

Could the *New England Journal of Medicine* Be Biased Against Arthroscopic Knee Surgery? Part 2

First, let us start by being explicit: the title of this editorial is rhetorical. The *New England Journal of Medicine* is biased against arthroscopic knee surgery.

Last month¹ we reported that ElAttrache and Lubowitz wrote a letter to *NEJM* criticizing their publication, "Arthroscopic Partial Meniscectomy Versus Sham Surgery for a Degenerative Meniscal Tear" by Sihvonen et al.² To review, ElAttrache and Lubowitz concluded their letter to *NEJM* as follows:

Disturbingly, in the 21st century, the *NEJM* has published only 4 original scientific articles on knee arthroscopy,²⁻⁵ all with "negative" results, while refusing to even consider for review submitted Level I evidence demonstrating good results.⁶

Could the *New England Journal of Medicine* be biased against arthroscopic knee surgery?

As we have said in editorials, and specifically last month, we believe "controversy demands debate, not bias."^{1,7} However, the *NEJM* decided to restrict academic deliberation. Worse yet is the explanation from the *NEJM* that the rejection of the ElAttrache and Lubowitz's letter to the editor was because of "lack of space."

Here's what happened next. In the spirit of healthy debate, Dr. Lubowitz wrote a note of appeal, reiterating to the editors of the *NEJM* that the *NEJM* was being accused of bias, and inquiring as to whether the *NEJM* might wish to reconsider their decision to limit the discussion. Lubowitz recommended to the *NEJM* that they find the space for the letter (of fewer than 175 words), and to address the accusation of bias in press, openly, and in an academic manner.

To which, the *NEJM* replied:

With respect to your concern that we are biased against arthroscopic surgery: We carefully evaluate all manuscripts submitted to us, including attention to methodologic strengths and weaknesses. We have not yet seen a carefully conducted sham-controlled trial that has shown a benefit of surgery; we would be pleased to have the opportunity to consider such a trial.

Sincerely,

Caren Solomon

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And there the matter rests.

While we do not condone the *NEJM* for rejecting controversial academic debate due to "lack of space," we now understand that they prefer sham-controlled trials. However, we wish to make the following points.

1. The recent *NEJM* article by Sihvonen et al.² is not a sham-controlled trial. The title of the article in question, "Arthroscopic Partial Meniscectomy Versus Sham Surgery for a Degenerative Meniscal Tear," is deceptive and misleading. The control group did not have sham surgery. The control group had knee arthroscopy and lavage, a powerful and effective treatment for diverse pathological knee conditions. Knee arthroscopic surgical lavage is not a sham, and knee arthroscopic surgical lavage is not a placebo.^{1,8,9}
2. Ethically, sham surgery is a questionable research method, when safer alternative methods exist for treatment of a control group. Physicians take an oath to do no harm. However, anesthetizing and cutting a research subject, without providing a therapeutic intervention, may be harmful, where the potential risks to the research subject may outweigh the benefits. As above, other control methods (e.g., oral, topical, or injectable analgesics, physical therapy) may be compared with surgical intervention, while at the same time providing a safer risk-to-benefit profile for the research subject. Moreover, there is also the alternative control of no treatment. In our zeal to answer scientific questions, we must not lose sight of the fact that human research subjects are our patients, to whom we swear an oath to do no harm.
3. Speaking frankly, sham surgery seems ludicrous. Really, what patient in his or her right mind, no matter how well intentioned to participate in research, would consent to sham surgery? We would not consent to the possibility of anesthesia and sham surgery, nor do we believe our right-minded patients would do so. We have a concern that methods of sham surgical trials result in selection bias,¹⁰ where patients who may not be of entirely sound mind are selected as research subjects, and research performed on such individuals would not be generalizable to mentally healthy patients.

Perhaps the *NEJM* has fallen into a trap set by the US Food and Drug Administration, which according to the *Wall Street Journal*, encourages sham surgical trials.¹¹

We suspect that those at the FDA and the *NEJM* who recommend sham surgery are not ethical surgeons, and we agree with Dr. Scott Gottlieb, who writes in the *Wall Street Journal*,

...research that introduces harm or risk with no opportunity for benefit would seem to conflict

with the principles governing research on humans. Some of these are reflected in the Declaration of Helsinki, an international treaty concerning the conduct of medical research. Other experiments using sham surgeries are obligating patients to undergo unnecessary anesthetics, radiation, abdominal incisions, endoscopy and injections into the rectum, to mention a few examples. The needless cutting means pain as well as the risks of anesthesia and infection...

This can suppress innovation. When a sham trial doesn't produce positive results, the company may have exhausted its resources and have no capital left to refine a good idea into a beneficial product.

Instead of clinging to inflexible testing requirements, the FDA should allow trials that are feasible, reflect clinical practice, and are morally defensible. There are methods for evaluating science that don't require such contrived experiments on people. The agency doesn't need to rely on research models that raise the opportunity costs so high that some valuable treatments or devices may never become available to patients.¹¹

Readers can draw their own conclusions, but we believe that sham surgical trials may themselves be a sham. The results of sham surgical trials should be interpreted with extreme caution.

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