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Aripiprazole Once-monthly is Superior to Paliperidone Palmitate in a Randomized, Head-to-head Clinical Study

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Introduction:

This study directly compares the effectiveness of aripiprazole once-monthly 400 mg (AOM) and paliperidone palmitate once-monthly (PP) on the validated and symptom-focused Heinrichs-Carpenter Quality-of-Life Scale (QLS) in schizophrenia.

Methods:

A 28-week, randomized, open-label rater-blinded, head-to-head study (NCT01795547) of AOM and PP in adult patients (18-60 years) needing a change from current oral antipsychotic treatment for any reason. The study comprised oral conversion, initiation of AOM or PP treatment according to labels, and treatment continuation with injections every 4 weeks. The primary endpoint assessed non-inferiority and subsequently superiority on change from baseline to week 28 in QLS total score analyzed using a mixed model for repeated measurements.

Results:

Of 295 randomized patients, 100/148 (67.6%) of AOM and 83/147 (56.5%) of PP patients completed 28 weeks of treatment. In treated patients, adverse events (AEs) were the most frequent reason for discontinuation; AOM: 16/144 (11.1%), PP: 27/137 (19.7%). The difference in change from baseline to week 28 on QLS total score was statistically significant (4.67 [95%CI: 0.32;9.02], p=0.036), confirming non-inferiority and establishing superiority of AOM compared to PP. The respective changes were 7.47±1.53 for AOM and 2.80±1.62 for PP. AEs occurring at rates ≥5% in either group in the treatment continuation phase were weight increased (AOM: 12/119 [10.1%]; PP: 17/109 [15.6%]), psychotic disorder (AOM: 3/119 [2.5%]; PP: 6/109 [5.5%]) and insomnia (AOM: 3/119 [2.5%]; PP: 6/109 [5.5%]).

Conclusion:

Superior improvements on the clinician-rated QLS and lower rates of all-cause discontinuation suggest greater overall effectiveness for aripiprazole once-monthly vs paliperidone palmitate.

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