

Letter-to-Editor

The critical role of pharmacovigilance in monitoring drug-induced QT prolongation

Sir,

In the recent cross-sectional study¹ on QT interval prolongation in schizophrenia published in the June issue of the Indian Journal of Medical Research, the authors have done a remarkable job in highlighting the prevalence of QTc prolongation in patients with schizophrenia, a serious cardiac adverse effect of antipsychotic medications.¹ Their findings, which report QTc prolongation 3.4% of participants using Fridericia's formula and 6.8% using Bazett's formula, are significant as they underscore a potentially fatal cardiac risk, Torsades de Pointes (TdP).

The study emphasises the need for regular screening and periodic assessment of cardiac rhythm in these patients. However, it needs to be stressed that such findings are not just for clinical awareness; they are crucial for a robust pharmacovigilance system. Every single adverse drug reaction (ADR), including QTc prolongation, identified at a hospital or tertiary care centre must be reported to the Pharmacovigilance Programme of India (PvPI). This can be done through the designated ADR Monitoring Centre (ADRMC) or by self-reporting *via* any of the available online or social media portals.² In this study, the authors have not clarified whether they had reported these adverse reactions to the respective ADR monitoring centre.

The data gathered from such systematic reporting is essential for enhancing patient safety. This allows for the collective analysis of real-world drug safety data, which in turn helps to identify emerging risk factors and evaluate the safety profile of drugs in diverse populations, and inform regulatory authorities.³ For example, this study noted that olanzapine was the most frequently prescribed antipsychotic and was linked to all three cases of QTc prolongation identified by Fridericia's formula. This kind of observation, when aggregated through nationwide reporting, can help confirm and quantify such risks on a larger scale.

Numerous studies from India have demonstrated poor knowledge, attitude, and practice of pharmacovigilance among medical professionals, which can be countered through robust sensitization measures undertaken by the ADR monitoring centres.^{4,5} Hence, all studies undertaken in academic institutions should also report their adverse effects to the respective ADR monitoring centres.

The author's conclusion that medical practitioners should be aware of these adverse effects and take necessary precautions is vital. This awareness extends to their responsibility to report any and all adverse events, thereby contributing to a larger database that protects not just a few patients but the entire population. The development of QTc prolongation leading to Torsades de Pointes (TdP) is a serious cardiac event. Timely interventions, such as screening for comorbidities, avoiding polypharmacy, and switching medications, are of utmost importance. Yet, none of these interventions are as powerful as a well-informed and comprehensive pharmacovigilance system fuelled by diligent reporting from the medical community.

Financial support and sponsorship: None.

Conflicts of Interest: None.

Use of Artificial Intelligence (AI)-Assisted Technology for manuscript preparation: The authors confirm that there was no use of AI-assisted technology for assisting in the writing of the manuscript and no images were manipulated using AI.

Jerin James¹

¹Department of Pharmacology, SRM Medical College Hospital and Research Centre, Chengalpattu, Tamil Nadu, India

jerinjames06@gmail.com

Received August 28, 2025; Accepted October 31, 2025;
Published February 28, 2026

References

1. Malani M, Das S, Saha A, Kumar A, Singh S, Somani A. QT interval prolongation in schizophrenia: A cross-sectional study from a tertiary care center in Raipur. *Indian J Med Res.* 2025;161:744–7.
2. National Coordination centre. Indian Pharmacopoeia Commission. *Pharmacovigilance Programme of India*. Available from: <https://www.ipc.gov.in/PvPI/faq.html>, accessed on July 30, 2025.
3. Zhu R, Vora B, Menon S, Younis I, Dwivedi G, Meng Z, et al. Clinical pharmacology applications of real-world data and real-world evidence in drug development and approval—an industry perspective. *Clin Pharmacol Ther.* 2023;114:751–67.
4. Thunl PRT, Chaitanya KK, Bharath D, Thota P. Knowledge, Attitude, and practice of pharmacovigilance among healthcare professionals in Warangal, India. *JHVD.* 2025;30:206–12.
5. Shenoy AK, Kamath A, Chowta MN, Bloor A, Aravind A, Thakur PB, et al. Knowledge of pharmacovigilance among healthcare professionals and the impact of an educational intervention. *Med Pharm Rep.* 2023;96:406–12.

DOI: 10.25259/IJMR_413_2026

Authors' response

We thank the author of the letter to Editor¹ for diligently reading our article². It is agreed that while it is important to assess adverse effects in a systematic manner, it is even more important to report them to the national authority concerned. This exercise could help in generating knowledge based on a large database. Findings from small studies conducted at any one center may not serve the desired purpose, *i.e.* improvement in patient safety. The findings of our study² were reported to the Indian Pharmacopoeia Commission, which is the national coordination center for the Pharmacovigilance Program of India (PvPI). The study hospital, All India Institute of Medical Sciences, Raipur, Chhattisgarh, India, is one of the adverse-drug reactions' (ADR) monitoring centers under the PvPI.^{3,4} It is continually engaged in sensitizing the clinicians and other stakeholders about PvPI and the importance of accurate monitoring and reporting of ADRs.^{4,5}

The given manuscript is an apt reminder to improve knowledge about and practices towards pharmacovigilance program (PVP).² Without getting

desired cooperation and active contribution from the practicing clinicians, the PVP shall not build desired database and serve its intended purpose.

Financial support and sponsorship: None.

Conflicts of Interest: None.

Use of Artificial Intelligence (AI)-Assisted Technology for manuscript preparation: The authors confirm that there was no use of AI-assisted technology for assisting in the writing of the manuscript and no images were manipulated using AI.

**Mishthi Malani,[†] Shrayasi Das,¹ Anirban Saha,¹
Ajay Kumar,¹ Satyajit Singh,² &
Aditya Somani^{1,*}**

Departments of ¹Psychiatry, and ²Cardiology, [†]All India Institute of Medical Sciences Raipur, Chhattisgarh, India

**For correspondence:*

dr.adityasomani@aiimsraipur.edu.in

Received August 28, 2025; Accepted October 31, 2025;

Published February 28, 2026

References

1. James J. The critical role of pharmacovigilance in monitoring drug-induced QT prolongation. *Indian J Med Res.* 2026;163:129–30.
2. Malani M, Das S, Saha A, Kumar A, Singh S, Somani A. QT interval prolongation in schizophrenia: A cross-sectional study from a tertiary care center in Raipur. *Indian J Med Res.* 2025;161:744–7.
3. Indian Pharmacopoeia Commission. List of ADR monitoring centers under pharmacovigilance programme of India (PVPI). Available from: <https://ipc.gov.in/PvPI/adr/ADR.pdf>, accessed on January 28, 2026.
4. Pharmacovigilance Program of India. Ministry of Health and Family Welfare, Government of India. *National Pharmacovigilance Week-2024. 17th September to 23rd September. Theme: Building ADR reporting culture for patient safety day*. Available from: <https://www.aiimsraipur.edu.in/upload/events/Consolidated%20PDF%20of%20daily%20reports.pdf>, accessed on January 28, 2026.
5. Press Information Bureau, Ministry of Health and Family Welfare, Government of India. *AIIMS Raipur marks world patient safety day with CME on safer care for newborns and children*. Available from: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2167938®=3&lang=2>, accessed on January 28, 2026.