Chelation Therapy: What To Do With Inconvenient Evidence

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What do we do with inconvenient evidence? Imagine studying a seemingly absurd practice that is used to an alarming extent by those who believe in it despite the lack of evidence – and finding that the intervention improves outcomes. And imagine that the people conducting that trial are famous scientists with impeccable credentials who have extensive experience with this type of investigation. Imagine that the practice is so out of the mainstream that the investigators cannot even posit how the treatment could reduce patient risk?

We live in a world of evidence-based medicine, where we are urged to base our medical recommendations and decisions on clinical studies. We base our guidelines on the medical literature and evaluate our practices by how well we adhere to the evidence. But what should we do with inconvenient evidence?

The National Institutes of Health sponsored a $31 million trial of chelation therapy, a therapy that involves the infusion of vitamins and a substance that binds certain minerals, such as calcium. Some practitioners embraced this therapy and have recommended it for patients with heart disease. Although I never learned about it in my training as a cardiologist, it is quite widespread with reportedly more than 100,000 people using it in 2007, an increase of 68% from 2002.

The trial, published in JAMA, compared 839 patients who had a heart attack. They randomized these individuals to chelation with 869 to a placebo infusion. **To the surprise of many (including me), after almost 5 years of follow-up, the chelation group had a lower risk of the combination of death, heart attack, stroke, hospitalization for angina or a procedure to improve blood flow to the heart.** There was an 18% lower risk in the chelation group – and for about every 25 patients treated with chelation, there was one few adverse event. Also, there were **no safety issues**. This trial, like most others, has some limitations – but it is a positive trial.

The authors, who are quite esteemed, seemed surprised. They noted that no one knows how this therapy works. They said that the results were not strong enough to support the routine use of chelation therapy. It is not clear what they mean by routine – they seem unable to make a strong recommendation – as if they have some uncertainty how to act on what they found.

The irony is that if a drug manufacturer had gotten this result, they would have celebrated. We have *billion dollar drugs* like niacin and fenofibrate and ezetimibe that *have less evidence than chelation therapy* has now. **None of those drugs has contemporary outcomes studies showing benefit** – and 2 of them (niacin and fenofibrate) have 2 recent negative trials.

So why are scientists not accepting the verdict of this study? Why the reluctance to incorporate this therapy into our armamentarium?

The answer is more than just a reluctance to accept results that we do not like (though medicine is not beyond that behavior – see the slowness with which medicine adopts new information into practice). I believe that the answer here is that when confronted with a truly surprising result that is hard to explain. In this situation **we need to examine our assumptions – and the consequences of being wrong**. The amount of evidence we require may vary based on the treatment. For example, I am more likely to demand strong evidence for the use of treatments that may cause risks and incur substantial costs – except perhaps in dire circumstances where no alternatives exists and in these cases we need to be able to track the effect after approval and spread so that the interventions can be reassessed over time. And I may want stronger empiric evidence where I have no underlying expectation that a treatment would be beneficial based on previous studies – or the absence of previous studies.

If we have little faith in chelation therapy, then it is hard to turn 180 degrees with a positive result and suddenly completely believe in it and recommend its use. Any trial can give an anomalous result and we need to be careful about jumping to a new position with each new piece of evidence. **However, we cannot on one hand promote evidence-based medicine and on the other hand ignore what we do not like**.

I am glad that we are subjecting popular but out of the mainstream practices to rigorous study. If I endorse that course I cannot ignore the evidence because it goes against what I expected. But I need to interpret the findings through the totality of what is known about it and determine if it is really ready for prime time. In this case, I want to see more studies of this approach to be sure. However, this study has opened my mind to the possibility that there may be something more to this therapy than I originally thought. And given what I thought about it before, I can hardly believe I am writing that.

NOTE: In the months following publication of this endorsement, further statistical analysis of the NIH study results showed that *diabetic* patients enjoyed about *DOUBLE* the benefit of non-diabetics who were treated similarly. I have seen spectacular results in compliant diabetic (and all other) patients during my 32 years of offering chelation therapy.

Incidentally, I disagreed with the protocol used in the study for two key reasons: (1) it failed to use most of the "chemical tricks" that we've used for dozens of years to enhance the effectiveness of the treatments; and (2) it allowed *no* "personalization" of the treatments, adjustments to the program that I make based upon 32 years of expertise and experience – and teaching chelation to physicians around the world.

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