New technology for assessment and treatment of colorectal dysfunction Ascona 23rd of April 2015



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
- → Difficult to use in clinical practice



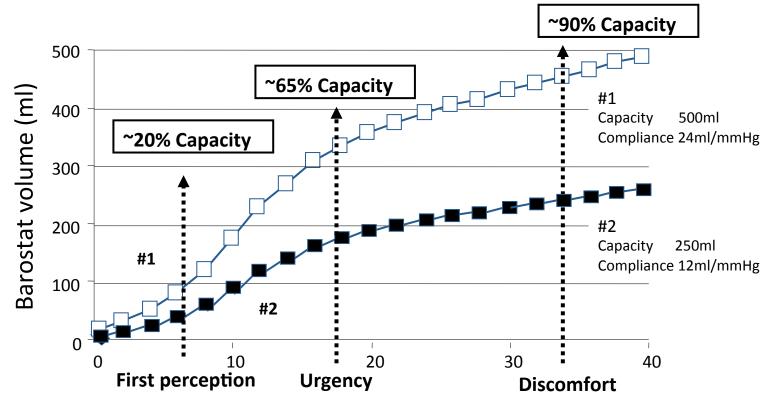
Aim

- 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







Barostat pressure (mmHg)

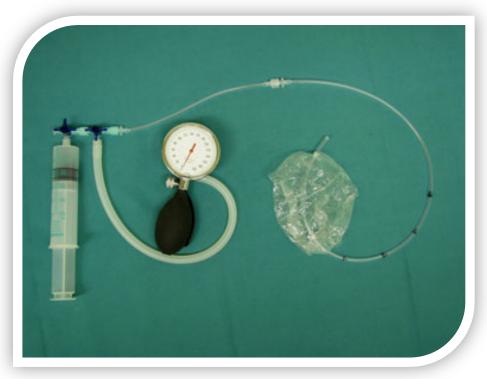
- Linear relationship between compliance and capacity
- Capacity determines ability to retain stool (i.e. reservoir volume)
- Distension volume relative to capacity (percentage filling) determines sensation



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

Short Protocol, Hand Held Barostat



Optional assessment of rectal compliance



Deflate to 50% rectal capacity.

After ~60s record pressure

(measurement correlates with compliance assessed by full barostat)



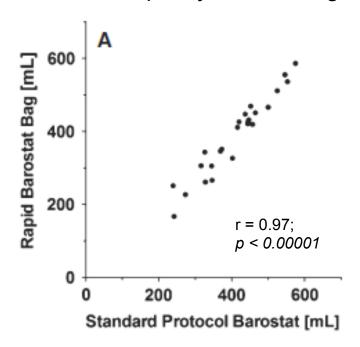
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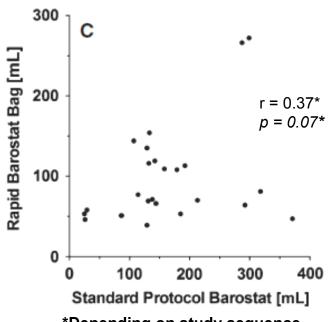
Results

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

Rectal capacity at 40mmHg



Initial sensation



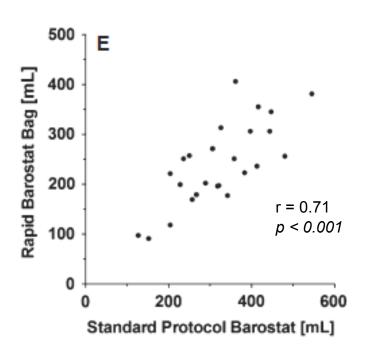
*Depending on study sequence (Standard protocol first: r=0.46)



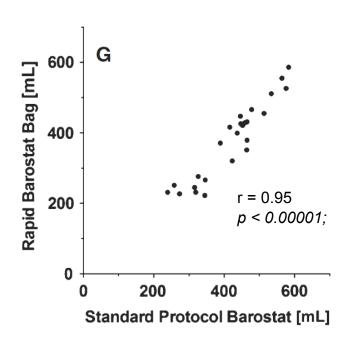
Results

Correlation of Standard Barostat versus Rapid Barostat Protocol

Urge to defecate



Discomfort



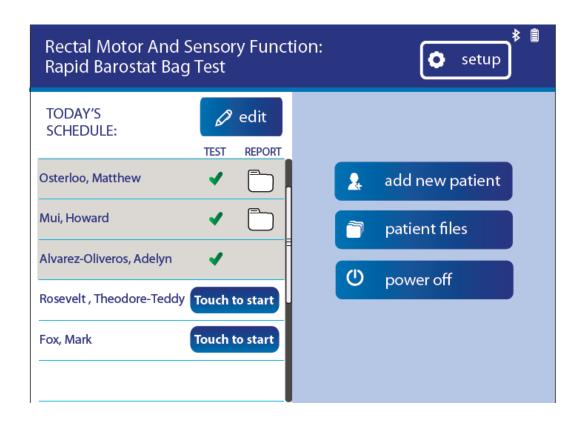






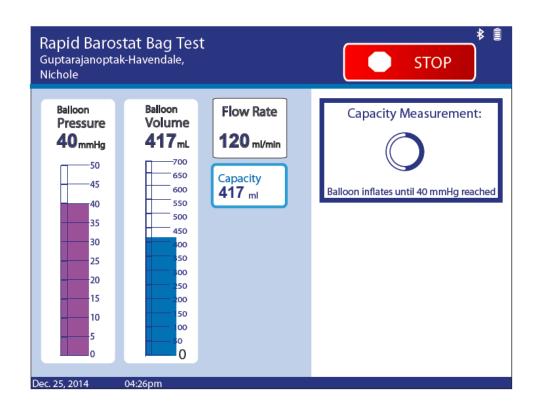


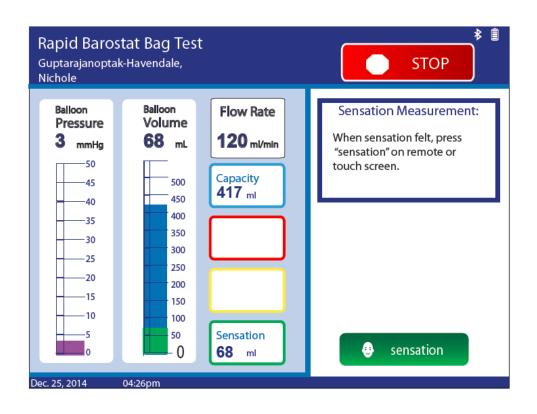






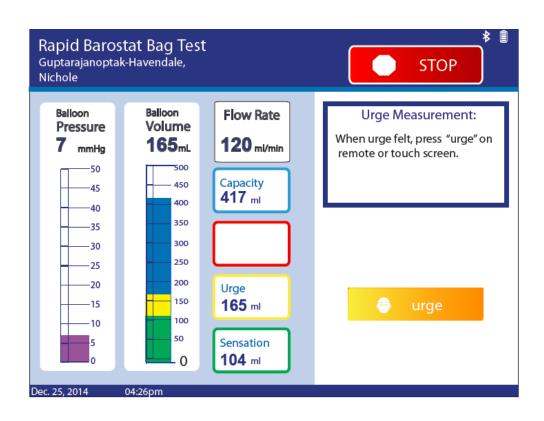


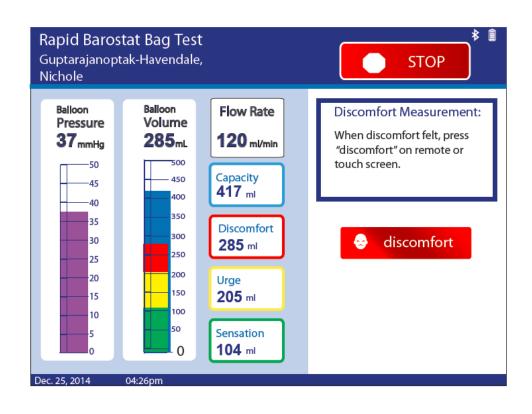






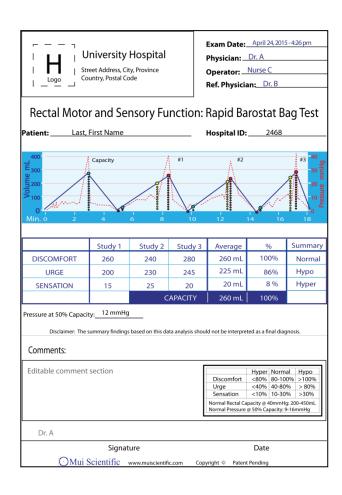












Development and Validation: Summary



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)

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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



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Patients 379 patients with FI referred for HRARM 77 incomplete studies 302 completed rapid n= 24 patients refused barostat bag study n= 53 other reasons 147 balloon + short 155 only barostat barostat

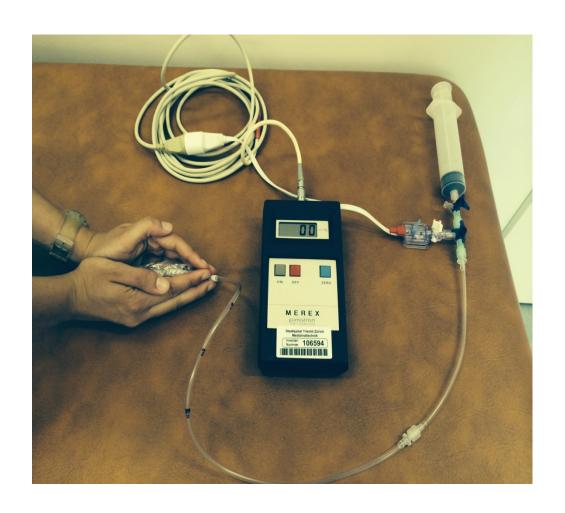


Patients II

- 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

Short Protocol, Hand Held Barostat Study



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

Short Protocol, Hand Held Barostat Study



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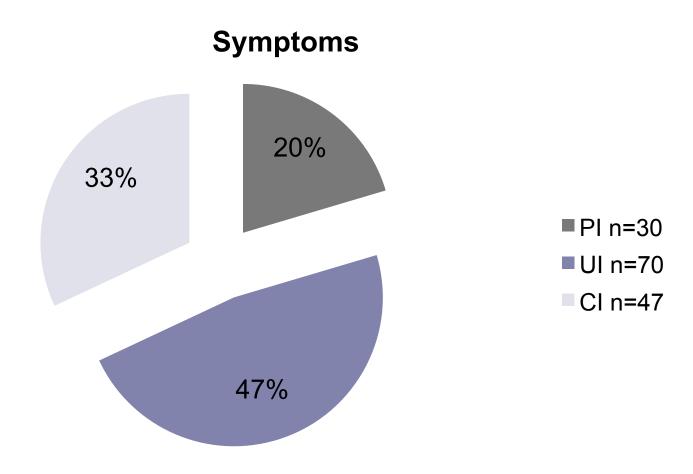


Methods - Definitions

- 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

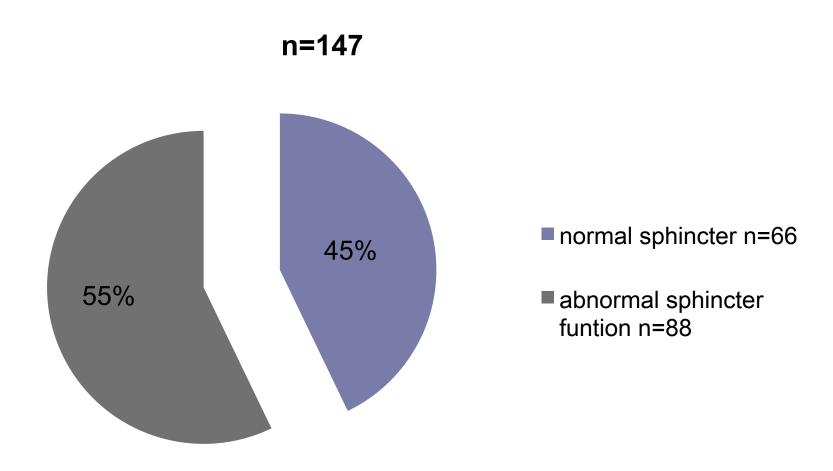


Incontinence - Symptoms





Incontinence – Sphincter pressures

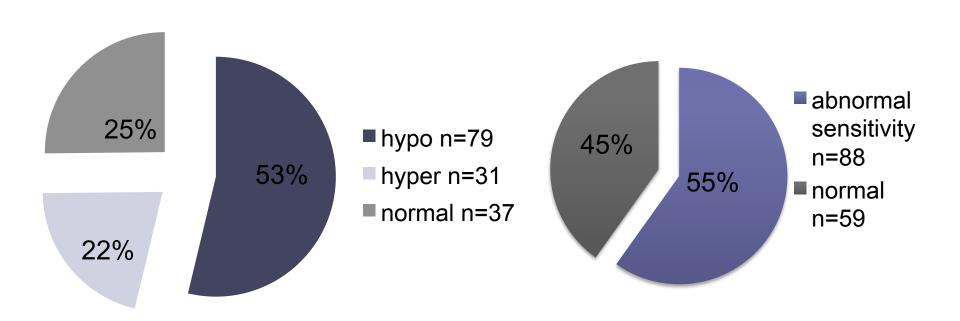




Balloon vs. Barostat – rectal sensitivity



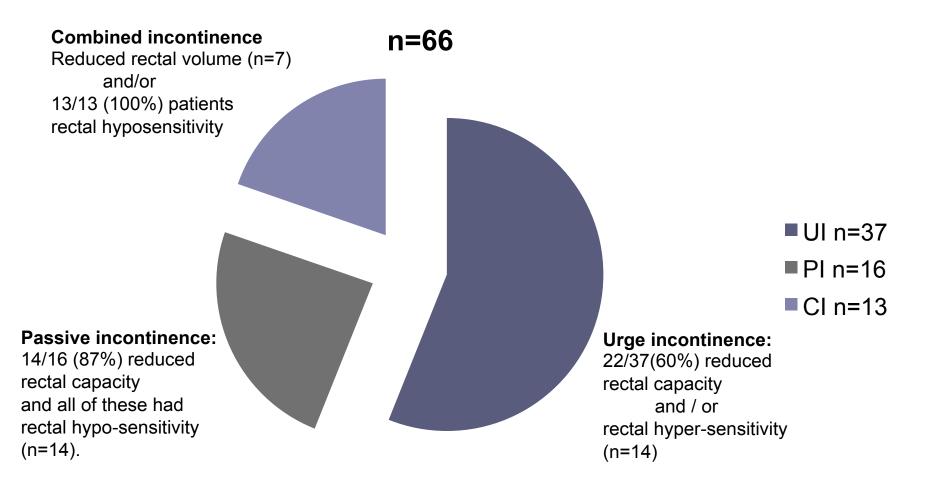
Elastic balloon



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)



Normal Sphincter Abnormal rectal function



17/66 (26%) had entirely normal manometry and barostat studies



Conclusions

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