

ASSESSING THE ANAL SPHINCTER WITH ACOUSTIC REFLECTOMETRY:- A NEW REPRODUCIBLE METHOD PROVIDING AN IMPROVED PHYSIOLOGICAL ASSESSMENT OF ANAL SPHINCTER FUNCTION.

Hypothesis / aims of study

Anal Acoustic Reflectometry (AAR) is a new method of measuring anal sphincter function that offers a far greater physiological insight than conventional manometry.

The aim of this study was to assess if the parameters measured with AAR are reproducible.

Study design, materials and methods

Study design:

This was a comparative study of reproducibility between AAR and conventional manometry.

Reproducibility was assessed in two forms: **Inter-Rater Reliability**, when the same subject was measured by two different operators, and **Test-retest Reliability**, when subjects were measured by the same operator on two separate occasions. Reproducibility was assessed according to Bland and Altman. The mean difference (bias) was calculated and the significance of the bias assessed using a paired t test. The repeatability coefficient (RC), the maximum difference likely to occur between repeated measurements, was calculated.

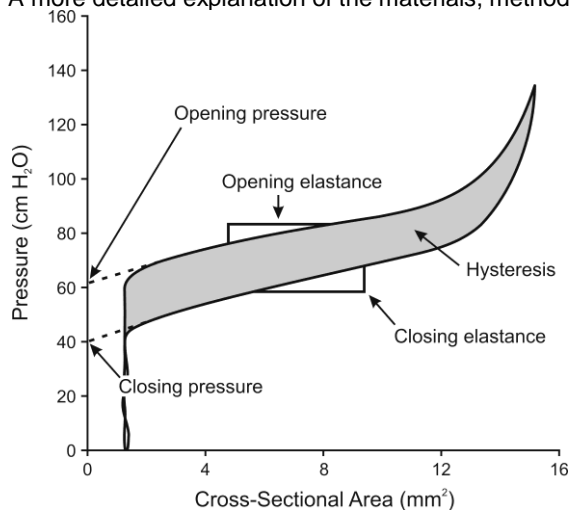
Materials and Methods:

In AAR a thin polyurethane bag is placed within the anal canal. It measures 6cm in length and 5mm in diameter when fully distended. A transmitter sends wide band sound waves (100Hz to 16KHz) into the bag and from the reflected sound waves the cross sectional area within the bag is calculated. Cross sectional area measurements within the bag are made every millimetre along the length of the bag and anal canal. A pressure pump inflates the bag from its collapsed form to fully distended (pressure increases from 0 to 100cmH₂O, in 5 cmH₂O pressure steps). The inflation of the bag causes the anal canal to open. The bag is deflated in a similar stepwise manner allowing the anal canal to close.

During inflation and deflation of the bag, while the anal canal is opening and closing, area measurements are made at each pressure step. Area measurements at each pressure level are plotted on a graph of pressure vs. area. From this graph we are able to calculate five parameters of collapsible biological tube function: **Opening and Closing Pressures** (the pressures at which the anal canal just opens/closes), the **Opening and Closing Elastances** (the resistance of the anal canal to opening and ability of the canal to close down against a reducing pressure) and the **Hysteresis** (an expression of the energy dissipated during opening and closing of the anal canal). See Figure below.

Manometry was performed with a closed water-filled micro-balloon system, using a station pull through technique.

A more detailed explanation of the materials, methodology and technique of AAR has recently been published (1).



Results

Inter-Rater Reliability.

20 subjects underwent measurement with both AAR and manometry by two different operators. **The mean difference (bias) was acceptable for all five AAR parameters during rest assessment and both AAR parameters during voluntary contraction.** Comparison with manometry is shown in the table below.

RESTING ASSESSMENT				SQUEEZE ASSESSMENT			
	BIAS	LOA	LOA		BIAS	LOA	LOA
<i>Opening Pressure (AAR)</i>	<i>0.57</i>	<i>-18</i>	<i>20</i>	<i>Squeeze Opening Pressure (AAR)</i>	<i>2.1</i>	<i>-42</i>	<i>46</i>
Maximum Resting Pressure (manometry)	0.25	-18	19	Maximum Squeeze Pressure (manometry)	-0.2	-44	43

AAR parameters in Italics, LOA=Limits of agreement. Values are cmH₂O

Test-retest Reliability

26 subjects underwent measurement with both AAR and manometry by the same operator on two different occasions. The median interval between repeated measurements was 37 days. **All of the acoustic parameters both during rest and squeeze assessments had an acceptable bias and no evidence of a significant difference between the measurements with the paired t test.** Comparison with manometry is shown in table below.

RESTING ASSESSMENT				SQUEEZE ASSESSMENT			
	BIAS	LOA	LOA		BIAS	LOA	LOA
<i>Opening Pressure (AAR)</i>	<i>-1.5</i>	<i>-30</i>	<i>27</i>	<i>Squeeze Opening Pressure (AAR)</i>	<i>-1.5</i>	<i>-43</i>	<i>40</i>
Maximum Resting Pressure (manometry)	1.3	-38	41	Maximum Squeeze Pressure (manometry)	8.7	-78	95

AAR parameters in Italics, LOA=Limits of agreement. Values are cmH₂O

Interpretation of results

The reproducibility of AAR, assessed in terms of Inter-Rater and Test-retest reliability, is comparable to conventional manometry, the current 'gold standard' test of sphincter function.

Concluding message

Anal Acoustic Reflectometry is a new technique of assessing the anal sphincter, offering a greater physiological assessment of sphincter function. This study has proven that the parameters measured in AAR are reproducible. Further work is in progress to clarify the role of AAR in improving the understanding and management of patients with Faecal Incontinence.

References

1. Anal Acoustic Reflectometry: a new technique for assessing anal sphincter function. Mitchell PJ, Klarskov N, Hosker G, Lose G, Kiff ES. Colorectal Dis 2010 Jan 12 epub ahead of print. PMID20070337

<i>Specify source of funding or grant</i>	NIL
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Stockport NHS Research Ethics Committee. REC Ref No. 08/H1012/47
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes