

Virtual Mentor

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Clinical Case

Prescribing placebos

Commentary by Perry G. Fine, MD

Dr. Gibson, a second-year family medicine resident, spends two afternoons a week working in a busy urban clinic. His attending physician, Dr. Marshall, asks him to see a patient named Ms. Wood. “She’s a challenging patient, but not in the medical sense,” she winks at him. “Just try not to spend too much time in there,” she further cautions. “A regular frequent flyer,” says one of the medical assistants handing Dr. Gibson the chart. He glances through the 3-inch thick file quickly as he walks down the hall to the examining room.

Ms. Wood has had a surprising number of medical workups for a person of 39 who is, on the whole, pretty healthy, though overweight. Two weeks before she had undergone a complete cardiac workup, including a stress test. With the exception of a finding of chronic hypertension, all of her extensive diagnostic testing has been normal. Her current medication list includes an antihypertensive and a variety of vitamin supplements. Today she says she is terribly fatigued and has some “pretty bad stomach gas” pain at night. “I just can’t seem to get out of bed these days, Doctor,” she tells him. “You’ve got to give me something to boost my energy!” Dr. Gibson performs a careful physical examination, including a complete abdominal exam, the results of which are unremarkable. He suspects, based on further discussion, that her gas pains are due to gastroesophageal reflux disease (GERD) and tells her that he will prescribe an antireflux medication. He also spends some time explaining measures she can take to minimize her reflux symptoms. “But what about my fatigue?” she complains. “You haven’t given me anything for that and it’s worse than the stomach thing!”

Dr. Gibson sympathetically agrees with her and tells her he needs to step out for a few minutes to discuss the fatigue with her regular physician, Dr. Marshall. He is firmly convinced that Ms. Wood would benefit from a psychiatric evaluation and treatment for anxiety or depression, but he has not seen any mention of either in her chart. Her blood work from two weeks ago rules out thyroid problems and anemia as possible causes for the fatigue.

“I am sure that you must have considered a psychiatric condition at some point?” queries Dr. Gibson. “Of course,” says Dr. Marshall, “but she absolutely refuses to meet with a psychiatrist and she will not take any psychiatric medications for

insurance reasons. She is afraid that she will lose her life insurance if she has a documented history of being treated for depression or anxiety.

“I’ve just been giving her some herbal and vitamin therapy and occasional shots of vitamin B-12, which seem to help her energy levels,” reveals Dr. Marshall, “and I’m encouraging her to exercise, of course. A B-12 shot should do the trick for a few more weeks at least,” he tells Dr. Gibson. “Go ahead and have the nurse draw it up.”

Commentary

The presumption in the case of Ms. Wood is that, because no specific etiology is identified for her complaint of fatigue, her physician decides that a nonspecific treatment (injection of vitamin B-12) is warranted to relieve her symptoms. In and of itself, this is not necessarily “bad medicine,” given adequate assessment and thoughtful balance of benefits versus burdens of both the further evaluation and the treatment chosen. The real fault in this case is the failure of Drs. Gibson and Marshall to engage the patient in an open, honest discussion of risks, benefits and alternatives; in other words, to seek her informed consent. Translated into ethical terms, the patient’s autonomy has not been respected. This may not be of concern to Ms. Wood, but how can her physicians know, if she is not given the opportunity to engage in open, frank discussion? Not only has her regular physician used a subordinate in the commission of this act, a rather minor trespass in itself, but she also failed to model key elements of the patient-physician relationship: mutual trust and shared responsibility for health care decisions [1].

Whether or not vitamin B-12 is beneficial for nonspecific fatigue is debatable, and so it is a questionable example upon which to base a discussion about placebo use in clinical practice. A search of the Cochrane Collaboration Library on the evidence for efficacy of B-12 for this indication is not revealing, but countless anecdotal reports and at least one small crossover placebo-controlled clinical trial suggest some benefit with virtually no harm [2]. Sadly, this level of evidence is not too much different from the level upon which many other routine clinical practices are based. So why didn’t the physician opt for candor and say, “I think your fatigue would be greatly improved by exercise and other healthy lifestyle choices, but I am willing to give you a shot of vitamin B-12 because it has very little risk of causing harm, except for the cost, and maybe it will help you get motivated enough to start the supervised exercise program I am going to prescribe. What are your thoughts about that, Ms. Wood?”

But what if an inactive placebo such as isotonic saline were chosen by the physician instead of the disputable B-12 injection? In that case, the breach in the patient-physician relationship extends beyond insufficient engagement of the patient in the treatment plan and into the more troubling realm of frank deception. Physicians are ethically obligated to promote patients’ welfare by balancing the anticipated benefits of a given intervention against its potential harms. Deception undermines patient trust, erodes the patient-physician relationship and can potentially result in medical harm to the patient [3, 4]. Full disclosure of the (possible) use of an inert substance

that may result in a therapeutic effect (the placebo effect) or an untoward effect (the “nocebo” effect) legitimizes active or inactive placebo controls in clinical research, including “n of 1” clinical trials [5, 6]. This ethical “safe harbor” cannot be invoked when a patient is intentionally misled [7].

Dangers of deception

If patients learn that they have been fooled intentionally by their doctors (for perhaps well-intended but nonetheless spurious reasons), how will they be able to regain confidence in the medical profession? Although difficult to measure, this betrayal may carry more profound and enduring harm, negatively impacting the present and future relationships between the patient and health care professionals, including their willingness to seek help when it is needed. This is a high price to pay to learn how suggestible a patient is or, worse, simply to avoid a difficult conversation with a poorly compliant patient.

In summary, the relief of pain, fatigue and other distressing symptoms is a fundamental duty of medical doctors, and relief is what patients commonly seek from us, whether or not a cure is possible. Recent years have brought vast improvements in our palliative capabilities, especially in treating patients with well-defined etiologies for their signs and symptoms. But we still struggle to help patients with ill-defined medical—much less emotionally based—causes for constitutional symptoms such as fatigue. The use of placebos in clinical practices marginalizes patients with these sorts of complaints. Failure to use effective therapies or, in their absence, the power of the relationship itself in favor of placebos puts the patient at risk and makes the practitioner highly vulnerable, subject to ethical and, perhaps, legal sanctions. Concern over the use of placebo as a medical expedient has caused several medical professional organizations to create policies proscribing their use [8, 9]. The American Medical Association’s Council on Ethical and Judicial Affairs is in the midst of creating a report on this topic, admonishing against the deceptive use of placebos in (nonresearch) clinical practice, which should be issued within the year [10].

Notes and references

1. American Medical Association. Council of Ethical and Judicial Affairs. *The Patient-Physician Relationship*. 1-A-01, 2001. Available at: http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_1a01.pdf. Accessed March 13, 2006.
2. Ellis FR, Nasser S. A pilot study of vitamin B-12 in the treatment of tiredness. *Br J Nutrition*. 1973;30:277.
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5. Evans D. *Placebo: Mind Over Matter in Modern Medicine*. New York, NY: Oxford University Press; 2004.
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8. American Geriatrics Society Panel on Persistent Pain in Older Persons. The management of persistent pain in older persons. *J Am Geriatr Soc*. 2002;50:S205-S224.
9. American Academy of Pain Medicine Council on Ethics. *AAPM Ethics Charter, 2004*. Available at: <http://www.painmed.org/productpub/pdfs/EthicsCharter.pdf>. Accessed March 13, 2006.
10. The Council on Ethical and Judicial Affairs (CEJA) report prohibits the deceptive use of placebos. The use of placebos is ethically acceptable provided that physicians have previously secured their patient's informed consent. CEJA's recommendations on this matter do not constitute official AMA policy until they have been adopted by the House of Delegates.

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Related article

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