



Probiotics: The Emperor has no Clothes



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Opinion

Patients with a variety of disorders of the gastrointestinal tract seek advice from a variety of physicians and gastroenterologists regarding complementary and alternative medicines to manage their symptoms, including the use of probiotics. Even healthy patients often take probiotics with the belief that these “supplements” promote a healthy state. While most patients begin taking the probiotics based on interactions with the media, print advertising and so called “health” stores, increasingly, physicians are recommending these supplements. While a decade ago, a physician could be ambivalent about their use, numerous studies have been performed that clearly show a lack of evidence of efficacy. Despite the basic science and physiologic possibilities, the clinical data fail to demonstrate that clinicians should be recommending, encouraging or supporting patients taking probiotics [1].

The situation is similar to the little boy who yelled “The emperor has no clothes”. The adults standing at the parade of the emperor all knew there were no clothes on the emperor. The problem was no one wanted to reveal the truth. Once confronted by a child who innocently brought forth the truth, the adults quickly realized the truth, that the emperor had no new clothes, that he was, in fact, “naked as the day he was born.” On a daily basis, I feel like this child with my colleagues as I confront them on the use of probiotics. When confronted, most clinicians quickly admit the foolery and see the charade of probiotics. Many clinicians claim that patients seem to appreciate the “pill”, considering a placebo effect. Routinely claiming these supplements pose no harm, and their experience shows that they work, some physicians choose to join the parade while the emperor wears no clothes. This is a disservice to patients and threatens the honesty, scientific integrity and clinical training of our profession.

At a time when healthcare costs continue to rise, when patients complain about copays, costs of medications and increasing deductibles, why have so many physicians chosen to

assist in the profiteering of probiotic manufacturers and health food stores perpetuating fact-less falsehoods. While data from animal studies have shown that the intestinal microbiota have a direct effect on the host through modulation of gene expression, immunological, physiological, and psychological functions, the translation to clinical use does not exist! Probiotics contain dozens of different species of bacteria in scores of combinations. In addition, even though the labels make the claims of the contents, the products are not well regulated. The FDA requires the caveat emptor label for the consumer: “The Food and Drug Administration has not evaluated this product. This product is not intended to diagnose, prevent, treat or cure any disease.” Despite the label telling the consumer the facts, over \$20 billion is spent annually by patients who are led to believe that these “supplements” improve health.

My interest in probiotics began, as with most of my research, in the field of pancreatitis. Studies had shown that most patients with sepsis in acute pancreatitis and infected necrosis suffered from a translocation of harmful bacteria from the colon into the peritoneum and vascular system. Studies designed to prevent this translocation during an attack of acute pancreatitis, ranging from prophylactic antibiotics to “decontamination of the colon” had poor results [2]. The idea of using probiotics to change the bacterial flora, to alter the harmful E. Coli, Klebsiella and gram positive cocci to a more “friendly environment” led to a well-designed randomized, double blinded trial with probiotics. The result was devastating as the mortality rate of persons in the probiotics arm was shown to be higher than those in the placebo arm [3].

It is understandable that as the recognition of the importance of the intestinal microbiota and their interaction with the host grew, so did the interest in using probiotics to maintain and promote health. However, studies in humans have failed to show a significant benefit. I am fully aware that there are a handful of studies that show some slight benefits of various formulations of

probiotics. The reader aware of these studies may be questioning whether I have read and evaluated these studies. The answer is yes. However, the idea that a single study or two showing some slight benefit with a number needed to treat (NNT) to yield a marginal benefit in 1 in 10 does not justify the use of probiotics.

Clinicians need to be more critical about claims. Access to publishing papers today has expanded to the point that almost anyone can publish a scientific paper with minimal effort. Annually over 12 million scientific papers focused on healthcare are published in medical journals, the majority of the results and claims are false. Clinicians are taught from medical school onward that greater consideration should be given to top tier journals, consensus guidelines and expert reviews [4]. The brutal fact is that when evaluating the studies not funded by the company manufacturing the probiotic, when they are randomized blinded studies, free of the placebo effect and bias, probiotics are no better than placebo.

It must be recognized that little is truly known about probiotics given the heterogenous contents, financial pressure to market and lack of regulation. While few side effects have been reported, the hundreds of studies published were powered for evaluating efficacy but not adverse reactions. As the study on acute pancreatitis shows, severe consequences can result from taking probiotics. Further study may demonstrate more harmful effects from attempting to change the bacterial flora in the absence of evidence of benefit. Worse, in the absence of FDA regulation, the true contents of the probiotics are largely unknown. The patient consumer is trusting the profiting manufacturer, seller and unfortunately, the clinician who has crossed the line of science to “belief”.

Despite the lack of evidence that probiotics are helpful in irritable bowel syndrome, inflammatory bowel disease and other disorders of the GI tract, many physicians and gastroenterologists recommend these supplements. Sadly, some clinicians have begun selling their own brands, even falsely claiming to have done the research in developing the probiotics being sold. Companies are partnering with physicians, putting the doctors name on the bottle, and then assisting in the sale from the

physician to the patients. Physicians are prohibited by law from selling medications as the conflict of interest would encourage physicians to sell more medications, perhaps unnecessarily for financial gain. Yet, the sale of supplements by physicians is not regulated. Telling a patient that they have a disorder in which the patient needs to buy probiotics for \$35 from the physician, especially when there is a lack of evidence of efficacy, is clearly unethical.

There is no doubt that it takes more time to talk to patients about evidence based decisions than simply provide a pill. It is perhaps more difficult to explain to a patient that while you care about their health, probiotics are useless and a waste of money. The patient may hold beliefs about the bacterial flora and probiotics that are as tightly held as religious beliefs. However, once a physician crosses the line of “science” to “belief”, failing to fully inform the patient of the evidence available and the potential risks, the physician does the patient great disservice. Patients eventually may discover the truth, then when discovering the physician’s collaboration with the untruthful potion, the patient may question important truthful interventions which the physician has recommended such as blood pressure control, cholesterol lowering medication, screening colonoscopy and mammography. We must help patients understand evidence based care, explain the science, help them distinguish what care is truly needed and what is untrue. Physicians must assist the people see the truth like the child who helped the crowd to see that the emperor had no clothes.

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