Original Article

METHODS AND DEVICES FOR ANAL SPHYNCTER TONOMETRY: CHALLENGES AND SOLUTIONS

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Received: November 20, 2011
Revision received: December 01, 2011
Accepted: December 22, 2011

Summary

Anal tonometry contributes to objective assessment of the functional status of the anal sphincter complex. There are a variety of methods used in measuring the difference in pressures, generated by this complex, as well as various devices. In everyday practice, few health establishments in this country have such devices. We aimed to evaluate the requirements to devices of this kind in view of choosing an appropriate method and a device, so as to invent and put to the test in everyday practice a relevant device. We created a 5-channel anal sphincter tonometer connected to a computer. The software specially developed for the purpose makes it possible to obtain and record real-time results from the tonometry, carried out simultaneously or in sequence at different levels of the anal canal.

Keywords: sphinctertonometry, sphincter pressure gauges, anal sphincter, rectoinhibitory reflex, anal sphincter pressure

Methods in sphincter tonometry: advantages and disadvantages

Anal sphincter tonometry helps to objectively assess the functional status of the anal sphincter complex. In clinical practice, any surgical intervention on the anal canal and the distal part of the colon should be undertaken after a careful preliminary assessment of the sphincter tone. It is important to know what the effect of a surgical operation on anal continence might be. The latter helps to determine the adequacy of any specific method of treatment.

What is measured and why? Parameters that could be measured by anal tonometry

Resting anal pressure

The anal pressure at rest (RAP) is responsible for continence of the anal sphincter complex. If the values of RAP decrease below a specific level, anal incontinence of varying degrees may occur. The internal sphincter is in physiological tonic contraction while the external sphincter is in partial contraction even during sleep [1, 2, 3]. Resting anal pressure is mainly determined by the contractions of the external anal sphincter. The muscle is in continuous tone due to phase variations of slow

waves. They are most commonly observed when the resting pressure is high and they occur at a rate of 6 to 20 per minute with an amplitude of 10-20 cm H_2O [4, 5]. Extremely slow waves with a high pressure and a rate of 1-3 per minute are registered in 5% of healthy volunteers examined [6].

The value of the anal pressure is formed by the internal sphincter which contributes for 50 to 80 % of it, the external sphincter – 25-30% and the hemorrhoid tissue – 15-20%.

Resting anal pressure is lower in females than in males [7, 8] and decreases with age [8]. Usually, a value of 50-100 cm H_2O is considered normal.

Volitional contraction anal pressure

Volitional contraction anal pressure (VCAP) is responsible for controlling the urge to defecate and overcoming the increased intraabdominal pressure. When the values of VCAP lower than a definite threshold, anal incontinence of a varying degree occurs and the urge cannot be controlled. The external sphincter is responsible for volitional contraction pressure which is measured as the difference between resting anal pressure and the maximum value measured in volitional contraction pressure [9]. It is lower in females and decreases with age [7]. The reflex of contraction of the external anal sphincter as a response to increased intraabdominal pressure is tested while coughing during the examination, which should be routinely performed during anal manometry [10].

Cough anal pressure

Cough anal pressure (CAP) shows the difference occurring in the rectal pressure caused by increased intraabdominal pressure during coughing and the pressure in the anal canal, determined by the tone of the external sphincter and a transitory volitional contraction of the external sphincter, accompanies the cough reflex. When the values of CAP become lower than the values of pressure in the rectum, varying degrees of anal incontinence may occur.

Rectoanal inhibitory reflex

Rectoanal inhibitory reflex (RAIR) is the decrease in the values of resting anal pressure by 20%, while the pressure in the rectum increases as a result of distension or contraction [11, 12], generated by the intramural nerve path [13;14] with subsequent return to normal values.

The reflex can be examined by balloon dilation of the rectum, during which anal pressure values are recorded. A balloon is attached to the tip of a perfusion catheter and placed in the rectum. The anal pressure is then stabilized and the balloon is filled with 20-50 ml of air or liquid. This leads to a decrease of the rest anal pressure by 20% with a subsequent return to normal ranges (positive reflex). This reflex is absent in patients with Hirshsprung disease [15]. A significant relaxation of the anal sphincter occurs in cases of increased rectal pressure is found in patients with fecal incontinence and patients with constipation [16].

How is it measured? Advantages and disadvantages of methods. Devices and techniques for sphincter tonometry

Laeven was the first to apply anorectal tonometry in assessing the tone of the anal sphincter in 1928. Later, Gaston (1948), V. N. Demin (1954), Janchev (1959), A. M. Aminev (1965) and other authors suggested new approaches in sphincter tonometry and improved the technique. In 1960, Hill proposed registering the gradient of pressure in the ano-rectum with placing a hydro-perfusion system. In 1974, Holschneider applied the method for distinguishing different forms of chronic obstipation.

Today we have a large variety of methods for recording the pressure gradient, generated by the anal sphincter complex. The pressure can be measured simultaneously or step by step at different levels of the anal canal. This is usually accomplished at intervals of 1cm, although some perfusion systems can make recordings at intervals of 0.75cm.

Simultaneous recording of all the values is preferable because it saves time for the sphincter complex to adapt to the catheter and time it takes to measure the normal rest pressure which is about 3 minutes. The use of the pull-through technique requires calibration of the rest pressure on each level of the anal canal. The maximal diameter of the recording device should be less than 5 mm.

Catheters with larger diameter increase pressure in the anal canal because of irritation of the anal sphincter complex with a subsequent increase in muscle tone [2, 17, 18].

Perfusion systems

Perfusion catheters are set of small tubes with low stretch coefficient and side holes connected to sensor for registering the pressure, perfused with gas-free water at constant rate which may be 0.4 to 0.6 ml/min. Constant perfusion is needed for keeping the side holes open all the time. The pressure in the catheter is the index of resistance

of the liquid flow leaking out of it. Catheters used have 4 or 6 channels. A perfusion catheter can be also applied using a pull-through technique.

A possible cause for inaccurate results when using this technique is the likelihood of the liquid to leak out, irritate the anal mucosa, thus causing contraction of the sphincter complex.

Advantage: The perfusion systems are considered most accurate.

Disadvantages: This is very expensive laboratory equipment, requiring continuous water flow and generating positional differences in values registered. Perfusion systems are not suitable for routine out hospital practice**.**

Balloon systems

Balloon systems consist of a balloon filled with liquid or air, attached to a smooth non-expandable tube that is connected to a sensor to register the gradient of pressure. The balloon systems filled with water yield results comparable to those filled with air [19, 20]. Modern balloon systems use micro balloons with a diameter of 4mm. A stationary pull-through technique can be applied. With this method, no information is obtained about the about variations in radial pressure because the balloon only records the maximal pressure in every zone.

Advantage**:** They are suitable for everyday practice outside the hospital.

Disadvantage: they are not as precise as perfusion systems and no information about changes in radial pressure are obtained.

Sleeve catheters

Catheters of this type have an elastic membrane, fixed on a catheter to form a closed chamber through which water is perfused [21]. The sleeve stretches through the whole anal canal and can measure the pressure on every level. This technique is applied to measure pressure during defecation, while the patient is sitting on a toilet dish thus registering movement of the anus in caudal direction. The use of sleeve catheters is limited only to physiological studies in special laboratories.

Advantage: They are highly precise and demonstrate physiological changes during defecation.

Disadvantages: This is very expensive laboratory equipment necessitating specific conditions. It is not suitable for routine everyday practice.

Straingauge catheters (deformation sensors)

The now available strain gauge transducers have resistors that are fixed on a metal diaphragm placed into vacuum. The pressure applied on the diaphragm changes the resistance in the system, and this resistance is converted into units for measuring pressure [22, 23].

The catheters used can consist of one or more transducers, applied with stationary pull-through technique or simultaneous recording device. A stationary system or ambulatory system can be used for obtaining real time values.

Advantage: Strain gauge catheters can be used in everyday practice in a setting outside the hospital.

Disadvantages: The equipment is rather expensive, the price depending on the number of transducers used. The device is not as precise as perfusion systems. No information can be obtained regarding the changes in radial pressure.

Vector manometry

The use of a perfusion catheter to record radial pressure makes it possible to generate a 3D graph indicating the tone of the anal sphincter. The catheter has 8 side openings and a stationary pull-through technique or continuous pull-through technique is used [25]. Vector manometry is useful for determining the origin of the sphincter deficit, regardless of the cause – muscular defect or a neurogenic lesion with a non-damaged sphincter ring.

Advantage: The device provides a high level of precision and reliability in detecting defects of sphincter lesions, and a 3D presentation of the sphincter dysfunction can be obtained.

Disadvantages: The device can be used in a specialized laboratory setting, rather than in everyday practice. The reliability of results obtained is comparable to those obtained using endoanal echography.

Ambulatory manometry

The systems available for measuring anal tone use stain gauge transducers. They are easy to handle but probes with a sufficient number of transducers are very expensive and ambulatory perfusion systems are necessary. The probe should have three transducers – one at the top to measure rectal pressure, and two for anal pressure. The minimum distance between the transducers in a flexible probe is 2 cm.

However, if the anal canal is short, it is impossible to use two locations. The application of one anal transducer implies its positioning midway along the anal canal.

Advantage: These systems are applicable in everyday practice.

Disadvantage: The measurement is not reliably precise.

Requirements to devices in view of needs of everyday practice and related problems

The problem remains how to identify a reproducible method for objective quantitative evaluation of sphincter dysfunction. At present, the assessment is based on a digital rectal examination and a subjective interpretation of a semi-quantitative scale. The specialized equipment available on the market is unaffordable and suitable for use in a laboratory setting.

We defined the requirements to the device we needed:

- It should be portable and suitable for use in both laboratory and ambulatory conditions.
- It should measure the pressure at different levels in the anal canal and the rectum.
- There should be a balloon to allow using liquid to register the changes in RAIR,
- Calibration should be possible to standard manometric apparatuses and make the results obtained comparable to values obtained by other devices.
- It should work with precise sensors for pressure and microprocessor analog-digital converter.
- The probe of the device should be not more than 10mm in diameter
- The connection to a laptop computer and power supply should be of 5 volts maximum.
- The software should register data frequently enough – up to three readings per second and present the data graphically in real time.
- The software should integrate all data required by the protocol of the investigation: personal data, diagnosis, treatment administered.
- There should be the option to print out the graphs representing the data obtained and the statement of the investigator.
- The device and the software should be relatively non-expensive and allow to be updated.
- The software should provide export of data for the purposes of processing.

Ambulatory sphincter tonometry device

We constructed a device and developed software for anal tonometry which has the advantages and the precision of the devices for laboratory studies and a compact size like that of portable devices.

The probe used is a five channel balloon catheter, 7 mm in diameter and 5cm in length, correlating with the sizes of the zone with increased pressure in the anal canal, which is 4-5sm in length. The pressure gradient is measured in the zone with a length of 4cm for the anal canal, and that of 1cm registers the pressure in the rectum. We also took into consideration the diameter of the probe, recommended in studies – less than 10 mm, because a probe of this size does not provoke an increase in the sphincter tone when inserted in the anal canal.

The balloons are 0.1mm thin and 1cm long. They are placed along the 5-cm zone, and then filled with distilled water. The first balloon registers the pressure in the rectum and is used for examination of the rectoanal inhibitory reflex. It is connected to a syringe for injecting air or liquid. The second balloon registers the pressure in the anal canal at the level of the deep part of the external anal sphincter and puborectal muscle. The third balloon registers the tone at the level of the medial part of the external anal sphincter. The fourth balloon registers the pressure in the anal canal at the level of the superficial external sphincter. The fifth balloon registers the pressure in the anal canal at the level of the subcutaneous part of the external anal sphincter. The probe is presented schematically in Figure 1.

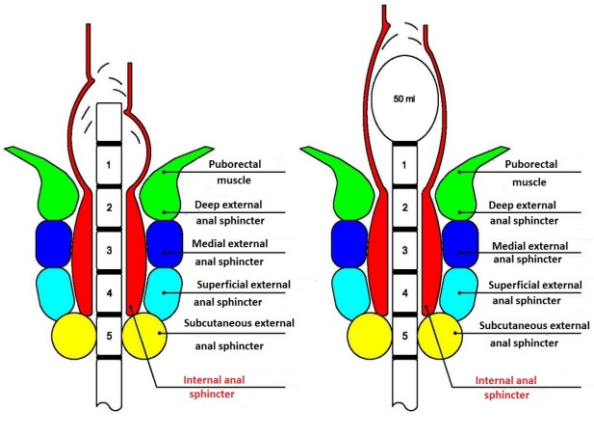

Figure 1. The probe of the sphincter manometer

The sphincter manometer registers in real time the pressure in the anal canal in rest, in volitional contraction and while coughing.

The software created by us can digitally present the data recorded. The data is recorded every second. Every sensor measures the

pressure in the anal in a circular zone 1cm in length. Before examination the device is calibrated in a horizontal position, in which the pressure from the five balloons is registered. During examination, the data received is a result of the values acquired during the study minus the values received during calibration. The data has a graphic and numeric expression and can be recorded in cm H_2O or mm Hg. The software allows reading the peak levels and automatically records them in an EXCEL table.

First, we examine the sphincter tone at rest, which is a result of the tone of the internal anal sphincter, and partly the tone of the external anal sphincter. While coughing and in volitional contraction, the data obtained objectively reflects the data about the tone of the external anal sphincter at the anatomical levels mentioned above. The following inflation of the rectal balloon with 50 ml of liquid allows the registration of the status of the rectoanal inhibitory reflex (presence or absence). If a 20% increase in the values of the anal pressure at rest is seen after inflation of the rectal balloon with 50ml, with a subsequent return to normal ranges, we assume that the rectoanal inhibitory reflex is positive. If there is no change in the anal tone at rest and after inflating the rectal balloon, the reflex is negative (lack of reflex). A graphic presentation of the recorded values is shown on Figure. 2.

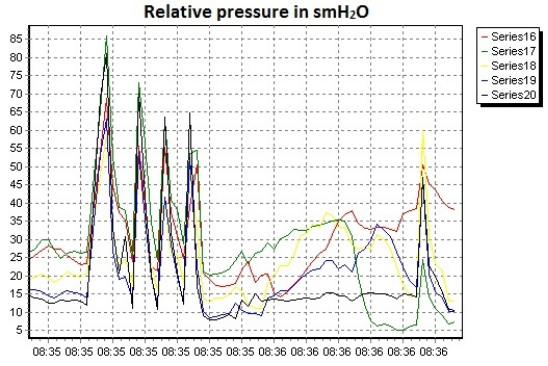

Figure 2. Graphic presentation of the registered values of anal canal pressure at rest, in volitional contraction and while coughing, and RAIR

On the graph the rectoanal inhibitory reflex is negative. Figure 3 demonstrates a positive rectoanal inhibitory reflex. When the pressure is increased in the rectal ampulla by inflating a balloon with 50 ml of water until a value of 240 cm H_2O, a decrease is registered in the pressure of the sphincter complex with more than 20% from the one measured while at rest, with a subsequent return to normal ranges after the rectal balloon is deflated.

The values measured in the subcutaneous anal sphincter are shown in black, the ones in the superficial anal sphincter – in blue; the ones in the medial anal sphincter – in yellow, yellow –; green – the ones in the deep anal sphincter – in green, and these in the puborectal muscle – in red.

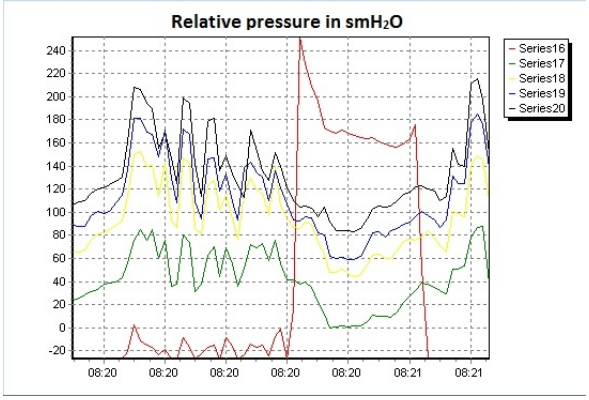

Figure 3. Graphic presentation of the registered values of anal canal pressure in rest, in volitional contraction and while coughing, and RAIR

Examination protocol

The examination is performed on a patient who is in supine position on his/her left side, with legs bent at the hip and knee joints. After the probe is inserted into the anus, a period of 5 minutes is required for the sphincter to adapt. After this period, a series of three volitional contractions, each for 5 seconds is conducted. Between each volitional contraction there is a period of 30 seconds. This is followed by a single cough; inflation of the rectal balloon with 50 ml of liquid which stays inflated for 1 minute. This allows us to examine the rectoanal inhibitory reflex. Finally, the balloon is deflated which is followed by one last volitional contraction.

Problems with data interpretation.

When normal, the anal canal is elastic and can expand when using different catheters for measuring anorectal pressure and the catheters do not change the results from the examination. In cases of old scars present, or 2nd and 3rd degree hemorrhoids when probes with a larger diameter

are used, the values obtained may be higher than normal. The anal pressure increases when the examination is performed in a standing position because of the increased intraabdominal pressure which in turn increases the tone of the external anal sphincter. When examining RAIR in a stand-up position, it is necessary to inflate the balloons with air because of its low relative weight. The inflation of the rectal balloon with liquid is applied when the examination is performed in supine position of the patient. The decrease in the anal pressure at rest by 20%, followed by return to normal ranges is considered as positive rectoanal inhibitory reflex. When the results from the examination are interpreted, age, previous surgical procedures, presence of illness at the time of the examination, the equipment used and the protocol of the examination are taken into consideration. Figure 4 presents the device itself.

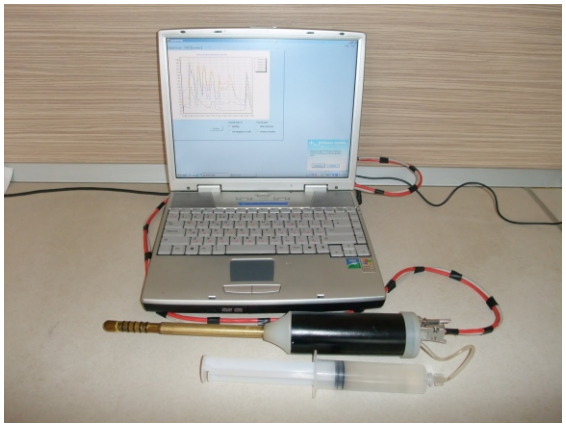

Figure 4. Ambulatory sphinctertonometry device developed

Discussion

The device we propose is easy to handle. Calibration before each time the device is used helps to achieve results that are accurate and comparable to results obtained using similar devices. Calibration takes one minute. Once a week, the device is checked with an external manometer fore accuracy of calibrations and settings of the program with a specially designed set.

Every examination takes 3-5 minutes. The results are printed out on the patient examination form. The device has so far been used to examine:

- Healthy volunteers to serve as a control group.
- Patients with anal fissure.
- Patients with anal fistula.
- Patients with gynaecological diseases.
- Patients with oncological diseases.

A total of 143 males and 164 females were examined.

The changes in the values of anal pressure found were determined according to the diseases and the treatment administered. The changes in RAIR were found in patients with cancer of the anorectum, in patients with anal fissure and patients with anal fistula.

The results also correlated with the complaints of the patients, the subjective assessment based on digital rectal examination of the tone (R^2=0.77) and the evaluation based on the scale of incontinence (R^2=0.87).

Conclusion

Sphincter tonometry on its own is not a gold standard for assessment of the functional status of the anal sphincter complex. It is an addition to the other instrumental methods for diagnostics and complex assessment of the anal function. The device proposed by us is easy to use. It helps to objectively assess the sphincter tone on every anatomic level. It also gives information about the presence or absence of RAIR. Sphincter tonometry is an objective method to help determine the treatment plan and outcome and the degree of anal continence before and after treatment.

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