

DER DEUTSCHE SCHMERZ- und PALLIATIVTAG 2008

Anmeldung eines wissenschaftlichen Beitrages

Titel: PAIN CONTROL AND TREATMENT SATISFACTION WITH OROS® HYDROMORPHONE (JURNISTA®) DURING A 3 MONTH PERIOD IN PATIENTS WITH CHRONIC SEVERE PAIN DUE TO OSTEOPOROSIS IN A DAILY ROUTINE SETTING

Autoren: J.D. Ringe¹, M. Stumpf², K. Bornhövd²

Institution: ¹Med. Klinik 4, Klinikum Leverkusen, ²Janssen-Cilag GmbH, Neuss

Objective:

The efficacy of strong opioids for the management of chronic non-malignant pain, such as low-back pain and osteoarthritis, has been demonstrated consistently in a number of studies and has been implemented in guidelines. Few data however, have been published about the use of strong opioids in the treatment of pain in osteoporosis. A once-daily, extended-release hydromorphone formulation was developed that uses the oral osmotic (OROS®) push-pull system to provide pain relief during a 24 hours dosing interval.

Method:

Planned interim analysis of a multicenter, prospective, non-interventional, open study (OROS-ANA-4001) to obtain data on pain control and treatment satisfaction under a therapy with OROS® hydromorphone of the first 100 patients (300 planned in total) with chronic severe pain due to osteoporosis during a 3 month treatment under daily routine conditions. With the exception of short-acting opioids for break-through pain, patients should not be treated with other opioids of WHO-stage III. A total of 6 visits should be performed, on day 0 (V1), 6 and 15 as well as at the end of first, second and third month (V6). Dose regimen was at the discretion of the treating physician. For assessment of pain control the 'average pain at rest/movement during last 24 hours'

for day and night were documented. Patients determined a degree of pain they would set as target for a successful pain treatment at V1. Both were assessed on a numeric rating scale (NRS 0-10). Patients/Investigators rated satisfaction with pain control and tolerability [verbal rating scale: very satisfied, satisfied, sufficiently satisfied, not satisfied]. Impact of pain on activities of daily living was measured using the Brief Pain Inventory (BPI). Previous/concomitant medication and adverse events were documented. Pre-post-changes between V1 and V6 were tested with the Wilcoxon test for dependent samples. Missing values were replaced using the last observation carried forward (LOCF) method.

Results:

100 patients were available for the safety analysis (80.0% of the patients were female. Mean age was 69.1 years), 94 for the ITT analysis. On average patients suffered from chronic pain for 6.1 years. Average dose of OROS® hydromorphone was 15.1 mg/d (median: 8.1). At V1 patients had a mean pain intensity of 6.0 (day at rest) and 7.8 (day on movement), 5.2 (night at rest) and 7.0 (night on movement). At their last assessment patients documented a mean reduction of 2.4 and 2.7 during the day and 2.4 and 2.7 at night, respectively ($p < 0.0001$ for all). A pain intensity of 4 or less was considered a successful pain treatment and was reached by 71.3 % of patients. Pain ratings obtained by BPI were consistent with these results and improved significantly ($p < 0.0001$ for all). Impact of pain on all activities of daily living measured by the BPI decreased significantly ($p < 0.0001$). At last assessment 67.4 % of patients rated their pain control as better (75.6 % of investigators) compared to prior pain treatment ($p < 0.0001$). 69.6 % of patients ($n = 39/58$) did not use breakthrough pain medication at visit 6. 232 adverse events were observed in 75 patients, in 4 patients serious adverse events (all not related to study drug). Adverse event profile was consistent with the one known for OROS® hydromorphone.

Conclusion:

Under routine conditions it was documented that OROS® hydromorphone once daily leads to a very good pain control combined with a high treatment satisfaction in patients with chronic severe pain due to osteoporosis. OROS® hydromorphone is a useful treatment option for patients with chronic severe pain due to osteoporosis.