

## Pain Characteristics of Patients Prescribed Opioid Therapy for Chronic Noncancer Pain: Data From the Opioid Utilization Study

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### Purpose

Clinical trials are not sufficient for addressing outcomes in opioid therapy for chronic noncancer pain (CNCP) because they may not accurately reflect clinical practice. The Opioid Utilization Study (OPUS) is a 12-month, multicenter, prospective, observational study to gather data on current clinical practice in opioid therapy for CNCP, including the economic impact of opioid titration, switching, and rotation; pain relief and quality-of-life measures; economic patient-reported outcomes; and healthcare resource utilization. We assessed pain intensity and pain interference with activities of daily living over a 12-month period in patients with chronic low back pain (cLBP) and osteoarthritis (OA) enrolled in OPUS.

### Method

OPUS entry criteria were broad: age  $\geq 18$  years, CNCP for  $\geq 3$  months, and currently receiving or starting opioid pain therapy. Exclusion criteria were cancer pain, history or high risk of substance abuse, or an open workers' compensation claim. Participating physicians followed their routine practice of pain management with no direction from the study sponsor. At baseline, 6-month, and 12-month follow-up visits, patients completed the Brief Pain Inventory (BPI) to assess pain intensity (worst pain in last 24 h, average pain) and interference of pain with activities (general activity, work, and enjoyment of life). BPI scores were analyzed using descriptive statistics (mean [SE], counts, percentages) and summarized using frequency distributions of mild (0-3), moderate (4-6), and severe (7-10) pain/impairment. At the cutoff date for this analysis, baseline data was available for the full cohort, 6-month follow-up data was available for approximately 2/3 of the cohort, and 12-month follow-up data was available for approximately 1/2 of the cohort.

### Results

Of 2003 patients enrolled in OPUS, baseline, 6-month, and 12-month data, respectively, were available for  $\leq 1302$ , 832, and 563 patients with cLBP and for  $\leq 407$ , 266, and 134 patients with OA. In these groups at baseline, 60% were women,  $\geq 86.0\%$  were white,  $\geq 84.8\%$  had a  $>1$ -year history of chronic pain, and  $\geq 68.1\%$  had used opioids for  $>1$  year. Mean (SE) baseline BPI scores for patients with cLBP and OA indicated average pain intensity that was moderate (5.8 [0.06], 5.7 [0.10], respectively), worst pain intensity that was severe (7.5 [0.06], 7.3 [0.10]), and moderate pain interference with general activity (6.2 [0.07], 5.9 [0.13]), work (6.5 [0.08], 6.2 [0.14]), and enjoyment of life (5.6 [0.09], 5.2 [0.16]). At 1 year, mean (SE) BPI scores in patients with cLBP and OA indicated no change in average pain intensity (5.7 [0.08], 5.7 [0.15]) or worst pain intensity (7.4 [0.08], 7.4 [0.15]) or in pain interference with general activity (6.3 [0.11], 6.1 [0.22]), work (6.4 [0.11], 6.4 [0.23]), and enjoyment of life (5.6 [0.13], 5.2 [0.25]). Frequency distributions were stable between baseline and 1 year for average pain intensity (severe impairment: cLBP, 37.1% and 37.0%, respectively; OA, 34.6% and 37.1%), pain interference with normal work (severe impairment: cLBP, 55.5% and 56.0%; OA, 50.4% and 51.5%), and pain interference with enjoyment of life (severe impairment: cLBP, 42.2% and 44.0%; OA, 36.4% and 38.8%). Frequency distributions were stable or slightly improved at 1 year for worst pain intensity (severe impairment: cLBP, 76.6% and 74.8%; OA, 73.4% and 66.4%) and slightly worsened for pain interference with general activity (severe impairment: cLBP, 49.4% and 53.5%; OA, 43.6% and 48.9%).

## **Conclusions**

This preliminary analysis of OPUS data found that patients prescribed opioid therapy for OA and cLBP in clinical practice exhibited stability (no worsening or slight improvement) of BPI measures of pain and function over 1 year of observation. The majority of this cohort had been prescribed opioids for more than 1 year before enrollment, representing a population with established tolerance to opioids. Further analyses of the OPUS database will continue to evaluate the impact of opioid therapy for CNCP in clinical practice.