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Through-the-Scope Balloon Dilation for EUS Staging of Stenosing Esophageal Cancer

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Abstract

Background—Dilation of malignant esophageal strictures is often required to complete staging by EUS. The aim of this study is to determine the successful dilation rate (ability to complete staging) and complication rate of TTS balloon dilation for malignant esophageal strictures during EUS.

Methods—We retrospectively reviewed EUS reports for all cases of primary esophageal cancer staged at five centers between 1/2002 and 10/2004. All dilations were performed with TTS balloons (Boston Scientific, Natick, MA).

Results—Among 272 EUSs, dilation was required in 77 (28%) and was successful in 73 cases (95%). There was one esophageal perforation following dilation (1.3%; 95% CI 0.2-7.0) and one esophageal perforation following EUS without dilation (0.5%; 95% CI 0.1-2.8; $p=0.48$ by 2-sided Fisher's Exact test). There were no other major complications.

Conclusions—TTS balloon dilation is highly successful in permitting complete staging of obstructing tumors. The rate of complications following dilation with a TTS balloon dilator is low and similar to the baseline rate of EUS in this setting.

Keywords

Esophageal Cancer; EUS; Staging; Esophageal Dilation

INTRODUCTION

The evaluation of patients with esophageal cancer includes staging for both prognostication and therapeutic decision-making. Patients with stage I cancer are potential candidates for curative surgery while those with stage II and III disease are typically treated with neoadjuvant chemoradiotherapy prior to esophagectomy. Patients with stage IV disease receive palliative measures [1]. Endoscopic ultrasound (EUS) is currently the most accurate method for both tumor (T) and node (N) staging of esophageal cancer and should be part of the evaluation of all patients free of metastatic disease as determined by non-invasive imaging [2]. Unfortunately, up to 40% of esophageal cancers present with a malignant

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stricture that limits passage of an endoscope, and therefore prohibits complete staging by EUS [3-10]. In this setting, the endoscopist may dilate the stricture in an effort to complete staging. Dilation of malignant strictures carries a reported risk of perforation ranging from 0 to 24%, [5-9,11-13] but is successful in permitting complete cancer staging in 74 to 100% of cases [7-9,11,14].

The majority of literature about this subject describes the use of bougienage for malignant esophageal strictures, although there have been reports including small numbers of patients undergoing balloon dilation of malignant strictures. Balloon dilation is becoming more commonplace in this setting, perhaps because there is no need for fluoroscopy or repeated esophageal intubations. In some centers balloon dilation has become the only method used during EUS staging of stenotic cancers. The aim of this study was to determine the efficacy and safety of TTS balloon dilation of malignant strictures by reviewing the collective experience from several institutions nationwide.

METHODS

We retrospectively reviewed EUS reports for all cases of esophageal cancer staged at four university medical centers and one Veteran's Administration hospital between 1/2002 and 10/2004. We included only cases of primary esophageal carcinoma and not cases in which the esophagus was a site of metastatic or recurrent disease. We excluded EUSs performed after chemotherapy, radiation therapy, or any combination of the two. We included both cases with and without dilation, but excluded those performed with an EUS probe (catheter miniprobe or the Olympus MH908 tapered blind probe) or in which bougienage was performed. Informed consent was obtained prior to all endoscopic procedures and the study was approved by the Institutional Review Board at each participating site.

EUS examinations were performed with a radial echoendoscope (GF-UM130, outer diameter 12.7mm; or GF-UM160, outer diameter 12.7mm, Olympus America, Melville, NY). Fine needle aspiration (FNA) was performed when appropriate using a curved linear array echoendoscope (GF-UC30P, outer diameter 12.8mm or GF-UC140P, outer diameter 14.2mm, Olympus America, Melville, NY; or FG-36UX, outer diameter 12.1mm, Pentax of America, Montvale, NJ). Dilation was undertaken when resistance by a malignant stricture precluded passage of a standard diagnostic upper endoscope or when a radial echoendoscope could not traverse the tumor. Dilation was not performed empirically or solely due to dysphagia. All dilations were performed with through-the-scope (TTS) controlled radial expansion (CRE) dilators (Boston Scientific, Natick, MA). In most cases dilation was performed through at least two balloon expansion sizes, and usually through three sizes of a single balloon. All dilations were performed without the use of fluoroscopy. Patients were observed for at least thirty minutes after their procedure but contrast radiography was not routinely performed after dilation. Complications were assessed according to local protocol. At four sites this involved a telephone call to patients within 48 hours of EUS (representing 75% of the cases). At the fifth site, calls were made to patients when the endosonographer had concerns (e.g. patients with a tight stricture, chest pain post-procedure, or an unusual recovery period) or when FNA was performed. Nevertheless, because of the retrospective nature of this study, only complications occurring during the EUS and major complications, defined as perforation, hemorrhage, death, and cardiovascular or infectious events requiring hospitalization, were deemed valid for review.

We recorded age, gender, tumor histology and length, TTS balloon dilator sizes (when used), EUS T, N, and M stage, institution where procedure was performed and complications available from endoscopy, pathology, and hospital records. Staging was based upon the guidelines of the American Joint Committee on Cancer [15]. Major complication

rates were calculated with 95% confidence intervals [16]. We compared demographic and tumor variables between those patients who did and did not require dilation for complete EUS staging using Fisher's Exact test or the Wilcoxon Rank-Sum test when appropriate. Logistic regression was used to determine which variables were independently associated with having had dilation performed. For multivariate analyses, variables were categorized as follows: M0 vs M1a/M1b, T1/2 vs T3/4, age <65 and ≥65, length <5cm and ≥5cm, squamous cell carcinoma vs other types, and institution 2 versus all others. A two-sided p value <0.05 was considered significant. Statistical calculations were made using SAS version 8e (SAS Institute, Cary, NC).

RESULTS

We reviewed the EUS reports from 313 consecutive cases and excluded 41 of these from analysis. Reasons for exclusion included prior chemoradiotherapy (n=20), dilation by bougienage (n=6), cases performed with the MH908 tapered echoendoprobe (n=5), cases performed with catheter miniprobe (n=5), cases of recurrent or non-primary esophageal carcinoma (n=4), and one case in which EUS was performed through a Wallstent. The remaining 272 cases were included for final analysis. The majority of patients were male (85%), and the mean age was 64 (SD 12) years. There were 210 adenocarcinomas (78%), 55 squamous cell carcinomas (21%), and 4 undifferentiated carcinomas (1%). Median tumor length was 5cm (range 1-25; IQR 3-6). There were 45 T1, 55 T2, 152 T3, and 20 T4 tumors, with 186 (68%) having N1 disease, 35 (13%) having M1a disease and 6 (2%) having M1b disease discovered during endosonography.

Dilation of a malignant stricture was performed during 77 (28%) of these procedures. The tumor could be traversed after dilation in 73 (95%) cases. A comparison between cases that did and did not undergo dilation is presented in Table 1. Univariate analyses suggested that dilation was performed more often for female patients, those with squamous cell carcinoma, longer tumors, tumors with more advanced stages, and when the EUS was performed at institution 2. However, multivariable analyses revealed that only advanced T stage (odds ratio 4.6; 95% confidence interval 1.9-10.7) and having an EUS at institution 2 (odds ratio 2.9; 95% confidence interval 1.6-5.4) were independently associated with the use of dilation.

In the four instances when the echoendoscope could not pass beyond the tumor, the maximum balloon inflation diameter was 12mm (n=2), 16.5mm, and 18mm respectively. There was one case in which dilation was not attempted yet the echoendoscope could not traverse the tumor (staged T3 N1 by limited endosonography). When dilation was performed, the mean largest balloon size used was 15mm (SD 2; range 12-20). Table 2 demonstrates the frequency of maximum balloon diameter size used, the mean starting balloon size for each subsequent maximum balloon size used, and the rate of successful traversal of tumor for each maximum diameter attained.

There was one esophageal perforation following dilation (1.3%; 95%CI 0.2-7.0) and one esophageal perforation following EUS without dilation (0.5%; 95%CI 0.1-2.8; p=0.49 for the comparison). When considering only T3 or T4 tumors (n=172), the perforation rates with and without dilation were 1.5% and 1.0% respectively (p=1.00). For historical context, Table 3 provides previously published data about perforation and complete staging rates following dilation with both bougies and balloon dilators. In our one case of perforation following dilation, a TTS balloon was inflated directly to 16.5mm in a 6cm long, T3N1 adenocarcinoma. The patient reported severe chest pain in the recovery area after the EUS and a contrast study demonstrated a free perforation. He underwent an esophagectomy that same day and required a 21 day hospitalization. In the one case of perforation following EUS without dilation, the patient experienced chest discomfort the day following the

procedure. A CT scan of the chest revealed air in the mediastinum. He was made NPO, managed non-operatively with I.V. antibiotics, and discharged 5 days later.

There were no other complications noted that resulted in hospitalization. In one case, dilation to 12mm was associated with transient, self-limited bradycardia in an 81-year-old man. Further dilation was not attempted, resulting in one of the failures to completely stage a cancer despite dilation.

DISCUSSION

In this retrospective study, we found a need to dilate a malignant stricture in approximately one-third of EUS cases done for esophageal cancer staging. Using TTS balloon dilators, we completed staging in 95% of cases, resulting in only one major complication (esophageal perforation) and one minor complication (transient bradycardia). This perforation rate was similar to that observed during EUS staging without dilation.

Not surprisingly, we found a significant association between advanced tumor stage and the need to dilate a malignant stricture. Interestingly, it appeared that one institution relied upon dilation more often than the others, independent of tumor stage. This may reflect practice variation, the use of larger instruments (endosonographers at that institution used the largest diameter echoendoscope in our series), or residual confounding by advanced cancer stages as seen at that medical center.

To determine the complication rate of esophageal cancer dilation, it is important to establish the baseline rate during EUS without dilation [4,17-18]. Siemsen and colleagues reported EUS staging without any dilation among 104 patients [4]. One patient with a traversable T4 lesion experienced a perforation at the level of the tumor. Mortensen, et al. reported three esophageal perforations during staging EUS without attempts at dilation, as well as two perforations in the setting of dilation [13]. There were 532 esophageal cancer stagings in their series (overall perforation rate of 0.9%) but the numbers of cases requiring dilation was not provided, precluding calculation of a specific rate of perforation associated with and without dilation. Our finding of one perforation among 195 EUS examinations without dilation provides more support that, while the incidence of perforation is low in this setting (<1%), complications do occur.

Previous investigators have documented the occurrence of an obstructing malignant stricture in 21-40% of esophageal cancers [3,4,8-10]. When performing EUS for staging, the clinical management of these strictures has been a source of debate. Some investigators perform limited staging above the stricture, without dilating, to avoid complications [4,19-21]. However, failure to traverse a malignant stricture is associated with a significant decrease in the accuracy of EUS T- and N-staging [4,7,19,22-23]. The ability to perform FNA of celiac or perigastric lymph nodes adds significantly to EUS N- and M-stage accuracy, and may not be feasible without dilation of a malignant stricture [5-6,24-25]. Our study was not designed to answer questions about how dilation altered management, staging accuracy, FNA made possible by dilation, or whether CT/PET scanning might be a superior method for celiac axis node staging in stenotic tumors. However, in our series 15 patients (19%) requiring dilation were found to have celiac axis adenopathy. These cases would not have been appropriately staged by EUS without dilation. Other options to attempt complete staging include use of high-frequency EUS probes [26-28] and use of a tapered, wire-guided echoendoscope (Olympus MH908, Olympus America, Inc., Melville, N.Y.) [3,14]. However, neither alternative permits FNA of visualized nodes. It is important to stress that documentation of celiac axis adenopathy may significantly impact upon patient management as it confers M1a status (stage IVa) which is considered inoperable in many centers.

While one earlier study reported a 24% perforation rate when dilating malignant strictures [7] (Table 3), others have subsequently documented the safe use of Savary dilators in this setting, often with the suggestion that dilator size be restricted. Wallace et. al. reported no complications after 42 Savary dilations to no more than 16mm, and found dilation provided new critical staging information in 19% of cases [9]. Complete staging was possible after Savary dilations in only 74% of all patients, but in 87% of those dilated to at least 14mm. Similarly, Pfau et. al. had no complications after 81 dilations prior to EUS using mainly Savary dilators to a mean diameter of 14mm [8]. The authors of these studies concluded that Savary dilation to between 14 and 16mm was safe and sufficient for complete staging in most patients. In our series, there was a single perforation associated with dilation. This occurred during expansion of a balloon directly to 16.5mm. While little definitive advice can be gleaned from our experience, previous investigators' suggestion of limiting dilation to no more than 14 to 16mm [8-9] is probably sound. Newly released electronic radial echoendoscopes (e.g., the Olympus GF-UE160) have larger outer diameters than the mechanical radial echoendoscopes used in our study, and therefore may require more aggressive stricture dilation for passage of these instruments. Another alternative for endosonographers with both types of radial equipment would be to choose the instrument with the narrowest outer diameter to limit risk of complications.

Prior studies suggest that both fixed-size and balloon dilators are equally effective and safe in the dilation of benign esophageal strictures [29-31]. Complication rates and successful dilation rates appear similar between the two types of dilators (Table 1) but prospective, randomized studies directly comparing their performance in the setting of malignant strictures are lacking. Potential benefits of TTS balloon dilators over fixed-size dilators include a lack of additional esophageal intubations and lack of requirement for fluoroscopy. However, reusable fixed-size dilators may have cost advantages over TTS balloon dilators [32]. Based upon our findings, the inherent risk of perforation should not be a factor when choosing dilator type in this setting.

A limitation of our study is its retrospective nature, without a standardized method for stricture dilation. However, this reflects a range of clinical practice and likely represents the actual collective experience of endoscopists practicing nationwide. Because many of our patients were referred from gastroenterologists at outside institutions, we did not have access to all prior endoscopy reports. Therefore, we are unable to report how often our patients had undergone prior stricture dilation. Another limitation was the lack of a standardized method for capturing complications, leaving the possibility that some complications, particularly those that were delayed, might have been missed. It was for this reason that we restricted our analysis to major complications that would likely manifest within the procedure recovery time or would be communicated back to the endosonographer. In addition, most participating centers (accounting for 75% of cases) contacted patients within 48 hours of EUS to identify delayed complications.

In summary, TTS balloon dilation of malignant esophageal strictures prior to EUS appears to be safe, albeit with a definite risk of perforation. This risk does not appear to be excessively greater than the baseline risk of perforation when staging esophageal cancer without dilation. In the setting of a malignant stricture, one must choose between the potentially lower accuracy of incomplete EUS staging and the risk of dilation to permit complete cancer staging. Based upon the collective published literature, when one does dilate a malignant stricture, the safest practice may be to limit the dilation to approximately 15mm.

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Table 1

Comparison between institutions, patient characteristics, and tumors based upon whether or not dilation was performed

	Not Dilated (n = 195)	Dilated (n = 77)	p-value
Participating Institution			<0.001 *
1	37	13	
2	48	41	
3	38	9	
4	16	3	
5	56	11	
Mean Age (SD)	64 (12)	63 (11)	0.34
Male	88%	78%	0.04
Tumor histology			0.01
Adenocarcinoma	159	51	
Squamous cell carcinoma	31	24	
Undifferentiated carcinoma	4	0	
Median tumor length (range; IQR)	4cm (1-25;2-6)	5cm (1-12;4-7)	0.01
T stage			<0.001
T1	45	0	
T2	45	10	
T3	95	57	
T4	10	10	
N stage			<0.001
N0	75	11	
N1 or N2	120	66	
M stage			0.04
M0	172	59	
M1a	20	15	
M1b	3	3	
Perforation	1	1	0.50
Other major complications	0	0	>0.5

* Comparison is for institution 2 vs. all other sites. No other differences between institutions were significant.

Table 2

TTS-Balloon Dilators Used

Maximum Balloon Size Used (mm)	Frequency of Use (% of all dilations)*	Starting Balloon Size (mean +/- SD)	Staging Completed (% of times used)
12	12 (16%)	9 +/- 1	10/12 (83%)
13	2 (3%)	11 +/- 1	2 (100%)
15	41 (54%)	12 +/- 1	41 (100%)
16.5	4 (5%)	16 +/- 1	3 (75%)
18	15 (24%)	11 +/- 2	14 (93%)
20	2 (3%)	10 +/- 0	2 (100%)

Note: Balloon size(s) was not documented for one of the 77 patients who underwent dilation.

* Numbers add to >100% because of rounding.

Table 3

Rates of Perforation with Dilator of Esophageal Cancer in the Literature

Source	Year of Publication	No. of Patients/No. of Dilations*	Type of dilator(s)	Max Dilator Size (mean with range)	Incomplete Staging†	Rate of Perforation
Current series		77/77	TTS balloon	15mm (10-20)	5%	1%
Vazquez-Sequeiros et al. ⁶	2003	16/16	TTS balloon	NR (12-18mm)	33%	0%
Parmar et al. ²⁵	2002	16/16	TTS balloon	NR (8-18mm)	0%	0%
Vazquez-Sequeiros et al. ⁵	2001	9/9	TTS balloon	15mm (all to 15)	0%	0%
Pfau et al. ⁸	2000	81/86	Savary-Gilliard (n=72), TTS balloon (n=5) and combined (n=4)	14mm (9-18)	15%	0%
Wallace et al. ⁹	2000	42/44	Savary-Gilliard	13.6mm (11-16)	26%	0%
Kallimanis et al. ¹¹	1995	17/24	Savary-Gilliard	12.6mm (9-17)	18%	0%
Binnmoeller et al. ¹⁴	1995	9/9	Savary-Gilliard	NR (all dilated to 11mm)**	0%	0%
Van Dam et al. ⁷	1993	21/21	Savary-Gilliard	NR (16-18)	9.5%	24%‡

NR = not reported

* Some patients underwent multiple dilations.

† Failure to traverse stenosis with echoendoscope despite dilation

** Authors used a 7.9mm diameter prototype esophagoprobe

‡ Four perforations were due to passage of a dilator. In one case of malignant stenosis without passage of a dilator, dilation with the echoendoscope itself was deemed the mechanism of injury.