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The use of functional luminal imaging probe (FLIP) for assessment of anal canal dimensions and resistance in normal controls, a cross sectional study

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ABSTRACT

Objectives: Fecal incontinence and obstructed defecation are two topics in the field of functional coloproctology that are not fully understood yet. Our study aims at measuring the anal canal length (ACL) and average anal canal diameter (ACD) using endo-FLIP. This is used to calculate the average anal canal resistance (ACR) in normal controls to set a reference level for diagnosis and treatment of patients with anal incontinence according to the flow-equation theory.

Materials and Methods: This was a cross-sectional study on forty normal volunteers. ACL, ACD and intra-balloon pressure, were measured in forty normal controls using the endo-FLIP. The ACR was measured using the flow calculator specially designed for this purpose using ACL and ACD.

Results: Forty volunteers 33 males and 7 females were included. Mean ACL during rest and squeeze were 3.04 cm and 3.24 cm respectively ($p<0.001$), Mean ACD during rest and squeeze were 7.18 mm and 7.07 mm respectively ($p=0.254$). Mean ACR at rest and squeeze were 9268.4 kg $m^{-1}s^{-}$ and 10302.83 kg $m^{-1}s^{-}$ respectively ($p=0.012$). Mean balloon pressure at rest was 31.39 mmHg and during squeeze was 51.57 mmHg ($p<0.001$).

Conclusion: Endo-FLIP is a novel technique used in measurement of ACL and ACD to calculate the resistance and this can set a reference level to be used in diagnosis and treatment of patients with anal incontinence.

Keywords: Anal canal length; anal canal diameter; anal canal resistance; endo-FLIP; flow equation; faecal incontinence and obstructed defecation

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INTRODUCTION

The ability to maintain fecal continence is a complex and balanced interaction between the anal sphincter complex, stool consistency, the rectal reservoir, ano-rectal sensation and the neurological innervation of the pelvic floor.[1] The intrinsic resistance offered by the anal canal to control the flow of the stools through its lumen had been suggested by many authors to be a more important factor in maintaining continence than just the contraction of the muscles to squeeze around the anal canal.[2,3] However, attempts to measure the anal canal resistance (ACR) using probes, catheters, small balloons, and obturators had been largely unsuccessful.[4,5]

According to the Poiseuille's, flow equation (flow=pressure/resistance). The recto-anal interaction can be further viewed as pressure/resistance interaction rather than pressure/pressure interaction.[6-8] By applying this equation to anal flow, the ACR can be calculated as being directly proportional to the dynamic viscosity (DV) or consistency of stools and the anal canal length (ACL), and inversely proportional to the anal canal diameter (ACD) and can be presented as follows,

$$\text{AC Resistance} = \frac{128 \times DV \times ACL}{3.14 \times (ACD)^4}$$

These parameters particularly the ACR can be examined by functional luminal imaging probe (FLIP). This technology facilitates the assessment of lumen size and sphincter distensibility in the gastrointestinal tract.[9] Endo-FLIP had been modified to provide detailed information about the length of the anal canal[10,11] and the resistance of the anal canal to distension. In one study the ACR to distension was significantly reduced in fecal incontinence.[11,12] Using of the endo-FLIP, intra-operatively, during colorectal surgery can provide detailed visualization of the anal canal geometry and these measurements can provide invaluable input to predict the surgical outcomes.[13]

The aim of our study was to use the endo-FLIP technology to simultaneously measure the length of the anal canal, the diameter of the anal canal and calculate the ACR in normal adult healthy controls in order to optimally characterize anal flow dynamics.

MATERIALS AND METHDOS

This is a cross-sectional study in which forty adults, volunteers were evaluated in the colorectal unit of the General Surgery Department of Cairo University in the period from November 2016 to June 2017. Using the endo-FLIP ACL and diameter were measured so that the resistance could be calculated per the flow equation.[8]

All volunteers provided written consent. The study was approved by the Local Research Ethics Committee of Faculty of Medicine Cairo University. The study is totally funded by Cairo University.

Volunteers were patients who presented to the colorectal unit for any general surgery complaints apart from ano-rectal complaints in the period. All of them had minor conditions such as lipomas, sebaceous cysts or Ingrowing toenails. Their preoperative work-up proved that they are otherwise healthy.

All the measurements were taken by the first author who is an expert professor in the field of colorectal surgery.

Inclusion Criteria

Volunteers from both sexes and all age groups with no colorectal disorders or previous anal surgery were included in the study and no other systemic disease.

Exclusion Criteria

Volunteers with previous anal surgery or any anal complaint (e.g., fecal incontinence, constipation) and patients with known or suspected systemic disease were excluded from this study.

Interventions

All volunteers went through proper history taking and full general and local examination to assess the tone and to identify any disorder. Incontinent patients were assessed and excluded using Wexner score.[9] Patients with constipation were assessed and excluded using Cleveland scoring system.[10]

The volunteers were prepared by a Saline rectal enema to evacuate the rectum completely half an hour before the test. The volunteers were examined in the left lateral position, with hips and knee flexed. Before using the system, any air was removed from the endo-FLIP (Figure 1) assembly by using an automated purge sequence and the system then was calibrated. The FLIP probe was inserted into the anal canal until the bag straddled the anal canal. The diameter of the FLIP probe without the balloon is 2.3 mm, the balloon is made of polyurethane, the length of the balloon 85 mm flat section 135 mm including the cones at each end. When balloon is fully inflated (volume 50 cc), its diameter is 25 mm. At 30 mm it is not fully inflated and will depend on the sphincter tightness, and other physical properties.

The FLIP bag was inflated to a small volume (30 mL), so that three distal measurements were seen on the FLIP display and ensure correct measurement taken. The probe was held in this position by an assistant. A snap shot of the anal canal was taken at rest.

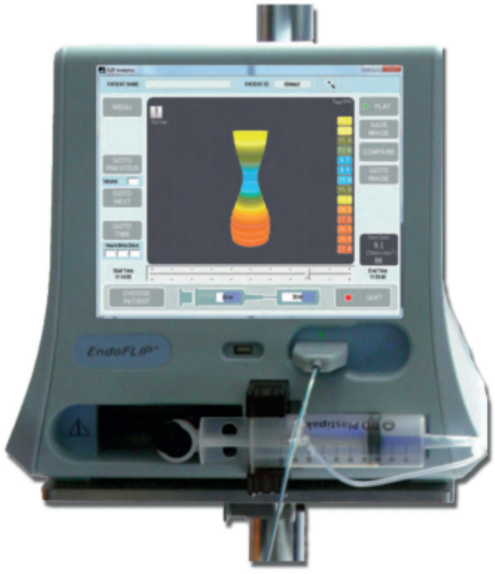

Figure 1. The enod-flip

The volunteer was then asked to squeeze and another snap shot was taken. Subsequently we compared the bio-mechanical changes between rest and squeeze as shown in Figure 2.

The length of the anal canal at rest and squeeze were calculated by the number of blue electrodes that are each located 0.5 cm apart. By using the calculator especially designed for this equation the resistance was calculated.[14] Look Figure 3.

Statistical Analysis

All collected data were checked for completeness and accuracy. Pre-coded data was entered on the computer using the statistical package of Social Science Software Program, version 21 (SPSS) to be statistically analyzed. Data was summarized using mean and standard deviation (SD) for quantitative variables, number and percent for qualitative variables. Comparison between

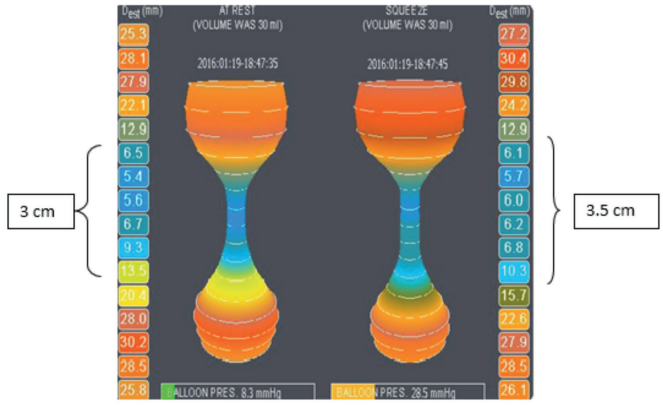

Figure 2. Anal canal length and diameter during rest and squeeze (blue segment)

quantitative variables were done using independent t-test and paired t-test for variables which were normally distributed. Non-parametric data were compared using Mann-Whitney U test and Wilcoxon test for quantitative variables which were not normally distributed. Spearman correlation was used to test for linear relations between variables. *P*-value less than 0.05 was considered of statistical significance.

RESULTS

In the example shown in Figure 2, the length of anal canal was 3 cm at rest and 3.5 cm during squeeze. Also, the average ACD was calculated (the sum of diameters/their number). So, in this patient the average ACD at rest was 7.7 mm and during squeeze was 7.7 mm. According to the modified flow equation shown in the introduction section the ACR was calculated.

Forty volunteers including 33 males and 7 females with a mean age of 41.63 years (SD =15.59), the minimum was 9 years the maximum was 75 years with a range 66 year. Six of the females were multiparous and one was nulligravida were evaluated in

Figure 3. Flow equation calculator

this study. The endo-FLIP measurements of the ACL and diameter and these data were used to calculate the resistance according to the flow equation.[9]

Mean age, mean ACL during rest and squeeze and mean ACD during rest and squeeze are shown in Table 1. Mean ACR at rest and squeeze are also shown in Table 1.

The ACL measured during rest was 3.04 cm (SD =0.41) and during squeeze was 3.24 cm (SD =0.44), which showed a statistically highly significant increase during squeeze (p<0.001).

The average ACD measured during squeeze was 7.18 mm (SD =0.63), while during squeeze was 7.07 mm (SD =0.45), which showed a statistically non-significant decrease during squeeze.

The ACR calculated during rest was 9268.4 kg $m^{-1}s^{-1}$ (SD =2813.07), while during squeeze it was 10302.83 kg $m^{-1}s^{-1}$ (SD =2725.46), which showed a statistically significant increase during Squeeze (p=0.012). This is shown in Table 1.

Correlations

The ACL at rest shows a positive correlation with resistance at rest with a p-value (0.015) which is statistically significant. The ACL during squeeze shows a positive correlation with resistance during squeeze with a p-value (0.041) which is statistically significant Table 2.

The ACD at rest shows a negative correlation with resistance at rest with a (p-value<0.001) which is statistically significant. The ACD during squeeze shows a negative correlation with the resistance during squeeze with a (p-value <0.001) which is statistically significant Table 3.

DISCUSSION

The endo-FLIP system uses a technique called impedance planimetry (IP) to characterize the geometry of the measurement area. IP is an established technique for performing measurements of cross-sectional areas in the alimentary tract.[15]

Here, we applied the endo-FLIP technology to characterize features of the anal canal. We found that the mean ACL during rest was 3.04 cm with standard deviation 0.41. The mean ACL during squeeze was 3.24 cm with SD 0.44, where the ACL showed a statistically highly significant increase during squeeze. The mean ACD at rest 7.18 mm with standard deviation 0.63. Mean ACD during squeeze 7.07 mm with standard deviation 0.45. The statistically significant difference between the AC resistance measured during squeeze between male and female patients in our study may be a false result due to the small number of the female patients recruited in the study "Type 2 error".

Shorvan et al.[16] used the defecography in measuring the length of the anal canal and it was 2.2 cm in men at rest and then increased by an average of 6 mm during squeeze to become 2.8 cm, and it was 1.6 cm in females that increased by 3 mm to become 1.9 cm during squeeze.

Likewise, Kang et al.[17] used water perfused ano-rectal manometry to measure the ACL and it was determined to be 3.8 cm, and by

Table 1. Showing ACL at rest and squeeze, ACD at rest and squeeze and anal canal resistance at rest & squeeze

	Age (years)	ACL during rest (cm)	ACL during squeeze (cm)	ACD during rest (mm)	ACD squeeze (mm)	Anal canal resistance rest (kg $m^{-1}s^{-1}$)	Anal canal resistance squeeze (kg $m^{-1}s^{-1}$)
Mean	41.63	3.04	3.24	7.18	7.07	9268.40	10302.83
SD	15.59	0.41	0.44	0.63	0.45	2813.07	2725.46
Range	66.00	1.50	2.00	2.80	1.90	10733.00	12408.00
Minimum	9.00	2.50	2.50	6.30	6.10	3930.00	4699.00
Maximum	75.00	4.00	4.50	9.10	8.00	14663.00	17107.00
P-value between parameters during rest and squeeze		<0.001		0.254		0.012	

SD: standard deviation; ACL: anal canal length; ACD: anal canal diameter

Table 2. Correlations between length and resistance

	Resistance rest		Resistance squeeze	
	r	p-value	r	p-value
ACL rest	0.100	0.538	0.382	**0.015**
ACL squeeze	0.253	0.116	0.324	**0.041**

ACL: anal canal length

Table 3. Correlations between diameter and resistance

	Resistance rest		Resistance squeeze	
	r	p-value	r	p-value
Average ACD at rest	-0.902	**<0.001**	-0.376	**0.017**
Average ACD at squeeze	-0.403	**0.010**	-0.865	**<0.001**

ACD: anal canal diameter

using high resolution ano-rectal manometry, the ACL was 2.4 cm.

Using solid state catheter Rao et al.[18] reported the ACL of average =3.7 cm, in a group of 45 healthy volunteers, including 19 males where ACL was average of 4 cm and 26 females where the ACL was average of 3.6 cm. A statistically significant difference between males and females.[18]

Using a 3D HRM, Coss-Adame et al.[19] reported the ACL to be 4.1 cm on a group made of 78 volunteers, including 36 males where the ACL was reported to be 4.3 cm, and 42 females where the ACL was reported to be 4 cm. There was no statistically significant difference between the ACL in males and females.[19]

In 2011, Olsen[20] use the endo-anal transducer to measure the mean ACL and it was found to be 3.28 cm in a group of nine women, and 2.57 cm in a group of 20 women, both groups consist of nulliparous women, and 2.3 cm in a group of 21 multiparous women, using the vaginal transducer the ACL measured 3.64 cm in the same 20 nulligravida women. It became 3.86 cm during the squeeze maneuver.[20]

In our study the length was 3.04 cm at rest and became 3.24 cm during squeeze. Then according to the flow equatio[6-8] the resistance was calculated

$$\text{AC Resistance} = \frac{128 \times DV \times ACL}{3.14 \times (ACD)^4}$$

The flow equation will be finally as follows:

$$\text{Flow} = \text{IRP (intra- rectal pressure)} \times \frac{3.14 \times (ACD)^4}{128 \times DV \times ACL}$$

Using the flow equation as a mathematic model in functional coloproctology, Farag[6-8] suggested that other mechanical factors are secondary factors operating through one or more of the above-mentioned primary factors. Type of food intake, amount of fluids ingested, rate of gastric emptying, small and large bowel absorption and motility, work through the DV factor. Rate of rectal filling, rectal capacity and rectal compliance work through the factor of intra rectal pressure, while the pelvic floor muscles, anal sphincters and pelvic supporting connective tissue and fascia work through the factors of ACL and ACD.[6-8]

The designed "flow equation calculator" was used in this study and the resistance was calculated to be as follow: The mean ACR at rest is 9268.4 kg $m^{-1}s^{-1}$ with standard deviation 2813.07 changed to 10302.83 kg $m^{-1}s^{-1}$ with standard deviation 2725.46 during squeeze with (p=0.012) which was statistically significant. The present study showed that ACR is directly proportional to ACL and inversely proportional to ACD.

The findings in the present study tends to establish a reference reading for the ACL, the ACD and the ACR in a control group in Egypt using endo-FLIP, for future assessment of patients suffering from anal incontinence and for intraoperative adjustment of anal sphincter repair or augmentation as was described by Farag.[13]

In this discussion section, we tried to discuss the previous studies that use similar or other devices to measure the anal canal dimensions and try to compare it to our measures, however we

Significance of the study:

How might it impact on clinical practice?

In the present work we measured the anal canal length, diameter and resistance in normal anal canals in controls in order to set a standard to be used intra-operatively for repair of the anal sphincter in patients suffering from anal incontinence due to sphincter causes.

What are the new findings?

1- Our study aims at measuring the anal canal length and average anal canal diameter hence measuring anal canal resistance using endo-FLIP.

2- This is a novel technique for detecting anal canal dimensions and calculating its resistance.

3- The endo-FLIP can be used in the assessment and adjustment of treatment of the incontinent and obstructed defecation as per the flow equation. The concept is explained in details in the cover letter.

What is already known about this subject?

1- Functional coloproctology is an area of major debate in medicine where the factors maintaining normal continence and defecation are still an unclear.

2- Our knowledge in functional coloproctology had been obtained from disseminated research data which increase confusion especially in the field of anal incontinence.

3- The major defect in the current research methodology lies in the lack of integration between the colon, the rectum and the anal canal which are highly integrated with each other and needs an integrated approach to assess their function.

think that the endo-flip gives a better idea of measurements and morphology of the anal canal.

Study Limitations

Small number of female volunteers due to difficulties in recruiting female volunteers in Egypt for such studies and the need to establish the standard measurements in each ethnic group and different ages.

CONCLUSION

Endo-FLIP is a novel technique in the detection of the ACL and ACD, Hence the resistance can be calculated by providing real time images. Furthermore, it can be used in diagnosis and management of cases with incontinence by adjusting ACL, ACD and AC.

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ETHICS

Ethics Committee Approval: The study was approved by the Local Research Ethics Committee of Faculty of Medicine Cairo University.

Informed Consent: All volunteers provided written consent.

Peer-review: Internally and externally peer-reviewed.

Contributions

Surgical and Medical Practices: A.F., M.M.R., H.A.B., A.N.M., M.Y.E.; Concept: A.F., M.Y.E.; Design: A.F., M.M.R., H.A.B., A.N.M., M.Y.E.; Data Collection or Processing: A.F., M.M.R., H.A.B., A.N.M., M.Y.E.; Analysis or Interpretation: A.F., M.M.R., H.A.B., A.N.M., M.Y.E.; Literature Search: A.F., M.M.R., H.A.B., A.N.M., M.Y.E.; Writing: A.F., M.M.R., H.A.B., A.N.M., M.Y.E.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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