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Major Complications of Pneumatic Dilation and Heller Myotomy for Achalasia: Single Center Experience and Systematic Review of the Literature

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Abstract

Background & Aims—Pneumatic dilation (PD) and laparoscopic Heller myotomy (LHM) can be definitive therapies for achalasia; recent data suggest comparable efficacy. However, risk must also be considered. We reviewed the major complication rate of PD and LHM in a high volume center and reviewed the corresponding literature.

Methods—We reviewed 12 years of our institution's achalasia treatment experience. During this interval a consistent technique of PD was used utilizing Rigiflex dilators. Medical records were reviewed for post-procedure complications. We administered a telephone survey and examined medical records to assess efficacy of treatment. We also performed a systematic review of the literature for comparable clinical data and examined 80 reports encompassing 12,494 LHM and PD procedures.

Results—At our center, 463 achalasia patients underwent 567 PD or LHM procedures. 78% of the PDs used a 30 mm Rigiflex dilator. 157/184 (85%) patients underwent 1 or 2 PD without any subsequent treatment. There were seven clinically significant perforations; one from PD and 6 from LHM. There were no resultant deaths from these perforations; two deaths occurred within 30 days of LHM from unrelated causes. Complications and deaths post-PD were significantly fewer than those post-LHM ($p=.02$).

Conclusions—Esophageal perforation from PD at our high-volume center was less common than often reported and lower than that associated with LHM. We conclude that, in the hands of experienced operators using conservative technique, PD has fewer major complications and deaths than LHM.

Keywords

Esophageal achalasia; pneumatic dilation; Heller myotomy

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Introduction

Achalasia is a rare neurodegenerative disease selectively involving the esophagus and resulting in absent peristalsis with impaired lower esophageal sphincter (LES) relaxation after swallowing (1). Although there is no cure for the disease, there are highly effective treatments to disrupt the LES thereby reducing or eliminating esophageal outflow obstruction. Endoscopic botulinum toxin injection, pneumatic dilation (PD), laparoscopic Heller myotomy (LHM), open Heller myotomy, and per-oral endoscopic myotomy are all potentially effective treatments, but with substantial variability in their respective utilization among centers (2, 3). Currently, PD and LHM are the most widely accepted durable therapies for achalasia. However, consensus is lacking as to which treatment is preferable (4). Data from a recent European randomized controlled trial comparing these two treatments suggests comparable efficacy (5, 6).

Key to evaluating the relative merits of alternative treatments is an assessment of both benefit and risk. Ideally, this is done with randomized controlled trials, but in the case of achalasia that is difficult owing to the rarity of the disease and the inconsistencies among centers in the fine details of the therapies rendered. In the case of LHM the main variability in technique pertains to the antireflux procedure coupled with the myotomy: Dor fundoplasty, Toupet fundoplication, or none at all (7, 8). In the case of PD, there has been nearly uniform use of Rigidflex dilators (Boston Scientific, Natick, MA) since the mid 1990s, but enormous variability among centers in dilation protocol and in the utilization of 30, 35, or 40 mm diameter dilators (9). A major complication of both PD and LHM is esophageal perforation and these technical variables likely impact on the magnitude of that risk. Given the recent data suggesting equivalence between PD and LHM in terms of efficacy (5), we thought it timely to compare complication rates of the two procedures in the hands of relatively few highly experienced operators at a single, high volume institution. Hence, we reviewed our twelve-year experience of complications from PD and LHM and compared it to published data obtained from a systematic review of the literature pertinent to the same procedures.

Methods

Northwestern Experience

We searched the clinical database of Northwestern Memorial Hospital for the period encompassing the lifespan of its electronic medical record (January 2000 to our cutoff of November 2011) for achalasia, esophageal dilation, and myotomy; ICD-9 CM codes for achalasia (530.0), esophagomyotomy (42.7), esophageal dilation (42.92), and perforation of esophagus (530.4) were used. Medical records were individually reviewed to confirm that patients underwent PD or LHM as verified by review of the procedure notes. LHM review also included procedures two years prior to this period as that aspect of the medical record extended back to 1998. Dilations other than those done with Rigidflex dilators, open myotomies, and peroral endoscopic myotomies were excluded. Dilations done with smaller balloon dilators or bougie dilators were not included; there were no other achalasia-type dilators used at our center during this interval. Procedure notes, post-operative notes, inpatient notes, and post-operative imaging for up to 30 days post procedure were reviewed for evidence of postoperative perforation or death. Perforations that occurred intra-operatively during LHM were excluded as these were judged to be clinically insignificant. Treatment outcome was assessed by chart review of post-procedure clinic visits at three months and by a telephone survey administered for the purposes of this study to patients (or, in some cases, their spouses or children) 3 months to 10 years post-procedure assessing dysphagia over the past 30 days (Figure 1).

Literature review

Studies reporting complication experiences for LHM and PD were identified from the literature using the Ovid and PubMed search engines for our medical school library. This was done using the search words, 'esophageal achalasia', 'balloon dilation', and 'Heller myotomy' for English language publications. Reference lists from papers identified with the search were also scrutinized for potentially relevant secondary citations. Studies were included if they met the following criteria: they were consecutive series, they encompassed at least 50 procedures, the method and type of dilator and/or operative technique used were specified, complication data for at least one month post-procedure were reported, and the occurrence of post-operative esophageal perforation was specifically addressed. Studies on PD were only included if Rigiflex dilators were used. Identified publications were reviewed independently by two of the authors. Any disagreements between them were to be resolved by consensus.

Statistical Analysis

Comparison of post-procedure perforations and deaths in patients who underwent PD versus LHM were made using Fisher's exact test.

Results

Northwestern Experience

During our 12-year experience, 463 achalasia patients underwent a total of 567 PD and LHM procedures (Table 1). One hundred eighteen patients underwent more than one procedure (including botulinum toxin injection). Seventy-eight percent of the PDs were done with the 30 mm Rigiflex dilator. Three highly experienced gastroenterologists with prior experience of at least 75 procedures each performed all of the PDs using a very similar protocol. The essential details of that protocol were: 1) use of fluoroscopy for guidewire control and localization of the dilation balloon, 2) initial dilation procedure using only a 30 mm Rigiflex dilator, 3) balloon inflation was done only once providing that there was good visualization of the sphincter on the fluoroscopic silhouette of the dilator and that full effacement of the dilator silhouette was achieved (in instances that this was uncertain, the balloon was deflated, repositioned, and inflation repeated until the sphincter was confidently localized), 4) there was no pre-specified target inflation pressure and no notation was made of inflation pressure, 4) the balloon dilator was deflated after sphincter effacement was evident by fluoroscopy with no pre-specified duration of inflation, 5) Gastrografin swallows were routinely obtained by one operator, and not routinely obtained by the other operators, and 6) the identical protocol was repeated with a 35 mm Rigiflex dilator (or in some cases 30 mm) 2–52 weeks after the 30 mm dilation in instances of inadequate symptomatic response and rapid recurrence of LES dysfunction as verified by follow-up manometric and/or timed barium swallow evaluation. The 40 mm Rigiflex dilator was not used at all in this series.

During the same 12-year period six operators performed LHM with a Dor fundoplasty (68%) or Toupet fundoplication. All operators used a similar technique performing an anterior myotomy with extension 6–8 cm up the esophagus and 2–3 cm onto the stomach to capture the gastric sling fibers.

There were seven clinically significant perforations in our series; six post-LHM and one post-PD (Table 2). Among these, only one patient had a prior achalasia treatment (botulinum toxin injection). Three of these perforations, including the one following PD, were managed operatively. There were no deaths resultant from these perforations.

Two patients died post-Heller myotomy of complications other than esophageal perforation. One patient developed rapid atrial flutter post-operatively requiring treatment with intravenous anti-arrhythmic drugs. A barium swallow image one day postoperatively showed no evidence of a leak. However, repeat imaging two days later showed a possible contained leak. Shortly after this image was obtained, the patient developed polymorphic ventricular tachycardia and could not be resuscitated. The patient was afebrile with a normal white blood cell count at that time. No autopsy was obtained. The second death involved a splenic capsular tear sustained during LHM leading to hemodynamic instability. The patient required aggressive fluid resuscitation and blood transfusions, complicated by acute respiratory failure and death. Perforation or death combined were significantly more frequent post-LHM than post-PD ($p=0.02$).

Patients who did not achieve an adequate clinical response to their initial PD underwent further treatment. The primary criterion for repeat dilation was an inadequate symptomatic response with respect to dysphagia. Prior to a second dilation being done, a repeat manometry and/or timed barium swallow were done to corroborate persistent sphincter dysfunction. The criterion for sphincter dysfunction on high resolution manometry was an integrated relaxation pressure greater than 15 mmHg. On studies done prior to the introduction of the high resolution manometry, the criterion was of a nadir relaxation pressure >10 mmHg. The criterion on a timed barium swallow was of a barium column height greater than 5 cm. Of the 184 patients who underwent initial treatment with PD, 118 (64%) had a single PD and did not require repeat PD or LHM. Twenty-seven percent had subsequent PD (almost all 35 mm) and there were 16 (8.7%) patients who ultimately underwent myotomy after PD. These results are summarized in Figure 2. Thus, based on the need for further therapy, 91% of patients were adequately treated by PD.

Attempts were made to contact 123 PD patients by phone of whom 48 proved unreachable and 9 were deceased, leaving 66 (54%) who were successfully interviewed. Among these individuals, sixty (91%) had a satisfactory response to PD, reporting less than one occurrence a month of odynophagia, trouble swallowing liquids, trouble eating soft foods, or choking. Of the remaining six, five had a moderate response reporting some scores of three or four on the phone survey (Figure 1) and one patient reported a poor response evident by some scores greater than four. Nonetheless, these six patients pursued no further treatment.

Literature review

The specified inclusion criteria for the literature search identified 80 studies suitable for review (Figure 3). These studies reported on a total of 6834 patients treated with LHM (Table 3a) and 5660 with PD (Table 3b and 3c). The methodology utilized for LHM among studies was generally consistent with that used at our center as was the experience with complications. However, the methodology used for PD among centers was highly variable and often more aggressive (Tables 3b and 3c). Furthermore, the pooled perforation rate was greater than in our series.

Discussion

Pneumatic dilation and LHM are the mainstay treatments for achalasia and recent data suggest them to have similar efficacies (5). However, in weighing the relative merits of the techniques, risk as well as benefit must be considered in selecting between these options. The major finding from our retrospective analysis was that the risk of perforation from PD was modest when done with a consistent conservative protocol in a high-volume setting by a select group of highly experienced operators. In fact, the risk of perforation or 30-day mortality following PD was significantly lower than the combined risk of perforation or postoperative mortality from LHM in the same practice setting.

Esophageal perforation is the most common major complication for both LHM and PD with varying rates reported in the literature. The rate of clinically significant esophageal perforation reported in the literature for PD and LHM ranged from 0–14% and 0–4.6%, respectively (10–12). As seen in Tables 3a–3c, perforation and mortality rates varied greatly by institution. This variation can probably be explained by differences in technique, number, and experience of operators, and the size of the reported experience. The esophageal perforation rate from PD at our center (0.37%) was notably lower than most previously reported series, and was also lower than that associated with LHM. Thus, the risk of esophageal perforation from PD appears to be at least partly dependent on PD technique and operator experience, two variables that were held relatively constant at our center for the duration of the 12-year period reviewed.

One potential explanation for the wide range of perforation reported for PD is publication bias with relatively few large studies reporting low rates and some small series tending to report high perforation rates. Figure 4 illustrates the relationship between case series size and perforation rate from our literature search of series of PD performed with a Rigiflex balloon; the perforation rate from our institution is displayed as a square symbol in Figure 4. Studies with a small number of procedures have generally reported higher perforation rates (or none at all). A notable exception is the study by Sanchez-Pernaute (75) in which there were 15 perforations from 330 PDs using only a 35 mm Rigiflex balloon. With the exception of this outlier, there are no studies with large numbers of procedures and a high percentage of perforations. An additional consideration is that we report our perforation data both per procedure and per patient rather than only per patient as some have done in the past.

Patients who did not achieve full response to their initial treatment underwent repeated procedures. Of the 184 patients who underwent initial treatment with a pneumatic dilation, 118 (64%) underwent no further treatment. These can be considered treatment successes as inferred by the lack of need for further procedures. Sixteen (8.7%) patients ultimately underwent LHM after PD and were considered treatment failures. This is comparable to efficacy rates reported in prior studies (5). Alternatively, efficacy was also assessed by a phone survey administered to patients who were not referred on for LHM; among the 66 patients successfully contacted and interviewed, 91% reported a good response to PD. That result needs to be qualified, however, in view of the fact that only 54% of the intended population was available for follow-up and the instrument used for assessment had not been specifically validated for achalasia.

Death is a very rare consequence of achalasia treatment. There were no deaths in our entire PD experience. With respect to LHM, the pooled all-cause mortality rate was 0.15% (Table 3a). Similarly, the 30-day mortality for LHM at our center was low (0.68%). These deaths were attributable to a variety of post-operative issues such as urinary tract infection, pulmonary embolus, and myocardial infarction with very few being directly related to the myotomy itself.

In conclusion, we have reviewed our large single-center experience to compare the complication rates of PD and LHM in the treatment of achalasia. In our 463 patient experience, both modalities had low complication rates and mortality, with that of PD being significantly lower than that of LHM. Review of the literature suggests that a low perforation rate is consistent with that of other high-volume achalasia treatment centers. Thus, in selecting between these treatment options, the risk side of the equation may slightly favor PD. Of course, there are other considerations in making this choice such as relative efficacy in treating dysphagia, the likelihood of post-procedure reflux, the manometric subtype of achalasia, and the severity of anatomical distortion associated with advanced

disease. However, these considerations can only be optimally addressed by randomized controlled trials that currently do not exist. Consequently, with the currently available data suggesting equivalence between PD and LHM, PD should remain a mainstay treatment option in the primary treatment of idiopathic achalasia.

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Abbreviations

LES	Lower esophageal sphincter
PD	Pneumatic dilation
LHM	Laparoscopic Heller myotomy

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Study Highlights

WHAT IS CURRENT KNOWLEDGE?

- A major complication of both definitive therapies for achalasia (pneumatic dilation (PD) and laparoscopic Heller myotomy (LHM)) is esophageal perforation and technical variables likely impact on the magnitude of that risk.
- Recent data suggest equivalence between PD and LHM in terms of efficacy.

WHAT IS NEW HERE?

- The actual perforation rate from PD in a large single center experience using a uniform conservative methodology was 1/272 (0.37%), lower than reported in prior studies that may have been influenced by publication bias.
- In comparing pneumatic dilation and LHM, the risk side of the equation favored PD in this series.

Score	1	2	3	4	5	6
Over the past 30 days, how often have you had the following:	Never	Less than once a month	1-9 times a month	10-19 times a month	20-29 times a month	Daily
a. Trouble eating solid food (meat, bread)						
b. Trouble swallowing liquids						
c. Pain while swallowing						
d. Trouble eating soft food (yogurt, pudding)						
e. Choking or coughing while swallowing food						

Figure 1.

Questions administered in phone survey of treatment response to pneumatic dilation. A score of less than 2 in each category qualified patients as having a good treatment response. Scores of 3 in a category were considered marginal and scores of 4 or more were considered poor.

Figure 2.
Flow diagram of the disposition of pneumatic dilation patients.

Figure 3. Search results for LHM (panel A) and PD (panel B) treatment. Of 319 and 422 citations identified, 48 and 32 were ultimately included in the analysis, respectively.

Figure 4.

Funnel diagram of reported perforation rates from PD as a function of study sample size illustrating the PD data demonstrates substantial bias. The square symbol represents the current study. The outlier large study with a 4.5% perforation rate used only 35 mm Rigiflex dilators.

Table 1

Achalasia treatment population characteristics by treatment type

	LHM (n=295)	PD (n=272)
Number of patients [†]	295	198
Age at procedure, mean (range) yrs	49 (12–89)	54 (13–90)
History of prior PD, n	16	63
History of prior LHM, n	0	14
History of prior Botox, n	20	24
History of any prior treatment, n (%)	38 (13%)	101 (37%)

[†]Some patients underwent two or more procedures

Table 2

Complication rates and characteristics by treatment type

	LHM (n=295)	PD (n=272)
Perforation rate per procedure, n (%)	6 (2.0%)	1 (0.37%)
Perforation rate per patient treated, n (%)	6 (2.0%)	1 (0.51%)
30-day mortality, n (%) [†]	2 (0.68%)	0 (0%)
Perforation after prior achalasia treatment, n (%)	1 (2.6%)	0 (0%)
Surgical intervention for perforation, n (%)	2 (33%)	1 (100%)
Average hospital stay after perforation, days	11	8
Post-perforation deaths, n (%)	0 [†] (0%)	0 (0%)

[†] One patient died peri-operatively with equivocal CT evidence of a small contained leak; this was judged clinically insignificant and scored as neither a perforation nor perforation-related death.

Table 3a

Reported complications from LHM

First author (reference), year	Procedures (or patients) (n)	Post-operative perforations, n (%)	30-day mortality, n (%)
Horgan (13), 1999	57	0 (0)	None reported
Patti (14), 1999	133	0 (0)	0 (0)
Stewart (15), 1999	63	0 (0)	0 (0)
Bonavina(16), 2000	92	0 (0)	None reported
Hunt (17), 2000	70	1 (1.4)	0 (0)
Ackroyd (18), 2001	82	0 (0)	1 (1.2)
Zaninotto (19), 2001	148	1(0.7)	0(0)
Decker (20), 2002	73	0 (0)	0 (0)
Donahue (21), 2002	81	0 (0)	None reported
Sharp (22), 2002	95	0 (0)	0 (0)
Chapman (23), 2004	139	1 (0.7)	1 (0.7)
Douard (24), 2004	52	1 (1.9)	0 (0)
Frantzides (25), 2004	53	0 (0)	0 (0)
Perrone (26), 2004	100	0 (0)	0 (0)
Raftopoulos (27), 2004	88	0 (0)	0 (0)
Melvin(28), 2005	104	0 (0)	0 (0)
Bonatti (29), 2005	75	0 (0)	0 (0)
Burpee (30), 2005	66	0 (0)	0 (0)
Deb (31), 2005	211	0 (0)	0 (0)
Horgan (32), 2005	62	0 (0)	0 (0)
Khajanchee (33), 2005	121	1 (.83)	1 (0.9)
Portale (34), 2005	248	2 (.81)	0 (0)
Rossetti (35), 2005	195	4 (2.1)	0 (0)
Galvani (36), 2006	54	0 (0)	0 (0)
Gholoum (37), 2006	52	0 (0)	0 (0)
Iqbal (38), 2006	66	0 (0)	0 (0)
Omura (39), 2006	66	0 (0)	None reported
Richardson (7), 2006	69	0 (0)	1 (1.4)
Smith (40), 2006	209	0 (0)	None reported
Torquati (41), 2006	200	0 (0)	1 (0.5)
Huffmanm (42), 2007	61	0 (0)	0 (0)
Rosen (43), 2007	101	0 (0)	0 (0)
Kilic (44), 2008	55	0 (0)	0 (0)
Rebecchi (45), 2008	144	0 (0)	0 (0)
Robert (8), 2008	106	0 (0)	0 (0)
Schuchert (46), 2008	200	2 (1.0)	0 (0)

First author (reference), year	Procedures (or patients) (n)	Post-operative perforations, n (%)	30-day mortality, n (%)
Sweet (47), 2008	201	0 (0)	None reported
Finan (48), 2009	106	0 (0)	0 (0)
Roller (49), 2009	54	0 (0)	None reported
Craft (50), 2010	51	0 (0)	0 (0)
Finley (51), 2010	261	0 (0)	0 (0)
Mattioli (52), 2010	60	3 (5.0)	0 (0)
Roll (53), 2010	162	1 (0.6)	0 (0)
Rosemurgy (12), 2010	505	1 (0.2)	3 (0.6)
Di Martino (54), 2011	56	0(0)	0 (0)
Parise (55), 2011	137	1 (.73)	0 (0)
Rawlings (56), 2011	60	0(0)	0 (0)
Reynoso (57), 2011	1390	6 (0.4)	1 (0.07)
Total	6834	25 (.37)	9 (0.15)

Table 3b

Reported complications from PD, Rigiflex (RF) dilators only

Series	Dilations (n)	Dilator sizes (mm)	Perforations, n (%)
Barkin (58), 1990	61	30, 35, 40	2 (3.3)
Molina (59), 1996	50	30, 35, 40	2 (4.0)
Sabharwal (60), 2002	76	15, 20, 30, 40	0 (0)
Chan (61), 2004	66	30, 35, 40	3 (4.5)
Dobrucali (62), 2004	65	30, 35	1 (2.3)
Farhoomand (63), 2004	118	30, 35, 40	0 (0)
Ghoshal (64), 2004	126	30, 35, 40	1 (0.79)
Guardino (65), 2004	96	30	2 (2.1)
Mikaeli (66), 2004	262	30, 35	3 (1.1)
Boztas (67), 2005	63	30, 35, 40	0 (0)
Katsinelos (68), 2005	74	30, 35, 40	4 (5.4)
Khan (69), 2005	311	30, 35	2 (0.6)
Mehra (70), 2005	85	30, 35, 40	0 (0)
Rai (71), 2005	56	35	0 (0)
Vela (72), 2006	106	30, 35, 40	2 (1.9)
Zerbib (73), 2006	150	30, 35, 40	2 (1.3)
Dagli (74), 2009	207	30, 35, 40	3 (1.4)
Sanchez-Pernaute(75), 2009	330	35	15 (4.5)
Bravi (76), 2010	120	30, 35, 40	2 (1.7)
Howard (77), 2010	55	30, 35, 40	2 (3.6)
Huselmans (78), 2010	391	30, 35, 40	6 (1.5)
Kroupa (79), 2010	51	30, 35	0 (0)
Tanaka (80), 2010	57	30, 35	0 (0)
Boeckxstaens (5), 2011	95	30, 35	4 (4.2)
Total	3071		56 (1.8)

Table 3c

Reported Complications from PD in studies utilizing mixed dilator types and not specifying which was associated with perforations.

Series	Dilations (n)	Dilators & sizes (mm)	Perforations, n (%)
Prewett(81), 1990	80	RM [±] (44), W [±] (27), and RF 30, 35, 40 (9)	7 (9.0)
Ciarolla(82), 1993	110	BM ^{††} and RF 35, 40	7 (6.4)
Anselmino(11), 1997	67	RM [±] and RF at 200–300 mmHg for 1–3 minutes	8 (12.0)
Metman(83), 1999	504	SP [‡] until 1989, then RF 30, 35, 40	7 (1.4)
Hunt(17), 2000	445	RM [±] until 1990, then RF 30, 35, 40	0 (0)
Salis(84), 2004	184	FC ^{//} , RM [±] , and RF 35, 40	7 (0.4)
Karamanolis(85), 2005	214	H [#] until 1994 then RF 30, 35	1 (0.5)
Alderliesten(86), 2011	985	H [#] until 1976, then RF 30, 35, 40	13 (1.3)
Total	2589		50 (1.9)

[±] Rieder-Moeller

Witzel

^{††} Brown-McHardy

[‡] Sippy balloon design (25–48 mm)

^{//} Finocchietto (40 mm)

[#] Homemade dilator