Ambulatory monitoring of oesophageal pH in reflux oesophagitis using a portable radiotelemetry system

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SUMMARY Gastro-oesophageal reflux has been assessed in 10 symptomatic patients and 10 asymptomatic normal subjects during a study period of 24 hours at work and in the home using a newly developed pH sensitive radiotelemetry capsule¹ and a portable receiving system.² Oesophageal pH was continuously monitored by the tethered radiotelemetry capsule and recorded with a portable receiver and a 24-hour cassette recorder,³ allowing the patient complete freedom of movement so that ambulatory studies could be undertaken during a normal working day. The number and duration of reflux episodes was greater in symptomatic patients than normal subjects during 24-hour studies at home ($p < 0.002$). In both groups, reflux occurred more during the day than at night ($p < 0.01$). Patients refluxed significantly more at home than when they were in hospital ($p < 0.01$). Ambulatory outpatient oesophageal pH monitoring may be useful in the management of patients with atypical symptoms and may demonstrate significant reflux when inpatient investigations and endoscopy findings show minimal abnormality.

Many tests are available to diagnose gastro-oesophageal reflux and there is a need for a single, reliable, easily performed method for its evaluation.⁴ Short-term recordings of oesophageal pH during the day are less reliable than overnight measurements in the detection of pathological reflux and its differentiation from reflux which is sometimes found in normal persons after meals.⁵ Symptoms are an unreliable guide to the severity of reflux oesophagitis. Twenty per cent of 226 patients with oesophageal strictures studied by Demeester *et al*⁶ did not have reflux symptoms severe enough to require medical attention before the development of dysphagia. Patients rejected for surgical treatment of gastro-oesophageal reflux because of their mild symptoms sometimes returned with a fully developed stricture or advanced oesophagitis. Twenty-four hour oesophageal pH monitoring may allow identification of these high risk patients.⁶

Many patients claim that symptoms are most troublesome during activities at work which involve bending or stooping, manoeuvres that have been shown to increase intra-abdominal pressure resulting in episodes of reflux.⁷ The use of a flexible

pH probe for the assessment of reflux involves unpleasant continuous intubation and ambulatory studies are not possible.⁸ Early pH sensitive radiotelemetry capsules suffered from electrical and temperature drift problems and proved unsuitable in clinical practice.⁹ The development of an improved pH sensitive radiotelemetry capsule (Model 7006, Rigel Research)¹⁰ and a portable receiving system² have made the present study possible.

Method

RADIOTELEMETRY SYSTEM

The pH sensitive radiotelemetry capsule consists of a glass envelope 28×6.6 mm. This contains a glass electrode, a transmitter, a small mercury battery, and a self-contained reference cell measuring pH in the range 1 to 9. Although the approximate battery life is 40 days, the reference cell functions for only about 10 days from the time of activation, as sodium chloride diffuses out and eventually breaks the contact.

Before it was swallowed, the radiotelemetry capsule was sterilised in a solution of 0.1% cetrimide for three to four hours and calibrated in buffer solutions at pH 4.0, 9.0, and 7.0 at 37°C. The radiotelemetry capsule was swallowed without

difficulty and tethered in the oesophagus by a fine bore Polyvinyl tube (O.D. 0.54 mm), which was attached to a thin silastic sleeve fitting tightly over the capsule. A 10 cm length of Clinifeed tubing was guided over the Polyvinyl tube and positioned at the angle of the mouth to minimise discomfort, the tube being fixed to a metal T-piece taped to the cheek. The radiotelemetry capsule was recalibrated at the conclusion of each study to determine the degree of drift during the test.

PATIENTS

Patients with symptomatic gastro-oesophageal reflux were investigated by means of oesophageal manometry, acid perfusion studies, upper gastrointestinal endoscopy, and biopsy. Ten patients (mean age 45.5 years, range 33–69 years) with histologically confirmed reflux oesophagitis subsequently underwent oesophageal pH monitoring for two study periods of 24 hours. Patients' symptoms and degree of oesophagitis, noted at endoscopy and biopsy, were graded according to the criteria defined by Reed and Davis¹¹ (Table 3). In addition, oesophageal pH monitoring was carried out in 10 asymptomatic normal subjects (mean age 31.7 years, range 28–69 years) for a 24 hour study period during normal everyday activities. All subjects were provided with a diet sheet detailing food and drinks with a pH value of less than 5 to be avoided and medication for oesophageal reflux was withheld for the period of the test. The radiotelemetry capsule was positioned 5 cm proximal to the lower oesophageal sphincter high pressure zone, previously determined by a station pull-through technique of oesophageal manometry.

AMBULATORY PH MONITORING

Studies were performed in the 10 patients and the 10 normal subjects using a portable receiving and

recording system.² This consisted of a battery operated FM receiver and combined aerial switching unit which recorded on to a Medilog 4-channel cassette recorder (Oxford Medical Systems, Oxon).³ Signals from the radiotelemetry capsule were detected with a three-aerial belt worn on the upper chest with the aid of shoulder straps. The directional characteristics of the radiotelemetry capsule were minimised by using the three aerials in the orthogonal arrangement, the aerial with the greatest signal strength being automatically switched to the receiver to ensure continuous recording with minimal signal loss during the test. The portable receiving system weighed only 1 kg and was worn by the subject with ease during normal activities. At night the patient continued to wear the chest aerial belt, the waist belt containing receiver and recorder being placed at the bedside to allow unrestricted sleep. Signals recorded on tape were replayed on standard Oxford high speed replay equipment³ at 25 times real time.

RECOGNITION OF ARTEFACT

Artefact on the records occurred as a result of signal loss. During analysis of recordings, periods of signal loss could be confused with changes in pH and therefore a simultaneous recording of signal strength on a separate channel of the Medilog recorder was made to enable signal loss to be identified (Fig. 1). Signal losses during ambulatory studies were less than 10% of the total recording time, the majority being less than 5%. Signal losses during inpatient studies were always low, as patients were largely immobile.

INPATIENT STUDIES

Inpatient studies were undertaken in the same group of 10 patients using the tethered radiotelemetry capsule and standard receiver (Model 7040, Rigel

Fig. 1 Temporary signal losses in the pH recording indicated by the addition of a signal strength channel.

Research, Sutton) and aerial switching unit (Model 7043, Rigel Research, Sutton). The output of the receiver was continuously recorded on a multi-channel pen recorder (Grass Polygraph, Quincy, Mass., USA). This technique, which used conventional receiving and recording systems, restricted the movement of the patients in hospital to the length of the aerial leads and thus to the immediate vicinity of the bedside.

INTERPRETATION OF RESULTS

Reflux episodes were defined in three ways: a fall in pH of at least 2 pH units, the return to the baseline being the duration of the episode; a fall in pH to less than pH5, or a fall to less than pH4, the duration in these cases being the time to return to pH5 or pH4 (Fig. 2).

The data were analysed using the Wilcoxon matched pairs sign rank test to compare ambulatory and hospital studies in the patients. The Mann-Whitney U test was used to compare the normal subjects and the patients.

Results

The baseline level of oesophageal pH was sufficiently constant to be easily recognisable, varying between 6.5–8.0. Twenty-four hour recordings were analysed as day and night records

for a 16 hour day (6.30 am–10.30 pm) and an eight hour night (10.30 pm–6.30 am). For each recording period of 24 hours the period of signal loss was calculated to give a corrected duration of oesophageal reflux. Significant drift (>1 pH unit) was observed in only one instance, necessitating a repeat study.

PATIENT STUDIES

The most important finding was the significantly greater frequency and duration of reflux episodes during ambulatory studies than was observed in hospital. The median number and duration (minutes) or reflux episodes with a fall in pH to less than pH5 per hour were 3.68 (range 0.79–5.18) and 16.7 (range 0.48–38.47) for ambulatory studies during the day compared with 1.09 (range 0–1.84) and 3.94 (range 0–16.12) in hospital ($p < 0.01$, $p < 0.05$ respectively) (Figs. 3 and 4, Tables 1 and 2).

For ambulatory studies the median number and duration (minutes) of reflux episodes with a fall in pH to less than pH5 during the night were 0.67 (range 0–2.7) and 2.07 (range 0–27.54) compared with 0.07 (range 0–1.63) and 0.02 (range 0–11.55) for investigations performed in hospital (Figs. 3 and 4, Tables 1 and 2). The frequency and duration of reflux episodes were significantly greater during the day than at night, both for ambulatory and inpatient studies ($p < 0.01$, $p < 0.01$ respectively).

Fig. 2 pH recording during an ambulatory reflux episode of eight minutes' duration.

Fig. 3 Comparison of the frequency of reflux episode during ambulatory and inpatient recordings in symptomatic patients. Boxes represent the median and quartile values, vertical lines indicate the range.

Fig. 4 Comparison of the duration of reflux episodes during ambulatory and inpatient recordings in symptomatic patients. Boxes represent the median and quartile values, vertical lines indicate the range.

NORMAL SUBJECTS

In the normal subjects studied more reflux was observed during the day than at night. The median frequency and duration (minutes) of reflux episodes with a fall in pH to less than pH5 for ambulatory

studies during the day were 0.62 (range 0.21–1.56) and 0.97 (range 0.02–5.9) compared with 0.07 (range 0–0.75) and 0.09 (range 0–0.73) during the night ($p < 0.01$, $p < 0.01$ respectively) (Tables 1 and 2).

Table 1 Median number of reflux episodes per hour during day and night for ambulatory and inpatient studies

	Symptomatic patients						Normal subjects		
	Inpatient recordings			Ambulatory recordings			Ambulatory recordings		
	All	Fall to pH<5	Fall to pH<4	All	Fall to pH<5	Fall to pH<4	All	Fall to pH<5	Fall to pH<4
Day	1.8 (0.9–4.2)	1.1 (0–1.8)	0.5 (0–1.5)	3.7 (1.3–7.5)	3.7 (0.8–5.2)	2.3 (0.4–4.4)	1.17 (0.55–2.58)	0.62 (0.21–1.56)	0.41 (0.14–0.88)
Night	0.2 (0–2.0)	0.1 (0–1.6)	0.1 (0–1.5)	1.0 (0.2–3.1)	0.7 (0–2.8)	0.3 (0–2.3)	0.20 (0–1.50)	0.07 (0–0.75)	0 (0–0.15)
Total	2.0 (0.9–5.9)	1.2 (0–3.5)	1.6 (0–2.8)	4.8 (1.5–9.2)	4.6 (0.8–7.1)	2.8 (0.4–5.5)	1.63 (0.34–2.75)	0.89 (0.34–1.71)	0.46 (0.23–0.88)

Table 2 Median duration of reflux episodes per hour during day and night for ambulatory and inpatient studies

	Symptomatic patients						Normal subjects		
	Inpatient recordings			Ambulatory recordings			Ambulatory recordings		
	All	Fall to pH<5	Fall to pH<4	All	Fall to pH<5	Fall to pH<4	All	Fall to pH<5	Fall to pH<4
Day	12.4 (1.5-34.9)	4.0 (0-16.1)	1.6 (0-10.8)	23.8 (3.1-38.9)	16.7 (0.5-38.5)	6.1 (0.2-28.8)	3.00 (0.77-9.82)	0.97 (0.02-5.90)	0.24 (0.08-1.06)
Night	2.9 (0-11.9)	0 (0-11.6)	0 (0-5.0)	6.9 (0.6-30.5)	2.1 (0-27.5)	0.3 (0-26.7)	0.84 (0-3.47)	0.09 (0-0.73)	0 (0-0.26)
Total	16.6 (1.5-46.9)	4.4 (0-27.5)	1.6 (0-15.9)	27.4 (4.0-69.3)	17.4 (0.5-66.0)	6.3 (0.2-55.5)	5.17 (0.77-10.66)	1.13 (0.19-6.22)	0.25 (0.11-1.19)

AMBULATORY STUDIES IN PATIENTS COMPARED WITH NORMAL SUBJECTS

The median number of reflux episodes was significantly greater during the day in patients when compared with normal subjects. This was observed when all reflux episodes with a fall in pH of >2 pH units were considered, including those episodes with a fall in pH to less than pH5 and less than pH4 ($p<0.002$) (Fig. 5, Table 1).

The frequency of reflux episodes with a fall in pH to less than pH5 was also significantly greater at night in patients when compared with normal subjects ($p<0.05$) (Fig. 5).

The duration of reflux episodes was similarly greater during the day in patients when compared with normal subjects. This was evident when all reflux episodes with a fall in pH of >2 pH units were considered, including episodes with a fall in pH to less than pH5 and less than pH4 ($p<0.002$) (Fig. 6).

The median duration per hour of reflux episodes with a fall in pH to less than pH5 was also significantly greater during the night in patients when compared with recordings in normal subjects ($p<0.02$) (Fig. 6).

RELATIONSHIP OF SYMPTOMS, ENDOSCOPY, AND ACID PERFUSION TESTS TO ACID REFLUX EPISODES
In four patients with mild (grade 1 to 2) symptoms, the median frequency and duration of acid reflux episodes with a fall in pH to less than pH5 per hour of the day were significantly greater for ambulatory studies compared with inpatient monitoring ($p<0.01$, $p<0.05$) (Table 3). Similarly, in five patients with mild (grade 1 to 2) endoscopy findings the median frequency and duration of acid reflux episodes with a fall in pH to less than pH5 were greater in ambulatory studies than in hospital ($p<0.01$, $p<0.02$) (Table 3). The median frequency and duration of reflux episodes with a fall in pH to less than pH5 per hour in patients with a positive acid perfusion test¹² were significantly greater when

Fig. 5 Comparison of the frequency of reflux episodes during ambulatory recordings in symptomatic patients and normal subjects. Boxes represent the median and quartile values, vertical lines indicate the range.

Table 3 Comparison of symptoms and endoscopy grades with number and duration of reflux episodes with fall in pH to <pH5 per hour during ambulatory and inpatient studies for patients

Patient	Symptom grade	Endoscopy grade	Acid perfusion test	No. of reflux episodes		Duration of reflux episodes (min)	
				Inpatient	Outpatient	Inpatient	Outpatient
PH	2	3	+	0.72	3.79	0.4	5.03
JH	4	1	+	0.59	3.54	3.0	16.89
DH	2	3	+	0	2.04	0	25.13
FC	3	1	+	0.82	0.89	2.53	9.17
BE	1	1	+	1.12	3.62	10.75	7.48
PK	3	4		1.77	3.63	14.45	34.83
BW	3	4		1.15	0.53	6.18	0.32
PB	4	1		0.71	2.50	9.98	13.83
GG	2	1		0.09	3.27	0.05	13.78
RL	3	2	+	0.82	0.90	2.11	9.15

Fig. 6 Comparison of the duration of reflux episodes during ambulatory recordings in symptomatic patients and normal subjects. Boxes represent the median and quartile values, vertical lines indicate the range.

ambulatory than when in hospital ($p < 0.002$, $p < 0.003$) (Table 3).

Discussion

The study of oesophageal reflux using the system described here proved to be accurate and acceptable to patients. During pH monitoring by radio-telemetry, ambulatory subjects could, without difficulty, undertake 24 hours of normal activity including eating a normal diet and carrying out heavy manual work. Our results showed that both the frequency and duration of gastro-oesophageal reflux episodes were significantly greater in the home than was observed in hospital.

In one patient, however, (BW, Table 3) with severe symptoms and marked oesophagitis, acid reflux episodes were more frequent and of longer duration in hospital when compared with the ambulatory study. Although patients were expressly instructed to omit all medication prescribed for the treatment of gastro-oesophageal reflux, we believe that in this case, as symptoms were severe, the ingestion of antacids during the study may well have occurred contrary to instruction. This highlights the need for patients' co-operation during ambulatory studies.

It is known that the severity of oesophagitis is related to the frequency and duration of reflux episodes, particularly the percentage time that oesophageal pH is less than 5.^{13 14} The only previously reported home recordings of oesophageal pH¹⁵ failed to demonstrate any difference in the frequency of reflux episodes between home and hospital study. This technique, however, used conventional methods, which are difficult to tolerate for long periods and render subjects largely immobile.

Studies of normal subjects, using the ambulatory

recording technique described here, show that episodes of gastro-oesophageal reflux occur with a frequency and duration comparable with those observed in normal subjects studied in hospital by other workers.^{14 16} Studies conducted in hospital have shown that patients with reflux oesophagitis experience a greater frequency and duration of reflux episodes than is observed in normal asymptomatic persons.¹⁷ We have found a greater degree of gastro-oesophageal reflux in ambulant patients with reflux oesophagitis when compared with normal subjects.

Further work is required to identify a reliable discriminant of normal and abnormal reflux in ambulatory persons if outpatient recordings of oesophageal pH in symptomatic patients are to be of clinical and diagnostic importance.

It is known that some subjects reflux more while upright than when supine; upright reflux being associated with severe post-prandial symptoms and, in many cases, the eventual appearance of an oesophageal stricture.¹⁷ Although symptoms are severe, histological oesophagitis is often minimal in these patients. Supine pH monitoring in hospital may fail to show significant reflux abnormalities and surgery is considered inadvisable.

If a satisfactory discriminant of abnormal reflux in ambulant patients can be determined, perhaps this group could be identified more accurately by the use of the radiotelemetry ambulatory system.

Ambulatory monitoring of oesophageal reflux using radiotelemetry can be performed acceptably in subjects exposed entirely to their normal environment and may prove to have a useful role to play in the evaluation of the severity of reflux and for the assessment of the efficacy of anti-reflux medication and surgical procedures.

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References

- 1 Colson RH, Watson BW. In: Amlaner CJ Jr, MacDonald DW, eds. Improved techniques in the construction of pH sensitive radio-pills. *A handbook on biotelemetry and radio tracking*. Oxford, New York: Pergamon Press, 1979: 209-12.
- 2 Evans DF, Foster GE, Hardcastle JD, Slater E. *Proceedings of the IIIrd international ambulatory monitoring symposium*. Stott F, ed. London and New York: Academic Press, 414-21.
- 3 McKinnon J. A miniature 4-channel cassette recorder for physiological and other variables. *Biotelemetry IIrd International Symposium, Davos 1974*. Basel: Karger, 1974: 67-70.
- 4 Lipschutz WH. Physiology of the gastro-oesophageal junction and hiatus hernia. In: Bouchier IAD, ed. *Recent advances in gastroenterology*. Edinburgh: Churchill-Livingstone, 1976: vol 3: 1-26.
- 5 Atkinson M, Van Gelder A. Oesophageal intraluminal pH recording in the assessment of gastro-oesophageal reflux and its consequences. *Am J Dig Dis* 1977; **22**: 365-70.
- 6 Demeester TR, Johnson LF, Joseph GJ, Toschano MS, Hall AW, Skinner DB. Patterns of gastro-oesophageal reflux in health and disease. *Ann Surg* 1976; **184**: 459-70.
- 7 Fisher RS, Cohen S. Gastroesophageal reflux. *Med Clin North Am* 1978; **62**: 3-20.
- 8 Wallin L, Madsen T, Boesby S, Sorensen O. Gastro-oesophageal reflux and oesophageal peristalsis method for 12 hour simultaneous recording of pH and peristaltic activity in the oesophagus. *Scand J Gastroenterol* 1979; **14**: 481-7.
- 9 Baron JH. Tubeless tests. *Clinical tests of gastric secretion, histology, methodology, interpretation*. London: Macmillan, 1978: 66-7.
- 10 Colson RH, Watson BW, Fairclough PD *et al*. An accurate longterm pH sensitive radio pill for ingestion and implantation. *Biotelemetry Patient Monitor* 1981; **8**: 213-27.
- 11 Reed PI, Davies WA. Controlled trial of a new dosage form of carbenoxolone (pyrogastrone) in the treatment of reflux oesophagitis. *Am J Dig Dis* 1978; **23**: 161-5.
- 12 Bennett JR, Atkinson M. Oesophageal acid perfusion in the diagnosis of precordial pain. *Lancet* 1966; **2**: 1150-2.
- 13 Moosa AR, Skinner DB. Gastro-oesophageal reflux and hiatal hernia. A re-evaluation of current data and dogma. *Ann R Coll Surg Engl* 1976; **58**: 126-32.
- 14 Stanciu C, Hoare RC, Bennett JR. Correlation between manometric and pH tests for gastro-oesophageal reflux. *Gut* 1976; **18**: 536-40.
- 15 Falor WH, Hansel JR, Chang B, Kraus FC, White HA. Outpatient 24-hour oesophageal pH monitoring by telemetry. *Gastroenterology* 1980; **78**: 1163.
- 16 Boesby S. Gastro-oesophageal acid reflux and sphincter pressure in normal human subjects. *Scand J Gastroenterol* 1975; **10**: 731-6.
- 17 Demeester TR, Wang Ching I, Wernly JA *et al*. Techniques, indications and clinical use of 24-hour oesophageal pH monitoring. *J Thorac Cardiovasc Surg* 1980; **79**: 656-70.

1 Colson RH, Watson BW. In: Amlaner CJ Jr, MacDonald DW, eds. Improved techniques in the construction of pH sensitive radio-pills. *A handbook on*