

Timed barium esophagogram in the assessment of patients with achalasia: Reproducibility and observer variation

S. Kostic,¹ M. Andersson,² M. Hellström,² H. Lönroth,¹ L. Lundell³

Departments of ¹Surgery and ²Radiology, Sahlgrenska University Hospital, Göteborg and ³Department of Surgery, Karolinska University Hospital, Huddinge, Sweden

SUMMARY. The timed barium esophagogram (TBE) is a further development of the barium swallow, introducing functional and dynamic dimensions to the assessment. The purpose of our study was to assess the day to day variability of TBE parameters when scored in healthy subjects, in untreated and in previously treated patients with confirmed diagnoses of achalasia and to assess the intra- and interobserver agreement. After fasting, the subjects drank 250 mL of low-density barium sulfate suspension. Radiographs of the esophagus were exposed at 1, 2 and 5 min after the start of the barium ingestion. The heights and widths of the barium column and changes in these parameters over time (esophageal emptying) were assessed. Each subject was re-tested after a median time interval of 8 days. Healthy individuals emptied their esophagi effectively and promptly with no significant amount of contrast remaining in the lumen after 2 min. In the achalasia patients all TBE variables differed profoundly compared to the controls. There was an excellent intra- and interobserver agreement for all measured variables. The reproducibility of the static TBE variables from day-to-day was good, but not so for the functional assessment of esophageal emptying, having a correlation coefficient of only 0.50. The usefulness of TBE as a clinical and research tool in achalasia patients requires further evaluation.

KEY WORDS: achalasia, esophagus, observer variation, radiography, reproducibility of findings.

INTRODUCTION

A progressive degeneration of enteric neurons is pathognomonic for achalasia, leading to deficient bolus passage through the gullet. The dominating symptom in patients with achalasia is therefore a wide spectrum of severity of dysphagia. These symptoms commonly lead to various diagnostic procedures, including manometry, which is crucial in the evaluation process.¹ The landmark diagnostic criteria for achalasia are incomplete or absent relaxation of the lower esophageal sphincter in response to appropriate stimulation, with or without concomitant deterioration or absence of esophageal body motility.

Another consequence of the nerve degeneration is impaired sensory perception from that region. Taken together, these pathogenetic circumstances give a

reasonable explanation for the lack of correlation between symptom severity and objective criteria.^{2,3}

In order to simplify the management of achalasia patients it would be advantageous to have a diagnostic modality that could be used outside the specialized institutions, which offers acceptable accuracy before the diagnostic work-up process demands more advanced technology. Barium swallow has long been used to diagnose achalasia. A further development of the barium swallow concept has been presented in the form of the timed barium esophagogram (TBE)⁴ which has been applied to untreated achalasia patients as well as patients treated with pneumatic dilatation and surgery.^{5,6} The potential advantage of TBE is that it offers dynamic information and standardized assessment of the esophagus. Therefore, we embarked on a study to formally address intra-individual day-to-day variations of the TBE parameters as well as intra- and interobserver reliability in the assessment of these parameters. By estimating the accuracy of the technique, a solid basis would be created for the eventual use of this modality in pre- and postoperative evaluation of patients with achalasia.

Address correspondence to: Dr Srdjan Kostic, MD, Department of Surgery, Sahlgrenska University Hospital, SE-413 45 Göteborg, Sweden. Email: srdjan.kostic@vgregion.se

MATERIALS AND METHODS

Patients

Timed barium esophagogram was performed on 21 patients managed for achalasia at the Department of Surgery, Sahlgrenska University Hospital, from March 2001 to May 2003. There were 12 men and nine women with a mean age of 44 years (range, 20–77 years). Sixteen of the patients had a previously diagnosed achalasia and five had a newly established diagnosis. Nine patients had a history of one or two balloon dilatations and Heller myotomies had been done in seven. The diagnosis had been based on characteristic history; manometric findings compatible with the disease and conventional radiographic barium swallow examination. The TBE examinations in each subject were performed approximately 1 week apart (median 8 days, range, 3–100 days). Four patients had their TBE-examinations performed more than 20 days apart. In two of them the disease had been newly diagnosed. One patient had the TBE-examinations separated by 100 days, but the measured parameters differed minimally between the respective test occasions.

For comparison eight healthy volunteers were recruited. They reported no current or previous esophageal or gastrointestinal symptoms. None of them took any medications known to have effects on esophageal or gastrointestinal function. In six subjects the examination was repeated after about 1 week. Thus, there were a total of 14 examinations in healthy subjects available for assessment.

Technique

All subjects were tested by full size conventional radiography in an upright, slightly left posterior oblique position, after 4 h of fasting. The patients were instructed to drink 250 mL of low-density barium sulfate suspension (45% weight in volume). Patients were instructed to drink the amount of barium they could tolerate without regurgitation or aspiration. Thereafter, three radiographs of the esophagus were exposed 1, 2 and 5 min, respectively, after the start of barium ingestion. These images were exposed three-on-one X-ray film (35 × 35 cm) to simplify the comparison (Fig. 1). The patients were told not to drink any remaining barium after the exposure of the 1 min film. If barium was completely cleared from the esophagus at the 2 min exposure, the 5 min film was not taken. The second investigation was identically performed and carried out about 1 week later at the same time of the day. Eleven of the 21 patients were able to drink the allocated volume of 250 mL during both test occasions. At their second examinations two patients could only drink half of the volume that they had

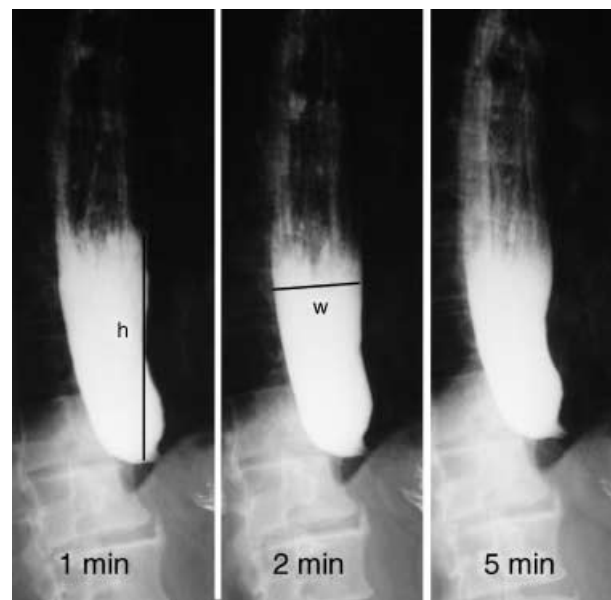


Fig. 1 Thirty-year-old woman with achalasia. Timed barium esophagogram, exposed on a spot film 1, 2 and 5 min after patient has ingested 250 mL of low density barium contrast material. The height (h) is measured from the 'bird's beak' at the level of the cardia to the top of the barium column. The maximum diameter (w) is measured at the widest point perpendicular to the long axis of the esophagus.

ingested at the first examinations. The variation of the TBE parameters in these two patients did, however, not differ significantly from the variability observed in the whole group. The remaining eight patients could not drink the whole volume at one or both examinations, but the difference between the ingested volumes was less than 40 mL in all cases.

Image interpretation and analysis

All subsequent radiological assessments of patients and controls were done blindly in random order without knowledge of the history or diagnosis of the respective subjects. The distance (cm) from the distal esophagus to the top of the barium column (height) and the maximum diameter (Fig. 1), as well as the mean diameter of the barium column (width) were measured on the films (Fig. 2). The distal extent of the barium column was identified by the 'bird's beak' appearance at the level of the lower esophageal sphincter. The top of the barium column was measured from the level at which the barium–foam interface was best defined. If it was impossible to distinguish such an interface, the top of the barium column was assumed to be situated half way between the top of the foam layer and the level at which the foam first was observed to mix with contrast. For accurate assessment of emptying, care was taken to measure the top of the barium column consistently on both 1- and 5-min films. Due to the potential difficulties in



Fig. 2 The mean width (*d*) is measured by drawing two lines parallel to the respective outer margins of the barium column from the top to the bottom. The lines are drawn in such a way that the estimated area containing contrast material outside the line equals the area not containing contrast material inside the line. The mean width is the distance between the two parallel lines.

differentiating a small barium column in the distal esophagus from mere coating of contrast material on the mucosa, residual barium with a height of 2 cm or less was considered as complete emptying, unless a distinct fluid level was observed. The differentiation between coating of the mucosa and the existence of a true barium column may also be complicated on a too lightly exposed film. For this reason, if the observer considered that the film was inadequately exposed, the examinations were excluded from analysis. The maximum width was measured perpendicular to the approximated long-axis of the barium column, at its widest point. Since the maximum width may not represent the mean width of the total barium column, leading to an overestimation of the total amount of barium in the esophagus in some instances, we added the mean width to our measurements. For measurements of the mean width, two lines were drawn parallel to the respective outer margins of the barium column from the top to the bottom. The lines were drawn in such a way that the estimated contrast-containing area outside the line equaled the area not containing contrast inside the line (Fig. 2). The mean width was recorded as the distance between the two lines.

We considered the product height times mean width to be a rough estimate of the area of the esophageal barium column. The percentage of change in this area from the 1 min to the 5 min film formed the basis for the analysis of the degree of esophageal emptying. Emptying was, however, also assessed by just calculating the percentage of change in barium column height from 1 to 5 min.

In order to test the intraobserver reproducibility, 21 randomly selected investigations were re-assessed by the same observer (M.A.) after a time interval of more than 3 months.

A second observer (M.H.) also measured all of the TBE-parameters in 30 examinations to provide evaluation of interobserver agreement. The observers were blinded to all patient data and all clinical and radiological information.

Statistics and ethics

The analysis of agreement was done according to methods proposed by Bland and Altman.⁷ Differences between pairs of measurements were plotted against the respective means to obtain Bland–Altman plots. Limits of agreement were calculated as the 95% confidence interval of the individual differences. The coefficient of variation (CV) was defined as the standard deviation of the individual differences relative to the mean value of the parameter, expressed in per cent. The linear association between measurements in test and retest as well as within and between observers was also assessed using linear regression analysis and correlation coefficients (*r*). The means were compared by paired samples *t*-test. Inter-group evaluation between patients and controls was performed by use of the two-sided Mann–Whitney test. A *P*-value of less than 5% was considered significant. (For expert statistical advices we acknowledge Gunnar Ekeröth, biostatistician, Statistiska Konsultgruppen, Göteborg, Sweden.)

This study was part of a larger prospective study, comparing pneumatic dilatation and surgery in achalasia, and the local ethics committee had approved the study protocol. Informed consent was obtained from each subject before each series of investigations.

RESULTS

The results of the measurements of the TBE parameters by observer A (M.A.) in patients as well as in healthy controls are summarized in Table 1. The individual TBE parameters of healthy controls are shown in Fig. 3 and those of patients in Fig. 4. Some of the healthy individuals retained small amounts of barium in the esophagus after

Table 1 Demographic characteristics and timed barium esophagogram data from all examinations performed in patients with achalasia and normal controls. For descriptions of methods of measurement, see the text. Results are expressed as medians (interquartile range, 25% to 75%). The difference in parameters between patients and controls was analyzed using the Mann–Whitney test for unpaired non-parametric data

Parameter	Achalasia patients (<i>n</i> = 21)	Normal controls (<i>n</i> = 8)	<i>P</i> Value
Age	44 (28–60)	48 (42–54)	
Sex (M : F)	12:9	4:4	
Barium height 1 min (cm)	12.4 (6.2–17.7)	0 (0–7.5)	< 0.001
Barium height 2 min (cm)	11.8 (5.9–15.6)	0 (0–0)	< 0.001
Barium height 5 min (cm)	8.8 (2.5–14.4)	0 (0–0)	< 0.001
Maximum width 1 min (cm)	4.2 (3.3–5.1)	0 (0–0.9)	< 0.001
Maximum width 2 min (cm)	3.7 (2.6–5.5)	0 (0–0)	< 0.001
Maximum width 5 min (cm)	3.5 (2.6–5.0)	0 (0–0)	< 0.001
Mean width 1 min (cm)	2.9 (2.2–3.9)		
Mean width 2 min (cm)	2.7 (2.1–4.3)		
Mean width 5 min (cm)	2.2 (1.8–3.5)		
Percentage emptying 1–5 min (area method)	43.2 (15–76)	100 (100–100)	< 0.001
Percentage emptying 1–5 min (height method)	34.2 (0–59)	100 (100–100)	< 0.001

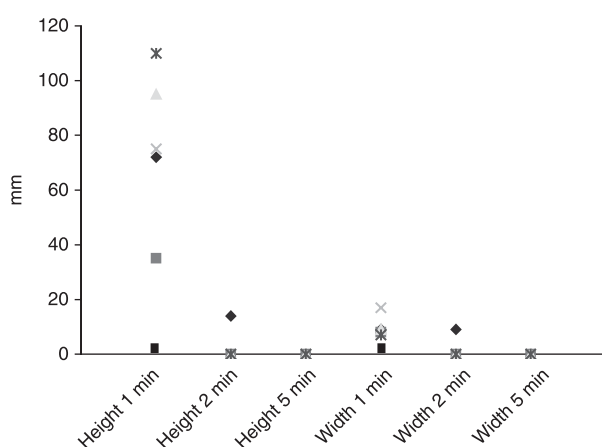


Fig. 3 Individual timed barium esophagogram parameters (barium column height and maximum width) in normal controls. Each dot represents one patient (results of 14 examinations in eight subjects). The numbers on the Y-axis represent barium column height and width in mm.

1 min, but all had emptied their esophagi after 2 min with no significant amount of contrast remaining in the lumen. No healthy subject showed signs of dilatation of the esophagus (i.e. had maximal width over 2 cm). *All TBE variables in patients differed significantly from those observed in the healthy controls.* All but one examination performed in the achalasia patients showed a column of barium in the esophagus after 1 min and an esophagus that tapered into a ‘bird-beak’ at the gastroesophageal junction. In one (untreated) achalasia patient, one of the two examinations demonstrated complete emptying of the esophagus already after 1 min.

The measurements of TBE parameters in the patient group in the test and re-test situation are listed in Table 2. There was no significant difference between the means of the measured, respective variables. The relations of the corresponding barium heights at 1, 2 and 5 min are depicted in Fig. 5. The correlation coefficients ranged from 0.73 to 0.86.

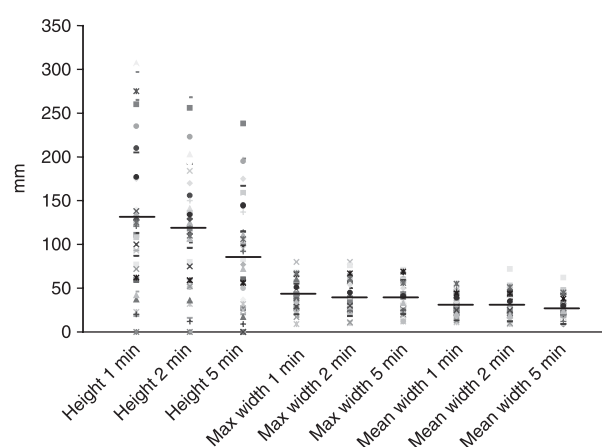


Fig. 4 Individual timed barium esophagogram parameters in patients with achalasia (results of 42 examinations in 21 patients). The horizontal lines denote group medians.

The differences between repeated measurements of barium heights were also plotted against the respective means, to obtain Bland–Altman plots indicating the limits of agreement (i.e. 95% confidence interval)⁷ between different observations (Fig. 6). Table 3 summarizes the reproducibility analysis with correlation coefficients, 95% confidence intervals and coefficients of variation for all TBE-variables. *We were unable to demonstrate any differences in the day-to-day variability of the parameters when untreated and treated patients were compared, but the limited number of patients in each group has to be recognized.*

The day-to-day variability in the assessment of esophageal emptying is shown in Fig. 7. The percentage emptying calculated using the area of the barium column (height times mean width) at 1 and 5 min, attained an *r*-value of 0.50, whereas the percentage emptying using only the relative change in barium column height reached a correlation coefficient of only 0.28. Four of the patients had emptied

Table 2 Measurements of timed barium esophagogram parameters on two occasions in 21 patients. Measurements are presented as means (SD). The means were compared by paired samples *t*-test

Parameter	Measurements at first examination	Measurements at second examination	<i>P</i> Value
Barium height 1 min (cm)	13.5 (7.6)	12.8 (9.0)	0.49
Barium height 2 min (cm)	12.2 (5.7)	11.0 (5.7)	0.16
Barium height 5 min (cm)	9.1 (5.7)	8.3 (7.6)	0.49
Maximum width 1 min (cm)	4.1 (1.6)	4.1 (1.5)	0.98
Maximum width 2 min (cm)	4.1 (1.9)	3.9 (1.6)	0.34
Maximum width 5 min (cm)	3.6 (1.8)	4.1 (1.6)	0.51
Mean width 1 min (cm)	3.1 (1.1)	3.1 (1.2)	0.75
Mean width 2 min (cm)	3.1 (1.5)	3.0 (1.2)	0.56
Mean width 5 min (cm)	2.7 (1.5)	2.6 (1.1)	0.39
Percentage emptying 1–5 min (area method)	37.8 (31.7)	49.1 (36.3)	0.14
Percentage emptying 1–5 min (height method)	28.3 (29.7)	42.6 (40.1)	0.09

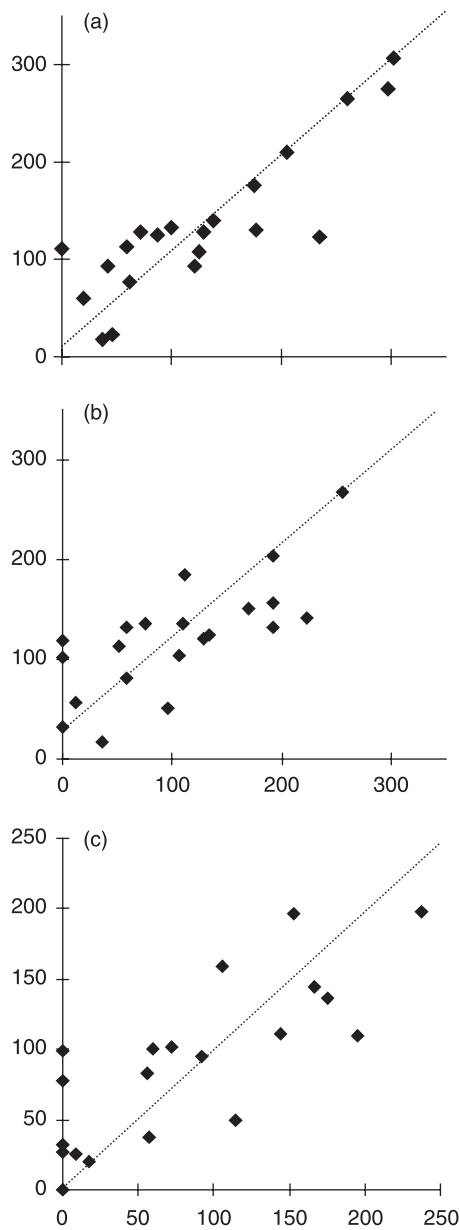


Fig. 5 Relationship of barium column height at repeated examinations in patients with achalasia. Numbers on the axes represent barium column height in mm. The line of equality is shown. Examples show barium column height at: (a) 1 min ($r = 0.86$); (b) 2 min ($r = 0.73$); and (c) 5 min ($r = 0.79$).

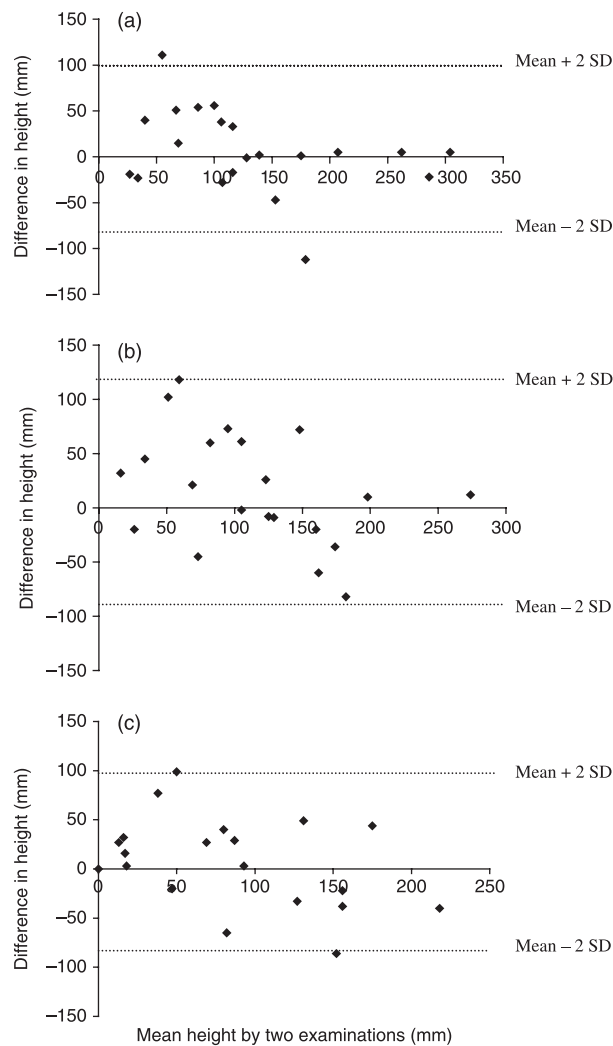


Fig. 6 Bland–Altman plots showing the differences in the measurements at repeated examinations (Y-axis) plotted against their respective means (X-axis). Examples show measurements of height: (a) at 1 min; (b) at 2 min; and (c) at 5 min.

Table 3 Agreement between measurements of timed barium esophagogram parameters in repeated examinations of patients

Parameter	Correlation coefficient	Coefficient of (%) variation	95% CI (cm)†
Barium height 1 min	0.86	37	± 9.2
Barium height 2 min	0.73	45	± 10.6
Barium height 5 min	0.79	52	± 9.2
Maximum width 1 min	0.76	26	± 2.2
Maximum width 2 min	0.79	32	± 2.4
Maximum width 5 min	0.84	29	± 2.0
Mean width 1 min	0.85	21	± 1.2
Mean width 2 min	0.82	33	± 1.8
Mean width 5 min	0.72	50	± 2.2
Percentage emptying 1–5 min (area method)	0.50	79	± 68%
Percentage emptying 1–5 min (height method)	0.28	124	± 84%

†95% CI, limits of agreement of differences in individual measurements.

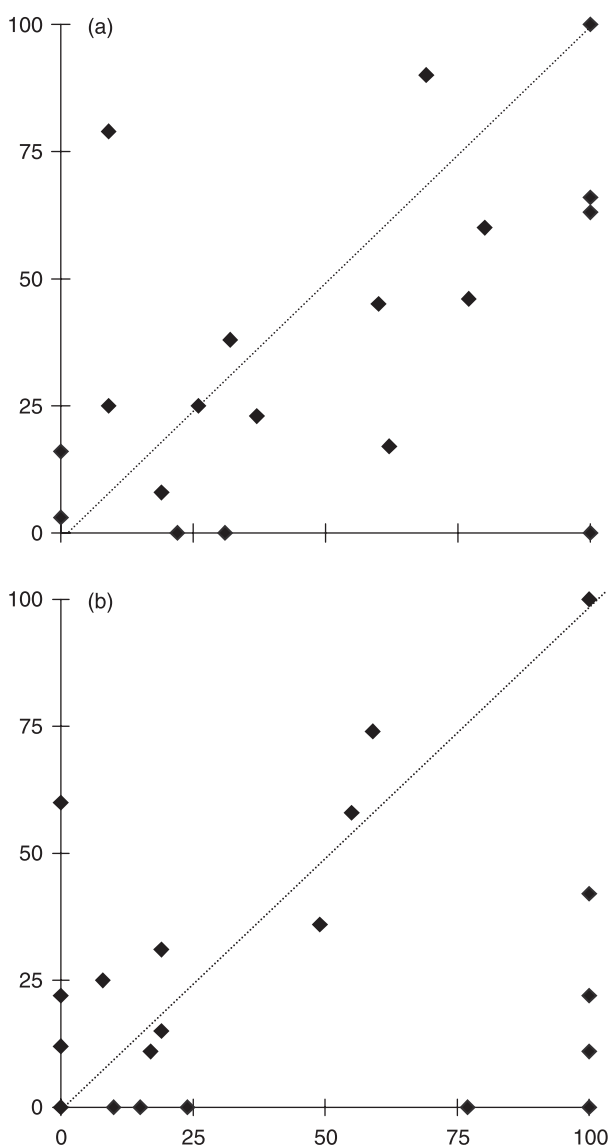


Fig. 7 Relationships of measurements of percentage emptying between test and re-test. Figures show percentage emptying: (a) calculated using the area of the barium column (height times mean width) at 1 and 5 min; and: (b) percentage emptying using only the relative change in barium column height. The correlation coefficients are 0.50 and 0.28, respectively.

their esophagi completely by 5 min at one of the examinations but had residual amounts of contrast (mean barium height 5.9 cm) by 5 min at the ensuing examination. *We could not observe any differences in these variables when operated and unoperated achalasia patients were compared.*

Intra- and interobserver variability is summarized in Tables 4 and 5. The interobserver variation was of the same magnitude as the intraobserver variation. There was a tendency for somewhat higher variation of measurements at the 5-min time point compared with the 1-min time point.

DISCUSSION

A variety of diagnostic modalities are utilized for clinical as well as research purposes in patients with achalasia. Currently there are few, if any, associations between symptom severity and the outcomes of these investigations. This is problematic, not least when trying to evaluate different therapeutic management strategies in newly diagnosed achalasia patients. Furthermore, it would be very helpful to clinicians, particularly those in non-specialized units, to have a simple diagnostic and follow-up tool that displays reasonable accuracy. The timed barium esophagogram has been introduced and applied in clinical practice because it has the potential to allow direct measurements of esophageal emptying. This investigation is easy to perform, inexpensive and comfortable for the patient and offers quantitative data. TBE has been prospectively used in patients before and after a Heller myotomy to which was added an antireflux procedure.⁶ In the preoperative setting, TBE variables correlated weakly with symptoms, except for the severity of regurgitation, which correlated moderately with the height of the barium column. In that study, post-myotomy symptoms were rare and they correlated poorly with residual barium column height and

Table 4 Interobserver variability between two independent observers ($n = 30$ subjects)

Parameter	Measurement difference		r	CV (%)	95% CI (cm)
	Mean \pm SD (cm)	Range (cm)			
Barium height 1 min	0.4 ± 1.2	0.0–3.0	0.99	10.3	± 2.3
Barium height 2 min	0.2 ± 0.8	0.0–2.2	0.99	8.3	± 1.5
Barium height 5 min	0.2 ± 1.2	0.0–4.7	0.98	19.7	± 2.4
Maximum width 1 min	-0.1 ± 0.3	0.0–1.4	0.99	10.2	± 0.6
Maximum width 2 min	-0.1 ± 0.3	0.0–1.3	0.99	11.1	± 0.6
Maximum width 5 min	-0.1 ± 0.6	0.0–3.1	0.95	30.0	± 1.2
Mean width 1 min	-0.2 ± 0.3	0.0–1.6	0.98	12.5	± 0.6
Mean width 2 min	-0.1 ± 0.4	0.0–1.8	0.97	19.0	± 0.8
Mean width 5 min	0.0 ± 0.4	0.0–2.2	0.96	26.7	± 0.8

CV, coefficient of variation; r , correlation coefficient; 95% CI, limits of agreement of differences in individual measurements (cm).

Table 5 Intraobserver variability ($n = 21$ subjects)

Parameter	Measurement difference		r	CV (%)	95% CI (cm)
	Mean \pm SD (cm)	Range (cm)			
Barium height 1 min	0.1 ± 0.8	0.0–2.6	0.99	5.8	± 1.6
Barium height 2 min	0.1 ± 0.5	0.0–1.2	0.99	4.2	± 1.0
Barium height 5 min	0.3 ± 1.2	0.0–4.8	0.98	15.8	± 2.4
Maximum width 1 min	0.0 ± 0.1	0.0–0.3	0.99	2.8	± 0.2
Maximum width 2 min	0.1 ± 0.2	0.0–0.6	0.99	6.3	± 0.4
Maximum width 5 min	-0.1 ± 0.6	0.0–2.5	0.93	25.0	± 1.2
Mean width 1 min	0.2 ± 0.2	0.0–0.5	0.97	7.1	± 0.4
Mean width 2 min	0.0 ± 0.2	0.0–0.7	0.98	8.0	± 0.4
Mean width 5 min	0.3 ± 0.5	0.0–2.0	0.91	27.8	± 1.0

CV, coefficient of variation; r , correlation coefficient; 95% CI, limits of agreement of differences in individual measurements (cm).

width. Vaezi *et al.* evaluated the symptom response and TBE results of 53 pneumatic dilatations in 37 achalasia patients and found a moderate correlation between improvement in patient symptom scores and esophageal barium column height.⁵ Interestingly, 10 (30%) of a group of 34 patients who reported almost complete symptom resolution, had a TBE with less than 50% improvement in esophageal emptying as assessed by barium height. *The patients with poor objective emptying were significantly less likely to be in remission, than those with both symptomatic and objective improvements at 1-month postdilatation, when a long-term follow up perspective was applied.*⁸

Thus, TBE may be a valuable tool for evaluation of treatment response in achalasia. However, it carries an inherent risk to use such a method without having done a proper study to assess its validity, not only of the intraobserver agreement when measuring on X-ray film, but more importantly of the day-to-day variation of these variables when retested in healthy volunteers as well as in patients. These aspects are crucial in the evaluation process for instruments to be used both for clinical and for research purposes.

We found that the intra- and interobserver variability of the measured static variables (height and width of the barium column) was generally small and well within clinically acceptable limits. In some

instances it was difficult to judge whether there was a true barium column or only a coating of the mucosa with barium, and this was probably a source of deviating measurements in some cases.

We found that all TBE variables in achalasia patients differed significantly compared to corresponding variables in healthy controls. When measurements from repeated test occasions were compared in the patient group, the analysis of the Bland–Altman plots revealed a rather large scattering for all TBE parameters. The limits of agreement were fairly wide, in the range of ± 10 cm for the height of the barium column. This fact may not prevent the use of TBE for treatment evaluation in most patients, since the mean height of the barium column in the whole group was greater than 10 cm at both the 1 and 2 min time point. However, if the barium columns are lower than 10 cm at the baseline study it may not be meaningful to perform a follow-up study to evaluate treatment response, since even subsequent complete esophageal emptying may be within the ranges of day-to-day variability.

In the original description of the technique de Oliveira *et al.* addressed the intra- and interobserver variability by use of four separate observers and found good agreement when calculating the percentage of esophageal emptying between 1 and 5 min evaluated on digitized images.⁴ The interobserver agreement of percentage emptying, estimated

by calculating the product of height and width, as well as by qualitative estimation, was also good. This approach to the assessment of esophageal emptying has, however, not been used in later studies^{5,6,9} possibly due to problems with reproducibility. We found that the time-related changes in the estimated area of the barium column showed considerable day-to-day variation. An alternative method to evaluate changes in esophageal emptying may be to compare the height of the barium column at 5 min at the baseline study with that of the post-treatment study.^{5,9} In this instance, it is important that the patient ingests the same volume of barium at the follow-up studies.

When performing pneumatic dilatation for achalasia, it has been stated, that one of the goals of therapy is to achieve complete esophageal emptying at the 5 min time point of the TBE.⁵ It has, for example, been shown that patients with complete esophageal emptying and complete symptom relief post pneumatic dilatation have a better long-term prognosis than patients with poor esophageal emptying at TBE.⁸ In fact it has also been proposed that the former patients may not benefit from close follow-up observation. On the other hand, failure to improve esophageal emptying can lead to progressive esophageal dilatation, to the point at which the esophagus becomes non-compliant and non-functional and assumes a sigmoid shape.^{1,5} Further research has to assess the usefulness of these functional parameters in the therapeutic evaluation of patients with achalasia, but presently all similar data have to be interpreted with great caution.

We found that some patients had difficulties in promptly swallowing the allocated 250 mL of contrast medium. This may account for some of the variability between results at repeated examinations. This suggests that the volume of contrast medium to be ingested should be reduced. Another factor that might jeopardize the preoperative assessment is the presence of remaining fluid and food remnants in the esophagus of untreated patients, diluting and mixing with contrast medium to complicate the estimates.

We present data that show that TBE has the potential to be a useful clinical and research instrument in patients with achalasia, at least when the low intra- and interobserver and day-to-day variation of the static TBE variables are concerned. In assessing esophageal emptying, we found measurement of percentage changes in the height and area of the barium column to have rather poor reproducibility. A further step in the evaluation process of TBE is *now* to apply this investigation in the pre- and postoperative evaluation of newly diagnosed achalasia patients who subsequently will be randomized to either surgery or endoscopic pneumatic dilatation. Within the framework of such a study it will be possible not only to score the true role of TBE in the diagnosis of the disease, but also its ability to indicate the severity of the disorder and its ability to accurately predict the outcome of the various treatment modalities.

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