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A novel model used to compare water-perfused and solid-state anorectal manometry

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Abstract Background Anal pressures are commonly measured using water-perfused and solid-state manometers. We constructed a dynamic model of the anus to compare the agreement and reproducibility of the two types of manometers. **Methods** The model system was constructed using a pig anorectum together with an inflatable bowel sphincter. The pig anorectum was mounted on a jig and the sphincter was inserted external to the internal sphincter. The sphincter pressure was adjusted over the range 20 to 185 mmHg. At each of 24 constant sphincter pressures, triplicate readings were carried out with both manometers. The first measurement by each method was used for the comparison. The replicate measurements were used to calculate measures of repeatability for each method. **Results**

Measurements by the two manometers were highly correlated ($r=0.97$). Measurements by the solid state manometer were higher than the water-perfused manometer by 8.1 ± 12.2 mmHg (mean \pm SD). Precision (coefficient of variation) for the solid-state manometer (2.8%) was better than for the water-perfused manometer (8.3%). **Conclusions** The new model of the anal canal shows promise as a tool for assessing physiological interventions. The solid-state manometer has many advantages over the water-perfused manometer, providing more consistent measurements at clinically relevant pressures.

Key words Model • Manometry • Anorectal

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Introduction

Various manometric techniques are used for measuring pressures in the anal canal. Until the advent of solid-state manometers, the water-perfused device was the most widely used. The water-perfused manometer allows recording of multiple pressure channels from one catheter and is relatively inexpensive. However it has several disadvantages. It has a limited frequency response, is difficult to set up and use, and it is prone to artefacts due to movement of the connecting tubing or air bubbles in the system. From the patient's perspective, its appearance is much more daunting than the solid-state manometer [1, 2]. Advantages of solid-state manometers are good high frequency response, application in ambulatory subjects and ease of use.

The objective of the present work was to construct a stable model to replicate the conditions of the human anal canal, then to assess this model's ability to examine the agreement between water-perfused and solid-state manometers for anal pressure measurement. The repeatability of the two types of manometers was also assessed and compared.

Materials and methods

A model of the anal canal was constructed, consisting of pig anorectum together with an inflatable bowel sphincter (Fig. 1a, b). As each pig anorectum with a wide margin of perianal tissue was obtained from the abattoir from already slaughtered animals, ethical approval was not required for this study. The perianal skin, anal canal and rectum were mounted on a jig using circumferential sutures. After dissecting the plane between the internal and external sphincters, the artificial bowel sphincter (Acticon Neosphincter, American Medical Systems, Minnetonka, USA) was inserted into this plane.

The solid-state manometer consists of a balloon catheter of 2-mm outside diameter attached to the transducer port of a Stryker 295-1 intracompartmental pressure monitor (Stryker, Kalamazoo, USA). The water-perfused manometer was a Dentsleeve MMS (Dentsleeve, Bel Air, Australia) system using a five channel 4.5-mm outside diameter catheter (Zinetics Medical, Salt Lake City, USA) which allows the recording of multiple pressures from one catheter. This system was calibrated at 50 cm H₂O (37 mmHg).

The model provided an anal canal with a variable intraluminal pressure. The sphincter pressure was adjusted in a random sequence to provide pressures over the range 20 to 185 mmHg. This was achieved with the artificial sphincter balloon that could be inflated and deflated to apply a pressure that remained constant during each set of measurements. Twenty-four pressures were measured by the water-perfused manometer followed by the solid-state manometer. Three measurements were obtained with each device at each fixed sphincter pressure in order to assess repeatability. Four channels on the water-perfused manometer were used and measurements were taken at 1-cm intervals in the anal canal using the catheter markings and manual advancement of the catheter. Because the channels measured pressures in four different quadrants, values from each channel at the high pressure zone were combined and averaged. For the solid-state manometer the highest attained stable pressure was recorded. Thus, all values were measured in the high pressure zone in the anus. All measurements and recordings were performed by the same investigator.

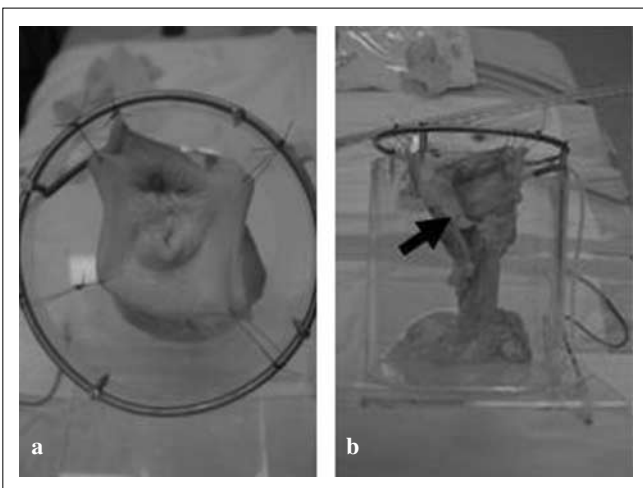


Fig. 1a, b Dynamic *in vitro* model of anus composed of pig anorectum and inflatable, artificial bowel sphincter. **a** Top view: note that the anus is the upper structure. **b** Side view: note the artificial bowel sphincter (arrow) placed around the anal canal

Statistical methods

The two manometers were compared, using the first measurement by each manometer, by the method described by Bland and Altman [3, 4]. Spearman's rank correlation coefficient was used to measure association between the methods. For repeatability assessment, one-way analysis of variance was used to calculate an overall standard deviation (SD) and coefficient of variation (CV) for each method based on the three replicate measurements [5].

Results

The model performed well during the measurements with the pressure remaining constant at each level during testing. The measurements were easy to perform on this model.

The complete set of 3x24 triplets of measurements by the water-filled manometer and the solid-state manometer are compared in Fig. 2 ($r=0.97$, $p<0.0001$) along with the line of identity. The linearity of the association between the two manometers may be poorer beyond 150 mmHg.

The first sets of paired measurements were compared by the Bland and Altman method, in which the differences between the two manometer readings are plotted against the means of the readings (Fig. 3). The mean difference (solid state - water-perfused) was 8.1 mmHg (SD=12.2 mmHg) with 95% limits of agreement -16.3 and 32.5 mmHg.

To examine repeatability, measurements with each manometer were performed in triplicate. Figure 4 shows the SD for the three measurements plotted against the mean of these measurements for the water-perfused and the solid-state manometers. The overall SD was 6.0 mmHg (CV=8.3%) for the water-perfused manometer and 0.5 mmHg (CV=2.8%) for the solid-state manometer. These respective CVs reduce to 7.1% and 1.5% when the outliers at 70 mmHg for the water-perfused manometer and at 160 mmHg for the solid-state manometer are excluded.

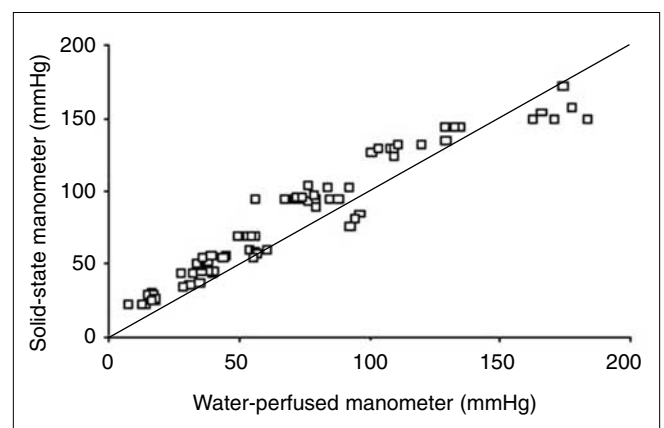


Fig. 2 Pressures readings (in triplicate) at 24 fixed sphincter pressures from the solid-state and the water-perfused manometer ($r=0.97$). The line of identity is shown

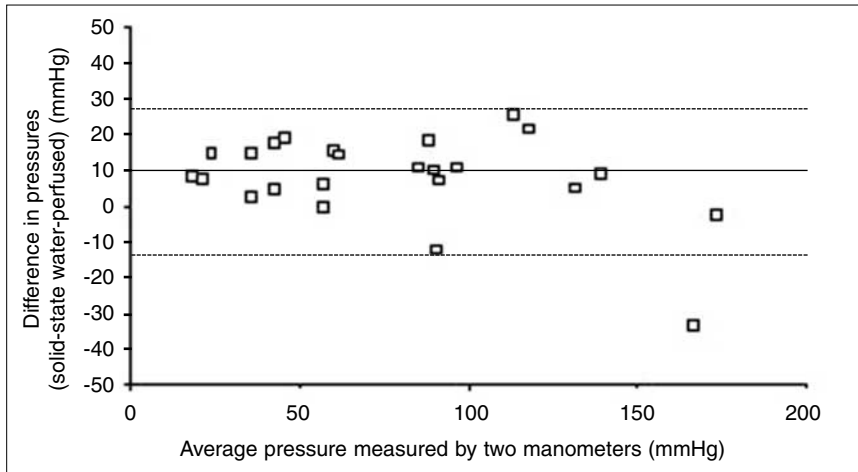


Fig. 3 Differences in pressure measurements by the solid-state and water-perfused manometers at 24 fixed sphincter pressures plotted against the average of both measurements. The mean difference is shown by the solid line and 95% limits of agreement by the dotted lines

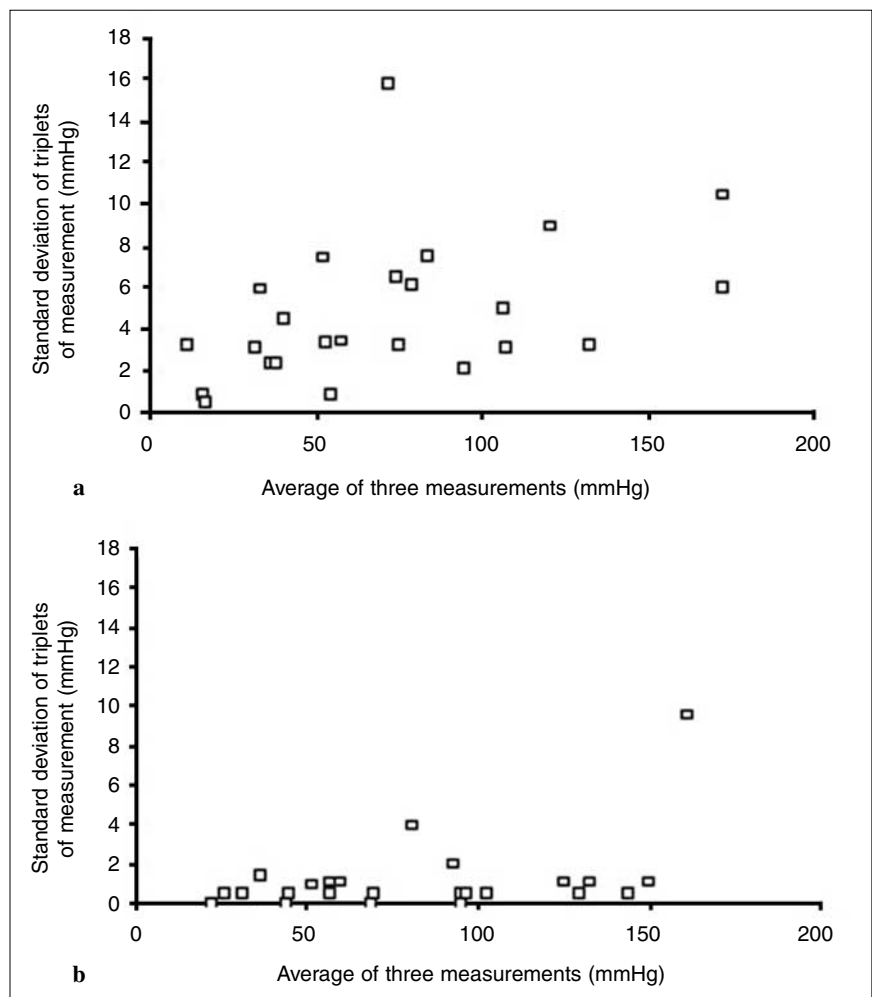


Fig. 4a, b Repeatability of manometric readings of intraluminal pressure in a dynamic model of anus, based on pig anorectum. Values are standard deviations of triplicate readings at 24 fixed sphincter pressures. **a** Water-perfused manometer. **b** Solid-state manometer

Discussion

The described anal physiology assessment model was easy to use and remained stable during the study. This model was used to compare two methods of measuring pressures in the anal canal. While it is an artificial system, it elimi-

nates problems with intra-patient variability and muscle fatigue [6, 7] and thereby provides an accurate comparison of the performance of the two devices.

The solid-state manometer read 8.1 mmHg higher on average than the water-perfused manometer. From a clinical standpoint this is a small difference and is not likely to affect decisions on patient management. However, the

95% limits of agreement are wide, ranging from -16.3 to 32.5 mmHg. There was a marked difference in the repeatability of the two manometers with the solid-state device being more precise (CV, 2.8% vs. 8.3%). While the precision of the water-perfused manometer may be clinically acceptable, the solid-state manometer is clearly capable of highly reproducible measurements.

The consistently lower readings obtained using the water-perfused system may be explained by the different method of measuring the high pressure zone. In the solid-state manometer the balloon was manipulated until it was positioned in the high pressure zone and a single reading was taken, whereas the water-perfused catheter was positioned at 1-cm intervals and the pressures from the four quadrants at the high pressure zone were averaged. If the highest anal canal pressure was not exactly at the site of one of the water-perfused catheter's 1-cm readings, then the water-perfused catheter may obtain a lower reading. This is a shortcoming that is difficult to overcome as the two systems function in different ways, one measuring the pressure in a single quadrant and the other measuring the overall pressure exerted circumferentially on a balloon catheter. The averaging of the pressures from the 4 quadrants at the highest pressure site was the best method that we could devise to overcome this and the close correlation between the two methods of recording would appear to justify this approach. Our measurements covered a pressure range up to 185 mmHg. Over the range suitable for use in most clinical situations, our results confirm the observation of Orrom et al. [8] that the solid-state manometer, being a balloon catheter attached to a transducer, provides accurate measurements. The accuracy of the solid-state balloon manometer at pressures over 150 mmHg needs further study as it may record lower pressures than the water-perfused catheter at these levels. Caution is required in interpreting results of the solid-state manometer in the very hypertonic sphincter although this is not usually of clinical importance.

Similar studies have been performed in this area. Miller et al. [9] and Varma and Smith [10] show that a microtransducer-tipped catheter technique correlates well with a water-perfused system if a continuous pull through technique is used for the solid-state manometer or when radial variation is taken into account. Miller et al. [2] and Fang et al. [11] stated that an air-filled balloon system connected to a transducer has many advantages over the water-perfused manometer, but they performed the tests on patients rather than using a stable model.

The present study is an *in vitro* model of the anorectum relying wholly on the pressure generated by the artificial sphincter. It has demonstrated that in this stable state the two manometers give comparable results. It may not, however, predict their comparability in the *in vivo* state as the different catheters may produce differing responses from

the intact anus and rectum. The water-perfused manometer was more difficult to use and read, required considerable effort in setting up and, because of its complex appearance, may not appeal to patients. On the other hand, the solid-state manometer was simpler to use and more convenient. In the setting of the *in vitro* model, the solid-state manometer appeared to offer more consistent pressure readings than the water-perfused manometer. In view of these advantages, the solid-state manometer appears preferable to the water-perfused system for anorectal physiology assessments in the setting of the pelvic floor clinic.

The model designed using a pig anorectum and an artificial sphincter is simple to construct and gives consistent results with manometry. It offers promise as a model to test other physiological interventions such as the influence of differing volumes and injection sites of bulking agents on intra-anal pressures.

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