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Postoperative Vocal Cord Dysfunction Despite Normal Intraoperative Neuromonitoring: An Unexpected Complication With the Risk of Bilateral Palsy

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Abstract

Background Intraoperative neuromonitoring (IONM) has become standard practice in thyroid surgery for many surgeons. It reduces the risk of vocal cord palsy in high-risk patients and has led to two-stage operations to prevent bilateral palsies. The specificity of detecting nerve injuries is not 100 %, leading to patients with vocal cord dysfunction (VCD) despite regular neuromonitoring (false-negative IONM). We aimed to evaluate possible risk factors for this phenomenon and its importance regarding bilateral palsies.

Methods We performed a retrospective analysis of all patients with false-negative IONM.

Results A total of 2152 patients (3426 nerves at risk) underwent surgery for benign disease between January 2008 and October 2010. Sensitivity for predicting VCD was 85.4 % and specificity 99.0 %. The positive predictive value was 68.0 % and the negative predictive value 99.6 %. We were not able to identify risk factors for false-negative IONM. We found four patients with delayed occurrence of VCD after regular IONM (1–8 weeks). We registered two patients with bilateral VCD after false negative IONM on the first side of bilateral resections (2/7) and four patients with bilateral palsy after correct IONM (4/1256). The relative risk for bilateral VCD between patients with false-negative IONM on the primary resection side and patients with correct IONM was 89.7.

Conclusions Although seldom, false-negative IONM is of clinical importance as it bears a high risk of bilateral VCD if it occurs on the first side of a bilateral resection. It can also have a latent occurrence after surgery.

Introduction

Intraoperative neuromonitoring (IONM) has become standard practice in thyroid surgery for many surgeons [1–5]. It reduces the risk of postoperative vocal cord palsy (VCP) in high-risk patients [1, 6, 7] and has lead to two-stage operations to prevent life-threatening bilateral VCP [2, 8]. The specificity of detecting nerve injuries has reached 94 to 99 %—but still not 100 % [1–3, 9]. For this reason, we performed a retrospective analysis of prospectively gathered data regarding patients with normal intraoperative IONM stimulation but postoperative vocal cord dysfunction (VCD). It was a large cohort of patients with benign thyroid disease, all of whom underwent IONM. We aimed to evaluate possible risk factors for this phenomenon and its importance regarding bilateral palsies.

Materials and methods

We used a standardized protocol for all patients undergoing benign thyroid surgery. All patients underwent preoperative sonography administered by their surgeon and preoperative laryngoscopy by an ear/nose/throat (ENT) specialist in our center on the day before the operation to establish their baseline vocal cord function.

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During intubation, the anesthesiologist checked the correct position of the tracheal tube and its electrodes via video-assisted laryngoscopy. Long-acting muscle relaxants were not used. The first major step of the operation was visualization and stimulation of the vagal nerve on the first resection side. The current for stimulation was set at 1 mA. IONM was defined as positive if a characteristic curve with a peak amplitude of >100 μV was achieved. A curve with a peak amplitude ≤100 μV was considered a loss of signal (LOS) [10, 11]. A vessel loop was placed around the vagal nerve to simplify further neuromonitoring if the performing surgeon found it necessary because of the anatomical situation. The recurrent laryngeal nerve was visualized and stimulated next, before or after dissection of the superior thyroid artery. The stimulation of the vagal and recurrent laryngeal nerves was repeated after the final dissection of the thyroid lobe. If a bilateral resection was required and IONM was regular, the surgeon proceeded in the same manor on the second side. After LOS, the surgeon consulted the senior endocrine surgeon in our center, who then decided to either continue the operation or abort in favor of a two-stage procedure. All thyroid operations included the use of intermittent IONM via electrodes in the tracheal tube and stimulation via a hand-held probe. All IONM data were registered on paper and collected in the patient's file.

Patients with LOS or any form of change of voice underwent repeat laryngoscopy on postoperative day (POD) 1. If VCD was discovered, patients were prescribed professional speech therapy and underwent regular ENT checkup examinations. The ENT specialist performing the laryngoscopy differentiated between complete VCP and reduced mobility of the vocal cords, referred to as impaired vocal cord mobility (IVCM).

In contrast to the definitions we used in previous publications [1, 2], we defined a positive IONM signal with normal vocal cord function as true negative and LOS followed by VCD as true positive. Postoperative VCD despite regular IONM was defined as falsely negative and LOS without VCD as falsely positive. We chose these definitions for coherence with publications by other authors such as Dralle et al. [7, 12] and Chan et al. [13]. Permanent VCD was declared after 18 months [2].

We performed a retrospective analysis of all patients' files with false-negative IONM. We registered the sex and age of the patients, the duration of their respective surgery, and their IONM curves. We also evaluated the patients for a history of smoking, anticoagulants, obesity, a difficult intubation as documented by the anesthesiologist, and a recurrent laryngeal nerve (RLN) lying ventral of the inferior thyroid artery as possible risk factors for false-negative IONM. We used the true-negative IONM data of the same patients as a control group for comparison and statistical evaluation. All data were collected in a database (Microsoft Excel). Our statistical analysis was performed with SPSS software (SPSS, Chicago, IL, USA). Statistical significance was regarded as levels >95 % using Fisher's exact test.

Results

Patients

A total of 2152 patients—3426 nerves at risk (NAR)—underwent thyroid surgery for benign disease in our center between January 2008 and October 2010. We registered 76 patients with a total of 82 vocal cords with postoperative VCD (70 with unilateral VCD and 6 with bilateral VCD). In all, 11 of these patients had intact IONM signals (Table 1). 9 of these 11 patients underwent bilateral surgery and two patients suffered from bilateral VCD, one of whom experienced false negative IONM on both sides of resection (12 cases of false negative IONM). Furthermore, we registered 33 patients without VCD despite LOS (false positive IONM) and 70 NAR with VCD after LOS (true positive IONM) (Table 2).

Sensitivity, specificity, and predictive values of IONM for predicting VCD

The sensitivity for predicting VCD—true positive = (true positive + false negative)—was 85.4 %. The specificity—true negative = (true negative + false positive)—was 99.0 %. The positive predictive value—true positive = (true positive + false positive)—was 68.0 %. The negative predictive value—true negative = (true negative + false negative)—was 99.6 % (Table 3).

Evaluation of possible risk factors for VCD despite regular IONM

The average age in this collective was 53 years at the time of surgery (range 38–79 The sex ratio was three males versus eight females (3:8). The average body mass index (BMI) was 26 kg/m^2 (range 23–34 kg/m^2). Only 1 of the 11 patients with false-negative IONM took anticoagulants. The anesthesiologist documented one case of difficult intubation. In all, 5 of the 11 patients were smokers. We registered three patients whose RLN lay ventral to the inferior thyroid artery. In all three patients this anatomic variant was bilateral. Two of these patients experienced unilateral VCD, and one suffered bilateral VCD. The average duration of surgery was 101 min (range 61–143 min). Vessel loops were used on the vagal nerves

Table 1 Patients with false-negative intraoperative neuromonitoring

Pt.	Sex	Age (years)	Diagnosis	Operation	Uni vs. bilat resection	IVCM vs. RLNP	Side of VCD	VCD side of resection	Delay VCD	Temp vs. Perm	Time to recovery from VCD
U.F.	M	45	Goiter	Dunhill	BI	RLNP	R	1st	No	Temp	<1 mo
H.L.	M	79	Goiter	TX	BI	RLNP	L	1st	Yes	Temp	<6 mo
R.N.	F	59	Goiter	TX	BI	RLNP	L	2nd	Yes	Temp	<6 mo
O.O.	F	39	Goiter	HTX (L)	UNI	RLNP	L	1st	No	Lost	Lost
S.V.	F	41	Goiter	TX	BI	RLNP	L	2nd	No	Temp	<6 mo
M.H.	F	57	Goiter + PHPT	TX + PTX CR (R)	BI	IVCM	R	1st	No	Temp	<6 mo
M.L.	M	38	Goiter	TX	BI	RLNP	L	1st	No	Temp	<6 mo
P.A.	F	48	Goiter	HTX (R) + Isthmus	UNI	RLNP	R	1st	Yes	Perm	–
E.K.	F	48	Goiter + PHPT	Dunhill + PTX CR (R)	BI	RLNP	R	1st	No	Temp	<1 wk
M.B.	F	49	Graves' goiter	TX	BI	IVCM	L+R	1st + 2nd	Yes	Temp	<6 mo
B.R.	F	53	Goiter	TX	BI	RLNP	L+R	1st + 2nd[a]	No	Temp	<6 mo

Pt patient, *Uni* unilateral, *Bilat* bilateral, *IVCM* impaired vocal cord mobility, *RLNP* recurrent laryngeal nerve palsy, *VCD* vocal cord dysfunction, *Delay VCD* delay in occurrence of VCD, *Temp* temporary VCD, *Perm* permanent VCD, *PHPT* primary hyperthyroidism, *Dunhill* Dunhill resection, *TX* thyroidectomy, *HTX* hemithyroidectomy, *PTX* parathyroidectomy, *Isthmus* thyroid isthmus resection, *L* left, *R* right, *CR* cranial, *mo* month, *wk* week, *Lost* lost to follow-up examinations)

[a] True positive intraoperative nuromonitoring (IONM) result on the second side of the resection

Table 2 Overview of patients and IONM results

IONM result	Patients/nerves at risk VCD	VCF	Total
Regular	11/12	2043/3311	2054/3323
Loss of signal	65/70	33/33	98/103
Total	76/82	2076/3344	2152/3426

IONM intraoperative neuromonitoring, *VCD* vocal cord dysfunction, *VCF* regular vocal cord function

Table 3 Sensitivity, specificity, and predictive values of IONM for predicting VCD

Parameter	Value	%
Sensitivity	70/(70 + 12)	85.4
Specificity	3311/(3311 + 33)	99.0
PPV	70/(70 + 33)	68.0
NPV	3311/(3311 + 12)	99.6

PPV positive predictive value, *NPV* negative predictive value

of nine patients. The average duration of all operations was 89 min (Table 4).

Comparison of IONM data

We registered 12 NARs with false-negative IONM (11 patients, including one case of bilateral, false-negative IONM). For the sake of comparison, we evaluated the IONM data of those patients in this group, who underwent a bilateral resection. After excluding one patient with incorrectly documented IONM (U.F., Table 1) and one patient with true-positive IONM (B.R., Table 1), we were left with six NARs with true negative IONM to evaluate. The amplitude of vagal stimulation was reduced in five NARs with false-negative IONM (42 %), and it remained equal or improved in seven NARs (58 %). In comparison, the amplitude of vagal stimulation was reduced in four NARs with true-negative IONM (67 %) and remained equal or improved in two NARs (33 %). This difference was not statistically significant ($p = 0.6$) (Table 5). The interval between stimulation and response did not differ significantly in any of these patients.

Recovery after false-negative IONM

Recovery after VCD and false-negative IONM was seen in one patient in <1 week, in one patient within 1 month, and in seven patients within 6 months. We registered one patient with permanent unilateral VCD. One patient was lost to follow-up (Table 1). Thus, the total rate of recovery after false-negative IONM was 91 % (10/11 VCD).

Table 4 Possible risk factors for false-negative IONM

Pt.	Sex	Age (years)	Diagnosis	Anticoag	BMI (kg/m^2)	Nicotine	RLN over	Diff intub	VN loop
U.F.	M	45	Goiter	No	29	Yes	No	No	Yes
H.L.	M	79	Goiter	Yes	28	No	No	Yes	Yes
R.N.	F	59	Goiter	No	24	No	No	No	No
O.O.	F	39	Goiter	No	31	Yes	No	No	No
S.V.	F	41	Goiter	No	22	Yes	No	No	Yes
M.H.	F	57	Goiter + PHPT	No	27	Yes	Yes	No	Yes
M.L.	M	38	Goiter	No	23	No	Yes	No	Yes
P.A.	F	48	Goiter	No	27	No	No	No	Yes
E.K.	F	48	Goiter + PHPT	No	24	No	No	No	Yes
M.B.	F	49	Graves' goiter	No	22	Yes	No	No	Yes
B.R.	F	53	Goiter	No	34	No	Yes	No	Yes

Anticoag anticoagulants, *RLN over* recurrent laryngeal nerve ventral to inferior thyroid artery, *Diff intub* difficult intubation, *VN loop* use of vessel loop on vagal nerve

Table 5 Comparison of vagal stimulation

Amplitude	False-negative IONM vagal	True-negative IONM vagal
Reduced	5	7
Equal or increased	7	2

$P = 0.6$ (Fisher's exact test)

Four patients with delayed occurrence of VCD, including one permanent VCP

We registered four patients with delayed occurrence of VCD following their thyroid operations. The first patient (H.L.) was a 79-year-old man who suffered from a benign, second- to third-degree goiter. We performed thyroidectomy. The anesthesiologist documented a difficult intubation. However, the IONM was regular, and the patient was discharged without any symptoms of VCD on POD 2. After noticing a change in his voice, the patient consulted an ENT specialist on POD 8. The specialist diagnosed unilateral VCP. The patient vocal cord mobility was restored within 6 months after speech therapy.

The second patient (R.N.) was a 59-year-old woman with a benign, first- to second-degree goiter. After an unproblematic intubation, we proceeded with thyroidectomy. The surgery took 65 min, and the IONM was regular. The patient was discharged with no apparent symptoms on POD 2. She returned after 2 months for a follow-up examination because of hoarseness. Laryngoscopy revealed unilateral VCP. The patient underwent speech therapy, and her vocal cord recovered within 6 months of the operation.

The third patient (P.A.) was a 48-year-old woman with second-degree goiter. As we found relevant nodes only in the right thyroid lobe, we performed hemithyroidectomy. Intubation was nonproblematic, and the duration of the procedure was 61 min. IONM was regular. The patient was discharged on POD 1, showing no signs of VCD. The patient returned 6 weeks later after noticing a change of voice. The ENT examination showed unilateral VCP. Despite intensive speech therapy and some alleviation of the patient's symptoms, the VCP remained and was classified as permanent after 18 months.

The fourth patient with delayed occurrence of VCD (M.B.) suffered bilateral VCD (see below).

Two patients with bilateral VCD despite regular IONM

We registered two patients with bilateral VCD despite regular IONM. The first patient (M.B.) was a 49-year-old woman suffering from a benign second-degree goiter in conjunction with Graves' disease. The patient took regular spasmolytic medication for her allergic asthma and was a smoker. The operation was performed under thyrostatic conditions. Intubation was nonproblematic, and the total duration of the thyroidectomy was 67 min. IONM was regular on both resection sides. On POD 1, the patient showed no clinical signs of VCD. During the evening of POD2, however, she developed stridor and dyspnea. An ENT specialist performed laryngoscopy, which demonstrated reduced mobility and edema of both vocal cords. We proceeded with a combination of inhalants and systemic steroids. On POD 5, the patient's symptoms worsened. She was transferred to our intensive care unit (ICU) and received antihistamines because of her multiple allergies. The patient's symptoms were alleviated under this therapeutic regimen, and she was transferred back to the surgical ward and discharged soon thereafter. The ENT department in our center performed regular examinations. A full recovery of vocal cord function was registered within 6 months of the operation.

The second patient with bilateral VCD (B.R.) was a 53-year-old woman suffering from a benign, second-degree

Table 6 Relative risk of VCD despite regular IONM in bilateral resections

IONM on first side of resection	Bilateral VCD	
	Yes	No
False-negative ($n = 7$)	2	5
True-negative ($n = 1256$)	4	1252

$p < 0.05$ (Fisher's exact test), relative risk $= 2/(2 + 5)$: $4/(4 + 1252) = 89.7$

goiter. Intubation was not difficult, and the thyroidectomy took 102 min. As IONM on the first resection side was regular and there was no difficulty identifying the RLN, the surgeon proceeded with the second side as planned. The IONM signals over both the vagal and RLNs were primarily suspicious on the second resection side. The signal did not improve after lobectomy. Directly after extubation the patient suffered from stridor and dyspnea. Immediate laryngoscopy confirmed bilateral VCP. The patient was transferred directly to our ICU. During the following weeks she underwent multiple procedures by our ENT department, including a temporary tracheostoma. Within 6 months both vocal cords had regained complete mobility.

Relative risk of bilateral VCD

We performed 1274 bilateral operations for benign thyroid disease and registered a total of 6 patients with bilateral VCD (0.5 %). We registered seven patients with false-negative IONM on the first side of a bilateral resection and 11 patients with false-positive IONM. In the remaining 1256 cases, IONM was true on the first side of resection. In four patients, the bilateral VCD resulted after continuation of the surgery despite LOS on the first side [2]. The remaining two cases of bilateral VCD occurred after regular IONM signals on the first resection side. The rate of bilateral VCD after false-negative IONM on the primary resection side was 28.6 % (two of seven patients). The relative risk (RR) for bilateral VCD between patients with false-negative IONM on the primary resection side and patients with true IONM on the first side was 89.7 (Table 6).

Discussion

IONM has been shown to reduce the risk of unilateral VCD in high-risk patients [1, 6, 7, 14] and the risk of bilateral VCD in bilateral operations [2, 8]. The accuracy of IONM in detecting nerve damage has been demonstrated in multiple publications [1–3, 9]. However, the fact that the NPV does not reach 100 % leads to rare cases of VCD that are not detected during the operation. This fact led us to analyze the patients who suffered from VCD despite regular IONM signals.

As in our previous publication [2], we chose to define VCD as permanent after 18 months because we have witnessed recovery after the more commonly used 12 months [15]. This observation is backed by similar findings of Streuer et al. [16].

We were not able to identify specific risk factors for false-negative IONM. Further prospective evaluation is necessary to determine possible items. The possibility of VCD being caused by trauma during intubation has been suggested by multiple authors [17–22]. This has led the German Interdisciplinary Study Group on Intraoperative Neuromonitoring of Thyroid Surgery to publish a statement in favor of not only simple laryngoscopy but also stroboscopy and intra- and extralaryngeal electromyography as tools in the differential diagnosis of postoperative VCD [23]. A weakness of our analysis lies in the fact that we performed postoperative laryngoscopy only in patients with LOS or symptoms of postoperative VCD. Tomoda et al. called for routine postoperative laryngoscopy or laryngofiberoscopy to check for vocal cord mobility [24]. We adopted this approach at our center in 2011 and now perform routine laryngoscopy on every patient on the first day after thyroid surgery. This decision was made after witnessing the delayed occurrence of postoperative VCD and because of the need to differentiate between truly delayed VCD and primarily asymptomatic VCD in the future. We saw four patients with a delayed occurrence of postoperative VCD, including one case of permanent palsy. It is possible that these patients suffered from immediate postoperative VCD but were asymptomatic or inconspicuous at voice examination. The majority of authors perform postoperative laryngoscopy within the first few days after surgery [1–7]. In our experience, later examinations are also needed to detect delayed palsies and should be considered when developing and refining algorithms for follow-up examinations after thyroid surgery.

The fact that false-negative IONM does occur is also relevant in malpractice claims. A review by Dralle et al. demonstrated four claims of malpractice regarding the use of IONM [25]. Plaintiff verdicts resulted in three cases because the IONM routine did not follow international standards, which still seem debatable to us. Despite the high accuracy of IONM and the influence of neuromonitoring on strategy in bilateral procedures [2], we have now shown a relevant risk for bilateral VCD (RR 89.7) in the case of false-negative IONM on the first resection side.

Conclusions

Although rare, false-negative IONM is of clinical importance as it bears a high risk of bilateral VCD if it occurs on

the first resection side of a bilateral resection. Also, it can have a latent occurrence after surgery.

Conflict of interest None.

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