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Recurrent Laryngeal Nerve Palsy after Anterior Cervical Spine Surgery

The Impact of Endotracheal Tube Cuff Deflation, Reinflation, and Pressure Adjustment

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Background: **Vocal fold immobility (paresis or paralysis) from recurrent laryngeal nerve injury remains an important cause of morbidity after anterior cervical spine surgery. A maneuver involving endotracheal tube (ETT) cuff manipulation has been proposed to reduce its incidence. This study is a randomized, prospective, double-blind investigation to test the hypothesis that ETT cuff manipulation reduces the incidence of postoperative vocal fold immobility after anterior cervical spine surgery.**

Methods: **One hundred patients scheduled to undergo anterior cervical spine surgery were randomly assigned to one of two groups. After inducing general endotracheal anesthesia, patients in the intervention group had their ETT cuff pressures maintained at 20 mmHg or less. After placement of self-retaining retractors, the ETT cuff was deflated for 5 s and then reinflated. Patients in the control group had no further manipulation of their ETT once the cuff was inflated after intubation. Cuff pressures in both groups were recorded before skin incision (baseline) and after placement of self-retaining retractors (peak). Patients' vocal fold motion was evaluated by indirect laryngoscopy performed preoperatively and postoperatively. The examination was videotaped and reviewed by a blinded otolaryngologist. Postoperative vocal fold motion was graded as normal, paretic, or paralyzed.**

Results: **Complete data were available in 94 patients. The incidence of vocal fold paralysis was 3.2% (95% confidence interval, 0.7–9.4%). Cuff manipulation decreased ETT cuff pressure but did not reduce the incidence of vocal fold immobility (15.4% *vs.* 14.5%).**

Conclusion: **Endotracheal tube cuff deflation/reinflation and pressure adjustment do not reduce the incidence of vocal fold immobility in anterior cervical spine surgery.**

VOCAL fold dysfunction remains an important cause of postoperative morbidity after anterior cervical spine surgery (ACSS).[1] It is thought to be the result of intraoperative recurrent laryngeal nerve (RLN) trauma, the precise nature of which is debated. Apfelbaum *et al.*[1] suggest that injury is the result of nerve compression. They argue that the tube is tethered proximally at its point of fixation to the face and distally by its inflated cuff. Insertion of the surgical retractor causes a marked lateral bowing of the tube, which they demonstrated radiographically in fresh cadavers. Presumably, any structures caught between the tube and the retractor are compressed. Deflating the cuff for a few seconds lessens its curvature and allows its shaft to migrate away from the tracheal wall. In this way, compression of any intervening tissue is alleviated. Endotracheal tube (ETT) cuff deflation and reinflation thus became one step in a two-part maneuver designed to reduce nerve compression and prevent injury.[1] The second step required cuff pressure regulation, to avoid direct nerve compression by an unrecognized and overinflated, high-riding cuff.[2,3] The efficacy of the maneuver was validated by demonstrating a decrease in the incidence of vocal fold paralysis from its historic norm,[1] after implementing the maneuver.

An alternate view of the pathogenesis of vocal fold dysfunction proposes that the nerve is stretched[4,5] as the self-retaining surgical retractor is opened during exposure. Excessive stretch disrupts blood flow in the vasa nervorum,[6] resulting in an ischemic injury.

Because of the retrospective nature of the study by Apfelbaum *et al.* and because it made no allowances for changes in surgical practice between historic controls and later cases, it seemed prudent to repeat the study in a prospective and randomized fashion. The primary objective of this study was to determine the impact of ETT cuff manipulation on the incidence of vocal fold dysfunction. We reasoned that RLN trauma would present with a spectrum of vocal fold immobility (VFI) ranging from paresis in its mildest form to complete paralysis in its most severe. We hypothesized that the cuff deflation–reinflation and pressure adjustment maneuver as described by Apfelbaum *et al.* would reduce the incidence of postoperative VFI as determined by videolaryngoscopic examination. We proposed to compare the incidence of new VFI in patients for whom intervention was instituted with control patients receiving "standard of care." Secondary objectives included identifying the role of factors such as site of surgery (right *vs.* left), duration of procedure, and splay of retractors on the incidence of VFI.

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Materials and Methods

The study was approved by the institutional review board of Jefferson Medical College, Philadelphia, Pennsylvania. Written informed consent was obtained from all subjects. All patients were scheduled to undergo ACSS at a university hospital with a busy spine practice. Patients were excluded for any one of the following: (1) preoperative vocal fold dysfunction; (2) previous neck surgery; (3) symptomatic gastroesophageal reflux; (4) planned fiberoptic intubation, rapid sequence induction, or postoperative mechanical ventilation.

On the morning of surgery, each patient was randomly assigned by coin toss into either a control or an intervention group. After minimal sedation, a preoperative nasopharyngolaryngoscopy and examination of the vocal folds was performed in all patients by an otolaryngologist. The examination was recorded onto a videotape for later viewing.

The patients were then transferred to the operating room, where general anesthesia was induced with a combination of propofol and fentanyl. Succinylcholine (1–1.5 mg/kg) or rocuronium (0.5 mg/kg) was used to facilitate tracheal intubation. A skilled laryngoscopist with more than 2 yr of experience secured an atraumatic intubation using a size 7.0 ETT (Mallinckrodt, St. Louis, MO) for women and size 7.5 for men. Intubation was performed only if the laryngeal inlet could be visualized after no more than two attempts. Midtracheal positioning of the ETT was confirmed by cuff ballottement in the suprasternal notch.[7,8] The ETT was secured to the angle of the mouth contralateral to the side of the proposed incision. To facilitate somatosensory and transcranial motor evoked potential monitoring, anesthesia was maintained with an infusion of propofol and either remifentanil or sufentanil. After the initial dose, no more neuromuscular blocking drug was administered. Nitrous oxide was not used. At the conclusion of surgery, residual neuromuscular blockade was reversed in patients who demonstrated fade with tetanus of 50 Hz. Patients were extubated in the operating room and transferred to the recovery room. Nasopharyngolaryngoscopy was repeated 1–2 h after extubation, before discharge from the recovery room.

Endotracheal Tube Manipulation

For patients in the control arm of the study, the anesthesia provider was instructed to "manage the endotracheal tube as you normally would if the patient were not in a study." All providers insufflated the ETT cuff with enough air to prevent a leak. They then palpated the pilot balloon and released some air if they felt that it was overinflated. After the provider was satisfied, the pressure in the pilot balloon was measured by research personnel and recorded as "baseline." Besides measuring the cuff pressure, no further manipulation was performed until the cuff was deflated, before extubation.

For patients in the intervention arm, the ETT was insufflated using the "just seal" method as follows: With the ETT cuff deflated, positive pressure (20–25 cm H_2O) was generated in the breathing circuit while listening for an air leak around the ETT. The cuff was then insufflated with air until the leak was obliterated. The pressure in the cuff was measured and recorded. If it exceeded 20 mmHg, then some air was removed, but only if a seal could still be maintained. Therefore, all efforts were made to keep the pressure at 20 mmHg or less. In a few patients, a seal could only be achieved with pressures that exceeded 20 mmHg. Whatever minimum pressure that was required to prevent a leak was recorded as the "baseline" pressure. After placement of the retractor, the ETT cuff was completely deflated for 5 s and then reinflated in the manner described above. In either group, the cuff pressure after retractor placement was considered the "peak" cuff pressure. Cuff pressure monitoring was achieved using a modified invasive blood pressure transducer setup.[9,10]

Examination of Vocal Folds

An attending otolaryngologist, who was blinded to the randomization, reviewed the videotapes of the examination. Vocal fold motion (abduction, adduction and bowing) was graded as "normal," "paretic" (movement present but decreased from baseline examination), or "paralyzed" (no movement). VFI was defined as either paresis or paralysis.

Additional data that were collected included patient demographics, medical history, surgical time (skin incision to last stitch), retractor time (retractor in to retractor out), operative procedure, and retractor splay (the distance between the retractor blades in the depth of the surgical wound, as determined by the surgeon, using calipers).

Statistical Analysis

At the time of study design, the incidence of VFI was unknown. Unpublished data from clinical notes of an otolaryngologist at our institution (Dr. D. Zwillenberg, 1994–1996) indicated a range between 20% and 30%. We therefore estimated an incidence of 25% and considered any intervention that could decrease it to 5% as clinically significant. A sample size of 49 per group was required ($\alpha = 0.05$, $\beta = 0.2$) We planned to recruit an initial cohort of 100 patients and revise the sample size upward, if necessary, based on the determined incidence of VFI. We have decided to publish the findings of this initial phase because we believe they have important implications.

Data are reported as mean ± SD unless otherwise stated. The Student *t* test was used for comparing categorical data, and the chi-square test was used for comparing frequencies. $P < 0.05$ was considered statistically significant.

Table 1. Distribution of Demographics and Other Data between Control and Intervention Groups

	Control	Intervention
Sex, male/female	26/13 (67%/33%)	28/27 (49%/51%)
Age, yr	48 ± 10.5	46 ± 11.1
Height, cm	172.7 ± 9.4	170.1 ± 9.1
Weight, kg	88.0 ± 20.0	83.9 ± 19.5
Incision site, left/right	35/4	48/7
Duration of surgery, min	151 ± 58	139 ± 50
Retractor time, min	82 ± 51	82 ± 40
Pressure, mmHg		
Baseline	50 ± 49*	18 ± 14*
Peak	61 ± 47*	18 ± 13*
Splay, cm	2.9 ± 0.7	2.8 ± 0.5
Paralysis	1 (2.6%)	2 (3.6%)
Paresis	5 (12.8%)	6 (10.9%)
Paresis/paralysis	6 (15.4%)	8 (14.5%)

* $P < 0.001$.

Results

Of the 100 patients recruited, complete data were acquired for 94 and are summarized in table 1. There were 39 patients in the control and 55 in the intervention group. The asymmetry in group size was the result of the mode of randomization. There was a greater male preponderance in the control group than intervention group. Average baseline and peak ETT cuff pressures were higher in control patients than in those who received intervention. Otherwise, the groups were similar with respect to demographics, incision site (right *vs.* left), surgical and retractor times, and splay of retractor blades (table 1). The groups were also similar with respect to type and level of surgery (data not shown). There were 14 patients with VFI (11 paresis and 3 paralysis), making the incidence 14.9% (95% confidence interval, 9.0–23.6%). The incidence of VFI was similar between control and intervention groups (15.4% and 14.5%). The demographics of the 14 patients with VFI were similar to those of the remaining patients (table 2). Surgical and retractor times, baseline and peak pressures, and splay of the retractor blades did not differ between patients with and those without VFI.

Table 2. Comparison between Normal Patients and Those with Vocal Fold Immobility

	Normal	Injured
Sex, male/female	45/35	9/5
Age, yr	47 ± 11	49 ± 9
Height, cm	172.7 ± 9.4	170.1 ± 9.7
Weight, kg	84.8 ± 20.9	89.4 ± 14.5
Incision, left/right	72/8	11/3
Duration of surgery, min	141 ± 53	165 ± 65
Retractor time, min	80 ± 41	100 ± 60
Pressure, mmHg		
Baseline	33 ± 39	28 ± 26
Peak	37 ± 40	35 ± 30
Splay, cm	2.8 ± 0.6	3.1 ± 0.5

$P > 0.05$ for all data.

The incidence of paralysis *per se* for the study population was 3.2% (95% confidence interval, 0.7–9.4%). Three of the 11 patients operated from the right side developed VF paralysis (27%), compared with none of the 83 patients (0%) who had a left-sided approach. The average surgical and retractor times for these 3 patients were 173 and 263 min, respectively, *versus* 80 and 141 min for the rest of the study population.

Discussion

Until recently, most studies that attempted to define the incidence of VFI after ACSS were retrospective reviews. Investigators used clinical criteria (hoarseness and dysphagia[11]) to identify patients with possible laryngeal dysfunction. Visual laryngoscopy (when performed) was only performed in symptomatic patients.[1,5,12–15] Because only one third of patients with vocal fold dysfunction are symptomatic,[16] these studies tend to underestimate the actual incidence. Not surprisingly, the combined incidence of paresis and paralysis in our study exceeds those reported in previous retrospective series.[1,13] In a recent prospective study, Jung *et al.*[16] performed indirect laryngoscopy on 120 patients before and a few days after ACSS. The incidence of paralysis and paresis in that series was 24%. All patients in that study had right-sided incisions, which may have contributed to the higher incidence observed.

The incidence of paralysis in our series was much less than that reported by Jung *et al.*[16] (3% *vs.* 20.8%). In Jung's series, all exposures were right sided. By contrast, surgeons in our practice performed, almost exclusively, either right- or left-sided approaches, depending on their training and personal preference. The paralysis rate for our right-sided procedures compares closely with the overall paralysis rate reported by Jung *et al.* This apparent predilection for vocal fold paralysis after a right-sided approach has previously been documented.[1,4] Surgeons, the majority of whom were right hand dominant, found the right-sided approach technically easier and so operated from that side more frequently.[1,15,17] The preponderance of right-sided events was presumed to be a function of the frequent use of that approach. But there are also anatomical differences between the RLN on the right and left[18] that may result in a greater propensity of right-sided injury. The right RLN is shorter and travels up the neck in a more oblique angle than its left counterpart. It has less redundancy and lies outside the tracheoesophageal groove for most of its course. Consequently, it is more susceptible to retractor-mediated stretch injury.[4,5,18] Our observations corroborate, but by no means prove, this viewpoint; and if indeed vocal fold dysfunction is the result of RLN stretch, it would explain the ineffectiveness of cuff manipulation in mitigating injury. But this study was not designed to answer the question

of laterality. Other confounding variables, such as differences in surgical expertise or complexity of cases, could account for our observations. Further prospective studies are required to clarify the role of laterality. Notwithstanding, as a result of this data, some surgeons involved in this study who previously favored a right-sided approach have now switched to a left-sided approach.

Our findings agree with observations by others suggesting that ETT cuff insufflation using the just seal method prevents overinflation (> 20 mmHg).[9] This might explain the high prevalence of cuff overinflation in control patients. Before this study, our standard of care entailed the use of digital palpation to estimate cuff pressures. This technique is inaccurate and results in cuff overinflation,[19] which can lead to tracheal mucosal ischemia and postoperative sore throat.[20] As a consequence of these findings, we are revising our institutional practice.

Although cuff manipulation successfully prevented its overinflation, it did not decrease the incidence of VFI. There are a number of possible explanations. The intervention may indeed have been unhelpful. The rationale for cuff manipulation presupposes a nerve compression injury mechanism. If the actual mechanism were *via* nerve stretch, the maneuver would be ineffective. Admittedly, we would need to enroll 140 patients in each arm to ensure an adequately powered study (because the actual incidence of VFI we detected is far less than we had initially estimated). The viability of this enterprise in the absence of even a slight trend toward improvement is questionable. A second point worth noting is the difference in endpoints. In the study by Apfelbaum *et al.*, they looked at paralysis. Duplicating this study would have required a prohibitively large number of patients. To reduce the number of enrollments necessary, we chose to test the efficacy of intervention on VFI (paresis or paralysis). Although unlikely, it is conceivable that the intervention was only effective for paralysis but not paresis, and thus we could not demonstrate any impact on VFI.

Our study was limited in that we did not perform follow-up examinations and thus cannot comment on the long-term outcome after VFI. In the study by Jung *et al.*, the combined incidence of paralysis and paresis decreased from 24% in the immediate postoperative period to 13% at 3 months.[16] In one retrospective series, 80% of injuries had resolved without specific intervention, by 1 yr.[15] Vocal fold dysfunction, it seems, eventually resolves in most instances without specific intervention.

In conclusion, the incidence of VFI (paresis and paralysis) after ACSS is 15%. The incidence of paralysis is 3%. ETT cuff deflation, reinflation, and pressure adjustment did not reduce the incidence of VFI after ACSS. There was no trend toward protection of vocal fold function in those who received intervention. This suggests that the mechanism of VFI might be unrelated to nerve compression by the ETT.

There may be a greater risk of VF paralysis after a right-sided approach. Further studies are needed to confirm this.

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