Conclusion: Clinically relevant improvements in psychopathology were observed in patients with acute schizophrenia treated with brexpiprazole or aripiprazole. Brexpiprazole was well tolerated with a lower incidence of EPS-related adverse events than aripiprazole.

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Long-term safety of brexpiprazole (OPC-34712) in schizophrenia: results from two 52-week open-label studies

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Abstract

Background: The long-term safety and tolerability of brexpiprazole were evaluated in patients with schizophrenia, based on pooled data from two large open-label extension studies.

Methods: These two studies were open-label, 52-weeks, flexible-dose (study 1 [NCT01649557]: 1 to 6mg/day and study 2 [NCT01397786]: 1 to 4mg/day) studies with brexpiprazole. Study 1 enrolled patients who had completed a phase II study (NCT00905307) while study 2 enrolled de novo patients as well as patients who had completed one of the two pivotal phase III studies in acute schizophrenia (NCT01396421[1] or NCT01393613[2]). As study 2 is still ongoing, the data presented are based on a data-cut from 15-May-2015.

Results: A total of 1059 patients entered the studies [28 from study 1 and 1031 from study 2 of which 224 were de novo patients]. Of these, 34.0% (360/1059) completed 52 weeks of treatment. Adverse events reported by ≥5% of the patients in the extension studies were schizophrenia (10.7%), insomnia (8.0%), weight increased (7.7%), headache (6.0%), and agitation (5.2%); the adverse event profile was similar to what was observed in the short-term lead-in studies. The mean weight gain was 1.5kg at week 26 (N=485) and 2.2kg at week 52 (N=357) for the observed cases, and 0.5% (5/1059) of patients discontinued due to treatment-emergent adverse events associated with weight increase. The increases in body weight were not accompanied by meaningful changes in lipid profiles or glycemic parameters.

Conclusion: Long-term treatment with brexpiprazole (1 to 6mg daily) was safe and well tolerated in patients with schizophrenia, as evaluated in two open-label extension studies.

References

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An Assessment of Injection Site Reactions and Injection Site Pain of Once-Every One Month and Three-Month Long-Acting Injectable Formulations of Paliperidone Palmitate

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Abstract

Background: Injection site reactions and pain associated with long-acting antipsychotics is of interest to healthcare professionals. Safety data of a randomized, double blind (DB), parallel group, multicenter, non-inferiority study (NCT01515423) evaluated paliperidone palmitate 3 month (PP3M) and 1 month (PP1M) injection site reactions and pain.

Methods: Patients (N=1429) with schizophrenia were initially treated with PP1M (50–150 mg eq.) in a 17 week open-label (OL) phase. Upon meeting clinical stabilization criteria, patients were randomized 1:1 to PP1M or PP3M in a 48 week DB phase. Patients assigned to PP3M received a 3.5 multiple of the PP1M dose received at week 13; patients in the PP1M group continued to receive the same dose as week 13. Injections occurred every month with PP3M patients receiving placebo injections to maintain blind. Investigators assessed injection site reactions within 30 minutes of each injection. Patients assessed pain using a visual analog scale (VAS; 0 [no pain] to 100 [maximum pain]).

Results: Overall, injections were well-tolerated. Incidence of induration, redness, and swelling were low in the OL (9–12%) and DB (7–13%) phases, and mostly mild in severity. Mean (SD) visual analog scale (VAS) pain scores decreased from 22.0 (21.6) at OL baseline to 19.2 (20.8) at OL week 17. At DB baseline mean (SD) VAS scores for PP3M and PP1M were 19.5 (20.7) and 18.4 (20.4), respectively; at DB endpoint mean (SD) VAS scores were 15.6 (17.9) and 15.5 (18.3) respectively. No notable changes in injection site reactions or pain were observed by injection site location (deltoid vs gluteal) during the OL and DB phases or by final OL dose (50–75 mg eq., 100 mg eq. or 150 mg eq.) of PP1M during the DB phase.

Conclusion: Injection site reactions and pain were low and similar between PP1M and PP3M, regardless of last dose of OL PP1M.

Keywords: Injection site reaction, pain, paliperidone palmitate, schizophrenia, 3-month formulation.

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A preliminary study of antipsychotics polypharmacy among schizophrenia patients who admitted to national mental hospital

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Abstract

Antipsychotics polypharmacy is commonly used in treatment of schizophrenia, despite a lack of evidence to support its safety and efficacy. Antipsychotics polypharmacy often results in high dose prescribing, additional adverse effect, difficulty identifying the drug that resulted in adverse effect, and relatively high cost compared to antipsychotics monotherapy. This study investigated the prevalence of antipsychotics polypharmacy and related clinical characteristics among schizophrenia patients who admitted to national mental hospital. Data of demographic characteristics, length of hospital stay, and prescribed antipsychotics was collected retrospectively using electronic medical record for inpatients with diagnosis of schizophrenia or schizoaffective disorder who discharged from National Chuncheon Hospital from 1st April 2011 to 30th 2013. Among 794 patients, antipsychotics polypharmacy was found in 500(63.8%) patients. Among these, 384(76.8%) patients were prescribed two kinds of antipsychotics, 98(19.6%) with three, 17(3.4%) with four, and 1(0.2%) with five, respectively. Clozapine was prescribed in 152(19.4%) patients. In patients with antipsychotics polypharmacy, quetiapine was most frequently prescribed antipsychotics(242 cases), followed by risperidone(171 cases). Length of hospital stay was significantly longer in patients with antipsychotics polypharmacy than patients with antipsychotics monotherapy. In this preliminary study, higher rate of antipsychotics