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A prospective, randomized, pragmatic, health outcomes trial evaluating the incorporation of hylan G-F 20 into the treatment paradigm for patients with knee osteoarthritis (Part 1 of 2): clinical results.

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OBJECTIVE: First, to assess the clinical effectiveness of hylan G-F 20 in an appropriate care treatment regimen (as defined by the American College of Rheumatology (ACR) 1995 guidelines) as measured by validated disease-specific outcomes and health-related quality of life endpoints for patients with osteoarthritis (OA) of the knee. Second, to utilize the measures of effectiveness and costs in an economic evaluation (see accompanying manuscript).

DESIGN: A total of 255 patients with OA of the knee were enrolled by rheumatologists or orthopedic surgeons into a prospective, randomized, open-label, 1-year, multi-centred trial, conducted in Canada. Patients were randomized to 'Appropriate care with hylan G-F 20' (AC+H) or 'Appropriate care without hylan G-F 20' (AC). Data were collected at clinic visits (baseline, 12 months) and by telephone (1, 2, 4, 6, 8, 10, and 12 months).

RESULTS: The AC+H group was superior to the AC group for all primary (% reduction in mean Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale: 38% vs 13%, $P=0.0001$) and secondary effectiveness outcome measures. These differences were all statistically significant and exceeded the 20% difference between groups set a priori by the investigators as the minimum clinically important difference. Health-related quality of life improvements in the AC+H group were statistically superior for the WOMAC pain, stiffness and physical function (all $P < 0.0001$), the SF-36 aggregate physical component ($P < 0.0001$) and the Health Utilities Index Mark 3 (HUI3) overall health utility score ($P < 0.0001$). Safety (adverse events and patient global assessments of side effects) differences favoured the AC+H group.

CONCLUSION: The data presented here indicate that the provision to patients with knee OA of viscosupplementation with hylan G-F 20 within an appropriate care treatment regimen provides benefits in the knee, overall health and health related quality of life at reduced levels of co-therapy and systemic adverse reactions. Copyright 2002 OsteoArthritis Research Society International. Published by Elsevier Science Ltd. All rights reserved.

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