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Practice variations in voice treatment selection following vocal fold mucosal resection

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Abstract

Objective—To characterize initial voice treatment selection following vocal fold mucosal resection in a Medicare population.

Study Design—Retrospective analysis of a large, nationally-representative Medicare claims database.

Methods—Patients with >12 months of continuous Medicare coverage who underwent a leukoplakia- or cancer-related vocal fold mucosal resection (index) procedure during calendar years 2004–2009 were studied. The primary outcome of interest was receipt of initial voice treatment (thyroplasty, vocal fold injection, or speech therapy) following the index procedure. We evaluated the cumulative incidence of each post-index treatment type treating the other treatment types as competing risks, and further evaluated post-index treatment utilization using the proportional hazards model for the subdistribution of a competing risk. Patient age, sex and Medicaid eligibility were used as predictors.

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Results—2041 patients underwent 2427 index procedures during the study period. An initial voice treatment event was identified in 14% of cases. Women were significantly less likely to receive surgical or behavioral treatment compared to men. From age 65–75 years, the likelihood of undergoing surgical treatment increased significantly with each 5-year age increase; after age 75 years, the likelihood of undergoing either surgical or behavioral treatment decreased significantly every 5 years. Patients with low socioeconomic status were significantly less likely to undergo speech therapy.

Conclusions—The majority of Medicare patients do not undergo voice treatment following vocal fold mucosal resection. Further, the treatments analyzed here appear disproportionately utilized based on patient sex, age and socioeconomic status. Additional research is needed to determine whether these observations reflect clinically explainable differences or disparities in care.

Level of Evidence—2c

Keywords

dysphonia; Medicare; practice patterns; speech therapy; thyroplasty; vocal fold injection; voice therapy

INTRODUCTION

Vocal fold injury frequently results in dysphonia and, in cases of extensive, repeated, or chronic mucosal insult, can lead to fibrosis, profound voice impairment, and significant voice-related handicap.^{1–6} Such damage can be caused by chronic inflammation, trauma, radiation or surgery; the primary cause of vocal fold mucosal damage and fibrosis is iatrogenic injury resulting from surgical resection of benign and malignant disease.⁷

There are a wide array of surgical and behavioral approaches to improving voice function in patients with persistent dysphonia following vocal fold mucosal resection.^{8–22} Although both surgical and behavioral interventions have demonstrated clinical benefit,^{9,23–26} neither approach fully addresses the combination of volumetric loss, medial edge contour deficiency, and fibrosis that can occur following mucosal resection. As a result, complete voice recovery is unlikely;^{7,27} many patients continue to present with residual dysphonia and voice handicap despite having undergone treatment.²⁸ This challenge has spurred significant preclinical research interest over the past 15 years and a number of promising biomaterial and molecular therapies are currently under investigation.^{29–31} Until these next-generation therapies are translated into practice, however, providers need to care for this patient population using currently available tools. To date, there are no randomized controlled trials investigating the treatment of dysphonia resulting from vocal fold mucosal resection and few multi-arm treatment studies exist.²⁸ As a result, despite the significance of this problem, there are limited data on the relative efficacy of current treatments, creating a substantial knowledge gap.

Given the lack of strong clinical evidence for any particular voice treatment, we herein evaluated practice patterns for initial voice treatment following mucosal resection, including utilization and predictors of treatment choice. We specifically studied Medicare beneficiaries

because typical indicators for a substantial mucosal resection, such as recalcitrant vocal fold leukoplakia or cancer, show increased prevalence with increased age;³² therefore, they are presumably identified most often in this population. Our assessment of treatment selection focused on medialization thyroplasty, vocal fold injection and behavioral speech therapy – three mainstay voice treatments with robust procedure codes and widespread adoption at the national level. Improved understanding of these practice patterns may inform targeted improvements in care and help facilitate the effective translation of emerging therapies.

METHODS

Dataset and Cohort

In this retrospective analysis, patients who had undergone vocal fold mucosal resection and were continuously enrolled in Medicare from 2004 to 2009 were identified in the Center for Medicare and Medicaid Services (CMS) National Chronic Condition Warehouse dataset (CCW; <http://www.ccwdata.org>). The CCW is a 5% random sample of US Medicare beneficiaries that contains de-identified full claims data. We examined 5 years of continuous claims data to obtain a sufficient cohort size for statistical query. As there is currently no ICD-9-CM diagnostic code for vocal fold fibrosis or scarring, we designed proxy inclusion criteria whereby patients were required to have had a surgical procedure known to result in clinically significant vocal fold mucosal volumetric loss, fibrosis, and glottal incompetence.^{33–35} We focused on the following procedures: (i) partial laryngectomy with a resection margin that included the vocal fold mucosa (HCPCS 31375, 31380, 31382; ICD-9-CM 30.2, 30.29, 30.1, 30.22), and (ii) direct laryngoscopy with vocal fold stripping (HCPCS 31540, 31541; ICD-9-CM 30.09) when coded alongside a vocal fold leukoplakia or cancer diagnosis (ICD-9-CM 161.0, 161.2, 161.8, 161.9, 231.0, 478.5). These specific procedure-diagnosis combinations, collectively referred to as the index procedure in this study, were implemented to capture surgical procedures with sufficiently sized resection margins to result in a high likelihood of dysphonia.^{33,34,36,37} Dysphonia itself (ICD-9-CM 784.40, 784.41, 784.42, 784.49) was not used as an inclusion criterion as surgeons typically code for the primary laryngeal pathology at the time of resection, rather than the functional voice deficit. To ensure that we did not miss relevant claims processed by alternate insurers, patients were excluded if they had coverage under the Railroad Retirement Benefits Program (<http://www.rrb.gov>) at any time during the study period, or coverage under a Medicare Health Maintenance Organization (HMO) plan during the 12-month period following the index procedure.

Unit of Analysis

An initial data query showed that 264 of 2041 patients in the cohort (13%) underwent multiple index procedures during the five-year study period. We therefore implemented an event-based (rather than patient-based) analysis strategy (Fig. 1) in order to capture every opportunity for voice intervention following a given index procedure. Each index procedure and subsequent post-index voice treatment formed the basic unit for analysis. The analytical dataset creation process is described in detail in Online Supporting Information (Supplementary Methods; Table SI, SII; Fig. S1).

Patient and Institutional Variables

We collected and analyzed the following patient and institutional variables as predictors of post-index treatment events: age, sex, history of Medicaid eligibility (used as a proxy for socioeconomic status),³⁸ area of residence as determined by the Rural-Urban Commuting Area codes (RUCA; <http://www.ers.usda.gov>), duration of pre-index Medicare coverage, and distance between the patient's home and the index hospital location (based on zip code centroids). Additional variables of clinical interest were history of radiation to the head and neck, history of dysphagia or aspiration pneumonia, and total laryngectomy or death during the study period.

Outcome Variables

The primary outcome of interest in this study was receipt of initial voice treatment (thyroplasty, vocal fold injection or speech therapy) following vocal fold mucosal resection (index). These three treatment event types were defined as: medialization thyroplasty (HCPCS 31588), vocal fold injection (HCPCS 31570, 31571, 31513; ICD-9-CM 31.0) and speech therapy (HCPCS 92507, 92508; ICD-9-CM V.57.3). Individual post-index treatment events were linked to the occurrence of an immediately preceding index event and were counted as viable provided one or more of the following censoring events had not yet occurred: a subsequent index procedure, total laryngectomy, death, or end of data (Fig. 1B).

Statistical Analysis

Cohort characteristics were summarized using descriptive statistics. The duration to each post-index event was calculated from the date of immediately preceding index hospitalization discharge and reported in days. For simplicity and clarity of interpretation, we focused on the timing and type (thyroplasty, vocal fold injection or speech therapy) of the first (initial) post-index event, and based analysis on the cumulative incidence of each event type, treating the other event types as competing risks. For example, the cumulative incidence of speech therapy was defined as the proportion of patients, as a function of time, who had speech therapy as their first post-index treatment. The sum of the cumulative incidences for speech therapy and each surgical procedure therefore represented the cumulative incidence of any post-index treatment, again as a function of time. Cumulative incidence and 95% confidence intervals (CI) for survival data whose endpoints are subject to competing risks were calculated using the SAS %CIF macro.³⁹ To assess the predictive association of patient and institutional variables, post-index utilization of surgery and speech therapy treatments was further evaluated by the proportional hazards model for the subdistribution of a competing risk.⁴⁰ Surgery events thyroplasty and vocal fold injection were pooled in these competing risks hazard models to obtain an adequate sample size for evaluating four predictors. Patient age, sex and Medicaid eligibility were used as predictors. Age was expressed in units of 5 years using a linear spline with a knot at 75 years, allowing for a different age slope before 75 years compared to after 75 years. Follow-up logistic regression analyses (with the same predictors) were then used to predict thyroplasty versus vocal fold injection utilization within the subgroup of patients receiving surgery as their first post-index treatment.

RESULTS

Cohort and Index Procedure Characteristics

The study cohort was comprised of 2041 patients who underwent a total of 2427 vocal fold mucosal resection (index) procedures during calendar years 2005–2009 (Table I). Mean age was 70 years; 63% of patients were male. Sixty-two percent of patients lived in an urban area and 22% had a history of Medicaid eligibility, used as a proxy for low socioeconomic status. Mean distance from the patient's home to the index hospital, based on zip code centroids, was 42 miles. The most commonly performed index procedure was direct laryngoscopy with stripping (95% of all index procedures, uniformly coded in combination with a vocal fold leukoplakia or cancer diagnosis). A small number of patients (representing <1% of initial treatment events) underwent multiple index procedures during a single hospitalization. The mean duration of pre-index Medicare coverage was 869 days.

The majority of patients in the cohort (1777, 87%) underwent a single index procedure during the study period; 264 patients (13%) underwent 2–9 index procedures and were therefore represented by multiple analytic units in our event-based analysis.

Initial Treatment Events

The median duration from index procedure hospitalization discharge to treatment event or no-treatment censoring event was 715 days (Table I). Of 296 initial treatment events, 55 were surgery (26 thyroplasty, 29 vocal fold injection) and 241 were speech therapy; 2131 index procedures were followed by no treatment during the study period. At the time of initial treatment, 29% of patients had a documented history of dysphagia and/or aspiration pneumonia and 3% had a documented history of radiation treatment to the head and neck. No patients with a positive radiation history underwent surgery. Of the 2131 no-treatment (censoring) events, 34 were total laryngectomy, 408 were death, and 1689 represented the end of follow-up.

The cumulative incidences of any initial treatment event at 1 and 3 years post-index were 10 and 14%, respectively (Table II; Fig. 2). The majority of these treatment events were speech therapy encounters; 57% of all speech therapy encounters occurred within 6 months of the index procedure. The cumulative incidences of surgery as an initial treatment event were 2 and 3% at 1 and 3 years, respectively. Approximately half (56%) of all initial surgeries (whether thyroplasty or vocal fold injection) were performed during the same hospitalization as the index procedure.

Competing risks hazard modeling showed that female patients were only 59% as likely to receive speech therapy ($P < .001$), and 53% as likely to receive surgery ($P = .047$), compared to male patients, after controlling for age and Medicaid eligibility (Table III). Between ages 65 and 74 years, patients were 55% more likely to undergo surgery with each 5-year age increase, whereas for those 75 years and above the likelihood of having surgery decreased by 39% every 5 years ($P = .003$). Patients with a history of Medicaid eligibility were only 65% as likely to receive speech therapy compared to patients with no such history ($P = .024$); a positive Medicaid history did not predict the likelihood of undergoing surgery ($P = 0.571$).

Follow-up logistic regression modeling of assignment of the 55 surgery patients to thyroplasty versus vocal fold injection showed no significant differences based on sex, age, or Medicaid eligibility parameters ($P > .05$; Table IV).

DISCUSSION

In this study, we used a nationally-representative Medicare claims dataset and focused on a cohort of patients who underwent vocal fold resections that were sufficiently extensive to result in clinical-grade dysphonia. Our primary research goal was to analyze provider practice patterns when selecting an initial voice treatment following such a resection procedure. To our knowledge, this analysis represents the first application of a nationally-representative claims dataset to characterizing outcomes in this clinical population. Notably, despite targeting patients with presumed sufficiently sized resection margins to result in clinically significant mucosal loss, fibrosis and impaired vocal function,^{33–35} we observed a cumulative incidence of any initial voice treatment event at 3 years post-index of just 14%. This finding suggests that a large number of Medicare patients with post-resection dysphonia do not receive voice-focused care, presumably due to: (i) limited clinical indication (or contraindication), (ii) limited patient interest, or (iii) limited treatment access. Additional work is needed to fully characterize this issue, develop standard-of-care guidelines for this population, and (if needed) enhance treatment availability at the national level.

Cohort Characteristics

Our study cohort was predominantly male (63%), consistent with previously reported prevalence data for laryngeal cancer in the United States,^{32,41,42} and included a subset of patients with a positive history of dysphagia or aspiration pneumonia (29%), as well as a subset of patients with a positive history of radiation to the head and neck (3%). While our study design precluded statistical evaluation of treatment assignment based on these medical comorbidities (due to patients being followed for varying durations and therefore having varying opportunities for comorbidity accumulation), it is interesting to note that patients with a potential dysphagia or aspiration pneumonia risk represented 40% of all surgical cases, compared with 31% of all speech therapy cases and 29% of no-treatment cases. This observation is consistent with standard clinical practice algorithms, in that patients with concomitant dysphonia and dysphagia (an especially common outcome following partial laryngectomy)^{43,44} are strong candidates for surgical medialization, given the quality-of-life and mortality risks associated with aspiration pneumonia, especially beyond age 65 years.⁴⁵

Low Incidence of Post-Resection Treatment Events

As noted above, the majority of the 2427 index procedures were not followed by a voice treatment event during the study period. This low treatment incidence might be due to one or more of the following factors. First, given that the majority of patients entered our cohort via an index procedure that was coded alongside a vocal fold leukoplakia or cancer diagnosis, it is possible that the primary focus of care during the post-index period was on cancer surveillance rather than voice restoration. This is particularly likely in the 13% of patients who underwent multiple index procedures (suggestive of recurrent disease) as well as the

1% of index procedures that were followed by total laryngectomy. Certain patients in this situation may have been solely focused on their cancer management and had no interest in subsequent voice treatment, despite residual dysphonia. Second, as our analysis was performed on a nationally-representative sample, a subset of patients in our cohort likely had limited access to subspecialty laryngology or speech-language pathology care. Due to the nature of our claims data, it is unknown what proportion of index procedures were performed by a general otolaryngologist compared to a fellowship-trained laryngologist for whom thyroplasty and vocal fold injection procedures would be routine. Third, while our practice pattern analysis was focused on thyroplasty, vocal fold injection and speech therapy – three mainstay voice treatments with robust procedure codes – some post-resection patients with dysphonia may have been treated with alternate approaches that were not captured by our HCPCS and ICD-9-CM-based coding criteria. Laryngology remains a code-poor subspecialty; consequently, many recently introduced treatments are billed using nonspecific procedure codes. Fourth, despite carefully designed inclusion criteria, we were unable to precisely control for differences in surgical technique or extent of resection. Therefore, certain patients in our cohort may have experienced favorable post-resection voice outcomes with no need for subsequent voice treatment, perhaps due to the use of lamina propria preserving techniques such as ultra-narrow margin resection.^{34,46}

Demographic Differences in Treatment Utilization

Our competing risks hazard models identified several demographic differences in post-resection voice treatment utilization. First, compared to males, female patients were significantly less likely to receive either surgical or behavioral treatment. This difference might, in part, be explained by sex-based differences in initial disease severity. Our claims dataset did not include tumor staging data; however, it is well documented that males have a higher incidence of head and neck (and specifically, laryngeal) cancer^{32,41,42} and are less likely to engage in health screenings or see a physician on a regular basis.^{47,48} If the males in our cohort exhibited more advanced vocal fold leukoplakia or cancer at the time of initial presentation and consequently required more extensive mucosal resection, they may have experienced more severe dysphonia and therefore undergone voice treatment at a higher rate.

Second, the likelihood of patients undergoing surgical treatment increased progressively (and significantly) with increasing age until 75 years, and then decreased with increasing age beyond 75 years. No such effect was observed for speech therapy. Similar to the effect for males discussed above, this finding is consistent with an increase in primary disease burden with increasing age,^{32,41} potentially driving the need for more extensive mucosal resection followed by more aggressive (i.e., surgical, as opposed to behavioral) follow-up voice treatment. The reversal of this effect beyond age 75 years may reflect reduced utilization of surgery due to the risks associated with increased accumulation of medical comorbidities.^{49,50}

Third, patients with a history of Medicaid eligibility (our proxy for low socioeconomic status) were significantly less likely to receive speech therapy than patients with no such history. This effect was not observed for surgery. A possible explanation for this effect is that, despite being covered by Medicare (no patients in the cohort had sole Medicaid

coverage at any time during the study period), speech therapy is underutilized by certain patients: committing to a multi-visit course of behavioral treatment may be more challenging for patients with limited economic resources.

Limitations

This study holds a number of limitations. It is important to note that the CCW dataset is sampled from Medicare claims, which are not generated for research purposes. As a result, although our cohort size is large compared to the majority of prospective clinical studies in the voice literature, our inclusion criteria, index and treatment procedure definitions are dependent on the specificity of the HCPCS and ICD-9-CM coding systems, as well as the accuracy of the claims submitted by the providers. Such limitations are evident in our use of: (i) procedure codes for partial laryngectomy and vocal fold stripping in lieu of an available diagnostic code for vocal fold fibrosis, even though these procedures cover a range of clinical scenarios (e.g., a non-specialist surgeon might resect a benign lesion without using a microflap, using codes CPT 31540/31541 and ICD-9-CM 478.5); (ii) procedure codes for vocal fold injection despite the fact that their clinical use encompasses a variety of biomaterials, pharmaceuticals such as steroids, and biologics such as botulinum toxin (HCPCS J-codes for injectable drugs were inconsistently available in our dataset; however, we confirmed that no patients had a diagnostic code for laryngeal dystonia during the study period); and (iii) procedure codes for speech therapy even though they include behavioral treatment of a range of communication and auditory processing disorders (we confirmed that all patients who received speech therapy had a diagnostic code for dysphonia, typically concurrent with the therapy encounter but occasionally preceding it).

Finally, to maximize our cohort size, we discarded the common practice of following patients for a predetermined period prior to the index event to capture comorbidity profiles. This tradeoff meant that we were unable to statistically evaluate the impact of medical comorbidities on treatment utilization in our population sample.

CONCLUSIONS

Our analysis suggests that the majority of Medicare patients do not undergo surgical or behavioral voice treatment following vocal fold mucosal resection. Of those patients who do undergo treatment, most initially participate in speech therapy. Treatment utilization appears to vary as function of patient sex, age and socioeconomic status: additional research is needed to determine whether these observations reflect clinically explainable differences or disparities in care, and to definitively characterize the factors that drive them. Our findings, based on claims data, may be augmented by complementary analyses using medical records review, prospective clinical studies, and the inclusion of patient-centered outcomes measurement.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Hirano M, Tanaka S, Yoshida T, Hibi S. Sulcus vocalis: functional aspects. *Ann Otol Rhinol Laryngol*. 1990; 99:679–683. [PubMed: 2396804]
2. Thibeault SL, Gray SD, Bless DM, Chan RW, Ford CN. Histologic and rheologic characterization of vocal fold scarring. *J Voice*. 2002; 16:96–104. [PubMed: 12002893]
3. Rousseau B, Hirano S, Scheidt TD, et al. Characterization of vocal fold scarring in a canine model. *Laryngoscope*. 2003; 113:620–627. [PubMed: 12671417]
4. Welham NV, Dailey SH, Ford CN, Bless DM. Voice handicap evaluation of patients with pathologic sulcus vocalis. *Ann Otol Rhinol Laryngol*. 2007; 116:411–417. [PubMed: 17672242]
5. Welham NV, Montequin DW, Tateya I, Tateya T, Choi SH, Bless DM. A rat excised larynx model of vocal fold scar. *J Speech Lang Hear Res*. 2009; 52:1008–1020. [PubMed: 19641079]
6. Hirano S, Minamiguchi S, Yamashita M, Ohno T, Kanemaru S, Kitamura M. Histologic characterization of human scarred vocal folds. *J Voice*. 2009; 23:399–407. [PubMed: 18395421]
7. Benninger MS, Alessi D, Archer S, et al. Vocal fold scarring: current concepts and management. *Otolaryngol Head Neck Surg*. 1996; 115:474–482. [PubMed: 8903451]
8. Koufman JA, Isaacson G. Laryngoplastic phonosurgery. *Otolaryngol Clin North Am*. 1991; 24:1151–1177. [PubMed: 1754218]
9. Zeitels SM, Mauri M, Dailey SH. Medialization laryngoplasty with Gore-Tex for voice restoration secondary to glottal incompetence: Indications and observations. *Ann Otol Rhinol Laryngol*. 2003; 112:180–184. [PubMed: 12597293]
10. Dailey SH, Ford CN. Surgical management of sulcus vocalis and vocal fold scarring. *Otolaryngol Clin North Am*. 2006; 39:23–42. [PubMed: 16469653]
11. Pontes P, Behlau M. Treatment of sulcus vocalis: auditory perceptual and acoustical analysis of the slicing mucosa surgical technique. *J Voice*. 1993; 7:365–376. [PubMed: 8293069]
12. Mortensen M, Woo P. Office steroid injections of the larynx. *Laryngoscope*. 2006; 116:1735–1739. [PubMed: 17003727]
13. Sataloff RT, Spiegel JR, Hawkshaw M, Rosen DC, Heuer RJ. Autologous fat implantation for vocal fold scar: a preliminary report. *J Voice*. 1997; 11:238–246. [PubMed: 9181548]
14. Hsiung MW, Woo P, Minasian A, Schaefer Mojica J. Fat augmentation for glottic insufficiency. *Laryngoscope*. 2000; 110:1026–1033. [PubMed: 10852525]
15. Neuenschwander MC, Sataloff RT, Abaza MM, Hawkshaw MJ, Reiter D, Spiegel JR. Management of vocal fold scar with autologous fat implantation: Perceptual results. *J Voice*. 2001; 15:295–304. [PubMed: 11411484]
16. Hsiung MW, Kang BH, Pai L, Su WF, Lin YH. Combination of fascia transplantation and fat injection into the vocal fold for sulcus vocalis: Long-term results. *Ann Otol Rhinol Laryngol*. 2004; 113:359–366. [PubMed: 15174762]
17. Pinto JA, da Silva Freitas MLA, Carpes AF, Zimath P, Marquis V, Godoy L. Autologous grafts for treatment of vocal sulcus and atrophy. *Otolaryngol Head Neck Surg*. 2007; 137:785–791. [PubMed: 17967647]
18. Dailey SH, Gunderson M, Chan R, Torrealba J, Kimura M, Welham NV. Local vascularized flaps for augmentation of reinke's space. *Laryngoscope*. 2011; 121(suppl 3):S37–S60. [PubMed: 21271606]

19. Mortensen MM, Woo P, Ivey C, Thompson C, Carroll L, Altman K. The use of the pulse dye laser in the treatment of vocal fold scar: a preliminary study. *Laryngoscope*. 2008; 118:1884–1888. [PubMed: 18641533]
20. Lieberman, J. Principles and techniques of manual therapy: applications in the management of dysphonia. In: Harris, T.; Harris, S.; Rubin, J.; Howard, D., editors. *Voice Clinic Hand Book*. London: Whurr; 1998. p. 91-138.
21. Verdolini, K. Resonant Voice Therapy. In: Stemple, JC., editor. *Voice Therapy: Clinical Case Studies*. 2. San Diego: Singular Publishing Group; 2000. p. 46-61.
22. Titze IR. Voice training and therapy with a semi-occluded vocal tract: rationale and scientific underpinnings. *J Speech Lang Hear Res*. 2006; 49:448–459. [PubMed: 16671856]
23. Ford CN, Bless DM, Loftus JM. Role of injectable collagen in the treatment of glottic insufficiency: A study of 119 patients. *Ann Otol Rhinol Laryngol*. 1992; 101:237–247. [PubMed: 1543333]
24. Woo P, Casper J, Colton R, Brewer D. Diagnosis and treatment of persistent dysphonia after laryngeal surgery: a retrospective analysis of 62 patients. *Laryngoscope*. 1994; 104:1084–1091. [PubMed: 8072354]
25. Björck G, D'Agata L, Hertegård S. Vibratory capacity and voice outcome in patients with scarred vocal folds treated with collagen injections--case studies. *Logoped Phoniater Vocol*. 2002; 27:4–11. [PubMed: 12375628]
26. Van Gogh CDL, Verdonck-De Leeuw IM, Boon-Kamma BA, et al. The efficacy of voice therapy in patients after treatment for early glottic carcinoma. *Cancer*. 2006; 106:95–105. [PubMed: 16323175]
27. Hirano S. Current treatment of vocal fold scarring. *Curr Opin Otolaryngol Head Neck Surg*. 2005; 13:143–147. [PubMed: 15908810]
28. Welham NV, Choi SH, Dailey SH, Ford CN, Jiang JJ, Bless DM. Prospective multi-arm evaluation of surgical treatments for vocal fold scar and pathologic sulcus vocalis. *Laryngoscope*. 2011; 121:1252–1260. [PubMed: 21557241]
29. Chen X, Thibeault SL. Biocompatibility of a synthetic extracellular matrix on immortalized vocal fold fibroblasts in 3-D culture. *Acta Biomater*. 2010; 6:2940–2948. [PubMed: 20109588]
30. Hirano S, Mizuta M, Kaneko M, Tateya I, Kanemaru SI, Ito J. Regenerative phonosurgical treatments for vocal fold scar and sulcus with basic fibroblast growth factor. *Laryngoscope*. 2013; 123:2749–2755. [PubMed: 23553343]
31. Welham NV, Chang Z, Smith LM, Frey BL. Proteomic analysis of a decellularized human vocal fold mucosa scaffold using 2D electrophoresis and high-resolution mass spectrometry. *Biomaterials*. 2013; 34:669–676. [PubMed: 23102991]
32. Cohen SM, Kim J, Roy N, Asche C, Courey M. Prevalence and causes of dysphonia in a large treatment-seeking population. *Laryngoscope*. 2012; 122:343–348. [PubMed: 22271658]
33. Leonard RJ, Charpied G, Kiener D, Kelly A. Effects of repeated stripping on vocal fold mucosa in cats. *Ann Otol Rhinol Laryngol*. 1985; 94:258–262. [PubMed: 4014946]
34. Zeitels SM, Healy GB. Laryngology and phonosurgery. *N Engl J Med*. 2003; 349:882–892. [PubMed: 12944575]
35. Zeitels SM. Optimizing voice after endoscopic partial laryngectomy. *Otolaryngol Clin North Am*. 2004; 37:627–636. [PubMed: 15163606]
36. Keilmann A, Bergler W, Artzt M, Hörmann K. Vocal function following laser and conventional surgery of small malignant vocal fold tumours. *J Laryngol Otol*. 1996; 110:1138–1141. [PubMed: 9015426]
37. Mendenhall WM, Parsons JT, Stringer SP, Cassisi NJ. Management of Tis, T1, and T2 Squamous Cell Carcinoma of the Glottic Larynx. *Am J Otolaryngol*. 1994; 15:250–257. [PubMed: 7978023]
38. Bonito, AJ.; Bann, C.; Eicheldinger, C.; Carpenter, L. Final Report. Rockville, MD: AHRQ; 2008. Creation of New race-ethnicity codes and socioeconomic status (SES) indicators for Medicare beneficiaries.
39. Klein, JP.; Moeschberger, ML. *Survival Analysis: Techniques for Censored and Truncated Data*. 2nd. New York: Springer; 2003.

40. Fine JP, Gray RJ. A proportional hazards model for the subdistribution of a competing risk. *J Am Stat Assoc.* 1999; 94:496–509.
41. Misono S, Marmor S, Yueh B, Virnig BA. Treatment and survival in 10,429 patients with localized laryngeal cancer: A population-based analysis. *Cancer.* 2014; 120:1810–1817. [PubMed: 24639148]
42. Zevallos JP. International head and neck cancer epidemiology consortium: update no. 16. *Head Neck.* 2014; 36:1391.
43. Rademaker AW, Logemann JA, Pauloski BR, et al. Recovery of postoperative swallowing in patients undergoing partial laryngectomy. *Head Neck.* 1993; 15:325–334. [PubMed: 8360055]
44. Ciufelli MA, Piccinini A, Grammatica A, et al. Voice and swallowing after partial laryngectomy: Factors influencing outcome. *Head Neck.* 2013; 35:214–219. [PubMed: 22307985]
45. Ney DM, Weiss JM, Kind AJH, Robbins J. Senescent swallowing: impact, strategies, and interventions. *Nutr Clin Pract.* 2009; 24:395–413. [PubMed: 19483069]
46. Friedman AD, Hillman RE, Landau-Zemer T, Burns Ja, Zeitels SM. Voice outcomes for photoangiolytic KTP laser treatment of early glottic cancer. *Ann Otol Rhinol Laryngol.* 2013; 122:151–158. [PubMed: 23577566]
47. Heidelbaugh JJ, Tortorello M. The adult well male examination. *Am Fam Physician.* 2012; 85:964–971. [PubMed: 22612046]
48. Hsiao C-J, Cherry DK, Beatty PC, Rechtsteiner EA. National Ambulatory Medical Care Survey: 2007 summary. *Natl Health Stat Report.* 2010; 27:1–32. [PubMed: 21089986]
49. Fischer B. Benefits, risks, and best practice in regional anesthesia: do we have the evidence we need? *Reg Anesth Pain Med.* 2010; 35:545–548. [PubMed: 20975472]
50. White PF, White LM, Monk T, et al. Perioperative care for the older outpatient undergoing ambulatory surgery. *Anesth Analg.* 2012; 114:1190–1215. [PubMed: 22467899]

Figure 1. Schematics illustrating data flow at the patient and event levels. Panel A shows the patient-level data flow over time. Patients enter the study cohort upon having a vocal fold (VF) mucosal resection index event. Following an index event, a patient can progress to a new event (either voice treatment or a final censoring event) or repeat the index event (i.e., undergo an additional resection procedure). Following a treatment event, a patient can progress to a final censoring event, repeat the same or undergo a different treatment event, or regress to a repeat index event. No events can occur following a final censoring event. Panel B shows the event-level data flow and analysis approach implemented in the current study. In this approach, each index event and subsequent voice treatment (or no-treatment censoring event) form the basic unit of analysis. Individual patients who undergo multiple resection procedures can therefore be represented by multiple events.

Figure 2.

Cumulative incidence plots showing time to initial treatment event following vocal fold mucosal resection. Panel A shows cumulative incidence of any treatment (n = 296), speech therapy (n = 241), and surgery (n = 55). Panel B shows cumulative incidence of the two surgical procedures: thyroplasty (n = 26) and vocal fold injection (n = 29). Treatment events at time 0 occurred during the same hospitalization as the mucosal resection (index) procedure. Cumulative incidence values at 0, 1 and 3 years post-resection are reported in Table II.

TABLE I

Demographics and Characteristics of Initial Treatment Events for 2041^a Patients following Vocal Fold Mucosal Resection.^b

Characteristic	Surgery (n = 55) ^c	Speech Therapy (n = 241)	No Treatment (n = 2131) ^d	Total (n = 2427)
Age in years, mean/SD	73/9	70/10	69/11	70/11
Male, n (%)	43 (78)	180 (75)	1298 (61)	1521 (63)
Medicaid eligibility, n (%) ^e	11 (20)	34 (14)	499 (24)	544 (22)
Patient area of residence, n (%)				
Urban	40 (73)	151 (63)	1296 (62)	1487 (62)
Non-urban	15 (37)	88 (37)	811 (38)	914 (38)
Prior dysphagia/aspiration pneumonia, n (%)	22 (40)	74 (31)	616 (29)	712 (29)
Prior radiation to head and neck, n (%)	0	13 (5)	54 (3)	67 (3)
Medicare coverage before index in days, mean/SD	953/562	764/535	879/608	869/601
Distance to index hospital in miles, mean/SD	42/48	52/177	41/170	42/169
Index procedure, n (%) ^f				
Partial laryngectomy	13 (24)	22 (9)	107 (5)	142 (6)
Direct laryngoscopy with stripping	42 (76)	221 (92)	2037 (96)	2300 (95)

^a2041 patients underwent 2427 treatment events (35 patients had 55 surgery events, 174 patients had 241 speech therapy events, 1848 patients had 2131 no-treatment events).

^bMedian duration from index procedure hospitalization discharge to treatment event or no-treatment censoring event was 715 days.

^cComprised of 26 thyroplasty events and 29 vocal fold injection events.

^dComprised of 34 total laryngectomy events, 408 patient deaths and 1689 cases of no treatment receipt before end of the study period.

^eData reported are limited by Centers for Medicare and Medicaid Services confidentiality rules.

^f15 treatment events occurred following a single hospitalization during which multiple index procedures were performed. Each index procedure was counted, however these patients were allowed only one opportunity for an initial treatment event. Therefore, percentages do not total to 100%.

SD = standard deviation.

TABLE II
Cumulative Incidence of Initial Treatment Events 0, 1 and 3 Years Following Vocal Fold Mucosal Resection.

Variable	Cumulative Incidence ^a	95% CI ^a
Any treatment (during index hospitalization)	13	(9, 18)
Any treatment (1 year post)	96	(84, 109)
Any treatment (3 year post)	140	(125, 157)
Speech therapy (during index hospitalization)	0	(0, 0)
Speech therapy (1 year post)	76	(66, 88)
Speech therapy (3 year post)	116	(101, 131)
Surgery (during index hospitalization)	13	(9, 18)
Surgery (1 year post)	20	(15, 26)
Surgery (3 year post)	25	(19, 32)

^a per 1000 patients. Corresponding plots are shown in Figure 2.
CI = confidence interval.

Competing Risks Hazard Models for 296 Patients Receiving Speech Therapy or Surgery as their Initial Treatment Event.

TABLE III

Treatment Event	Parameter	HR	95% CI of HR	DF	Chi-Square	P > Chi-Square
Speech therapy ^a						
	Female vs. male	0.588	(0.438, 0.789)	1	12.489	<0.001
	Age (per 5 years) for age <75	1.045	(0.955, 1.144)	2	5.860	0.053
	Age (per 5 years) for age 75	0.751	(0.588, 0.959)			
	Medicaid eligibility vs. not	0.653	(0.450, 0.946)	1	5.065	0.024
Surgery ^b						
	Female vs. male	0.527	(0.280, 0.992)	1	3.939	0.047
	Age (per 5 years) for age <75	1.551	(0.942, 2.554)	2	11.463	0.003
	Age (per 5 years) for age 75	0.614	(0.340, 1.110)			
	Medicaid eligibility vs. not	0.771	(0.314, 1.896)	1	0.320	0.571

^a241 speech therapy events; 55 competing events; 2131 censoring events.

^b55 surgery events; 241 competing events; 2131 censoring events.

CI = confidence interval; DF = degrees of freedom; HR = hazard ratio.

TABLE IV

Logistic Regression Model for 55 Surgical Patients Receiving Thyroplasty versus Vocal Fold Injection as their Initial Treatment Event.

Parameter	OR	95% CI of OR	DF	Chi-Square	P > Chi-Square
Female vs. male	1.393	(0.351, 5.531)	1	0.222	0.490
Age (per 5 years) for age <75	0.886	(0.594, 1.321)	1	0.354	0.552
Age (per 5 years) for age 75	0.819	(0.252, 2.668)	1	0.110	0.741
Medicaid eligibility vs. not	1.927	(0.300, 12.389)	1	0.478	0.490

Thyroplasty (n = 26) is modeled as the treatment event; vocal fold injection (n = 29) is modeled as the competing event.

CI = confidence interval; DF = degrees of freedom; OR = odds ratio.