CME

Clinical Effects of Colonic Cleansing for General Health Promotion: A Systematic Review

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The practice of colonic cleansing to promote general health and well-being continues to generate interest among the lay population. These practices are widely touted as adjuncts to improve vitality and as therapeutic modalities to minimize the symptoms, or prevent the actual development, of a variety of chronic disease states. The data supporting colonic cleansing and body "detoxification" have not been studied well in a systematic manner. This report describes a systematic review of the published literature of both the traditional and complementary and alternative medicine arenas that was performed in an attempt to qualify and quantify the value of colonic cleansing. The investigators concluded that there are no methodologically rigorous controlled trials of colonic cleansing to support the practice for general health promotion. Conversely, there are multiple case reports and case series that describe the adverse effects of colonic cleansing. The practice of colonic cleansing to improve or promote general health is not supported in the published literature and cannot be recommended at this time.

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INTRODUCTION

Queries regarding the possible merits and risks of colonic cleansing and hydrotherapy are among the most commonly received questions from the lay population and press to the American College of Gastroenterology (1). Fueled by infomercials and advertisements touting the health benefits of maintaining an evacuated colon or performing periodic colonic purges, it is clear from the context of these inquiries that many individuals have embraced, or are at least considering, colonic hydrotherapy or other forms of colon cleansing with the expectation of improved health and wellbeing. Colon cleansing is not a new concept. The origins of this practice date back to the "autointoxication" theories that abounded in ancient medicine (2). Colonic cleansing therapy reached its heyday in the mid-nineteenth to the early twentieth centuries and then declined, largely secondary to condemnation from professional societies, such as the American Medical Association. Over the last 2-3 decades, however, advertising and promotion of the purported health effects of colonic cleansing have dramatically increased and it is now a multi-million-dollar industry. However, the benefits of colon cleansing remain largely anecdotal and the claims of benefit within many of the advertisements for these therapies are

medically and physiologically questionable. We undertook a systematic review to assess the outcomes associated with colon cleansing in an effort to clarify the medically appropriate recommendations that should follow inquiries regarding these practices.

METHODS

Literature search

We conducted a search of the online bibliographic databases MEDLINE and EMBASE to identify all relevant articles published regarding colonic cleansing between 1 January 1966 and 3 January 2009. The search criteria included the terms "colonic irrigation," "warm water irrigation," "colon cleansing," and "humans." The search was further supplemented by the addition of other descriptive key words, such as "lavage," "enema," "hydrotherapy," and "irrigation." Additional searches with these terms linked through "AND" were applied to the terms "hypertension," "asthma," "mucous colitis," "ulcerative colitis," "arthritis," "alcoholism," "sinus congestion," and "mental disorders," as all of these terms have been cited as possibly benefiting from colonic therapy (3). Additional searches limited to the complemen-

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tary and alternative medicine subset of PubMed as well as the Cochrane Collaboration Database were conducted. An expert medical librarian was utilized to maximize search techniques and the retrieval of targeted information. The bibliographies from all potentially relevant articles were manually searched, and abstracts from the annual scientific meetings of the American Gastroenterological Association (DDW) and the American College of Gastroenterology (1998–2008) were reviewed.

Study selection criteria

Criteria for properly designed reviews and studies of therapeutics have been defined (4,5). These criteria include (i) randomization, (ii) concealed allocation, (iii) double blinding, (iv) complete follow-up of patients, and (v) data reporting in an intention-to-treat analysis.

Potentially relevant articles were reviewed in an independent, unblinded manner by two authors (B.D.C. and R.A.) to determine whether they met the validity criteria specified above. Reviewers rated each article as being eligible, not eligible, or as having insufficient information to make a judgment as to eligibility. Any disagreement among reviewers was resolved by consensus.

Qualitative assessment of study methodology

Previous studies have established criteria by which to assess the quality of clinical studies and abstracts (6). Using the methods described in the study by Timmer et al., a quality score for each study included in this review was determined by assessing the study design and specific study quality indicators shown in Figure 1. The summary score is calculated as the ratio of the points awarded to the maximum possible score. The maximum possible score depends on the number of items that are applicable based on the type of research. There are more applicable items for more sophisticated designs (such as controlled clinical trials) than for simpler studies (such as case reports). For each quality assessment item, a maximum of 2 points is awarded (0 if not met, 1 if partially met, and 2 if fully met), resulting in a maximum of 38 if all quality assessment items are applicable and fully met, plus 5 points for design. Points awarded on the basis of design serve to counterbalance inequalities caused by the applicability of the various items. Thus, the points for design do not constitute a value judgment of design. Rather, the appropriateness of the design was considered to depend on the nature of the research question and was assessed in item 2 of the quality instrument, "description and appropriateness of the study design." Moreover, there is a deduction of 2 points for any

Appendix A: Quality scoring instrument Study design Points Human Interventional Parallel controlled trial 4 Randomization reported?(+1) Crossover trial 3 Time-series trial (before-after) 2 2 Non-concurrent/historic controls Natural experiment 2 Observational Cohort, prospective 4 Cohort, retrospective 3 Cross-sectional 3 Case-control 3 Descript., case report/series 1 Basic science Interventional: Parallel controlled 4 3 Crossover trial Set of before-after trials 3 Before-after, no controls 2 Observational Comparative 3 Case series 1 Other 2 Meta-analysis Instrument validation 1 Literature review 1 • . Other 0 • Do not know/not sure 0

Figure 1. Study quality assessment tool. For each applicable item, 0-2 points are awarded (2 if fully met, 1 if partially met, and 0 if not met). In addition, points are awarded on the basis of the study design and on whether randomization was present (0-5). The maximum possible total is (19×2)+5=43. For each item that is not applicable, such as blinding of subjects in basic science research, 2 points are subtracted from 43, resulting in the total possible score. The summary score is calculated by dividing the total score achieved by the total possible score.

First Author Year

Scorer

Qu	ality assessment	Yes	Partial	No	N/A
1.	Question / objective sufficiently described?				
2.	Design evident and appropriate to answer study question?				
3.	Subject characteristics sufficiently described?				
4.	Subjects appropriate to the study question?				
5.	Controls used and appropriate? (if no control, check no)				
6.	Method of subject selection described and appropriate?				
7.	If random allocation to treatment groups was possible, is it described? (if not possible, check n/a)				
8.	If blinding of investigators to intervention was possible, is it reported? (If not possible, n/a)				
9.	If blinding of subjects to intervention was possible, is it reported? (If not possible, n/a)				
10.	Outcome measure well defined and robust to measurement bias? Means of assessment reported?				
11.	Confounding accounted for?				
12.	Sample size adequate?				
13.	Post hoc power calculations or confidence intervals reported for statistically non-significant results?				
14.	Statistical analyses appropriate?				
15.	Statistical tests stated?				
16.	Exact P-values or confidence intervals stated?				
17.	Attrition of subjects and reason for attrition recorded?				
18.	Results reported in sufficient detail?				
19.	Do the results support the conclusions?				
Sur	n (items 1–19)				

Journal

Figure 2. Study quality assessment score sheet.

uncontrolled design. Using this technique, the highest possible summary score is 1.0. Studies were classified as low quality if they scored in the lowest tertile (0-0.33) or as medium-high quality if they scored in the middle to high tertile.

Data extraction and statistical analysis

Eligible articles were reviewed in a blinded manner by two different investigators (B.D.C. and R.A.), and the results of the primary research studies were abstracted onto specially designed data extraction forms. Data were extracted with regard to (i) population, (ii) condition being treated with colonic cleansing, (iii) intervention evaluated, (iv) measured outcomes, and (v) complications. The frequency of agreement between reviewers was >95% and disagreement was resolved through discussion. Owing to the wide variation of study methodology, study results were too diverse to combine in a true meta-analysis (4). Therefore, data were collected in tabular form (**Figure 2**).

RESULTS

Characteristics of selected studies

In total, 297 abstracts were identified through the search strategies described previously. Reviews of the titles and

abstracts followed by a review of the full manuscripts of potentially relevant articles identified 16 published manuscripts (2,3, 7–14, 16–21) and 1 letter (15) that met inclusion criteria. Selected characteristics and quality scores of these articles are included in **Table 1**. Only two of the manuscripts were clinical trials (9,21), whereas the others represented case reports, case series, and review articles. In all, 6 of the 17 articles received summary scores in the lowest tertile, indicating low methodological quality, whereas the other 11 articles were scored in the middle tertile. As none of the identified articles received summary scores in the top tertile, none were judged to be of high methodological quality.

Colonic hydrotherapy and enema therapy for general health promotion and well-being

Colonic hydrotherapy implies the instillation of potentially large volumes of water (alone or with other substances), which are not retained and are almost immediately evacuated in the lateral recumbent position. Enema therapy consists of typically smaller volumes of fluid that are instilled into the colonic lumen, retained for a pre-specified period of time, and then evacuated in the sitting position. We were unable to

Table 1. Qualitative assessment of selected studies

Reference	Total possible score	Points awarded	Summary score
Richards <i>et al.</i> (2)	21	5	0.24
Kelvinson (3)	21	2	0.09
Shevchuk (7)	13	2	0.15
Horne (8)	19	3	0.16
Sha <i>et al.</i> (9)	43	12	0.28
Sisco <i>et al.</i> (10)	13	2	0.15
lstre <i>et al.</i> (11)	21	10	0.48
Norlela <i>et al.</i> (12)	21	10	0.48
Topcu (13)	21	10	0.48
Taffinder <i>et al.</i> (14)	21	10	0.48
Handley <i>et al.</i> (15)	21	8	0.38
Eisele and Reay (16)	21	8	0.38
Margolin and Green (17)	21	10	0.48
Lee <i>et al.</i> (18)	21	10	0.48
Choi <i>et al.</i> (19)	21	8	0.38
Sashiyama <i>et al.</i> (20)	21	10	0.48
Sloots and Felt-Bersma (21)	43	21	0.49

Total possible score=(eligible quality criteria \times 2)+design score; summary score=total possible score/points awarded.

identify any published articles describing the effects of colonic hydrotherapy or enema therapy on the promotion of general health or well-being in humans. We were also unable to identify any published reports of the effects of orally administered colonic cleansing therapies for the same outcome. We did identify one study evaluating the effects of colonic cleansing on colonic transit time in patients with chronic constipation (21). No publications that evaluated the effects of colonic cleansing for any of the conditions previously cited such as hypertension, asthma, irritable bowel syndrome, ulcerative colitis, arthritis, alcoholism, or sinus congestion were identified.

One clinical trial did evaluate the addition of colonic hydrotherapy to accepted medical therapy for the treatment of heroin addiction (9). The investigators randomized 75 heroin addicts into two groups: one group was treated with combined dihydroetorphine and methadone therapy, whereas the other group received dihydroetorphine and methadone, as well as colon dialysis (hydrotherapy) with Chinese herbal medicine on days 3–8 of treatment. According to the authors, patients who received hydrotherapy had faster resolution of opiate withdrawal symptoms and achieved a higher rate of abstinence than did the group that did not undergo hydrotherapy. The methodology of this study is unclear as only the abstract is published in English, and the authors base their conclusions regarding the benefit of hydrotherapy on the rate of cutaneous pigmentation changes, a questionable end point for the stated objectives of

Adverse effects

this trial.

Most of the articles that satisfied the selection criteria were devoted to adverse effects of colonic cleansing. Among these was a case report of a 42-year-old Chinese woman who presented with a transient confusion and memory loss due to acute water intoxication-mediated hyponatremia complicating colonic irrigation (enemas) used to "promote health" (12). There have been reports of deaths associated with electrolyte imbalances due to coffee enemas (16), and there are multiple reports of coffee enema-associated septicemia and colitis (17–20).

The risk of rectal perforation from colonic irrigation and enema therapy was documented in several reports (13,15). One of these reports consisted of three cases of perforation of the rectum from colonic irrigation administered by alternative medicine practitioners in Australia (13). Each patient in this case series had undergone colonic irrigation to "cleanse" or "clear out stale feces." None of the patients had primary colonic or rectal pathology. None of the three patients were warned about the complication of perforation. Importantly, one patient initially denied the use of colonic irrigation, even with direct inquiry, presumably because of embarrassment. Another report involved a perforation suffered after a man administered a retrograde enema with a garden hose directly attached to the water source (15). The patient who suffered a perforation with the garden hose-administered enema suffered from chronic constipation symptoms, although the methods used also raise questions regarding the psychological status of that individual. All of these cases of perforation required surgical intervention.

In one of the most striking examples of the risks of colonic hydrotherapy, at least 36 cases of amebiasis occurred in individuals who had undergone colonic-irrigation therapy at a chiropractic clinic in Western Colorado from June 1978 through December 1980 (11). In all, 10 of these patients required colectomy and 6 died. Among the 176 individuals who had been to the clinic in the last 4 months of 1980, 80 received colonic irrigation therapy and 96 received other forms of treatment. Overall, 21% of the colonic-irrigation group experienced bloody diarrhea compared with 1% of the non-irrigation group (P<0.05). In all, 37% of the patients who underwent colonic irrigation who submitted specimens had evidence of amebic infection demonstrated by stool examination or serum titer, compared with 2.4% in the non-irrigation group (P < 0.05). Individuals who were given colonic irrigation immediately after a person with bloody diarrhea had received the same therapy were at the highest risk for the development of amebiasis. Tests of the colonic irrigation machine after routine cleaning showed heavy contamination with fecal coliform bacteria.

DISCUSSION

This systematic review was carried out in an effort to scientifically evaluate the therapeutic value and possible risks associated with as the use of colonic cleansing to promote general health and a therapy for specific conditions. The most striking observation from this analysis is the lack of published, methodologically rigorous trials of these therapies. Although multiple review articles (3,7–8) allude to the potential benefits of colonic cleansing in very general terms, these claims are not substantiated by a review of the mainstream or complementary and alternative medicine literature. We identified more reports addressing the possible risks and adverse outcomes associated with colonic cleansing than those that described measurable health benefits.

The most obvious potential role of colon cleansing in the realm of gastrointestinal medicine is for patients with constipation symptoms, and it is not uncommon for patients undergoing colonoscopy to remark about an improved sense of well-being that they attribute to cathartic preparation. In patients with chronic constipation, cathartic therapy with large volumes of an osmotic laxative has been shown to decrease colonic transit time in women with chronic constipation (21). Some investigators have also found that chronic constipation may be associated with changes in fecal flora, intestinal permeability, and even in the systemic immune response (22). These investigators have shown that successful laxation may normalize some of these observed alterations, suggesting that these changes are actually secondary to constipation. However, the patients in this study were treated with bisacodyl rather than with colonic hydrotherapy or colon cleansing preparations per se; therefore, it is impossible to conclude whether these therapies would have the same physiological effect as the stimulant laxative or even whether the measured effects achieved with bisacodyl confer any long-term benefit to the subjects.

The rationale for colonic cleansing therapy as an adjunct to general health was originally based on the concept of "autointoxication." This concept holds that putrefaction of a person's stool causes disease, and reports of this theory can be found in records from healers in ancient Egypt (23). They believed that a putrefactive principle associated with feces was absorbed into the general circulation, in which it acted to produce fever and pus. This description represents the earliest forerunner of the present notion of endotoxin and its effect. The early Greeks extended the concept of putrefaction to involve not only the residues of food, but also those of bile, phlegm, and blood, incorporating it into their humoral theory of disease (23). During the nineteenth century, early biochemical and bacteriological studies lent credence to the idea that degradation of protein in the colon by anaerobic bacteria generated toxic amines (24). The leading proponents of autointoxication hypothesized that intestinal toxins shortened lifespan (25). However,

it was believed that the toxic process could be reversed by the consumption of lactic acid-producing bacteria, which would change the colonic micro-flora and prevent proteolysis (26). In the late nineteenth and early twentieth centuries, prominent medical professionals such as Sir William Arbuthnot Lane and Dr James Kellogg advocated the use of surgery and detoxification therapy by colonic cleansing to promote health and well-being, respectively (26,27). In the early 1900s, several investigators reported the results of trials, which were generally believed to disprove intestinal autointoxication theories that had been invoked to explain a multiplicity of symptoms and diseases (28,29). Around this time, the American Medical Association embarked on an active campaign condemning the practice of colonic cleansing and detoxification and by 1920–1930s these practices fell into disrepute (30).

Despite the lack of evidence of any health benefit caused by colonic cleansing, these practices seem to be once again reemerging in public consciousness. It is unclear what is fueling this renewed interest, but the results obtained by Taffinder et al. (14) when they administered a questionnaire in an attempt to assess patients' experience with colonic irrigation sheds some light on this question. After analyzing the responses collected from the 242 subjects who returned their questionnaires, the authors concluded that people who undertook colonic cleansing were often unhappy with orthodox medicine and seemed satisfied enough with the experience of colonic hydrotherapy to undergo regular treatments. No serious side effects were reported by any of the respondents. The authors also postulated that economic factors could be a driving force for the promotion of colon cleaning therapy, as the monies earned were not inconsiderable.

An examination of the advertisements of companies promoting colonic cleansing therapies (typically oral products) gives some insight into the possible exploitation of concerns of the general public as well as the general lack of understanding regarding the function of the gastrointestinal tract. These promotions most often are in the form of television infomercials, radio spots, and print advertisements. Television advertisements are particularly evocative, using visuals of toxic-appearing waste water being discharged from large drainage pipes into streams or pictures of very large stool "casts" purportedly evacuated in response to the cleansing action of the product being advertised. Claims regarding "feeling lighter" and having "radiant hair and skin" developing as a result of being freed from the "impacted old fecal matter from within your colon" play directly to the emotions of lay people who may be unaware that such claims are without scientific merit and have not been evaluated by the Food and Drug Administration (31).

Some of the herbs used in these products are depicted in **Table 2** along with their purported mechanism of action (8). Artichoke leaf, which is termed "bitter," is purported to promote bile flow and aid in liver detoxification. Burdock root traditionally has been used to "improve" liver and digestive function. Cascara sagrada bark has the properties of a stimulant laxative. Cat's claw (uña de gato) inner bark reduces intes-

Table 2. Common oral cleansing preparation ingredients and their proposed mechanisms of action

Ingredient	Mechanism of action				
Artichoke leaf	Promotes bile flow and aids liver detoxification				
Burdock root	Improves liver and digestive function				
Cascara sagrada bark	Stimulant laxative				
Cat's claw (uña de gato)	Reduces intestinal inflammation and gut permeability				
Chamomile flowers	Stimulates digestive function and reduce intestinal inflammation				
Dandelion root	Mild diuretic and hepatic herb				
Gentian	Promotes digestive secretion				
Ginger	Stimulates digestion and blood flow to abdominal organs				
Licorice	Anti-inflammatory action and has a soothing effect on mucous membranes				
Milk thistle	Aids in liver detoxification, protects lover tissues from toxins, and promotes bile flow				
Turmeric	Anti-inflammatory and antioxidant effect: aids both liver and digestive function				
Yellow dock	Purifies the blood and improves liver function; has a mild laxative effect and reduces intestinal inflammation				

tinal inflammation and gut permeability. Chamomile flowers are touted to "stimulate digestive function and reduce intestinal inflammation." Dandelion root has the properties of a mild diuretic. Gentian is a bitter herb that is used to promote digestive secretions. Ginger stimulates digestion and blood flow to abdominal organs. Licorice has an anti-inflammatory action and a soothing effect on mucus membranes. Milk-Thistle aids in liver detoxification, protects liver tissue from toxins, and promotes bile flow. Turmeric is believed to have an anti-inflammatory and antioxidant effect and to facilitate both liver and digestive "function." Finally, Yellow Dock, which has been used to "purify" the blood and improve liver function, is believed to have a mild laxative effect and to reduce intestinal inflammation. This list serves to emphasize the myriad of possible ingredients that could be included in a colonic cleansing preparation. These products and their effects are very difficult to evaluate or regulate in a scientific manner.

Coffee enemas are another possible variant on the theme of colonic hydrotherapy. Some practitioners have used these enemas as part of an unorthodox anticancer diet, which can be administered on a 4-h basis "to help relieve pain, nausea, and other symptoms accompanying detoxification." Its proponents claim that caffeine absorbed in the colon leads to vasodilation in the liver, which in turn enhances the process of toxin elimination (32). The efficacy of coffee enemas is based on six different claims: the claim that anaerobic energy production by fermentative metabolism causes cancer; that vital organs, poisoned by toxic substances in processed foods, are detoxified when bile flow is stimulated; that coffee enemas stimulate bile formation; that kahweol and cafestol, compounds present in the coffee solutions used for enemas, act as detoxicants; that various enzymes help to restore normal function to poison-damaged organs; and finally, that essential organs in the body, when detoxified, can kill cancer cells by an allergic inflammatory reaction. Unfortunately for the proponents of these theories, the overwhelming weight of scientific evidence substantiates the concept that damage to DNA, disruption of gene regulation, and alterations in oncogenes are the genesis of rapidly cancerous cells. These facts make the rationales offered for coffee enemas unacceptable (33).

CONCLUSIONS

One of the limitations of our analysis is that complications and adverse outcomes gain attention in the medical community and may represent a bias for publication. This may be especially true for approaches such as colonic cleansing and hydrotherapy that fall outside the mainstream medical approach to health and disease. This possible bias could have influenced the results of our literature search, resulting in a predominance of publications reporting the adverse effects of these therapies. This does not, however, negate the fact that there are no high-quality clinical trials published in the medical literature supporting the use of regular or periodic colonic cleansing or purges to promote general health.

Colonic cleansing as an adjunct to general health has been around for centuries and will likely continue to be used by uninformed and suggestible individuals, often in response to commercial inducements involving questionable claims of health benefit. Our review of the current mainstream and complementary and alternative medicine literature failed to identify any methodologically rigorous studies to support the use of colonic cleansing administered per os or per rectum for general health promotion or well-being. To date, there have not been any convincing clinical trials or even case series to substantiate any claims of persistent general health benefits from routine or periodic cleansing of the colon. There are, however, numerous reports of serious adverse reactions to colonic cleansing therapy, primarily related to complications caused by colonic hydrotherapy. Orally administered cleansers are not regulated by the Food and Drug Administration and may contain ingredients with which many practitioners are unfamiliar. These issues should give one pause regarding the efficacy and safety of colonic cleansing and should be communicated to patients who inquire about the health effects of such therapies. Theories such as autointoxication, espoused by many advocates of these forms of therapy, have been convincingly discounted. Better education of the lay population regarding the physiology and functions

CONFLICT OF INTEREST

Guarantors of the article: Ruben D. Acosta, MD and Brooks D. Cash, MD, FACP, FACG, AGAF.

Specific author contributions: Drafts of the analysis were distributed to and approved by various members of the Public Relations Committee of the American College of Gastroenterology before submission. Brooks D. Cash conceived the concept of this review and both authors were actively involved in the literature search, selection of articles, scoring of articles, and writing and editing of this paper. **Financial support:** None.

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