Optimizing Cost-Effective Care for Chronic Constipation in General Gastroenterology Using an Office-Based, Point-Of-Care Test (RED): Cost-Effectiveness and Cost-Minimization Analysis

Eric D. Shah, MD, MBA, FACG[1] and William D. Chey, MD, FACG[1]

INTRODUCTION: **We aimed to evaluate the cost-effectiveness/cost-savings of point-of-care anorectal function testing with an investigational device (RED) to triage therapy for chronic constipation in general gastroenterology.**

METHODS: **A Markov model was constructed to evaluate cost-effectiveness/cost-savings over a 1-year time horizon comparing empiric drug/pelvic floor physical therapy to testing guided care.**

RESULTS: **RED appears to inform the cost-effective strategy for chronic constipation. Compared with usual care without RED, it reduces insurer costs by $810 and patient costs by $6,903.**

DISCUSSION: **Point-of-care testing using RED appears cost-effective/cost-saving to triage chronic constipation care in general gastroenterology.**

KEYWORDS: constipation; anorectal manometry; balloon expulsion testing; health economics

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INTRODUCTION

Chronic constipation is a common reason for referral to general gastroenterology (1). The status quo anchors on minimizing testing, giving empirical advice, and prescribing over-the-counter interventions in an effort to minimize costs for the majority of patients who seek care (2). Whether or not this treatment strategy is correct, the bar that must be reached is a sensible one—to ensure that routine care is cost-effective. We recently developed an investigational, point-of-care device called RED that is designed to align with clinical workflow and rapidly triage patients to the physiologically appropriate therapy during the initial office consultation with the gastroenterologist (3). A prospective clinical trial validated the accuracy of RED in predicting treatment outcomes with community-based pelvic floor physical therapy (4).

We aimed to compare the cost-effectiveness from a patient perspective and cost-savings from an insurer perspective of using RED to the *status quo* of empirical prescription drug or pelvic floor physical therapy approaches in routine care.

METHODS

We adapted a previously published Markov model developed on a base-case patient referred to general gastroenterology, failing a simple trial of soluble fiber and/or osmotic laxative (5). This study adhered to the Consolidated Health Economic Evaluation Reporting Standards checklist and methodologic guidance from the Second Panel on Cost-Effectiveness in Health and Medicine (6). Outcomes and cost estimates for model inputs were derived from systematic reviews of clinical trials and national databases that were previously described. An abnormal RED defined by expulsion within 5 seconds (weak pelvic floor) or greater than 120 seconds (dyssynergia) would prompt referral to pelvic floor physical therapy (4). A normal RED would prompt a prescription drug after failing empiric over-the-counter laxatives (7). Four routine management strategies were subsequently modeled: (i) empiric pelvic floor physical therapy, (ii) empiric prescription drug, (iii) usual care, or (iv) care directed by RED. While empiric pelvic floor physical therapy and empiric prescription drugs are discrete interventions, usual care consists mainly of repeated over-the-counter laxatives based on national observational data. Costs and quality-adjusted life years (QALY) were reported with each strategy over a 1-year time horizon with a standard 3% discount rate. Incremental cost-effectiveness ratios were calculated by dividing costs by QALY. In previous analyses, the likelihood of clinical response to pelvic floor physical therapy was the most important predictor of whether pelvic floor physical therapy or prescription drugs were cost-effective. Namely, a likelihood of

[1]Michigan Medicine, Ann Arbor, Michigan, USA. **Correspondence:** Eric D. Shah, MD, MBA, FACG. E-mail: ershah@umich.edu.
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Table 1. Routine, up-front point-of-care testing with an investigational device (RED) to triage patients to appropriate constipation care is more cost-effective than empiric prescription drug or empiric pelvic floor physical therapy strategies

Strategy	Total cost ($/yr)	Total effectiveness (QALY gained/yr)	Incremental cost ($)	Incremental effectiveness (quality-adjusted life year or QALY)	Incremental cost-effectiveness ratio or ICER ($/QALY-gained)
Insurer perspective					
Continued usual care (rotating over-the-counter products and dietary advice)	$2,566	0.813	Reference	Reference	Reference
Empiric pelvic floor physical therapy	$1,964	0.838	$602 saved	+0.025	Dominates usual care
Empiric prescription drug	$7,146	0.832	$4,580 additional cost	+0.019	$241,053/QALY-gained compared with empiric pelvic floor physical therapy
Care directed using RED	$1,756	0.844	$810 saved	+0.031	Dominates all strategies
Patient perspective					
Continued usual care (rotating over-the-counter products and dietary advice)	$13,761	0.813	Reference	Reference	Reference
Empiric prescription drug	$9,607	0.832	$6,154 saved	+0.019	Dominates usual care
Empiric pelvic floor physical therapy	$7,971	0.838	$5,790 saved	+0.025	Dominates usual care and prescription drug
Care directed using RED	$6,858	0.844	$6,903 saved	+0.031	Dominates all strategies

Costs and outcomes with empirical strategies and usual care and footnotes are reproduced from a recent publication.
ICER, incremental cost-effectiveness ratios; QALY, quality-adjusted life years.

clinical response to pelvic floor physical therapy below 26% would favor prescription drugs, while pelvic floor physical therapy would be preferred if the likelihood of response exceeded 26%. If it is cost-effective, RED should be able to cross this threshold cut point and thereby change cost-effective management on a routine basis. Analysis was performed using TreeAge Pro 2022 R2 (TreeAge Software, Williamstown, MA).

RESULTS

Costs and effectiveness gains are described for each strategy in Table 1, including estimates for empirical strategies and usual care that were recently published in a separate report. RED was designed to be used in a left lateral position to align with clinical workflow in the office. As previously described, the cost of usual care to insurers was $2,566/yr due to repeated diagnostics and office visits and $13,761/yr to patients due to reduced work presentism due to constipation symptoms. Identifying patients with an abnormal RED to receive pelvic floor physical therapy would reduce insurer costs by $810/yr and reduce patient costs by $6,903/yr compared with usual care without RED. RED would add 11 healthy d/yr (0.03 QALY/yr) over usual care. Compared with an empiric prescription drug strategy for all patients, up-front testing with RED would reduce insurer costs by $4,293 by identifying the therapy to which the patient is most likely to respond at the outset. Using RED appears cost-effective regardless of the test result because RED appears sufficiently able to identify the most cost-effective therapy based on the likelihood of response to pelvic floor physical therapy (Figure 1).

DISCUSSION

RED is a novel point-of-care, office-based test to triage patients presenting to general gastroenterology with chronic constipation failing an empiric trial of over-the-counter laxatives to appropriate index therapy (Figure 1). RED appears cost-saving to insurers and cost-effective to patients compared with usual care that consists mainly of repeated over-the-counter laxatives. By identifying the optimal treatment modality at the index visit, RED also appears cost-saving to insurers and cost-effective to patients compared with routine empirical pelvic floor physical therapy or prescription drug therapy strategies (5,8). Compared with a water-filled or air-filled balloon expulsion test, the compressibility of RED approximates stool consistency. This likely explains why RED appears to predict clinical outcomes with pelvic floor physical therapy in general gastroenterology populations, whereas balloon expulsion testing does not appear to inform clinical outcomes in general gastroenterology and can therefore not be cost-effective with routine use (9). Therefore, RED is not interchangeable with balloon expulsion testing. Compared with anorectal manometry, RED mitigates the need for capital equipment costs to routinely evaluate constipation as a common symptom in general gastroenterology.

Limitations of our study surround the practical realities of offering personalized management approaches in routine care.

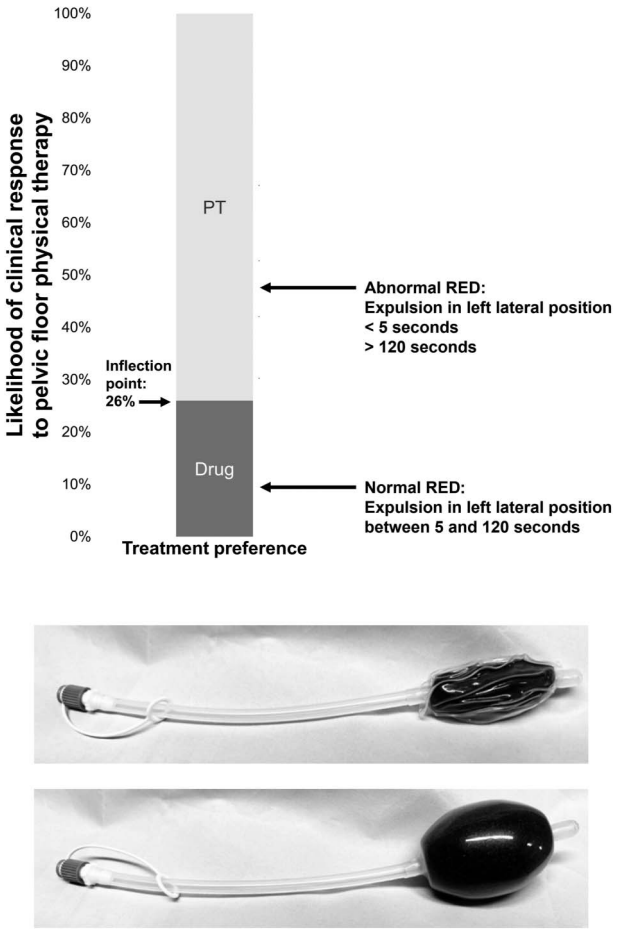

Figure 1. (Top) RED can identify the cost-effective treatment modality for chronic constipation failing fiber/laxatives based on the predicted likelihood of response to pelvic floor physical therapy. The original figure is adapted from Shah ED, Ahuja NK, and Brenner DM et al. Optimizing the management algorithm for adults with functional constipation failing a fiber/laxative trial in general gastroenterology: cost-effectiveness and cost-minimization analysis. *Am J Gastroenterol*, October 2023. (Bottom) RED is shown in compressed and inflated states.

First, our data do not apply to patients who would decline RED and pelvic floor testing after appropriate counseling. Second, our findings do not apply to patients with abdominal pain as the dominant symptom. Finally, our findings apply to patients in general gastroenterology who receive pelvic floor physical therapy and not treatment-refractory patients in referral centers who have received high-intensity anorectal biofeedback on the basis of anorectal manometry and balloon expulsion testing. Notably, pelvic floor physical therapy is an increasingly widespread field, and local access to trained physical therapists is improving (10).

In summary, RED appears to hold the promise of disrupting the care paradigm to support the cost-effective adoption of recent joint American College of Gastroenterology and American Gastroenterological Association guidelines that promote consideration of pelvic floor physical therapy in routine care.

CONFLICTS OF INTEREST

Guarantor of the article: Eric D. Shah, MD, MBA, FACG.

Specific author contributions: All authors were involved in the study's concept, design, and interpretation of data. E.D.S. authored the initial draft of the manuscript and performed statistical analysis, and all authors critically revised the manuscript and approved the final copy.

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