Clinically Relevant Outcomes in Osteoarthritis: Analysis of Pooled Data From Two Randomized, Placebo-controlled Trials of Duloxetine in Patients With Osteoarthritis of the Knee

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Purpose

To determine response to duloxetine versus placebo in patients with osteoarthritis (OA) of the knee using Outcome Measures in Rheumatology Arthritis Clinical Trials-Osteoarthritis Research Society International (OMERACT-OARSI) criteria, and to assess the comparability and correlation with minimal clinically important improvement (MCII) and patient acceptable symptom state (PASS) for pain and function.

Method

Data were pooled from two 13-week, double-blind, randomized controlled trials comparing duloxetine 60 to 120 mg/day (n=239) and placebo (n=248) in patients with symptomatic OA of the knee. Treatment response was determined according to the OMERACT-OARSI criteria, in addition to MCII and PASS for pain and function using criteria developed by Tubach and colleagues. Agreement among the efficacy outcomes is reported in terms of the kappa (κ) coefficient.

Results

Patients randomly assigned to duloxetine were 33% more likely to experience an OMERACT-OARSI response compared to placebo (relative risk [RR]=1.33, 95% confidence interval [CI]: 1.15 to 1.55, p≤.001). The greatest agreement was between OMERACT-OARSI responders and ≥30% reduction in pain (κ=0.78), defined as clinically meaningful improvement by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations. Moderate agreement was demonstrated between OMERACT-OARSI response and achieving a MCII for pain (κ=0.59), PASS for pain (κ=0.58), PASS for function (κ=0.43), and ≥50% reduction in pain (κ=0.55).

Conclusions

Significantly more patients receiving duloxetine than placebo achieved an OMERACT-OARSI response, achieved improvements in pain and function exceeding the level accepted as MCII, and achieved PASS. These results support the efficacy of duloxetine for symptomatic OA of the knee.