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CLINICAL PHARMACY NEWSLETTER

A Newsletter of Drugs and Prescribing Information

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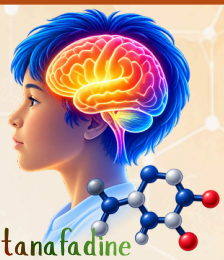
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ORIGINAL ARTICLE

Clinically Meaningful Within-Patient Change in Core ADHD Symptoms in Children and Adolescents Treated With Centanafadine: *Two Phase 3 Randomized Clinical Trials*

Ward CL, et al. J Atten Disord. 2026:10870547261483444.



1 Introduction

Attention-deficit/hyperactivity disorder (ADHD) is characterized by persistent inattention, hyperactivity, and impulsivity. Many established ADHD medications primarily modulate dopamine and norepinephrine pathways. In contrast, Centanafadine is a novel norepinephrine, dopamine, and serotonin reuptake inhibitor (NDSRI), simultaneously influencing all three monoamine systems. This distinct pharmacological profile offers a differentiated approach to managing core ADHD symptoms.

AT A GLANCE

- Two Phase 3 Randomized Double-Blind, Placebo-Controlled Trials
- Novel Norepinephrine, Dopamine & Serotonin Reuptake Inhibitor
- Children & Adolescents With ADHD
- 6-week comparative study of Centanafadine vs placebo
- Acceptable & Generally Well Tolerated Safety Profile

KEY FINDINGS

01 Rapid Onset

Significant improvement observed from **Week 1** and maintained through Week 6.

02 Core ADHD Symptoms

Symptom improvements in inattention and hyperactivity/impulsivity were observed.

03 Clinically Meaningful Change

Children had a **55% higher** and adolescents **65% higher** likelihood of improvement.

04 Safety & Tolerability

Centanafadine showed an acceptable and generally well-tolerated **safety profile**.

2 Methodology

Study Design

Two Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trials in children and adolescents with ADHD.

Intervention

Once-daily extended-release Centanafadine compared with placebo for 6 weeks, without initial titration.

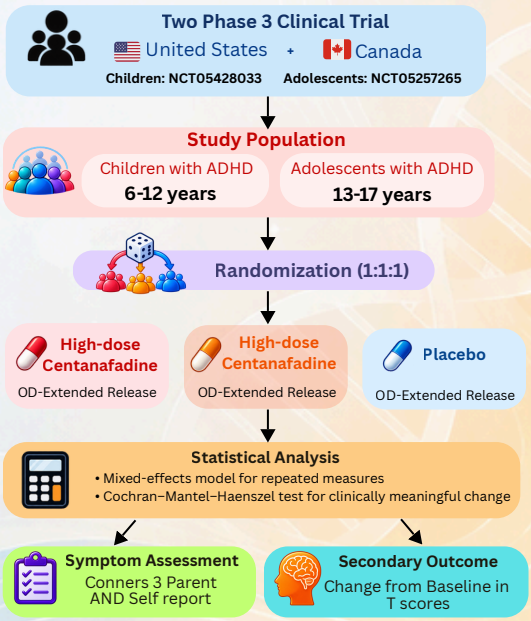
Primary Endpoint

Change in core ADHD symptoms using Conners 3–Parent Short and Conners 3–Self-Report Short scales.

Secondary Endpoint

Clinically meaningful improvement in inattention and hyperactivity/impulsivity over the 6-week treatment period.

3 Study Design Flow



4 Results

Week 6 Change from Baseline in Conners T-scores (Least Squares Mean)

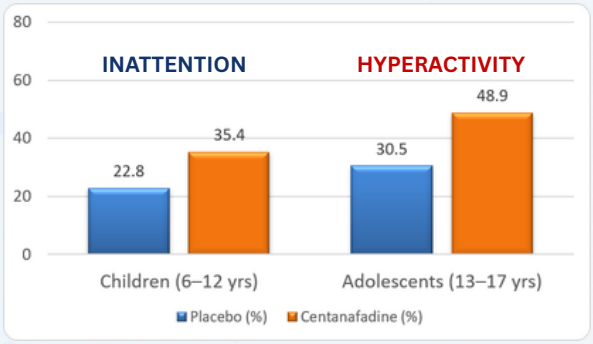
Population and Scale	Centanafidine	Placebo	p value
Children (6-12 yrs)			
Inattention	-11.9	-6.4	0.0002
Hyperactivity / Impulsivity	-11.5	-6.9	0.0022
Adolescents (13-17 yrs)			
Parent Inattention	-14.4	-8.1	< 0.0001
Parent Hyperactivity/Impulsivity	-14.0	-8.5	0.0002
Self-report Inattention	-15.3	-10.0	0.0001
Self-report Hyperactivity/Impulsivity	-11.6	-8.9	0.0282

Symptom Improvement Over Time

Week 1 → Week 2 → Week 3 → Week 4 → Week 5 → Week 6

Separation from placebo was observed as early as Week 1 (the first postbaseline time point), and significant improvements continued through Week 6 in children and adolescents.

5 Clinical Significance



Meaningful change threshold: ≥14-point improvement for Conners 3–Parent Short Inattention and ≥13-point improvement for Hyperactivity/Impulsivity. These analyses were based on the Conners 3–Parent Short.

6 Discussion

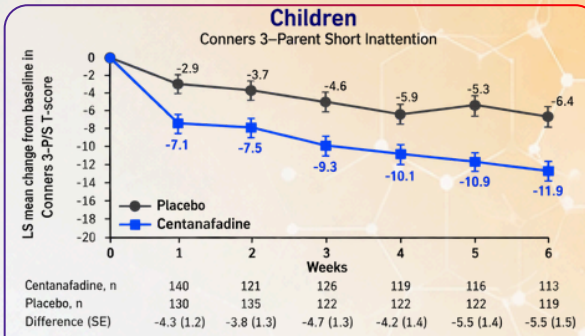
Safety and Tolerability: Generally well tolerated; no new age-related safety concerns reported.

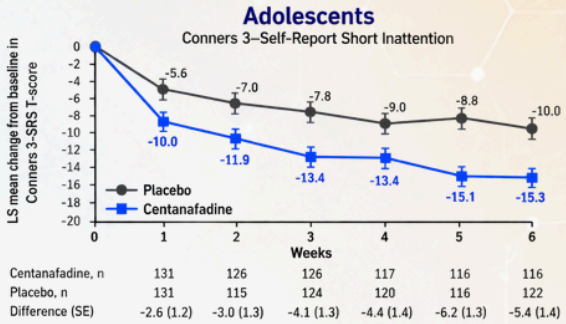
Adverse Event	Children (6-12 yrs)	Adolescents (13-17 yrs)
Decreased Appetite	8%	15%
Rash	6%	6%
Nausea	-	10%
Headache	-	6%

- All adverse events were mild or moderate.
- AE occurring ≥5% and greater than placebo

Discontinuation due to AEs was low: 1% with Centanafadine and 0% with placebo.

7 Key Limitations





Conners Scoring

1. **Item Scoring:** 0–3 scale, Not true → Very much true
2. **Raw Score:** Sum of domain item scores
3. **T-Score:** Age/sex-specific conversion (Mean 50, SD 10)
4. **Interpretation:** Higher T-score = greater severity; ≥10-point change = clinically meaningful.

8 Key Limitations

North American population only.

- No teacher ratings
- No active comparator

6-week duration limits conclusions about longer-term response and tolerability.

Clinically meaningful thresholds were not independently validated, and p-values were not multiplicity-adjusted.

9 CONCLUSION

1. **Broad Symptom Control** – Improves both inattention and hyperactivity/impulsivity.
2. **Consistent Benefit** – Symptom improvements were maintained and increased through Week 6.
3. **Meaningful Improvement** – Changes exceeded the ≥10-point clinical significance threshold in key Conners measures.
4. **Low Treatment Discontinuation** – Few patients discontinued treatment because of adverse events.

ARTICLE INFORMATION

- **Journal** : Journal of Attention Disorders
- **Publisher** : SAGE Publications
- **Impact Factor** : 3.2 (2025 JCR)
- **Quartile** : Q1
- **DOI** : 10.1177/10870547261483444

Case Report

Shared Decision Making on *Methylphenidate* in Hypertrophic Cardiomyopathy and ADHD in a Young Athlete

Rechcińska A, Rechciński T. JACC Case Rep. 2026;31(28):108797. doi:10.1016/j.jaccas.2026.108797.



1 Executive Summary

This case describes a 26-year-old man with hypertrophic cardiomyopathy (HCM) and newly diagnosed ADHD who was evaluated before starting Methylphenidate. Cardiac imaging showed stable disease, preserved systolic function, and no major high-risk features. QT dispersion was 74 ms, below the proposed high-risk threshold. After multidisciplinary counseling regarding potential arrhythmic risks and ECG monitoring, the patient declined Methylphenidate and chose psychotherapy-based ADHD management. The case emphasizes individualized risk assessment and shared decision-making in HCM.

Age 16
Hypertrophic cardiomyopathy confirmed

Age 18
Social anxiety diagnosed - Paroxetine 50 mg/day initiated

Age 16–26
Clinically stable
No cardiovascular symptoms; remained physically active

Age 26
ADHD diagnosed
Methylphenidate treatment proposed

Age 26
Cardiac risk assessment
QT dispersion: 74 ms
5-year SCD risk: 2.75%

Age 27
Treatment decision declined; chose psychotherapy-based ADHD management

2 Patient Summary

Age / Gender
26 years / Male

History
Hypertrophic cardiomyopathy (HCM)
Diagnosed at age 16

Presnting illness
Newly diagnosed attention-deficit/hyperactivity disorder (ADHD)

Clinical Status
No cardiovascular symptoms; regularly participated in recreational sports.

Key Findings

- ECG: Left ventricular hypertrophy with T-wave inversion
- QT dispersion: 74 ms
- Echocardiography/CMR: Stable asymmetric septal hypertrophy
- 5-year SCD risk: 2.75%

3 Risk Assessment

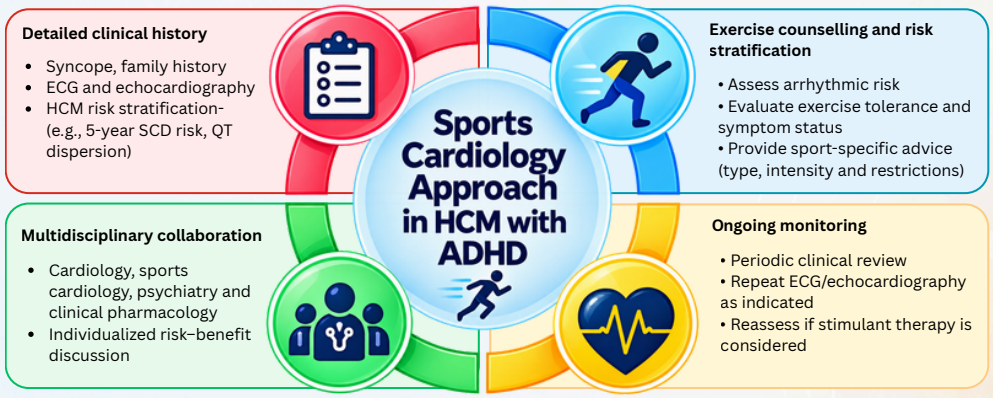
ADHD + Cardiac Sympathetic Drive
ADHD is associated with increased sympathetic activity (higher heart rate and blood pressure).

Stimulant Increase CV Demand
Medications for ADHD (e.g., Methyphenidate, Atomoxetine) can raise heart rate and blood pressure, increasing myocardial workload.

Potential Risk in HCM
These cardiovascular effects may precipitate arrhythmias or worsening symptoms in patients with HCM.

Guides Mangement
Baseline and periodic cardiovascular risk assessment helps inform safe medication choice, dosing and monitoring.

4 Sports Cardiology



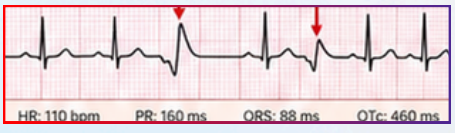
5 Key Takeaways

- Individualized cardiac risk assessment is essential for patients with HCM and ADHD
- Methylphenidate may be considered in selected low-risk HCM patients with ECG monitoring.
- QT dispersion of 74 ms was below the high-risk threshold, which shows relatively low arrhythmic-risk profile.
- Shared decision-making balances ADHD treatment and cardiac safety.
- Psychotherapy provided a suitable non-pharmacological alternative.

Normal ECG



Arrhythmias



ARTICLE INFORMATION

- **Journal** : JACC: Case Reports
- **Publisher** : Elsevier
- **Impact Factor** : 0.3
- **Quartile** : Q3
- **DOI** :10.1016/j.jaccas.2026.108797

7 Future Implications

- More data are needed to determine the long-term arrhythmic safety of Methylphenidate in patients with hypertrophic cardiomyopathy.
- Develop ECG-based protocols for stimulant initiation and dose titration.
- Define safe exercise and sports participation levels for young patients with HCM and ADHD.
- Strengthen collaboration between sports cardiology, psychiatry, and clinical pharmacy for safer ADHD management.

Drug Profile

Centanafadine (Simtriyo)



Targeting Dopamine, Norepinephrine & Serotonin in ADHD

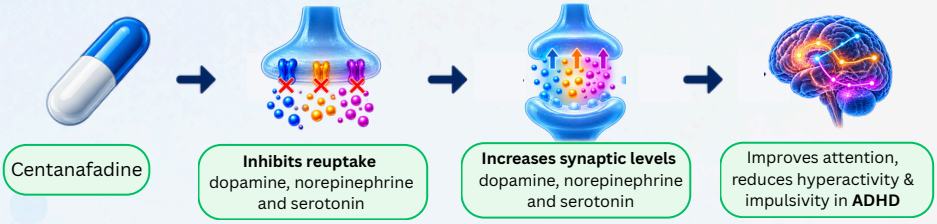
FDA Approval
July 24, 2026

Therapeutic class
CNS Stimulant
Norepinephrine–dopamine–serotonin reuptake inhibitor (NDSRI)

Indication
Attention-deficit/hyperactivity disorder (ADHD) in adults and pediatric patients ≥6 years weighing ≥20 kg

Regimen Type
Oral, once-daily extended-release therapy administered in the morning, with or without food.

1 Mechanism of action



- Centanafadine blocks **DAT, NET and SERT,** limiting reuptake of three key monoamines.
- This increases dopamine, norepinephrine and serotonin signaling within relevant brain circuits.
- Enhanced monoaminergic activity supports attention, impulse control and behavioral regulation.
- The multimodal mechanism targets multiple neurotransmitter pathways involved in ADHD.

2 Clinical Advantage



Centanafadine offers a multimodal mechanism by enhancing **dopamine, norepinephrine** and **serotonin** signaling, unlike drugs primarily targeting dopamine or norepinephrine. Its **once-daily extended-release formulation** may support adherence, while providing an additional treatment option for patients who have inadequate response or tolerability concerns with existing ADHD medications.

3 Dosage & Administration

- **Tablet:** 140 mg, 210 mg, and 280 mg extended-release capsules.
- **Recommended Dose:** Adults: 210 mg once daily; may increase to 280 mg once daily. Adolescents (13–17 years): 280 mg once daily. Children (6–12 years): Weight-based 140–280 mg OD.
- **Renal Dose Adjustment:** Renal impairment: No dosage adjustment is recommended based on renal function.
- **MAOI use:** Allow at least 14 days after stopping an MAOI before starting Centanafadine.

Pk	Characteristics
Absorption	Tmax: 5 hours; high-fat meal increases Cmax by 29% with no change in AUC, Half life ~5.2 hours; clearance ~410 mL/min
Distribution	Protein bound: >99%; Vd: ~167 L
Metabolism	Primarily metabolized by monoamine oxidase A (MAO-A); major lactam metabolite is inactive
Excretion	88% of administered radioactivity excreted in urine as metabolites; 7% in feces

4 Safety Profile

Contraindications

- **Hypersensitivity** to Centanafadine or any component of SIMTRIYO.
- Concurrent MAOI use or use within 14 days of stopping an MAOI, due to the risk of serious interactions, including **hypertensive crisis** and **serotonin syndrome**.

Warnings & Precautions

- **Suicidal thoughts** will occur, Monitor paediatric patients for new or worsening suicidal ideation or behaviour.
- Avoid use in patients with **hypertrophic cardiomyopathy (HCM)**, structural cardiac abnormalities, serious cardiac arrhythmias, or other serious cardiac disease.

Adverse Drug Reactions

- **Gastrointestinal:** Decreased appetite, nausea, dry mouth.
- **Nervous System:** Headache, dizziness, somnolence.
- **Psychiatric:** Irritability, anxiety, insomnia.
- **Cardiovascular:** Increased heart rate, increased blood pressure.

5 Patient Counselling

How to Take
Take once daily in the morning, with or without food.

Missed Dose
Take when remembered unless it is nearly time for the next dose; do not double the dose.

Do Not Stop
Do not discontinue abruptly without medical advice.

Drug Interactions
Inform your doctor about all medicines; avoid MAOIs.

Watch for Symptoms
Watch for loss of appetite, nausea, headache, rash, or mood changes.

Monitoring
Monitor BP, heart rate, weight, ADHD response, and psychiatric symptoms.

DRUG INFORMATION

Scan to see Full Drug Proffile

FDA (Drugs@FDA): SIMTRIYO (centanafadine) NDA 218145.

भारतीय भेषजसंहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सैक्टर - 23, राज नगर
गाजियाबाद - 201 002 (उ.प्र.), भारत

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar
Ghaziabad - 201 002 (U.P.) INDIA

File No. P.17019/03/2026-DSA **Dated: July 27, 2026**

Drug Safety Alert

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following;

S. No.	Suspected Drug	Indication(s)	Adverse Drug Reaction
1	Polymyxin B	• For the treatment of Infections of the urinary tract, meninges and blood stream caused by susceptible strains of Pseudomonas aeruginosa. It may also be used as subconjunctival injection in the treatment of infections of the eye caused by susceptible strains of Pseudomonas aeruginosa. • It may be indicated in serious infections caused by susceptible strains of the organisms- Haemophilus influenzae specifically meningeal infections, Escherichia coli specifically urinary tract infections, Aerobacter aerogenes specifically bacteremia, Klebsiella pneumoniae specifically Bacteremia.	Hypotension

भारतीय भेषज संहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सेक्टर - २३, राज नगर,
गाजियाबाद - २०१ ००२, उत्तर प्रदेश, भारत

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector - 23, Raj Nagar
Ghaziabad- 201 002 (U.P.), INDIA

File No. P.17019/03/2026-DSA **Dated: September 30, 2026**

Drug Safety Alerts

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following;

S. No.	Suspected Drugs	Indication(s)	Adverse Drug Reactions
1	Levetiracetam	• As monotherapy in partial onset seizures with or without secondary generalisation in patients with 16 years of age with newly diagnosed epilepsy. • As adjunctive therapy in myoclonic seizures in adults and adolescents from 12 years of age with Juvenile. • As adjunctive therapy in adult (16 years and older) with the following types of seizures: 1. Partial onset seizures 2. Myoclonic seizures in patients with juvenile myoclonic epilepsy 3. Primary generalized Tonic-Clonic seizures in adults with idiopathic generalized epilepsy.	Gingival hypertrophy
2	Xylometazoline/ Oxymetazoline	Nasal decongestant.	Rebound nasal congestion

A report of "AI-Enabled Therapeutic Drug Monitoring (TDM): Translating Precision- Dosing into Safer And Outcome-Driven Clinical Practice"

Coordinator: Dr. Deepalakshmi M
Associate Professor

Date: 27.08.2026 - 29.08.2026

The three-day hands-on workshop on AI-Enabled Therapeutic Drug Monitoring (TDM) was organized by the Department of Pharmacy Practice at JSS College of Pharmacy, Ooty in collaboration with Anusandhan National Research Foundation (ANRF), New Delhi. Through expert-led sessions on Bayesian pharmacokinetics, antibiotic stewardship, and end-to-end case simulations, attendees were equipped with actionable, practical skills to optimise drug therapy. Ultimately, the workshop achieved its primary objective: empowering healthcare professionals to translate precision dosing into safer, outcome-driven, and highly personalized patient care. The event was attended by 08 keynote speakers and resource persons, along with 32 registered participants.



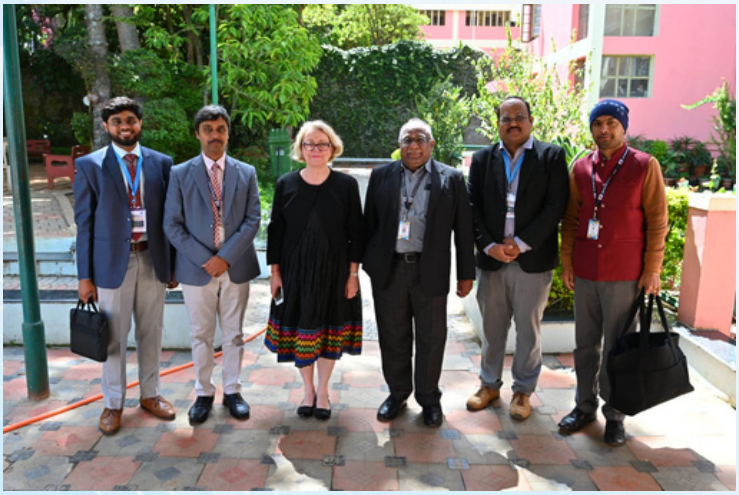


Visit of Dr. Debra Rowett to JSS College of Pharmacy, Ooty - A Report

Coordinator: Dr. Ponnusankar S
Professor & Head

Date: 25.08.2026 - 28.08.2026

The Department of Pharmacy Practice hosted Dr. Debra Rowett, Professor, Adelaide University, South Australia, marking a milestone on academic engagement, professional exchange, and the advancement of pharmacy practice education and practice. Dr. Rowett delivered the Keynote Address at the three-day workshop on "AI-Enabled Therapeutic Drug Monitoring (TDM): Translating Precision Dosing into Safer and Outcome-Driven Clinical Practice." She also interacted with faculty and students, and reviewed and appreciated the work of PhD research scholars. Discussions were held on expanding collaboration between JSS AHER and Adelaide University in research, faculty development, and student and staff exchange. The visit reaffirmed that lasting international partnerships are built on sustained relationships, mentorship and a shared commitment to advancing the pharmacy profession.





Report on visit of Mr Hemant Patel, Celebrating Three Decades of International Partnership in Pharmacy Practice

Coordinator: Dr. Ponnusankar S
Professor & Head

Date: 05.09.2026 - 07.09.2026

The Department of Pharmacy Practice welcomed Mr. Hemant Patel, Past President, Royal Pharmaceutical Society of Great Britain (RPS), and Past Member, English Pharmacy Board, RPS, London, marking nearly three decades of professional association. Mr. Patel delivered a lecture on “Lessons in Leadership, Practice and Service” for Pharm D and M Pharm (Pharmacy Practice) students, sharing insights on professional leadership, accountability and the pharmacist’s role in geriatric care and pain management. He also interacted with academic leadership, faculty, students and research scholars. Discussions were held on future collaboration in academic and professional exchange, pharmacy practice education, and faculty and student engagement. The visit reaffirmed that international partnerships are bridges connecting expertise, cultures and generations of pharmacy professionals.





6th National Pharmacovigilance Week 2026 - A Report

Coordinator: Dr. Jeyaram Bharathi J, Clinical Resident
Dr. Jeevanantham I, Assistant Professor

Date: 21.09..2026 - 23.09.2026

JSS Drug Safety Intelligence Centre (JSS-DSIC), Department of Pharmacy Practice, in association with the Indian Pharmaceutical Association (IPA), The Nilgiris Local Branch, observed the 6th National Pharmacovigilance Week from 21–23 September 2026. The programme featured a Pharmacovigilance Essay Competition and two expert webinars on career opportunities in pharmacovigilance and promoting rational use of medicines. Over 125 students took part in the sessions, and three outstanding essays were selected. The initiative aimed to strengthen student awareness of adverse drug reaction reporting, medication safety, rational use of medicines and emerging careers in drug safety.

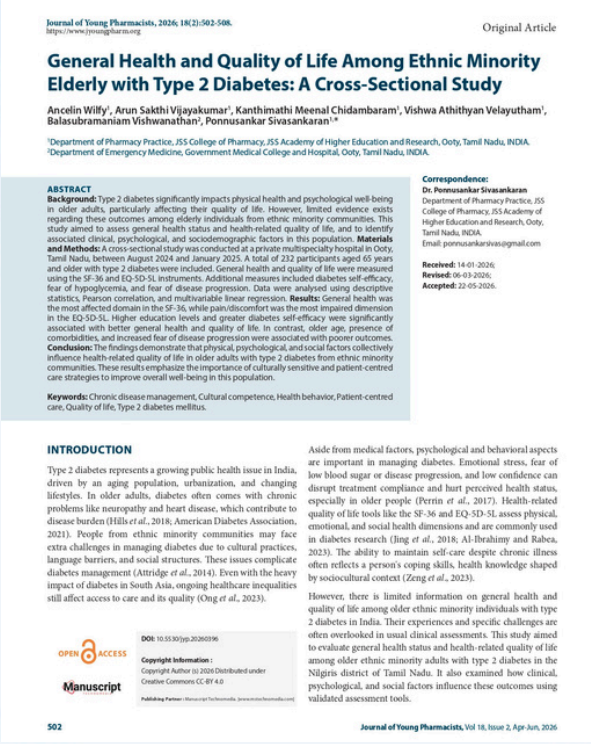






PUBLICATIONS OF THE DEPARTMENT (JUL - SEP 2026)

1. Ancelin Wilfy, Arun Sakthi Vijayakumar, Kanthimathi Meenal Chidambaram, Vishwa Athithyan Velayutham, Balasubramaniam Vishwanathan, **Ponnusankar Sivasankaran***. General Health and Quality of Life Among Ethnic Minority Elderly with Type 2 Diabetes: A Cross-Sectional Study. Journal of Young Pharmacists. 2026; 18(2):502-508.
2. Chandramohan T, Kasi D, Thomas A, Reddy SS, **Vishwas HN***, Dhivya C. Development, Translation and Validation of COPD Awareness Questionnaire (COPD-AQ): A Pilot Study.Journal of Young Pharmacists. 2026;18(2):530-6.
3. Nithya Shree, Suvitha Sri M, Ragunath S, Varsha K, R. DhyanesH, **Jeevanantham I***. Dermatological and Systemic Reactions to Hair Dyes: Current Evidence and Management. International Journal of Applied Pharmaceutics. 2026;18(4):86-95.



Journal of Young Pharmacists, 2026; 18(2):502-508.
https://www.jyoungpharm.org

Original Article

General Health and Quality of Life Among Ethnic Minority Elderly with Type 2 Diabetes: A Cross-Sectional Study

Ancelin Wilfy[1], Arun Sakthi Vijayakumar[1], Kanthimathi Meenal Chidambaram[1], Vishwa Athithyan Velayutham[1], Balasubramaniam Vishwanathan[2], Ponnusankar Sivasankaran[1,*]

[1]Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Ooty, Tamil Nadu, INDIA.
[2]Department of Emergency Medicine, Government Medical College and Hospital, Ooty, Tamil Nadu, INDIA.

ABSTRACT

Background: Type 2 diabetes significantly impacts physical health and psychological well-being in older adults, particularly affecting their quality of life. However, limited evidence exists regarding these outcomes among elderly individuals from ethnic minority communities. This study aimed to assess general health status and health-related quality of life, and to identify associated clinical, psychological, and sociodemographic factors in this population. **Materials and Methods:** A cross-sectional study was conducted at a private multispecialty hospital in Ooty, Tamil Nadu, between August 2024 and January 2025. A total of 232 participants aged 65 years and older with type 2 diabetes were included. General health and quality of life were measured using the SF-36 and EQ-5D-5L instruments. Additional measures included diabetes self-efficacy, fear of hypoglycemia, and fear of disease progression. Data were analysed using descriptive statistics, Pearson correlation, and multivariable linear regression. **Results:** General health was the most affected domain in the SF-36, while pain/discomfort was the most impaired dimension in the EQ-5D-5L. Higher education levels and greater diabetes self-efficacy were significantly associated with better general health and quality of life. In contrast, older age, presence of comorbidities, and increased fear of disease progression were associated with poorer outcomes. **Conclusion:** The findings demonstrate that physical, psychological, and social factors collectively influence health-related quality of life in older adults with type 2 diabetes from ethnic minority communities. These results emphasize the importance of culturally sensitive and patient-centred care strategies to improve overall well-being in this population.

Keywords: Chronic disease management, Cultural competence, Health behavior, Patient-centred care, Quality of life, Type 2 diabetes mellitus.

Correspondence:
Dr. Ponnusankar Sivasankaran
Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Ooty, Tamil Nadu, INDIA.
Email: ponnusankarsivas@gmail.com

Received: 14-01-2026;
Revised: 06-03-2026;
Accepted: 22-05-2026.

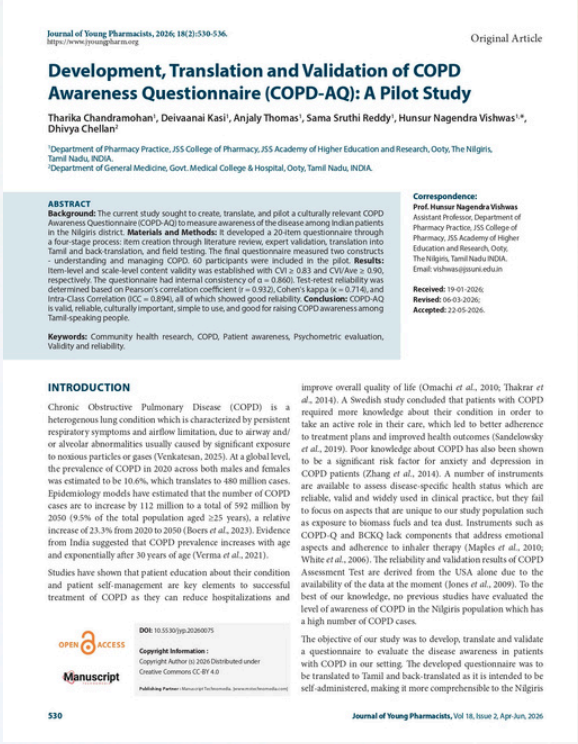
INTRODUCTION

Type 2 diabetes represents a growing public health issue in India, driven by an aging population, urbanization, and changing lifestyles. In older adults, diabetes often comes with chronic problems like neuropathy and heart disease, which contribute to disease burden (Hills *et al.*, 2018; American Diabetes Association, 2021). People from ethnic minority communities may face extra challenges in managing diabetes due to cultural practices, language barriers, and social structures. These issues complicate diabetes management (Attridge *et al.*, 2014). Even with the heavy impact of diabetes in South Asia, ongoing healthcare inequalities still affect access to care and its quality (Ong *et al.*, 2023).

Aside from medical factors, psychological and behavioral aspects are important in managing diabetes. Emotional stress, fear of low blood sugar or disease progression, and low confidence can disrupt treatment compliance and hurt perceived health status, especially in older people (Perrin *et al.*, 2017). Health-related quality of life tools like the SF-36 and EQ-5D-5L assess physical, emotional, and social health dimensions and are commonly used in diabetes research (Jing *et al.*, 2018; Al-Ibrahimy and Rabea, 2023). The ability to maintain self-care despite chronic illness often reflects a person's coping skills, health knowledge shaped by sociocultural context (Zeng *et al.*, 2023).

However, there is limited information on general health and quality of life among older ethnic minority individuals with type 2 diabetes in India. Their experiences and specific challenges are often overlooked in usual clinical assessments. This study aimed to evaluate general health status and health-related quality of life among older ethnic minority adults with type 2 diabetes in the Nilgiris district of Tamil Nadu. It also examined how clinical, psychological, and social factors influence these outcomes using validated assessment tools.

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Journal of Young Pharmacists, 2026; 18(2):530-536.
https://www.jyoungpharm.org

Original Article

Development, Translation and Validation of COPD Awareness Questionnaire (COPD-AQ): A Pilot Study

Tharika Chandramohan[1], Deivaanai Kasi[1], Anjaly Thomas[1], Sama Sruthi Reddy[1], Hunsur Nagendra Vishwas[1,*], Dhivya Chellan[2]

[1]Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Ooty, The Nilgiris, Tamil Nadu, INDIA.
[2]Department of General Medicine, Govt. Medical College & Hospital, Ooty, Tamil Nadu, INDIA.

ABSTRACT

Background: The current study sought to create, translate, and pilot a culturally relevant COPD Awareness Questionnaire (COPD-AQ) to measure awareness of the disease among Indian patients in the Nilgiris district. **Materials and Methods:** It developed a 20-item questionnaire through a four-stage process: item creation through literature review, expert validation, translation into Tamil and back-translation, and field testing. The final questionnaire measured two constructs – understanding and managing COPD. 60 participants were included in the pilot. **Results:** Item-level and scale-level content validity was established with CVI ≥ 0.83 and CVI/Ave ≥ 0.90, respectively. The questionnaire had internal consistency of α = 0.860). Test-retest reliability was determined based on Pearson's correlation coefficient (r = 0.932), Cohen's kappa (κ = 0.714), and Intra-Class Correlation (ICC = 0.894), all of which showed good reliability. **Conclusion:** COPD-AQ is valid, reliable, culturally important, simple to use, and good for raising COPD awareness among Tamil-speaking people.

Keywords: Community health research, COPD, Patient awareness, Psychometric evaluation, Validity and reliability.

Correspondence:
Prof. Hunsur Nagendra Vishwas
Assistant Professor, Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Ooty, The Nilgiris, Tamil Nadu INDIA.
Email: vishwas@jssuni.edu.in

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a heterogenous lung condition which is characterized by persistent respiratory symptoms and airflow limitation, due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases (Venkatesan, 2025). At a global level, the prevalence of COPD in 2020 across both males and females was estimated to be 10.6%, which translates to 480 million cases. Epidemiology models have estimated that the number of COPD cases are to increase by 112 million to a total of 592 million by 2050 (9.5% of the total population aged ≥25 years), a relative increase of 23.3% from 2020 to 2050 (Boers *et al.*, 2023). Evidence from India suggested that COPD prevalence increases with age and exponentially after 30 years of age (Verma *et al.*, 2021).

Studies have shown that patient education about their condition and patient self-management are key elements to successful treatment of COPD as they can reduce hospitalizations and improve overall quality of life (Omachi *et al.*, 2010; Thakrar *et al.*, 2014). A Swedish study concluded that patients with COPD required more knowledge about their condition in order to take an active role in their care, which led to better adherence to treatment plans and improved health outcomes (Sandelowsky *et al.*, 2019). Poor knowledge about COPD has also been shown to be a significant risk factor for anxiety and depression in COPD patients (Zhang *et al.*, 2014). A number of instruments are available to assess disease-specific health status which are reliable, valid and widely used in clinical practice, but they fail to focus on aspects that are unique to our study population such as exposure to biomass fuels and tea dust. Instruments such as COPD-Q and BCKQ lack components that address emotional aspects and adherence to inhaler therapy (Maples *et al.*, 2010; White *et al.*, 2006). The reliability and validation results of COPD Assessment Test are derived from the USA alone due to the availability of the data at the moment (Jones *et al.*, 2009). To the best of our knowledge, no previous studies have evaluated the level of awareness of COPD in the Nilgiris population which has a high number of COPD cases.

The objective of our study was to develop, translate and validate a questionnaire to evaluate the disease awareness in patients with COPD in our setting. The developed questionnaire was to be translated to Tamil and back-translated as it is intended to be self-administered, making it more comprehensible to the Nilgiris

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DERMATOLOGICAL AND SYSTEMIC REACTIONS TO HAIR DYES: CURRENT EVIDENCE AND MANAGEMENT

NITHYA SHREE, SUVITHA SRI M., RAGUNATH S., VARSHA K., R. DHYANESH, JEEVANANTHAM I.*

Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Ooty, Nilgiris-643001, Tamil Nadu, India
*Corresponding author: Jeevanantham I.; *Email: jeevaimayavam@gmail.com

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ABSTRACT

To critically evaluate the dermatological and systemic adverse effects associated with hair dye use, with particular emphasis on para-phenylenediamine (PPD), a common oxidative dye component implicated in allergic reactions and toxicological emergencies. A narrative review of published clinical, epidemiological, and experimental studies was conducted to summarize reported adverse effects, diagnostic approaches, and management strategies related to hair dye exposure. Dermatological reactions are the most frequently reported adverse effects, with PPD-induced allergic contact dermatitis representing the predominant clinical manifestation. Common symptoms include erythema, pruritus, edema, vesiculation, and, in some cases, hair loss. Diagnosis is primarily confirmed through patch testing to detect sensitivity to PPD or structurally related compounds. Additional reported effects include hair fragility, xerosis of the scalp, and irritant dermatitis. Rare but serious systemic reactions such as angioedema, respiratory distress, and acute kidney injury have been documented, particularly following severe hypersensitivity reactions or accidental ingestion. Epidemiological evidence regarding long-term systemic risks, including bladder cancer and hematological malignancies, remains inconsistent, although some studies suggest a possible association with prolonged use of dark permanent dyes. Occupational exposure among hairdressers increases the risk of sensitization. Management includes immediate discontinuation of the offending agent, topical corticosteroids and antihistamines for mild to moderate dermatitis, and systemic corticosteroids for severe reactions. Preventive strategies include pre-application patch testing, use of protective gloves, patient education, and substitution with formulations free of PPD or other high-risk sensitizers. Hair dye use is associated with well-established dermatological risks and rare but potentially severe systemic effects. Early recognition, evidence-based management, and preventive strategies are essential to minimize adverse outcomes, and continued research into safer alternative formulations remains warranted.

Keywords: Hair dye, Para-phenylenediamine (PPD), Allergic contact dermatitis, Occupational exposure, Toxicological emergency

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INTRODUCTION

Hair dyes are among the most frequently implicated cosmetic products in dermatological adverse reactions worldwide, due to repeated scalp exposure and the presence of potent sensitizers such as para-phenylenediamine (PPD). Among cases of cosmetic-related contact dermatitis, hair dyes are consistently identified as a leading cause, particularly in developing countries where regulation and consumer awareness are limited. Permanent oxidative hair dyes account for the majority of reported adverse reactions because they penetrate the hair cortex and involve reactive intermediates formed during oxidation. PPD, the principal intermediate in permanent hair dyes, is the most commonly detected allergen in patch-tested patients with cosmetic dermatitis in India and other Asian countries. Clinical manifestations of hair dye reactions range from localized allergic contact dermatitis to severe systemic reactions such as angioedema, anaphylaxis, and acute renal failure following ingestion. Repeated exposure to hair dye ingredients increases the risk of sensitization, even in individuals who previously tolerated the product without adverse effects. Occupational exposure among hairdressers further elevates the risk of chronic hand dermatitis, respiratory sensitization, and asthma due to frequent contact with oxidative dyes and persulfates. Epidemiological studies suggest a possible association between long-term use of dark permanent hair dyes and hematological malignancies, although findings remain inconsistent across populations. Experimental and mechanistic studies demonstrate that certain aromatic amines used in hair dyes can induce DNA damage, oxidative stress, and endocrine disruption, supporting biological plausibility for systemic toxicity [1]. Hair dye-related adverse effects are therefore a critical focus of cosmetovigilance systems, which play a key role in early signal detection, regulatory intervention, and consumer safety education. The extent of sensitivity to numerous allergic ingredients has increased in tandem with the usage of cosmetics. The most common cause of contact dermatitis in our country is hair coloring. In southern India, Kumkum dermatitis was very common. Use of a sticker (bindi) has also been identified as a significant risk factor for contact dermatitis. In addition to the active ingredient, other constituents of cosmetic products are linked to adverse effects after use. Even though many ADRs happen at the population level, very few are reported to the regulatory body [2]. The majority of individuals with contact dermatitis in a research report negative reactions to cosmetics. In their investigation, they discovered that a large number of patients with contact dermatitis had positive results from cosmetic patch tests, leading them to draw the conclusion that cosmetics are a significant contributing factor to the development of contact dermatitis [3-5].

Common reaction happens due to cosmetics

Itching (70.9%), skin dryness (63.3%), and burning feeling (50%) were the most common complaints. Rhagades, scales, blisters, patches, redness, and no changes at all were among the skin signs. Sneezing after shaving, shortness of breath after using perfume spray, enlargement of local lymph nodes after using deodorant, eye irritation as evidenced by wet and burning eyes, and nausea after applying perfume were among the other complaints. The hands and face were most frequently impacted. Tenderness, swelling, itching, and pimples were the most frequent adverse drug reactions (ADRs) that occurred during permanent cosmetics procedures in the United States. There were products with no license number on the label. High levels of lead have been identified in many cosmetic products. High concentrations of heavy metals (lead, zinc, and cadmium) have been discovered to be present in a variety of cosmetic goods, including eyeshadow, lip gloss, lipstick, and henna hair dye [6]. Chemicals in cosmetics can affect salon and parlour hair stylists, and hand dermatitis is a common ailment among them. Given that female hair professionals are more susceptible to reproductive problems and negative pregnancy outcomes, this is particularly problematic. Hair technicians are also at a higher risk of developing asthma as a