

Katz JN, Brophy RH, et al. Surgery versus Physical Therapy for a Meniscal Tear and Osteoarthritis. N Engl J Med 2013;368:1675-84.

Design: randomized clinical trial

Study question: In patients with knee osteoarthritis (OA) and a torn meniscus, do outcomes differ between arthroscopic surgery and nonoperative physical therapy?

Population/sample size/setting:

- 330 patients (143 men, 187 women, mean age 58) who completed a 6 month followup of a study of arthroscopy for knee OA and a torn meniscus at seven academic centers in the United States
- Eligibility criteria were age over 45 with at least 4 weeks of a symptomatic meniscal tear and OA detected on imaging [from Appendix]
 - o Patients with normal x-ray but cartilage defects on MRI were eligible; defects needed to be Kellgren-Lawrence Grade 3 ($\leq 50\%$ joint space narrowing) or milder
 - o At least one symptom consistent with a torn meniscus: clicking, catching, popping, giving way, pain with pivot or torque, pain that is episodic, pain that is acute and localized to one joint line
 - o Symptoms had been managed with one or more of: medications, activity limitations, or PT
- Exclusion criteria were a chronically locked knee, Kellgren-Lawrence Grade 4 OA, inflammatory arthritis or chondrocalcinosis, viscosupplementation in the past 4 weeks to index knee, contraindication to surgery or PT, bilateral symptomatic meniscal tears, or prior surgery to index knee

Interventions and comparisons:

- 351 patients were originally randomized to either arthroscopic partial meniscectomy (APM, n=174) or to physical therapy (PT, n=177)
 - o APM consisted of trimming the meniscus back to a stable rim, removing loose fragments of cartilage and bone, but not penetrating the subchondral bone
 - Preoperative antibiotics were routinely used
 - Postoperatively, weight bearing as tolerated was used, but bracing was not used
 - After surgery, patients were referred for PT with the same protocol that was used in the group randomized to PT
 - o PT program was an individualized progressive home exercise routine structured to control inflammation, restore range of motion, and improve strength, with elements of manual therapy, neuromuscular re-education of the

quadriceps, and exercises such as resistive exercise, bicycle, treadmill, and other activities

- An acute phase lasted 1-10 days
- A subacute phase lasted 10 days to 4 weeks
- An advanced activity phase lasted 4-7 weeks

Outcomes:

- Outcomes were assessed at 3 months, 6 months, and 12 months after randomization, with the primary outcome assessed at 6 months
- Primary outcome was the physical function scale of the Western Ontario OA Index (WOMAC) between baseline and 6 months
 - o Secondary outcomes were pain score on the Knee Injury and OA Outcome Score (KOOS) and the physical activity scale of the SF-36
- In the intention-to-treat analysis, the mean improvement in the 6 month WOMAC physical function was 20.9 points in the APM group and 18.5 points in the PT group, with a group difference of 2.4 points; the 95% confidence interval for this difference, which was between -1.8 and 6.5 points, included the value of 0 for no difference between treatments (statistical non-significance)
 - o Similarly, the 6 month KOOS pain scores did not have a significant difference between groups
- Among 330 patients who remained active in the study at 6 months, 51 patients in the PT group (30.2%) had changed treatment plans and undergone APM, and 9 patients (5.1%) assigned to APM had not undergone the procedure
 - o Between 6 and 12 months, another 8 patients in the PT group crossed over to undergo APM
- The authors specified an 8 point improvement in the 6 month WOMAC score as clinically meaningful; this endpoint was achieved by 67.1% of the APM group and by 43.8% of the PT group
 - o Patients assigned to PT who crossed over and underwent APM had similar WOMAC scores at 12 months as the patients who had been assigned to APM in the first place
 - o The patients who crossed over from PT to APM were those who had not had substantial improvement over their baseline status
 - o In the PT group, 21 patients received intraarticular steroid injections, as did 9 patients in the APM group
- Total knee replacement took place in 8 patients, 5 of whom were allocated to APM and 3 of whom were allocated to PT; no significant differences in adverse events were reported between groups

Authors' conclusions:

- There were no significant differences in pain and function between patients assigned to surgery and PT after 6 and after 12 months from randomization
- These results were achieved with a 30% crossover from PT to APM at 6 months
- Because only 26% of all eligible patients were enrolled in the study, a form of selective enrollment may have created bias (Katz et al 2011)
- The data do provide some reassurance that an initial nonoperative strategy, which will lead to great improvement in 70% of patients, is appropriate, even the other 30% may need a change of treatment plan inside of about 6 months

Comments:

- Many crucial features of a high-quality study were reported and executed in this study
 - o The study could not be blinded between surgery and PT, but a sham meniscal operation would have been possible
 - o Given the precedent of clinical trials of arthroscopic lavage in knee OA, in which sham surgery was done, showing no difference between lavage and sham lavage, such a sham control trial does seem to be called for
 - Such a study was done several months after this one (Sihvonen 2013), and showed no difference between sham and actual APM
- The direction of the potential bias arising from selective enrollment is not clear without more information about the eligible patients who declined to enroll; the Katz 2011 article suggests that there may be an underestimate of the effect of arthroscopy if enrollment in the study is disproportionately weighted to more severe cases; regrettably, the necessary data are not routinely collected in standard reporting of clinical trials
- The crossover rates are difficult to interpret, and understanding them would greatly improve the interpretation of the study as a whole
 - o There was wide variation between centers in the rate of crossover, from 0% to 59.5%; these differences are large and seem unlikely to be attributed to biological differences between patients enrolled at the different centers
 - o The intent-to-treat analysis predicts the likely outcomes of treatment plans, provided that these plans are flexible enough to change treatment if a desired response does not occur in a few months
 - o That is, the study could mean that it is reasonable to start the treatment of a torn meniscus with OA using PT, bearing in mind that a significant percentage of patients may not respond to PT
 - o However, the characteristics of the 30% crossover patients are not well described, except for the fact that they did not improve with PT alone

Assessment: High quality study supporting good evidence that in the initial management of knee OA with a torn meniscus, it is reasonable to start with nonoperative physical therapy, and that about 30% of patients may not respond to PT alone. The appropriate treatment changes for the patients who do not do well with PT are not evident from the study, since little is known about what accounts for their lack of benefit from the PT program.

Reference:

Katz JN, Wright RW, et al. Departures from community equipoise may lead to incorrect inference in randomized trials. *J Clin Epidemiol* 2011;64:280-285

Sihvonen R, Paavola M, et al. Arthroscopic partial meniscectomy versus sham surgery for a degenerative meniscal tear. *N Engl J Med* 2013;369:2515-24.