

Suspect Stem Cell Treatments Touted for Knee Arthritis

Laird Harrison

March 08, 2018

NEW ORLEANS — Hundreds of clinics in the United States are selling stem cell treatments for knee osteoarthritis without solid evidence of their claims, researchers warn.

"People's expectations have gotten ahead of the science," said investigator George Muschler, MD, from the Cleveland Clinic, and orthopedic surgeons must be prepared to help their patients evaluate these claims.

"The quality of the literature is relatively sparse," he told *Medscape Medical News*.

In a previous study that Muschler was involved in, investigators conducted a systematic review of stem cell treatments for knee osteoarthritis and focal cartilage defects of the knee, and found only four randomized controlled trials and two well-designed controlled trials without randomization (*J Bone Joint Surg Am.* 2016;98:1511-1521). The other 420 reports they identified were not well-designed trials. Although the results from the six trials were positive, the placebo effect could not be discounted, the team concludes.

This has not, however, stopped clinics from offering these treatments.

Muschler and his colleagues examined the current market for stem cell treatment for knee osteoarthritis, and presented their results here at the American Academy of Orthopaedic Surgeons (AAOS) 2018 Annual Meeting. The findings were previously published online (*J Knee Surg.* Published online July 24, 2017).

From October 28, 2016 to January 28, 2017, one of Muschler's colleagues contacted 273 of 317 clinics that offer stem cell treatments for orthopedic conditions that had previously been identified (*Cell Stem Cell.* 2016;19:154-157).

Using phone or email, he presented himself as a 57-year-old patient with moderate right knee osteoarthritis, and reported a score of 6 on a 10 cm visual analog pain scale.

This "simulated patient" told clinic personnel that he had seen other orthopedic professionals who offered him pain medication and corticosteroids and told him that he would eventually need a knee replacement. He then asked how well the stem cell treatments would work for his complaint, and what the treatments would cost.

At the 65 centers that provided pricing information for a same-day stem cell unilateral knee injection, the mean cost was \$5156, but prices ranged widely — from \$1150 to \$12,000. Muschler and his colleagues interpreted this to mean that the prices were not related to fixed costs, but rather to the amount that the clinics wanted to charge for their labor.

Insurance companies do not reimburse for these unproven treatments, so some patients could be paying more for the treatment than for a total knee replacement, the team pointed out.

Of the 36 centers that provided information on clinical efficacy, the proportion reporting "good results" or "symptomatic improvements" ranged from 55% to 100% (mean, 82.2%).

Table. Effectiveness of the Treatment Reported by 36 Clinics

Reported Success Rate	Number of Clinics
90%–100%	10
80%–90%	15
70%–80%	10
55% or more	1

It is possible that responsible clinics surveyed did not want to report success rates or pricing to the simulated patient until

he could be evaluated in person. However, it is also possible that clinics wanted the patient to visit so they could deliver a marketing pitch, the researchers explained.

In a related study, researchers from the Cleveland Clinic presented an assessment of social media reports of stem cell treatments for musculoskeletal treatments (*Cytotherapy*. 2017;19:1392-1399).

Although 94% of posts were positive in tone, most were from businesses advertising their services. Of the messages posted by patients, 60% were positive and 40% were negative. A 60% success rate is about what would be expected from the placebo effect alone, explained Muschler, who was also involved in this study.

Most of the practitioners offering the treatments appear to have a background in anesthesiology or rehabilitation, not orthopedics, he added.

Under US Food and Drug Administration (FDA) regulations, human cell and tissue products must be minimally manipulated; intended for homologous use only; not combined with another article, such as a drug; and have a systemic effect from the metabolic activity of the living cells.

Because cultivating cell lines is more than minimal manipulation, clinics cannot legally create large amounts of stem cells for injection.

"Stem Cell Treatment" a Misnomer

Instead, most are extracting blood or bone marrow aspirate — often from the patient being treated — using centrifuges to concentrate the cells, and then injecting them into the patient, Muschler explained. But only a tiny proportion of the cells concentrated in this way are actual stem cells that are capable of differentiating themselves into cartilage. So it is actually misleading to refer to these treatments as stem cell treatments, Muschler said.

That does not mean that such products do not have benefits, said Nicolas Piuze, MD, from the Cleveland Clinic, who was involved in both the studies presented. But the benefits are more likely to be derived from other effects, such as anti-inflammation, than from the repair of damaged cartilage. "It's not what we think about as the primary function of stem cells," he said.

Piuze explained that his own laboratory offers these treatments for knee osteoarthritis. However, it does not exaggerate the evidence for efficacy. It measures outcomes, attempts to profile the cells involved, studies whether the cells are rejected, and follows patients for at least 6 months.

Muschler and Piuze are working with other experts, on behalf of the AAOS and allied associations, to standardize treatment protocols. After a February 2018 symposium, convened by the AAOS at Stanford University in California, the team began work on a white paper stating best practices and summarizing the evidence so far.

"Everyone is trying to figure out how we can get our arms around this," said Scott Rodeo, MD, from Weill Medical College of Cornell University in New York City, who cochaired the Stanford symposium.

The FDA is formulating vigorous plans to enforce rules against unproven biologic treatments and easing the path to approval for those with strong evidence. "There is a sense that they do need to police this better," he told *Medscape Medical News*.

Rodeo reported that he has sometimes used concentrates derived from bone marrow for difficult-to-treat cases of knee osteoarthritis, such as those in a "biologically challenging environment." But, he acknowledged, the evidence for efficacy is "not clear at all."

"There definitely is great potential here," he said. "We just need more data. We need to figure out what works and what doesn't."

Muschler reports financial relationships with Fortus and the National Institutes of Health. Piuze has disclosed no relevant financial relationships. Rodeo reports financial relationships with the Joint Restoration Foundation, Ortho RT, and Rotation Medical.

American Academy of Orthopaedic Surgeons (AAOS) 2018 Annual Meeting: Abstracts P0147 and P0265. Presented March 6, 2018.

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Cite this article: Suspect Stem Cell Treatments Touted for Knee Arthritis - *Medscape* - Mar 08, 2018.

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