Arthroscopic surgery was not effective for relieving pain or improving function in osteoarthritis of the knee


QUESTION: In patients with osteoarthritis of the knee, is arthroscopic surgery effective for relieving pain and improving function?

Design
Randomised (allocation concealed*), blinded (patients and outcome assessors),* placebo controlled trial with 2 years of follow up.

Setting
A Veterans Affairs medical centre in Houston, Texas, USA.

Patients
180 patients who were ≤ 75 years of age (mean age 52 y, 93% men), had osteoarthritis of the knee as defined by the American College of Rheumatology, reported at least moderate knee pain (scored ≥ 4 on a visual analogue scale of 0–10) despite maximal medical treatment for ≥ 6 months, and had not received arthroscopy in the previous 2 years. Exclusion criteria were severity grade ≥ 9 (maximum 12), severe deformity, or serious medical problems. Follow up was 89% at 1 year and 91% at 2 years.

Intervention
After stratification for severity of osteoarthritis, patients were allocated to 1 of 3 groups: lavage (n=61), debridement (n=59), or placebo (n=60). In the lavage group, the joint was lavaged with ≥ 10 litres of fluid. Anything that could be flushed out through arthroscopic cannulas was removed, and unstable meniscal tears were removed. Debridement consisted of lavage with ≥ 10 litres of fluid, shaving rough articular cartilage, removing loose debris, and trimming torn or degenerated meniscal fragments. Lavage and debridement were done under general anaesthesia with endotracheal intubation. The placebo group received three 1 cm skin incisions under a light anaesthetic and breathing oxygen-enriched air.

Mean outcome measures
Pain in the study knee at 24 months (Knee-Specific Pain Scale, scores 0–100 [most severe]). Secondary outcome measures were general arthritis pain (Arthritis Impact Measurement Scales [AIMS2]), body pain (pain subscale of the 36 item Short Form General Health Survey [SF-36]), and physical function (5 item walking bending subscale from the AIMS2 and the 10 item physical function score from the SF-36).

Main results
Lavage and debridement did not differ from placebo for pain in the study knee at 1 or 2 years (table) or for any secondary outcome measure.

Conclusion
In patients with osteoarthritis of the knee, arthroscopic surgery did not relieve pain or improve function more than a placebo procedure.

*See glossary.

COMMENTARY
Many surgeons have recognised the uncertainty surrounding the efficacy of arthroscopic lavage and debridement for the painful osteoarthritic knee. Most clinicians, in my experience, have concluded that a randomised controlled trial with a sham placebo might resolve that uncertainty but would probably be unethical. The study by Mooney et al is comprehensively reported and referenced and seems to have been carefully done. The methods used for analysis are appropriate. The study found no evidence that lavage or debridement was superior to placebo in this patient group. Furthermore, the 95% confidence intervals for most comparisons did not include a level considered to constitute the minimal important difference, which instead of being prespecified was calculated post hoc from available literature and trial data.

The argument for ethical approval may have focused around equipoise and patient competence. Primum non nocere (“first, do no harm”) is breached by this trial; sham surgery is not a harmless placebo, even though it involved only three 1 cm skin incisions under a light anaesthetic regimen. But if the single surgeon who performed all procedures was in a state of individual equipoise (ie, had a genuine uncertainty about the therapeutic merits of each treatment) and the participants, having signed a declaration accepting the possibility of a sham procedure, were competent, informed, and in equipoise, an acceptable argument for ethical approval might emerge. The fact that 44% of eligible patients declined to participate suggests that the information given was clear enough for them at least; those who chose to participate may have been less informed or driven by altruism.

The fact that so many potential participants declined raises the possibility of selection bias, which may threaten generalisability. The authors note that, compared with those who declined, participants were younger, more likely to be white, and had more severe arthritis. It would have been useful to see follow up data on those who declined to be randomised but who subsequently had either lavage or debridement. Nevertheless, this study makes a case for questioning the value of arthroscopic lavage and debridement in active men younger than 65 years of age with osteoarthritis of the knee.

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Lavage or debridement v placebo for osteoarthritis of the knee

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mean score</th>
<th>Mean score difference (95% CI)</th>
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<tbody>
<tr>
<td></td>
<td>Lavage</td>
<td>Debridement</td>
</tr>
<tr>
<td>Pain at 1 year (KSPS)</td>
<td>54.8</td>
<td>48.9</td>
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<tr>
<td>Pain at 2 years (KSPS)</td>
<td>53.7</td>
<td>51.6</td>
</tr>
</tbody>
</table>

KSPS – Knee-Specific Pain Scale (scores 0–100 [most severe]). All differences are statistically nonsignificant.