

Off Label Uses of Antipsychotic Drugs: A Concern

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Antipsychotic medications have revolutionized the treatment of psychiatric disease. Although approved initially for schizophrenia, antipsychotic medications also are used for numerous other conditions, including psychoses, bipolar disorder, delirium, depression, personality disorders, dementia, and autism (1).

Recently, antipsychotics are increasingly used for conditions where FDA approval and associated clinical evidence is less certain ie off label use of this group has shown increasing trend (2).

In a study Darshan *et al* (3), psychopharmacological agents most frequently used in off-label manner are clonazepam 31 (12.4%), lorazepam 30 (12%), and trihexyphenidyl HCl 25 (10%). Benzodiazepines such as clonazepam, lorazepam, and diazepam are used in depression, mania, bipolar disorder, obsessive compulsive disorder in off label manner. Trihexyphenidyl HCl is used in bipolar disorder, obsessive compulsive disorder and schizophrenia in their study. (3)

In one of the study, the high rates of off-label prescription of psychotropic medication have been documented even among children and adolescents. Adolescents age group has been the maximumally prescribed (62%), followed by children (29%), infants (8%) and neonates (1%). The percentage of off-label prescriptions by medication class prescribed in decreasing order of prescription frequency includes: anxiolytics 65%; antipsychotics 69%; antidepressants 92%; antiepileptics 51%; stimulants 30%; antiparkinsonians 100% and hypnotics 100%. The 5 drugs most commonly prescribed off label have been risperidone (12%), clobazam (12%), amitriptyline (11%), hydroxyzine (10%) and diazepam

(7%). Nearly half (47%) of all off-label prescriptions have been associated with 3 disorders: anxiety (24%), disruptive behaviour (12%) and pain (11%) in their study (4).

In our preliminary experience studying non psychotic indications of Psychopharmacological agents in medical OPD, the point prevalence of such prescription was substantially high (1.78%). Nortryptaline, clonazepam and gabapentine were the most frequently used drugs for medical indications like Neurological Headache, Restless leg syndrome, non specific arthralgias and sinus tachycardias (5).

The increasing use of antipsychotic drugs for off label indications warrant the attention of drug regulatory authorities and clinical researchers to establish highest level of available scientific evidence so that their regulatory status can be revised. This will also be in the interest of drug safety of group that has potential to cause serious long term adverse events.

References

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