
Design: Randomized clinical trial

Study question: In patients with a degenerative tear of the medial meniscus, is there a difference between surgery and sham surgery with respect to functional outcomes?

Population/sample size/setting:

- 146 patients (89 men, 57 women, mean age 52) treated for degenerative meniscal tears at 5 orthopedic clinics in Finland
- Eligibility criteria were age 35 to 65 with at least 3 months of medial joint line pain provoked by palpation or a positive McMurray test, tear of the medial meniscus on MRI which is confirmed on diagnostic arthroscopy, and pain which persists after conventional conservative treatment
- Exclusion criteria were acute, traumatic meniscal injury, a locked knee that cannot be straightened normally, past surgery on the index knee, osteoarthritis of the knee greater than Kellgren-Lawrence grade 1, fracture of the knee in the past year, decreased range of motion of the knee, instability of the knee, MRI or arthroscopy showing anything other than a degenerative tear of the medial meniscus requiring surgical intervention
  - Half of each group had grade 0 OA (normal joint) and half had grade 1 (minor degenerative changes)

Interventions:

- All patients underwent diagnostic arthroscopy in which the surgeon evaluated the patellofemoral joint compartments and graded the pathology (tear size, chondral degeneration, local synovitis)
- Randomization was done during the diagnostic arthroscopic examination, when the surgeon asked a nurse to open an envelope containing the study group assignment
- Randomization was to either arthroscopic partial meniscectomy (APM, n=70) or to sham surgery (n=76)
- APM consisted of removal of damaged and loose parts of the meniscus until solid meniscal tissue was reached, probing the meniscus to ensure that the unstable fragments had been removed, preserving as much of the meniscus as possible
- Sham surgery consisted of a simulation of APM, with the surgeon asking for all instruments, placing a mechanized shaver with the blade removed, and using suction as with the standard surgical procedure; the patient was kept in the OR for the same time to do an actual procedure
- Neither group received any intra-articular medication; both groups had a standardized postoperative protocol of graduated exercise and walking aids
Outcomes:

- Three primary outcomes were knee pain after exercise, the Lysholm knee score, and the Western Ontario Meniscal Evaluation Tool (WOMET), all three assessed 12 months after the procedure
  - Secondary outcomes included the knee pain and WOMET scores at 2 and 6 months after surgery, as well as a generic health-related quality of life questionnaire
  - Four general questions were also asked 12 months after the procedure
    - Is your knee better now than before the procedure?
    - Are you satisfied with your knee at present?
    - Would you choose to have the same procedure again if you were to make the decision now?
    - Which procedure do you think you got?
- For the primary outcomes both groups had marked improvements in knee pain and in Lysholm scores and WOMET scores, but for all three outcomes, the improvements were equal in both groups
  - For example, both groups started with Lysholm scores of about 60 on a 100 point scale, and both improved about 22 points to about 82 points
- The secondary outcomes were also very similar in both groups, with no differences in the amount of improvement at the 12 month evaluation
  - The sham surgery and the APM groups were similarly unsuccessful in guessing which group they were in
- Two patients in the APM group had additional surgery: one had a total knee replacement because of aseptic necrosis of the medial femoral condyle; the other had a second resection of the meniscus because of recurrent symptoms
  - 5 patients in the sham surgery group crossed over to have surgery during the study period, but these are not described

Authors’ conclusions:

- In patients with a degenerative medial meniscus tear and no arthritis, arthroscopic partial meniscectomy provides no benefits over sham surgery
- These results argue against the current practice of performing APM in patients with a degenerative meniscal tear
- These results are applicable only to patients with a nontraumatic degenerative tear, since trauma was an exclusion criterion
- Longer followup would be needed to estimate the effect of APM on the later development of osteoarthritis in the affected knee

Comments:
- Overall a very high quality trial with control of bias at every step of the process
  - In addition to usual blinding practices, the trial gave the study results to the writing committee, identifying the interventions as group A and group B without revealing which was APM and which was sham surgery; the codes were revealed only after the interpretation was complete
- In addition to the results applying only to patients with nontraumatic degenerative tears, they also do not apply to patients with a locked knee which cannot be straightened
  - Although patients were excluded if they could not extend their knee due to locking, almost half had symptoms of catching or locking
- The 95% confidence intervals are not compatible with a large advantage of APM over sham surgery, since the retention of patients in the study met the requirements of the original sample size calculation
- The low rate of crossover from sham surgery to APM (7%) was much lower than the rate of crossover in the RCT of PT versus APM by Katz et al 2011 (30%); one interpretation is that the placebo effect of sham surgery is greater than the placebo effect of PT
- The authors may have gone too far in concluding that APM has no justification in the treatment of degenerative meniscal tears
  - The sham operation was as effective as the real one; this is supported by the data
  - Nonoperative medical management is just as good as surgery; this is not supported by the data
  - Both groups improved greatly after their trial interventions
  - Both groups had qualified for inclusion by reason of having failed an (undefined) course of “conventional conservative treatment”
  - Therefore, it does not follow that the same patients would have had the same improvements if they had continued with the conservative treatment whose failure qualified them for inclusion in the study to begin with; this is a speculative inference not supported by the data
  - Therefore, this study does not provide evidence for a conclusion that arthroscopic partial meniscectomy is worthless in this setting

Assessment: High quality study supporting good evidence that in patients with nontraumatic degenerative meniscal tears who have full knee range of motion and mild or no osteoarthritis, whose symptoms have not resolved with three months of conventional conservative treatment, both arthroscopic partial meniscectomy and a diagnostic arthroscopic intervention are followed by clinically important improvements in pain and function, and that arthroscopic meniscotomy is not superior to the diagnostic procedure which leaves the meniscus intact
Reference: