The Placebo Effect and Medical Instruments in Biofeedback

IAN WICKRAMASEKERA, Ph.D.
Peoria School of Medicine
University of Illinois College of Medicine
Peoria, Illinois

This article defines a "placebo effect" and identifies some of its parameters in pain control and in other areas of medicine. It proposes a new model of the placebo effect and advances the hypothesis that biomedical instruments used in biofeedback studies, like drugs, can acquire and generate placebo effects. Such placebo effects can complicate the interpretation of specific experimental treatments in human clinical research in which biomedical instruments are used.

Key Words: Placebo Effect, Biofeedback, Patient Compliance.

Introduction

Currently, psychological factors in medicine and, more specifically, in pain control are regarded as nonspecific, and have been loosely lumped together under the title of the "placebo effect." It is the primary hypothesis of this article that biomedical instruments, like "pills," have powerful placebo effects. The first part of this article discusses the placebo effect. In the second part, the author discusses how biomedical instruments can acquire placebo properties in biofeedback studies.

Placebo Effect

The "placebo effect" relates to those "nonspecific variables" which have unreliably influenced the outcome of an intervention (drug, surgery, or psychotherapy). The variables are regarded as nonspecific because, in controlled research, they are not found to reliably and durably influence the outcome of an intervention. These nonspecific variables do not appear to be logically related to the known etiology of the disease or condition. Further, both the nature of these nonspecific variables and the mechanism of their action have been uncertain.

A "placebo" is defined as: "Any therapy, or the component of any therapy, that is deliberately used for its nonspecific, psychological, or psychophysiological effects, or that is used for its presumed specific effect on patient, symptom, or illness, but which, unknown to the patient and therapist, is without specific activity for the condition being treated" (27). Placebos have been known to be more powerful than, and to reverse the action of, potent active drugs (27). Placebos can have powerful effects on organic illness and malignancies, and can even mimic the effects of active drugs (27,29). For example, studies have found that "dose-response" and "time-effect" curves for an active drug and a placebo are similar, and that the side effects of a placebo and an active drug may be similar (10). Further, the effects of a placebo and an active medication may interact and become additive. For example, Lasagna, et al., (19) found in 1954, that for placebo non-responders, a standard dose of morphine was only 54% effective, but for placebo responders, morphine was 95% effective.

Management of Pain

Specifically with respect to the management of pain, Beecher reviewed 15 double-blind studies of severe clinical pain (3). He found that a placebo reduced the pain by at least half of its original intensity in 35% of the patient population. Evans (11), reviewed 11 double-blind studies, and found that clinical pain was reduced by half of its original intensity in 36% of the patients.

In 1974, Evans found that a review of seven studies indicated that a placebo was 56% as effective as a standard dose of morphine, which is a powerful analgesic. In a review of ten studies, he found that a placebo was 54% as effective as aspirin and 56% as effective as Darvon. The latter is, of course, an analgesic of intermediate strength. He concluded that the effectiveness of a placebo as compared to a standard dose of any analgesic is a constant under double-blind conditions. In other words, if a therapist believes he is administering a strong drug, a strong placebo effect is obtained. If he believes he is ad-
ministering a weak drug, a weak placebo effect is obtained. The strength of the placebo effect is, among other things, related to the therapist’s belief. The patient may infer from the therapist’s verbal and nonverbal behavior the degree of confidence the therapist has in the medicine he is prescribing.

The mechanism through which the placebo effect exerts its influence on clinical pain is unknown; but, there appears to be good consensus among authorities that the mechanism is psychological in nature.

The Placebo Effect as a Conditioned Response

It is proposed that the placebo per se, the context in which it is administered, and the individual administering it, may come to function for the patient as a stimulus for conditioned recovery from discomfort or pain. In other words, classical and operant conditioning that may occur during the course of the individual’s history of social learning may, through association, establish “medical” stimuli as a conditioned stimuli for recovery from pain. For example, pills, injections, white coats, hospitals, surgery, doctors, nurses, etc., can become conditioned stimuli or discriminative stimuli for relief from pain, dysfunction, or illness. These conditioned or discriminative stimuli may have, in the past, been associated with events or specific ingredients that were active in the relief of pain or illness.

Contemporary research on conditioning and learning demonstrates that interstimulus intervals are not immutable particularly with human subjects (17). There are some controlled experimental observations (8, 12, 13, 25, 36, 37) in animal preparations to support the view that neutral stimuli can, through association, elicit complex biological and biochemical changes, as postulated by the conditioned-response model of the placebo effect. Pavlov (22) himself suggested that the administration of a drug can be viewed as a conditioning trial with environmental cues present at the time of drug administration as the conditioned stimuli, and the active pharmacological stimulation as the unconditioned stimulus.

This view regards the placebo as a conditioned stimulus, which elicits the conditioned emotional response of hope (21). The learned cognitive components of this critical emotion may trigger the psychophysiological alterations and stimulate the energy mobilization that reduces the probability of anxiety, depression, and guilt. The nature of this conditioned placebo response is uncertain. It is probably a patterned psychophysiological reaction (26), which is subjectively labelled emotion. This conditioned-response mechanism, once acquired, probably becomes increasingly abbreviated and automatic. At acquisition, the conditioned placebo response may involve some degree of verbal media-
tion, but with increasing association, the verbal mediation may become so abbreviated as to be imperceptible. Developmentally, it may begin like what Spence and Taylor (28), and others (6, 15), describe as a “V” form of classical conditioning. The basis of this distinction is the degree of verbal mediation and volition involved in the conditioned response. The mechanism of the placebo probably is most effective when, in the “C” stage, it increasingly involves a bypass of the dominant or verbal hemisphere.

There is increasing evidence (2, 14, 16, 18) that “hypnotizability” or suggestibility is a right hemisphere (nondominant) function. There is a high probability that under low-arousal conditions (1, 24), or high-arousal conditions, most people will inhibit or bypass the critical analytic functions of the dominant verbal hemisphere. They will tend to shift to more holistic, diffuse, simultaneous, or “primary process” modes of mentation.

In terms of the present model, the strength of the placebo response is hypothesized to be primarily a function of the following variables:

1. Credibility of the therapist.
2. The credibility of the placebo.
3. The credibility of the setting in which the placebo is administered.
4. The credibility of the administration ritual.
5. The level of arousal of the patient (low or high).
6. The patient’s level of attention to the placebo elements.
7. The baseline suggestibility of the patient.

Placebo and Biomedical Instruments

Credibility refers to the magnitude and durability of an expectancy or belief. This paper presents the hypothesis that medical instruments have as much credibility today as pills and medicines. Medical instruments probably mobilize as much faith and trust as other medical paraphernalia. Hence, it is very likely that many patients and therapists will approach the instruments, each other, and biofeedback rituals with positive expectancies—interest, warmth, and a strong motivation to make the therapy work. In addition, the biofeedback instruments themselves, and the rituals of graphing and charting, recall the hard physical and medical sciences, and in doing so, increase the probability that there will be discriminative or conditioned stimuli for hope and even recovery. The conditioned stimuli or discriminative stimuli can come to elicit conditioned responses for healing. This statement is not to imply that biofeedback procedures do not have specific or active ingredients, but it is important to recognize that they also have the active ingredients for a powerful placebo. In one sense, arranging the active ingredients for a
powerful placebo is equal to arranging the preconditions for high motivation in clinical subjects. Patient compliance is an essential pre-condition for the activity of “specific effects.”

Biofeedback and Increased Suggestibility

Any form of low-arousal training (biofeedback, transcendental meditation, etc.) appears to increase suggestibility. In 1971, Wickramasekera demonstrated that EMG feedback training significantly increased the “hypnotizability” of previously unresponsive subjects (32). In 1973, (again in the context of EMG feedback) the previous observations were replicated in a double-blind study (33). This author hypothesized that the induction of a state of low arousal was the mechanism through which hypnotizability was increased. Two 1974 studies (35, 34), elaborated on the hypothesis that low-arousal training increases the pliability or plasticity of cognitive-imaginal events and potentiates the verbal control of complex human behavior. The former study dealt with chronic rheumatoid arthritis pain (unpublished); the latter was a published case study dealing with cardiac neurosis. In 1975, Melzack and Perry reported a study of severe, chronic, clinical pain, in which a combination of suggestion and feedback variables was found to be more effective than the feedback variable alone (20).

To the extent that biofeedback training involves low arousal and sensory restriction conditions, it may potentiate “hypnotizability” and increase the probability of placebo effects.

In medical or psychological therapy with human subjects, the patient’s compliance with treatment procedures is critical to a positive outcome. Even active or specifically effective ingredients in the treatment may be ineffective if the patient does not follow treatment procedures (for example, if he does not take his medicine at the right time, in the right quantity, etc.). In medical literature, this problem has been termed the patient compliance problem.

The importance of the patient’s attitude toward therapy is also documented in the placebo literature. The placebo literature has shown that the known properties of active or specifically effective medications can be negated or reversed through the use of negative suggestions and negative context cues. The biofeedback literature has also produced evidence of the importance of patient compliance with the home practice of relaxation for the reduction and continued remission of headache pain (4, 5, 7, 9, 23, 30, 31).

In typical biofeedback studies, we have no information about baseline suggestibility or “hypnotizability” of headache patients, either within or outside of a hypnotic induction procedure. In addition, we also have little or no systematic information about what type of “verbal or imaginal” activity occurs in the patient’s mind before, during, and after therapy, in terms of self-statements, inferences, images, and treatment-related fantasies. When such information is available, and when it is used systematically, the placebo effect can be mobilized to support and sustain the “specific” learning effects of biofeedback.

Conclusion

It is predicted that the placebo effect, which has plagued drug research, will increasingly influence any human study in which medical instruments are used. Fortunately, progress in understanding the mechanism of the effect may enable us to design experiments with improved controls for the placebo effect. Increased understanding of the conditions under which the effect is potentiated and attenuated may enable us to use the effect to reduce the clinical problem of patient compliance.

REFERENCES


Address for Reprints: Ian Wickramasekera, Ph.D., 300 E. Memorial Drive, Peoria, Illinois 61614.

**BIOGRAPHY: I. WICKRAMASEKERA**

Ian Wickramasekera, Ph.D., is Assistant Professor of Psychiatry at the Peoria School of Medicine, University of Illinois College of Medicine, and also conducts a private practice. He is a diplomate of the American Board of Examiners in Hypnosis, a Clinical Fellow of the Behavior Therapy and Research Society, and President of the Illinois Biofeedback Society. Recently, he has completed a book, *Biofeedback Behavior Therapy and Hypnosis*. Dr. Wickramasekera serves as a consultant to several psychological, psychiatric, and medical journals and institutions, including the Veterans Administration. His research interests include biofeedback, behavior therapy, hypnosis, and sexual and psychosomatic disorders.