Introduction of Rapid barostat bag (RBB) protocol for the assessment of rectal function

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Background

**Barostat measurements:**

- Best established investigation of rectal physiology
  - capacity, compliance, sensation
- Large bag with infinite compliance
- Repeated, pressure or volume guided inflations (computerized electronic pump)
- Superior to measurements by elastic balloon

- **BUT**
  - time-consuming (>1h)
  - expensive equipment
  - not widely available
  \( \rightarrow \) Difficult to use in clinical practice
Aim

- To develop a tool to assess rectal function in routine practice
  - Short in duration
  - Easily available
  - Simple protocol
  - Cheap

- Delivers clinically relevant volume measurements
Barostat: Rectal Compliance and Capacity

- Linear relationship between compliance and capacity
- Capacity determines ability to retain stool (i.e. reservoir volume)
- Distension volume relative to capacity (percentage filling) determines sensation

#1
- Capacity 500ml
- Compliance 24ml/mmHg

#2
- Capacity 250ml
- Compliance 12ml/mmHg

#1 ~20% Capacity
#2 ~65% Capacity
~90% Capacity
Setup

- Rectal Barostat Catheter and >600ml bag (~$60)
- Standard sphigmanometer (~$40 reusable)
- 60ml Luer Lock Syringe and 3 way tap (~1$)
Study Design

• 26 healthy volunteers without gastrointestinal symptoms or disease
• AR-HRM (data not shown)
• Standard Barostat and Rapid protocol studies in randomised order
  • Both protocols
    • Conditioning distention
    • Index distention
      • Rectal sensation
      • Rectal compliance
      • Rectal capacity at 40mmHg
  • Standard protocol:
    • Minimal distending pressure (MDP)
    • 2mmHg increments every 30sec up to 40mmHg
  • Rapid protocol:
    • 1-2ml/sec Increments
Short Protocol, Hand Held Barostat

Conditioning inflation
- 1-2ml/sec
- until 40mmHg

Record rectal capacity

Deflate bag
Short Protocol, Hand Held Barostat

Index inflation: 1-2ml/s with syringe

Patient reports threshold sensation.
Absolute Volume recorded;
Percentage filling (% capacity) calculated
“First Sensation”
“Urgency”
“Discomfort /Pain” threshold

Deflate bag
Optional assessment of rectal compliance

Deflate to 50% rectal capacity. After ~60s record pressure (measurement correlates with compliance assessed by full barostat)

Finish
Results

- No Correlation of Standard Barostat to Elastic Balloon
- Correlation of Standard Barostat versus Rapid Barostat Protocol

Rectal capacity at 40mmHg

- $r = 0.97$; $p < 0.00001$

Initial sensation

- $r = 0.37^*$; $p = 0.07^*$

*Depending on study sequence (Standard protocol first: $r=0.46$)
Results

- Correlation of Standard Barostat versus Rapid Barostat Protocol

Urge to defecate

Discomfort

\[
\begin{align*}
E: & \quad r = 0.71 \\
& \quad p < 0.001 \\
G: & \quad r = 0.95 \\
& \quad p < 0.00001;
\end{align*}
\]
Rapid Barostat Bag Test
Rapid Barostat Bag Test

Rectal Motor And Sensory Function:
Rapid Barostat Bag Test

TODAY'S SCHEDULE:

Osterloo, Matthew

Mul, Howard

Alvarez-Oliveros, Adelyn

Rosevelt, Theodore-Teddy

Fox, Mark

add new patient

patient files

power off

Touch to start

Touch to start
Rapid Barostat Bag Test

Guptarajanoptak-Havendale, Nichole

Balloon Pressure 40 mmHg

Balloon Volume 417 mL

Flow Rate 120 mL/min

Capacity Measurement:
Balloon inflates until 40 mmHg reached

Dec. 25, 2014 04:26pm
Rapid Barostat Bag Test
Guptarajamoptak-Havendale, Nichole

Balloon Pressure
3 mmHg

Balloon Volume
68 mL

Flow Rate
120 mL/min

Capacity
417 ml

Sensation Measurement:
When sensation felt, press "sensation" on remote or touch screen.

Dec. 25, 2014  04:26pm
Rapid Barostat Bag Test

Guptaranoptak-Havendale, Nichole

Balloon Pressure: 7 mmHg
Balloon Volume: 165 mL
Flow Rate: 120 mL/min
Capacity: 417 mL
Urge: 165 mL
Sensation: 104 mL

Urge Measurement:
When urge felt, press "urge" on remote or touch screen.
Rapid Barostat Bag Test
Guptarajanoptak-Havendale, Nichole

Balloon
Pressure 37 mmHg

Balloon
Volume 285 mL

Flow Rate 120 mL/min

Discomfort Measurement:
When discomfort felt, press "discomfort" on remote or touch screen.

Capacity 417 mL
Discomfort 285 mL
Urge 205 mL
Sensation 104 mL

Dec. 25, 2014 04:26pm
Rapid Barostat Bag Test

Rectal Motor and Sensory Function: Rapid Barostat Bag Test

<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
<th>Average</th>
<th>%</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>DISCOMFORT</td>
<td>260</td>
<td>240</td>
<td>280</td>
<td>260 mL</td>
<td>100%</td>
<td>Normal</td>
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<tr>
<td>URGE</td>
<td>200</td>
<td>230</td>
<td>245</td>
<td>225 mL</td>
<td>86%</td>
<td>Hypo</td>
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<tr>
<td>SENSATION</td>
<td>15</td>
<td>25</td>
<td>20</td>
<td>20 mL</td>
<td>8%</td>
<td>Hyper</td>
</tr>
<tr>
<td>CAPACITY</td>
<td></td>
<td></td>
<td></td>
<td>260 mL</td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

Pressure at 50% Capacity: 12 mmHg

Disclaimer: The summary findings based on this data analysis should not be interpreted as a final diagnosis.

Comments:

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Dr. A

Signature

Date

Mui Scientific  www.muiscientific.com  Copyright © Patent Pending
Development and Validation: Summary

Rapid Barostat Bag (RBB) Study

• Fast, easily available option to assess rectal capacity and sensation

• Good correlation to Standard Barostat procedure in healthy subjects
  • *If relevant, repeat initial sensation measurement at end of study*

• Commercial device soon to be available (Mui Scientific)
Additional diagnostic yield of a rapid barostat bag (RBB) study designed for use in clinical practice

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Background and Aim

Background:
• Abnormal anorectal function not identified by clinical investigation with manometry and elastic rectal balloon in up to 50% FI patients referred for studies.

Aim:
• Impact of rapid rectal barostat measurements on yield of physiologic investigation in FI patients
379 patients with FI referred for HRARM

302 completed rapid barostat bag study

77 incomplete studies
n= 24 patients refused
n= 53 other reasons

155 only barostat

147 balloon + short barostat
Patients II

- 147 patients 121F: 26M
  - mean Vaizey score 11.5/24

- Symptoms
  - Urge Incontinence (UI) n=30
  - Passive Incontinence (PI) n=70
  - Combined Incontinence (CI) n=47

- Medical History
  - 75/121 women had given birth
  - 112 patients had history of abdominal surgery

- Medication use
  - n=24 stool regulation
  - n=33 on loperamide, opiate
**Short Protocol, Hand Held Barostat Study**

- **Conditioning inflation:** until 40mmHg
- **Record rectal capacity**
- **Deflate bag**
Index inflation: 1-2ml/s with syringe

Patient reports threshold sensation. Absolute Volume recorded; Percentage filling (% capacity) calculated
“First Perception”
“Urgency”
“Discomfort /Pain” threshold

Deflate bag
Optional assessment of rectal compliance

Deflate to 50% rectal capacity.
After ~60s record pressure
(measurement correlates with compliance assessed by full barostat)

Finish
Methods - Definitions

• Normal values (n= 60 healthy subjects) 
  representative age and sex distribution

• Low rectal capacity: <200ml at 40mmHg intra-bag pressure
• Hyposensitivity: first sensation at >30% and/or sense of urge >70% of rectal capacity
• Hypersensitivity: first sensation below 10% of rectal capacity and /or sensation of urge and discomfort <40% and <80% of rectal capacity
Incontinence - Symptoms

Symptoms

- PI n=30: 33%
- UI n=70: 47%
- CI n=47: 20%
Incontinence – Sphincter pressures

- normal sphincter n=66
- abnormal sphincter function n=88

n=147

55%

45%
Correlation between volume measurements by elastic balloon and barostat was poor-moderate (first sensation $r^2=0.36$, urge $r^2=0.44$, discomfort $r^2=0.39$)

79/147 (53%) had abnormal abnormal capacity on barostat
Normal Sphincter
Abnormal rectal function

Combined incontinence
Reduced rectal volume (n=7)
and/or
13/13 (100%) patients
rectal hyposensitivity

Passive incontinence:
14/16 (87%) reduced rectal capacity
and all of these had rectal hypo-sensitivity (n=14).

Urge incontinence:
22/37 (60%) reduced rectal capacity
and/or rectal hyper-sensitivity (n=14).

17/66 (26%) had entirely normal manometry and barostat studies
Rapid Barostat Bag (RBB) Studies

- Simple description of rectal capacity and function
- Mechanistic explanation for fecal incontinence in patients with normal anal sphincter function

- Similar results were not obtained using a standard rectal balloon