

9-19-2017

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Recommended Citation

Denk, J. (2017). Placebos: Their Effectiveness in Medicine and Implementation in Health Care. *D.U.Quark*, 2 (1). Retrieved from <https://dsc.duq.edu/duquark/vol2/iss1/8>

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Placebos: Their Effectiveness in Medicine and Implementation in Health Care

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D.U.Quark 2017(2) pgs. 48-54

Published September 19, 2017

Peer Reviewed Articles

ABSTRACT

Placebos are drugs that have no active therapeutic effect, yet they are often used in medicine. With a combination of physiological and neuroscientific factors, placebos can relieve a person of their symptoms even though they are not actually taking a real drug. As the cost of pharmaceuticals has risen astronomically in recent years, the need for an inexpensive, alternative to actual drugs has increased. In this review, placebos and their role in medicine will be analyzed. This will consist of a placebo's function in pain management, usefulness in other areas of medicine, and the ethical dilemmas surrounding placebos. Future research of placebos is aimed at whether they should be separated based on their mechanism of action or based on the disease that is being treated.

KEY WORDS: placebo, pain, medicine, ethics, deception

INTRODUCTION

Pharmaceutical drugs prescribed by one's physician can treat most diseases and illnesses, yet alternatives to such medicine have become more prominent in recent years. A less costly alternative to pharmaceuticals, a placebo, is a substance that has no active therapeutic effect. Placebos rely heavily on a physiological and neuroscientific approach [1]. Similar to an actual drug, placebos are given to patients who are told to take it as prescribed. These patients may either be informed or deceived into taking a placebo which is known as the deceptive versus non-deceptive approach [2]. After a certain period, some patients find symptom relief or they are cured of their illness even though they did not actually receive a real drug. Such a phenomenon in which one's body-mind unit changes due to the psychosocial context between the patient and the therapy is described as the placebo effect [1]. Placebos are employed in many fields of medicine, thus they treat a diverse set of medical conditions including, but not limited to, pain, anxiety, and urologic related issues [3]. Not only are placebos used in clinical trials, they are also employed regularly as a drug in healthcare by various physicians [4]. In this review, the placebo effect will be examined in the context of pain management, treating people with irritable bowel syndrome, and patients who take antidepressants. Ethical

dilemmas of the placebo effect will also be reviewed as many have questioned the morality of using placebos in medicine.

PLACEBOS AND PAIN MANAGEMENT

Using Placebos to Stop Induced Pain

Patients who suffer from either acute or chronic physical pain may be prescribed an actual drug to provide them with pain relief. Unlike a real drug, when a placebo is administered to patients for pain relief, it is given with a set of physiological conditions that either inform or subvert the patient into thinking what they are taking. In one study, performed by the Danish Pain Research Center in Denmark, forty-eight healthy patients' responses to different pain injections were examined [5]. These participants had no outstanding physical or mental health problems. One injection contained hypertonic saline, which is a painful stimulant, and patients were told that the injection contained only that. The other injection however, contained hypertonic saline with a placebo but the same patients were told that the injection contained hypertonic saline with a pain killer. Participants were more intolerant to the first injection than they were to the second. Thus, even though patients should have felt the same amount of pain from both injections, the second injection did not feel as painful since they had been convinced that it contained a pain killer. In this case, administering a placebo with deception proved to be more effective than not administering a placebo at all.

In a related study, healthy participants, who had no scars, were blindfolded and subjected to different interventions that caused placebo-induced somatic sensations [6]. For example, one intervention involved a placebo irritant solution, which consisted of a cotton swab with room temperature tap water. Participants were told that the solution was a food additive that could possibly cause an allergic reaction or skin reddening. At the end of the experiment, 90% of the subjects reported a strong to moderate sensation when exposed to this stimulus [6]. Therefore, because the patients were deceived, they were psychologically prepared to feel a strong sensation even though the cotton swab contained only water.

Using Placebos to Stop Existing Pain

Other experiments have examined whether placebos can be employed in pain management outside of the primary care setting. With physical therapy, patients perform various exercises to rehabilitate their mobility or function. One particular study tested whether receiving active interferential current (IFC), which is a type of therapy

that sends strong currents or vibrations from a device to the pain area, before Pilates exercises is more effective than using a placebo before Pilates exercises in patients with chronic low back pain [7]. Patients in the placebo group received a device but the current did not reach the pain area. In the end, no significant differences were found between the two groups. Thus, active IFC before Pilates exercise is no more effective than using a placebo before Pilates in relieving pain in patients. Ultimately, since the placebo was ineffective on the participants in the placebo group, no placebo effect occurred. This was different than what was observed in the experiments encompassing placebo use and induced-pain. However, other studies have shown that patients who are prescribed a placebo to treat their pain, may actually find symptom relief [8]. This may not be as true in patients who have metastatic diseases, or cancer, in which a placebo is used to provide pain relief for those who have become intolerant to opioids [9]. Essentially, these studies indicate that a placebo's effectiveness widely varies depending on the condition causing pain and whether it is used as a drug or as an exercise in physical therapy.

OTHER USES FOR PLACEBOS

In addition to pain management, placebos are also used in many other medical disciplines. One intercontinental study analyzed a placebo's efficacy in treating irritable bowel syndrome patients [10]. Participants were randomly divided into two groups, with one group being told that they would receive a placebo and another group being deceived into thinking that they were taking an effective drug that combats irritable bowel syndrome. At the end of the study, participants who were informed that they would be given a placebo and explained what that meant actually saw more relief than those who were deceived into taking a placebo [10]. This suggests that patients, at least those with irritable bowel syndrome, who are prescribed a placebo, do not necessarily have to be deceived into taking it for treatment to be effective.

Placebos can also be used to treat patients who suffer from Major Depressive Disorder (MDD). In one study, a two-week single-blind phase was performed in which two identical oral placebos were prescribed to MDD participants [11]. These participants were told that the two placebos had either active or inactive fast-acting antidepressant-like effects [11]. Following the two weeks, a ten-week open-label treatment plan was followed with a serotonin reuptake inhibitor (SSRI), which is a class of drugs normally used in treating depression [11]. In addition, the placebos and the SSRI looked identical to one another. Participants were also told that the placebos that they were taking may be associated with brain activation, or mood improvement. Subjects who were treated with the "active" placebo rather than the "inactive" one were associated with significant reductions in depression [11]. Thus, when all subjects are given a placebo, those who are convinced that they are receiving the more effective one, perform better than those who do not.

PLACEBO ETHICAL DILEMMAS

Ethical concerns regarding placebos have arisen overtime as their prevalence in health care has increased. A doctor's view on placebos may be different than that of a patient. Surveys that analyzed this doctor-patient relationship in the primary care setting on how these two groups felt about placebos revealed that patients generally have more negative views of placebos if they had been predisposed to the notion that placebos do not work [4,12]. Primary care physicians (PCPs) on the other hand, have a more favorable view of placebos, yet some remain skeptical [13]. This brings into question whether these doctors would have a more favorable view if placebos alternated between impure and pure interventions. Pure placebos have no pharmacological effect, such as sugar pills, while impure placebos have a pharmacological effect, such as antibiotics in viral infections, but not on the condition being treated [13]. When PCPs were asked to define a placebo, the majority of them described pure placebos. In fact, most of the PCPs did not regard impure placebos as placebos at all. Even more importantly, all the PCPs would have preferred ethical guidelines on how to approach the process of prescribing placebos to their patients [13]. Essentially, from these studies, PCPs have a more varied opinion of placebos than do patients, yet doctors are still unsure how to handle the ethical ramifications surrounding placebos when it comes to prescribing them to their patients.

Although one PCP may prescribe a placebo different than how another one does, there is a general process followed in prescribing placebos (Fig. 1). This process is nearly identical to how a PCP would prescribe an actual drug. The only difference is that PCPs have to choose between a pure or impure placebo and a deceptive or non-deceptive approach. The actual contents of placebos are rarely reported [4]. In other words, when a doctor goes to prescribe a placebo, they do not simply write "sugar pill" or "placebo" and send the script off to a pharmacy. Instead, the general consensus is that after the two ways of administering a placebo are decided upon, the doctor will write down a drug name on the script. This drug may be either a pure or impure placebo but it will have a name that the pharmacy will use to identify it.



Figure 1. The Process of Prescribing a Placebo by Primary Care Physicians (PCPs). When a PCP first decides to treat a patient with a placebo, they will examine two factors: (1) whether the placebo should be pure or impure, and (2) whether to use a deceptive or non-deceptive approach. After these steps are taken, the doctor will prescribe the placebo and the patient will pick up it up at their pharmacy just as they would with any other pharmaceutical drug.

*Note: Starred items are the general preferred method of placebo prescription by PCPs [13].

Clinical trials and placebo use also remains controversial. Certain criteria must be met in order to reduce the labeling of placebos as unethical [14]. One such criterion states that placebo-controlled trials can be ethical when there are compelling methodological reasons for using placebos and the research is intended to develop future interventions for treating patients. Another criterion states that placebos can be used when there is no proven effective treatment for the condition. Although the debate continues, it is important that one of these criteria are followed to reduce controversy surrounding placebos.

Another ethical dilemma becomes evident once a placebo-controlled clinical trial is approved that will use deception. A survey administered to patients asking them to rate their knowledge of placebos and their efficacy for relieving pain showed that almost all patients had limited knowledge of placebos [15]. After being explained what a placebo's function is, most people were practical and said that they would consider taking a placebo and even a variety of treatments to deal with a condition. A related study refutes the idea that placebos are unethical because they require deception by using the irritable

bowel syndrome study to explain that not all placebos have to be prescribed deceptively in order to work [2]. Naturally, more studies need to be performed to examine how the ethical controversy embodying placebos can be reduced.

CONCLUSION

Placebos have demonstrated their efficiency in various experimental studies. In pain-related experiments, placebos have reduced the pain intensity of patients who were told that they were receiving a painful injection containing a pain relief medication.

However, when placebos are not used as a drug such as in physical therapy, they do not show the same promising results as a pill would. Placebos can also be used to treat conditions other than pain such as irritable bowel syndrome and major depression disorder. There are still lingering ethical concerns regarding placebos as some believe that it is unethical to essentially prescribe a fake drug and deceive the patient into taking it. Placebos may never fully be considered ethical, however there are certain criteria that can be followed to make them more ethical. Although a possible alternative to actual pharmaceuticals, placebos require much more research to further improve their effectiveness. Future research is currently aimed at answering whether placebos should be separated based on their mechanism of action or based on the disease being treated [1]. These studies will examine where (in which disease), when (in which circumstance), and how (with which mechanism) placebos work [1]. Placebos, as ineffective as they may seem, have nevertheless, proven their effectiveness in medicine in treating various patients and it is without a doubt, that doctors will continue to prescribe them where they best see them fit.

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Denk, Jordan. "Placebos: Their Effectiveness in Medicine and Implementation in Health Care." *The D.U.Quark*, 2, 1 (2017): 48-54. <https://duquark.com/2017/09/19/placebos-their-effectiveness-in-medicine-and-implementation-in-health-care/>