oxycodone CR (opioid-naive, 7.4 to 4.6; opioid-experienced, 7.7 to 4.7). Overall incidences of treatment-emergent adverse events (TEAEs) were 80.0% and 71.9%, respectively, for opioid-naive and opioid-experienced patients treated with tapentadol ER, and 84.0% and 85.5%, respectively, for opioid-naive and opioid-experienced patients treated with oxycodone CR. Incidences of gastrointestinal-related TEAEs for opioid-naive and opioid-experienced patients, respectively, were as follows: tapentadol ER, 49.8% and 39.3%; oxycodone CR, 59.5% and 64.2%. TEAE-related discontinuation rates were lower for tapentadol ER than for oxycodone CR for both opioid-naive (13.6% vs 33.7% [20.1% reduction]) and opioid-experienced (19.1% vs 30.9% [11.8% reduction]) patients.

Conclusions: Regardless of previous opioid treatment, tapentadol ER provides effective analgesia for moderate-to-severe chronic low back pain, with lower incidences of gastrointestinal-related TEAEs and discontinuations related to TEAEs compared with oxycodone CR.

MSE, DYS, AO, IVH, and JH are Johnson & Johnson employees and shareholders. CL is a former employee of Grünenthal GmbH.

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RESULTS OF A RANDOMIZED, DOUBLE-BLIND, PLACEBO- AND ACTIVE-CONTROLLED TRIAL OF TAPENTADOL EXTENDED RELEASE FOR CHRONIC LOW BACK PAIN

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Background and Aims: The efficacy and safety of tapentadol extended release (ER) for treatment of moderate-to-severe chronic low back pain were assessed.

Methods: Randomized patients received controlled, adjustable bid doses of tapentadol ER (100–250 mg), oxycodone HCl controlled release (CR; 20–50 mg), or placebo over a 12-week maintenance period. Maintenance was preceded by a 3-week titration period when each patient adjusted their dose to achieve an optimal, stable dose. The primary endpoint for non-US regulatory authorities was change from baseline in average pain intensity (0–10 NRS) over the maintenance period. Last observation carried forward was used for imputing missing values.

Results: Of 981 randomized patients, 965 were evaluable for safety and 958 for efficacy. Tapentadol ER and oxycodone CR treatment resulted in greater reductions in average pain intensity than placebo over the maintenance period (least-squares mean difference from placebo, −0.7 and −0.8, respectively; $P < 0.001$ for both). For placebo, tapentadol ER, and oxycodone CR, respectively, incidences of treatment-emergent adverse events (TEAEs) were 59.6%, 75.5%, and 84.8%; incidences of specific TEAEs were nausea, 9.1%, 20.1%, 34.5%; vomiting, 1.6%, 9.1%, 19.2%; constipation, 5.0%, 13.8%, 26.8%; headache, 13.8%, 19.8%, 16.8%; dizziness, 5.6%, 11.9%, 17.1%; somnolence, 2.5%, 13.2%, 16.2%; and pruritus, 1.9%, 7.2%, 16.8%. In the placebo, tapentadol ER, and oxycodone CR groups, respectively, TEAEs led to study discontinuation in 4.4%, 16.7%, and 31.7% of patients.

Conclusions: Tapentadol ER (100–250 mg bid) was significantly superior to placebo in relieving moderate-to-severe chronic low back pain, with lower incidences of TEAEs and fewer TEAE-related discontinuations than oxycodone CR (20–50 mg bid).

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EFFICACY AND SAFETY OF TAPENTADOL EXTENDED RELEASE (ER) IN PATIENTS WITH DIABETIC PERIPHERAL NEUROPATHIC PAIN: RESULTS OF A RANDOMIZED-WITHDRAWAL STUDY

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Background and Aims: The analgesic efficacy and safety of tapentadol ER were evaluated in patients with painful diabetic peripheral neuropathy (DPN).

Methods: Patients were titrated to an optimal dose of tapentadol ER (100–250 mg bid) during a 3-week open-label phase; patients with ≥ 1-point improvement in pain intensity (11-point NRS) were randomized to placebo or their optimal dose of tapentadol ER for a 12-week double-blind phase. Efficacy was evaluated as change in mean pain intensity from pre-titration to week 12 of double-blind treatment using the last observation carried forward and linear interpolation. Responders were grouped by percentage change in average pain intensity from the start of open-label treatment. Percentages of patients with ≥ 30% or ≥ 50% improvement were compared using Cochran-Mantel-Haenszel methods; patients who discontinued double-blind treatment were non-responders. Safety was assessed.

Results: Of 588 patients in the open-label safety population, 395 were randomized in the double-blind period and 389 were analyzed for safety and intent-to-treat. Higher percentages of patients treated with tapentadol ER experienced ≥ 30% and ≥ 50% improvement in pain intensity than with placebo (≥ 30%: 53.6% vs 42.2%, respectively; $P = 0.017$; ≥ 50%: 37.8% vs 27.6%, respectively; $P = 0.028$). The safety profile for tapentadol ER was similar to that reported in previous phase III trials. Treatment-emergent adverse events led to discontinuation in 20.1% of patients during open-label treatment, and 5.7% of placebo- and 11.2% of tapentadol ER-treated patients during double-blind treatment.

Conclusion: In patients with painful DPN and an initial response to tapentadol ER, 12-week treatment was effective and well-tolerated, with superior response rates versus placebo.

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OUR EXPERIENCE WITH INTRA-ARTICULAR HYALURONIC ACID INJECTIONS INTO KNEE JOINTS FOR PAIN RELIEF

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Background and Aims: At the Department of Physical Medicine and Rehabilitation, University Clinical Centre Maribor, we offer rehabilitation services for patients with arthrotic knees. The aim of our study was to assess the efficacy of intra-articular hyaluronic acid injections on pain relief in those patients.

Methods: From 2006 to 2008, we gave intra-articular injections of hyaluronic acid to 36 patients, of which 25 were female and 11 male with an average age of 58 and 62 years, respectively. For the treatment we used natrium-hyaluronate. Each patient received 5 injections with a one week interval between each injection. X-ray images and clinical diagnostic tools (mobility, pain) were used for assessment. Majority of patients exhibited grade 1 and 2 osteoarthritic changes (mild degenerative changes). The initial average pain level measured by VAS was 8 (out of 10).

Results: Assessment was done with the help of a questionnaire, evaluation of mobility and VAS pain scale. 6 months after the treatment the mobility improved in 55% of the male patients and 44% of the female patients (exceeding 90°) while the initial average VAS scale value dropped from 8 to 3. During this period the patients were not taking any non-steroid antirheumatic drugs