

## ORIGINAL ARTICLE

# Efficacy of etanercept delivered by perispinal administration for chronic back and/or neck disc-related pain: a study of clinical observations in 143 patients

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## SUMMARY

*Objective:* Documentation of the clinical results obtained utilizing perispinal etanercept off-label for treatment-refractory back and neck pain in a clinical practice setting.

*Research design and methods:* The medical charts of all patients who were treated with etanercept for back or neck pain at a single private medical clinic in 2003 were reviewed retrospectively. Patients were treated if they had disc-related pain which was chronic, treatment-refractory, present every day for at least 8 h, and of moderate or severe intensity. Patients with active infection, demyelinating disease, uncontrolled diabetes, lymphoma or immunosuppression were excluded from treatment with etanercept. Etanercept 25 mg was administered by subcutaneous injection directly overlying the spine. Visual Analogue Scales (VAS, 0–10 cm) for intensity of pain, sensory disturbance, and weakness prior to and 20 min, 1 day, 1 week, 2 weeks, and 1 month after treatment were completed. Inclusion criteria for analysis required baseline and treatment VAS data.

*Main outcome measures:* Before and after treatment VAS comparisons for intensity of pain, sensory disturbance, and weakness.

*Results:* 143 charts out of 204 met the inclusion VAS criteria. The 143 patients had a mean age of  $55.8 \pm 14$ , duration of pain of

$9.8 \pm 11$  years, and an initial Oswestry Disability Index of  $42.8 \pm 18$ , with 83% having back pain, 61% sciatica, and 33% neck pain. 30% had previous spinal surgery, and 69% had previously received epidural steroid injections (mean  $3.0 \pm 3$ ). The patients received a mean of  $2.3 \pm 0.7$  doses of perispinal etanercept separated by a mean interval of  $13.6 \pm 16.3$  days. The mean VAS intensity of pain, sensory disturbance, and weakness were significantly reduced after perispinal etanercept at 20 min, 1 day, 1 week, 2 weeks, and 1 month with a  $p < 0.0001$  at each time interval for the first dose in this patient population.

*Conclusions:* Perispinal etanercept is a new treatment modality which can lead to significant clinical improvement in selected patients with chronic, treatment-refractory disc-related pain. Generalizability of the present study results is limited by the open-label, uncontrolled methodology employed. Based on this and other accumulating recent studies, etanercept may be useful for both acute and chronic disc-related pain. Further study of this new treatment modality utilizing double-blind placebo controlled methodology is indicated.

*Note:* This treatment method is protected by multiple patents awarded to Edward Tobinick MD, including U.S. patents 6 015 557; 6 177 077; 6 419 944; 6 537 549 and Australian patent 758 523.