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Evaluation of the Portable THD® Anopress Device in Patients with Faecal Incontinence

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Abstract

Background: THD® Anopress has been promoted as a new portable anal manometer providing measurements of whole anal canal pressures. This study aims to report the anorectal function of patients suffering from Faecal Incontinence (FI) using this new device and the associated patient comfort.

Methods: We reviewed data from patients suffering from FI who had been evaluated with the THD® Anopress device. The St Mark's score had been routinely used to evaluate the severity of FI. Manometric parameters and pressures were evaluated. Acceptability of this test was also assessed using the Visual Analogue Scale (VAS).

Results: THD® Anopress device device was used to assess 60 patients with FI. The median baseline St Mark's FI score was 14 (7-24). A mixed FI was seen in 34 (57%) patients. Resting pressures were 25 (0-60) in the female group and 30 (0-52) mmHg in the male group. Maximum squeeze increments were 27 (6-106) in the female and 42 (6-99) mmHg in male subject group. Maximum endurance squeeze in 10 seconds were 32 (5-89) in the female and 31 (10-65) mmHg in the male groups. Involuntary maximum squeeze was 33 (6-103) in the female group and 27 (7-90) mmHg in the male group. These values were significantly reduced when compared to previously report normative values. The median VAS is of 0 at insertion and during the procedure.

Conclusion: The THD® Anopress device appears to detect anal sphincter dysfunction in those with symptomatic FI and is well tolerated.

Keywords: Anorectal function; Anorectal manometry; Faecal incontinence; Anorectal physiology studies; THD® Anopress device

Introduction

Faecal Incontinence (FI) is a socially debilitating condition with multiple aetiologies [1-5]. Its management includes Anorectal Physiological testing (ARP) which aims to define the function of the anorectum, providing diagnostic and prognostic information for a range of anorectal pathologies [6-9].

Manometric assessment of anal canal pressures is reflective of anal sphincter function. This includes the anal canal resting pressure, maximum voluntary squeeze increment, involuntary squeeze increment, and endurance squeeze increments [10-13]. Anal manometry is traditionally performed using a multi-channel water perfused catheter, which records along both longitudinal and radial axes [7,13-15].

These catheters are durable, require little maintenance and are reliable. More recently, high resolution solid state catheters and three dimensional High Resolution Manometry (HRM) have been introduced [10,12,16]. They have a greater number of sensors per surface area and a topographical display aiding easier interpretation of data.

THD® Anopress device (THD SpA, Correggio (RE), Italy) is a new portable anal manometry device which uses high resolution air filled catheters to evaluate the sphincter pressures generated from the whole of the anal canal [17].

It is promoted as a small, portable, wireless device which can perform rapid manometric assessments away from the anorectal physiology laboratory [11,17,18]. It is CE (European Conformity) marked and has United States of America Food and Drug Administration approval.

The aim of this study was to determine whether this new device is able to detect anal sphincter dysfunction in patients with FI and compare these manometric parameters to previously reported normative values [17]. Acceptability of the device was also assessed.

Materials and Methods

We reviewed prospectively collected data on adult patients with symptomatic Faecal Incontinence (FI) who had been assessed in the outpatient clinic using the Anopress device. All patients were examined in a single tertiary care specialist centre. Research and Development office approval was gained prior to data review (R&D No. SE16/039 London North West NHS Trust).

A full clinical history had been taken, including the severity of FI estimation using the St Mark's FI score [19]. THD® Anopress

assessment was performed by an experienced physician with a specialist interest in anorectal manometry and physiology (CAL).

A standard protocol was followed for all patients [17]: patients were instructed to defecate if required prior to the procedure and no bowel preparation was given. It was confirmed that all subjects understood the commands squeeze, cough and push prior to performing each procedure [20].

Resting pressure, voluntary squeezes, involuntary squeezes (cough manoeuvre) and endurance pressure increments were recorded in keeping with a previous published protocol [17].

Endurance was defined as the progressive duration of contraction of up to 50% of the maximum squeeze pressure, and as a value expressed in mmHg at a maximum of ten seconds [11]. The data generated by this investigation had been recorded for each patient using the THD® Anopress device (Figure 1).

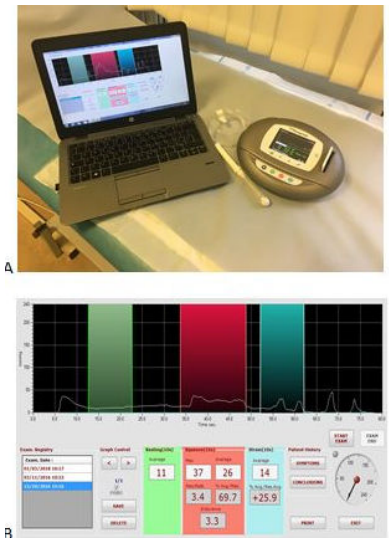

Figure 1: (A) The THD® Anopress device and the air filled manometric catheter. THD® Anopress results in a symptomatic patient. **(B)** Tracks and figures give an immediate report of the manometric parameters. In this case Resting Pressure, voluntary and involuntary squeeze increments and endurance are very low as expected.

A Visual Analogue Scale (VAS) pain score had been recorded for all patients during this test with the descriptor extremes "0=no pain at all" and "10=my pain is as bad as it could possibly be" to evaluate how comfortable patients found this new device [21].

Descriptive statistics are presented using median and range values. The Mann-Witney-U test was used analyse the study data using commercially available software (GraphPad Prism Software Version 6, La Jolla, CA, USA). A p value<0.05 was considered statistically significant.

Results

Between June 2016 and June 2017, 60 patients with symptomatic FI underwent assessment using the THD® Anopress device. Of these, 45 (75%) were female. The median (range) age was 51 (21-88) years for females and 61 (22-87) years for males respectively.

The predominant symptom was a combination of urge and passive FI in 34 (57%) patients, urge FI was found in 18 (30%) patients and the remaining 8 (13%) patients had pure passive FI. The median St Marks FI score was 15 (7-24) in females and 11 (9-24) in males respectively.

Resting pressures were 25 (0-60) mmHg in the female group and 30 (0-52) mmHg in the male group. Maximum squeeze increments were 27 (6-106) mmHg in the female and 42 (6-99) mmHg in male groups. Endurance squeeze increments were 3.9 (0.4-10) seconds in the female and 3.3 (0.3-4.3) seconds in the male groups.

Maximum endurance at 10 seconds was 32 (5-89) mmHg in the female group and 31 (10-65) mmHg in the male group. Involuntary maximum squeeze pressures were 33 (6-103) mmHg in the female group and 27 (7-90) mmHg in the male group.

Recorded measures are shown in Table 1. These results were compared to normal values previously published [17]. A statistically significant ($p<0.05$) reduction in all pressure measurements was seen (Table 1). Patients with higher incontinence scores had lower manometric results as expected.

The procedure was well tolerated by all patients with a median VAS pain score of 0 (0-2) during insertion and 0 (0-1) during the procedure.

Discussion

Statistically significant reductions in all of the measured parameters in patients with symptomatic FI were demonstrated by this study, which indicates that the THD® Anopress device is able to detect impaired sphincter function in those with symptomatic FI.

The major advantage of this device includes the ease with which it can be calibrated taking only few seconds, the fact that water perfusion is not necessary and ease of catheter placement and positioning with minimal effort. Also this device appears to be well tolerated by the patients. This is suggested by the mean VAS scores of zero during both insertion and assessment.

Another significant advantage of the THD® Anopress device is that pressure measurements are taken from the entire anal canal: The catheters are air-filled and they provide measurements from the whole surface without the need for receptors or channels allowing the estimation of the average pressure from the whole anal canal at one time.

This may provide more clinically useful information also improving reproducibility of assessment when compared to existing anal manometry techniques which can take measurement from multiple points along the anal canal [16].

The device has some disadvantages. Firstly THD® Anopress is unable to measure anal canal length. Secondly a separate catheter with a balloon was needed to measure rectal sensitivity to distension and the recto-anal inhibitory reflex.

Parameters	Female symptomatic (No. 45)	Female Normal values	P-value	Male symptomatic (No. 15)	Male Normal values	P-value
Age	51 (21-88)	39.5 (19-79)	Not compared	61 (22-87)	41 (18-74)	Not compared
St Mark's score	15 (7-24)	0	<0.05	11 (9-24)	0	<0.05
Resting Pressure	25 (0-60)	40.0-103.0	<0.05	30 (0-52)	38.3-99.6	<0.05
Max Squeeze Increment	27 (6-106)	35.0-140.6	<0.05	42 (6-99)	42.5-154.8	<0.05
Endurance in mmHg	32 (5-89)	44-98	<0.05	31 (10-65)	43-103	<0.05
Endurance in sec	3.9 (0.4-10)	1.3-9.0	<0.05	3.3 (0.3-4.3)	2.0-10.0	<0.05
Involuntary Squeeze	33 (6-103)	41.1-120.8	<0.05	27 (7-90)	40.0-123.6	<0.05

Table 1: Demographic details and manometric parameters recorded in the cohort of 60 patients symptomatic for faecal incontinence. Parameters are expressed in Median and Range. Pressures are expressed in mmHg.

This is in contrast to existing catheters, in which the balloon is part of the manometry catheter. It is understood that newer generations of THD® Anopress catheters may combine these two additional parameters.

In conclusion further studies are required for comparison with manometric devices. This study demonstrates that THD® Anopress device appears able to detect anal sphincter dysfunction in those with symptomatic FI. It is also well tolerated in patients.

Conflicts of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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