

ADALIMUMAB IN SEVERE AND ACUTE SCIATICA A MULTICENTRE, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

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Background

In addition to nerve compression, the presence of inflammation in tissues surrounding the herniated disc seems to play an important role in sciatica. Animal studies have shown that tumor necrosis factor (TNF)-alpha plays an important role in this inflammatory process. In addition, we have recently shown that TNF-alpha levels are increased in the periradicular fat of patients with sciatica. The objective was to determine the role of TNF-alpha in the pathogenesis of sciatica and whether adalimumab, a human anti-TNF agent administered subcutaneously, could fasten the evolution of severe acute sciatica.

Methods

A multicentre, double-blind, randomised controlled trial was conducted between May 2005 and December 2007 in Switzerland. Patients with acute (< 12 weeks) and severe (Oswestry Disability index > 50) radicular leg pain and imaging-confirmed lumbar disc herniation were randomised to receive as adjuvant therapy either two subcutaneous injections of adalimumab (40 mg) at 7 days interval or matching placebo. The primary outcome was leg pain, which was recorded every day for 10 days and at 6-weeks and 6-months based on a visual analogue scale (0 to 100).

Results

Of the 265 patients screened, 61 were enrolled (adalimumab= 31) and 4 were lost to follow-up. Over time, the evolution of leg pain was more favourable in the adalimumab group than in the placebo group ($p < 0.001$). However, the effect size was relatively small and at last follow-up the difference was 13.8 (CI95% -11.5 - 39.0). In the adalimumab group twice as many patients fulfilled the criteria for "responders" and for "low residual disease impact" ($p < 0.05$) and fewer surgical discectomies were performed (6 versus 13, $p = 0.04$).

Conclusion

The addition of a short course of adalimumab to the treatment regimen of patients suffering from acute and severe sciatica resulted in a small decrease in leg pain and in significantly fewer surgical procedures.

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