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Abstract

Rediscovering Clozapine, identification of Barriers, and its place in treatment.

Gross Jason A.
Department of Pharmaceutical Executive, Canada

Abstract:

In 1989, Clozapine was approved in the United States for Treatment Resistant Schizophrenia (TRS), which after thirty years of use is still the only known treatment for TRS. In the United States, there are more than 3.5 million people living with schizophrenia, of which approximately 1 million have what is known as treatment resistant schizophrenia. However, this treatment option is only offered to about 3% of the 30% eligible TRS patients, and on average patients diagnosed with TRS wait 5 years before they are offered clozapine. Patients that should be placed on clozapine remain at risk for disease progression, pain and suffering, and the lack of treatment decreases their probability of having benefit once treatment is offered. Clozapine is the only medication licensed for treatment-resistant schizophrenia (TRS), which affects about one-third of those suffering from the disorder. Recently, there has been increased interest in redefining the role of clozapine in the treatment of schizophrenia in view of the evidence of superior efficacy and safety, despite serious side-effects.1 Meta-analyses have demonstrated that clozapine is significantly better at treating symptoms than first-generation antipsychotics and some (but not all) second-generation antipsychotics.2 This superior efficacy was also supported by two large, independently funded studies.3,4 Clozapine also appears to have broader effects, with evidence for efficacy in suicidality, aggression and substance misuse.1 In the USA, clozapine is approved by the Food and Drug Administration for the management of suicidality in people with schizophrenia or schizoaffective disorder. In addition, clozapine has been shown to have anti-aggressive properties5 and may also be effective in diminishing substance misuse.6,7 Tiihonen et al7 found, using a large database, that that people regularly taking clozapine had the lowest risk of premature mortality compared with both those on other antipsychotics and those not taking regular medication, despite the fact that the drug is associated

with a number of serious adverse side-effects. Although clozapine is the medication with the clearest benefits in treatment-resistant schizophrenia, many eligible patients never receive it.

Biography:

Dr. Gross is a pharmaceutical executive with over 28 years of experience in roles of increasing responsibility, spanning both FDA and industry. He has led and advised teams in the areas of scientific affairs, pharmaceutical development, pharmacovigilance, medical affairs, clinical development, operations and compliance. Dr. Gross's has spent most of his carrier providing incisive strategic and technical expertise to start-up pharmaceutical companies and venture capital. For the last four years, he has served as the Vice President of Scientific Affairs for HLS Therapeutics, responsible in part for managing the safety programs for CLOZARIL (clozapine). HLS manages the largest CLOZARIL (clozapine) education program worldwide in Canada, and is introducing new advancements in both the United States and Canada to better manage white blood cell testing of patients.

Publication of speakers:

1. Lieberman JA, et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. N Engl J Med. 2005;353:1209–23.
2. Lewis SW, et al. Randomized controlled trial of effect of prescription of clozapine versus other second-generation antipsychotic drugs in resistant schizophrenia. Schizophr Bull. 2006;32(4):715–23.

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