

Reproducibility of ambulatory oesophageal pH monitoring

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SUMMARY To evaluate the reproducibility of ambulatory 24 hour intraoesophageal pH monitoring, 20 patients were randomly selected to undergo two consecutive investigations. Fifteen patients were classified as either abnormal, or normal on both test days. The amount of acid reflux, expressed as percentage of time with oesophageal pH below 4.0 during the two 24 hour periods, showed 77% concordance. The upright and recumbent periods of measurement showed different degrees of concordance: 83% and 62%, respectively. The reproducibility during time periods of different length was found to increase with increasing length of day time pH recording. A 16 hour period during evening and night had a reproducibility of only 58%, however. It is concluded that there is fairly good reproducibility when measuring gastro-oesophageal reflux over 24 hours, but that the reproducibility is poorer at night, during the postprandial period and when daytime monitoring is shorter than 10 hours.

Extended pH monitoring has been found to be a useful test for pathological gastro-oesophageal reflux. Different authors have reported a sensitivity of slightly less than 90% and a specificity close to 100%.¹⁻⁴ Ambulatory monitorings have been introduced to provide a physiologic quantification of reflux with the patient in his normal surroundings.^{4,7} pH monitoring has increased our understanding of reflux disease as various patterns or reflux have been identified.^{8,9} Furthermore, the test is useful in the evaluation of medical and surgical therapy of gastro-oesophageal reflux disease¹⁰⁻¹⁴ and may help in patient management. Factors provoking reflux such as exercise and food may be evaluated by 24 hour pH monitoring. It may also be useful to correlate the patients' symptoms to reflux episodes.¹⁵

Despite the numerous reports of the usefulness of 24 hour pH monitoring and its widespread use in clinical research, very few reports of the reproducibility of the test have been published.^{16,17} The present study was undertaken in order to identify which time period has the best reproducibility. Furthermore, the reproducibility during time periods of different

lengths has been investigated to determine if it is possible to shorten the monitoring time while maintaining reliability.

Methods

PATIENTS

We have studied 20 patients, eight women and 12 men, with a mean age of 51 years (range 35-69). All were referred to our oesophageal laboratory because of suspected gastro-oesophageal reflux disease and were randomly selected for this study. They underwent ambulatory oesophageal pH monitoring during 48 hours - that is, during two consecutive days. Before pH monitoring, endoscopy was carried out to diagnose erosive oesophagitis and to exclude the possibility of an oesophageal stricture. Standard oesophageal manometry with water perfused catheters was also done in order to identify the pressure and position of the distal oesophageal high pressure zone. The pressure was measured end expiratory at the point of respiratory reversal. Furthermore, the diagnoses of scleroderma, achalasia, and diffuse oesophageal spasm were excluded.

Ambulatory oesophageal pH-monitoring was done using Synectics portable pH-measuring equip-

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ment consisting of an antimony pH electrode, a silver-silverchloride reference electrode and a solid state memory box. After calibration at pH 7 and 1 the pH electrode was introduced nasally and the pH recording tip placed 5 cm above the oral margin of the distal oesophageal high pressure zone previously located by oesophageal manometry. The reference electrode was placed on the chest and the memory box was worn on a waistbelt. During the pH monitoring the patients were told to lead as normal life as possible, at home or at work, with a similar degree of activity during the two days of monitoring. They were instructed to eat similar food during the two days and at the same hours. Acid food and beverages and alcohol consumption was not allowed. The patients were told to go to bed and to rise in the morning according to their usual routine. After 24 hours the patients returned to the laboratory in order to check the position of the electrodes and to zero the solid state memory. At the end of the study the baseline level of the pH recording was controlled in order to exclude the possibility of base line drift. Furthermore, another check of the position of the electrodes was done. The reflux found on each day was separately analysed by a computer program (Esophogram, Gastrosoft) on an IBM personal computer.

Reflux, expressed as the percentage of time with pH below 4, was calculated for the total monitoring and the upright and recumbent periods. The test was considered pathological if the percentage of time with pH below 4 during 24 hours exceeded 3.4%.⁴ Furthermore, postprandial reflux (two hours after the main meal), various lengths of day time reflux (4, 6, 8, 10, and 12 hours) and overnight 16 hour reflux (4 pm to 8 am) were recorded.

STATISTICAL ANALYSIS

The reproducibility was calculated by performing a linear regression between the variables of the first and second day and expressed as the square of the correlation coefficient. In order to better express reproducibility the regression line was passed through the origo.

Wilcoxon's test for paired data was used for the comparison of the amount of reflux between the two study days.

Results

The amount of gastro-oesophageal reflux during the two days expressed as the percentage of time with pH below 4 for the total 24 hours is shown in Figure 1. For 24 hours the degree of concordance was 77% ($r=0.87$). The corresponding figures for the upright and recumbent periods were 83% ($r=0.91$) and 62% ($r=0.79$), respectively.

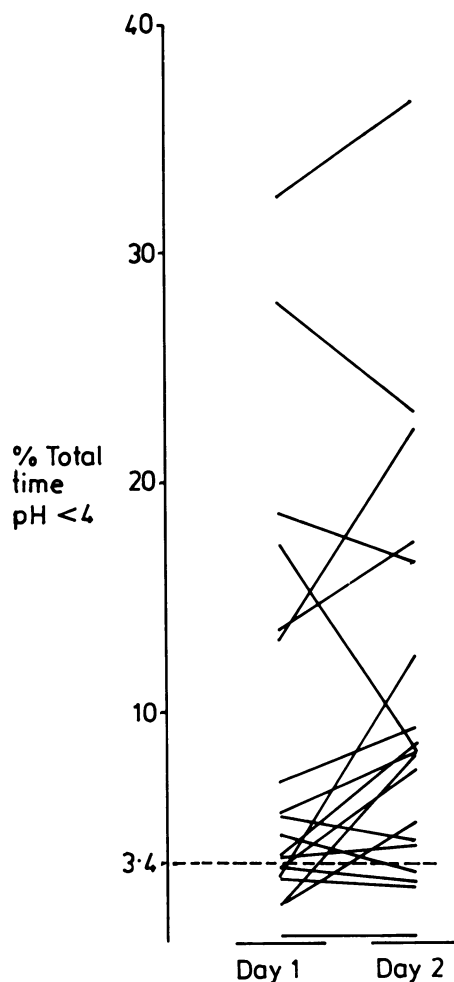


Fig. 1 Amount of gastro-oesophageal reflux at pH-monitoring during two consecutive 24 hour periods.

The reproducibility of postprandial reflux was 11% ($r=0.33$), of four hour day time monitoring 0% ($r=0$), of six hour 23% ($r=0.48$), of eight hour 41% ($r=0.64$), of 10 hour 77% ($r=0.87$), and of 12 hour 83% ($r=0.91$). The corresponding figure for overnight 16 hour monitoring was 58% ($r=0.76$) (Fig. 2).

Gastro-oesophageal reflux was found to be either normal or abnormal on both days in 15 (75%) of the 20 patients. On the first day eight patients exhibited normal reflux and 12 pathological, while on the second day five had normal and 15 pathological reflux.

During the first study day the median time with oesophageal pH below 4 was 4.3% of the total time (range 0.1–32.5). The corresponding figure for the second day was 8.2% (0.1–36.8). This difference was not statistically significant ($p=0.1474$).

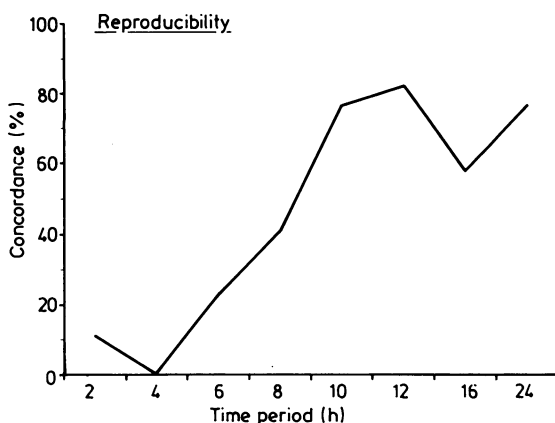


Fig. 2 Reproducibility of monitoring periods of different length. The two hour period is postprandial, four hour to 12 hour are day time and the 16 hour period is overnight (4 pm–8 am).

The median pressure of the distal oesophageal high pressure zone was 11 mmHg (range 4–7–30). Erosive oesophagitis was found in four patients, the remaining 16 patients had no oesophagitis at endoscopy.

Discussion

We have shown that the reproducibility of ambulatory 24 hour pH monitoring is 77%, when the test is done during two consecutive 24 hour periods.

The variability of the test results in this study mainly stems from the variation in gastro-oesophageal reflux that is seen with time. Variations in gastro-oesophageal reflux are known to occur with meals⁸ and activity,¹⁸ and even if we have tried to make the two days as similar as possible, it is obvious that these factors vary in an ambulatory environment. It is possible – for example, that the patients would be more active on the second day when they got used to the monitoring equipment. There was, however, no significant difference in the amount of reflux between the first and second day. Rather surprisingly, the concordance between the two days was better in the upright period than in the recumbent in our study. The opposite could be suspected as the recumbent period implies more standardised conditions. Comparison of the degree of concordance between different time periods should be done with caution because great variations in the amount of reflux between the two days in some patients will strongly affect the degree of concordance. It is, however, obvious that factors other than food and activity affect the amount of reflux during the night and lead to the variability in our results. The exact mechanisms are unknown, but the pressure of the

distal oesophageal high pressure zone is known to vary considerably with time.¹⁹ Other factors of importance could be the amount and the acidity of the gastric juice, oesophageal motor activity and the amount and pH of saliva. The weaker concordance of recumbent monitoring could also be due to the fact that this monitoring period was considerably shorter than the upright period. In most patients the recumbent period lasted about eight hours.

It should be noted that the study design implies that we have not studied the variability of the test that may be because of the placement of the pH electrode. In our experience, however, the use of oesophageal manometry to identify the distal oesophageal high pressure zone make misplacement of the pH electrode a rare problem. Furthermore, technical errors in the monitoring are discovered during the computer analysis. In fact, two additional patients were studied but excluded because of loss of electrical contact at the reference electrode the second day.

Sontag *et al*²⁰ have suggested that the postprandial reflux is responsible for oesophageal mucosal injury and postprandial pH testing has been reported to be highly accurate in the diagnosis of pathological reflux by Fink *et al*.¹ The present study shows, however, that postprandial recording has poor reproducibility and cannot be recommended. If a short day time pH test is done it has to last for at least 10 hours and preferably for 12 hours to provide an acceptable reproducibility. It may be difficult to fit these time periods into the hospital routine, especially if oesophageal manometry is carried out before the pH test the same day. Furthermore, the importance of monitoring reflux in the recumbent position has been stressed by others.^{8,21} Fink *et al*¹ have reported that an overnight test of 12 hours (four hours upright and eight hours recumbent) is highly accurate and could be adopted to outpatient telemetry. In our patients the overnight test has a considerably poorer reproducibility than the 24 hour test. Furthermore, the 24 hour test fits well into the hospital routine. Another important aspect is that by pH-monitoring it may be possible to correlate the patients' symptoms to reflux events. From this point of view, it may be useful to record an entire circadian period.

Identification of gastro-oesophageal reflux as either normal or abnormal coincided in 15 of our 20 duplicate studies. Interestingly, this is exactly the same result as Bontempo *et al* have reported.¹⁶ In what way do these results affect the opinion of 24 hour pH-monitoring as a highly sensitive and specific test for gastro-oesophageal reflux? The reports on this subject^{1–4} are generally carried out on a selected group of patients, often with endoscopic signs of reflux disease, comparing their results of the test with

those of normal subjects. This means that patients with mild gastro-oesophageal reflux and border line cases may not be included in the studies which is understandable for precision. The present study indicates, however, that there is a considerable number of patients with suspected gastro-oesophageal reflux disease that are in a 'grey zone' near the limit of normality. This implies that the results of the test should, in such patients, be interpreted with caution and that it is advisable to repeat the test in doubtful cases. Furthermore, the day-to-day variations in gastro-oesophageal reflux that are seen in this study emphasises the importance of obtaining information from pH metry, manometry, and endoscopy when future therapy, medical, or surgical, is designed in reflux patients. The results of the study must also be taken into account when pH-monitoring is used in the evaluation of medical and surgical therapy.

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