Sham treatment

In a sham treatment, some people get the real treatment while others get the sham treatment. Then the results are compared.

When a person who is taking the inactive substance or who has had a sham treatment reports that symptoms have improved, this improvement is called the placebo effect. It is probably a result of the brain releasing “feel-good” hormones such as endorphins in response to treatment. Active drugs and therapies can also have a placebo effect. It can be difficult for researchers or doctors to know if the reason a drug works is because of its active ingredient or because of the placebo effect.

Regulations govern studies that use placebos or sham treatments. These studies are always done with the participants' consent.

As compared with no therapy, physiotherapy following first-time disc herniation operation is effective in the short-term. Because of the limited benefits of physiotherapy relative to “sham” therapy, it is open to question whether this treatment acts primarily physiologically in patients following first-time lumbar disc surgery, but psychological factors may contribute substantially to the benefits observed [1].

Gu et al., conducted a systematic search for randomized controlled clinical trials comparing any type of surgery to a corresponding sham placebo group and compared improvements in the sham treatment arms in subjective, objective, categorical and continuous outcomes, as well as complication rates and mortality. Effect sizes were reported as standardized mean differences (SMD).

The overall effect size for pain improvement following sham surgery was SMD=0.22 (95%CI=0.08-0.35) with improvement most marked at 1-month (SMD=0.34, 95%CI=0.26-0.43). There was a higher rate of improvement in subjective outcomes compared to objective outcomes for both dichotomized (number of patients with improvement) (42.8% compared to 27.1%) and continuous outcomes (SMD=0.12, 95%CI=-0.05-0.30 versus SMD=-0.01, 95%CI=-0.05-0.03). There were no deaths in the sham treatment arms and major complications were very rare (0.2%, 95%CI=0.0%-0.6%).

Sham surgery is associated with a large improvement in pain and other subjective patient reported outcomes but with relatively small effect on objective outcomes. Sham surgeries are overwhelmingly safe. The magnitude of this effect should be used when planning future sham-controlled surgery trials [2].

1)
Erdogmus CB, Resch KL, Sabitzer R, Müller H, Nuhr M, Schöggl A, Posch M, Osterode W, Ungersböck K, Ebenbichler GR. Physiotherapy-based rehabilitation following disc herniation operation: results of a randomized clinical trial. Spine (Phila Pa 1976). 2007 Sep 1;32(19):2041-9. PubMed PMID: 17762803.
2)
Gu AP, Gu CN, Ahmed AT, Murad MH, Wang Z, Kallmes DF, Brinjikji W. Sham surgical procedures for pain intervention result in significant improvements in pain: Systematic-review and meta-analysis. J Clin Epidemiol. 2017 Jan 4. pii: S0895-4356(16)30851-4. doi: 10.1016/j.jclinepi.2016.12.010. [Epub ahead of print] PubMed PMID: 28063914.