What do US orthopaedic surgeons think about placebo-controlled surgical trials?

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INTRODUCTION

Randomized placebo controlled trials are the gold standard for testing treatment efficacy, but are rarely used for evaluating orthopedic surgeries (Harris, 2016; Louw et al., 2017; Wartolowska et al., 2014). We queried attitudes among orthoepdic surgeons of placebo controlled surgery studies where patients are randomized to a real surgery condition or a sham-surgery condition.

Question 1
How ethical is a placebo controlled surgery study?

Imagine a researcher wants to test the effectiveness of a particular orthopaedic surgery related to joint pain. Previously, a Randomized Clinical Trial (RCT) showed the surgery moderately outperformed Physical Therapy. Now the researcher wants to compare the real surgery to a placebo surgery in a second RCT. The placebo surgery condition mimics all aspects of the real surgery condition (e.g. anaesthesia, incision, etc.), but without the essential therapeutic manoeuvre. Patients provide informed consent, and know they will receive either the real surgery or placebo surgery, but are blind to condition.

Do you think this is ethical?

Response options from completely unethical to completely ethical

Question 2
How valuable is a placebo controlled surgery study?

You are considering whether to integrate a new surgery into your clinical practice. Rank the following pieces of evidence from which you would value the most (1) to the least (5).

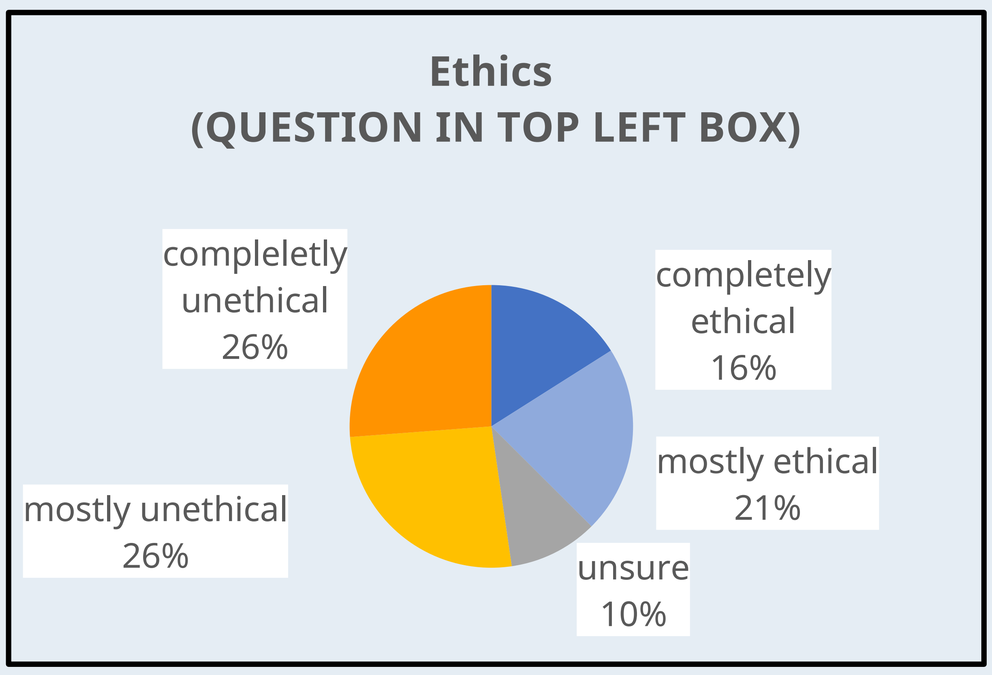
Note: Order below determined randomly

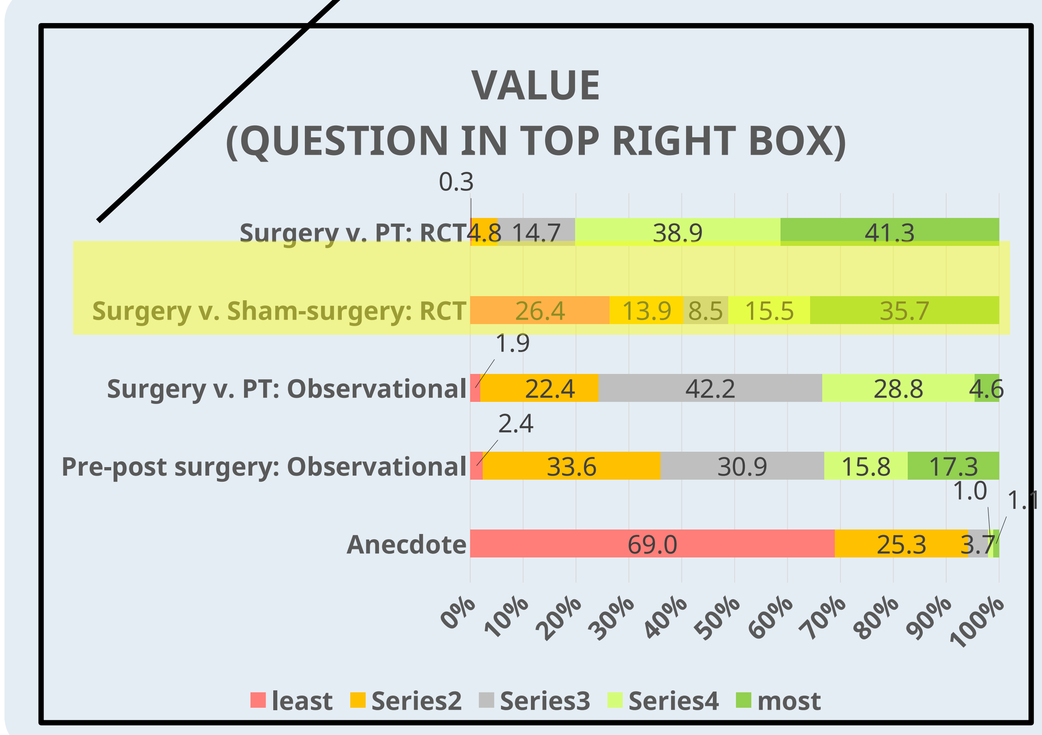
- A study shows that patient outcomes are better after versus before the surgery. (Pre-post surgery: Observational)
- A study shows that patients who choose to undergo the surgery have better outcomes than patients who choose to undergo physical therapy. (Surgery v. PT: Observational)
- A study shows that patients randomized to undergo the surgery have better outcomes than patients randomized to undergo physical therapy. (Surgery v. PT: RCT)
- A case study is written suggesting that a well-respected surgeon had good success with the surgery. (Anecdote)
- A study shows that patients randomized to undergo the surgery have better outcomes than patients randomized to undergo a placebo surgery. (Surgery v. Sham-surgery: RCT)

Randomized Placebo Controlled Surgery Design

Methods and Results

- A survey was distributed to 15,700 orthopedic surgeons across the U.S.
- 687 responded (response rate=4.4%). 93% male, 87% White, *M* age=57.4 (*SD*=11.6)
- Two relevant questions are displayed in **boxes above**
- Corresponding results are displayed in **boxes below**





Conclusion/Summary

- Mixed ethical views with a slight majority (52%) viewing placebo-controlled surgery trials as unethical
- The value of placebo-controlled surgery trials was polarizing, with 26% viewing it as the *least* valuable (even less so than an anecdote) and 36% viewing it as the *most* valuable
- It is unlikely that surgeries will be subject to the most rigorous type of experimental design in evaluating efficacy so long as many surgeons hold the attitudes observed here

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