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Does intraoperative neuromonitoring of recurrent nerves have an impact on the postoperative palsy rate? Results of a prospective multicenter study

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Background. The impact of intraoperative neuromonitoring on recurrent laryngeal nerve palsy remains debated. Our aim was to evaluate the potential protective effect of intraoperative neuromonitoring on recurrent laryngeal nerve during total thyroidectomy.

Methods. This was a prospective, multicenter French national study. The use of intraoperative neuromonitoring was left at the surgeons' choice. Postoperative laryngoscopy was performed systematically at day 1 to 2 after operation and at 6 months in case of postoperative recurrent laryngeal nerve palsy. Univariate and multivariate analyses and propensity score (sensitivity analysis) were performed to compare recurrent laryngeal nerve palsy rates between patients operated with or without intraoperative neuromonitoring.

Results. Among 1,328 patients included (females 79.9%, median age 51.2 years, median body mass index 25.6 kg/m^2), 807 (60.8%) underwent intraoperative neuromonitoring. Postoperative abnormal vocal cord mobility was diagnosed in 131 patients (9.92%), including 69 (8.6%) and 62 (12.1%) in the intraoperative neuromonitoring and nonintraoperative neuromonitoring groups, respectively. Intraoperative neuromonitoring was associated with a lesser rate of recurrent laryngeal nerve palsy in univariate analysis (odds ratio = 0.68, 95% confidence interval, 0.47; 0.98, P = .04) but not in multivariate analysis (odds

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ratio = 0.74, 95% confidence interval, 0.47; 1.17, P = .19), or when using a propensity score (odds ratio = 0.76, 95% confidence interval, 0.53; 1.07, P = .11). There was no difference in the rates of definitive recurrent laryngeal nerve palsy (0.8% and 1.3% in intraoperative neuromonitoring and non-intraoperative neuromonitoring groups respectively, P = .39). The sensitivity, specificity, and positive and negative predictive values of intraoperative neuromonitoring for detecting abnormal postoperative vocal cord mobility were 29%, 98%, 61%, and 94%, respectively.

Conclusion. The use of intraoperative neuromonitoring does not decrease postoperative recurrent laryngeal nerve palsy rate. Due to its high specificity, however, intraoperative neuromonitoring is useful to predict normal vocal cord mobility. (Surgery 2017;160:XXX-XXX.)

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Thyroidectomy is a relatively common operative procedure. Although considered very safe, it remains associated with a risk of hypoparathyroidism, injury to the recurrent laryngeal nerve (RLN), and compressive hematomas. The following rates of thyroidectomy-related complications have been reported in large case series studies: hematoma, 1.2–2.1%[1-4]; transient hypoparathyroidism, 6.4–35.2%[1,2,4-6]; permanent hypoparathyroidism, 0.9–6.3%[1-3,5,6]; transient RLN injury, 0.36–20%[1-5,7]; and permanent RLN injury, 0.7–1.4%.[1-3,5] Voice impairment diminishes quality of life and may lead to litigation.[7] Because many RLN palsies are asymptomatic, the objective evaluation of vocal cord function requires systematic postoperative laryngoscopy.[8] A vocal cord examination should be performed at least at 6 months postoperatively to diagnose a definitive RLN palsy. While the postoperative laryngoscopy is usually accepted, some patients refuse the 6-month evaluation because they consider that it would provide them no benefit, whatever the status of their voice. In a series of 3,605 patients who underwent total thyroidectomy, Lifante et al showed recently a fairly good correlation between the rates of immediate and permanent RLN palsy (r = 0.70, *P* = .004).[9] Therefore, the rate of postoperative RLN palsy is predictive of the definitive rate and should be considered as a criterion of quality in thyroidectomy. Postoperative RLN palsy rate depends on surgical experience, identification of the nerve and type of thyroid disease (Hashimoto or Grave's disease).[8-10] Intraoperative neuromonitoring (IONM) of the RLN has been used widely in thyroid surgery for many years. Although IONM tends to become a standard of care, its impact on nerve protection remains debated. The aim of this study was to evaluate the protective effect of IONM on RLN during total thyroidectomy.

Methods

In this study, we performed a preplanned analysis of data collected in the FOThyr trial, which is being submitted elsewhere for potential publication. Briefly, FOThyr is a prospective, randomized, multicenter, single blind study comparing a single-use device to conventional hemostasis in total thyroidectomy (TT). All patients aged 18 to 80 years scheduled to undergo TT were eligible if they had Graves' disease, toxic or nontoxic thyroid goiter, or any thyroid nodule requiring TT via a transcervical approach. The exclusion criteria were thyroid cancer, known or suspected preoperatively based on ultrasonography or cytologic assessment (to avoid lymph node dissections associated with the TT); a calcitonin level >30 pg/mL; a planned partial thyroidectomy; abnormal motility of the vocal cords (based on abnormal voice); substernal goiter (>3 cm below the sternal notch); a minimal access videoscopic TT; and a prior history of cervical surgery. Preoperative serum levels of calcium, phosphorus, calcitonin, Thyroid Stimulating Hormone, and albumin were measured for all patients. Preoperative vocal cord examination was only performed in case of any abnormality in the voice.

All TTs were performed according to the same protocol, except for the utilization of IONM, which was left to the surgeon's choice. Therefore, our population was divided into 2 groups: IONM and non-IONM. The operation started with intubation of patients using an IONM-specific tracheal tube (Medtronic, Jacksonville, FL) for the IONM group and a usual tracheal tube for the non-IONM group. Anesthesiologists were instructed to restrain the use of long-acting muscle relaxants in case of IONM. After a cervical Kocher incision, the infrahyoid muscles were opened along the midline and muscles were divided as necessary. Vessels of the upper pole were controlled, preserving the superior laryngeal nerve (whenever possible). Then, the parathyroid glands (whenever possible) and the RLN (mandatory) were visualized. Postoperative drainage was left at the surgeon's discretion. In the IONM group, after resection of the first lobe and before closure, the RLN was stimulated. All surgeons were experienced in thyroid surgery (>30 thyroidectomies a year) and had used IONM for at least 1 year. For all patients operated with IONM, RLN was tested systematically via a sterile, single-use, pulse-generated, monopolar stimulator probe with the stimulation level set at 1.0 mA. In 6 centers, both RLN and vagal nerves were tested. The nerve function was confirmed by acoustic signals in all patients within the IONM group. Thyroid hormone replacement was begun on postoperative day 1.

Postoperative RLN function was evaluated systematically by vocal cord examination with transnasal fiberoptic laryngoscopy carried out before hospital discharge and 6 months postoperatively in case of postoperative abnormal motility. Serum calcium and albumin levels were performed in the laboratories of local hospitals. Immediate hypocalcemia was defined by a serum calcium level <2 mmol/mL corrected for albumin level at postoperative day 2. Postoperative bleeding was defined as the occurrence of a compressive hematoma requiring revisional surgery. Permanent hypocalcemia was

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