Synvisc-One® – Exzellentes Sicherheitsprofil bei erster und wiederholter Anwendung

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A single intra-articular injection of hylan G-F 20 (6 mL) provides pain relief for up to 6 months in patients with symptomatic knee OA.

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Viscosupplementation is an effective treatment for patients suffering from knee osteoarthritis (OA) (Bellamy et al, Cochrane Database Syst Rev. 2006). Most available products use 3 or 5 injection regimens. The objective of this study was to compare the safety and efficacy of 1 x 6 mL intra-articular administration of hylan G-F 20 with placebo.

In this prospective, multicenter, randomized, double-blind study, patients diagnosed with knee OA were randomized to one 6-mL injection of hylan G-F 20 or saline. The primary efficacy analysis (WOMAC A) was performed on the intent-to-treat population and was based on a repeated-measures model over the 26 weeks of the study.

253 patients were randomized to hylan G-F 20 (n=124) or placebo (n=129). Mean age was 63 years (42-84), BMI 29.4 (19.5-52.4 kg/m2), 71% were female, and all had primary knee OA of Kellgren Lawrence grade 2 (45%) or 3 (55%). Patients in the hylan G-F 20 group experienced a mean change from baseline in their WOMAC A Likert pain score (0-4 scale) over 26 weeks (primary efficacy criteria) of -0.84, which was statistically significantly different from the change reported in the placebo group (-0.69, p=0.047). Statistically significant differences favoring hylan G-F 20 were also reported for most of the secondary efficacy criteria: WOMAC A1 (estimate Odds Ratio over 26 weeks placebo/hylan G-F 20, 0.64, p=0.013), patient global assessment (0.69, p=0.029), and clinical observer global assessment (0.71, p=0.041); WOMAC B and C changes were not statistically significant between groups. The responder analysis for WOMAC A1 walking pain (defined as >1 category improvement and no knee related adverse event) indicated that 71% of the patients were responders at week 18 in the hylan G-F 20 group versus 54% in the placebo group (p=0.003), and 64% versus 50% at week 26 (p=0.028). The OMERACT-OARSI responder analysis indicated that 59% of the patients were responders in the hylan G-F 20 group versus 51% in placebo group (0.66, p=0.059). There was no statistically significant difference in the use of rescue medication (acetaminophen) between the 2 groups.

This double-blind placebo-controlled study showed one injection of hylan G-F 20 provided symptomatic relief lasting up to 6 months in patients with knee OA; it avoids the need for multiple injections.

Quelle: Jerosch et al. AAOS

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