Original article

Loss of the nerve monitoring signal during bilateral thyroid surgery

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Background: **This study aimed to assess current use of recurrent laryngeal nerve monitoring (RLNM) for bilateral thyroid surgery in Germany. It explored the willingness of surgeons to change strategy after loss of signal (LOS) on the first side of resection.**
Methods: **Surgical departments in Germany equipped with nerve monitors were asked to complete a structured questionnaire, specifying the number of thyroidectomies done in 2010, and the frequencies of RLNM, vagal stimulation, and electromyographic (EMG) recording before and after thyroidectomy. They were also asked about the surgical plan for bilateral goitre after LOS on the first side of resection.**
Results: **Based on manufacturers' sales data, 1119 (89·1 per cent) of 1256 surgical departments in Germany were equipped with nerve monitors in 2010. A total of 595 departments (53·2 per cent), accounting for approximately 75 per cent of all thyroidectomies in Germany during that year, returned a completed questionnaire. RLNM was used in 91·7–93·5 per cent of thyroidectomies, with the addition of routine vagal stimulation in 49·3 per cent before, and 73·8 per cent after resection. EMG responses to vagal stimulation were recorded in 54·8 per cent before, and 72·5 per cent after resection. Some 93·5 per cent of surgeons changed the resection plan for the other side in bilateral thyroid surgery after LOS had occurred on the first side.**
Conclusion: **RLNM is now the standard of care during thyroidectomy in Germany. After LOS on the first side of resection in bilateral goitre, more than 90 per cent of respondents declared their willingness to change the resection plan for the contralateral side to avoid the risk of bilateral recurrent laryngeal nerve palsy.**

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Introduction

After several decades of controversy surrounding the benefit of visual identification of the recurrent laryngeal nerve (RLN) during thyroidectomy[1–3], the advent of technology combining anatomical nerve localization with intraoperative assessment of nerve function has rekindled interest in RLN electrophysiology[4–11]. This new technology sparked discussion about its clinical value[12–14] and the medicolegal implications[15–18].

Even though the advantage of electrophysiological nerve identification over the former standard of visual nerve identification[8] was immediately apparent, cost issues[19], clinical pitfalls[6,20,21] and conflicting outcome research[4,8,10,11] cast doubt over the technology proposed for RLN monitoring (RLNM). Although RLNM can facilitate identification of RLN anatomy under difficult circumstances (atypical course of the nerve, extrathyroidal tumour growth, or reoperation)[22], particularly for low-volume thyroid surgeons[4], many surgeons continued to rely on visual identification alone.

The proportion of surgeons using nerve monitors for thyroid surgery, routinely or selectively, increased from 24 per cent in 2005 to 29 per cent in 2007 and 37 per cent in 2009 according to surveys from the USA and the UK[23–25]. Surgeons stated that the use of a nerve monitor improved safety (34 per cent), facilitated reoperations and operations on large goitres (33 per cent), and offered some protection against medicolegal claims (22 per cent)[24]. Non-users were older, had lower case volumes and less access to nerve monitors for thyroid surgery; they were

less familiar with the technology and less frequently had patient-initiated discussions about nerve monitoring[25].

Although it remains unknown whether RLNM can reduce the rate of postoperative RLN palsy owing to the rarity of the event, there is good evidence that the electromyographic (EMG) response signal predicts postoperative vocal cord function reasonably well; a normal signal indicates intact vocal cord function in 98–99 per cent of patients[21]. This suggests that it may be prudent to postpone completion of the contralateral side in bilateral goitre if the nerve monitoring signal is lost on the first side of resection, to avoid the risk of bilateral RLN palsy. In addition to clinical evidence, medicolegal judgements also need to consider whether the technology was sufficiently disseminated to represent a standard of care, and whether a defendant surgeon applied the technology according to relevant publications and guidelines[4,8,17,26,27].

The present survey of 1119 surgical departments was undertaken to clarify the dissemination and use of RLNM for thyroidectomy in Germany in 2010. This survey concentrated on three key elements of nerve monitoring: the frequency of vagal stimulation, recording of the EMG response signal before and after resection, and the surgeons' willingness to change their surgical plan for bilateral goitre after loss of the RLNM signal (LOS) occurred on the first side of resection.

Methods

This survey was designed to collect detailed information on usage patterns from German general surgery, and ear, nose and throat (ENT) departments supplied with nerve monitoring devices from any of the three manufacturers of RLNM devices: Inomed Medizintechnik (Emmendingen, Germany), Dr. Langer Medical (Waldkirch, Germany) and Medtronic (Meerbusch, Germany). No other company was known to have marketed a nerve monitor for thyroid surgery in Germany at that time. The surgical departments were identified from company sales data and asked to participate in the survey by completing a structured questionnaire. Institutional review board approval was not required under German law because the survey gathered only aggregate data regarding surgical performance and outcome.

Data captured by the questionnaire

The following data elements were captured in a standard fashion: the type of surgical department (general surgery *versus* ENT); the number of thyroidectomies in 2010; the proportion of thyroidectomies conducted under RLNM in bands of 100 per cent (routine use), 75–99 per cent (predominant use), 50–74 per cent (more than selective, but less than routine use) and less than 50 per cent (selective use); stimulation of the vagus before and after resection (routinely, surgeon- or circumstance-dependent, or only as an exception); recording of the EMG response to vagal stimulation before and after resection (yes or no); and the surgical consequences after LOS on the first side of resection in bilateral goitre (none or only exceptional resection on the other side, reduced extent of resection on the other side compared with the original surgical plan, proceed with the bilateral resection as planned).

Statistical analysis

The characteristics of surgical departments and RLNM usage patterns were tabulated using descriptive statistics of absolute frequencies with percentages for categorical variables.

Results

A total of 1119 (89·1 per cent) of all 1256 surgical departments in Germany[28], 1047 general surgery (93·6 per cent) and 72 ENT departments (6·4 per cent), were identified from company sales data as current or past recipients of nerve monitors for thyroid surgery. Of these, 595 departments (53·2 per cent) completed and returned the questionnaire, comprising 47·4 per cent of all surgical departments in Germany. These 595 departments included a total of 83 577 thyroidectomies done in Germany in 2010, accounting for approximately 75 per cent of all thyroidectomies performed in Germany each year[29]. The following survey data, reflecting current treatment strategy, were derived from information supplied by the senior thyroid surgeon of each of these 595 surgical departments.

Demographics

The majority of departments equipped with nerve monitors and conducting thyroidectomies had a general surgery background (582 centres, 97·8 per cent); the remainder were ENT departments (13 centres, 2·2 per cent). Altogether, general surgeons conducted 82 987 thyroidectomies (99·3 per cent) and ENT surgeons 590 (0·7 per cent). The institutional thyroidectomy caseload in 2010 varied markedly across the 595 departments (*Table 1*). The 572 departments that provided information recorded a mean of 80 thyroidectomies in 2010, with a wide range from five to 1500. Most of these operations (92·3 per cent) were conducted with the use of nerve monitors (*Table 1*).

Table 1 Institutional thyroidectomy caseload and frequency of recurrent laryngeal nerve monitoring

Institutional thyroidectomy caseload	Surgical departments	Thyroidectomies	
		Total	With RLNM (%)*
< 50	128 (21·5)	3679	93·1
50–99	202 (33·9)	13 949	93·5
100–199	128 (21·5)	17 521	93·1
≥ 200	114 (19·2)	48 428	91·7
Not indicated	23 (3·9)		
Total	595 (100)	83 577†	92·3†

Values in parentheses are percentages. *Weighted average. †Excluding 23 departments with unspecified caseloads. RLNM, recurrent laryngeal nerve monitoring.

Vagal stimulation

Vagal stimulation was routinely carried out in 49·3 per cent of thyroidectomies before, and in 73·8 per cent after resection (*Table 2*). It was less frequently employed by departments with an institutional caseload of 50–99 thyroidectomies and most commonly by departments with an institutional caseload of at least 200 thyroidectomies. Surgical departments that always used RLNM had the highest rates of routine vagal stimulation before and after resection (*Table 2*).

Recording of electromyographic responses to vagal stimulation

EMG responses to vagal stimulation were recorded more often after (72·5 per cent), than before (54·8 per cent) resection, increasing with institutional caseload. No such effect was noted for the frequency of RLNM during thyroidectomy (*Table 3*). EMG responses to vagal stimulation were recorded more often after (86·5 and 81·2 per cent) than before (77·5 and 63·1 per cent) resection, whether routine vagal stimulation was carried out before or after thyroid resection (*Table 3*).

Change in surgical plan after unilateral loss of signal

The majority of departments stated that they would never, or only exceptionally, proceed with resection on the contralateral side in a bilateral goitre after LOS on the first side of resection (*Table 4*). All in all, 93·5 per cent of departments declared they were willing to change their surgical strategy in this setting, resulting in discontinuation of surgery (84·7 per cent) or undertaking a less extensive resection for completion of the other side than originally planned (8·8 per cent). Departments with the heaviest institutional caseload (at least 200 thyroidectomies) reportedly changed their surgical plans more often than those with a lower institutional caseload (95·3 per cent *versus* 91·1, 91·9 and 90·6 per cent for those with caseloads of less than 50, 50–99 and 100–199 respectively). Likewise, departments that routinely employed vagal stimulation and recording of EMG responses refrained from continuing the resection on the unaffected side more frequently than those that did not (*Table 4*).

Table 2 Routine vagal stimulation before and after thyroidectomy by institutional caseload and frequency of recurrent laryngeal nerve monitoring

	Thyroidectomies with RLNM*	Routine vagal stimulation (%)†	
		Before resection	After resection
Institutional thyroidectomy caseload			
< 50	3400	47·1	72·4
50–99	13 000	36·1	64·4
100–199	16 300	42·5	70·4
≥ 200	44 400	55·9	77·8
Frequency of RLNM (%)			
< 50 (selective)	700	38·6	44·1
50–74	400	8·7	28·3
75–99	10 300	20·7	66·0
100 (routine)	65 800	54·2	75·6
Total	77 200	49·3	73·8

*Number of thyroidectomies multiplied by the rate of recurrent laryngeal nerve monitoring (RLNM), rounded to the nearest 100. Owing to rounding, not all numbers add up. †Routine vagal stimulation including all unconditional affirmative responses (disregarding conditional responses such as 'surgeon- or situation-dependent' or 'only exceptionally').

Table 3 Recording of electromyographic responses to vagal stimulation by institutional caseload, frequency of recurrent laryngeal nerve monitoring and routine vagal stimulation

		Recording of EMG responses to vagal stimulation (%)	
	Thyroidectomies with RLNM*	Before resection	After resection
Institutional thyroidectomy caseload			
< 50	3400	38·2	64·0
50–99	13 000	39·2	62·0
100–199	16 300	45·8	66·5
≥ 200	44 400	63·8	78·5
Frequency of RLNM (%)			
< 50 (selective)	700	66·8	66·8
50–74	400	40·0	49·9
75–99	10 300	57·4	68·8
100 (routine)	65 800	54·3	73·3
Routine vagal stimulation before resection†			
Yes	38 100	77·5	86·5
No	39 100	32·5	58·8
Routine vagal stimulation after resection†			
Yes	56 900	63·1	81·2
No	20 300	31·6	48·2
Total	77 200	54·8	72·5

*Number of thyroidectomies multiplied by the rate of recurrent laryngeal nerve monitoring (RLNM), rounded to the nearest 100. Owing to rounding, not all numbers add up. †Routine vagal stimulation including all unconditional affirmative responses (disregarding conditional responses such as 'surgeon- or situation-dependent' or 'only exceptionally'). EMG, electromyographic.

Table 4 Surgeons' willingness to change the surgical plan after unilateral loss of signal by institutional caseload, frequency of recurrent laryngeal nerve monitoring, routine vagal stimulation and recording of electromyographic responses

		Resection on the other side (%)		
	Thyroidectomies with RLNM*	As planned	Reduced extent	No, or only exceptionally
Institutional thyroidectomy caseload				
< 50	3400	8·9	20·4	70·7
50–99	12 800	8·1	18·3	73·6
100–199	16 000	9·4	14·9	75·7
≥ 200	44 200	4·7	3·0	92·3
Frequency of RLNM (%)				
< 50 (selective)	400	4·4	19·6	75·9
50–74	400	0·0	2·2	97·8
75–99	10 100	6·6	10·9	82·5
100 (routine)	65 400	6·5	8·5	85·1
Routine vagal stimulation before resection†				
Yes	37 800	5·8	7·0	87·2
No	38 600	7·0	10·6	82·4
Routine vagal stimulation after resection†				
Yes	56 300	5·5	8·4	86·0
No	20 200	8·9	10·0	81·1
Routine EMG documentation before resection				
Yes	41 700	3·3	6·6	90·0
No	34 700	10·1	11·5	78·4
Routine EMG documentation after resection				
Yes	55 400	4·8	8·5	86·8
No	21 100	10·8	9·8	79·4
Total	76 400	6·4	8·8	84·7

*Number of thyroidectomies multiplied by the rate of recurrent laryngeal nerve monitoring (RLNM), rounded to the nearest 100. Owing to rounding, not all numbers add up. †Routine vagal stimulation including all unconditional affirmative responses (disregarding conditional responses such as 'surgeon- or situation-dependent' or 'only exceptionally'). EMG, electromyographic.

Discussion

Germany, having only a short coastline to the north (North Sea and Baltic Sea), is a country with longstanding iodine deficiency and a high prevalence of bilateral multinodular goitre. It has a long tradition of goitre surgery[30] and continued debate about the appropriate extent of thyroid resection and RLN management[31]. In this specific environment, the arrival of intraoperative nerve monitoring was greeted with enthusiasm by the German endocrine surgical community, perceiving this new technology as a valuable adjunct to visual RLN identification[4,31–33]. Notwithstanding the inherent limitations of self-reported data, the present study reflects more than a decade of extensive experience with RLNM at a national level, providing important insights into the current dissemination and use of RLNM in Germany. In 2010, 1119 (89·1 per cent) of all 1256 German surgical departments had nerve monitors for thyroid surgery at their disposal.

The 595 departments participating in the survey accounted for approximately 75 per cent of all thyroidectomies in Germany each year[28,29]. These departments employed RLNM in 92·3 per cent of their thyroidectomies, independent of institutional caseload. Even if none of the other 661 surgical departments, whether they had a nerve monitor or not, used any form of RLNM in the remaining thyroidectomies, a minimum of 69 per cent of thyroidectomies in Germany were being done using RLNM, the highest percentage ever reported for any country. This high rate of dissemination may explain why RLNM as a risk minimization tool is increasingly taking centre stage in medicolegal claims following RLN palsy in Germany[4].

Recent guidelines describing the various steps of nerve monitoring[21,26,27], vagal stimulation and recording of its EMG responses perhaps have been the most contentious issues since RLNM was introduced into clinical practice. The present survey data showed this conflict of opinion. The 595 participating departments employed RLNM in 92·3 per cent of thyroidectomies, but in only 49·3 per cent of thyroidectomies before, and in 73·8 per cent after thyroid resection. Surgeons seemed to be counting more on LOS, all or nothing, than on electrophysiological criteria such as waveform, amplitude and latency[34], the interpretation of which hinges on direct comparison with the baseline EMG findings before resection. These attitudes obviously mirrored the chronological sequence of RLNM development that started with a simple acoustic signal indicating the presence or absence of a response signal. Not all EMG changes developing during resection imply vocal cord dysfunction. The usage patterns for vagal stimulation varied by institutional caseload and the frequency of RLNM. Vagus stimulation was used less frequently before than after resection. Highest rates of vagal stimulation were reported from centres with a very low or fairly high caseload or frequency of RLNM. These data confirmed previous findings that institutions performing fewer thyroidectomies do not necessarily use RLNM or vagal stimulation less often[19]. As pointed out by Sturgeon and colleagues[25], the use of RLNM and vagal stimulation is more dependent on familiarity with, and access to, nerve monitoring devices than on institutional caseload.

One of the key objectives of this survey was to explore the willingness of surgeons to act on abnormal intraoperative nerve monitoring signals by changing their surgical plan during the operation. Although RLNM does not decrease the rate of postoperative vocal cord palsy, as many as one-third to one-half of RLN injuries give rise to medicolegal claims involving bilateral RLN palsies[15,18]. This is why it is so important to use RLNM for bilateral thyroid resections, enabling a change to the surgical plan during the operation after LOS on the first side[8,17,35,36]. In the present survey, most surgeons declared their willingness to act on a unilateral LOS to prevent bilateral RLN palsy, by discontinuing bilateral goitre surgery (84·7 per cent) or by reducing the planned extent of resection on the unaffected side (8·8 per cent), staying as far as possible from the RLN. Such a change in strategy was associated with the regular use of vagal stimulation with, or without, recording of EMG response signals. Owing to the low positive predictive value for LOS of just 10–60 per cent[8], the strategy of staged bilateral resection after unilateral LOS has been disputed as it may lead to unnecessary completion thyroidectomies in the event of a false-positive LOS. Recently, Goretzki and co-workers[36], applying the strategy of staged bilateral resection after unilateral LOS, demonstrated the feasibility of diminishing the rate of bilateral palsy from 17 to 0 per cent. The concept of staged thyroidectomy in bilateral goitre after unilateral LOS seems well founded.

The present study shares many of the limitations of surveys relying on self-reported aggregate data, including volunteer and recall bias. It obviously cannot replace outcome studies that analyse prospectively the impact of intraoperative RLNM or staged bilateral resection after unilateral LOS on the rate of RLN palsy. In spite of these methodological weaknesses, the present population-based survey uncovered a remarkable evolution in RLNM: a nationwide dissemination of RLNM technology in Germany (89·1 per cent), a high rate of use for thyroidectomy when nerve monitoring devices were available (over

90 per cent), and the wide adoption of staged bilateral thyroid resection after unilateral LOS. Yet there is still room for improvement with regard to the routine use of vagal stimulation after (73·8 per cent in this survey) and especially before (49·3 per cent) resection, and the regular recording of EMG response signals to vagal stimulation (72·5 and 54·8 per cent respectively).

Further experimental and clinical studies are needed to determine whether the new generation of nerve monitoring devices, allowing continuous vagal stimulation[37,38], are better suited to meet this requirement. For the time being, the possibility of changing surgical plans for bilateral goitre surgery in the event of unilateral LOS should be discussed frankly with each patient as a risk minimization strategy to avoid bilateral nerve palsy.

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Commentary

Loss of the nerve monitoring signal during bilateral thyroid surgery (*Br J Surg* 2012; 99: 1089–1095)

In the past decade an increasing number of surgeons have embraced the concept that the risk of recurrent laryngeal nerve (RLN) injury would be better assessed by intraoperative electrophysiological information about RLN function rather than relying on visual assessment of its integrity. This paper reports that the overwhelming majority (93·5 per cent) of respondents to a national survey in Germany declared that they were willing to change their surgical strategy if intraoperative nerve monitoring (IONM) suggested RLN injury. The high negative prediction rate of IONM (loss of signal correlates with postoperative vocal cord dysfunction/palsy) can therefore be used to guide changing or avoiding contralateral surgery to prevent bilateral RLN injury.

It appears that in recent years German surgeons moved from considering IONM an adjunct of their surgical technique to using its findings to modify the extent of operation. This is a leap forward in accepting that IONM is an integral part of modern thyroid surgery. It is also in strong contrast with the attitude of the majority of surgeons in many countries where the technique is less valued. For example, the 2007 National Institute for Health and Clinical Excellence review was lukewarm[1], hence the technique has been adopted by few UK surgeons. The reason for this contrasting attitude remains difficult to explore and it is certainly not solely due to financial concerns related to the cost–benefit ratio.

As technology plays an increasing role in modern medicine, monitoring vital functions is accepted widely. Surgeons are exposed daily to complex monitoring of a large number of parameters during anaesthesia that have never been proven beneficial in randomized controlled trials. The introduction of IONM remains opposed by many thyroid surgeons because there are no level I data to allow an evidence-based change in the traditional practice of relying solely on visual identification of the RLN. As no randomized trial can be constructed to estimate the impact of IONM on an adverse event that occurs in fewer than 1–2 per cent of procedures (100 000 patients might need to be recruited), acceptance of IONM will depend on the personal analysis of published data. Furthermore, some of the benefits can be assessed only by individual surgeons through direct exposure to this new technology.

Although in 2012 it is unlikely that a German patient will have thyroid surgery without IONM, it remains rare for it to be offered to a patient in the UK. In the coming years, however, is likely that the standard of practice will shift towards the German model described in this paper.

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Reference

1 National Institute for Health and Clinical Excellence. *Interventional Procedure Overview of Intraoperative Nerve Monitoring During Thyroid Surgery.* 2007; http://www.nice.org.uk/ip654overview [accessed 29 May 2012].