Expectations, Intent and Sham Surgery by Dr. Christopher Kent

Seasoned clinicians recognize the importance of expectation, intent and touch in the healing process.[1] As reported in the popular press, "Placebo treatments or no treatment appeared to work just as well as drugs in a large percentage of headache patients participating in more than 100 studies."[2-3] Detractors of alternative health have suggested that positive results from alternative and complementary approaches may be nothing more than the placebo effect.[4] Placebo effects are so strong that a recent article stated 97 percent of U.K. doctors have prescribed placebos. The physicians reported using placebos to create psychological treatment effects, because patients asked for treatment, or to reassure patients.[5]

Many scientists and clinicians consider the placebo-controlled trial the "gold standard" for evidence-based practice. Coulter[6] notes that according to the Office of Technology Assessment, "Objections are rarely if ever raised to the principles of controlled experimentation on which RCTs are based." Others have stated that placebo-controlled trials are needed to provide data on effectiveness of active treatment.[7]

What, really, is a placebo? Is it merely part of a research design, or is it a clinical strategy, used knowingly or unknowingly, by virtually all clinicians? There are many definitions of placebo. Typical is this one: "The beneficial effect in a patient following a particular treatment that arises from the patient's expectations concerning the treatment rather than from the treatment itself."[8]

Guterman observed, "Expectation releases substances, molecules, in your brain, that ultimately change your experience. The mind, it seems, may play a critical role in treating diseases. And its services come free of charge, with no co-payment or deductible. Getting a person to boost their own machinery to improve health – that's something that medicine needs to know."[9]

The Rise of Placebo-Controlled Surgical Trials

Interestingly, surgical procedures are often exempt from the scrutiny of placebo-controlled trials. Ethical considerations are considered barriers to the use of placebo-controlled investigations for surgical procedures.[10-11] However, there have been five studies in which placebo surgery was used as a control. The placebo group generally did as well or better than the group receiving the real operation.

In 1939, a surgeon named Feischi developed a surgical procedure for angina pectoris. He reasoned that if the blood flow to the myocardium could be increased, the symptoms of angina would diminish. It was felt that ligating the internal mammary artery would increase myocardial blood flow. The clinical results were favorable and the operation became popular, with three-quarters of patients reporting improvement or elimination of symptoms.[12]

Twenty years later, *The New England Journal of Medicine* (*NEJM)* published the results of a placebo-controlled trial of internal mammary artery ligation.[13] Of 17 patients, eight got the actual operation; the other nine were anesthetized and got incisions, but nothing else. The fake operations worked as well as the real thing. As a result, internal mammary artery ligation surgery was soon abandoned.

The next wave of placebo surgery involved the human brain. Fetal pig nerve cells were implanted into the brains of 10 patients with Parkinson's disease. Eight patients had holes drilled into their heads, but received no implants. It was reported that "no significant improvement resulted from implanting the fetal cells of pigs into patient brains when compared with subjects who received placebo surgery."[14]

A second study, involving the implantation of stem cells from aborted human fetuses into the brains of patients with Parkinson's disease, was reported in *NEJM*.[15] Twenty of 40 patients received sham surgery, while 20 got the real thing. Holes were drilled into the skulls of the patients receiving sham surgery. Thankfully, the authors noted that "the dura was not penetrated." Some younger subjects reported experiencing some benefit. Older subjects receiving the stem cells reported a worsening of their condition.

Another significant study was a controlled trial of arthroscopic surgery for osteoarthritis of the knee. A total of 180 patients with osteoarthritis of the knee were randomly assigned to receive arthroscopic debridement, arthroscopic lavage or placebo surgery. Pain and function were assessed over a 24-month period. The result? "At no point did either of the intervention groups report less pain or better function than the placebo group."[16] This investigation followed a smaller pilot study with similar results.[17]

"Sham" Surgery: A Sham?

The notion of being subjected to unnecessary surgery is horrifying enough. Yet that is only part of the story. According to one report, arthroscopic surgery for osteoarthritis of the knee is done on at least 225,000 Americans each year, termed "a sham" by Baruch Brody, an ethicist at Baylor College of Medicine.[18] The cost of this intervention is estimated at $3.25 billion per year.[10] They continue to this day, more than 10 years later. Evidence-based practice? Hmm...

The power of the placebo cannot be denied – mobilization of the inherent recuperative powers of the body. But with placebo surgery, we must ask, "At what cost, and at what risk?" Keep this in mind the next time someone tells you they have to have surgery. Where's the science? Or are anecdotes and conjecture good enough?

References

1. Kent C. "Healing From Within: The Power of You." *Dynamic Chiropractic* – Oct. 7, 2012.
2. Boyles S: "'Placebo Effect' May Be Common in Headache Treatment. Study Shows Many Patients Feel Better Even When Their Medicine Is Just a 'Dummy Pill'." *Psychology Today*, June 28, 2011.

3. De Groot FM, Voogt-Bode A, Passchier J, et al. Headache: the placebo effects in the control groups in randomized clinical trials; an analysis of systematic reviews. *JMPT*, June 2011;34(5):297-305.
4. "Think Yourself Better. Alternative Medical Treatments Rarely Work. But the Placebo Effect They Induce Sometimes Does." *The Economist,* May 19, 2011.
5. "97% of UK Doctors Prescribe Placebos." *Medical News Today*, March 21, 2013.
6. Coulter H. "The Controlled Clinical Trial. An Analysis." Washington (DC): Center for Empirical Medicine. Project Cure; 1991.
7. "Placebo Mania. Placebo Controlled Trials Are Needed to Provide Data on Effectiveness of Active Treatment" (editorial). *British Med J*, 1996;313:1008.
8. Definition of *placebo*. *American Heritage Dictionary of the English Language, Fourth Edition*. Houghton Mifflin Co., 2004.
9. Guterman L. "Duping the Brain Into Healing the Body." *Chronicle of Higher Education*, Dec. 2, 2005.
10. Horng S, Miller FG. "Is Placebo Surgery Unethical?" *N Engl J Med,* 2002;347(2):137.
11. Weijer C. "I Need a Placebo Like I Need a Hole in the Head." *J Law Med Ethics* ,2002;30(1):69.
12. Stolberg S. "Sham Surgery Returns as a Research Tool." *The New York Times,* April 25, 1999.
13. Cobb LA, Thomas GI, Dillard DH, et al. An evaluation of internal mammary artery ligation by a double-blind technic. *N Engl J Med,* 1959;260:1115.
14. Hung M. "Placebo Surgery Gains Wider Acceptance." March 23, 2001.
15. Freed CR, Greene PE, Breeze RE, et al. Transplantation of embryonic dopamine neurons for severe Parkinson's disease. *N Engl J Med,* 2001;344(10):710.
16. Moseley JB, O'Malley K, Peterson NJ. et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *N Engl J Med*, 2002;347(2):81.
17. Moseley JB, Wray NP, Kuykendall D, et al. Arthroscopic treatment of osteoarthritis of the knee: a prospective, randomized, placebo-controlled trial. Results of a pilot study. *Am J Sports Med,* 1996;24(1):28.
18. Kolata G. "A Knee Surgery for Arthritis Is Called a Sham." *The New York Times*, July 11, 2002.