Safety and cost-effectiveness of intra-office flexible videolaryngoscopy with transoral vocal fold injection in dysphagic patients

Pedro A. Andrade Filho, MD\textsuperscript{a}, Ricardo L. Carrau, MD, FACS\textsuperscript{a,*}, Robert A. Buckmire, MD\textsuperscript{b}
\textsuperscript{a}Department of Otolaryngology, Eye and Ear Institute, University of Pittsburgh Medical Center, Pittsburgh, PA, USA
\textsuperscript{b}Department of Otolaryngology, The University of North Carolina at Chapel Hill, USA

Received 12 August 2005

Abstract
Setting: A tertiary care referral-based otolaryngology practice.

Objectives: To evaluate the safety of office-based transoral oral vocal fold injection in an ambulatory dysphagic population and to evaluate cost-effectiveness in comparison with traditional injection laryngoplasty done under general anesthesia in the operating room.

Abstract: Dysphagia is a nonspecific and common symptom of many head and neck and systemic disease processes. In patients with glottal incompetence, the presenting complaint of dysphagia generally portends to more global oropharyngeal dysfunction than dysphonia alone. Although many authors have reported on and advocated the use of office injection technique in the management of dysphonia caused by glottal insufficiency, there is a paucity of literature regarding the use of this technique in a more medically compromised dysphagic patient population (\textit{Ann Otol Rhinol Laryngol} 1997;106:778-83). We describe our experience with vocal fold injection in the office setting using a transoral technique under flexible videolaryngoscopy for the treatment of glottal insufficiency in dysphagic patients. The safety and cost-effectiveness of this approach are highlighted.

\textcopyright{} 2006 Elsevier Inc. All rights reserved.

1. Introduction
The coordinated act of swallowing is a complex interaction between the motor and sensory innervations \cite{1}. The protective mechanisms of the larynx during swallowing include closure of the glottis and supraglottis (including the aryepiglottic folds and the false vocal folds) and epiglottic deflection of the bolus. The anterosuperior movement of the larynx during the swallow places it in a protected position “beneath” the base of the tongue \cite{2}. In addition, a complete and sustained glottal closure allows a rise in subglottic air pressure to compensate for the rise in pressure in the pharynx during deglutition \cite{3}. Aspiration may be directly related to vocal fold adductor dysfunction, which causes an incompetent glottic valve, eliminating this level of mechanical protection of the lower airway during deglutition. Glottic closure is additionally necessary for the development of sufficient subglottic airway pressure for effective pulmonary toileting or the use of a “cough-clear” compensatory maneuver in response to laryngeal penetration or aspiration of an ingested bolus.

Alternatives for the treatment of glottal insufficiency include speech therapy, vocal fold injection (VFI), and laryngeal framework surgery. The choice of treatment depends largely on the functional deficit (ie, dysphagia or dysphonia), the size of the glottal gap, as well as the surgeon’s clinical preferences and experience \cite{4,5}. Other important factors include the patient’s specific vocal needs, compensatory mechanisms, medical comorbidities, and the prognosis for spontaneous recovery. Many patients presenting with dysphonia as their only symptom may be managed conservatively with voice therapy while waiting for spontaneous recovery or for the development of effective compensatory mechanisms. Patients presenting with glottal...
insufficiency and aspiration, who do not respond to compensatory swallowing maneuvers, are candidates for vocal fold medialization or augmentation to improve their glottic competency [5].

Laryngeal framework surgery provides immediate and reliable rehabilitation of glottic closure. We advocate laryngeal framework surgery to decrease the risk of aspiration in patients with permanent and/or large glottal gaps and those with limited pulmonary reserve. Vocal fold injection, however, is a reasonable alternative for those patients with small anterior glottal gaps, enough functional respiratory reserve to tolerate limited amounts of aspiration, and in whom early recovery is expected. Vocal fold injection should also be considered for patients who are poor operative candidates for open laryngeal framework surgery. Traditionally, VFI has been performed via a direct endoscopic approach in the operating room. In the current environment of medical cost containment, however, many procedures previously performed under general anesthesia have now been successfully transitioned into the outpatient clinic setting under local anesthesia. This transition optimizes patient convenience and avoids the potential cardiovascular risks attendant to a general inhalational anesthetic while improving cost-effectiveness in the delivery of medical care.

We describe our experience with VFI in the office setting using a transoral technique under flexible videolaryngoscopy for the treatment of glottal insufficiency in dysphagic patients. The safety and cost-effectiveness of this approach are highlighted.

2. Materials and methods

Fifty-two consecutive patients presenting with symptoms of dysphagia, aspiration, and an associated glottic gap who were treated with VFI in our Swallowing Disorders Clinic were included in the study. The clinical charts were retrospectively reviewed for demographic data, characteristics of the vocal fold deficit, methods of treatment, and outcome. Comparative costs of patients undergoing VFI in the operating room were determined by averaging the hospital billing of 10 uncomplicated patients (same day surgery candidates) undergoing laryngoscopy and VFI under general anesthesia in our institution.

3. Operative preparation

Each patient received 40 mg of prednisone and a broad-spectrum oral antibiotic beginning the evening before the procedure (the VFIs are performed at the end of our clinic session, to avoid scheduling conflicts). Sedation was generally unnecessary, although occasionally we have prescribed a mild oral tranquilizer to be taken 30 minutes before the office procedure in selected patients. In the office, the patients were seated in a conventional examination chair; the nasal cavity was decongested with oxymetazoline 0.05% spray; the nasal cavity, pharynx, and larynx were anesthetized with 4% lidocaine topical spray. In addition, several milliliters of 4% lidocaine was dripped onto the epiglottis, false vocal folds, and true vocal folds using a curved cannula placed transorally guided by transnasal videolaryngoscopy (Fig. 1). This step also served as a “screening test” to ascertain whether the patient will or will not gag during the transoral injection. Additional anesthesia to suppress cough and laryngospastic reflexes can be obtained using a superior laryngeal nerve block, injecting lidocaine 1% 2 cm below the inferior edge of the ipsilateral greater cornu of the hyoid. In our patients, this was rarely necessary.

4. Procedural detail

An assistant inserts the flexible video laryngoscope providing the surgeon with a continuous and clear view of the vocal folds. A distal-chip, video laryngoscope Pentax VNL-1330 was used for laryngeal visualization. A Bruenning’s syringe connected to a curved injection needle with a no. 18 or 19 gauge tip is filled with the material of choice, such as micronized acellular dermis, gelatin powder, or polytet. The curvature of the needle is adjusted to conform to the patient’s anatomy. The surgeon depresses the patient’s tongue digitally, and the needle is then guided into the oropharynx under direct vision and then into the laryngeal introitus. The first injection is placed in the posterior third of the affected vocal fold, just lateral of the vocal process. Material is injected until the vocal process and/or vocal fold is displaced toward midline (Fig. 2). A second injection may be placed at the junction of the middle and anterior third of the vocal fold if needed to correct a membranous glottal gap caused by a deficient or flaccid fold (Fig. 3).

The volume of injection is determined visually. Auditory monitoring of the patient’s voice is not particularly useful as the fold is customarily over-injected by 15% to 20% to account for the early resorption of water contained within.
the injectate (Fig. 2). Polytef, however, is an important exception to this guideline. Polytef is injected only until the glottic gap and the dysphonia are corrected because no appreciable resorption of this permanent injectate is anticipated. Postoperatively, the patient is observed for 20 to 30 minutes in our clinic before returning home. Patients are advised to wait 1 hour before eating or drinking and to limit their conversation to short phrases for 3 days.

5. Results

Our cohort was composed of 29 men and 23 women with a mean age of 65.6 years (range, 27–95 years). All patients had a history of dysphagia with symptoms suggestive of laryngeal penetration or aspiration (eg, choking, coughing, or the sensation of “food going into the wrong pipe”) and a glottal gap on maximal closure by videolaryngoscopy. The etiology of their glottal insufficiency included bilateral vocal fold atrophy (n = 5), head and neck neoplasms (n = 14), head and neck trauma (n = 3), myasthenia gravis (n = 1), lung cancer (n = 6), esophageal cancer (n = 4), and iatrogenic (intubation or surgery) (n = 19). Forty-five patients had unilateral vocal fold mobility deficit, 5 had a glottic gap from bilateral vocal fold atrophy, one had an incomplete closure caused by myasthenia gravis, and one had undergone a partial resection of a vocal fold. All patients were evaluated by flexible endoscopic evaluation of swallowing and/or modified barium swallow, which demonstrated aspiration in 14 (27%) patients and penetration in 21 (40%). Thirty-seven (71%) patients were diagnosed with additional swallowing deficits including poor laryngeal elevation and pharyngeal propulsion, swallow delay, and bolus residue in the oropharynx suggestive of base of tongue weakness.

Materials used for the VFI included micronized acellular dermis in 21 patients, gelatin powder in 27 patients, and polytef in 4 patients. The choice of the material was based on the clinical prognosis of the glottic incompetence and the patient’s disease process. Patients with paresis or paralysis after endotracheal intubation were deemed to have excellent prognosis for recovery and were therefore injected with gelatin powder. Conversely, polytef was only used in patients with terminal illnesses. There were no immediate perioperative complications within the study population. Flexible endoscopic evaluation of swallowing and/or modified barium swallow were repeated 2 to 6 weeks after the injection to verify an improvement in swallowing safety (ie, less penetration/aspiration, better cough, and clearing of secretions). All patients showed improvements in the postinjection study, in relation to closure of the glottic gap. The mean maximum phonation time increased from 5.4 seconds before the injection to 10.4 seconds after the injection. Subjectively, all patients reported improvement after the VFI including decreased subjective swallowing difficulty and, although not the primary objective for the injection, improvement of voice. No significant complications such as epistaxis, laryngeal edema with airway compromise, laryngospasm, subjective shortness of breath, or pulmonary sequelae were encountered in any of these patients. The office billing for this procedure ranged from $1200 to $1386. The charges from a similar patient cohort with VFI performed in the operating room with direct laryngoscopy were reviewed and ranged from $12 400 to $13 300.

6. Discussion

Most patients with oropharyngeal dysphagia present with more than isolated glottic incompetence. Management is ideally performed by a multidisciplinary clinical team including both speech language pathology and otolaryngology. In our cohort, 71% demonstrated at least one additional abnormality of the swallowing mechanism including poor laryngeal elevation, weak pharyngeal propulsion, swallow delay, and bolus residue. The initial treatment in such patients with glottic incompetence should include the use of appropriate compensatory swallowing maneuvers and diet modifications before the consideration of surgical intervention. Surgery is recommended for those patients who...
continue to have an unsafe swallow despite these conservative measures or those who are incapable of producing adequate subglottic pressure for effective pulmonary toileting. Surgical therapy aims to medialize or to add bulk to the affected vocal fold, thus restoring the laryngeal valve during phonation, deglutition, and coughing [1]. One must recognize that the success in eliminating aspiration by vocal fold medialization is dependent upon the relative contribution of glottic incompetence to the individual patient’s multifactorial swallowing deficit. Isolated vocal fold medialization in such patients, without addressing other swallowing deficits, frequently fails to restore them to safe, unrestricted oral alimentation [6].

Surgical approaches for intra-office VFI include both direct or indirect laryngoscopy and transoral vs transcutanous routes. The primary disadvantages of VFI via direct laryngoscopy is discomfort. Thus, sedation is usually needed for completion of the procedure. This limitation can be minimized or eliminated with transcutanous injection under flexible fiberoptic videolaryngoscopy. By eliminating oropharyngeal stimulation, the transoral cutaneous technique is advantageous in patients with strong gag reflexes. Disadvantages of this technique include the need for additional cutaneous anesthesia and the difficulty in estimating the depth of the injection while advancing the tip of the needle blindly into the vocal fold. This latter challenge may result in the inadvertent injection of the injectate into the Reinke’s space, negatively impacting voice quality. In addition, if the surgeon directs the needle through the thyroid ala rather than the cricothyroid membrane, plugging of the needle’s lumen with cartilage is occasionally encountered.

Conversely, the transoral technique is difficult to perform in patients with a strong gag reflex and incurs the risk of injury to the tongue base, pharynx, and supraglottic larynx. Oropharyngeal and laryngeal topical anesthesia and proper patient selection are critical requirements for successful completion of this procedure. A cooperative patient with normal laryngeal anatomy, able to tolerate flexible laryngoscopy, and without a strong or psychogenic gag reflex or a history of vasovagal reactions is considered a good candidate for this injection technique. It is our clinical impression that the depth of injection is better controlled using a transoral technique and that it is associated with minimal trauma, thus with minimal morbidity. In selected patients, the technique is a safe and a cost-effective alternative to traditional injections in the operating room.

The reported cost advantage in our transoral oral injection group results from a dramatically decreased utilization of hospital resources such as operating rooms, recovery suites, prolonged cardiopulmonary monitoring, intravenous medications, and the skilled medical staff required to provide a safe general anesthetic and recovery. The magnitude of this disparity, as reflected in patient billing, was roughly 10:1 in our patient cohort. This figure does not take into account lost patient productivity from absent workdays commonly associated with recovery from an uncomplicated general anesthetic. Consequently, the larger societal cost disparity is significantly greater than reported herein.

7. Conclusion

Intra-office transoral VFI is a safe and effective method of managing dysphagia complicated by concurrent glottal insufficiency. In comparison with laryngoscopy and VFI performed under general anesthesia in the operating room, this method provides a substantial cost advantage. Attention to appropriate patient selection as well as medical economic factors should play a role in operative management decisions in an ambulatory dysphagic patient population.

References
