

## Short and long term results of the laparoscopic Heller–Dor myotomy. The influence of age and previous conservative therapies

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### Abstract

**Aims** To evaluate the long-term outcome and quality of life (QoL) data, and to assess the potential influence of age and different conservative procedures on laparoscopic surgery.

**Background** Current therapies for achalasia can palliate dysphagia, but other symptoms may persist, making it difficult to quantify and compare. To understand if they could influence results, we analyzed short- and long-term results and correlated them to age and previous conservative treatments using a specific QoL test.

**Methods** Functional examinations (endoscopy, 24-hr pH manometry, upper GI X-rays) and the gastrointestinal quality of life index (GIQLI) were used before and after a laparoscopic Heller–Dor myotomy. Data were analyzed by the Mann–Whitney *U* test, Wilcoxon signed rank test, and Spearman’s  $\rho$  coefficient for bivariate correlations ( $p < 0.05$ ).

**Results** From January 1996 to January 2004, 31 consecutive patients out of 35 diagnosed with achalasia, in clinical stages I–III, were operated on by laparoscopy. Two groups were identified using the break point of 70 years of age, (20 younger and 15 older) and two subgroups according to the conservative therapy performed (20, none; 15, some). Patients underwent a clinical manometry evaluation at six and 12 months, and then yearly, and pH-metry at six, 24, and 60 months. In 78% of patients dysphagia disappeared and the incidence of reflux was 13%. Age and previous treatments did not influence surgical outcome.

Patients completed a GIQLI questionnaire before surgery, six months after surgery, and then yearly (for five years). The median preoperative GIQLI score was 78 (range 38–109) out of a theoretical maximum score of 144. At a median follow-up of 49 months (range 24–72 months), the score had significantly improved to 115 (range 71–140). There was no significant statistical difference between the groups.

**Conclusions** Laparoscopic Heller–Dor myotomy is an effective palliation for achalasia; the long-term outcome is not significantly affected by preoperative conservative treatments or by the age of the patients. The GIQLI questionnaire is a reliable instrument to compare the impact of achalasia symptoms on health-related QoL before and after surgery.

**Keywords** Achalasia · Clinical papers/trials/research · Quality-of-life score · Laparoscopic Heller–Dor procedure · Influence of age · Conservative treatments

Oesophageal achalasia is a motor disorder caused by an irreversible degeneration of the oesophageal myenteric plexus, with an estimated annual incidence of 1/100,000 individuals in Western countries. It is characterized by aperistalsis or uncoordinated contractions of the body and impaired relaxation of a frequently manometrically hypertensive lower sphincter (LES). The therapeutic procedures tend to the palliation of dysphagia and other symptoms caused by the stasis as no available treatment can restore the motility or the coordination of the oesophagus. According to the only prospective, randomized trial by Csendes et al. (1989) [1] comparing the long-term results of the pneumatic dilation and oesophagomyotomy, the procedure of choice for idiopathic achalasia should be surgical myotomy of the LES,

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as initially reported by Heller in 1913, with some modifications. Until the beginning of 1990 the approaches were laparotomy or thoracotomy, with overall good long-term results in about 80% of patients, but with a perceived relatively high morbidity associated with open surgical treatment that led to most patients and physicians favouring endoscopic dilation as the primary conservative option for achalasia. More recently several nonrandomized studies showed conclusively that the mini-invasive approaches, mainly laparoscopic, are associated with shorter operative time and hospitalization, lower morbidity, and lower incidence of postoperative reflux [2–3]. Compiled series of laparoscopic myotomies noted the improvement of symptoms in 85 to 100% of patients, showing very low rates of morbidity and mortality. The incidence of symptomatic reflux disease (GERD) was 0 to 18%, as shown in both series with a relatively short follow-up (average < 2 years) [4–5], and longer than six years [6]. Moreover it has been shown that prior use of botulinum toxin and oesophageal dilation, often in sequence, can induce fibrosis of the submucosa, leading to a more-difficult and longer mini-invasive procedure with a higher risk of intraoperative perforation but without a negative impact on long-term outcome [7]. These satisfying outcomes, however, led to the more frequent choice of surgery as the primary treatment [5].

This study analyzes the short- and long-term surgical and health-related QoL outcomes of laparoscopic Heller–Dor myotomy, looking at the influence of the age of the patients and of previous conservative treatments on postoperative outcome.

## Patients and methods

A consecutive series of 35 patients with the diagnosis of achalasia and a median preoperative duration of symptoms of 42 months (range 6–180 months) who underwent treatment from January 1996 to January 2004 at our institution were analyzed. There were 21 women and 14 men with a mean age of 43 years (28–82); 15 of them were older than 70 years. All of them complained of dysphagia, 24 patients of regurgitation (68.6%), 10 patients of heartburn (28.6%), nine patients of chest pain (25.7%), five patients of upper abdominal pain (14.3%), and 10 patients of varying degrees of respiratory symptoms (28.6%). All patients underwent preoperative upper GI endoscopy, contrast radiographs, oesophageal manometry and pH-metry, and were scored with the gastro-intestinal quality of life index (GIQLI).

Patients were distributed in two groups: those under 70 years old (group A, 20 patients) and those over 70 years-old (group B, 15 patients), and each group was then split into two subgroups depending on whether conservative therapies were performed or not (Table 1).

**Table 1** Patients' demographics (1996–2004) 35 pts. 14♂ - 21♀ symptoms duration 8–180 months

Group	A <70 yrs (31–68) 20 pts		B >70 yrs (70–83) 15 pts	
	Stage 1: <40 mm	3 pts		1 pts
Stage 2: 40–60 mm	8 pts		5 pts	
Stage 3: ≥ 60 mm	9 pts		8 pts	
Stage 4: sigmoid	-		1 pts	
Other therapies (11 dilat./4 botox)	A1 nil:12	A2 yes:8	B1 nil:8	B2 yes:7
<u>Comorbidity</u>				
Hiatal hernia	1 pt		1 pt	
Barrett	-		1 pt	

Four patients (3A–1B) (11.4%) had normal or mild (<4 cm) oesophageal dilation (stage 1), 13 patients (8/A–5/B) (37.1%) had moderate (4–6 cm) oesophageal dilation (stage 2), 17 patients (9/A–8/B) (48.6%) had stage 3 dilation (>6 cm), and one patient (group B) (2.9%) had a stage 4 sigmoid-shaped oesophagus. A hiatal hernia was present in two patients (one patient stage 2 and one at stage 3 of oesophageal dilation), one patient had histological evidence of a mild Barrett's metaplasia. Aperistalsis of the oesophageal body (>35% non-propelling waves) was present in 25 patients (71.4%), 10 patients (28.6%) had less than 35% of non-propelling contractions including one with vigorous achalasia (hypertonic non-propelling contractions). The mean LES resting pressure was 27.1 mmHg (range 24–36 mmHg). Eight patients (22.8%) had complete absence of LES relaxation, 21 patients (60%) had <50% LES relaxation from their baseline value, and six patients (17.1%) had >50% LES relaxation. In one patient the probe did not pass the LES. Medical treatment was attempted in 26 patients (74.3%) before operation, including proton pump inhibitor (PPI), prokinetic, anxiolytic, and dinitrate, without any clinic improvement. Eleven patients (5/A–6/B) (22%) underwent oesophageal pneumatic dilation with a 30 mm Rigiflex balloon (10 psi/30"/three times); four patients (2/A–2/B) had botox injections. The success rate was 23.5%, which means that four patients (2/A–2/B), including the stage –4 patient, were still satisfied at the control (18–36 months) and did not accept further treatment.

Thirty-one patients (18A–13B) underwent laparoscopic Heller–Dor myotomy using a standard technique with five trocars, a median minimal open access above the umbilicus, and a 30° laparoscope, preserving the attachments of the oesophagus to the crura, and dissecting the muscle layers with a myotomy of 7–9cm (2–2.5cm on the gastric side) with plain scissors or ultrasound harmonic scalpel, carefully ensuring that inactive blade was in contact with the inner layer, and with gentle distraction of the fibers

under endoscopic control. The anterior gastric valve was fixed with 2–3 stitches to both edges of the myotomy. After surgery they were followed up in the outpatient clinic and we refer the results of a follow-up of 24–72 months (median 49) including a complete clinical evaluation at six and 12 months and then every year, a manometry and pH-metry and a radiographic study at six, 24, and 60 months.

### Quality-of-life assessment

Health-related QoL was assessed with the GIQLI [8], preoperatively and then systematically every year. The GIQLI explores the patient's self-evaluation of the two-week period before the questionnaire is filled out. It includes 36 items covering four domains: gastrointestinal symptoms (19 questions), physical function (seven questions), social function (four questions), emotional function (five questions), and one item about subjective treatment assessment. Every item is scored from 0 (least desirable option) to 4 (most desirable option), the sum of the GIQLI score ranges from 0 to 144 and in a healthy control population scored 125.8 points (95% confidence interval: 121.5–127.5) [8].

Questions relating to achalasia included: item 27, exploring regurgitation (“How often during the past two weeks have you had trouble with fluid or food coming up into your mouth?”); item 29 exploring dysphagia (“How often during the past 2 weeks have you had trouble swallowing your food?”), item 35 exploring heartburn (“How often during the past 2 weeks have you had trouble with heartburn?”). Other items related to achalasia included item 1 concerning abdominal pain, item 28 concerning the speed of eating and item 5 relating to the frequency of burping and belching.

### Statistical analysis

The results are expressed as means  $\pm$  standard deviation (SD) of the mean or median (range), as appropriate. The Mann–Whitney *U* test, Wilcoxon signed rank test, and Spearman's  $\rho$  coefficient for bivariate correlations were used to compare each item before surgery and at follow-up. A binary logistic regression model has been applied in order to analyse the influence of age and previous conservative treatment as independent variables on surgical outcome. *p* values < 0.05 were considered significant.

### Results

As far as surgery is concerned there was one conversion to laparotomy due to sticky multiple adhesions from previous

**Table 2** Heller–Dor myotomy: functional outcome

	Short term	Long term
Excellent-good		
Our experience	84%	77%
Literature [6,12]	85–95%	48–80%
Gastroesophageal reflux disease (GERD)		
Our experience	15%	13%
Literature	2–7%	17–28%
Dysphagia		
Our experience	10%	16.1%
Literature	4–7%	13–22%

abdominal surgery. In two patients with hiatal hernia a hiatoplasty was carried out; in one patient a cholecystectomy was associated. The median operative time was 110 minutes (range 70–210 mins) and the median postoperative hospital stay was 4.5 days (range 3–14 days). Intraoperative complications occurred in four patients (2A–2B) (13%). Two oesophageal mucosal perforations were sutured immediately with an uneventful postoperative course. One splenic capsule tear was treated conservatively. One postoperative abdominal bleeding required a blood transfusion without reoperation. Other postoperative complications were: pneumonia, superficial wound haematoma, and urine infection. Operative mortality was nil. The postoperative instrumental follow-up ranges from 24 to 72 months (median 49), with one patient lost because of a car accident. Details of the functional results referred to the main symptoms are reported in Table 2 and reflect the short- and long-term results of the performed manometry (Table 3) and pH-metry, (Table 4).

Clinic assessment showed that dysphagia was efficiently treated in 25 patients (15/A–7/B) (80.6%): 16 patients had no residual episodes of dysphagia, five patients had only rare episodes (<1 per week), and four had occasional (>1 per week) during the two weeks preceding the evaluation. Five patients (16.1%) were improved but still had some degrees of dysphagia during most or all of their meals. Regurgitation persisted in four patients (16.7%) (frequently in two patients and most of the time in two patients). Significant heartburn (most of the time) was reported by four patients (13%) and they took antacids, as did nine patients preoperatively. Mild upper-abdominal pain was reported by five patients (18%). Chest pain more often than once per week was reported by two patients (6%), who referred daily chest pain preoperatively. Four patients complained of occasional chest pain (13.3%). Only one patient noted some respiratory distress, as they had done preoperatively. The compared results by age and previous treatments evidences a significant difference between the

**Table 3** Manometric features

	Group A			Group B		
	Preop	Postop*	5 yrs.**	Preop	Postop*	5 yrs.**
Percentage of aperistaltic waves						
≥ 35	72%	11%	6%	69%	8%	4%
≥ 20	22%	22%	16%	31%	25%	20%
< 20	5%	67%	78%	–	69%	76%
	* $p < 0.0001$			* $p < 0.0001$		
LES mean rest. press	27.1 mmHg	10.7 mmHg	11.4	25.8 mmHg	11.5 mmHg	12.6
	$P < 0.0001$			$P < 0.0001$		
LES relaxation						
Absent	22%	–	–	15%	–	–
<50%	61%	12%	17%	70%	15%	15%
>50%	17%	88%	83%	15%	85%	85%
	** 23/31pts					

**Table 4** pH-metric 24-hour data

	Normal mean value	Group A			Group B		
		Preop	Postop	5 yrs	Preop	Postop	5 yrs
Total	1.82	2.6 + 0.65	18.53 + 10.3	16.4 ± 1.71	2.93 ± 0.6	20.5 + 9.4	14.6 ± 2.5
Upright % Time pH<4	1.5	2.5 ± 0.46	11.9 ± 4.7	7.5 + 1.7	2.75 ± 0.5	13.7 ± 12.8	8.2 ± 3.4
Supine % Time pH<4	1.3	1.7 ± 0.1	13.7 ± 11.2	11.4 ± 2.6	1.5 ± 0.2	14.1 ± 10.7	11.5 ± 5.7
Total no. of episodes	37	25.2 + 4.3	42 ± 20.6	33.3 ± 12.4	26.1 ± 3.9	39 ± 13.5	31.7 ± 7.9
Episodes >5 minutes	0.9	1.8 ± 0.8	9.2 ± 4.2	7.4 ± 3.9	1.6 ± 0.3	10.2 ± 4.2	6.4 ± 2
Longest episode	6.8	4.5 ± 3.3	22 + 11	9.8 ± 4	7.5 ± 3.8	27 ± 12	9.5 ± 3.6

untreated and treated subgroups as far as dysphagia is concerned at the postoperative control ( $\rho = 0.58$ ,  $p < 0.05$ ). At five-year follow-up the results have largely converged (Table 5). A further evaluation of the two main variables by a binary logistic regression model, coding age as <70 years and >70 years, and the previous conservative therapy as independent variables and the abatement (yes/no) of the dysphagia symptoms after the laparoscopic procedure as dependent variable, did not highlight any significant effect,  $p > 0.05$ .

Figure 1 shows the comparison between overall preoperative and postoperative responses to the GIQLI questionnaire, distributed in four domains. The median GIQLI score at follow-up was 115 points (range 71–140) and was significantly higher than the preoperative score of 78 (range 38–109) ( $p < 0.0001$ ). Significantly higher subtotals were found at follow-up for each domain: symptoms ( $p < 0.0001$ ), physical function ( $p < 0.0001$ ), social function ( $p < 0.001$ ), and emotional function ( $p < 0.001$ ) as well as for subjective treatment assessment (item 24,  $p < 0.005$ ), (Table 6). The analysis shows an improvement at follow-up in the patients with the preoperative lower scores, and

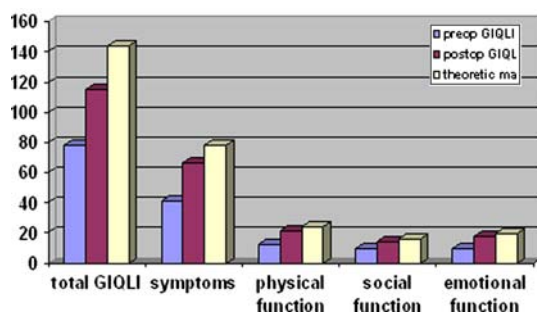
convergence in the two groups with no significant differences as far as the age of the patients was concerned. Oesophageal forceful pneumatic dilation did not affect surgical outcome or the GIQLI score, even in the two patients with intraoperative mucosal tears. Patients over 70 years old, however, tended to have more-pessimistic criteria of self-assessment as far as social life and overall outcome of surgery were concerned, as reported in Table 7.

## Discussion

Idiopathic achalasia is a disease that can be palliated but not cured, which is why symptoms are generally managed with medical therapy for a long time before taking the decision to inhibit or cut the LES fibers. The indication to treat patients who are very poor operative risks with conservative endoscopic procedures, either botulinum toxin or endoscopic pneumatic dilation, should lead us to analyze series of patients with oesophageal achalasia who have undergone surgical laparoscopic treatment retrospectively with the aim of answering the question: should preoperative conservative

**Table 5** Symptoms' clinic evaluation: not treated vs. treated patients

	NIL			Previous treatment*		
	Preop	Postop	5 yrs	Preop	Postop	5 yrs
Dysphagia						
Nil	–	79%	74%	–	62%	66%
Mild	15%	15%	20%	10%	19%	20%
Moderate	25%	7%	7%	27%	12%	7%
Severe	60%	–	–	64%	7%	7%
			* $\rho = 0.58$	$p < 0.05$	* $\rho = 0.16$ n.s.	
Heartburn	35%	14%	8%	27%	22%	11%
Regurgitation	65%	21%	10%	63%	18%	10%
Abdominal pain	25%	13%	6%	28%	8%	–
				* $\rho = 0.17$ – $0.25$ n.s.		

**Fig. 1** Pre- and postoperative gastrointestinal quality-of-life index (GIQLI)

therapy and age greater than 70 be predictive factors that should influence therapeutical strategy? It is widely accepted that the majority of patients should be treated by the modality that appears to warrant a combination of low initial morbidity, high success rate and good long-term outcome. Pneumatic dilatation and surgical myotomy improve dysphagia in the short term in a high percentage of patients [9], but beyond five to 10 years, only 26 to 49% of patients after pneumatic dilatation [1, 10, 11] versus 33 to 79% after surgical myotomy [1, 6, 10, 12] are free from dysphagia. However, 33 to 38% of patients with recurrent dysphagia manage symptoms without any medical help [10]. According to the only available prospective randomized study of surgical myotomy with pneumatic dilation [1], myotomy is more efficient for the treatment of dysphagia at five year follow-up. Controversy over the best treatment continues, as both the endoscopic and surgical techniques have evolved. From the early 1990s, Heller myotomy has been performed using a transthoracic or transabdominal mini-invasive approach [13]. Laparoscopy became the technique of choice as it has the same short-term efficiency for the treatment of dysphagia as open cardiomyotomy while reducing overall morbidity [2, 5], and to date, long-term outcome also seems to be very good [6, 14]. In most retrospective surgical and

endoscopic series, outcome assessment has been based on a variety of symptom scores that evaluate the main symptoms of achalasia (e.g., dysphagia, regurgitation or heartburn), so that the different criteria used do not allow reliable comparison. The physical, psychological, and social consequences of these symptoms, and hence the QoL impairment they produce, should be evaluated. So, in the preoperative patient assessment and postoperative analysis of the outcome of the therapy we applied the gastroenterological self-questionnaires of QoL GIQLI score, in association with instrumental tests of oesophageal functions. The present study population is homogeneous, as patients had the same operative technique and all operations were performed by the same team of surgeons. Follow-up can be considered long term with an acceptable median of 42 months. According to the literature [15, 16], a minimum interval of six months was used between surgery and QoL evaluation to exclude potential interference of immediate postsurgical sequelae on QoL. The comparison between results of the instrumental control and the self-assessment questionnaire shows substantial overlap and validates the literature reports on the better long-term outcome of the laparoscopic Heller–Dor procedure versus conservative therapies [17]. This study also shows that patients undergoing surgical myotomy have a similar favorable outcome independent of age and previous treatment. In the patients included in this study, there was no evidence that repeated dilations render surgery more difficult even if mucosal tears occurred in patients who have undergone previous treatments.

## Conclusions

Our results confirm that laparoscopic Heller–Dor myotomy reaches a functional recovery of the oesophageal function in about 80% of the patients regardless of age and previous treatments; these factors regarded either alone or together

**Table 6** Total gastrointestinal quality of life index (GIQLI) and domain scores

	Preop GIQLI (median, range)	Follow-up GIQLI (median, range)	<i>P</i> value
Total GIQLI score	78 (38–109)	115 (71–140)	<0.0001
Symptoms	41 (19–62)	60 (39–74)	<0.0001
Physical function	12 (4–24)	22 (8–27)	<0.0001
Social function	10 (4–17)	13 (8–15)	<0.001
Emotional function	10 (3–18)	15 (6–20)	<0.001
Subjective therapy Assessment	2 (0–3)	3 (1–4)	<0.005

**Table 7** GIQLI score: preoperative versus postoperative median values

	Group A			Group B		
	Preop	Postop	<i>p</i> value	Preop	Postop	<i>p</i> value
Total GIQLI score	74	120	<0.001	69	113	<0.001
Symptoms	44	63	<0.001	41	59	<0.001
Body activity	11	24	<0.001	9	20	<0.001
Social life	9	14	<0.005 *	10	12	<0.05*
Emotional life	9	16	<0.001	2	14	<0.001
Subjective assessment	1	4	<0.005*	1	2	<0.05*

\*  $p = 0.10\text{--}0.16$  n.s.

do not significantly affect the clinical results of the surgical procedure, which are correlated, yet not significantly, to the levels of preoperative scores. The long-term follow-up (median 49 months) allows us to draw definitive conclusions about the overall positive functional and clinical outcome with residual pathologic symptoms in about 20% of patients including the incidence of 13% of reflux and symptoms correlated (heartburn and chest pain), which could be considered an expected consequence of myotomy and are easily controlled by therapy. These results confirm that the Heller procedure does not need an association with 360° or 270° fundoplication, provided that the dissection is limited to the anterior oesophagus. Laparoscopic surgery seems to be the treatment of choice for achalasia either as a primary or secondary procedure. These results indicate that health-related QoL is significantly improved in all the domains tested: symptoms, physical function, social, and emotional function. Indeed the median postoperative GIQLI score of 115 is close to the 95% confidence intervals of the GIQLI for a healthy control population, while no significant difference at long-term evaluation was identified between the two age groups or subgroups used in this study. Only two patients at the four- and five-year controls showed a decreasing GIQLI score, confirming that the postoperative outcome settles down within the first 12–18 months as reported in the literature [6].

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