

In Defense of the Placebo in Clinical Practice

by Kristen Coros

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Abstract: Placebos, treatments or substances that are either inert or believed to be pharmacologically ineffective against the medical condition to which they are applied, are a well-established feature of clinical research. By contrast, their use by physicians in clinical practice, while common according to research, is fraught with controversy. This paper defends the use of the placebo in the clinical context by examining it from the angles of safety, effectiveness, and public support. Concerns about deception are considered in light of research showing this not to be necessary for placebo treatment to be successful. The paper concludes with an acknowledgement of the risks inherent in the practice of placebo-prescribing, and a brief discussion of guidelines.

Introduction

The placebo has played a longstanding role in medicine [1, 2]. From the Latin for “I shall please,” the term has taken on different meanings in various contexts, but is often understood as an inert treatment which may induce a therapeutic effect, known as the placebo effect, through psychological mechanisms [3, 4]. Placebos are a mainstay of clinical research, where they serve as a comparison in investigations of new treatments; in clinical practice, by contrast, their role is less secure. The American Medical Association defines a placebo in this context as “a substance that the physician believes has no specific pharmacological activity against the condition being treated” [5, p.58]. A distinction is made between “pure” placebos, such as sugar pills or saline injections, and “impure” ones such as vitamins [3, 6]. A systematic review found that the proportion of physicians prescribing placebos around the globe ranged from 17% to 99%, with impure placebos used more often [7]. One physician author termed the placebo “a central item of our pharmacopeia” [4, p.215]; despite this ubiquity, its use has been shrouded in controversy, and dogged by accusations of unethical conduct as well as “quackery” [2, p.4].

This paper provides a defense of the placebo in the clinical setting, by discussing the aspects of safety, appropriateness and public/patient support relating to its use. It addresses the common criticism that a placebo prescription necessarily involves deception, and concludes with an overview of guidelines that can help to keep the practice of placebo-prescribing ethical and fair for patients.

Safety and Harm Avoidance

A placebo containing no active substance is by definition safe. While most active medicines come with side effects, the pure placebo, by virtue of being inert, does not impose any risk to the patient [8], and thus aligns with the physician's imperative to do no harm. An impure placebo (e.g., a vitamin or antibiotic), by contrast, has the potential for negative interactions with other medications, side effects, and so on [9]. However, even impure placebos might be considered to support safety and avoidance of harm in certain cases: when surveyed about their use of placebos, British GPs mentioned employing them in a protective role, as a way to avoid a more harmful treatment or to reduce the risk of substance abuse in patients [9].

Placebo as effective—even best—medicine

In recent years, the placebo has emerged as an effective treatment for several medical conditions. One of these is depression [10]; another is pain. In the latter context, the mechanisms of the placebo effect are well understood: a placebo can trigger the production of cannabinoids and endogenous opioids, the body's own painkillers, through the psychological mechanisms of expectation and conditioning [11]. Studies have found placebos to be comparable to established treatments in terms of their efficacy in reducing pain [12]. Irritable bowel syndrome (IBS) has also shown a clinically significant response to placebo treatments [13, 14]. As with pain disorders, IBS can have a strong negative impact on an individual's quality of life; unlike pain, there is no safe and effective treatment available for IBS [15], making a compelling case for the placebo as best treatment strategy.

Public Support

A growing literature is demonstrating support for placebos among the general public and in patient populations. A majority of those sampled from both groups support the use of placebo treatments in theory, especially if prescribed in the context of a patient-physician relationship in

which trust has been established [16, 17, 18]. In one study, the effectiveness of a placebo therapy was judged to be more important than any ethical issues surrounding it [19]. There is also evidence that the more people understand the workings of placebos, the more they support them: a recent study providing an educational intervention (versus a non-educational control condition) on the mechanisms of placebo analgesia led to increased openness to using such a treatment among individuals with chronic musculoskeletal pain [20].

Concerns Surrounding Deception

It is often assumed that the use of placebos in clinical practice automatically implies the use of deception, with the being patient unaware that they are being offered a placebo, and the clinician being guided by a paternalistic attitude [1, 15]. The tricking of patients is something to which many are understandably opposed, even when this is couched as “benevolent deception” [2, p.4], and it is this issue that many cite when claiming that placebos are unethical [21, 22]. However, these criticisms are being overturned by research showing that a placebo treatment may be effective even when the patient is fully aware of its status. When researchers tested an open-label placebo against no treatment for irritable bowel syndrome in a randomized controlled trial, they found that despite patients in the “treatment” group knowing that they were receiving a pure (inert) placebo, these patients scored significantly higher on IBS-specific measures including a global improvement scale and a quality of life measure, while also showing statistically significant reduction of symptom severity [15]. Subsequent trials have furnished evidence for open-label placebos in allergic rhinitis [23] and chronic low back pain [24].

Conclusion

The practice of prescribing placebos in clinical settings is to be upheld, given that it can lead to safe and effective treatment that preserves the physician’s integrity while also respecting the patient and allowing them to be an active participant in their care. However, the different ways in which the placebo can be prescribed to patients, such as with or without deception, leads to potential for abuse and a need for guidelines. An existing set are the three conditions set forth by the American Medical Association, according to which a physician should: enlist patient cooperation by explaining the rationale for the placebo; obtain the patient’s consent; and not prescribe a placebo “merely to mollify a difficult patient” [5, p.60]. With such safeguards in

place, the rights and interests of patients might be ensured as doctors harness the power of the placebo as one tool in their overall attempt to deliver the best possible medicine.

References

1. Biller-Adorno, N. (2004). The use of the placebo effect in clinical medicine—ethical blunder or ethical imperative? *Science and Engineering Ethics*, 10, 43-50.
2. Koshi, E.B., & Short, C.A. (2007). Placebo theory and its implications for research and clinical practice: a review of the recent literature. *Pain Practice*, 7(1), 4-20.
3. Louhiala, P. (2012). What do we really know about the deliberate use of placebos in clinical practice? *Journal of Medical Ethics*, 38, 403-405.
4. Lichtenberg, P. (2008). The role of the placebo in clinical practice. *McGill Journal of Medicine (MJM)*, 11(2), 215-216.
5. Bostick, N.A., Sade, R., Levine, M.A., & Stewart, D.M. (2008). Placebo use in clinical practice: report of the American Medical Association Council on Ethical and Judicial Affairs. *The Journal of Clinical Ethics*, 19(1), 58-61.
6. Meissner, K., Hoefner, L., Fässler, M., & Linde, K. (2012). Widespread use of pure and impure placebo interventions by GPs in Germany. *Family Practice*, 29, 79-85.
7. Fässler, M., Meissner, K., Schneider, A., & Linde, K. (2010). Frequency and circumstances of placebo use in clinical practice – a systematic review of empirical studies. *BMC Medicine*, 8, Article 15. <https://doi.org/10.1186/1741-7015-8-15>
8. Foddy, B. (2009). A duty to deceive: placebos in clinical practice. *The American Journal of Bioethics*, 9(12), 4-12.
9. Bishop, F.L., Howick, J., Heneghan, C., Stevens, S., Honns, F.D.R., & Lewith, G. (2014). Placebo use in the UK: a qualitative study exploring GPs' views on placebo effects in clinical practice. *Family Practice*, 31(3), 357-363.
10. Kirsch, I. & Sapirstein, G. (1999). Listening to Prozac but hearing placebo: a meta-analysis of antidepressant medications. *Prevention & Treatment*, 1(2), Article 2a. <https://doi.org/10.1037/1522-3736.1.1.12a>
11. Colloca, L., Klinger, R., Flor, H., & Bingel, U. (2013). Placebo analgesia: Psychological and neurobiological mechanisms. *Pain*, 154, 511-514.

12. Linde, K., Witt, C.M., Streng A., Weidenhammer W., Wagenpfeil S., Brinkaus B., Willich S.N., & Melchart, D. (2007). The impact of patient expectations on outcomes in four randomized controlled trials of acupuncture in patients with chronic pain. *Pain, 128*, 264-271.
13. Patel, S.M., Stason, W.B., Legedza, A., Ock, S.M., Kaptchuk, T.J., Conboy, L., Canenguez, K., Park, J.K., Kelly, E., Jacobson, E., Kerr, C.E., & Lembo, A.J. (2005). The placebo effect in irritable bowel syndrome trials: a meta-analysis. *Neurogastroenterology and Motility, 17*, 332-340.
14. Kaptchuk, T.J., Kelley, J.M., Conboy, L.A., Davis, R.B., Kerr, C.E., Jacobson, E.E., Kirsch, I., Schyner, R.N., Nam, B.H., Nguyen, L.T., Park, M., Rivers, A.L., McManus, C., Kokkotou, E., Drossman, D.A., Goldman, P., & Lembo, A.J. (2008). Components of placebo effect: randomised controlled trials in patients with irritable bowel syndrome. *BMJ, 336*, 999. <https://doi.org/10.1136/bmj.39524.439618.25>
15. Kaptchuk, T.J., Friedlander, E., Kelley, J.M., Sanchez, M.N., Kokkotou, E., Singer, J.P., Kowalczykowski, M., Miller, F.G., Kirsch, I., & Lembo, A.J. (2010). Placebos without deception: a randomized controlled trial in irritable bowel syndrome. *PLoS One, 5*(12), Article e15591. <https://doi.org/10.1371/journal.pone.0015591>
16. Hull, S.C., Colloca, L., Avins, A., Gordon, N.P., Somkin, C.P., Kaptchuk R.J., & Miller, F.G. Patients' attitudes about the use of placebo treatments: a telephone survey. *BMJ, 347*, Article f3757. <https://doi.org/10.1136/bmj.f3757>
17. Ortiz, R., Hull, S.C., & Colloca, L. (2016). Patient attitudes about the clinical use of placebo: qualitative perspectives from a telephone survey. *BMJ Open 2016, 6*, Article e011012. <https://doi.org/10.1136/bmjopen-2015-011012>
18. Tandjung, R., Tang, H., Fässler, M., Huber, C.A., Rosemann, T., Fent, R., & Badertscher, N. (2014). The patient's perspective of placebo use in daily practice: a qualitative study. *Swiss Medical Weekly, 144*, Article w13899. <https://doi.org/10.4414/smw.2014.13899>
19. Köteles, F., & Fetentzi, E. (2012). Ethical Aspects of clinical placebo use: what do laypeople think? *Evaluation & the Health Professions, 35*(4), 462-476.
20. Kisaalita, N., Hurley, R.W., Staud, R., & Robinson, M.E. (2016). Placebo use in pain management: a mechanism-based educational intervention enhances placebo treatment acceptability. *Journal of Pain, 17*(2), 257-269.
21. Powell, T., & Jason, B. (2009). Against placebos. *American Journal of Bioethics, 9*(12), 23-25.

22. Cox, C.L., & Fritz, Z. (2016). Should non-disclosures be considered as morally equivalent to lies within the doctor-patient relationship? *Med Ethics*, 42, 632-635.
23. Schaefer, M., Harke, R., & Denke, C. (2016). Open-label placebos improve symptoms in allergic rhinitis: a randomized controlled trial. *Psychotherapy and Psychosomatics*, 85(6), 373-374.
24. Carvalho, C., Caetano, J.M., Cunha, L., Rebouta, P., Kaptchuk, T.J., & Kirsch, I. (2016). Open-label placebo treatment in chronic low back pain: a randomized controlled trial. *Pain*, 157(12), 2766-2772.