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Empiric Dilation in Non-obstructive Dysphagia

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Abstract

Aims—To study practice patterns in the management of non-obstructive dysphagia among US gastroenterologists.

Data source—Endoscopic data repository from 100 U.S. gastroenterology practices during 1998-2003 (Clinical Outcomes Research Initiative, CORI).

Methods—All initial EGDs in adult patients between 1998 and 2003 (n=181,261) were evaluated for demographic data, endoscopic findings, and the occurrence of esophageal dilation. A case population of 7,256 patients receiving empiric dilation for dysphagia for non-obstructive dysphagia was compared to a control population of 5,764 patients with dilation for peptic strictures.

Results—The group of patients with empiric dilation was younger than the group of patients with peptic strictures and contained more women. Reflux symptoms and erosive esophagitis were less frequent in the empiric dilation than in the strictures group. Empiric dilations were mostly performed using rubber bougies, whereas strictures were most frequently dilated over a guidewire. For all types of dilators, the diameters were significantly larger in empiric than stricture dilation. Repeat dilations within one year after the initial procedure occurred in 4% of the empiric and 13% of the stricture dilations.

Conclusions—Compared with dilation of peptic strictures, empiric dilation of non-obstructive dysphagia is a more common clinical practice that is performed in a different patient population and utilizes different techniques.

Keywords

dysphagia; esophageal dilation; peptic stricture; esophageal ring; gastroesophageal reflux disease; peptic stricture; Schatzki ring

Introduction

Dysphagia secondary to benign esophageal strictures has been extensively studied, and there are well-defined practice guidelines that recommend dilation as a safe and effective first-line therapy.[1-4] In contrast, dysphagia in the absence of radiographic or endoscopic signs of stenosis is poorly understood and lacks agreement on how to best manage it. In the guidelines of the American Gastroenterological Association (AGA) from 1999, a trial of empiric bougienage was considered a reasonable option in patients who complained of dysphagia for solid food and who had normal findings on endoscopic examination.[1] The current UpToDate algorithm, which many physicians use, cites the AGA practice guidelines

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by Spechler and still recommends empiric dilation for non-obstructive dysphagia.[5] A recent "Educational Practice" article also recommended this approach.[6-7] Marshall and coworkers published the first study to actually test the efficacy of empiric dilation. In this retrospective study, half of the forty patients with non-obstructive dysphagia improved after dilation.[8] Three subsequent randomized trials, however, found little or no benefit associated with empiric dilation.[9-11] Based on the outcomes of these trials, the most recent guidelines of the American Society for Gastrointestinal Endoscopy (ASGE) from 2006 no longer advocate empiric dilation.[12]

Although empiric dilation for non-obstructive dysphagia is rather common in gastroenterological practice,[11,13] there have been no large-scale studies to delineate the practice patterns of its use, and no study has evaluated the rate of recurrent dilations following the initial therapy. The American Society for Gastrointestinal Endoscopy initiated the Clinical Outcomes Research Initiative (CORI) to develop a database of endoscopic procedures. The database was designed to store records from gastrointestinal endoscopy procedures that would reflect a wide range of endoscopic practice. The present study utilized this unique database to study the practice patterns of empiric esophageal dilation in patients with non-obstructive dysphagia. These practice patterns of empiric dilation were compared with those of dilation in peptic strictures.

Methods

The study was performed using the CORI database, which is an endoscopic database formed in 1995 in collaboration with the American Society for Gastrointestinal Endoscopy. The CORI national endoscopic database collects endoscopy reports containing the standard reporting elements recommended by the ASGE. Reports are entered by participating gastroenterologists and then submitted electronically on a weekly basis to the CORI headquarters in Portland, Oregon. Prior to electronic submission, reports are stripped of information that could compromise the confidentiality of patient, physician, or participating institution. Data objects are then pooled for analysis. The CORI database is designed to sample a broad cross-section of the population in the United States. It has now grown into one of the largest of its kind with over 1.3 million total procedures on record from 65 practice sites in 26 states.

All esophago-gastro-duodenoscopies (EGDs) in the CORI database from 1/01/1998 to 4/30/2003 were considered for the present analysis with the exception of EGDs in patients younger than 20 years. Based on the endoscopic reports of a patient's initial EGD during the study period (n=181,261), the following two groups were formed: (a) case subjects who received empiric dilation for dysphagia in the *absence* of endoscopic evidence of stricture or ring (n=7,256), and (b) a control group of subjects who received dilation for peptic stricture of the esophagus (n=5,764). Data on prior esophageal barium studies were available for a minority of patients. Patients with an esophageal stenosis seen on prior barium studies were excluded from the non-obstructive dysphagia group even if they had a negative EGD.

Information about age, sex, ethnicity (White, Black, Hispanic), and site type (community, Department of Veterans Affairs Medical Centers (VA), university), are currently required fields in all CORI reports. These demographic characteristics were evaluated for the initial EGD during the study period. Prior to the year 2001 endoscopists were not required to enter ethnicity data, and as a result a fraction of the total study population lacks ethnicity data. Analysis of ethnicity data was, therefore, restricted to patients receiving an initial endoscopy after 1/01/2001. Gender data were analyzed after exclusion of the predominately male VA population. EGD indications were also available for all case and control subjects and were

evaluated for the initial EGD during the study period. Some patients presented with multiple indications for endoscopy.

The presence of endoscopically apparent reflux-induced esophageal inflammation was recorded in the CORI database. For a minority of patients with gastro-esophageal reflux disease, data graded according to the Los Angeles classification were also available. The presence of dysphagia was listed among the indications for endoscopy. The CORI entry form for endoscopic diagnoses contained a specific check box for the presence of esophageal stricture/stenosis with a submenu listing various etiologies, such as benign stricture secondary to reflux disease, lower esophageal ring, web, malignancy, outside compression, and others. In instances of dilation, the physician was also asked to check one of several reasons for the procedure itself. Besides the causes for dysphagia listed above, the second submenu included: achalasia, anastomotic stricture, damage secondary to radiation, various cancer types of the upper gastrointestinal tract, motility disorder, neurologic disease, and dysphagia without stricture. In addition, all free text entries in the diagnostic and therapeutic descriptions were screened for the presence of key words associated with possible esophageal stenosis, such as compression, narrowing, obstruction, ring, scarring, or stricture. The records listed the types of dilator used and the number of dilators passed during the initial treatment. Because this information was not a required component of the CORI report, such data were not available for all patients. Repeat dilations occurring within year after the initial EGD were evaluated to determine the rate of repeat dilation. The computerized records also included data on dilation-related complications. The CORI database listed only intra and immediate post-procedure complications, but not complications that became noticeable after the initial endoscopy report had been completed.

Results were expressed as average values with their standard deviation. The occurrence of discrete events among different patient groups was compared using the chi-square test. Differences with respect to continuous variables, such as age or interval lengths, were compared using Student's t-test

Results

Patient characteristics

In **Table 1**, the demographic characteristics of patients with empiric dilation are compared to those of patients with stricture dilation. The group with empiric dilation contained younger patients ($p<0.001$) and more women ($p<0.001$) than the group with stricture dilation. The distributions by ethnicity and practice site were similar for both patient groups. **Table 2** summarizes the indications for the initial endoscopy in the two populations with empiric and stricture dilation. Besides dysphagia reflux symptoms constituted the most common indication for endoscopy in both groups, although reflux symptoms occurred significantly less often in the group with empiric dilation ($p<0.001$). **Table 3** lists the occurrence of endoscopically apparent reflux-induced esophageal inflammation for the two populations with empiric and stricture dilation. Inflammation was almost twice more common in the stricture than in the empiric dilation group ($p<0.001$). Data concerning severity of inflammation (LA Classification) was available for 295 control patients and 254 empiric dilation patients. The grade of inflammation was significantly less severe in the patient group with empiric than stricture dilation ($p<0.001$).

Techniques of dilation

Data on the type and size of dilator used for the empiric dilation were available for 4,263 patients, while similar type data were available for 4,112 patients with stricture dilation (**Table 4**). Empiric dilations were most often performed using rubber bougies, whereas

strictures were most frequently dilated over a guidewire. For all types of dilators used, the diameters were significantly larger in empiric than stricture dilation ($p<0.001$). The number of dilators passed during the initial treatment session was known in 254 patients with empiric and 295 patients with stricture dilation (**Table 5**). Compared with dilation of strictures, empiric dilation was less likely to be associated with multiple dilators ($p<0.001$). Repeat dilations within a year after the initial dilation treatment occurred in 4% (310/7256) of patients with empiric dilations and 13% (749/5764) of patients with stricture dilation ($p<0.001$). The mean (±SD) interval between the first and subsequent dilation was 177±681 days in the empiric dilation group compared to 82±228 in the stricture group ($p=0.017$). CORI records only complications occurring during and immediately after the procedure.

Immediate complications were reported in 44/7256 (0.61%) empiric dilations and in 39/5,768 (0.68%) stricture dilations. Esophageal perforation and significant bleeding occurred in two and three patients, respectively, after emperic dilation. Esophageal perforation and significant bleeding occurred in two and four patients, respectively, after stricture dilation. No data were available on *late* complications outside the endoscopy suite.

Discussion

The CORI database has provided a unique opportunity to study the practice patterns for dilation of non-obstructive dysphagia and to compare them with those of peptic strictures. Our study revealed that empiric dilation was more common than dilation for peptic strictures. When compared with patients dilated for peptic strictures, non-obstructive dysphagia patients were younger and had a female predominance. The distributions by ethnicity and practice site were similar for both populations. Reflux symptoms and esophageal inflammation occurred less frequently in the empiric dilation group. The empiric dilation group was significantly less likely to undergo repeat dilation when compared with the peptic stricture group, and when repeat dilation occurred, it was usually scheduled after a significantly longer time interval.

Our data support the findings of a survey by Ramirez et al. that showed empiric dilation for non-obstructive dysphagia to be a common practice. In their survey, 400 community gastroenterologists estimated the extent at which they performed empiric dilations. One-third of respondents reported the “routine” empiric use of a single Maloney dilator, while another third reported the “occasional” use of empiric dilation.[13] Lavu et al. reported that 67% of all esophageal dilations at an academic institution were performed to treat non-obstructive dysphagia.[11] Our study revealed similarly that esophageal dilation was more commonly used for treatment of non-obstructive dysphagia than peptic strictures. This finding is surprising, considering that esophageal dilation is universally accepted as the first-line therapy for benign strictures, whereas its role in non-obstructive dysphagia has remained controversial.

The first study to test the efficacy of empiric dilation was published by Marshall and coworkers in 1996.[8] Forty patients with dysphagia to both liquids and solids but a negative endoscopy were questioned about their symptoms 18 months after an empiric dilation with a 54-French Maloney dilator. Twenty-one of the 40 patients reported a complete resolution of their symptoms. The study did not include a control group for comparison. The positive results of this study need to be contrasted with the negative results of three more recent randomized trials, which compared the efficacy of empiric dilation to sham dilation in patients with non-obstructive dysphagia. Colon et al. studied 23 patients with either solid or liquid dysphagia and a negative EGD and barium pill study.[9] Two weeks after the treatment, the patients’ dysphagia scores had improved, but no statistical improvement in dysphagia frequency was observed between the two groups. However, the study by Colon et al. did

show a significant improvement in the patients' diet score, and 80% of the patients in the treatment group had their improvement sustained for 2 years. The largest study was published by Scolopio et al. in 2001.[10] Eighty-three patients with solid food dysphagia and normal EGD were randomly assigned to either dilation with a single 54-French dilator or sham dilation and then followed for six months. While both groups showed improvement of their dysphagia symptoms, no statistically significant differences were found between the two groups. The study by Lavu et al. examined not only the effect of 56-French empiric dilation on dysphagia but also diet scores and quality of life.[11] The investigators found no difference between the outcome scores of the 17 study and 13 control patients. The authors argued that since both, study and control group, improved to equal degree, the results might reflect the beneficial effects of proton pump inhibitors, on which both the groups were placed, highlighting the possibility of involvement of visceral hypersensitivity in the pathogenesis in non-obstructive dysphagia.

Besides visceral hypersensitivity, other possible causes for non-obstructive dysphagia include gastroesophageal reflux, non-specific motility disorders, or endoscopically undetectable mild stenosis.[14-18] Despite the lack of evidence in its favor, gastroenterologists may be willing to try empiric dilation in patients with non-obstructive dysphagia, because esophageal dilation is generally a safe procedure and easy to perform in the absence of stricture. Gastroenterologists may perform empiric dilations under the assumption that they are treating subtle symptomatic strictures that are endoscopically undetectable. Moreover, some patients with non-obstructive dysphagia may gain some "placebo" benefit from the dilation itself.

The patients with non-obstructive dysphagia were less likely to complain of reflux symptoms than patients with peptic strictures. Moreover, they were less likely to show endoscopic signs of reflux esophagitis. These results were expected based on the well-established association between peptic strictures and severe reflux disease.[1-4] Dilation therapy for non-obstructive dysphagia was mostly performed with a single relatively large dilator, while stricture dilations frequently employed multiple dilator passes over a guide-wire. Because in non-obstructive dysphagia no esophageal lesion is seen, physicians may feel more confident utilizing a single large dilator.

Our study showed that patients with non-obstructive dysphagia were less likely to undergo repeat dilation over the course of one year when compared to patients with the peptic strictures. Additionally, the interval between dilations for non-obstructive dysphagia was more than twice as long as that for peptic strictures. This could be explained by the fact that strictures are often gradually dilated over the course of several acute dilation sessions. This allows the physician to safely expand tight strictures.[1] In contrast, there is no proven benefit to employing multiple treatments for non-obstructive dysphagia. Moreover, if the initial treatment for a non-obstructive dysphagia did not relieve the symptoms, the physician may have been hesitant to repeat a procedure of unproven benefit. Alternatively, non-obstructive dysphagia patients could have undergone less repeat dilations because their disease process represented a more benign form of dysphagia with a naturally limited course, as opposed to the progressive nature of peptic strictures.

The utilization of the CORI database for the purpose of the present study was associated with several potential limitations. The patient records in the database were not collected prospectively with respect to the aims of the present study. All diagnoses relied solely on the physicians entering the endoscopy report and assigning a correct diagnosis to the presence of a possible esophageal obstruction. The endoscopists entering data into the CORI database did not utilize a set of pre-established uniform diagnostic criteria for esophageal stenosis. No means existed, therefore, to assess the validity of individual data entries. In rare instances,

incomplete forms of the CORI database may have resulted in a missed diagnosis of esophageal obstruction. Some patients may have been lost to follow-up, because they received a repeat dilation at facility uninvolved with the CORI database. Most of these potential pitfalls would have affected the case and control group alike.

In summary, although prospective clinical studies have failed to show a clear-cut benefit of empiric dilation in non-obstructive dysphagia, it represents a rather common practice that is utilized even more frequently than the dilation of true peptic strictures. The patient population subjected to empiric dilation is different from the stricture population, comprising more women and younger patients. A different technique is used for empiric as opposed to stricture dilation in that it is frequently done using rubber bougies and involves a single one-time dilation with large-diameter dilators. Future studies will need to address the rationale for performing such procedures and assess their long-term outcomes.

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References

1. Spechler SJ. AGA technical review on treatment of patients with dysphagia caused by benign disorders of the distal esophagus. Gastroenterology. 1999; 117:223–54.
2. Silvis SE, Nebel O, Rogers G, et al. Results of the 1974 ASGE Survey. J Am Med Ass. 1976; 235:928–30.
3. Kozarek RA. Hydrostatic balloon dilation of gastrointestinal stenosis: a national survey. Gastroint Endosc. 1986; 32:15–19.
4. Richter JE. Long-term management of gastroesophageal reflux disease and its complications. Am J Gastroenterol. 1997; 92:30S–35S. [PubMed: 9127624]
5. [08/24/2006] UpToDate online, version 14.2. http://www.utdol.com/application/search.asp.
6. Arora AS. Management strategies for dysphagia with a normal-appearing esophagus. Clin Gastroenterol Hepatol. 2005; 3:299–302. [PubMed: 15765451]
7. Lavu K, Garretson RF, Minocha A. Empiric esophageal dilation for nonobstructive dysphagia (letter). Clin Gastroenterol Hepatol. 2005; 3:714. Arora AS. Author reply 2005;3:714. [PubMed: 16206506]
8. Marshall JB, Chowdhury TA. Does empiric esophageal dilation benefit dysphagia when endoscopy is normal? Dig Dis Sci. 1996; 41:1099–1101. [PubMed: 8654140]
9. Colon VJ, Young MA, Ramirez FC. The short and long-term efficacy of empirical esophageal dilation in patients with nonobstructive dysphagia: a prospective, randomized study. Am J Gastroenterol. 2000; 95:910–13. [PubMed: 10763936]
10. Scolapio JS, Gostout CJ, Schroeder KW, Mahoney DW, Lindor KD. Dysphagia without endoscopically evident disease: to dilate or not? Am J Gastroenterol. 2001; 96:325–30.
11. Lavu K, Mathew TP, Minocha A. Effectiveness of esophageal dilation in relieving nonobstructive esophageal dysphagia and improving quality of life. South Med J. 2004; 97:137–40. [PubMed: 14982261]
12. Standards of Practice Committee. Egan JV, Baron TH, Adler DG, Davila R, Faigel DO, Gan SL, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Rajan E, Shen B, Zuckerman MJ, VanGuilder T, Fanelli RD. Esophageal dilation. Gastrointest Endosc. 2006; 63:755–60. [PubMed: 16650533]

13. Shaukat M, Ramirez FC, Sanowski RA. Community experience in esophageal dilation: techniques and complications (abstract). Gastroint Endosc. 1994; 40(Part 2):34. Ramirez FC, personal communication 08/02/2003.

14. Sonnenberg, A. Esophageal disease.. In: Everhart, JE., editor. Digestive diseases in the United States: epidemiology and impact. NIH publication no 94-1447. US Government Printing Office; Washington, D.C.: 1994. p. 300-55.

15. Triadafilopoulos G. Nonobstructive dysphagia in reflux esophagitis. Am J Gastroenterol. 1989; 84:614–24. [PubMed: 2729232]

16. Timmer R, Breumelhof R, Nadorp JH, Smout AJ. Oesophageal motility and gastrooesophageal reflux before and after healing of reflux oesophagitis. A study using 24-hour ambulatory pH and pressure monitoring. Gut. 1994; 35:1519–22. [PubMed: 7828965]

17. Schlesinger PK, Donahue PE, Schmidt B, et al. Limitations of 24-hour intrasesophageal pH monitoring in the hospital setting. Gastroenterology. 1985; 89:797–804. [PubMed: 4029559]

18. DeMeester TR, Wang CI, Wernly JA, et al. Technique, indications, and clinical use of 24 hour esophageal pH monitoring. J Thorac Cardiovasc Surg. 1980; 79:656–70. [PubMed: 7366233]

Table 1

Demographic characteristics

	Empiric dilation	Stricture dilation
Sum	7,256 (100%)	5,764 (100%)
Age (SD)	58.9 (15.3)	62.6 (14.4)
Gender	6,229 (100%)	4,979 (100%)
Male	2,368 (38%)	2,688 (54%)
Female	3,861 (62%)	2,291 (46%)
Ethnicity	4,824 (100%)	3,167 (100%)
White	4,216 (87%)	2,811 (89%)
Black	283 (6%)	107 (3%)
Hispanic	122 (3%)	82 (3%)
Unknown/Other	203 (4%)	167 (5%)
Site type	7,256 (100%)	5,764 (100%)
University	611 (8%)	382 (7%)
VA Hospital	1,027 (14%)	785 (14%)
Community	5,618 (77%)	4,597 (80%)

Age and site type were analyzed using the entirety of both populations. VA patients were excluded from the gender analysis. Patients treated prior to 2001 were excluded from the ethnicity analysis.

Table 2

Indications for the initial endoscopy

	Empiric dilation	Stricture dilation
Sum of Patients	7,256 (100%)	5,764 (100%)
Dysphagia	7,256 (100%)	5,427 (94%)
Reflux symptoms	2,391 (33%)	2,133 (37%)
Abd. pain/dyspepsia	448 (6%)	440 (8%)
GI Bleed	51 (1%)	80 (1%)
Nausea/vomiting	221 (3%)	150 (3%)
Anemia	93 (1%)	93 (2%)
Barrett's esophagus	214 (3%)	145 (3%)
Peptic ulcer disease	13 (0%)	20 (0%)
Varices	4 (0%)	11 (0%)

Individual patients could present with more than one indication.

Table 3

Severity of reflux-induced esophageal inflammation

	Empiric dilation	Stricture dilation
Total number of Patients	7,256 (100%)	5,764 (100%)
Patients with esophagitis	842 (12%)	1,285 (22%)
LA classification		
Data available for n patients	403 (100%)	423 (100%)
LA grade 0	112 (28%)	29 (7%)
LA grade A	158 (39%)	97 (23%)
LA grade B	88 (22%)	164 (39%)
LA grade C	30 (7%)	77 (18%)
LA grade D	15 (4%)	56 (13%)

Reflux esophagitis graded according to the Los Angeles (LA) classification.

Table 4

Dilator type

	Empiric dilation	Stricture dilation
Number of patients	4,263 (100%)	4,112 (100%)
Type of dilation (%)		
Balloon	363 (9%)	820 (20%)
Wire-guided	1,768 (41%)	2,307 (56%)
Bougie	2,132 (50%)	985 (24%)
Mean dilator diameter in mm (SD)		
Balloon	17.5 (1.7)	15.7 (1.1)
Wire-guided	17.0 (1.7)	14.6 (1.9)
Bougie	17.0 (1.4)	15.8 (0.9)

Table 5

Number of dilators used during initial treatment session

	Empiric dilation	Stricture dilation
Number of patients	254 (100%)	295 (100%)
1 dilator	219 (86%)	187 (63%)
2 dilators	25 (10%)	32 (11%)
3 dilators	9 (4%)	60 (20%)
4 dilators	1 (0%)	15 (5%)
5 dilators	0 (0%)	1 (0%)