femoris 3+, positive left (L) Hoffman's reflex. Chemosensory Testing: Olfaction: Brief Smell Identification Test: 12 (normosmia). Retronasal Olfactory Testing: Retronasal Smell Index: 1 (Anosmia). Gustatory Testing: Propylthiouracil Disc Taste Test: 10 (normogeusia). Waterless Empirical Taste Test: sweet: 4, sour: 3, salty: 7, bitter: 5, brothy: 0, total: 30 (ageusia to umami, otherwise normogeusia). Neuropsychiatric Testing: Go-No-Go Test: 2/6 (abnormal).

Discussion. Perhaps hypergeusia may not have been true hypergeusia but a misperception of retronasal smell associated hyperosmia with physiologic synesthesia manifested as taste. Peradventure, the perceived hypergeusia, is just one component of a generalized delusional paradigm, where many sensory perceptions are intensified. The perceived delusional hyperosmia may be intensification of the sensory misperception due to an underlying dysgeusia. This may represent a variant of the two-factor hypothesis of delusions whereby a distorted sensory perception is then misrepresented in a delusion. Dysfunction of the right hemisphere, which normally acts to censor the left, allows the delusion to manifest. While two different anatomical abnormalities (one left and one right hemisphere) have been postulated to be the foundation of such delusions, it is distinctly possible that a single lesion of the inferior parietal lobule may be sufficient for both sensory distortions to be produced as well as loss of inhibition of delusional interpretation of distorted sensation of the frontal lobe by the right parietal lobe, yclept the sensorialist hypothesis. In those who present with hypergeusia, search for delusional origin is warranted and in those who present with delusions, query as to perceived hypergeusia may be revealing.

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Number Needed to Treat and Number Needed to Harm From Two Phase 3 Studies of Sublingual Dexmedetomidine for Treating Acute Agitation in Patients With Schizophrenia and Bipolar Disorder

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Abstract

Background. Episodes of acute agitation can occur in individuals who suffer from schizophrenia or bipolar disorder and these can be a significant challenge for patients and for those who provide care to them. Sublingual dexmedetomidine is a selective alpha2-adrenergic receptor agonist that was recently approved by the US Food and Drug Administration for the treatment of agitation in adults with schizophrenia or bipolar disorder. The sublingual form of dexmedetomidine does not undergo first-pass hepatic metabolism, thus resulting in greater absorption than when ingested. In two Phase 3 studies of adults with schizophrenia or bipolar disorder, sublingual dexmedetomidine significantly reduced acute agitation at 2 hours, as measured by the five-item Positive and Negative Syndrome Scale-Excited Component (PEC). When initially appraising the potential utility of a new medication, number needed to treat (NNT) and needed to harm (NNH) can be helpful to assess the size of the treatment effect and, hence, clinical relevance.

Objective. Calculation of NNT and NNH through post hoc analysis of Phase 3 data.

Methods. Post hoc analysis of data were performed on data from two double-blind, randomized, placebo-controlled studies of sublingual dexmedetomidine in adults with schizophrenia or bipolar disorder experiencing acute agitation. Patients were randomized to a single dose of sublingual dexmedetomidine 180 µg, 120 µg, or placebo. The primary endpoint was mean change from baseline in the PEC total score. A therapeutic response was defined as a ≥40% reduction from baseline in PEC total score at 2 hours. NNT was calculated for PEC response rate for sublingual dexmedetomidine versus placebo. NNH was calculated using the incidence of adverse events for sublingual dexmedetomidine versus placebo. Likelihood to be helped or harmed (LHH) was calculated as the ratio of NNH to NNT.

Results. NNT (95% CI) was 3 (2, 3) for 180 mcg and 3 (3, 4) for 120 ug in patients with schizophrenia and 3 (2, 3) for 180 mcg and 4 (3, 6) for 120 ug in patients with bipolar disorder. NNH was greater than 10 for all AEs except somnolence, where NNH was 7 (5, 10) for all doses pooled from both studies. LLH values were greater than 1 for efficacy versus applicable tolerability outcomes in all cases.

Conclusions. This post hoc analysis demonstrated favorable NNT and NNH values for sublingual dexmedetomidine. In all instances therapeutic response was encountered more frequently than any adverse event. These values compare favorably to similar analyses for other approved agents for the treatment of agitation associated with schizophrenia or bipolar disorder, including intramuscular and inhaled formulations.

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Clinical Determinants, Patterns, and Outcomes of Antipsychotic Medication Prescribing in the Treatment of Schizophrenia and Schizoaffective Disorder: A Naturalistic Cohort Study

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