

COLONIC IRRIGATIONS: A REVIEW OF THE HISTORICAL CONTROVERSY AND THE POTENTIAL FOR ADVERSE EFFECTS

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Abstract

Colonic irrigations enjoy widespread popularity in the alternative medicine community, while being viewed with considerable skepticism by the conventional medical community. While proponents make claims of substantial health benefits, skeptics cite the lack of evidence for health benefits, and emphasize the potential for adverse effects. Yet historically, there are clinical reports of effectiveness, and virtually no research refuting these reports. Instead there was a campaign against exaggerated claims by non-medical practitioners that resulted in a movement away from this form of therapy without any scientific study of efficacy. Given the current popularity of colonic irrigations, it is important that such research be performed, but it is first necessary that a quantitative estimate of the potential for adverse effects be made for the purposes of informed consent. Although there is little specific literature on colonic irrigations, a review of the literature on related procedures such as enemas and sigmoidoscopies suggests that the risk of serious adverse effects is very low when the irrigations are performed by trained personnel using appropriate equipment.

Introduction

Colonic irrigations enjoy widespread popularity in the alternative medicine community, while being viewed with considerable skepticism by the conventional medical community. The medical objections include a belief that scientific research has proven that colonics are not effective therapy, and that they pose a high risk of serious adverse effects (e.g., infection, perforation of the wall of the colon) (Ernst, 1997). Furthermore there is a concern that those administering colonics are primarily unlicensed, non-medical practitioners who make exaggerated claims of health benefits, "quacks" (Barrett, 2004; Jarvis, 2004). Our interest arose from the need for information on the safety and efficacy of colonics for informed consent for clinicians and researchers. We found that there is very little information on either the safety or efficacy of colonic irrigations, and that modern sources have not addressed the historical debate among medical professionals.

The goal of this paper is to provide a balanced perspective for clinicians and researchers through a review of the historical information on the safety and efficacy of colonic irrigations, and bring in relevant information on adverse effects from related procedures (e.g., enemas and sigmoidoscopies). Although there have been many books promoting colonic irrigations and making claims of efficacy for a wide variety of conditions (e.g., Tyrrell, 1913; Jensen, 19xx), this paper will look primarily at the peer-reviewed literature, rather than attempting to evaluate those claims.

This paper will use the terms "colonic irrigation," "colonic," and "colon hydrotherapy" interchangeably. The term "colonic irrigation" has never referred to a single procedure, but there are some common elements. Colonics are distinguished from enemas in that (1) they are not self-administered, but instead are administered by a person with some professional training, and (2) they are administered using some type of device to control the water flow. Their purpose is to infuse the entire colon with water, in contrast to the more limited infusion of water in an enema. In its modern form, the forty-five minute procedure involves a gentle infusion of warm, filtered water into the rectum. The water circulates throughout the colon, removing its contents, while the client lies on a table. Water temperature and pressure are closely monitored and regulated during a series of fills and releases to aid in the peristaltic action of the colon. As the method involves an enclosed system, the waste materials are removed without the unpleasant odors or discomfort usually associated with enemas.

The modern medical attitude toward colonic irrigations suffers from a lack of information about the historical debate on their safety and efficacy. The history that has been presented by some modern authors (e.g., Ernst, 1997; Whorton, 2000) does not address the debate among physicians regarding the value of colonics, instead focusing on the campaign against the practitioners with exaggerated claims, called "quacks" by their opponents. Ernst states that in the early 1900s, "rigorous scientific investigation into the theory of autointoxication was initiated for the first time. The hypothesis was soon found to be wrong." A search of the literature, however, reveals little evidence of scientific investigation. In parallel with the crusade against quackery, there was a reasoned debate among physicians, conducted in JAMA and other medical journals, on the therapeutic value of colonics. That debate was not resolved by scientific research on colonics, but rather from a combination of hostility toward colonics by the opponents of quackery that made it difficult for research to be done, and the shift in medical practice from physical therapies to drug therapies. Here we look at the literature from the 1920s and 30s that shows a serious debate on the value of colonics, beginning with a historical overview.

Historical Background

The rationale for colonic irrigation was originally based on the concept of "autointoxication." Autointoxication is an ancient theory based on the belief that toxins originating in the intestine can enter the circulation and poison the body. The idea probably originated in Egypt or Greece. Until the early 20th century, autointoxication was widely accepted, and various therapies were commonly used for a variety of systemic disorders. The modern colonic machine was developed about one hundred years ago as a gentler alternative to the more extreme treatments of surgery and purgatives.

Whorton (2000) provides a detailed history of the concepts of constipation, inner hygiene and colon cleansing. He describes in eloquent detail the rationale behind regarding the colon as a "toxic sewer" responsible for disease in the 1800s. In the late 1800s, "Thanks to the germ theory, constipation was transformed into an even greater menace: autointoxication" (Whorton, 2000, p. 22). Whorton explains the concept of autointoxication: "The term was generally understood to denote intoxication of the body by absorption of poisonous compounds from the large intestine" (p. 22). "Autointoxication made a great deal of sense. Poisoning from the bowel had always had a powerful intuitive appeal, and now this age-old suspicion appeared to have the blessing of modern bacteriological science" (p. 24). The autointoxication concept enjoyed a golden age from 1900 into the 1930s.

Colonic irrigations as a treatment for autointoxication became popular in the late 1800s and early 1900s. An early English version was known as the "Harrogate System of Intestinal Lavage," and in the years around 1905 15,000 patients annually were receiving irrigations at the Harrogate spa (Whorton, 2000). According to Whorton, colonic irrigations were popular among physicians and frequently prescribed. This was quite reasonable. Enemas and colonics were seen as substitutes for laxative pills and their dangers. Kelvinson (1995) cites a variety of respected physicians of the time who advocated colonic irrigations, noting that even the Royal Society of Medicine in 1913 cited the colon as a major factor in health. But by 1918, "autointoxication was already falling out of professional favor, and drug therapy entering an era of revolutionary expansion that would relegate spa therapy and like traditional methods to quaint obsolescence in most physicians' minds" (Whorton, 2000, p. 123).

Nevertheless, colonic irrigation remained popular as a therapy. "Irrigationists flocked to the field from all corners; from the conscientious MD who still believed in autointoxication but wished to purify the bowel without harsh drugs, to the amoral quack who saw a bull market and grabbed it by the horns, an irrigationist of some stripe was never far from hand during the 1920s and '30s" (Whorton, 2000, p. 136).

Whorton (2000) says, "By the 1930s, most physicians no longer believed in autointoxication, and doubted that real gastrointestinal problems would benefit from lavage, either. The majority

demonstrated a 'prevalent tendency to ridicule' that frustrated irrigation's proponents....Snide dismissals of that sort - and they were common - betray an emotional overlay on the objective medical evaluation of lavage. Even the most sober and fair minded physicians found it difficult to be dispassionate about colonic irrigation and evaluate it purely on its merits, because of their anger at the rampant exploitation of public gullibility by bowel purity hucksters" (p. 138).

The political reaction against lay practitioners is most clearly seen in the position of Arthur Cramp, in what was originally called the "Propaganda Department" of the American Medical Association (Ernst, 1997). The book, *Nostrums and Quackery*, that he edited for the AMA Press (Cramp, 1911, 1921), particularly takes issue with Charles Tyrrell's "J.B.L. Cascade," a home enema device that consisted of a water-filled cushion with a nozzle. The criticism comes in a chapter on "Mechanical Fakes." The issue is not that the device does not clean the colon, but that Tyrrell makes excessive claims in his advertising, such as "there is only one disease," and "there is only one cause for disease and that is autointoxication" (Cramp, 1911, p. 312, italics in original). Cramp says, "It is unnecessary to tell physicians that the claims made by Tyrrell for his 'J.B.L. Cascade' are as silly as they are false. It is equally unnecessary to tell them that indiscriminate use of rectal enemas is not only harmful but may be dangerous" (Cramp, 1911, p. 314). A later edition of the book says that for enemas, "The common fountain syringe is both safer and more efficient" (Cramp, 1921, p. 705). The primary criticism, again, is the excessive advertising, "Tyrrell urges the public to take rectal enemas both in sickness and in health - in other words, as a routine part of one's living. This advice is mischievous to the point of viciousness. The 'enema habit' is just as harmful as the 'cathartic habit'" (p. 705). Wharton's (2000) book also documents many letters sent by Cramp criticizing colonic irrigations in general and the J.B.L. Cascade in particular.

Wharton's book may be somewhat biased in favor of the official position of the American Medical Association; he acknowledges that a major source of research material was the collection in the AMA's "Historical Health Fraud and Alternative Medicine Collection" in Chicago. A reading of *JAMA* and other journals of the time offers a somewhat different picture. Despite the concern with "quackery" and the extravagant claims of lay practitioners, conventional MDs continued to debate the usefulness of colonics well into the 1930s.

For example, despite the anti-colonic stance of Cramp and his committee, the editor of *JAMA* (1927) was willing to provide specific advice to a medical doctor with a question on whether claims for a specific colon tube used in high colonic irrigations were extravagant. The response gave a favorable description of the tube and how it can be passed into the colon. Again, there seem to be two separate communities, the anti-quackery advocates, and the doctors seriously interested in the therapeutic possibilities of colonic irrigations.

There seem to have been several trends that combined to marginalize colonic irrigation. The first was a change in philosophy in the medical profession, toward relying more on drug therapy and less on various types of physical therapies. The second was a political reaction against lay practitioners, "quacks," distinguished by their excessive claims and aggressive marketing practices (in contrast to the orthodox medical shunning of advertising). The third was a lack of scientific evidence for the efficacy of colonics.

Experimental Research Related to Colonic Irrigations

Notably absent, both from Whorton's (2000) historical account, and reviews like that of Ernst (1997) are references to objective research (controlled or otherwise) on either the safety or efficacy of colonic irrigations. Ernst cites Donaldson (1922) as refuting the autointoxication hypothesis, yet Donaldson's study involved enemas, not colonic irrigations, had only five subjects, and ruled out autointoxication only by inference. In fact, Donaldson demonstrated a strong positive subjective effect from relief of constipation, for which he could only speculate on the mechanism. We have been unable to find any other examples of experimental investigation of colonic irrigations. All the evidence

presented on both sides of the question comes from clinical experience and opinion, not "rigorous scientific investigation."

Donaldson's results are actually supportive of the clinical value of enemas. Donaldson, skeptical of the autointoxication hypothesis, performed an experimental study in which five subjects voluntarily made themselves constipated for four days. He then observed (and in some cases measured) the symptoms of "autointoxication" that appeared. These included coated tongue, markedly foul breath, canker sores, impaired appetite, mental sluggishness, depression, restlessness, irritability, unrefreshing sleep, and headache. He measured reaction time of the nervous system, basal metabolism, blood sugar, and rate of muscle fatigue - all showed impairment. The subjects then took cleansing enemas (in this study not full colonic irrigations). In all cases the sense of oppression and marked mental depression was gone immediately, and mental alertness and feelings of physical fitness increased. Post-enema tests of reaction time, muscle fatigue and blood sugar were all back to their baseline levels. Donaldson concluded that the rapid relief was in far too short a time to be due to toxins as causative agents, and concluded that the result had to be due to relief of mechanical pressure (distention and irritation of the lower bowel by fecal masses). In this conclusion he was following Alvarez (1919), who had found that mechanically plugging the rectum resulted in the same sorts of toxic symptoms. Donaldson replicated the Alvarez finding by packing and unpacking the rectums of four further subjects, with the same results as the constipation experiment. Donaldson, convinced of the mechanical explanation for the symptoms, supports relief of constipation by occasional enemas, but argues against autointoxication as an explanation.

In another experiment, Donaldson (1922) explored the effect of rectal plugging on blood pressure in a dog, and observed a rise in blood pressure from 122 to 138 mm Hg in four minutes. A variety of other dog experiments demonstrated that there can be toxic substances in the bowel, but that these are unlikely to be a significant factor in typical constipation. On the other hand, he does admit that in some cases, especially persistent diarrhea, autointoxication is likely to be responsible. He also acknowledges, "It is pretty generally agreed that stasis in the small bowel probably does give rise to toxemia" (p. 885).

Alvarez (1919), writing in JAMA, discusses the lack of evidence for the theory of intestinal toxemia, challenging the relevance of the existing literature, saying, "Although there are many clinical facts which strongly suggest that poisons are absorbed from the digestive tract during constipation, we have as yet little actual proof for this assumption" (p. 10). Alvarez makes a case for the "toxic" symptoms being produced by nervous system reflexes. He speaks of "how profoundly sensory inputs from our digestive tracts can influence our emotions, our mental processes and our vasomotor balance" (p. 11).

"Particularly in sensitive people the brain is profoundly influenced by afferent impulses coming from a distended, overactive or wrongly acting bowel. The effects follow so closely on the appearance and disappearance of the stimulus that we cannot drag in a cumbersome and roundabout chemical mechanism to explain them; they must be produced directly through the nervous system" (Alvarez, 1919, p. 11). Alvarez's therapeutic recommendation is for enemas to relieve the pressure, in contrast to purgatives or surgery. Although Alvarez is highly critical of the autointoxication hypothesis, his article could be seen as supporting the concept of colonic irrigation (or at least enemas) for symptomatic relief.

It is not surprising that there are reflexes from the colon that affect the entire nervous system, given the importance of the "abdominal brain" or enteric nervous system (McMillin et al., 1999). It is estimated that 80% of vagal fibers are visceral afferents (Davenport, 1978). There is also a vast overlap of neuropeptide activity in the gut and the brain (Pert et al., 1985). As early as 1907, Robinson documented the vast and complex nervous system of the abdominal viscera. The enteric nervous system has become an active area in physiological research with over 600 articles on Medline since 1985. Modern medicine recognizes abdominal nervous system involvement in several neurological disorders, including migraine, epilepsy, and autism (McMillin et al., 1999).

What is especially interesting here is the broad variety of symptoms that can be caused by

constipation, and relieved by an enema. The reflex mechanisms for these phenomena would make a very interesting study in themselves. If relief in this experimental situation can be obtained by a simple enema, might a higher colonic irrigation provide more extensive stimulation to the same reflexes to provide longer lasting relief for more chronic symptoms? And could the chronic symptoms be due to, not toxins, but reflexes from other dysfunctional aspects of the colon that can be treated with irrigations?

In later article, Alvarez and Freedlander (1924) addressed the question of the transit time of feces through the colon in an experiment involving ingestion of glass beads. They were surprised to find that transit time was quite variable, with the colon often retaining some food residues from the entire preceding week. They were concerned that this result might be seen as supportive of a mechanism for autointoxication. However, they found no correlation of transit time with health status. Their conclusion was that wide variations are perfectly compatible with good health. It is interesting from a methodological perspective, however, that while they describe their method and results on transit time in detail, they provide no information on how they measured health status.

Another issue regarding intestinal toxemia was addressed by Dragstedt et al. (1922), from the Mayo clinic. They accepted that intestinal toxemia could cause disorders, but questioned whether administration of antiseptics was a useful treatment. Working with dogs, by surgically closing isolated segments of bowel, they were able to produce the symptoms of toxemia, and showed that the symptoms disappear when the closed segment is removed. However, they found that the direct application of antiseptic solutions to the segments of the colon did not effect sterilization or inhibit the production of intestinal poisons.

Regardless of the correctness of the autointoxication hypothesis, early experiments like those of Alvarez, Donaldson, and Dragstedt demonstrate the widespread systemic effects of relatively minor manipulations of the colon. It is interesting, then, that both proponents and opponents of colonics have paid no attention to this finding, providing little new information beyond that from the 1920s.

Clinical Experience with Colonic Irrigations

A variety of books from the 1920s and 1930s by the proponents of colonic irrigations attest to their clinical value (e.g., Russell, 1932; Tyrrell, 1913; Stemmerman, 1928; Wiltsie, 1938). At the same time, the American Medical Association was zealously attacking "quackery," with colonic irrigations as a particular target (e.g., Cramp, 1912). But in the absence of peer review, there is no way to evaluate the claims that are made on either side of the debate. Instead we will focus on the articles in the refereed journals of the time, especially JAMA. Our goal is not to demonstrate the efficacy of colonics, because standards were very different in those days, but to show that there was a reasoned debate by professionals occurring at the same time as the campaign against quackery.

Satterlee and Eldridge (1917), writing in JAMA, discussed the symptomatology of the nervous system in chronic intestinal toxemia. Far from considering autointoxication an outdated hypothesis, they note the "newly found and rapidly developing relationship between mental and nervous conditions and disturbances of the intestinal tract" (p. 1414). "It is a significant fact that in practically all of the cases considered in this article the nervous manifestations have either cleared up or have been markedly improved by treatment directed toward intestinal toxemia" (p. 1414). These nervous manifestations included mental sluggishness, memory problems, phobias, depression and hallucinations as well as others. They describe a variety of treatments, some far more severe than colonic irrigations (e.g., surgery to remove parts of the colon). It is easy to see why, given the apparent relief from symptoms, the far less invasive colonic irrigations were preferred by many physicians (e.g., Kellogg). In a discussion section following the paper. Dr. Nathan Rosewater notes that "In cases of headache due to mechanical causes, particularly from constipation, the relief is almost immediate after taking a cathartic or enema, showing that there was a mechanical cause, not toxemia. If it were toxic it would take twenty-four hours or more before we could remove enough of the toxic matter absorbed from the bowels into the circulating fluid; so that there is a large class of cases of this purely mechanical

type" (p. 1418). This agrees with the conclusion of Alvarez (1919) and Donaldson (1922) cited previously.

Further evidence that colonic irrigations were not universally condemned in the 1920s and 1930s is provided by an article by Bastedo (1928) in the *New England Journal of Medicine*. Bastedo was opposed to the "commercialized irrigation specialists, who are unduly numerous but do a thriving business" (p. 736). But Bastedo emphasizes that "The insertion of liquids into the rectum has been an approved therapeutic procedure since ancient times" (p. 865), distinguishes irrigations of the entire colon from simple enemas, and gives detailed recommendations for their administration. It should be noted that he does not advocate antiseptics in the water, since "experiments have shown that the strongest antiseptics permissible in the bowel do not kill the bacteria and are prone to be injurious to the host" (p. 865), though he does not specifically cite Dragstedt et al. (1922), the most likely source of this information. He recommends plain water, rather than saline or soda. He sees colonics as "of definite value in mucous colitis" and other conditions, but does not discuss systemic conditions such as arthritis. He also recommends against repetitive colonics because they will irritate the bowel.

Bastedo (1932) writing in *JAMA*, offered a balanced discussion of the therapeutic application and dangers of colonic irrigations: "When one sees the dirty gray, brown or blackish sheets, strings and rolled up wormlike masses of tough mucus with a rotten or dead-fish odor that are obtained by colon irrigations, one does not wonder that these patients feel ill and that they obtain relief and show improvement as the result of the irrigation" (p. 736). This is a case where autotoxicity is a more reasonable hypothesis than in Alvarez's 4-day induced constipation study. And it shows that it is not just the non-medical proponents that have observed these extreme cases.

Bastedo (1932) notes the positive effect of the colonic on the blood supply and tone of the colon. He warns of specific dangers, all resulting from high insertion of a stiff tube; these include perforation, injury to a polypus, tearing of a rectal valve, and abrasion of the wall. In contrast, Bastedo sees none of these dangers in colonics employing a tube inserted not more than six inches, by a trained professional. Bastedo says, "I trust that my warnings against its improper administration, its dangers and abuse will not discourage physicians in the proper utilization of this valuable therapeutic measure" (1932, p. 736).

Soper (1932) responds to Bastedo's *JAMA* article with a well-reasoned Letter-to-the-Editor in *JAMA*, aimed at physicians who might consider using colonics, which is skeptical of their value, without ranting about quackery. Soper cites some literature as well as his own clinical experience. His primary concern is with the administration of repetitive colonics; in his experience, these result in irritation of the colon and produce symptoms like excess mucus that colonics are supposedly cleaning. He summarizes the literature on colonic function, making the point that the natural function of the colon is to dehydrate feces, and that this needs no help from repeated colonics. The only disorder that he addresses explicitly is mucous colitis (today's irritable bowel syndrome), making the point that colon spasms are related to a multiplicity of factors, and that irrigations (as well as purgatives and enemas) cause further irritation and more tendency to spasm. He does not address any of the other claims for the value of colonics, e.g., as therapy for autointoxication, or to tone the muscle of the colon.

Arthritis is a disorder where there seemed to be some clinical evidence of efficacy of colonics. Pemberton's (1935) book advocates their use. Pemberton (1920), writing a lengthy article in *JAMA*, discusses the nature of arthritis and rheumatoid conditions. Pemberton (1920, 1935) was a proponent of the hypothesis that arthritis was due to a focal infection, a commonly held viewpoint at the time. He notes early in the article, "It is true that among the ancients of Greece and Rome the benefits to be obtained from hydrotherapy were already appreciated, and it is alleged that the important influence of focal infection was known to some of the fathers of medicine" (p. 1759). For Pemberton, the appropriate treatment was removal of the cause, some focus of infection (including the colon). He concludes, "External measures, such as hydrotherapy, have undoubtedly real value but have fallen in some disrepute because of their frequent failure and because of the injurious consequences from them when pushed in the effort to obtain results. Used cautiously, however, hydrotherapy, massage and various medicinal agents, when administered in conjunction with a cautiously reduced diet, may carry benefit far beyond the point that would otherwise have been reached" (p. 1765).

Snyder and Fineman (1927) give several case reports suggestive of efficacy in cases of arthritis. Snyder and Fineman's perspective is that in a subset of cases of arthritis, the lack of response to conventional treatment may be due to toxin absorption from the gastrointestinal track. Snyder and Fineman cite several clinicians in addition to Pemberton who have this perspective (Persson, 1923; Smith, 1922; Carter 1923; Forbes 1924). Thus as late as 1927, the autointoxication hypothesis has not gone away. Snyder and Fineman clearly state that the colon is not the etiologic factor in all cases of arthritis, but that, based on clinical experience, "when indicated the elimination of colonic stasis has been of definite value in the management of the disease" (p. 28). Another clinical observation is that cathartics have no positive effect on arthritis, and usually result in adverse effects. Similarly, home administered enemas produced inferior results to professionally administered colonics. Snyder and Fineman also give a call for research: "The ascertainment, however, of the exact value of each factor in this system of irrigations is a difficult matter and will require prolonged study with carefully checked controls in a large series of cases" (p. 31). This is a strong contrast to those physicians who simply dismiss colonics as "quackery."

Arthritis is no longer thought to be an infectious disease, and it is likely that the use of colonics for arthritis therapy became unpopular in the absence of this rationale. However, there is extensive modern literature linking arthritis to digestive system disorders, particularly inflammatory disorders (Palm et al., 2001; Lindsley and Schaller, 1974; Holden et al., 2003; Rees et al., 2004). The modern explanation involves immune system dysfunction, rather than autointoxication. Bowel dysfunction is also found in fibromyalgia syndrome, which has much in common with the "toxic" manifestations treated by colonics in the 1920s and 1930s (Barton et al., 1999; Triadafilopoulos et al., 1991; Veale et al., 1991). Alba et al. (2001) even discuss several cases of arthritis as a rare manifestation of acute sigmoid diverticulitis. They found that the arthritis promptly improved after surgical resection of the sigmoid colon. This harkens back to the days of the late 1800s when colon surgery was the therapy of choice for such problems. Could colonic irrigation provide a less invasive treatment?

Colonic irrigation was also sometimes recommended for mental illness. Whorton (2000), with a very skeptical tone, notes the psychotherapeutic effect of simply being treated by an elaborate colonic machine. But he also cites the report of Marshall (1936) in *Medical Record* regarding the efficacy of colonic irrigations on mental illness. "Psychoses were favorably affected as well, at least according to a Massachusetts physician who administered 'upwards of fifteen thousand colon irrigations' to mental patients during the early 1930s, for the 'sedation' they accomplished. Typical was the manic-depressive woman who received 835 irrigation treatments between 1930 and 1935; by the end of the regimen, 'her manic episodes are less violent, she is tidier in her habits and more moderate in her language' (P. 136). While this sounds like an example of an excessive use of colonics, there may have been some valid clinical observations, considering the effects on the nervous system reported by Alvarez, Donaldson, and others.

Colonic irrigations were also a significant component of the cleansing regimen at the Still-Hildreth osteopathic sanatorium for mental illness. "Hydrotherapy is another valuable aid for which we are equipped. Baths and hot packs are used to quiet the nerves, to induce sleep, and especially to stimulate elimination through the kidneys and skin...Many patients have a history of long continued constipation with evidence of resulting autointoxication...some assistance is necessary. For it our main reliance is colonic irrigation, by which the colon is thoroughly cleansed by large quantities of normal salt solution...The value of this is obvious" (Hildreth, 1929, p. 519).

The Friedenwald and Morrison Review

The article by Friedenwald and Morrison (1935) is especially detailed, and at a relatively late date, 1935, assesses colonic irrigations very positively. These doctors (from the Gastro-Enterological Clinic of the Department of Medicine at the University of Maryland) begin with a historical perspective, noting that only recently (1932) the approval of the Council on Physical Therapy of the American Medical Association was sought for a large number of new colonic irrigation devices. Friedenwald and Morrison identify a number of situations in which colonic irrigations appear to have some efficacy, including "cleansing the colon mucous membrane of abnormal mucus, infection, debris and foreign

bodies" (p. 1615). They also note the value of colonics in cases of atony of the colon, using temperature to stimulate or relax the bowel musculature. They say, "There has always been, there will, in all probability continue to be considerable discussion pro and con concerning the use of colonic irrigation in the treatment of so-called 'intestinal toxemia' associated with constipation. There are arguments perhaps equally good in favor or and against the measure" (p. 1615). They point out that the subjective symptoms of intoxication seem to disappear as a result of colonic irrigation. However, they also note that, "It is interesting that the symptoms of what has been termed 'auto-intoxication' can be produced by merely distending the rectum with some foreign body" (p. 1616) (the result of Alvarez and Donaldson). They also point out quite reasonably that, "The whole problem becomes less controversial when the physician considers each case individually instead of subjecting all to the same routine therapeutic procedure without a complete objective examination" (p. 1616). This statement effectively rejects the "quack" cure-all approach, while encouraging the use of colonics as a medical procedure.

Friedenwald and Morrison go on to review in detail the clinical observations of various physicians on the appropriate indications for colonics, noting a considerable diversity of opinions. They say, "To omit or even condemn the use of colonic irrigations in their entirety as a therapeutic procedure is unwarranted...Perhaps the employment of this measure without proper supervision and study is its greatest single objection" (p. 1618).

In contrast to the autointoxication hypothesis often cited by the skeptics as the only (and erroneous) justification for colonics, an alternative is the concept that colonics are helpful in restoring muscle tone to the colon. W. Kerr Russell, for example, is quoted by Friedenwald and Morrison as writing, "This intensive stimulation reeducates the bowel, increases the blood supply and improves the tone of the muscles" (p. 1617). Friedenwald and Morrison partially agree, saying, "It seems that within limits colonic calisthenics, using the method of irrigation, may have a tonic effect in certain instances, more often temporary, however, than lasting, depending largely on the associated treatment. In some cases the tonic effect of the irrigation may be all-important and actually curative; this, too, would depend to a great extent upon the type of previous treatment, the patient and the associated therapy" (p. 1618).

Friedenwald and Morrison conclude by saying, "It is our opinion that if colonic irrigations are correctly used in selected cases they fulfill an important therapeutic need" (p. 1628). They call attention to the possible dangers of mechanical trauma and perforation. They advise the use of simple apparatus, only plain water, salt solution and bicarbonate of soda as irrigating solutions, and the desirability of medical supervision.

The Krusen Review

In 1936 JAMA published a review of colonic irrigations authorized by the Council on Physical Therapy, authored by Frank Hammond Krusen, Professor of Physical Medicine at the Mayo Clinic. Although generally skeptical, Krusen gives a balanced review of the pros and cons of colonics. He acknowledges that "One can hardly fail to be impressed with the violently opposing views expressed in most of the literature on this subject. One writer, for instance, tells of 'phenomenal success in the treatment of many diseases due to consistent and thorough colonic treatments,' whereas another bitterly and somewhat facetiously decries the existence of too many 'colon filling stations.'.... One finds that among physicians of unimpeachable medical integrity there are widely divergent views concerning the value of colonic irrigations" (p. 118).

On the "pro" side he cites physicians treating a variety of conditions. For example, he points out that "Pemberton, in a careful evaluation of the pros and cons of colonic irrigation in the treatment of arthritis, while graphically outlining the shortcomings, makes clear that he uses colonic irrigation in conjunction with colonic massage in some of his cases of arthritis" (p. 119). He also cites Stroud (1932) who advocates colonics in the treatment of cardiovascular disease, and Weisenberg and Alpers (1932) who note that "High colonic irrigations are of value in some cases of so-called toxic

myelitis" (p. 119). Krusen comments that the same effect "can probably be achieved by means of the simple enema, proper medication, or modification of diet," but he does not deny the value of the concept of bowel cleansing in these examples. Krusen also cites Morgan and Hite (1932), who see value in colon cleansing, but notes the need for recognition that such a treatment can be harmful if carried beyond limits called for by the specific ailment. Like many physicians, Morgan and Hite are concerned about administration of colonics by "the unskilled both in and outside the profession."

Krusen discusses opposing viewpoints on ulcerative colitis, comparing Lockhart-Mummery (1934), who advocates use of colonics and gives specific recommendations, to Bergen (1934) who finds that colonic irrigations are "rarely indicated."

He also discusses viewpoints on the technique of colonic irrigation, contrasting the "high colonic" where a 52-inch tube is passed through the colon directly into the cecum, and the type more common today, where a tube not more than 4 to 6 inches long is used. He agrees with Bastedo that the short-tube colonic irrigation is far safer. Regarding colonic machines, Krusen is skeptical of the value of elaborate colonic machines, preferring a simple system with a glass jar and tubes. Although Krusen himself found that the machine he purchased for his own hospital was of little use, he concedes, "In all fairness, it must be admitted that some of the manufacturers of these devices are sincere in their misguided belief that their machines will prove a great boon to mankind. It must also be stated that a great many hospitals have equipped themselves with some such elaborate device" (p. 120).

On the con side, Krusen has two main points. The first is that colonics can have adverse effects, such as cramps, irritation, and perforation of the wall of the colon. It is interesting, though, that his source for these adverse effects is Bastedo, who is a proponent of the careful use of colonic irrigations. His second main point is that, in his own experience, colonic irrigations have little use in the hospital setting; his preference is for simple enemas to relieve constipation when necessary.

Krusen also makes the point that, "One must also consider that in conjunction with the lavage there are possibly other factors present (such as pressure, temperature, motion and osmosis) which may act to influence normal and disturbed physiological processes in the gastro-intestinal tract" (p. 121). That is, in considering the mechanism by which colonics produce therapeutic (or adverse) effects, the autointoxication hypothesis is not the only one that needs to be addressed.

In his 1941 book, *Physical Medicine*, Krusen continues with his doubts about the value of colonic irrigations in most situations, but gives details on the appropriate technique to be used, based on Bastedo and Pemberton.

As late as 1939, there were proponents of colonics among other respected physicians. W. F. Dutton was Medical Director for the hospital at the Graduate School of Medicine at the University of Pennsylvania. In the preface to his book on headaches (Dutton, 1939) he speaks positively of the AMA's campaign against quackery, and says that, "The lay press, unscrupulous manufacturers and radio advertising of nostrums and cure-alls to the public present a serious problem" (p. iii). He says that his book, aimed at physicians, is "a summary of the available literature, with authoritative references," and that "dogmatic statements on controversial subjects have been avoided purposely" (p. v). However, he also notes the importance of "autointoxication products absorbed from the gastrointestinal tract" in the etiology of some headaches (p. xvi). He includes a section on "enemata" for headache therapy, illustrating techniques for enemas. He also talks about more extensive irrigation of the colon, and says regarding colonic irrigations, "The procedure has become one of the most valuable therapeutic measures we possess" (p. 97; italics in the original). Dutton's book is an example of how a physician, writing for other physicians, could be supportive of the value of colonic irrigations, while acknowledging the problem of quackery.

Thus, in the late 1930s, there was a reasoned debate on colonic irrigations, documented in *JAMA*, despite the crusaders against "quackery." The themes in these *JAMA* articles up through the 1930s are clear: the problem is not that there is anything intrinsically wrong with colonic irrigations. Rather,

(1) there are clinical observations from a variety of physicians and studies such as that of Donaldson supporting the efficacy of colonics for some conditions, (2) the autointoxication hypothesis is not supported for most apparent "toxicity," although there is evidence for nervous system reflexes, and (3) while administration under a physician's supervision is a reasonable therapeutic procedure, the inflated claims and sometimes extreme procedures employed by non-medical practitioners are not advised.

As Whorton (2000) has noted, the zealous critics of quackery tend to offer ridicule in place of specific citations of research demonstrating the inefficacy of colonics. A prime example is the letter to the editor of JAMA from Smithies (1926), labeled "Colon Filling Stations," in which he primarily makes fun of the "colon therapists," and states, "This 'new' colon therapy rests on no basis of fact, is employed by none of the country's leading gastro-enterologists, and is permitted in no institution of recognized standing" (p. 691). Contrast this with the reasoned discussions by such authors as Krusen, Friedenwald and Morrison, Pemberton, and Bastedo. It is important to note that none of these authors is advocating colonic irrigations as the cure for all diseases, nor for their administration by personnel who are not professionally trained, but they all see a value in the procedure and support their arguments with clinical observations. It is this perspective that appears to have been squeezed out by the crusaders against quackery.

Modern Viewpoints on Colonic Irrigations

Up through the 1930s, the question of the proper use of colonic irrigations was at least debated with the help of some experimental data and clinical observations. Modern medical education, on the other hand, is characterized by a simple lack of information on colonic irrigations. An example in JAMA of an attack on colonic irrigations without references or supporting documentation is the response to a letter to the editor by Merar (1961), in which he states, "The much vaunted colonic irrigations used chiefly by cultists and pseudohealth clinics are of no benefit and may be harmful or even dangerous. Their use was, and no doubt still is, based on the theory of auto-intoxication and absorption of poisons through the bowel wall; this is pure nonsense in the light of scientific investigations" (p. 642).

Franklin (1981) in a Questions and Answers column in JAMA, responded to a question about the efficacy and safety of colonics with two answers. For efficacy, he looked at three major gastroenterology texts (from 1976 to 1978) which revealed no mention of colonic irrigations as a therapeutic technique (i.e., no mention either for or against their use), and concluded that there is no rationale for their use. For safety he referred to a single report on the adverse effects of repeated (every two hours) coffee enemas (Eisele & Reay, 1980); however, the concerns regarding fluid and electrolyte problems from such extreme measures have little relevance to colonics as normally administered (see section of this paper on adverse effects).

Jensen (1995) in a recent review of the medical treatment of constipation discusses enemas in detail and mentions colonic irrigations. He lists a variety of substances that have been including coffee enemas for alternative cancer treatment. He also notes a variety of adverse effects from soap and coffee enemas (not specifically colonic irrigations) and mentions the single outbreak of amebiasis spread by contaminated colonic equipment (Istre et al., 1982). He states, "Little scientific evidence has been reported concerning the effectiveness of any of these alternative treatment regimens with respect to constipation. Perhaps their widespread use has precluded further objective evaluation" (p. 149). Our perspective is that their widespread use should call for further objective evaluation, rather than simple dismissal.

As already discussed, Ernst (1997) strongly advises against colonic irrigations (again citing only the Istre et al., 1982 paper as a specific example of an adverse effect), yet he offers little evidence of either scientific research refuting their effectiveness, or a quantitative assessment of relevant adverse effects.

Current Status of Autointoxication

As Ernst (1997) has discussed, the primary justification for colonic irrigation (dating back into the 19th century) is usually that toxic wastes build up in the colon, that toxins leak into the general circulation, and that these toxins are responsible for a variety of symptoms. This autointoxication hypothesis was quite controversial; much of the controversy centered around extreme claims that autointoxication was responsible for all disease (Cramp, 1921). Ernst claims that autointoxication has been refuted, yet there is significant modern literature that suggests that a modified version of autointoxication is quite reasonable in some cases.

The modern perspective focuses on dysfunction of the immune system caused by toxins leaking from the gut, as well as bacterial translocation from the gut to the systemic circulation caused by a breakdown of the intestinal wall. This breakdown can be caused by a variety of types of injury to the body at locations far from the gut. Swank and Dietch (1996) state, "It is clear that increased gut permeability and bacterial translocation play a role in multiple organ failure (MOF). Failure of the gut barrier remains central to the hypothesis that toxins escaping from the gut lumen contribute to activation of the host's immune inflammatory defense mechanisms, subsequently leading to the autointoxication and tissue destruction seen in the septic response characteristic of MOF."

Similarly Person and Bernhard (1986) in an article entitled, "Autointoxication revisited," invoke an immune system mechanism, stating, "The pustular dermatitis associated with small bowel bypass surgery and the cutaneous manifestations of inflammatory bowel disease are well known and generally assumed to be due to the absorption of microbial antigens from the bowel. Monomeric serum IgA is assumed to originate in the gastrointestinal tract, and circulating IgA immune complexes, as seen in dermatitis herpetiformis, should make us suspicious of a gastrointestinal tract source."

Kelvinson (1995) reviewed several physiological factors that suggest the importance of the colon in disease processes. These include evidence of absorption of toxins and macromolecules, and heightened immune system reactions, due to injured intestinal mucosa.

Numerous drugs can be absorbed from the colon, to varying degrees (Muranishi, 1984; Riley et al., 1992; Kimura et al., 1994). Rectal suppositories are a popular way of rapidly delivering medicine to the circulation without passing through the rest of the digestive tract (van Hoogdaem et al., 1991). The rate and extent of rectal drug absorption vary depending on the type of drug and the formulation, and on the presence or absence of absorption-promoting agents. The suppository route has been found particularly effective for such drugs as sumatriptan for migraine, where the effects are comparable to oral doses, and provide relief within two hours (Bertin et al., 1999). Various toxic substances can also be absorbed from the colon (e.g., sodium phosphate, Martin et al., 1987; iodine, Kurt et al., 1996; aspirin, Watson & Tagupa, 1994; cyanide, Ortega & Creek, 1978). Given that these substances can be easily absorbed, it seems reasonable that bacterial toxins might be absorbed as well.

It is important to distinguish between (1) the common observation that a constellation of symptoms (fatigue, headache, joint pain, etc.) were correlated with constipation, and could be relieved by enemas or colonic irrigations, (2) autointoxication, a mechanism suggested for these systemic effects originating in the colon, but expressing throughout the body, and (3) the recognition that there are problems directly related to the colon (such as ulcerative colitis) that might or might not benefit from colonic irrigations. These three are not necessarily related. That is, there may indeed be system-wide effects originating in the colon, but autointoxication may not be the correct explanation for the observations. Autointoxication (including immune system responses) may be a factor in some cases, but not as the "cause for all disease." It is also possible that direct treatment of the colon for serious colon problems like ulcerative colitis is not a useful therapy (and possibly harmful), but that colonic irrigations are effective for these other, system-wide problems.

Adverse Effects

The potential for adverse effects from colonic irrigations must be addressed, both for informed consent in research, and for the purpose of assessing risk for therapeutic applications. There is a need to determine to what degree the common medical criticism of colonic irrigations, that there are serious adverse effects (e.g. Ernst, 1997), is valid. For informed consent it is important to have a quantitative estimate of the potential for adverse effects. However, reports of adverse effects from colonic irrigations of the type we are discussing (performed on individuals without serious bowel disease, by trained colon hydrotherapists, using disposable nozzles) appear to be very rare, despite the widespread popularity of colonics as an alternative health modality. We have found only two reports on Medline. One is the oft-cited case of amebiasis from improperly sterilized equipment at a chiropractic clinic in Colorado (Istre et al., 1982). The other is a case of rectal perforation in Singapore (Tan & Cheung, 1999). Looking beyond the Medline literature, there is a case of rectal perforation currently in litigation in Texas, and the Texas Attorney General's website claims that one death and four serious injuries involving patients with perforated colons occurred in 2003 following the treatments, with no supporting documentation (Texas Attorney General, 2003). However, there has been no systematic collection of data published on colonic irrigations.

Since there is no specific data on colonic irrigations, the closest comparisons would be enemas and sigmoidoscopies, so it is also worth a look at the adverse effects of these procedures to determine if they are relevant to colonic irrigations. Enemas typically only stimulate the first part of the colon, the sigmoid colon, and are not intended to cleanse the entire colon as is a colonic irrigation. However, the term enema is a broad one, and such procedures as a barium enema can introduce material throughout the colon. Often an enema is given before a more invasive procedure such as a sigmoidoscopy or a colonoscopy, in which a tube is introduced into the colon. In a sigmoidoscopy, the tube (with a fiber optic camera) goes only as far as the sigmoid colon; however, this may be up to 25 inches. In a colonoscopy, the tube may go as far as the cecum. Both may include biopsies or removal of polyps. In contrast, the tube for a colonic irrigation is inserted approximately 3 inches into the colon, and no procedure such as biopsy is performed. For these reasons, any estimate of adverse effects based on sigmoidoscopies would likely show a substantially greater risk than is actually found with colonic irrigations.

The adverse effects from enemas and sigmoidoscopies can be classified into four types. The first type is perforation of the wall of the colon. The second type is a reaction to something in the enema, ranging from an allergic reaction to the nozzle tip, to substances such as coffee or soap. The third type is primarily a pediatric problem - an electrolyte imbalance resulting from an enema in a small child - but has also been seen in geriatric patients. The fourth type is infection from contaminated equipment (e.g., Istre et al., 1982).

Risk of Perforation

Perforation of the wall of the colon is often seen as the most serious adverse effect of any procedure that introduces something into the colon. Perforation can be mechanical, such as when the tip that injects the water or the tip of the endoscope causes damage, or it can be from overpressure causing failure of a weak spot in the colon wall. The risk of perforation is related to the invasiveness of the procedure, the health status of the patient, and the competence of the person administering the procedure. Enemas, for example, are the least invasive procedure, but are also often self-administered. Colonoscopies are the most invasive procedure and have the highest rate of adverse effects, since they involve deep penetration into the colon. Sigmoidoscopy, with insertion only into the first part of the colon, is substantially less invasive. Both procedures are performed by professionals, with FDA-approved equipment. As noted previously, both are substantially more invasive than the 3 inch nozzle insertion of the colonic irrigation.

Colon Perforation from Cleansing Enemas

Cleansing enemas are the closest comparison to colonic irrigations, but differ in the amount of fluid administered and the high frequency of self-administration. No systematic data have been collected on the incidence of perforation compared to the total number of enemas given. Only case reports exist. Nevertheless, there are far more reports of injuries from enemas than from colonic irrigations. In the following discussion, it is important to bear in mind that these case reports of adverse effects represent a tiny fraction of the enemas given.

Paran et al. (1999) review all the cases of colon perforation from cleansing enemas over a three-year period in their surgical unit. These consisted of 13 elderly patients, with a mean age of 64.3, suffering from chronic constipation. Ten had perforations from enemas administered by nursing home staff; three had administered the enemas themselves at home. The authors note that, "Perforation of the rectum and sigmoid colon caused by cleansing enemas, used by chronically constipated patients, has not been previously described." This suggests that perforation is a rare occurrence, but the authors note that the true incidence of enema-induced perforations is unknown.

Gayer et al. (2002) report on 14 cases of perforations of the rectosigmoid colon induced by cleansing enemas. It is important to note that the average age of the patients was 80 years, since perforations appear to be far more likely in the elderly.

The remaining reports address rare single cases. Larson (1966) reports a case of a 72-year-old man whose rectum was perforated by an enema given by a hospital orderly. He also cites the three other cases of injury caused by disposable enemas that he was able to find in the literature (Blatt, 1960; Scott, 1960; Turell, 1960). Larson notes that, "A two-inch enema tip is sufficiently long for satisfactory administration of an enema and provides a degree of safety" (p. 448), and that a tip constructed of softer material than the common semi-rigid plastic would be safer.

Wolfe and Silver (1966) discuss a case of rectal perforation with profuse bleeding following an enema given in a hospital. They note that that, "The vast majority of enemas produce their desired effect without any accompanying complications" (p. 715). However, they cite additional cases reported by Large and Mukheiber (1965), Wechisser and Putnam (1962), Klein and Scarborough (1963), Roland and Rogers (1959), and Szunyorgh (1958).

Classen et al. (1975) cite several cases of iatrogenic perforation of the rectum during cleansing enemas. They note that, "The vast majority of the rectal injuries and perforations resulting from enema tubes occur in the anterior rectal wall. This can be readily understood when one realizes that these injuries almost always occur with the patient in a sitting position" (p. 1425). Another position, therefore, may be less risky.

Hool et al. (1980) note that only a few cases of enema-nozzle injuries to the rectum are reported in the literature, but that they are aware of more that go unreported. They present two cases, both from enemas given in hospitals. They conclude that, "This injury, with its very serious consequences, should be entirely preventable if rigid, hard enema nozzles are avoided. More attention should be given to the design of disposable enema nozzles. Some disposable enema nozzles which are widely used are long, and not sufficiently soft and flexible" (p. 381). The example in their picture appears to be about 4 inches long.

Bell (1990) reports a case of colonic perforation with a phosphate enema administered at a hospital, and again recommends that enema nozzles be short and pliable. He also makes the point that the toxicity of the phosphate solution passing into the peritoneal cavity made the problem more serious

Perforation may also occur from extreme self-administered enemas using non-standard means. For example, Topcu (2003) reports a case where a chronically constipated man administered a rectal enema using a garden hose directly connected to the water until he felt a sudden sharp abdominal pain resulting from a perforation.

In none of these reports is there any estimate of the percentage of perforations compared to the total number of cleansing enemas. This may be impossible to obtain, given that enemas are often self-administered at home. However, perforations would seem to be very rare, given that enema kits are obtainable over-the-counter, and that hundreds of thousands are probably given every year. Presumably based on the rarity of injuries, enema kits are classified by the FDA as Class I devices, and do not require a prescription or any specific training for administration. It is difficult to see why the FDA would classify colonic irrigation devices as Class III devices when used for routine colon cleansing, and as "significant risk devices" when used in research studies (FDA Warning Letter, 2003), since there is no evidence that the risks are greater than with enemas, and probably less, given that colonics are usually administered by people with some professional training. However, it is also important to note that several authors point out that perforations can occur with enemas even when administered by trained professionals, and that these professionals need to be made aware of the potential for injury even from this "benign" procedure (e.g., Classen et al., 1975; Paran et al., 1999).

Colon Perforation from Sigmoidoscopy and other Medical Procedures

Better quantitative data is available on medical procedures such as sigmoidoscopies, colonoscopies, and barium enemas, but it is much less relevant to colonic irrigations, since barium enemas involve the introduction of a potentially toxic substance and sigmoidoscopies and colonoscopies are substantially more invasive.

The two most extensive studies related to colonoscopy and sigmoidoscopy are those of Gatto et al. (2003) and Anderson et al. (2000). Gatto et al. (2003) determined perforation rates from colonoscopy and sigmoidoscopy in a large cohort of people aged 65 and older in the Medicare program. The incidence of perforation from colonoscopy was 0.196% in 39,286 procedures, and from sigmoidoscopy 0.088% in 35,298 procedures. The risk of perforation increased with age and with the presence of two or more comorbidities, particularly with diverticulosis and abdominal pain. The authors point out that their findings may not be directly generalizable to people younger than 65 years.

Anderson et al. (2000) report a substantially lower rate of perforation in a study of patients at the Mayo Clinic (mean age 72 years, age range 48 - 87 years). There were 20 (0.19%) perforations and two (0.019%) deaths in 10,486 colonoscopies, and two perforations with no deaths in 49,501 sigmoidoscopies (0.004%). Of particular importance, electrocautery injury was responsible for 36% of the perforations; this is a surgical procedure irrelevant to colonic irrigations. The authors note, "The most important safety factor is most likely the sensory feedback from the patient to the endoscopist, which is retained in the alert patient [during sigmoidoscopy] and blunted by intravenous sedation [during colonoscopy]." They also note that not all of the perforations were necessarily caused by the procedures, because, "spontaneous perforations associated with inflammatory bowel disease or diverticular disease were not at all rare."

Korman et al. (2003) report the incidence of perforations of the colon occurring within a network of endoscopic ambulatory surgery centers. A total of 116,000 colonoscopies were performed within one network of 45 endoscopic ambulatory surgery centers in the United States during 1999. There were 37 (0.03%) perforations; 27 in women and 10 in men. Median patient age was 75 years (range 39-87 years); 18 patients (49%) had diverticular disease and 20 (54%) had a history of pelvic or colonic surgery. They conclude that reported perforations for procedures performed in endoscopic ambulatory surgery centers occurred most frequently during diagnostic colonoscopy in older women with a history of surgery or diverticular disease.

Fry et al. (1989) found perforations in 5 of 2200 (0.2%) barium enemas - most patients had active ulcerative colitis or rectal lesions. Blakeborough et al. (1997) report on a survey of all consultant radiologists in the United Kingdom over a 3 year period. The 756 respondents performed a total of 738,216 examinations. There were 30 reported cases of bowel perforation (0.004%).

In a review by Nelson, Abcarian, and Prasad (1982), "In eight years at Cook County Hospital, 42,000 barium enemas, 16,325 proctosigmoidoscopies, and 1207 colonoscopies were performed. All endoscopic procedures were done by the house staff. There were three perforations due to proctosigmoidoscopy (0.02%), with one death; three perforations due to colonoscopy, with no deaths; and seven perforations due to barium enema [0.017%], with no survivors. The adjuvant effect of barium sulfate is proposed as the most likely cause for this excessively high mortality in barium-enema perforation."

An important issue relevant to the risk from colonic irrigations is the occurrence of spontaneous perforation of the colon in the absence of an irrigation. Spontaneous perforation can occur from various colonic diseases, e.g., a ruptured stercoral ulceration (Chen and Shen, 2000). Johnson and Baker (1990) report colonic perforation following mild trauma (being hit in the abdomen during a basketball game) in a patient with Crohn's disease. Ledley et al. (1988) report perforation of the sigmoid colon from endometriosis. Avinoah et al. (1987) note that even "severe untreated chronic constipation may, on rare occasions, cause free perforation of the sigmoid colon." There are also rare cases of spontaneous perforation of the colon from Ehlers-Danlos syndrome (a hereditary connective tissue disorder) (e.g., Sykes, 1984; Kinnane et al., 1995; Fuchs and Fishman, 2004), and of perforation resulting from enemas in patients with this condition (e.g., Sentongo et al., 1998).

It is also important to note that colonic perforation can occur in rare cases from events not involving insertion of anything into the rectum. Farbin et al. (1996) discuss a case of perforation of the sigmoid colon by hydrostatic pressure resulting from sitting on a public water fountain. Li and Ender (2002) discuss cases of colon perforation resulting from the swallowing of a toothpick.

Thus a rare perforation of the colon in association with a colonic irrigation may have other causes than the colonic irrigation itself, particularly when there is already colon disease.

To summarize, the most important risk factors for perforation relevant to colonic irrigations are advanced age and diseases of the colon such as diverticulitis and inflammatory bowel disease. The greatest risk (for those over 65 with bowel disease) would be about 1 in 10,000 (based on the perforation rate for sigmoidoscopy), with the risk for younger people without bowel disease much lower. Given the much smaller insertion distance into the colon, the perforation risk for colonic irrigations should be substantially less than for sigmoidoscopy, and probably similar to that for enemas. Several authors have pointed out that, although such perforations are very rare, it is important for professionals to be aware of their possibility, how to minimize the potential for perforation, and what to do if one occurs.

Risk of Other Adverse Effects

Warnings against colonic irrigations often take the form of cautions about the adverse effects of substances administered during enemas. This is not relevant to colonics using only filtered tap water, which is a common application, but is important if any substances are to be added to the water. There are no reports of adverse effects from tap water colonic irrigations in adults, although there is a concern based on the possibility of depletion of electrolytes.

Again, enemas are the closest comparison available to colonic irrigations. Schmelzer et al. (2000) have published a small (25 subject) study on colonic cleansing, fluid absorption, and discomfort following tap water and soapsuds enemas. Their perspective is that enema administration is a basic nursing skill, and that (as we agree for colonic irrigations), nurses need information about possible solutions, their effectiveness, and possible side effects. Schmelzer et al. point out that both tapwater and soapsuds enemas have been given routinely for over 100 years, but that little is known about their effectiveness, the precise indications for their use, or their side effects.

As Schmelzer et al. describe it, the ideal enema would effectively cleanse the colon with minimal side effects, essentially the same as the goal of the colonic irrigation. Enemas, like colonics, cleanse

the colon by stimulating propulsion and secretion. The relevant factors include enema volume, the presence of chemical irritants, and the osmolality or tonicity of the solution. The instillation of a large fluid volume into the colon stimulates propulsion; this is especially relevant to colonic irrigations which typically use pure tap water with a larger fluid volume than enemas. Chemical irritants stimulate both propulsion and secretion to rapidly empty the colon; using a hypertonic solution to draw fluid from the body into the colon through osmosis, and directly irritating the mucosa are the principles of the popular Fleets sodium phosphate enema. Soapsuds enemas use the principles of high volume and chemical irritation.

Schmelzer et al. (2000) found that soapsuds enemas produced significantly greater output than tap water and were equally well tolerated. Most subjects who received tap water enemas retained more fluid than was eliminated. Based on these findings, they advised that nurses should use caution when giving repeated enemas to patients sensitive to large fluid loads. This is relevant to the question of the fluid load resulting from a colonic irrigation, in which a larger volume of water is used than in the typical enema.

Cohan et al. (1992) also compared tapwater to phosphate enemas in a study with 66 patients. They found that there was a significant increase in the serum phosphorus in the phosphate enema group. However, absolute serum phosphorus values remained within the normal range in all but one patient, and the changes in other electrolytes, minerals, and venous pH were insignificant.

Aware of the occasional adverse effects of tapwater enemas from electrolyte imbalance, particularly in children, Collins and Mittman (19xx) have performed the only study that has specifically looked at the effect on serum electrolytes of colonic irrigations as they are given in naturopathic clinics. Seventeen healthy volunteers free of cardiovascular disease, kidney disease, and hypertension, as well as bowel disease, were given before/after measurements of serum electrolytes (sodium chloride, calcium, potassium and phosphorus) with a tapwater colonic irrigation. Although there were small changes in some electrolyte levels, the subjects experienced none of the symptoms of water intoxication. The authors also note that their experience at the Portland Naturopathic Clinic has been that even in debilitated and chronically constipated patients, serious reactions to colonic hydrotherapy have not occurred. They conclude: "The data presented here may help support the safety of hypotonic solutions employed in colonic irrigation in normal patients with no known risk factors for acute water intoxication, such as neurogenic constipation, heart failure, renal failure and recent fluid electrolyte depletion or dilution."

Phosphate enemas are far more likely than tapwater colonics to cause adverse effects. They are a common form of self-administered preparation prior to flexible sigmoidoscopy screening (Atkin et al., 2000), are also frequently administered in hospitals and nursing homes, and are considered effective and acceptable. But phosphate enemas can occasionally cause serious problems in the elderly, especially those with renal failure (e.g., Korzets et al., 19992; Knobel and Petchenko, 1996). Groskopf et al. (1991) have reviewed the adverse effects of phosphate enemas and concluded that Fleets enemas carry a potential risk for acutely ill elderly patients. There is also a case reported of a pregnant woman who caused serious bone growth problems for the fetus by self administering multiple hypertonic phosphate enemas during pregnancy.

Adverse effects due to electrolyte imbalance from pediatric enemas have also been the source of numerous case reports in the literature. Ordinary phosphate enemas have caused illness or death (Walton et al., 2000; Ismail et al., 2000; Helikson et al., 1997; Craig et al., 1994; Martin et al., 1987). Harrington and Schuh (1997) acknowledge this problem, and offer specific guidelines for administration of Fleet enemas in a pediatric emergency department. Another problem seen primarily in children, is water intoxication (due to hyponatremia - electrolyte depletion) from tap water enemas (Blanc et al., 1995; Chertow and Brady, 1994).

Adverse reactions (some fatal) to other substances in enemas have been reported for chamomile tea (Jensen-Jarolim, 1998; Thien, 2001), ozone (Eliakim et al., 2001), hydrogen peroxide (Bilotta and Wayne, 1989; Bollen et al., 1998; Meyer et al., 1981), isopropyl alcohol (Barrett et al., 1990; Haviv,

1998), hot water (Schapira et al., 1996; Sternberg et al., 1995), iodine (Kurt et al., 1996), glycerin (Chang et al., 1995), aspirin (Watson and Tagupa, 1994), acetic acid (Kawamata et al., 1994), hydrofluoric acid (Cappell and Simon, 1993), formalin (Munoz-Navas and Garcia-Villareal, 1992), magnesium sulfate (Ashton et al., 1990), soap (Orchard and Lawson, 1986), coffee (Eisele and Reay, 1980), detergent (Kirchner et al., 1977; Kim et al., 1980), laetrile (cyanide) (Ortega and Creek, 1978), food coloring (Trautlein and Mann, 1978), lye (Unger, 1978), tobacco (Bele-Binda, 1975), and milk and molasses (Walker et al., 2003)

Eisele and Reay's (1980) report of deaths from coffee enemas is often cited as an argument against colonic irrigations, but it has little relevance. In one case, the patient received 10 or 12 coffee enemas in a single night, as frequently as three or four an hour. In the other case the patient received coffee enemas four times a day over several weeks. In both cases, both the presence of the coffee and the extreme frequency of the enemas could have been contributing factors, but neither is standard practice for the typical colonic irrigation.

There have also been cases of allergic reactions to the latex or plastic enema tip itself (Lozynsky et al., 1986; Kokoszka and Nelson, 1993; Misselbeck et al., 1994), and to the lubricant jelly (Jones, 1988).

Schmelzer and Wright (1996) note that the enema has evolved through trial and error, not scientific investigation. They examined current nursing practice by asking 24 experienced registered nurses to describe how they give enemas, and if they had seen any complications. They found that the nurses emphasized patient cooperation, preparation, and comfort; had observed few complications, and had difficulty describing quantitative aspects of enemas (e.g., amount of solution given, speed of administration).

Schmelzer and Wright (1993) offer advice for minimizing the risk from enemas, noting that the primary danger comes from a combination of injury by the enema tip, and the toxicity of the phosphate. They note that patients at highest risk are those with hemorrhoids. They suggest precautions including determining if the patient has a history of hemorrhoids or colon disease, and performing a brief fingertip rectal exam to feel for hemorrhoids or other abnormalities and to identify the optimal angle for insertion of the enema tip. They also suggest using tap water or saline solution in preference to phosphate, since they are less likely to cause harm if perforation does occur.

To summarize, for colonic irrigations, the risk to healthy adults of adverse effects from tapwater or saline solutions is probably extremely small. The risk when other substances are introduced into the colon varies substantially based on the nature of the substance. However, it is important not to confuse the basic colonic irrigation with therapeutic procedures such as coffee enemas that may carry greater risks.

Transmission of Pathogens

The potential for transmission of pathogens through enemas and irrigations was described as early as 1929 (Hervey, 1929), and followed by reports by Gilbert (1938), Steinbach et al (1960), and Meyers (1960), all making the point that pathogens ranging from bacteria to protozoa can survive on the parts of enema equipment that are insufficiently sterilized, and be transmitted rectally. Steinbach et al. suggest that the most practical solution is an inexpensive disposable enema reservoir, tube and tip. Ever since the cases of amebiasis from improperly sterilized irrigation equipment reported by Istre et al. (1981), disposable parts have become standard for colonic irrigation equipment. It seems clear that there is no reason to use any other type of equipment.

Conversely, it has been suggested that colonic irrigations might remove beneficial indigenous microflora in the colon, encouraging the growth of pathogens (Sisco et al., 1988), although there is no evidence that this actually occurs. In fact, Bornside and Cohn (1969) found that mechanical cleansing of the bowel (2 Fleet enemas per day for 3 days) and low residue diet without antibiotics

had no quantitative effect on the bacterial flora preceding bowel surgery. Antimicrobial therapy delivered through a colonic irrigation (e.g., with an antiseptic solution) might have a more significant effect. Sisco et al. also point out the possibility that irritation of the bowel by an irrigation might promote translocation of indigenous microflora into the bloodstream, again providing no evidence that this actually occurs. Clearly, research on the effect of colonic irrigations on bowel microflora would be worth pursuing.

Precautions

Generalizing from the data on adverse effects of enemas suggests some contraindications for colonic irrigations. The first is a lower age limit; colonic irrigations should probably not be performed on young children due to the potential for electrolyte depletion. Others, especially the elderly, should be carefully screened for colon-related problems before a colonic irrigation is performed. The list of contraindications should include as a minimum diverticulitis, ulcerative colitis, colon cancer, rectal fissures, and bleeding hemorrhoids. Second, great caution should be exercised when using anything other than tap water as the irrigation solution, and patients should be fully informed of the potential for allergic reactions and other adverse effects from the solutions. Third, as discussed below, frequent colonic irrigations, like frequent enemas, may interfere with normal bowel function.

Barloon and Shumway (1995) discuss medical malpractice cases resulting from adverse events during radiologic colon examinations, including perforation of the colon. Their strategies to prevent medicolegal litigation include performing digital rectal examinations on all patients to detect distal rectal lesions or strictures, recognizing colon perforation, and obtaining immediate surgical consultation if colon perforation occurs.

Saltzstein et al. (1988) note that injuries to the anorectum from enemas can be prevented by pre-enema rectal examination and attention to perianal anatomy and patient complaints of discomfort during the procedure.

Equipment Standards

Another issue is that of appropriate equipment. In the early days of colonic irrigations, a variety of types of equipment was available, some intended for self-administration (e.g., the JBL Cascade, Tyrrell, 1913). Some equipment, no longer in use, involved tubes intended to be inserted all the way to the cecum (e.g., the "high colonic" equipment judged as unsafe by Bastedo, 1932 and Krusen, 1936). Recently, however, standards for colonic equipment have been established, and most equipment in use is registered with the Food and Drug Administration (FDA). This equipment features temperature controlled water mixing and back flow prevention valves, pressure and temperature sensors, and a built-in chemical sanitizing unit and/or water purification unit. The tube is intended for insertion only about 3 inches into the rectum, and the equipment is designed to prevent infection by using disposable single-use parts. However, these devices are approved only as Class II medical devices for bowel cleansing, and technically can only be sold to a physician or on a physician's prescription.

One of the obstacles to research is that, when these devices are used for "colon cleansing routinely for general well being" they are classified as Class III medical devices (FDA, 2004), and it is the FDA's position that they are "significant risk devices" when used in research studies of this application (FDA Warning Letter, 2003). The wording of the FDA classification is rather ambiguous, however. Logically, colon cleansing for general well being that is being done specifically for a research project would not be routine. The frequency of colonic irrigations is certainly an issue requiring study. It would not be surprising if frequent colonics, like frequent enemas, resulted in adverse effects and interference with normal bowel function, but "routine" is not a useful word. As noted earlier in this review, it is also hard to understand why a colonic irrigation performed for general well being would have a greater risk than one performed as preparation for a colonoscopy. Since the risk of adverse effects increases with the age of the patient and the pathology of the colon, one would expect an

occasional cleansing for general well being of an average person to be far less risky than a cleansing for the typical elderly patient with colon disease. It seems more reasonable to classify colonic equipment used for general well being in the same category as cleansing enemas (Class I), since they perform essentially the same purpose. They are likely to be somewhat less risky than enemas since they are administered by trained professionals, not ordinarily self-administered. This raises the issue of professional standards, since it is clearly possible to cause harm by improper administration of colonic irrigations, and there is a risk even with proper administration (as there is with enemas).

Professional Training

The issue of the appropriate training and professional status to administer colonic irrigations is significant. Our assumption in this paper is that the person administering the colonic irrigation has had training at least equivalent to that involved in certification by the International Association for Colon Hydrotherapy (I-ACT). I-ACT standards include 100 hours of training for their basic level of certification (I-ACT, 2004). However, the professional status of colon hydrotherapists varies widely from state to state, and I-ACT is not necessarily recognized as a professional association.

In Florida, the Department of Health issues a Certification in Colonic Irrigation, which is an add-on to Certification in Massage Therapy. For a person currently licensed to practice massage therapy in Florida, the colonic certification requires successful completion of a course of study in Colonics at a Board of Massage Therapy Approved Massage School which is approved to offer colonics, or completion of a Board approved apprenticeship program in the area of colonics; and must pass the Colonics Examination administered by the Department of Health. This training includes completion of a 2-hour course on the prevention of medical errors (Florida Department of Health, 2004).

As another example, in Nebraska, colonic irrigation is included under the definition of the practice of chiropractic, with no additional certification required (Nebraska Health and Human Services System, 2004). In contrast, in the state of Washington, chiropractic explicitly shall not include colonic irrigation (Washington State Legislature, 2004). In some states naturopaths perform colonic irrigations, but naturopaths are only licensed in a few states. In Texas there is an ongoing lawsuit where the attorney general's opinion is that a physician's supervision is necessary (Texas Attorney General, 2004).

Again, professional training is not an issue unique to colonic irrigations, and is probably a more serious problem with enemas. Paran et al. (1999), in their study of colon perforations from cleansing enemas, discuss the importance of information about the possible problem for making a rapid diagnosis. Vague and misleading information from nursing home staff made diagnosis difficult, and the authors specifically note that, "The information given by the nursing homes' personnel who referred the patients may be misleading, especially when future litigation is considered." They recommend that, "Awareness of the possible injury should be stressed to the general population and, especially, to the nursing and medical staff of institutions for the elderly, where chronic constipation in the patients and the use of enemas are common" (p. 1612). They note the relevance of their observations to colonic irrigations used in alternative medicine as well. Schmelzer et al. (2000) note that enema administration is a basic nursing skill, and it seems reasonable that administration of colonic irrigations could also be seen as a nursing skill.

Given these conflicting regulations on training and certification, there is great potential for misunderstanding by practitioners and clients. This also makes research on safety and efficacy more difficult. However, that research must be conducted for there to be reasonable regulations on colonic irrigation.

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