Conclusion In conclusion, under the conditions of this study, low-energy laser stimulation plus exercise did not provide a significant advantage over exercise alone.

FRI0237 ASSESSMENT OF A FUNCTIONAL RESTORATION PROGRAM FOR PATIENTS WITH CHRONIC LOW BACK PAIN

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Background

Objectives The aim of this open study was to evaluate the effectiveness of a functional restoration program for patients suffering from chronic disabling low back pain. Return to work 12 months after the end of the program was chosen as the main outcome.

Methods A questionnaire was sent to 125 patients (115 M, 10 F, mean age 40 years). The mean duration of absence from work before entry in the program was 4 months. All patients had followed an identical functional restoration program in a hospital setting 12 months before. The program included 6 h of physical therapy and ergonomics, 5 days per week for 3 weeks.

Results 109 questionnaires could be assessed. 57 patients (52%) were back to work, 39 (36%) full time and 18 (17%) at half time. 42 patients were not working. A shorter duration out of work before entry in the program, an improvement of the isokinetic trunk strength at the end of the program, a positive self assessment of the program and the absence of psychiatric comorbidity were all separate predictors of a favourable outcome.

Conclusion Our results are in agreement with those of the European literature. An intensive restoration functional program had positive effects in 53% of our selected population.

FRI0238 EFFICACY AND SAFETY OF LOXOPROFEN IN ACUTE LOW BACK PAIN

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Background Nonsteroidal anti-inflammatory drugs (NSAIDs) are the most frequent and effective prescribed medication to treat patients with low back pain (LBP) but are associated with a high incidence of GI adverse events. Loxoprofen sodium, a NSAID prodrug from phenylpropionic group, claimed to have lesser GI and renal toxicity, has a large clinical experience in Japan, but its use in occidental people is scarce. Thus, it was conducted a clinical trial with Loxoprofen in the treatment of acute LBP in comparison with diclofenac K, using a validated assessment questionnaire for monitoring the outcome.

Objectives Objective of this double blind, randomised, controlled, multicentre study was compare efficacy and safety of Loxoprofen with that of diclofenac in the treatment of acute LBP.

Methods Patients of both gender, aged >18 years, with non-specific lumbar pain complying with exclusion criteria were admitted to the study. After the informed consent, patients were randomly allocated into the treatment groups – Loxoprofen 60 mg t.i.d. (LOX) or diclofenac 50 mg t.i.d. (DIC). Duration of

treatment was 2 weeks. Patients were evaluated at pre-treatment and weekly during therapy for the following parameters: overall severity of symptoms; pain at rest, on pressure, and on movement using a visual analogue scale (VAS); physical examination (Schober and lateral flexion indexes, finger-floor distance); physician and patient global impression; side-effects; and Roland-Morris Questionnaire for LBP duly validated to Brazilian patients.

Results A total of 96 patients were treated in 5 centres ? 47 with LOX (19 M and 28 F), and 49 with DIC (16 M and 33 F). There was no significant difference between groups. 83% of cases were classified as acute in LOX; in DIC, 57% of cases were acute, 29% were sub acute and 14% recurrent. Severity of symptoms, pain (at rest, on movement, and on pressure), and objectives indexes showed statistically significant improvements compared with baseline ($p < 0.001$? chi square) with both treatments; there were no statistically significance differences between groups. Roland-Morris Questionnaire showed a good correlation with evolution of symptoms. 14 patients in LOX reported adverse events, being 12 GI effects (25.5%), and 23 patients in DIC, with 18 GI effects (36.7%) ($p < 0.001$). Epigastralgia was the most prevalent GI event reported. Four patients in LOX and 7 in DIC discontinued therapy due to GI adverse events. Tolerability assessments were classified as both very good and good in 97% in LOX and in 90% in DIC ($p < 0.05$). Physician and patient overall assessment were >95% as either very good or good in both groups (n.s.).

Conclusion Loxoprofen 60 mg, t.i.d., showed efficacy and excellent tolerability and safety in acute low back pain, superior to that of an established NSAID, diclofenac 50 mg, t.i.d. Rolland-Morris Questionnaire was a useful tool to assess the disease outcome.

FRI0239 PAIN THERAPY OF FAILED BACK SURGERY SYNDROME PATIENTS (FBSS): SUCCESSFUL LONG-TERM TREATMENT WITH FENTANYL TTS

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Background Patients with a FBSS suffer from chronic severe back pain. Most of these patients have had a postlaminectomy in the lumbosacral region. 10% of patients with a postlaminectomy develop chronic pain after the surgery. The percentage of positive outcomes after a re-surgery amount about 30–75%. In general the outcome of these patients is unfavourable. At present pain therapy with opioids is not generally recommended in patients with FBSS.

Objectives Documentation of long-term efficacy and safety of fentanyl TTS treatment for patients who have had at least one surgical intervention for chronic back pain and who continue to suffer from severe back pain.

Methods Subgroup analysis of an open, international, multicentre study (FEN-INT-13) with a duration of 12 months. 85 patients (mean age 50 years; 46 women; mean pain duration 9 years) with failed back surgery syndrome received fentanyl TTS in an initial dosage of equivalent analgesic strength to prior opioid therapy. The dose was subsequently adjusted to provide optimum pain therapy. Visits have been scheduled day 1, week 1, month 1–12. The primary target parameter was the subjective weekly assessment of pain control (very good, good, moderate,