A popular operation for arthritis of the knee worked no better than a sham procedure in which patients were sedated while surgeons pretended to operate, researchers are reporting today.

The operation -- arthroscopic surgery for the pain and stiffness caused by osteoarthritis -- is done on at least 225,000 middle-age and older Americans each year at a cost of more than a billion dollars to Medicare, the Department of Veterans Affairs and private insurers.

It involves making three small incisions in the knee; inserting an arthroscope, a thin instrument that allows surgeons to see the joint; and then flushing debris from the knee or shaving rough areas of cartilage from the joint and then flushing it.

In the study, to be published today in The New England Journal of Medicine, investigators at the Houston Veterans Affairs Medical Center and Baylor College of Medicine report that while patients often said they felt better after the surgery, their improvement was just wishful thinking. Tests of knee functions revealed that the operation had not helped, and those who got the placebo surgery reported feeling just as good as those who had had the real operation.

"Here we are doing all this surgery on people and it's all a sham," said Dr. Baruch Brody, an ethicist at Baylor who helped design the study.

But Veterans Affairs Department officials stopped short of saying they would no longer pay for the surgery. Medicare and private insurers typically review such studies before deciding whether to change their reimbursement practices.

The 180 participants in the study were randomly assigned to have the operation or to have placebo surgery in which surgeons simply made cuts in their knees so the patients would not know if they had the surgery.

After they recovered from the procedures, most patients said their knee pain had improved, and they continued to say they were better for the two years that the researchers followed their progress. But Dr. Nelda P. Wray, chief of health services research at Baylor, said, "On the objective scale, no one was better at any time point."

Some orthopedists interviewed about the study said they had wondered for some time about the operation's effectiveness. Dr. Kenneth Fine, an orthopedic surgeon at the George Washington University School of Medicine, said the procedure had long seemed to do nothing for patients' underlying arthritis.
The research began when an orthopedic surgeon at the Houston veterans' hospital, Dr. J. Bruce Moseley approached Dr. Wray suggesting a study that would compare washing the knee joint with washing and scraping in patients with arthritis. Dr. Wray had a bolder idea.

"She said, 'How do you know that what you are seeing is not a placebo effect?' " Dr. Moseley recalled. "My response was, 'This is surgery.' She said, 'I hate to tell you this, but surgery may have the biggest placebo effect of all.' "

Placebo studies of surgery are almost never done. Many doctors consider them unethical because patients could undergo risks with no benefits. Working with Dr. Brody, the ethicist, the group tried to make the placebo treatment no more dangerous than daily life. Still, of 324 consecutive patients who were asked to participate, 144 declined.

For those who agreed, the day of surgery meant being wheeled into an operating room while neither they nor any of the medical staff knew what their treatment would be. When they were on the operating table, Dr. Moseley, who did all the operations, opened a sealed envelope telling him whether the patient was to have the surgery or not.

Those in the placebo group received a drug that put them to sleep. Unlike those getting the real operation, they did not have general anesthesia.

Dr. Moseley made small cuts in their knees to simulate an operation. He bent and straightened the knee and asked for surgical instruments, just in case the patient was partly conscious. An assistant sloshed water in a bucket to make the sound of a knee being flushed clean.

The paper in The New England Journal is accompanied by two editorials. One, by Sam Horng and Dr. Franklin G. Miller of the National Institutes of Health, asks whether placebo surgery is unethical. The controversy, they wrote, comes because doctors assume that patients in clinical research should not be put at risk if they cannot benefit, and placebo surgery involves risk.

But, they say, clinical research is different from medical therapy; its aim is not to help those in the study but to help future patients.

To be ethical, they say, a study with placebo surgery must meet three criteria: it must not place patients at undue risk; the benefits of learning whether the surgery works must be worth any potential risk to the patients; and the patients must give informed consent.

In the current case, they wrote, all those objectives were met and the study "exemplifies the ethically justified use of placebo surgery."

"Although the study may not have been large enough to permit the detection of any small effects," they wrote, "the data presented do not suggest that there were any,"