Rescue Injection of Amniotic Suspension Allograft Improves Pain and Function in Patients with Knee Osteoarthritis

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INTRODUCTION: Osteoarthritis affects 30.8 million Americans; over 54% of these patients are estimated to require joint replacement surgery during their lifetime. Intra-articular injections have the potential to delay total knee replacement, thus potentially reducing the number of costly revisions required. The purpose of the current study was to evaluate the efficacy of an amniotic suspension allograft (ASA) injection following failed treatment with saline or hyaluronic acid (HA).

METHODS:
Two-hundred patients were originally randomized 1:1:1 to receive saline, HA, or ASA. Blinded patients in the saline or HA groups who self-reported unacceptable pain relief at 3 months following the index injection were deemed treatment failures and eligible to receive a rescue injection with ASA. Subjects in the rescue arm (n=95; saline=51 and HA=44) were followed for an additional 12 months post rescue injection and PROs including KOOS were collected. Additionally, changes from baseline to 3 months after the original injection were compared to changes from rescue baseline to the 3-month rescue visit following ASA treatment using patient-reported outcomes. Statistics were computed using a mixed effects model for repeated measures (MMRM) and least squares means (LSMEANS).

RESULTS:
Patients had significantly greater improvements in KOOS pain (original \( \Delta4.62 \) (15.46), rescue ASA \( \Delta12.29 \) (15.21); \( p=0.0044 \), KOOS activities of daily living (original \( \Delta5.55 \) (14.62), and rescue ASA \( \Delta10.94 \) (15.56); \( p=0.0432 \)) at 3 months post-ASA injection compared to their original randomized treatment (Figure 1A). Comparing the randomized ASA group to the rescued ASA group, there were no significant differences between responses when considering KOOS Pain, ADL, and VAS pain at 3 months. When evaluating the full 15 study months for rescue patients (n=95), we found overall that post-rescue patients improved from ASA injection (KOOS Pain and ADL, Figure 1B) and that this improvement persisted for up to 12 months. Using the OMERACT-OARSI simplified responder criteria, 55.8%, 62.1%, and 58.9% of subjects rescued with ASA, at 3, 6, and 12 months were considered responders, respectively. Of note, there were no statistically significant differences in rates of response between previously failed HA and saline patients. During the rescue time course, treatment related adverse events occurred in 5.3% of patients (5 of 95), with none of those being severe in nature.

DISCUSSION AND CONCLUSION: Patients who received a rescue injection of ASA showed significantly greater improvement compared to their original treatment with saline or HA (over 3 months); these improvements persisted for up to 12 months. These data provide evidence supporting the use of ASA in patients with symptomatic knee osteoarthritis who experience persistent pain following HA or saline injections.