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Letter to the Editor

Whether Common Colds Actually Affect Clozapine Serum Levels Requires Appropriately Designed Studies

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We were interested to read the article by Cao *et al*. on a retrospective study on the influence of cold periods on clozapine serum levels in 65 schizophrenic patients [1]. It was found that clozapine serum concentrations increased during the cold period compared to baseline, that clozapine serum concentrations were increased in female patients compared to male patients, and that clozapine serum concentrations correlated positively with changes in white blood cell (WBC) counts and neutrophil counts [1]. The study is impressive, but some points should be discussed.

The first point relates to the term "common cold" [1]. Since the common cold is defined as a viral infectious disease of the upper respiratory tract that primarily affects the mucous membranes of the nose, throat and bronchial system, all viruses that potentially cause an upper respiratory tract infection can be responsible for a common cold. Therefore, the causative pathogen may be different in each patient and may affect clozapine levels differently in each patient. Since each virus may have a different effect on clozapine serum levels, the study group is inhomogeneous and does not allow general conclusions to be drawn.

The second point relates to the exclusion criteria [1]. One of these was "combined use of medications that affect clozapine blood concentrations" [1]. How did the authors know to what extent a combination of three, four or more drugs affects clozapine levels. Such combinations are not usually tested for drug-drug interactions, and it is quite conceivable that such arbitrary combinations influence clozapine serum levels in one direction or another.

The third issue is the retrospective design of the study [1]. Retrospective designs have several disadvantages. A retrospective design does not allow control of the accuracy of the stored data, does not systematically apply the same examinations to all included patients, produces missing data, does not allow the completion of missing data and is not suitable to generate desirable new data.

The fourth point is that clozapine has agranulocytosis as one of its side effects [2]. Since clozapine serum levels increase with an increased number of leukocytes and neurtrophils [1], we should know how many patients developed a low leukocyte count and how this affected the relationship with clozapine serum levels.

To summarize, this interesting study has limitations that put the results and their interpretation into perspective. Clarifying these weaknesses would strengthen the conclusions and could improve the study. Homogeneous groups in terms of infectious agents, comedications and degree of agranulocytosis are needed to assess the effect of colds on clozapine serum levels.

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