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Original article ■

Clinical Quality of Life and Manometric Findings in Newly Diagnosed Achalasia Patients

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SUMMARY

Scanty information is available regarding the clinical characteristics, quality of life (QoL) profile and manometric findings in unselected newly diagnosed cases of achalasia.

Fifty-six consecutive cases of newly diagnosed achalasia have been characterized regarding the symptoms when a standardized protocol was applied, to which was added a more detailed instrument enabling a comprehensive description of the character of the swallowing difficulties. The functions of the esophageal muscle wall and distal sphincter (LES) were recorded by use of standard manometry technologies and a specialized sleeve catheter. These patients' health related quality of life (QoL) has been characterized by use of the instruments-Psychological well-being index Gastrointestinal symptom Symptom rating scale Scale.

Most patients presented with a long duration of symptoms (54,5 months). The doctor's delay amounted to 5,5 months despite profound swallowing difficulties (Watson score 30.5+/- 1.7; m+/- SE). QoL was significantly impaired both when generic (PGWB) and disease specific (GSRS) instruments were applied. This deterioration was most likely caused by the eating disturbances. At the time of diagnosis the motor characteristics of the esophageal body as well as the LES were severely affected.

The vast majority of patients with achalasia are diagnosed at a stage when the disease process has already profoundly destroyed the motor function of the esophagus and the gastroesophageal junction and the quality of life are severely impaired.

Key words: achalsia, symptoms, dysphagia, manometry, lower oesophageal sphincter, quality of life, 24- hour pH monitoring

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INTRODUCTION

Achalasia is an uncommon disease, which on an annual basis affects roughly 1-2 individuals per 100.000 inhabitants (1-4). The disease is characterized by progressive destruction of the myenteric neurons of the esophagus and gastroesophageal junction (GEJ) (5). It is not known at what stage of this process specific symptoms present themselves. Consequently, scanty information is available on the spectrum, appearance and further development of symptoms up to the point when the diagnosis is made. Another factor that adds to the sparse amount of base line data from patients presenting with newly diagnosed disease is that most reports originate from referral centres, suggesting a presentation of cases at a later stage of the disease process (6). Moreover, most of these patients have at that particular time point already received some treatment, which is either endoscopic and/or pharmacologic in character.

The present study was aimed at describing the clinical history, prevalence of symptoms and the esophageal manometric characteristics of patients with achalasia at the time when the diagnosis was established. Furthermore, we carefully described the Quality of Life (QoL) characteristics of these patients. Corresponding information is of particular relevance in the light of the abundance of information available in patients with another more frequent but different type of motor dysfunction of the GEJ, i.e. gastroesophageal reflux disease (7-11).

PATIENTS AND METHODS

From January 2000 until March 2005, all patients, who for the first time received the diagnosis of achalasia in the region of Västra Götaland and the county of Jönköping, Sweden, were prospectively recruited into the study. The total population of that area was 1.800.000 inhabitants. During the last two years of the enrollment period, similar patients were also included who were investigated at the GI motility laboratory at Karolinska University Hospital, Huddinge, Sweden. Some of these patients (see below) had a history of unspecified pharmacological therapy, which frequently was initiated based on an incomplete diagnostic workup. However, none of the patients had been submitted to pneumatic dilatation. We based our diagnosis on a history suggestive of bolus obstruction without endoscopic signs of other specific causes, typical radiological signs always combined with incomplete swallow-induced relaxation of the lower esophageal sphincter (LES), with or without motor dysfunction of the esophageal body, as assessed during manometry.

During that time period, fifty-six patients were found to fulfill the diagnostic criteria and the demographic characteristics of those are detailed in Table 1. Forty-one of these were examined at the GI motility laboratory at Sahlgrenska University Hospital, 3 at the

GI motility laboratory at Jönköping Central Hospital and 12 at the Karolinska University Hospital, Huddinge.

Diagnostic evaluation

All patients were interviewed according to a standardized protocol, parts of which have been extensively used and validated in patients before and after anti reflux surgery (13, 14). In addition, we applied a more detailed instrument enabling a comprehensive description of the character of the swallowing difficulties (15, 16). The so-called Watson dysphagia score included 9 items from liquid to solid (for details see figure 1b). In that situation, a report by the patient to have dysphagia always rendered 1 point, sometimes =0.5 point, never =0 point. A composite score can then obtain the range from 0 (no dysphagia) to 45 (severe dysphagia) by multiplying the score for each substance by adjusting line number and then summarizing all lines.

Endoscopy was regularly carried out on an outpatient basis but most patients had already had one or more endoscopic investigations before the actual diagnostic workup.

Manometry was carried out according to a predefined standardized protocol in forty - eight patients when the functional characteristics of the LES were assessed by use of a sleeve sensor (17, 18). Basically, the manometric device was equipped with side holes located 5 cm apart to record the motor events in the proximal, mid portion and distal esophagus. To the distal end was attached a 6 cm long sleeve sensor which straddled the GEJ. The distal end of the sleeve device contained a side hole to record the intra - gastric pressure. In eight patients this sleeve catheter was not available, why another design of the manometric assembly was used, comprising three distal side holes located at the same level to simultaneously record the LES pressure. All side holes were continuously perfused with degassed water through a low compliance perfusion pump (Arndorfer System, Arndorfer Medical Specialities, Greendale, Wisconsin, USA). A pressure transducer was connected to each perfusion site. The signals were transmitted to a computerized recording system (Medtronic, Stockholm, Sweden). Each catheter had a pharyngeal port, which allowed swallowing signals to be recorded.

All investigations were carried out in patients' fasting over-night. Before introduction of the catheter, each pressure port had been calibrated to standard pressure levels at room temperature. With the patient in the supine, right lateral position, the pressure transducers were positioned in the mid axillary plane of the patient and the recordings were completed accordingly.

The manometric catheter was introduced through one nostril and thereafter positioned to allow the side holes to register motor activities in the entire esophagus. Evaluation of esophageal peristalsis was based on the observation of the response to 10 swallows of 5 ml

each of room-temperature water. We allowed an interval between each swallow of at least 15 seconds. The mean contraction amplitude of the peristaltic wave in respective segments of the esophageal body was calculated as well as the speed and duration of each contraction if judged to be propulsive. The mean contraction amplitude was assessed as the peak pressure in relation to the end expiratory intra-luminal pressure of the esophageal body. The duration of each contraction was defined as the length (in seconds) between the intercept points of the steep up and down stroke of the contraction and estimated in relation to the base line intra-luminal pressure of the esophageal body.

Failed peristalsis was scored to exist if either the swallow-induced peristaltic wave disappeared during the aboral transmission through the esophagus or if the contraction amplitude reached a level less than 10 mm of Hg.

To assess the intraabdominal length and the total length of the LES, a station pull-through technique was used. Hereby, the side hole just proximal to the sleeve sensor was used or the recordings were made through the three side holes located at the same distal level in the other type of manometric catheter used. The probe was withdrawn in 0.5 cm increments and kept at each level for at least 30 seconds, or until the recording stabilized. The length of the intra abdominal part of the LES was calculated as the distance from the point of the first stable pressure rise above the intra-gastric pressure to the first point of negative pressure to occur on inspiration. The basal LES pressure was recorded at 1-minute intervals, in periods of stable pressure levels with no interference from swallows. The intra-luminal end-expiratory gastric pressure served as reference. The nadir pressure was defined as the lowest pressure level achieved following a standard 5 ml water swallow. Maximal LES relaxation was instituted by allowing the patient to drink 100 ml of water through a straw and simultaneously record LES pressure. Accordingly, the lowest pressure plateau hereby reached was registered. The LES relaxation characteristics were also analyzed in more detail by recording the relaxation duration (sec.) and velocity (mm Hg/s). The eventual slope of the post swallowing relaxation was estimated on each tracing allowing the assessment of relaxation velocity. The duration of maximal inhibition was calculated from the plateau inhibition when the change in LES pressure varied less than 1 mm Hg.

Ambulatory 24-hour pH monitoring was carried out using an antiimony pH electrode (Medtronic, Stockholm, Sweden) passed through one nostril and positioned 5 cm proximal to the LES, which previously had been located at stationary manometry. Each pH electrode was calibrated before and after the respective investigation and the pH data were acquired every 4 seconds and stored in a computerized memory. Each subject was instructed to follow normal daily activities during the

recording hours. The relevant normal values used by the laboratory have been presented elsewhere (19).

Quality of life (QoL) was described by the use of one generic instrument and one more disease specific. Psychological well-being index (PGWB) is a well-validated generic instrument, which includes 22 items divided into six dimensions: anxiety, depressed mood, positive well being, self control, general health and vitality (20-23). Each dimension contains 3-5 items, which are graded using a six - point scale. The higher the score the greater is the well-being. This instrument has the advantage of being well established with age and sex adjusted normal values. Moreover it has been extensively used in clinical research focusing on e.g. dyspepsia, gastro-esophageal reflux disease, peptic ulcer disease and gallstone disease.

Additional aspects on the patients QoL were gained by the use of the disease specific instrument Gastrointestinal Symptom Rating Scale (GSRS). This instrument includes 15 items divided into six dimensions: diarrhea syndrome, indigestive syndrome, intestinal obstruction, abdominal pain syndrome, reflux syndrome and swallowing difficulties. GSRS uses a seven-point scale and higher score means more pronounced symptoms (24, 25). This instrument was chosen due to the huge database available from patients with a variety of upper GI diseases in addition to values from the healthy adult Swedish population.

Statistics and ethics

For the overall presentation of data only descriptive analyses were used. To elucidate the association between manometric and clinical characteristics, Spearman rank correlation analysis was applied. All variables were stored in an Excel database on which the SPSS statistical programme was utilised. If not otherwise stated, the mean values and SEM were given.

Each local ethic committee had approved the study protocol.

RESULTS

During the recruitment period 56 patients fulfilled the diagnostic criteria to have idiopathic achalasia. The demographic details of this cohort are given in detail in Table 1.

Some apparent features emerged such as the wide age ranges, low level of co morbidities, long duration of complaints, few endoscopies carried out before the establishment of the diagnosis and the quite substantial length of the doctors' delay. Two patients had a history of established achalasia in first-degree relatives, whereas 6 patients recalled similar complaints compatible with the disease in first-degree relatives. A more detailed characterization of their obstructive complaints is given in Figure 1a and b, where the distribution of composite scores according to Watson and coworkers

(15, 16) are given. A mean score of 30.5±1.7 was calculated with no difference between males and females. A focused analysis of the food components that raised the greatest concern for these patients are summarized in Fig 1b, showing as expected the most pronounced difficulties with meat. However, fresh fruit and soft bread/pastries regularly also caused symptoms of impaired bolus passage. The additional spectrum of symptoms are given in Table 2 showing that interestingly enough quite a few patients complained of heartburn-like complaints and chest pain.

The manometric characteristics of the esophageal body, at the time of the diagnosis, are summarized in Table 3. None of the patients presented with a swallow induced propulsive peristaltic wave that propagated along the entire organ. Only exceptionally did we observe failed primary peristaltic activity (2±1.7%). Essentially, all contractile activities were thus segmental. The amplitudes of the segmental contractions were of similar size in the three studied portions of the esophagus, with a mean duration of 7.5±0.5 seconds in the proximal part and 8±0.6 seconds in the distal third.

The details of LES capacity to relax are given in Figure 2 revealing a mean basal pressure amounting to 21±1.9 mm Hg. The mean nadir pressure, following a 5 ml water swallow, was 10 mm Hg but varied from 2-29 mm Hg. All patients with a nadir pressure below 10 mm Hg had also a sleeve sensor study. Interestingly, maximal LES relaxation, elicited by repetitive water swallows, attained the same plateau pressure as a single swallow. The mean duration of the LES relaxa-

tion was 2.9±0.3 seconds with a slope of 6.4±0.6 mm Hg/sec. The total and intra abdominal lengths of the sphincter were 3.4±0.2 and 2.7±0.2 cm, respectively.

Ambulatory 24-hours pH-metry was carried out in 25 patients during the diagnostic workup (Table 4). As expected, the total acid exposure time was within the "normal range". However, some abnormal values were found which were entirely due to some very long intraesophageal acidic episodes both in the upright as well as in the recumbent body position.

Logistic regression analyses were carried out to elucidate the associations between the LES characteristics and relevant clinical parameters. Neither specific symptoms nor duration of symptoms and severity of those were related to the basal LES tone or to its ability to relax upon proper stimulation.

The quality of life assessments as reflected by the PGWB and GSRS scores are summarized in Table 5a and b, where also the "normal" values have been inserted.

The overall outcome of these recordings showed that the QoL of these patients was clearly inferior to what is recorded in an adult general Swedish population. In the generic instrument this deterioration was expressed primarily through the items general health and vitality. In the disease specific GSRS questionnaire the swallowing related items scored worst. Noteworthy was the quite high scores recorded for the items indigestion, abdominal pain as well as constipation.

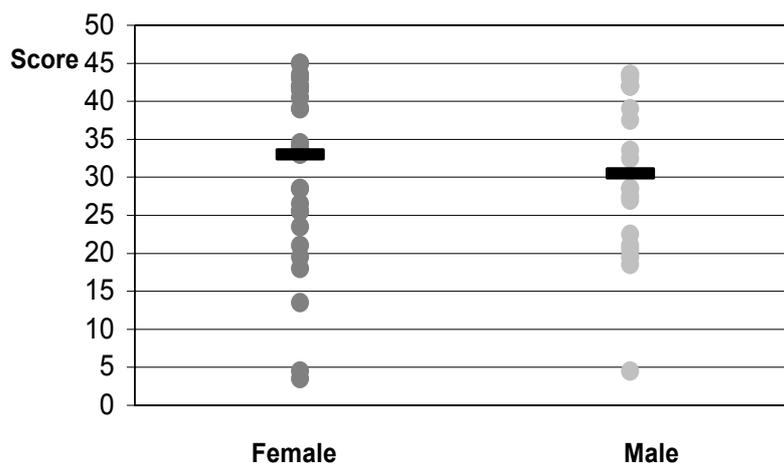


Figure 1a. Distribution of dysphagia complaints when scored according to Watson and co-workers (16). The median values are also given.

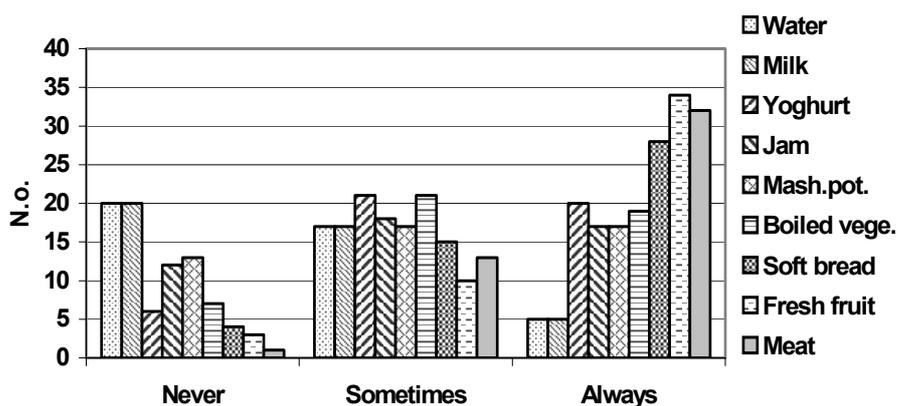


Figure 1b. Details of dysphagia complaints according to the Watson score in newly diagnosed achalasia patients

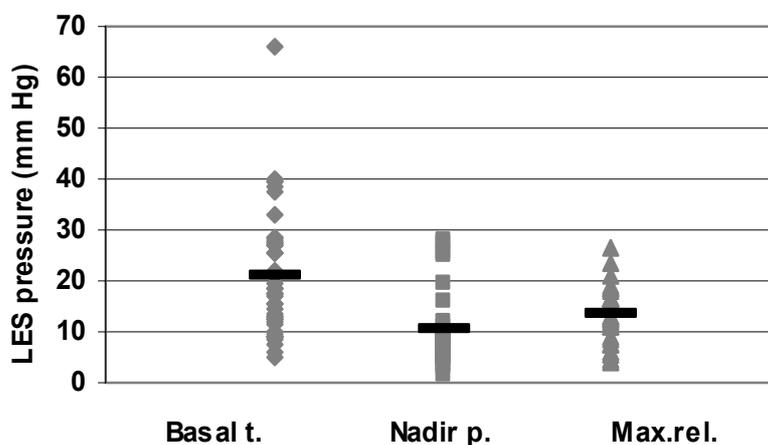


Figure 2. LES characteristics in the basal state, after single water swallow (nadir pressure) and after maximal inhibitory stimulation (repeated swallows). The median values are also given.

Table 1. Demographic characteristics and clinical history in patients with newly diagnosed achalasia. The mean, SE and ranges are given unless otherwise specified

Age (yr)	45.+/-16 (17-78)
Gender (M/F)	28/28
Weight (kg)	60+/-12 (45-80)
Co morbidity (no of subjects)	
Previous myocardial infarction	2
Angina	1
Pulmonary Disease	3
Diabetes	1
GI diseases	9
Family history	2 (6 possible)
Symptom duration (months) (range)	54.5 (1-240)
Other achalasia directed treatments	0
Number of previous endoscopies	range (0-2)
Doctor delay (months) (range)	9 (0.3-108)

Table 2. Distribution and severity of “reflux like symptoms” at the time of diagnosis

	None	Rare	Occasional	Frequent	Very often	Severe
Heartburn	18	14	10	13	2	1
Chest pain	6	8	14	11	5	5
Regurgitation	18	11	10	4	6	1

Table 3. Motor characteristics of the esophageal body in patients with newly diagnosed achalasia

	MEAN	SEM
Contractile amplitude mmHg		
Proximal	30	2.9
Middle	31	3.3
Distal	32	3.4
Contractile duration (sec)	7.9	0.6
Proximal	7.5	0.5
Middle	7.9	0.6
Distal	8	0.6
Simultaneous contractions %	98	1.8
Failed contractions %	2	1.7

Table 4. 24-hour pH monitoring in the distal esophagus in untreated achalasia patients (n=24)

		MEAN	SEM
Fraction time % with pH<4	Total	3.1	1.4
	Upright	3.8	1.6
	Supine	2.5	1.4
Longest reflux (minutes)	Total	23.7	9.6
	Upright	14.4	4.9
	Supine	14.8	8.8
Number of reflux episodes >5 min	Total	1.3	0.5
	Upright	1.1	0.4
	Supine	0.3	0.2
Number of reflux periods (n)	Total	9.8	6.1
	Upright	9.5	6.0
	Supine	0.8	0.4

Table 5a. Quality of life at the time of the diagnosis of achalasia as assessed by use of the generic instrument psychological general well being index (PGWB). CI stands for confidence intervals

PGWB	Mean	CI 5%	CI 95%	Normal
Anxiety	21.5	19.9	23.0	24.1
Depressed mood	14.1	13.1	15.2	15.5
Positive well-being	14.2	13.2	15.2	16.1
Self-control	14.2	13.3	15.0	15.3
General health	11.6	10.8	12.5	14.6
Vitality	13.2	11.9	14.5	17.2
Tot. Score	89.7	83.7	95.6	102.9

Table 5b. Quality of life at the time of the diagnosis of achalasia as assessed by the use of the disease specific gastrointestinal symptom rating scale (GSRS). CI stands for confidence intervals. Normal values relevant for an adult Swedish control population are also given.

GSRS	Mean	CI 5%	CI 95%	Normal
Diarrhoea syndrome	1.8	1.4	2.2	1.4
Indigestion syndrome	3.3	2.9	3.7	1.8
Constipation syndrome	2.5	2.0	2.9	1.6
Abdominal pain syndrome	3.3	2.9	3.8	1.6
Reflux syndrome	2.9	2.4	3.4	1.4
Swallowing difficulties	5.4	4.7	6.0	1.5
Total	3.2	2.7	3.7	1.5

DISCUSSION

It has been claimed that with the current wide spread use of e.g. esophageal manometry, more patients with early stage achalasia and milder symptoms are being diagnosed and treated (26). The present study was partly designed to carefully and prospectively assesses the symptom severity at the time of the first diagnosis of the disease. Our data would suggest that both from a manometry as well as from a symptom severity perspective the primary diagnosis is obtained at a stage when all objective criteria would suggest that a fairly advanced stage of the disease has already been reached. The present observations on the mean age of the patients accord well with what has previously been reported (27-31). Moreover, these patients apparently have a long history of symptoms to which then is added, on an average, about 5.5 months of delay in the diagnosis due to the physician. Apparently the patients

adapt and accommodate to the problems caused by the combined effects of aperistalsis, failure of the food boluses to stimulate forceful propulsive contractions and the abnormal relaxation of the LES. In our patients, as reported by many others, the vast majority of cases reported dysphagia. Although the currently applied dysphagia scale (15, 16) has been developed and validated in gastro-esophageal reflux disease patients, the current results revealed some novel insights into the spectrum of swallowing difficulties characterising achalasia patients. The most pronounced difficulties were reported with meat. However, fresh fruit and soft bread/pastries regularly also caused symptoms as did boiled vegetables and fish. This contrasted to mashed potatoes and jam where the picture was less consistent.

The burden of symptoms causes impairment in quality of life. In gastroesophageal reflux disease, it has been found that there is a relationship between the severity as well as duration of symptoms and the subse-

quent level of impairment in each individual's quality of life (32). Although the currently used instrument GSRS and PGWB have not been specifically validated in achalasia patients, it is reasonable to assume that they can be used in other more specific motor disorder of the esophageal body and GEJ as represented by achalasia. We found that patients with newly diagnosed achalasia suffered from a very poor quality of life, in the same range or even worse than reported in untreated gastroesophageal reflux disease. By use of the generic instrument PGWB we found that the largest deviation from normal was seen in the items social functioning and vitality. It is most likely that grave swallowing difficulties are appreciated as a significant social handicap severely restricting each affected individual's ability to enjoy food in a normal social environment. As expected, the GSRS instrument picked up the impaired swallowing, where the untreated patients scored exceedingly high (mean=5.8) affected also the total score. It is noteworthy that also epigastric pain and constipation added to the impaired total GSRS score. This might well also be due to the dysphagia-odynophagia complex and the patient's preferences for semisolid minced food, minimising the bulk components of the diet. However, these patients not only minimize bulk, but they often limit their oral intake which in addition to impaired physical activity, along with a change in the type of food ingested, add to the risk of constipation. It remains to be determined if it is possible to "normalise" these patients' quality of life by effective therapy (32-36) and above all if clinically relevant differences emerge if pneumatic dilatation is practised compared to surgical cardiomyotomy.

Heartburn is not an uncommon symptom in achalasia patients. It has been noticed that this symptom differs slightly from gastroesophageal reflux disease patients in that it is usually not postprandial among the former and of course does not respond to antisecretory drug therapy (26, 30). We found, in accord with other investigators, that ambulatory 24-hour pH recording frequently revealed excessive acid exposure times. This is most likely not due to gastroesophageal reflux but instead caused by delayed esophageal clearance of exogenous ingested acidic food material or in situ production of lactic acid from retained, fermented food particles.

Dysfunction of the LES is always present in achalasia. Traditionally, it has been suggested that an elevated LES basal tone is pathognomonic for the disease. Many studies have shown that achalasia patients, as a group, have a high basal sphincter tone irrespective of whether it is assessed by conventional perfused side hole manometry technique or by use of a sleeve sensor (6, 26, 28, 29). However, in the present study, we observed that about one quarter of the patients had a LES pressure, which was considered to fluctuate closed to the normal ranges. It has been proposed that the basal tone should exceed, and the nadir pressure at the most reach 10 mm Hg to be compatible with the diagnosis (29). It should, however, be noticed that we re-

corded basal pressures over a considerable period of time and with increasing experience with the use of corresponding technologies, the dynamic characteristics of the LES even in achalasia patients become less elusive (28). Moreover, we noticed that the total length as well as the intra abdominal portion of the sphincter had the same profile as in healthy adult individuals. On the other hand a low basal LES tone is never seen in achalasia patients. The typical finding is the incomplete relaxation of the sphincter in response to water swallows (nadir pressure) (28, 29). It is important to emphasise that complete LES relaxation does not exclude achalasia and it has been proposed that up to 20% of achalasia patients can present with sphincter relaxations down to or in the neighbourhood of intra-gastric pressure (37-39). Similar relaxations seem to be of very short duration and are probably functionally inadequate. It has been proposed that similar achalasia patients may represent an early stage of the disease and present with a shorter history of symptoms, again emphasising the heterogeneity of the disease states (28). In the present study we did not observe one single patient with even a short complete LES relaxation. Neither did we find a relationship between the duration of the disease manifestations or the symptom severity and the LES characteristics. It has to be recalled that corresponding previous observations come from tertiary referral centres, which introduces a significant selection bias that may affect the recognition of the true prevalence of similar complete LES relaxations at the time when the diagnosis was first established. When it comes to the LES ability to relax, we tried to challenge the sphincter further by applying a maximal inhibitory stimulation by repeated standardised wet swallows. Apparently, this test did not add further diagnostic information on the potential of the LES to occasionally relax to the level of intra-gastric pressure.

By use of an advanced manometric recording system, von Herwaarden and co-workers (39) were able to perform prolonged ambulatory LES recordings in eleven achalasia patients. They observed that postprandial LES tone was lower than in the fasting state and complete relaxations occurred roughly at a frequency of 0.5 per hour, again more frequently during the postprandial period. There seemed to be no association between these observations and LES characteristics observed during stationary manometry. It is therefore vital to keep similar findings in mind when exposed to patients with some rare and atypical manifestations of achalasia. The clinician has to recognise the limitations of stationary manometry to fully reveal the functional behaviour of the LES and its ability to capture the full spectrum of the disease. The issue of misclassification of some of our patients has of course always to be addressed. We never based our diagnosis solely on manometric findings but instead on a composite evaluation of the clinical picture, lack of endoscopic specific findings, radiological observations and manometry.

In conclusion, the vast majority of patients with achalasia are diagnosed at a stage when the disease process has already profoundly destroyed the motor function

of the esophagus and the gastroesophageal function and the quality of life is severely impaired.

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KLINIČKI KVALITET ŽIVOTA I MANOMETRIJSKI NALAZI KOD IN NOVODIJAGNOSTIFIKOVANIH SLUČAJEVA SA AHALAZIJOM

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Sažetak

Još uvek ima malo informacija koje se tiču kliničkih karakteristika, kvaliteta života (QoL) i manometrijskih nalaza kod neselektovanih novodijagnostikovanih slučajeva ahalazije.

Opisano je pedeset šest novodijagnostikovanih slučajeva ahalazije sa propratnim simptomima, pri čemu je primenjen standardni protokol i upotrebljen detaljni instrument koji je omogućio detaljni opis problema sa gutanjem. Funkcije mišićnog zida i distalnog sfinktera (LES) su beležene primenom standardnih manometrijskih tehnologija i kanalnih katetera. Kvalitet života ovih bolesnika je opisan pomoću instrumenta - Psychological well - being index i skale za procenjivanje gastrointestinalnih simptoma.

Kod mnogih bolesnika simptomi su dugo trajali (54,5 meseci). Čekanje kod lekara je bilo čak 5,5 meseci uprkos ozbiljnim problemima sa gutanjem (Watson skor 30.5+/-1.7; m+ /- SE). Pokazalo se da je kvalitet života bio značajno poremećen kada su primenjeni generički PGWB i specifični GSRS instrumenti. Ovo pogoršanje je najverovatnije bilo uzrokovano poremećajima u gutanju. U vreme postavljanja dijagnoze motorne karakteristike tela ezofagusa i distalnog sfinktera su bile ozbiljno oštećene.

Kod većine bolesnika sa ahalazijom dijagnoza se postavlja u stadijumu kada je bolest već uveliko oštetila motornu funkciju jednjaka i gastroezofagijalnog spoja, a kvalitet života vidno poremećen.

Ključne reči: ahalazija, simptomi, disfagija, manometrija, donji ezofagijalni sfinkter, kvalitet života, 24-časovni monitoring