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Lateral spread of heat during thyroidectomy using different haemostatic devices

Zbigniew Adamczewski[1,2], Aleksander Król[2], Karolina Kałużna-Markowska[3], Jan Brzeziński[2], Andrzej Lewiński[1,2], Marek Dedecjus[4]

[1] *Department of Endocrinology and Metabolic Diseases, Medical University, Łódź, Poland*
[2] *Department of Endocrinology and Metabolic Diseases, Polish Mother's Memorial Hospital/Research Institute, Łódź, Poland*
[3] *Laser Diagnostics and Therapy Centre, Technical University, Łódź, Poland*
[4] *Department of Oncological Endocrinology and Nuclear Medicine, Maria Sklodowska-Curie Memorial Cancer Centre and Institute of Oncology, Warsaw, Poland*

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Abstract

Introduction. The presented study is an attempt to comprehensively analyze the lateral spread of heat during thyroidectomy. Obtained results may be valuable in other surgical disciplines in which thermal analysis is difficult or impossible.
Objective. The aim of the study was to evaluate the temperature distribution in the operating field during thyroidectomy performed with the use of modern haemostatic instruments, and to define the safety margin for the investigated devices.
Materials and methods. Ninety-three patients were thyroidectomised due to thyroid neoplasm. During all the operations the thermovisual measurements were carried out along with continuous intraoperative neuromonitoring of the recurrent laryngeal nerve (CIONM). Investigated patients were divided into 5 groups, named according to the applied haemostatic technique: LigaSure (N=17); ThermoStapler (N=20); Focus (N=19); SonoSurg (N=17) and Monopolar (N=20).
Results. At maximal performance settings, the highest working temperature was observed for the ThermoStapler, while the lowest temperature was recorded for the Monopolar. Safety margin and working time were increased in Focus and SonoSurg, compared to LigaSure and ThermoStapler. The differences in the necrosis thickness were negligible. The largest distance of the midline of the active blade from isotherm of 42°C observed in the study was 5.51 mm; none of investigated devices used at a bigger distance had influence on the morphology of the electric signal of CIONM.
Conclusion. The thermo-visual camera allows non-invasive, safe, and real-time monitoring and analysis of temperature distribution in the operation area during thyroidectomy. Proposed minimal safety margin for the analysed devices is 5.51 mm.

Key words

haemostatic devices, thermography, thyroidectomy, neuromonitoring

INTRODUCTION

The 19th and 20th centuries were a time of tremendous progress in thyroid surgery, starting from the great contribution of Kocher in the standardization of the operative technique, minimizing mortality rates and postoperative complication, to recent achievements in minimally invasive approaches [1]. Recurrent laryngeal nerve (RLN) palsy remains the most threatening complication of thyroidectomy with the frequency ranging from 1% – 5%, for permanent and transient RLN palsy respectively [2, 3]. The risk factors of the RLN palsy have been identified [4, 5, 6], and one of the most important factors for safe thyroid surgery and event-free follow-up is meticulous preparation and effective haemostasis. The last two decades have seen the introduction of new energy-based haemostatic devices which, in spite of being effective in maintaining haemostasis, are sources of heat that might be a threat for the RLN [7, 8]. There are still only a few studies concerning the distribution of temperature in the operating field in thyroid surgery when using these instruments.

Address for correspondence: Andrzej Lewiński, Department of Endocrinology and Metabolic Diseases, Polish Mother's Memorial Hospital – Research Institute, Rzgowska 281/289, Lodz, Poland
E-mail: alewin@csk.umed.lodz.pl

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OBJECTIVE

The aim of this study was the thermo-graphical analysis of the temperature distribution in the operating field during thyroidectomy performed with the use of modern haemostatic devices. This analysis was used to compare thermic effect of different devices and define safety margins for the investigated surgical instruments. Moreover, to confirm the safety of the analysed devices, the function of the RLN using continuous intraoperative neuromonitoring (CIONM) was monitored during all the procedures.

MATERIALS AND METHODS

The study included 93 euthyroid women, aged 22–65 years (average age 48.2 years) with thyroid neoplasm qualified for thyroidectomy. Patients with the history of surgical treatments in the neck were excluded from the study. All of the thyroidectomies were performed in the Department of General and Endocrine Surgery in the Polish Mother's Memorial Hospital/Research Institute. Informed consent was obtained from all of the patients and the study approved by the local Ethics Committee.

The instruments described in Table 1 were investigated. The patients were divided into 5 groups, named according

Table 1. Characteristics of the investigated devices

Instrument	Manufacturer	Generator	Catalog No. (active tip)	Blade width (mm)
Monopolar	Emed	Spectrum	520–500	1.8±0.1
SonoSurg	Olympus	G2	T3955	2.0±0.1
Focus	Ethicon	Harmonic 300	FCS9	1.9±0.1
ThermoStapler	Emed	Spectrum	801–116	3.0±0.1
LigaSure	Covidien	Ligasure	LS1200	3.0±0.1

to the applied haemostatic technique: 1) LigaSure group; 2) ThermoStapler group; 3) Focus group; 4) SonoSurg group and 5) Monopolar group. The groups were statistically similar in terms of the and type of operation performed.

The data was collected for 2 power settings (30W and 50W) for monopolar coagulation, LigaSure and ThermoStapler. To maximize the comparability of the different devices, the power of the Focus and the SonoSurg was set at medium and maximal settings of their generators (level 3 and 5 for Focus; 60% and 100% for SonoSurg).

After being removed, the thyroid glands were fixed in 4% buffered formalin for 24 hours. The specimens were dehydrated in increasing concentrations of alcohol, clarified in xylol, and embedded in paraffin. The paraffin blocks were cut in 5 μm slides and stained with haematoxylin and eosin. The width of lateral thermal damage to the margins of unchanged nearby tissue was measured using a light microscope and measurement grid.

Thermographic analysis of temperature distribution in the operating field. The thermographic analysis was based on the effect of infrared emission, proportional to the temperature of the observed object. The infrared camera is an ultrasensitive remote thermometer and in the presented study an infrared thermographic camera – FLIR A40 MF (FLIR System, Inc.) was used. The camera was placed vertically, 0.6 meter (±0.01) above the operating field in order to standardize the size of the projected pixel to 0.65 millimetres. The temperature of 42 °C was accepted to be the ultimate temperature which did not cause irreversible effects in the neural tissue. The safety margin was defined as the distance from the midline of the active blade to the isotherm of 42 °C.

One of the major aims during the procedure was to protect the recurrent laryngeal nerve function. All operations were performed using a CIONM ('C2 NeuroMonitor', Inomed Medizintechnik GmbH). An active V3 (Inomed Medizintechnik GmbH) electrode was placed in the carotid sheet on the vagus nerve on each side, consecutively. The receiving electrode was placed on the tracheal tube in the proximity of the vocal folds. Vocal muscles stimulation was than registered and analysed.

Measured values are presented as mean ± standard deviation. Student's t-test was used to compare the means of continuous variables with a normal distribution, and Mann -Whitney test for continuous variables without normal distribution. A p value less than 0.05 was considered statistically significant. Statistical analysis was performed with Statistica software, version 10.

RESULTS

All the patients were euthyroid, qualified for total thyroidectomy because of thyroid neoplasm, and the analysed groups were matched for age, gender and BMI. The estimated mean temperature of the operating field was 36.58 °C. As described above, the measurements were collected for 2 power settings for each instrument. For the lower setting, the mean exposure time was 5 seconds, for the higher setting – 4 seconds (Tab. 2). In some prolonged exposures (up to 10 seconds), the maximum temperature was achieved in the 8th second, later reaching a plateau (Fig. 1).

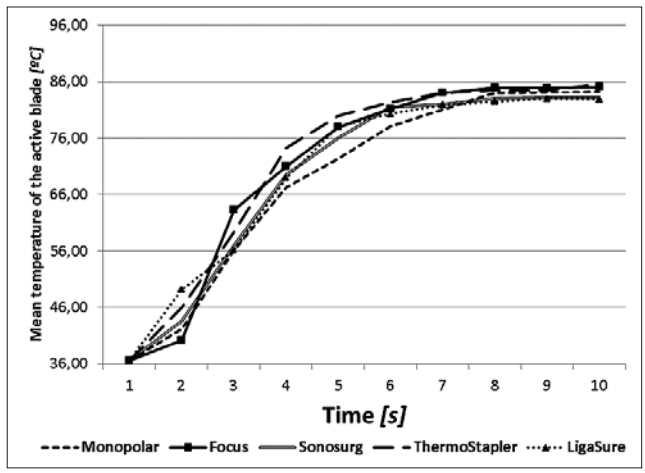

Figure 1. Mean temperature of active blade of investigated devices during prolonged use

The highest recorded temperature was for the Focus group, rising to 116.08 °C (SonoSurg – 115.41 °C, LigaSure – 97.68 °C, ThermoStapler – 99.10 °C, Monopolar coagulation – 97.26 °C). Mean recorded temperature for the lower power setting was the highest for ThermoStapler – 82.30 °C (Tab. 2). For the

Table 2. Results of histologic and thermographic analysis. Data calculated from 20 measurements for each patient from each group, presented as means ± SD

	Medium power settings					Maximum power settings				
	Necrosis *[mm]*	Time *[s]*	Temp. [C°]	Diameter of 42ºC isotherm *[mm]*	Safety margin *[mm]*	Necrosis *[mm]*	Time *[s]*	Temp. *[C°]*	Diameter of 42ºC isotherm *[mm]*	Safety margin *[mm]*
Monopolar	0.28±0.02	5.01±0.21	78.12±4.96	9.60±0.34	3.90±0.15	0.34±0.03	3.54±0.23	82.14±5.19	12.20±0.59	5.20±0.19
Focus	0.28±0.02	5.46±0.29	81.20±5.09	9.62±0.36	3.81±0.13	0.34±0.03	4.53±0.19	98.70±6.29	12.42±0.65	5.21±0.26
SonoSurg	0.27±0.02	5.33±0.2	81.50±5.12	9.70±0.35	3.75±0.14	0.36±0.03	4.57±0.21	99.20±5.26	12.64±0.68	5.22±0.25
ThermoStapler	0.26±0.02	4.95±0.27*	82.30±5.29	10.58±0.4	3.79±0.18	0.35±0.03	4.14±0.22*	100.7±6.39	12.80±0.89	4.90±0.18
LigaSure	0.27±0.02	4.96±0.31*	80.30±6.09	9.80±0.38	3.40±0.15*	0.35±0.03	4.13±0.21*	90.50±5.24	12.40±0.74	4.7±0.21*

*p<0.05 vs. Focus and SonoSurg

higher power setting, the highest recorded temperatures did not differ significantly: (ThermoStapler – 100.70 °C, the SonoSurg – 99.20 °C and the Focus shear – 98.70 °C). In contrast, the mean safety margin defined as 0.5 × (diameter of isotherm 42 °C – width of the blade), was significantly lower for LigaSure comparing to Focus and SonoSurg, both for the medium and high settings. A similar tendency was observed for ThermoStapler, but it did not reach the level of significance. Mean working time of the devices was significantly longer for the Focus and SonoSurg groups, compared to LigaSure and ThermoStapler (Tab. 2). Mean cooling-down time of the devices to the initial temperature –36.58 °C – after their use was 15±4.2 seconds. The largest safety margin registered in all the patients and all the groups was 5.51 for the prolonged coagulation in the Monopolar group. The range of safety margins comparing different instruments reached approximately 0.5 mm of difference (Tab. 1). No significant changes in the CIOM signal were recorded. The width of necrosis did not differ significantly between the groups.

DISCUSSION

The last two decades were the time of the great progress in the development of new homeostatic technologies. New instruments are widely used in general and endocrine surgery [7, 8, 9, 10]. The majority of those instruments are based on the thermal or mechanical effect which denatures proteins and forms a coagulative sealant, and the main factors, determining the safety of these instruments are the durability of the formed tissue sealant, and the amount of the energy released to the surrounding tissue. It is thought that heating the tissue to 42 °C still does not cause any irreversible changes [11]. Exceeding this temperature results in coagulation of proteins and loss of their normal structure. Above 90 °C, fluids evaporate from the tissue, and temperature exceeding 200 °C causes carbonization of tissue. There is no agreement on the exact minimal temperature that might be destructive for neural tissue.

The classical electrocoagulation uses a high frequency current to obtain the thermal effect. Recently, vessel sealing devices, such as LigaSure, were developed which combine the electrical current with the mechanical compression effect. This technology allows obtaining a stable coagulum with poor lateral spread of the heat. This system also includes a feedback loop, hence informs and stops the device once the coagulum has already formed, limiting the possibility of overheating. It has been shown that LigaSure is safe in closing vessels from 4–7 mm.

Many reports have demonstrated the safe use of these devices in general surgery, resulting in decreased blood loss, less swelling and shorter hospitalization [12]. Similar observations have been made in thyroid surgery [8, 10]. There are no defined guidelines for using LigaSure in the proximity of nerves, but there are no reports demonstrating a higher risk of the RLN palsy during thyroidectomy performed with this technique. The cost-effectiveness analysis in some papers also seems to be in favour of thermostapling devices and LigaSure, compared to traditional techniques, as they allow the shortening of operating time [13, 14].

Recently, ultrasonic devices have been introduced, which use high frequency vibrations (55.5 kHz) to denaturate proteins and form a haemostatic coagulum. Additionally, the active blade, besides its coagulating function, separates the tissue. It has been reported that ultrasonic scalpels produces less heat and a smaller lateral spread of heat than more classic electrical instruments. In several trials it has been proved that the Focus can be safely applied in general and thyroid surgery, reducing blood loss and decreasing operating time [15, 16]. Some of the randomized trials suggest that there is also a slight reduction of complication rates [15]. Shorter operation time also results in the reduction of costs when using the Focus [10, 13, 17, 18].

Thermo-visual measurements taken during thyroid gland surgery – the human organ with one of the best blood supplies – allowed for a careful analysis of the temperature distribution in the operating area. In association with the clinical data, these images make possible estimation of the range of thermal injury, and simultaneously, to establish safe operating conditions for particular surgical instruments. Obtained results can be used in different surgical disciplines in which thermal injury estimation is difficult or impossible due to the inconvenient location of an operated organ.

Several researches have been conducted in order to assess the lateral spread of heat when using some of new haemostatic devices [19, 20]. Unfortunately, the majority were conducted in conditions which differed from those in the typical operating field. Sutton et al. [21] studied the temperature at the verge of standardized portions of porcine meat and found the highest temperature was achieved while treated with the monopolar coagulation, lower with LigaSure, and the lowest with the harmonic scalpel. Družijanic et al. [22] revealed a significantly smaller lateral spread of temperature for the harmonic scalpel and LigaSure, compared with the traditional monopolar electrocautery on the human peritoneum obtained during laparotomy, although there were no statistically important differences comparing the harmonic scalpel and LigaSure together. All these studies were based on histopathological examination; however, in the opinion of the authors of the presented study, the irreversible changes in the tissue might extend beyond the zone of necrosis. The only way to verify the extent of irreversible changes is to visualize directly the exposure to overheating during the procedure, for instance, via used the thermographic infrared camera used in this study.

The obtained mean safety margins were markedly differeent from the margins mentioned by Sutton. The differences are the consequence of a lower threshold of the isotherm (42 °C) which is crucial, in our opinion, for the safety of the recurrent laryngeal nerve. In studies based on histological examination, the zone of necrosis ranged for LigaSure from 144.18 μm and for Harmonic scalpel 127.48 μm [22] to 197.79 μm and 205.61 μm, respectively [15].

Although the highest temperature of the blade was obtained generally on recent instruments, compared to the monopolar coagulation, the observed safety margins were minimal for the ThermoStapler and LigaSure, and slightly larger for the Focus and SonoSurg. Considering the nature and efficiency of monopolar coagulation (widely used mainly as an adjunct to knot tying, it is not suitable for closing larger vessels) it cannot be compared with other techniques. On the other hand, since it is used very frequently, the surgeon should be aware of wide lateral heat spread during its use, which makes it the least safe for surgical manipulation in proximity of thermo-fragile structures.

The instruments in the presented study were applied for a relatively short time (mean time of 5 seconds for medium settings, and 4 seconds for high settings). When applied for a longer period of time, exceeding 10 second, maximum heating of the active blade was observed in the 8th second (similarly for all instruments) followed by a plateau. This confirms the observation of Pogerlic et al. [23], who suggested applying the ultrasonic devices for a 5 second period, rather than in a continuous mode. The increased working time and safety margin in Focus and SonoSurg, compared to ThermoStapler and LigaSure, is then effect of the dissecting properties the former two (ultracision), which is not observed in the latter two. The mean cooling down time of the devices is relatively long – 15±4.2 seconds, which suggests that energy-based haemostatic devices should not be used continuously, and after longer application, cooling in water or saline should be considered.

CONCLUSIONS

The presented study is an attempt to comprehensively analyze temperature distribution appearing during thyroid surgery, and the thermographic camera proved to be minimally-invasive safe and effective way to monitor the temperature distribution in the operating field in real time. Analysis of the thermic image, together with clinical data, allowed definition of the safety margin which in this study was 5.51 mm. The device functioning time (in studied range) had important influence on the thermal safety margin; therefore, a safe distance should be maintained by the surgeon, even if a tool is applied for a short period of time, and the devices should not be used continuously, and after prolonged application cooling should be considered.

The investigated devices in the hands of an experienced surgeon, and applied at a distance exceeding the safety margin, had no influence on the amplitude or latency of the electrical signal originating from continuous simulation of the recurrent laryngeal nerve. Obtained results can be used in other surgical disciplines in which thermal injury estimation is difficult or impossible due to the inconvenient location of an operated organ.

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