


Office-Based Esophageal Dilation in Head and Neck Cancer: Safety, Feasibility, and Cost Analysis

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Objective: To review experience, safety, and cost of office-based esophageal dilation in patients with history of head and neck cancer (HNCA).

Methods: The medical records of patients undergoing esophageal dilation in the office were retrospectively reviewed between August 2015 and May 2017. Patients were given nasal topical anesthesia. Next, a transnasal esophagoscopy (TNE) was performed. If the patient tolerated TNE, we proceeded with esophageal dilation using Seldinger technique with the CRE™ Boston Scientific (Boston Scientific Corp., Marlborough, MA) balloon system. Patients were discharged directly from the outpatient clinic.

Results: Forty-seven dilations were performed in 22 patients with an average of 2.1 dilations/patient (range 1–10, standard deviation [SD] \pm 2.2). Seventeen patients (77%) were male. The average age was 67 years (range 35–78 years, SD \pm 8.5). The most common primary site of cancer was oral cavity/oropharynx (n = 10), followed by larynx (n = 6). All patients (100%) had history of radiation treatment. Four patients were postlaryngectomy. The indication for esophageal dilation was esophageal stricture and progressive dysphagia. All dilations occurred in the proximal esophagus. There were no major complications. Three focal, superficial lacerations occurred. Two patients experienced mild, self-limited epistaxis. One dilation was poorly tolerated due to discomfort. One patient required pain medication postprocedure. Office-based esophageal dilation generated \$15,000 less in health system charges compared to traditional operating room dilation on average per episode of care.

Conclusion: In patients with history of HNCA and radiation, office-based TNE with esophageal dilation appears safe, well-tolerated, and cost-effective. In a small cohort, the technique has low complication rate and is feasible in an otolaryngology outpatient office setting.

Key Words: Radiation-induced esophageal stricture, head and neck cancer, office-based esophageal dilation, transnasal esophagoscopy.

Level of Evidence: 4.

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INTRODUCTION

Radiation-induced esophageal stricture represents a significant long-term complication in patients treated for head and neck cancer (HNCA). Radiation therapy, a common treatment modality used in HNCA, has been shown to cause esophageal injury in a dose-dependent manner.^{1,2} As many as 40% of HNCA patients develop dysphagia following radiation, and between 3.3% to 23% develop esophageal strictures.³

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In patients with a history of HNCA presenting with dysphagia, transnasal esophagoscopy (TNE) is a validated tool for evaluation and diagnosis of esophageal pathology.^{4–6} Office-based TNE is a safe, effective, and well-tolerated procedure that can be performed using only topical anesthesia.^{4,5,7} A multi-institutional prospective TNE study found that in patients with a history of HNCA with dysphagia, TNE led to a change in management.⁶ Furthermore, TNE may provide particular benefit to the HNCA population compared to conventional esophagoscopy due to its ease of use and ability to negate risks of general anesthesia in patients with post-treatment functional or anatomical abnormalities.⁸

The role of TNE in HNCA patients is evolving to allow for its application to therapeutic procedures. One such procedure is office-based TNE with balloon dilation for esophageal stricture. Esophageal dilation is an established and effective technique to improve symptoms of dysphagia in radiation-induced esophageal stricture.^{9–11} Esophageal dilation is traditionally done under general anesthesia or IV sedation using conventional esophagoscopy with bougie or balloon dilators with or without a guidewire. Moss et al. performed a systematic review and meta-analysis of esophageal dilation in HNCA

patients and found that HNCA patients experience a higher complication rate than patients with benign esophageal pathology but had an overall acceptable success rate of 72.9% per patient. Furthermore, they found that the number of repeat dilations was variable. However, on average, each patient underwent a mean of three procedures in less than 2 years of follow-up data.¹¹

The expansion of esophageal balloon dilation from the operating room (OR) to the otolaryngologist office prevents the risks and healthcare costs associated with undergoing general anesthesia.^{12,13} Rees et al. has the only description of 54 in-office TNEs with balloon dilation of the upper and lower esophagus using only topical anesthesia in 2009, in which 15 patients (30%) had a history of HNCA.¹⁴ They reported a low complication rate and good tolerability of the procedure. There are no further studies in the literature regarding the safety of office-based esophageal dilation specifically in the HNCA population. Furthermore, the potential cost savings to the patient, insurance companies, and healthcare system of performing esophageal dilation in the office has not yet been explored. The objective of this study is to review experience, tolerance, safety, and cost-effectiveness of office-based esophageal dilation under topical anesthesia in patients with history of HNCA.

MATERIALS AND METHODS

This study was approved by the institutional review board at the University of Cincinnati. The medical records of patients were identified using the current procedural terminology (CPT) code 43214 (flexible esophagoscopy with balloon dilation) billed in the otolaryngology ambulatory setting. Patients undergoing esophageal dilation with balloon in the office were retrospectively reviewed between August 2015 and May 2017 as part of the quality improvement process. For the purposes of cost analysis only, charges were reviewed for nine patients undergoing flexible esophagoscopy with balloon dilation with a history of HNCA in the OR. Safety and efficacy was not directly compared from outpatient to inpatient procedures according to this study. Patients were eligible to undergo esophageal dilation in the office if they had a history of HNCA, symptoms of dysphagia, and if they tolerated a TNE. Information that was collected included demographic data, HNCA location and staging, cancer treatment, and esophageal dilation procedural reports with any noted complications. Complications were considered minor if they were self-limited and did not require any medical intervention. Minor gagging or discomfort that did not result in termination of the procedure were not considered complications. In addition, the results of the predilation 10-item Eating Assessment Tool (EAT-10), a validated self-administered symptom-based instrument to classify dysphagia severity, were reviewed.¹⁵ A score of ≥ 3 on the EAT-10 was considered abnormal.

To begin the procedure, patients were given nasal topical anesthesia consisting of 1:1 oxymetazoline: 4% lidocaine. Next, a TNE was performed. The entire esophagus was examined and the area of stenosis identified. If the patient tolerated the TNE, we then proceeded with esophageal dilation using CRE™ Boston Scientific balloon system (Boston Scientific Corp., Marlborough, MA). A guidewire was placed through the esophagoscope past the area of narrowing. The balloon was then placed over the guidewire using Seldinger technique, with direct visualization of the larynx and airway. The TNE was used to visualize the passage of the balloon over the guidewire through the nasal

cavity, passed through the nasopharynx, and into the hypopharynx. When the top of the balloon and the black marker on the CRE™ Boston Scientific balloon system (Boston Scientific Corp.) were visible in the proximal esophagus, the TNE rested in the home position for continuous visualization and monitoring of the balloon expansion with respect to the larynx. Secretions were suctioned as needed (see Fig. 2c). The appropriate sized balloon was incrementally filled with isotonic saline to a maximum tolerated pressure. After dilation, the balloon and guidewire were removed and the area of dilation was examined for esophageal injury. Patients were discharged directly from the outpatient clinic following the procedure.

Finally, the itemized billing records were obtained for nine of the patients undergoing office-based esophageal dilation during the study period and compared to the itemized billing records of nine comparable patients who underwent esophageal dilation in the OR during the same study period. Again, these patients were all identified using the CPT code 43214 (flexible esophagoscopy with balloon dilation) and minimizing multiple additional coded procedures (e.g., biopsy, bronchoscopy). Total inpatient and outpatient cost were nonparametric continuous variables; thus, comparisons were made using the Wilcoxon rank sum test. Significance was assessed at $\alpha = .05$. R statistical software package was used to perform statistical analysis (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Forty-seven dilations were performed in 22 patients with an average of 2.1 dilations per patient (range 1–10, standard deviation [SD] ± 2.2). In 38 dilations (81%), the patients tolerated 15- to 18-mm CRE™ Boston Scientific balloon (Boston Scientific Corp.). In 32 of these, the patient tolerated maximum dilation (18 mm, or 7.5 atmospheres [atm]). The remaining nine dilations were performed using the 13- to 15-mm CRE™ Boston Scientific balloon system (Boston Scientific Corp.), and this was based solely on surgeon discretion. Demographic information and cancer characteristics for all patients are presented in Table I. Seventeen patients (77%) were male. The average age at dilation was 67 years (range 35–78 years, SD ± 8.5). The most common primary site of cancer was oral cavity/oropharynx ($n = 11$), followed by larynx ($n = 6$), nasopharynx ($n = 2$), parotid gland ($n = 1$), hypopharynx ($n = 1$), and unknown primary ($n = 1$). All patients (100%) had a history of radiation therapy for HNCA. Eight patients were treated with both surgery and radiation. Nine patients received surgery, radiation, and chemotherapy. Four patients received chemoradiation. One patient received only radiation. Six patients were postlaryngectomy.

The indications for esophageal dilation in all patients were esophageal stenosis and progressive dysphagia. The EAT-10 prior to the first in-office esophageal dilation was measured in 18 patients, and the average score was 21.9 (SD ± 8.2). In 77% (17:22), patients underwent modified barium swallow, confirming narrowing of the upper esophageal segment. The average duration between the completion of radiation therapy and the first office-based esophageal dilation was 8.1 years (range 1 month–22 years, SD ± 6.1). Twelve patients (55%) had previously been dilated under general anesthesia. The remaining 10 patients underwent their first

TABLE I.
Demographic and HNCA Data.

Patient	Age at First In-Office Dilation (years)	Gender	Primary Cancer Site	TNM Tumor Staging	Treatment
1	58	M	Larynx	T4aN0M0	XRT + surgery*
2	55	F	Tongue	T1N2b	XRT + surgery + chemo
3	65	M	Unknown	TxN2M0	XRT + surgery + chemo
4	75	M	Tongue	T2N1	XRT
5	68	M	Tongue	T2N2bMx	XRT + chemo
6	71	F	Tongue	Unknown	XRT + surgery
7	71	M	Tongue	T2N3	XRT + surgery + chemo
8	59	M	Tongue	T1N0M0	XRT + surgery
9	69	F	Larynx	T4N2ccM0	XRT + surgery* + chemo
10	50	M	Nasopharynx	Unknown	XRT + surgery + chemo
11	75	M	Parotid gland	Unknown	XRT + surgery
12	54	F	Tongue	T4N2M0	XRT + surgery + chemo
13	63	M	Larynx	T4aN0MX	XRT + surgery*
14	78	F	Hypopharynx	T2N1M0	XRT + chemo
15	76	M	Larynx	Unknown	XRT + surgery*
16	60	M	Tongue	Unknown	XRT + surgery + chemo
17	71	M	Nasopharynx	Unknown	XRT + chemo
18	59	M	Tongue, palate, tonsil	T1N0M0	XRT + surgery + chemo
19	69	M	Tongue	T3N2bMx	XRT + surgery + chemo
20	61	M	Larynx	T2N0M0	XRT + surgery*
21	71	M	Tonsil	T2N0mM0	XRT + chemo
22	35	M	Larynx	T4N0M0	XRT + surgery*

*Total laryngectomy.
chemo = chemotherapy; F = female; HNCA = head and neck cancer; M = male; NA = nonapplicable; OR = operating room; TNM = tumor, node, metastasis; XRT = radiation therapy.

esophageal dilation in the office. All dilations occurred in the proximal esophagus.

There were no major complications. Minor complications occurred in five of the 47 dilations (10.6%). Three patients received focal, superficial lacerations, which did not require further medical management (Fig. 1). All of the patients who experienced a superficial laceration reported minimal pain and were able to go home after the procedure with instructions to resume an oral diet as tolerated. In addition, two patients experienced mild, self-limited epistaxis. One dilation was poorly tolerated by the patient due to discomfort. One patient required pain medication after the procedure. All patients were discharged from the outpatient setting following the procedure.

Table II shows the itemized hospital charges for nine patients who received esophageal dilation in the OR. Table III shows the itemized hospital charges for nine patients who underwent unsedated esophageal dilation in the office. The cost of the balloon and the device to inflate the balloon used in the clinic was \$392, which was included in the outpatient services charge in Table III. The average total hospital charges were \$18,803 (range \$10,834–\$27,018) for traditional esophageal dilation in the OR and \$3,414 (range \$3,053–\$4,432) for office-based esophageal dilation, resulting in an average cost reduction of \$15,389 per episode of care ($P < 0.0004$).

DISCUSSION

Our retrospective review of 47 office-based esophageal balloon dilations in patients with a history of HNCA is the largest published series. Here, we have reviewed both safety and tolerability of this procedure in the HNCA population. Additionally, the cost analysis of performing esophageal dilation in the office compared to in the OR demonstrated a \$15,000 savings, which is equivalent to a five-fold reduction in relative cost.

Prior studies have demonstrated significant cost reduction with moving otolaryngology procedures into the office.^{16–18} Assuming cost reduction of over \$15,000 per dilation and a similar safety and effectiveness profile, office-based esophageal dilation provides superior value when compared to the same procedure done in the OR across stakeholders. From the patient perspective, office-based dilation may have decreased postoperative recovery times and potentially lower out-of-pocket costs, especially for those with high deductible plans. Similarly, from the payor perspective, office-based dilation delivers a safe alternative to OR dilation at lower price per enrollee. From the provider or health system perspective, office-based delivery may mean lower collections per episode; however, moving lower acuity cases into the office means expanded OR capacity for those cases requiring higher acuity resources that also are

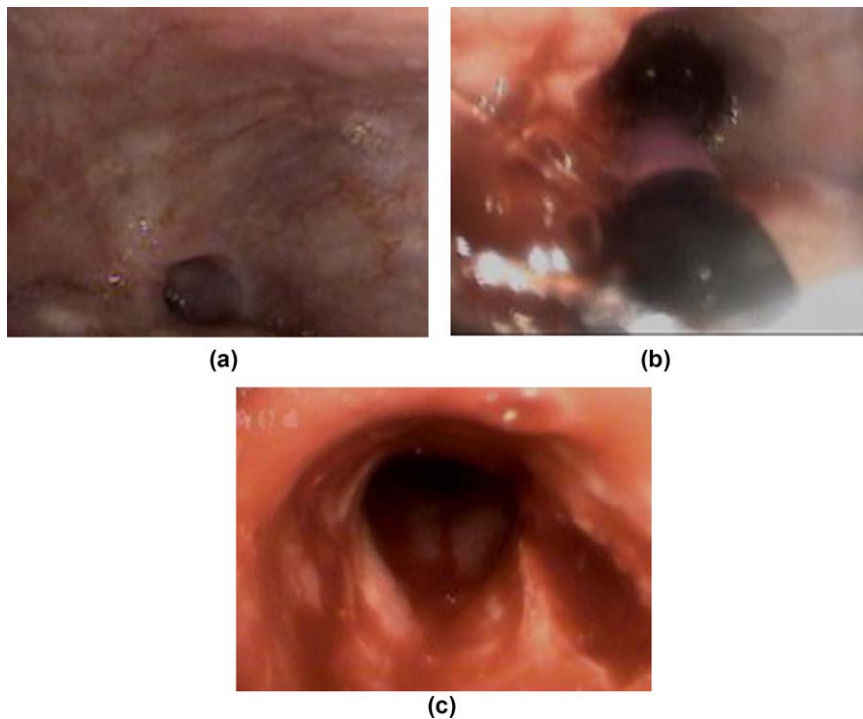


Fig. 1. A superficial esophageal laceration occurred in three patients undergoing office-based esophageal dilation. (A) Area of esophageal narrowing prior to dilation. (B) Balloon dilator over guidewire at the level of the esophageal stenosis. (C) Superficial esophageal laceration (lower right of image). [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

likely to generate greater reimbursement for the health system. In addition, when esophageal dilation is incorporated into a bundled payment, delivering the same outcome at a lower internal cost means higher returns for the provider system. With the ongoing evolution of the U.S. healthcare system, the efficiency

provided by office-based procedures will likely continue to gain traction as a cost-effective alternative to the traditional OR setting.

Esophageal stenosis in the HNCA population represents a significant treatment challenge. These patients develop widespread fibrosis, xerostomia, and neuronal

TABLE II.
Itemized Charges for Operating Room Esophageal Dilation.

Charge Category	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Average
Anesthesia	\$2,267.00	\$2,162.00	\$1,088.00	\$1,847.00	\$2,508.00	\$983.00	\$2,848.00	\$2,440.00	\$1,939.00	\$2,009.11
Laboratory	NA	NA	\$348.00	\$152.00	NA	\$152.00	NA	NA	\$72.00	\$181.00
Laboratory/pathology	NA	\$458.00	NA	NA	NA	\$172.00	\$337.00	NA	NA	\$322.33
Supplies and devices	\$1,147.26	\$51.00	\$51.00	\$653.49	\$398.30	NA	\$1,183.50	\$1,358.15	\$51.00	\$611.71
OR services	\$12,590.00	\$12,116.00	\$7,540.00	\$10,694.00	\$13,586.00	\$6,835.00	\$15,116.00	\$20,277.00	\$11,380.00	\$12,237.11
Pharmacy	\$450.00	\$971.70	\$2,025.25	\$1,577.40	\$1,477.35	\$616.25	\$1,201.35	\$960.55	\$741.90	\$1,113.53
Pulmonary function	NA	NA	\$282.00	NA	NA	NA	NA	NA	NA	\$282.00
Recovery room	\$2,442.00	\$2,843.00	\$1,305.00	\$2,442.00	\$3,149.00	\$2,076.00	\$2,371.00	\$1,982.00	\$2,308.00	\$2,324.22
Respiratory services	NA	NA	\$1,332.00	NA	NA	NA	NA	NA	NA	\$1,332.00
Room and board	NA	NA	\$1,446.00	NA	NA	NA	NA	NA	NA	\$1,446.00
Speech therapy	NA	NA	\$425.00	NA	NA	NA	NA	NA	NA	\$425.00
Total	\$18,896.26	\$18,601.70	\$15,842.25	\$17,365.89	\$21,118.65	\$10,834.25	\$23,056.85	\$27,017.70	\$16,491.90	\$18,802.83

NA = nonapplicable; OR = operating room.

TABLE III.
Itemized Charges for Unsedated Office-Based Esophageal Dilatation.

Charge Category	Patient 10	Patient 11	Patient 12	Patient 13	Patient 14	Patient 15	Patient 16	Patient 17	Patient 18	Average
Anesthesia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Clinic visit	NA	\$123.00	NA	NA	\$123.00	NA	NA	NA	NA	\$123.00
Laboratory	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Laboratory/ pathology	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Supplies and devices	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OR services	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Outpatient services	\$3,450.00	\$3,450.00	\$3,053.00	\$3,450.00	\$3,450.00	\$3,053.00	\$3,053.00	\$3,450.00	\$3,053.00	\$3,273.56
Pharmacy	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pulmonary function	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Recovery room	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Respiratory services	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Room and board	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Speech therapy	\$982.00	NA	NA	NA	NA	NA	NA	\$427.00	NA	\$704.50
Other		NA	NA	NA	NA	NA	NA	-\$387.00	NA	-\$193.50
Total	\$4,432.00	\$3,573.00	\$3,053.00	\$3,450.00	\$3,573.00	\$3,053.00	\$3,053.00	\$3,490.00	\$3,053.00	\$3,414.44

NA = nonapplicable; OR = operating room.

damage as long-term sequelae of radiation therapy to the head and neck.¹⁹⁻²¹ The resultant dysphagia and decreased sensation to the upper aerodigestive tract, as

well as anatomical changes from surgery, place the patients at increased risk for anesthetic complications.¹³ However, these same radiation-induced changes to the

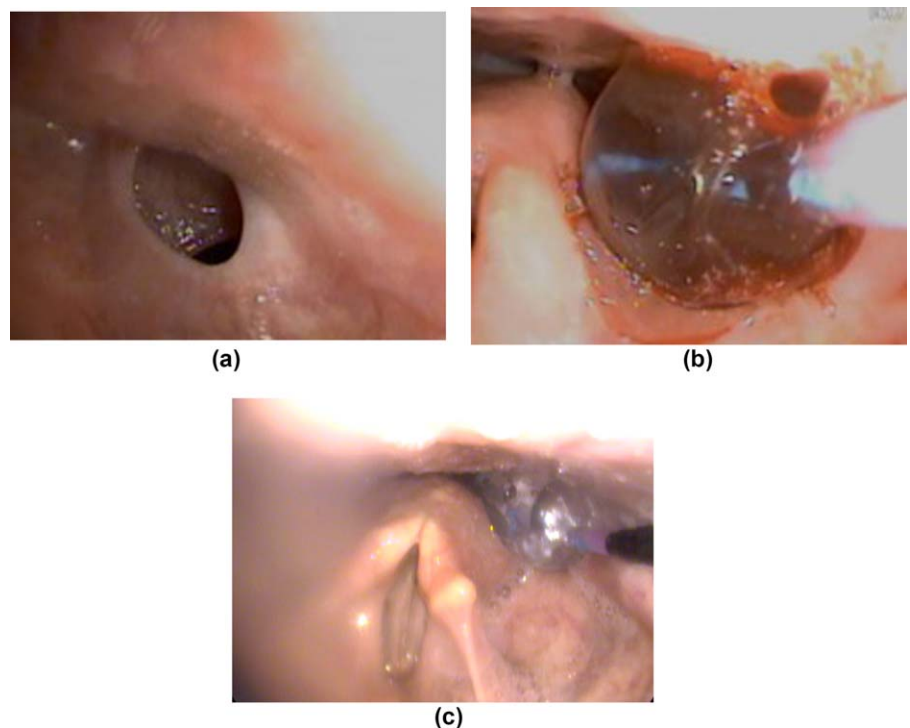


Fig. 2. Esophageal dilation of a patient with an esophageal web resulted in a superficial laceration. (A) Thin membrane of the esophageal web creating an area of stenosis. (B) Balloon dilator at the level of the esophageal web. (C) Balloon dilation at the home position. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

esophagus perhaps allow for improved tolerability of unsedated office-based esophageal dilation in the HNCA population. Because radiation-induced esophageal stricture is often treatment-resistant, patients frequently have to undergo serial dilations. Our series demonstrated an average of 2.1 dilations/patient, which is comparable to the current literature (3 dilations/patient).¹¹ Thus, HNCA patients stand to benefit from the incorporation of office-based esophageal dilation into the otolaryngologist's treatment armamentarium.

Moss et al. conducted a recent meta-analysis and systemic review of the safety of esophageal dilation specifically in the HNCA population.¹¹ They reported an overall 7.4% complication rate per dilation in the HNCA population, which was higher than those previously described for patients with benign strictures.^{9,10} All 15 studies included esophageal dilations done under general anesthesia using balloon or bougie dilators with or without a guidewire. Approximately half of the complications were esophageal perforations. There were two reported complications requiring tracheostomy and two deaths.

Our study had no major complications, including esophageal perforation or death. There was a low overall complication rate per dilation of 10.6%, all of which were minor complications from superficial lacerations and spontaneously resolving epistaxis. The complication rate in this study is comparable to the complication rate of 10% experienced by Rees et al. in the only other published series of in-office TNE with balloon dilation.¹⁴ In that study, which included both benign esophageal stricture and stricture following radiation treatment, two minor complications were documented—self-limited laryngospasm and intractable gagging—both of which occurred in the HNCA subgroup consisting of 20 total dilations. There were also no major complications.

The most common minor complication in this study was a superficial laceration to the esophagus. When a superficial laceration occurred, the area was closely examined to ensure the integrity of the muscular wall of the esophagus. One of the superficial lacerations occurred in a patient with a thin, membranous esophageal web, which was intentionally stretched by the balloon (Fig. 2). The other two lacerations were seen in two patients, for which only 4.5 atm of pressure was used; that is, bleeding was seen and the procedure was completed prior to maximum dilation. Although we considered these minor complications in this safety and feasibility study, in reality controlled tears would be expected in most patients with adequate dilation. Particular caution should be exercised when dilating patients with significant esophageal strictures with a lower threshold to stop the dilation at a decreased pressure and planned staged dilations. A TNE has a 5 mm diameter; if a TNE was not able to transverse the stricture, the dilation was not performed. Narrow segment (<5 mm) and complete esophageal strictures would be better treated in the OR, possibly utilizing both antero-grade and retrograde techniques in challenging cases.

It is important to consider this study's limitations. It only describes the experience of a small cohort of

patients at a single institution. Therefore, other institutions may vary in patient selection, criteria to define a complication, as well as differences between surgeons. Hemodynamic changes during in-office laryngology procedures have been described; we did not use any prescreening protocol.²² In addition, the tolerability of the procedure was not quantified with a questionnaire or with *physiologic monitoring*, which would have allowed for improved assessment of patient tolerance. The retrospective design of the study leads to the possibility for selection bias because patients receiving in-office dilation may be healthier at baseline than those dilated in the OR. Ultimately, dilation in the OR will likely remain the preferred approach in patient who require concurrent procedures or in narrow/complete esophageal strictures. The relatively short time period analyzed for this study limits the ability to assess long-term efficacy of the procedure and differences in how frequently dilations are needed for each dilation technique. In addition, the tolerability of the procedure was not quantified with a questionnaire, which would have allowed for improved assessment of patient tolerance. A future prospective study is needed to evaluate for efficacy and dysphagia outcomes as compared to conventional sedated esophagoscopy with dilation. Costs rather than reimbursements were analyzed in this study, which vary across institutions and may not as accurately reflect overall savings. Finally, this study does not compare the cost of office-based dilation to esophageal dilation performed under light sedation in an outpatient endoscopy setting, which is another viable alternative to esophageal dilation under general anesthesia.

CONCLUSION

In patients with a history of HNCA and radiation, office-based TNE with esophageal dilation appears to be safe, well-tolerated, and cost effective. In a small cohort, the technique has a low minor complication rate and is feasible in an otolaryngology outpatient office-based setting.

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