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Expert group recommendations on the use of antipsychotic drugs in patients with somatic diseases. Part II: renal failure, liver failure, neurological diseases

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Summary

Selecting appropriate psychiatric treatment can be challenging. It is particularly difficult in a group of patients burdened a priori by serious somatic conditions, i.e., kidney or liver failure, neurological diseases or glaucoma. When the use of antipsychotics is warranted, in addition to an adequate clinical effect profile, attention should also be paid to other features of the drug, such as its pharmacodynamic and pharmacokinetic properties and possible side effects.

Almost all, with the exception of pimavanserin (not available in Poland), currently registered antipsychotics are D2 receptor antagonists. Second-generation drugs additionally exert significant effects on serotonergic transmission, primarily by blocking 5HT2A receptors. On the other hand, modern third-generation antipsychotics, in addition to antagonism to D2 receptors, also exhibit partial agonism towards dopamine receptors, which allows modulation of dopaminergic transmission. This profile of interactions may influence the type of side effects.

The purpose of this paper is to provide practical recommendations on the safety of antipsychotic drugs in groups of patients burdened by somatic conditions frequently encountered in clinical practice, i.e., renal failure, neurological conditions, including Parkinson's disease and epilepsy, liver failure, benign prostatic hyperplasia and glaucoma. The paper represents a continuation of recommendations on the use of neuroleptics in patients with somatic diseases.

Key words: antipsychotic drugs, safety, somatic diseases

1. Introduction

Selecting appropriate psychiatric treatment can be challenging. It is particularly difficult in a group of patients burdened *a priori* by serious somatic conditions, i.e., kidney or liver failure, neurological diseases or glaucoma When the use of antipsychotics is warranted, in addition to an adequate clinical effect profile, attention should also be paid to other features of the drug, such as its pharmacodynamic and pharmacokinetic properties and possible side effects.

The purpose of this paper is to provide practical recommendations on the safety of antipsychotic drugs in groups of patients burdened by somatic conditions frequently encountered in clinical practice, i.e., renal failure, neurological conditions, including Parkinson's disease and epilepsy, liver failure, benign prostatic hyperplasia and glaucoma.

2. Recommendations for the use of antipsychotics in specific somatic conditions

2.1. Renal failure

The use of antipsychotic drugs is associated with a small but significant risk of acute kidney injury (AKI). First-generation neuroleptics may be associated with a lower risk in this regard than newer-generation drugs, but the number of reports on this subject is small [1]. The pathogenesis of drug-induced renal damage is complex; among the potential mechanisms responsible for this complication in the case of neuroleptics are rhabdomyolysis or metabolic syndrome [2]. Scientific findings are inconclusive. When the increased risk of kidney damage and/or chronic kidney disease (CKD) was analyzed, some studies suggested greater nephrotoxic potential with first-generation drugs, while others suggested second-generation drugs [2-4]. All atypical neuroleptics (especially clozapine), with the exception of aripiprazole, were also found to increase the risk of CKD, but only in patients younger than 65. No clear dose dependence or risk factors have been proven. A study comparing haloperidol with other antipsychotics showed a higher risk of hospitalization for AKI with the use of olanzapine, quetiapine, and ziprasidone. There was a lower risk with the use of aripiprazole, risperidone, and fluphenazine. The overall incidence of AKI was low [3].

A meta-analysis by Ong et al. [4] (2024), in which the effect of atypical neuroleptics on renal damage was studied, showed that patients taking second-generation antipsychotics had the highest risk of renal damage with quetiapine > olanzapine > risperidone, respectively. It was also confirmed that there was an increased risk of CKD with quetiapine > risperidone; the risk with the use of clozapine, olanzapine and aripiprazole was not statistically significant. It was also proven that AKI occurred most frequently with quetiapine > olanzapine > risperidone [4].

Before initiating therapy with a nephrotoxic drug, a thorough benefit-risk assessment should be performed — a detailed analysis of baseline factors that increase the risk of drug-induced kidney damage is necessary (e.g., older age, kidney disease,

diabetes, hypertension, dehydration), and it is necessary to monitor renal parameters during therapy [5]. No recommendations were found for first-line antipsychotics in patients with concomitant renal disease. In this group of patients, it seems advisable to avoid antipsychotics with the highest risk of renal damage — quetiapine, olanzapine, risperidone and clozapine, which have an additional risk of metabolic side effects. Aripiprazole seems to have the least nephrotoxic potential [3, 4].

Table 1. **Safety of antipsychotics with concomitant renal failure [1]**

Medication	**Risk of use in patients with CKD**
Chlorpromazine	contraindicated
Levomepromazine	contraindicated in severe renal failure
Perazine	does not require dosage modification
Haloperidol	does not require dosage modification
Chlorprothixene	no data available
Flupentixol	does not require dosage modification
Zuclopenthixol	does not require dosage modification
Sulpiride	requires dosage reduction to 75/50/25 % *
Tiapride	requires dosage reduction to 70/50/33 %*
Clozapine	requires dosage reduction, contraindicated in severe renal failure
Olanzapine	use with caution, initial dose should be reduced by half
Quetiapine	initial dose should be reduced by half, increase doses up to a max. of 50 mg/d
Risperidone	use with caution, initial dose should be reduced by half, max. 4 mg/d
Paliperidone**	mild – 3-6 mg/d moderate – 1.5-3 mg/d contraindicated in severe
Ziprasidone	does not require dosage modification
Lurasidone	for moderate to severe – starting dose 18.5 mg/d, max. 74 mg/d
Sertindole	does not require dosage modification

table continued on the next page

Amisulpride	requires dosage reduction, contraindicated in severe renal failure
Aripiprazole	does not require dosage modification
Brexpiprazole	requires dosage reduction
Cariprazine	contraindicated in severe renal failure
Legend: * – for mild/moderate/severe renal insufficiency, respectively ** – paliperidone palmitate does not require dosage reduction in mild and moderate renal insufficiency	

2.2. Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is common in older men, affecting about 50% of men over the age of 60, while more than 90% of men over 85 present symptoms. The clinical manifestation of BPH is urinary retention, which may require medical intervention. Neuroleptics can cause or exacerbate urinary retention due to the interaction of various receptors in the bladder. Anticholinergic action reduces the contraction force of the bladder detrusor muscle, which can lead to incomplete bladder emptying and urinary retention. Other mechanisms include central serotonergic effects, central blockade of D2 receptors and peripheral stimulation of α1 urinary tract receptors. These effects can lead to incomplete bladder emptying and urinary retention in patients using neuroleptics [6].

The study proved an increased risk of urological complications, such as incontinence or urinary retention, mainly for classical neuroleptics, such as phenothiazine and thioxanthene derivatives, and atypical neuroleptics like clozapine. An analysis by Winkler et al. [8] assessed the risk of urological conditions in hospitalized patients receiving psychotropic drugs. Urinary retention was more common in patients treated with promethazine, haloperidol, pipamperone, olanzapine, perazine, levomepromazine, flupentixol and chlorprothixene [7]. The risk of urologic complications, including urinary retention, significantly increases when more than one substance is used, indicating the risk of additive effects of polypragmasy [8]. In patients diagnosed with mild benign prostatic hyperplasia, the use of neuroleptics may exacerbate the symptoms of the condition [6], so extreme caution should be exercised when starting treatment in patients with pre-existing urological problems or when choosing high-risk drugs [8]. When urinary retention is caused by psychopharmacotherapy, a reduction in the drug dose or a change in the drug should be considered [9].

2.3. Neurological conditions

2.3.1. Parkinson's disease and Parkinsonian syndromes

In the course of Parkinson's disease, psychotic symptoms may appear in the form of hallucinations and, somewhat less frequently, delusions. There are several possible explanations for this phenomenon, including the accumulation of Lewy bodies in the cerebral cortex, stimulation of D2 receptors by the drugs used to treat Parkinson's disease, and an imbalance between serotonergic and dopaminergic neurons [10]. It is noteworthy that these symptoms tend to worsen over time and, after excluding factors that may cause them (infection, insomnia, dehydration, excessive doses of anticholinergic drugs, amantadine, D2 receptor agonists or levodopa), require treatment with antipsychotic drugs. The choice of antipsychotic drugs that will be effective yet safe in this group of patients is quite difficult. First-generation neuroleptics, due to their strong blocking effect on the D2 receptor (high affinity), are contraindicated [10, 11]. Psychosis in Parkinson's disease is an extra-motor symptom that is observed in up to 60% of patients. Pimavanserin, a selective inverse 5-HT2A agonist/antagonist, is the only drug approved by the FDA for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. Studies are ongoing on the safety profile of pimavanserin in Parkinson's disease and other neurodegenerative diseases, such as Alzheimer's disease [12].

A PubMed database review (accessed October 2024; time-limited search 2018-2024, narrowed to "Clinical Trial Meta-Analysis Randomized Controlled Trial") yielded 31 records for the selected term "antipsychotics, Parkinson's disease" and 27 records for the selected term "Parkinson's disease psychosis treatment".

Srisurapanont et al. [13] (2024) indicated that clozapine was the most effective and safest among second-generation antipsychotics (SGAs) for the treatment of psychotic symptoms in Parkinson's disease, with pimavanserin in second place (not available in Poland), and olanzapine and quetiapine ranked much lower. Yunusa et al. [14] (2023) presented comparable results, identifying clozapine and pimavanserin as safe, with quetiapine as the last choice. Iketani et al. [15] (2020), in a meta-analysis, showed that clozapine has efficacy with little effect on motor function, in line with previous reports. The efficacy of pimavanserin is slightly lower than that of clozapine; however, it has a favorable profile in the treatment of psychosis in Parkinson's disease. Tariot et al. [16] (2021), in a study on the use of pimavanserin for psychosis in dementia (of various etiologies: Alzheimer's disease, dementia associated with Parkinson's disease, dementia with Lewy bodies, frontotemporal dementia or vascular dementia) confirmed its efficacy compared to placebo [16]. In the Isaacson et al. [17] (2020) study, pimavanserin, although well tolerated, did not show an advantage in efficacy over placebo after 4 weeks of 34 mg/day use. After 6 weeks, the observed benefits of pimavanserin treatment werer sustained for up to 10 weeks. In a study of psychosis symptoms in Alzheimer's disease, Ballard et al. [18, 19] (2019) indicated that the efficacy of pimavanserin positively correlated with the severity of psychotic symptoms

at the start of treatment. In addition, the authors reported that the drug was well tolerated. The results described by Weintraub et al. [20] (2024) indicate that pimavanserin is the most effective and safest treatment in patients with psychosis associated with Parkinson's disease dementia. The antipsychotic effect of pimavanserin is evident in patients with Parkinson's disease and cognitive impairment and can be enhanced by the concomitant use of cognitive-enhancing drugs [21]. In addition, it has shown potential in the treatment of depression in Parkinson's disease [22]. Stan et al. [23] (2024) compared treatment with clozapine, pimavanserin and the new molecule mesdopetam (a D3 receptor antagonist and, to a lesser extent, also a D2 antagonist, still in the clinical trial phase) in an animal model. Neurophysiological analyses of these animal models suggest that mesdopetam may represent a novel treatment option for psychotic symptoms in Parkinson's disease [24].

Asenapine (not available in Poland) is an example of an atypical antipsychotic that shows high affinity for serotonin receptors. The drug appears to be moderately safe [25] for treating psychotic symptoms in Parkinson's disease; however, conclusive study results are lacking. Table 2 summarizes the safety profiles of individual neuroleptics in patients with Parkinson's disease.

Table 2. **Heat map of the estimated safety of antipsychotic drugs in Parkinson's disease [13-15, 25]**

Medication	Risks of use in patients with Parkinson's disease
Amisulpride	No data available
Aripiprazole	No data available
Asenapine	1
Brexpiprazole	No data available
Chlorpromazine	4
Chlorprothixene	4
Flupentixol	4
Haloperidol	4
Cariprazine	No data available
Clozapine	1
Quetiapine	1
Levomepromazine	4
Loxapine	No data available
Lurasidone	No data available
Olanzapine	1

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Paliperidone	No data available
Perazine	4
Risperidone	No data available
Sertindole	No data available
Sulpiride	No data available
Zuclopenthixol	4
Ziprasidone	No data available
Legend: scale of 1 to 4, where: 1 indicates a drug that is relatively safe in terms of its use in Parkinson's disease, and 4 indicates a drug with the least favorable profile in this regard. Green indicates the safest drugs, and red indicates those with the least favorable safety profile. No data available indicates that sufficient clinical data are not available.	

2.3.2. Epilepsy

In epilepsy, psychotic symptoms may manifest as part of comorbid psychiatric disorders or as a consequence of the neurological condition itself. This phenomenon may affect up to 6% of epileptic patients, while co-occurring psychiatric disorders affect up to 30% of these patients [26]. Treatment of psychotic symptoms is challenging in this population, as most antipsychotics, due to their antidopaminergic effects, lower the seizure threshold [27, 28]. However, Arora et al. [29] (2024) did not observe an increase in seizures in patients treated with antipsychotics. The literature highlights that clozapine is the least safe neuroleptic in the context of epileptic seizures, as it significantly lowers the seizure threshold [29, 30]. The authors unanimously highlight factors other than the choice of antipsychotic that influence the induction of seizures. These include drug interactions, the course of neurological disease, prior history of seizures, drug metabolism, and rapid dose escalation of antipsychotics [28]. Table 3 summarizes the safety profiles of individual neuroleptics in patients with epilepsy.

Table 3. **Heat map of the estimated safety of antipsychotic drugs in epilepsy [27-30, 35-37]**

Medication	**Risks of use in patients with epilepsy**
Amisulpride	No data available
Aripiprazole	1
Asenapine	No data available
Brexpiprazole	No data available
Chlorpromazine	4

table continued on the next page

Chlorprothixene	No data available
Flupentixol	No data available
Haloperidol	1 Some sources question safety (Bhatti et al. 2017) [37]
Cariprazine	No data available
Clozapine	4
Quetiapine	1
Levomepromazine	3
Loxapine	No data available
Lurasidone	No data available
Olanzapine	3
Paliperidone	No data available
Perazine	No data available
Risperidone	1
Sertindole	No data available
Sulpiride	1
Zuclopenthixol	1
Ziprasidone	No data available
Legend: scale of 1 to 4, where: 1 indicates a drug that is relatively safe in terms of its use in epilepsy, and 4 indicates a drug with the least favorable profile in this regard. Green indicates the safest drugs, and red indicates those with the least favorable safety profile. No data available indicates that sufficient clinical data are not available.	

2.4. Hepatological conditions

Drug-induced liver injury is a possible complication of antipsychotic use. The literature indicates that it is generally quite rare [31]. Classical neuroleptics are reported to be more hepatotoxic than atypical agents [32]. Among antipsychotics, chlorpromazine, olanzapine and clozapine are considered potentially the most hepatotoxic. Risperidone, quetiapine and haloperidol carry a moderate risk of damage. Relatively safe are paliperidone, aripiprazole, and lurasidone. [31] Sulpiride is regarded as one of the safest drugs in this group, with hepatotoxic effects generally mild and transient [33]. Table 4 summarizes the safety profiles of individual neuroleptics in patients with liver dysfunction.

Table 4. **Heat map of the estimated safety of antipsychotic drugs in patients with hepatic impairment [31-32]**

Medication	Risk of use in patients with liver dysfunction
Amisulpride	No data available
Aripiprazole	1
Asenapine	No data available (not available in Poland)
Brexpiprazole	No data available
Chlorpromazine	4
Chlorprothixene	No data available
Flupentixol	No data available
Haloperidol	3
Cariprazine	No data available
Clozapine	4
Quetiapine	3 (not very effective)
Levomepromazine	No data available
Loxapine	No data available
Lurasidone	1
Olanzapine	4
Paliperidone	1
Perazine	No data available
Risperidone	3
Sertindole	No data available
Sulpiride	1
Zuclopenthixol	No data available
Ziprasidone	No data available

Legend: scale of 1 to 4, where: 1 indicates a drug that is relatively safe in terms of its use in patients with liver dysfunction, and 4 indicates a drug with the least favorable profile in this regard.
Green indicates the safest drugs, and red indicates those with the least favorable safety profile.
No data available indicates that sufficient clinical data are not available.

2.5. Glaucoma

Antipsychotic drugs can cause ophthalmic side effects, including ocular hemorrhages and blockages, infections, hemorrhages into the vitreous, retina and choroid, cataracts and glaucoma, among others [34]. The authors conducted a review of reports of ophthalmic side effects associated with second-generation neuroleptics. The type and frequency of complications vary depending on the specific neuroleptic. Cariprazine has been associated with adverse ocular reactions related to cataracts. Overall, the highest number of ophthalmic complications was reported with aripiprazole and quetiapine. The fewest complications were observed in association with clozapine use.

Regarding glaucoma, Mu and Chen [34] (2024) reported the highest number of cases in patients using olanzapine (specifically acute closed-angle glaucoma) and quetiapine, followed by aripiprazole (also associated with acute closed-angle glaucoma).

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