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Review Article

Antipsychotic Risk Mitigation: Informed Consent, Deprescribing and Psychoeducation Talking Points for Lifestyle and Behavior Modification

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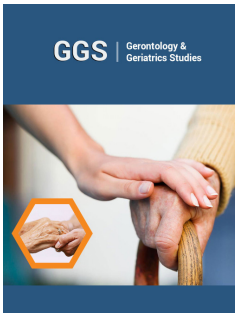
ISSN: 2578-0093



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Submission: November 13, 2024
Published: November 25, 2024

Volume 9 - Issue 2

How to cite this article: Cynthia Lewis, Catherine J Monetti and Melissa Scollan-Koliopoulos*. Antipsychotic Risk Mitigation: Informed Consent, Deprescribing and Psychoeducation Talking Points for Lifestyle and Behavior Modification. Gerontol & Geriatric Stud. 9(2). GGS. 000709. 2024.
DOI: 10.31031/GGS.2024.09.000709

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Abstract

Antipsychotics are high risk medications that require informed consent due to their high risk of adverse events, especially in the aging population. Adverse events include ischemic events, falls and a risk of death. A review of interventions to offset antipsychotic risks was conducted searching for major health, medicine and nursing databases. Risks and side effects of antipsychotics were reviewed and ways to mitigate the risks, including education in lifestyle to prevent metabolic derangement. Healthcare providers can contribute to deprescribing efforts when alternatives may be safer by ensuring informed consent during psychoeducation. Once the decision to prescribe an antipsychotic is made, risk mitigation education should begin. Lifestyle interventions and behavior management talking points are evidence-based ways to mitigate risks and promote deprescribing efforts. Talking points can increase self-efficacy to discuss risks and ways to mitigate the risks during psychoeducation. Antipsychotic risk mitigation: Informed consent, deprescribing and psychoeducation talking points for lifestyle and behavior modification.

Keywords: Antipsychotic risks; Deprescribing; Psychoeducation; Ischemia; Metabolic syndrome

Introduction

Antipsychotics are utilized for rapid de-escalation of agitation and aggressive behaviors in older institutionalized adults [1]. Antipsychotic use in the United States is on the rise, with 42.6 million prescription fills as of 2018 by 6.1 million people and an expenditure of $269 a prescription [2]. Patients prescribed antipsychotics require high risk medication monitoring for safety. Healthcare providers play a key role in monitoring for risks and developing psychoeducation interventions to help patients reduce risks. The purpose of this paper is to create an awareness regarding serious risks associated with antipsychotic use and to increase both provider and patient self-efficacy to discuss risks during psychoeducation. Informed consent can be a robust mechanism to facilitate deprescribing efforts, especially when safer alternatives are an option. Healthcare providers may benefit from more information regarding predictors of adverse ischemic events and falls due to metabolic derangement and anticholinergic side effects associated with antipsychotics.

Healthcare provider's role in psychoeducation in prescribing of antipsychotics

Psychoeducation is an essential healthcare provider care activity and has been reported to improve medication adherence [3] and behavior modification, including increased awareness of how to incorporate healthy lifestyles in older adults [4] and manage behavioral and psychological symptoms in those affected by dementia [5]. When alternatives to antipsychotics are used for rapid de-escalation of agitation or unsafe behaviors, adherence may become a concern. Medication persistence for dementia treatment to manage behavior ranges from 49-75% depending on the environment and circumstances [6]. Alternatives to antipsychotic use require persistence in chronic use for prevention of behavior escalation to prevent

resorting to antipsychotics. For example, Citalopram is an effective antidepressant treatment and alternative to antipsychotics for agitation in dementia [7]. Predictors of adherence include positive attitudes toward medication, family involvement and illness insight [8] all impactable by psychoeducation. Generally, sub-optimal adherence to antidepressant therapies can result in reduced effectiveness and this could lead to overuse of antipsychotic prescriptions [9]. Yet, second generation antipsychotics have negligible effect on agitation and typical antipsychotics have only a slight decrease in agitation in older adults [1].

A possible under-recognized essential element of adherence is informed consent and ensuring patients understand the risks versus benefits of antipsychotic use. Informed consent should be re-affirmed during ongoing care interactions and ethical care provisions [10]. Psychoeducation is essential to ensuring informed consent, especially when medications have permanent side effects (i.e. Tardive dyskinesia) or risks of serious adverse events (i.e. Atherosclerotic events leading to heart attack or stroke; or falls). This is especially true when antipsychotics are used without an indication, such as off-label use or in the absence of evidence-based protocols. However, in the United States for example, the Food and Drug Administration does not mandate explicit consent for off-label use because it is often being used for the patient's best interest [11]. When nurses are unaware of antipsychotic risks, a missed care opportunity to provide psychoeducation exists. Missed care is defined as any aspect of patient care that is omitted or delayed [12]. Nurses play a key role in ensuring that psychoeducation elements of care are not missed to prevent mortality risk [13]. Nurses maintain a critical frontline role in the treatment of patients with behavioral difficulties [14]. Nurses are responsible for providing psychoeducation to patients who are prescribed high risk medications. Some nurses may not feel they have adequate skill to deliver practical education interventions to reduce the risk of injury or complications due to antipsychotic use [15]. Nurses could benefit from interventions they can use to increase their self-efficacy to identify and mitigate risk factors for antipsychotic use injury and morbidity and/or mortality for preventing injury, diabetes, heart disease and stroke. Healthcare providers can also help patients by ensuring they have provided informed consent and are knowledgeable in the risks and can question their prescribers regarding safer alternatives. Providing information needed in a ready to deliver format, talking points can be delivered to patients and families to help consider alternatives overcoming an identified barrier to deprescribing of antipsychotics when appropriate [16]. One study revealed significant knowledge gaps by nurses regarding the risk of appropriate indications for antipsychotic use in elders and the side effects of antipsychotics [17]. Another study revealed beliefs that antipsychotics are beneficial to helping nursing home patient behaviors [18] but do not address risks of ischemic event knowledge. Most research on nursing knowledge of antipsychotics is related to perceptions and beliefs regarding use in managing dementia symptoms [15]. When alternatives to antipsychotic use are not effective or appropriate, psychoeducation of mitigation of the risks is essential.

Psychoeducation to mitigate the risks of appropriate antipsychotic use

Antecedents to the most serious injuries from antipsychotic use include modifiable factors such as metabolic derangement leading to diabetes and dyslipidemia and hypertension that can result in ischemic injury (i.e. cerebrovascular accidents and myocardial infarction) [19]. Other factors leading to serious injury include anticholinergic side effects that can lead to falls from orthostatic hypotension [19]. Other identified risks include less movement when used as a chemical restraint, including pneumonia, kidney injury, thromboembolism, stroke, fracture from falls and myocardial infarction and heart failure [19]. Healthcare providers play a role in educating patients regarding lifestyle behaviors and symptoms self-monitoring when it comes to health prevention education. Yet, few studies reveal healthcare provider, or nurse's knowledge rates regarding antipsychotic risks. Once antipsychotics have been determined to be medically necessary, many of the risks can be mitigated by ensuring safer lifestyle behaviors. Psychoeducation can include lifestyle behaviors to reduce obesity, prevent diabetes and incorporation of a heart healthy diet, safe physical activity, monitoring of symptoms, falls prevention efforts and sleep hygiene and behavior modification to reduce the need for psychopharmacologic interventions [20]. Patient-centered communication skills training has been shown to improve staff self-efficacy with delivering communication regarding medical care [21]. The philosophical assumptions from Bandura's theoretical framework include the belief that behavior is influenced by personal factors, environmental factors and cognitive processes and that learning occurs through observation, imitation and role-modeling [22]. Providing pre-scripted talking points to healthcare providers on what to say to patients is a form of role-modeling. Role-modeling can increase self-efficacy for psychoeducation in clinical practice [3].

Methods

Electronic data bases PubMed, CINAHL, Johanna Briggs Institute, Cochrane Library, OVID Nursing database, Nursing reference Center Plus, PsycINFO, National Library of Medicine and ProQuest were searched to identify the significance of the problem of antipsychotic use risk and the evidence-based interventions to develop psychoeducation to mitigate the risks of antipsychotic use. The scope of the review included appropriate indications, off-label use and interventions to reduce side effects and/or adverse events that could be translated for psychoeducation at the bedside. Taking points derived from the literature review that can be used in psychoeducation were scripted and presented in tables in this paper.

Results of Literature Review

Antipsychotic prescribing patterns

The number of adults being prescribed an antipsychotic from 2013-2018 increased from 5.0 million to 6.1 million with upwards of 42.6 million prescriptions released [2]. The expenditures of

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those antipsychotic prescriptions were $11.5 billion dollars in 2018 alone [2]. Within that small percentage is a large amount of unnecessary and inappropriate and/or off label uses without identifiable clinical indications in nursing home residents [23]. On-label clinical indications for the use of antipsychotics include psychosis, schizophrenia and bipolar disorder [24], as well as agitation in people with Alzheimer's dementia using brexpiprazole, a second-generation medication [25]. It is important that the risks do not outweigh the benefits when utilized and that patients provide informed consent. The identified barrier to deprescribing antipsychotics includes low levels of staff education, lack of resources and time, poor medication reviews [15]. Antipsychotics are used off-label to promote sleep and treat agitation in dementia. Oftentimes, antipsychotics are used without clinical indication and may lead to harm [23].

Serious risks associated with antipsychotic use

In the United States Antipsychotics come with a black box warning administered by the food and drug: Administration (FDA) to warn prescribers and patients of the risk of cerebral ischemia and stroke [26]. Both stroke and myocardial infarction have been associated with antipsychotic use [27]. It is unknown how aware prescribers or patients are regarding the risk of adverse cerebral vascular ischemic events. Antipsychotic use is implicated in premature mortality and dangerous adverse events including strokes, motor side effects and anticholinergic side effects that result in falls risk, agitation, confusion, restlessness, cognitive decline and seizures [28]. There is an increased risk of pneumonia, sedation, delirium and urinary retention and weight loss. Additionally, antipsychotics are associated with cardiometabolic risks including hyperglycemia, hypertension, long-QT syndrome, dyslipidemia and increased abdominal girth and weight [28]. The rate of emergency department visits due to life-threatening adverse effects of antipsychotics are as high as 23.7% and 50.8% for non-serious adverse events [29]. One such threatening event attributed to antipsychotic use is ischemic stroke [27]. Exposure (defined as use for 3 days within 30 days of a hospitalization) to an antipsychotic increased the risk of ischemic stroke 1.8 times higher than those not exposed to antipsychotics in a Veteran's health study [30]. Meta-analyses reveal more than a two-fold increased risk of stroke in those using antipsychotics [27]. The pathophysiologic mechanisms explaining the increased risk of Venous thromboembolism (VTE) among patients receiving antipsychotic medication remains unclear. The factors that may contribute to the occurrence of VTE include the psychotic disorders itself and the exposure to antipsychotic drugs [31]. Immobilization resulting from social withdrawal due to negative symptoms of schizophrenia and major depressive disorders in addition to the sedative side effect of antipsychotic drugs can cause significant venous stasis, a well-known risk factor contributing to VTE [31]. Binding of atypical antipsychotic drugs to a serotonin receptor type 2A with high affinity may increase the platelet aggregation that can play a role in VTE. An increased level of antiphospholipid antibodies found in the patient receiving antipsychotic drugs is an established risk for VTE, however the clinical impact of such high levels is uncertain [31]. Antipsychotics increase cardiometabolic risk and patients need psychoeducation in risk mitigation to prevent diabetes, heart attack and stroke [32]. Meta-analyses show a rapid rise in diabetes, a predictor of stroke and myocardial infarction following the initiation of second-generation antipsychotics [33].

Mitigating risks through evidence-based interventions

The risks of developing diabetes and heart disease are greater in all populations using antipsychotics, but even greater for racial and ethnic minority populations [34]. Identifying risks for diabetes and heart disease by reviewing health history information in the electronic medical record can help identify who to target with tailored psychoeducation on lifestyle factors to mitigate risk once antipsychotics have been determined to be medically necessary to prescribe. Melamed [35], showed that guidelines for metabolic risk screening of individuals taking antipsychotics have been issued, but with little uptake into clinical practice [35]. A moderate effect was seen in risk mitigation when monitoring for body mass index, waist circumference, blood pressure, lipids and glucose levels despite barriers to monitoring counselling about Cardiovascular and metabolic health [36]. A systematic review by Ali et al. [36], investigated barriers to monitoring and management of Cardiovascular co-morbidities in patients prescribed antipsychotic medicines which, included barriers to screening, monitoring and management of Cardiovascular and Metabolic side effects [36].

Cezaretto, de barros et al. [37] reported on the comparison of lifestyle psychoeducation and the effects of a traditional lifestyle intervention for type 2 diabetes prevention and an interdisciplinary approach using psychoeducation [37]. The psychoeducation approach did not have improved outcomes above the traditional approach with improved lipid, glucose indicating that any lifestyle intervention education is helpful for diabetes prevention when educating patients in nutrition and physical activity. Weight gain is associated with antipsychotic nonadherence. Dayabandara et al. [38] conducted a review of the literature and indicated that dietary counseling, exercise programs and cognitive behavioral strategies are equally effective at helping to reduce weight, including adding metformin to the regimen [38]. Weight gain is indicated as being a primary risk factor for increased mortality rates in those using antipsychotics as a predictor of cardiac disease [38]. Weight gain is greatest in the first few weeks of use and patients continue to gain weight for 1-4 years over time [38]. Raza et al. [15] presented a comprehensive literature search and showed implications for practice and education that included barriers to deprescribing antipsychotics due to staff education about dementia and its management, perceived needs of staff for education and training of patients, financial resources and support from other clinical staff [15]. The belief by staff regarding antipsychotics plays an important role in whether to prescribe to patients with dementia [15].

Healthcare providers play an important role in educating patients regarding lifestyle behaviors and symptoms to monitor when it comes to health prevention education. One study revealed significant knowledge gaps in nurses regarding the risk of appropriate indications for antipsychotic use in elders and the side effects of antipsychotics [17]. Most research on nursing knowledge

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of antipsychotics is related to perceptions and beliefs regarding use in managing dementia symptoms [15]. Staffing ratios can play a role in the use of prescribing antipsychotic medications. If patients are aggressive due to dementia symptoms and nursing homes are short staffed it is easier for prescribers to order an antipsychotic regardless of the risks under the guise of patient safety to keep them calm.

Utilizing talking points derived from evidence-based practice

Evidence-based interventions can help mitigate the risk of antipsychotic-induced cardiometabolic disease risk, including diabetes, heart disease and stroke risk through lifestyle education. The evidence-based psychoeducation interventions are presented in the following (Table 1) patient's ability to provide informed consent; (2) antipsychotic use risks; (3) monitoring for cardiometabolic risks; (4) lifestyle changes to reduce the cardiometabolic risks; (5) sleep alternatives and (6) coping with problem-behaviors in dementia (Tables 2-7). The evidence-based interventions to mitigate the risk of antipsychotic-induced cardiometabolic disease risk, including diabetes, heart disease, or stroke risk would be to provide lifestyle education as part of mental health visits. There are many programs that have been shown to have effective interventions, such as the National Diabetes Prevention Program [39] and the heart disease and Stroke Prevention Program [40]. A Healthy People 2030 focus is on preventing and treating heart disease and stroke and improving overall cardiovascular health [41]. The existing lifestyle programs could potentially be translated into routine practice for psychoeducation to mitigate the risks associated with antipsychotic use to prevent atherosclerotic and ischemic events. During the informed consent phase of prescribing, weighing the risks and benefits of antipsychotic treatment is particularly important for healthcare providers treating patients with multiple comorbid risk factors for stroke [30]. Psychoeducation can include ensuring informed consent for antipsychotic use and teaching patient's strategies to self-advocate for cardiometabolic risk screening to prevent cardiovascular disease, stroke and diabetes. Patients should have reinforcement of informed consent principles, including being encouraged to ask their prescriber if safer alternatives are an option especially if the use is for off-label reasons such as sleep [42] or fall prevention [43].

Table 1: Talking points: Patient's ability to provide informed consent.

Do you know the risks and side effects of your medication?
Do you know you can ask your prescriber if there are safer alternatives for you?
You should make sure you are comfortable with this plan and if not express concerns to your prescriber.

Table 2: Talking points: Antipsychotic use risks.

Explain That Antipsychotics Increase the Risk of:
Weight Gain
Hypertension
Hyperglycemia
Dyslipidemia
Thrombocytopenia
Sodium Deregulation
Prescribed to the elderly with dementia are at double the risk of death
Linked to falls due to the side effects of dizziness, blurred vision, weakness and permanent movement disorders
Associated with stroke and cardio-metabolic risks including hyperglycemia, hypertension, long-QT syndrome, dyslipidemia and increased abdominal girth and weight

Table 3: Talking points: Monitoring for cardiometabolic risks factors.

Reduce Smoking
Consider nicotine patches or bupropion or other medications for smoking cessation
Monitor platelets
Consider anti platelet therapy
Monitor lipid levels
Nutritional support Mediterranean diet

Table 4: Talking points: Lifestyle changes to reduce cardiometabolic risks.

Consider DASH Diet
Low sodium fat-free or low-fat dairy, fish, poultry, beans and nuts.
Regular exercise
Smoking Cessation
Monitor Blood Pressure
Monitor Lipids and glucose levels

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Prevention of Diabetes(ie. Consider Mediterranean Diet)
Monitor weight and HbA1c levels
Encourage nutritional health using Mediterranean diet
High fiber (nuts, seeds, legumes, dried fruits)
Adequate protein (fish, chicken, meat)
Low saturated fat (olive oil, whole grains)
Low Glycemic index (whole fruit instead of fruit juice)
Encourage daily exercise (Can be any continuous repetitive motion or walking)

Table 5: Talking points: Sleep alternatives.

Encourage good sleep habits to improve sleep health
Be consistent
Go to bed at the same time each night and get up at the same time each morning
Make sure bedroom is quiet, dark, relaxing and at a comfortable temperature (cooler room)
Remove electronic devices, such as computers, smart phones and televisions from the bedroom and decrease the screen time prior to going to sleep
Avoid large meals, caffeine and alcohol before bedtime
Be physically active during the day can help you fall asleep more easily at night
Ask Prescriber if there are any alternative to antipsychotics

Table 6: Talking Points: Coping with Problem Behaviors in Dementia.

MONITOR personal comfort: check for pain, hunger, thirst, constipation, full bladder, fatigue and infections. Maintain comfortable room temperature
Advise caregivers
Avoid being confrontational
Redirect the person's attention
Create a calm environment
Allow adequate rest
Provide security object
Acknowledge requests
Look for reasons behind each behavior
Explore various solutions
Question provider on safety and alternatives for dementia-related behavior

Table 7: Talking points: Falls prevention.

Risk for fall and home environment
Side effects for anti-psychotic medications such as: Dizziness, Blurred vision, Movement effects - tremor, stiffness, agitation, Sedation-causing sleepiness or low energy, Risk of orthostatic hypotension
Encourage vision checks, strength and balance exercises
Suggest adding brighter and or more lighting in the home and declutter

Once prescribed, healthcare providers should assist patients in obtaining cardiometabolic screening and prompt prescribers to order cardiometabolic laboratory tests when indicated. Patients should be educated in the benefits of having their weight, blood pressure, glucose and lipid levels monitored frequently while using antipsychotic medication. Weighing the risks and benefits of antipsychotic treatment is particularly important for providers treating patients with multiple comorbid risk factors for stroke [30]. Evaluating individual risk factors assessment for VTE before commencing antipsychotic drugs should be considered especially, in high-risk situations where adding such agents will increase the risk of VTE. The individuals who are at high risk for VTE and using antipsychotic drugs should be informed and educated about the symptoms of DVT and PE in addition to the importance of seeking immediate medical care [30].

Conclusion

Injury from antipsychotic use can be due to falls or associated with ischemic events and sudden cardiac death or stroke, due in part to metabolic derangement that can be altered with lifestyle changes [19]. In some cases, the best practice maybe to find alternatives, such as when antipsychotics are used off label for sleep or dementia behaviors [44], especially given the paradox that they are sometimes prescribed to improve cognitive function, yet they

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may cause cognitive decline with long-term use [45]. Providing healthcare providers caring for older adults with scripted talking points to reduce risk from antipsychotic use is a means of ensuring gaps in knowledge do not impede certainty in content deliverables for psychoeducation. It is especially important that all prescribers understand the limitations of evidence and weigh it against the risks when prescribing with off-label use, as is commonly seen with antipsychotic use [46]. Psychoeducation ensuring informed consent is essential in psychoeducation of older individuals and their caregivers [47]. Once the decision has been made to utilize an antipsychotic, mitigation of risks is a priority in psychoeducation provision with lifestyle and self-monitoring education to prevent injury and falls.

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