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Presumed laryngo-pharyngeal reflux: investigate or treat?

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Abstract

A review of a combined gastroenterology and laryngology clinic was conducted to determine the effectiveness of treatment and the predictive value of clinical findings and investigations.

Data were collected prospectively. Investigations were performed according to clinical criteria. Patients with symptoms suspected to be due to laryngopharyngeal reflux (based on a positive oesophageal pH test and/or changes on videolaryngoscopy consistent with posterior laryngitis) were treated with omeprazole for at least two to three months.

There were 87 patients; the most common symptoms were cough (38 per cent) and hoarseness (36 per cent); 77 per cent had some symptoms suggestive of gastro-oesophageal reflux. Sixty-seven patients were given omeprazole. A good response to laryngo-pharyngeal symptoms was seen in 37 patients (55 per cent). The presence of reflux symptoms was not a predictor of a good response. Increasing severity of oesophageal acid exposure over the 24 hours of pH testing was associated with a better symptom response (Spearman rank correlation, $p = 0.01$). Posterior laryngitis was not associated with the response to treatment, although there was a trend towards an association between improvement in laryngitis (after treatment) and improvement in symptoms ($p = 0.08$).

The response to proton pump inhibitors was lower than other published results. Oesophageal pH monitoring may have a role in predicting which patients will respond to proton pump inhibitors. This study does not support the decision to treat with anti-secretory therapy, based only on the presence of posterior laryngitis.

Key words: Oesophagitis, reflux; Larynx; Pharynx; Clinical protocols

Introduction

There has been increasing interest in the possible relationship between laryngo-pharyngeal symptoms and gastro-oesophageal reflex.[1,2] The possible mechanisms of any association are unclear.[1,3] The issue has been difficult to resolve because the measurement of oesophageal and, more particularly, pharyngeal acid exposure is not precise.[3,4] Ambulatory 24 hour oesophageal pH monitoring fulfills some of the need for an accurate diagnosis of reflux but has limitations in terms of reproducibility. There is continuing debate on the interpretation of oesophageal pH data; in particular which features may predict a good response to gastric anti-secretory treatment or to anti-reflux surgery (fundoplication).[2–3,5–6] There is also uncertainty regarding the interpretation of posterior laryngitis.[7] Some ORL otorhinolaryngology specialists would treat with anti-secretory therapy on the basis of the presence of posterior laryngitis. Inter-observer variation may be significant and the predictive value of this finding for a good symptom response is not established. Many different symptoms have been grouped together as being possibly related to laryngo-pharyngeal reflux of gastric contents. However, it is likely that the mechanisms of association are very difficult. For example only 20–35 per cent of patients with persistent cough have a positive oesophageal pH monitoring test compared to up to 80 per cent of patients with hoarseness.[3,8–11]

The results of treatment studies provide important data for the clinician. Most treatment studies have been short-term and there have been few studies with long-term follow-up.[12–14] This study is a review of a combined clinic with co-operation between gastroenterology, ORL and speech therapy.

Methods

Referral

Patients were normally assessed first in a general ORL clinic. Those patients with laryngeal and pharyngeal symptoms of unknown cause were referred to the combined clinic for further assessment. There was some selection bias based on reflux symptoms and the presence of a posterior laryngitis.

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A few patients were seen initially in a gastroenterology clinic or by a speech therapist and then referred to the combined clinic on the basis of laryngo-pharyngeal symptoms considered to be related to gastro-oesophageal reflux.

Data collection

Data was collected prospectively using a standardized database form. The patient was asked to define the main laryngo-pharyngeal symptom. Information on all other relevant symptoms was also collected during the initial interview. Patients were specifically asked about heartburn, regurgitation and belching. Details on previous anti-reflux treatment and the response of the main symptom to treatment were recorded. Information on medical and surgical history was noted.

Endoscopy was not routinely performed. Preference was given to oesophageal pH monitoring as the initial investigation, but some patients required both tests on clinical criteria.

Oesophageal pH monitoring

Most patients were offered this test which was usually performed using a dual channel probe (proximal and distal electrodes placed 15 cm apart) (Synectics Digitrapper). The distal electrode was placed 5 cm above the lower oesophageal sphincter (identified using the pH step-up technique). The duration of the test was 22–24 hours. Patients were encouraged to have a normal diet apart from avoiding carbonated drinks. The results were analysed using Synectics software. The results for the percentage oesophageal acid exposure (pH < 4) in the distal probe were categorized using the following definition: normal 0–2.9 per cent, borderline reflux 3.0–5.9 per cent, moderate reflux 6.0–9.9 per cent and severe reflux > 10 per cent. Significant proximal reflux was defined as pH < four for > one per cent in the proximal electrode (20 cm above lower oesophageal sphincter).[15] Proximal supine reflux was considered abnormal if pH < 4 was recorded for > 0.1 per cent of the recumbent period.[15]

Video-laryngoscopy

Video-laryngoscopy was performed using either a rigid 90° or 70° telelaryngoscope, or if this was not tolerated, a 6 mm flexible nasopharyngoscope. The endoscope was illuminated using a Wolf stroboscope with projection onto a video monitor with simultaneous capture on a video recorder. Erythema and oedema of the mucosa for both the arytenoid and inter-arytenoid regions was graded as normal (0), mild/moderate (1) or severe (2). A score for posterior laryngitis was obtained from the summation of the scores for oedema and erythema for each region. Abnormalities of vocal folds were noted but not included in the score. Mild laryngitis was defined as a score of 1–2, moderate laryngitis 3–4 and severe laryngitis as a score of 5 or more.

Treatment and follow-up

Most patients with a history of reflux symptoms had been treated previously with H_2-antagonists but the use of proton pump inhibitors in this population group had been infrequent. In New Zealand, during the period of the review, omeprazole was restricted by the New Zealand Department of Health regulation to patients with endoscopically proven oesophagitis or abnormal ambulatory oesophageal pH studies. Anti-reflux treatment was given if oesophageal acid exposure was greater than three per cent or if posterior laryngitis was observed. Agreement on the presence and grading of posterior laryngitis was achieved between the investigators after examination of the video recordings. All patients were treated with omeprazole 20 mg daily for two to three months initially. If there was no response the dose was increased to 40 mg daily for another three months. Patients' responses were classified after six months of treatment. Overall assessment of response was graded as complete, near complete, partial, minimal or nil response. These assessments were based on patient symptoms as reported to the combined clinic, and agreed to by the patient. The assessment was ranked for statistical analysis. Complete and near complete response were combined together as a 'good response' and partial, minimal and nil responses grouped together as a 'poor response' for the tables.

Other possible contributing factors were considered at each visit. The speech pathologist provided voice therapy when a functional component to the symptoms was suspected. This judgment was based on such findings as over-closure of the vestibular folds (false cords), paradoxical movement of the vocal folds, habitual or persistent throat clearing, muscle tension dysphonia or inappropriate breathing patterns. Regular follow-up was arranged. Videolaryngostroboscopy was performed, where possible, during follow-up visits.

Statistical analysis

Data was analysed using SPPS for Windows, version 7.5.1. Categorical data were compared using the Chi-squared test. Nominal ranked data (severity of oesophageal acid exposure, posterior laryngitis score, and clinical response) were correlated using the Spearman rank correlation test. Logistic regression was performed to identify variables that could predict a good or poor response to treatment.

Results

There were 87 patients; 57 women, 30 men, with an average age of 56 years. The main symptoms are shown in Table I. The most common symptom was cough and hoarseness. Excessive voice use (from occupation) was noted for eight patients. Other relevant symptoms were nasal obstruction (nine) and sinusitis (eight). Thirteen patients had an allergic diathesis with either hay fever or asthma. Upper gastrointestinal endoscopy was performed for 32 patients. The endoscopic findings were normal for 19

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TABLE I
RESPONSE OF LARYNGO-PHARYNGEAL SYMPTOMS TO TREATMENT WITH OMEPRAZOLE

	Cough	Hoarseness	Sore throat	Choking sensation	Globus	Total
Good response	13	18	2	4	0	37
Poor response	12	8	7	1	2	30
Overall good response to treatment	(52%)	(69%)	(22%)	(80%)	(0%)	(55%)
No treatment given	8	5	4		3	20
Total	33	31	13	5	5	87

patients, six had mild oesophagitis and six had moderate or severe oesophagitis. One patient had a gastric ulcer. The medical history included five patients with a history of depression, two with irritable bowel syndrome, seven had thyroid problems, three had used oral steroids recently, two had severe recent stress, and one patient had received radiotherapy for nasopharyngeal carcinoma nine years ago. Previous ORL surgery was noted for 16 patients – septoplasty, three, sinus surgery, three, tonsillectomy, two, uvulo-pharyngo-palatoplasty, one and vocal fold surgery, seven.

Sixty-one patients had typical symptoms of heartburn. Twenty-nine patients reported regurgitation and 16 had excessive belching. Overall, 67 patients (77 per cent) gave a history suggesting gastro-oesophageal reflux. Anti-reflux treatment had been given to 55 patients prior to clinic review. Thirty-five patients had been treated with H_2-antagonists only, five had antacids only and 15 had taken omeprazole (nine had taken H_2-antagonists prior to a trial of omeprazole). None of the 44 patients who had used H_2-antagonists had a good response of the main symptom to treatment.

Omeprazole treatment was given to 67 patients following initial clinic review. Forty-six patients were treated mainly on the basis of a positive oesophageal pH study, three had posterior laryngitis and a normal pH study, five had posterior laryngitis and did not have a pH study and 13 were treated on symptoms alone. Treatment was not given to 20 patients because of a negative oesophageal pH study and/or normal laryngoscopy (seven – negative pH study only; six – normal laryngoscopy only, and seven patients had both tests negative). The response to treatment for each symptom type is shown in Table I. For all symptoms, 37/67 had a 'good response' (55 per cent) – near complete 19 and complete 18. Thirty patients were defined as having a 'poor response' (45 per cent) – partial response, six, minimal response, eight, and no response, 16. The best response rates were observed for patients with hoarseness and choking sensation. Patients with cough, sore throat or globus sensation appeared less likely to have a good response, although this trend was not statistically significant ($p = 0.1$). Only two out of five patients with globus (as the main symptom) were treated because three patients had both a normal pH study and normal video-laryngoscopy. Nineteen patients had globus as part of their symptom complex, 12 patients were treated and only four had a good response. Thirty-one of the 57 patients with a history suggestive of reflux had a good response and six of 10 patients without reflux symptoms had a good response (p = ns). Seven patients who had a good response to omeprazole have proceeded to a laparoscopic Nissen fundoplication.

Twenty patients, based on clinical assessment, had symptoms that could be attributed, at least in part, to a functional component. Eight patients with a significant functional component had a good response; 11 had a poor response and one patient was not given treatment. Three of five patients with a history of depression had a good response.

Oesophageal pH monitoring

Sixty-three patients had an oesophageal pH study; 46 patients had a dual channel pH study. This was normal for 16, borderline for 18, moderate for 12, and severe for 17 patients. Twenty-nine patients (46 per cent) had definite reflux (moderate and severe categories combined). If patients with borderline studies are included 47 (75 per cent) could be defined as having some evidence of gastro-oesophageal reflux. There was good correlation between acid reflux events and heartburn for 15 patients; only one patient had poor symptom correlation. Nine patients had used the marker for heartburn on only one or two episodes therefore the correlation could not be reliably assessed for these patients. Thirty-one

TABLE II
OSEOPHAGEAL PH MONITORING DATA ACCORDING TO MAIN SYMPTOM TYPE

	Oesophageal acid exposure (% of time < pH 4)					
	Normal (0–2.9%)	Borderline (3–5.9%)	Moderate (6–9.9%)	Severe (> 10%)	Not done	% Positive test
Choking				3	2	100% (100%)*
Cough	6	10	4	5	8	36% (76%)*
Globus	2	1		1	1	25% (50%)*
Hoarseness	5	6	6	7	7	46% (79%)*
Sore throat	3	1	2	1	6	43% (57%)*
Overall	16	18	12	17	24	45% (74%)

*Percentage of positive tests if borderline tests (oesophageal acid exposure 3–5.9 per cent) are included.

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TABLE III
OESOPHAGEAL PH MONITORING DATA AS A PREDICTOR OF RESPONSE OF MAIN SYMPTOM TO OMEPRAZOLE TREATMENT

	Normal	Borderline	Moderate	Severe	Not done
Good response	2	4	9	13	
Poor response	1	13	3	4	
Overall good response to treatment	(30%)*	(75%)	(76%)		
No Rx given	13	1			
Total	16	18	12	17	24

$p = 0.01$ (Spearman rank correlation test; response ranked according to complete (5), near complete (4), partial (3), minimal (2), nil (1)).
*Normal and borderline results combined.

patients had no symptoms over the 24 hour period, (19 of these patients had reported the symptom of heartburn at initial clinic review).

The association of oesophageal pH monitoring and symptom type is shown in Table II. There were no significant differences in the severity of oesophageal acid exposure between symptom types. There was a significant association between the severity of oesophageal acid exposure and the response of the main symptom to omeprazole (Spearman rank correlation, $p = 0.01$, Table III). Proximal reflux (pH > one per cent in proximal probe) was observed in 23 patients (50 per cent). All 12 patients with severe reflux (pH < four for greater than 10 per cent in the distal probe) who had dual channel monitoring showed significant proximal reflux. Reflux to the proximal electrode during the supine period was observed for 15 patients. There was no association between the presence of proximal reflux or proximal supine reflux with symptom type, posterior laryngitis or the response to treatment.

Video-laryngoscopy

Fifty-eight patients had video-laryngoscopy. The findings were normal for 29 patients. Thirteen patients had mild posterior laryngitis, nine had moderate posterior laryngitis and seven had severe changes. Vocal fold abnormalities were seen in five patients – three had a granuloma (all patients were graded as having severe posterior laryngitis), one an intra-cordal cyst and one patient had candidiasis involving the folds. There was no association between posterior laryngitis and symptom type although six of the seven patients with severe posterior laryngitis had hoarseness as the main symptom (Table IV). Nine patients with the symptom of hoarseness and moderate or severe laryngitis all had some improvement in the laryngitis score after treatment and eight out of nine had a good response to treatment.

There was no association between the presence or absence of posterior laryngitis and the response of the main symptom to treatment. Eleven of 23 patients (48 per cent) without posterior laryngitis (or only mild changes) had a good response to treatment compared with 12/22 (54 per cent) patients with moderate to severe posterior laryngitis ($p = 0.76$). Forty-two patients had both video-laryngoscopy and an oesophageal pH study. There was no association between the oesophageal pH monitoring data (both the total oesophageal acid exposure and the presence or absence of proximal reflux) and the appearances at video-laryngoscopy ($p = 0.38$). Thirty-two patients had video-laryngoscopy before, and after, omeprazole treatment. There was a trend towards an association between an improved laryngitis score after treatment and a good symptom response ($p = 0.08$). Logistic regression analysis was performed to determine predictive factors for good or poor response to treatment. Only the severity of oesophageal acid exposure was predictive and no other variable added any accuracy to the model.

Previous treatment

Most of the patients in our study that had been previously treated with anti-reflux therapy had received an H_2-receptor antagonist. There were 15 patients that had previously had omeprazole therapy. Most (12) of these had further treatment; five were classified as poor responders and seven as good responders. Nine had video-laryngoscopy of whom five had moderate to severe posterior laryngitis.

Discussion

The overall 'good response' rate of 55 per cent was disappointing when compared with other series that

TABLE IV
APPEARANCES AT INITIAL VIDEO-LARYNGOSCOPY ACCORDING TO MAIN SYMPTOM TYPE

	Posterior laryngitis				
	Normal	Mild	Moderate	Severe	Not done
Choking sensation	2				3
Cough	10	5	3		15
Globus	3	1			1
Hoarseness	9	4	5	6	7
Sore throat	5	3	1	1	3
Total	29	13	9	7	29

p = ns

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report good treatment responses between 70 and 90 per cent.[12–14,16–18] A trial of treatment for laryngo-pharyngeal symptoms needs to be significantly longer than usually given for symptoms suggestive of heartburn. Our experience is that anti-reflux treatment needs to be continued for three to six months before a clear response can be determined. This is supported further by the fact that a proportion of our patients had failed previous anti-reflux therapeutic trials but responded well to management in our combined clinic. The lack of correlation with features of posterior laryngitis does not support any treatment protocol that determines the use of anti-reflux therapy based on this finding. Gastroscopy has minimal value as the findings are usually normal or reveal only mild changes in the oesophagus.

It is possible that a referral bias may account for our low overall response rate, however, our experience would suggest that investigation by oesophageal pH monitoring is preferable to an empirical approach based on laryngoscopic appearances. A negative oesophageal pH monitoring test may be helpful to avoid prolonged and unwarranted treatment trials.

Many symptoms appeared to have a multifactorial basis. Some patients with a good response to omeprazole had other potentially relevant factors that could have contributed to their symptoms. Close attention to problems of abnormal voicing and the supportive nature of the multi-disciplinary clinic were possibly part of the therapeutic effect. Several patients had depression or recent significant life stressors that may have been helped to some degree by the close attention of the multidisciplinary team. Overall, heartburn appears to be of mild severity and low frequency in our group of patients. This observation is supported by the infrequent use of the symptom marker during oesophageal pH monitoring tests. The majority of patients with heartburn had a good response of this symptom to treatment, but heartburn was not a predictor of a good response of the laryngo-pharyngeal symptoms to anti-reflux treatment. Some patients who had a poor response of the laryngo-pharyngeal symptoms to treatment wished to continue with omeprazole because of the cessation of heartburn. Some patients were only clear about the benefit of the treatment after discontinuing treatment for one to two months. Many patients maintained a symptom response after discontinuing the omeprazole. This could imply a placebo response but may represent a break in a cycle of injury. The initial injury could have come from excessive voice use, excessive and harsh throat clearing, smoking or viral laryngitis. The injury becomes chronic because of acid exposure but is allowed to heal with intensive anti-reflux treatment and attention to other risk factors.[3,14]

Proton pump inhibitors, such as omeprazole, are significantly more effective than H_2-receptor antagonists in lowering gastric pH. High-dose ranitidine has been shown to be effective for patients with presumed laryngo-pharyngeal reflux in a placebo-controlled study. H_2-receptor antagonists, given as standard doses in short courses prior to referral to our combined clinic, were ineffective. Nevertheless, the modest gastric acid suppression achieved with H_2-receptor antagonists may be sufficient for some patients to respond.[19] Such people would not have been referred to us but may be represented in other reports.

Most of the patients in our study that had been previously treated with anti-reflux therapy had received an H_2-receptor antagonist which provides only modest acid suppression that has little impact on laryngo-pharyngeal symptoms. Fifteen patients had received omeprazole but most of them had the medication for a period of time too short to be regarded as an adequate therapeutic trial. The previously treated patients were otherwise similar to those not previously treated, and all patients had their pH testing off treatment. Patients responded to proton pump inhibition in a similar manner irrespective of whether or not they had received previous anti-reflux treatment. Prior treatment did not appear to affect the rate of observed laryngeal changes (noted in 55 per cent of patients, irrespective of previous treatment).

Our clinic had a cautious approach to referral for fundoplication. Some centres have advocated fundoplication as the preferred long-tem option based on the concept that even small amounts of acid or bile exposure will continue the cycle of injury. It has been suggested that bile exposure of the oesophagus and potentially pharynx and larynx can persist during maintenance treatment with proton pump inhibitors. This has been refuted by a study using ambulatory monitoring of bile concentrations in the oesophagus that found low levels of bile after fundoplication and similarly low levels during maintenance treatment with proton pump inhibitors.[3,20]

There was a trend for the symptoms of hoarseness and choking sensation to respond better to treatment than other symptoms in our study. Hoarseness has been the most studied symptom in other studies. In several studies, oesophageal pH studies have been abnormal in between 55–78 per cent of patients.[9–11,21] Objective measures of response of hoarseness to treatment are possible using measurement of acoustic signal data and analysing for jitter, shimmer and signal-to-noise ratio.[13,17,22] Chronic persistent cough has many possible diagnoses – perhaps only 20 to 30 per cent of cases are related to gastro-oesophageal reflux (depending on the referral bias).[3,8] Even when gastro-oesophageal reflux is proven the mechanism of a proposed link with cough is unclear. In one study, 15 patients with possible reflux-induced cough had combined oesophageal manometry and pH studies. Only one per cent of coughing episodes were linked to episodes of gastro-pharyngeal reflux.[23] In our study, patients with globus or sore throat did not respond well to anti-reflux treatment. Most studies have shown a low rate of abnormal oesophageal pH studies in patients with globus and a poor response to treatment.[24–26]

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It is unclear whether patients with laryngo-pharyngeal symptoms have an abnormal pattern of reflux compared to patients with reflux symptoms without laryngo-pharyngeal symptoms. Jacob *et al.* found more proximal reflux in patients with posterior laryngitis compared to controls who had heartburn but no laryngeal symptoms[6] however there are some concerns regarding the reproducibility of proximal pH data.[4] There seems to be no additional clinical value using dual channel pH monitoring to predict outcome to treatment.[5] Pharyngeal pH monitoring may provide more diagnostic information but does have some technical problems.[3,21,27]

The presence of posterior laryngitis on examination did not predict a good response. An improvement in laryngitis after treatment with proton pump inhibitors may correlate with a symptom response, but the number of patients with paired data in our study was too small to reach a conclusion. This study supports the view of other authors that posterior laryngitis is not a helpful sign and may not relate to laryngo-pharyngeal reflux.[7] The term 'reflux laryngitis' assumes an association with reflux that is not supported by the data. The descriptive term 'posterior laryngitis' is to be preferred. Patients with normal appearances of the larynx may respond well to anti-reflux treatment and should not be denied a trial of treatment. Routine video-laryngoscopy after two to three months of treatment is probably not helpful but may be prudent for patients with more significant changes of posterior laryngitis. Moderate to severe changes of posterior laryngitis may have some correlation with the symptom of hoarseness and follow-up examination may be of some clinical benefit. These conclusions are based on a laryngitis score that was derived from the consensus agreement in the clinic on the appearances after reviewing the video recordings. The scoring system is arbitrary as it is not known which features of the examination may be the most important.[30,31] There are problems with the assessment of the degree of erythema. Computerized assessment of colour may provide more accuracy.[32] A study of inter-observer variation of the interpretation of video-laryngoscopy is in progress.

A recent paper has reported the results of a double-blind randomized placebo-controlled trial of proton pump inhibitor therapy.[33] Entry to the study was on the basis of posterior laryngitis. Data were available on only 15 of the 20 patients entered into the study and showed no difference between active agent and placebo in reduction of symptoms or improvement of laryngeal symptoms. The small size of this study severely limits its power but the authors noted that the results indicated that factors other than reflux were likely to contribute to posterior laryngitis. This is in keeping with our observations in this present study.

A consensus statement on the treatment of laryngeal symptoms presumed to be associated with reflux has advocated an empirical approach to treatment using a short course of proton pump inhibitor (one month) reserving oesophageal pH monitoring for non-responders.[28] This approach has been studied in practice and has some success.[14,29] If oesophageal pH studies are reserved for non-responders, there is some debate as to whether this investigation should be performed on or off treatment.[3,14] The results of our study would support the use of oesophageal pH monitoring (perhaps on a selected basis) before giving anti-reflux treatment. Based on our clinical experience we would advocate follow-up for at least three to six months before deciding on the success or failure of anti-secretory treatment.

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