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Identification and Monitoring of the Recurrent Laryngeal Nerve During Thyroidectomy

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Thyroidectomy is a procedure with a rich history that by some accounts spans nearly three millennia. Throughout its evolution, surgery of the thyroid gland has attracted the attention of some of each generation's most revered physicians and surgeons. Moreover, the approach to and technique of thyroidectomy preferred by these individuals often have spurred tremendous disagreement and debate. Spirited discourse regarding the conduct of thyroidectomy continues in the 21st century, and among the most contested discussed topics is that of recurrent laryngeal nerve (RLN) monitoring. But before discussing monitoring in detail, it behooves the reader to understand some of the history and earlier controversies that have led to the topic at hand.

Early concerns regarding surgery of the thyroid gland stem from the fact that operative management of goiter carried not only a high degree of morbidity, but also mortality. Indeed before the 1860s, hemorrhage and infection were commonplace, and the mortality rate for thyroidectomy exceeded 40% [1,2]. By the mid-1800s, the procedure was so feared and marginalized that it was actually banned by the French Academy of Medicine [3]. The modern era of thyroid surgery, however, soon was ushered in by the near-simultaneous development of aseptic technique, general anesthesia, and meticulous hemostasis. Application of these advances to the field of thyroid surgery by pioneers such as Kocher and Billroth brought about a dramatic reduction in the mortality rates associated with thyroidectomy. By the dawn of the 20th century, these numbers had fallen to less than 1% [1].

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By the 1920s, there was little debate as to whether thyroidectomy could be performed without significant risk to the life of the patient. This allowed for subsequent technical advances to focus on limiting iatrogenic morbidity. Perhaps most notable among these is the potential for injury to the RLN. As early as the 6th century A.D., voice changes after manipulation of the thyroid gland were recognized [2]. As the sciences of anatomy and surgery grew more sophisticated, the role of RLN injury in these changes became better understood. Kocher and his pupils, regarded by many as the fathers of modern-day thyroidectomy, believed that the best way to avoid injury was to avoid the nerve entirely. Thus it became dogmatic among thyroid surgeons that any RLN seen during thyroidectomy was very likely to have been injured. Lahey officially called this practice into question in the 1920s and 1930s [4,5]. Lahey reported his experience with deliberate exposure and identification of the RLN during over 10,000 thyroidectomies. The less than 1% RLN injury rate was significantly lower than any previously published series and led him to advocate the routine identification and dissection of the nerve during thyroid surgery. In essence, it can be said that Lahey was the first surgeon to actively monitor the RLN during thyroidectomy with routine visualization of the structure.

Although Lahey's assertions and practices are accepted widely as a means of reducing the risk of injury to the RLN, the degree to which one uses ancillary tools and techniques for this purpose continues to spark debate. This article was undertaken to better familiarize endocrine surgeons with the development and potential applications of RLN monitoring for thyroid surgery—ultimately helping them to better establish the role that it may or may not play in their own practices. It is not intended to be an endorsement or a criticism of monitoring in this context. In the interest of full disclosure, however, it should be noted that the authors do use intraoperative monitoring for all thyroid and parathyroid surgeries performed at their home institution.

Anatomy of the recurrent laryngeal nerve

In advocating the routine identification of the RLN during thyroidectomy, Lahey essentially devised the earliest system for neuro-monitoring. It is understood that the most basic concept in monitoring is active localization and dissection of the nerve to protect and preserve its function. It follows that a thorough understanding of the anatomy of the recurrent laryngeal nerve is vital to its detection during surgery of the thyroid gland. It is foolhardy to assume that any monitoring technology—regardless of its sensitivity or presumed benefit—can replace the surgeon's fundamental anatomical knowledge and careful technique. This is particularly true when one considers the fact that RLN anatomy renders it particularly vulnerable to iatrogenic injury. Among both novice and expert thyroid surgeons, careful attention to these features and their variations ultimately will assist in the protection of the nerve. This holds equally true for individuals choosing to use monitoring technology and those who do not.

RLNs arise from the vagus nerve at the level of the aortic arch on the left and at the level of the subclavian artery on the right. From this point, they ascend into the tracheoesophageal grooves as the paired inferior laryngeal nerves until terminating within the substance of the larynx. The asymmetry of the RLNs may be accounted for by their differing embryogenesis and relationship to the developing cardiovascular system. The fetal cardiovascular system initially contains six pairs of aortic arches, beneath which the vagus nerves give off branches to the primordial larynx. Development is marked by gradual alterations in these vessels that eventuate in the appearance of mature aortic and pulmonic vessels.

Around week 7 of gestation, the right sixth arch partially involutes. This structure remains intact on the left and becomes the putative proximal aorta. Simultaneously, the fifth arch arteries regress bilaterally. As the fetus continues to grow, the larynx moves cranially, carrying with it what are now the recurrent laryngeal nerves. Proximally, these will become trapped beneath the lowest remaining arches: arch six on the left (the aortic arch) and arch four on the right (the subclavian artery) (Fig. 1) [6]. The result is a more vertical orientation of the RLN on the left and a more oblique orientation of the right RLN in the adult (Fig. 2).

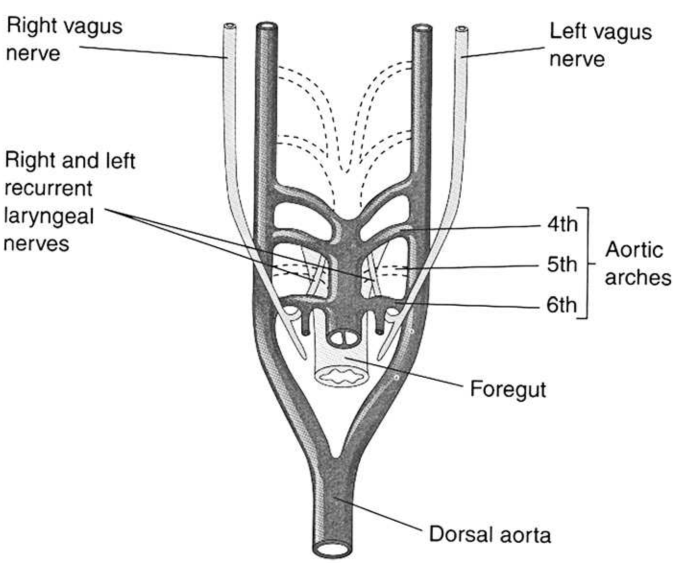

Fig. 1. Embryology of the recurrent laryngeal nerve. The fifth and sixth aortic arches regress on the right. The recurrent laryngeal nerve thereby passes beneath the subclavian artery on the right and the aortic arch on the left. (*From* Moore KL, Persaud TVL. The developing human: clinically oriented embryology. Philadelphia: W.B. Saunders: 1998. p. 387; with permission.)

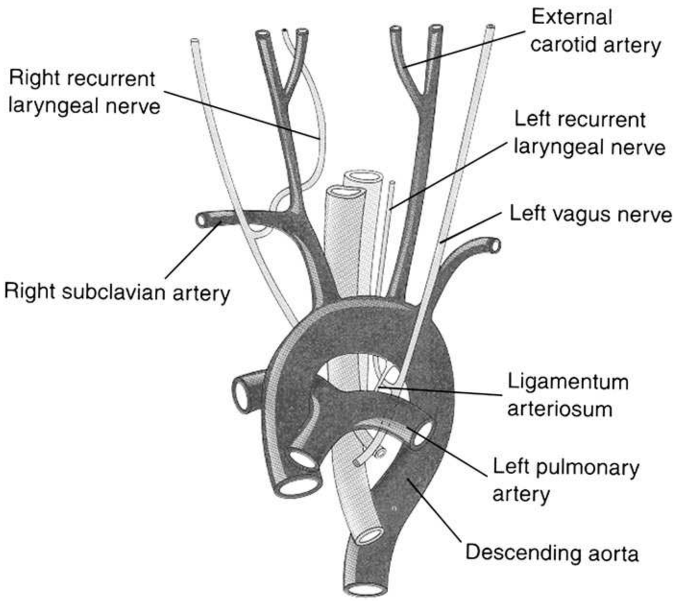

Fig. 2. The position of the recurrent laryngeal nerves relative to the great vessels differs from right to left. This results in a more vertically oriented nerve on the left and a more oblique course of the right recurrent laryngeal nerve. (*From* Moore KL, Persaud TVL. The developing human: clinically oriented embryology. 1998. Philadelphia: W.B. Saunders; 1998. p. 387; with permission.)

This embryology may be used to provide a general framework for localization of the RLN as it courses into the tracheoesophageal groove. It, however, is imprecise and not entirely reliable. Consequently, several authors have attempted to further characterize the relationship of the RLN to the trachea and the esophagus. Although it appears that most inferior laryngeal nerves ascend within the groove, variability is the rule (Table 1) [7–9]. Hence it may not be a safe assumption that the RLN will be found simply by exploring this region.

Additional landmarks have been proposed, but none has proven universally successful. The most widely examined of these is the inferior thyroid artery. Similar to its position relative to the tracheoesophageal groove, the RLN maintains an inconstant relationship to the inferior thyroid artery. It may be found anterior to, posterior to, or even between branches of the artery without a clear predilection (Table 2) [8–14]. In one series examining the recurrent laryngeal nerves of 50 cadaveric specimens (100 nerves), more than 20 different patterns are described [14].

Likewise, attempts have been made at defining relationships between the RLN and other structures along its path toward the larynx. The posterior suspensory (Berry's) ligament, the tubercle of Zuckerkandl, and the

Table 1
Anatomic relationship between recurrent laryngeal nerve, the trachea, and the esophagus

	Tracheoesophageal groove		Paratracheal	Other
Hunt (1968) [7]	Left	77%	22%	1%
	Right	65%	33%	2%
Skandalakis et al (1976) [8]	Left	56%	35%	9%
	Right	41%	49%	10%
Ardito et al (2004) [9]	Left	67%	31%	2%
	Right	61%	38%	1%

cartilaginous framework of the larynx itself have been examined as markers of the position of the RLN.

Not surprisingly, there is disagreement as to the exact relationship between the RLN and Berry's ligament. At least one series [15] found that the RLN passed dorsolateral to this ligament in 100% of cases (over 700 nerves were evaluated). The authors concluded that careful dissection along the capsule of the thyroid gland with separation of the adjacent tissues would assure preservation of the RLN. This should be interpreted with caution, as the RLN also has been found to traverse the ligament in up to 40% of patients and pass through the substance of the gland in up to 10% [8,16].

The tubercle of Zuckerkandl is an embryological remnant of the primordial thyroid that is present in 60% to 90% of adult glands [17]. The tubercle is actually a thickening of the gland located at its most posterolateral extent. These are found most commonly on the right-hand side and are thought to be constant landmarks for the identification of the RLN. The nerve is said to be in a position deep and medial to an enlarged tubercle approximately 95% of the time [17,18]. It has been argued that maintaining a dissection path superficial and lateral to the tubercle of Zuckerkandl will assure preservation of the nerve. Although this assertion may be valid, it should be remembered that a tubercle of Zuckerkandl may be absent or unrecognized in a significant number of patients. As such, it cannot be thought of as a reliable marker for the RLN.

Cartilaginous reference points tend to be more readily identifiable and have been promoted as dependable RLN localizers. Specifically, the RLN has been found to be in close apposition to the cricothyroid joint, in most cases ascending at a 15° to 45° angle [19]. Other geometric relationships between the distal RLN and the surrounding cartilaginous framework of the larynx have been established in cadaveric specimens and are said to be highly predictive of the nerve's position [20]. Detection of the RLN in this fashion, however, requires that a series of measurements be made intraoperatively. This may prove to be cumbersome and less accurate when applied to living patients. Although these approaches may facilitate nerve identification in a rapid and reliable manner, they necessitate that dissection be performed in a retrograde direction. Exposure of the RLN from distal to proximal ultimately may place it at an increased risk of injury. This is

Table 2
Position of the recurrent laryngeal nerve relative to the inferior thyroid artery

	Right recurrent laryngeal nerve (RLN)				Left RLN			
	Nerve anterior to ITA	Nerve posterior to ITA	Nerve between branches	Other	Nerve anterior to ITA	Nerve posterior to ITA	Nerve between branches	Other
Skandalakis, et al (1976) [8]	31%	20%	48%	1%	10%	64%	26%	—
Sturniolo, et al (1999) [11]	22%	31%	29%	18%	19%	37%	22%	22%
Page, et al (2002) [12]	67%	33%	—	—	11%	89%	—	—
Monafred, et al (2002) [13]	21%	28%	50%	1%	21%	50%	28%	1%
Ardito, et al (2004) [9]	12%	61%	27%	—	2%	77%	21%	—
Yalcxin, et al (2006) [14]	40%	34%	26%	—	23%	58%	19%	—

Abbreviation: ITA, inferior thyroid artery.

because extralaryngeal branching is a common occurrence [9,11,12,20,21]. Proximal arborization of the RLN has a reported incidence of 20% to 95%, and the branching patterns are predictably unpredictable. One or more of these branches may be sacrificed inadvertently in the event that the nerve being dissected is not the primary trunk.

Although imperfect, these anatomical relationships serve as valuable tools in the performance of a safe thyroidectomy. Even if a particular landmark was highly predictive of the RLN's position, its utility would be significantly limited in particular cases. Tissue planes may be obscured during revision surgery or following radiation therapy. Anatomy may be distorted as in the case of large goiters or inflammatory processes and carcinomas. Excessive bleeding may limit the surgeon's ability to recognize or use familiar landmarks. Inexperienced surgeons may not have adequate familiarity with the landmarks. These and a host of other reasons explain why even in the hands of a skillful and knowledgeable surgeon, iatrogenic RLN injury does indeed occur.

The recurrent laryngeal nerves at risk

As one discusses monitoring of the RLN, it is important to consider the true risk of iatrogenic injury. This is a difficult question to answer for two primary reasons. First: one must assume that the reporting of RLN injury rates is honest and accurate. There is an inherent risk of bias in any circumstance where complications are being reported, and thyroidectomy is no exception. Second: the definition of RLN injury is applied inconsistently throughout the literature. Much of the data pertaining to RLN injury is a reflection of subjective or observed changes in voice rather than objective assessment of vocal fold motion. Subjective voice complaints and observed hoarseness may not be predictive of a patient's findings on laryngoscopy. As postoperative laryngoscopic examination is not the rule for a great number of thyroid surgeons, the true incidence of RLN injury may be underestimated.

Based upon the existing body of literature, the rate of RLN injury is relatively low. Among patients undergoing thyroidectomy for any reason, the rate of temporary paresis ranges from less than 1% to approximately 6%, while the rates of permanent paralysis are anywhere from 0.05% to about 2.5% [9,11,22–29]. For those patients with thyroid carcinoma, temporary RLN injury occurs in approximately 0.7% to 4% of cases, while paralysis rates range from 1.6% to 10.6% [22–24,27,30]. Likewise, reoperative thyroid surgery carries an increased risk. RLN paresis is seen in up to 10.1% of cases, while permanent injury has been reported up to 8.1% of thyroidectomy patients [24,31–34].

The evolution of recurrent laryngeal nerve monitoring

Although his postoperative voice assessments were subjective rather than laryngoscopic, Lahey presented the first large series of patients with a rate of

RLN injury similar to what is seen today [4,5]. This is in stark contrast to predecessors such as Billroth, who reported a RLN injury rate of around 30% [2]. Much of Lahey's success in reducing the incidence was attributed to the active identification and preservation of the RLN during surgery. Numerous subsequent studies support this practice [24,35–37]. As a consequence, the following becomes the essential question regarding the use of a monitor during thyroidectomy: Can intraoperative monitoring improve a procedure with an already low rate of reported iatrogenic injury? Although the answer to this question continues to be debated (a subject to be discussed in the following sections), its pursuit most certainly has led to significant innovations and technological advances in the field of thyroid and parathyroid surgery.

Early technologies

The first use of technology in an attempt to reduce the risk to the RLN was published by Shedd and Durham [38] in 1965. They argued that despite having "knowledge of anatomy and careful surgical technique," the RLN still might be vulnerable to injury. They cited among the reasons for this vulnerability the presence of anomalous anatomy (ie, nonrecurrent nerves), extralaryngeal branching, displacement or involvement by pathologic processes, and a similar appearance of the nerve to other filamentous structures in the region. Recalling prior experience with intraoperative stimulation of the facial nerve during parotidectomy, an attempt was made at stimulating the RLN and recording a physiologic response. Although facial nerve function could be monitored by observing muscular twitches in response to electrical stimulation, the RLN required an indirect means of monitoring be used. As a result, the authors devised a balloon pressure transducer that was fitted to an endotracheal tube and subsequently placed at the level of the glottis. Initially used in a canine model, this method allowed for the successful identification and confirmation of the RLN. In a follow-up study [39] the technique was employed in people. Again the authors could record vocal cord motion reliably in response to electrical stimulation by pneumatic spirography. They concluded that the use of electrical identification of the RLN increases safety and feasibility of thyroidectomy, particularly in the presence of the aforementioned anatomic distortions. Subsequent authors [40,41] attempted to improve on Shedd's original model, but their success was limited by numerous design flaws. As a consequence, pneumatic monitoring of the vocal folds never gained widespread appeal.

Noting the difficulties experienced with the pneumatic balloon designs, Hvidegaard and colleagues [42] developed a device based upon the acoustic properties of an air column (ie, the trachea) with variable impedance. This instrument consisted of a sound oscillator that was placed into the trachea. The oscillator transmitted a pure tone frequency to a microphone positioned just above the vocal folds. This signal then was amplified and recorded by an external device. During RLN stimulation, the vocal folds close, thereby altering the impedance within the air column and hence, the output signal. Any change in the output signal during stimulation therefore could be interpreted as evidence of functionality of the RLN. Although the initial results were promising, the acoustic impedance monitor did not develop beyond the prototype stages.

These early devices paved the way for many of the electrophysiologic monitoring systems employed today, but the evolution was gradual. In the interim, much attention was given to vocal fold observation as a means of establishing the identity and integrity of the RLN.

Vocal fold visualization

Through his experience with [35] over 1700 thyroidectomies, Riddell noted a reduced risk of postoperative RLN paresis in those patients whose nerves had been identified and dissected deliberately. The author went on to describe a subpopulation of patients (132 patients with 200 nerves at risk) in whom the RLN not only was identified, but also electrically stimulated. Feeling that the glottic pressure transducer was unreliable, Riddell relied upon intraoperative direct laryngoscopy for confirmation of RLN integrity. There was no difference in the rates of RLN paresis between the cases in which it had been stimulated and those in which it simply had been identified. Despite this, the author called intraoperative RLN stimulation "an additional safety measure" that might assist with differentiating ectopic nerve from nearby non-nervous tissue. More importantly, he noted that stimulation, or the absence thereof, was helpful in preventing and identifying a possible bilateral paresis, something he called "an iatrogenic horror, a surgical tragedy, and a disaster likely to be followed by the misery of litigation."

Kratz [43] similarly advocated for vocal fold visualization (using a self-retaining rigid laryngoscope) during surgery as a means of monitoring the RLN. There are inherent limitations to this method, however, including draping, positioning, and a less than ideal view of the larynx and its motion secondary to the presence of an endotracheal tube. Technology has allowed some of these difficulties to be overcome. Premachandra and colleagues [44] described a technique in which intraoperative flexible laryngoscopy was used for this purpose. The flexible laryngoscope is a less cumbersome alternative to rigid laryngoscopy. Positioned beside the endotracheal tube in the hypopharynx, the fiberoptic scope can transmit an image to a video monitor, allowing the surgeon to continuously observe vocal fold motion while dissecting or stimulating the RLN. Again, the limitation in this technique is that an endotracheal tube passed through the glottis reduces the observer's ability to detect vocal fold motion.

The development of the laryngeal mask airway (LMA) in the early 1980's [45] presented an interesting solution to this problem. The LMA is positioned above the vocal folds and allows for positive pressure ventilation in the absence of endotracheal intubation. Tanigawa and colleagues [46] were the first to explore this device for thyroidectomy. Numerous other authors since have described their experience with the method [47–51]. The principal benefit of the LMA in this context is that there is not an endotracheal tube passing through the glottis. A bronchoscope delivered through the lumen of the LMA therefore offers a continuous and unobstructed view of vocal fold motion. Additional benefits of using the LMA for this purpose include relative simplicity of the setup, low capital cost of the monitoring system as compared with other devices, decreased postoperative throat pain, and the lack of instrumentation of the vocal cords, which may in and of itself lead to temporary dysphonia in the postoperative period.

Disadvantages to using the LMA are not necessarily unique to thyroid surgery. The principle concern is that of potential loss of control of the airway. Extrinsic compression, malpositioning of the LMA cuff, or laryngospasm may compromise the security of the airway [51–53]. Indeed up to 10% of patients undergoing thyroidectomy using this form of anesthesia ultimately required endotracheal intubation [47–49]. An additional concern is that of potential aspiration of gastric contents. Certain patients may be more prone to aspiration risk during LMA anesthesia, including those with gastroesophageal reflux disease (GERD), hiatal hernias, and those taking gastroparetic drugs [52–54]. The surgeon choosing to employ an LMA for monitoring purposes must be acutely aware of the potential risks and proceed to endotracheal intubation before issues arise. One creative means at circumventing the difficulties associated with the LMA method of RLN monitoring was presented by Hillerman and colleagues [55]. They proposed a double-intubation technique in which a small (5-0 microlaryngeal) endotracheal tube is passed as a means of securing the airway with simultaneous use of an LMA as a conduit for a flexible laryngoscope. The small-sized tube did not limit the motion of the vocal folds during stimulation. At the same time, it provided a more secure airway than the LMA alone. This and other methods employing laryngeal mask anesthesia have been successful in confirming the identity of the RLN and in predicting postoperative paresis. Many surgeons continue to use them today.

The desire to avoid additional instrumentation and equipment in the operating room has led to the consideration of less cumbersome and expensive approaches to observing vocal fold motion. Spahn and colleagues [56] used a 2 in needle (27 g) placed into the vocal folds through the cricothyroid membrane as a means to observe their movement during electrical stimulation of the RLN. This avoided the inherent difficulty in performing intraoperative laryngoscopy, the poor reliability of the pneumatic balloon, and the extra equipment and cost associated with laryngoscopy or electromyography (EMG).

Simple palpation of the posterior cricoarytenoid (PCA) muscle during stimulation of the RLN also has been promoted as an inexpensive and accurate means of confirming its identity and integrity [57]. Detection of vocal fold motion by this method has been compared with electromyography by Randolph and colleagues [58]. In nearly 500 patients studied, it was found that the stimulus required to elicit a palpable PCA twitch was nearly identical to that needed to evoke a suprathreshold EMG response. The author concluded that the presence of a palpable twitch at a stimulus of 1 mA or less was predictive of postoperative vocal fold motion. In the absence of such a twitch, it is suggested that any efforts at contralateral lobectomy be deferred pending a formal vocal fold evaluation. Given that palpation is not a continuous means of monitoring, this technique is advocated as an adjunct to formal intraoperative EMG.

Electromyographic methods

During the 1950s and 1960s, numerous authors experimented with EMG of the laryngeal muscles to evaluate their activity during respiration and phonation. In 1964, Nakamura [59] presented a series of experiments in dogs, whereby the larynx was dissected, and the laryngeal nerves were cut. These then were stimulated externally to demonstrate the motor functions simultaneous with EMG tracing. Flisberg and Lindholm [60] are credited with bringing this technique into the operating room in 1970.Their initial work involved placement of EMG recording needles through the cricothyroid membrane and into the vocalis muscle. Muscle action potentials in response to RLN stimulation were recorded successfully in 15 patients. Davis improved upon this design by taking the recording electrodes out of the operative field and inserting them laryngoscopically [61,62]. The Davis EMG system was an important advance for two principal reasons. First: it was an intralaryngeal device. The electrode was not in the operative field and was less likely to be displaced during dissection. Monitoring thereby could continue without interruption during the surgery. Second: the recording device was equipped with an audible alert. This helped to eliminate the immediate need for expertise in interpreting EMG, which was required by the Flisberg/Lindholm model. Successively smaller electrodes were designed and used for this purpose over the next 10 to 15 years [63–65]. Concurrently, the NIM-Response system (Medtronic Xomed, Jacksonville, Florida) was gaining popularity for facial nerve monitoring during parotidectomy. The availability of commercially prepared electrodes and monitoring equipment prompted a new interest in electromyographic monitoring during thyroidectomy. As Eisele [66] outlined, however, there were several limitations to be overcome. Electrode placement was skill- and time-dependent. The electrodes were small and easily displaced, and their replacement often delayed or prolonged surgery. Likewise, there was a potential risk of foreign body aspiration.

It was Rea [67] in 1992 who ushered in the modern era of RLN monitoring by adapting an existing postcricoid surface electrode for use during thyroidectomy. The electrode was designed by Payne and colleagues to evaluate the function of the PCA muscle during phonation and respiration [68,69]. The original device consisted of two electrodes on the anterior surface that contacted the PCA muscles and a posterior ground electrode that contacted the posterior hypopharyngeal wall. A long insertion handle was included in the design for ease of placement during laryngoscopy. Contraction of the PCA muscles in response to electrical stimulation of the RLN resulted in an audible tone on an EMG recording device. Postcricoid surface

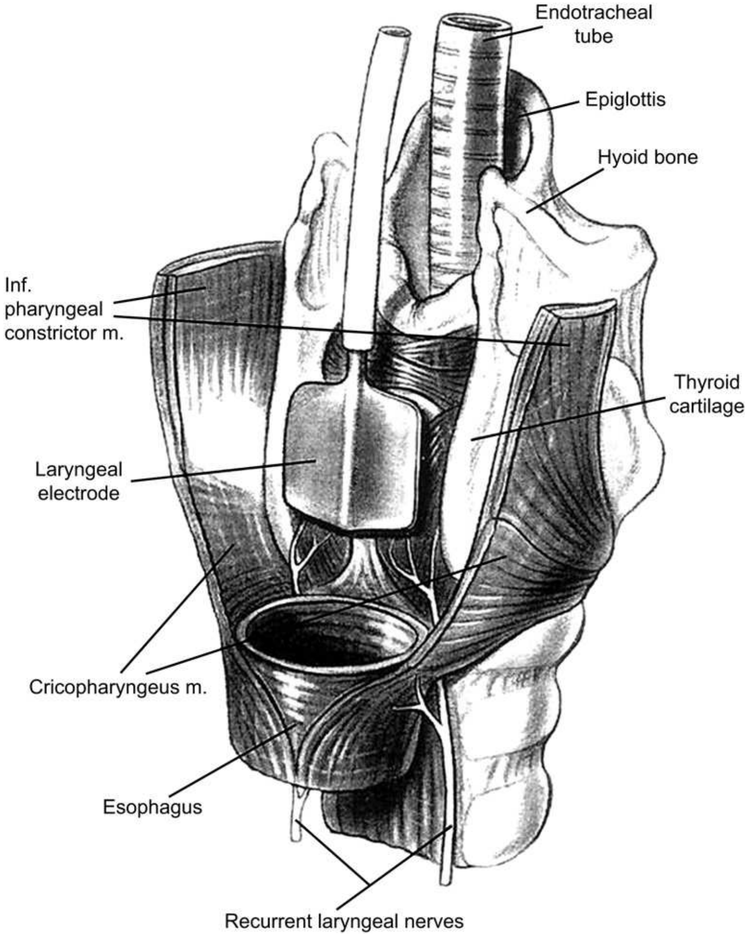

Fig. 3. Postcricoid surface laryngeal electrode. (*From* Rea JL, Khan A. Recurrent laryngeal nerve location in thyroidectomy and parathyroidectomy: use of an indwelling laryngeal surface electrode with evoked electromyography. Operative Techn Otolaryngol Head Neck Surg 1994;5:91–6; with permission.)

electrodes are now available commercially (RLN Systems, Incorporated, Jefferson City, Missouri) (Fig. 3).

Recording surface potentials from laryngeal musculature were not an entirely novel idea. In their paper describing laryngoscopically placed needle electrodes, Davis and colleagues [62] remarked that they also had experimented with an endolaryngeal surface electrode consisting of gold foil positioned on the endotracheal tube. EMG potentials were recorded successfully, but the authors found that it was difficult to maintain the position of the electrode during general anesthesia. This concept was revisited in the early 1990s and eventuated in the introduction of fully integrated electrode systems such as the NIM endotracheal tube (Fig. 4) [66,70]. Other endolaryngeal surface electrode types have been designed and validated for use during thyroid and parathyroid surgery [70–76]. Although a discussion of each such device's individual features and merits is beyond the scope of this article, most consist of electrode arrays that are affixed to standard endotracheal tubes, thereby obviating the need for and costs associated with any one particular company's monitor and equipment.

A few series have compared the broader categories of surface electrode monitors (ie, endolaryngeal and postcricoid types) [77,78]. Both types of monitoring system were helpful in identifying and confirming the RLN, and clear superiority of one type was not demonstrated in this regard. Several advantages and disadvantages of each were identified. The postcricoid electrode was found to be less expensive. It may be cut to size so that only one size needs to be stocked by an operating room. A distinct heartbeat artifact could be observed when this array was positioned properly in the postcricoid space, a reassuring finding to the surgeon. This electrode has the disadvantage that it must be placed by an individual familiar with postcricoid anatomy. In addition, it is highly sensitive to downward pressure, and as a result, artifactual EMG activity may be observed during dissection. Furthermore, extralaryngeal tumors potentially can impede proper positioning. The endolaryngeal type electrode was found to be inserted more easily. Proper positioning may be confirmed by either laryngoscopy

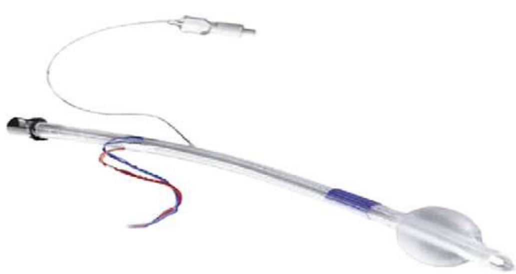

Fig. 4. NIM-II endotracheal tube with integrated electrodes. (*Courtesy of* Medtronic Xomed, Jacksonville, FL; with permission.)

(Fig. 5) or observation of electrode impedances (less than 10Ω is required; less than 1Ω is ideal). Unlike the postcricoid electrode, the endotracheal tube electrode receives input from each vocal fold individually and generates a higher amplitude EMG response for a given stimulus. Disadvantages include the need to stock multiple sizes, the increased cost associated with each disposable tube, and the inability to use the system in circumstances where modified tubes are needed (eg, double lung ventilation, laser surgery) [77].

Sensitivity and specificty of modern monitoring devices

Modern monitoring devices may be used to identify nerve from surrounding tissues, to provide feedback during dissection, to confirm the integrity of a dissected nerve, or any combination thereof. These instruments are designed to record baseline and evoked EMG (eEMG) potentials elicited by dissection or stimulating electrodes for this purpose. But is the absence of an eEMG the sine qua non of vocal fold paresis, and vice versa? To answer this question, one must consider the sensitivity, specificity, and predictive values of monitoring. Sensitivity refers to the ability of monitoring to detect a paralyzed nerve (ie, it is the number of electrically paralyzed nerves as a percentage of the true number [as observed by laryngoscopy] of paralyzed nerves). Tests with high false-negative rates will have a low sensitivity. False negatives suggest neural integrity when in fact it has been compromised. They may result from stimulation distal to an injury or scatter effect to the vocalis muscle from monopolar electrodes [79,80].

Specificity refers to the number of electrically intact nerves as a percentage of those with normal vocal fold motion. Any circumstance in which the false-positive rate is increased (ie, situations in which a functional nerve fails to generate an eEMG when stimulated) can reduce the specificity of the test. Dislodged grounding wires, misplaced electrodes, inadequate

Fig. 5. Proper positioning of the endotracheal electrodes may be confirmed by direct laryngoscopy.

stimulus amplitude, and elevated event threshold voltage settings on the EMG recorder may have this effect. Other potential confounders include temporary neurapraxia, the presence of anesthetic muscle relaxant, or a pseudocholinesterase deficiency [79,80]. Positive predictive value is the probability that in the absence of an eEMG, a patient truly has a vocal fold paresis. Negative predictive value, on the other hand, is the probability that in the presence of an eEMG (or the palpated equivalent), the vocal folds will be mobile.

Several authors have examined evoked stimulation of the RLN as a predictor of postoperative vocal fold motion. Most have found that monitoring possesses a high specificity and negative predictive value [80,81], whereas the sensitivity and positive predictive values are low [81–87]. The message here is that patients who have electromyographically normal nerves are likely to be laryngoscopically normal. Conversely, if a nerve appears to be compromised by eEMG, there is still a greater than 50% probability that the patient will have normal vocal fold motion.

The rationale for and data regarding recurrent laryngeal nerve monitoring

Nerve monitoring

To this point, the anatomy of the recurrent laryngeal nerve has been described; the rates of iatrogenic injury have been presented; the evolution of intraoperative identification and monitoring has been chronicled, and the validity of evoked vocal fold potentials has been characterized. From all of this, it is clear that although complex and potentially capricious in its course toward the larynx, the RLN may be exposed safely and dissected during thyroidectomy with minimal risk of permanent damage. Indeed exposure of the nerve has been shown to reduce this risk [4,5,35,37]. Its identity may be reliably confirmed and its function monitored by numerous methods that involve electrical stimulation and observation of an evoked electromyographic or physical response within the larynx.

This begs the fundamental question regarding RLN monitoring. If identification of the nerve allows for the preservation of its function, does it not follow that any means by which the precise location and identity of the nerve could be confirmed readily might also aid in preserving function?

Several arguments can be made to support a role for monitoring during thyroidectomy. First, identification does not translate necessarily to functional integrity. Eliciting an evoked vocal fold response provides confirmation that the anatomically preserved nerve is also electrophysiologically intact. This in turn may dictate plans for second-side surgery, particularly in the rare circumstance of a patient who presents with a pre-existing vocal fold paresis on the contralateral side. As mentioned previously, there are a host of variables that may lead to unanticipated changes in the expected anatomy of the RLN. The use of continuous, real-time monitoring with audible alerts also provides immediate feedback regarding surgical technique. Gentle and meticulous dissection is in no way assured by an alarming nerve monitor, but it may signal to the surgeon a need to alter his or her current course of action. This may be particularly helpful for resident training purposes [66,88–90].

Potential disadvantages of routine RLN monitoring include the additional costs associated with monitoring equipment, additional setup time at the beginning of surgery, and the potential for false negative EMG [66,88,89,91,92]. In this circumstance, the surgeon mistakenly might sacrifice the RLN based upon its erroneous lack of response to a suprathreshold stimulus. Also worrisome is the theoretical risk of inducing paresis by repeatedly stimulating the RLN [93]. Although not unique to thyroidectomy, one final concern is that surgeons simply will rely upon technology as a means of protecting the RLN rather than using sound anatomical knowledge and careful technique. Indeed the fear that the availability of new technologies and devices will supplant the application of reason and clinical judgment is pervasive throughout medicine today.

Despite the number of arguments in favor of and opposed to RLN monitoring (and the passion with which these positions are held), the collective body of literature has failed to conclusively support or refute its routine use in this regard. Indeed only a handful of reports directly compare the outcomes in between monitored and unmonitored cases. In a 2001 study, Brennan remarked that the rates of RLN paresis observed among 96 monitored nerves at risk compared favorably with historical controls that had undergone appropriate postoperative laryngeal examination [92]. Although this study lacks widespread applicability and is limited by methological flaws, it represents the first attempt at an objective comparison of outcomes between monitored and nonmonitored patients. Subsequent reports were more rigorous in their scientific method and examined increasingly larger patient populations. Robertson and colleagues [94] published a retrospective study that compared RLN injury rates among 116 monitored nerves at risk and an unmatched control group of 120 unmonitored nerves at risk. Although the rates of paralysis and paresis were found to be lower in the monitored group, the differences were not statistically significant. The authors noted that with a larger sample size, more robust differences may very well have been observed.

With this in mind, a multi-institutional prospective trial was undertaken to compare the rates of transient and permanent RLN paralysis among monitored and unmonitored patients with benign goiter [90]. Across 7133 nerves at risk, the rates of transient and permanent RLN palsy were lower for those cases in which monitoring had been employed. These results were highly statistically significant. In a follow-up to this study, Dralle and colleagues [95] analyzed the outcomes of nearly 30,000 nerves at risk. Comparisons were made between cases in which the nerve had not been identified, those in which it had been identified, and those in which it had been identified and monitored. When compared with thyroidectomy without nerve identification, there was a significant difference in paralysis rates favoring visual identification of the RLN, either with or without the addition of a nerve monitor. When comparing neuromonitoring to simple visual identification of the RLN, there was no added benefit. Other significant risk factors for postoperative RLN paralysis included surgical volume (less than 45 nerves at risk per surgeon or less than 275 nerves at risk per hospital annually). Subgroup analysis of patients who had only benign or malignant thyroid disease did not disclose a benefit to monitoring.

Chan similarly found no difference in the incidence of RLN paresis or paralysis when comparing 501 monitored and 499 unmonitored (identified by routine visualization only) nerves [86]. On subgroup analysis, however, monitoring was associated with a reduction in the postoperative paresis/paralysis rate for patients undergoing secondary thyroidectomy. This finding is in contrast to a Mayo Clinic study from 2004 [96]. In it, 52 patients undergoing cervical re-exploration with continuous monitoring for pathology related to a primary thyroid or parathyroid disorder were compared with 59 matched unmonitored controls (151 nerves at risk). The rates of permanent RLN injury were nearly identical (1.4 versus 1.3%, favoring the unmonitored group). The authors felt that monitoring added substantial cost while providing no apparent clinical benefit. Table 3 presents the pertinent findings of the previously mentioned reports.

One of the principal difficulties in substantiating any claim of efficacy rests in the fact that the incidence of thyroidectomy-associated RLN paresis and paralysis is exceedingly low. Given the low prevalence, the amount of statistical power necessary to demonstrate a difference in outcomes attributable to nerve monitoring alone would exceed what is practical for most investigators. This is particularly true, because thyroidectomy is performed for numerous clinically distinct indications, each with differing rates of associated RLN injury. Beldi and colleagues [81] noted that a homogeneous population of over 21,000 nerves at risk would be needed to discern a difference in risk attributable to monitoring alone. Dralle and colleagues [95] further illustrates this point, noting that among patients with thyroid carcinoma, a population of over 39,000 nerves at risk would need to be examined. For benign multinodular goiter, they estimated that this number exceeds nine million. Even more conservative estimates of these numbers exceed the total number of thyroidectomies that many surgeons will perform during their career!

Medicolegal implications

It has been shown that 30% to 50% of endocrine malpractice litigation involves thyroid and parathyroid surgery. Of these, 70% to 90% pertain

Table 3
Rates of temporary and permanent laryngeal nerve paresis in the presence or absence of intraoperative monitoring

		Temporary paresis			Permanent paresis			
Study	Nerve at risk	Electromyography (EMG)	None	*p*	EMG	None	*p*	Additional risk factors
Thomusch et al (2001) [90]	7133 (benign goiter)	1.4%	2.1%	< 0.008	0.4%	0.8%	< 0.004	—
Robertson et al (2004) [94]	236	3.45	4.35	NS	0.86	0.62	NS	Advanced T stage
Dralle et al (2004) [95]	29,998	—	—	—	0.21–5.65	0.0–4.74	NS	Absence of nerve identification, low-volume surgeons/hospitals
Yarbrough et al (2004) [96]	151 (reoperative)	12.5%	10.1%	NS	1.4%	1.3%	NS	—
Chan et al (2006) [86]	1000	3.4	4.0	NS	0.8%	1.2	NS	Absence of monitoring in reoperative cases

Additional independent predictors of postoperative paresis are noted for their respective studies.

to RLN injury, with bilateral paresis accounting for nearly 30% of the cases. In the end, only about one in three judgments is in favor of the defendant [97,98]. So despite the lack of clear-cut evidence in support of or against the routine use of RLN monitors for thyroidectomy, there will be ongoing medicolegal questions about the role of this technology in current practice. In an era of evidence-based medicine, do the existing data support RLN monitoring as a standard of care? The answer to this question is not simple and necessitates an understanding of a few basic principles.

The first is the concept of standard of care. This is a legal rather than a medical term. It refers to the level at which the average, prudent provider in a given community would practice. More simply, it is what a similarly qualified physician would have done to manage a given patient under a similar set of circumstances. Moreover, standard of care is an acceptable minimum that may or may not be supported by evidence-based medicine. Malpractice implies that an established standard of care has been breached [99].

One can appreciate therefore the difficulty in defining neuromonitoring of the RLN as a standard of care. Variability in the diseases treated with thyroidectomy, in the experience of the surgeons, and in the patients themselves makes it difficult to apply a standard to thyroidectomy. Additionally, there is variability in the usage patterns of monitoring technology. Although some surgeons only use the monitor as a means to confirm the identity of a visualized nerve, others dissect it completely, stimulating only at the completion of the operation to confirm integrity. Still others may probe the thyroid bed freely in an attempt to electrically uncover the location of the nerve. It is difficult to define a standard of care when there is not a universally accepted method of using the monitor.

It is interesting that in nearly every article written on the subject of nerve monitoring for the thyroid, regardless of the author's conclusions, time is taken to include a sentence or two stating something akin to the following: "Despite any real or perceived benefits of nerve monitoring, it cannot replace experience, sound clinical judgment, and technical skill and should therefore not be considered the standard of care." Each author has crafted these words carefully as to lay the groundwork for his or her own defense or the defense of a physician peer. Going just so far, but not defining it as a gold standard, brings about the concept of best clinical practice.

Contrasted to the standard of care, best clinical practice is a medical term that is qualitative and fluid. It is physician- and circumstance-specific and takes into account one's background and training, knowledge, and experience. Best clinical practice also may be influenced by the severity and complexity of the disease being treated, regulatory bodies, third-party payers, and other outside forces. Implicit in the definition is that a specific physician at a particular time and place is providing the best possible care for a specific patient under a given set of circumstances. Best clinical practice may or may not coincide with what is considered to be the standard of care [99].

A report by Sosa and colleagues [100] sheds some light on this concept. The authors explored the relationship between surgeon experience and outcomes in thyroidectomy in a statewide cross-sectional analysis. They found that the highest volume had the fewest complications (including RLN injury) and the shortest length of stay, even though they were treating the most complicated patients. Similar observations were made by Dralle and colleagues [95].

By the best clinical practice model, one might argue that the expertise of these surgeons might obviate the need to use nerve monitoring. Conversely, less experienced surgeons may be more apt to be assisted by the use of a monitor. Although the issue is certainly more complex than can be described in these few paragraphs, it behooves endocrine surgeons to maintain best clinical practice based on their own experience and results as well as supporting ongoing clinical research in RLN monitoring.

Summary

The recurrent laryngeal nerve is complex and is often in harm's way when performing a thyroidectomy. Visualizing and dissecting the recurrent laryngeal nerve are tantamount to performing a safe thyroid operation. In an attempt to increase the margin of safety, numerous monitoring devices have been developed that are now readily available, of high specificity, and that provide high negative predictive value in confirming the integrity of the RLN. At the same time, data regarding their efficacy in limiting or preventing injury to the nerve are inconclusive. And although it may indeed represent the best clinical practice for a given surgeon to use neuromonitoring for thyroidectomy, it does not necessarily represent the standard of care. In cases where monitors are used, they should be used judiciously and interpreted cautiously. Use of such devices cannot and should not supplant clinical judgment, anatomic knowledge, and meticulous technique.

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