

the perceived symptoms/disabilities was found in 94% (n=73), it was partial in 3.8% (n=3) and no agreement occurred in 2.2% (n=2, both of whom needed support). The understanding was rated very good in 98% and difficult in 2% (both elderly persons >80 years). The formulation "my symptoms are ..." was preferred by everybody compared to "which symptoms do you have". In general the overall rating was good or very good for all persons, although older people with comorbidities needed help.

Conclusions: The questionnaire accurately documented the symptoms and disabilities present in people with active musculoskeletal disorders; it also revealed the range of symptoms. The agreement between the answers in the questionnaire and the perceived symptoms/disabilities is high. Older people may need help to fill it out, and this can markedly reduce the rate of misunderstanding and misinterpretation. Most people can fill it out within 15 minutes. The questionnaire and the way to perform the assessment from the standpoint of the persons/patients was welcomed by all persons.

P360

PHYSICAL FUNCTION AND PROPERTIES OF QUADRICEPS FEMORIS MUSCLE IN MEN WITH AND WITHOUT KNEE OSTEOARTHRITIS

T. Liikavainio¹, T. Lyytinen¹, E. Tyrväinen², S. Sipilä³, J.P. Arokoski⁴

¹Department of Physical and Rehabilitation Medicine, Kuopio University Hospital, Kuopio, Finland, ²Department of Radiology, Kuopio University Hospital, Kuopio, Finland, ³Department of Health Sciences, University of Jyväskylä, Jyväskylä, Finland, ⁴Kuopio University, Kuopio, Finland

Purpose: The aim of this study was to assess the subjective joint pain, stiffness and function and the objective physical function of lower extremities and the quadriceps femoris muscle thickness and density in men with knee osteoarthritis (OA) and to compare the results with those from age- and sex-matched controls.

Methods: Fifty-four men (aged 49-68 years) with unilateral or bilateral hip OA and 53 age-matched randomly selected healthy men were studied. According to the side of the highest radiographic score (Kellgren-Lawrence grading scale) from the patients with clinical knee OA, 22.2% had grade 1, 27.8% grade 2, 35.2% grade 3, and 14.8% grade 4 OA. The range of motion (ROM) of the hip and knee joints was measured with goniometry and the Western Ontario and McMaster Universities (WOMAC) OA index was determined. Musculoskeletal function was assessed with a test battery. The isometric knee flexion and extension strength (peak torque (Nm/kg)) was determined. The thickness and density of quadriceps femoris muscle compartments were determined with muscle ultrasonography. Differences between the radiographic OA subgroups and between OA and control groups were determined by the Kruskal-Wallis and general linear univariate model with analysis of covariances (age, knee pain, BMI and height).

Results: In WOMAC OA index both stiffness and function, but not pain were positively related ($p < 0.05$) with radiographic severity of OA. Most of the WOMAC items were significantly ($p < 0.05-0.001$) related to the performance tests. Knee flexion and hip inner rotation were 8.4% and 19.4% lower ($p < 0.001$) in the OA group than in the controls, respectively. The controls were significantly ($p < 0.001$) better at ascending and descending stairs, performing a 20-meter walk, 5-min walking and straight line walking (10 m) tests and in repeated sit to stand and in the timed 'up and go' tests compared to the knee OA patients. The knee isometric flexion and extension strength was 11-18% lower ($p < 0.001$) in OA subjects than in controls. The thickness of rectus femoris, vastus lateralis and vastus intermedius muscle compartments were 7-14% lower ($p < 0.001$) in the OA group than in the controls.

Also muscle density was significantly lower in rectus femoris and vastus intermedius, but not in vastus lateralis compartment.

Conclusions: The physical function tests and WOMAC OA index are useful measures in evaluation of functional severity of the knee OA patients. The decrease of muscle size may contribute to the decrease of musculoskeletal function in knee OA.

P361

THE FIVE PILLARS OF PAIN MANAGEMENT: A SYSTEMATIC APPROACH TO TREATING OSTEOARTHRITIS

A.S. Gordon

Mount Sinai Hospital, Toronto, ON, Canada

Purpose: Increasingly pain management of osteoarthritis as carried out by arthritis specialists needs to embrace techniques used in pain management clinics. The authors have developed a comprehensive approach to pain management entitled The Five Pillars of Pain Management. This presentation demonstrates how it can be applied to the treatment of osteoarthritis

Methods: The author developed the Five Pillars initially for treatment of pelvic pain and also neuropathic pain. It came after years of experience in pain management and explaining the complexities to those not considered experts

Results: *Pillar 1:* Assessment of pain in the individual including a risk assessment as described in "Universal Precautions in Pain Management" (Gourlay et al 2005)

Pillar 2: Doing a history and physical exam and coming up with an anatomical diagnosis and a pathological diagnosis and then treat the underlying condition

Pillar 3: Making a pain diagnosis: acute or chronic; mild, moderate, severe; cancer or non-cancer; nociceptive or neuropathic and then going down the evidenced based path of treatment.

Pillar 4: Assessing and treating co-morbidities and complications including anxiety, depression, sleep disturbance; addiction; and sexual dysfunction

Pillar 5: Patient buy-in, practicing self management and appropriate expectations

Conclusions: Pain management is often considered a 'swamp' full of treacherous opiates, manipulative patients and many frustrations. The Five Pillars paradigm can be used to provide structure to a pain management program and allow the practitioner to use a variety of techniques to improve the condition of the patient.

P362

LUMIRACOXIB SHOWS COMPARABLE EFFICACY AND A FAVOURABLE BLOOD PRESSURE PROFILE COMPARED TO INDOMETHACIN FOR THE TREATMENT OF ACUTE FLARES OF GOUT

E.F. Mysler¹, R.E. Willburger², S. Litschig³, G. Krammer³, G.A. Tate¹

¹OMI, Buenos Aires, Argentina, ²Orthopaedic University Clinic, Bochum, Germany, ³Novartis Pharma AG, Basel, Switzerland

Purpose: Acute gout is a painful inflammatory disease affecting an estimated 20 million people worldwide [1]. The NSAID indomethacin is often regarded as the gold standard for treatment of acute flares of gout. Hypertension is reported as a frequent condition in patients with acute gout, therefore managing BP during treatment of acute gout needs to be considered.

In TARGET, lumiracoxib at a dose of 400 mg od has demonstrated a superior BP profile compared to the NSAIDs ibuprofen and naproxen after long-term treatment [2].

This study assessed whether the structurally distinct selective

COX-2 inhibitor lumiracoxib (400 mg once daily [od]) has comparable efficacy to indomethacin (50 mg three times daily [tid]) for the treatment of acute flares of gout. Secondary analysis of safety and tolerability included a specific, pre-defined comparison of differences in blood pressure.

Methods: This was a 1-week, multicentre, randomized, double-blind, double-dummy, active-controlled, parallel-group study of lumiracoxib 400 mg od (n=118) vs indomethacin 50 mg tid (n=117) (safety population) in patients with acute flares of gout. The primary analysis was a test of non-inferiority in the per protocol population of the mean change from baseline in pain intensity in the study joint over Days 2-5.

The blood pressure profile was assessed by a pre-defined analysis of the mean change from baseline for systolic and diastolic blood pressure.

Results: In the per protocol population, lumiracoxib 400 mg od (n=112) was non-inferior to indomethacin 50 mg tid (n=110). Least square mean (LSM) change from baseline in pain intensity for lumiracoxib was 1.29 (1.47) vs 1.29 (1.50) over Days 2-5 (Days 2-7) treatment period for lumiracoxib and indomethacin, respectively. Both drugs were also comparable in all secondary efficacy assessments.

50% of the patients had a medical history of hypertension. The table below shows the mean change from baseline in BP for lumiracoxib vs indomethacin at study end, after 7 days of treatment (safety population*).

Mean change/(SD)	Lumiracoxib 400 mg od n=114	Indomethacin 50 mg tid n=116	Two sided T-test p-value
Systolic blood pressure (mmHg)	-1.0 (9.74)	2.5 (10.68)	0.009
Diastolic blood pressure (mmHg)	-1.3 (6.06)	0.5 (6.57)	0.028

*Only patients with BP measurement at both baseline and study end were included.

None of the patients in the lumiracoxib group showed a clinically relevant increase in blood pressure (defined as change from baseline of at least 25%), as compared to 1.7% of patients in the indomethacin group.

Only 1.7% of the patients on lumiracoxib 400 mg od discontinued study drug compared with 8.5% on indomethacin 50 mg tid. AEs were reported in 10.2% of patients in the lumiracoxib group compared with 22.2% of patients in the indomethacin group. Due to suspected Good Clinical Practice non-compliance, a post-hoc sensitivity analysis was performed after database closure excluding a center containing 8 patients. The sensitivity analysis revealed no substantial change of the study results, the only exception was diastolic blood pressure (p=0.057).

Conclusions: Lumiracoxib 400 mg od is effective in the treatment of acute gout with efficacy comparable to indomethacin 50 mg tid. In addition, even after short-term treatment, lumiracoxib shows a favourable blood pressure profile as compared to indomethacin, and with fewer AEs and discontinuations. Lumiracoxib may thus provide an alternative effective treatment option for acute gout.

References

- [1] Rothschild, B. Gout CME. eMedicine from WebMD. <http://www.emedicine.com/orthoped/topic124.htm>. Accessed June 1, 2006.
- [2] Farkouh ME et al. *Lancet*. 2004;364:675-684.

Surgical Treatment of OA

P363

THE ASSOCIATION BETWEEN ECTOPIC BONE FORMATION AFTER HIP REPLACEMENT SURGERY AND CLINICAL OUTCOMES. RESULTS FROM THE HIPAID CLINICAL TRIAL

M. Fransen

The HIPAID Collaborative Group; The George Institute, Camperdown Sydney, Australia

Purpose: To determine if there is an association between the severity of ectopic bone formation after hip replacement surgery, chronic hip pain and physical disability.

Methods: HIPAID was a double-blind randomised placebo-controlled clinical trial conducted in 20 orthopaedic surgery centres in Australia and New Zealand.

902 patients undergoing elective primary or revision total hip replacement surgery were randomly allocated to 14 days treatment with ibuprofen (1200mg daily) or matching placebo commenced within 24 hours of surgery. Participants were required to have hip radiographs, complete self-reported questionnaires measuring of pain and physical function (WOMAC), report analgesia use and undergo several physical performance measures (hip flexion, up and go, 50ft walk time) six to twelve months after surgery.

Results: Hip radiographs were obtained from 798 (88%) participants and scored for ectopic bone formation severity using the Brooker grading (0-4). Among the 294 (37%) of HIPAID participants with radiographic evidence of ectopic bone formation, 108 (37%) had at least moderate severity (Brooker grade 2, 3 or 4). Brooker grade 3 and 4 demonstrated increased pain and function scores, compared with less severe grades of ectopic bone formation; however this trend was not significant. There were also a trend in the physical performance measures, but again this trend was not significant.

Ectopic bone formation and clinical outcomes

Brooker Grade	Pain (0-10) mean (sd)	Function (0-10) mean (sd)
0	0.97 (1.47)	1.56 (1.57)
1	0.99 (1.49)	1.43 (1.57)
2	0.97 (1.57)	1.87 (1.79)
3 and 4	1.25 (1.85)	2.23 (1.95)

Conclusions: These data, from the largest-ever trial of prophylaxis against ectopic bone formation, suggest that only a small proportion of patients undergoing elective hip replacement surgery will develop clinically relevant ectopic bone around the new hip implant.

P364

NON-ANIMAL STABILIZED HYALURONIC ACID FOR KNEE OSTEOARTHRITIS: COMBINED ANALYSIS OF TWO PLACEBO-CONTROLLED TRIALS

R. Altman¹, C. Åkermark², N. Arden³

¹UCLA, *Agua Dulce, CA*, ²Ortopediska Huset, *Stockholm, Sweden*, ³MRC Epidemiology Resource Centre, *Southampton, United Kingdom*

Purpose: With the increased controversy associated with long-term use of NSAIDs and COX-2 inhibitors, there is renewed interest in the use of intraarticular (IA) injections, including hyaluronans (HA), for the management of patients with knee osteoarthritis (OA). Non-animal stabilized hyaluronic acid (NASHA; Durolane®) is administered as a single IA injection for OA of the knee, and has an extended IA residence time (half-life: 4