Clinical trial: 24-h pH monitoring patterns and clinical response after achalasia treatment with pneumatic dilation or laparoscopic Heller myotomy

P. A. Novais* & E. M. O. Lemme*

*Gastroenterology Division, Federal University of Rio de Janeiro, and Clementino Fraga Filho University Hospital, Rio de Janeiro, Brazil.
†Esophagus Unit of the Gastroenterology Division, Federal University of Rio de Janeiro, and Clementino Fraga Filho University Hospital, Rio de Janeiro, Brazil.

Correspondence to:
Dr P. A. Novais, Av. das Américas 3500, Bl 7, Sala 709, Barra da Tijuca, Rio de Janeiro, CEP 22640-102, Brazil.
E-mail: paulanovais@gmail.com

Publication data
Submitted 23 November 2009
First decision 15 December 2009
Resubmitted 26 August 2010
Accepted 27 August 2010

SUMMARY

Background
The most effective treatment for achalasia is pneumatic dilation or myotomy. The best option is still controversial and incidence of complications could help choosing. Gastro-oesophageal reflux (GER) is the most frequent complication after treatment for achalasia. The 24-h pH monitoring (24-h pH) is the best method to evaluate true GER.

Aim
To analyse the 24-h pH patterns after treatment, correlating with therapeutic success.

Methods
Untreated patients with achalasia were randomized to pneumatic dilation or laparoscopic Heller myotomy with fundoplication (LHM+Fp) and evaluated with clinical/manometric results and 24-h pH.

Results
Ninety-four patients were analysed pre-treatment and 85 post-treatment. Clinical success was 73.8% in pneumatic dilation group and 88.3% in LHM+Fp group ($P = 0.08$). The incidence of GER was 31% in pneumatic dilation, and 4.7% in LHM+Fp ($P = 0.001$). The occurrence of hypotensive lower oesophageal sphincter (LES) was 53.3% in patients who developed GER and 28.6% in patients with 24-h pH suggesting fermentation ($P = 0.019$). The rates of dysphagia resolution in patients with 24-h pH of GER and fermentation were respectively 86.7% and 85.7% ($P = 0.89$).

Conclusions
True GER 24-h pH is more frequent after pneumatic dilation for achalasia, and it is associated with a hypotensive LES. A 24-h pH suggestive of fermentation or true GER is not associated with worse clinical/manometric results.

Aliment Pharmacol Ther

© 2010 Blackwell Publishing Ltd
doi:10.1111/j.1365-2036.2010.04461.x
INTRODUCTION

Achalasia (AC) is a motor disorder characterized by aperistalsis of the oesophageal body and abnormal lower oesophageal sphincter (LES) relaxation in response to swallowing. It is caused by changes in the intrinsic innervation of the oesophagus, with loss of inhibitory neurons in the myenteric plexus.1

The aetiology of idiopathic AC remains unknown. The diagnosis is suspected by the clinical symptoms, barium swallow, endoscopy and confirmed by oesophageal manometry (EMN).2 The main clinical finding is dysphagia followed by regurgitation. Other symptoms include chest pain, weight loss, halitosis and night cough. Heartburn may be observed in 27–48% of patients.2–5

Among the different therapeutic options for AC, only pneumatic dilatation (PD) or surgery (heller myotomy with or without fundoplication) is considered definitive treatments. The best option between them is still controversial and the relative prevalence of complications could help choosing.

Gastro-oesophageal reflux (GER) is the most frequent complication after surgery (13%) as well as after PD (4–8%).6–8 Some authors recommend routine performance of 24-h pH monitoring (24-h pH) for all AC patients, mainly if they complain of heartburn and/or chest pain.9–11 The 24-h pH tracing may differentiate true GER from persisting oesophageal food stasis in patients inadequately treated.11–14

The objective of this study was to analyse the pattern of 24-h pH after both PD and laparoscopic heller myotomy with fundoplication (LHM+Fp), correlating them with therapeutic success and postprocedural heartburn.

MATERIAL AND METHODS

This is a prospective randomized clinical study. During the period from June 2005 to June 2009, patients suspected of having AC were investigated for symptoms, and they underwent an upper endoscopy to rule out other organic diseases. After that, a barium swallow study was performed, as well as EMN and serological testing for Chagas’ disease. Once the diagnosis of AC was confirmed, patients who agreed to participate in the study signed an informed consent. Only patients with good surgical risk were included. Patients were randomized, by order of arrival, to two therapeutic groups: PD or LHM+Fp. After treatment, they were investigated for existing symptoms, and they underwent EMN and 24-h pH independent from clinical status. This study was approved by the local ethics committee with the number 239/04.

Pre-treatment analysis

Clinical presentation. Patients were investigated for symptoms such as dysphagia, regurgitation, weight loss and heartburn. Heartburn was considered present when occurring more than once a week. Demographic data were inserted.

Barium swallow study. A standard technique was used, with anterior and left posterior-oblique views. Special attention was given to the distal oesophageal diameter (measured at 5 cm from the gastro-oesophageal junction). This diameter was staged according to Ferreira-Santos radiology classification (stage I: distal oesophagus diameter <4 cm; Stage II: distal oesophagus of 4–7 cm. Stage III: distal oesophagus >7 cm. Stage IV: distal oesophagus >7 cm with tortuosity).13 Patients with stage IV megaoesophagus were excluded.

Oesophageal manometry. Manometry was used to confirm the diagnosis of achalasia, to evaluate the LES pressure (LESP) before and after treatment and also to guide the position of the 24-h pH catheter. Patients were instructed to fast for 4 h before the test. An eight lumen, 4.5 mm diameter polyvinyl catheter with four proximal openings spaced at 5 cm intervals and the distal four side holes arranged radially on the same level, was passed through one of the nostrils. Each opening was connected to external pressure transducers and continuously perfused with distilled water at 0.6 mL/min by a low-compliance pneumohydraulic capillary infusion system. The intraluminal pressures were recorded on a polygraph (Alacer Medical, São Paulo, Brazil) and digital information was transferred to a computer and analysed using appropriate software. The LES was studied with the four distal openings and slow pull-through technique. LESP was the mean of end-expiratory maximum values. LES relaxation was assessed with swallows of 3–5 mL of water. Oesophageal body recordings were performed by positioning the four proximal opening 3, 8, 13 and 18 cm above the LES. Ten 3–5 mL wet swallows were recorded 20 s apart. The diagnosis of achalasia was made in the event of an impaired LES relaxation. Absence of relaxation was mentioned when no drop of LESP was seen after a wet swallow, and incomplete relaxation was defined when there was a drop in LESP, but a residual pressure of more than 8 mmHg remained. Aperistalsis was mentioned in the event of absent contractions of the oesophageal body or when all wet swallows evoked simultaneous nonpropulsive contractions hypotensive.
LES was defined when the LESP was lower than 10 mmHg.\textsuperscript{16}

**24-h pH monitoring.** All tests were performed keeping the subjects as out-patients. They were performed using a portable digital system (MKIII, Synectics, Stockholm, Sweden; AL2 Alacer, São Paulo, Brazil and SMP 2128, Sigma, Belo Horizonte, Brazil), catheter with antimony electrode and an external reference electrode. Patients were instructed to fast for 4 h before the test. The catheter was introduced through one of the nostrils and placed 5 cm above the superior limit of LES as defined by manometry. Patients were on normal activity and a regular diet. Proton pump inhibitors were discontinued for at least 7–10 days, H2 blockers for 48–72 h and prokinetic agents for 24 h before the test. A reflux episode was defined as the recording of an oesophageal pH <4 for at least 15 s. Abnormal reflux was defined when the percentage of total time of recorded pH <4 was greater than 4.5%.\textsuperscript{17} The 24-h pH tracings were classified as: (i) 24 h abnormal pH, with a true GER pattern (Figure 1a) = sharp sudden pH drops, reaching values below 3 and then returning to usual oesophageal pH (pH 6-7);\textsuperscript{9–14, 18} (ii) 24 h abnormal pH with a pattern suggesting oesophageal fermentation due to retained food (Figure 1b) = steady drop of pH not reaching values below 3.0;\textsuperscript{11–13} (iii) Negative 24-h pH = presence of physiological reflux (reflux episodes occurring in less than 4.5% of total examining time) or zero reflux (absence of any episode of pH lower than 4.0).

**Treatment modalities**

Patients were randomized to each treatment group by order of arrival, after the definition of diagnosis and surgical risk.

**Pneumatic dilation.** The PDs were performed on an out-patient basis, after a minimum of 12 h fast, using polyethylene pneumatic balloons of the Rigiflex type (Boston Scientific, Boston, MA, USA) with diameters of 30, 35 and 40 mm, introduced with the help of a guide wire, and then inflated for 1 min at 10 psi pressure. The inflation of the balloon was monitored by direct endoscopic view, starting with the lowest calibre. When there were small lacerations or lack of lacerations on endoscopy, a 35 mm balloon was used in the same session. If mild or deeper lacerations occurred, the procedure was interrupted. If not, the procedure continued up to a 40 mm balloon. Patients were observed for at least 4 h

---

**Figure 1** | Post-treatment 24-h pH tracing of achalasia patient. True gastro-oesophageal reflux (a) and fermentation (b).
after the procedure. At discharge, they were requested to keep on a liquid diet for 24 h and gradually progress to normal food consistency. All patients underwent only one session of PD.

**Laparoscopic heller myotomy with fundoplication.**
Patients were hospitalized and fasted for at least 12 h before surgery. Laparoscopic heller myotomy was performed under general anaesthesia, consisting of sectioning the longitudinal and circular muscle layers, encompassing approximately the distal 6 cm of the oesophagus and 2 cm into the cardiac region. A partial anterior fundoplication (180°) was performed in all patients. Twenty-four hours after surgery, a soft diet was introduced and maintained for at least 7 days with a gradual increase in food consistency. –Patients remained in hospital for a total of 48 h.

**Post-treatment evaluation**

**Evaluation of the clinical response.** The Vantrappen and Hellemans criteria were used to classify response (Excellent result: absence of dysphagia. Good: occasional dysphagia, less than once a week, associated with regurgitation. Poor: dysphagia more than once a week, associated with regurgitation. Fair: dysphagia more than once a week, associated with regurgitation and weight loss). Three months after treatment, this evaluation was carried out. ’Clinical therapeutic success’ was considered when the patient presented excellent or good results.

**Evaluation of manometric response.** This was performed 1–3 months after treatment. ’Manometric therapeutic success’ was considered when the post-treatment LESP dropped more than 50% as compared with baseline and/or when postprocedure LESP was lower than 10 mmHg (hypotensive LES). The degree of LESP pressure drop was calculated according to the following formula

\[
\frac{\text{Post-treatment LESP} - \text{Pre-treatment LESP}}{\text{Pre-treatment LESP}} \times 100
\]

**24-h pH monitoring evaluation.** It was performed 1–3 months after treatment. Evidence of abnormalities in the 24-h pH suggesting true GER or food fermentation was evaluated and associated with each therapeutic procedure. The 24-h pH patterns (true GER/food fermentation) were associated with complaints of heartburn, and with clinical and manometric therapeutic success.

**Statistical methods**

Statistical analysis was processed by statistical software from SAS System (Cary, North Carolina, USA). Mann–Whitney test was used to analyse numerical variables. The \( \chi^2 \) test, Fisher exact test and McNemar test were applied to compare categorical data. The relationships between 24-h pH and LESP were analysed using the Kruskal–Wallis variance (ANOVA). A \( P \) value <0.05 was considered significant.

**RESULTS**

**Pre-treatment analysis**

One hundred and two patients were included in the study. Eight patients were excluded for failure to follow-up. There were 94 patients studied, 47 were allocated to PD, and 47 to LHM+Fp. Both groups were similar in terms of age, gender, incidence of Chagas AC, percentage of different megaesophagus stages, baseline LESP and 24-h pH patterns (Table 1).

**Post-treatment analysis**

Nine patients were excluded; two patients had oesophageal perforation during PD and seven refused to repeat EMN and 24-h pH. Eighty-five patients were evaluated, 42 from the PD group and 43 from the LHM+Fp group. True GER was present in 13 patients (31%) of the PD group and in two patients (4.7%) of the surgical group and a significant statistical difference was observed. The surgical group presented better pHmetric results, because besides a lower incidence of GER, it showed a lower incidence of 24-h pH suggestive of fermentation and a higher percentage of 24-h pH negative for reflux (Figure 2/Table 2).

**Correlation between post-treatment 24-h pH results and therapeutic success**

Clinical therapeutic success was observed in 81% (\( n = 69/85 \)) of the patients. The surgical group presented better results as compared with the group that underwent PD, 88.3% (38/43) vs. 73.8% (31/42) respectively. Despite this trend, the difference was not statistically significant \( (P = 0.08) \). Patients with 24-h pH negative for reflux or indicative of GER or fermentation presented similar clinical response rates (Table 3). There was no correlation between 24-h pH patterns and the clinical result (Table 3).

Post-treatment mean LESP was similar among groups: 14.7 mmHg in the PD group and 15.2 mmHg in the surgical group \( (P = 0.44) \). When manometric results were associated with the 24-h pH patterns, it was observed
that patients who developed true GER presented lower post-treatment mean LESP (Table 3).

The degree of LESP decrease from baseline was 48% in the PD group and 49.8% in the surgical group ($P = 0.62$). A LESP drop $>50\%$ from baseline was observed in 45.2% ($19/42$) in the PD group, and 53.4% ($23/43$) in the surgical group, and it was not significantly associated with the higher incidence of 24-h pH of true GER (Table 3). However, there was a predominance towards statistical significance of manometric therapeutic success in the group of patients who developed GER (Table 3). Patients with 24-h pH suggestive of fermentation presented a predominance of unsatisfactory manometric results (5 of 7 patients in this group)

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Pre-treatment analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>PD ($n = 47$)</td>
</tr>
<tr>
<td>M</td>
<td>53% ($n = 25$)</td>
</tr>
<tr>
<td>F</td>
<td>47% ($n = 22$)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>52.3 $\pm$ 13.6*</td>
</tr>
<tr>
<td>Chagasic achalasia</td>
<td>8.5% ($n = 4$)</td>
</tr>
<tr>
<td>Oesophageal diameter</td>
<td>I ($n = 15$)</td>
</tr>
<tr>
<td></td>
<td>II ($n = 28$)</td>
</tr>
<tr>
<td></td>
<td>III ($n = 4$)</td>
</tr>
<tr>
<td>Mean LESP (mmHg)</td>
<td>28.3 $\pm$ 13.7*</td>
</tr>
<tr>
<td>24-h pH analysis</td>
<td>GER ($n = 2$)</td>
</tr>
<tr>
<td></td>
<td>FERM ($n = 7$)</td>
</tr>
<tr>
<td></td>
<td>NEG ($n = 38$)</td>
</tr>
</tbody>
</table>

PD, pneumatic dilation; M, male; F, female; LESP, lower oesophageal sphincter pressure; $n$, number of patients; WA, without analysis (few cases); GER, 24-h pH suggesting true gastro-oesophageal reflux; FERM, 24-h pH suggesting food fermentation; NEG, negative 24-h pH; N.S., not significant.

* s.d., standard deviation.

Figure 2 | Post-treatment patterns of 24-h pH monitoring. $n$, number of patients. TRUE GER: 24-h pH of true gastro-oesophageal reflux. FERM, 24-h pH monitoring suggestive of food fermentation; NEG pH, negative 24-h pH monitoring; PD, pneumatic dilation.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Pre-treatment and post-treatment 24-h pH monitoring and LESP analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>LESP pre-treatment</td>
<td>PD ($n = 47$)</td>
</tr>
<tr>
<td>LESP post-treatment</td>
<td>GER ($n = 42$)</td>
</tr>
<tr>
<td>24-h pH analysis pre-treatment</td>
<td>FERM ($n = 47$)</td>
</tr>
<tr>
<td></td>
<td>NEG ($n = 47$)</td>
</tr>
<tr>
<td>24-h pH analysis post-treatment</td>
<td>GER ($n = 42$)</td>
</tr>
<tr>
<td></td>
<td>FERM ($n = 42$)</td>
</tr>
<tr>
<td></td>
<td>NEG ($n = 42$)</td>
</tr>
</tbody>
</table>

PD, pneumatic dilation; LESP, lower oesophageal sphincter pressure; $n$, number of patients; GER, 24-h pH suggesting true gastro-oesophageal reflux; FERM, 24-h pH suggesting food fermentation; NEG, negative 24-h pH; N.S., not significant.

* s.d., standard deviation.
presented LESP reduction <50% from pre-treatment values).

The incidence of post-treatment LES hypotension was significantly higher in patients who underwent PD, 35.7% (15/42) when compared with 16.3% (7/43) in the group of patients who underwent surgery (P = 0.04). Patients who showed post-treatment 24-h pH suggestive of true GER showed a higher incidence of hypotensive LES (P = 0.019 - Table 3).

**Correlation between 24-h pH and heartburn**
Heartburn was observed in 43.5% (37/85) of the patients. Heartburn occurred in 7 of 15 patients with 24-h pH of true GER, and in 2 of 7 patients with 24-h pH, suggestive of fermentation and in 25 of 63 patients with negative 24-h pH. This symptom was not significantly associated with any post-treatment 24-h pH pattern (Figure 3).

**DISCUSSION**
The most efficient treatments for AC are PD and surgical myotomy of the LES. Multiple trials have compared these methods, with different success rates, although the superiority between them is not well established. The evaluation of response and the evidence of complications vary widely in the literature, as studies use different methods.

Gastro-oesophageal reflux is the most frequent complication in AC treatment, as the therapeutic options have the objective of reducing the pressure gradient across the LES to improve oesophagus emptying, and that could result in reflux of gastric contents. We believe, the lowest complication rates should decide what treatment to choose. The real incidence and severity of post-treatment GER are underestimated because several studies evaluated only the presence of symptoms and the need for proton pump inhibitors, without performing pH studies.6, 8, 21 Very few studies have used the 24-h pH, which is considered the best diagnostic method for GER.

The routine use of 24-h pH, before and after AC treatment, allows evaluating the real incidence of GER. The 24-h pH tracing can distinguish true GER patterns from other findings due to oesophageal food stasis in patients inadequately treated. In true GER, the drop in pH levels (usually pH 1.0 to 2.0) occurs abruptly, and is followed by return to normal oesophageal pH (around 6.5), whereas in food fermentation, the drop in pH is slow (around 6 h), usually happening during the night and the pH does not reach values below 3.0.9-14, 18 Among the papers published using 24-h pH tracings, the one by Crookes et al. is outstanding, because it has proved ‘in vitro’ that food and saliva incubated at

---

**Table 3 | Correlation between post-treatment 24-h pH monitoring results and therapeutic success**

<table>
<thead>
<tr>
<th></th>
<th>GER 24-h pH n = 15</th>
<th>FERM 24-h pH n = 7</th>
<th>NEG 24-h pH n = 63</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical therapeutic success</td>
<td>86.7% (n = 13)</td>
<td>85.7% (n = 6)</td>
<td>79.4% (n = 50)</td>
<td>N.S.</td>
</tr>
<tr>
<td>Manometric therapeutic success</td>
<td>Post-treatment mean LESP (mmHg)</td>
<td>11.8 ± 5.8*</td>
<td>13.6 ± 9.3*</td>
<td>16 ± 6.6*</td>
</tr>
<tr>
<td></td>
<td>LESP drop ≥50%</td>
<td>73.3% (n = 11)</td>
<td>28.6% (n = 2)</td>
<td>43.6% (n = 27)</td>
</tr>
<tr>
<td></td>
<td>Hypotensive LES</td>
<td>53.3% (n = 8)</td>
<td>28.6% (n = 2)</td>
<td>17.7% (n = 11)</td>
</tr>
</tbody>
</table>

LESP, lower oesophageal sphincter pressure; LES, lower oesophageal sphincter; 24-h pH, 24-h pH monitoring; GER, 24-h pH monitoring of true gastro-oesophageal reflux; FERM, 24-h-pH monitoring suggesting food fermentation; NEG, negative 24-h pH monitoring; N, number of patients; N.S., not significant.

* s.d., standard deviation.

---

**Figure 3 | Correlation between heartburn and post-treatment 24-h pH monitoring.**
GER pH, 24-h pH monitoring of true gastro-oesophageal reflux; FERM pH, 24-h pH monitoring suggesting food fermentation; NEG pH, negative 24-h pH monitoring; n, number of patients; N.S., not significant.
physiological body temperatures underwent fermentation by lactobacilli generating lactic acid, which resulted in decrease in the pH to below 4.0, therefore justifying the findings in AC patients.\textsuperscript{12} Despite that the LES is often hypertensive in AC, GER may occur in patients not undergoing any treatment. It is probable that acid reflux content occurs during transitory relaxation of the LES and remains longer in contact with oesophageal mucosa because of poor oesophageal acid clearance due to lack of peristalsis.\textsuperscript{4, 18, 22}

Both our groups were homogeneous in respect of incidence of pre-treatment 24-h pH patterns (Table 1). In the evaluation of post-treatment 24-h pH tracings, we have used the same parameters published by Crookes et al.\textsuperscript{12} and found that 17.7\% (15/85) of the patients presented abnormal 24-h pH readings showing true GER and 8.2\% (7/85) with a pattern consistent with fermentation. We have noted that the PD group presented a significantly higher incidence of post-treatment true GER, when compared with myotomy (31\% \times 4.7\%, Figure 2), which probably resulted from the association of partial Fp with myotomy in surgical patients. Most published articles evaluated this variable separately for each type of treatment, but most of them did not use 24-h pH for this purpose and therefore it is difficult to compare them with our findings. Some authors reported a much lower percentage (4–10\%) of GER in patients undergoing PD, with our findings. Some authors reported a much lower percentage of GER in patients undergoing PD, with our findings. Most published articles evaluated this variable separately for each type of treatment, but most of them did not use 24-h pH for this purpose and therefore it is difficult to compare them with our findings. Some authors reported a much lower percentage (4–10\%) of GER in patients undergoing PD, with our findings.

The literature on the incidence of GER after heller myotomy (with or without Fp) mentions it in about 11–37\% of patients,\textsuperscript{7, 23–30} rather higher than our findings in the present trial. The meta-analysis published by Campos et al., reviewed 39 articles (only 20 with 24-h pH analysis) and showed that 8.8\% of the 2507 patients undergoing heller myotomy with Fp developed GER.\textsuperscript{21}

The need for and efficacy of antireflux procedures continue to be debated in surgical circles.\textsuperscript{12, 31–37} At our institution, partial Fp is performed routinely in all patients who underwent myotomy. Many studies reporting on the incidence of post-operative GER used different surgical techniques. Likewise, studies evaluating the incidence of GER after PD used different numbers of dilation sessions, procedure techniques, type and size of balloon used.

This is the first randomized study published using post-treatment 24-h pH to compare the true incidence of GER in the two procedures (PD vs. LHM+Fp). We found only two articles using 24-h pH to compare the incidence of reflux in both methods.\textsuperscript{22, 38} Felix et al. have found a higher incidence of GER, observed at 24-h pH, in patients with initial AC who underwent PD when compared with those who underwent heller myotomy with Fp, although the balloon they used was not pneumatic, but hydrostatic.\textsuperscript{38} Shoenut et al. evaluated 24-h pH in 32 AC patients, comparing pneumatic dilation with heller myotomy. However, no patient received fundoplication. The rate of total time pH<4.0 (TT) was similar in both groups, and 38\% of patients presented with TT <4.0 more than 6\% of the time (a parameter used by the authors to diagnose GER). This incidence of GER must be overestimated once the 24-h pH tracing was not evaluated.\textsuperscript{22}

In the present study, answers to questionnaires obtained in the third month after treatment indicated that the surgical group presented with a better clinical outcome than the group undergoing PD, with therapeutic clinical success (excellent and good results) of 88.3\% and 73.8\% respectively, although it did not reach statistical significance (P = 0.08). In a more recent review by Campos et al., the success rates for both therapeutic modalities, including 3086 patients who underwent myotomy (with or without Fp) and 1065 patients who underwent PD, were 89.3\% (mean follow-up of 35.4 months) and 68.2\% (follow-up of 12 months) respectively.\textsuperscript{21} We believe that in our study, it was not possible to find statistical difference between the dysphagia improvement rates in PD x myotomy because of the short follow-up period (3 months).

We tried to investigate whether the development of GER as evaluated by 24-h pH tracings would in fact influence the clinical response to treatment. We also investigated whether food stasis and fermentation would be associated with worse clinical results, as such patients would still present difficulties in oesophageal emptying. It is interesting to note that in spite of the development of reflux, clinical therapeutic success occurred in most patients evaluated (Table 3). These findings suggest that dysphagia is such an important limitation to these patients and they feel totally satisfied when it is relieved. Also, in agreement with our findings, the meta-analysis published by Abir et al. showed a clinical recovery rate of 94\%, despite 13\% of postmyotomy GER,\textsuperscript{7} and in that reported by Campos et al., the overall clinical recovery was 89.3\% in a group with 14.9\% GER.\textsuperscript{21}

Regarding our results, we believe that the short period of evaluation may have been a determining factor in the lack of association between the 24-h pH findings and the clinical response. It is possible that patients with 24-h
pH suggestive of fermentation may show recurrent dysphagia earlier, and those who present 24-h pH suggestive of true GER, if not adequately treated, may develop reflux complications (oesophagitis, peptic stenosis, Barrett oesophagus and oesophageal adenocarcinoma) in the future. Therefore, 24-h pH can serve as a prognostic tool, aiding in the follow-up of these patients and indicating the need for treatment.

Oesophageal manometry is an excellent test to evaluate response to treatment, as it supplies objective information about LESP. Post-treatment LES hypotension and the drop of LESP from baseline values are the main manometric parameters used for this purpose. Katsinelos et al. observed 39 patients who underwent one or more PD sessions and concluded that the success rate was really associated with the decrease of LESP >50% from baseline and to the postprocedure presence of LESP <10 mmHg. In our study, the mean post-treatment LESP was similar among both groups (Table 2). We have observed that patients who developed true GER presented the lowest mean post-treatment LESP, thus confirming the fact that the lower the LESP, the higher is the occurrence of GER (Table 3).

There was a predominance of manometric therapeutic success in patients who developed true GER (Table 3). Patients with 24-h pH suggestive of food fermentation were those with a predominance of unsatisfactory manometric results (Table 3). These findings were expected, as patients who develop GER are those with lowest LESP and those with a 24-h pH pattern suggestive of food stasis may present higher LESP, probably due to a less efficient treatment. We have found only one study that evaluated 24-h pH in comparison with post-treatment LESP drop. Anderson et al. used this method in 23 patients undergoing PD or myotomy and found 43.5% of patients with GER related to the presence of LES hypotension. GER is probably superestimated in this study because true GER was not distinguished from fermentation in 24-h pH tracings. In our study, 25.8% developed LES hypotension after treatment. Compared with the abnormal 24-h pH groups, patients with 24-h pH of true GER presented a higher percentage of LESP <10 mmHg (Table 3).

The incidence of LES hypotension was significantly higher in patients undergoing PD than in the group undergoing surgery. In the study by Tuset et al., GER was present in 10% of 56 AC patients who underwent PD. In agreement with our findings, these authors also found a correlation between GER incidence and LES hypotension.

Heartburn is present in a significant portion of AC patients and can suggest either GER as a complication of efficacious treatment or oesophageal food stasis resulting from insufficient treatment. We compared the results of 24-h pH with the incidence of heartburn and observed that the complaint was not associated with any pattern of post-treatment 24-h pH, but patients who complained were predominantly those with 24-h pH suggestive of fermentation (Figure 3). Some authors have also demonstrated in their studies that the presence of heartburn did not correlate with the real incidence of GER or oesophageal food fermentation. Therefore, it is important to remind that the absence of symptoms of GER does not rule out the possibility of this complication, which stresses the need to perform 24-h pH routinely in all AC patients treated with PD or surgery.

In summary, 24-h pH is an important tool in the differential diagnosis between true GER and food fermentation. A correct diagnosis of abnormal 24-h pH is necessary to avoid complications. The higher incidence of true GER in the PD group suggests that surgery is a better therapeutic choice, as both are very effective. True GER was associated with higher incidence of hypotensive LES and lower post-treatment LES pressure. Evidence of post-treatment true GER was not associated with greater dysphagia improvement. In this short follow-up, 24-h pH tracings suggestive of food fermentation were not associated with worse clinical or manometric results. Heartburn should be investigated both before and after therapeutics, but it seems to be not enough to orient the type of follow-up to be established, as it was not associated with any pH pattern.

We believe, it is important to combine clinical, manometric, radiological and pHmetric findings. Further studies will define the real contribution of 24-h pH in the evaluation of AC patients, mainly if the method is capable of anticipating the relationship between the persistence of food stasis and early recurrence of dysphagia.

ACKNOWLEDGEMENTS

The authors thank Professor Delta Madureira and his team for the excellent surgical approach, and to all physicians from Gastroenterology Division of Clementino Fraga Filho University Hospital for the motility studies and endoscopic approach. They also thank Felix R Zygier for the careful review of this paper.

Declaration of personal and funding interests: None.
REFERENCES


