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Design of a bag to assess esophageal sensation with a barostat and to encourage students in technology design

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***Abstract*— the design and performance of an esophageal barostat bag taking into account the physical and mathematical variables involved, and encouraging students to gain skill at designing a new methodology — were the objectives of this work. We designed the esophageal bag using mathematical formulas for ellipses. With data based on a cylindrical shape, we determined the radius. Then, we calculated the volume for a cylinder with ellipsoidal ends to conform to the ellipsoid-shaped esophageal region we were targeting, using the following formula: $v = \pi d^2 (l/4 + e/3)$. Having obtained the mathematical data, the bag was constructed manually. To test the bag, we used a barostat to assess esophageal sensation in healthy volunteers. We constructed an ultra-thin polyethylene bag, 5 cm in length, with a maximum diameter of 6.1 cm, and a 154.6-ml capacity. With the barostat, we determined that the bag could support a maximum inflation of 40 mm Hg. The data obtained in all the subjects were similar between them as evidenced by the short standard deviation obtained. Esophageal tone was 2.5±1.2 (CI:1.4-3.6) ml. The esophageal sensory threshold was perceived at 11.8±3.6 (CI:8.7-15) mm Hg, the sensation of discomfort at 18±7 (CI:11.9-24.4) mmHg, and the esophageal pain sensation at 24.4±4.9 (CI:20-28) mm Hg. The design and performance of the bag, taking into account the physical and mathematical variables involved, can encourage students to acquire the skills needed to design new methodologies and to have a more complete mental approach to research problems.**

***Index Terms*— barostat bag, design, esophageal visceral sensitivity, science education**

I. INTRODUCTION

A number of curriculum developments incorporating technology [1-3] have appeared recently. We mainly advocate for the need to better train graduates in the diverse, multiple skills that they will need to succeed in obtaining and then excelling in a faculty position [4]. We especially support their development of creative thinking. When students arrive for the first time at a research laboratory, they usually find a fully established and equipped installation with plenty of equipment, instruments and devices for performing their research. However, they ignore the technology behind the fancy, sophisticated equipment and, most of all, the ideas of those who originated the development and probably the patents of those instruments. In our motility research laboratory, we have always believed that ideas are the most important part of the research — not the methodology or strictly following the scientific method, but ideas. This emphasis on ideas is why we have patents [5-7]. Therefore, we teach the students the importance of ideas to encourage them as they develop their potential to acquire the skills necessary to design and implement new methodologies while simultaneously adopting a more complete intellectual approach to research problems.

In the last few years, we have been assessing esophageal [8] and rectal [9;10] visceral afferent sensation by means of an electronic barostat-distender assembly (Distender Series IITM dual drive barostat; G&J Electronics Inc., Toronto, Ontario, Canada). The electronic barostat is a device that maintains a constant pressure in an air-filled bag or balloon through a feedback mechanism, which consists of a monitoring computer (Protocol Plus™ Deluxe software) linked to an air injection/aspiration system. Physiological and mechanical barostat variables are set taking into account previously established guidelines [11]. In this context, the understanding of pain and other sensory symptoms are among the most important issues in the diagnosis and assessment of patients with gastrointestinal (GI) disorders [9;12;13]}. This approach is made possible by means of devices — in this case, the bag with which physiologic responses to noxious and non-noxious stimuli can be elicited by mechanical stimulation [9;10;14]. The design of the bag is customized to the organ or part of the gut in which the bag will be utilized [11]. Usually the specific bag must be purchased or imported, which is onerous because it is expensive and leaves the researcher dependent on imported technology. Alternatively, it must be made in the laboratory, which in some cases can be considered a simple thing to do, unless the task requires designing the bag while taking into account the physical and mathematical variables involved. Using this approach to the design and performance of the bag can encourage the potential skills of the students to design new methodologies, and to have a more complete mental approach to the research problem. Both — the design and performance of an esophageal bag taking into account the physical and mathematical variables involved, and encouraging students to gain skill at designing a new methodology — were the objectives of this work.

II. MATERIALS AND METHODS

The study was conducted in the Bioengineering Section of the Experimental Medicine and Motility Unit at the Gastroenterology Service of the Mexico City General Hospital. Healthy volunteers were recruited by public advertisement. The hospital's Ethical and Research Committee approved the protocol, and signed consent was

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obtained from subjects and members of the interdisciplinary team involved.

To assure that the investigation used current information [15], a MEDLINE and PubMed search were performed up to 2016. We entered research results into the Reference 12 Manager Program (ISI ResearchSoft, Berkeley California, USA) to assure that our citations adequately supported our assertions and to facilitate writing the article so that our formatting and citation styles would meet the standards of the journal selected. Except for the electronic barostat, which could be found in a laboratory that researches motility, all materials that we used (see Table 1) can easily be found in electronics supply stores.

III. Design of the Bag

According to guidelines established by an international working team [11] a barostat bag should be flaccid, meaning that bag inflation should not increase its internal pressure until its maximum capacity has been attained. The selection of the material with which the bag will be constructed is an important issue. The most important characteristics to consider are the type of the material (latex, polyethylene), resistance, compatibility, flexibility, thickness, hardness, and potential secondary effects for the patient. Because polyethylene fulfills all requirements and the established recommendations, and due to its resistance to hydrochloric acid, we used it for the construction of the barostat bag, utilizing an ordinary sandwich bag. The shape of the barostat bag must be adapted to the organ to be studied. Therefore, studies of such tubular regions of the GI tract as the esophagus recommend a cylindrical bag with a fixed length [11]. However, as a careful review of the anatomic literature reveals that the shape of the esophagus is elliptical [16;17], not cylindrical, we designed the esophageal bag using mathematical formulas for ellipses. Based on the reported cylindrical-shaped [18] design of esophageal bags in the literature [11], a volume of 150 ml, and a length of 5 cm, the next step was to obtain the radius of the cylinder as shown in Figure 1A. Subsequently, to calculate the volume, considering that we have an elliptical space with ellipsoidal ends as shown in Figure 1B, the formula is as follows:

$$v = \pi d^2 (l/4 + e/3) \quad (1)$$

Where
l (length) = 5 cm
d (diameter) = 6.16 cm (r = 3.08 cm)
e (length of spherical zone) = 0.5 cm
Substituting
$v = [3.1416 \times 6.16^2] \times [(5/4)+(0.5/3)]$
$v = 119.2 \times [1.25 + 0.16]$
$v = 119.2 \times 1.41$
yields a bag with a volume equal to 168.84 ml. However, as the calculated volume of 168.84 ml corresponds to just the elliptic cylinder, we proceeded to obtain the volume of the internal probe, which was a French 16 with five perforations of 1 mm diameter each, as Figure 1C shows.

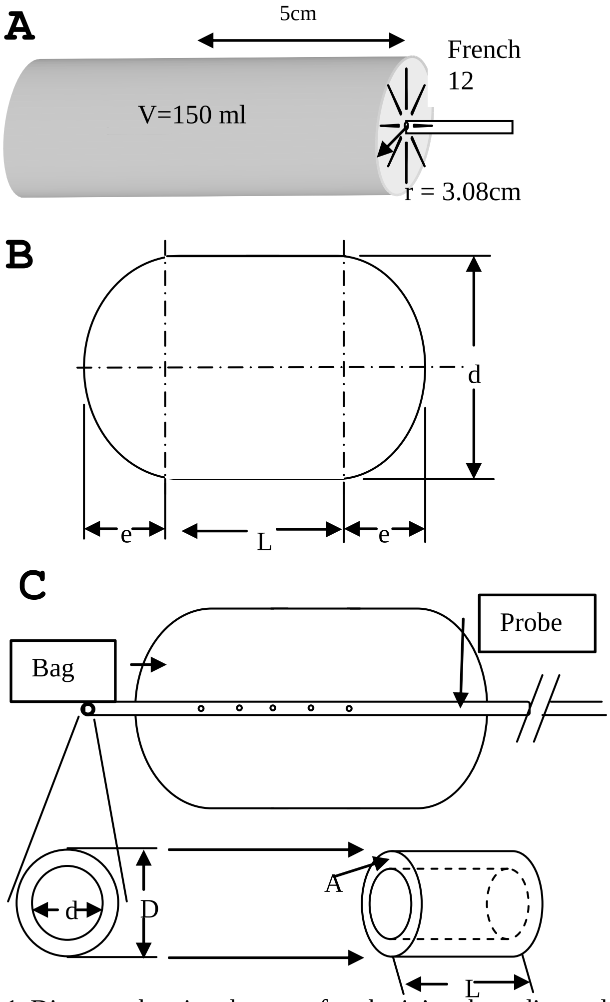

Fig. 1. Diagram showing the steps for obtaining the radius and volume of the esophageal bag, considering an elliptic form.

The next step was to obtain the area of the probe ring, for which the equation follows:

$$a = \{\pi (d^2 - d^2)\}/4 \quad (2)$$

Where
d_1^2 = greatest diameter = 5 mm
d_2^2 = lesser diameter = 3 mm
Substituting $a = \{3.1416 \times (5^2-3^2)\}/4$, we calculate that the area of the probe ring = 1.256cm². Afterward, we obtained the volume of the probe (Fig. 1) with the following equation.

$$v = al \quad (3)$$

Where
a = area of the ring
l (length) = 10.7cm²
Substituting
$v = 1.256\ cm^2 \times 10.7\ cm$
vs (volume of the probe) = 13.43 cm³
So, to obtain the total volume of the bag the equation is as follows.
vt = bag volume – probe volume
vt = 168.84 ml - 13.43 ml, which yields a final volume equal to 154.64 ml.
Having obtained the mathematical data, we constructed the bag manually in the laboratory. Figure 2 shows the steps followed.

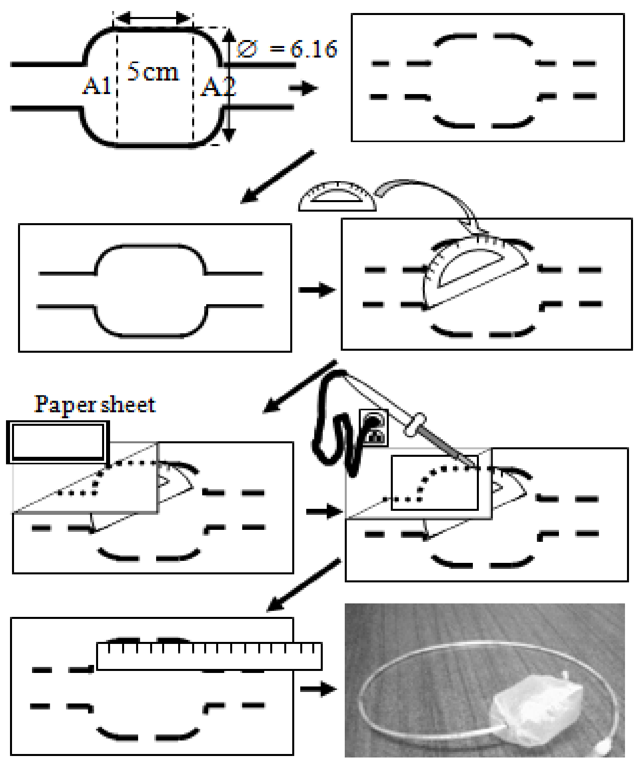

Fig. 2. Steps in constructing the bag.

Table 1. List of materials and construction cost

Item	Number	Cost (USD)
Box of sandwich bags	1	3.00
Soldering iron	1	15.00
Silk thread	1	5.00
Paraffin	1	5.00
French 12 tube	1	5.00
Glue	1	2.00
Basic tools		
Total (approx)		35.00

Subjects

To test the bag, five healthy, paid volunteers without esophageal or gastric symptoms (21 ± 3, range 16–25 years, four females) were studied. For all subjects, we took a clinical history, and all subjects underwent standard laboratory tests, upper GI endoscopy, and esophageal manometry before we started the barostat esophageal studies.

Study protocol

Visceral sens,ation was assessed using an electronic barostat-distender assembly (Distender Series II^{TM} dual drive barostat; G&J Electronics Inc., Toronto, Ontario, Canada) in the esophagus. The electronic barostat is a device that maintains a constant pressure in an air-filled bag or balloon through a feedback mechanism. As designed by the manufacturer and used by other researchers [19], especially for the esophagus a 200-ml cylinder was installed in the barostat with an inflation rate of 280 ml/min. The bag that we developed consisted of an ellipsoidal, ultra-thin polyethylene bag of infinite compliance and a maximum inflation of 150 ml, tightly attached at both ends to a single-lumen polyvinyl catheter that was connected to a 12 Fr flexible double-lumen polyvinyl catheter. After fasting overnight, unsedated subjects were placed in a quiet, isolated room and were studied in a seated position with the distal end of the bag positioned 5 cm above the lower esophageal sphincter, which had been previously located by manometry [20;21]. Subjects were instructed concerning the nature of the distension protocol and had no visual or auditory cues to anticipate the intensity of distension. After obtaining the individual operation pressure (IOP), the bag was inflated two steps up from that level to ensure that it was totally unfolded and in complete contact with the subject's esophagus. To test muscle tone, the bag was inflated to the IOP, and the volume was recorded for a 15-minute period.

Distension protocol

All procedures were performed according to other protocols [11;22;23]. The barostat was programmed to deliver a series of phasic isobaric esophageal distensions that were 30 seconds in duration and separated by 30-second periods during which bag pressure returned to the IOP. Distension stimuli were programmed to increase by 2 mm Hg with each successive distension until the subject reported pain. Sensations in response to distension were determined by means of a patient Perception Panel™ (G. & J. Electronics) interfaced with the software of the barostat. The questionnaire for sensations consisted of a graphic rating scale with combined numerical descriptors on a visual analog scale graded from 0–3. Each sensation was graded independently. Orientation descriptors were provided on the electronic patient response monitor to indicate that 0 represented no sensation, 1 represented first (initial) sensation, 2 represented heartburn, and a score of 3 represented the first sensation of pain. Each trial ended when the patient pressed the panic button or when a maximum pressure of 28 mm Hg was achieved.

1) Statistical Analysis

Statistics were calculated using the 2000 GraphPad Software package of statistical programs (San Diego, CA, USA). Data have been expressed as mean ± standard deviation (SD) and binominal 95% confidence interval.

IV. RESULTS

Bag

We constructed an ultra-thin polyethylene bag, 5 cm in length, with a maximum diameter of 6.16 cm, and a 154.64-ml capacity (Fig. 2). The physical reliability of the bag was tested. First, with a 50-ml glass syringe, the bag was inflated to 150 ml and introduced into water in order to observe possible leaks of air. Then, we measured with the barostat, reaching a volume of 154.64 ml, the 4.64 ml being a negligible 3.09% increase in volume. With the barostat, we determined that the bag could support a maximum inflation of 40 mm Hg. After these tests, we were ready to use the bag with the human volunteers.

Esophageal tone and sensory thresholds to esophageal distension

Esophageal tone was 2.5±1.2 (CI: 1.4–3.6) ml. The esophageal sensitivity data obtained in all the patients were very similar between them as evidenced by the short standard deviation obtained. The esophageal sensory threshold was perceived at 11.8±3.6 (CI: 8.7–15) mm Hg, the sensation of discomfort at 18±7 (CI:11.9–24.4) mmHg, and the esophageal pain sensation at 24.4±4.9 (CI:20–28) mm Hg.

Education skills enhancement

Students learned how to review the background literature by accessing MEDLINE and PubMed, how to incorporate the obtained data into a reference program, and how to manage the references to assure their adequate study and to manage writing their article with the format and citation style corresponding to the journal selected. With the data obtained, they gave a PowerPoint presentation at a national meeting and published preliminary reports as abstract (participating as co-authors) [8;24].

V. DISCUSSION

This article presents a curriculum for the students that integrate the teaching of gastroenterology by a clinical faculty, the application of a barostat physiological protocol led by a research scientist, and the application of engineering principles – discussed in this report – to design and make the bag based on computational and mathematical formulas taught by an engineer. The use of these formulas is now considered to be computational physiology [25]. We agree with the concept that such multimodal methods undoubtedly represent a major step forward in the future characterization and treatment of patients with various diseases of the gut [26]. In this context, our curriculum for the students incorporates technology, as others advocate [4], but also stimulates creative engineering thinking by involving them in the design and construction of the barostat bag.

Our bag was made of polyethylene, a material utilized earlier by Mayrand and Diamant [27] to make a balloon, and further established as suitable to be utilized for the bag by the working team [11]. We created an esophageal bag that was 5 cm long, identical to the 5 cm used by Mearin et al. [18], and similar to the 4.5 cm used by Hu et al. [23], Mayrand and Diamant [27], and recently by Karamanolis et al.[19]. The maximum volume of our esophageal bag came to 154.64 ml compared to the 120 ml of maximal capacity reached by Mearin et al [18], a difference that seems to be negligible. Our esophageal bag could be inflated to 28 mm Hg, which is less than the 48 mm Hg reached by Hu et al. [23] with their esophageal balloon, but similar to the 25 mm Hg reached by Mayrand et al. [27]. In this regard, we believe that caution has to be taking in the inflation of the esophagus. The basal esophageal tone of 2.5 ± 1.2 ml measured in healthy volunteers with our bag seems not to be statistically different from the value of 4.1 ± 0.7 ml reported by Mearin et al. [18]. Our first measured sensation of 11.8 ± 3.6 mm Hg is similar to the median of 12 mm Hg reported by Hu et al. [23], and our pain threshold of 24.4 ± 4.9 is similar to their median value of 29.8 mm Hg [23], and to the value of 32.2 ± 3.5 mm Hg reported by Brackbill et al. [22].

A possible weakness of this work could be the shape of the bag. However, the esophageal bag developed in this work was comparable to others found in the literature. Yet, we made modifications according to data based on our research of the anatomic literature, which revealed that the structure of the esophagus is elliptical [16;17] instead of cylindrical as was reported for the working team and considered by other researchers. Lately, it was reported that the shape of resting esophagus in normal subjects is oval with no visible lumen and that shortly after ingestion of a water bolus, esophageal shape became circular [17]. This data made us look for a formula appropriate for an ellipse for the construction of the bag.

From the educational point of view, we share the view of Brann and Sloop that active participation enhances learning [4] and add, from our own experience, that the knowledge is in the searching. Research supporting these strategies demonstrates that the skill groups important for the success of academic science faculty include organization and review of relevant literature, as reported by O`Loughlin [15], oral communication and presentation, and writing skills [4]. The objective of our present work was to support the establishment of an educational paradigm based on interdisciplinary research made by a team of scientists, as reported by Humphrey et al. [3], which promotes a new approach for training biomedical engineers, life scientists, and mathematicians.

In conclusion, with the application of this multidisciplinary approach the students can learn how to build professionally a bag for the barostat studies. Furthermore, our curriculum could provide an adequate educational environment to prepare students to assume the multiples roles of an academic faculty member, as well as providing them with the knowledge that they can generate ideas as others have done and, most important of all, helping them to acquire the skill of generating tools, which supports the goal of not depending on imported technology.

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Author contributions: Awad RA conceived of the idea, performed the protocol, evaluated data, recruited subjects, acquired data, performed statistical analysis, and drafted the manuscript. MS contributed to the performance of the bag. All authors contributed to the interpretation of the results and the revisions of the manuscript.

Informed consent: Signed informed consent was obtained from all subjects for all procedures.

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