Gastro-oesophageal reflux—initial experience with a radiotelemetry system for prolonged oesophageal pH monitoring

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SUMMARY

A radiotelemetry system has been used to monitor gastro-oesophageal reflux over a prolonged period in 27 asymptomatic control subjects and in 15 patients with reflux symptoms. In control subjects, the frequency of reflux episodes (pH < 5) ranged from 0.1 – 0.7 per hour of recording (median 0.36) by day, and from 0 – 1.0 per hour (median 0.12) by night. The duration of reflux (pH < 5) per hour of recording ranged from 0.4 – 5.4 minutes (median 2.1) by day and from 0 – 5.1 minutes (median 0.27) by night. Patients with reflux symptoms had more frequent episodes of daytime reflux and a longer duration of daytime reflux than control subjects. The frequency and duration of nocturnal reflux were similar in patients and in control subjects. Of two patients with Barrett's metaplasia of the lower oesophagus, one had markedly increased frequency and duration of both daytime and nocturnal acid reflux, while the other had only a moderate increase in the frequency of daytime reflux episodes.

INTRODUCTION

Reflux oesophagitis is one of the commonest conditions encountered in clinical practice. Although fibreoptic endoscopy greatly assists in the diagnosis, it provides an assessment only of the extent of oesophageal mucosal damage and gives no indication of the severity of gastro-oesophageal reflux.

Prolonged intra-oesophageal pH monitoring has been developed so that a quantitative assessment of gastro-oesophageal reflux may be made. Early studies used a small glass pH electrode which was connected to a large bedside pH recording device.1–3 Patients were rendered relatively immobile by the apparatus and the relevance of the reflux patterns obtained was questioned. A major advance has been the refinement of a radiotelemetry system for pH monitoring so that fully ambulatory studies of oesophageal pH are now feasible.4

We present our initial experience with this new technique and describe the pattern of gastro-oesophageal reflux in a group of asymptomatic healthy human volunteers and in a group of patients with symptoms of gastro-oesophageal reflux.

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METHODS

A pH sensitive radiotelemetry capsule emits a radio signal which alters according to the pH of the surrounding environment. The signal is then detected by a portable radio-receiver and stored on a 24-hour cassette tape. The radiotelemetry capsule (model 7006 Rigel Research) consists of a glass envelope (28.0 x 6.6 mm) and is similar in size to an antibiotic capsule. The envelope contains a glass electrode, a radio-transmitter, a small mercury battery and a self-contained reference cell measuring pH in the range 1 to 9. The capsule is attached to a 40 cm length of fine bore polyvinyl tubing (OD = 0.54 mm).

Before it was swallowed by each patient or volunteer, the capsule was calibrated at pH 4.0, 7.0 and 9.0 at 37°C. When the capsule was swallowed, the upper end of the polyvinyl tubing was taped to the patient's cheek, so that the capsule was maintained in the oesophagus 5 cm above the oesophago-gastric junction. The distance from mouth to oesophago-gastric junction was recorded during previous endoscopy or manometric studies. The capsule was re-calibrated at the end of each study to check pH 'drift' during the test.

A compact portable receiving and recording system was used for pH monitoring (Fig 1). This consisted of a battery-operated FM radio receiver and aerial switching unit which recorded on to a Medilog four-channel cassette recorder (Oxford Medical Systems). An aerial belt, worn across the chest, was used to detect the signal from the radiotelemetry capsule. Signals recorded on the 24-hour tape cassette were replayed on a Devices MX4 unit so that a graphical record of each patient's reflux pattern was obtained (Fig 2). The apparatus included an event button which patients could press if they...
experienced the sensation of heartburn. All studies were conducted during an overnight hospital stay. Subjects were fully mobile but activity was standardised to allow comparison between different groups. Food and drink of pH < 5 were excluded from the hospital diet. The radiotelemetry capsule was inserted at approximately 3.30 pm and removed at 9.00 am the following morning so that 17-18 hours of recording were available for analysis.

Acid reflux episodes were arbitrarily defined at two levels — when the oesophageal pH fell from the normal value of 7 to less than 5 pH units or when it fell further to less than 4 pH units. These two levels are necessary because there is no simultaneous measure in these patients of gastric juice pH which may rise to between 4 and 5 pH units in the postprandial period. The duration of reflux (minutes per recorded hour) and the number of reflux episodes per recorded hour were determined. Reflux data for daytime and for night-time were analysed separately. Inter-group comparisons were made using the non-parametric Mann-Whitney-U test. The upper limit of the normal range for reflux frequency or duration was defined as the 95th centile, since the data were not normally distributed.

PATIENTS

Group 1 consisted of 28 asymptomatic healthy volunteers, (14 men, 14 women) whose ages ranged from 20 to 63 years (mean age 36 years). No volunteer was taking medication likely to influence gastrointestinal motility nor gave a history of gastro-oesophageal reflux symptoms.

Group 2 consisted of 15 patients (7 men, 8 women) whose ages ranged from 21 to 63 years and who presented with symptoms of heartburn. In some cases, regurgitation or dysphagia was also present. Endoscopy was performed in all cases, and significant erosive oesophagitis was noted in 10 patients, two of whom (males, aged 36 and 38 years) had associated Barrett's metaplasia in the lower 5-10 cm of oesophagus. In five patients the oesophagus appeared normal or had mild erythema only. No patient was taking any medication other than simple antacids prior to the study, and no antacids were supplied during the pH monitoring study.

RESULTS

Most patients and volunteers experienced little difficulty in swallowing the radiotelemetry capsule. One control subject retched at frequent intervals and rejected the capsule after only 1½ hours. Her recording was not included in the analysis of data. One patient tolerated the capsule well until 11 pm, at which time she regurgitated the capsule and was reluctant to swallow it again. Eight hours of daytime recording were obtained from this patient. With the capsule in situ, all patients and volunteers were fully mobile and, thus, the aim of ambulatory monitoring was achieved. Some individuals experienced difficulty in eating food during the study.

Acid reflux was detected in all asymptomatic volunteers and yet no volunteer complained of heartburn during the study. The Table shows that most reflux episodes occurred by day when volunteers were upright, and of these episodes most were observed to occur post-prandially. Nocturnal reflux was an infrequent phenomenon and did not occur at all in several individuals.

Patients with reflux symptoms had more frequent episodes of daytime reflux than asymptomatic control subjects (p < 0.001) (Fig 3). The time of oesophageal
TABLE
Frequency and duration of gastro-oesophageal reflux episodes in 27 control subjects

|          | Frequency (episodes/hour) | Duration (minutes/hour) |
|----------|---------------------------|-------------------------|
|          | Day | Night | Day | Night |
| pH < 5   |     |       |     |       |
| Median   | 0.4 | 0.1   | 2.1 | 0.3   |
| Range    | 0.1–0.7 | 0–1.0 | 0.4–5.4 | 0–5.1 |
| 95th Centile | 0.6 | 0.4 | 5.0 | 2.3 |
| pH < 4   |     |       |     |       |
| Median   | 0.3 | 0.11  | 1.73 | 0.15 |
| Range    | 0.1–0.7 | 0–0.9 | 0.3–3.8 | 0–4.4 |
| 95th Centile | 0.6 | 0.3 | 3.2 | 1.9 |

exposure to pH < 5 during the daytime was significantly longer in the patient group than in the control subjects (p < 0.01) (Fig 3). Although the duration at pH < 4 by day tended to be longer in the patient group, this did not reach statistical significance (p = 0.18). The frequency and duration of nocturnal reflux were similar in the patient group and in the control group, no statistically significant differences being detected.

One of the two patients with Barrett’s oesophageal metaplasia had grossly abnormal daytime reflux (18.9 min/hr at pH < 5) and nocturnal reflux (4.3 min/hr at pH < 5), whereas the other patient had no nocturnal reflux detected, a normal duration of daytime reflux (2.9 min/hr at pH < 5) and a moderate increase in the frequency of daytime reflux episodes (1.2 episodes of pH < 5/hr).

More severe reflux tended to occur in the 10 patients with significant erosive oesophagitis than in the five patients with minimal change or normal appearance. Overlap between these groups was noted and formal statistical evaluation was not applied in view of the small number in the second group. Only four of the reflux patients had evidence of abnormal nocturnal reflux and all four had significant erosive oesophagitis.

DISCUSSION
Our data illustrate clearly that gastro-oesophageal reflux occurs in asymptomatic volunteers. Other investigators have described similar findings in control subjects who were confined to bed and in ambulatory subjects. However, those studies
were based on smaller numbers of volunteers who were mostly young adults. We have examined reflux patterns in healthy men and women of a wider age group and our control values for reflux are more broadly based for comparison with different patient groups.

The normal occurrence of gastro-oesophageal reflux when upright, by day, has been highlighted in this study and most episodes were observed post-prandially. Clearly, gravity and the supine position exert little influence on the competence of the lower oesophageal sphincter. After a meal, however, several factors, including the intra-gastric pressure and volume, and the release of gastro-intestinal hormones, may modify lower oesophageal sphincter tone and promote gastro-oesophageal reflux. Continuous pressure recordings have recently documented the occurrence of transient, inappropriate relaxations of the lower oesophageal sphincter post-prandially and further studies are required to elucidate the mechanism of this phenomenon.

Studies of acidity in patients with reflux symptoms have given an insight into the varying patterns of abnormal gastro-oesophageal reflux and have raised many questions about the nature of this disorder. DeMeester and colleagues emphasised the importance of supine, nocturnal reflux in patients with severe oesophageal mucosal damage. However, our own observations and those of Branicki and colleagues suggest that excessive nocturnal reflux occurs in a relatively small sub-group of patients with significant oesophagitis. The time-honoured practice of advising patients to raise the head of the bed is unlikely to benefit the majority of patients with reflux symptoms.

Our data have highlighted the occurrence of frequent short episodes of reflux in some individuals with reflux symptoms and fewer episodes of much longer duration in other patients. As more patients are studied in the coming years, it is hoped that the significance of these differing reflux patterns can be determined. Some of our patients with erosive oesophagitis had normal or only mildly abnormal reflux patterns. There are several possible explanations for this observation. Reflux may not be responsible for the problem and a different mucosal damaging agent may be involved, such as a viral illness or a mucosal irritant in the diet. Severe duodenogastric reflux may occur in some individuals so that bile contaminated gastric juice which is no longer acidic may be refluxing into the oesophagus.

Our observations on the two patients with Barrett's oesophageal metaplasia fuel the controversy about the aetiology of this disorder. The current hypothesis is that these patients develop a metaplastic change in the oesophagus as a consequence of severe, prolonged gastro-oesophageal reflux. Barrett believed that the condition was the result of a failure of the embryonic lining of the oesophagus to achieve normal maturity. One of our patients had grossly abnormal daytime and nocturnal gastro-oesophageal reflux, whereas the other had no nocturnal reflux at all and his daytime reflux was only mildly increased.

It is clear that prolonged oesophageal pH monitoring is an important research tool which gives invaluable information about the pathophysiology of reflux oesophagitis. It also has many applications in clinical practice. The effectiveness of anti-reflux surgery and of current medical therapy on the severity of gastro-oesophageal reflux can be readily assessed. New drug treatments can be examined. Diagnostic problems may be solved with the technique. Some patients have atypical symptoms such as cough, wheezing and chest pain which are
secondary to gastro-oesophageal reflux, and pH monitoring may assist the assessment of such individuals. The contribution of reflux to the collection of symptoms associated with gallbladder disease and peptic ulcer may also be unravelled by this investigation.

The radiotelemetry system of pH monitoring has proved accurate and reliable in our hands, and patient tolerance has been good. Our subjects have been studied under hospital conditions to allow inter-group comparisons, but the apparatus could be used in the home or at work so that environmental factors peculiar to each individual can make their contribution to the degree of gastro-oesophageal reflux detected with the equipment.

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