



SAT0265 IMPACT OF ETANERCEPT ON PATIENT-REPORTED OUTCOMES: RESULTS FROM A RANDOMIZED, DOUBLE-BLIND STUDY OF PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Patients with ankylosing spondylitis (AS) are generally young, have few substantive treatment options, and tend to report impaired health-related quality of life.

Objectives: To evaluate the impact of etanercept (ETN) compared with suphasalazine (SSZ) on patient-reported outcomes (PROs) among patients with AS.

Methods: PROs were assessed using the Short Form-36 (SF-36, range 0-100), a generic health-related quality-of-life (QoL) measure consisting of 8 domains, at baseline and at week 16 as part of a double-blind, randomized trial in which patients received either ETN 50 mg once weekly (n=379) or SSZ up to 3 g daily (n=187). Eligible patients had active AS based on 1) BASDAI VAS ≥ 30 ; 2) morning stiffness VAS ≥ 30 ; and 3) VAS ≥ 30 for at least two of the following: patient global assessment of disease activity; pain; or BASFI. Mean changes from baseline in the SF-36 scores were analyzed using analysis of covariance in the intention-to-treat population. In addition, correlations between SF-36 and clinical parameters at week 16 were determined.

Results: The mean age was 41 years, 74% were male, and the average disease duration was 7.6 years. Overall, 354 in the ETN group and 165 in the SSZ group had evaluable SF-36 scores. The two groups had similar baseline SF-36 scores with substantially impaired QoL. Baseline scores were notable in that all 8 domains were impaired. In particular, the physical function domain score at baseline (see table) in this AS population was comparable or lower than that reported in patients with diabetes (67.7), congestive heart failure (47.5), and hypertension (73.4).¹ All SF-36 domains improved after treatment at week 16. There was a significantly greater improvement in the ETN group than the SSZ group in all the domains, with the exception of role-limitations emotional. The Pearson correlation coefficient of SF-36 domains ranged from -0.43 to -0.71 for BASDAI, -0.45 to -0.78 for BASFI, and -0.15 to -0.48 for BASMI. Improvement in SF-36 scores was the greatest in patients achieving ASAS70 response for all 8 domains (mean improvement ranged from 15 to 51 points) and virtually no change was observed in patients who did not reach an ASAS20 response.

Table:

SF-36 Domain	Mean (% improvement) at baseline and week 16			
	Baseline ETN	Baseline SSZ	Week 16 ETN	Week 16 SSZ
Physical function	51.3	49.1	67.6 (32%)*	60.7 (24%)
Vitality	41.6	41.5	57.0 (37%)**	48.8 (18%)
Social functioning	58.0	58.3	73.8 (27%)**	65.3 (12%)
Mental health	61.5	63.0	71.9 (17%)**	66.2 (5%)
Role-limitations physical	23.8	24.6	54.0 (127%)*	43.9 (79%)
Bodily pain	32.8	33.2	59.1 (80%)**	47.9 (44%)
Role-limitations emotional	47.8	49.8	68.2 (43%)	62.0 (25%)
General health	38.1	37.5	52.5 (38%)**	43.9 (17%)

* $P < 0.01$; ** $P < 0.001$

Conclusion: In this study, etanercept treatment significantly improved multiple dimensions of PROs compared with SSZ. There was a relationship between PROs and clinical status, with the greatest PRO benefit in patients who achieved greater clinical improvement.

References: 1. Ware JE, Kosinski M, Gandek B. SF-36^R Health Survey: Manual & Interpretation Guide. Lincoln, RI: Quality Metric Incorporated, 1993.

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