SIR HIGHLIGHT

Interim Results Show Reduced Pain and Improved Function in US Study of Geniculate Artery Embolization for Knee Osteoarthritis

Early findings from the first United States–based study exploring geniculate artery embolization (GAE) for knee osteoarthritis (OA) indicate the potential for reductions in pain and stiffness, as well as improved function. The data were presented by Sandeep Bagla, MD, at the Society of Interventional Radiology's (SIR) 2018 annual scientific meeting in Los Angeles, California. Dr. Bagla is Director of Interventional Radiology at the Vascular Institute of Virginia in Woodbridge, Virginia.

BACKGROUND

"Knee arthritis affects more than 30 million Americans, and the current treatment options are not very effective in treating pain, short of replacement surgery," said Dr. Bagla in comments to *Endovascular Today*. Treatment options such as joint injections and knee replacement surgery are limited by short-term efficacy and invasiveness, respectively, he noted. The injections may not last more than a few months, and knee replacement surgery requires hospitalization and a prolonged recovery period. Dr. Bagla further stated that although the results of surgery are good in older patients, many middle-aged patients are not ready for knee surgery.

Common OA symptoms include pain, stiffness, swelling, and difficulty moving the associated joint. Dr. Bagla commented that it is now understood that much of the pain associated with knee OA comes from inflammation of the synovial membrane or lining. The goal of the outpatient, catheter-based GAE approach is to delay or defer knee surgery by reducing pain and improving physical function.

"After spending many years investigating embolization for other areas, I had come across Dr. Yuji Okuno's pilot study in 2015 and found the concept very intriguing," said Dr. Bagla. "We then spent a great deal of time reviewing the rheumatology and pathology literature to further investigate the role of abnormal hypervascularity and osteoarthritis. Once we confirmed this, we then launched our plan to study GAE in the setting of arthritis."

EARLY UNITED STATES STUDY OUTCOMES

In the study reported at SIR 2018, GAE was performed via a femoral approach, with microparticle embolization of the capillaries in the area of the synovium to reduce inflammation and associated pain. The group is currently using 100-µm particles, although more will be learned about ideal sizing as the studies progress. To date, Dr. Bagla has observed that the relatively smaller size has produced good clinical outcomes with limited adverse events.

Taking place at two United States clinical centers, the 20-patient study has enrolled all subjects. At the time of abstract submission, data on 13 enrolled patients were available, with eight patients completing follow-up.

The investigators measured certain clinical outcomes before and after the GAE procedure. MRI was performed to assess bone marrow, ligaments, meniscii, and cartilage appearance (additional data from the MRI studies were also presented at SIR). Patients were also assessed using two validated clinical scales, the Visual Analog Scale (VAS) for pain and the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, which are well established in the orthopedic literature for assessing both pain and disability from knee OA, commented Dr. Bagla. To be enrolled, patients had to have moderate or severe OA-related pain and a VAS score > 50 mm.

The procedure was successfully completed in all 13 patients for whom data were available at the time of abstract submission. Pain and stiffness were assessed at 1 month in the patients who had reached that follow-up point (n = 8). In those eight patients, the mean decrease in pain from baseline was 58 mm (P = .016). On average, the patients started at a baseline of 72 mm. Dr. Bagla also described a decrease of 36.3 in global WOMAC score (P = .0008). Both findings were reported to be statistically significant.

Patients saw overall improvements in physical function in the knee after the procedure, and there were no major adverse events related to the treatment. "While we have seen minor adverse events, they have been transient or self-limited," said Dr. Bagla when asked to describe potential adverse outcomes. "There is, of course, a potential for nontarget embolization to sites including the bone, nerves, or lower extremity, and a cautious approach is needed. This would include a detailed understanding of the anatomy, particle choice, and meticulous technique to avoid reflux or aggressive embolization. The best way to plan for this is to have in-depth knowledge of these areas and be deliberate in your approach."

WHAT'S NEXT?

Final results from all 20 enrolled patients are expected to be available in July 2018. The investigators will soon begin a second study, which is a blinded, sham-controlled, randomized clinical trial to better understand how the procedure works and ideal patient candidacy. Full publication of the data are anticipated in the fall 2018 time frame.

The group is also nearing submission to the US Food and Drug Administration to investigate the role of embolization in adhesive capsulitis or "frozen shoulder."

Contextualizing the potential role of GAE in joint pain management, Dr. Bagla hopes that the largest impact will be on reducing the number of people who take daily or routine pain medications. "With the opioid epidemic, it is important for researchers to study nonmedication avenues for the treatment of chronic pain."

Dr. Bagla envisions a significant role for interventional radiologists in the treatment of all pain-related conditions, pointing to the specialty's background in image-guided palliative care. "We have been so successful in the treatment of cancer-related pain and osteoporotic fractures," he said. "And there is no reason why we should not become more involved in the global pain management spectrum." ■