

Thyroid surgery: comparison between “ultrasonic scalpel-SonoSurg” and classic “clamp and tie” technique

Tiroid cerrahisi: “Ultrasonic scalpel-SonoSurg” ile “clamp and tie” tekneiklerinin karşılaştırılması

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ABSTRACT

Objective: The purpose of this prospective study was to evaluate the efficacy and safety in the application of ultrasonic scalpel compared to conventional operative technique in open surgery of the thyroid gland.

Methods: The study included 100 patients operated between May 2013 and August 2013. Patients were divided into two groups - 50 patients were operated using SonoSurg® and 50 patients were operated using classic “clamp and Tie” technique. We evaluated and compared the outcome between the two groups.

Results: Both groups had a similar distribution in the demographic features such as gender, age, functional activity and malignant diseases of the thyroid gland. When comparing the results, we found a significant reduction in the duration of surgery in patients operated with SonoSurg® (SST group) (72 ± 20 min vs 100 ± 32 min, $p = 0.01$). There was no difference for fluid in the vacuum drainage during the first 24 hrs. Hospital stay of patients in both groups was similar - an average of 3 days stay into the clinic.

Conclusion: Our results showed that “ultrasonic scalpel” is an effective, easy to use and completely reliable method for achieving hemostasis with visible advantages over classical operational technique. *J Clin Exp Invest* 2015; 6 (3): 209-213

Key words: Total thyroidectomy, ultrasonic scalpel, clamp and tie technique

INTRODUCTION

According to several authors, modern thyroid surgery began in 1861 in Zurich [1]. Then Theodor Billroth was appointed chief of the surgical unit in Zurich. Despite his immense desire Billroth discontin-

ÖZET

Amaç: Bu prospektif çalışmanın amacı tiroid bezi açık cerrahisinde “ultrasonic scalpel” yönteminin etkinliğini ve güvenilirliğini değerlendirmek ve konvansiyonel operasyon tekniği ile karşılaştırmaktır.

Yöntemler: Bu çalışma Mayıs 2013 ile Ağustos 2013 arası dönemde opere edilen 100 hastayı içermektedir. Hastalar iki gruba ayrıldı - 5 hasta SonoSurg® tekniği kullanılarak, 50 hasta da klasik “Klemp ve bağlama” tekniği kullanılarak opere edildi. Hasta sonuçlarını değerlendirdik ve iki grup arasında karşılaştırdık.

Bulgular: Her iki grup cinsiyet dağılımı ve yaş gibi demografik özellikler ve fonksiyonel aktivite ile tiroid bezinin malign hastalıkları bakımından benzer dağılım gösterdi. Sonuçları kıyasladığımızda, SonoSurg® (SST) ameliyat grubunda cerrahinin süresinde anlamlı kısalma saptadık (72 ± 20 dk. ve 100 ± 32 dk, $p = 0,01$). 24 saatlik sıvı vakum drenajında iki grup arasında fark yoktu. Her iki grupta hastanede kalış süresi benzerdi, ortalama 3 gün klinikte kaldılar.

Sonuç: Sonuçlarımız, “ultrasonic scalpel” yönteminin klasik operasyon tekniğine göre belirgin avantajları ile birlikte hemostazı sağlamada etkin, kolay uygulanabilir ve güvenilir bir yöntem olduğunu gösterdi.

Anahtar kelimeler: Total tiroidektomi, ultrasonic scalpel, klamp ve bağlama tekniği

ued operations on the thyroid gland because of their high mortality (40%) due to sepsis. His proposed surgical technique was modified in 1872 by Theodor Koher and thus laid the foundations of modern surgical treatment of thyroid disease. Since then, their proposed technique is constantly changing due to

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the introduction of new techniques to improve security, efficiency and even invasiveness of surgery on the thyroid gland.

Despite modern innovations, intraoperative and postoperative bleeding remains a major problem for the modern endocrine surgeon. Gold standard for optimal hemostasis nowadays remains the proposed by Kocher Classic "clamp and tie" technique. Two technical innovations are currently fighting to become its effective alternative - bipolar sealing system and ultrasonic scalpel [2]. Several studies argue that these new methods can be able to reduce blood loss, postoperative downtime and the risk of postoperative complications in surgery of the thyroid gland [3]. Unfortunately, these methods increase the cost of the operation [4].

The purpose of this prospective study was to evaluate the efficacy and safety in the application of ultrasonic scalpel compared to conventional operative technique in open surgery of the thyroid gland.

METHODS

The prospective study included 100 patients operated for nodular goiter in the Department of Endocrine Surgery, USBALE for the period May 2013 - August 2013. The patients were selected from that undergoing thyroid operation during this time period. All patients with benign thyroid disease were included in this study. All with diagnosed malignancies preoperatively were excluded from this study. Patients treated with corticosteroids, nonsteroidal anti-inflammatory drugs, with different pathological coagulation disorders, pregnant or with recurrent thyroid disease were not included in this study. In Bulgaria ultrasonic scalpel - SonoSurg® is registered for thyroid operations. We obtained informed consent from all patients. The same team operated all patients and the operation was total thyroidectomy. Patients were divided into two groups, the first consisted of 50 (Classical Thyroidectomy - CT group) patients and for their operation we used conventional "clamp and tie" technique. The second group also consisted of 50 patients (SonoSurg® Thyroidectomy - SST Group) and for their operation we used ultrasonic scalpel Ultrasonic SonoSurg® G2 (Olympus). Ultrasonic scalpel consisted of a generator and a handle with a probe in the form of scissors (SonoSurg® Extra Short Curved Scissors) (Figure 1).

The handle contains the ultrasonic transducer. The probe is mounted directly to the transducer. The ultrasonic generator supplies high frequency

impulses to the transducer in the handle. In this way the probe in the handle begins to vibrate in harmonic frequency of 47 kHz. In order to obtain homogenous groups, patients were randomized in equal proportions with respect to age and the size of the thyroid gland. Preoperatively all patients conducted ultrasonography of the thyroid gland, FT4, TSH and serum Ca. We used standard surgical technique for the treatment of the patients. Intraoperatively the only difference was whether hemostasis was achieved with standard ligatures or SonoSurg®. During the mobilization we identified four parathyroid glands and the two recurrent laryngeal nerves (RLN).



Figure 1. SonoSurg® Extra Short Curved Scissors and Transducer

When comparing both groups we used the following parameters: duration of surgery, amount of fluid in the evacuated vacuum drainage for the first 24 h, postoperative pain, hospital stay, presence of postoperative complications (hypoparathyroidism and damage to the recurrent nerve). After surgery all patients were asked whether they detect a voice change for 24 and 48 h after surgery. If so, they were directed to the otorhinolaryngologists to conduct indirect laryngoscopy. Thus we detected the presence of recurrent nerve damage. To assess the degree of pain in the postoperative period, we used a visual analog scale - we explained to the patient that the value of 0 is equivalent to no pain, at a level 5 pain is moderate and the maximum value of 10 means that the pain is unbearable.

Postoperative serum calcium levels were estimated twice (24 h and 48 h after surgery). Calcium supplementation was given if serum calcium levels dropped below 2.0 mmol/l. If the patient could be weaned from calcium supplement within six months, hypoparathyroidism was considered transient. If there was laryngoscopic evidence of RLN recovery

within six months of operation the RLN palsy was defined as transient. Oral thyroxin supplementation was started from the second day after the operation at a dose of 75-150 micrograms per day, according to body weight. Follow up was planned after a month, after three months, and after six months of discharge.

The data analysis and interpretation was performed on SPSS 19.0 software package (SPSS Inc., Chicago, IL). The difference between groups was analyzed with Chi-square test and $p < 0.05$ was considered significant.

RESULTS

Both groups had a similar distribution in the demographic features such as gender, age, functionally active and malignant diseases of the thyroid gland. Overall, 27 patients had thyroid carcinoma: in 14 patients (28%) of the SST group and in 13 patients (26%) of the CT group. Forty-one patients had functionally active benign thyroid disease: 20 patients (40%) of the SST group and 21 patients (42%) of the LC group (Table 1).

When comparing the results we found a significant reduction in the duration of surgery in patients operated with SonoSurg® (SST group) (72 ± 20 vs 100 ± 32 , $p = 0.01$). There was no difference in the amount of fluid in the vacuum drainage during the first 24 hrs.

We found transient hypoparathyroidism in 10 patients from the SST group and permanent in 2 patients (Table 2). In the group with classical thy-

roidectomy we detected transient hypoparathyroidism in 9 patients. Permanent hypoparathyroidism was not found in any patient in this group. When we compared the two groups for this indicator, we did not detect a statistically significant difference ($p > 0.05$).

In terms of RLN palsy permanent or transient, we also didn't find statistically significant difference ($p > 0.05$) (Table 2).

We did not find any intraoperative complications in both groups. Three patients operated with SonoSurg® were revised due to post-operative bleeding. In two patients operated with conventional methodology we detected postoperative hematoma that did not require revision. For the postoperative pain score we detected very similar results in the two groups (Table 2).

Hospital stay of patients in both groups was similar - an average of 3 days stay into the clinic.

Table 1. Distribution of patients by diagnosis and demographic characteristics

| | SST Group | CT Group | p |
|---|-------------|-------------|-------|
| Age (mean \pm SD) (years) | 51 \pm 14 | 48 \pm 15 | 0.635 |
| Gender (n) | | | 0.113 |
| Male | 8 | 9 | |
| Female | 42 | 41 | |
| Functionally active thyroid disease (n) | 20 | 21 | 0.254 |
| Thyroid carcinoma (n) | 14 | 13 | 0.385 |

SST Group - SonoSurg® Thyroidectomy Group; CT group - Classical Thyroidectomy Group, SD: Standard deviation

Table 2. Comparative table of operative and postoperative results

| | SST group | CT group | p |
|--|----------------------|----------------|-------|
| Operative time, minute (mean \pm SD) | 72 \pm 20 | 100 \pm 32 | 0.01 |
| Evacuated fluid for the first 24 h, ml (mean \pm SD) | 70 \pm 20 | 80 \pm 15 | 0.191 |
| Postoperative pain | Mild- Moderate (3-4) | Moderate (4-5) | 0.833 |
| Hypoparathyroidism | | | |
| Transient, n (%) | 10 (20) | 9 (18) | 0.252 |
| Permanent, n (%) | 2 (4) | 0 | |
| Damage to the laryngeal nerve | | | |
| Transient, n (%) | 3 (6) | 3 (6) | 0.848 |
| Permanent, n (%) | 1 (2) | 0 | |
| Postoperative bleeding (reoperation), n (%) | 3(6) | 0 | 0.094 |
| Postoperative hematoma, n (%) | 0 | 2(4) | 0.596 |
| Hospital stay, days (mean \pm SD) | 2.9 \pm 1 | 3 \pm 1 | 0.792 |

SST Group: SonoSurg® Thyroidectomy Group, CT group: Classical Thyroidectomy Group, SD: Standard deviation

DISCUSSION

Thyroidectomy is one of the most frequently performed surgeries in general surgery. It is based on ligation of feeding vessels of the two lobes and extra capsular resection of the thyroid gland. The results are astonishing - the incidence of complications is low and mortality is extremely rare [5,6].

From a surgical point of view, the thyroid is distinguished from other parenchymal organs by the strong vascularity and the extremely sensitive location. It is these two characteristics that indicate the need for a perfect hemostasis with minimal damage to surrounding tissues. Failure to achieve this goal can lead to severe complications: postoperative hemorrhage, asphyxia, vocal cord paralysis, hypoparathyroidism, death [6-8].

Over the years since its introduction the technique introduced by Kocher has undergone minor changes, until now. It is based on clamping the two ends of the vessels before tissue cutting and subsequent ligation. This is an extremely reliable technique of hemostasis, but unfortunately time consuming and involves the use of a large number of ligatures [9]. As surgeons gained experience a new technique of hemostasis was introduced - monopolar and bipolar current. Its goal was to accelerate the achievement of hemostasis. Unfortunately, monopolar current was found extremely dangerous because of the large lateral heat dissipation (up to 400°C) and the damage it inflicted on the surrounding tissues. Bipolar current was found to be safe due to minimal lateral heat dissipation, but unfortunately it is not applicable in all surgical steps [10,11]. It is because of these negative characteristics that alternative methods to achieve hemostasis have emerged in recent years. Ultrasonic scalpel provides hemostasis by applying mechanical energy for both cutting and coagulation. Transducer vibrates at a frequency 47 kHz, and thus through a hydrogen bonds destruction causes denaturation of proteins in the temperature range from 50 to 100°C. The low temperature is a factor that ensures minimal lateral thermal dissipation [12]. The results of our study showed a statistically significant reduction in operative time (average 30 minutes). We have found that the use of the ultrasonic scalpel, does not lead to a significant increase in postoperative hemorrhage. From our data we can say that the ultrasonic scalpel achieves a fast and effective hemostasis.

Our results showed no statistically significant increase in RLN palsy. Most studies show similar results [4,13], but there are such showing a slight

increase in the frequency of Transient recurrent paresis due to the use of the ultrasonic scalpel. Our study showed no statistically significant difference in the frequency of hypoparathyroidism. Pregomet et al also reached the same conclusion [3]. [14]. However compared to other papers the main limitation of our study is the number of patients. We found 2 patient with permanent hypoparathyroidism and 1 patient with permanent RLN damage in the SSD group compared to zero in the classical group. However, because of the small number of patients our statistical analysis showed no statistical value of the results. In a study consisting of a large number of patients it would actually be possible to establish statistically significant increase of transient recurrent paresis due to the use of the ultrasonic scalpel. Postoperative bleeding requiring redo surgery was found in three patients operated with ultrasonic scalpel, while we found two patients with postoperative hematoma operated using classic "clamp and tie" technique.

The main criticism of the ultrasonic scalpel is its price [2,15,16]. This criticism is fully justified in cases where disposable instruments are used. Unlike other ultrasonic scalpels on the market "SonoSurg®" uses autoclavable reusable instruments. Therefore, the cost of use is drastically reduced.

In conclusion, our results showed that "ultrasonic scalpel" is an effective, easy to use and completely reliable method for achieving hemostasis with visible advantages over classical operational equipment. Its use helps maintain a nearly bloodless operative field, which contributes to better visualization and identification of key operation structures. Its use helps to reduce the duration of surgery without increasing postoperative complications.

Conflict of interest: The authors have not received funding for this study so they have no conflict of interest.

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