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Complications During Pneumatic Dilation for Achalasia or Diffuse Esophageal Spasm

Analysis of Risk Factors, Early Clinical Characteristics, and Outcome

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A retrospective cohort study was performed to assess risk factors, early clinical characteristics, and outcome of complications in patients undergoing pneumatic dilation. Of 178 patients with achalasia or diffuse esophageal spasm who underwent 236 dilations with a Browne-McHardy dilator, 16 patients experienced a complication (9.0%). Nine major complications developed: perforations (4), hematemesis (2), fever (2), and angina (1). A prior pneumatic dilation and use of inflation pressure ≥11 PSI were independent risk factors by multivariate analysis for developing a complication. An esophagram immediately following the dilation identified three of the four perforations. Three postdilation findings were identified as indicators of patients with an increased risk of having developed a perforation: blood on the dilator, tachycardia, and prolonged chest pain lasting >4 hr after dilation. In all patients incurring a major complication, one of the three indicators, or the complication itself was recognized within 5 hr of dilation. All patients with complications, including the four with perforation who received prompt surgical repair and esophagomyotomy, recovered uneventfully. The symptomatic relief of dysphagia in patients with perforation undergoing emergent surgical repair and esophagomyotomy was similar to patients undergoing elective esophagomyotomy. Conclusions: (1) Pneumatic dilation is a safe treatment of achalasia, with a 1.7% risk of perforation. (2) The risk of developing a complication is increased by having had a previous pneumatic dilation or by use of inflation pressures ≥11 psi. (3) All patients with a major complication were identified within 5 hr after dilation. (4) Complications following pneumatic dilation, if recognized and treated promptly, were not associated with adverse, long-term sequelae.

KEY WORDS: esophageal perforation; esophagomyotomy; esophageal motility disorders.

Pneumatic dilation is the most effective nonsurgical treatment of achalasia (1, 2). The most serious complication of this procedure is esophageal perforation, with a reported incidence varying from 0 to 21% (2–4). Other complications of this procedure include bleeding and aspiration. Risk factors for these complications have not been critically examined. Clarification of the relationship between patient characteristics and the incidence of complications would permit a more rational approach to determine when elective surgical treatment is necessary.

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The treatment parameters used to perform pneumatic dilations vary considerably (2, 5). Dilation pressures that have been used range from 3 to 15 psi, and the duration of inflation ranges from a few seconds to 5 min (2, 6–8). The effect of inflation pressure and duration of inflation on the incidence of complications is not known.

Following a pneumatic dilation, patients usually undergo an esophagram with water-soluble contrast to detect a perforation. There have been several reported cases, however, of false negative esophagrams (9, 10). To protect against this, patients generally are observed for 24 hr to ensure that a complication does not develop. If early signs and symptoms of the patients who will develop complications from pneumatic dilation can be identified, patients without these findings may not require overnight hospitalization, thereby decreasing the cost of this procedure.

Finally, the long-term outcome of patients who develop complications from dilation has not been well characterized. Although patients with a perforation often undergo immediate surgical repair and esophagomyotomy (11–13), there have been no studies to determine if the clinical outcome in patients who perforate during dilation and undergo immediate surgery differs from patients undergoing elective esophagomyotomy.

In an effort to address these issues, we performed a retrospective cohort study of patients who had undergone pneumatic dilation or Heller esophagomyotomy at the Hospital of the University of Pennsylvania. The specific aims of this study were: (1) to examine factors that may be associated with an increased risk of perforation or other complications from pneumatic dilation; (2) to identify those patient signs and symptoms following dilation that will be useful in differentiating perforated patients from uncomplicated patients; and, (3) to compare the long-term outcome of perforated patients who had surgical repair with esophagomyotomy to patients who had a primary Heller esophagomyotomy.

MATERIALS AND METHODS

We reviewed the records of every adult patient treated with pneumatic dilation for idiopathic achalasia or diffuse esophageal spasm (DES) during the years 1976–1986 at the Hospital of the University of Pennsylvania. During this time period, the Browne-McHardy dilator (14) was used for pneumatic dilations at our hospital. Eligibility criteria for entry into the study required: (1) a diagnosis of achalasia or DES by esophageal manometry, as defined below; (2) the absence of obstructive intrinsic or extrinsic esophageal lesions by x-ray and endoscopy; and (3) treatment with pneumatic dilation using a Browne-McHardy dilator. Patients were excluded if the procedure was performed in the presence of: (1) gastric or esophageal carcinoma; (2) a peptic stricture; or (3) prior surgical fundoplication.

Patients treated with elective Heller esophagomyotomy for idiopathic achalasia during the same time period were also evaluated to compare their hospital course and clinical outcome to patients sent for emergent surgery for repair of an esophageal perforation occurring during pneumatic dilation. Elective surgical patients were excluded if another operation was planned simultaneous with the esophagomyotomy.

Hospital charts were reviewed for clinical demographic information, the type of treatment used for each procedure, complications of treatment, hospital course after dilation, and subsequent procedures performed for achalasia. The esophageal manometry tracings were reviewed for basal LES pressure (measured at mid-respiratory excursion), LES relaxation in response to swallowing, and esophageal peristalsis. The esophageal manometries were performed measuring basal LES pressure using the station pull-through technique, and averaged from three separate ports (15, 16). Intraluminal esophageal pressures during 10 consecutive swallows were measured simultaneously from manometry ports 5, 10, and 15 cm above the LES.

Each patient was sent a questionnaire to assess their clinical symptoms. The questionnaires inquired about the severity of dysphagia to solids and liquids, both for before treatment and at present, on a visual analysis scale from 0 (no symptoms) to 4 (very severe symptoms). This questionnaire also asked if and when subsequent treatments for achalasia were performed.

The diagnosis of achalasia required manometric demonstration of aperistalsis of the esophagus and incomplete relaxation of the LES on swallowing (15). If the LES could not be entered by the perfusion catheter, an esophagram demonstrating esophageal dilation and a narrow LES, in addition to aperistalsis on manometry, was sufficient. The diagnosis of DES required manometric evidence of high amplitude, simultaneous esophageal contractions in response to >30% of swallows, with preservation of normal peristalsis (17). These patients with DES undergoing pneumatic dilation had coexisting LES dysfunction with either an elevated baseline pressure or incomplete relaxation and had symptoms of dysphagia that were unresponsive to medical therapy. Pneumatic dilation in these patients has previously been shown to be an effective form of therapy (18).

Technique of Pneumatic Dilation. A clear liquid diet was maintained for 24 hr followed by an overnight fast. After application of a local anesthetic to the pharynx and intravenous administration of a sedative and analgesic, an esophagogastroduodenoscopy was performed. If retained food or fluid was present, the esophagus was emptied of all residual contents by Ewald lavage. With the patient in the left semirecumbent position and continuous oral suction, the Browne-McHardy dilator (Narco Scientific, Fort Washington, Pennsylvania) was passed orally. The

Browne-McHardy dilator consists of a graduated mercury filled bougie with an inflatable rubber-covered radiopaque cloth bag (14). On inflation, the balloon diameter is ~3.8 cm. Fluoroscopic guidance was used to position the balloon to straddle the diaphragmatic hiatus, and to ensure that balloon movement did not occur during the procedure. Inflation pressure, duration of inflation, and the number of inflations varied between patients at the discretion of the gastroenterologist. Dilation was performed with a pressure in the range of 7–17 psi, the duration of balloon inflation varied between 10 and 75 sec, and one to three inflations were used. Following pneumatic dilation, patients had nothing by mouth and an esophagram was performed initially using water-soluble contrast (Gastrografin, Squibb Diagnostics, New Brunswick, New Jersey). If no perforation was detected with water-soluble contrast, barium was used to complete the study (19). All patients were observed for complications in the hospital for 24 hr following dilation.

Surgical Technique. Patients developing an esophageal perforation from pneumatic dilation were placed on intravenous broad spectrum antibiotics and brought to the operating room as soon as possible. The surgical procedure involved a left thoracic incision. The pleural space was irrigated and drained. The esophageal perforation was closed with placement of a Thal fundic patch and a modified Heller esophagomyotomy was performed (20). An antireflux procedure was also performed at the discretion of the surgeon.

The operative procedure for patients undergoing elective surgical treatment for achalasia usually involved an abdominal approach, a modified Heller esophagomyotomy (incision of the esophageal muscular layer to a length of 5–8 cm, with extension onto the gastric surface for up to 1 cm), and performing a loose, partial fundoplication (20).

Definition of Complications from Pneumatic Dilation. Major complications were defined as sequelae of pneumatic dilation that delayed discharge greater than 24 hr past the planned overnight admission for this procedure. Minor complications were defined as complications related to the procedure that did not delay the discharge greater than 24 hr.

Statistical Methods. Results are expressed as either percentages or mean ± SD. Statistical analysis was performed using Fisher's exact test, Mann-Whitney U test, and Student's t test, as appropriate (21). A P value <0.05 was considered statistically significant. Multivariate analysis was performed to assess the independent significance of risk factors using logistic regression by the SAS procedure CATMOD (SAS Institute, Cary, North Carolina).

RESULTS

Patient Groups

A total of 236 pneumatic dilations in 178 patients were performed for treatment of achalasia or diffuse esophageal spasm at the Hospital of the University of Pennsylvania during the years 1976–1986. Included were 165 patients with achalasia and 13 patients with diffuse esophageal spasm. Of the 236 pneumatic dilations performed, no complications occurred in 220 pneumatic dilations performed in 162 patients (93.2% of procedures, 91.0% of patients).

Sixteen complications developed as a consequence of pneumatic dilation (Table 1). Nine of these complications resulted in a delay of hospital discharge over 24 hr and were thereby considered major complications. Included were four patients with esophageal perforations (2.2% of patients, 1.7% of dilations), two who developed gastrointestinal hemorrhage, two who developed fever (102°F and 103°F), and one patient who had angina following the procedure. Of the patients with hemorrhage, one had hematemesis with a 4 g/dl drop in hemoglobin, and the other had melena and required transfusion of four units of packed red cells. Neither patient underwent upper endoscopy. The febrile patients had normal chest x-rays and esophagrams and were treated with intravenous antibiotics with resolution of the fever. The patient with angina had underlying coronary artery disease and had chest pain with transient ischemic electrocardiographic changes.

Seven patients had minor complications including: fever in three (101.2, 100.6, and 100.2°F; all resolved spontaneously without antibiotics), two had hemorrhage with hematemesis (without a fall in hemoglobin, resolved spontaneously), and two with abnormal findings on the postprocedure gastrografin swallow. These radiographic abnormalities included an esophageal mucosal tear and an esophageal hematoma. Both patients were asymptomatic from the radiographic abnormalities.

Risk Factors for Complications

The clinical and manometric characteristics of the patients who had no complications are compared to those patients who developed complications in Table 2. Of these factors present at the time of treatment, only the number of previous dilations differed significantly between the complicated and uncomplicated groups. A history of one or more previous pneumatic dilations was also significantly associated with an increased incidence of complications (Figure 1). Compared to patients undergoing their initial dilation, patients with one or more previous dilations had an increased risk of complications (17.2% vs 4.5%, $P = 0.006$), major complications (10.9% vs 1.8%, $P = 0.020$) and tended to have more perforations (4.7% vs 0.9%, $P = 0.116$).

TABLE 1. PATIENTS WITH COMPLICATIONS FROM PNEUMATIC DILATION

Pt	Age (yr)	Sex	Diagnosis	Duration (yr) of dysphagia	Number of prior PDs	LES pressure (mm Hg)	Inflation pressure (psi)	Complication	Outcome*
Major complications									
L.B.	37	F	DES	1.5	1	50	12	Perforation	Surgical repair 3 hr after PD; minimal dysphagia 3 years after surgery
M.A.	47	F	Achalasia	20	2	N/A	12	Perforation	Surgical repair 9 hr after PD; mild/mod dysphagia 8 years after surgery
J.C.	52	F	Achalasia	20	0	28	11	Perforation	Surgical repair 29 hr after PD; lost to f/u
C.F.	65	M	Achalasia	4	3	42	10	Perforation	Surgical repair 9.5 hr after PD; no dysphagia at 5 months after PD; patient died 18 months after PD
A.G.	66	F	Achalasia	6	4	N/A	10	Hemorrhage	Hgb fall: 4 g/dl; resolved spontaneously; myotomy performed 2 years after PD
B.C.	58	M	DES	0.5	0	35	10	Hemorrhage	Tx 4 units PRBC. Resolved spontaneously; patient lost to f/u
L.R.	39	M	Achalasia	2	3	N/A	11	Fever	Treated with antibiotics with resolution; myotomy performed 3 months after PD
E.W.	46	F	Achalasia	5	1	21	9	Fever	Treated with antibiotics with resolution; patient lost to f/u
M.F.	73	M	Achalasia	13	4	N/A	11	Angina	Ruled out for myocardial infarction; patient lost to f/u
Minor complications									
T.T.	29	M	Achalasia	2.5	3	N/A	12	Fever	Resolved spontaneously; patient lost to f/u
D.J.	56	M	Achalasia	31	0	25	8	Fever	Resolved spontaneously; patient died 3 years later of esophageal cancer
R.A.	38	M	Achalasia	6	1	N/A	10	Fever	Resolved spontaneously; mild dysphagia 5 years after PD
E.M.	41	M	Achalasia	8	3	10	13	Hemorrhage	Resolved spontaneously; patient lost to f/u
P.W.	58	F	Achalasia	0.5	0	N/A	8	Hemorrhage	Resolved spontaneously; no dysphagia 9 years after PD
H.S.	75	M	Achalasia	48	3	N/A	11	Esophageal mucosal tear	Asymptomatic from tear; myotomy performed 3 months after PD
H.S.	66	M	Achalasia	0.5	0	N/A	9.5	Esophageal hematoma	Asymptomatic from hematoma; patient lost to f/u

*Abbreviations: PD, pneumatic dilation; f/u, follow-up.

Treatment Parameters

The treatment parameters used to dilate patients with and without complications are shown in Table 2. Of these dilation parameters, only the inflation pressure differed significantly between the complicated and uncomplicated groups. The incidence of perforation was greater in patients treated with higher inflation pressures (Figure 2). In patients treated with an inflation pressures <10 psi, there were no perforations, a 1.1% incidence of major complications, and only a 4.5% rate of all complications. In contrast, in patients with dilations using inflation pressure ≥10 psi, 4.6% perforated (P = 0.06), 9.2% had a major complication (P = 0.02), and 13.8% had any type of complication (P = 0.03). An inflation pressure ≥11 psi significantly increased the risk of perforation compared to inflation pressures <11 psi (9.1% vs 0.7% perforations, P = 0.02). Dilation pressure and a history of prior pneumatic dilations were independent significant risks for complications by multivariate analysis.

Identification of Complications

The postdilation esophagram detected three of the four perforations on initial examination (Figure

TABLE 2. CHARACTERISTICS OF PATIENTS WITHOUT AND WITH COMPLICATIONS AFTER PNEUMATIC DILATION FOR ACHALASIA*

	No complications (N = *162*)	*All complications* (N = *16*)	P *value*
Demographic factors			
Age	46 ± 15.8	52.8 ± 13.9	NS
Sex (% female)	52.5	37.5	NS
Race (% white)	85.6	81.3	NS
Historical characteristics			
Duration of dysphagia (years)	6.3 ± 6.0	10.5 ± 13.3	NS
Number of previous dilations	0.6 ± 1.0	1.8 ± 1.5	0.005
LES pressure (mm Hg)†	37.0 ± 16.2	30.1 ± 13.4	NS
Pneumatic dilation parameters			
Inflation pressure (psi)	9.7 ± 1.2	10.5 ± 1.4	0.014
Duration of inflation (sec)	29.3 ± 12.6	31.2 ± 12.1	NS
Number of inflations	1.5 ± 0.6	1.6 ± 0.5	NS
Postdilation signs and symptoms			
Blood on dilator (%)	33	50	NS
Chest pain during dilation (%)	91.0	91.7	NS
Prolonged chest pain postdilation (%)	13.4	40	0.016
Tachycardia (%)	1.5	25	0.001

*Results expressed as mean ± SD. NS = not significant ($P > 0.05$).
†Normal LES pressure is 15 to 30 mm Hg. LES pressure measurements were available in 90/162 uncomplicated patients and 7/16 complicated patients.

3). In one patient, the initial esophagram showed no extravasation, but because of prolonged chest pain, a subsequent esophagram was performed 18 hr later that revealed an esophageal perforation (patient J.C. in Table 1). The esophagram findings also did not predict the complications of fever or hemor-

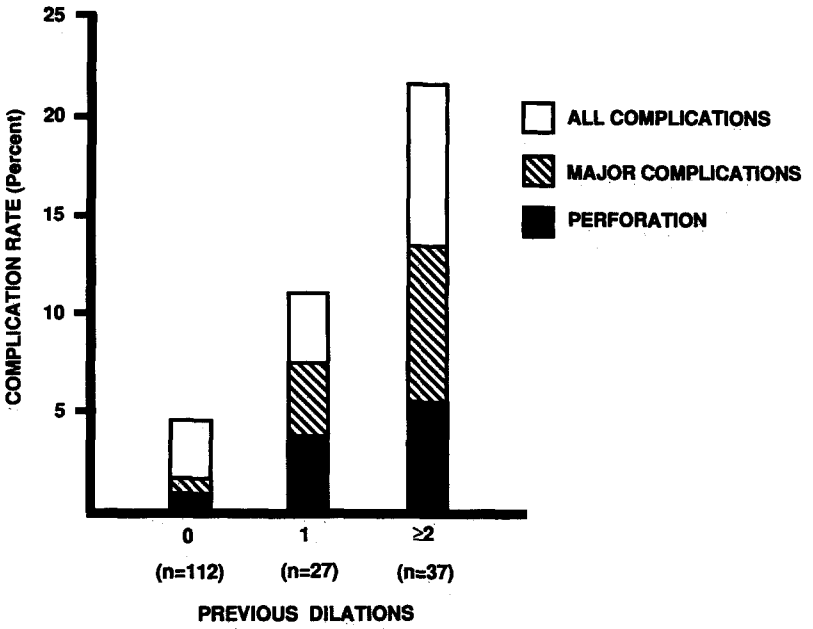

Fig 1. The risk of complications in patients undergoing a pneumatic dilation is increased in patients previously treated by pneumatic dilation. In patients with no previous dilation, the overall rate for all complications was only 4.5%. In contrast, patients with one previous dilation had an 11.1% complication rate and patients with two or more previous pneumatic dilations had a 21.6% complication rate ($P = 0.006$). This progressive increase in complication rate with prior pneumatic dilation was also present for major complications that resulted in a delay of discharge ($P = 0.020$). A similar trend was present for perforations. The number of patients in each group is indicated in parentheses.

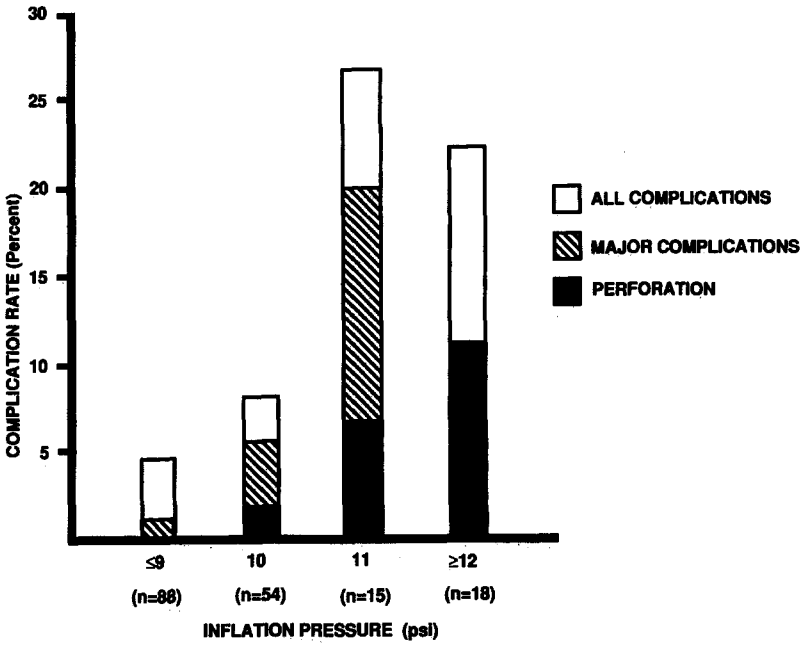

Fig 2. Increasing inflation pressure with the Browne-McHardy dilator was associated with an increasing rate of complications in patients undergoing a pneumatic dilation. An inflation pressure of ≥10 psi was associated with an increased incidence of all complications ($P = 0.030$) and major complications ($P = 0.016$). A pressure of ≥11 psi yielded a significantly greater risk of perforation (9.1% for ≥11 psi versus 0.7% for <11 psi, $P = 0.020$).

rhage. The esophagrams detected the two patients with radiographic abnormalities: an esophageal mucosal tear and an esophageal hematoma. Because of the limitations of radiographic techniques in detection of all complications, other clinical signs and symptoms following pneumatic dilation that might be associated with complications were examined.

Blood on the Dilator. The finding of a blood-stained dilator after pneumatic dilation was present in 33% of those who had no complications (Table 2). Of the patients who perforated, a blood-stained dilator was observed in all three where this information was recorded ($P = 0.04$). Blood on the dilator was found in five of seven of the patients with a major complication and in six of 12 complicated cases where this information was recorded; but these rates were not significant ($P > 0.05$, Table 2). In the 93 procedures where there was no blood on the dilator, there were no perforations and only a 6.5% total complication rate (Figure 4). In the 49 procedures with the presence of blood on the dilator, 6.1% of patients developed a perforation ($P = 0.07$); and 12.2% developed a complication of any kind ($P = 0.09$) (Figure 4).

Chest Pain. The incidence of chest pain during pneumatic dilation had no influence on the development of complications (91.0% of uncomplicated patients versus 91.7% of patients with complications). The incidence of prolonged chest pain (lasting >4 hr after dilation), however, was significantly different (Table 2). Only 13.4% of the uncomplicated patients had prolonged chest pain. In contrast, chest pain lasting >4 hr following dilation occurred in all four of the perforated patients ($P = 0.003$), four of eight (50%) of the patients with a major complication ($P = 0.02$) and in six of 15 (40%) of all the complicated patients ($P = 0.016$). In 26 patients with prolonged chest pain, three patients (15%) had a perforation, compared to none of 138 (0%) patients without prolonged chest pain ($P = 0.01$, see Figure 4).

Tachycardia. Tachycardia (pulse >100 bpm) occurred in only 1.5% of patients without a complication, but was noted in two of four (50%) with a perforation ($P = 0.004$), three of nine (33.3%) with a major complication ($P = 0.02$), and four of 16 (25%) of all patients with any complication ($P = 0.001$, see Table 2). Of the six patients with tachycardia following the dilation, four had complications, three of which were major, including two perforations (see Figure 4).

Other Possible Identifying Factors. Changes in the diastolic blood pressure or the maximum tempera-

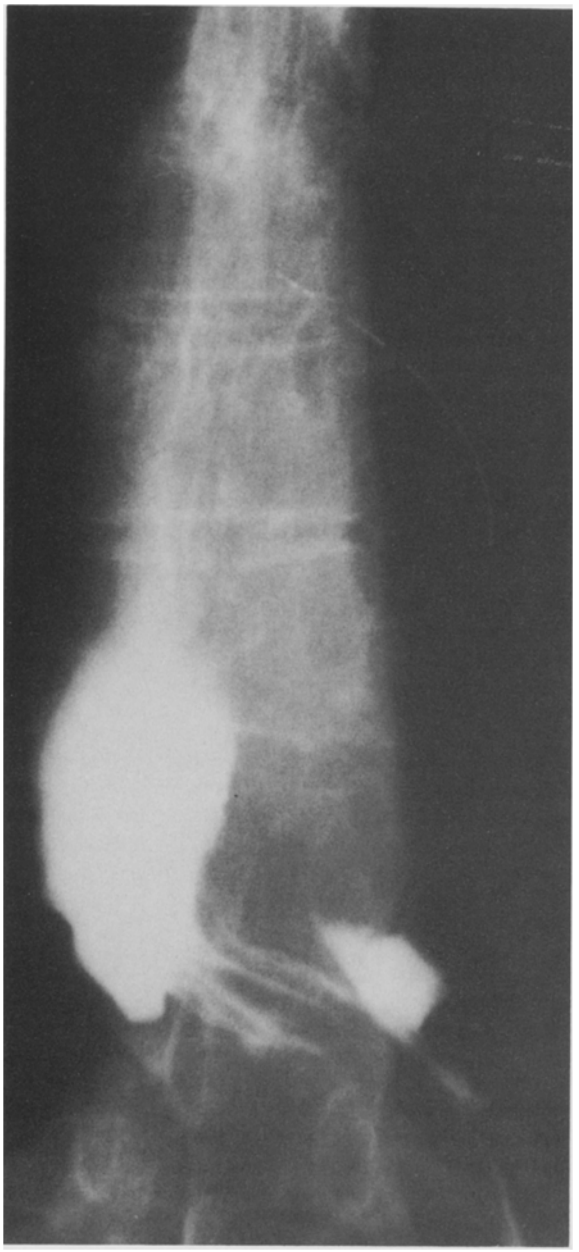

Fig 3. Radiographic demonstration of a perforation from pneumatic dilation. This postdilation esophagram demonstrates extravasation of contrast from the distal esophagus into the mediastinum.

ture were not significantly associated with an increased risk of perforation. Only one patient with a perforation had a fever (100.2°F); five patients without a perforation were febrile but were also considered forms of complications.

Time Course of Recognition of Complications. All the patients with a major complication (including perforations) had their complication recognized or had developed tachycardia or prolonged chest pain within 5 hr of the procedure. Furthermore, all but one minor complication were recognized within 12 hr of dilation. There were three patients who developed their complication after 5 hr past the procedure: one had a fever at 12 hr, another had a fever at 20 hr, and one patient developed chest pain, tachycardia, and hematemesis at 11.5 hr after the dilation. All three were considered minor complications, as there was no delay in their discharge from the hospital.

Outcome of Complications

All patients with complications, including the four with perforations, had uneventful hospital recoveries (Table 1). The four patients with esophageal perforation underwent prompt surgical treatment with esophageal repair and esophagomyotomy.

The long-term clinical outcome of the four patients with perforation were compared to patients undergoing an elective Heller esophagomyotomy for achalasia (Table 3). There were 15 patients with achalasia who had an elective Heller esophagomyotomy during the years 1976–1986. One patient was excluded due to the simultaneous operative procedures of coronary artery bypass grafting with the esophagomyotomy. Thus, 14 patients comprised this comparison group. In this retrospective comparison, there were no significant baseline patient differences in the emergent surgical and elective surgical groups with respect to age, sex, duration of dysphagia, lower esophageal sphincter pressure, and severity of dysphagia (Table 3, Figure 5). Patients undergoing emergent surgery for repair of a perforation with simultaneous esophagomyotomy had a longer duration of intensive care and postoperative hospitalization days and longer lengths of antibiotic administration and narcotic analgesic administration (Table 3).

Assessment of the patients' clinical status after long-term follow-up was performed by a mailed questionnaire to assess their current symptoms. Of the perforated patients, one patient was free of dysphagia at five months after the pneumatic dilation but died of unrelated causes 18 months after treatment, and another patient was lost to follow-up. Thus, only two patients with perforation were available with known follow-up clinical status. Both patients are doing well at 3.1 and 7.8 years after treatment, having improved from both having markedly severe dysphagia to only mild to moderate dysphagia (Figure 5).

Of the 14 patients undergoing elective esophagomyotomy, follow-up is available on all 14 for an

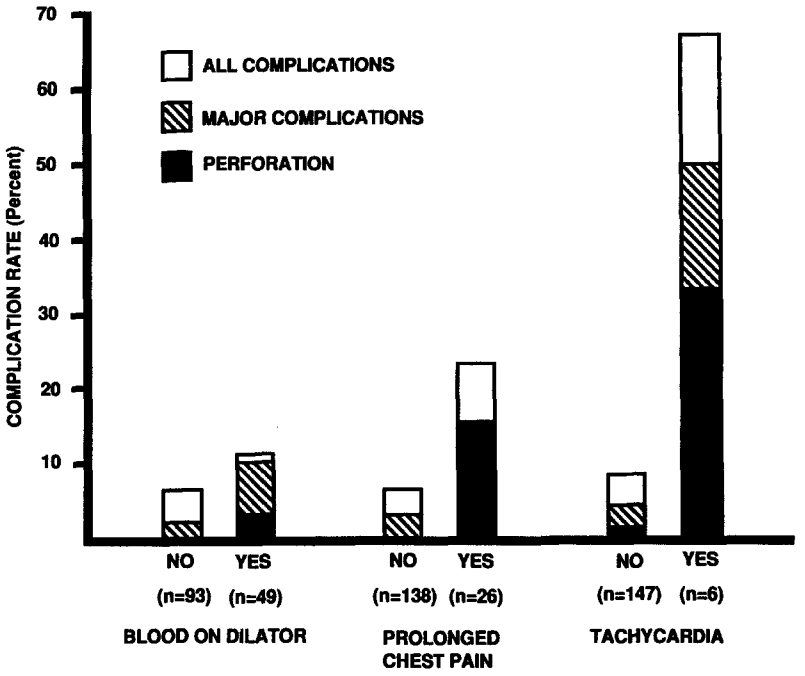

Fig 4. Three postdilation factors were useful clinical indicators to detect patients who subsequently developed a perforation: blood on the dilator, chest pain lasting >4 hr after dilation, and tachycardia. Prolonged chest pain and tachycardia, but not blood on the dilator, were also significantly associated with major complications and all complications.

average follow-up of 4.5 ± 2.5 years. The symptom improvement of patients undergoing emergent surgery for esophageal perforation with performance of Heller esophagomyotomy was not significantly different between patients undergoing an elective esophagomyotomy (Figure 5).

As seen in Table 1, two patients with the complications of hemorrhage and a mucosal tear required subsequent treatment for dysphagia. Both patients underwent elective esophagomyotomy rather than another attempt at dilation.

DISCUSSION

This study reports on a retrospective analysis of risk factors, dilation techniques, and identification

TABLE 3. CHARACTERISTICS OF PATIENTS UNDERGOING EMERGENT SURGERY FOR ESOPHAGEAL PERFORATION AND PATIENTS UNDERGOING ELECTIVE HELLER ESOPHAGOMYOTOMY*

	Emergent surgery (N = *4*)	*Elective esophagomyotomy* (N = *14*)	P *value*
Demographic factors			
Age (years)	50.3 ± 11.6	49.5 ± 15.4	NS
Sex (% female)	75	42.9	NS
Historical characteristics			
Duration of dysphagia (years)	11.4 ± 10.0	10.5 ± 12.7	NS
LES pressure (mm Hg)	40.0 ± 11.1	39.0 ± 8.5	NS
Number of previous dilations	1.5 ± 1.3†	1.9 ± 1.9	NS
Hospital course			
Duration of intensive care (days)	2.0 ± 1.0	0.4 ± 0.7	0.005
Postoperative hospitalization (days)	15.5 ± 4.4	8.7 ± 1.5	0.001
Antibiotic administration (days)	9.0 ± 2.2	4.3 ± 3.1	0.011
Narcotic analgesic use (days)	11.8 ± 5.2	5.6 ± 2.7	0.004

*Results are expressed as mean ± SD.
†Number of previous dilations for the emergent surgery group does not include the dilation immediately prior to surgery that resulted in perforation.

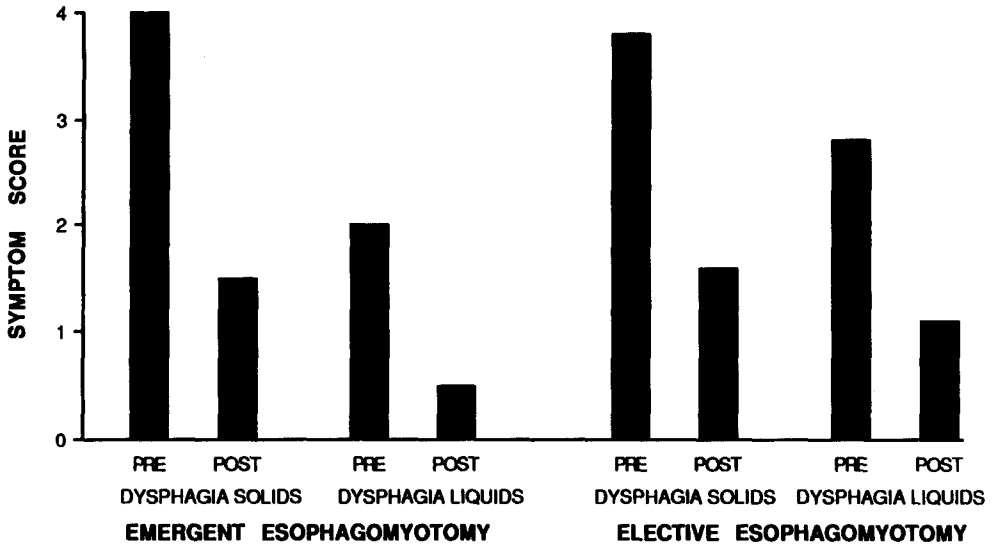

Fig 5. The symptom improvement of patients undergoing emergent surgery for repair of an esophageal perforation with performance of esophagomyotomy ($N = 2$) was not significantly different from patients undergoing elective esophagomyotomy ($N = 14$). Both groups had improved symptoms from the treatment. Symptom scoring: 0 = no symptoms, 1 = mild, 2 = moderate, 3 = severe, and 4 = very severe.

parameters for complications during pneumatic dilation. The influence of these factors on the development of complications has not previously been critically addressed. Reports have suggested that the presence of a hiatal hernia (22, 23), epiphrenic diverticulum (1, 24), or fibrous stricture (23) may increase the risk of perforation during dilation. In addition, complete LES relaxation or decreased LES pressure has been suggested to increase the risk of perforation (25).

In this study, we have analyzed demographic, historical, and manometric parameters in 178 patients undergoing 236 pneumatic dilations with a Browne-McHardy dilator. Our findings must be examined prospectively before absolute conclusions are drawn. Although dilations were performed by several physicians without a prescribed protocol, all dilations were performed after endoscopic evaluation, using the same dilator, under fluoroscopic guidance. Following dilation, all patients underwent radiographic examination of the esophagus and were hospitalized for 24 hr, which increased the likelihood that all important complications were identified.

No significant correlation between age, sex, race, duration of dysphagia, or LES pressure and the incidence of perforation was found in this series. A history of prior treatment by pneumatic dilation was a significant risk factor for the development of a complication. The risk of complications becomes greater with subsequent dilations, rising from 4.5% for the initial dilation to 21.6% in patients with two or more previous dilations.

Careful dilation technique is important in preventing esophageal perforation. The importance of ruling out secondary achalasia, such as carcinoma or stricture, by a preceding endoscopy is generally accepted (26). The use of fluoroscopic guidance ensures proper balloon placement and helps to prevent movement of the dilator during the inflation. Little else is known about the relationship between dilation techniques and the incidence of perforation.

Published dilation techniques indicate a tremendous variability in the inflation pressure (5–31 psi), duration of inflation (2 sec to 5 min), and the number of inflations performed (2, 5). This variability in dilation techniques emphasizes the lack of studies to assess the importance of inflation parameters. Our results suggest that inflation pressure is an important factor in the development of complications following pneumatic dilation. The risk of all types of complications and of major complications were significantly increased at inflation pressures $\geq$10 psi, and the risk of perforation increased when pressures exceeded 11 psi. A review of dilation techniques reported in series larger than 40 patients supports this finding. The lowest perforation rates (0 and 1.6%) were reported by Kurlander et al (3) and Fellows et al (27), who used an average pres-

sure of 5.8 and 5.6 psi, respectively. Much higher risks of perforation (5.9 and 9.8%) were reported when the mean inflation pressure exceeded 11 psi (28–30). This association between inflation pressure and distribution of complications has been noted previously (30). Although repeat dilations in symptomatic patients are often performed with increasing inflation pressures, in our study, these two factors were independently associated with an increased risk of complications.

The relevance of our findings revealing an increased incidence of perforation with higher inflation pressures using a Browne-McHardy dilator to other dilators is unclear. Csendes et al (8) and Heimlich et al (7) reported no perforations using a Mosher dilator, which does not expand beyond its maximal diameter regardless of the pressure used. The Rigiflex Achalasia Dilator, which has a polyethylene balloon, is now used by many centers. The Rigiflex dilator is placed over a guide wire and is often preferred for patients with a markedly dilated and tortuous esophagus (31). Several studies have found that the Browne-McHardy dilator and the Rigiflex dilator have similar clinical benefits (32, 33). A recent report suggests that the perforation rate with the Rigiflex dilator may be higher than with the Browne-McHardy dilator used in this study (34).

While the identification of other risk factors for developing complications is confounded by the variety of techniques used, a review of the literature suggests that institutional experience may also be an important factor (2). Mansour et al (4) report a 21.4% incidence of perforation in 14 patients treated over 13 years. In contrast, our 2.2% incidence of perforation in 178 patients over 11 years compares favorably with the 2.6% incidence reported by Vantrappen and Hellemans in 537 patients reported over 22 years (1).

Complication following pneumatic dilation frequently may not be recognized for many hours. There has been no critical examination of specific signs and symptoms that can identify patients who may develop a complication. Identification of such factors would have important clinical and economic implications. Early identification of complications would permit prompt treatment of the complications while obviating the need for prolonged hospital observation of all patients. A water-soluble contrast esophagram following pneumatic dilation may not detect all perforations and is insensitive in detecting other major complications (9, 10, 19). Reported symptoms and signs of patients who have developed a perforation include chest, back, or epigastric pain; hematemesis; fever; cervical subcutaneous crepitus, and blunting of the left costophrenic angle (9, 11, 22, 24, 35, 36).

Blood on the dilator, chest pain lasting >4 hr, or tachycardia were present in all of our patients who developed a major complication, including those who perforated, and thus may be valuable predictors of perforation. Both blood on the dilator and prolonged chest pain were found in all four patients who developed a perforation, while both findings were present in only a minority of those without complications (13.4% had prolonged chest pain for >4 hr; 33% had blood on the dilator). Tachycardia was found in half of those with a perforation but only 1.5% of the uncomplicated patients. The presence of these factors in a patient should be a strong indication for further observation in the hospital. Major complications (including perforation), or factors associated with a major complication (tachycardia, prolonged chest pain) occurred within 5 hr of dilation. Therefore, in the appropriate setting, if there is absence of blood on the dilator, tachycardia, and prolonged chest pain, and the water-soluble contrast esophagram is normal, most patients can be safely discharged on the day of the procedure. Recently, studies have suggested that pneumatic dilation may be performed as an outpatient procedure with postprocedure observation for 6 hr with admission reserved for those with perforation or prolonged chest pain (37). Our study provides objective data on the importance of this 5- to 6-hr observation period.

The outcome of patients who develop a complication during a pneumatic dilation has not been well described. Not surprisingly, those patients who suffered a perforation and underwent immediate surgical repair and an esophagomyotomy had a more prolonged postoperative hospitalization than did patients who had elective surgical esophagomyotomy. The duration of treatment with antibiotics and narcotic analgesics was also significantly greater for the group of perforated patients. The patients with a perforation, however, had no postoperative infections or complications of hospitalization. This low incidence of postoperative infections may be related to ensuring that the esophagus and stomach are empty prior to pneumatic dilation so that in patients who perforate, there is not gross contamination of the pleural space. Of clinical interest, there was no apparent difference between the long-

term clinical outcome following emergent surgical repair with performance of esophagomyotomy and the elective esophagomyotomy group. Recently, it has been suggested that clinically stable patients with confined perforations may not require emergent surgery and may improve with intravenous antibiotics, taking nothing by mouth and parenteral nutrition (38–40). The long-term clinical outcome of the symptoms of achalasia with this nonsurgical treatment is not well defined.

We conclude that pneumatic dilation is a relatively safe treatment for achalasia with a low, but definite risk of perforation. Two independent factors are associated with increased risk for complications following pneumatic dilation with a Browne-McHardy dilator: one or more prior dilations and an inflation pressure ≥ 10 psi. In addition to the post-dilation esophagram in evaluating for a perforation, three risk factors were found to suggest a complication of dilation: blood on the dilator, tachycardia, and prolonged chest pain after dilation. Since all major complications were identifiable within 5 hr, it may be possible to perform pneumatic dilation as an outpatient procedure in the vast majority of patients if, during a 5-hr follow-up, the patient has a negative esophagram and no chest pain, fever, or tachycardia. Finally, in those patients who incur a perforation requiring emergent surgical repair with the performance of an esophagomyotomy, the clinical outcome is similar to patients undergoing elective esophagomyotomy.

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