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Evidence Based Guidelines for Preparation Before Upper Gastrointestinal Endoscopy (UGIE)

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1. Introduction

Current endoscopic guidelines advice a 6 hour fast for solids and a 4 hours fast for liquids before UGIE¹, while most anaesthesia guidelines advice a 6 hour fast for solids and a 2 hour fast for clear liquids^{1,2}. The purpose for fasting before UGIE is two fold. The first is the same as in anaesthesia prior to surgery, to prevent the aspiration of food contents³. The second, which is specific for endoscopy, is to provide clear vision⁴. However, prolonged fasting may result in patient discomfort and undue stress⁵. Due to practical delays the fasting period for endoscopy can become much longer than the stipulated six hours, thus causing even more patient discomfort. This may become especially difficult to tolerate for patients with gastro-esophageal reflux disease (GERD). Physiological studies have shown that clear fluids leave the stomach rapidly⁶, and several anesthetic guidelines now recommend a 2-hour pre-operative fast for clear fluids and a 6-h fast for solids before general anesthesia^{2,7}. A pilot study done by us on 20 patients using real-time ultrasonography showed the time taken for a clear liquid (plain tea) or water to empty from the stomach was one hour.

The second issue with the guidelines was that these guidelines focus on a Western type diet¹. Rice is the staple diet in many Asian countries which include more than half the worlds population. Rice consumption is also increasing in many western societies⁸. Normally, the proximal part of the stomach acts as a reservoir for food and the distal end acts as the grinder⁹. Gastric emptying in normal subjects is complicated process, and is affected by, various meal related factors like the fat content, consistency and the size of the meal¹⁰. However, patient dependant factors like age, sex and body mass index (BMI) have been shown to have no significant association with gastric emptying¹¹. In a pilot study using real time ultrasound scanning we found that the time taken for complete gastric emptying after a standard rice meal was 10 hours. To the best of our knowledge there are no published guidelines on endoscopic preparation for a rice based diet. We therefore decided to investigate whether a six hour fast after a rice based meal was sufficient prior to UGIE.

2. Aims

The aim of the first study was to determine whether a 6-hour fast for solids and a one-hour fast for water prior to UGIE gives good endoscopic vision and less patient discomfort.

The aim of the second study was to determine whether a six hour fast after a standard rice based meal is sufficient to achieve good endoscopic vision during UGIE.

2.1 Methods (1)

Consecutive patients referred for UGIE to the Professorial Medical Unit of the Colombo North Teaching Hospital, Ragama, Sri Lanka, between the ages of 18 to 65 years, who were not pregnant, and had no alarm symptoms previous gastric surgery or clinically obvious motility problems were recruited from 2005 September to 2006 August. Patients on drugs known to affect gastrointestinal motility and acid secretion were requested to stop them for two weeks prior to endoscopy. Patients who could not / refused to comply were excluded from the study. All patients gave informed written consent.

All patients were given a standard meal consisting of two slices of bread and jam 6 hours before endoscopy. Patients were then randomized, using a computer generated random allocation table, to either nil by mouth for 6 hours (Group A) or no solids for six hours but allowed to drink water according to thirst for up to one hour prior to endoscopy (Group B). Patients in Group B were requested to keep a record of the amount of water they drank. Just prior to endoscopy patients were requested to indicate any discomfort due to fasting on a visual analog scale (0 - no discomfort, to 10 - severe discomfort). The endoscopist was blinded to the period of fasting but not to the indication for endoscopy. Endoscopies were performed in the afternoon because patients were given the standard meal in the morning. Commencing at 7 am meals were given to consecutive patients at twenty minute intervals, in order to maintain uniform periods of fasting. Before endoscopy, sterile water was aspirated through the suction channel and then drained dry. All patients had throat spray before endoscopy, and pulse-oxymetry during endoscopy. Endoscopies were performed by the same operator. Endoscopic vision was graded as good, average or poor. During endoscopy, any fluid in the gastric fundus was aspirated and the volume and pH of the aspirate were measured. Endoscopies were recorded on video, and two other endoscopists (ASD and HJdeS), independently assessed the adequacy of endoscopic vision. Patients were seen in the out-patient clinic one week later to detect any late complications.

2.1.1 Ethical clearance and trial registration

Ethical approval for this study was obtained from the Ethics Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka.

2.1.2 Statistics

We assumed that 50% of patients awaiting endoscopy will have discomfort due to fasting. By allowing them to drink water up to one hour prior to endoscopy we expected to reduce this to 20%. We calculated that a sample size of 80 was needed to give the study 80% power at $\alpha = 0.05$. The outcome variables were, endoscopic visibility, pH of gastric content, the number of patients with fluid in the gastric fundus, and the level of patient discomfort due to fasting. Statistical significance of the difference between the two groups was tested using the Mann-Whitney U test for continuous variables and Fisher's Exact Test for categorical variables. Kappa was used to calculate the degree of agreement between the endoscopist and the two independent assessors who viewed videos of the endoscopies. The p values are presented uncorrected for multiple testing.

2.2 Methods (2)

After informed written consent, consecutive patients referred for UGIE, to the Professorial Medical Unit of the Colombo North Teaching Hospital, Ragama, Sri Lanka, between the ages of 18 to 65 years, who were not pregnant, and had no alarm symptoms, previous

gastric surgery or clinically obvious motility problems were recruited from September 2007 to June 2008 (Table 1).

Variables	R6	R10	P value
Number of patients Randomized	105(49.5%)	107(50.5%)	
Male : Female	47:58	56 :51	0.270*
Median age (Range) years	40(18 - 65)	44(18 - 65)	0.082*
GERD Symptoms	82	76	0.238*
Dyspeptic symptoms	20	27	0.278*
Non specific abdominal pain	3	4	0.072*

Table 1. Demographic and endoscopic findings of patients

Patients on drugs known to affect gastrointestinal motility and acid secretion were requested to stop them for two weeks prior to endoscopy. Patients who could not or refused to comply with this request were excluded from the study. Patients were then given a standard rice meal, which contained rice, dhal and an egg. All meals were isocaloric, and the caloric value of meals was calculated assuming a daily requirement of 2500 kcal (Table 2).

Standard Meal	Unit	Energy per unit (kcal)*	Total energy (kcal)
(Parboiled) White Rice 200g	per 100 g	371	742
Egg, whole, cooked, hard-boiled (one)	1 large = 50g	78	78
Lentils, mature seeds, cooked, boiled, with salt 100g	per 100 g	114	114
Total energy provided			934

Table 2. The standard rice based meal

U.S. Department of Agriculture, Agricultural Research Service (USDA:ARS) 1998 USDA Nutrient Database

The patients were then randomized into two groups in preparation for UGIE: fasting for 6 hours after the rice meal (R6) or fasting for 10 hours after the rice meal (R10). All patients were given the meal at 7 am and endoscopies were performed in the afternoon. Endoscopies were done using Olympus GIF 0145 video endoscopes. All endoscopies were performed by two operators (MN and UK). The endoscopists were blinded to the period of fasting, but not to the indication for endoscopy. Another endoscopist (JM), who was also blinded to the period of fasting, was present during all endoscopies and independently graded endosocopic vision. Endoscopic vision was graded as poor, average or good. If there was any discrepancy between the two endoscopist, grading the lower was taken. All patients were reviewed in the out-patient clinic one week later to detect any late complications.

2.2.1 Ethical clearance and trial registration

Ethical approval for this study was obtained from the Ethics Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka. Trial registration number: SLCTR/2008/004.

2.2.2 Statistics

We calculated that 105 subjects in each arm will give the study 80% power at an alpha of 0.05. We expected the percentage of subjects with good endoscopic vision to be 90% in R10 group compared to about 75% seen in our clinical practice (R6). The association between the different grades of endoscopic vision and period of fasting was assessed using the Extended Mantel-Haenszel χ^2 test for trend in Winpepi (Abramson, J.H. WINPEPI (PEPI-for-Windows): computer programs for epidemiologists. Epidemiologic Perspectives & Innovations 2004, 1:6). Kappa was used to calculate the degree of agreement between the endoscopist and the independent assessor who viewed the endoscopies. The p values are presented uncorrected for multiple testing.

2.3 Results (1)

190 Patients were referred to us for endoscopy during the study period (Figure 1).

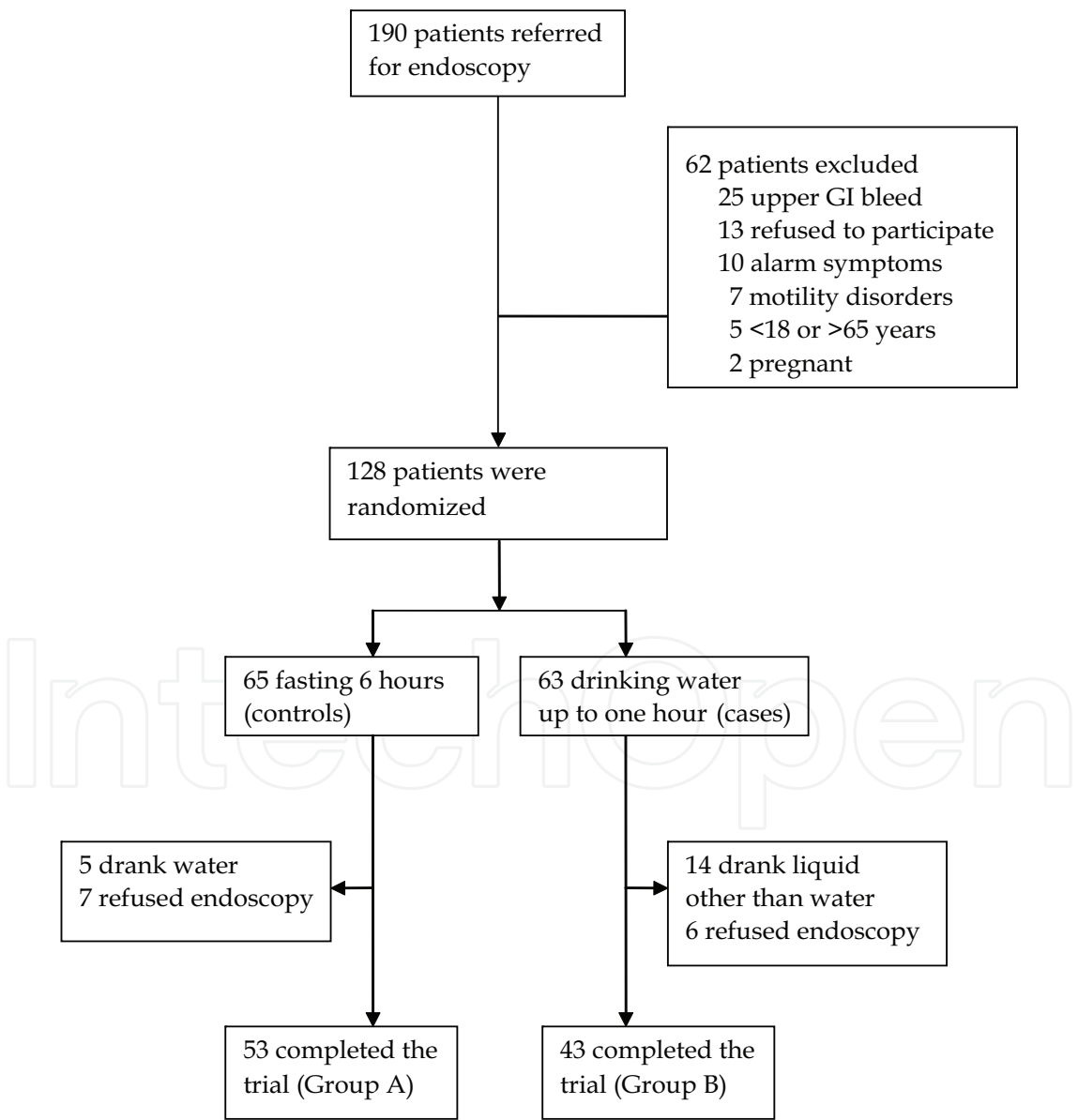


Fig. 1. Trial profile

62 were excluded. 128 were randomized to the two interventions, 65 to nil by mouth (Group A) and 63 to those allowed to drink water according to their thirst for up to one hour prior to endoscopy (Group B). The two groups were comparable for age and gender (Table 3).

32 patients (12 in group A and 20 in group B) did not complete the study; 19 had not followed instructions regarding pre-endoscopy preparation, 13 refused endoscopy after randomization (Figure 1). 96 patients completed the study; 53 in group and 43 in group B. All patients in group B had consumed at least 200 ml water (range 200 to 410) before endoscopy. Discomfort due to fasting was significantly lower in group B than in group A. According to the endoscopist, endoscopic vision was good in all 53 patients in group A and 40 patients in group B, and average in 3 patients in group B. None were graded as poor. There was good agreement between the endoscopist and independent assessors who viewed the videos of the endoscopies (Kappa= 0.64) (Table 3).

Fluid in the gastric fundus was noted in 11 patients in group A and 16 in group B. There were no significant differences in volume or pH of the gastric aspirate between the two groups. There were no complications attributable to the endoscopy in either group.

Variables	Group A	Group B	P value
Number of patients randomized	65	63	
Male : Female	32:33	31:32	0.9*
Median age (Range) years	48 (18-65)	49 (20-64)	0.9***
Indications of Endoscopy			
GERD Symptoms	35	33	0.88*
Dyspeptic symptoms	23	18	0.48*
Non specific abdominal pain	7	12	0.33*
Number of patients completed trial	53	43	
Male: Female	29:24	24:19	0.42*
Median age (Range) years	49(19-65)	48(20-64)	0.91**
Visual analog score [Median (IQR)] for discomfort	9.7(9.6-9.8)	5.6(4.3-8.5)	<0.0001**
Endoscopic vision			
Endoscopist	Good 53 Average 0	Good 40 Average 3	
Independent Assessor 1	Good 50 Average 3	Good 40 Average 3	0.00 [1.1-19]***
Independent Assessor 2	Good 52 Average 1	Good 41 Average 2	
Number of Patients with fluid in the gastric fundus (%)	11(21%)	16(37%)	0.12*
Volume of gastric aspirate (ml) [Median (Range)]	8(0-65)	10 (0-78)	0.56**
pH of gastric aspirate[Median(Range)]	1.3(0.9-6.3)	2.9(0.9-5)	0.99**
Principal endoscopic diagnosis (%)			
GERD	18 (34%)	24 (56%)	0.04*
Gastritis	17 (32%)	6 (14%)	0.054*
Esophageal / gastric varices	6 (11%)	1 (2%)	0.13*
Gastric ulcer	2 (4%)		
Normal	10 (19%)	12 (28%)	0.33*

Table 3. Demography and indication for endoscopy in patients

2.4 Results (2)

A total of 335 patients were referred to us for endoscopy during the study period. Of these, 123 were excluded (61 had upper GI bleeding, 23 did not give consent, 15 had alarm symptoms, 6 had motility problems, 5 were <18 years or >65 years old, 8 not able to comply with the request for cessation of medication, 5 were pregnant). 212 patients were randomized to the two interventions: 107 to the R10 group and 105 to the R6 group. The two groups were comparable for age, gender and indications for enoscopy (Table 4). In the R10 group endoscopic vision was graded as poor in 2 (1.9%), average in 7 (6.5%), and good in 98 (91.5%), while in the R6 group it was graded as poor in 30 (28.6%), average in 19 (18.1%), good in 56 (53.3%). The observed difference of percentages among the two groups for endoscopic vision was significant (M-H Chi-Square for trend=25.67; df=1; P<0.001). There was good agreement between the endoscopists and the independent assessor who witnessed the endoscopies (Kappa = 0.97). There were no immediate or late complications due to endoscopy.

Variable	R6 (n=105)	R10 (n=107)	X ²	P value
Endoscopic vision				
Endoscopist	Good 56 (53.3%) Average 19 (18.1%) Poor 30 (28.6%)	Good 98 (91.6%) Average 7 (6.5%) Poor 2 (1.9%)	41.478	<0.0001**
Independent Assessor	Good 58 (55.2%) Average 19 (18.1%) Poor 28 (26.7%)	Good 99 (92.5%) Average 6 (5.6%) Poor 2 (1.9%)		
Number of Patients with fluid in the gastric fundus (%)	21 (20.0%)	25 (22.9%)	0.353	0.552*
Principal endoscopic diagnosis (%)				
GERD	22 (21.1%)	19 (17.8%)	0.347	0.556*
Gastritis	29 (27.6%)	36 (33.6%)	0.905	0.341*
Peptic Ulcers	12 (11.4%)	12 (11.2%)	0.002	0.961*
Bile reflux	1 (0.9%)	1 (0.9%)	0.000	0.989*
Any other pathology	3 (2.8%)	7 (6.5%)	1.601	0.206*
Normal	38 (36.2%)	32 (29.9%)	0.946	0.331*

*Based on Pearson Chi-square Value
**Based on Extended Mantel-Haenszel X² test for trend

Table 4. Endoscopic findings of patients

3. Conclusions

We have shown that a 6-hour fast for solids and one-hour fast for water prior to UGIE, gives good endoscopic vision and causes minimum patient discomfort. This confirms the results of an earlier study done more than 10 years ago^{12,13}. Our study was designed mainly to assess the quality of endoscopic vision and patient discomfort. Even though we did not

detect any complications, we admit that the numbers studied are too small to make firm conclusions regarding safety. As none of our patients were sedated, our results on safety may not be applicable to situations where sedation prior to endoscopy is routine.

Although the American Society for Gastrointestinal Endoscopy guidelines for UGIE advises fasting for at least 4 hours for liquids¹, we advised our controls to fast for 6 hours since this is the current practice in our unit, and some guidelines still advice 6 hours fasting for both solids and liquids. This may have had some effect on the degree of patient discomfort indicated by our controls. Another shortcoming in our study was the high drop out rate after randomization. Even though the instructions given were simple, several patients failed to follow them. Most patients who ultimately refused to undergo endoscopy expressed apprehension regarding the procedure.

Prolonged fasting for solids and clear liquids prior to endoscopy still remains in many guidelines¹. Prolonged fasting for clear fluids is illogical because the stomach secretes up to 50ml of acidic fluid per hour even in the fasting state, and empties rapidly after ingestion of clear fluids¹⁴. This would explain why the volume and pH of gastric aspirate was similar in the two groups in our study; the fluid aspirated in Group B was more likely to be gastric secretion than any residual ingested water¹⁵. Endoscopic vision is affected when patients drink milk¹⁶. For this reason we allowed our patients to drink only water. To maximize practicalities we allowed them to drink water according to their thirst. As various types of food can affect the rate of gastric emptying we used a standard meal¹¹. We also attempted to eliminate observer bias by having two other independent assessors.

In conclusion allowing patients to drink water for up to one hour prior to endoscopy together with a 6-hour fast for solids seems to be preferred by patients, and does not hamper endoscopic vision. Two studies done on two different populations more than ten years apart have now shown similar results⁵.

We recommend that current guidelines on preparation for patients undergoing UGIE be reviewed.

Our second study shows that fasting for 6 hours after a rice based meal is inadequate to provide good vision during UGIE. Fasting for 10 hours significantly improves endoscopic vision. Our finding has several implications. Firstly, if patients consume a rice meal and fast for six hours they may be potentially at risk for aspiration. Although we did not encounter this complication, we admit that the numbers studied were too small to make firm conclusions regarding safety. Secondly, poor vision would hamper detection of lesions and would necessitate repeating the procedure. Thirdly, endoscopist may wrongly assume that these patients have slow gastric emptying and subject them to unnecessary and costly investigations. Our study also has implications for patients being prepared for general anaesthesia before surgery as none of the anaesthetic guidelines specify the period of fasting required after a rice based meal¹⁷.

In an attempt to reduce individual bias as much as possible two operators performed all the endoscopies. We also attempted to reduce observer bias by having another independent assessor. The agreement between them was good, and whenever there was any disagreement on endoscopic vision grading between the endoscopist and the independent assessor, the lower grading was used. We did not attempt to measure the volume of left over food in the stomach.

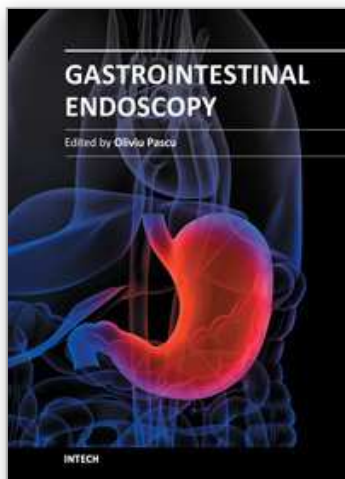
In conclusion, patients consuming a rice based meal prior to UGIE need to fast for at least ten hours prior to the procedure in order to obtain good endoscopic vision. Current guidelines need to be re-evaluated for populations where rice is the staple diet, and this is especially important in the Asian setting.

Based largely on the evidence of our studies we have suggested that the following guidelines be used before for preparation for upper GI endoscopy in the Asian setting.

1. Patients can eat two slices of bread with jam six hours before the procedure.
2. Clear liquids mainly water, plain tea, or king coconut water may be consumed according to thirst up to one hour before the procedure
3. Patients who consume a rice based meal will have to fast for at least ten hours.
4. Patients may take their medications before the procedure.
5. These guidelines apply to patients between 18 to 65 yr and who do not have any obvious motility disorders. Other patients may need longer fasting time.

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