

# VUMC Reporter

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## Clinical trial to assess shoulder pain treatments

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Nitin Jain, M.D., MSPH, associate professor of Physical Medicine and Rehabilitation and Orthopaedics, has been awarded a \$7.5 million contract to determine whether surgery or non-operative therapy works better for a common age-related injury that costs the health care systems billions of dollars — rotator cuff tears.

“More likely than not, each one of us knows someone who has either had a rotator cuff tear, causing shoulder pain, or has actually had surgery,” Jain said. “That’s what led us to this work. This is a question patients were asking, that doctors were asking. ‘If a patient comes into my clinic with a rotator cuff tear, what should I do for that? Should I offer them surgery or should I offer them physical therapy?’ This is one of the most common reasons patients go to see their doctors — not just specialists, but any doctor. It’s an important public health issue.”



Nitin Jain, M.D., MSPH

About 275,000 rotator cuff surgeries are performed each year in the United States. The randomized clinical trial will involve a dozen sites across the nation and will enroll 700 patients. Patients who agree to participate will be randomized for either surgery or non-operative therapy.

The study will compare outcomes, according to age and the size of the rotator cuff tear. It will involve physicians with an established record of recommending either treatment option. Physical therapists involved in the study will follow standardized treatment protocols for patients in both arms of the study.

“It’s a difficult study to do,” Jain said. “It is very, very difficult to recruit patients and randomize them to surgery versus non-operative treatment. First of all, you have to have equipoise among the recruiting physicians. That’s not easy to find. Secondly, you have to have enough

volume of patients who have rotator cuff issues. We know that for every four patients who are eligible, one of them agrees to participate. That's why someone hasn't done such a large scale trial on rotator cuff tears previously."

The funding from the Pragmatic Clinical Studies initiative, which was launched by the Patient-Centered Outcomes Research Institute (PCORI) in 2014, supports large-scale comparative trials to address high priority inquiries. The rotator cuff study is one of 24 Pragmatic Clinical Studies contracts awarded thus far by PCORI and is the first such contract for VUMC.

"This project was selected for PCORI funding not only for its scientific merit and commitment to engaging patients and other health care stakeholders in a major study conducted in real-world settings, but also for its potential to answer an important question about treatment options for patients with rotator cuff tears and fill a crucial evidence gap," said PCORI Executive Director Joe Selby, M.D., MPH. "We look forward to following the study's progress and working with VUMC to share its results."

The genesis for the VUMC study began in 2013 when Jain met with rotator cuff tear patients in an effort to better understand their perspectives. Patients, who are not actually being treated as part of this clinical trial, will be involved as team members — particularly as it relates to results dissemination and offering feedback on recruitment and questionnaires, Jain said.

This study involves patients 50 and older, many of whom may think their rotator cuff tears are related to one specific injury when the shoulder problems are actually caused from degenerative wear-and-tear actions, Jain said. The tears are equally common in men and women, he said.

The study will compare whether surgery versus rehabilitation works better in patients with increasing age and size of tear based on MRI findings.

"This challenging randomized trial has the ability to directly inform patient care," Jain said. The study team includes:

- John "Jed" Kuhn, M.D., Kenneth Schermerhorn Professor of Orthopaedics and Rehabilitation
- Gregory Ayers, M.S., senior associate in Biostatistics
- Jeffrey Blume, Ph.D., associate professor of Biostatistics
- Kristin Archer, Ph.D., DPT, associate professor of Orthopaedics and Physical Medicine and Rehabilitation
- Brian Richardson, physical therapist
- Rebecca Dickinson, physical therapist

- Helen Koudelkova, project manager

Jain's award has been approved pending completion of a business and programmatic review by PCORI staff and issuance of a formal award contract.

PCORI is an independent, nonprofit organization authorized by Congress in 2010. Its mission is to fund research that will provide patients, their caregivers and clinicians with the evidence-based information needed to make better-informed health care decisions.


To learn more about the Strategic Directions, [go here \(https://ww2.mc.vanderbilt.edu/strategic-directions/\)](https://ww2.mc.vanderbilt.edu/strategic-directions/).

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