REML - fixed-effects - model, rose-hip resulted in a statistically significant small reduction in pain (ES [95% CI]: -0.21 [-0.35 to -0.07]; p=0.004), disability (-0.22 [-0.36 to -0.07]; p=0.003), with more patients likely to respond to treatment when compared to the untreated controls (OR: 3.04 [2.04 to 4.52]; $p<0.0001$). This OR - adjusted for the weighted control event rate - corresponded to a NNT of 4 (3 to 6) patients.
Conclusions: Based on the available evidence, we conclude that a supplement of rose-hip might result in some symptomatic relief in many osteoarthritis patients. The clinical efficacy was small and in the same range as that of paracetamol (acetaminophen).

425

PREDICTIVE FACTORS OF RESPONSE IN A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED EVALUATION OF THE EFFICACY OF A SINGLE DOSE OF 6 ML OF HYLAN G-F 20 IN PATIENTS WITH SYMPTOMATIC KNEE OSTEOARTHRITIS

F. Bailleul[1], X. Chevalier[2], K. Pavelka[3]
[1]Genzyme Biosurgery, Medical Affairs, France; [2]Hôpital Henri Mondor, Créteil, France; [3]Institute of Rheumatology, Prague, Czech Republic

Purpose: To compare the efficacy of 1x6mL intra-articular (IA) administration of hylan G-F 20 (Synvisc-One™) against placebo in different sub-populations of patients with symptomatic OA of the knee.
Methods: Prospective, multicenter, randomized, double-blind (patient, independent clinical observer) study comparing 1 IA injection of 6mL of hylan G-F 20 (H) or saline (S). Patients must have documented diagnosis of OA of the target knee made at least 3 months prior to screening. Patients with symptomatic OA of the contralateral knee or either hip not responsive to paracetamol and requiring other therapy were excluded. The primary efficacy analysis used WOMAC A Likert pain and was performed on the ITT population, based on a repeated-measures model over the 26 weeks of the follow up.
Results: 253 patients were randomized (H N=124, S N=129). Mean age 63 years (42-84), BMI 29.4 (19.5-52.4), 71% female, primary knee OA Kellgren Lawrence (KL) grade 2 (45%) or 3 (55%). Overall, patients in the H group experienced a mean change from baseline in their WOMAC A pain score over 26 weeks which was statistically significantly different from the change reported in the S group (Δ = -0.15, p = 0.047).
The OA status in the contralateral knee and hips made a difference with hylan G-F 20 being more effective over 26 weeks in the patients without other joints involvement (N = 105, Δ = -0.31) as compared to patients with symptomatic OA in lower limbs (N = 148, Δ = -0.04, treatment by OA interaction p = 0.03).
Similarly, hylan G-F 20 tends to have a greater effect over 26 weeks in patients with KL grade 0-II tibio-femoral OA (N = 114, Δ = -0.22) as compared with grade III-IV (N = 139 Δ = -0.08, interaction p = 0.17).
In the subgroup of patients with severe baseline WOMAC A1 pain, hylan G-F 20 demonstrated a greater symptomatic effect at week 26 (N = 90, Δ = -0.28) than in the subgroup with moderate baseline pain (N = 163, Δ = -0.13), but there was no statistical difference over the 26 weeks of the study.
Conclusions: In this study, the positive predictive factors of symptomatic response after IA injection of a single 6 ml dose of hylan G-F 20 in patients with knee OA were high level of baseline pain, early grade OA and no concurrent lower limb OA.

426

THE ROLE OF MSM IN KNEE OSTEOARTHRITIS: A DOUBLE BLIND, RANDOMIZED, PROSPECTIVE STUDY

R. Debi, G. Fichman, Y. Bar Ziv, R. Kardosh, E. Debbi, N. Halperin, G. Agar
Asaf Harofe Medical Center, Tel Aviv, Israel

Purpose: Osteoarthritis (OA) is among the most common causes of disability in the elderly. Since the recent publications illustrating the lethal adverse affects of cox-2 selective anti-inflamatory drugs, there has emerged a need for safe long term treatment in OA. As a result, patients have begun using dietary supplements sold OTC. These include glucoseamine, chondroitine sulfate and methylsulfonylmethane (MSM). MSM is a natural substance produced in our body that has analgesic and anti-inflammatory properties. There is lack of research on the efficacy of MSM in treating knee OA. The aim of the study was to determine the efficacy of MSM in treating knee OA patients.
Methods: This study is a prospective, randomized, double-blinded, controlled study. 60 men and women, 45-90 (68 $\pm$7.3) years of age with knee OA graded 1-4 (3 $\pm$1) according to Kellgren & Lawrence, were enrolled in the study and randomly assigned into 2 groups: One receiving MSM in doses of 1.125 milligrams 3 times daily, and the other receiving a placebo. Patients were assessed at baseline, 6, and 12 weeks. During their appointments, the patients were asked to fill out questioners on their pain and physical function: SF-36, WOMAC, KFS, and KSS. The patients physical function was also assessed using Aggregated Locomotor Function (ALF).
Results: There were significant improvements in pain, stiffness, and physical function in the experimental group according to both the WOMAC questioner (p-value=0.009) and the SF36 questioner (p-value=0.031). No significant differences between the groups were found using the KSS and KFS questioners. A seven second improvement in the total time measured (ALF) was also found in the study group, while no such improvement was seen in the placebo group (p-value=0.009). No adverse effects were recorded.
Conclusions: The findings demonstrate that methylsulfonylmethane (MSM) is effective and significantly improve function and reduce pain in knee OA patients.

427

COMPARATIVE EVALUATION OF THE EFFICACY SAFETY AND TOLERABILITY OF LORNOXICAM AND DICLOFENAC IN INDIAN PATIENTS WITH OSTEOARTHRITIS

V.P. Baliga[1], A. Goregaonkar[2], K.J. Mathiazhagan[3], R.R. Shah[4], P. Taneja[5], A. Sharma[1]
[1]Glenmark Pharmaceuticals Ltd, Mumbai, India; [2]LTMM College aand General Hospital, Mumbai, India; [3]Govt Kilpauk Medical College, Chennai, India; [4]Khaja Banda Nawaz Institute of Medical Sciences, Gulbarga, India; [5]RGS Healthcare Pvt. Ltd., Mohali, India

Purpose: Reports of cardiovascular adverse events associated with the use of GI-COX-2 specific inhibitors for chronic therapy of osteoarthritis have prompted the quest for a safer NSAID. The present study was undertaken to compare the efficacy, safety and tolerability of oral lornoxicam and diclofenac in adult Indian patients with osteoarthritis.
Methods: This prospective, double-blind, randomized, comparative, multicentric study was undertaken in 260 adult Indian patients, in 5 centers across the country. The study protocol was approved by respective Institutional review boards. Written informed consent was obtained from each patient prior to un-