CNS Abstract

Multicenter Clinical Study Evaluating Oxiplex in Lumbar Surgery

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"Multicenter Clinical Study Evaluating Oxiplex in Lumbar Surgery" (Abstract No: 73)

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Introduction:
This study was a randomized, third-party blinded, multicenter, pivotal clinical trial to evaluate the safety and effectiveness of Oxiplex gel to reduce postoperative back and leg pain as well as related symptoms following surgery at L4-L5 or L5-S1.

Methods:
Subjects undergoing single-level lumbar laminectomy or laminotomy, with decompression and/or a discectomy were randomized to receive either surgery plus Oxiplex (N=177) or surgery alone (N=175). Subjects were assessed 1, 3 and 6 months following surgery using 1) the Lumbar Spine Outcomes Questionnaire: LSOQ, BenDebba et al, Spine J. 7:118-132; and 2) clinical evaluations. Safety was evaluated by analyzing adverse events and clinical symptoms.

Results:
Baseline demographics, surgical procedures, LSOQ scores and clinical evaluations were balanced between Oxiplex (N=177) and surgery-only (N=175) groups. There were no statistically significant differences in the number of adverse events, laboratory values or physical findings between Oxiplex-treated subjects and Controls. Oxiplex subjects in the challenging patient population having severe back pain at baseline showed greater reductions in pain and symptoms from baseline across all LSOQ variables compared to surgery-only Controls. In that population, there was a statistically significant reduction of back pain [P=0.013] and leg pain [P=0.012] in the Oxiplex group compared to Controls at 6 months following surgery. More Oxiplex subjects were satisfied with the outcome of their surgical treatment than Control subjects (P=0.045). Fewer subjects in the Oxiplex group had abnormal musculoskeletal physical exams at 6 months compared to Controls. Subjects in the Oxiplex group had less hypoesthesias, paraesthesias, and sensory loss compared to Controls. Subjects in the Oxiplex group had fewer re-operations during the 6-month follow-up than Controls (1 vs. 6).

Conclusions:
Taken together, these data demonstrate a consistent clinically significant improvement in outcomes resulting from the use of Oxiplex gel in lumbar spine surgery.

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