

ANAL ACOUSTIC REFLECTOMETRY – A NOVEL METHOD FOR PREDICTING OUTCOME OF SACRAL NERVE STIMULATION FOR FAECAL INCONTINENCE

Hypothesis / aims of study

Sacral nerve stimulation (SNS) has become an established treatment for faecal incontinence. Prior to the insertion of a permanent implant, patients undergo a test period of percutaneous nerve evaluation (PNE) to evaluate the efficacy of treatment.

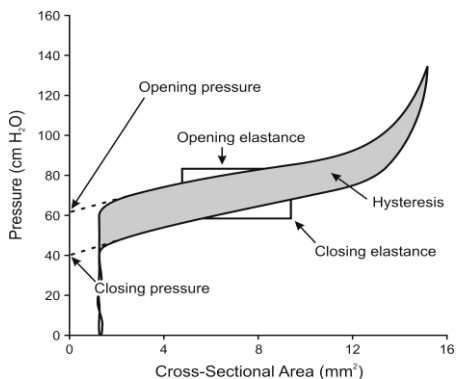
Anal acoustic reflectometry (AAR) is a new, clinically reliable and reproducible technique of assessing anal sphincter function, offering a dynamic assessment and providing greater physiological insight compared to conventional manometry.(1)

The aim of this study was to assess whether the parameters measured with AAR could predict the outcome from PNE.

Study design, materials and methods

Data were collected prospectively from patients with faecal incontinence undergoing PNE at our institution. AAR and conventional anal manometry were performed on the day of surgery prior to the PNE procedure.

- In AAR, a very thin, collapsible polyurethane bag measuring 6cm in length and 5mm in diameter (when fully inflated), is inserted into the anal canal.
- Cross-sectional area measurements are calculated along the entire length of the bag by the reflection co-efficients of sound waves sent into the bag by a transmitter.
- The bag is slowly inflated and deflated, during which simultaneous cross-sectional area and pressure measurements are taken along the entire length of the anal canal.
- The cross sectional area of the High Pressure Zone at each pressure level is plotted on a graph of Area vs. Pressure, allowing the AAR parameters to be determined.
- The **Opening and Closing Pressures** represent the pressure at which the anal canal just begins to open/close.
- The **Opening and Closing Elastances** represent the resistance of the anal canal to opening and the ability of the anal canal to close down against a reducing pressure.
- The **Hysteresis** is an expression of the energy dissipated during opening and closing of the anal canal. An example of this graph is shown below.



Patients underwent a 2 week test period of PNE, after which bowel diary results and Vaizey incontinence score were compared with pre-operative values. A successful test was defined as a greater than 70% improvement in incontinence episodes and/or Vaizey incontinence score.

Results

During the study interval a total of 31 patients underwent PNE, of which 17 patients had a successful test and 14 had an unsuccessful test. The study was powered to 80% in relation to differences between the two groups for the parameter of Opening Pressure at the 5% level of significance. Continuous data are presented as median and range and the two groups (successful and unsuccessful) were compared with the Mann-Whitney U test for non-parametric data and the Chi-squared test for categorical data. A p value ≤ 0.05 was taken as significant.

During measurement at REST:

Parameter	Successful PNE (n=17)	Unsuccessful PNE (n=14)	p value

Opening Pressure [^]	28 (8 - 73)	17 (9 - 68)	0.016*
Opening Elastance [~]	1.09 (0.41 - 2.11)	0.99 (0.41 - 2.00)	0.184
Closing Pressure [^]	20 (8 - 61)	14 (6 - 62)	0.127
Closing Elastance [~]	1.11 (0.49 - 3.15)	0.84 (0.53 - 1.23)	0.047*
Hysteresis (%)	21 (-21 - 57)	21 (-11 - 44)	0.766
Manometry Resting Pressure [^]	53 (17 - 155)	48 (10 - 131)	0.244

During VOLUNTARY CONTRACTION:

Parameter	Successful PNE (n=17)	Unsuccessful PNE (n=14)	p value
Squeeze Opening [^] Pressure	48 (11 - 83)	29 (8 - 200)	0.211
Squeeze Opening [~] Elastance	1.33 (0.55 - 2.72)	1.39 (0.67 - 2.33)	0.544
Manometry Squeeze Pressure [^]	75 (32 - 167)	88 (14 - 245)	0.771

Values are medians with range in brackets. *=significant at 0.05 level. [^]=measured in cmH₂O, [~]=measured in cmH₂O/mm².

Interpretation of results

The acoustic parameter of Opening Pressure was significantly greater in those patients who had a successful PNE outcome, however, no significant difference was found in the manometric equivalent of Resting Pressure. The Closing Elastance was also significantly greater in the successful group. The acoustic parameters may therefore have greater sensitivity than routine anal manometry in determining those patients who are more likely to have a successful result from sacral nerve stimulation. This may have time and cost implications.

Concluding message

Anal acoustic reflectometry is a novel, clinically reliable technique providing a dynamic assessment of anal sphincter function. Its use in the assessment of patients with faecal incontinence and the evaluation of therapeutic strategies is being established. This study has shown that it is a sensitive technique which may aid our use and application of SNS.

References

1. Mitchell PJ, Klarskov N, Hosker G, Lose G, Kiff ES. Anal acoustic reflectometry: a new technique for assessing anal sphincter function. *Colorectal Dis* 2010;12(7):692-7.

Specify source of funding or grant	None
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	North West 8 Research Ethics Committee - Greater Manchester East
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes