

Diagnostic accuracy of pH monitoring in gastro-oesophageal reflux

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SUMMARY One hundred and eleven children admitted with suspected gastro-oesophageal reflux were studied, with 24 hour oesophageal pH monitoring as the first line of investigation. Barium swallow examination, or oesophagoscopy, or both, were carried out only in children with abnormal pH, who subsequently had a trial of 1-12 months medical treatment. All patients were followed up for eight months to two years. A final diagnosis of gastro-oesophageal reflux was made in 41 patients, in all of whom the pH study was abnormal (100% sensitivity). The final diagnosis was different in 70 patients; 66 of these had a normal pH (94% specificity). All children with gastro-oesophageal reflux were treated with drugs. All those with a percentage reflux time of more than 27 and more than 20 episodes of reflux lasting more than 5 minutes failed to improve and needed operation.

We conclude that monitoring of the oesophageal pH should be the first line of investigation in patients with gastro-oesophageal reflux and should be used together with clinical data and other investigations, to identify those children who will need operation.

Early diagnosis of gastro-oesophageal reflux is important for the prompt institution of antireflux treatment and the prevention of potentially serious complications—for example, severe oesophagitis, oesophageal stenosis, and aspiration syndrome.

Several methods for the diagnosis of gastro-oesophageal reflux are available. Among them 24 hour oesophageal pH monitoring is considered the most sensitive and the most specific.¹⁻² Nevertheless it is not yet common practice to use this as the initial investigation for patients with suspected gastro-oesophageal reflux. There is a tendency to prefer traditional tests like barium swallow,³⁻⁵ which are considered to be more practical.

In addition, no investigation seems able to predict those patients who will eventually need operation. In fact it is still widely held that the decision to recommend operation should be based upon the clinical history and failure of drug treatment.³⁻⁸

We have therefore evaluated 24 hour oesophageal pH monitoring as the first line of investigation in the diagnosis of gastro-oesophageal reflux to determine whether predictions can be made based solely on this investigation as to which patients will require surgical and which will require medical treatment.

Patients and methods

From January 1985 to December 1987, 111 infants and children aged 1 month to 13.5 years (median 9.3 months) were admitted with signs and symptoms typical of gastro-oesophageal reflux. The presenting complaints are listed in table 1.

Twenty four hour oesophageal pH monitoring was routinely carried out in all patients with a 3 mm diameter combined glass probe (pH electrode plus

Table 1 *Presenting symptoms in the 111 infants and children admitted for suspected gastro-oesophageal reflux*

	No (%) of infants
Vomiting	69 (61)
Failure to thrive	29 (26)
Feeding difficulties	20 (18)
Haematemesis	15 (13)
Recurrent pneumonia	14 (12)
Recurrent wheezing	12 (11)
Chronic cough	11 (10)
Apnoeic spells	11 (10)
Iron deficiency anaemia	10 (9)
Epigastric pain	10 (9)
Irritability	7 (6)

reference electrode: lot 440/M3 Ingold), connected to a computerised pH recorder (Proxima 1-2 Exor). This instrument allows the collection of data about oesophageal pH by sampling, which can be programmed for frequency and duration. We use the 24 hour pH monitoring with sampling every eight seconds.

The probe was calibrated in pH 4 and pH 7 buffer solutions before and after use. It was introduced into the stomach transnasally and then retracted and placed above the lower oesophageal sphincter at a point equal to 13% of the distance between the nares and the lower oesophageal sphincter calculated by the formula of Strobel *et al.*⁹

During the test, children were allowed unrestricted diet and activity. The instrument is battery powered, small and light weight. It is carried in a leather case fitted with a shoulder strap so the patients are able to enjoy considerable freedom of movement.

The data are memorised on a solid state memory and are rapidly analysed and printed out: the instrument prints the pH graph as a function of time, and also records the following measurements: (i) total percentage reflux time; (ii) total number of episodes of reflux in 24 hours; (iii) number of episodes of reflux lasting more than five minutes in 24 hours; (iv) duration (in minutes) of the longest episode of reflux; (v) the mean duration (in minutes) of all the reflux episodes.

An episode of reflux is defined as a drop in the oesophageal pH to a value of 4 or less for at least eight seconds.

Normal values (table 2) have been obtained from 14 asymptomatic infants and children aged from 3 to 68 months (median 12.5 months), who had no history or symptoms suggestive of gastro-oesophageal reflux. The upper limit of normal for all measurements was arbitrarily defined as two standard deviations above the mean value of each value measured in the control subjects.

In patients with a normal oesophageal pH tracing no further investigations were carried out and no treatment was instituted, but regular follow up was arranged for a period of time ranging from eight months to two years.

A barium swallow examination or oesophagoscopy, or both, were carried out only in children whose oesophageal pH was abnormal. This group of patients then underwent a one to 12 months' trial of medical treatment, which consisted of a combination of thickened feeding, sleeping in the prone position with their shoulders raised by 30°, bethanechol and, for documented oesophagitis, antacids, and ranitidine. Only patients in

Table 2 Mean (SD) normal values of 24 hour pH monitoring in control group (n=14)

Percentage reflux time	2.08 (1.75)
No of episodes of reflux	23.71 (20.70)
No of episodes of reflux lasting >5 minutes	0.85 (0.86)
Duration of the longest episode of reflux (min)	7 (4.37)
Mean duration of all episodes of reflux (min)	1.33 (0.52)

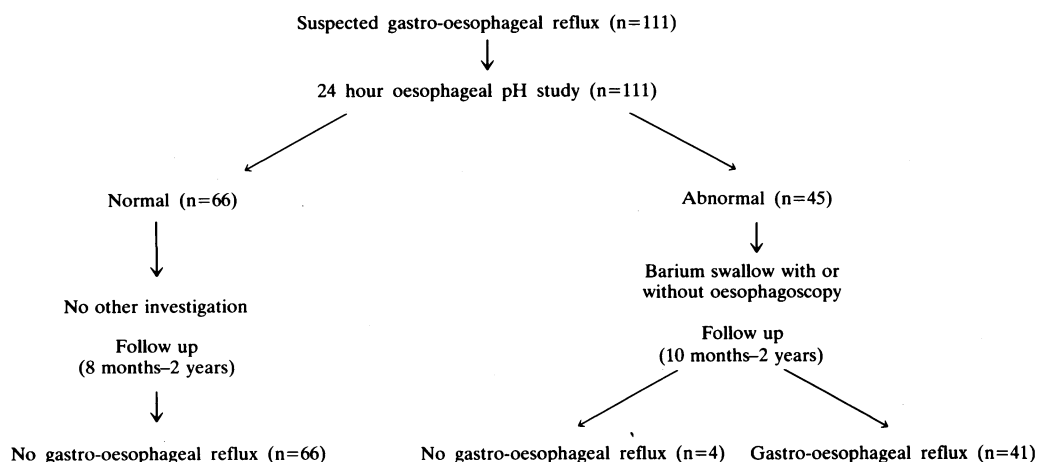


Fig 1 Diagnostic flow chart.

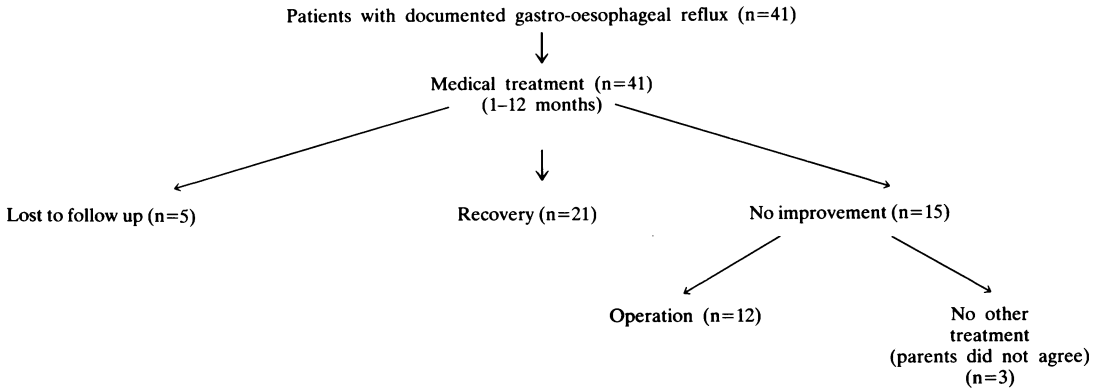


Fig 2 Therapeutic flow chart for 41 patients with gastro-oesophageal reflux.

whom medical treatment had failed were offered operation.

The sensitivity, specificity, and positive predictive value of 24 hour pH monitoring for the detection of gastro-oesophageal reflux were calculated.

Results from those patients who responded to

medical treatment and those who required operation were compared by the Student's *t* test.

Results

The diagnostic procedures and the first results are summarised in fig 1.

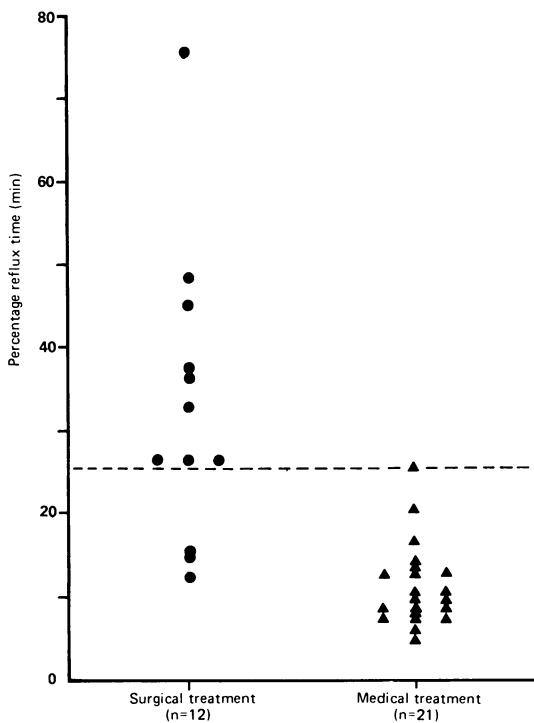


Fig 3 Percentage of reflux time in the two groups. Mean and three standard deviations is shown for group receiving medical treatment (-----).

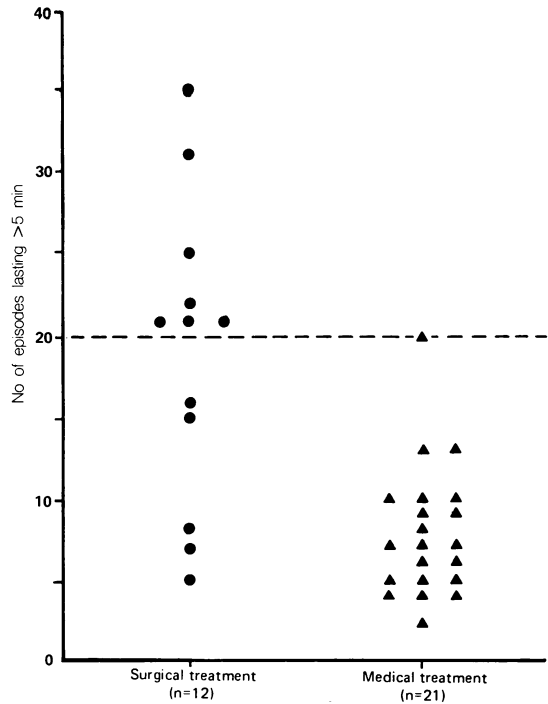


Fig 4 No of episodes of reflux lasting longer than 5 minutes in the two groups. Mean and three standard deviations is shown for group receiving medical treatment (-----).

Table 3 *Comparison of the mean (SD) reflux values between surgically and medically treated patients*

	<i>Surgical treatment (n=12)</i>	<i>Medical treatment (n=21)</i>	<i>p Value*</i>
Percentage reflux time	33.46 (16.88)	11.69 (4.98)	0.001
No of episodes of reflux	157.75 (59.76)	80.57 (61.42)	0.002
No of episodes of reflux lasting >5 minutes	19.75 (9.47)	7.81 (3.96)	0.001
Duration of longest episode of reflux (min)	52.83 (42.76)	28.05 (31.28)	0.1
Mean duration of all episodes of reflux (min)	3.42 (2.39)	2.86 (1.66)	0.5

*Student's *t* test.

Of the 111 pH studies performed, 66 were normal. The diagnosis of gastro-oesophageal reflux in these patients was further ruled out during the clinical follow up.

In the remaining 45 the percentage of reflux time as well as at least two other measurements were abnormal.

In 41 of the 45 children with abnormal pH studies the diagnosis of gastro-oesophageal reflux was confirmed by a barium swallow examination or oesophagoscopy, or both. Four children had different final diagnoses (coeliac disease, parasternal hernia of Morgagni, recurrent urinary tract infections, and megaesophagus).

The test has 100% sensitivity (41 out of 41) in the diagnosis of gastro-oesophageal reflux and a specificity of 94% (66 out of 70), with a positive predictive value of 91%.

Symptoms disappeared in 21 (51%) of the 41 children suffering from gastro-oesophageal reflux who underwent medical treatment (fig 2), while they persisted in 15 (37%). Of this last group, 12 children underwent operation with complete resolution of symptoms and normalisation of the oesophageal pH.

In three patients who are still suffering from gastro-oesophageal reflux, operation has not yet been carried out as parents have withheld consent. Five children (12%) were lost to follow up.

The success of medical treatment was higher in children under 18 months of age (17 of 23, 74%) compared with those who were older (four of 13, 31%).

Severe neurological damage was present in four children: two did not respond to conservative treatment and required operation.

Table 3 shows the pH results in the medically treated and the surgically treated patients. There were significant differences between the two groups for three measurements: the percentage of total reflux time ($p=0.001$), the number of episodes lasting longer than five minutes in 24 hours

($p=0.001$), and the total number of episodes of reflux in 24 hours ($p=0.002$).

The results of the pH studies in the three children who did not improve after 12 months of medical treatment and who have not yet had operations were similar to those of the surgical group.

On analysing the measurements for each patient we found an overlap for each measurement of the values of the medically and surgically treated groups: the least overlap was seen in the percentage of reflux time and in the number of episodes of reflux lasting longer than five minutes. In 9/12 (75%) and 7/12 (58%) of cases, respectively, these values were higher than both the maximum value and the average value plus three standard deviations of those of the patients successfully treated medically (figs 3 and 4).

Discussion

Some authors routinely carry out a barium swallow examination,³⁻⁵ which is thought to be more useful than pH monitoring despite its poor sensitivity and specificity,^{10 11} and others recommend further investigations (oesophagoscopy, gastric scintiscan, and manometry) usually in children with atypical manifestations of the disease.^{5 8 12}

Our findings showed that 24 hour pH monitoring has high sensitivity and specificity, confirming the work of other authors^{1 2}; we believe that it should be used as the first line of investigation in the diagnosis of gastro-oesophageal reflux.

Contrary to Schlesinger *et al*¹³ we did not find any false negatives, so we conclude that a negative result must be thought of as being sufficient to rule out gastro-oesophageal reflux. This avoids further less sensitive and specific as well as potentially more harmful investigations such as barium swallow examination. In our experience the 24 hour pH monitoring was easy to do, well tolerated, and free from complications.

We believe that a barium swallow examination or

oesophagoscopy, or both, are justified after a positive pH study or when an upper gastrointestinal malformation, an oesophageal stenosis, or oesophagitis are suspected. Gastric scintiscan should be used to detect bronchopulmonary aspiration.

After a diagnosis of gastro-oesophageal reflux has been reached, the therapeutic options (especially the indications for operation) must be considered.

Most authors agree that the clinical picture is of utmost importance in the therapeutic approach. The presence of serious symptoms or complications (such as severe oesophagitis with or without associated oesophageal stenosis, apnoeic spells, aspiration), or anatomical defects (such as severe hiatal hernia and previous oesophageal atresia) are often considered to be indications for operation.³⁻⁸

Apart from these, operation may become necessary after the failure of medical treatment, which according to different authors can be given for a period of time varying from six weeks⁶ to three years.¹⁴

The age of the patients should also be considered. In the cases we studied the indication for operation was much higher among children older than 18 months of age (9/13, 69%) as opposed to those who were younger (6/23, 26%). This confirms previous work¹⁵ and is in accordance with the natural spontaneous improvement of the disease up to 18 months of age.^{8, 16}

Surgery is particularly indicated in children with central nervous system abnormalities in which vomiting, poor growth, and pulmonary complications are important, and who usually respond poorly to medical treatment.^{5, 12, 14} In our study there were only four patients with such abnormalities and two of them had operations.

The role of diagnostic procedures in identifying patients at particular risk for surgery is not well documented, but most of them seem to be useless. In a recent study the presence of severe oesophagitis confirmed histologically was reported as having a prognostic value in identifying those patients in whom medical treatment was most likely to fail.¹⁷

Few and contradictory data have been published about the use of prolonged oesophageal pH probing in predicting which patients will need operation. In 1986 Koch reported that 24 hour oesophageal pH probing is useless in the prediction of which patients need operation.¹⁸ In the same year Ramenofsky *et al* found a significant correlation between a low number of episodes of reflux (less than 38-43) and the success of medical treatment.¹⁹ Evans *et al* showed that a frequency duration index (calculated, before starting medical treatment, by multiplying the cumulative duration/hour by the mean frequency of reflux/hour) was significantly lower in the

medically treated patients than in those who subsequently underwent operation.²⁰

Our findings also suggest the usefulness of 24 hour pH monitoring in order to identify those patients who will not benefit from medical treatment. We studied the 'classical' measurements described by DeMeester *et al*.¹ Among them the more significant and those with the least overlap between medical and surgical patients were the percentage of reflux time and the number of episodes of reflux lasting more than five minutes in 24 hours. All patients with a percentage of reflux time higher than 27, or with more than 20 episodes of reflux lasting more than five minutes, or both, needed operation. In addition, the total number of episodes of reflux in 24 hours was significantly greater in the surgically treated patients than in those who received medical treatment even though, in contrast to the data presented by Ramenofsky *et al*,¹⁹ we found considerable overlap between the two groups.

Our findings therefore show that patients with a percentage of reflux time greater than 27, or more than 20 episodes of reflux lasting more than 5 minutes, or both, have little chance of improving on medical treatment. In such patients medical treatment should, however be given for a short period, certainly less than a month.

To come to definitive conclusions about the role of oesophageal pH monitoring in predicting the need for operation, a larger number of patients should be studied. Nevertheless our data suggest that the pH probing should be used together with clinical data or other investigations, or both, to identify those children who will not respond to medical treatment, but rigid criteria cannot yet be set.

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