

Minimally-invasive treatment for 'frozen shoulder' improves patients' pain and function

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A new nonsurgical treatment decreases errant blood flow in the shoulder to quickly reduce pain and improve function in patients with adhesive capsulitis, also known as "frozen shoulder," according to a research abstract presented during a virtual session of the Society of Interventional Radiology's 2020 Annual Scientific Meeting on June 13. Frozen shoulder gradually causes significant pain and stiffness of the shoulder joint in an estimated 200,000 people in the U.S. each year. The symptoms are often treated with physical therapy or pain medications, until they resolve within one to three years.

"Patients with frozen shoulder are essentially told to tough it out until their symptoms improve, but considering the significant pain and decreased function many experience, we looked to determine if this treatment model of embolization, already in use in other areas of the body, could provide immediate and durable relief," said Sandeep Bagla, MD, CEO of Vascular Interventional Partners, NOVA and lead author of the study. "We were shocked at the profound and dramatic improvement <u>patients</u> experienced in pain and use of their shoulder."

In this Phase II FDA-approved Investigational Device Exemption clinical trial on arterial embolization of the shoulder (AES), interventional radiologists inserted a catheter through a pinhole-sized incision in patients' wrists that was used to feed microsphere particles into as many as six arteries in the shoulder to reduce inflammation. The



treatment was conducted on an outpatient basis and took approximately one hour. Each patient's pain, disability, and blood flow in the shoulder were measured before and after the treatment using three scales, in addition to MRI imaging to visualize the <u>shoulder</u> joint.

The treatment was successfully completed in 16 patients whose symptoms had not responded to conservative treatment over 30 days. Minor adverse events such as temporary skin discoloration were reported in nine patients. One month later, researchers followed the progress of 11 patients and found that pain significantly decreased after AES (-57 mm on the Visual Analog Scale) and improved physical function in all patients (+28 mm on the Single Assessment Numeric Evaluation and +30 mm on the American Shoulder and Elbow Surgeons Shoulder Score). Additional progress was reported at the three-month follow up.

"We are early in the investigation of this treatment but are inspired by its effectiveness in reducing <u>pain</u> and range of motion in patients' shoulders," said Bagla.

The research was conducted as a collaboration between interventional radiology and orthopedic surgery to build on international studies of the procedure by adapting the treatment design and embolic agent to be more durable. The team plans to expand the study to additional patients in 2020.

The authors note that this treatment is still investigational and that conservative therapies should still be considered first. Additionally, there are several important limitations of the research, including <u>small sample</u> <u>size</u> and lack of control arm.

Additional information about the clinical trial is available at <u>ClinicalTrials.gov</u>, using the identifier <u>NCT03676829</u>. The trial is funded through Terumo Medical Corporation, a medical device



company.

More information: Abstract: Arterial Embolization of the Shoulder for Pain Secondary to Adhesive Capsulitis: Interim results from an Investigational Device Exemption U.S. trial. S. Bagla, R. Piechowiak, S. Nagda, J. Orlando, C. Xavier, A. Sajan, A. Isaacson.

Provided by Society of Interventional Radiology

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