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EFFICACY AND TOLERABILITY OF QUETIAPINE XR 400/600/800MG/DAY IN ACUTE SCHIZOPHRENIA: A POST-HOC ANALYSIS OF DATA FROM TWO POOLED RANDOMISED STUDIES

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Introduction: Data from two, identically designed, placebo-controlled, randomised, double-blind clinical trials (D1444C00132+D1444C00133) for once-daily extended-release quetiapine fumarate (QTP-XR) were pooled and analysed.
Objective: Evaluate dose response, efficacy and safety for QTP-XR in schizophrenia.
Methods: Post-hoc analysis of data from patients receiving QTP-XR 400, 600, 800mg/day or placebo. Endpoints: least squares means (LSM) change from baseline to Day 42 in PANSS total and positive and negative subscale scores. No corrections for multiplicity were performed. Adverse events (AEs) were recorded.
Results: 914 patients were included; PANSS scores were assessed in the MITT population (n=889). LSM change from baseline in PANSS total score diverged significantly from placebo at: Day 14 for QTP-XR 800mg/day (-15.3 vs -12.1 for placebo; p=0.018); Day 21 for 600mg/day (-17.3 vs -14.2; p=0.039); Day 42 for 400mg/day (-19.2 vs -15.4; p=0.033). Jonckheere-Terpstra analysis of change in PANSS total score at Day 42 showed a significant QTP-XR dose response (p=0.0196; p< 0.001 with placebo). PANSS positive scores diverged by Day 21 for both QTP-XR 800 (-5.7 vs -4.8; p=0.049) and 600mg/day (-5.8 vs -4.8; p=0.046). PANSS negative scores diverged by Day 21 (-4.0 vs -3.2; p=0.040) and 42 (-4.8 vs -3.6; p=0.009) for QTP-XR 800 and 600mg/day, respectively. AEs occurred in 59.4%, 66.5%, 62.1% and 56.2% of patients in the QTP-XR 800, 600, 400mg/day and placebo groups, respectively. Most common AEs were somnolence, dry mouth, sedation, insomnia, dizziness, headache, constipation and nausea.
Conclusions: QTP-XR was generally well tolerated and demonstrated efficacy that increased with dose in schizophrenia.
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