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Continuous intraoperative neuromonitoring (CIONM) of the recurrent laryngeal nerve is sufficient as the only neuromonitoring technique in thyroidectomy performed because of benign goitre

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Abstract

Introduction. Recently, intraoperative neurophysiological neuromonitoring (IONM) of recurrent laryngeal nerves (RLN) has been evolving quickly. This evolution touched many aspects of the technique, leading to continuous stimulation of the RLN with real time analysis of the electrical signal.
Objective. The aim of the study was to estimate the value of continuous intraoperative neuromonitoring (CIONM) as the only technique for intraoperative neuromonitoring in thyroidectomy performed because of benign goitre.
Material and methods. The study comprised 80 women qualified for thyroidectomy due to nodular goitre. The patients were divided into 4 groups depending on the technique used for RLN integrity verification: group 1 – thyroidectomy with CIONM; group 2 – thyroidectomy with direct, intermittent stimulation of RLN and vagus nerve (NX); group 3 – both CIONM and intermittent stimulation of RLN and NX; group 4 – thyroidectomy without any IONM.
Results. Mean operation time did not differ significantly among the groups with IONM, but was significantly longer in comparison to group 4, as well as the operation's cost. In the analysed groups there was no significant difference in complication ratio.
Conclusion. CIONM with RLN visualization in thyroidectomy performed because of benign goitre is as safe as other methods of IONM and gives a continuous confirmation of the electrical integrity of the loop NX-RLN-vocal folds during almost the entire procedure. There is a clinical need for the development of external stimulation of NX (transdermal or trancranial), particularly for minimally invasive techniques in which access to NX is limited (i.e. transoral thyroidectomy).

Key words

recurrent laryngeal nerve, intraoperative neuromonitoring, thyroidectomy

INTRODUCTION

Recently, important progress in thyroid surgery have been observed. This includes rapid development of minimally-invasive, robotic and transoral thyroid surgery [1]. The new operative techniques require evolution in the intraoperative neuromonitoring (IONM) technique. Already in the thirties of the twentieth century, intraoperative recurrent laryngeal nerve (RLN) visualization was introduced as a safe and valuable method that could reduce the percentage of recurrent laryngeal nerve damage during thyroid surgery [2]. Implementation of intraoperative naked-eye visualization of RLN led to a significant reduction in the risk of nerve damage. Moreover, it was shown that extensive dissection facilitates visual control of nerve integrity during thyroid resection and is superior to limited exposure of the nerve [3]. Due to the still existing risk of RLN injury during thyroidectomy, in the early sixties a new diagnostic tool in the form of IONM of RLN was proposed [4]. Since then, a number of different techniques of IONM of RLN have been tested [5, 6, 7, 8, 9], but none of them enabled continuous monitoring of RLN function during surgery. The first study on continuous IONM (CIONM) in an animal model was published in 1997 [10], and the first human study on CIONM of RLN by stimulating the vagus nerve (NX) during thyroidectomy was released in 2000 [11]. Nowadays, visualization of the RLN is a gold standard in thyroid surgery, and the use of IONM as routine is suggested in several countries [12]. Recently, important progress has been made, particularly in the field of CIONM – new electrodes and new analytical tools [13, 14]. However, to-date, limited data have been published comparing the safety and effectiveness of CIONM with other techniques of IONM [15].

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OBJECTIVE

The aim of the study was to estimate the value of CIONM as the only technique of IONM in thyroidectomy performed because of simple goitre. Moreover, the influence of the applied IONM's techniques on duration, cost and complication's rate of thyroidectomy were assessed.

MATERIAL AND METHODS

The study was approved by the local Bioethics Committee and written informed consent obtained from all the patients qualified for the study. The study included 80 euthyroid women, aged 22–65 years (average age 48.2 years) with benign thyroid diseases and qualified for thyroidectomy. Patients who in the past had any surgical treatments in the neck and patients with preoperatively diagnosed abnormal mobility of the vocal folds, were excluded from the study. All the operations were performed in the Department of General and Endocrine Surgery in Polish Mother's Memorial Hospital/Research Institute. The patients were divided into 4 groups of 20 persons each. In all the patients, RLNs were visualized on both sides prior to resection.

In the first group, intraoperative laryngeal nerve monitoring was performed by CIONM of NX. In the second group, IONM was made by direct, intermittent stimulation of RLN and NX. In the third group, both direct intermittent IONM and CIONM of NX were carried out. The last, fourth group, included patients in whom thyroidectomy was performed without use of IONM. All patients had a medical examination before surgery, including electrocardiography. Blood cell count, coagulogram, blood group and serum TSH, fT_3 and fT_4 levels were also performed. Each patient underwent ultrasonography examination of the thyroid gland and neck in order to determine the exact size of the goitre, its location in the neck, and morphology of the lesions. An *ultrasound-guided fine-needle aspiration biopsy* of the most suspected lesions of the thyroid was made and the obtained material was passed for the cytological examination. In patients from all groups, preoperative evaluation of vocal fold motion was performed with the use of laryngoscope and Doppler ultrasonography [16].

The total thyroidectomy were carried out under general anaesthesia without administration of muscle relaxants. In groups 1–3, before intubation, a pre-sterilized, receiving passive electrode was attached to the endotracheal tube to receive changes in the pattern of the electrical potentials from the medial surface of the vocal folds during their work. The lower tip of the electrode was placed approximately 7–10 mm above the upper edge of the endotracheal tube cuff. In the 1–3 group of patients, prior to exteriorization of the thyroid lobe, the internal jugular vein and common carotid artery were dissected free at a distance of about 3 cm that allowed visualizing NX. Next, to check the electrical continuity of the entire RLN, the initial intermittent vagal stimulation was carried out using a hand-guided stimulation probe. The active electrode was then placed between the vein and the artery to be in a direct contact with NX (group 1 and 3). After this, continuous stimulation of the vagus nerve was started.

Additionally, in the second and the third group of patients, prior to naked-eye visualization of RLN, in order to determine the approximate location of the RLN, a monopolar active electrode was used (so-called 'mapping'). Then, to determine the exact location of the RLN, the bipolar electrode was used. The neuromonitoring unit sensitivity threshold level was set at 100 μV – 200 μV. Current used for the stimulation varied from 1 mA – 2 mA; frequency 4 Hz, pulse duration 200 μs.

In the case of CIONM, after the removal of the first lobe of the thyroid and dissection of the contralateral NX, the active vagal electrode was moved to the other side. After resection of the goitre, in the first and third group of patients, the vagal electrode was removed.

On the second postoperative day, laryngoscopy and Doppler ultrasound vocal fold mobility examination were performed. The examinations were repeated one, two and six months after the operation in the outpatient department. To monitor the electrical activity of the RLN and NX during surgery a 'C2 NerveMonitor' unit, V3 electrode and handheld electrodes were used (Inomed Medizintechnik GmbH).

Statistical analysis. 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. Categorical values were compared using the χ^2 test. 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 nodular non-toxic and nodular toxic goitre, and the analysed groups matched for age, gender, height, weight, and BMI (Tab. 1). Mean duration of the surgical treatment did not differ significantly between the groups in which different methods of IONM were used (groups 1–3 – respectively: 89.7±12.1, 85.2±15.64, 93.6±13.6), and was significantly longer in comparison to group operated on without the use of IONM (group 4–70.2±12.51, p<0.05 vs. groups 1, 2 and 3).

Table 1. Clinical characteristic of operated women

	Group 1	Group 2	Group 3	Group 4
Height (cm)	163.8±6.1	160.2±7.2	161.9±6.9	162.3±5.9
Weight (kg)	69.7±5.1	71.8±5.4	70.4±6.1	73.8±6.7
BMI (kg/m²)	27.1±4.8	26.4±3.9	26.9±4.3	28.3±4.9
Age (year)	51.3±5.8	49.6±6.4	47.8±6.2	50.8±3.82
Nodular non-toxic goitre	15 (0.75)	16 (0.8)	17 (0.85)	16 (0.8)
Nodular toxic goitre	5 (0.25)	4 (0.2)	3 (0.15)	4 (0.2)

No patient required revision of the wound for bleeding. There were no statistical differences between the groups for the incidences of unilateral permanent RLN paralysis. Only in the group of patients in which simultaneous intermittent stimulation of RLN and CIONM of NX were used (group 3), there was no permanent damage of RLN diagnosed. In the other groups, the incidence of permanent postoperative RLN's palsies was similar, ranging from 5 (group 1 and 2) to 10% (group 4) – the percentage is relatively high, probably because of the small number of patients in the analysed groups. Bilateral postoperative permanent RLN paralysis was not diagnosed in any of the studied groups.

Table 2. Cost of IONM's electrodes used during total thyroidectomy presented as percentage of reimbursement by National Health Found of Poland. Cost of the main unit (C2 Neuromonitor) and extra labour cost are not included

	Group 1 [%]	Group 2 [%]	Group 3 [%]
Laryngeal adhesive recording electrode	5.40	5.40	5.40
Monopolar stimulation probe		6.8	6.8
Bipolar stimulation probe		6.8	6.8
V3 Vagus electrode*	2.2		2.2
Total cost of electrodes	7.6	18.9	21.2

* Cost of V3 Vagus electrode (reusable) is calculated for 30 procedures

The increase in treatment costs incurred was connected with the cost of the equipment used (Tab. 2) and the longer operation time (extra labour costs of medical personnel).

DISCUSSION

Due to the variability of laryngeal nerve topography it is very important to know all the options of the recurrent laryngeal nerve routes. This knowledge is necessary to avoid intraoperative injury of the nerve that can lead to hoarseness, aphonia and serious breathing problems [17].

Postoperative phonation change can have a very significant impact on the quality of life of the patient. It should also be noted that the complications associated with damage of recurrent laryngeal nerves related to thyroidectomy are the most common cause of legal claims for damages in the patients who underwent this kind of surgical procedure [18]. It should be remembered that, in the case of operations of giant goitres, inflammatory goitres, thyroid cancers, reoperations, and in the case of central lymphadenectomy, there is an increased risk of nerve damage during the surgery [17, 18]. Therefore, particularly in those patients in order to protect RLNs, great attention should be paid to the meticulous dissection leading to their visualization. Already in the thirties of the twentieth century the intraoperative visualization of RLN was introduced as a safe and valuable method that could reduce the percentage of RLN damage during thyroid surgery [2]. Implementation of intraoperative eye visualization of RLN led to a significant reduction in the risk of intraoperative nerve damage [3]. Nowadays, a routine naked-eye intraoperative identification of recurrent laryngeal nerve is a gold standard in thyroid surgery and is performed in almost all centres of endocrine surgery.

However, the naked-eye visualization method has some disadvantages: there is no possibility to identify the nerve damage if the continuity of the nerve is preserved (ex. thermal damage, crush, traction). In contrast to a naked-eye visualization, this kind of damage can be detected while using neuromonitoring. IONM also assists the surgeon in preventing nerve damage, and in the case of using CIONM, even to stop the activity that causes signal disturbances, and thus reduce the extent of the damage [19]. Some published studies have shown that less postoperative RLN damages have been observed after thyroid surgery performed while using of IONM [20]. Moreover, the use of IONM, compared with naked-eye visualization, might have decreased the prevalence and severity of upper aerodigestive symptoms occurring one year or more after thyroidectomy [21]. Some researchers agree that IONM does not fully protect the patient from postoperative transient or permanent paralysis of the vocal cords, but its use as an aid in identifying the RLN topography, especially in reoperations, operations of large goitres, and in cases of atypical course of the RLN, is beneficial [22]. The better option of the IONM seems to be indirect CIONM via NX, in comparison to the direct stimulation of RLN. Some multicentre trials demonstrated a better efficacy of RLN indirect stimulation to the direct, as a method reducing the risk of RLN intraoperative injury during thyroid surgery [23]. This is probably due to the ability to identify the potential risk of RLN intraoperative injury during surgery. The changes of the signal received from the detecting electrodes while using the indirect continuous IONM, (ex. pulling the nerve) can be warning signs for the surgeon, and gives him time to modify the operational strategy to prevent the RLN damage. If a naked-eye and a direct RLN IONM visualization is negative during the operation, the surgeon may be kept informed about the current electrical conductivity of the nerve thanks to the vagal indirect stimulation of RLN, and when the signal changes can adequately respond quickly and change the operational tactic.

It is estimated that to assess adequate statistical power, a randomized study utilizing approximately 7,000 patients undergoing thyroidectomy (with or without IONM), will be required to show a difference in the outcome with reference to RLN paralysis [17, 19]. In the presented study, only in the group of patients in which simultaneous intermittent stimulation of recurrent laryngeal nerves and continuous stimulation of vagus nerves were used, there was no permanent damage diagnosed of RLN. In the other groups, the amount of permanent damage to the RLN occurred during thyroidectomy, was similar. It should be noted that in the presented study, all the RLN injuries identified with the use of intraoperative neuromonitoring were related to the second thyroid lobes operated on. This is why there was no 'stage thyroidectomy' performed in the current study. Mean duration of the surgical treatment did not differ significantly between the groups in which different methods of IONM were used, and was significantly longer in comparison to operations without the use IONM.

The current study shows that continuous intraoperative electrophysiological neuromonitoring is a safe method for the verification RLN's electrical continuity. The use of CIONM extended the time of surgery in comparison with the non-IONM guided thyroidectomy. It was also shown that there were no statistically significant differences in the average duration of thyroidectomy between the groups in which different methods of IONM were used. As in groups 2 and 3, this increased the cost of the surgical treatment that was 16%-25% higher than the cost of traditional thyroidectomy. The proportion of the cost of IONM as a part of total cost of thyroidectomy *varies depending on the country,* because of different reimbursement of the thyroidectomy, which is higher in western Europe than in Eastern Europe [24]. IONM did not affect the postoperative complications rate, probably because of the small number of patients in the groups and overall low frequency of RLN paralysis, no statistical difference between the groups was reached.

On the basis of the results obtained, it cannot be definitively stated that the CIONM of recurrent laryngeal nerves is a better method than other methods of IONM and the naked eye visualization; however, documentation of the electrical conductivity behaviour of the entire recurrent laryngeal nerves at the end of surgery may increase the legal security of the surgeon. Loss of electrical signal during the RLN stimulation while removing the first, dominant lobe of the thyroid gland, allows the surgeon to decide to postpone surgery on the contralateral side (so-called stage thyroidectomy), thereby eliminating the risk of bilateral vocal fold paralysis.

Because of the possibility of intraoperative control of the entire RLN, continuous electrical stimulation of the vagus nerve appears to be the optimal technique for IONM in thyroid surgery, although the method of CIONM implementation should be a less invasive one. Performing CIONM is difficult in the case of video-assisted thyroidectomy because of the lack of the room in the operation field. In these procedures, IONM may be performed only between the surgical manoeuvres [25]. Further studies should therefore be carried out to introduce external (transcutaneous or transcranial) continuous stimulation of the vagus nerve that would be a less invasive, and would not occupy space in the operation field. It would also retain all the advantages of continuous IONM without affecting the extent of preparation and timing of the surgery.

CONCLUSIONS

In the case of benign goitre, the use of IONM during thyroidectomy increased the average duration and cost of the procedure, did not affect the postoperative complications rate, and documentation of the electrical conductivity behaviour of the RLNs during surgery may increase the legal security of the surgeon.

CIONM used as a sole IONM technique (without intermittent IONM with use of handheld probe) during thyroidectomy performed because of benign goitre is safe, and cost-effective; however, there is a clinical need for the development of a technique for external stimulation of NX (transdermal or trancranial), particularly for the minimally invasive procedures in which the access to NX is limited (i.e. transoral thyroidectomy).

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DISCLAIMER

No financial association exists between the authors and the producer of the presented neuromonitoring device.

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