Operative vs. Nonoperative Treatment of Proximal Hamstring Avulsions: A Preference-Tolerant Noninferiority Randomized Trial.

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INTRODUCTION:
Operative treatment is widely used for acute proximal hamstring avulsions (PHA), yet its effectiveness compared to nonoperative treatment remains unproven in randomized trials. Despite a general belief in the superiority of surgery, many operative procedures, especially within orthopedics, lack robust evidence from such trials. Proximal hamstring avulsions, often resulting from slips or falls during sports or daily activities, are severe injuries that affect middle-aged, physically active individuals and cause significant pain. While retrospective case series and cohort studies have suggested favorable outcomes for surgical intervention, recent cohort and case-control studies have not found evidence supporting the superiority of operative treatment. Given the costs and risks associated with surgery, our trial was designed to test for noninferiority of nonoperative treatment.

METHODS: In this noninferiority trial, ten centers in Sweden and Norway enrolled patients aged 30–70 years old with a proximal hamstring avulsion in a randomized trial and a parallel observational cohort. Treatments were operative reinsertion of the tendons or nonoperative management. The primary endpoint was the Perth Hamstring Assessment Tool (PHAT) at two years of follow-up. Secondary outcomes included scores on the Lower Extremity Functional scale (LEFS).
RESULTS:
We enrolled 119 patients in the randomized trial and 97 in the observational cohort. In the per protocol analysis of the randomized trial, the mean (±SD) PHAT scores were 79.9 (19.5) and 78.5 (19.4) in the operative and nonoperative groups, respectively (PHAT scores range from 0-100, with higher scroes indicating higher function). The prespecified non-inferiority limit of 10 points was not crossed (mean difference, -1.2; 95% confidence interval [CI], -8.6 to 6.2; p=0.009 for noninferiority). Analyses of secondary outcomes, including a mean difference in the LEFS score of -1.6 (CI, -5.2 to 2.0), aligned with the primary outcome. The observed numbers of adverse events in the randomized trial were 9 in the operative vs. 3 in the nonoperative group (odds ratio: 0.30 [CI, 0.1to 1.2]). In the analysis of the observational cohort, the mean PHAT score difference between the nonoperative and operative treatment groups was -2.6 (CI, -9.9 to 4.6).
DISCUSSION AND CONCLUSION: In patients aged 30–70 years with proximal hamstring avulsions, nonoperative treatment was found to be noninferior to operative treatment. These findings challenge the widely held practice of favoring operative repair for proximal hamstring avulsions. The noninferiority of nonoperative treatment suggests it is a viable and effective option for middle-aged patients with acute proximal hamstring avulsions, potentially offering a less invasive alternative without compromising clinical outcomes. This evidence supports reconsidering current treatment guidelines to include nonoperative management as a standard care option.