

# Esophageal 24-Hour pH-Metry after Esophageal Manometry Facilitated by a New Medical Device, A Mini-Overtube

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**Abstract:** Esophageal manometry (EM) and ambulatory 24-hour esophageal pH-metry (EP) are techniques employed in the management of patients with gastroesophageal reflux disease (GERD). For these examinations, two consecutive probes must be placed nasally. To evaluate the introduction-time (IT) and patient tolerance (PT) during introduction of the EP probe after EM with and without the assistance of a new medical device, a mini-overtube (MOT). A series of 115 patients referred to our Gastroenterology Unit to undergo EM and EP were divided into two groups: group 1 underwent EM and EP by the traditional procedure, group 2 with the MOT. The mean IT for the EP probe was significantly shorter in group 2 than group 1 ( $7.4 \pm 2.0$  sec vs.  $93.2 \pm 57.1$  sec;  $p < 0.01$ ). In group 1 no patients reported excellent tolerance to introduction of the EP probe, 22.7% reported good tolerance, 50% medium and 29.3% bad. In group 2, 61.4% reported excellent tolerance, 33.3% good, 5.3% medium and none bad. Six group 1 patients (10.3%) refused the introduction of the EP probe after  $239.7 \pm 113.9$  seconds of unsuccessful efforts. This device facilitates the introduction of the EP probe in all patients, even those who would not otherwise agree to a second attempt.

## INTRODUCTION

Esophageal manometry (EM) and 24-hour esophageal pH-metry (EP) are accepted clinical tools for investigating esophageal disease [1,2]. These procedures are most frequently required in patients with dysphagia but no evidence of esophageal mechanical obstruction, and in patients with suspected non-cardiac chest pain or gastro-esophageal reflux disease (GERD). GERD is in fact the most common indication for EM and EP [3]. The standard approach in most esophageal motility units uses a water-perfused multichannel catheter system connected indirectly to a physiograph through a series of transducers [4-6]. EM was primarily employed in the past to check low esophageal sphincter (LES) pressure but it is not indicated for placement of a pH probe. Manometry is in fact recommended for precise positioning of the pH probe 5 cm above the upper margin of the LES [7,8].

Prolonged ambulatory monitoring of esophageal pH-metry is the most reliable method for diagnosing GERD. First described by Spencer in 1969 and popularized by Johnson and DeMeester in 1974 [9], the procedure evolved from dissatisfaction with previous tests for reflux. Data are collected for 24 hours in a small lightweight box worn on a waist belt and the information is analyzed by computer. Patients are allowed to smoke and drink alcohol and most centers no longer restrict the pH of foods.

However, each time patients need both EM and EP, two separate probes have to be introduced. Generally introduction of the EM probe is comfortable enough because of the blunt distal end but the EP probe is not nearly so well tolerated. Nasal intubation is complicated by its excessive flexibility and the distal end, made of glass or antimony, can cause trauma to the nasal mucosa, small bleeds, repeated sneezing, pain in the nostril, and tears. Even when the pH probe is introduced, it often takes much longer than the EM probe. Many patients insist on stopping attempts at introducing pH-metry or pH-impedance probes because of the discomfort or pain [10].

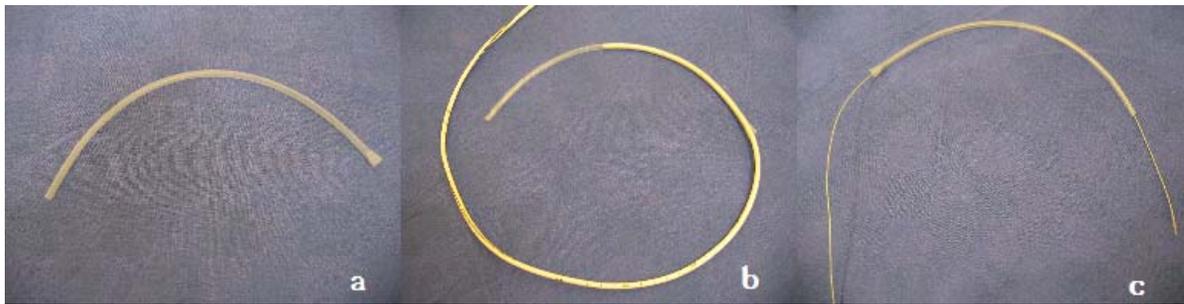
To overcome this problem we tested a new medical device, a mini-overtube (MOT), in patients requiring EM with EP. We also evaluated intubation time (IT) and patient tolerance (PT) with and without the MOT.

## MATERIALS AND METHODS

We consecutively enrolled 115 patients referred to our center for EM with EP and divided them into two groups: group 1 comprised 58 patients (33 F and 25 M; mean age  $52.5 \pm 15.3$  years) who were examined by EM and EP with the traditional technique; group 2 comprised 57 patients (29 F and 28 M; mean age  $52.6 \pm 15.4$  years), in whom the examinations were "facilitated" with the MOT. All patients gave their written informed consent to the EM and EP, with or without the MOT, and to the publication of their data for scientific purposes.

The MOT is a small tube made of polyethylene, a material that allows the esophageal manometric probe to skim through without any resistance. The new device is 30 cm

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**Fig. (1).** (a) MOT with the funnel-shaped distal extremity to facilitate introduction of the probes. (b) The MOT put over the manometric probe. (c) The EP probe inserted into the MOT.

**Table 1. Intubation Time (IT) in the Two Groups**

	<b>Group 1 (n = 57 pts)</b>	<b>Group 2 (n = 58 pts)</b>	<b>p</b>
Intubation Time (IT) (in seconds)	93.2 ± 57.1	7.4 ± 2.0	p<0.01

**Table 2. Patients' Tolerance (PT) to pH-Probe Introduction in the Two Groups**

<b>Tolerance to pH Probe Introduction</b>	<b>Group 1</b>	<b>Group 2</b>	<b>p</b>
Excellent	0% (0 pts)	61.4% (35 pts)	< 0.01
Good	22.7% (12 pts)	33.3% (19 pts)	ns
Medium	50% (29 pts)	5.3% (3 pts)	< 0.01
Bad	29.3% (17 pts)	0% (0 pts)	< 0.01

long, curved, with a 20-cm cord, 13 Fr inner diameter and 14.5 Fr outer diameter. Its distal extremity is funnel-shaped, to facilitate introduction of the pH-metry probe. The proximal part of the MOT is blunted to avoid trauma during transnasal introduction (Bioengineering Laboratories s.p.a., Cantù, CO, Italy).

Before starting EM, the MOT is placed over the manometric probe at its distal extremity. EM is done using a six-lumen, water-perfused, PVC esophageal manometry catheter, with maximum diameter 4 mm (12 Fr) (Bioengineering Laboratories s.p.a., Cantù, CO, Italy). After EM, the MOT is skimmed down over the manometric probe, before it is extracted, so that the distal extremity goes some centimeters beyond the upper esophageal sphincter (UES). Then, when the EM probe is extracted, with the MOT still stationary over the UES, the EP probe is inserted inside the MOT, which serves as a guide. Subsequently the MOT is pulled back on the EP probe, up to the electrical connector, and left on the probe throughout the examination (Fig. 1).

For 24-h EP monitoring we used a glass electrode (diameter 1.5 mm) connected to a portable digital memory unit (LoT 142; Mettler Toledo, M.I.C., Champagne au Mont D'Or; France). We defined the EP probe IT as the time needed to insert the probe into the esophagus, starting when the distal tip is at the nostril and stopping when the proximal marker is at the nostril. The marker is put on the probe after EM when the distance from the nostril to the LES has been obtained. We also assessed patients' tolerance (PT) to intro-

duction of the pH probe, rating it on a subjective scale as bad, medium, good or excellent.

## STATISTICAL ANALYSIS

As the data showed a Gaussian distribution, Student's t-test for unpaired data was used, and Fisher's exact test for the frequency data. Data are presented as median ± standard deviation.

## RESULTS

The EP probe IT was 12.6 times shorter in group 2, where the procedure was facilitated with the MOT, than group 1 (93.2 ± 57.1 vs. 7.4 ± 2.0; p<0.01) (Table 1). Six patients (10.3%) in group 1 refused further attempts at introducing the EP probe after 239.7 ± 113.9 sec of unsuccessful tries.

In group 1 no patients reported excellent tolerance to introduction of the probe, 12 rated it good (22.7%), 29 medium (50%) and 17 bad (29.3%). In group 2, 35 patients reported excellent tolerance (61.4%), 19 good (33.3%), 3 medium (5.3%) and none bad. The difference was significant (p<0.01) except for good tolerance (Table 2).

## DISCUSSION

Esophageal manometry has to be done to place a pH-metry probe correctly. With this technique the distance from the nostril to the LES can be measured, though Showalter *et*

*al.* reported a mean difference of up to 0.7 cm in the radially determined location of the lower esophageal margin [11]. EM is currently employed in many centers, but it is followed by EP only in highly specialized referral units. Patients tolerate the manometry well, but some of them refuse EP because of intolerance to the introduction of the pH probe, or consequences such as small hemorrhages, repeated sneezing, pain in a nostril, or tears, probably caused by the potentially traumatic distal tip of the probe. It is always easier and less traumatic to introduce the manometry probe than the pH probe, and patients tolerate it better. This is because of the material it is made of and the non-traumatic distal tip.

The new device avoids the risk of trauma from the probe when pH-metry is done after EM. It also allows a single intubation and reduces the IT by 12.6 times compared to the traditional procedure, giving a better quality examination.

Finally, besides remarkably easing the introduction of the EP probe, the MOT enables the probe to be introduced in all patients, even those who would normally not agree to a second attempt. In our opinion this new device should be used for every patient needing both EM and EP, considering its utility and ease of use.

## CONCLUSION

With the MOT the EP probe can be introduced, with significant time saving, in all patients, even those who would not otherwise agree to a second probe introduction.

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