Reproducibility of oesophageal pH monitoring

Stib—We were interested to see the data which Vandenplas et al presented on the reproducibility of oesophageal pH monitoring for use in asymptomatic European children.1 There are, however, two ways in which our own, similar, study1 differs from theirs which we think merit discussion. The first is that Vandenplas et al document the child’s meal times, position, and behaviour on the first day and exactly mimics this on the second day. In our study we did not impose such limitations with a view to gaining a better understanding of the likely variation in the amount of gastro-oesophageal reflux occurring from day to day. In the normal situation behaviour varies in a way which may influence the pattern of gastro-oesophageal reflux.

The second point which must be discussed relates to the analysis and interpretation of their results. As correctly discussed, the use of correlation coefficients is inappropriate for examining reproducibility and difference analysis should be used. As shown diagrammatically and stated in the text, the differences between the two results increase as the mean result increases—that is, the difference is proportional to the mean. Thus the differences should be analysed after logarithmisation of the results and expressed either as a ratio or a percentage difference and not as absolute values as used here.1 Using this method we showed a 95% chance that a second reflux index would be between 0·27 and 3·7 times the first.

Vandenplas et al’s unlogged results for reflux index give a 95% chance of a second study having a result within 8% of the first (as shown in their Fig 3). This would mean that a reflux index of 10% one study would be followed by a second study with a result anywhere between 2% and 18%. Although none of the children studied had results which changed from normal to abnormal, this potential variation is considerable. We support the contention that the pH study is ‘highly reproducible’. If the logged results had been used the difference would have been a proportion rather than an absolute value and thus less with lower reflux indices and more with higher ones.

The data presented show that considerable differences may occur in 24 hour oesophageal pH studies in children even when restrictions are placed on their behaviour. Our own study supports this argument: such restrictions differences are even greater. This must be taken into account both clinically and in trials of treatment.

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Reply

Stib—The comments of Dr Hampton and Dr MacFadyen are very interesting and confirm our opinions. The study by Hampton et al is a logical continuation of our study: once pH data had been shown to be reproducible, all factors of possible influence being standardised (our study),1 a second study was necessary to analyse how much point variation (i.e. 5% difference index of reflux) data (Hampton study).1 It is logical that data recorded under these study conditions are less reproducible.

The study on the reproducibility shows that if data are clearly within normal ranges there is a good possibility of the results being comparable when recorded a second day. The same is true if data are clearly ‘abnormal’, although differences between two consecutive recordings might be higher. Using our study data and MacFadayen confirm this in their letter: if the logged results had been used, there would be less difference with lower reflux indexes and more with higher ones. So, the conclusion with unlogged or logged results is exactly the same.

We knew of Bland’s book.1 It is our opinion, however, that it is preferable to compare data in the same way they are presented. Taking logarithmics might be mathematically correct, but pH monitoring data for comparison are typically presented as such. Reproducibility also depends on the material that is used: comparability of simultaneous recordings with two identical oesophageal electrodes for the same patient (r=0·90 for the % time pH <4 reflux index) is statistically inferior to the comparability obtained with two glass electrodes (r=0·99 for the reflux index).4 Therefore, the results of the reproducibility study of Johnson and Joelson are excellent and comparable to ours: they report a correlation coefficient of 0·87 for two consecutive 24 hour recordings with antimony electrodes.

We stated in the article that we were lucky to have no patient who changed from ‘normal’ to ‘abnormal’, or the other way around. Normal ranges of physiological gastro-oesophageal reflux have been shown to vary ‘quite a lot’ in large groups of asymptomatic controls. The percentiles for the reflux index in a ‘normal’ population were shown to vary from 0 to 10% (P<0·05).5

As we stated in a recent review article,6 the answer to the simple question ‘is normal’ or ‘abnormal’ is clear cut in only a few cases. There is a considerable overlap between ‘normal’ and ‘pathological’.

The results of our study show that there are only a few percentage points difference of, for example, a reflux index of <5% or >15%, since the risk that the interpretation of the results of a second day’s recording would be different is minimal. There remains a problem for the practitioner in that new treatment for this is the ‘all’ or ‘none’ interpretation of pH monitoring data by a computer using a ‘cut off’ limit. For a software program pH 3·99 is ‘abnormal’ and pH 4·01 is ‘normal’. For the patient, however, there is no difference at all. Therefore, we think that the development of new parameters, such as the ‘oscillatory index’ is of great interest. This parameter calculates the percentage of time the pH oscillates around pH 4·00—that is, between 3·7 and 4·3—and therefore quantifies the all or none consequences of the application of a cut off limit.

Our results show that 24 hour pH monitoring data are ‘highly reproducible’. When data are clearly within normal limits (and this is related more to the use of a cut off limit than to patient or technique related factors) they should be interpreted with care, and use of the percentiles instead as well as the oscillatory index might be very helpful.

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10 Vandenplas Y, Loeb H. The interpretation of
From fibreoptic concernings the contaminated instruments appropriately. Manufacturers’ manual beforehand can be put into automated systems effectively.

Elimination of high titre HIV from fibreoptic endoscopes

Str.- I would like to congratulate Dr Hanson and his colleagues on their encouraging paper concerning the elimination of high titre HIV from fibreoptic endoscopes. It confirms that thorough cleaning and removal of all organic material is the most important step in the decontamination process and necessary for disinfectants to be fully effective. Unfortunately, the last sentence of Dr Hanson’s excellent article, which advocates the use of machines to ensure good cleaning, may be misunderstood in three ways:

(1) That trained and experienced endoscopy staff need not be employed or existing staff can be replaced by a machine;

(2) That equipment does not need manual cleaning before being put into automated systems;

(3) That even in the absence of pre-disinfection manual cleaning, equipment has been decontaminated effectively because it has been put through an automated ‘cleaning’ and disinfection cycle.

There are at present no automated disinfection machines available which can replace manual cleaning with brushes before disinfection. Trained and experienced staff are required because endoscopes and their accessories need to be dismantled according to manufacturers’ instructions so that all contaminated areas can be cleaned and disinfected appropriately. In inexperienced hands contaminated instruments may be left to be cleaned at a more convenient time, allowing organic material to dry in the channels. Disinfection machines, which are often claimed to be effective cleaners, cannot carry out proper disinfection unless equipment has been cleaned manually beforehand and all organic material has been removed. The presence of any organic material will prevent adequate penetration of disinfectants. This has been shown in a case report where an endoscope, which was later found to be contaminated with Salmonella typhimurium, was put into an automated cleaning/disinfection machine without prior manual cleaning. Nine days after the presumed contamination, S. typhimurium could still be recovered from the endoscope despite it having gone through several automated cleaning/disinfection cycles during that time. Another efficacy failure of an automated machine has been reported from the United States, where, after adopting an automated method of cleaning endoscopes, a hospital noted a dramatic increase in the prevalence of bile cultures positive for Pseudomonas aeruginosa. They traced the organism to a single endoscope contaminated with P. aeruginosa. Although the instrument had been cleaned and disinfected repeatedly with an automated system, several channels were not adequately cleaned or dried by the washer/disinfector.

Despite rejecting the use of automated cleaning/disinfection machines without prior manual cleaning I do advocate their appropriate use for consistent disinfection. Moreover, they reduce staff contact exposure to glutaraldehyde liquid and to vapour during the disinfection cycles, though they may increase vapour exposure during the filling and emptying of machines. (J R Babb, personal communication). Automated machines are complementary to manual cleaning and to trained and experienced staff, but cannot replace them.

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1 Hanson PJV, Gor D, Jeffries DJ, Collins JV. Elimination of high titre HIV from fibreoptic endoscopes. Gut 1990; 31: 657-9

Reply

Str.- We agree entirely with the points raised by Ms Neumann. It is only through misinterpretation of the first part of the sentence that the large reductions in HIV achieved in our study were the result of manual cleaning. It has been suggested that endoscopes contaminated with HIV must be cleaned in an automated machine and our findings do not support this view. I welcome Ms Neumann’s reminder that there is no substitute for trained endoscopy personnel and that endoscopes must be precleaned before being placed in any of the currently available ‘automatic’ machines.

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Systemic chemotherapy for Helicobacter pylori eradication?

Str.- Recent studies indicate the involvement of Helicobacter pylori in several upper gastrointestinal disorders including antral type B gastritis, duodenal ulcers, and non-ulcer dyspepsia. The approach to delivery of drug treatment for H. pylori infection is currently based on the concept of therapeutic delivery from the gastric juice after drugs have been given orally. The aim of this is eradication. Ucer relapse rate has been found to correlate with recurrence of infection. Success rates range from 33-100% for immediate eradication of H. pylori, with many patients having a recurrence within one month of stopping treatment, often with the same bacteria. The fact that bacteria are sensitive in vitro but much less so in vivo to a number of antimicrobials has

Illustration of alternative concepts of delivery of xenobiotics to gastric Helicobacter pylori.
(A) Proposed mechanism. (B) The alternative interpretation. (C) The rationale of intravenous treatment with antibiotics.