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I4 Effect of Intrathecal Ziconotide as the First Agent in Pump on Patient-Reported Outcomes

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PURPOSE
The Patient Registry of Intrathecal Ziconotide Management (PRIZM) evaluated intrathecal (IT) ziconotide use in clinical practice settings.

METHODS
PRIZM was an open-label, long-term, multicenter, observational study of adult patients with severe chronic pain who met ziconotide prescribing information criteria. This analysis of ziconotide as the first versus second-or-later IT agent in pump reports Patient Global Impression of Change (PGIC) and change from baseline in 36-Item Short Form Health Survey version 2 (SF-36v2) and Brief Pain Inventory-Short Form (BPI-SF) scores at month 18.

RESULTS
Of the 93 enrolled patients, 30 patients were still active in the study at month 18, of whom 56.7% (17/30) remained on ziconotide monotherapy. Fifty-one patients (54.8%) received ziconotide as the first agent in pump (FIP+), whereas 42 patients (45.2%) did not (FIP-). PGIC improvement was reported in 100.0% of FIP+ patients (n=9) versus 37.5% of FIP- patients (n=8) at month 18 relative to baseline. At month 18, mean change in SF-36 physical component score was 6.5 and 1.4 in FIP+ and FIP- patients, respectively, and mean change in SF-36 mental component score was 8.0 and -1.8, respectively. Mean change in BPI-SF Pain Severity domain score at month 18 was −2.6 and 0.2 in FIP+ and FIP- patients, respectively. Mean change in BPI-SF Pain Interference score was −3.3 and 0.4 in FIP+ and FIP- patients, respectively, at month 18. The most common adverse events (≥15% of overall population) were nausea (25.8%), confusional state (22.6%), dizziness (20.4%), auditory hallucination (18.3%), and diarrhea (16.1%).

CONCLUSION
In this PRIZM study, for those remaining on therapy, greater improvement in patient-reported outcomes (PGIC, SF-36, and BPI-SF) was observed when ziconotide was initiated as first-line IT therapy versus second-or-later IT agent in pump. The adverse event profile of ziconotide was consistent with the prescribing information.

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