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Placebo Physiology in Otolaryngology Practice

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Introduction

In every double blind study, the actual drug shows a % of effect. However, the placebo also shows a % of similar outcome. Sometimes it is as high as 50 percent. When the placebo shows a 50% benefit, the FDA dismisses the new drug. But is this a correct response [1]?

The purpose of this article is to discuss why placebos have the effect they do, and how to utilize those principles in Otolaryngology practice. By employing these principles, often, instead of taking 10 mg, perhaps only 5mg will be just as effective! Doctors and patients certainly appreciate if, instead of 2 weeks of therapy, maybe only one week may be sufficient. Knowing that stress delays surgical recovery is enough to making every doctor want to reduce their patient's stress [2,3].

The term placebo may immediately bring resistance and scorn from the viewer. In Justman's article, *The Lie that Comes True*, he argues against deliberately "tricking" patients with known placebos. By no means, is that the purpose of this article. Here, I state the known physiology to explain the surprising % of double blind patients that respond to the sugar pill, and how to apply those principles to every day practice. Surely there is no ethical reason not to engage the whole person in order to speed the healing process. Any otolaryngologist who performs surgery desires the best possible outcome for his or her patient. Nevertheless, the confusion exists – numerous articles similar to Justman's criticize doctors who specifically treat with a placebo. However here, I am recommending that the physiology of why they work can be a significant factor in the Otolaryngologist's armamentarium [4].

The term placebo itself is misleading and confusing. When a patient is connected to a biofeedback device that demonstrates the EMG output of the muscles being studied via a screen, she is asked to reduce that EMG output. When she sees the EMG amount, and she reduces the EMG output from 30 microvolts to 5, and the pain and spasm is reduced without medication, is that a placebo effect? When the painful TMJD is relieved by looking in the mirror to see the face, jaw and shoulders relax, is that placebo [5]?

In PubMed today the number of references reported:

- Placebo: 209,335
- Placebo Physiology: 94,985
- Placebo Effect: 82,182

When PubMed best match order is asked, Benefit of Placebo Therapy: then the number of references is 23,510.

Many of these peer reviewed articles discuss use of measured physiology, chemistry, and functional MRI to evaluate placebo effect.

A significant study by Preskom details the difficulties of evaluating psychiatric drugs based on dosage measured in the blood stream. Irrespective of the blood levels, approximately 1/3 of the patients responded to a dose, 1/3 of the placebo patients responded, and 1/3 of the patients did not respond to the medication/dosage. He recommends that all studies of Therapeutic Drug Monitoring consider these factors in evaluating any medication, and the need to recognize certain individual responses, as well as placebo mechanisms [6].

Definitions

The word placebo comes from Latin that means "I shall please."

Nocebo comes from Latin noceo means "I shall harm." Nocebo refers to adverse side effects unrelated to pharmacological action of the drug. For example, in placebo controlled studies, both the real drug or the placebo may report impotence, catching a common cold or increased appetite.

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Many “natural” products may report beneficial effects, but lack a full study. Often this is because a full double blind study has not been performed, therefore the FDA does not recommend this product for the disease. However, it is next to impossible to get funding for an OTC “natural” product that can’t be patented, where there is no profit to be had. For example, a patient takes Bromelain for chronic sinusitis, and reports his Rheumatoid Arthritis symptoms have improved. Is this placebo? However, once the study has been done, and objective evidence shows it’s mechanism of action, then the Bromelain’s benefit is no longer a placebo [2].

There are hundreds of actions that may be dubbed placebo. Humming to clear sinusitis. Hot tea before getting out of bed to reduce allergy. Smiling to prevent the common cold. However, when studies can be done, humming vibration stimulates nasal cilia movement; smiling reduces stress chemistry and increases immune response; hot green tea is rich in l-theonine that stimulates cilia and immunity, and hot liquids before getting out of bed raises body temperature and helps avoid the allergic response to sudden temperature changes that accompanies allergy [7,8].

After reviewing some of PubMed’s listing of 23,510 peer reviewed citations, I feel that the lessons of placebo therapy should include:

Fully detailed directions

When a migraine drug contained details of how it works, why it works and how to take it, the results were significantly superior to just handing over the pills. Knowing what and how a drug works, enables participation of the brain into the healing process [9].

Reduce stress chemistry

In one study, psychology tests predicted surgical outcomes by identifying stressed individuals. FMRI studies demonstrated the stress centers using more metabolism than the healing centers of the brain. It doesn’t seem to matter how stress is reduced; apparently the doctor’s favorite means – exercise, breathing, Tai Chi, dancing – most can be effective in speeding post-op healing by reducing stress chemicals [10].

The patient may be stressed remaining in bed post-op, and may be less stressed getting out of bed earlier, able to sit and watch TV comedies while eating ice cream.

Use biofeedback when possible

The mirror can be used to feed back to the patient if face, jaw, and shoulders are relaxed. The home blood pressure monitor can feed back if the therapy is reducing blood pressure. Measuring blood oxygen, finger temperature, blood glucose is useful.

Temporomandibular joint pain often is due to jaw opening to the side. When a straight vertical line is marked on the patient’s mirror, she can determine if the jaw opens in the midline, and then make corrections [11].

Smiling and humor

The benefits of these have been objectively measured and the physiology is well understood. Adding these to the healing will improve healing in almost any situation [12,13]. At many hospitals there are now two comedy channels for the patients [14].

When the brain heals

Currently we do not know all that the brain can do to heal. Most doctors have reported on unusual cases of healing: Eighty five year old Mrs. A, was expected to expire in January due to inoperable

cancer. Yet, she managed to survive until June, at the birth of her first grandchild, or the daughter’s wedding. Science has not yet explained all the miraculous cures at shrines and prayers. We do know that hypnosis may get a patient previously chair bound to walk.

In therapy, there is a device that reverses the leg or arms viewed by the patient in the device. The patient thinks she sees the impaired right leg. But the mirror device projects the normal left leg. When directed to move the impaired right leg, she clearly sees the left leg move, believing it is the right leg. However, often the doctor actually sees the impaired right leg showing movement! The brain does this.

In nearly every peer reviewed psychiatric journal there may be a case report of a significant medical condition that was cured by the psychologist or psychiatrist. The asthmatic patient resistant to therapy, now symptom free after psychotherapy. Why did the pain of fibromyalgia clear after psychiatric treatments? The brain did it [8]?

Action program

The patient is instructed to relax and take it easy. Or worse, “just live with it”. Mostly, this advice does not bring the brain into the healing process. But, if the patient is advised to apply heat (or cold) 20 minutes each day, or breathe in count four and out count six, for one minute every hour for four weeks, following that action program speeds healing and helps the healing power of the brain. Whatever the details of the action plan may be, this allows the brain to participate in the healing process.

The Tinnitus patient comes to the American Tinnitus Association meeting distressed and in tears. She was diagnosed Tinnitus and told to just live with it. But the patient advised to follow the recommendations of the Otolaryngology Academy Program of masking, cognition, and stress reduction has a set of actions to follow that can be successful [15].

Cognitive therapy

What is migraine? What is TMJD? What is Tinnitus? When these conditions are clearly defined with simple explanations and pictures, then the healing powers of the brain can enter into the healing. In one report, cognitive therapy significantly reduced migraine headaches.

Discussion

Every year, suicide by Tinnitus patients is reported. Would those suicides have happened if an action program had been prescribed?

The identical twins with identical acute illness. Jim heals in one week. Brother Joe takes two weeks. Did Jim have less stress somehow? Did Joe follow the doctor’s program of warm compresses?

The patient returns home after a thorough examination by her doctor. Her husband asks, “What did the doctor say?” She answers, “He didn’t say anything.” Here, there is little chance of the brain taking part in the healing.

There are various schools of psychology, and thus different methods that are used. Most studies report that nearly every method works equally, depending mostly on the skill of the individual psychologist.

The group in New York studies the new drug and report that 45% of the patients felt better from the drug. However, the group in Los Angeles reported 85% of patients felt better. Why the difference? Turns out that the Los Angeles group demonstrated clearly when to take the pills and what exercises to perform in the program. The New

York group simply handed out a printed sheet of instructions.

Or, in a multicenter study, one group shows a 60% failure rate. But, the three other centers only show a 25% failure rate. Turns out that the directions were simply handed to the patients without emphasis or making certain that the directions were fully understood and followed.

Montefiore Hospital Headache department, reported that when a drug was being tested, if the patient was seen every week, they derived more benefit than the patients seen every two weeks. Similarly, patients seen every two weeks did better than patients seen every month.

The patients given a nurse's number to call for any questions, healed better than those not given that special number, and were more adherent to the program, even if they never made any such calls.

Is it placebo when you tell the child that she will get special ice cream when she gets home after her tonsillectomy? Or is it good medicine? Doesn't it reduce stress and anxiety when the emphasis and assurance is that she will be coming home?

Double Blind Study

Typically the patients are given the same background evaluation. Which patient gets the real pill and which gets the placebo is unknown to the examiners.

Patients are chosen based on specific ills – say cardiac irregularities with hypertension.

The mechanism of the pill is thoroughly explained. "In the body there is a beta adrenergic system that raises blood pressure and excites the heart excessively. This pill blocks that system sufficiently to improve heart function. Take one pill in the morning with a full 4 ounces of water – we provide a measuring cup. Check your blood pressure at 8 AM, noon, and in the evening at seven. Record the pressure on this form. No change in diet or other actions is needed. Here is a phone number to call if you have any questions. If your blood pressure is below 90/60 call that number. Any questions?"

Note: Full explanation. Exact actions to follow. Full opportunity to contact advisors. Cognition with explanation of hypertension. Little wonder that 10% of the placebo patients had excellent results on the placebo. But, in one group, 16% of the placebo patients had this benefit. Here, instead of handing out a phone number, nurse Adrianna, in uniform, was introduced as the person to call anytime. She personally spoke to each of the participants, explained any concerns, etc. A 16% benefit because the mind entered into the healing process enabled 16% of the patients to improve on the placebo!

Conclusion

PubMed lists, under Benefit of Placebo Therapy, some 23,510 references. Essentially these include:

- Smiling and Humor
- Cognition

- Stress Reduction
- Action Program
- Biofeedback
- Bringing in Brain Healing

All doctors want the best for their patients. I believe that applying the known principles of placebo therapy will aid in this endeavor. I do not recommend specifically using placebos; my goal is to apply physiology to every day therapy by understanding how they work.

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