

The ethical conundrum surrounding placebos and its evaluation in the Indian setting

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Abstract

Placebos have become rapidly integrated into modern clinical practice. With further advancement of science, it has become harder and harder to distinguish placebos from genuine medical care and judge their ethical standing. Placebos take a varying stand on the moral spectrum depending on the observer’s vantage point. The subsequent article aims to analyze placebo administration in an Indian clinical setting and furthermore evaluate its moral nature by looking at data from 125 participants. The participants were required to answer an online questionnaire and then the data received was analyzed to produce solid figures.

Keywords: Placebo, Placebo Effect, Clinical Practice, Ethical Nature

Introduction

Placebos in general definition are inert substances which when administered mimic the comforting effect of a drug by working on the psychology of the patient. An article published by Tilburt *et al.* Describes the placebo effect

as “positive clinical outcomes caused by a treatment that is not attributable to its known physical properties or mechanism of action” [1]. Recent research suggests that placebo effect is a genuine psychological episode which contributes to a general therapeutic experience and that placebo experiences can be helpful in both clinical as well as laboratory settings. The widespread interest in placebos has started fairly recently even though the practice itself has existed for centuries.

With the ubiquitous adoption of randomized control trials (RCT) after world war II there was an increase in research around the subject. An article published in ‘The Lancet’ claims that this is where the moral ambiguity surrounding placebos started. With its rapid acceptance, placebos quickly shifted from its meek humbug nature to a powerful practice generating genuine, documented results that can simulate reactions similar to potent drugs. Results received from the use of placebos are compared with those obtained from the administration of a drug prove that the said drug is effective beyond the

psychological results of a belief in the ability of a drug to cure and identify potential side effects.

Placebos themselves come with limitations like every other medical treatment, they would not be effective in shrinking a tumour or treating broken bone, they work on symptoms arising from the brain such as the perception of pain. The efficacy of placebo is used in every field of medical practice but its effect is particularly profound in psychiatry specifically in the treatment of depression, schizophrenia and disorders of anxiety [2]. Thus, placebos have been integrated into common medical practice because of their favorable outcome in clinical trials, a demonstration which cannot be ignored. The aim of the study was to obtain an understanding on the placebo prescribing practices of doctors all throughout India and evaluate their outcome.

Method

To carry out the study a questionnaire was created and circulated amongst the doctor community. The questionnaire required the doctors to answer questions based on placebos, their prescription and whether the results were favorable or not. The form was allowed to circulate for a total of 48 hours before retrieving its data. The data was then tabulated and analyzed.

Results - Placebos in Indian Clinical Practice

The traditional Indian setting proves to be a welcome market for placebos. The study done on 125 participants from across the subcontinent found that 69.6% of the participants have at some point, during the course of their practice, prescribed placebos to their patients. Most of the doctors stuck to pure placebo administration while some also indulged in impure placebos (see Figure 1.1). Out of these 97.6% of the doctors reported a favorable response in their patients while the remaining were unsure of the outcome. However, the extent to which

these placebos have been helpful cannot be measured, they have proven to be a strong component of medical practice. The most commonly prescribed placebos were multivitamins or distilled water injections in lieu of hard medicines and antibiotics because the symptoms and reactions did not present themselves in tests and reports. Multiple doctors also claimed to have prescribed placebos for cases of globus pharynges.

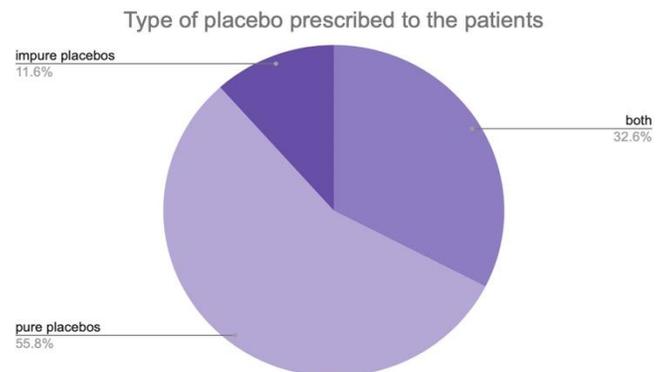


Figure 1: Diagrammatic representation of the 'Type of placebo' administered by the participants of the study

Discussion - Ethical Questions

Having been integrated in common medical practice, placebos often pose a threat to the integrity of the doctor. Prescription of placebos is out right unethical when proven effective treatment exists [3].

Additionally, maximum effectiveness of placebos arises from total ignorance on the part of the patient regarding their administration. In this situation the physician is in effect deceiving the patient and violating the principle of informed consent. Supporters of placebos argue that this is untrue since open label placebos are administered after informing the affected that they will be receiving placebos [4]. In a paper by Lichtenberg et al. It is claimed that uninformed administration of placebos also reduces the autonomy a patient has when deciding the course of their medical treatment since they are not completely aware of their available options [5].

The hippocratic oath is a statement of ethics historically taken by physicians [6]. The modern adaptation of this oath by Dr. Louis Lasagna was adopted by the World Medical Association in the 'Declaration of Geneva' and it outlines the professional duties of physicians in concise terms and affirms the ethical principles of the medical profession. One potential argument opposing the subject is that if impactful treatment already exists then placebo-controlled trials stand in violation of the (modern version) of the hippocratic oath which states that "I will apply, for the benefit of the sick, all measures [that] are required, avoiding those twin traps of overtreatment and therapeutic nihilism" [7]. In other words, this is a violation of "clinical equipoise" which is that the clinicians do not know if the proposed drug or new treatment is as good as the standard treatment [8]. Moreover, it is argued that when proven impactful treatment exists, placebo involving practice lacks merit both scientifically and clinically.

Additionally, the subject of consent adds further ambiguity to the moral grey area surrounding the administration of placebos. Children and adults of unsound mind going through a life-threatening condition are unable to consent to partake in clinical trials or certain medical practices with full responsibility causing decisions to be taken by other individuals on their behalf which may be detrimental to their health eventually.

Placebos also prove to be helpful when in case of a fatal condition the treatment being administered has severely harmful side effects and hence to prolong the effect of the treatment it is mixed with placebo so that the adverse effect on the patient is not nearly as intense.

Several studies have shown that placebos play a vital role in medical treatment. Like most practices in the field of science, placebos raise complex questions about

the nature of its ethicality. There are several ways one might view this puzzle, looking at placebos from the perspective of an individual will tend to highlight the negative aspect of them but one can also give them a larger community-based angle that tends to paint them in a positive light. Additionally, the morally grey nature of the subject often forces an individual to examine the responsibility they have as a doctor towards the wellbeing and qualitative treatment of their patients. Having established this, it is safe to say that judging where placebos stand on the ethical spectrum is futile without the context of the situation a clinician faces while treating a particular individual, condition or testing a new drug for the market.

It is vital that the consequences of administering placebos are weighed out in great detail before the patients or test subjects are involved. Furthermore, it is crucial that informed consent is obtained before the administration of any medical procedure but because placebo involving procedures are a psychological phenomenon such an act might tamper with the best possible outcome.

Conclusion

There is no universal judgement that can be passed on the subject of placebos as a lot is still unclear but with further research it only continues to grow in complexity. It is evident that we need to delve deeper into the subject matter which might eventually give us more insights on how it works and perhaps even its ethical standing.

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