



Published in final edited form as:

ORL J Otorhinolaryngol Relat Spec. 2013 ; 75(2): 68–73. doi:10.1159/000345501.

Comparison of ventilation and voice outcomes between unilateral laryngeal pacing and unilateral cordotomy for the treatment of bilateral vocal fold paralysis

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Abstract

Background/Aims—Rehabilitation of the bilaterally paralyzed human larynx remains a complex clinical problem. Conventional treatment generally involves surgical enlargement of the compromised airway, but often with resultant dysphonia and risk of aspiration. In this retrospective study, we compared one such treatment, posterior cordotomy, against unilateral laryngeal pacing: reanimation of vocal fold opening by functional electrical stimulation of the posterior cricoarytenoid muscle.

Methods—Post-operative peak inspiratory flow (PIF) values and overall voice grade ratings were compared between the two surgical groups, and pre and post-operative PIF were compared within the pacing group.

Results—There were five patients in the unilateral pacing group and 12 patients in the unilateral cordotomy group. Within the pacing group, post-operative PIF values were significantly improved from pre-operative PIF values ($p=0.04$) without significant effect on voice (grade) ($p=0.62$). Within the pacing group, the mean post-operative PIF value was significantly higher than that in the cordotomy group ($p=0.05$). Also, the mean post-operative overall voice grade values in the pacing group were significantly lower (better) than that of cordotomy group ($p=0.03$).

Conclusion—Unilateral pacing appears to be an effective and superior treatment to posterior cordotomy with respect to post-operative ventilation and voice outcome measures.

Keywords

Ventilation

INTRODUCTION

Despite recent advances in otolaryngology, rehabilitation of the paralyzed larynx remains a complex clinical problem. Unilateral vocal fold paralysis is more common than bilateral vocal fold paralysis (BVFP), yet the exact incidence of BVFP is unknown in the current literature. Etiologies of vocal fold paralysis include iatrogenic injury during thyroid, neck, and thoracic surgery, intubation, trauma, neurologic disorders, and extralaryngeal

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Conflicts of interest: None

malignancies [1]. While normal ventilation and voice can be relatively spared with only one vocal fold paralyzed, reduction of airway area in BVFP can be life-threatening.

The recurrent laryngeal nerve carries motor fibers that innervate the abductor [posterior cricoarytenoid (PCA)] muscle of the vocal folds. Damage to bilateral nerves compromises this “opening” function and arrests the vocal folds in a near-closed position. Both voice and airway are affected, and airway compromise is often severe enough to warrant tracheotomy to relieve inspiratory stridor and dyspnea [2–4]. If immobility is permanent and the patient suffers from a large degree of airway compromise, a tracheotomy may be necessary for the patient to avoid living with a tenuous and limited airway. Although permanent tracheostomy provides the best possible airway from a size standpoint, complications include tracheal stenosis, chronic infection, and psychosocial impairment [5–7]. For this reason, laryngeal surgery is offered to enlarge the airway and improve breathing through the mouth or nose.

Surgical treatment options for BVFP include temporizing, reversible treatments and/or permanent treatments. Reversible treatment options include the previously mentioned tracheostomy, endo-extralaryngeal suture lateralization as popularized by Lichtenberger and Toohill [8], or laryngeal botox injection in carefully selected cases [9]. Long-term, permanent surgical solutions include endoscopic laser arytenoidectomy [10], endoscopic partial arytenoidectomy [11], arytenoid abduction [12, 13], posterior cordotomy [9], and laryngeal selective reinnervation [15–18]. A number of the new techniques appear to be promising: arytenoid abduction has been performed urgently in patients in place of a tracheostomy with dramatic airway improvement [13]. As well, selective reinnervation for BVFP has been described in animal [16, 19] and cadaver models [20], yet human studies are sparse due to the variability and complexity of the nerve supply and the procedure [17]. However, Marie JP does describe successfully performed selective reinnervation in 12 human patients with BVFP and noted improvement in patient dyspnea [18].

Endoscopic arytenoidectomy, and more commonly, posterior cordotomy, are currently regarded as the standard of care for surgically enlarging the airway in the setting of BVFP. The posterior cordotomy procedure was the preferred surgical treatment for BVFP by 91% of fellowship-trained laryngologists in a recent survey [21], and at our institution, it was the most commonly performed treatment for BVFP during the study period. However, both arytenoidectomy and cordotomy have inherent limitations [22–25]: vibratory characteristics of the operated vocal fold are permanently altered, and thus patients often complain of a weak, breathy, and easily fatigued voice [22]. Scarring and granulation tissue can occur at the site, especially in repeat procedures, further worsening voice quality and potentially re-narrowing the surgically improved airway [14]. Such limitations have prompted investigation into the previously mentioned novel techniques, and what we believe provides a more physiologic, dynamic approach to laryngeal rehabilitation: reanimation of the paralyzed vocal fold by functional electrical stimulation of the PCA muscle.

In 1996, our lab performed the first successful human implantation of a laryngeal pacing device that involved direct electrical stimulation of one of the PCA muscles in patients with BVFP. This approach has been termed “unilateral pacing” [26]. The electrodes were connected to a neurostimulator device that provided stimulation of the PCA during the inspiratory phase of respiration to abduct the vocal fold. During non-inspiratory phases, stimulation ceased and the vocal fold passively relaxed to the midline to allow for normal voice production and airway protection. Subsequent studies culminated in results from six human subjects that demonstrated the safety and efficacy of laryngeal pacing, with restoration of a functional airway through the mouth or nose.

The aim of this study was to retrospectively compare measurements of pulmonary function and voice quality between patients with bilateral vocal fold paralysis treated with unilateral vocal fold pacing and the current approach of cordotomy.

METHODS

A retrospective chart review was carried out after approval from the Institutional Review Board at Vanderbilt University Medical Center. Records were obtained from five unilateral pacing patients, implanted between 1995 and 1997. Specific data extracted from the charts included pulmonary function tests with peak inspiratory flow rate (PIF), and overall voice grade ratings of voice quality obtained from electronic recordings of patients reading the Rainbow Passage. The records of cordotomy patients treated between 2009 and 2010 were reviewed, and the same pulmonary function data and overall voice grade ratings of audio clips of each patient reading the Rainbow Passage [27] were analyzed. Due to the retrospective design of this study, the time from surgical intervention to ventilation and voice testing varied across patients.

Pulmonary Function Tests

Pulmonary function assessment was performed by trained technicians in the Department of Pulmonary Medicine at Vanderbilt University (SensorMedics, model 2200). Both pre- and post-operative results were collected for pacing patients, and postoperative results for cordotomy patients. The volume and rate of air exchange was measured during a maximum forced expiration followed by a maximum forced inspiration. Peak Inspiratory Flow (PIF) was measured through the mouth with the patient's nose and tracheostomy site (if any) occluded. For pacing patients, ventilatory measures were made with the neurostimulator device on. The PIF value taken from the inspiratory phase of the flow-volume loop was considered the critical indicator of glottal resistance to inspiratory flow [26]. The Spirometry software automatically calculated "Best PIF" after each patient performed 3–4 volume loops, and this value was used for each calculation.

Voice Assessment

All available previously recorded digital audio-taped voice samples of each patient reading the standardized Rainbow passage were collected from the charts of both pacing and cordotomy patients. These were de-identified and randomly ordered into an audio-only compilation of all patients' audio clips, with three clips entered twice to establish inter-rater reliability. The compiled audio clips were presented to three trained speech-language pathologists who served as perceptual judges and were blinded to treatment group assignment. Subjective perceptions of changes in voice quality were rated according to overall voice grade of on a 4-point scale from 0 (normal) to 3 (severe). The lower the overall grade score, the better the quality of voice.

Statistical analysis was performed using SPSS (Version 20, IBM Corp. Armonk, NY, USA) and Matlab (R2010b, The MathWorks Inc. Natick, MA, USA). A non-parametric "permutation test" was performed on PIF values and the perceptual voice score rating compared between the two treatment groups. One-tailed tests had significance set at $p < 0.05$. Good inter-rater agreement was shown for three blinded reviewers on overall voice grade ratings (Fleiss's Kappa=0.53). Assessment on test-retest reliability showed good intra-rater consistency (Cronbach's Alpha=0.71).

RESULTS

A total of 17 patients were included. There were five pacing patients, ranging in age from 41–77 years with a mean age of 63.4 (SD=14.4). Twelve cordotomy patients were included, ranging in age from 44–72 years, with a mean age of 57.6 (SD=10.0). The majority of patients (94%) were females. No significant difference was found between the two groups in age or gender. Overall results are detailed in Tables 1 and 2.

Mean post-operative PIF for pacing patients was 1.60 L/sec (SD=0.38), which was significantly higher ($p=0.05$) than the mean post-operative PIF for cordotomy patients (Mean=1.19L/sec, SD=0.47). Pre-operative PIF information was available for the 5 pacing patients. Comparison between pre-operative and post-operative PIF values in pacing patients showed significant improvement in PIF (0.54 ± 0.58 versus 1.60 ± 0.38 , $p=0.04$) as previously reported [26].

Post-operatively, the mean outcome grade score from 0–3 for the pacing group was 1.40 (SD=0.55), which was significantly lower ($p=0.03$) than the mean grade score for the cordotomy group (2.25, SD=0.79). In essence, overall voice quality outcome was notably better in the pacing patients than in the cordotomy patients. Pre-operative grade information was available for the pacing patients. Comparison between pre-operative and post-operative grade values in pacing patients showed no significant change ($p=0.60$) as previously reported [28].

DISCUSSION

Cordotomy is a minimally invasive, often one-step endoscopic laser procedure but the term can represent multiple surgical approaches including posterior [14] and transverse techniques [29]. The goals of treatment are improvement in airway patency through the glottis and thus improved ventilation, maximal allowable preservation of voice, and minimization of post-operative scarring and granulation tissue formation. Studies have attempted to quantify and qualify the benefits of cordotomy, particularly with focus on ventilation, voice quality, quality of life, and aspiration. Available data is relatively sparse, yet the majority of studies conclude that after cordotomy, spirometry values, mean airflow, and subglottic pressures improve from preoperative values, yet voice is generally worsened or at least, unchanged [22–25, 30–32]. Anecdotally, although not often quantified, many physicians note altered voice in post-cordotomy patients consequent to necessary alteration of vocal fold vibration. Therefore, cordotomy improves ventilation and can provide a stable airway, yet it permanently alters voice and potentially causes granulation tissue formation with scarring at the incision site [30, 33, 34].

Our results indicate unilateral pacing is better than cordotomy regarding ventilation post-operatively. We selected to use PIF as our main correlate of ventilation, since it is a good index of the mean inspiratory airflow and rate of gas exchange in the lung. During inspiration, negative intrapulmonary pressures create suction forces on the glottis, and increase the resistance to airflow due to the Bernoulli effect and turbulence. Thus inspiratory flow, rather than expiratory flow, is the rate-limiting step in determining the ventilation of the lung [26]. In turn, the magnitude of PIF governs the level of metabolic expenditure and gives an index of the patient activity that can be tolerated. Comparison of post-operative PIF between the two groups revealed significantly higher PIF values in the unilateral pacing group compared to cordotomy patients. While we recognize many factors affect airflow dynamics in a surgical airway [35], our presented results are reasonable given that in the pacing procedure, full cord abduction is restored to one half of the patient's glottis. This

varies from the cordotomy procedure in which airflow is minimally increased by creating a graduated opening in a vocal fold.

For the purposes of our retrospective study, PIF was selected as a consistent, objective measure of ventilation. A future prospective investigation should include measurement of additional components of spirometry such as forced expiratory volume at 1 second (FEV₁), FEV₁/FVC ratio, and forced vital capacity (FVC). Additionally, future analysis would benefit from inclusion of decannulation rates, exercise tolerance quantification, quality of life tools such as a patient-reported dyspnea scale, and patient satisfaction ratings [14, 30, 32, 34].

Our results show a better voice outcome after pacing over cordotomy. Ratings of pre- and post-operative voice quality were unchanged in the unilateral pacing group. This was to be expected, since the integrity of the vibrating vocal fold is left intact with pacing intervention, and thus voice is preserved. Unfortunately, due to the retrospective design of our study, post-intervention data points were not standardized, yet research has shown that voice outcomes after cordotomy can improve over time, with some results not appreciable until 6 or more months after surgery [30]. Therefore, prospective studies warrant standardized post-operative time points for finer analysis. Additionally, while performed blinded in this study, overall voice grade is a subjective measure of voice now considered somewhat “outdated” compared to the newer rating system: Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V) [36]. Therefore, CAPE-V and more objective measures such as harmonic to noise ratio (HNR), maximum phonation time (MPT), and maximum and minimum vocal intensities, could be considered for future studies. Lastly, patients’ subjective report of voice quality was not measured in the current study, but use of the Voice Handicap Index [37] or quality of life measurements [38] would lend further insight into voice outcomes.

These findings represent the first published comparison between unilateral laryngeal pacing and cordotomy for patients with BVFP. Our study demonstrated unilateral pacing to be an effective means of treatment, superior to cordotomy with respect to outcome measures of ventilation and voice.

Acknowledgments

Financial support or funding: David Zelear has received NIH Grants R01-DC001149 and R01-DC008429 to support this research.

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Table 1

Outcomes of BVFP patients treated by unilateral laryngeal pacing

Patient No.	1	2	3	4	5	Mean±SD
Sex	F	F	F	F	F	
Age	64	41	75	60	77	63.4±14.4
Pre-op PIF (L/s)	0.00	0.60	0.70	1.39	0.00	0.54±0.58
Post-op PIF (L/s)	1.81	0.92	1.70	1.71	1.85	1.60±0.38
Pre-op Grade#	2.00	1.00	2.00	0.00	1.00	1.20±0.84
Post-op Grade#	1.00	1.00	2.00	1.00	2.00	1.40±0.55

#Grade: A number from 0 (normal) to 3 (severe) to describe overall voice quality

Table 2

Outcomes of BVFP patients treated by cordotomy

Patient No.	1	2	3	4	5	6	7	8	9	10	11	12	Mean±SD
Sex	F	F	F	F	F	F	F	F	F	F	F	M	
Age	45	72	53	52	61	65	73	44	62	48	52	64	57.6±10.0
Post-op PIF (L/s)	0.94	0.71	0.53	0.65	1.34	1.78	1.25	1.33	1.68	0.82	1.98	1.25	1.19±0.47
Post-op Grade	2.00	2.67	3.00	3.00	3.00	1.00	1.00	1.67	3.00	2.00	1.67	3.00	2.25±0.79