Clinical Utility of Anorectal Manometry and Balloon Expulsion Testing to Predict Outcomes With Community-Based Pelvic Floor Physical Therapy: A Pragmatic Clinical Trial of Patients With Chronic Constipation

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BACKGROUND

- Chronic constipation drives 2.1 million referrals to general gastroenterologists each year in the US.
- Functional evacuation disorders are common causes of chronic constipation that are diagnosed on anorectal manometry (ARM) and balloon expulsion time (BET).
- The availability of pelvic floor physical therapists is increasing across the United States.
- The question in general gastroenterology:
  Does the test inform management?

AIMS

To assess the predictive accuracy of ARM and BET to inform the likelihood of achieving clinically meaningful symptom improvement with pelvic floor physical therapy in the community, among patients referred to general gastroenterology that fail a usual empiric trial of soluble fiber or osmotic laxative.

METHODS

- Study design: Single-arm observational clinical trial
- Enrollment: 60 patients meeting Rome IV functional constipation criteria failing osmotic laxative or soluble fiber supplementation for at least 2 weeks
  - Exclusion: unable/unwilling to participate in pelvic floor PT; neurodegenerative conditions or uncontrolled IBD; abdominal pain as primary symptom; experienced to ARM, BET or PT; prior colorectal surgery; use of opioids or prescription drugs to IBS-C or CIC within the past 30 days
- All patients underwent 3D-high definition ARM + BET (London Consensus) followed by empiric community-based pelvic floor physical therapy in routine care
- Assessments: Baseline and 12-weeks
- Primary endpoint: Reduction in PAC-SYM score of at least 0.4 vs. baseline (i.e. definition of MCID)
- Analysis groups:
  1) Abnormal anorectal function test
  2) Normal anorectal function test
- Statistical analysis: Receiver operator curve to evaluate predictive accuracy, Youden index to identify optimal parameters, chi-square test on optimal parameters

RESULTS

FIGURE 1: Trial design

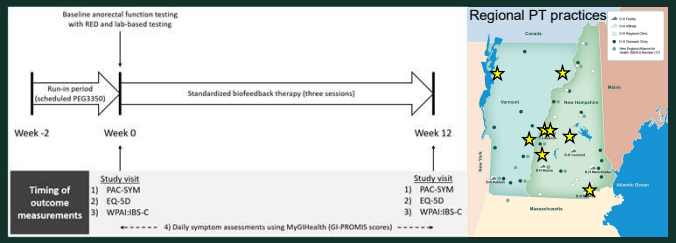

TABLE 1: Clinical response on dyssynergia metrics

Test result	Abnormal BET (> 60 seconds)	Normal BET (≤60 seconds)
Presence of a dyssynergic pattern on ARM during simulated defecation	43.8% likelihood of response (7/16 patients)	33.3% (4/12 patients)
Normal relaxation pattern	42.9% (3/7 patients)	41.2% (7/17 patients)

TABLE 2: Predictive accuracy across all available metrics

Test parameter	Area-under-the-curve (95% CI)	Optimal predictive cut-off to predict positive response	Sensitivity	Specificity	p-value
Balloon expulsion	0.54 (0.38 to 0.69)	> 6.5 seconds	100%	12.9%	0.237
Resting pressure	0.55 (0.40 to 0.71)	> 67.5 mmhg	57.1%	61.3%	0.305
Squeeze pressure	0.63 (0.46 to 0.79)	> 192.5 mmHg	47.6%	83.9%	0.032
Squeeze duration	0.64 (0.49 to 0.76)	> 20 sec	71.4%	58.1%	0.070
Cough reflex	0.49 (0.36 to 0.62)	Present	100.0%	0.0%	---
Defecation					
1 attempt	0.44 (0.30 to 0.59)	Any DD	100.0%	0.0%	---
2 attempts	0.46 (0.31 to 0.61)	Any DD	100.0%	0.0%	---
3 attempts	0.51 (0.35 to 0.66)	Type 3 or 4	28.6%	80.6%	0.661
4 attempts (air)	0.54 (0.39 to 0.69)	Type 3 or 4	28.6%	87.1%	0.294
% anal relaxation	0.47 (0.37 to 0.63)	> 38%	33.3%	77.4%	0.589
First sensation	0.45 (0.29 to 0.62)	> 45mL	45.0%	58.1%	1.000
Urge to defecate	0.59 (0.41 to 0.74)	< 115 mL	94.4%	30.0%	0.099
Maximum volume	0.48 (0.32 to 0.65)	> 115 mL	61.9%	56.7%	0.307

TABLE 3: Likelihood of response on squeeze pressure

Test result	Clinical response
Squeeze pressure >192.5 mmHg	66.7% (10/15 patients)
Squeeze pressure <192.5 mmHg	29.7% (11/37 patients)

FIGURE 2: Predictive accuracy of dyssynergia metrics

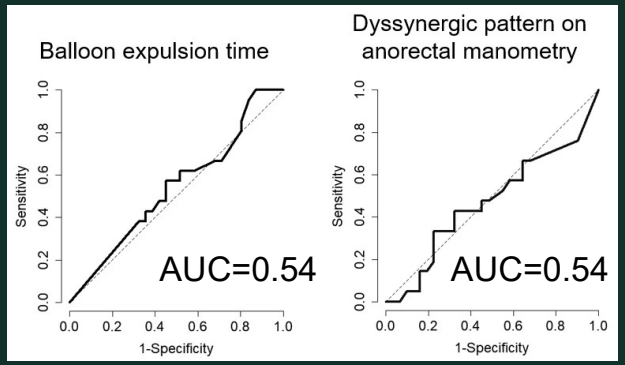

TABLE 4: Likelihood of response on optimized squeeze duration and balloon expulsion time metrics

Test result	BET >6.5 seconds	BET ≤6.5 seconds
Squeeze duration < 20 seconds	52.0% (13/25 patients)	
Squeeze duration at least 20 seconds	34.8% (8/23)	0% (0/4)

CONCLUSIONS

Among relatively treatment-naïve patients referred to general gastroenterology failing two weeks of soluble fiber and/or osmotic laxatives:

- Anorectal manometry may predict response to up-front pelvic floor physical therapy on simple and novel squeeze profiles
- Traditional balloon expulsion time (60 seconds) and dyssynergic patterns appear non-informative of clinical outcomes in this care setting

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