

Physical Therapy or Arthroscopic Surgery for Treatment of Meniscal Tears

Is Noninferiority Enough?

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Knee arthroscopy is among the most common surgical procedures performed worldwide. Each year, an estimated 500 000 meniscus procedures are performed in patients older than age 45 years in the United States and more than 2 million procedures are performed worldwide.^{1,2} Magnetic resonance imaging studies indicate that 60% of individuals without knee pain older than 50 years have evidence of meniscus degeneration, which often occurs in the presence of osteoarthritis (OA).³ In symptomatic patients, the clinical challenge is determining the cause for pain (meniscal, arthritic, or other reasons). With health care costs increasing throughout the world, scientific evidence should be used to determine the most effective and cost-effective regimens.

In this issue of *JAMA*, van De Graaf and colleagues⁴ report results of a randomized trial designed to determine whether physical therapy (PT) was noninferior to arthroscopic partial meniscectomy (APM). The authors enrolled 321 participants aged 45 to 70 years with degenerative meniscus tears without knee locking, instability, or severe OA and randomized them to receive APM or a PT protocol of 16 sessions over 6 weeks. The primary outcome measure was patient-reported knee function on the Subjective Knee Form of the International Knee Documentation Committee (IKDC) (scores range from 0-100, with higher scores indicating fewer symptoms and limitations) assessed from baseline and over the 24-month follow-up, with a noninferiority threshold of 8 points.

Over 24-month follow-up, mean knee function scores improved by 26.2 points (from 44.8 points to 71.5 points) in the APM group and by 20.4 points (from 46.5 points to 67.7 points) in the PT group. In the primary mixed-model analysis of the overall effect, the between-group difference was 3.6 points (97.5% CI, $-\infty$ to 6.5) in favor of APM, but met the criterion for noninferiority. The authors concluded that the trial results justify an initial conservative approach using PT in patients with degenerative meniscal tears.

Prior studies comparing arthroscopy vs PT have yielded mixed results. Patients with significant OA who have nondisplaced meniscus degeneration do not benefit from knee arthroscopy.⁵⁻¹⁰ Among these patients, arthroscopy is generally considered by orthopedic surgeons to be ineffective. However, patients with minimal or mild OA and meniscal pathology were previously considered reasonable surgical candidates. More recently, 6 randomized clinical trials (sample sizes,

17-340, for a total of 838 patients) that primarily enrolled patients with simple meniscus degeneration all showed no benefit of APM compared with nonsurgical treatment or sham surgery at up to 2-year follow-up.^{5-9,11} The benefits of arthroscopy are now being questioned and, in some situations, insurance coverage for the procedure has been rescinded if patients have not completed a course of PT.¹²

A systematic review and meta-analysis reported a similar conclusion.¹³ The data suggested a statistically significant, but clinically unimportant, benefit of APM for knee function and pain at 3- to 6-month follow-up compared with PT, with no difference at longer follow-up. Studies involving sham arthroscopy also concluded there was no difference between performing an APM vs creating arthroscopic portals (incisions) alone and other sham procedures.¹¹ However, these prior studies, as is the case with some randomized trials, were limited by selection bias because some patients who preferred surgery opted out of randomization. It is important to point out that these studies focused on degenerative meniscal tears. Displaced, obstructive (bucket-handle) type tears present an entirely different clinical problem. For patients with this clinical entity, APM was effective even in the presence of mild OA.¹⁴

Based on increasing evidence that patients with minimal or mild OA and a nondisplaced and nonobstructive degenerative meniscus tear may not benefit from APM compared with PT, why has the orthopedic community been slow to reduce APM?¹⁵ There are several possible reasons. First, if patients do not appear harmed and symptoms appear improved following surgery, surgeons will rely on their prior professional experience to anticipate surgical benefit, when there may be regression to the mean or a placebo effect, rather than benefit from the surgery.¹⁶ Second, community norms around the usefulness of the treatment may strengthen the perceived benefit of surgery or encourage continued use because surgery is standard of care among surgeons.¹⁷ Third, in a health care environment that continues to be based on volume, rather than outcomes or value, financial incentives exist to perform more procedures, sometimes to please the patient or enhance the surgeon's prestige or income.¹⁸ As long as insurance companies do not limit authorization for these procedures, APM may continue to be used in this patient population. However, the use of APM may change substantially if insurance companies are more restrictive in their coverage of these procedures.

The study by van de Graaf et al⁴ should be interpreted in the context of several limitations. The trial used a noninferiority trial design, which is appropriate because PT may have other advantages over APM, such as lower cost, noninvasive nature, and fewer adverse effects such as surgical complications.¹⁹ However, the choice of the noninferiority threshold, or margin, was suboptimal. The authors used the estimated minimum detectable change in the IKDC score from a study by Crawford et al.²⁰ However, this threshold was estimated from a patient group that was very different from the patients included in the randomized trial, and had shorter follow-up. Of note, the minimal detectable change in the study by Crawford et al²⁰ was estimated from patients who completed a preoperative and postoperative IKDC score after 12 months' follow-up (not 24 months as in the current study) and had different characteristics from the current study, including an older mean age (ages 18-81 years [mean, 47.9]), inclusion of multiple surgical procedure types (partial meniscectomy, repair, or articular cartilage shaving, and lack of confirmation of the presence of OA.²⁰ Therefore, the selection of the noninferiority threshold in the trial by van de Graaf et al has limitations. Given that the current randomized trial showed only a 5.8-point difference before and after surgery in

the intention-to-treat, unadjusted analysis, the threshold deserves careful scrutiny and probably should have been lower to be more confident about noninferiority.

Despite these limitations, the trial by van de Graaf et al provides new evidence about treatment of meniscal tears. Combined with previously published evidence, the trial by van de Graaf et al provides further support for a structured nonoperative treatment approach for meniscal tears in the setting of degenerative OA. Orthopedic surgeons should recognize the value of this nonoperative approach and incorporate it into their treatment approach with the expectation that many patients will be treated successfully. The evidence clearly supports this approach.

However, to change clinical practice, it may be necessary to establish a consortium of all groups involved in the management of this knee condition—orthopedic surgeons, physiatrists, physical therapists, professional organizations, and insurance companies—to develop evidence-based treatment guidelines that each group can support. The guidelines should be focused on the best interests of the patients, rather than the clinicians, therapists, and other groups or entities who may gain from the different treatments for degenerative meniscal tears.

ARTICLE INFORMATION

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