RISPERIDONE: PHARMACY STUDENTS' OPINIONS AND KNOWLEDGE ABOUT ITS USES AND SIDE EFFECTS

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ABSTRACT

Risperidone, a second-generation antipsychotic (SGA), also known as an atypical antipsychotic, was the topic of this survey research, with 44 first-year students at Howard University College of Pharmacy participating. The study gathered data on the knowledge base and opinions of the survey respondents. Ten survey questions were prepared, five related to opinion-centered and five on the participants' knowledge. The survey found that the respondents had a slightly above-average knowledge base (64.6%) on risperidone, and strong opinions (85.9%) in favor of its use in clinical settings.

KEYWORDS: Survey; risperidone; therapeutic range; toxicity; schizophrenia; side effects

INTRODUCTION

Risperidone is an atypical, or second generation, antipsychotic medication that is used to treat schizophrenia, bipolar I disorder with manic or mixed episodes, and autism-associated irritability. It was first approved by the United States Food and Drug Administration (FDA) in 1993. Its off label uses include a long list of psychotic conditions, such as borderline personality disorder, delusional disorder, delirium, depression, brain injuries, posttraumatic stress injury and others. Risperidone comes in various formulations: tablets, oral solutions, dissolvable forms ranging from 0.25 mg to 4 mg. The extended-release injectable intramuscular formulations are available in 12.5 mg to 50 mg doses, while the subcutaneous pre-filled syringes range from 50 to 250 mg doses.[1] According to the product label,

contraindication for risperidone use is hypersensitivity to risperidone, excipients in the formulations and hypersensitivity to the related product paliperidone. Hypersensitivity includes anaphylaxis and angioedema.[2]

Open-label reports suggest that the serotonin$_{2A}$–dopamine D$_2$ antagonist risperidone may be safe and effective in reducing the interfering symptoms of patients with autism. In a 12-week double blind, placebo-controlled study that enrolled 31 adult patients with autistic disorder, risperidone was shown to be more effective than placebo in the short-term treatment of symptoms of autism.[3]

When risperidone was compared with haloperidol, risperidone showed a significant improvement on Positive and Negative Syndrome Scale (PANSS) in patients with schizophrenia. More patients in the risperidone group than the haloperidol group (33% vs 24%) were rated as showing clinically significant outcomes on the PANSS scale. Other studies also supported the superiority of risperidone.[4]

A large study of 2,493 cases and 7,478 matched controls showed an association between the use of antipsychotics such as haloperidol, aripiprazole, quetiapine, olanzapine, risperidone, sulpiride and chlorpromazine and an increased risk of cardiovascular disease (CVD) in patients with schizophrenia. The authors recommend that clinicians thoroughly assess the risk of CVDs when considering treating schizophrenia patients with antipsychotics.[5] The potential efficacy and safety of risperidone has been a subject of numerous investigations. In a prospective open-label study by Choure et al.[6] involving 64 patients with schizophrenia, risperidone fared better in cardiovascular safety. The study compared risperidone and olanzapine. It was concluded that patients on olanzapine were at a higher risk of postural hypotension than those who were treated with risperidone.

As a side effect, antipsychotics have been implicated in causing metabolic syndrome in schizophrenia patients. In a study of 60 patients divided into groups and a control group, it was determined that patients treated with risperidone and olanzapine had a greater risk of metabolic syndrome than those treated with aripiprazole.[7] Guntam and Meena.[8] also investigated metabolic syndrome side effects in patients who were treated with conventional (typical) versus second-generation antipsychotics. In the study, 120 patients were divided into groups of four, each comprising 30 patients: haloperidol (conventional antipsychotic), risperidone, olanzapine, clozapine (second-generation or atypical antipsychotics). After 4

months of continuous therapy, patients were evaluated for metabolic syndrome, using parameters such as blood pressure, fasting blood glucose, HDL levels, fasting triglyceride levels and waist circumference. About 11.7% of the total 120 patients exhibited metabolic syndrome, the highest being for olanzapine (13%). The risperidone group had a 3% rate of metabolic syndrome. The haloperidol group of patients did not develop the syndrome.

Although there are no adequate studies to elaborate the safety of risperidone in pregnant women, placental transfer has been reported in rat models. It is recommended to used risperidone in pregnant women if only the potential benefits outweigh the potential risk to the fetus.[2]

In summary,[2] risperidone is primarily indicated for: 1. **Schizophrenia:** It is approved for treating schizophrenia in adults and adolescents aged 13-17 years. Schizophrenia is a chronic mental health disorder that affects a person's ability to think clearly, manage emotions, and relate to others. 2. **Bipolar Disorder**: Risperidone is used to treat manic or mixed episodes associated with bipolar I disorder in adults and children aged 10 years and older. These episodes may include elevated mood, increased energy, or irritability. 3. **Irritability in Autism**: It is also FDA-approved to treat irritability, aggression, self- injury, and temper tantrums in children and adolescents with an autism spectrum disorder.

Risperidone carries a black box warning for its use in elderly patients with dementia-related psychosis. Studies have shown that antipsychotic drugs like risperidone can increase the risk of death in these patients. Most of the deaths appear to be cardiovascular in nature (such as heart failure, sudden death) or infectious (such as pneumonia). Therefore, risperidone is not approved for the treatment of dementia-related psychosis.

The black box warning highlights the necessity for healthcare providers to carefully weigh the benefits and risks when prescribing risperidone, particularly in vulnerable populations, such as the elderly with dementia.

Patient Counseling Points

When counseling patients on the use of risperidone, several important factors should be considered to ensure safe and effective treatment

1. Adherence to Medication: Patients should be encouraged to take risperidone exactly as prescribed. Using a calendar and a pillbox labeled with days and times can

enhance adherence to medication schedules. In the case of long-acting injectable risperidone, it is important to adhere to scheduled appointments for injections. Setting a reminder on your phone or calendar is beneficial.

2. Potential Side Effects: Patients should be informed of the common side effects, which include drowsiness, dizziness, weight gain, increased appetite, and fatigue. Patients should be instructed to report any muscle stiffness, unusual movements, or difficulty speaking.

3. Metabolic Concerns: Risperidone may increase the risk of metabolic changes, such as weight gain, hyperglycemia, and increased cholesterol or triglycerides. Patients should be counseled to maintain a healthy diet and lifestyle, and routine monitoring of blood sugar and lipids may be necessary, particularly for those with a history of diabetes or obesity.

4. Orthostatic Hypotension: Patients may experience dizziness or lightheadedness, especially when standing up quickly due to a decrease in blood pressure (orthostatic hypotension). This is particularly important for elderly patients. To avoid falls, patients should be advised to rise slowly from a sitting or lying position.

5. Risk in Elderly with Dementia: The black box warning should be discussed with family members or caregivers if the patient is an elderly individual with dementia-related psychosis. Due to the increased risk of mortality in this population, the use of risperidone should be avoided unless deemed necessary by a healthcare provider.

6. Pregnancy and Breastfeeding: Patients who are pregnant, planning to become pregnant, or breastfeeding should consult their doctor before starting risperidone. The drug may pass into breast milk and could affect a nursing infant.

7. Alcohol and Drug Interactions: Patients should be advised to avoid alcohol while taking risperidone, as it can exacerbate side effects like drowsiness and dizziness. Furthermore, it is crucial to inform the prescribing physician of all medications, supplements, and herbal products being taken to avoid potential drug interactions.

Risperidone is an effective antipsychotic with a range of indications but must be prescribed and monitored carefully to minimize risks, particularly in vulnerable populations. Through proper patient counseling and adherence to safety guidelines, risperidone can significantly improve the quality of life for individuals with serious mental health conditions.

METHODS

The survey collected data on demography, opinions and knowledge of first year pharmacy students at Howard University College of Pharmacy. A total of 44 students took part in the survey. Students were required to input their demographic information including gender, work experience, prior knowledge of or experience with black box warnings, and their level of education. A total of 10 questions were administered, with five assessing student knowledge on treatment practices of lithium and five focusing on opinion questions to determine any trends amongst the students. Before conducting the survey, the questions were reviewed by one of us (BH) a Drug Informatics professor, and a licensed pharmacist to ensure clarity, relevance, and alignment with the research objectives. The survey was administered online during class, where students were asked to use their phones or laptops and record their answers. The survey responses were compiled by the same professor who reviewed the survey questions.

A descriptive statistical data analysis, such as means, standard deviation and variance was conducted. A Likert scale was used to collect data and record opinions: 1=strongly agree; 2=agree; 3=disagree; 4=strongly disagree. A two-tailed Fisher Exact Test was utilized to evaluate the significance of differences *(p* values) in the knowledge-based questions.

RESULTS

Demographic Data

The demographic data of the class is presented in Table 1. The class of pharmacy consisted of a majority female student population at 72.7%. About half of the students (48.8%) worked or are currently working for more than 3 years. The table also shows that most students have worked in a pharmacy-related setting prior to taking this survey. Additionally, it provides a summary of the participants' educational history, indicating that the majority of students attended a four-year college and majored in basic science or health science.

Table 1: Demographic data of the participants (*n*=44).

Demographic characteristics		*n* (%)
Gender	Male	12 (27.3)
	Female	32 (72.7)
Work experience*	In healthcare-related job	7 (15.9)
	Pharmacy-related job	27 (61.4)
	In non-health related job	9 (20.4)
If worked, for how many years?	< 1 years	6 (14.0)
	1-3 Years	16 (37.2)
	>3 years	21 (48.8)
Education (highest level attended)	2-year college	2 (4.5)
	4 years (BSc/BA)	28 (68.2)
	MSc or higher	8 (18.2)
	Other	4 (9.1)
What was your major as an undergraduate student?	Basic or health sciences	28 (63.6)
	Social Science	1 (2.3)
	Business	1 (2.3
	Other	14 (3.2)

*One respondent never worked.

The data in Table 2 shows that a little over half of the student population has relative familiarity with Black Box warnings and has either experienced or knows someone who has experienced the effects of Black Box Warnings prior to taking this survey.

Table 2: Participants familiarity and experience with Black Box Warning.

Question posed	Response	Number of respondents [*n* (%)]
Have you heard of black box warning before joining the pharmacy program?	Yes	23 (52.3)
	No	16 (36.3)
	Maybe	5 (11.4)
Have you or any member of your family or friends experienced related adverse drug reactions in the past? *	Definitely yes	10 (23.3)
	Probably yes	25 (58.1)
	Definitely not	8 (18.6)

*One participant did not provide an answer.

Categories of opinion-based questions

1. How strongly do you agree that Risperidone should still be used for the management of schizophrenia and bipolar 1 disorder despite its black box warning? (Category: Drug Indication)

2. How do you believe healthcare providers can best address patient concerns about the stigma associated with taking antipsychotic medications like risperidone, and what role does effective communication play in this process? (Category: Patient Counseling)

3. In your opinion, what monitoring practices should be prioritized for patients on risperidone to ensure safety and efficacy, and how can healthcare providers effectively communicate the importance of these practices to their patients? (Category: Monitoring Requirements)

4. What is your perspective on the impact of the black box warning for risperidone regarding increased mortality in elderly patients with dementia-related psychosis, and how should this influence prescribing practices and patient counseling? (Category: Black Box Warning)

5. How important is it for healthcare professionals to communicate the potential interactions between Risperidone and other medications? (Category: Management of warnings)

Table 3: Opinion-based questions (Reponses of survey participants; *n* = 44).

Question	SA (*n*, %)	A (*n*, %)	DA (*n*, %)	SA (*n*, %)	Mean LK ± SD	Variance
How strongly do you agree that risperidone should still be used for the management of schizophrenia and bipolar 1 disorder despite its black box warning?	20 (45.5)	18 (40.09)	6 (13.6)	0 (0.0)	1.7391±0.7353	0.5406
How do you believe that heath care providers can best address patient concerns about stigma associated with taking antipsychotic medications like risperidone, and what role does effective communication play in this process?	20 (45.5)	20 (45.5)	4 (19.1)	0 (0.0)	1.6364±0.6428	0.4132
In your opinion, should monitoring practices be prioritized for patients on risperidone to ensure safety and efficacy and should healthcare	21 (47.7)	16 (36.4)	5 (11.4)	2 (4.5)	1.7273±0.8357	0.6983

providers effectively communicate the importance of these practices to their patients?						
What is your perspective on the impact of the black box warning for risperidone regarding mortality in elderly patients with dementia-related psychosis, and how should this influence prescribing practices and patient counseling?	23 (52.3)	14 (31.8)	5 (11.4)	2 (4.5)	1.6818±0.8467	0.7169
How important is it for healthcare professionals to communicate the potential interactions between risperidone and other medications?	22 (50)	15 (34.1)	6 (13.6)	1 (2.3)	1.6818±0.7912	0.6260
Average (%)	48.2	37.7	11.8	2.3	1.6932 ± 0.7704	0.5990

Abbreviations: SA=Strongly agree; A=Agree; DA=Disagree; SD=Strongly disagree; LK=Likert Score; SD=Standard deviation

Categories of Knowledge-Based Questions

1. Risperidone can be effective in treating both positive and negative symptoms of schizophrenia. (Category: Drug Indications). True

2. Risperidone can lead to an increased risk of metabolic syndrome. (Category: Black Box Warning). True

3. Risperidone is contraindicated in individuals with a history of cardiovascular disease. (Category: Management of Warnings). False.

4. The dosage of risperidone may need to be adjusted for elderly patients due to increased sensitivity to its effects. (Category: Drug Monitoring). True.

5. Risperidone is safe for use during pregnancy without any considerations. (Category: Black Box Warning) False.

Table 4. Results of the knowledge-based questions (participants, *n*=44).

Questions	Correct Answer	True (*n*)	False (*n*)	Participants with correct answers: *n* (%) *	Mean correct answer rate out of 1 (±SD)	Variance
1. Risperidone can be effective in treating both positive and negative symptoms of schizophrenia	True	36	8	36 (81.8)	0.8182±0.3857	0.1489
2. Risperidone can lead to an increased risk of metabolic syndrome	True	38	6	38 (86.4)	0.8636±0.3432	0.1178
3. Risperidone is contraindicated in individuals with a history of cardiovascular disease	False	36	7	7 (16.3)	0.1628±0.3692	0.1363
4. The dosage of risperidone may need to be adjusted for elderly patients due to increased sensitivity to its effects.	True	37	7	37 (84.1)	0.8409±0.3658	0.1338
5. Risperidone is safe to use during pregnancy without any considerations	False	20	24	24 (54.5)	0.5455±0.4979	0.2479
Average correct answer				64.6%	0.6462±0.3924	0.1570

Participants with Correct*P values for correct an   SD=Standard deviation. *P values for correct answers: 3 vs 1 (*p*=0.0001); 3 vs 2 (*p*=0.0001); 3 vs 4 (*p*=0.0005); 3 vs 5 (*p*=0.0003); 5 vs 1 (*p*=0.0008); 5 vs 2 (*p*=0.0001); 5 vs 4 (*p*=0.0003)

DISCUSSION

In the demographic data, there were a larger number of female participants than males, which appears to be common in health science-related degree programs. The majority (68.2%) had a bachelor's degree prior to joining the pharmacy program. Over 77% of the respondents worked in pharmacy or healthcare-related jobs, and those who worked over 3 years accounted for about 49% of the survey participants. The opinion-based data revealed most participants supporting the use of, and proper patient counseling risperidone overall. Data gathered from the questionnaire reflected slightly above average knowledge level.

In response to the five-statement panel on aspects of risperidone, there is an overall positive agreement reflected in the high 85.9% agreement rate. The average Likert scale score of 1.6932 aligns with the positive agreement trend. A score of 1 to 2 shows a clear proclivity to agreement on the 1 to 4 scale, with 3 and 4 measuring a general disagreement score.

The correct recorded responses on the knowledge-based questions ranged from 16.3% to 86.4%, with the highest correct score being on the question whether risperidone can lead to an increased risk of metabolic syndrome. The least correct answer rate of 16.3% recognized that risperidone is not contraindicated in cardiovascular patients. When the two lowest incorrect answer rates of 16.3% and 54.5% were compared in turn with the three higher correct answers at 86.4%, 84.1% and 81.8%, the differences were found to be statistically significant ($p< 0.05\%$).

Limitations to this study included a small sample size, as well as the lack of face-to-face surveying, which may have provided a more quality and accurate level of response as opposed to an online qualtrics link.

CONCLUSION

A survey was conducted among 44 first-year pharmacy students at Howard University, regarding the antipsychotic medication risperidone. Demographic data showed females in the majority at 72.7%. Most of the pharmacy students (68.2%) had a Bachelor's degree prior to joining the pharmacy program. Over 77% had work experience for over three years. The rest of the survey questionnaire consisted of five related to five opinion-based and five knowledge questions on the drug. The respondents had a slightly above-average knowledge level (64.6%) on risperidone, and strong opinions (85.9%) in favor of its use in clinical settings.

Compliance with ethical standards

Acknowledgement

Conflict of interest

The authors declare no conflict of interest.

Statement of informed consent

Informed consent was not required from the survey participants, because it was part of a Drug Informatics course given by BH, one of the authors.

REFERENCES

1. McNeil, S.E.; Gibbons, J.R.; Cogburn, M. Risperidone. [Updated 2024 Nov 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing, 2025 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK459313/

2. Accessdata.fda.gov. Highlights of Prescribing Information: Risperidone. https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020272s056,020588s044,021346s033,021444s03lbl.pdf*, 2009.

3. McDougle, C.J.; Holmes, J.P.; Carlson, D.C.; Pelton, G.H.; Cohen, D.J.; Price, LH. A Double-blind, Placebo-Controlled Study of Risperidone in Adults With Autistic Disorder and Other Pervasive Developmental Disorders. *Arch Gen Psychiatry,* 1998; 55(7): 633–641. doi:10.1001/archpsyc.55.7.63.

4. Umbricht, D.; Kane, J.M. Risperidone: Efficacy and Safety, *Schizophrenia Bulletin*, 1995; 21(4): 593–606. https://doi.org/10.1093/schbul/21.4.593.

5. Peng, P.; Li, J.; Chen. Y. et al. Associations between antipsychotics and the risk of incident cardiovascular diseases in individuals with schizophrenia: a nested case–control study. *BMJ Ment Health*, 2023*;* 26: e300501

6. Choure, B.K.; Gosavi, D.; Nanotkar, S. Comparative cardiovascular safety of risperidone and olanzapine, based on electrocardiographic parameters and blood pressure: a prospective open label observational study. *Indian J Pharmacol*, 2014; 46(5): 493-7. doi: 10.4103/0253-7613.140579. PMID: 25298577; PMCID: PMC4175884.

7. Koricanac, A.; Tomic, L.A.; Veselinovic, M.; Bazic, S.D, et al. Influence of antipsychotics on metabolic syndrome risk in patients with schizophrenia. *Front Psychiatry*, 2022; 13: 925757. doi: 10.3389/fpsyt.2022.925757. PMID: 35958655; PMCID: PMC9357900

8. Gautam, S.; Meena, P.S. Drug-emergent metabolic syndrome in patients with schizophrenia receiving atypical (second-generation) antipsychotics. *Indian J Psychiatry*, 2011; 53(2): 128-33. doi: 10.4103/0019-5545.82537. PMID: 21772644; PMCID: PMC3136014.