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An Analysis of 5 Years of Randomized Trials in Gastroenterology and Hepatology Reveals 52 Medical Reversals

Margot C. Yopes¹ · Alexander M. Mozeika¹ · Simon Liebling² · Alyson Haslam³ · Vinay Prasad³ · Benjamin Lebwohl^{4,5} 

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Abstract

Background and Aims One manifestation of low-value medical practice is the medical reversal, a practice in widespread use that, once subjected to a randomized controlled trial (RCT), is found to be no better—or worse—than a prior established standard of care. We aimed to determine the prevalence of medical reversals in gastroenterology (GI) journals and characterize these reversals.

Methods We searched the American Journal of Gastroenterology, Clinical Gastroenterology and Hepatology, Gastroenterology, Gut, Hepatology, and the Journal of Hepatology, reviewing studies published in 2015–2019. We identified RCTs that tested an established clinical practice and produced negative results, considered tentative reversals. Any systematic review or meta-analysis that included the article was categorized as confirming the reversal, refuting the reversal, or providing insufficient data.

Results During the 5-year period, we identified 5,898 original articles, of which 212 tested an established practice and 52 were categorized as unrefuted medical reversals (25% of articles testing standard of care). Of the reversals, 21 (40%) tested procedures and devices, 15 (29%) tested medications, and 8 (15%) tested vitamins/supplements/diet. Twenty-three (44%) considered the alimentary tract, 12 (23%) considered the liver, pancreas, or biliary tract, and 17 (33%) considered endoscopy. Thirty-eight (73%) were funded exclusively by non-industry sources.

Conclusion This review reveals a total of 52 reversals across all subfields of GI and medical, procedural, screening, and diagnostic interventions, occurring in 25% of randomized trials testing an established practice. More research is needed to determine the optimal way to engage stakeholders and remove reversed practices from medical care.

Keywords High-value care · Healthcare economics

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Introduction

There is a growing body of literature describing and identifying low-value medical practices, which are defined as practices which are ineffective or similarly effective to but economically inferior to other options [1–4]. In addition to wasted healthcare dollars, use of low-value medical practices may harm patients and the healthcare system, and there have been efforts to identify and recommend avoidance of these practices by task forces [3, 5]. One particular type of low-value medical practice is the medical reversal, which is a practice in widespread use that, once subjected to a randomized controlled trial (RCT), is found to be no better than—or sometimes worse than—a prior established standard of care [1, 2]. Identifying medical reversals is important to help minimize wasteful or harmful medical care. Recent work has shown that 14% of all RCTs published in three general medicine journals over a 10-year period were reversals, 13 (3%) of which occurred in the field of gastroenterology (GI) [4]. The prevalence of medical reversals in GI journals is unknown.

We aimed to determine the prevalence of medical reversals in GI journals and to characterize these reversals. Our goal was to contribute to the growing study of medical reversals and low-value medical practices in the medical specialty of gastroenterology and to support efforts to identify and eliminate the use of these practices.

Methods

Search Strategy

We searched six medical journals in the field of gastroenterology and hepatology: the American Journal of Gastroenterology, Clinical Gastroenterology and Hepatology, Gastroenterology, Gut, Hepatology, and the Journal of Hepatology, reviewing studies published in the years spanning 2015–2019. These journals were selected based on their impact factor and diversity of articles with respect to intervention type and subfield of GI. Using methods similar to those previously established by Prasad et al., [4] we reviewed all articles in the “Articles” section of the American Journal of Gastroenterology, all papers labeled “Original Articles” in Clinical Gastroenterology and Hepatology, Gut, and Hepatology, all articles in the “Original Research” section in Gastroenterology, and all articles in the “Research Articles” section of the Journal of Hepatology. Articles in issues that exclusively summarized conference proceedings or reviewed single topics without original research were excluded from the total article count.

Articles Included

We reviewed 5,898 articles and identified all RCTs that tested a clinical practice. We defined a clinical practice as anything that could be used in the delivery of patient care, i.e., any medication, surgical intervention, behavioral intervention, screening or diagnostic tool, or treatment algorithm. Of the RCTs we identified, we excluded those that tested a novel practice, which we defined as any practice that was not in common clinical use in the USA for the indication being tested prior to the publication of the RCT. If it was not clear whether a practice was novel or established, we reviewed it with one or more gastroenterologists with expertise in the practice area to confirm our categorization. Subsequently, we excluded any trial with a positive result (i.e., any trial that met its primary outcome) and any trial with an inconclusive result (i.e., any trial that met only some of its primary outcomes). This left us with a group of RCTs that tested established medical practices and produced null results, which we considered tentative reversals.

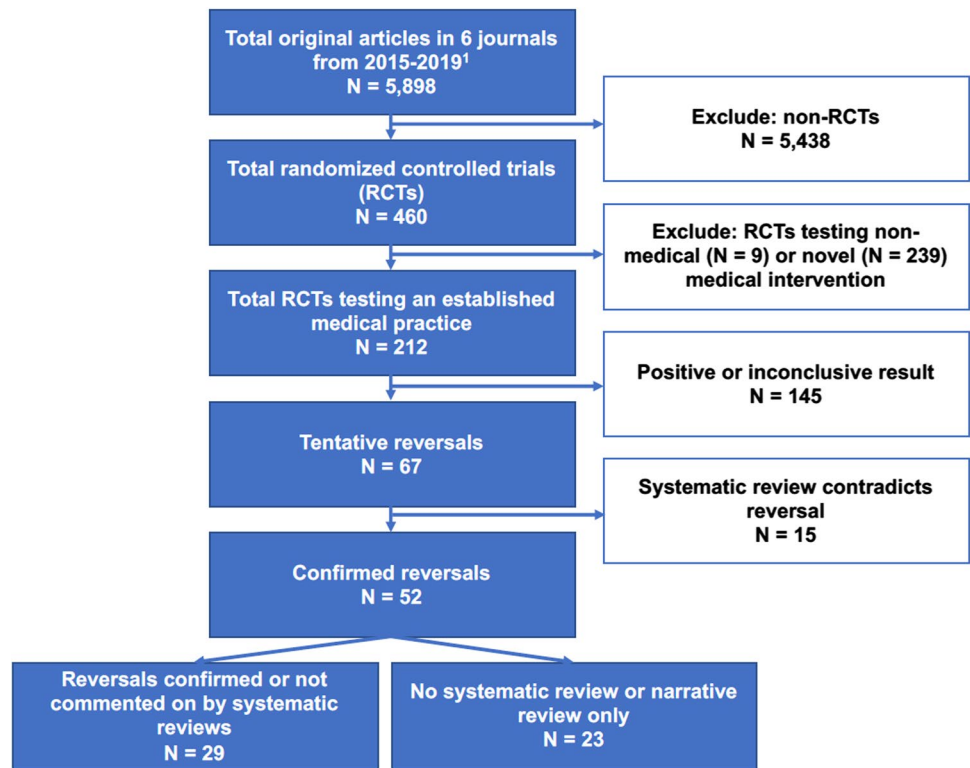
We performed a search to find a systematic review (SR) or meta-analysis (MA) that evaluated each practice. Using the method outlined by Prasad and colleagues [4], we searched for any SR/MA that included each tentative reversal. Cochrane reviews were prioritized, and if no Cochrane review was available, the most recent SR/MA that addressed the practice was used. Narrative reviews were not used. For each tentative reversal, any SR/MA found was categorized as confirming the reversal, refuting the reversal, or providing insufficient data on the reversal. Any tentative reversal that was refuted by a SR/MA was excluded from the total. For all steps, at least two reviewers (MY, BL, AM, SL) examined information for each article. All categorizations had to be reached by unanimous decision. Study inclusion is depicted in Fig. 1.

Articles were grouped by type of intervention (medication, procedure, vitamins/supplements/diet, screening test, diagnostic algorithm, or system intervention) and by GI subspecialty (alimentary tract, liver, pancreas, or biliary tract, and endoscopy). For all reversals, we also abstracted funding data when available and categorized articles by type of funding (industry only, non-industry only, industry and non-industry, or none).

Data Analysis

Data are presented using descriptive statistics. Analyses were conducted using Microsoft Excel. This study was exempted from institutional review board approval because it involved publicly available data and did not involve individual patient data.

Fig. 1 Study inclusion flow chart. ¹Gut, Gastroenterology, Hepatology, the American Journal of Gastroenterology, the Journal of Hepatology, and Clinical Gastroenterology and Hepatology between January 2015 and December 2019



Results

We identified 5,898 original articles (Fig. 1), of which 460 (7.8%) articles reported the results of RCTs. Of these articles, 451 (98.0% of RCTs) reported on trials of clinical practices. Articles were further classified into those that tested novel practices or established practices and then by outcome (positive, negative, or inconclusive). After excluding articles reporting RCTs of novel therapies, we found 212 articles

testing an established medical practice. Among this set, 67 (32%) were classified as tentative medical reversals. Fifteen of these were excluded after a SR/MA refuted the reversal, leaving 52 medical reversals (25% of all RCTs testing standard of care, 11.3% of all randomized control trials and 0.9% of all original articles; see Table 1). Of these, 29 (55.7%) had been the subject of meta-analyses which confirmed the reversal or did not comment on the specific practice in question, and 23 had not been cited by a SR/MA or had only been included in a narrative review.

Table 1 Reversal characteristics

	Gut	Gastroenterology	Hepatology	Am. J. Gas- troenterol.	Am. J. Hepatol.	J. HepClin. Gastro- enterol. Hepatol.	Total
Intervention type							
Procedure or device	5 (56%)	3 (25%)	1 (33%)	8 (53%)	0 (0%)	4 (50%)	21
Medication	2 (22%)	2 (17%)	2 (67%)	4 (27%)	3 (60%)	2 (25%)	15
Vitamins/ Supplements/ Diet	2 (22%)	4 (33%)	0 (0%)	0 (0%)	1 (20%)	1 (13%)	8
Treatment algorithm	0 (0%)	3 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3
Screening test	0 (0%)	0 (0%)	0 (0%)	1 (7%)	0 (0%)	1 (13%)	2
System intervention	0 (0%)	0 (0%)	0 (0%)	2 (13%)	0 (0%)	0 (0%)	2
Radiation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	1
Discipline							
Alimentary tract	4 (44%)	8 (67%)	0 (0%)	8 (53%)	0 (0%)	3 (38%)	23
Endoscopy	4 (44%)	3 (25%)	0 (0%)	7 (47%)	0 (0%)	3 (38%)	17
Liver, pancreas, and biliary	1 (11%)	1 (8%)	3 (100%)	0 (0%)	5 (100%)	2 (25%)	12

Of the reversals identified, 21 (40%) tested procedures and devices, 15 (29%) tested medications, 8 (15%) tested vitamins/supplements/diet, 3 (6%) tested a treatment algorithm, 2 (4%) tested a screening tool, 2 (4%) tested a system intervention, and 1 (2%) tested radiation. With regard to practice areas within gastroenterology, 23 (44%) considered the alimentary tract, 12 (23%) considered the liver, pancreas, or biliary tract, and 17 (33%) considered endoscopy. With respect to funding, the majority of the reversals identified—38 (73%)—were funded by non-industry sources only. Seven (13%) were funded by both industry and non-industry sources, four (8%) were funded by industry sources only, and three (6%) were not funded.

Table 2 identifies a representative subset of reversals, selected for their broad applicability in clinical practice. Supplemental Table 1 includes a list of all reversals identified.

Discussion

Here we present a list of 52 practices within the field of GI that subsequent RCTs have demonstrated to be clinically or economically inferior to the prior standard of care. This work expands the list of medical reversals in GI previously identified in a review of general medical journals [2, 4] by evaluating articles published in leading GI-specific journals.

There is risk of harm to patients and unnecessary cost to the medical system in continuing to use low-value practices. Many strategies have been employed to identify low-value practices, including surveys of practitioners, systematic searches, searches of insurance claims databases, and identification of medical reversals [1, 2, 4, 6–9]. As more reversals and other low-value practices are identified, systematically organizing and prioritizing them has become increasingly difficult [7]. The cost of continuing to use low-value practices is significant, with one analysis of only the 26 most commonly used low-value services suggesting a cost to Medicare of \$1.9–\$8.5 billion in 2008–2009 [10]. Prior work identified almost 400 medical reversals published in the *New England Journal of Medicine*, *JAMA*, and the *Lancet*; given the number of medical reversals identified in these journals, it is likely that tens or hundreds of billions of dollars are spent annually on medical interventions which were subsequently demonstrated to be economically or clinically inferior to a prior standard of care [4].

Within the field of gastroenterology, there is awareness of the need to practice value-based medicine [11]. The American Gastroenterological Association provided five value-based recommendations to the Choosing Wisely campaign: use proton pump inhibitors at the minimum effective dose for gastrointestinal reflux disease, repeat colonoscopy only every 10 years in average-risk patients

without findings and only every 5 years for patients with one or two small (< 1 cm) adenomatous polyps, screening for dysplasia only every three years for patients with Barrett's esophagus who have had two negative endoscopies, and not repeating CT scans for patients with functional abdominal pain syndrome [6, 9]. Other work has identified serologic *H. pylori* testing and colorectal cancer screening in certain populations, such as those with life-limiting comorbidity or who were re-screened too early based on colonoscopy findings, as overused practices within GI [12–16]. A review by Camilleri et al. addressed 12 clinical questions within GI and offered high-value approaches to answering them [17]. These included questions regarding the workup of common symptoms such as constipation and dyspepsia and clinical indications for imaging. Overall, their work suggests that in some conditions, clinical features should be used to guide further testing, but it does not explicitly highlight practices that have been reversed. Finally, one study examined the use of low-value practices within GI among non-specialized resident trainees and found that the most overused practices were routine measurement of serum lipase in acute pancreatitis, rechecking *Clostridium difficile* toxin polymerase chain reaction after resolution of diarrhea to confirm cure, and testing for occult blood in gastric aspirate or emesis [18]. Although this prior work offers a few high-yield practices to reinforce and low-yield practices to de-adopt, our work, to our knowledge, is the first systematic review that identifies dozens of additional practices in the field of gastroenterology that were reversed by high-quality evidence.

Our analysis demonstrates reversals across all subfields of gastroenterology and in practices involving medications, procedures, vitamins/supplements/diet, screening tests, diagnostic algorithms, and system interventions. Reversals made up 11.3% of all RCTs, but constituted 25% of all RCTs testing established practice—in line with the percentage found in large, multi-specialty journals by previous studies of medical reversals [4]. Our analysis raises concern that among the many practices that are currently offered, and not based on robust randomized evidence, further reversals would be identified if such rigorous trials were conducted. Impartial research funding for such efforts, such as those from the National Institutes of Health, is vital.

The reversals we identified were weighted toward procedures, with similar numbers in medications and vitamins/supplements/food—reflecting that within the field of GI, diet is a commonly investigated medical intervention. These facts underscore the importance of evaluating medical reversals by sub-specialty, as the noteworthy and significant interventions which have the largest impact on the field vary greatly across the medical, surgical, and procedural disciplines.

It can be challenging for practitioners to respond to new evidence and discontinue the use of established but low-value practices. A review reported that physicians

Table 2 Representative subset of reversals

Citation	Conclusion	Systematic review	Funding
Long-Term Effects of Omitting Antibiotics in Uncomplicated Acute Diverticulitis. van Dijk ST et al. <i>Am. J. Gastroenterol.</i> 2018	“Omitting antibiotics in the treatment of uncomplicated acute diverticulitis did not result in more complicated diverticulitis, recurrent diverticulitis or sigmoid resections at long-term follow up.”	Only narrative reviews available	Netherlands Organization for Health Research and Development, Digestive Diseases Foundation
Histamine-2 Receptor Antagonist Cannot Prevent Recurrent Peptic Ulcers in Patients With Atherosclerotic Diseases Who Receive Platelet ADP Receptor Antagonist Monotherapy: A Randomized Controlled, Double-Blind, and Double-Dummy Trial. Hsu PI et al. <i>Am. J. Gastroenterol.</i> 2017	“Famotidine cannot decrease the incidence of peptic ulcer or ulcer bleeding in thienopyridine users with atherosclerotic disease and a history of peptic ulcer.”	None	Research grants from the Research Fund of the Kaohsiung Veterans General Hospital
Adherence to Competing Strategies for Colorectal Cancer Screening Over 3 Years. Cross RK et al. <i>Am. J. Gastroenterol.</i> 2016	“Participants offered a choice between FOBT and colonoscopy continued to have relatively high adherence, whereas adherence in the FOBT group fell significantly below that of the choice and colonoscopy groups.”	Included in American College of Gastroenterology guidelines	Agency for Healthcare Research and Quality and the University of Maryland General Clinical Research Centers Program
Montelukast Does not Maintain Symptom Remission After Topical Steroid Therapy for Eosinophilic Esophagitis. Alexander JA et al. <i>Clin. Gastroenterol. Hepatol.</i> 2017	“We found montelukast to be well tolerated; 40% of patients remained in remission, but this proportion did not differ significantly from that of the placebo group.”	Only narrative reviews available	Merck
Pantoprazole to Prevent Gastrointestinal Events in Patients Receiving Rivaroxaban and/or Aspirin in a Randomized, Double-Blind, Placebo-Controlled Trial. Moayyedi P et al. <i>Gastroenterol.</i> 2019	“Routine use of proton pump inhibitors in patients receiving low-dose anticoagulation and/or aspirin for stable cardiovascular disease does not reduce upper gastrointestinal events, but may reduce bleeding from gastroduodenal lesions.”	None which included this trial	Bayer AG
Cost-effectiveness of laparoscopic ileocaecal resection versus infliximab treatment of terminal ileitis in Crohn’s disease: the LIRIC Trial. de Groof EJ et al. <i>Gut.</i> 2019	“Laparoscopic ileocaecal resection is a cost effective treatment option compared with infliximab.”	Only narrative reviews available	The Netherlands Organisation for Health Research and Development
Midodrine and albumin for prevention of complications in patients with cirrhosis awaiting liver transplantation. A randomized placebo-controlled trial. Sola E et al. <i>J. Hepatol.</i> 2018	“There were no significant differences between both groups in the probability of developing complications of cirrhosis during follow-up or one-year mortality.”	“Based on very low-certainty evidence, there is considerable uncertainty about whether interventions for ascites in people with decompensated liver cirrhosis decrease mortality, adverse events, or liver transplantation compared to paracentesis plus fluid replacement in people with decompensated liver cirrhosis and ascites.” Benmassaoud A et al. <i>Cochrane Database Syst Rev.</i> 2020	Instituto de Salud Carlos III, European Regional Development Fund (ERDF), Agencia de Gestió d’Ajuts Universitaris I de Recerca (AGAUR), CERCA programme/ Generalitat de Catalunya

Table 2 (continued)

Citation	Conclusion	Systematic review	Funding
Impact of combined selective internal radiation therapy and sorafenib on survival in advanced hepatocellular carcinoma. Ricke J et al. <i>J. Hepatol.</i> 2019	“Addition of SIRT to sorafenib did not result in a significant improvement in OS [overall survival] compared with sorafenib alone.”	“Evidence showing effects of radioembolisation with or without sorafenib compared with sorafenib alone in people with unresectable hepatocellular carcinoma is highly insufficient. We cannot determine if radioembolisation plus sorafenib compared with sorafenib alone affects all-cause mortality or the occurrence of adverse events.” Abdel-Rahman and Elsayed Z. <i>Cochrane Database Syst Rev.</i> 2020	Sirtex Medical and Bayer Healthcare
Randomized Comparison of 3 High-Level Disinfection and Sterilization Procedures for Duodenoscopes. Snyder GM et al. <i>Gastroenterol.</i> 2017	“In a comparison of duodenoscopes reprocessed by standard high-level disinfection, double high-level disinfection (dHLD), or standard high-level disinfection followed by ethylene oxide gas sterilization (HLD/ETO), we found no significant differences between groups for multidrug-resistant organisms or bacteria contamination. Enhanced disinfection methods (dHLD or HLD/ETO) did not provide additional protection against contamination.”	Meta-analysis did not comment on sterilization process	American Society for Gastrointestinal Endoscopy and from Beth Israel Deaconess Medical Center
A randomized trial of endoscopic submucosal dissection versus endoscopic mucosal resection for early Barrett’s neoplasia. Terheggen G et al. <i>Gut.</i> 2017	“In terms of need for surgery, neoplasia remission and recurrence, endoscopic submucosal dissection (ESD) and endoscopic mucosal resection (EMR) are both highly effective for endoscopic resection of early Barrett’s Esophagus (BO) neoplasia. ESD achieves a higher R0 resection rate, but for most BO patients this bears little clinical relevance. ESD is, however, more time consuming and may cause severe AE.”	Only narrative reviews available	Evangelisches Krankenhaus
Differences in Weight Loss Between Persons on Standard Balanced vs Nutritional Diets in a Randomized Controlled Trial. Franchiwich KA et al. <i>Clin. Gastroenterol. Hepatol.</i> 2015	“A nutrigenetic-based diet did not increase weight loss compared with a standard balanced diet.”	“We have observed that carriage of the fat mass and obesity associated (FTO) minor allele was not associated with differential change in adiposity after weight loss interventions. These findings show that individuals carrying the minor allele respond equally well to dietary, physical activity, or drug based weight loss interventions and thus genetic predisposition to obesity associated with the FTO minor allele can be at least partly counteracted through such interventions.” Livingstone K et al. <i>BMJ.</i> 2016	Pathway Genomics Corporation, NIH

continue to use practices against guidelines because of lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy, lack of outcome expectancy, inertia of previous practice, and external barriers as hinderances to guideline adherence [19]. Patient preference can also play a role, evidenced by patient's requests for continued colorectal cancer screening no longer indicated by revised guidelines [20]. A comprehensive literature review and analysis by Niven et al. proposed a framework for de-adoption [21]. Key to the process are the identification and prioritization of low-value practices, which are embodied in the aim of the present study. Subsequently, engagement of stakeholders is the next crucial step in the process. The authors cite social, historical, political, and economic factors as potential barriers to this process. Further, they highlight changes to policies and/or the restructuring of funding associated with the low-value practice as successful strategies to encourage de-adoption. The most effective strategy for de-adoption is market withdrawal of a drug or piece of equipment, though our data demonstrate that reversed interventions are often merely ineffective, rather than harmful in a manner that would lead to such withdrawal.

Our analysis of funding sources for medical reversals reveals that a majority (73%) were funded exclusively by non-industry sources. This finding accords with prior analysis of medical reversal funding [4]. Our finding show the importance of federal and non-profit funding.

A limitation of our study is that while we included six high-quality journals, they represent only a subset of the original articles published in the field of GI. However, given their impact factors and broad applicability, we feel that our work represents a thorough review of GI literature. Additionally, we excluded major journals which include multiple disciplines within internal medicine, which are likely to have published RCTs in the field of GI in the past. However, medical reversals found in these journals are likely to be acknowledged and reported by the work of previous investigators of medical reversal [1, 2, 4, 8]. All articles were reviewed by at least two members of our team, but concepts such as medical practice and established practice are necessarily subjective. We aimed to minimize bias introduced during this process by requiring consensus classification by multiple reviewers.

In summary, within the field of GI, this review of five years of articles in six high-quality journals reveals a total of 52 reversals across all subfields and medical, procedural, screening, and diagnostic interventions. While this review aims to address the first steps in ensuring widespread acceptance of reversals, more research is needed to determine the optimal way to engage stakeholders and monitor for removal of reversed practices from medical care.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10620-021-07199-5>.

Author's contribution MCY contributed to the conception and methodology of the study, data acquisition and analysis, and original draft preparation. AMM and SL contributed to data acquisition and analysis and original draft preparation. AH and VP contributed to the conception and methodology of the study and draft review and editing. BL contributed to the conception and methodology of the study, data analysis, and draft review and editing.

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Ethical approval This was a retrospective study of publicly available, previously published literature. As no patient data was included, no ethical approval was required.

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