performed on Statistical Program for Social Sciences software version 17 (SPSS v17, IBM, USA).

RESULTS

Hundred and forty-nine patients were operated with LS and 75 patients with HS. The choice of HS or LS use during the surgery was changed according to the surgeon's preference. Thirty-eight patients were male, and 206 patients were female. The patients in the LS group were significantly older than patients in HS group (53.1 versus 48.9 years, $p=0.012$). The comorbidity rates, preoperative thyroid functions, distribution of preoperative diagnosis, scintigraphy, fine needle aspiration rates, operation time, pathology results and recurrent laryngeal nerve palsy were similar between LS and HS groups (Table 1).

The distribution of complication rates was also evaluated between two study groups. Postoperative bleeding, dysphonia rate, hypocalcemia, postoperative serum calcium level and postoperative parathormone levels were similar between LS and HS groups. Prolonged hospital stay rates were also similar between two groups (Table 2). A drainage was always used after total thyroidectomy and removed after 24 h. However 23 (15.4 %) patients in LS and 3(4%) patients in the HS group had a too much postoperative drainage so that was not removed on the following day. This difference was statistically significant ($p=0.012$).

Table 1: Demographic characteristics of the patients			
	Total Thyroidectomy		P Value
	LigaSure(n= 149)	Harmonic Scapel(n=75)	
Gender			
Female	121 (81.2%)	65 (86.7%)	0.304
Male	28 (18.8%)	10 (13.3%)	
Age (mean + standard deviation) years	53.1±11.5	48.9±12.4	0.012*
Duration of operation (median and range) minutes	60 (45-95)	65 (45-90)	0.099
Comorbidities			
Hypertension	43 (28.9)	19 (25.3)	0.578
Type 2 Diabetes Mellitus	21 (14.1)	8 (10.7)	0.471
Coronary Artery Disease	1 (0.7)	3 (4.0)	0.110
COPD	10 (6.7)	4 (5.3)	0.778
Hyperlipidemia	1 (0.7)	1 (1.3)	0.999
Preoperative Thyroid Functions			
Normoactive	120 (80.5)	51 (68.0)	0.078
Hypoactive	4 (2.7)	2 (2.7)	
Hyperactive	25 (16.8)	22 (29.3)	
Preoperative Diagnosis			
MNG	118 (79.2)	53 (70.7)	
Toxic MNG	27 (18.1)	20 (26.7)	0.376
Graves-Basedow Disease	3 (2.0)	1 (1.3)	
PTC	1 (0.7)	1 (1.3)	
Scintigraphy	(n=52)	(n=17)	
Hypoactive Nodule	22 (42.3)	11 (64.7)	
Hyperactive Nodule	9 (17.3)	4 (23.5)	0.209
Diffuse Hyperplasia	9 (17.3)	1 (5.9)	
Hypo-Hyperactive	12 (23.1)	1 (5.9)	
Fine Needle Aspiration results	(n=79)	(n=41)	
Benign	64 (81.0)	33 (80.5)	0.999
Atypia with undetermined importance	9 (11.4)	5 (12.2)	
Follicular neoplasia	6 (7.6)	3 (7.3)	
Pathologic analysis results			
Benign	126 (84.6)	58 (77.3)	0.293
Malign	21 (14.1)	16 (21.3)	
Undetermined	2 (1.3)	1 (1.3)	

COPD: Chronic Obstructive Pulmonary Disease MNG: Multinodular Goiter PTC: Papillary Thyroid Carcinoma

Table 2 : Summary of the data regarding the operation, postoperative complications and duration of hospitalization			
	LigaSure(n= 149)	Harmonic Scapel(n=75)	P Value
Postoperative hemorrhage rate	1 (0.7 %)	2 (2.7%)	0.260
Dysphonia rate	1 (0.7%)	2 (2.7%)	0.260
Hypocalcemia rate	14 (9.4%)	8 (10.7%)	0.763
Postoperative serum calcium levels (mg/dl)(median and range)	8.3 (5.6-11.8)	8.4 (6.9-11.4)	0.110
Postoperative serum PTH (pg/mL) (median and range)	43 (2.0-1052.3) (n=22)	40 (7.9-112.2) (n=13)	0.918
Reoperation rate rate	1 (0.7%)	2 (2.7%)	0.260
Delay rate in drain removal	23 (15.4%)	3 (4.0%)	0.012*
Delay rate in patient discharge	34 (22.8%)	9 (12.0%)	0.052

PTH: Parathormone

DISCUSSION

Thyroid surgery can be performed safely with meticulous hemostasis and a very good knowledge of anatomy(10,11). Bleeding is a major intraoperative and postoperative complication in thyroid surgery that leads to prolonged operative time, length of hospitalization and in certain circumstances it may even lead to reoperations (11).

Hemostasis can be achieved by ligatures, monopolar and bipolar diathermy, clips or certain energy-based vessel sealing devices such as LS or HS. Ligature is an effective hemostasis technique but prolongs the operation time. Energy-based vascular sealing devices have been developed and introduced for use in clinical practice to reduce surgical time and postoperative complication rates (10).

Although the blood vessels are similar in their ability to quickly seal, the actual mechanism is not the same. LS utilizes both electrothermal energy and pressure to liquefy and reform collagen and elastin in vessel walls and tissue up 7 mm diameter to provide hemostasis. Audio-feedback of the device cuts the power and automatically prevents excess energy transfer to the tissue (12). On the other hand, HS oscillates in 55.5 KHz frequency and denaturates proteins in the tissue by breaking the hydrogen bonds in between and can achieve hemostasis in vessels 5 mm in diameter. Tissue friction of the active blade does not emit excess heat to cause collateral damage (1). First generation LS devices did not have a cutting function and therefore was considered as disadvantageous. However, currently both devices have coagulation and cutting capabilities. In 2003 the experiences with LS in thyroidectomy had been introduced in the scientific platform and had been reported to reduce recurrent laryngeal nerve injury and hypoparathyroidism rate (10). There are many studies comparing LS or HS with and classical ligature in thyroid surgery (13-16). The efficacy of HS and LS has been indicated in various studies also (17-20). McNally et al (21) in 2009 have reported that there were no significant difference in terms of adverse effects among the two energy devices; however they have found that severe asymptomatic hypocalcemia had been present in 6.7% of the cases being the most frequent complication. In addition, another study published

in 2011 reported that there were no significant difference among the two devices in terms of transient dysphonia and hypocalcemia, hematoma and persistent recurrent nerve palsy in total thyroidectomy patients (1). In this study, we did not find any significant difference between the two devices in terms of complications of thyroid surgery. Although hypocalcemia was more common in the HS group, this difference was not statistically significant. In our routine practice, a drain is usually place, and removal of it depends on the drain output below 20cc in the 24-hour period. Zarebczan et al (1) have reported increased hematoma incidence with LS use in total thyroidectomy patients. However, in our study hematoma rates among LS and HS groups were similar 1 (0.7%) versus 2 (2.7%), but long-term drainage and delayed drain removal were significantly higher in the LS group than in the HS group. However it was not statistically significant.

Various studies have emphasized the superiority of both devices to classical ligature technique by reducing the operation times (13,14,22,23). Moreover, HS had been reported to reduce the operation time significantly when compared to LS (1,18). In our study we found that there was no statistically significant difference in terms of duration of operations. This may be attributed to the fact that LS cutting capability reduced the operative times and therefore abolished this difference observed with older versions.

It has been reported that HS reduces the duration of hospitalization and therefore enables the surgeon to perform multiple operations in a day and thus led to reduced hospital costs (1). In 2005 cost effectiveness analysis performed on patients with laparoscopic colectomies and showed that LS, HS and electrocautery reduced operative time, blood loss and duration of hospitalization so may be considered cost-effective (24). In the present study we did not perform cost-effectiveness analysis however since the study groups were similar in terms of duration of hospitalization and the delay rate of patient discharge (22.8% in LS versus 12% in HS groups) we believe costs would be similar between two groups.

Different thyroid pathologies could safely be operated by both LS and HS because there was no difference in the percentage of patients who had a diagnosis of thyroid cancer on final pathology in the two groups (1).

The single institution results and the retrospective nature of this study are the limitations. Therefore, an increasing number of cases and randomized controlled trials may overcome this disadvantage in the future.

In conclusion, LS and HS can be used safely in total thyroidectomy because of low complication rate and similar operative statistics even if the patients are old.

REFERENCES

- Zarebczan, B., D. Mohanty, and H. Chen, A Comparison of the LigaSure and harmonic scalpel in thyroid surgery: a single institution review. *Ann Surg Oncol*, 2011.18(1): p.214-8.
- Giddings, A.E., The history of thyroidectomy. *J R Soc Med*, 1998. 91 Suppl 33: p. 3-6.
- Upadhyaya, A., et al., Harmonic versus LigaSure hemostasis technique in thyroid surgery: A meta-analysis. *Biomed Rep*, 2016. 5(2): p. 221-7.
- Chiang, F.Y., et al., Risk of vocal palsy after thyroidectomy with identification of the recurrent laryngeal nerve. *Kaohsiung J Med Sci*, 2004. 20(9): p. 431-6.
- Lo, C.Y., K.F. Kwok, and P.W. Yuen, A prospective evaluation of recurrent laryngeal nerve paralysis during thyroidectomy. *Arch Surg*, 2000. 135(2): p. 204-7.
- Snyder, S.K., et al., Elucidating mechanisms of recurrent laryngeal nerve injury during thyroidectomy and parathyroidectomy. *J Am Coll Surg*, 2008. 206(1): p. 123-30.
- Thomusch, O., et al., Multivariate analysis of risk factors for postoperative complications in benign goiter surgery: prospective multicenter study in Germany. *World J Surg*, 2000. 24(11): p. 1335-41.
- Zambudio, A.R., et al., Prospective study of postoperative complications after total thyroidectomy for multinodular goiters by surgeons with experience in endocrine surgery. *Ann Surg*, 2004. 240(1): p. 18-25.
- Adler, J.T., et al., Preserving function and quality of life after thyroid and parathyroid surgery. *Lancet Oncol*, 2008. 9(11): p. 1069-75.
- Sartori, P.V., et al., Ligasure versus Ultracision in thyroid surgery: a prospective randomized study. *Langenbecks Arch Surg*, 2008. 393(5): p. 655-8.
- Bliss, R.D., P.G. Gauger, and L.W. Delbridge, Surgeon's approach to the thyroid gland: surgical anatomy and the importance of technique. *World J Surg*, 2000. 24(8): p. 891-7.
- Cannizzaro, M.A., et al., Comparison between Focus Harmonic scalpel and other hemostatic techniques in open thyroidectomy: A systematic review and meta-analysis. *Head Neck*, 2016. 38(10): p. 1571-8.
- Siperstein, A.E., E. Berber, and E. Morkoyun, The use of the harmonic scalpel vs conventional knot tying for vessel ligation in thyroid surgery. *Arch Surg*, 2002. 137(2): p. 137-42.
- Lachanas, V.A., et al., The use of Ligasure Vessel Sealing System in thyroid surgery. *Otolaryngol Head Neck Surg*, 2005. 132(3): p. 487-9.
- Musunuru, S., S. Schaefer, and H. Chen, The use of the Ligasure for hemostasis during thyroid lobectomy. *Am J Surg*, 2008. 195(3): p. 382-4; discussion 384-5.
- Sandonato, L., et al., [Bipolar electrothermic coagulation (ligasure bipolar vessel sealing system) in thyroid surgery]. *Chir Ital*, 2003. 55(3): p. 411-5.
- Romano, F., et al., Laparoscopic splenectomy using Ligasure. Preliminary experience. *Surg Endosc*, 2002. 16(11): p. 1608-11.
- Robbins, M.L. and R.J. Ferland, Laparoscopic-assisted vaginal hysterectomy using the laparoscopic coagulating shears. *J Am Assoc Gynecol Laparosc*, 1995. 2(3): p. 339-43.
- Dubuc-Lissoir, J., Use of a new energy-based vessel ligation device during laparoscopic gynecologic oncologic surgery. *Surg Endosc*, 2003. 17(3): p. 466-8.
- Helal, M., et al., Laparoscopic nephrectomy using the harmonic scalpel. *J Endourol*, 1997. 11(4): p. 267-8.
- McNally, M.M., et al., A comparison of two methods of hemostasis in thyroidectomy. *Am Surg*, 2009. 75(11): p. 1073-6.
- Campagnacci, R., et al., Electrothermal bipolar vessel sealing device vs. ultrasonic coagulating shears in laparoscopic colectomies: a comparative study. *Surg Endosc*, 2007. 21(9): p. 1526-31.
- Pons, Y., et al., Comparison of LigaSure vessel sealing system, harmonic scalpel, and conventional hemostasis in total thyroidectomy. *Otolaryngol Head Neck Surg*, 2009. 141(4): p. 496-501.
- Targarona, E.M., et al., Energy sources for laparoscopic colectomy: a prospective randomized comparison of conventional

electrosurgery, bipolar computer-controlled electrosurgery and ultrasonic dissection. Operative outcome and costs analysis. Surg Innov, 2005. 12(4): p. 339-44.