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Barostat or Dynamic Balloon Distention Test: Which Technique is Best Suited for Esophageal Sensory Testing?

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Abstract

Background—Esophageal sensation is commonly assessed by barostat-assisted balloon distension (BBD) or dynamic balloon distension (DBD) technique, but their relative merits are unknown. Our aim was to compare the usefulness and tolerability of both techniques.

Methods—Sixteen healthy volunteers (M/F= 6/10) randomly underwent graded esophageal balloon distensions, using either BBD (n=8) or DBD (n=8). BBD was performed by placing a 5 cm long highly compliant balloon attached to a barostat, and DBD by placing a 5 cm long balloon attached to a leveling container. Intermittent phasic balloon distensions were performed in increments of 6 mm Hg. Sensory thresholds and biomechanical properties were assessed and compared.

Key Results—Sensory thresholds for first perception (mean $\pm$ SD; 21 ± 6 vs. 21.2 ± 5 , mm Hg, $p=0.9$), discomfort (38 ± 8 vs. 35 ± 9 , $p=0.5$), and pain (44 ± 4 vs. 45 ± 3 , $p=0.7$) were similar with BBD and DBD techniques. However, more subjects tolerated DBD (7/8, 88%) when compared to BBD (4/8, 50 %). Forceful expulsion of balloon into stomach (n=4), pulling around the mouth (n=4), chest discomfort (n=2) and retching (n=2) were overlapping reasons for intolerance with BBD. Esophageal wall distensibility was similar with both techniques.

Conclusions—Both techniques provided comparable data on biomechanical properties. However, DBD was better tolerated than BBD for evaluation of esophageal sensation. Hence, we recommend DBD for performing esophageal balloon distension test.

Keywords

Dynamic balloon distension; esophagus; barostat; sensory testing; chest pain

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Conflict of Interest: None

Introduction

Over the last two decades significant strides have been made towards an understanding of the pathophysiology of unexplained chest pain. In particular, esophageal hypersensitivity has been identified as a key mechanism and described as a hallmark for esophageal chest pain (1,2,3).

Over the years, several techniques have been used including acid perfusion test (4,5), edrophonium test (6,7), esophageal balloon distention test (4,8-12), and electrical stimulation to examine esophageal hypersensitivity (13,14,15). Amongst them, balloon distention test is generally accepted and most widely used as a method of assessing esophageal hypersensitivity (12). However, several methods and techniques of balloon distention have been described, including inflation of a balloon with air or water (8,10), balloon distention using either intermittent phasic or ramp distention techniques as well as the use of a hand held syringe (8,10) or computerized balloon distention technique using a barostat (9,16), or dynamic balloon distention technique using impedance planimetry (11,12).

Both the barostat-assisted balloon distention (BBD) and the dynamic balloon distention (DBD) techniques have been reported to be useful in clinical practice and in drug trials (9-12,16). However, the pros and cons of each technique are not known and have not been compared. Furthermore, there is no standard method of performing the esophageal balloon distention test and this has hindered progress in this field. These issues together with the lack of a commercial device has decreased enthusiasm among many centers for performing the esophageal balloon distention test and/or providing an accurate diagnosis for patients with unexplained and functional esophageal chest pain (4).

Here, we tested the hypothesis that both the BBD and the DBD tests provide useful and comparable information regarding esophageal sensori-motor function. Our aim was to assess and compare the esophageal sensory thresholds and biomechanical properties as well as the tolerability of balloon distensions in healthy subjects using both an esophageal barostat and a dynamic balloon distention technique using impedance planimetry.

Methods

Subjects

Sixteen healthy volunteers underwent stepwise graded balloon distensions of the esophagus using either BBD or DBD techniques in a random order. All subjects were healthy individuals and without any symptoms of cardiac, respiratory, neurological, metabolic, gastrointestinal or psychiatric disorders or drug allergies. None of the subjects were taking any prescription medication other than oral contraceptives or vitamins. They all had a normal physical examination.

All subjects were recruited through a hospital advertisement, and provided written informed consent that was approved by the human subjects Institutional Review Board and received compensation.

The following equipment and study protocols were used to perform each test:

Barostat Balloon Distension [BBD] Test

This test was performed in 8 subjects (3 male/5 female, mean age 36 years) by placing a custom-designed probe that was 4 mm in diameter, with three ports. One port was used for balloon inflation and one for recording the intraballoon pressure and volume, and the remaining port (water perfused) was used to measure intraesophageal pressures, and primarily to locate the lower esophageal sphincter (LES). A 5.0 cm long, highly compliant balloon (Mui Scientific, Toronto Canada) was tied on to the probe to enclose the side ports. The bag was inflated before initial use and after completion of each experiment to ensure that there was no leak. The probe was connected to a barostat (G & J Electronics; Toronto, Canada), a computer-controlled, balloon-distending device. The perfusion ports were connected to a low compliance pneumo-hydraulic pump (Arndorfer; Milwaukee; WI) through which water was perfused at a rate of 0.6 ml/minute and connected to an amplifier/recorder (Medtronic Synectics; Minneapolis; MN). After detection of the LES pressure and confirming the probe location, these ports were closed.

Study protocol—After an overnight fast, and topical oropharyngeal anesthesia (Tetracaine HCl (Pontocaine; Abbott Laboratories, Chicago, Illinois, USA) the lubricated probe was passed through the mouth and taped in position such that the center of the balloon was located at 10 cm above the upper border of the LES, as discussed above.

Few distentions (3, 6 and 9 mm Hg pressure) were performed to educate the subject regarding anticipatory sensations. After a rest period of 10 minutes, the balloon was distended in increments of 1 mm Hg to identify the intraoperating pressure (IOP). Thereafter, graded balloon distentions were performed in increments of 6 mm Hg above the IOP, including hysteresis by using intermittent phasic distension technique and either up to a maximum of 48 mmHg or until the subject reported pain (Figure 1). The balloon distentions were maintained for 2 minutes and then deflated. After a rest period of 2 minutes, the balloon was re-inflated to the next step. During each distention, the subjects were asked to rate their sensations on the following scale: 0=no sensation, 1=sensation of fullness or distension (first perception), 2=moderate discomfort (tolerable) and 3=pain. Subjects were instructed to expect balloon distentions in a random order and not in an incremental fashion.

Measurements and data analysis—The threshold balloon pressures that induced a sensation of first perception, discomfort and pain were recorded for each individual. Mean compliance (dV/dP) was calculated as the mean value of the individual slopes of the pressure/volume curves and was used to measure the distensibility of the esophageal wall.

Dynamic balloon distension (DBD) test

The sensory perception and biomechanical properties of the esophagus were evaluated by using DBD and impedance planimetry in 8 subjects (3 male/5 female, mean age 37 years). The equipment, which consisted of a probe and a signal processing system, has been described in detail elsewhere (2,11,12). In brief, we used a flexible plastic probe, 6 mm in diameter, that contained four ring electrodes (two outer and two inner electrodes) and five

side holes. A thin latex balloon, 5 cm long, was tied on the probe and this enclosed the four ring electrodes and three side holes. Two of these side holes were used to distend the balloon, and the third was used to measure the intraballoon pressure. The remaining two side holes on the probe were located 3 cm proximal and distal to the balloon and were perfused with water using a low compliance pneumo-hydraulic pump and were used for detecting intraluminal pressure. The leveling container, a 400 ml plastic jar was half-filled with 0.018% NaCl, and was connected to the probe with a plastic tube. The signal processing system consisted of a generator which gave a constant alternating current of 100 mA at 5 kHz, an amplifier, an impedance detector, an analogue–digital converter and a computer (2,11,12).

Study protocol—After an overnight fast, the subject's throat was sprayed with tetracaine HCl (Pontocaine; Abbott Laboratories, Chicago, Illinois, USA) and the lubricated probe was passed through the mouth into the stomach. Participants were asked to lie on a bed, which was tilted at the head end by 30°. After a rest period of 10 min, the catheter was gradually withdrawn and taped in position such that the balloon was located at 10 cm above the LES. After another 10 min rest period, the intraesophageal balloon pressure was zeroed by adjusting the height of the leveling container. The leveling container was located adjacent to the subject but was hidden behind a screen such that the subjects were unaware of the degree of balloon inflation. All subjects were told that the distending pressures were changed randomly and not in a stepwise manner, and at baseline a few random distensions were performed to familiarize the subject. Next, the balloon pressure was increased using intermittent phasic distentions at increments of 6 mm Hg (Figure 2), by raising the leveling container and infusing 0.018% NaCl (at 37°C) into the balloon. Each inflation was maintained for 2 minutes, after which the balloon was deflated by lowering the leveling container and after a rest period of 2 minutes, was re-inflated to the next pressure. Approximately one minute after each inflation, the subjects were asked to grade their sensations using the following scale: 0=no sensation, 1=sensation of fullness or distension (first perception), 2=moderate discomfort (tolerable) and 3=pain. The balloon distension pressures that induced each of these sensations were recorded. The balloon distensions were continued until chest pain was evoked or until a maximum pressure of 48 mm Hg was reached, whichever occurred first. During inflation, the subjects were asked to refrain from swallowing and to signal the onset of any reflex swallows. At the end of the study the balloon was tested to assess any leaks.

Measurements and data analysis—The threshold balloon pressures that induced a sensation of first perception, discomfort and pain were recorded in each individual. Biomechanical properties of the esophagus were also assessed and has been described in detail previously (2,11,12,17). In brief, we measured the steady state cross sectional area (CSA) of the esophagus at each level of balloon distension, the circumferential wall tension (T) and the strain (e), a ratio that expresses the deformability of the esophageal wall during balloon distension. The relationship between wall tension and strain was also calculated.

Statistical Analysis

Sensory thresholds (mean $\pm$ SD mm Hg) for first perception, discomfort and pain that were elicited during balloon distensions and with each technique were evaluated and compared. The tolerability of each procedure was also evaluated and compared. Sensory thresholds were compared using Mann-Whitney U test, and tolerability of the two techniques were compared using Fisher's exact test. A p value of < 0.05 was considered significant.

Results

Sensory thresholds

Stepwise graded balloon distension induced a first sensation of fullness with both techniques (Figure 3) and at comparable threshold pressure (mm Hg, mean $\pm$ SD; 21 ± 6 vs. 21.2 ± 5 , $p=0.9$). Likewise, moderate discomfort was induced at similar thresholds (38 ± 8 vs. 35 ± 9 , $p=0.5$). Although all 8 subjects who underwent DBD reported moderate discomfort, only 7/8 reported discomfort with BBD. Likewise, the thresholds for pain were similar between DBD and BBD (44 ± 4 vs. 45 ± 3 , $p=0.7$) (Figure 3), although only 4/8 subjects tolerated BBD.

Esophageal distensibility

In all subjects who could tolerate the BBD, a normal pressure/volume curve was obtained (Figure 3), and in all subjects who tolerated DBD, a tension/strain curve was obtained. The distensibility of esophagus in subjects who underwent BBD was assessed by plotting the pressure/volume relationship (dV/dP). Similarly, the distensibility of esophagus in subjects who underwent DBD was assessed by examining the esophageal wall tension/strain relationship. Both tests showed similar profiles suggesting similar and comparable degree of distensibility of esophagus.

Tolerability of balloon distension test

Only 4/8 (50%) subjects were able to tolerate the BBD until they reported pain when compared to 7/8 (88%) subjects with the DBD technique (Figure 4) ($p=0.14$). The reasons for intolerance with the BBD included, excessive forceful pulling of the distended balloon due to strong esophageal peristalsis ($n=4$), pulling around the angle of the mouth ($n=4$), and severe retching or gagging sensation ($n=2$). Some subjects reported more than one symptom. In 2 subjects the barostat balloon was repeatedly propelled into the stomach through forceful esophageal contractions, preventing assessment of esophageal function. One subject could not tolerate the DBD owing to an excessive and forceful pulling of the distended balloon. After the test, mild throat discomfort was reported by 4 subjects with BBD and in 3 subjects with DBD. At the end of the study no balloon leaks were found with either the DBD or BBD techniques.

Discussion

Balloon distension tests have been used to assess perception thresholds for pain and to characterize subjects with esophageal hypersensitivity and non cardiac chest pain (1-5,12) but data from several laboratories have reported inconsistent results (1,9,10,18), questioning the validity of this test).

In the early 1990's, a more dynamic esophageal balloon distension test using impedance planimetry was developed to assess the sensory and biomechanical properties of the esophagus (11) and for examining the pathophysiology of chest pain (2,17). A further development of the balloon distension technique has been the introduction of the electronic barostat, a computer driven balloon distending device that obviated the need for a hand-held syringe (4). However, whether these techniques provide comparable and useful information regarding sensorimotor function of the esophagus is not known. Also whether the barostat which is more widely available, may serve as the preferred method of evaluating subjects with esophageal sensorimotor dysfunction is unclear.

We found that both with the BBD and DBD techniques, the sensory thresholds for first sensation and discomfort were similar and comparable. However, somewhat unexpectedly, we noted that the intraesophageal balloon distension with the BBD caused bothersome symptoms such as severe and forceful pulling or dragging sensation at the side of the mouth, with oropharyngeal discomfort, and/or a retching or gagging sensation and/or displacement of the esophageal balloon into the stomach in our healthy subjects. These adverse effects were not seen with DBD technique. Hence, it appears that the DBD is better tolerated than BBD for the assessment of esophageal sensation.

It is likely that the abrupt and fixed distension of the narrow and less expandable lumen of the esophagus with the barostat method, most likely induced the strong, propulsive and reactive contractions of the esophageal wall that forced aboral displacement of the probe and severely compromised the performance of the test. Furthermore, the size of the balloon, the rate of inflation or the use of fixed balloon distension may have contributed to the poor tolerance with this technique. In contrast, the lack of probe displacement or forceful pulling around the mouth with the DBD technique, is probably due to the dynamic exchange of a small amount of fluid between the esophagus and the leveling container. This exchange of fluid and the plasticity of this system allowed displacement of some fluid back into the leveling container and facilitated gradual accommodation of the esophageal wall and allowed the esophagus to reach a steady state.

Because 50% of healthy controls were unable to tolerate balloon distensions at higher pressures with the barostat technique, it is likely that a higher proportion of subjects will be intolerant of this technique especially patients with a hypersensitive esophagus and chest pain. Fass and colleagues (4,9) have also previously reported that balloon distension of the esophagus with a barostat resulted in strong phasic esophageal contractions that increased with increments of balloon volume. These powerful contractions in association with a shortening of the esophagus may propel the balloon into the stomach and may escape detection by the subject or the investigator, as was seen in 25% of our subjects.

One of the limitations of our study is that the same subject was not tested with both techniques. This was in part because we had hoped to develop normal control data for both types of balloon distension techniques, and we did not wish to use the same subject twice as this could potentially bias and influence their next study. Other limitations of our study may be grouped under technical issues. It is possible that the rate of barostat balloon inflation and the incremental steps of 6 mmHg may have been excessive for the esophagus; perhaps a

slower rate of inflation and smaller increments of distending pressure may have been preferable. Similarly, whether a ramp distention method as opposed to the intermittent phasic distention protocol that was used in this study is a more suitable method is worthy of further study. However, others have used similar distention paradigms (16), and the 6 mm Hg increment is similar to what we have used in many studies over a decade with impedance planimetry. Also, in our experience we have never observed a 50% reduction in tolerance with any series of balloon distention studies. Thus, in the DBD method, if the esophageal wall reacts to the balloon distention by inducing reactive contractions, fluid is displaced from the esophageal balloon into the leveling container. This dynamic exchange of fluid allows the esophageal wall to accommodate and gradually reach a study state of distention. Finally, we sprayed the oropharynx with topical anesthetic to facilitate probe placement. This may have interfered with the assessment of sensory thresholds. However, subjects were instructed not to swallow for 5 minutes after topical application and balloon distentions were performed starting at least 30 minutes after topical application minimizing potential effects.

Hence, although the barostat is a useful balloon distending device and has been widely used by our group and others for the assessment of gastric, colonic and rectal sensory tone, and has been validated (19,20), our study suggests that the barostat is not suitable for routine assessment of esophageal sensorimotor function in humans.

In conclusion, our study shows that dynamic balloon distention appears to be the preferred technique for the assessment of esophageal sensory and biomechanical properties, and both for conducting mechanistic studies as well as for the clinical assessment of subjects with unexplained esophageal chest pain.

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References

1. Remes-Troche JM. The hypersensitive esophagus: pathophysiology, evaluation, and treatment options. *Curr Gastroenterol Report*. 2010; 12:417–26.
2. Rao SS, Hayek B, Summers RW. Functional chest pain of esophageal origin: Hyperalgesia or motor dysfunction. *Am J Gastroenterol*. 2001; 96:2584–9. [PubMed: 11569679]
3. Lembo AJ. Visceral hypersensitivity in noncardiac chest pain. *Gastroenterol Clin North Am*. 2004; 33:55–60. [PubMed: 15062437]
4. Fass R. Sensory testing of the esophagus. *J Clin Gastroenterol*. 2004; 38:628–41. [PubMed: 15319643]
5. Kaul B, Petersen H, Grette K, et al. The acid perfusion test in gastroesophageal reflux disease. *Scand J Gastroenterol*. 1986; 21:93–96. [PubMed: 3952458]
6. Nostrant TT. Provocation testing in noncardiac chest pain. Chest pain of undetermined origin. *Am J Gastroenterol*. 1991; 5A:S56–S64.
7. Richter JE, Hackshaw BT, Wu WC, et al. Edrophonium: a useful provocative test for oesophageal chest pain. *Ann Intern Med*. 1985; 103:14–21. [PubMed: 4003972]

8. Richter JF, Barish CF, Castell DO. Abnormal sensory perception in patients with esophageal chest pain. *Gastroenterology*. 1986; 91:845–52. [PubMed: 3743962]
9. Fass R, Naliboff B, Higa L, et al. Differential effect of long-term esophageal acid exposure on mechanosensitivity and chemosensitivity in humans. *Gastroenterology*. 1998; 115:1363–73. [PubMed: 9834263]
10. Trimble KC, Pryde A, Heading RC. Lowered oesophageal sensory thresholds in patients with symptomatic but not excess gastro-oesophageal reflux: evidence for a spectrum of visceral sensitivity in GORD. *Gut*. 1995; 37:7–12. [PubMed: 7672684]
11. Rao SS, Gregersen H, Hayek B, et al. Unexplained chest pain: The hypersensitive, hyperreactive, and poorly compliant esophagus. *Ann Intern Med*. 1996; 124:950–8. [PubMed: 8624062]
12. Nasr I, Attaluri A, Hashmi S, et al. Investigation of esophageal sensation and biomechanical properties in functional chest pain. *Neurogastroenterol Motil*. 2010; 22:520–6. [PubMed: 20067548]
13. Drewes AM, Arendt-Nielsen L, Funch-Jensen P, Gregersen H. Experimental human pain models in gastro-esophageal reflux disease and unexplained chest pain. *World J Gastroenterol*. 2006; 12:2806–17. [PubMed: 16718803]
14. Drewes AM, Schipper KP, Dimcevski C, et al. Multimodal assessment of pain in the esophagus: a new experimental model. *Am J Physiol Gastrointest Liver Physiol*. 2002; 283:G95–G103. [PubMed: 12065296]
15. Aziz Q, Andersson J, Valind S, Thompson D. Identification of human brain loci processing esophageal sensation using positron emission tomography. *Gastroenterology*. 1997; 113:50–97. [PubMed: 9207261]
16. Rodriguez-Stanley S, Zubaidi S, Proskin HM, et al. Effect of tegaserod on esophageal pain threshold, regurgitation and symptom relief in patients with functional heartburn and mechanical sensitivity. *Clin Gastroenterol Hepatol*. 2006; 4:442–50. [PubMed: 16616348]
17. Rao SSC, Mudipalli RS, Mujica VR, et al. Effects of gender and age on esophageal biomechanical properties and sensation. *Am J Gastroenterol*. 2003; 98:1688–95. [PubMed: 12907320]
18. Cannon RO 3rd, Benjamin SB. Chest pain as a consequence of abnormal visceral nociception. *Dig Dis Sci*. 1993; 38:193–6. [PubMed: 8425431]
19. Van der Schaar PJ, Lamers CBHW, Masclee AAM. The role of the barostat in human research and clinical practice. *Scand J Gastroenterol*. 1999; 34(Suppl 230):52–63.
20. Whitehead W, Delvaux P. Standardization of barostat procedures for testing smooth muscle tone and sensory thresholds in the gastrointestinal tract. *Dig Dis Sci*. 1997; 42:223–41. [PubMed: 9052500]

Figure 1.

A typical example of esophageal balloon distention study using the barostat balloon distension technique in a healthy subject with hysteresis. The upper panel shows the esophageal pressure profiles during graded pressure distentions and the lower panel shows the corresponding volume changes (tone) in the balloon. The horizontal axis represents time.

Figure 2.

Typical example of stepwise graded esophageal balloon distention during the dynamic balloon distention technique in a healthy subject including hysteresis. The distending pressures used to distend the esophageal balloon are shown above each esophageal cross sectional area profile. The balloon cross-sectional area is shown on the vertical axis and time on the horizontal axis.

Figure 3.

The distensibility of esophagus in subjects who underwent BBD was assessed by plotting the pressure/volume relationship (dV/Dp , left panel). Similarly, the distensibility of esophagus in subjects who underwent DBD was assessed by examining the esophageal wall tension/strain relationship (right panel). Both tests showed similar profiles of esophageal wall distensibility.

Figure 4.

Mean esophageal sensory thresholds during the two balloon distention techniques. The number of subjects who tolerated each device and reported the respective sensation is also shown within the horizontal bars.