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A Randomized Trial of Arthroscopic Surgery for Osteoarthritis of the Knee

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ABSTRACT

BACKGROUND

The efficacy of arthroscopic surgery for the treatment of osteoarthritis of the knee is unknown.

METHODS

We conducted a single-center, randomized, controlled trial of arthroscopic surgery in patients with moderate-to-severe osteoarthritis of the knee. Patients were randomly assigned to surgical lavage and arthroscopic débridement together with optimized physical and medical therapy or to treatment with physical and medical therapy alone. The primary outcome was the total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score (range, 0 to 2400; higher scores indicate more severe symptoms) at 2 years of follow-up. Secondary outcomes included the Short Form-36 (SF-36) Physical Component Summary score (range, 0 to 100; higher scores indicate better quality of life).

RESULTS

Of the 92 patients assigned to surgery, 6 did not undergo surgery. Of the 86 patients assigned to control treatment, all received only physical and medical therapy. After 2 years, the mean (\pm SD) WOMAC score for the surgery group was 874 ± 624 , as compared with 897 ± 583 for the control group (absolute difference [surgery-group score minus control-group score], -23 ± 605 ; 95% confidence interval [CI], -208 to 161 ; $P=0.22$ after adjustment for baseline score and grade of severity). The SF-36 Physical Component Summary scores were 37.0 ± 11.4 and 37.2 ± 10.6 , respectively (absolute difference, -0.2 ± 11.1 ; 95% CI, -3.6 to 3.2 ; $P=0.93$). Analyses of WOMAC scores at interim visits and other secondary outcomes also failed to show superiority of surgery.

CONCLUSIONS

Arthroscopic surgery for osteoarthritis of the knee provides no additional benefit to optimized physical and medical therapy. (ClinicalTrials.gov number, NCT00158431.)

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OSTEoarthritis of the knee is a degenerative disease that causes joint pain, stiffness, and decreased function.¹⁻³ Treatment is multidisciplinary and involves physical therapy, medication, and surgery. Arthroscopic surgery, in which an arthroscope is inserted into the knee joint, allows for lavage, a procedure that removes particulate material such as cartilage fragments and calcium crystals. It also allows for débridement, whereby articular surfaces and osteophytes can be surgically smoothed. The goal of this procedure is to reduce synovitis and eliminate mechanical interference with joint motion.

Although arthroscopic surgery has been widely used for osteoarthritis of the knee, scientific evidence to support its efficacy is lacking.⁴ No benefit of surgery was shown in a large-scale, randomized, controlled trial reported in the literature.⁵ However, the methods used in that study have been questioned,⁶⁻¹¹ and the authors' conclusion that arthroscopic surgery is ineffective for the treatment of moderate-to-severe osteoarthritis of the knee has not been generally accepted.¹²⁻¹⁴ Accordingly, the procedure remains widely used.¹⁵ We conducted a randomized, controlled trial to compare optimized physical and medical therapy alone with arthroscopic treatment in addition to optimized physical and medical therapy.

METHODS

PATIENTS

We conducted the trial between January 1999 and August 2007 at the Fowler Kennedy Sport Medicine Clinic, University of Western Ontario, London, Ontario, Canada. The investigators who assessed outcomes were unaware of treatment assignments. The protocol was approved by the institutional review board of the University of Western Ontario. All patients gave written informed consent.

Eligible patients were 18 years of age or older with idiopathic or secondary osteoarthritis of the knee^{16,17} with grade 2, 3, or 4 radiographic severity, as defined by the modified Kellgren–Lawrence classification.¹⁸⁻²⁰ Patients were excluded if they had large meniscal tears (“bucket handle” tears), as detected by clinical examination^{21,22} or, in a minority of cases, by magnetic resonance imaging. Other exclusion criteria were inflammatory or postinfectious arthritis, previous arthroscopic treatment for knee osteoarthritis, more than 5 degrees of varus or valgus deformity, previous

major knee trauma, Kellgren–Lawrence grade 4 osteoarthritis in two compartments (the medial or lateral compartments of the tibiofemoral joint or the patellofemoral compartment) in persons over 60 years of age, intraarticular corticosteroid injection within the previous 3 months, a major neurologic deficit, serious medical illness (life expectancy of less than 2 years or high intraoperative risk), and pregnancy. Patients who were unable to provide informed consent or who were deemed unlikely to comply with follow-up were also excluded.

BASELINE STUDIES

Patients referred to any of seven orthopedic surgeons were assessed for eligibility. The trial coordinator and one of two surgeons independently reviewed the diagnosis of osteoarthritis. Disagreements regarding eligibility, degree of malalignment (i.e., degree of varus or valgus deformity), and the Kellgren–Lawrence grade were resolved by consensus. Baseline scores on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC),^{23,24} the Short Form-36 (SF-36) Physical Component Summary,²⁵ the McMaster–Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR),^{26,27} and the Arthritis Self-Efficacy Scale (ASES)²⁸ and standard-gamble²⁹ utility scores were obtained. An orthopedic surgeon performed a detailed examination of the knee and documented the range of motion, the presence of an effusion, and the results of meniscal and stability tests.

STUDY TREATMENT

The patients were randomly assigned, with the use of a computer-generated schedule, to receive optimized physical and medical therapy alone (control group) or to receive both optimized physical and medical therapy and arthroscopic treatment. The randomization was stratified according to surgeon and disease severity (defined according to the Kellgren–Lawrence grade). To minimize the risk of predicting the treatment assignment of the next eligible patient, randomization was performed in permuted blocks of two or four with random variation of the blocking number. Both for patients assigned to surgery and for those assigned to control treatment, the date of treatment initiation was defined as the next available date of surgery.

Arthroscopic treatment was performed within 6 weeks after randomization with the patient under general anesthesia and with the use of a tour-

niquet and a thigh holder. The orthopedic surgeon evaluated the medial, lateral, and patellofemoral joint compartments, graded articular lesions according to the Outerbridge classification,³⁰ irrigated the compartment with at least 1 liter of saline, and performed one or more of the following treatments: synovectomy; débridement; or excision of degenerative tears of the menisci, fragments of articular cartilage, or chondral flaps and osteophytes that prevented full extension. Abrasion or microfracture of chondral defects was not performed.

Optimized physical and medical therapy was initiated within 7 days after surgery and followed an identical program in both groups. Physical therapy was provided for 1 hour once a week for 12 consecutive weeks. The intervention was standardized and based on a review of the literature and a formal survey of university physical therapists.³¹ Information regarding a home exercise program that emphasized range-of-motion and strengthening exercises was provided to all patients. Individualized exercises were recommended on the basis of the severity of osteoarthritis, the patient's age, and the patient's specific needs. Instruction was also provided regarding activities of daily living, walking, use of stairs, and methods of treatment involving cold and heat. The patients were asked to perform the exercises twice daily and once on the day of a scheduled physical-therapy session. After the patients had completed 12 weeks of supervised activity, they continued an unsupervised exercise program at home for the duration of the study. The patients received additional education from attendance at local Arthritis Society workshops, from a copy of *The Arthritis Helpbook*³² that was provided to them, and from an educational videotape.

After undergoing randomization, the patients reviewed their medical treatment plans with an orthopedic surgeon, and the plans were optimized according to an evidence-based treatment algorithm based on published guidelines² that recommended stepwise use of acetaminophen and nonsteroidal antiinflammatory drugs and intra-articular injection of hyaluronic acid. Hyaluronic acid and oral glucosamine were offered to the patients.

The patients were seen in the clinic 3, 6, 12, 18, and 24 months after the initiation of treatment. At each visit, the patients were evaluated by a nurse who was unaware of the treatment

assignment. To preserve blinding, each patient wore a neoprene sleeve over the knee so that the study nurse could not identify a surgical scar. Scores on the WOMAC, MACTAR, SF-36, and ASES questionnaires and standard-gamble utility scores were obtained at each visit. Medical treatment was reviewed at each visit, and treatment options were modified according to the algorithm. Records were kept of medical therapies used.

OUTCOME MEASURES

The primary outcome was the WOMAC score at 2 years after the initiation of treatment. The WOMAC is a validated, self-administered instrument specifically designed to evaluate knee and hip osteoarthritis. The WOMAC has subscales for pain, stiffness, and physical function. Total scores can range from 0 to 2400; higher scores indicate increased pain, increased stiffness, and decreased physical function.²³ Patients with moderate-to-severe osteoarthritis of the knee typically have a score of approximately 1000.^{24,33} A 20% improvement (typically, a decrease of about 200 points) in the total WOMAC score was considered clinically important.³⁴⁻³⁶ We also analyzed the three WOMAC subscales separately. The Physical Component Summary of the SF-36 was used to assess quality of life; scores can range from 0 to 100, with higher scores indicating better quality of life. The MACTAR and ASES are validated questionnaires that assess the symptoms and functional status of patients with osteoarthritis. MACTAR scores can range from 0 to 500; higher scores indicate greater disability. ASES scores can range from 10 to 100; higher scores indicate greater self-efficacy (i.e., perceived ability to cope with the consequences of arthritis). Health-related quality of life was assessed by the standard-gamble utility technique; scores can range from 0.0 (death) to 1.0 (perfect health).²⁹

STATISTICAL ANALYSIS

Baseline characteristics were analyzed by descriptive statistics. For the primary analysis, the total WOMAC score at 2 years was compared between the two study groups with the use of analysis of covariance, with adjustment for the baseline score and disease severity (as measured by the Kellgren-Lawrence grade). A two-sided P value of 0.05 was considered to indicate statistical significance. Post hoc analyses of the total WOMAC score were also performed at 3, 6, 12, and 18 months. Missing

