Ethics, deception, and placebo effects

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Abstract

Placebo studies have recently become an interdisciplinary research topic in sports science and sports medicine. Beyond medical science, humanistic analysis is essential to assess the desirability of new interventions or treatments. This chapter focuses on the ethics of deceptive placebo use in clinical practice in the care of athletes. These practices may be conducted by sports physicians and sports nutritionists, physiotherapists, among others. In this chapter, we develop four related themes. First, we analyze the traditional definitions of the placebo effect and its consequences for ethical analysis. Secondly, we showcase what sports medicine entails and why we should bring together evidence to understand it separately from medicine in general. Thirdly, we present the general principles of medical ethics and bioethics and apply them to sports medicine. Fourthly, we close with an understanding of the ethical problems surrounding the use of placebos in sports. We conclude by tentatively highlighting new avenues of investigation that suggest how placebo effects can come in different formats that reject the deceptive paradigm, presenting ethical alternatives for using placebos in clinical practice.

Introduction

Placebo studies have recently become an interdisciplinary research topic in sports science and sports medicine, arising from an intensification of scientific findings of the placebo mechanisms during the first decade of this century. Beyond medical science, humanistic analysis is essential to assess the desirability of new interventions or treatments. This chapter focuses on the ethics of using deceptive placebos in clinical practice (broadly conceived of as sports healthcare practices). These practices are conducted by sports physicians and sports nutritionists, physiotherapists, or other relevantly applicable specialization. In this chapter, we develop four related themes. First, we analyze the traditional definitions of the placebo effect and its consequences for ethical analysis. Secondly, we showcase what sports medicine entails and why we should bring together evidence to understand it separately from medicine in general. Thirdly, we present the general principles of medical ethics and bioethics and apply them to sports medicine. Fourthly, we close with an understanding of the ethical problems surrounding the use of placebos in sports. We conclude by showing new avenues of investigation that suggest how placebo effects can come in different formats that defy the deceptive paradigm, presenting ethical alternatives for using placebos in clinical practice.

The traditional definition(s) of placebo effects

We begin with some remarks on how placebo effects are understood in relation the medicine or healthcare practice more generally. Traditional definitions of placebo effects often include two necessary conditions. First, placebo effects are understood to be biologically "inert/innocuous". This element is understood alongside the effects being understood as a form of "treatment."[1] This enables their being, or potentially being aligned with that widespread goal of medicine. In this vein, Brody (2018) defines placebos as 'bodily change due to the symbolic effects of a treatment or treatment situation and not to its pharmacologic or physiologic properties'. Although a universally agreed definition of treatment is difficult to attain, it is commonly agreed that medicine's goal is the relief of suffering (Porter, 2004). By extension, one can say that a definition of treatment refers to an intervention that has as its goal the relief of suffering. Placebo administrations are often coherent with such a goal.

The majority of the placebo literature defines the placebo effect by pairing it with the notion of treatment. Yet the placebo effect has also been defined in a negative way (Alfano, 2015) because of its inert/innocuous aspect. In philosophy, a negative definition is a definition that employs the opposition or absence of a term as its necessary condition. This method is

[1] Those necessary conditions are needed for what we have called the "traditional definition" of the placebo effect. However, one can already identify a trend in the literature in avoiding those two. Accordingly, new definitions are designed to avoid the limitations offered by "treatment" and "inert/innocuous" conceptual elements for a definition of placebo (Colloca & Barsky, 2020). Nevertheless, there is no substantive consensus on the definition of placebo effects in the literature, despite the presence of putative "consensus statements" published in the literature.

evidenced in some of the placebo definitions. For example, for (Guijarro, 2015) a 'placebo is a treatment designed to simulate a medical intervention, but which does not exert a biological effect on the disease in question.' Guijarro follows Grünbaum's (1981) widely accepted conception of placebo effects as inert, which has the consequence that placebo effects are those not identified by the dominant therapeutic theory. Nocebo effects can also include negative definitions in relation to its inert/innocuous aspect. Yet they are also negative in relation to treatment, since they are expectations derived from a 'procedure intended to create negative expectations (e.g., giving a placebo along with verbal suggestions of worsening)' (Colloca & Miller, 2011, p. 598).

More recently, scholars and scientists have drawn attention to a putative characteristic of the received understanding of placebo effects, noting that an alternative understanding arises when we focus on the notion of placebo responses. The intensification of scientific findings related to placebo effects, and the establishment of neurobiological pathways associated with them, has raised questions of which side effects are to be thought of as placebo effects and which are associated with other variables present in the clinical encounter, such as regression to mean, patients' natural history, or bias. In what follows we accept this differentiation and follow Evers line of reasoning:

> (…) the *placebo and nocebo response* includes all health changes (i.e., differences in symptoms before and after treatment), thus including natural history and regression to the mean. The *placebo and nocebo effect*[, therefore,] refers to the changes specifically attributable to placebo and nocebo mechanisms, including the neurobiological and psychological mechanisms of expectancies. (Evers et al., 2018)

As we will show, these aspects of the traditional definitions of placebo effects conflict with and present issues for the ethical assessment of its use in clinical practice. While deemed "inert/innocuous," a placebo can be considered 'a substance provided to a patient that the physician believes has no specific pharmacological effect upon the condition being treated' (Bostick et al., 2008, p. 3). Therefore, their administration, usually combined with or in replacement of treatment, is considered deceptive and conflicts with patients' right to information through the informed consent process (Miller & Colloca, 2011). Moreover, because they are parasitic upon the more fundamental "treatment," it is unclear to which extent placebos may be ethically administered for, for example, the performance enhancement of elite athletes. Thus, it is questionable to what extent and under which conditions the use of placebo is ethically acceptable in e.g. the relief or management of pain, and whether their ethical use extends beyond treatment. What, one could ask, would justify their use for non-medical ends?

One possibility is to point to emerging empirical evidence that challenges the received "inert/innocuous" condition and holds that the placebo affects are genuine neurobiological mechanisms (Colloca, 2014). In that case, some may argue that this opens the door to their ethical use in performance enhancement (Carlino et al., 2014).

Understanding the problems with the use of (deceptive) placebos in clinical practice

Imagine the following scenario related to pain management in a clinical setting. A club physician administers a pill to an athlete after her complaints of muscular pain after a hard

training session. The physician chooses his words carefully to emphasize the positive aspect he wants her to grasp from his evaluation of a specific pill he appears to intend to prescribe: "This is a strong analgesic that has been extremely effective in cases such as yours." Not longer after ingestion, the athlete reports positive effects in that she is feeling relief from her pain and more confident about the day's training session. Although the physician intervened with the athletes best interests at heart, since experience and recent evidence on placebo effects suggest that sham administrations have a great potential to relieve pain, the situation represents a classic example of paternalistic intervention – where the athlete is deceived, but in the name of a beneficent cause – the relief of negatively perceived pain. How are we to evaluate this intervention by the physician. We can ask (a) is apparent intervention one that sport physicians are apt to conduct; and (b) is it ethically justified?. As to the former question, McNamee et al (2017) argue that it appears part of the professional arsenal of physicians. They cite a highly experienced surgeon working in sports medicine:

> 'That's where the art of medicine comes in […] we have patients with overload injuries or they are over-trained, maybe, and you'd like to take them out for three months and that's a lifetime for them. Then, you have to put on something that you do to avert their attention and to get them to do something other than their usual use […] I think this goes on in every aspect of medicine, I think because there are so many things that we think we know but we don't' know […] Any clinician will use placebo as part of their medication, so to speak. Any experienced physician' (2017, p. 357).

What of the question as to its ethical status? Deception is often included as a component of the placebo administration. Now here our clinician has skated a thin line; the physician has certainly directed the understanding of the athlete patient in a way that has undermined their autonomy. Morever, it is commonly held that such deception or - at least- mis-direction, is an important aspect in the modulation of the expectation that evoked the response, its administration is ethically problematic. This is because the right to information, the right of patient autonomy, their capacity to form a conception of their own best interests and express these to their healthcare providers, should generate a duty of respect in the healthcare provider (Beauchamp & Childress, 2019). The usurpation of that right may be conceived or as an ethical violation, or in some jurisdiction a legal one. Finally, although the patient responded successfully to the intervention, she *could* have presented negative side effects, namely, nocebo effects. Accordingly, these interrelated issues represent a variety of challenges that the literature on medical ethics have tried to respond to over the recent years. They may be summarized into the following topics of investigation: prevalence and physicians' attitudes towards placebos, patients' right to consent, codes and policies in medical care in sports, and the consistency of the evidence on placebo effects in the scientific literature (Kaptchuk et al., 2020)

Together, these issues exemplify some of the potential moral conflicts for clinical practice. However, the most central and discussed issue regarding the use of placebos in clinical practice is deception, defined as 'to intentionally cause to have a false belief that is known or believed to be false' (Mahon, 2016). While inadvertently or mistakenly deceiving others would not describe the physicians' example, intention in deceiving is a central problem for clinical practice's legitimacy. Particularly, intentionally deceiving patients can infringe on their right to information and consent (Beauchamp & Childress, 2019). Therefore, it is

pressing to understand sports medicine clinical practice and arguments underpinning the moral status of the use of placebos.

Pain, performance, and athletes

Placebo research is often related to pain and less frequently to performance enhancement (Colloca & Benedetti, 2005). In sports, pain and enhancement are an everyday preoccupation for sports healthcare professionals (SHP), where there is highly subjective preference prioritization. However, most research on placebo effects in sports is related to performance enhancement (Beedie & Foad, 2009; Hurst et al., 2020). Greater attention to the ethical use of placebos for pain management is therefore warranted. We shall assume what is a commonplace in western medical practice that where treatment is concerned, the patients' right to informed consent is paramount. The extension of that principle techniques to assisting performance enhancement is a moot point.

The IOC Consensus Statement on pain management defines pain as 'An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage' (Raja et al., 2020). Pain can be acute or chronic. The presence of chronic pain often renders the athlete a contender for retirement. Athletes reports of life playing with pain are legion. Nor are they restricted to the obvious contenders in collision and contact sports (Nixon, 1992; Huizinga, 1949). By contrast, take Rafael Nadal's statement after being defeated by Denis Shapovalov at the ATP Masters 1000 Rome of 2022, illustrates that: 'I am a player living with an injury; it is nothing new'. Living with pain, and playing in a condition that is not pain free are part and parcel of everyday elite sports (Howe, 2003). Even though pain is ineliminable from the human condition and a physical mechanism to protect individuals, elite athletes are more exposed to both acute and chronic pain than the average population.

In contact and collision sports pain is entirely foreseeable.[2] While some see value in the so-called "dangerous sports" (Russell, 2005), others question the moral justifications of some of them, such as boxing or MMA, since their 'goal (…) is to win by incapacitating opponents so that they are unable to fight back'. Whichever ethical stance is adopted on the intentional infliction of injury and therefore pain on one's opponent, there is no denying its ubiquitous presence. And, of course, it may be self-inflicted in sports that are essentially parallel tests. It is close to received wisdom in endurance cycling (e.g., the European tours) that the winner is often the cyclist who can endure the greatest pain, and therefore inflict the greatest suffering on their opponent.

Regardless of their moral status, all previous examples illustrate how pain is somewhat permissible within the realm of sports. Pain is a central preoccupation of sports medicine due to the prevalence in which athletes are exposed to risks of injury. Pain management, is one of the essential components of the care of elite athletes. Conceived broadly this has

[2] By affirming that pain is part of (some professional) sports we by no means intend to morally evaluate those sports here. Suffice here to identify those sports and their presence in widely acceptable international competitions.

implications also for recuperative and preventative practices and not merely therapeutic management (Hainline et al., 2017).

What is surprising, however, is the lacuna of research on using placebos for pain in sports, especially in the light of clinical discussion and when compared to other, non-sport, medical specializations. Beyond sports there is widespread use of placebos for pain management. For example, surveys in Denmark (over 80%) and the US (over 50%) have demonstrated that a large number of physicians from different specializations, such as general practitioners, hospital clinicians, private specialists, or rheumatologists, respond positively when asked of the administration of placebos in the previous year (Hróbjartsson & Norup, 2003).

A more recent preoccupation in sports medicine is the enhancement of performance. Unlike pain management, ethical consideration of performance enhancement often derives from its use as a form of cheating. Much of the available literature is related to the use of performance-enhancing drugs (PEDs) and their corrupt administration among sports participants (Divik et al., 2013; Murray, 2015). Concerning placebos, research in sports has shown how nutritional ergogenic aids might enhance performance by evoking the neurobiological mechanisms related to the placebo effects (Beedie & Foad, 2009; Hurst et al., 2020). More important for our purposes are the evidence of its use for enhancing performance. Contrary to the lack of evidence on the pain management administration of placebos in sports medical settings, some evidence suggests their use is common. For example, (Brooling et al., 2008), found that 62% of a sample of 30 national-level coaches have allegedly administered placebos to their athletes at some point, while 10% of them proceeded with weekly administrations. This evidence is reinforced by (Szabo & Müller, 2016) study, in which 90% of a sample of 96 coaches were aware of placebo effects, while 44% admitted administering placebos to their athletes in an attempt (successful or otherwise) to enhance their performance. However, these administrations need to be considered apart since coaches do not always or easily fit the SHPs category. Moreover, only some authors have addressed the issue from a moral point of view in understanding the relationship between placebos and doping (Kayser, 2020; Kirkwood, 2014).

The medical setting in sports and its particular aspects

Whether placebos are a problem for sports medicine (and for sports) requires understanding if there is any difference between them and general medical practice. Sports medicine has been considered to possess some peculiar aspects concerning athletes' health (Malcolm, 2005). This status can be represented by the link some have made between sports medicine physicians as "snake oil salesmen" (Franklyn-Miller et al., 2011). While medicine's goal has been widely conceived as the relief of suffering, this prominent precondition seems to be inconsistent with the variety of activities carried out by physicians (Edwards & McNamee, 2006), since sports medicine practitioners often operate in the grey zones between treatment and performance enhancement (Morgan, 2009).

Although sports medicine is a recent newcomer to the family of medical specialisms, some might argue that it differs from many traditional branches in terms of its conceptual and practical goals. In 2006, Steven D. Edwards and Mike McNamee challenged the class inclusion claim that sports medicine is a branch of medicine. The authors made a point by arguing that for a 'practice to fall within the class of medicine, it is necessary that it possess

the attribute of aiming to relieve suffering' (Edwards & McNamee, 2006). Conceptually speaking, to be considered a medicine, sports medicine shall attend to the necessary condition of the class: the relief of suffering. While sports medicine is usually conceived as a 'branch of medicine' and a discipline concerned with athletes' welfare and health through prevention, protection, and correction of injuries, as the Oxford Dictionary of Sports Science & Medicine states, among its objectives, it includes the practice of preparing 'an individual for physical activity in its full range of intensity' or the study of information 'used to optimize performance in sports' (Kent, 2006).

Capturing daily activities of sports medicine also conflicts with the claim that sports medicine is medicine. Although public discourse often shares the social image of the athletes' body as "health" – e.g., in sports such as swimming or track and field where "fitness" is often understood (incorrectly) as synonymous with "health" – this standardized conception of athletes' body does not show all of the functions an SHP exercises within elite sports contexts. For example, in football, SHP are not only concerned with athletes' recovery from injuries (often sport-related) or illnesses (usually non-sport-related), but with the numerous training sessions, and given the tight championship calendars, highly compressed recovery time-frames. Moreover, the permissiveness of the "machine-like" conception of the athletes' bodies (Gleyse, 2013) also offers conflicts with the elusive assumption that sports medicine coheres uniformly with the goals of medicine.

Sport medicine is not infrequently considered a practice at the borders of medicine. Two characteristics of sport illustrate this borderline status. They are commonplace scenarios faced by SHPs. First, from a legal point of view, athletes' mindset to enhance performance and their willingness to put their health at risk by consenting to participate in dangerous practices is an essential factor in the complexity of the everyday life of sports clinical contexts. In sports such as rugby or skiing, athletes accept the gratuitous logical structure underpinning the contest (Suits, 2014); that is to say, they undertake tasks that are made more complex by the nature and rules of the activity. In some cases this means that, they consent to the legitimization of risk of serious harm inflicted upon them (Parry, 1998; Dixon, 2016). Due to the risk of many athletes lives coexist with (often extreme) pain while trying to maintain or enhance performance. Secondly, from a sociological standpoint, athletes' willingness to live with pain is part of the culture of risk associated with the sport (Nixon, 1992), represented by what has been called "sportsnets," the social structure surrounding the clinical context of sport in which coexistence with pain is maintained. While such culture has been investigated through numerous normative lenses, such as confidentiality in sports settings (Waddington et al., 2019), less has been said about specific procedures, such as the use of placebos by SHPs.

The, albeit ambiguous, distinction between treatment and enhancement (Buchanan, 2011; Parens, 1995) might give some a platform to argue that sports medicine is unique but still within the family of medical specialisms, but this claim is flawed. In fact, claims of distinctness or uniqueness are exaggerated McNamee 2016: "what really exist are merely differences of degree, not differences of kind' (Camporesi et al., 2017). Therefore, sports medicine and other branches of medicine are ethically assessed by the same principles, and physicians should comply with the same medical principles. The question then arises as to how we ethically evaluate placebo within sport medicine thus conceived.

Ethical principles for medicine and sports medicine

To guide decision-making when ethical dilemmas appear in medical practice, mainstream medical ethics and bioethics have drawn heavily on principles as opposed to case-by-case casuistic processes. Tools for practical guidance help us to assess complex cases to comprehend SHPs' obligations, limits, or justifications, as well as the rationale behind healthcare policies in sports. Since the 70s, medical ethics and bioethics literature have relied extensively on principle-based approach (Ainslie, 2002). It was with the publication of *Principles of Biomedical Ethics,* in 1979, that Tom L. Beauchamp and James Childress 'not only played a pivotal part in creating the field but for the past 40 years (…) have remained two of its most influential figures' (Shea, 2020). Their four-principles approach to bioethics, also called "principlism," is the most influential approach in the fields of western medical ethics and bioethics, entailing appropriate correspondence to fields such as medicine and sports medicine. Moreover, Beauchamp and Childress' focus on what they call mid-level principles, have served as pivotal guides in understanding the ethical issues related to placebo effects, from RCT (Annoni, 2018) to clinical practice (Annoni & Miller, 2016; Miller & Colloca, 2011).

The four principles articulated by (Beauchamp & Childress, 2019) to guide clinical practice are (i) respect for autonomy, (ii) non-maleficence, (iii) beneficence, and (iv) justice. All four derived from what the authors have called the common morality's approach. In reality they draw from different moral philosophical sources. While respect for persons and non-maleficence draw from deontological (duty-based) ethics, aiming to benefit the patient (typically expressed at the best interests of the patient) is a guide as to consequential considerations, albeit based on a duty like formulation. The focus on justice is often a critical issue in the allocation of scarce resources, allowing for a rational basis concerning who gets what in terms of healthcare. Let us elaborate a little further before moving to application specifically concerning placebo use.

The use of placebos by SHPs potentially breaches the widely accepted principles of respect for autonomy (patients' right to choose the treatment) and beneficence (physician's duty to act in the patients' best interest). Autonomy occupies a central place in contemporary moral and political philosophical theories, especially in discussions such as the principles of justice, limits of free speech, or the nature of liberal states (Dworkin, 2017). Notwithstanding this, the concept of autonomy has been regarded as a pivotal element in practical and applied ethics, such as medical ethics and bioethics, especially in discussions about decision-making and informed consent (Beauchamp & Childress, 2019) . According to Beauchamp & Childress, (2019), virtually all theories of autonomy support two essential conditions: liberty and agency (the possibility of rational choice over, and responsibility for, one's actions). While the former represents independence from external control, the latter represents the capacity to decide what actions to do intentionally independently.

While the principle of non-maleficence owes it roots to the Hipporatic Oath of the early Greek physicians, and was canonized in the classical period with the latin motto "*primum non-nocere*" (first do no harm), it is important to understand that the role of this principle is understood both as a goal and a constraint on physician's action. By contrast, beneficence has to do with undertaking beneficial actions or promoting good. It was, in previous decades,

a widespread assumption that the doctor both knew best and would always act in the patient's best interest. This, of course, can clash with the first principle of respect for autonomy especially when aiming at patients' welfare may involve decision. Yet the principle of beneficence draws on the long standing 'moral obligation to act for the patients' benefit, helping them to further their important and legitimate interests, often by preventing or removing possible harms' (Beauchamp, 2019, para. 3). Although most western societies are now wary of untrammeled medical paternalism, it is also true that in other parts of the world it is very much commonplace.

Classic paternalistic interventions of placebos typically conflict with the principles of respect for autonomy and beneficence. By deceiving the patient, the physician breaches the principle of respect for autonomy since significant and materially relevant information about the intervention is not provided and thus consent is obviated. Moreover, due to the incipient scientific findings of placebo effects, even though promising, a better regulated approach to the use of placebos is still needed in order to be in compliance with evidence-based medicine (EBM). Therefore, if the issue of beneficence can be satisfied by scientific evidence and translational research, how placebo use can align with respect for autonomy is still problematic. What might that look like? We turn now to the idea of open label placebo use.

Ethics of placebos and open-label placebos (OPL) in sports

Recently, (Colloca & Barsky, 2020) have defined placebo effects as the effects of patients' positive expectations concerning their state of health. Two things should be considered here. First, their definition does not include deception as a prerequisite for a placebo effect to exist. Secondly, the use of inert/innocuous substances has also been eschewed, because of new discoveries in placebo studies such as the open-label placebo (OLP). Recent contributions to the definition of placebo such as Colloca and Barsky's, suggest the need for a broader conception of the placebo effect, which includes new strategies in contemporary research for understanding placebo effects.

Because the traditional definitions of placebo include deception, placebo effects are considered to work only when patients believe that they are being treated with a real treatment (despite its inert/innocuous status). Recently, however, results have demonstrated that patients can experience placebo effects, such as pain relief, even when knowing they are taking a placebo (Kaptchuk et al., 2020). Despite recent emerging evidence and excitement with OPL findings, it is still too soon to establish the real conditions in which this intervention will not infringe the principle of beneficence itself since translational research and scientific markers are needed. Moreover, concern exists about how explicit information can be conveyed in a manner that will not unethically manipulate patients' understanding and choices (Annoni, 2018; Annoni & Miller, 2016). Finally, the lack of guidance concerning the framing the informed consent process while managing patient expectations is a concern (Miller & Colloca, 2011).

Conclusion

It is reasonable to assume that the use of placebo in sport medicine has been very widespread. This commonplace assumption is supported by an older medical ethical perspective that placed significant emphasis on the principle of paternalism - acting in the

patient's interest – without a broader evaluation of the relations that pertained between respect for autonomy, non-maleficence and beneficence. It may well be that deceptive placebos did more harm than good though it is unlikely we could ever know this. Given that absence of evidence, and the rising acknowledgement of respect for patient autonomy as a central principle of clinical professionalism, there will be a need to explore further the balance between ethics and efficacy in, for example, the use of open label placebo. Clearly, the resultant ethical evaluation will benefit from a stronger scientific body of evidence concerning its effects, both negative and positive.

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