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Study finds common knee surgery no better than placebo

HOUSTON--(July 10, 2002)--Patients with osteoarthritis of the knee who underwent placebo arthroscopic surgery were just as likely to report pain relief as those who received the real procedure, according to a Department of Veterans Affairs and Baylor College of Medicine study published in the July 11 New England Journal of Medicine.

The researchers say their results challenge the usefulness of one of the most common surgical procedures performed for osteoarthritis of the knee.

"The fact that the effectiveness of arthroscopic lavage or debridement in patients with osteoarthritis of the knee is no greater than that of placebo surgery makes us question whether the one billion plus dollars spent on these procedures might not be put to better use," said lead investigator Dr. Nelda P. Wray, a health services researcher at the Houston VA Medical Center and at Baylor.

In the study, 180 patients with knee pain were randomized into three groups. One group received debridement, in which worn, torn, or loose cartilage is cut away and removed with the aid of a pencil-thin viewing tube called an arthroscope. The second group underwent arthroscopic lavage, in which the bad cartilage is flushed out. The third group underwent simulated arthroscopic surgery; small incisions were made, but no instruments were inserted and no cartilage removed.

Dr. Bruce Moseley, a clinical associate professor of orthopedics at Baylor, recruited all the patients in the study and performed all surgeries, both real and placebo. Dr. Baruch Brody, director of the Center for Medical Ethics and Health Policy at Baylor, was instrumental in assessing the ethical issues involved in the study and in developing the stringent consent process for the study.

Of the 324 participants who met inclusion criteria for the study, 44 percent declined to participate, demonstrating they understood that they might not receive the actual surgery. Before undergoing surgery, participants also wrote in their chart, "On entering this study, I realize that I may receive only placebo surgery. I further realize that this means that I will not have surgery on my knee joint. This placebo surgery will not benefit my knee arthritis."

During two years of follow-up, patients in all three groups reported moderate improvements in pain and ability to function. However, neither of the intervention groups reported less pain or better function than the placebo group. Indeed, the placebo patients reported better outcomes than the debridement patients at certain points during follow-up. Throughout the two years, the patients were unaware of whether they had received real or placebo surgery.

In past clinical trials of arthroscopic knee surgery, the majority of patients reported pain relief. Though others have suggested that improvement results from flushing out of the knee joint or the removal of cartilage, these studies did not compare the actual procedures to placebo. The authors of the new study say their findings raise
questions about what really causes the improvements seen with lavage or debridement. Their results suggest the same therapeutic benefits may be achieved through non-invasive placebo surgery. Osteoarthritis, a degenerative joint disease, is the most common form of arthritis, and commonly occurs in the knee. Symptoms include pain, stiffness, and swelling. Treatment typically involves pain-relieving and anti-inflammatory drugs, along with heat-therapy and exercise. When these fail, surgery is often recommended. In the United States, it is estimated that more than 650,000 arthroscopic debridement or lavage procedures are performed each year, many of these for arthritis, at a cost of about $5,000 each.

"This study has important policy implications," Wray said. "We have shown that the entire driving force behind this billion dollar industry is the placebo effect. The health care industry should rethink how to test whether surgical procedures, done purely for the relief of subjective symptoms, are more efficacious than a placebo."
The research was funded by VA and conducted through the agency's Houston Center for Quality of Care and Utilization Studies, based at the Houston VA Medical Center. The Center is co-funded by the department of medicine at Baylor.