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### Alimentary Tract

# Normal values of 24-h ambulatory intraluminal impedance combined with pH-metry in subjects eating a Mediterranean diet

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#### **Abstract**

**Background and aims.** Multichannel intraluminal impedance combined with pH-metry is a novel technique for studying gastro-oesophageal reflux. As refluxes are particularly frequent after meals, we carried out this study in order to assess the impact of a Mediterranean diet on normal values of impedancemetry.

**Methods.** Twenty-five Italian healthy subjects (13 men, median age 29 years, range 22–67 years) without reflux symptoms were recruited for this study. They underwent oesophageal 24-h impedance + pH-metry. A Mediterranean diet was given to all subjects on the day of examination and its total energy intake was 9668.5 kJ (2300 kcal).

**Results.** A total of 1518 refluxes were recorded during 24h with more upright than recumbent episodes (median 15 versus 0; p < 0.01). The median total acid exposure time was 0.5% (range 0–4.2%). Acid and weakly acidic refluxes were equally reported (49% versus 51%). Weakly acidic episodes were more frequent than acid ones during 1-h postprandial periods (68% versus 32%; p < 0.0001). Liquid-only and mixed refluxes reached the proximal oesophagus (15 cm above lower oesophageal sphincter) in 42.6% of cases. Median acid clearing time was longer than median bolus clearing time (28 s versus 12 s; p < 0.01).

**Conclusions.** This study provides normal values of pH-impedancemetry in Italian people eating a Mediterranean diet and are suitable for comparative pathophysiological investigations on reflux patients who have dietary habits similar to those of our country. © 2006 Editrice Gastroenterologica Italiana S.r.l. Published by Elsevier Ltd. All rights reserved.

Keywords: Gastro-oesophageal reflux; 24-h ambulatory pH-impedance

#### 1. Introduction

Multichannel intraluminal impedance (MII) combined with pH-metry is a new interesting technique for the study of gastro-oesophageal reflux disease (GORD). This examination can be performed in ambulatory conditions and throughout the entire 24-h period, just like the traditional oesophageal pH monitoring. With respect to the latter method, the measurement of impedance allows us to know the physical properties of refluxate, that is if reflux episodes are composed by gas, liquid or mixed (gas+liquid) material [1–3]. More-

over, the combination of pH-metry with impedance has the relevant advantage to distinguish acid from weakly acidic reflux events, thus contributing to overcome the most important limitation of pH monitoring alone, which is not able to detect reflux events different from the acid ones [4,5]. Finally, the use of catheters with multiple impedance electrode pairs gives us an additional useful information, in that we know the antegrade or retrograde direction of the bolus along the oesophagus and, in case of the latter event, we can immediately observe how much proximally the refluxate migrates [6,7]. Two recent papers have also shown that measurements obtained with electrical impedance are highly reproducible during both the postprandial period [8] and the circadian cycle [9].

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As with all the new techniques with potential widespread applicability in both research and clinical practice, the assessment of normal values is of paramount importance in order to define what is 'GORD' and 'not GORD'. So far, few studies in this field have been published. Two of them were mainly performed in healthy U.S. subjects [10,11] and, although volunteers had presumably common dietary habits, important differences in normal values were observed. In fact, Shay et al. [10] found that acid reflux was two-fold more frequent than weakly acidic reflux in their 60 healthy volunteers, while Balaji et al. [11] observed that the majority of 24-h reflux events (59%) were non-conventional acid refluxes in their 17 normal subjects. Moreover, reflux reached the proximal oesophagus in 34% of episodes of the former and in 11% of the latter study. A third investigation by Zerbib et al. [9] provides normal values from French and Belgian healthy subjects and they are partially at variance with those of U.S. studies in terms of median number of reflux events and number of acid and weakly acidic refluxes.

We believe that one of the major reasons for the above discrepancies was the different meal composition adopted in the three studies, because it is well known that the majority of reflux events occur in postprandial periods, particularly in healthy subjects [12,13]. Zerbib et al. [9] and Shay et al. [10] encouraged the volunteers to eat their usual daily meals, but dietary habits partially differ between European and American populations and the daily caloric intake was not mentioned in both studies, whereas Balaji et al. [11] gave a refluxogenic meal consisting of a hamburger, fries and milkshake, even though how many times during the 24 h this kind of food was given is not reported.

So, we think that there is need for a better definition of normal values in relation to a more precise characterisation of the meal composition, its energy content and timing, which can differ from country to country around the world. Therefore, we carried out this study in a group of Italian healthy volunteers, who ate a well-characterised diet, in order to assess whether our normal values obtained with MII-pH technology differ from those already published in normal people from other countries.

#### 2. Subjects and methods

Twenty-five Italian healthy volunteers without symptoms of GORD and other gastro-enterological or systemic diseases were recruited for this study. Subjects with previous oesophageal and gastric surgery were excluded. Their demographic and manometric characteristics are reported

in Table 1. Each subject provided informed consent to the investigation, which was approved by our local Ethics Committee.

#### 2.1. Study equipment

A 2.1 mm diameter catheter (Sandhill Scientific, Denver, CO, USA) which comprised one antimony pH sensor between the second and the third impedance rings and six electrode pairs measuring intraluminal impedance positioned at 3, 5, 7, 9, 15 and 17 cm above the lower oesophageal sphincter (LOS). An ambulatory recorder stored the signals taken at 50 samples per second from both the six impedance rings and the pH channel during the whole 24-h period (Sleuth<sup>TM</sup>, Sandhill Scientific).

#### 2.2. Study protocol

Ambulatory impedance studies were performed in each subject as outpatient after an overnight fast and a standard manometric evaluation to exclude important motility disorders was also done. The MII-pH catheter was positioned in order to have the pH sensor at 5 cm above the upper limit of LOS, as defined on the basis of the manometric study. The pH sensor was calibrated with buffers at pH 4.0 and 7.0 and an external reference electrode was attached to the anterior chest. Every MII-pH probe was used once only and we did not observe any malfunctioning of them. Each subject ate three standard meals during the examination (breakfast at 8.00 a.m., lunch at noon and dinner at 6.00 p.m.) and their composition was as follows: breakfast included 11.2 g protein, 13.2 g fat, 54.3 g carbohydrate; lunch consisted of 52.3 g protein, 33.3 g fat, 136.6 g carbohydrate and 400 ml non-sparkling water; dinner consisted of 30.4 g protein, 35.8 g fat, 107 g carbohydrate and 500 ml non-sparkling water. At breakfast, subjects ate milk and bread, at lunch and dinner pasta or rice, white meat or beef and fish or low-fat cheese, bread, vegetables and fruits. The total daily energy intake was 9668.5 kJ, corresponding to 2300 kcal (32% were supplied by fat, 16% by proteins and 52% by carbohydrates). Subjects were provided with a list of beverages with a pH < 5.0 units to be avoided between meals because they could interfere with interpretation of MII-pH data. Subjects were also asked to maintain their normal daily activities and their usual sleep schedule. Event markers on the ambulatory monitoring device recorded meal times and posture changes. Data recording was concluded after 24 h, when subjects returned to our hospital service.

Table 1
Demographic and manometric characteristics of 25 healthy subjects

Normal subjects (number)	Median age (25th–75th–95th percentiles)	Males/ females	LOS median pressure (25th–75th–95th percentiles)	Median amplitude of peristaltic waves (25th–75th–95th percentiles)
25	29 years (24.0–46.0–60.0 years)	13/12	21 mmHg (16.0–27.0–34.0 mmHg)	90 mmHg (80.0–95.0–160.0 mmHg)

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