# ORIGINAL ARTICLE

# Outcomes of pneumatic dilatation and Heller's myotomy for achalasia in England between 2005 and 2016

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### ABSTRACT

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Received 4 April 2018 Revised 25 November 2018 Accepted 30 November 2018 **Introduction** Achalasia is a disorder characterised by failed relaxation of the lower oesophageal sphincter. The aim of this study was to examine, at a national level, the long-term outcomes of achalasia therapies.

**Methods** Hospital Episode Statistics include diagnostic and procedural data for all English National Health Service—funded hospital admissions. Subjects with a code for achalasia who had their initial treatment between January 2006 and December 2015 were grouped by treatment; pneumatic dilatation (PD) or surgical Heller's myotomy (HM). Procedural failure was defined as time to a further episode of the same therapy or a change to a different therapy. Up to three PDs were permitted without being considered a therapy failure.

**Results** 6938 subjects were included; 3619 (52.2%) were men and median age at diagnosis was 59 (IQR 43–75) years. 4748 (68.4%) initially received PD and 2190 (31.6%) HM. The perforation rate following PD was 1.6%. Mortality at 30 days was 0.0% for HM and 1.9% for PD, and <8% after perforation following PD. Factors associated with increased mortality after PD included age quintile 66–77 (OR 4.55 (95% CI 2.00 to 10.38), p<0.001), >77 (9.78 (4.33 to 22.06), p<0.001); Charlson comorbidity score >4 (2.87 (2.08 to 3.95), p<0.001); previous HM (2.47 (1.33 to 4.62), p<0.001); and repeat PD 1–3 (1.58 (1.15 to 2.16), p=0.005), >3 (1.97 (1.21 to 3.19), p=0.006). Durability of up to 3 PD and HM over 10 years of follow-up was 86.2% and 81.9%, respectively (p<0.001).

**Discussion** The efficacy of PD for achalasia appears to be greater than HM over 10 years. There was no mortality associated with HM, but 1.9% of subjects died within 30 days of PD. Mortality was associated with increasing age, comorbidity, previous HM and repeat PD.

ised by failed relaxation of the lower oesophageal

sphincter. The pathogenesis is unknown, but it is

thought that a viral infection in a genetically suscep-

tible individual triggers gradual loss of nitrergic

neurons in the lower oesophageal sphincter over

many years.<sup>1</sup> There are currently three established

treatment modalities: endoscopic pneumatic dila-

tation (PD), surgery (most commonly by laparo-

scopic Heller's myotomy (HM)) and endoscopic

botulinum toxin injection. Per oral endoscopic

#### Check for updates

INTRODUCTION Achalasia is an uncommon condition character-

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# Significance of this study

#### What is already known on this subject?

- Achalasia is best treated by Heller's myotomy or pneumatic dilatation with similar outcomes at 5 years.
- Older patients generally undergo pneumatic dilatation.

#### What are the new findings?

- At 10 years of follow-up, up to three pneumatic dilatations demonstrate a modest increase in durability compared with Heller's myotomy.
- Following pneumatic dilatation, the 30-day mortality in patients over 77 years of age is 5.3% compared with 0.3% in those less than 65 years of age.
- The volume of procedures undertaken by a provider does not appear to affect the durability of treatment.

# How might it impact on clinical practice in the foreseeable future?

- 10-year outcome data assist patients and clinicians when making an informed choice between a single operation and up to three pneumatic dilatations.
- Older patients can be accurately informed of the risk associated with pneumatic dilatation.

myotomy (POEM) is a recently developed technique for treating achalasia; however, it is not widely performed in the UK at present.

A recent randomised control trial compared pneumatic dilatation with laparoscopic HM.<sup>2</sup> Outcomes were reported in 201 achalasia subjects with success rates of greater than 90% for each modality at 1-year follow-up. Five years after enrolment, 128 subjects remained under active follow-up in the trial, and there was still no difference in outcomes between the two treatment modalities.<sup>3</sup> A meta-analysis comparing botulinum toxin injection to both single PD and HM reported both to be more durable than botulinum toxin.<sup>4</sup> Similarly, a randomised study confirmed that despite similar outcomes at 6 months, HM was more durable than botulinum toxin injection over longer periods.<sup>5</sup>

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Relatively few studies have reported outcomes beyond 5 years of follow-up. Those that have are small with limited power to accurately describe outcomes. In a tertiary hospital cohort of 300 subjects, with a mean follow-up 9.3 years following a successful dilatation, 19/24 and 50/74 were symptom free following repeat dilatation or no further treatment, respectively.<sup>6</sup> Thirteen subjects had undergone an alternative treatment. The proportion lost to follow-up highlights the challenges acquiring long-term outcome data in achalasia.

As a chronic disease, for which the underlying aetiology is incurable, long-term outcome data following intervention are essential. Furthermore, due to the demographic changes in many Western countries, such procedures are being potentially performed on an increasingly ageing population. It is therefore essential to establish the risks associated with procedures for achalasia to facilitate individually tailored therapy.

The aim of this study was to provide long-term outcome data and complication rates including mortality for treatments of achalasia at a national level.

#### **METHODS**

#### Data sources

The Hospital Episode Statistics (HES) database is the administrative record of all hospital care episodes provided within England under the National Health Service (NHS). Subject information is contained within each hospital episode including demographic, diagnostic (International Classification of Diseases 10 (ICD-10)) and procedural data (Office of Population Census and Surveys Classification of Interventions and Procedures V.4 (OPCS4) codes). HES can be linked to the Office of National Statistics to provide mortality data.

#### Subject cohort

Subjects were initially identified by the presence of a primary diagnosis code for achalasia, defined by ICD-10 codes (see online supplementary appendix 1), between January 2006 and December 2015. Subjects were also required to have a suitable procedure code for treatment of achalasia (see online supplementary appendix 2). Subjects were then grouped by initial treatment into HM and PD groups. PD procedures in England are performed by secondary care providers and are all coded in HES, even though they are usually performed as a day case or outpatient procedure. Subjects were excluded if they had a prior diagnosis of achalasia in the preceding 5 years since the introduction of ICD-10 coding in 2001. The following subjects were excluded: those without a treatment code, any subject not resident within England, as we would potentially lose any follow-up data if they went to a hospital within their own country; those under 18 years of age or with missing age or sex, as these variables are used along with the NHS number to validate subject identity; and subjects with Chagas' disease. All subjects within HES have a unique identification number, allowing complete follow-up of subjects throughout the study period.

#### **Data extraction**

Demographic data were extracted from HES based on initial treatment, including age, gender, ethnicity, Index of Multiple Deprivation (2010) quintiles (1 being the most deprived, 5 being the least) and Charlson comorbidity scores.<sup>7</sup> The use of Charlson scores has previously been validated for HES in several settings, including accurately representing the comorbidity burden in subjects undergoing urological surgery,<sup>8</sup> and a good correlation to comorbidities as documented in primary care.<sup>9</sup>

Repeated treatment or a change in treatment modality (including botulinum toxin injection) for achalasia was collected as a surrogate for failure of the previous treatment. Any treatment beyond a single HM or more than three PDs was considered to represent treatment failure as these were the criteria used in the largest multicentre randomised controlled trial of achalasia.<sup>2</sup> A series of PDs including any procedures within a 30-day period were considered permissible as a single dilatation treatment, as per trial criteria.<sup>2</sup>

Complications within 30 days after treatment were recorded as mortality, emergency re-admission, perforation, bleeding, complications of sedation and complications of surgery for the relevant groups, by way of ICD-10 codes (online supplementary appendix 3). The proportion of perforations not diagnosed on the day of procedure, as demonstrated by an emergency re-admission at least 1 day after PD, is also reported. Provider volume was described by index procedure, with only a single procedure permitted per subject when calculating provider volume, to reduce potential confounding due to multiple ineffective procedures potentially leading to more procedures being undertaken by a provider and obscuring an association between provider volume and outcome.

#### **Data validation**

Subjects with achalasia were sought over the duration of the study period at Sandwell and West Birmingham Hospitals NHS trust including data on initial treatment modality. Endoscopy reporting software, GI physiology laboratory records and coding records of surgical procedures were interrogated for potential cases. Reports and electronic medical records were then reviewed to confirm a diagnosis of achalasia, that the date of diagnosis corresponded to the study period and that treatment was provided and its modality. Data obtained were then compared with that recorded in HES for Sandwell and West Birmingham Hospitals NHS trust for the same period.

#### Statistical analysis

Comparisons between treatment groups were made using  $\chi^2$ tests for categorical and Kruskal-Wallis for continuous variables. Multivariable cumulative incidence regression models were used to measure treatment failure for PD and HM groups after adjusting for age, sex, deprivation, ethnicity, Charlson comorbidity score and provider volume. Subjects who died during their index admission with an achalasia diagnosis were excluded from these models. A multivariable logistic regression model was also constructed for PD to measure associations with 30-day mortality after adjusting for demographic variables as previously described. Incidence rates for further treatments are reported per 1000 person-years, censoring on the date of treatment failure, death or end of follow-up (31 December 2016). Time to treatment failure was compared between PD and HM by cumulative incidence regression, allowing for death as a competing risk.<sup>10</sup> Proportionality was checked for cause-specific hazards and satisfied using Schoenfeld residuals. All analysis was conducted using Stata SE V.14 (Stata Statistical Software; StataCorp LP, College Station, Texas, USA).<sup>11</sup> P values < 0.05 were considered significant.

This study has been registered as a clinical audit and reviewed by the University Hospital Birmingham clinical audit department (CARMS-13755).

### RESULTS

#### Validation

At Sandwell and West Birmingham Hospitals NHS Trust during the study period, 50 eligible subjects were found, compared with

Initial treatment code	Heller's myotomy n (%)	Pneumatic dilatation n (%)	P value
Sex	÷		<0.001
Male	1219 (55.7)	2400 (50.5)	
Female	971 (44.3)	2348 (49.5)	
Deprivation quintile			0.251
1	427 (19.5)	829* (>17.5)	
2	427 (19.5)	940 (19.8)	
3	444 (20.3)	983 (20.7)	
4	447 (20.4)	1019 (21.5)	
5	439 (20.4)	968 (20.4)	
Unknown	6 (0.3%)	<5* (<0.1)	
Ethnic group			<0.001
White	1801 (82.2)	4172 (87.9)	
Asian or Asian British	33 (1.5)	25 (0.5)	
Black or Black British	140 (6.4)	213 (4.5)	
Mixed	74 (3.4)	125 (2.6)	
Any other ethnic group	39 (1.8)	73 (1.5)	
Unknown	103 (4.7)	140 (2.9)	
Age quintile			< 0.001
18–38	798 (36.4)	676 (14.2)	
39–52	662 (30.2)	788 (16.6)	
53–65	457 (20.9)	934 (19.7)	
66–77	231 (10.5)	1114 (23.5)	
78+	42 (1.9)	1236 (26.0)	
Charlson comorbidity score			< 0.001
0	1886 (86.1)	3673 (77.4)	
1–4	238 (10.9)	475 (10.0)	
>4	66 (3.0)	600 (12.6)	
Total	2190	4748	

\*Value censored from publication due to Hospital Episode Statistics data sharing guidelines to protect subject anonymity.

48 in HES (96% agreement). Individual treatment modalities also correlated strongly; 36 PDs were identified in HES compared with 39 locally (92.3%) and 12 HMs in HES compared with 11 locally (91.6%).

# Demographics

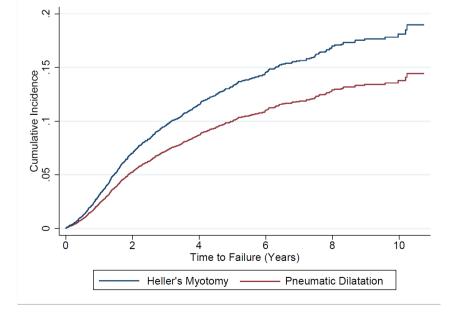
From all hospital episodes (source population), 11415 subjects were identified with a new achalasia ICD-10 code within the study period. A total of 6938 subjects were included in the final analysis and the list of reasons for exclusion is shown in online supplementary appendix 4. Furthermore, 2190 (31.6%) underwent HM and 4748 (68.4%) PD, and the full demographic details of each group are described in table 1. The HM group were younger, with a median age of 44 (IQR 32–57) years compared with 65 (48–78) for PD (p<0.001). More men underwent HM (55.7%) than PD (50.5%) (p<0.001). Subjects undergoing HM had lower Charlson scores than PD subjects.

At the time of HM, 95.0% of subjects also underwent a surgical treatment to prevent gastro-oesophageal reflux.

# Achalasia treatment failure

A total of 19608 and 9600 person-years of follow-up were included for PD and HM subjects, respectively, over the study period. The median follow-up per subject was 4.0 (range 0–10.7) years. Within 5 years of initial treatment, the incidence rates of subjects requiring further treatment were 26.5 (95% CI 24.0 to 29.2) and 32.5 (95% CI 28.7 to 36.9) per 1000 person-years after PD and HM, respectively. Over the study period, the rate of subjects requiring further therapy was 24.0 (95% CI 21.9 to 26.2) per 1000 person-years post-PD and 28.3 (95% CI 25.2 to 31.9) post-HM.

If subjects undergoing PD as their first treatment are not permitted any further PDs prior to being considered a treatment failure, in contrast to three PDs as described above, the incidence rate of subjects requiring further therapy is 248.6 (95% CI 238.7



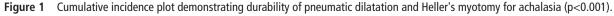


Table 2	Cumulative incidence regression analysis of factors
associated	d with failure of treatment in the Heller's myotomy and
pneumati	c dilatation groups

	Heller's myotomy	Heller's myotomy		Pneumatic dilatation	
	SHR (95% CI)	P value	SHR (95% CI)	P value	
Gender					
Female	1 (baseline)		1 (baseline)		
Male	0.77 (0.61 to 0.99)	0.038	0.93 (0.77 to 1.11)	0.412	
Age quintile					
18–38	1 (baseline)		1 (baseline)		
39–52	0.76 (0.56 to 1.03)	0.076	0.94 (0.65 to 1.36)	0.741	
53–65	0.78 (0.56 to 1.10)	0.161	1.38 (0.99 to 1.93)	0.098	
66–77	1.10 (0.74 to 1.62)	0.634	1.63 (1.18 to 2.26)	0.003	
>77	1.32 (0.62 to 2.79)	0.474	1.50 (1.08 to 2.10)	0.017	
Deprivation					
1	1.01 (0.69 to 1.48)	0.952	0.90 (0.66 to 1.22)	0.490	
2	0.97 (0.67 to 1.41)	0.879	1.00 (0.75 to 1.33)	0.982	
3	0.95 (0.65 to 1.38)	0.789	1.04 (0.79 to 1.38)	0.767	
4	0.78 (0.53 to 1.15)	0.204	1.03 (0.79 to 1.35)	0.825	
5	1 (baseline)		1 (baseline)		
Ethnic group					
White	1 (baseline)		1 (baseline)		
Not white	1.08 (0.95 to 1.91)	0.689	0.92 (0.64 to 1.34)	0.675	
Unknown	0.40 (0.19 to 0.84)	0.016	0.57 (0.31 to 1.04)	0.065	
Charlson comorb	idity score				
0	1 (baseline)		1 (baseline)		
1–4	1.35 (0.95 to 1.91)	0.096	1.06 (0.80 to 1.41)	0.694	
>4	1.09 (0.55 to 2.16)	0.805	0.66 (0.48 to 0.91)	0.011	
Provider volume	tertile*				
Low	0.94 (0.71 to 1.25)	0.812	0.91 (0.71 to 1.17)	0.480	
Medium	0.99 (0.72 to 1.35)	0.936	0.98 (0.79 to 1.21)	0.821	
High	1 (baseline)		1 (baseline)		

\*Provider volume tertiles for Heller's myotomy are <4, 4–14 and >14 for lower, medium and upper tertiles, respectively, and for pneumatic dilatation <3, 3–4 and >4 for lower, medium and upper tertiles, respectively. SHR. subdistribution HR.

to 258.9) and 207.6 (95% CI 199.5 to 216.1) per 1000 personyears after 5 years and 10 years, respectively.

At 10 years of follow-up, the cumulative incidence of treatment failure, treating death as a competing risk, was 13.8% in PD and 18.1% for subjects undergoing HM (p<0.001) (figure 1). During the study period, the rate of subjects undergoing HM after failing initial treatment with PD is 65.1 per 1000 person-years (95% CI 60.4 to 70.1) compared with 22.9 per 1000 person-years (20.2–25.9) for subjects undergoing PD following HM.

# Multivariable analysis of factors associated with treatment failure

Between 2006 and 2015, per provider, the median number of HM per annum was 5 (IQR 2–22) and PD per annum was 5 (IQR 3–9). In total, 174 providers were included.

In multivariable cumulative incidence regression models, male gender (subdistribution HR 0.77 (0.61 to 0.99), p=0.038) was negatively associated with treatment failure in the HM group. PD appeared to be less effective with increasing age (66–77 years (1.63 (1.18 to 2.26), p=0.003), >77 years (1.50 (1.08 to 2.10), p=0.021) and more effective in Charlson score >4 (0.66 (0.48 to 0.91), p=0.011). There was no association between the volume of procedures performed and failure of treatment in

 
 Table 3
 Logistic regression analysis of factors associated with 30day mortality following pneumatic dilatation therapy

	Pneumatic dilatation	Pneumatic dilatation		
	OR	P value		
Age group				
18–38	1 (baseline)			
39–52	0.95 (0.33 to 2.73)	0.919		
53–65	1.85 (0.75 to 4.53)	0.181		
66–77	4.55 (2.00 to 10.38)	<0.001		
>77	9.78 (4.33 to 22.06)	<0.001		
Deprivation				
1	1.36 (0.85 to 2.18)	0.196		
2	1.35 (0.87 to 2.12)	0.184		
3	1.19 (0.76 to 1.86)	0.451		
4	0.69 (0.42 to 1.13)	0.144		
5	1 (baseline)			
Ethnicity				
White	1 (baseline)			
Not white	0.82 (0.42 to 1.60)	0.555		
Unknown	0.44 (0.22 to 0.88)	0.020		
Gender				
Female	1 (baseline)			
Male	1.01 (0.75 to 1.35)	0.953		
Previous myotomy				
Yes	2.00 (1.05 to 3.79)	0.035		
No	1 (baseline)			
Charlson comorbidity score				
0	1 (baseline)			
1–4	0.77 (0.41 to 1.41)	0.393		
>4	2.87 (2.08 to 3.95)	<0.001		
No of prior dilatations				
0	1 (baseline)			
1–3	1.58 (1.15 to 2.16)	0.005		
4+	1.97 (1.21 to 3.19)	0.006		

either the PD or HM groups. There was no association between treatment failure and deprivation (table 2).

#### Mortality

The 30-day mortality over the study period was 0.0% for subjects undergoing HM and 1.9% following PD, of whom 1.3% died within the admission associated with PD. Mortality in subjects undergoing PD by age group was 0.3%, 1.3% and 5.3% in subjects aged 18–65 years, 66–77 years and >77 years, respectively. Less than 8% of subjects who suffered an endoscopic perforation died within 30 days (data censored). Multivariable regression analysis demonstrated that the following were associated with 30-day mortality after pneumatic dilatation: age 66–77, age >77, previous myotomy for achalasia, 1–3 previous pneumatic dilatations, >4 previous pneumatic dilatations and Charlson comorbidity score >4 (table 3).

## **Complications of therapy**

The coded complications of achalasia treatment are described in table 4. The 30-day emergency readmission rate over the study period was 2.6% and 3.8% for subjects undergoing HM and PD, respectively.

The coded perforation rate following dilatation was 1.6% and sedation complications were noted in 3.4%. Following PD, 55.8% of perforations were diagnosed and admitted to hospital

Table 4         Complications of achalasia treatment within 30 days			
Complication	Heller's myotomy n (%)	Pneumatic dilatation n (%)	
30-day readmission	57 (2.6)	181 (3.8)	
30-day mortality	0 (0)	89 (1.9)	
Endoscopic			
Bleeding	-	29 (0.6)	
Perforation	-	77 (1.6)	
Sedation	-	163 (3.4)	
Surgical			
Bleeding	22 (1.0)	-	
Perforation	151 (6.9)	-	
Venous thrombosis	6 (0.3)	-	
Anaesthetic complications	30 (1.4)	-	

on the same day. Multivariable regression analysis did not reveal any associated factors for perforation (data not shown). Mortality following PD perforation was low (<8%) (data censored due to low numbers).

#### DISCUSSION

This is the largest ever study of the outcomes of achalasia therapy. Long-term outcomes appear to be better following up to three PDs when compared with HM. There was no mortality associated with surgery suggesting excellent subject selection, which is consistent with other studies that include older subjects undergoing HM.<sup>12</sup> PD was associated with 1.9% 30-day mortality, which appears largely related to the comorbidity seen in this group. Increasing age, comorbidity and previous HM or PD were associated with increasing mortality in PD subjects. Perforation following PD was rare, generally recognised early and associated with relatively low mortality.

The durability of HM and PD demonstrated in this study at 5 years was similar to that reported in a large European randomised control trial comparing PD (82% vs 88% in the present study) with laparoscopic HM (84% vs 87% in the present study).<sup>3</sup> Moonen *et al* used an Eckardt score <4 as their primary end point, which is likely to result in a slightly higher failure rate than the current study, as those with limited residual symptoms not requiring further intervention may still be considered a failure in that study, but not in the present study. Unfortunately, this could not be addressed in the validation study, as Eckardt scores were not routinely recorded in the medical records examined. However, the similarity between the 5-year results reinforces the methodology of the current study and the validity of the longer term outcomes described.

The incidence rate of treatment failure is also provided for a single PD. This rate is significantly higher than for either up to three PDs or HM. A single PD therefore appears inferior to HM, but this is not consistent with current recommended best practice for PD, as described in a recent high-quality randomised controlled trial of PD and HM.<sup>2</sup> Although comparison of up to three PDs to a single HM may introduce a lead time bias in favour of PD, because three PDs can be spread out over a longer period, this represents current best practice and has therefore been chosen as the comparator with HM.

Durability is not reported in the present study for botulinum toxin injection treatment. Prospective, randomised data have compared injection to HM, demonstrating that although short-term benefit was seen, after 2 years only 34% of injection subjects were symptom free compared with 87.5% in the HM group.<sup>4</sup> Systematic reviews support this finding, concluding that injection therapy is less durable than either PD or HM.<sup>5 13</sup>

The present study has been able to report 10-year outcomes for PD and HM with sustained results for PD but some loss of benefit for HM. Although long-term outcomes for subjects with achalasia undergoing HM are reported elsewhere over periods beyond 5 years, the numbers described are often small. In a study of 54 subjects at a single site over a 10-year period following a single PD 36% remained symptom free at structured interview.<sup>14</sup> A further prospective 15-year review of 39 subjects demonstrated 58% symptom-free survival based on symptom score following a single PD.<sup>15</sup> Variations of treatment failure definition make comparisons with the present study of limited value.

An association was observed between older subjects (>66 years of age) and treatment failure following PD and subjects with higher Charlson comorbidity score (>4) and apparent treatment success. As these subjects become more frail over the 10-year follow-up period, they may undergo botulinum toxin injection rather than repeat PD, or in those with significant comorbidity, no further endoscopic treatment at all. This is the likely explanation for these minor associations with failure rate observed in the PD cohort.

The complication rates described in the present study are lower than those seen by Boeckxstaens *et al.*<sup>2</sup> The perforation rate in the present study was 1.6% compared with 4% for pneumatic dilatations and 6.9% compared with 12% for HM.<sup>2</sup> It is important to recognise that the impact for a patient of perforation during HM is much less than following PD. Perforations during HM can be recognised intraoperatively and treated at the time with no significant consequences. Multivariable regression did not identify any factors associated with perforation, which in combination with the low observed perforation rate is reassuring. However, under-reporting of complications is possible in HES data due to the coding structure. Subjects acquire a primary diagnosis per episode, and although significant complications can be added as a further diagnosis, this can be less complete. The coding is more accurate if a subject was discharged and returned in a new episode, which would have the complication as a primary diagnosis.

Significant variation in provider procedure volume for HM and PD was observed in the present study. No association between provider volume tertile and treatment outcome was seen on multivariable analysis.

Ascertainment bias is a concern in large database studies. However, the results of the local validation provide reassurance that both achalasia as a diagnosis and its treatment modalities are accurately coded in HES. Comparison with high-quality randomised data with similar outcomes reported provides further reassurance that the results of the present study are valid.<sup>3</sup> Selection bias is also important to consider when comparing treatment modalities, as subjects are not assigned randomly, resulting in different cohort demographics in those undergoing each treatment modality. Furthermore, diagnosis in the present study is based on ICD-10 codes. Due to the limitations of HES coding, consistent oesophageal manometry findings could not be included in the case selection criteria. Furthermore, distinct subtypes of achalasia cannot be distinguished from ICD-10 codes and therefore cannot be included in the logistic regression models. Achalasia subtype influences the response to treatment<sup>16</sup> and may have influenced the choice of treatment modality in some of the subjects studied.

Two key strengths of this study are the size of the cohort and 10-year duration of follow-up. As achalasia is a chronic condition, which subjects will live with for decades, it is important to

#### Oesophagus

be able to provide data mapping the likely long-term outcomes of each treatment modality, so that subjects can make an informed treatment choice. As there was only a small difference in outcomes seen between up to three PD episodes compared with a single HM, subjects can choose with a reassurance of a good outcome between one or more endoscopic procedures and a single, more invasive operation.

This study does not include POEM, as the procedure is not yet commonly undertaken in the UK and there is no OPCS4 code currently for POEM. Although a small number of POEM procedures may potentially have been coded as HM, their low numbers to date would have no significant impact on such a large HM cohort. However, the present study suggests that HM represents a safe, effective, single therapy in selected subjects, including those with higher Charlson comorbidity scores and advanced age. PD has similar outcomes for those unsuitable for surgery, with low mortality and few perforations. High-quality, long-term randomised trial data are now needed to establish which patients with achalasia would benefit from POEM instead of current established achalasia therapy options.

In conclusion, the present study demonstrates a small increase in durability of PD compared with HM for achalasia, in a large national database, over 10 years. There was no mortality associated with HM, suggesting excellent case selection. Thirty-day mortality following PD was 1.9% and was associated with advancing age, increasing comorbidity and previous HM or PD. Perforation was an uncommon event, was usually recognised rapidly and associated with relatively low mortality.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

**Data sharing statement** HES data are bound by a strict data sharing agreement, which prohibits dissemination of study data to protect patient anonymity. As data are pseudonymised, HES data have been shared by NHS Digital under a data sharing agreement for the purpose of service evaluation.

#### REFERENCES

- 1 Hirano I. Pathophysiology of achalasia. Curr Gastroenterol Rep 1999;1:198–202.
- 2 Boeckxstaens GE, Annese V, des Varannes SB, *et al*. Pneumatic dilation versus laparoscopic Heller's myotomy for idiopathic achalasia. *N Engl J Med* 2011;364:1807–16.
- 3 Moonen A, Annese V, Belmans A, et al. Long-term results of the European achalasia trial: a multicentre randomised controlled trial comparing pneumatic dilation versus laparoscopic Heller myotomy. Gut 2016;65:732–9.
- 4 Zaninotto G, Annese V, Costantini M, et al. Randomized controlled trial of botulinum toxin versus laparoscopic Heller myotomy for esophageal achalasia. Ann Surg 2004;239:364–70.
- 5 Wang L, Li YM, Li L. Meta-analysis of randomized and controlled treatment trials for achalasia. *Dig Dis Sci* 2009;54:2303–11.
- 6 Elliott TR, Wu PI, Fuentealba S, et al. Long-term outcome following pneumatic dilatation as initial therapy for idiopathic achalasia: an 18-year single-centre experience. Aliment Pharmacol Ther 2013;37:1210–9.
- 7 Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987;40:373–83.
- 8 Nuttall M, van der Meulen J, Emberton M. Charlson scores based on ICD-10 administrative data were valid in assessing comorbidity in patients undergoing urological cancer surgery. J Clin Epidemiol 2006;59:265–73.
- 9 Crooks CJ, West J, Card TR. A comparison of the recording of comorbidity in primary and secondary care by using the Charlson Index to predict short-term and long-term survival in a routine linked data cohort. *BMJ Open* 2015;5:e007974.
- Fine JP, Gray RJ. A proportional hazards model for the subdistribution of a competing risk. JAm Stat Assoc 1999;94:496–509.
- 11 Statacorp. Stata Statistical Software: release 14. TX: StataCorp LP, 2015.
- 12 Salvador R, Costantini M, Cavallin F, et al. Laparoscopic Heller myotomy can be used as primary therapy for esophageal achalasia regardless of age. J Gastrointest Surg 2014;18:106–12.
- 13 Campos GM, Vittinghoff E, Rabl C, et al. Endoscopic and surgical treatments for achalasia: a systematic review and meta-analysis. Ann Surg 2009;249:45–57.
- 14 Eckardt VF, Gockel I, Bernhard G. Pneumatic dilation for achalasia: late results of a prospective follow up investigation. *Gut* 2004;53:629–33.
- 15 Katsinelos P, Kountouras J, Paroutoglou G, et al. Long-term results of pneumatic dilation for achalasia: a 15 years' experience. World J Gastroenterol 2005;11:5701–5.
- 16 Rohof WO, Salvador R, Annese V, et al. Outcomes of treatment for achalasia depend on manometric subtype. Gastroenterology 2013;144:718–25.