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# Practical experiences and in vitro and in vivo validation studies with a new gastric tonometric probe in human adult patients☆,☆☆

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**Abstract**

**Purpose:** This study provides practical experiences with a new, simple, balloon-free gastric tonometric probe (probe) and reports the results of simultaneous in vitro and in vivo measurements with a conventional, ballooned gastric air tonometer (catheter) and the new device.

**Materials and Methods:** Ten healthy volunteers and 50 anesthetized surgical patients with different American Society of Anesthesiologists (ASA) scores, scheduled for neurologic, orthopedic, trauma, and cardiac operations, were enrolled in the study. The values of 60 in vitro and, in 12 surgical patients, 101 in vivo paired $P_{CO_2}$ measurements—performed simultaneously with the new tonometric probe and the catheter that was connected to a Tonocap monitor—were compared. The tolerability of the measurement with the new probe was examined, and the results of gastric tonometry and, in surgical cases, the gastric tonometric, end-expiratory, and arterial $P_{CO_2}$ values were registered. The results were evaluated by analysis of variance test. The data of the in vivo paired measurements were evaluated by Bland-Altman analysis.

**Results:** The use of the probe proved to be well tolerated and easily applicable in the studied cases. The results of 20 measurements obtained in healthy volunteers and those of 520 measurements in the surgical cases correspond to the data obtained with the classical methods published in the medical literature. During in vitro paired measurements, there was a good agreement between the data obtained with the 2 methods; however, in the in vivo studies, the results of measurements performed with the probe were mostly higher.

**Conclusions:** The differences between the results obtained with the 2 methods might have been caused by the quicker equilibration property of the probe and by the fundamental differences between the 2 methods. The new probe seems to be applicable for routine human measurements.



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## 1. Introduction

Following the first description of gastric tonometry [1] for measurement of the partial pressure of carbon dioxide in the gastrointestinal tract ($P_gCO_2$) and the demonstration of its adequacy in determining splanchnic perfusion failure [2], the method became extensively used in clinical practice, mainly to monitor the condition of critically ill patients [3-6]. Further progress was achieved with the development of an automated gas tonometer, which eliminated the potential errors of the previous saline method and provided easier measurement facilities [7-11].

Nevertheless, despite the huge amount of published studies demonstrating its utility, gastric tonometry so far has not been generally used in everyday clinical practice.

Recently, we have described a new, simple, balloon-free probe consisting of silicone rubber tubes, which seems to be an easily applicable, reliable instrument for gastric tonometry in patients of all ages and has certain advantages over the traditional method [12]. Both in vitro and in vivo validation studies of the method were performed comparing the results obtained with the probe to those acquired using the conventional balloon tonometer. These studies, however, were carried out using a nonautomated, manual technique, and in vivo experiments were performed only on animals.

The publications on the clinical experiences with the new tonometric technique and its utility in clinical practice have only reported studies carried out on children and infants (including neonates) [13,14].

In the present study,

1. we intend to summarize our practical observations on the new probe used in healthy volunteers and in anesthetized adult patients;
2. furthermore, we would like to present the results of both the in vitro and the in vivo human validation measurements with simultaneously inserted probe and catheter (TRIP, NGS catheter; Tonometrics, Helsinki, Finland).

## 2. Methods

The human application of the probe was approved by the ethical committee of the Hungarian Academy of Sciences, and the examinations were approved by the human investigation review board of the University of Szeged.

### 2.1. Technique and materials for the paired in vitro measurements with the catheter and the probe

For the measurement of the in vitro uptake of $CO_2$ by the probe and the catheter, a glass container, as an equilibration chamber, was used. The part of the probe up to the fastening ring and the balloon part of the catheter were inserted simultaneously into the chamber, which was then sealed in an airtight manner. For the measurement of different $P_{CO_2}$ levels, appropriate quantities of nitrogen and carbon dioxide were mixed with a precision gas blender to reach the desired $CO_2$ partial pressure inside the equilibration chamber. The mixtures were filling the chamber at a flow rate of 10 L/min. During the tonometric measurements, the $P_{CO_2}$ level of the gas mixture inside the chamber was determined by the microcapnograph (Sidestream Microcap Handheld Capnograph; Oridion Medical Ltd, Jerusalem, Israel) by measuring the $CO_2$ content of the gas flowing from the container. During the study, the equilibration chamber was submerged in water thermostated at 37°C.

### 2.2. Patients

Before the in vivo investigations, the individuals who met the eligibility criteria were fully informed during the preoperative visit about the purpose of the study and the insertion of the catheters, and their written consent was obtained. In the case of 2 critically ill, ASA V patients—because of their altered mental status —the written consent was obtained from the escorting first-grade relatives.

The first experiences on the insertion of and measurement with the probe were gathered in 10 healthy volunteers. In their cases, no special premedication was applied except for a light spray of lidocaine into the throat to facilitate the insertion process. In this pilot study, both fasting and 3-hour postprandial tonometric measurements were performed on 2 consecutive days, inserting a new probe each day. In this study group, only the gastric tonometric measurements were recorded. For ethical reasons, the $H_2$-blocker medication was not applied in their cases.

In the clinical part of the examinations, 50 adult patients, scheduled for neurologic, orthopedic, trauma, and cardiac surgery, were enrolled. The exclusion criteria were nonfasting state, pregnancy, a contraindication to nasogastric tube insertion (eg, any kind of nasal atresia or obstruction), erosive gastritis or esophagitis, and gastric or duodenal ulcer.

The characteristics of the healthy volunteers and the surgical population are shown in Table 1.

The numbers of patients classified to the different ASA categories are given in Table 2.

In each clinical case, preoperative $H_2$-receptor blocker medication was administered either orally (150 mg ranitidine

**Table 1** Clinical characteristics of the study population

| Group of patients | No. | Sex (M/F) | Age, mean (min.-max.) |
|---|---|---|---|
| Healthy volunteers | 10 | 6/4 | 31 (21-84) |
| Coronary surgery | 23 | 15/8 | 68 (52-81) |
| Aortic surgery | 3 | 2/1 | 62 (55-68) |
| Neurosurgery | 8 | 4/4 | 53 (17-79) |
| Orthopedic surgery | 7 | 3/4 | 52 (15-81) |
| Trauma surgery | 9 | 2/7 | 70 (21-86) |

M indicates male; F, female.