

Brief Report

Targeted Etanercept for Discogenic Neck Pain: Uncontrolled, Open-Label Results in Two Adults

Edward L. Tobinick, MD

Institute Research Associates, A Medical Group, Inc., Los Angeles, California

ABSTRACT

Background: Etanercept, a recombinant biologic anti-tumor necrosis factor (TNF)-alpha therapeutic, is approved for the treatment of certain autoimmune arthritides by subcutaneous (SC) injection. TNF-alpha has been suggested to play a central role in neuropathic pain and neuronal damage associated with intervertebral disc herniation. Directed local administration of etanercept, in anatomic proximity to the site of disc and neuronal abnormality, may result in an enhanced therapeutic response.

Objective: This study reviews findings from 2 patients with chronic, severe, discogenic cervical pain who were treated with a targeted cervical injection of etanercept with the objective of obtaining relief from their treatment-resistant pain.

Methods: In this uncontrolled, open-label study, the case histories of 2 patients (1 woman and 1 man) presenting with a history of chronic neck pain refractory to various treatments are reviewed. Both patients were treated with etanercept 25 mg by SC injection to the cervical region (case 1) or the posterior neck overlying the spine (case 2).

Results: Both patients experienced almost complete pain relief as assessed subjectively. In case 1, the Oswestry score decreased from 58 before treatment to 6 one day following treatment. In addition, 1 day after treatment the patient reported a subjective assessment of 98% pain improvement, 100% sensory improvement, and 100% weakness improvement. She has remained asymptomatic for >1 year. In case 2, the Oswestry score decreased from 44 before treatment to 4 two months after treatment. As with case 1, the patient reported 98% pain improvement, 100% sensory improvement, and 100% weakness improvement 1 day

Accepted for publication February 10, 2003.

Printed in the USA. Reproduction in whole or part is not permitted.

0149-2918/03/\$19.00

after treatment. At 8-month follow-up, pain improvement continued to be 100% and sensory improvement was 75%.

Conclusions: Etanercept, delivered by targeted SC injection, may be of benefit for selected patients with resistant pain associated with cervical disc disease. Further study of this new treatment modality is warranted. (*Clin Ther.* 2003;25:1211–1218) Copyright © 2003 Excerpta Medica, Inc.

Key words: discogenic pain, cervical radiculopathy, etanercept, TNF-alpha.

INTRODUCTION

Etanercept, a recombinant biologic anti-tumor necrosis factor (TNF)-alpha therapeutic, has been demonstrated to effectively reduce pain in patients with a variety of different inflammatory disorders.^{1–3} TNF-alpha has been suggested to play a central role in the inflammatory process that often accompanies intervertebral disc herniation.⁴ In addition, TNF-alpha has been suggested to have a key role in the development of neuropathic pain.⁵

In experimental models TNF-alpha inhibition has been shown to prevent TNF-alpha-mediated pain behavior and neuronal damage.^{6,7} TNF-alpha inhibitors may offer a more specific pharmacologic approach to discogenic pain than non-steroidal anti-inflammatory agents or epidural steroids.^{8,9} Intervertebral discs are in anatomic proximity to the subcutaneous (SC) space overlying the disc, particularly in the cervical region. Directed injection of etanercept into the SC space adjacent to the site of disc abnormality may allow the achievement of high local concentrations of the therapeutic TNF-alpha inhibitor, thereby leading to a more rapid onset of action and an improved therapeutic effect.

CASE REPORTS

Treatment results reported are for patients attending our private medical clinic. Treatment with etanercept was performed as part of routine clinical practice. The patients were informed that etanercept for neck pain had not been shown to be either safe or effective, and that this use represented an off-label indication for etanercept, which had been approved by the US Food and Drug Administration only for the treatment of rheumatoid arthritis and related diseases. The patients were given a manufacturer's patient handout to read, detailing the possible risks. After patients were informed of the risks, written informed consent was obtained prior to treatment.

Case 1

A 60-year-old woman presented to our clinic after 2 months of treatment-resistant neck pain caused by an intervertebral disc protrusion. The neck pain