Diagnostic test with omeprazole in patients with posterior laryngitis

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Keywords: posterior laryngitis, laryngopharyngeal reflux, omeprazole test, efficacy parameters.

Summary. The aim of the study was to evaluate the merit of empiric omeprazole therapy in patients with suspected laryngopharyngeal reflux (LPR), to determine the optimal dose and duration of diagnostic test, to compare the diagnostic value of upper gastrointestinal (GI) endoscopy and omeprazole test (OT). One hundred out-patients with posterior laryngitis and more than one atypical symptom of LPR, aged 14–68 years were treated with omeprazole for 4 weeks (clinical group). According to received omeprazole dose (20 mg, 40 mg, > 40 mg), three clinical subgroups were selected. Twenty patients treated only with life style modifications and diet composed dietary group. At the entry to the study, a symptom questionnaire (5 laryngeal and 3 esophageal scored from 0 to 3 points), well being in general (W-BVAS on 100-mm VAS scale), videolaryngoscopy, upper endoscopy, and voice assessment (4 voice range profile parameters and overall vocal dysfunction degree (VDD)) were completed. Total symptom index (TSI) was calculated multiplying sum of symptoms severity score by number of presented symptoms. Normal values of efficacy parameters were obtained from 113 healthy voice subjects (control group). Patients were evaluated twice during the treatment: after 1–2 weeks and after 4–5 weeks. Patients were confirmed as responders, if TSI improved at least 50%, and patients were satisfied with results. According to our data, the 1st control assessment showed significant improvement on symptoms, laryngoscopy scores, VDD, and W-BVAS only for clinical group patients (p<0.05). Responders rate also was advantageous for the clinical group patients in comparison to the dietary group (36.0% vs. 15%). The second control assessment showed significantly better results for the clinical group patients in comparison to the 1st (p<0.05 2nd vs. the 1st). Sixty five percent of them (65/100) were classified as responders (p<0.05). The better results were in patients receiving omeprazole more than 20 mg daily. Erosive esophagitis during upper GI endoscopy was found for 21.0% (21/100) clinical group patients, 18 of them were responders to omeprazole 4-week test (accuracy of OT with regard to confirmed diagnosis with upper endoscopy was 85.7%). At week 4, efficacy parameters were not in normal range. We concluded that short-term treatment with omeprazole might be useful in confirming the clinically based diagnosis of laryngopharyngeal reflux.

Introduction
Recent studies suggest the association between laryngeal, pharyngeal symptoms, and extraesophageal reflux as atypical presentation of gastroesophageal reflux disease (GERD) (1). According to the interdisciplinary New Orleans Conference report (1995), laryngopharyngeal reflux (LPR) refers to the backflow of stomach contents into the throat and larynx with presentation of atypical (upper and lower respiratory tract) symptoms and signs (2). The incidence of LPR over laryngological patients exceeds more than 50% confirmed by 24-hour double-probe pH monitoring (3). Even if LPR is common, its diagnosis may be difficult because of:

- variety of atypical LPR symptoms and low frequency of typical GERD symptoms (heartburn),
- low sensitivity of traditional tests of gastrointestinal tract for patients with LPR,
- no consensus on the diagnostic algorithm for LPR and gold diagnostic standard (4).

Although the diagnosis of LPR could be made on the basis of the symptoms and laryngal findings the association of gastroesophageal reflux with otolaryngologic disorders could be proven with the ambula-
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Tory 24-hour 2 or 3-site pharyngoesophageal pH monitoring as well as empiric acid suppressive therapy trials with most effective medicine (1, 5). Treatment with proton pump inhibitors (PPI) seems to be enough sensitive (up to 81%) and specific for the establishing this causal relationship (6–9). As omeprazole (OM) is the main PPI that has been employed as an empirical trial, this has led to the used term ‘the omeprazole test’. Although PPI empirical trial has some advantages compared to ambulatory 24-hour pH monitoring, only few studies have examined the utility of the PPI trial in patients with LPR (1, 8–11). Further evaluations of the dosing, treatment duration, efficacy parameters, as well as sensitivity of the empirical PPI test in the LPR diagnosis are needed.

The aim of this study was composed of three tasks: 1) to evaluate the merit of empiric omeprazole therapy in patients with suspected laryngopharyngeal reflux, 2) to determine the optimal dose and duration of diagnostic test, and 3) to compare the diagnostic value in LPR of upper gastrointestinal endoscopy and omeprazole test.

Materials and methods

One hundred twenty out-patients with posterior laryngitis and more than one atypical symptom of LPR with history of at least one month aged from 14 to 68 years (mean 40.4± (standard deviation) 13.6 years) were selected to the study. Subjects were excluded if they met the following criteria: active smoking, upper tract infections during one month, prior antireflux surgery, pregnancy during study period, and allergy to omeprazole. Patients randomized to the study received different dose of omeprazole n=100 (clinical group) or only lifestyle modification and diet (dietary group, n=20). According to received omeprazole dose three clinical subgroups in 1:2:1 rate were selected: 1) OM 20 (20 mg once day, n=28), 2) OM 40 (20 mg bid, n=48), 3) OM >40 (1 week 40 mg in the morning and 20 mg at night, others – 20 mg bid, n=24).

One hundred thirteen healthy voice persons confirmed perceptually and on laryngoscopy randomly selected from volunteers aged 20–67 years (mean 37.52 ±12.04), 26 male and 87 female composed the control group. Patients and control group were matched in respect to age, gender proportions, smoking history, and the professional voice training.

At the entry to the study a symptom questionnaire, self-rated quality of life (well-being) in general, laryngoscopy and voice assessment using voice range profile for all subjects were completed. Upper endoscopy of gastrointestinal tract was performed for patients only. Primary diagnosis was made on the basis of laryngoscopic findings and symptoms or/and erosive esophagitis during upper GI endoscopy.

Written informed consent was obtained from all patients. The protocol was approved by the Ethical committee of Kaunas University of Medicine.

Symptoms assessment

Eight reflux related symptoms – five laryngeal (hoarseness, throat clearing, globus pharyngeus, throat burning/pain and cough) and three esophageal (heartburn, regurgitation and dysphagia) were self-rated by the patients. Severity of each symptom was scored according to 4-point Likert scale: 0 – none (no symptom), 1 – mild (symptom minimal awareness, easily tolerated), 2 – moderate (definite awareness, bothersome but tolerable), and 3 – severe (hard to tolerate, interfered with planned activities). The sum of the five laryngeal symptoms score multiplied by the number of presented laryngeal symptoms was defined as laryngological symptoms index, sum of three esophageal symptoms scores multiplied by number of presented esophageal symptoms – as esophageal symptom index. Total symptoms index (TSI) was defined as the sum of LSI and ESI (0 to 102 points).

Quality of life or well-being in general was self-rated by the patients on a 100-mm visual analogue scale (W-BVAS): 0 – extremely bad and 100 – excellent. One millimeter measured by rule is equal to one point (0 to 100 points).

Laryngoscopy

Indirect laryngeal exams with laryngeal mirror or telescopic videolaryngoscopies with Kay Elemetrics 70° endoscope were performed by otolaryngologist. Each laryngeal finding of erythema, edema and nodularity was graded using 4 point severity scale: 0 – no sign, 1 – mild, 2 – moderate, and 3 – severe. Posterior laryngitis score (PLS) was defined as summation of the score (0 to 9 points). Two or more points were considered as positive. The investigator scoring the laryngoscopy findings was blinded to the findings of the previous control assessment.

Voice assessment

Voice quality was estimated by voice range profile method. Recording of minimum and maximum phonatory sound level as functions of fundamental frequency was registered in an ordinary 5×3 m room (the noise level did not exceed 40 dB(A)) in a classical way (by hand), according to the recommendations of the Union of European Phoniatricians (12). The
pitch range was measured with the help of electronic keyboard (Fujiyama 3 A) in a range of 4 octaves in a manner of half-tone step. Sound pressure level (SPL) was determined from a sound pressure level meter (VEB Robotron), using the slow meter damping and A weighted frequency scale – dB (A). A constant microphone distance of 30 cm from the mouth was held. Only precisely corresponding sounds sung for at least 2 sec. were registered. We used a modified by squares registration form (13). Quantitative overall vocal dysfunction degree (VDD) was calculated using original algorithm from the four most informative categorized (4 categories as parameter damage degree were stated from 0 – normal to 3 severe damage) VRP parameters: pitch range, maximum–minimum intensity range, total VRP area, and area in range of high frequency. According to the original rules four overall damage degrees from 0 point (norm) to 3 (severe dysfunction) were calculated (14).

**Upper endoscopy** of gastrointestinal tract was performed for all patients. The extent of esophageal mucosal damage was assessed using Los Angeles classification grading system. Four grades from A (one or more mucosal breaks no longer than 5 mm, none of which extends between the tops of the mucosal folds) to D (mucosal breaks which involve at least 75% of the esophageal circumference) were considered to confirm the diagnosis of GERD (15).

**Control assessments**

Patients were evaluated at the entry to the study and during control assessments. First control assessment was accomplished after 1 to 2 weeks (Post I), second, after 4 to 5 weeks (Post II). Patients of dietary group had one control assessment – after 2 weeks.

In addition, at each control assessment the satisfaction of results was self-rated by patients as symptoms resolved, improved, were the same, or worse.

Satisfaction showed the two first ratings.

According to the chosen criteria, overall benefit from therapy was assessed. Patients were classified as responders, if total symptoms index improved at least 50% and patients were satisfied with the results; improvement was stated, if TSI improved less than 50%; no change was stated, if TSI improved less than 10% and patients self-rated without improvement.

**Statistical methods**

Statistical analysis was performed with SPSS 10 for Windows. At the baseline the ANOVA model was used for comparing differences between groups in parametric data, Kruskal–Wallis, Mann–Whitney U, and χ2 test – in nonparametric data. The efficacy of evaluated quantitative parameters between groups (subgroups) was assessed using an ANOVA model; the significance level was adjusted for multiple comparisons by using Bonferoni inequality. Paired t-test was used to test the difference of quantitative normally distributed parameter (W-BVAS) in repeated measures; not normally distributed and non-parametric data were analyzed using the McNemar, \( \chi^2 \), Friedman and Wilcoxon tests for the depended sample. A level of significance of 0.05 was used. Since, some of quantitative efficacy parameters were not normally distributed, data without mean were presented in median, modes, quartiles.

**Results**

Demographic and baseline parameters. Clinical and dietary groups patients did not significantly differ in terms of demographic data: age, gender proportion, voice training (p>0.05). Baseline values of total symptom score (TSI) and laryngoscopic data – posterior laryngitis score (PLS) were also similar for both treatment groups (Table 1). No statistically significant difference was found in comparison of the clinical subgroups over the omeprazole dose with respect to posterior laryngitis score.

**Table 1. Baseline characteristics of enrolled patients**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Clinical group (n=100)</th>
<th>Dietary group (n=20)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ±SD years)</td>
<td>39.9±13.8</td>
<td>43.2±13.0</td>
<td>ns</td>
</tr>
<tr>
<td>Male/female (% (n))</td>
<td>25% (25) / 75% (75)</td>
<td>25% (5) / 75% (15)</td>
<td>ns</td>
</tr>
<tr>
<td>Untrained/trained voice (% (n))</td>
<td>77% (77) / 23% (23)</td>
<td>80% (16) / 20% (4)</td>
<td>ns</td>
</tr>
<tr>
<td>TSI points (median (min.–max.))</td>
<td>45.5 (5–154)</td>
<td>25.0 (2–146)</td>
<td>ns</td>
</tr>
<tr>
<td>PLS points (median (min.–max.))</td>
<td>5.0 (2–9)</td>
<td>5.7 (2–9)</td>
<td>ns</td>
</tr>
</tbody>
</table>

SD – standard deviation; ns – not significant difference.
to age, total symptom index and well being (p>0.05). All evaluated efficacy parameters did not depend on gender. Patients and control group did not significantly differ with regard to age, gender proportions, smoking history, and the professional voice training. Diagnosis based on esophagitis was confirmed for 21 of 100 (21%) clinical group patients and 2 of 20 (10%) patients treated with lifestyle modification and diet.

**Merit of empiric omeprazole therapy (comparison of patients groups with different treatment results at the 1st control assessment).** While accomplishing the first task to evaluate the merit of empiric omeprazole therapy in patients with suspected laryngopharyngeal reflux, data of efficacy parameters – total symptom index, well-being in general according VAS scale, posterior laryngitis score, overall vocal dysfunction degree and damage degree for separate VRP parameter at baseline and at the 1st control assessment after 2 weeks were compared in clinical and only dietary patients groups. Table 2 summarized the results. Analysis showed the significant changes (improvement) of efficacy parameters only for patients treated with omeprazole (p<0.001). Significant reduction was found in self-rated total symptoms score (at average 16.6 points); also posterior laryngitis score (at average 1.4 points) (p<0.0001). Healthy voice according VDD scale (VDD=0°) was found for 52 (52%) clinical group patients at week 2 in comparison with 42 (42%) patients at baseline assessment (p<0.001). VRP maximum-minimum intensity range was damaged more frequently (74% at baseline and 64% at post I); the greater positive change was achieved for VRP area in range of high frequency. Changes of all VRP parameters were significant (p<0.00). Mean values of well-being in general for clinical group patients raised to 11.4 points (p<0.0001). No significant improvement was found for patients treated only with lifestyle modification and diet. After 2-week treatment, 36 of 100 (36%) from clinical group patients and 3 of 20 (15%) from dietary group patients were classified as responders (p<0.06).

**Optimal dose and duration of diagnostic omeprazole test.** While accomplishing the second task, results of clinical group patients were analyzed with respect to dose regime and duration of treatment (4 weeks vs. 2 weeks). Changes of all tested parameters showed a significant advantage for 4-week omeprazole treatment (p <0.001 1st vs. 2nd assessment) (Table 3).

TSI median values at week 4 shifted down in 11.0 points in comparison to week 2 data, posterior laryngitis score – in 0.3 points (p<0.002). Sixty four of 100 patients at week 4 vs. 52 of 100 patients at week 2 were having healthy voice (VDD=0°) (p<0.0001). Fig. 1 demonstrated the changes of each separate VRP parameters (p<0.001). Well-being in general score during two to four weeks of treatment raised in 13 points (p<0.0001). None of evaluated efficacy parameters at week 4 returned to the normal range (p<0.000).

The overall response rate during the 2nd control assessment was 36 of 100 (36%) from clinical group patients and 3 of 20 (15%) from dietary group patients (p<0.06).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Clinical group (n=100)</th>
<th>p&lt;</th>
<th>Dietary group (n=20)</th>
<th>p&lt;</th>
<th>Control group (n=113)</th>
<th>p&lt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post I</td>
<td></td>
<td>Pre</td>
<td>Post I</td>
<td></td>
</tr>
<tr>
<td>Total symptom index (0–102 points)</td>
<td>mean 50.1</td>
<td>33.5</td>
<td>0.000</td>
<td>37.8</td>
<td>30.6</td>
<td>ns 3.0</td>
</tr>
<tr>
<td></td>
<td>median 45.5</td>
<td>26.5</td>
<td></td>
<td>25.0</td>
<td>22.5</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>mode 16</td>
<td>8</td>
<td></td>
<td>12</td>
<td>4</td>
<td>0.000</td>
</tr>
<tr>
<td>Posterior laryngitis score (0–9 points)</td>
<td>mean 5.1</td>
<td>3.7</td>
<td>0.000</td>
<td>5.3</td>
<td>4.8</td>
<td>ns 0.8</td>
</tr>
<tr>
<td></td>
<td>median 5.0</td>
<td>3.2</td>
<td></td>
<td>5.7</td>
<td>5.0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>mode 6</td>
<td>3</td>
<td></td>
<td>6</td>
<td>6</td>
<td>0.000</td>
</tr>
<tr>
<td>Well-being in general (0–100 points)</td>
<td>mean 47.2</td>
<td>58.7</td>
<td>0.000</td>
<td>55.1</td>
<td>61.2</td>
<td>ns 84.0</td>
</tr>
<tr>
<td></td>
<td>median 50.0</td>
<td>56.0</td>
<td></td>
<td>50.0</td>
<td>50.0</td>
<td>87.0</td>
</tr>
<tr>
<td></td>
<td>mode 50</td>
<td>50</td>
<td></td>
<td>50</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>Vocal dysfunction degree (0–3 points)</td>
<td>0° (%)</td>
<td>52.0</td>
<td></td>
<td>55.0</td>
<td>65.0</td>
<td>ns 97.3</td>
</tr>
<tr>
<td></td>
<td>1° (%)</td>
<td>29.0</td>
<td></td>
<td>40.0</td>
<td>30.0</td>
<td>2.7</td>
</tr>
<tr>
<td></td>
<td>2° (%)</td>
<td>25.0</td>
<td></td>
<td>5.0</td>
<td>5.0</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>3° (%)</td>
<td>4.0</td>
<td></td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

Table 2. Summary of efficacy parameters at entry and at week 2.

Pre – baseline data; Post I – data after 1–2 week treatment; ns – not significant; significance level p<0.05.
assessment was 65% versus 36% founded during the 1st control assessment (p<0.005) (Fig 2). Responders to the omeprazole therapy overdose are summarized in Fig 3. Statistical analysis of good response rates at week 4 showed significant advantage for OM 40 patients subgroup in comparison to OM 20 (p<0.05). The same tendency was stated in comparison OM>40 and OM 20 subgroups results. Changes in responders rates

**Fig. 1. Patients rate with normal values of separate voice range profile parameter across treatment for clinical group patients (n=100)**

Pre – baseline assessment; Post I – control assessment after 1–2 weeks; Post II – control assessment after 4–5 weeks.

**Table 3. Summary of efficacy parameters during omeprazole therapy in the clinical group (n=100)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Clinical group (n=100)</th>
<th>Control group (n=113)</th>
<th>p&lt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total symptom index (0–102 points)</td>
<td>Pre Q1 median Q3</td>
<td>Post I Post II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21.3 45.5 68.0</td>
<td>12.0 26.5 43.5</td>
<td>6.0 29.0 0.000&lt; 0.002&lt; 0.000&lt;</td>
</tr>
<tr>
<td>Posterior laryngitis score (0–9 points)</td>
<td>Pre Q1 median Q3</td>
<td>Post I Post II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.0 5.0 6.0</td>
<td>2.0 3.3 5.0</td>
<td>1.0 3.0 0.000&lt; 0.000&lt; 0.000&lt;</td>
</tr>
<tr>
<td>Well-being in general (0–100 points)</td>
<td>Pre Q1 median Q3</td>
<td>Post I Post II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30.0 50.0 61.0</td>
<td>42.5 56.0 75.7</td>
<td>50.0 69.0 80.0 0.001&lt; 0.000&lt; 0.000&lt;</td>
</tr>
<tr>
<td>Vocal dysfunction degree (0–3 points)</td>
<td>Pre 0° (%) 1° (%) 2° (%) 3° (%)</td>
<td>Post I Post II</td>
<td></td>
</tr>
<tr>
<td></td>
<td>42.0 29.0 25.0 4.0</td>
<td>52.0 26.0 22.0 4.0</td>
<td>64.0 28.0 7.0 0.001&lt; 0.000&lt; 0.000&lt;</td>
</tr>
</tbody>
</table>

Pre – baseline data; Post I – data after 1–2 week treatment; Post II – data after 4–5 week treatment; Q1: first quartile (25th percentile), Q3: third quartile (75th percentile); a – difference between baseline and 1st control assessment; b – difference between 1st and 2nd control assessment; c – difference between baseline and 2nd control assessment; significance level p<0.05.
Fig 2. Overall response to the omeprazole treatment; significance level p<0.05

Fig 3. Responders to the omeprazole therapy overdose

* – p<0.05 OM 40 vs. OM 20; difference between 1st (Post I) and 2nd (Post II) control assessments is significant for OM40 and OM>40 clinical subgroups (p<0.05).

4 week vs. 2 weeks were statistically significant only for OM 40 and OM >40 subgroups patients (p<0.05).

**Diagnostic value in LPR of upper gastrointestinal endoscopy and 4-week omeprazole test.** The third task was to compare the diagnostic value in LPR of upper gastrointestinal endoscopy and 4 week omeprazole test. Twenty one subjects from 100 (21%) had erosive esophagitis that confirmed diagnosis of GERD at baseline of evaluation; conversely the positive 4-week omeprazole test was stated for 65 of 100 (65%) patients. Most of the clinical group patients had mild esophagitis (esophagitis A according to Los Angeles classification) – 17 of 21 (80.9%), four patients had erosive esophagitis B. Eighteen of 21 patients with erosive esophagitis were classified as responders to 4-week omeprazole test. Overall accuracy in diagnostic methods was 85.7%. With the presence of esophagitis on upper GI endoscopy as the gold standard, the omeprazole test sensitivity and specificity was found to be 89% (18/21) and 40.5% (32/79), respectively. With positive omeprazole test as the gold standard for the diagnosis of LPR, the sensitivity and specificity of presence of esophagitis were 27.6% (18/65) and 91.4% (32/35), respectively (Table 4).

**Discussion**

Laryngopharyngeal reflux differs from classic GERD in many aspects, the most significant is that...
the majority of patients with LPR do not have esophagitis or its primary symptom, heartburn and the diagnosis of LPR can be made on the basis of the atypical symptoms and laryngeal findings (5). Posterior laryngitis is one of the most common manifestations of laryngopharyngeal reflux (1). When the diagnosis is in question, diagnostic ambulatory 24-hour double or triple probe pH monitoring is considered as the gold standard for diagnosing LPR, although recent studies have documented sensitivity of only 60–78% (10, 16). In addition to the limited sensitivity, the test is invasive, costly and in fact not readily available to community-based physicians. Recent studies suggest a short course of PPI as simpler, accurate and cost-effective approach to diagnose gastroesophageal and especially extraesophageal reflux (8–10). PPI empirical trial may provide a similar or even better diagnostic accuracy compared to 24-hour pH monitoring (8). In the cases of LPR, PPI test may be helpful for establishing a relationship between the extraesophageal reflux manifestation and GERD, avoiding a battery of invasive tests and reducing cost per average patient evaluated (10). Some investigators support the use of acid suppressive therapy in patients with posterior laryngitis regardless of documentation of pharyngeal acid reflux on 24-hour pharyngoesophageal pH monitoring (1). Symptom resolution or significant reduction after a PPI trial (cutoff of symptoms score improvement at least 50%) and patient’s satisfaction are the main efficacy parameters (4, 8, 10, 16). Improvement of voice parameters scores is on investigation and seems to be useful for monitoring of treatment effects (17–19). Only few studies have examined the utility of the PPI empirical trial in patients with suspected LPR. One of the tasks of our study was to evaluate the merit of empiric omeprazole therapy in patients with suspected laryngopharyngeal reflux. Our analysis showed a significant improvement of total symptoms score, posterior laryngitis score, overall vocal dysfunction degree as well as self-rated well-being in general for patients treated with omeprazole as far as after 2 weeks. No significant improvement was found for patients treated only with dietary and lifestyle modifications. Response rates after 2-week treatment was 36% vs. 15%. The results are in agreement to the published studies assessing the usefulness of the PPI for extraesophageal manifestations (6, 7, 20). T.M. Ours et al. (21) concluded that 14 days of omeprazole 40 mg twice a day could be used as an empirical trial in patients with chronic cough.

Another question that needs to be resolved is the dose and duration of diagnostic testing with PPI. Our results showed that four-week omeprazole test is significantly superior to two-week test, as well as dose no less than 20 mg bid. Twice a day dosing is supported because none of the PPIs exert acid suppression (intragastric pH>4) for >16.8 hours (22). Not less than one month of empirical trial with PPI as well as 20 mg bid dose for omeprazole also was suggested on First Multidisciplinary International Symposium on Supraesophageal Complications of Gastroesophageal Reflux Disease (23).

The third task of our study was to compare the diagnostic value in LPR of upper gastrointestinal endoscopy and 4-week omeprazole test. Our results showed that erosive esophagitis confirmed diagnosis in 21% (21/100) of patients with clinically proven LPR. The low sensitivity of traditional diagnostic methods was proven by other authors. Most studies found evidence of reflux esophagitis, usually mild, in only 10–30% of patients (5, 7). Sensitivity of omeprazole test with regard to confirmed diagnosis with upper endoscopy in our study was found to be 85.7% (18 of 21 patients with erosive esophagitis were classified as responders to 4 week omeprazole test). The

Table 4. Response to omeprazole 4-week test compared with the results of upper endoscopy

<table>
<thead>
<tr>
<th>Omeprazole response</th>
<th>+</th>
<th>–</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erosive esophagitis +</td>
<td>18</td>
<td>3</td>
<td>21</td>
</tr>
<tr>
<td>Erosive esophagitis –</td>
<td>47</td>
<td>32</td>
<td>79</td>
</tr>
<tr>
<td>Total</td>
<td>65</td>
<td>35</td>
<td>100</td>
</tr>
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</table>

With the presence of esophagitis as the gold standard, the omeprazole test sensitivity = 85.7% (18/21); specificity = 40.5% (32/79); with positive omeprazole test as the gold standard, the upper GI endoscopy with presence of esophagitis sensitivity = 27.6% (18/65); specificity = 91.4% (32/35).
efficiency of omeprazole test for all tested patients was 65% (65/100). Omeprazole test sensitivity in the medical literature ranged from 55% to 81% (6, 24). Other studies showed the omeprazole test sensitivity and specificity comparable to 24-h pH monitoring (8). In conclusions we could state that the short-term omeprazole therapy is attractive diagnostic test with overall accuracy up to 65%. It validated the further longer therapy for complete resolution of symptoms and laryngeal findings.

Conclusions
1. Short-term treatment with PPI (omeprazole) is significantly advantageous for patients with posterior laryngitis and suspicion for laryngopharyngeal reflux in comparison to dietary group. Total symptom index, posterior laryngitis score, voice range profile parameters and well-being in general could be used as relevant efficacy parameters.
2. Four-week omeprazole test is significantly superior to two-week test as well as omeprazole not less than 20 mg twice a day is more effective than 20 mg once a day.
3. Short-term treatment with PPI (omeprazole) may be useful in confirming the clinically based diagnosis of LPR after ORL evaluation. Four-week omeprazole test confirmed diagnosis for 65 of 100 (65%) patients in comparison to 21 of 100 (21%) patients with found erosive esophagitis during upper gastrointestinal endoscopy. Accuracy of omeprazole test with regard to upper endoscopy was 85.7%.
References


