Assessment of Efficacy and Safety of Haloxazolam in Psychiatric Patients with Insomnia

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To assess the usefulness of haloxazolam(Somelin), we evaluated the efficacy and safety of the drug in psychiatric patients with insomnia as an open trial manner.

Haloxazolam(5mg h.s.) was repeatedly administered to 38 subjects or the first week, and another dose was added to the previous one(total 10mg) during the next week in 10 patients whose insomnia had not been improved. Five-point global improvement scaling and 4 point safety scaling were performed before, 1 day, 3 day and 7 day after haloxazolam administration. Clinical utility as 5 point scale was assessed from both global improvement and safety scales.

The mean time to sleep induction was decreased from 118.3min to 77.6min and 57.2 min, at 1st day and 7th day of haloxazolam administration, respectively. The number of awakening in a night was decreased from 2.3 to 1.2 and 0.9 at 1st day and 7th day. The total duration of awkening was decreased from 84.8min to 52.4min and 24.9min at 1st and 7th day, respectively. Total sleep time was increased from 5.3 hour to 6.3 hour at 1st day and 6.7 hour at 7th day. All of these findings were statistically siginificant($p<0.01$). Haloxazolam improved insomnia in 72.3% of the patients and it was proved to be useful in 66.7% of them. Side effects were developed in 15.8% of the patients and those were mild and tolerable.

Haloxazolam proved to be useful in the management of insomnia in patients with some psychiatric disorders. The use of haloxazolam in many other medical and psychiatric conditions in general will need further evaluation on its clinical efficacy.