

Effectiveness of Premedication with Simethicone During Esophagogastroduodenoscopy

Sofia. Oubaha¹, Yomna Dannouni^{2*}, Adil Ait Errami², Zouhour Samlani², Khadija Krati²

¹Laboratory of Physiology, Cadi Ayyad University Faculty of Medicine and Pharmacy of Marrakech, Morocco

²Department of Gastroenterology, Mohamed VI University Hospital, Marrakech, Morocco

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*Corresponding author: Yomna Dannouni

Abstract

Original Research Article

Background and study aim: The presence of air bubbles and foam in stomach and duodenum is a common problem during esophagogastroduodenoscopy (EGD). The aim of this study was to evaluate the effectiveness of simethicone on enhancing endoscopic visibility in patients undergoing EGD. **Patients and methods:** This was a randomized, double-blind, placebo-controlled study of 129 patients referred for upper endoscopy who were premedicated 30 minutes before the procedure with 125 mg of simethicone or 3g of sugar as placebo. The primary outcome measure was the quality of mucosal visualization (Mucosal visibility score MVS). **Results:** Premedication by simethicone improved the endoscopic visibility by diminishing mean cumulative (9.39±0.57 vs 6.62±0.55, $p < 0.002$) and local scores of foam and bubbles at all areas. The simethicone group also had a significantly shorter procedure time (206±16 sec vs 291±94 sec, $p < 0.012$). The rate of reported lesions was higher in simethicone group with a statistical significance only in the fundus/body area. Simethicone increased endoscopist and patient satisfaction. **Conclusion:** Using simethicone 30 minute before endoscopy significantly improved endoscopic visualization and shorten gastroscopy time.

Keywords: esophagogastroduodenoscopy (EGD), endoscopy, simethicone, gastroscopy.

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INTRODUCTION

The oesogastroduodenal endoscopy is the main diagnosis and therapeutic test for the upper gastrointestinal tract lesions. However, intraluminal foam and bubbles can impair endoscopic visibility, potentially missing important subtle lesions and extending the time of exploration. An appropriate method should be able to remove the bubbles, not having side effects, be tolerable for patients and be applicable for most patients in different conditions. Simethicone is a defoaming agent, a chemical mixture of dimethyl polysiloxane and silica gel, not absorbed through gastrointestinal mucosa and it is not interacting with other drugs, rarely has adverse effects [1]. Simethicone acts mainly in gastrointestinal lumen by decreasing the surface tension, leading to coalescing of foam and bubbles [2]. Only fasting prior to endoscopy has been recommended for prior EGD preparation. Although, many studies reported that the addition of simethicone is useful by increasing endoscopic visibility, diagnostic accuracy and endoscopist satisfaction [3]. Therefore, we evaluate its effect on our Moroccan patients.

PATIENTS AND METHODS

Patient Selection

This was a single-center, prospective, double-blind, placebo-controlled, randomized study. 129 patients were referred to our department for upper gastrointestinal screening endoscopy were included in this study. Patients referred for emergency gastroscopy or with stenosis of the upper gastrointestinal tract or allergies to simethicone were not included in the study. The study was approved by the hospital ethics committee, and written informed consent was obtained from all patients.

Premedication and Endoscopic Procedure

Endoscopic procedures were performed in the endoscopy room of Mohamed VI University Hospital. Patients were randomized using the sealed envelope technique to assign them into one of the following premedication strategies: Group A: 125mg of simethicone, Group B: 3g of sugar as placebo. The premedications were administered about 30 minutes before starting the examination. The route of administration of the drug were the same for the two groups. Patients and endoscopists were both unaware of

the nature of the administered solution. Endoscopic examinations were performed by skilled endoscopists

(Figure-1).

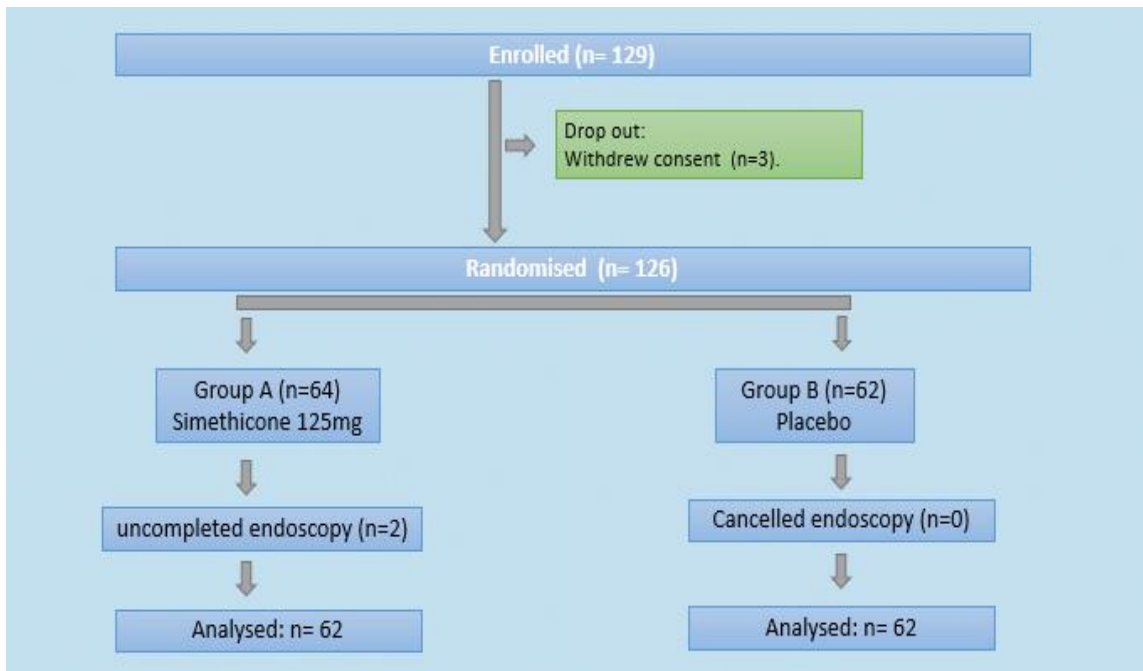


Fig-1: Workflow of patient enrollment

The endoscopist checked the mucosal visibility in four locations : Esophagus, Fundus/gastric body, Gastric antrum/pylorus, Duodenum. The scoring system was as follows: score 1) indicating no adherent mucus and clear view of the mucosa; score 2) a thin coating of mucus but not obscured vision; and score 3) adherent mucus obscuring vision. The total mucosal visibility score (TMVS) was calculated by the sum of scores in all the areas and ranged from 4 to 16. The secondary endpoints were to compare the differences between the two groups for the local score of foam and bubbles, total EGD examination time, endoscopist and patient satisfaction. the patients' satisfaction with the endoscopy procedure was scored on a numerical scale, in which 1 showed the least satisfaction level and 10 showed complete satisfaction.

STATISTICAL ANALYSIS

To estimate whether simethicone is a significantly effective gastric mucosa cleanser, 124 patients were needed to be recruited ($p < 0.05$, 95%

power). Due to follow up loss and data errors, additional patients were registered. Statistical analysis was performed using standard statistical analysis by SPSS software, using Chi-square test and independent sample t-test. The results were shown as mean \pm standard deviation. Calculated p-values of less than 0.05 were considered significant.

RESULTS

A total of 129 patients were prospectively enrolled to the present study. Three patients were excluded due to non cooperativeness ($n=3$), two patients does not tolerate the procedure. Finally 124 participants were randomized into two groups : 64 patients were allocated to receive 125 mg of oral simethicone and 64 patients received placebo. The median ages of groups A and B were 56 ± 12 and 51 ± 16 years, respectively. The two groups of patients did not differ with respect of demographic characteristics (age, sex and medical history) and indications for endoscopy (Table-1).

Table-1: Patients and procedure characteristics

Caractéristiques	Group A : Simethicone (n = 62)	Groupe B : Placebo (n = 62)
Age, mean ± SD, years	56 ± 12	51 ± 16
Sex, n (%)		
Male	27 (43.5)	22 (35.4)
Female	35 (56.5)	40 (64.6)
Medical history, n (%)		
Diabetes	22 (35.4)	18 (29)
Hypertension	19 (30.6)	11 (17.7)
Liver cirrhosis	31 (50)	36 (58)
Current smoking	17 (27.4)	9 (14.4)
Alcohol drinking	5 (8.06)	3 (4.8)
Indication for procedure, n (%)		
Dyspepsia	3 (4.8)	2 (3.22)
iron deficiency anemia	4 (6.4)	7 (11.2)
Chronic epigastric pain	21 (33.8)	24 (38.7)
Portal hypertension	17 (27.4)	15 (24.19)
Chronic diarrhea	12 (19.3)	9 (14.4)
Ascites	5 (8.06)	5 (8.06)

The total MVS of the two groups are shown in Table-2. The mean MVS was the lowest in simethicone group ($p = 0.002$). As shown in Table-3, the best visibility score was observed in the antrum of group simethicone. With the Chi- test, patients ingesting

simethicone revealed significantly less foam and bubbles compared to placebo at most anatomical locations (Simethicone vs Placebo: $p < 0.001$) (Figure-2 and 3).

Table-2: Total Mucosal visibility Scores

	Group A	Group B	p- value
Mucosal visibility scores	6.62±0.553	9.39±0.57	0.002

Values are presented as mean±SD.

Table-3: Mucosal visibility Scores at different locations

	Esophagus	Fundus/gastric body	Antrum/pylorus	Duodenum
Simethicone group	1.66±0.5	1.92±0.38	1.25±0.715	1.79±0.618
Placebo group	1.95±0.7	2.86±0.23	2.65±0.49	1.93±0.871

Values are presented as mean±SD.

Comparison of the two groups with respect to the duration of endoscopy procedure is demonstrated in Table-4. The duration of endoscopy procedure was eighty-five seconds shorter in the simethicone group (206 ± 16 vs 291 ± 94 , $p = 0.012$). Overall, The rate of reported mucosal changes was higher in simethicone group, with a statistical significance only in fundus ($p = 0.031$): In the esophagus 24.1% and 16.1%, for groups A and B, respectively; in the stomach 83.8 and 53.2%;

and in the duodenum 9.67% and 9.06% (Table-4). Simethicone enhanced endoscopist satisfaction significantly by showing higher proportion of very satisfying and satisfying endoscopic visibility scale in this group compared to placebo (75% vs 38%, $p < 0.001$) (Figure-4). Comparison of the two groups with respect to the patients' satisfaction with the endoscopy procedure: The two groups were not significantly different in this regard ($P = 0.098$).

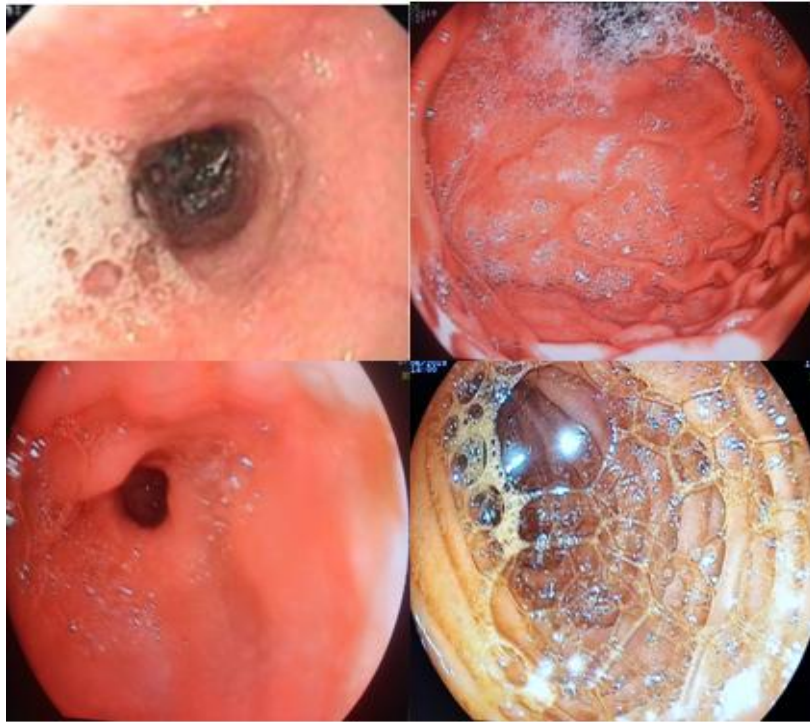


Fig-2: Endoscopic images of a patient in the placebo group

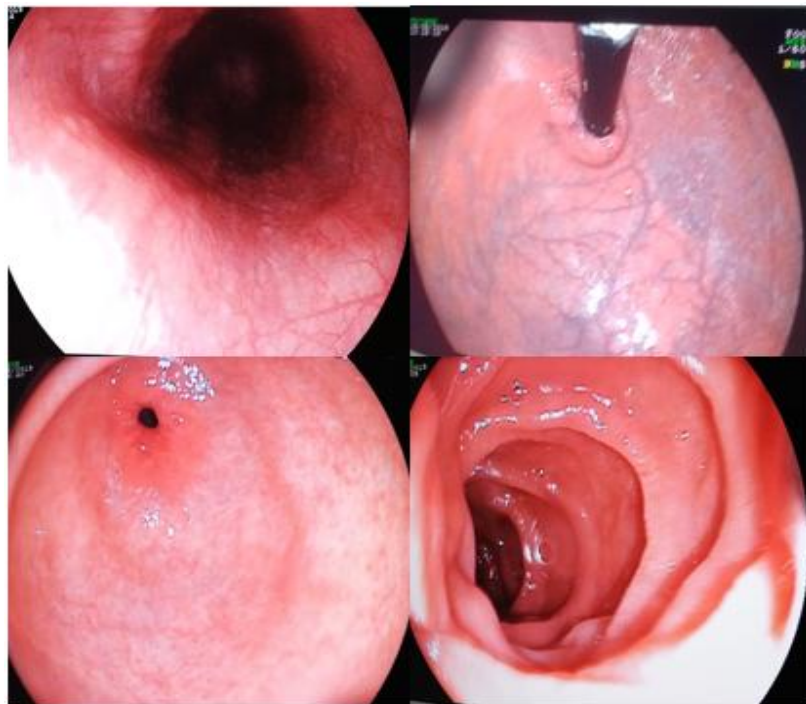


Fig-3: Endoscopic images of a patient in the simethicone group

Table-4: Abnormal findings by location

	Groupe A (Simethicone)	Groupe B (Placebo)	P value
Esophagus, n (%)	15 (24.1)	10 (16.1)	0.082
Fundus/gastric body, n (%)	48 (77.4)	29 (46.7)	0.031
Antrum/pylorus, n (%)	52 (83.8)	33 (53.2)	0.072
Duodenum, n (%)	6 (9.67)	5 (8.06)	0.255

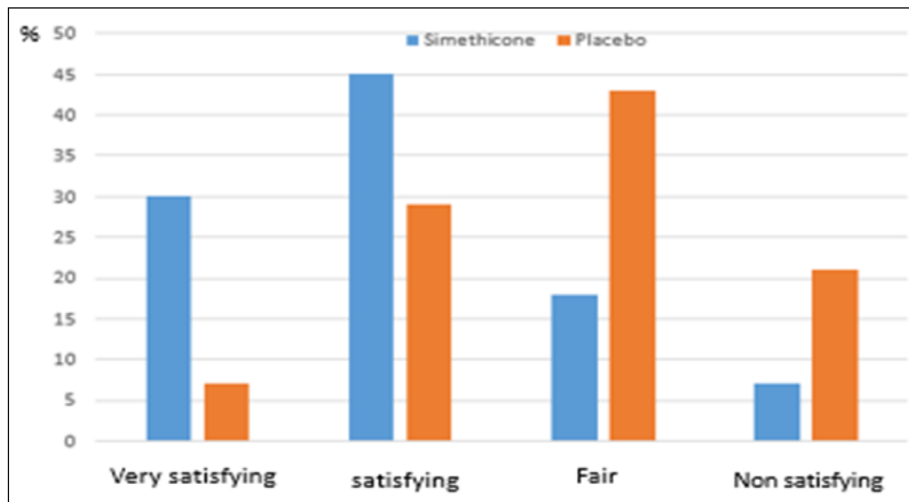


Fig-4: Endoscopist satisfaction

DISCUSSION

EGD is the procedure of choice for making diagnosis of upper GI tract diseases. However, the diagnostic yield may be reduced when visibility of the mucosal surface is impaired. Air swallowed or introduced during endoscopy admixed with gastric mucus and bile contents forming foam and bubbles. The excess of foam adherent to the mucosa interferes with the optimal visualization of the entire mucosal surface. Defoaming agents were tested to improve endoscopic visibility. Enhanced visibility could be obtained by different methods, such as prolonged fasting, pre-endoscopic prokinetic drugs use pre-endoscopic and/or intra-procedural simethicone washing [4]. Simethicone is a mixture of silicones activated by the addition of silica. Silicone are practically inert and tasteless polymers, not absorbed from the gut not pharmacologically active. They lower surface tension and cause bubbles to coalesce [5].

The aim of the study was to determine the effectiveness of simethicone in the preparation prior to EGD. Our results showed that premedication with simethicone improved the visualization of the upper GI mucosa when compared with placebo. Also, MVS was the highest in Fundus/ body and the lowest in the antrum across the two groups. We speculate that the exposure time to the premedication fluid contributed to such results. These results are in accordance with previous publications [6-8]. The present study showed that simethicone solution was more effective than placebo in reducing endoscopy procedure duration by 90 seconds in the simethicone group. Five previous studies presented procedure time, the procedure time in simethicone was shorter than that in water group without obvious heterogeneity [8-13].

Another noteworthy finding was the differences in reported lesions found during endoscopy were compared among the two groups. We found that simethicone group had the higher rate of detected

lesions, although the difference was statistically significant in fundus/body [13].

According to the results obtained, simethicone improve also endoscopist and patient satisfaction [9, 10].

CONCLUSION

Using simethicone before EGD enhances endoscopic visibility, reduces adjunctive washing and increases endoscopist and patient satisfaction. We found that the fundus/body had the poorest mucosal visibility score among all locations. Thus, endoscopists are required to observe this area more carefully.

We believe that this procedure improve mucosal visualization during endoscopy and could be implemented easily in medical centers around the world, because it requires only a single drug (simethicone) that is universally available at very low cost.

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Conflicts of interest: There are no conflicts of interest.

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