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Original Article

Novel pre-peroral endoscopic myotomy preparation for esophageal clearance: Simple yet effective!

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ABSTRACT

Background: Having a clean esophagus is an integral part of the peroral endoscopic myotomy (POEM) procedure for ensuring safety and success. Conventional preparation is a tricky, because there is no defined definite timeline of fasting for the different types of achalasia. The present study introduces a simple yet effective preparation of esophageal clearance.

Methods: All patients who underwent POEM were included. Patients were stratified in novel and conventional preparation groups by a random selection. In the novel preparation, the cases were maintained on lukewarm water and carbonated drink followed by nil per oral (NPO) prior to the procedure. In conventional preparation, the controls were maintained on clear liquid followed by NPO. Success rate of preparation and procedure related outcomes were compared using independent *t* tests and chi-squared tests.

Results: A total of 150 patients (male 54.0%; mean age 41.2 ± 15.5 years) were included in the study. Known baseline and clinical factors which could affect esophageal clearance were evenly distributed between the two groups. Novel preparation had provided absolute esophageal clearance (97.3%) without the requirement of pre-POEM endoscopic cleaning. Moreover, Novel preparation demonstrates several advantages over the conventional preparation: decreased anesthesia aspiration risk ($P < 0.0001$), reduced preoperative hospitalization ($P < 0.0001$), and hospital stays ($P < 0.005$). **Conclusion:** Evidently, the novel preparation is very simple, efficient, safe and appropriate for all types of achalasia. Moreover, novel preparation provides absolute esophageal clearance without requiring prolonged period of liquid diet, fasting and pre-POEM endoscopic cleaning.

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Keywords: Achalasia cardia; Esophagus; Peroral endoscopic myotomy

Introduction

Achalasia is the most common esophageal motility disorder, characterized by aperistalsis of esophageal body and incomplete relaxation of the esophageal sphincter. Treatment of achalasia has gradually transformed from invasive to minimal invasive. A minimally invasive technique, peroral endoscopic myotomy (POEM), has been developed for the treatment of achalasia with the use of advanced endoscopic tools and techniques. Nowadays, POEM has emerged as an effective and safe therapeutic tool for permanent cure.

POEM is technically complex procedure, requires high endoscopic skill and has a long learning curve. The prime requisite of the procedure is a clean esophagus with healthy mucosa. Mucosa

is the only cover over the myotomy to prevent post-operative leak and perforation. Hence having a clean esophagus is mandatory.² In achalasia, patient's esophagus is aperistaltic, significantly dilated, tortuous and angulated which can retain significant amount of food debris and fluid which increases the risk of postoperative infection and aspiration during POEM if not cleaned thoroughly pre operatively. In addition, clean esophagus ensures clear endoscopic view during POEM. Hence, it is essential to clean the esophagus in an appropriate manner prior to POEM.¹ Unfortunately, there is no reference to a standardized preparation for esophageal cleaning. Conventionally, the patient is given a liquid diet for 3 to 4 days except milk and an endoscopic assessment is performed on the day before the POEM. Esophagus is thoroughly lavaged with water and cleaned of all residual debris and fluid. The patient is then

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kept nil per orally (NPO) till the procedure is performed. Conventional preparation differs from centre to centre depending on the operator's choice and experience. Period of preoperative fasting is also variable depending upon the amount of residue the operator finds. Sigmoid esophagus would require prolonged fasting.

The idea of using warm water for esophageal clearance struck when one of the authors saw a radiologist perform a barium examination in a patient of achalasia. The barium column was not passing across a tight lower esophageal sphincter (LES). Then the radiologist asked his assistant to give a bolus of warm water to the patient, the LES opened and the barium column immediately passed into the stomach seen on fluoroscopy. This inspired us to perform a comprehensive literature search, which revealed that hot food/water and carbonated drink relieves spasm at the LES, alters esophageal motility and allows food and fluid to pass in the stomach.³⁻⁷ On these grounds, we designed a novel preparation using lukewarm water and carbonated drink to assess the effectiveness, safety and reduction in time required for esophageal clearance in patients of all types of achalasia before POEM procedure.

Methods

Patients

This was a single center, prospective case-control study that included all patients who underwent POEM for the treatment of achalasia between January 2017 and November 2019. The study was approved by institutional ethics committee of the Surat Institute of Digestive Sciences (protocol no. SIDS-17-01) and signed informed consent was taken from each patient. Diagnosis of achalasia was based on preoperative clinical assessment, barium bolus examination, an upper gastrointestinal (GI) endoscopy and high-resolution manometry (HRM). Depending upon the findings of upper GI endoscopy, we established a working scale for describing

the esophageal condition based on residue it had.

Grade I: clean esophagus with no or minimal fluid residue; Fig. 1A, Grade II: dilated sigmoid esophagus with significant fluid residue and white substance on walls; Fig. 1B, and Grade III: dilated esophagus with significant sigmoid transformation with thick food and fluid residue with white substance; Fig. 1C.

Esophageal clearance method

Based on the pre-POEM preparation protocol, patients were divided into two groups: cases (novel preparation) and controls (conventional preparation). The patients were assigned either group on a random selection basis. Novel and conventional preparations are briefly explained in Fig. 2.

In the Novel preparation, patients were allowed routine diet till 24 hours prior to the procedure. They were then asked to be on liquids from morning on pre procedure day. They were then given 2 L of lukewarm water (2 gulps at a time) accompanied by 1 L of carbonated drinks (Limca manufactured by Coca Cola; 1 gulp at a time) alternatively for 6-hours, starting previous afternoon and then they were fasting overnight (NPO) from 10 p.m. onwards. Procedure was done at 8am the next morning in all cases.

On the other hand, in conventional preparation, controls were made to stop diet 48 hours prior to procedure, allowed only clear liquid diet for 48-hours. Upper GI endoscopy was performed under sedation on the day prior to POEM to evaluate esophagus clearance and thorough lavage was given for complete cleaning. Patients were NPO for next 12-hour prior to procedure. Procedure was done at 8 a.m. the next morning. All patients were admitted to hospital day prior to the procedure.

Anesthesia aspiration risk was classified as Score 1, normal risk without fluid regurgitation; Score 2, moderate risk with minimal fluid regurgitation requiring minimal suction prior to endotracheal intubation at the time of the procedure; and Score 3, high risk with significant fluid and food regurgitation which required

Fig. 1. Classification of esophageal mucosa: (A) Grade I, clean esophagus with no or minimal fluid residue; (B) Grade II, dilated esophagus with significant fluid residue and white substance on walls; and (C) Grade III, dilated esophagus with thick food and fluid residue with white substance.

Fig. 2. Timeline of conventional and novel preparation. POEM, peroral endoscopic myotomy.

Table 1 Baseline Clinical and Demographic Characteristics of Study Population

Characteristic	Novel preparation (n=75)	Conventional preparation (n=75)	P-value
Age (yr)	42.9 ± 14.9	39.4 ± 15.9	0.169
Sex (male)	42 (56.0)	39 (52.0)	
Duration of symptoms (mo)	7.3 ± 8.2	10.1 ± 12.2	0.097
Integrated residual pressure (mmHg)	24.7 ± 10.0	24.3 ± 13.2	0.869
Type of achalasia			0.802
Type I	31 (41.3)	32 (42.7)	
Type II	30 (40.0)	32 (42.7)	
Type III	14 (18.7)	11 (14.6)	
Condition of esophagus before POEM			0.870
Grade I	0 (0.0)	0 (0.0)	
Grade II	38 (50.7)	39 (52.0)	
Grade III	37 (49.3)	36 (48.0)	

Values are presented as mean ± standard deviation or number (%).

POEM, peroral endoscopic myotomy.

P-values are derived from student's independent *t* tests and chi-squared tests; those that are < 0.05 are considered to be significant.

continuous suction at the time of endotracheal intubation.

This was a working score established in conjunction with our anesthesiologist to assess the quantitative risk of aspiration during endotracheal intubation objectively to assess if the new model of preparation helps to reduce the risk of aspiration. It is not a standardized scale as we could not find such a scale on doing research, but as our anesthetist observed the difference in aspiration during intubation, we established this scale to see if our observations were statistically significant.

In the conventional method all patients were scoped the day before and esophagus was cleaned thoroughly. In the new method, no prior day endoscopy was done and directly scope introduced after endotracheal intubation while doing POEM and rate of reflux assessed by the anesthetists for any increased risk.

Diabetic patients and patients with the specific age group (aged < 15 years, > 60 years) were closely monitored for esophageal clearance method. No patient in any group had difficulty if drinking the stipulated amount of fluid. A few took a little longer time but could drink it without vomiting.

Variables of clinical interest

Primary outcome measures of the study were: success of preparation, optimal fasting period for esophageal clearance, anesthesia aspiration risk and requirement of pre-POEM endoscopic cleaning. Secondary outcome measures include hospital stay, preoperative hospitalization and total cost. Preoperative hospitalization was defined by the duration between the hospital admissions to procedure (POEM) time. Moreover, Demographic details and clinical history of patients were collected, including age, sex, disease classification, and previous therapies. Pre-procedural baseline findings of HRM (4 second integrated relaxation pressure [IRP-4s] and resting pressure) and upper GI endoscopy were also collected.

Statistical analysis

Continuous data were reported as the mean and standard deviation and categorical data were presented as frequency and percentage. Comparison of continuous variables was done using student's independent *t* test and categorical variables were com-

pared using chi-squared test. A *P*-value of < 0.05 was considered statistically significant. All statistical analysis was performed using the SPSS ver. 16.0 software (SPSS Inc., Chicago, IL, USA).

Results

POEM was carried out in 150 patients (male 54.0%, mean age 41.2 ± 15.5 years) during the study period. All POEMs were performed by a single endoscopist with the assistance of a nurse, 2 technicians and a dedicated anesthesia team in our endoscopy unit. The patients were distributed in novel and conventional preparation group trying to have almost equal number of type I, type II, and type III cases in each arm. Type II and type III had cases with sigmoid esophagus, and these were considered in data analysis along with the other cases. An identical baseline characteristic of study population is summarized in Table 1.

All the patients of novel group completed the (2 L) of lukewarm water and (1 L) carbonated drink within 6 hours. In addition, 2 children and 14 diabetic patients were also enrolled in novel preparation group without any hassle and had a complete esophageal clearance. The novel preparation group provided grade I esophagus in 97.3% cases when compared to 13.3% in conventional method. Novel preparation had only 2.7% cases in Grade II and nil in Grade III as compared to (57.3%) Grade II and (29.3%) in Grade III in the conventional group. This proved that the novel method cleaned the esophagus more effectively (*P* < 0.0001) than conventional preparation (Fig. 3).

All patients in conventional group underwent pre-POEM endoscopic cleaning. Majority of cases in the conventional group were having anesthesia risk scores of 2 (62.7%) and 3 (34.7%). On the other hand, novel preparation group reported risk score 1 in 96.0% and score 2 in (4.0%) and score 3 in no cases. This suggests that in the novel preparation no prior cleaning of the esophagus was required (Fig. 4).

The detailed primary and secondary outcome measures were illustrated in Table 2.

The total procedure time was almost equal in both the groups (65.0 ± 13.0 vs. 68.0 ± 12.6 minutes; *P*-value not significant). With the novel preparation, preoperative hospitalization significantly reduced to 16.1 ± 9.03 from 24.8 ± 11.8 hours (*P* < 0.0001).

Fig. 3. Esophageal cleaning efficacy of conventional vs novel preparation: (1) Endoscopic cleaning of grade 3 esophageal mucosa with (A) before conventional preparation; (B) after conventional preparation; (C) before novel preparation; (D) after novel preparation. (2) Graphical representation of Esophageal cleaning by (E) conventional preparation; (F) novel preparation.

Fig. 4. Preparation related outcomes: pre-peroral endoscopic myotomy (POEM) endoscopic cleaning requirement with novel and conventional preparation; anesthesia aspiration risk score with novel and conventional preparation.

Eventual hospital stay decreased from 4.0 ± 0.6 to 3.7 ± 0.7 days ($P = 0.01$).

Discussion

A clean esophagus is a prime requisite for POEM procedure to ensure safety and success of POEM. Unfortunately, limited

literature is available describing the importance of esophageal cleaning before POEM. The present study is aimed to evaluate the importance, safety and efficacy of the novel pre-POEM preparation for esophageal clearance. Hence, the prolonged fasting with consumption of clear liquids in conventional preparation was substituted with lukewarm water and carbonated drink to achieve effective esophageal clearance before POEM. This substitution demonstrated several potential advantages to the patients as it shortened the period of fasting and reduced aspiration risk score. Most importantly the novel preparation minimizes necessity of pre-POEM endoscopic cleaning. Thus, reducing one more endoscopic procedure for the patient along with its incipient anesthesia risk and cost.

Studies have recommended that lukewarm water and warm food to the patients with achalasia increases motility of esophageal body, reduces LES pressure and increases LES relaxation. Thereby providing symptomatic relief.^{3,4,6} Moreover, carbonated drink causes disintegration of the food particles due to the release of carbon dioxide. The released carbon dioxide further triggers relaxation of LES to facilitate passage of bolus into the stomach.^{5,7} In addition we did testing of the effect of warm water on the LES during esophageal manometry of five patients to be sure of our protocol and we found that giving warm water causes transient relaxation of the LES and decrease in IRP which has been documented in Fig. 5.

To optimize the amount and duration of lukewarm water and carbonated drink, we performed an in-house analysis and obtained an absolute esophageal clearance with 2 L of lukewarm water and 1 L of carbonated drink within 6 hours. Three liter was

Table 2 Novel Preparation Related Outcome Measures

Parameter	Novel preparation (n = 75)	Conventional preparation (n = 75)	P-value
Total procedure time (min)	65.0 ± 13.0	68 ± 12.6	Not significant
Pre-POEM endoscopic cleaning	2 (2.7)	75 (100)	< 0.0001
Anesthesia aspiration risk score			< 0.0001
Score 1	72 (96.0)	2 (2.7)	
Score 2	3 (4.0)	47 (62.7)	
Score 3	0 (0.0)	26 (34.7)	
Pre-operative hospitalization (hr)	16.1 ± 9.0	24.8 ± 11.8	< 0.0001
Condition of esophagus after preparation			< 0.0001
Grade I	73 (97.3)	10 (13.3)	
Grade II	2 (2.7)	43 (57.3)	
Grade III	0 (0.0)	22 (39.3)	
Hospital stay (day)	3.7 ± 0.7	4.0 ± 0.6	0.016

Values are presented as mean ± standard deviation or number (%).

POEM, peroral endoscopic myotomy.

P-values are derived from student's independent *t* tests and chi-squared tests; those that are < 0.05 are considered to be significant.

Fig. 5. (A) Esophageal Manometry Showing No LES Relaxation to wet swallows with water at room temperature and IRP of 19 mmHg. (B) Same patient manometry findings showing Transient but significant LES Relaxation after a bolus of warm water with reduction in IRP to 12 mmHg. LES, lower esophageal sphincter; IRP, integrated relaxation pressure; DCI, distal contractile integral; CDP, contractile deceleration point.

chosen from our experience of preparation of the colon prior to colonoscopy where patients drink 2 L of polyethylene glycol solution in 2 to 3 hours and therefore we considered an additional 1 L in a total of 6 hours as a tolerable amount for the patient and all the patients complied very well with this formulation. Even children below 15 years and elderly above 65 years did not have any difficulty. The reason probably was that the retained fluid in the esophagus emptied with warm boluses as shown by our manometry findings also and the patients found it convenient to drink the stipulated amount of liquid.

Novel preparation offers several advantages over the conventional preparation which are previously discussed. Novel preparation requires only 14 hours for absolute esophageal clearance whereas the period of taking clear liquids and fasting in conventional procedure was at least 48 hours. The total duration of clear liquid diet and the period of NPO in conventional preparation vary from 24 to 72 hours in the literature.^{1,2} After such a prolonged period of fasting, pre-POEM endoscopic cleaning is required to ensure absolute esophageal clearance especially in the patients with advanced achalasia. The Novel preparation was well tolerated and accepted by children and diabetic patient population, too. Conventional preparation had 12 hours NPO, which requires intravenous fluids to maintain hydration. In the present study, adequate hydration was supplied by intravenous fluids whenever required. Thus, collectively the novel preparation re-

duces the total cost to the patients and became cost-effective. As the cost would be different in different admission categories of the patient we have not committed any absolute value for the cost.

Tanaka et al⁸ reported one novel endoscopic assisted esophageal clearance method for advanced achalasia. This novel technique performed one day before or immediately before POEM, to remove food debris using super-slim-gastroscope and gastric tube. Although this is an efficient technique for esophagus clearance, it has two major limitations: (1) utility only for advanced achalasia (2) requirement of anesthesia with a day before the procedure (high cost), limits its use in routine clinical practice.

The two patients who had Grade II esophagus after this method were both tertiary achalasia with massively dilated and sigmoid esophagus and had significant food residue at the primary endoscopy. Those two were the only cases where we needed lavage before the POEM started and not on the previous day as we found the esophageal cleansing lacking.

In conclusion, results of our present study demonstrate a simplified preparation in comparison to the cumbersome conventional preparation. Evidently, the novel preparation is efficient, safe and appropriate for the patients with any type of achalasia. However, for the further standardization of the novel preparation, a large, randomized control, multi-centre study is required.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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