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Contents

13 Editorial

Data Privacy and Data Breach in the Context of the DPDP Act — *Ranjan Bhattacharyya*

Original Articles

16 Evaluation of Various Tests for Diagnosis of *Helicobacter pylori* Infection Among Patients with Dyspepsia in a Tertiary Care Institute of North India — *Swati Khatri, Kunal Bansal, Ritu Aggarwal, Veena Gupta, Tarana Gupta, Aparna Yadav*

21 Correlation between Plasma D-dimer Levels and Infarction Volume in Acute Ischemic Stroke Patients — *Anjana L, Pravin Selvam, Nivya Manimozhian*

25 Next-generation Sequencing in Lung Adenocarcinoma: Which One is Better: Focus Oncomine Solid Tumor Panel or Epidermal Growth Factor Receptor Mutation Analysis? — *Meera C Parmar, Shyama M Chag, Sanjay N Chaudhari, Monica V Gupta*

30 Prescribing Pattern and Medication Adherence in Patients with Depression: A Cross-sectional Observational Study — *Mayuresh S Jadhav, Pradeep R Jadhav, Shubhangi Dere, Rakesh Ghildiyal*

36 Body Image Issues in Late Adolescence—The Impact of Body Mass Index and Social Media Use: A Prospective Crosssectional Study — *Anuradha Bansal, Harmesh Singh Bains, FNU Pawandeep, Kabir Bansal, Manpal Kaur Sandhu*

41 A Sensitivity Showdown—Comparing the Modified Bleach Concentration Method with Conventional Ziehl–Neelsen Staining for Detection of *Mycobacterium tuberculosis* in Extrapulmonary Sites — *Shafali Deopa, Banyameen Iqbal, Rutika Ghatge, Charusheela Gore*

Review Article

47 Antitubercular Treatment-induced Psychosis: A Systematic Review and Recommendations — *Shobhit Jain, Harjeet Kaur Kapoor, Pradeep Kumar, Vinod Verma, Ajeet Kumar, Amit Singh*

Case Series

53 Atypical Presentation of Chikungunya Virus Infection: More Than Meets the Eye — *Sandesh Sadanand Raut, Manaswini Edara, Sachin Shivnitwar*

Case Report

57 Multifocal Glioblastoma in a 61-year-old Woman: A Rare and Challenging Diagnosis — *Dessika Rahmawati, Wahyuni Ramadhani Suaib*

62 A Curious Case of Consciousness — *Kaushik Ghosh, Ranabir Ghosh, Sonali Ghosh, Sourav Das Chowdhury*

67 A Perfect Storm in a Young Male: Ischemic Stroke and Thyroid Storm Unmasking Hyperthyroidism A Perfect Storm in a Young Male: Ischemic Stroke and Thyroid Storm Unmasking Hyperthyroidism — *Shalini Pandya, Pares G Mody*

71 An Unusual Case of Syncope — *Supriya Barsode, Aryaa Rajendra Deshmukh, Shreyash Gulhane*

Contents

Letter To The Editor

- Unappreciated Work of Coauthors — *Rajashri Patil, Sriram Kannuri, Sahjid Mukhida, Sameena Khan, Nikunja Kumar Das*
- 73
- Reply to “Vitamin D3 Insufficiency and Its Correlation with Disease Severity and Diagnostic Biomarkers in Rheumatoid Arthritis: A Case-control Study” — *Astha Goyal, Nidhi Rohan Purandare*
- 75

Data Privacy and Data Breach in the Context of the DPDP Act

Ranjan Bhattacharyya

Journal of the Indian Medical Association (2026); 10.5005/jima-11070-0080

Data privacy is about how personal or sensitive data is collected, used, stored, shared, and protected. People should have control over their personal information. For example, (i) a hospital asks for consent before sharing medical records, (ii) a website explains in its privacy policy how it uses the data, and (iii) a company allows users to delete their account and personal data. There is growing demand to protect individuals' rights, ensure the lawful and ethical use of data, and comply with laws such as the General Data Protection Regulation (GDPR), India's Digital Personal Data Protection (DPDP) Act, 2023, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).¹

A data breach is a security incident in which unauthorized people access, steal, expose, or destroy data. Hackers may steal customer passwords from a company database. An employee may accidentally e-mail confidential files to the wrong person. For example, a laptop containing unencrypted customer data may be lost or stolen. The consequences of a data breach include identity theft, financial fraud, loss of customer trust, and legal penalties and fines. The differences between data privacy and a data breach are summarized in Table 1.

In a nutshell, data privacy implies "Who is allowed to use the data, and for what purpose?" whereas a data breach indicates that someone who was not allowed to access the data obtained access to it.

A company may have a good privacy policy, but if its systems are hacked, a data breach can still occur. Conversely, a company might never be hacked but could still violate data privacy laws by collecting or sharing data without proper consent.

India's Digital Personal Data Protection Act, 2023 (DPDP Act), highlights digital privacy as a person's right to control how their personal information is collected, used, stored, and shared in digital form. It includes data such as (i) name, address, and phone number; (ii) e-mail address; (iii) Aadhaar or other identity numbers; (iv) financial information; (v) health records; and (vi) online activity and location data. The objective is to protect individuals from misuse of their personal data and ensure transparency and consent in data handling.^{2,3}

DIGITAL PERSONAL DATA PROTECTION (DPDP) ACT, 2023—INDIA

The DPDP Act, 2023, is India's main law governing the processing of digital personal data. It was passed by Parliament in August 2023. The main objectives of this Act are (i) to protect the privacy of individuals, (ii) to regulate the processing of digital personal data, (iii) to create accountability for organizations handling personal data, and (iv) to provide remedies in cases of misuse or data breaches. Specific terminology used in this context is highlighted in Table 2.

Hony Editor, Journal of Indian Medical Association (JIMA, 2025–26); Hony Secretary, East Zone, Indian Psychiatric Society (EZ-IPS 2025–27)

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Key Provisions of the Act

Organizations must obtain clear and informed consent before processing personal data unless a lawful exception applies. A Data Principal has the right to (i) access information about their data, (ii) correct inaccurate data, (iii) erase personal data, (iv) withdraw consent, and (v) seek grievance redressal. Organizations also have certain duties. Data Fiduciaries must use data only for the stated purpose, keep data secure, delete data when it is no longer needed, and inform the authorities and affected individuals in the event of a data breach. Processing children's data requires parental consent, and tracking or targeted advertising directed at children is restricted. If a breach occurs, the organization must notify the Data Protection Board of India and affected users as prescribed.

Table 1: The differences between data privacy and a data breach

Aspect	Data privacy	Data breach
What is it?	Rules and practices for handling data	A failure or incident affecting data security
Focus	Proper use of data	Unauthorized access to data
Type	Policy/legal/ethical	Security incident
Example	Getting user consent	Database hacked
Can one exist without the other?	Yes	Yes

Table 2: Terminology used in the DPDP Act of India, 2023

Data principal	The individual whose data is being processed
Data fiduciary	The organization or person deciding how and why data is processed
Data processor	An entity that processes data on behalf of a Data Fiduciary
Personal data	Any data that can identify an individual

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Table 3: Legislation and laws in different Western countries

Country/region	Main data protection law
European Union (EU)	General Data Protection Regulation (GDPR)
United Kingdom (UK)	UK GDPR and Data Protection Act, similar to the EU GDPR, with rules tailored to UK law after Brexit
United States (US)	No single federal privacy law; sector-specific and state laws, e.g., the California Consumer Privacy Act (CCPA) and the California Privacy Rights Act (CPRA)
Canada	Personal Information Protection and Electronic Documents Act (PIPEDA)

The Act allows significant financial penalties for noncompliance, including failure to protect data or report breaches. The DPDP Act, 2023, strengthens citizens' privacy rights, increases trust in digital services, encourages responsible data handling by companies, and aligns India with global data protection practices.^{4,5}

Digital privacy is the right of individuals to control their personal information in digital environments. The Digital Personal Data Protection Act, 2023, is India's law for protecting digital personal data. It requires organizations to obtain consent before using personal data, ensure data security, allow individuals to access, correct, and erase their data, and report data breaches. The Act also provides special protection for children's data and imposes penalties for violations. Its main aim is to safeguard privacy and promote the secure and accountable use of personal data in the digital economy.⁶

Data protection in many Western countries is governed by laws that regulate how personal information is collected, used, stored, shared, and deleted. Although the specific rules differ by country, they generally emphasize privacy, transparency, and individual rights. Table 3 summarizes the countries or regions and their principal data protection laws.

Most Western data protection laws are based on similar principles:

- **Lawfulness and fairness:** Organizations must have a legal basis for collecting and using personal data.
- **Transparency:** Individuals should be informed about how their data will be used.
- **Purpose limitation:** Data should be used only for the purposes for which it was collected.
- **Data minimization:** Only the data necessary for a specific purpose should be collected.
- **Accuracy:** Organizations should keep personal data accurate and up to date.
- **Storage limitation:** Personal data should not be retained longer than necessary.
- **Security:** Appropriate technical and organizational measures must protect data from unauthorized access or loss.
- **Accountability:** Organizations are responsible for demonstrating compliance with data protection laws.

Many Western privacy laws give individuals rights such as access to their personal data, correction of inaccurate information, deletion of personal data (sometimes called the "right to be forgotten" under the GDPR in certain circumstances), restriction of or objection

to certain types of processing, receipt of their data in a portable format, and filing of complaints with a data protection authority. Organizations that violate these laws may face significant financial fines, orders to stop processing data, compensation claims from affected individuals in some cases, reputational damage, and regulatory oversight. Overall, Western data protection frameworks aim to balance the benefits of data use with individuals' rights to privacy and control over their personal information. The EU's GDPR is widely regarded as one of the most comprehensive privacy laws and has influenced legislation in many other countries.⁷

The Digital Personal Data Protection Act, 2023 (DPDP Act), is India's primary law governing digital personal data. Although it establishes a legal framework for privacy and data protection, it has also attracted criticism from legal experts, industry groups, and civil society organizations.

Some commonly discussed drawbacks include:

- **Broad government exemptions:** The Act allows the government to exempt certain government agencies from some provisions on grounds such as national security, public order, or sovereignty. Critics argue that these exemptions may reduce accountability and weaken privacy protections.
- **Limited rights compared with GDPR:**
 - Unlike the EU's GDPR, the DPDP Act does not provide certain rights, such as:
 - A broad right to data portability.
 - A general right to object to processing.
 - A comprehensive "right to be forgotten" in the GDPR sense.
 - The available rights are more limited in scope.
- **Reduced independence of the regulator:** The Data Protection Board of India is established by the central government. Some observers have questioned whether the appointment process provides sufficient institutional independence.
- **Broad rulemaking powers:** Many operational details are left to be specified through government rules rather than being fully defined in the Act. This can create uncertainty until those rules are finalized and may allow significant policy changes without amendment of the Act itself.
- **No distinction between sensitive and ordinary personal data:** Earlier draft bills proposed stronger safeguards for sensitive personal data, such as health or biometric information. The DPDP Act largely applies a uniform framework, with additional protections expected through rules where necessary.
- **Potential compliance burden:** Businesses, especially startups and small enterprises, may face costs related to consent management, security measures, and responses to user requests.
- **Consent management challenges:** The Act emphasizes consent as a primary basis for processing. Organizations may find it operationally difficult to obtain, track, and manage valid consent across multiple services.
- **Cross-border data transfer framework:** Instead of requiring most data to remain within India, the Act allows transfers except to countries that may later be restricted by the government. Some stakeholders view this as offering flexibility, whereas others argue that the framework's future scope depends heavily on government notifications.⁸

The DPDP Act has also been praised for creating India's first comprehensive digital personal data protection law, establishing rights for individuals over their digital personal data, requiring organizations to implement reasonable security safeguards, and providing penalties for certain types of noncompliance and data

breaches. Whether a particular feature is viewed as a drawback often depends on the perspective. Businesses may appreciate regulatory flexibility, whereas privacy advocates may prefer stronger individual rights and narrower government exemptions.

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Evaluation of Various Tests for Diagnosis of *Helicobacter pylori* Infection Among Patients with Dyspepsia in a Tertiary Care Institute of North India

Swati Khatri¹, Kunal Bansal², Ritu Aggarwal³, Veena Gupta⁴, Tarana Gupta⁵, Aparna Yadav⁶

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ABSTRACT

Background: *Helicobacter pylori* infection is responsible for a wide spectrum of diseases, including gastritis, peptic ulcer, gastric cancer, and mucosa-associated lymphoid tissue lymphoma. It can be diagnosed by various invasive and noninvasive techniques.

Aims and objectives: The present study aims at simplifying the selection of routine diagnostic tests in a developing economy like India for patients with *H. pylori*-associated dyspepsia, considering various parameters.

Materials and methods: A prospective study was conducted in the Department of Microbiology, Medicine, and Pathology over a period of 1 year. Upper gastrointestinal endoscopy was performed in enrolled patients after obtaining written informed consent. Culture and/or histopathological examination (HPE) findings were accepted as the gold standard. Results from bacteriological microscopic examination, rapid urease test (RUT), and stool antigen test (SAT) were then compared with it. Data were expressed as percentages and proportions. A Chi-square test was used to validate results.

Results: Culture and HPE were the most specific tests with 100% specificity and positive predictive values (PPVs). Maximum sensitivity was observed with RUT (100%) followed by SAT (94.4%). RUT was least specific (90.6%). The PPV of the SAT was 94.4% with accuracy equivalent to that of HPE (96%).

Conclusion: The SAT, being a simple and cost-effective noninvasive test with good sensitivity, accuracy, and PPV, can be considered a better alternative to invasive tests for diagnosing *H. pylori* infection in patients who do not require endoscopy. However, when endoscopy is specifically indicated, HPE and culture serve as an accurate and specific test, while SAT is still beneficial as a supplementary test for rapid screening.

Keywords: Gastric cancer, Gastrointestinal endoscopy, *Helicobacter pylori*, Rapid urease test, Stool antigen test.

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BACKGROUND

Helicobacter pylori infection causes a wide spectrum of diseases, including chronic gastritis, peptic ulcers, gastric carcinoma, and mucosa-associated lymphoid tissue lymphoma. Its successful cultivation requires a humid atmosphere maintained at 37°C with reduced levels of oxygen (5–10%) and increased levels of carbon dioxide (5–8%). It is highly fastidious and has a predilection for the cardia, corpus, and antrum regions of the stomach, where it tends to show patchy growth.¹

In developing countries, infection is acquired early in life, and a prevalence of 22–57% has been noted in children less than 5 years of age.¹ Transmission can occur through oral–oral and fecal–oral routes. A study conducted by Sharma *et al.* among Indian patients has shown the incidence of *H. pylori* to be 56.8% among patients with gastritis.² Another study conducted on dyspeptic patients in India has shown the prevalence of *H. pylori* to be 57.5%.³

Tests for diagnosis of *H. pylori* can be broadly categorized as invasive and noninvasive techniques. Invasive methods utilize a gastric biopsy specimen obtained by endoscopy, which is further processed for either bacteriological microscopic examination, rapid urease test (RUT), culture, histopathological examination (HPE), or molecular testing. Noninvasive methods mainly include the urea breath test (UBT), stool antigen test (SAT), and antibody detection in urine and saliva.¹ A disadvantage of UBT includes

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its high cost, requirement of specialized equipment for sample collection, and relative unavailability in developing countries. Accordingly, it was excluded in the present study, as it won't be easily accessible, especially in resource-limited facilities. Similarly, molecular techniques are sophisticated, highly expensive, and require a tertiary care setup along with technical expertise and are not

available everywhere. Serological testing of urine and saliva samples for detection of IgG antibodies is mainly useful in epidemiological studies and cannot be relied upon for diagnosis of *H. pylori* infection.

Various studies suggest different testing modalities, but there are no set guidelines, as the choice of test finally depends on sensitivity, specificity, reproducibility, ease of availability, cost-effectiveness, and rapidity of test results as well as on the condition of the patient. Some authors have suggested the use of various tests in combination, as no single test can be considered a gold standard.¹⁻⁴

After reviewing work done by various authors, it was thought worthwhile to conduct a prospective study in a tertiary-level healthcare setup to evaluate various techniques, which are economical and, at the same time, feasible at a routine microbiological laboratory in a developing nation, for the detection of *H. pylori* infection, which can eventually guide medical practitioners in the selection of particular diagnostic tests from the list of available testing modalities.

MATERIALS AND METHODS

Study Design, Setting, and Ethical Approval

A prospective study was conducted in the Department of Microbiology, Medicine, and Pathology over a period of 1 year from January 2018 to December 2018. Ethical approval from the Institutional Ethics Committee (IEC) was obtained vide letter no. IEC/Th/17/Micro-01 dated 11.12.2017.

Study Population

A total of 50 patients attending the medicine outpatient department (OPD) were enrolled in the study after obtaining written informed consent from them.

Inclusion Criteria

Patients above 18 years of age presenting with at least one of the following common chief complaints of dyspepsia, i.e., bloating sensation/dysphagia/epigastric pain/epigastric burning/frequent belching or occasional vomiting were enrolled in the study.

Exclusion Criteria

Excluded pregnant or lactating females and patients who refused to participate in the study/provide informed consent. Similarly, patients with gastric cancer, a previous history of gastric surgery or resection, severe renal/hepatic ailments, and also those taking antibiotics in the past 4 weeks and/or proton pump inhibitors (PPIs)/antacids containing bismuth in the previous 2 weeks were excluded from the present study.^{2,3}

Sample Size

It was calculated by taking prevalence to be 57.5% and using formula³:

$$\frac{4pq}{l^2} = \frac{4 \times 57.5 \times 42.5}{(15)^2} = 44$$

(p = prevalence, q = $1 - p$, l = absolute error)

Even if any loss to follow-up is considered with a dropout rate of 10%, the required sample size comes out to be 48. Still, a minimum of 50 subjects were registered in the present study.

Sample Collection

Upper gastrointestinal endoscopy of enrolled patients was done after obtaining written informed consent. Patients were asked to

bring stool samples on the day of endoscopy. Five gastric biopsy specimens were taken for best results as per the Sydney system. One each from the distal lesser and greater curvature of the antrum within 2–3 cm from the pylorus, two from the corpus within 8 cm from the cardia (each from both lesser and greater curvature), and one from the incisura angularis.⁴ Gastric biopsy specimens obtained were minced together aseptically and put immediately into Columbia agar broth with 10% horse serum (HiMedia®, Mumbai, India), urea broth and 10% buffered formalin.^{1,4}

Sample Processing

Invasive tests: The urea broth vial with the biopsy specimen inoculated was incubated at 37°C for 1–1.5 hours. The development of pink color in pale yellow broth indicated a positive result. A smear was prepared from one part of the specimen collected in Columbia agar broth and stained using a modified Gram stain. The appearance of curved Gram-negative *bacilli* with seagull-shaped morphology was indicative of *H. pylori*. The remaining portion of the minced biopsy was inoculated on Columbia agar (HiMedia®, Mumbai, India) plates supplemented with 10% defibrinated horse serum and Campylobacter Supplement-III (Skirrow) FD008 (HiMedia®, Mumbai, India). These plates were incubated at 37°C in a rectangular gas jar moistened with wet filter paper having AnaeroPack™-MicroAero (Thermo Fisher Scientific India Inc.) and later sealed with parafilm so as to provide a microaerophilic environment. Plates were examined on the 3rd, 5th, and 7th day.⁵ Suspected colonies were circular, convex, translucent, 0.5–1 mm in diameter; the secondary smear was stained with Gram's stain. Subsequent biochemical testing gave positive catalase, oxidase, and urease test results.

The biopsy specimen, added to 10% buffered formalin, was transported to the Department of Pathology at room temperature. It was embedded in paraffin and stained using Giemsa staining, hematoxylin and eosin staining, and immunohistochemical (IHC) staining methods.¹⁻³ Slides were screened for HPE and the presence of *H. pylori* using Giemsa staining, which was confirmed using IHC staining.

Noninvasive test: Stool samples were processed for detection of *H. pylori* antigen using the commercially available SD Bioline *H. pylori* Ag kit (Standard Diagnostics, Inc., Republic of Korea), based on lateral flow immunochromatographic technique (ICT).

Statistical Analysis

All data were collected, compiled, and entered into Microsoft Excel. It was analyzed using Statistical Package for Social Sciences (SPSS) software version 20. A p -value < 0.05 was considered statistically significant. Data were expressed as percentages and proportions. A Chi-square test was used to validate the results of the study and determine the association between infection with *H. pylori* and dyspepsia. Culture and HPE findings were used as the gold standard. Detection of *H. pylori* in at least one of these two tests was confirmatory.

Disposal of Waste

All biomedical waste generated in the laboratory was discarded as per the Biomedical Waste Management and Handling Rules, 2016 guidelines.

RESULTS

Findings of various methods employed have been compared with the gold standard in Table 1.

Table 1: Comparison of various test findings (n = 50)

Name of test	No. of positive cases (n = 50)	%	p-value (as compared to gold standard)
UGIE	23	46.0%	0.869
RUT	21	42.0%	<0.001*
Gram staining	14	28.0%	<0.001*
Culture	07	14.0%	<0.001*
HPE	16	32.0%	<0.001*
SAT	18	36%	<0.001*

* $p \leq 0.05$; UGIE, upper gastrointestinal endoscopy; RUT, rapid urease test; HPE, histopathological examination; SAT, stool antigen test

Table 2: Results of various tests as compared to gold standard

Name of test	Positive test result among gold standard positive cases (n = 18)	Positive test result among gold standard negative cases (n = 32)
RUT	18 (100%)	03 (9.4%)
Gram staining	13 (72.2%)	01 (3.1%)
Culture	07 (36.8%)	0
HPE	16 (88.9%)	0
SAT	17 (94.4%)	01 (3.1%)

RUT, rapid urease test; HPE, histopathological examination; SAT, stool antigen test

Helicobacter pylori positivity was detected in 18 (36%) patients by culture and/or HPE. Both HPE and culture were positive in 5 patients out of 18 positive cases. Among 18 *H. pylori*-positive patients, 11 (61.1%) were females, and the rest, 7 (38.9%), were males. No statistically significant difference was determined between male and female patients in terms of *H. pylori* positivity ($p = 0.585$).

Table 2 compares the results of 18 *H. pylori* positive patients with other tests. The RUT test was found to be positive in all these patients (100%), followed by SAT (94.4%), whereas the least rate of positivity was determined in culture (36.8%).

A statistically significant correlation was found between invasive and noninvasive techniques (SAT) as depicted in Table 3.

Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of various tests have been depicted in Table 4.

DISCUSSION

The most frequent presenting complaint was epigastric pain (84%), followed by bloating sensation (50%) and epigastric burning (28%). Pathological changes were found in 23 (46%), with antral gastritis being the most common finding (74%) on endoscopy. There was no statistically significant correlation between endoscopic findings and *H. pylori* infection ($p = 0.869$). Prevalence of *H. pylori* infection was 36%.

Helicobacter pylori positivity was determined in biopsy samples of 21 (42%) patients by RUT. Similar results were obtained by Yakoob et al., who reported positivity in 40% of cases by the RUT method.⁶ Statistically significant correlation was found between RUT and gold standard. Sensitivity for RUT as observed in our study (100%) correlated with similar studies conducted by Athavale et al. (96.38%) and Kazemi et al. (93%).^{7,8} A study conducted by Vagarali et al. had shown lower sensitivity (76.6%) for RUT as compared to the present study.⁹ Sensitivity of RUT is dependent on the site from where the biopsy is taken and the density of *H. pylori*

Table 3: Comparison of invasive and noninvasive techniques

SAT (Noninvasive test)	HPE + Culture				p-value
	N	%	Y	%	
N	31	96.9%	1	5.6%	<0.001*
Y	1	3.1%	17	94.4%	
Total	32	100%	18	100%	

* $p \leq 0.05$; SAT, stool antigen test; HPE, histopathological examination

Table 4: Sensitivity, specificity, positive, and NPVs of tests as compared to the gold standard

Name of test	Sensitivity	Specificity	PPV	NPV	Accuracy
RUT	100.0%	90.6%	85.7%	100.0%	94.0%
Gram staining	72.2%	96.9%	92.9%	86.1%	88.0%
Culture	38.9%	100.0%	100.0%	74.4%	78.0%
HPE	88.9%	100.0%	100.0%	94.1%	96.0%
SAT	94.4%	96.9%	94.4%	96.9%	96.0%

RUT, rapid urease test; HPE, histopathological examination; SAT, stool antigen test; PPV, positive predictive value; NPV, negative predictive value

in the mucosal biopsy, as a minimum of 10^4 organisms/biopsy is required for positive RUT, and many patients harbor bacteria in lesser proportions. Its performance is also adversely affected by the low density of bacteria postantibiotic treatment and patients who are bleeding or are on PPI therapy.^{9,10} There were three false positive cases reported by RUT in comparison with the gold standard, which could be due to contamination by other bacteria producing urease.

Sensitivity, specificity, PPV, and NPV for Gram staining were determined to be 72.2%, 96.9%, 92.9%, and 86.1%, respectively. Sharma et al., however, had reported sensitivity, specificity, PPV, and NPV to be 62.5%, 80%, 80.6%, and 61.5%, respectively.² This may be attributed to interobserver variability, patchy distribution of organisms, and prior antibiotic and PPI therapy, which may alter bacterial morphology. In the present study, there was one false positive result reported by Gram staining, as *H. heilmannii* and *H. bizzozeronii* can also have similar curved morphology.

Helicobacter pylori was isolated from gastric biopsy cultures of seven (14%) patients. Similar findings were reported by Oyedele et al. with 19.3% positivity by culture.¹¹ Culture sensitivity was 38.9% in the present study, which was higher than that reported by Sharma et al. (7.5%) and Vagarali et al. (13.3%).^{9,2}

False negative culture results were obtained in 11 cases as compared with the gold standard. This could be attributed to the patchy localization pattern of *H. pylori*, the oxygen sensitivity of bacteria, the highly fastidious nature of the organism, and the transformation of bacteria into coccoid forms under *in vitro* conditions.

Helicobacter pylori positivity was determined in 16 (32%) patients by HPE of gastric biopsy samples. Similar results were reported by Kokkola et al. with 30% positivity.¹² Vagarali et al. reported much lower positivity of 14.5%.⁹ Sensitivity of HPE in the present study was estimated to be 88.9%, which was similar to that reported by Kazemi et al. (89%).⁸ Calvet et al. have reported very good specificity of 98.8% for HPE, which is similar to findings in the present study (100%).¹³ However, Kazemi et al. have reported much lower specificity of only 78%.⁸ Sensitivity of HPE is influenced by site, number and size of biopsy sample, and experience of observer. Prior

antibiotics and PPI therapy may transform bacterial morphology. Two cases were found to be negative by HPE. This may have occurred due to patchy distribution of *H. pylori* in gastric mucosa.

Helicobacter pylori positivity was determined in 18 (36%) patients by SAT in stool samples of the 50 subjects. It was comparable to a study by Nair et al., who reported a positivity of 40.7% by SAT.¹⁴ The sensitivity of SAT was determined to be 94.4% in our study, which is comparable to the sensitivity (92.45%) reported by Calik et al.¹⁵ Specificity of SAT in our study was 96.9%, similar to values reported by Calik et al. (97.3%) and Jekarl et al. (96.2%).^{15,16} Diagnostic accuracy of SAT was determined to be 96%, comparable to 92.3% accuracy as reported by Kate et al.¹⁷ A statistically significant correlation was found between SAT and the gold standard in terms of *H. pylori* positivity.

There was one false negative result obtained with SAT in comparison with the gold standard. It may occur when there is gastrointestinal bleeding, patients are taking PPI or bismuth therapy, and there are variations in antigen excretion over time. Unformed or watery stool samples lead to less accurate test results due to diluted antigens. There was one false positive SAT as compared to the gold standard, which may be due to cross-reactivity with antigens from some other *Helicobacter* species.^{14–17}

Limitations

The present study had some limitations. It involved a comparatively smaller number of subjects and only those who visited the hospital during the study period. Secondly, patients were not followed up after their diagnosis, thereby limiting the prognostic value of diagnostic tests. Also, as *H. pylori* is a highly fastidious organism, culture can show less sensitivity despite our best efforts of ensuring complex nutritional growth requirements, i.e., a microaerophilic and humid environment supported with good microbiological laboratory practices. Since the present study was conducted in a tertiary care setting, the possibility of patients taking antibiotics or PPIs before admission cannot be ruled out, further affecting the sensitivity of gold standard tests utilized here.

CONCLUSION

The present study suggests SAT as a good alternative to invasive tests for determining the status of *H. pylori* infection for patients in whom endoscopy is not required. It can serve as a fast, low-cost point-of-care test, especially for developing countries, having an accuracy equivalent to HPE. However, when endoscopy is indicated, especially when a patient is presenting with alarming symptoms, culture and HPE are the most accurate and specific tests for *H. pylori* detection, and SAT can still be utilized as a simple and rapid point-of-care screening test for diagnosing *H. pylori* infection since it has good sensitivity with PPV and accuracy equivalent to that of HPE.

RECOMMENDATION

It is recommended that a large cohort study with follow-up be conducted by also enrolling pediatric patients to further strengthen diagnostic utility of SAT and confirm cure of *H. pylori* infection or schedule follow-up endoscopy if needed. It will further help in ensuring large-scale usage of SAT even at primary healthcare settings in developing countries, thereby reducing overall morbidity among patients while ensuring prompt case management.

ETHICS APPROVAL

Ethics approval was obtained from the Institutional Ethics Committee of PGIMS Rohtak Medical College (Letter No. IEC/Th/17/Micro-01, dated December 11, 2017).

INFORMED CONSENT

Written informed consent was obtained from all participants prior to enrolment.

CLINICAL TRIAL REGISTRATION

Not applicable.

DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this published article.

AUTHOR CONTRIBUTIONS

Conceptualization: Dr Swati Khatri, Dr Kunal Bansal, Dr Ritu Aggarwal, and Dr Aparna Yadav; Methodology: Dr Swati Khatri, Dr Kunal Bansal, Dr Ritu Aggarwal, Dr Veena Gupta, and Dr Tarana Gupta; Data Collection: Dr Swati Khatri; Writing – original draft: Dr Swati Khatri and Dr Kunal Bansal; Writing – review & editing: Dr Kunal Bansal.

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AI USE DECLARATION

No AI tools were used in the preparation of this manuscript.

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Correlation between Plasma D-dimer Levels and Infarction Volume in Acute Ischemic Stroke Patients

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ABSTRACT

Background: Acute ischemic stroke is one of the leading causes of morbidity and mortality. Timely intervention, including the diagnosis of stroke using biomarkers, plays an important role in minimizing impairment. Accordingly, the present study aimed to investigate the correlation between plasma D-dimer levels and infarction volume in patients with acute ischemic stroke.

Objective: The aim of the study was to establish the correlation between plasma D-dimer levels and infarction volume in patients with acute ischemic stroke.

Materials and methods: A cross-sectional study involving 100 acute ischemic stroke patients aged 51–70 years, with defined inclusion and exclusion criteria, was conducted in a tertiary health center hospital. The results of the study showed that D-dimer levels are strongly associated with the severity of the stroke among the individuals.

Results: A direct correlation was established between plasma D-dimer and infarct volume among ischemic stroke patients. The study suggests its important role as a biomarker for addressing infarction burden and severity of ischemic stroke. The study shows strengths as well as limitations, along with the prospective scope for future research on the specified domain.

Keywords: Acute ischemic stroke, Biomarker, Infarct volume, Morbidity and mortality, Plasma D-dimer.

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INTRODUCTION

Globally, acute ischemic stroke (AIS) is one of the leading causes of mortality. Timely intervention significantly enhances outcomes and minimizes impairment. Because one-third of stroke survivors rely on others for daily activities, stroke imposes a substantial monetary burden. Similarly, stroke exerts a significant strain on India's healthcare resources.^{1,2}

D-dimer has developed into a straightforward blood test that is utilized in diagnostic algorithms to exclude venous thromboembolism. It is the result of plasma-mediated breakdown of fibrin-rich thrombi. Because D-dimer levels are resistant to *ex vivo* activation, relatively stable, and have a long half-life, they offer certain benefits over other measurements of thrombin production. Due to the presence of this marker in several degradation products after the cleavage of cross-linked fibrin by plasmin, the concentration of D-dimer represents the amount of fibrin turnover in the circulation.^{3,4}

It has been suggested that moderately elevated circulating D-dimer levels reflect slight increases in blood coagulation, thrombin generation, and turnover of cross-linked intravascular fibrin (partially of intra-arterial origin), and that these increases are associated with coronary heart disease.⁵ D-dimer is positively associated with the incidence and recurrence of coronary heart disease, essentially independent of traditional risk factors.⁶ In addition, increased D-dimer concentrations have been associated with cerebral venous sinus thrombosis, acute pulmonary embolism, spontaneous intracerebral hemorrhage, and long-term neurologic sequelae in childhood-onset arterial ischemic stroke.^{7,8} Previous research has also shown that D-dimer levels are associated with stroke subtypes, prognosis, and worse outcomes in patients with ischemic stroke.

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D-dimer has been described as a prognostic predictor in ischemic stroke and an indicator of the severity of traumatic brain injury.^{9,10}

Unfortunately, fewer studies have been conducted on the correlations between plasma D-dimer concentration and AIS in South Indian patients. Thus, this research aimed at examining the correlation between plasma D-dimer levels and infarction volume in individuals with acute ischemic stroke.

MATERIALS AND METHODS

This cross-sectional study was conducted at a tertiary care hospital after approval from the ethics committee. It included 100 patients clinically diagnosed with acute ischemic stroke from February 2023 to December 2023.

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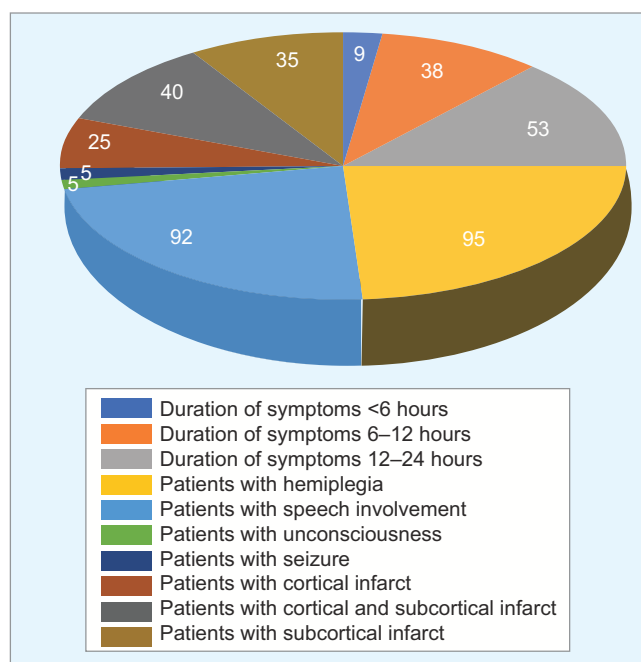


Fig. 1: Clinical presentation of patients during admission

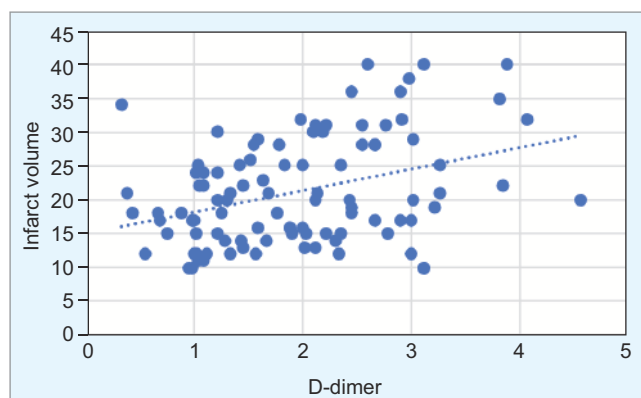


Fig. 2: Correlation between infarct volume and D-dimer level

Inclusion Criteria

First stroke episode and admission to the hospital within 24 hours of stroke onset.

Exclusion Criteria

Stroke-like conditions; intracranial hemorrhage; malignancy; febrile disorders; acute or chronic inflammatory disease at study enrollment; coma; or epileptic seizures.

After taking a proper history and thorough clinical examination, these patients were subjected to CT brain, and patients who fit the study (after screening for inclusion and exclusion criteria) were selected for the study.

At baseline, demographic data (age and sex) and histories of conventional vascular risk factors such as hypertension, diabetes mellitus, dyslipidemia, other cardiac diseases (including acute myocardial infarction and angina), and cigarette smoking were obtained. In addition, routine blood and biochemical tests, electrocardiography (ECG), and a baseline brain CT scan were performed at admission for all patients who met the inclusion and

Table 1: Distribution of patients' characteristics

Patients' characteristics	Frequency	Percent
Age group	<50	10
	51–60	38
	61–70	36
	>71	16
Gender	Female	41
	Male	59
Smoking	14	14.0
Hypertension	49	49.0
Diabetes	37	37.0
Valvular heart disease	10	10.0

Table 2: Clinical presentation of patients

Clinical presentation of patients during admission	Frequency	Percent
Duration of symptoms	<6 hours	9
	6–12 hours	38
	12–24 hours	53
Clinical features	Hemiplegia	95
	Speech involvement	92
	Unconsciousness	5
	Seizure	5
CT findings	Cortical	25
	Cortical and subcortical	40
	Subcortical	35

exclusion criteria. Venous blood samples were obtained within hours of symptom onset. Blood samples were collected at the bedside in 5-mL vacuum tubes containing 0.5 mL of buffered sodium citrate.

RESULTS

In this study, 38 (38%) patients were aged 51–60 years and 36 (36%) were aged 61–70 years, followed by 10 (10%) aged <50 years and 16 (16%) aged >71 years. There were 59 (59%) male patients and 41 (41%) female patients. Eighty-six (86%) patients were nonsmokers, and 14 (14%) were smokers. Forty-nine (49%) patients had hypertension, whereas 51 (51%) did not. Thirty-seven (37%) patients had diabetes, whereas 63 (63%) did not. Ninety (90%) patients had no valvular heart disease, and 10 (10%) had valvular heart disease. Symptoms had lasted 12–24 hours in 53 (53%) patients, 6–12 hours in 38 (38%) patients, and <6 hours in 9 (9%) patients. Hemiplegia was present in 95 (95%) patients and absent in 5 (5%). Speech involvement was present in 92 (92%) patients and absent in 8 (8%). Five (5%) patients were unconscious, and 95 (95%) were conscious. Five (5%) patients had seizures, and 95 (95%) did not. CT showed both cortical and subcortical infarcts in 40 (40%) patients, subcortical infarcts in 35 (35%), and cortical infarcts in 25 (25%). A significant weak positive correlation was found between infarct volume and D-dimer ($r = 0.363$, $p < 0.0001$) (Figs 1 and 2 and Tables 1 and 2).

DISCUSSION

Stroke is a morbid disease affecting 15 million people each year. Of these, 5 million die, and 5 million are left with permanent disability.¹¹

D-dimer has been assessed as a biomarker in earlier studies of deep venous thromboembolism, myocardial infarction, disseminated intravascular coagulation, trauma, and stroke. D-dimer and C-reactive protein have been used as markers of hemostatic activation associated with stroke diagnosis.^{12–14}

Skoloudik et al. reported that D-dimer levels increased within 6 hours after stroke onset in patients with arterial occlusion and cardioembolic stroke.¹⁵ In another study, D-dimer levels helped physicians target interventions to prevent early neurologic deterioration after ischemic stroke.¹⁶ The study by Lövblad et al. provided evidence that infarction volume predicted clinical severity and outcomes and was associated with the National Institutes of Health Stroke Scale (NIHSS) and the brain injury scoring system.^{17–19}

The present study reported the highest prevalence of AIS among patients aged 51–60 years (38%), followed by those aged 61–70 years (36%) and >71 years (16%). Male patients predominated (59%), and 14 patients reported smoking. Similar findings were reported by Zi and Shuai, who found a mean affected age range of 51–73 years, male predominance (69.2%), and smoking in 20.4% of patients.²⁰

Symptoms lasted 12–24 hours in 53 patients (53%), 6–12 hours in 38 patients (38%), and <6 hours in 9 patients (9%). Zi and Shuai reported that symptoms of acute ischemic stroke could last up to 48 hours.²⁰

The study found a high incidence of slurred speech and speech involvement in the patients (92%). However, hemiplegia (95%), unconsciousness (5%), and seizure (5%) were less prevalent. In contrast to the present study, Vaidya and Majmudar reported a high prevalence of hemiplegia (49.1%), followed by speech involvement (29.1%) and unconsciousness (9.1%).²¹

CT findings revealed cortical and subcortical infarcts in 40% of patients, subcortical infarcts in 35%, and cortical infarcts in 25%. However, Shah et al., Baidya et al., and Siddique et al. reported cortical infarcts in 77.1%, 59%, and 58.75% of patients, respectively.^{22–24}

A significant correlation was found between infarction volume and D-dimer, with $p < 0.0001$. Pearson correlation showed a direct association between D-dimer and infarct volume. Zi and Shuai reported similar findings and a significant association between elevated D-dimer levels and AIS. They also found high D-dimer levels in patients with AIS and used the biomarker to define stroke severity based on the NIHSS score and infarct volume.²⁰

Smith et al. reported that D-dimer levels predicted the incidence of stroke in the general population.²⁵ Age- and sex-related increases in D-dimer levels were reported in patients with stroke, similar to the findings of the present study.¹³ The D-dimer biomarker was also associated with assessing the severity of the stroke and detecting its outcome. The study reported that D-dimer was used to assess stroke severity.²⁶

CONCLUSION

The study concludes that D-dimer levels were strongly associated with the severity of the stroke, denoting the different stages of acute ischemic stroke. The elevated levels of D-dimer were also associated with a poor prognosis and were used for differential diagnosis of cardioembolic stroke. Hence, it was essential to carry out D-dimer quantification in patients with AIS stage or at high risk for stroke. It was found that there was a direct correlation between infarct volume and elevated levels of D-dimer. D-dimer was used as a biomarker for assessing the severity of ischemic stroke among patients within the 48-hour onset period of stroke. These

observations facilitate physicians in predicting the overall survival and mortality status.

The study did not extensively probe stroke classification, which enables the diagnostic process and other clinical research. The study did not involve population-specific genetic markers and allied risk factors. However, the present study holds good in exploring D-dimer level as a prognostic indicator in acute ischemic stroke patients, and the process of administering follow-up D-dimer levels is sure to benefit clinicians to evaluate neurological deterioration in acute ischemic stroke patients. Plasma D-dimer level as a potent diagnostic tool enables medical practitioners to analyze and address health issues related to cardiovascular and cerebrovascular diseases.

ETHICS APPROVAL

Ethics approval was obtained from the Institutional Ethical Committee of Vinayaka Mission's Kirupanandavariyar Medical College, Salem (Approval No. VMKVMCH/IEC/2023/021) on 10 August 2023.

INFORMED CONSENT

Informed consent was obtained from all participants involved in the study.

CLINICAL TRIAL REGISTRATION

Not applicable.

DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this article.

AUTHOR CONTRIBUTIONS

All authors contributed to conceptualization, methodology, data collection, writing of the original draft, and review and editing of the manuscript.

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AI USE DECLARATION

AI tools were used solely for language editing. All intellectual content was developed by the authors.

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Next-generation Sequencing in Lung Adenocarcinoma: Which One is Better: Focus Oncomine Solid Tumor Panel or Epidermal Growth Factor Receptor Mutation Analysis?

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ABSTRACT

This retrospective observational audit was conducted to compare the efficacy of single-gene testing vs multigene panel-based testing in the molecular characterization of lung adenocarcinoma and metastatic lung adenocarcinoma. A total of 39 histopathologically confirmed cases were analyzed. Of these, 20 underwent epidermal growth factor receptor (EGFR) mutation analysis using polymerase chain reaction (PCR) followed by automated sequencing, while 19 were subjected to a targeted next-generation sequencing (NGS)-based multigene solid tumor panel. Among the panel-tested group, mutations were detected in 15 of 19 cases (79%), including EGFR mutations in 27%, TP53 mutations in 20%, and concurrent EGFR and TP53 mutations in 27%. Additional findings comprised mutations such as KRAS and ATM (13%), APC and TP53 (6.6%), and KIT and TP53 (6.6%). In contrast, EGFR mutations were identified in only seven of 20 cases (35%) using single-gene testing, with no additional molecular alterations detected. This analysis, though limited in sample size, reaffirms existing evidence supporting the superiority of multigene panel testing over single-gene assays in terms of diagnostic yield, especially in uncovering coexisting or uncommon mutations that may carry therapeutic or prognostic significance. The findings underscore the advantages of panel-based approaches, particularly in clinical scenarios constrained by limited tissue availability, where broad genomic profiling offers a more comprehensive molecular landscape without requiring sequential tests. While the results corroborate already established data, they also highlight the practical value of implementing multigene testing in routine diagnostic workflows. A larger prospective study may further elucidate the clinical impact of such comprehensive molecular profiling in therapeutic decision-making for patients with lung adenocarcinoma.

Keywords: Driver genes, Epidermal growth factor receptor mutation study, Focus Oncomine Solid Tumor Panel, Lung adenocarcinoma, Next-generation sequencing.

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INTRODUCTION

Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer-related deaths worldwide. In India, lung cancer accounts for 5.9% of all cancers and 8.1% of all cancer-related deaths. Genetic alterations in lung adenocarcinoma (LUAD) have been well documented and are observed in more than 60% of cases.¹

Identifying a driver mutation in one of several oncogenes, such as epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, TP53, BRAF, KRAS, AKT1, HER2, MEK1, MET, NRAS, PIK3CA, and RET, can have therapeutic implications in LUAD. Driver mutation-based targeted therapies, whenever possible, improve the median overall survival of patients with metastatic LUAD by at least 1 year. EGFR is a transmembrane receptor tyrosine kinase protein encoded by exons 18–24 that regulates both cell proliferation and apoptosis through signal transduction pathways. In patients with nonsmall cell lung cancer (NSCLC), the most commonly found mutation is in EGFR.²

For identifying actionable driver mutations beyond EGFR sensitizing mutations and ALK and ROS1 fusion rearrangements, next-generation sequencing (NGS) is the most practical option, given the limited availability of biopsy material and the arduous nature of single-gene assays.³ NGS-based genetic profiling of solid tumors allows a comprehensive search for predictive biomarkers in a resource- and tissue-efficient manner.

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Conflict of interest: None

Patient consent statement: Patient data and genetic test results were retrieved from the pathology department archives.

The broader molecular profile provided by NGS allows evaluation of variants of potential clinical significance (Tier II genetic alterations), enabling many additional patients to benefit from targeted therapy. The Focus Oncomine Solid Tumor Panel covers 48 of the most relevant cancer driver genes and fusions. Based on the identified variant, this assay provides a detailed list of relevant biomarker information available from guidelines and clinical studies for clinical research support and patient management.

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It contains recommendations for oncologists and clinical laboratory professionals for interpreting NGS-based cancer tests and establishing standards for reporting somatic variants—mutations that occur (and are not inherited) in tumor cells.

The variant classification, according to the Association for Molecular Pathology–American Society of Clinical Oncology–College of American Pathologists (AMP-ASCO-CAP) guidelines, divides detected variants into four tiers as follows⁴:

- Tier I: Variants of strong clinical significance, further divided into Level A and Level B.
- Tier II: Variants of potential clinical significance, further divided into Level C and Level D.
- Tier III: Variants of unknown clinical significance.
- Tier IV: Variants deemed benign or likely benign.

METHODS

Study Design and Setting

This was a retrospective observational study conducted at the Department of Pathology.

Selection of Participants

All patients diagnosed with lung adenocarcinoma and metastatic lung adenocarcinoma between January 2022 and January 2024 who underwent mutation analysis were included in the study.

Inclusion criteria

Patients with histopathologically confirmed lung adenocarcinoma or metastatic lung adenocarcinoma who underwent genetic testing.

Exclusion criteria

Patients diagnosed with small cell carcinoma or nonadenocarcinoma subtypes of nonsmall cell lung carcinoma were excluded.

Interventions

No therapeutic interventions were applied, as the study was retrospective and observational in nature. Patients were grouped based on the type of molecular testing performed.

Methods of Measurement

Two molecular testing approaches were used:

The Focus Oncomine Solid Tumor Panel was performed on 19 cases using Ion AmpliSeq™ technology. Deoxyribonucleic acid (DNA) was extracted from formalin-fixed, paraffin-embedded tissue blocks for NGS. Ribonucleic acid (RNA) was also used for fusion gene detection. Sequencing was carried out with a minimum mean depth of >500× on the Ion Torrent platform.

Epidermal growth factor receptor mutation analysis was conducted in 20 cases using endpoint polymerase chain reaction (PCR) with gene-specific primers. Sequencing of the amplified product was performed using BigDye™ Terminator Chemistry on an ABI Genetic Analyzer 3500DX platform.

Data Collection and Processing

Patient data and genetic test results were retrieved from the pathology department archives. Variants detected were classified according to the Association for Molecular Pathology–American Society of Clinical Oncology–College of American Pathologists (AMP-ASCO-CAP) guidelines into Tiers I–IV. All data were reviewed and categorized manually.

Loss of Data

There were no dropouts or missing data, as all selected cases had complete molecular and histopathological records.

Outcome Measures

Primary outcome: Proportion of cases with detected mutations in each testing group.

Secondary outcomes: Spectrum of gene mutations and comutations observed across both groups.

Statistics

Statistical Universe and Sampling

The statistical universe included all lung adenocarcinoma and metastatic adenocarcinoma cases diagnosed at the institution from January 2022 to January 2024. All eligible cases were included using convenience sampling.

Group Allocation

Patients were retrospectively grouped based on the type of genetic test performed:

- Focus Oncomine Solid Tumor Panel group ($n = 19$).
- EGFR mutation testing group ($n = 20$).

Statistical Methods

Only descriptive statistics were used. Mutation frequencies were presented as percentages. No hypothesis testing or comparative statistical analysis was performed.

Software Used

Data were processed and analyzed using basic descriptive statistics in a spreadsheet program. No statistical software packages were used.

Ethical Considerations

The study was approved by the Institutional Ethics Committee. Patient confidentiality was maintained throughout the study. As this was a retrospective study using anonymized data, the requirement for informed consent was waived.

RESULTS AND OBSERVATION

Figure 1 shows the frequency distribution of gene mutations detected by the Focus Oncomine Solid Tumor Panel and the single-gene assay.

Figure 1 demonstrates the comparative mutation detection outcomes between the Focus Oncomine Solid Tumor Panel and EGFR single-gene mutation analysis in a cohort of 39 lung adenocarcinoma cases. Among the 19 cases evaluated using the multigene panel, mutations were detected in 15 cases (79%), with four cases (21%) yielding negative results. In contrast, of the 20 cases assessed using EGFR mutation analysis alone, only seven cases (35%) were positive for mutations, while the remaining 13 cases (65%) were negative. This visual representation underscores the markedly higher diagnostic yield of the multigene panel, highlighting its superiority in identifying a broader range of genetic alterations, including coexisting mutations that may be clinically relevant for therapeutic decision-making.

Figure 2 shows the spectrum of single mutations and comutations in patients with lung adenocarcinoma using the multigene Focus Oncomine Solid Tumor Panel.

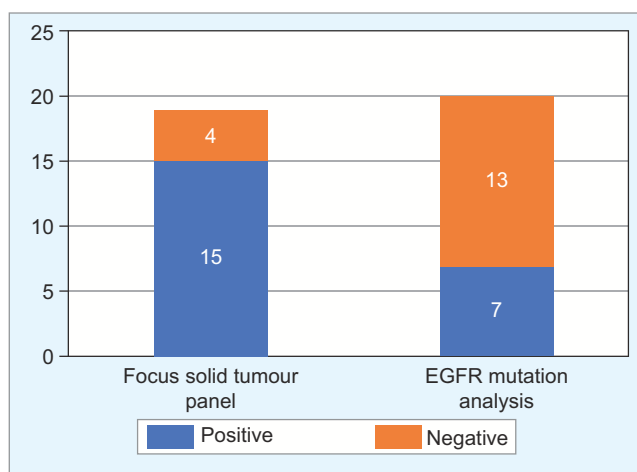


Fig. 1: Result of single-gene assay and Focus Solid Tumor Panel (39 cases)

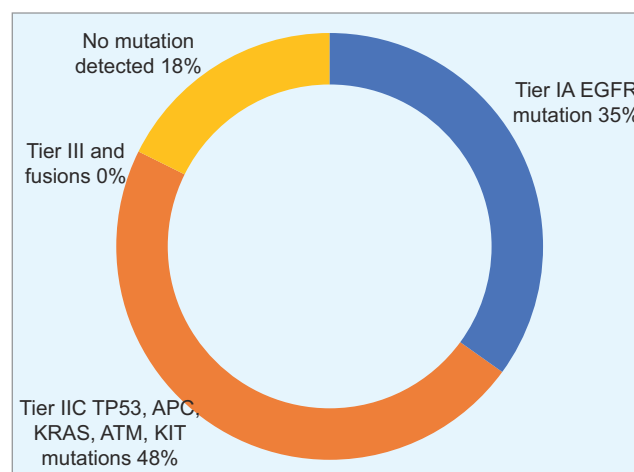


Fig. 3: Distribution according to tiers

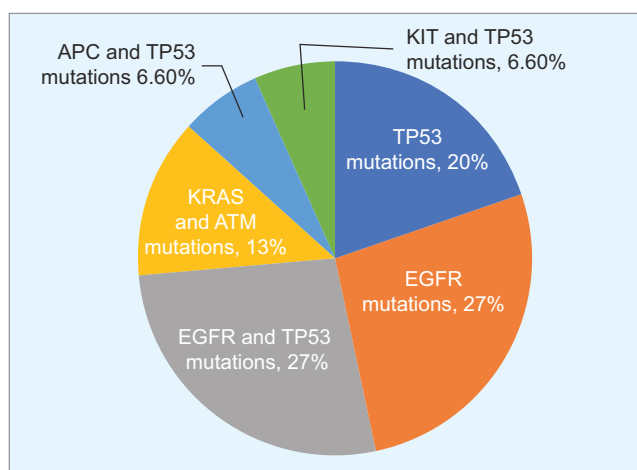


Fig. 2: Percentages of different mutations by Focus Oncomine Solid Tumor Panel (15/19 cases)

Figure 2 presents the distribution of various gene mutations identified in 15 of 19 cases (79%) tested with the Focus Oncomine Solid Tumor Panel. The most frequent alterations included EGFR mutations and EGFR–TP53 comutations, each observed in 27% of cases, underscoring their prominent role in lung adenocarcinoma pathogenesis and therapeutic relevance. TP53 mutations alone were detected in 20% of cases. Less common but notable findings included KRAS and ATM comutations in 13% and KIT–TP53 and APC–TP53 comutations, each identified in 6.6% of cases. This diverse mutation profile highlights the comprehensive detection capability of multigene panel testing, enabling identification of both isolated and concurrent driver mutations, which may have implications for targeted therapy selection and prognostication.

Figure 3 shows the distribution of different mutations detected according to the tier system commonly used for reporting.

Figure 3 depicts the tier-wise distribution of mutations detected by the Focus Oncomine Solid Tumor Panel. Tier IA mutations, comprising EGFR mutations with established clinical significance, accounted for 35% of the cases, reflecting their direct therapeutic relevance. Tier IIC mutations, which include alterations in genes such as TP53, APC, KRAS, ATM, and KIT, represented the largest subset at 48%, indicating the predominance of variants with

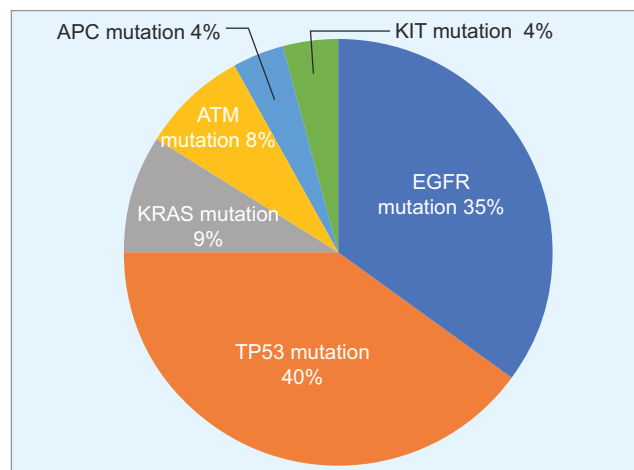


Fig. 4: Percentages of individual mutations detected via both methods

potential but less definitive clinical utility. Notably, Tier III mutations and fusions, which are often of uncertain significance, were not observed in this cohort (0%). Additionally, 18% of cases showed no detectable mutations. This classification highlights the practical utility of mutation tiering in prioritizing actionable targets, guiding treatment decisions, and stratifying patients based on the strength of clinical evidence.

Figure 4 shows the percentages of individual mutations detected by both methods.

Figure 4 illustrates the distribution of individual gene mutations detected through both single-gene and multigene panel testing methods. TP53 mutations were the most frequently observed, accounting for 40% of all mutations identified, underscoring their prominent role in lung adenocarcinoma pathogenesis and their frequent co-occurrence with other driver mutations. EGFR mutations were the second most common, detected in 35% of cases, highlighting their clinical relevance in targeted therapy. Mutations in KRAS were found in 9% of cases, ATM in 8% of cases, and APC and KIT each in 4% of cases. This spectrum of genetic alterations reflects the molecular heterogeneity of lung adenocarcinoma and supports the rationale for comprehensive molecular profiling over single-gene testing, which may fail to capture the full landscape of actionable and coexisting mutations (Table 1).

Table 1: Comparative analysis of different studies

<i>Our study</i>	<i>Similar study</i>
TP53 (40%)—most common	Mehta et al. and Tsoulos et al.
EGFR (35%)	The Cancer Genome Atlas (TCGA) data (51.8%)
EGFR and TP53 (27%)	Mehta et al. and Chougule et al. (lower)
Sole EGFR (27%)	Mehta et al.—inferior response to TKI therapy
	Mehta et al.—longer progression free survival

DISCUSSION

Predictive biomarker identification for targeted therapy has significantly improved treatment outcomes in patients with nonsmall cell lung carcinoma (NSCLC). However, conventional single-gene assays remain limited by tissue availability, time consumption, and their inability to provide a comprehensive overview of the tumor's genetic profile. NGS technology enables simultaneous detection of multiple cancer driver gene alterations, and this multiplexing capability allows for detailed genetic characterization even in samples with low tumor content. Furthermore, when sufficient sample volume is available, the use of sequencing chips or flow cells allows for efficient batching of samples, thereby reducing turnaround time.

The Focus Oncomine Solid Tumor Panel demonstrates several advantages over single-gene assays. At approximately the cost of three individual single-gene tests, this panel simultaneously evaluates 48 clinically relevant mutations and gene fusions in a single run. This comprehensive profiling significantly enhances both diagnostic yield and cost-effectiveness. The consolidation of multiple targets into a single assay not only reduces the financial burden on patients but also minimizes tissue exhaustion, which is an important consideration when biopsy samples are limited. This advantage is particularly relevant in resource-limited settings such as India, where a significant proportion of the population faces economic constraints.

Although this study is audit-style and retrospective in nature rather than a prospective clinical trial, it provides practical, real-world evidence supporting the established superiority of multigene panel testing. Importantly, while certain mutations identified, such as concurrent EGFR and TP53 alterations, may not yet have defined therapeutic pathways, their documentation is critical. This study serves as a reference point for future clinical interpretation as novel therapies emerge. The dataset may prove valuable when additional targeted or combination treatments become standard, especially in the context of complex molecular profiles.

In this analysis, TP53 was the most frequently mutated gene, observed in 40% of cases, which is consistent with previous findings by Mehta et al. and Tsoulos et al.^{3,5} While this is slightly lower than the 51.8% reported by The Cancer Genome Atlas (TCGA) in its pan-cancer analysis, it aligns closely with lung adenocarcinoma-specific data identifying TP53, EGFR, and KRAS as common alterations.^{6,7} EGFR mutations were detected in 35% of cases, a slightly higher rate than those reported in Indian studies by Mehta et al. and Chougule et al.^{3,8} Additionally, 27% of cases showed concurrent EGFR and TP53 mutations, which are associated with an inferior therapeutic response to tyrosine kinase inhibitors (TKIs), as noted by Mehta et al.³ In contrast, 27% of patients exhibited isolated EGFR mutations, which are

associated with significantly longer progression-free survival, as supported by prior Indian and East Asian studies.^{3,9}

While NGS allows multiplexing and offers broad coverage for oncogenes, it is associated with a variable error rate (0.1–15%), especially for short reads from formalin-fixed, paraffin-embedded (FFPE) samples. The estimated technical error rate is approximately 2% based on available data. Sequence alignment and data processing were conducted using standard bioinformatics algorithms and formats such as Burrows-Wheeler Aligner (BWA) and Sequence Alignment/Map tools (SAMtools).^{10,11} Identified variants were cross-referenced with population-level databases, including the 1000 Genomes Project, to ensure validity and distinguish pathogenic mutations from population-specific polymorphisms.¹²

Limitations

One of the limitations of this study is the use of different patient cohorts for single-gene and multigene testing, which may introduce bias in direct comparison. However, this design reflects real-world diagnostic practice and still offers valuable insight into the comparative detection efficiency of each method. Future studies using parallel testing on the same samples would enhance internal consistency and improve the clinical interpretability of such comparisons.

Despite its retrospective nature and methodological limitations, this study sets a valuable institutional benchmark, demonstrating the feasibility, clinical utility, and cost-effectiveness of NGS-based multigene testing in financially constrained health care environments. It also underscores the importance of integrating comprehensive molecular profiling into routine diagnostic workflows and provides a framework for designing larger, prospective studies in similar settings.

CONCLUSION

This study underscores the clinical value of multigene panel testing in lung adenocarcinoma, demonstrating its superiority over single-gene assays in detecting a broader range of actionable and co-occurring mutations. The regional data contribute to the molecular understanding of lung cancer in central Gujarat and highlight the feasibility of implementing comprehensive genomic profiling in resource-limited settings. Although some mutations lack current therapeutic pathways, their identification lays the groundwork for future clinical utility as targeted treatments evolve.

ETHICS APPROVAL

The study was approved by the Institutional Review Board (or Ethics Committee) of Pramukhswami Medical College, Bhaikaka University (approval ID-IEC/BU/2025/Ex.40/133/2025. Date of approval-13/04/2025).

CLINICAL TRIAL REGISTRATION

Not applicable.

DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this published article.

AUTHOR CONTRIBUTIONS

Conceptualization: Sanjay Chaudhari.

Methodology: Sanjay Chaudhari, Shyama Chag, Monica Gupta.

Data Collection: Meera Parmar.
Data Curation: Meera Parmar, Shyama Chag.
Data Analysis: Shyama Chag, Meera Parmar.
Writing – original draft: Shyama Chag, Meera Parmar.
Writing – review & editing: Shyama Chag, Meera Parmar, Monica Gupta.

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AI Use Declaration

AI tools were used only for language editing; all intellectual content was developed by the authors.

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Prescribing Pattern and Medication Adherence in Patients with Depression: A Cross-sectional Observational Study

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ABSTRACT

Background: With the advent of novel, highly efficacious, and safer antidepressant drugs in the management of depression, there is a need to identify physicians' preferences and prescribing practices for depression. Patients' drug adherence also plays a vital role in the management of depression.

Aim and objectives: This study evaluated the current prescribing pattern of antidepressant drugs and the level of medication adherence in patients with depression.

Materials and methods: This was a prospective, cross-sectional, observational, descriptive study conducted in a psychiatry outpatient department (OPD) from January 2021 to December 2021. Patients diagnosed with depression who had received antidepressant drug therapy for ≥ 3 months were included. The primary outcomes were prescribing patterns, World Health Organization (WHO) prescribing indicators, and medication adherence.

Results: The most common class encountered was selective serotonin reuptake inhibitors (SSRIs), among which escitalopram was the most commonly prescribed antidepressant, followed by sertraline and mirtazapine. Monotherapy prescriptions (79.84%) were more common than fixed-dose combinations (FDCs; 20.16%). As per the WHO core indicators, the average number of antidepressant drugs prescribed per prescription was 1.21. Around 28% of drugs were prescribed by generic name, and 64.3% were prescribed from the National List of Essential Medicines. Around 64% of patients were "adherent," whereas 36% were "nonadherent" to antidepressant medications.

Conclusions: Selective serotonin reuptake inhibitors (escitalopram) dominated the prescribing trend. However, there was a rising trend in the use of newer antidepressant drugs. There was restraint on polypharmacy, but ample scope remains for improvement in prescribing antidepressant drugs by generic name and selecting essential drugs. Medication nonadherence was quite prevalent (36%); hence, efforts should be made to improve antidepressant medication adherence.

Keywords: Adherence, Antidepressants, Compliance, Drug utilization, Prescribing patterns, World Health Organization indicators.

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INTRODUCTION

A drug utilization study (DUS) is essential to identify improper drug use, reduce patient risks, and prevent unnecessary healthcare expenses, thereby promoting the rational use of drugs.¹⁻³

Psychiatric illnesses, particularly major depression, play a substantial role in the mental health burden.⁴ The global weighted prevalence of lifetime depressive disorders is increasing, with India reporting a rate of 5.25%. The condition is more common among females and in the 40–59-year age-group.⁵

Treatment modalities for depression include pharmacotherapy, behavioral therapies, and social interventions.⁶ Pharmacotherapy is a cornerstone of the treatment of depression. Various heterogeneous classes of antidepressant drugs are utilized in the treatment of depression.^{6,7}

The trends in prescribing of antidepressants have changed globally in recent years, with traditional antidepressants increasingly being replaced by selective serotonin reuptake inhibitors (SSRIs) and newer agents.^{8,9} In India, drug utilization studies focused on depression have shown varying prescribing trends, ranging from conventional to newer antidepressant drugs.¹⁰⁻¹² These studies have also identified issues of polytherapy, prescribing drugs by brand names, and low selection of essential drugs from the essential drug list.¹⁰⁻¹² Studies have also identified low medication adherence to antidepressant drugs.^{13,14}

With the advent of novel, highly efficacious, and safer antidepressant drugs in the management of depression, there is a need to identify

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physicians' preferences and prescribing practices for depression. In depressive disorders, nonadherence to medication is quite prevalent and can increase the risk of recurrence, morbidity, care burden, and unnecessary health costs.¹⁴ Therefore, the purpose of this study was to assess the current prescribing pattern of antidepressant drugs and the level of medication adherence in patients with depression at a tertiary care hospital in Navi Mumbai.



New knowledge added by this study

Prescribing trends: SSRIs are the most commonly prescribed antidepressants, with a gradual shift toward newer options.

Generic use insights: Only 28% of prescriptions were written by generic names, highlighting a need for increased focus on generic prescribing.

Adherence challenges: A 36% nonadherence rate underscores the importance of exploring barriers to medication adherence.

Implications for clinical practice or policy

Generic prescribing promotion: Guidelines should be developed to encourage the use of generic medications, improving accessibility and reducing costs.

Adherence monitoring: Implementing routine monitoring and support systems can help identify and address barriers to medication adherence.

Patient education: Increased educational initiatives are needed to enhance patient understanding of treatment and the importance of adherence.

MATERIALS AND METHODS

The study was approved by the Institutional Ethics Committee (approval no. N-EC/2021/SC/02/20). The study was conducted in accordance with International Council for Harmonization–Good Clinical Practice (ICH–GCP), the Indian Council of Medical Research (ICMR) biomedical guidelines for research, the New Drugs and Clinical Trials Rules, 2019 (India), and the Declaration of Helsinki. Written informed consent was obtained before enrollment.

Study Design and Setting

This study was a prospective, cross-sectional, observational type of descriptive study conducted between January 2021 and December 2021. It was carried out in a psychiatry outpatient department (OPD) of a tertiary care teaching hospital, Navi Mumbai, India.

Participant Eligibility Criteria

Patients with depression attending the study site were screened for eligibility using the study criteria. The inclusion criteria were: (1) adult patients (≥ 18 years) of either sex diagnosed with depression; (2) patients diagnosed with depression who had received antidepressant drug therapy for ≥ 3 months; and (3) patients who gave voluntary informed consent.

We excluded patients aged < 18 years; patients admitted to the inpatient psychiatry ward; patients who attended only for counseling/cognitive behavioral therapy; and patients with repeat attendance. Patients unwilling to provide informed consent were also excluded. We also excluded patients who had recently started antidepressant drug therapy (< 3 months), as one objective was to assess medication adherence.

Study Assessments

Adult patients of either sex diagnosed with depression who attended the psychiatry OPD were informed about the purpose and procedure of the study, and a participant/patient information sheet was provided in their respective languages (English, Hindi, and Marathi). Those who fulfilled the inclusion criteria were enrolled, and written informed consent was obtained. Information from the OPD prescriptions/case papers of each patient was collected. The data included participants' demographic and clinical profiles, details of prescribed antidepressant drugs, drugs prescribed

from the National List of Essential Medicines (NLEM 2015),¹⁵ and medication adherence assessed using the Simplified Medication Adherence Questionnaire (SMAQ).^{16,17}

Simplified Medication Adherence Questionnaire (SMAQ)

Medication adherence was assessed using the patient self-rated SMAQ scale.¹⁶ The SMAQ scale was used to measure adherence to pharmacological treatment in patients with depression. Patients who scored all 6 points were considered adherent to antidepressant therapy, whereas those who scored 5 points or fewer were considered nonadherent.^{16,17}

Sample Size

The sample size was set at a minimum of 100 patients diagnosed with depression [minimum of 100 patients as per the World Health Organization (WHO) DUS manual].¹

Data Analysis

The recorded data were analyzed for the following parameters:

- Prescribing pattern/practices.
- Drug utilization according to WHO core prescribing indicators.^{1,2}
- Medication adherence: Based on the participants' responses and total SMAQ scores, they were classified as nonadherent (score of 5 or fewer) or adherent (score of 6).

Statistical Analysis

The data obtained were entered in Microsoft Excel and analyzed using SPSS version 21. Descriptive statistics were used to describe the data. Data were expressed as actual numbers, percentages, and means with standard deviations.

RESULTS

This study included 106 patients with depression who were prescribed antidepressants; 49.05% were male, and 50.94% were female. The average age was 42.17 ± 12.85 years. The most common age-group was 31–40 years. The average duration of depression diagnosis was 4.19 ± 4.76 years, and the mean duration of antidepressant treatment was 3.7 ± 4.65 years (Figs 1 and 2).

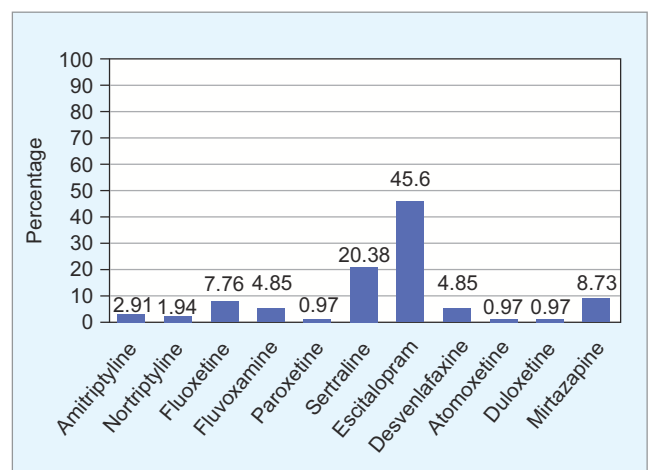


Fig. 1: Different types of antidepressant drugs prescribed as monotherapy

Prescribing Pattern

In this study, 106 patients' prescriptions contained a total of 129 prescribed antidepressant drugs/products, including monotherapy ($n = 103$) and fixed-dose combinations (FDCs; $n = 26$). The most common class of antidepressant drugs was SSRIs (79.84%), followed by tricyclic antidepressants (6.94%) and atypical antidepressants (TCA) (6.97%).

Overall, SSRIs were the most commonly prescribed antidepressants, with escitalopram (66%) being the most common, followed by sertraline (20.38%) among patients with depression (Table 1).

Among monotherapies, escitalopram was the most commonly prescribed drug (45.6%). Among FDCs, escitalopram-based therapy (80%) was prescribed most often. Newer antidepressants, such as the atypical antidepressant mirtazapine, were prescribed at 6.97%, and serotonin–norepinephrine reuptake inhibitors (SNRIs), such as desvenlafaxine, were prescribed at 4.6%, followed by atomoxetine and duloxetine at 0.77% each.

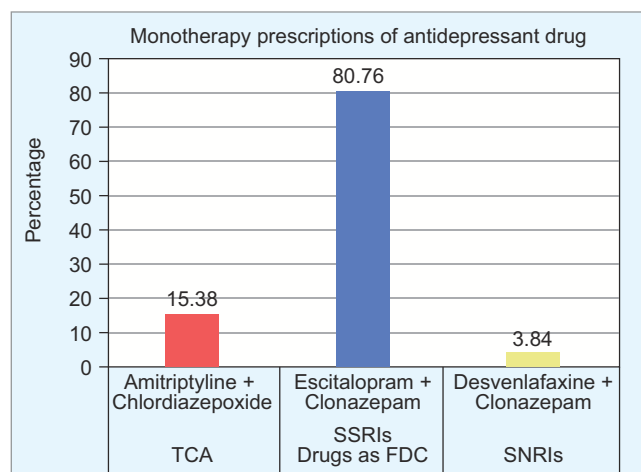


Fig. 2: Antidepressant drugs prescribed as fixed-dose combinations

Table 1: Classes of antidepressants prescribed with individual drugs

Antidepressant drug class	Drugs	Overall no. $n = 129$ (100%)		Monotherapy $n = 103$ (79.84%)		Fixed-dose combination $n = 26$ (20.15%)	
		n	%	n	%	n	%
Tricyclic antidepressants	Amitriptyline	7	5.42	3	2.91	4	15.38
	Nortriptyline	2	1.55	2	1.94	0	0
Monoamine oxidase inhibitors	None	0	0	0	0	0	0
Selective serotonin reuptake inhibitors	Fluoxetine	8	6.20	8	7.76	0	0
	Fluvoxamine	5	3.87	5	4.85	0	0
	Paroxetine	1	0.77	1	0.97	0	0
	Sertraline	21	16.27	21	20.38	0	0
	Escitalopram	68	52.71	47	45.6	21	80.76
	Desvenlafaxine	6	4.6	5	4.85	1	3.84
Selective norepinephrine reuptake inhibitors	Atomoxetine	1	0.77	1	0.97	0	0
	Duloxetine	1	0.77	1	0.97	0	0
Atypical antidepressants	Mirtazapine	9	6.97	9	8.73	0	0
Total products prescribed		129	100	103	100	26	100

Of the 129 prescribed antidepressant drugs/products, 103 were prescribed as monotherapy. SSRIs (79.56%) were the most frequently prescribed monotherapy, followed by atypical antidepressants (8.73%), SNRIs (6.79%), and tricyclic antidepressants (TCAs; 4.85%).

The most common drug prescribed as monotherapy was escitalopram (45.6%), followed by sertraline (20.38%). Mirtazapine, fluoxetine, fluvoxamine, and desvenlafaxine were moderately prescribed (8.73%, 7.76%, 4.85%, and 4.85%, respectively) in patients with depression (Fig. 1).

Among FDCs, the escitalopram-based combination was the most common and included escitalopram + clonazepam (benzodiazepine; 80.76%), followed by an amitriptyline-based FDC (amitriptyline + chlordiazepoxide; 15.38%) (Fig. 2).

Drug Utilization Using WHO Prescribing Indicators

Table 2 summarizes the percentage prescribing indices of the WHO core prescribing indicators. The average number of antidepressant drugs encountered per prescription was 1.21. Around 28% of the drugs were prescribed by generic names, and 64.3% were prescribed from the National List of Essential Medicines.

Table 2: WHO core prescribing indices

Sr. no.	Prescribing indicators assessed	Value
1	Total number of antidepressant drug products prescribed	129
2	Average number of antidepressant drug products per encounter	1.21
3	Percentage of antidepressant drugs prescribed by generic name	28.69%
4	Percentage of encounters with an injection prescribed	0
5	Percentage of encounters with an antibiotic prescribed	0

Table 3: Percentage of medication adherence observed for each SMAQ item

No.	Questions	No (%)	Yes (%)
1	Do you ever forget to take your medicine for depression?	87.8	12.2
2	Are you careless at times about taking your medicine for depression?	82	18
3	Sometimes if you feel worse, do you stop taking your medicine for depression?	84.9	15.1
4	Thinking about the last week. How often have you not taken your medicine for depression?	68.9	31.1
5	Have you not taken any of your medicine over the past weekend for depression?	84.9	15.1
6	Over the past three months, how many days have you not taken any medicine for depression at all (>2 days)?	77.3	22.7

Medication Adherence

The mean medication adherence score of the participants was 4.85 out of 6. As per the SMAQ cutoffs, 63.72% ($n = 69$) of patients had “good adherence” to treatment, whereas 36.28% ($n = 37$) were labeled “nonadherent” to treatment.

The individual responses of the study participants to the SMAQ questionnaire are summarized in Table 3.

DISCUSSION

The prescription reflects the physician’s knowledge of the illness and pharmacotherapy and aims to promote rational drug use in the community.^{1–3}

In clinical practice, heterogeneous classes of antidepressant drugs and their combination products are widely prescribed for depression.^{8,9} Newer antidepressants with better tolerability, faster onset of action, and high effectiveness are used in the treatment of depression.^{8,9,18} Therefore, the present study was conducted to evaluate prescribing patterns and medication adherence in this setting.

This study found a higher prevalence of depression in females (50.94%) than in males, with only a 2% difference. These results align with existing research showing that depression is more common in females. Hormonal changes during puberty may contribute to the increased risk of mood and anxiety disorders in women.¹⁹ A similar trend of a higher prevalence of depression in females was observed in drug utilization studies conducted by Hussain et al. (53.75%) and Lahon et al. (51.76%).^{10,11}

In our study, the mean age of participants was 42.17 ± 12.85 years, with the most common age group being 31–40 years, followed by 41–50 years. These results align with the study by Tripathi et al. across 5 psychiatric centers in India, where the mean age was 39 ± 14.28 years.²⁰

Prescribing Pattern

In our study, the most common class of antidepressant drugs prescribed was SSRIs (79.84%), followed by TCAs (6.94%) and atypical antidepressants (6.97%). Our findings that SSRIs were the most commonly prescribed class are similar to the prescribing trends documented by Hussain et al.¹⁰ and Tripathi et al.²⁰ However, a few drug utilization studies have documented varying trends in antidepressant prescriptions. In a drug utilization study by Lahon et al.,¹¹ SNRIs were the most commonly prescribed antidepressants, whereas in a drug utilization study conducted by Tejashwini et al.,¹² TCAs were the most commonly prescribed.

In our study, most patients were receiving monotherapy (79.84%), whereas fewer received combination therapy (20.15%). Monotherapy likely proved more effective in alleviating depressive symptoms and improving patient compliance. A study by Chatter et al. suggests that monotherapy increases compliance, reduces drug interactions, and causes fewer adverse effects than

polytherapy. This could explain the preference for monotherapy in treating patients effectively.¹⁸

In our study, monotherapy with escitalopram (45.6%) was the most common, followed by sertraline (20.38%) and mirtazapine (8.73%). Similar findings were observed in a study by Tripathi et al.,²⁰ in which escitalopram was the most widely prescribed antidepressant, followed by sertraline. A similar trend was observed in a drug utilization study conducted by Hussain et al.,¹⁰ in which escitalopram was the most widely prescribed drug, followed by sertraline, amitriptyline, and fluoxetine. However, studies by Tejashwini et al.,¹² Lahon et al.,¹¹ and Marasine et al.²¹ reported different prescribing trends. Tejashwini et al.¹² documented that fluoxetine was more widely prescribed, followed by sertraline, amitriptyline, and escitalopram. Lahon et al.¹¹ documented that duloxetine (56.5%) was the most widely prescribed drug, followed by escitalopram (25.3%) and mirtazapine (19.4%). Similarly, Marasine et al.²¹ documented that fluoxetine (22.98%) was the most widely prescribed antidepressant, followed by escitalopram (21.12%) and sertraline (13.79%).

SSRIs offer several benefits over conventional antidepressants: selective serotonin action, high efficacy, faster onset, fewer side effects, good tolerance at high doses, fewer drug interactions, and suitability for patients with comorbidities.²²

In our study, the prescription of atypical antidepressants (mirtazapine, 8.73%) and SNRIs (atomoxetine and duloxetine, 0.97% each) as monotherapy was low. Similar findings of low prescription of SNRIs (duloxetine) were noted in a study conducted by Tripathi et al.²⁰. However, a study conducted by Lahon et al.¹¹ found that duloxetine (SNRI) was the most commonly prescribed antidepressant. Among the atypical antidepressants, mirtazapine was prescribed. We found that mirtazapine (8.73%) was the preferred atypical antidepressant in patients with depression and comorbid conditions. The use of mirtazapine for major depressive disorder (MDD) is often considered after SSRI antidepressants, although it is used predominantly for insomnia and sleep disorders.²³

In our study, FDCs of SSRIs combined with benzodiazepines (escitalopram + clonazepam) were commonly prescribed. Other combinations included SNRIs with the benzodiazepine clonazepam and TCAs with chlorthalidone. These findings were similar to those of a study conducted by Tripathi et al.,²⁰ which found that FDCs of SSRIs were mostly combined with clonazepam. Combining SSRIs with clonazepam may potentiate the effects of SSRI antidepressants and reduce their side effects.^{20,24}

WHO Core Prescribing Indicators

In this study, we attempted to quantify prescribing patterns using the WHO core prescribing indicators. The average number of antidepressant drugs/products per prescription was 1.21. Previous studies have documented average numbers of drugs per prescription ranging from 1.6 to 2.7.^{10–12} The average number of antidepressant drugs per prescription observed in our study was

comparatively lower than those reported in drug utilization studies conducted by Hussain et al.¹⁰ (average, 2.7), Lahon et al.¹¹ (average, 2.32), and Tejashwini et al.¹² (average, 1.60). Our study showed restraint on polypharmacy and thus may minimize drug–drug interactions and reduce treatment costs.

In our study, prescribing drugs by generic names was low (28.69%). Most drugs were prescribed by brand/trade name (71.31%). Previous drug utilization studies by Hussain et al. (generic, 72.57%), Lahon et al. (generic, 88.54%), and Tejashwini et al. (generic, 75.65%) documented a higher trend of prescribing drugs by generic name.^{10–12} Prescribing drugs by generic name is cost-effective because these medications are cheaper than branded medications. The Medical Council of India recommends using generic names.²⁵ However, physicians may prefer brand names because of concerns about the quality and reliability of unbranded drugs.²⁶

In our study, no injectables were prescribed. This is similar to 3 documented studies in which neither injections nor antibiotics were prescribed.^{10–12}

In our study, 64.3% of drugs were prescribed from the National List of Essential Medicines (NLEM 2015).¹⁵ Our results were comparatively higher than those of drug utilization studies conducted by Hussain et al. (60%), Lahon et al. (1.56%), and Tejashwini et al. (46.81%).^{10–12} Essential drugs in the National List of Essential Medicines are selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.¹⁵

Medication Adherence

In this study, 64% of patients were “adherent,” whereas 36% were “nonadherent” to antidepressant medications. Previous studies using different scales have shown adherence levels ranging from 26.6% to 86%.^{13,21,27} Yadav et al., using the 4-item Morisky Medication Adherence Scale (MMAS-4), found high-level adherence in 26.66%, medium-level adherence in 49.3%, and low-level adherence or compliance in 24% of patients.¹³

Similarly, Tamburrino et al. found high-level adherence in 86% and low-level adherence in 10% of patients.²⁷ Al Jumah et al. documented that 52.9% of patients reported low medication adherence.¹⁴ Similarly, Yadav et al. documented that 73.33% of patients were nonadherent and 26.67% were adherent.¹³

In our study, we observed a relatively higher level of medication adherence (64%) to antidepressants than in previous studies.^{13,14,27} In most studies, the main causes of nonadherence were patients stopping medication because they felt better or worse, being careless, forgetting, believing that the medication could harm them, or worrying about side effects.^{16,17} Similar reasons for nonadherence were documented in our study’s questionnaire responses. Addressing these issues is crucial to improving treatment outcomes in depression. Medication adherence can be enhanced by (a) improving prescribing practices, (b) communicating effectively with patients, (c) conducting regular follow-ups, and (d) promoting psychoeducation.^{14,28} to help patients understand the importance of consistent medication use and the potential risks of nonadherence.

LIMITATIONS

The study had limitations, including its cross-sectional design, which prevents causal inference. A small sample size limits generalizability. Reliance on WHO prescribing indicators may omit key factors. Self-

reported adherence data could introduce bias. Finally, no inferential statistics were used because the study was purely descriptive.

CONCLUSION

Selective serotonin reuptake inhibitors (escitalopram) dominated the prescribing trend. However, there was a rising trend in the use of newer antidepressants. There was restraint on polypharmacy, but ample scope remains for improvement in prescribing by generic name and selecting essential drugs. Medication nonadherence was quite prevalent (36%); hence, efforts should be made to improve adherence.

ETHICS APPROVAL

Ethics approval was obtained from the Institutional Ethics Committee of MGM Medical College, Kamothe (Approval No. N-EC/2021/SC/02/20; approved on February 16, 2021).

INFORMED CONSENT

Written informed consent was obtained from all participants prior to enrolment.

CLINICAL TRIAL REGISTRATION

Not applicable.

DATA AVAILABILITY

All data generated or analyzed during this study are included in this published article.

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AUTHOR CONTRIBUTIONS

MJ and PJ: Conceptualization, methodology, data collection, writing – original draft.

SD and RG: Methodology; writing – review and editing.

All authors reviewed and approved the final version of the manuscript.

AI DISCLOSURE

The authors confirm that no generative artificial intelligence tools were used in the preparation of this manuscript.

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Body Image Issues in Late Adolescence—The Impact of Body Mass Index and Social Media Use: A Prospective Cross-sectional Study

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ABSTRACT

Background: Adolescents undergo many physical and emotional changes during and after puberty, significantly influencing their body image. These issues often intensify in late adolescence and may predict adverse psychological outcomes. This study assessed the incidence of body image dissatisfaction, its relationship with demographic and sociocultural variables, and its psychological impact on late adolescents.

Materials and methods: A cross-sectional study was conducted among medical students aged 17–19 years using a structured questionnaire (vide infra). The self-administered, well-structured questionnaire was used to analyze demographic variables, body image perception, and body image dissatisfaction-related problems to elicit the impact on adolescents' psychological health. The incidence of body image dissatisfaction, its relationship with sociocultural factors, social media use, and body mass index, and its impact on psychological health were assessed. Data were analyzed statistically using SPSS version 20.0, with $p < 0.05$ considered statistically significant.

Results: The incidence of dissatisfaction was 6.8%, showing a statistically significant ($p < 0.05$) relation with gender, social media use, social background, body image, body weight and height, physical disability, and body mass index (BMI). Body image dissatisfaction had a significant ($p < 0.05$) impact on the psychological health of adolescents, with participants reporting fatigue (72.7%), difficulty concentrating (68.2%), and loss of appetite. A statistically significant ($p < 0.05$) relation of BMI was observed with various issues related to body image.

Conclusion: BMI and social media use significantly influence body image dissatisfaction in late adolescents, impacting their psychological well-being. Effective interventions promoting healthy body perception and responsible social media use are necessary to reduce associated psychological distress.

Keywords: Body image dissatisfaction, Body mass index, Late adolescence, Psychological health, Social media.

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INTRODUCTION

"Body image" refers to the range of favorable to negative opinions that exist regarding how an individual views, feels, acts toward, and thinks about their body. It encompasses evaluations of body shape, size, attractiveness, and emotional responses to appearance.¹ The primary changes in identity formation and physical, social, cognitive, and emotional development occur during adolescence, making it a crucial developmental stage. Due to these changes, adolescents are particularly susceptible to body dissatisfaction.² Adolescents experience various physical and social changes during and after puberty that can significantly impact their body image and intensify by late adolescence.³

Traditional media has long placed pressure on adolescents, particularly girls, to maintain a slender body image; this issue is said to have gotten worse as social media has grown in popularity.⁴ Data from several social media platforms indicate that these values are constantly reinforced, which may contribute to eating disorders, negative self-perception, and bad body image in both males and females. Screen time on social media has been connected to obesity, which reinforces the unattainable beauty standards that are promoted on these platforms. Anxiety and depressive symptoms have been closely connected to body dissatisfaction.⁵

Obesity risk may also be exacerbated by negative body image. In most of the world's nations, children and adolescents'

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mean body mass index (BMI) and overweight have increased over the previous 40 years. A higher BMI has been associated with a less positive body image in young adults.⁶ Body dissatisfaction prospectively predicts adverse physical and psychological health consequences, such as depression, low self-esteem, and eating disorders among adolescents, which is a major concern.⁷ It has also been demonstrated that body dissatisfaction is a predictor of adolescents' participation in harmful body-change behaviors such as supplement use, excessive exercise, muscle-gaining techniques,

and restrictive eating. While it has been noted that teenage girls experience body dissatisfaction more frequently and profoundly than males do, recent data indicates that it is becoming a significant problem for both genders.⁸

Research on this topic is scarce in India, especially in North India, with gaps in understanding the variables affecting teenage attitudes and behaviors toward appearance and body weight. This study evaluates the incidence of body image dissatisfaction; its relationship with various demographic and sociocultural variables (gender, social background, social media, and body mass index); and its impact on the psychological health of late adolescents.

MATERIALS AND METHODS

Study Design

The present cross-sectional study was conducted in the Department of Pediatrics among subjects aged 17–19 years (late adolescents), over 2 years, in a tertiary care hospital in North India, from December 2021 to January 2024. The study was approved by the Institutional Ethics Committee (vide letter no. PIMS/DP/Gen 167/1898–99).

Study Subjects

The study included first, second and third year students from three different courses: MBBS, nursing, and pharmacy, after obtaining prior permission from their respective college authorities.

Data Collection

The objectives of the study were mentioned along with written informed consent in the questionnaires (vide infra), which were distributed randomly to the students. The self-administered, well-structured questionnaire was used to analyze the demographic variables, body image perception, and body image dissatisfaction-related problems to elicit an impact on adolescents' psychological health. The investigator addressed students' doubts and queries while they completed the forms. This ensured the complete filling of the questionnaires. Data thus obtained were kept anonymous and confidential. All participants were provided with the contact details of the principal investigator to sort out any doubts of study subjects later on. Incidence of body image dissatisfaction among late adolescents was assessed as a primary objective. The secondary objectives being assessed were as follows:

- The relationship of body image perception with individual parameters of physical appearance viz., body weight, height, skin color, physical handicap, graying of hair, acne, facial hair, and use of spectacles.
- Gender differences in dissatisfaction with body image.
- Effect of social background (rural vs urban) on body image dissatisfaction.
- Correlation between body mass index and body image issues.
- Impact of social media on body image dissatisfaction.
- Impact of body image dissatisfaction on adolescents' psychological health.

Sample Size and Statistical Analysis

Previous studies^{2,9} have found that around 70% of adolescents are dissatisfied with their bodies. Based on this, we calculated the sample size to be around 250. Convenience sampling was done and total of 323 students were enrolled after obtaining informed consent. Data were analyzed for the incidence of body image dissatisfaction and individual parameters, i.e., weight, height, body shape, skin color, and physical handicap. Gender-, social-, and educational background-based differences were compared statistically using SPSS IBM version 20.0 software, with a significance level of $p < 0.05$.

RESULTS

In this prospective study, of 323 participants, 64.7% were aged 18–19 years, with the mean age being 18 years. We observed almost equal gender distribution, with Hinduism (67.5%) being the prominent religion; most participants (54.8%) were first-year students, 70.6% had an urban background, and 82.7% had attended English-medium schools. The mean BMI was 23.01 ± 4.46 (Table 1). Statistically significant impacts ($p < 0.05$) were observed in relation to gender, social media use, social background, body image, body weight and height, physical disability, and BMI. In contrast, the association with skin color was not significant ($p = 0.067$). Significantly more males reported dissatisfaction with their bodies than females (63.64% vs 36.36%; $p = 0.045$). Students who checked social media frequently reported a higher degree of dissatisfaction with their bodies ($p = 0.002$) (Table 2). We found that body image dissatisfaction had a significant ($p < 0.05$) impact on adolescents' psychological health. It was observed that 72.7% of subjects felt fatigued, 68.2% had difficulty concentrating, 59.1% felt reduced interest in events or activities, and 45.5% felt sadness (Table 2). We also assessed the association of BMI with body image issues. We

Table 1: Demographic data

Variables		Frequency/ mean	Percentage/ SD
Age groups (years)	16–19	114	35.29
	18–19	209	64.71
Mean age		18.01	0.903
Gender	Female	158	48.9
	Male	165	51.1
Religion	Hindu	218	67.5
	Sikh	94	29.1
	Muslim	7	2.2
	Buddhist	1	0.3
	Christian	3	0.9
Present class (year) (MBBS/nursing)	1st year	177	54.8
	2nd year	72	22.3
	3rd year	74	22.9
Background	Urban	228	70.58
	Rural	95	29.4
Schooling	English medium	267	82.7
	Hindi medium	34	10.5
	Government school	18	5.6
	Public school	2	0.6
	Convent	2	0.6
Mean weight (kg)		63.42	14.77
Mean height (cm)		165.08	9.53
BMI		23.01	4.46

BMI, body mass index; SD, standard deviation

Table 2: Rate of incidence of dissatisfaction with body appearance in late adolescents and its relationship with various factors

Rate of incidence of dissatisfaction vs associations	Group/issue	Frequency (n)	Rate of incidence (%)
Rate of dissatisfaction vs gender	Female	8	36.36
	Male	14	63.64
χ^2 ; p-value	2.009; 0.045*		
Rate of dissatisfaction vs impact of social media (SM)	Once a day	10	45.55
	Checking updates hourly	12	54.55
	Do not use	0	0
χ^2 ; p-value	2.127; 0.002*		
Rate of dissatisfaction vs social background	Rural	6	27.27
	Urban	16	72.73
χ^2 ; p-value	2.110; 0.022*		
Rate of dissatisfaction vs body image	Graying hair	4	18.18
	Acne	8	36.36
	Facial hair	5	22.73
	Spectacles	8	36.36
χ^2 ; p-value	3.718; 0.049*		
Rate of dissatisfaction vs skin color	No	12	54.55
	Yes	10	45.45
χ^2 ; p-value	3.810; 0.067		
Rate of dissatisfaction vs physical disability	No	21	95.45
	Yes	1	4.55
χ^2 ; p-value	1.998; 0.001*		
Rate of dissatisfaction vs BMI	BMI <18	1	4.54
	BMI 18–25	8	36.36
	BMI >25	13	59.90
χ^2 ; p-value	2.005; 0.033*		

BMI, body mass index; SM, social media; * $p < 0.05$ is significant**Table 3:** Association between body mass index and body image issues

Body image issues	BMI <18 (n = 34)		BMI 18–25 (n = 210)		BMI >25 (n = 79)	
	n	%	n	%	n	%
Acne	14	41.17	78	37.14	26	32.91
Facial hair	10	29.41	83	39.52	30	37.97
Spectacles	10	29.41	80	38.09	31	39.24
Facial features	4	11.76	44	20.95	10	12.65
Gray hair	6	17.64	16	7.62	9	11.39
Voice change	3	8.82	12	5.71	1	1.27
Size/appearance of breast	0	0	9	4.28	5	6.30
Any other	2	5.88	11	5.24	4	5.10
Not concerned	2	5.88	8	3.81	4	5.10
χ^2 ; p-value	2.180; 0.014*					

BMI, body mass index; * $p < 0.05$ is significant

found a statistically significant ($p < 0.05$) relation of BMI with various issues related to body image (Table 3).

DISCUSSION

Between the ages of 12 and 18, a range of cultural, social, physical, and psychological changes that are typical of adolescence combine specifically to create body image. Adolescents are frequently targeted as potential customers by our appearance-focused culture, which has a detrimental effect on their body image.¹⁰ According

to recent studies, unhealthy adolescent body perceptions may be influenced by the diet, fitness, and cosmetic trends that are currently popular and promoted on reality television and social media. Further studies on the Internet, social media, and their impact on teenage body image are needed because these platforms are a constantly changing and pervasive source of information on ideal bodies.^{11–13} Thus, we planned a study to evaluate the incidence of body image dissatisfaction, to assess the impact of demographic and sociocultural factors on body perception, and the effect of dissatisfaction on the psychological health of late adolescents.

We found that 64.7% of subjects were aged 18–19, with almost equal gender distribution; Hinduism (67.5%) was the prominent religion, most of the subjects (54.8%) were first-year students, 70.6% had an urban background, and 82.7% had English-medium schooling. The mean BMI was found to be 23.01 ± 4.46 . Similar to our study, Ganesan et al.² observed that 66% of study participants came from urban backgrounds. 53.6% had normal BMIs, whereas the remaining groups were overweight (15.7%), obese (3.9%), and undernourished (26.7%). Similar to our study, Sarkkola et al.¹³ found that the prevalence of overweight was maximum 12.7%, followed by thinness (11%) and obesity (2.6%).

We observed that body image dissatisfaction among late adolescents was significantly associated with body weight, height, and BMI. Participants with BMI >25 (59.90%) were the most dissatisfied, followed by those with BMI 18–25 (36.36%); the lowest rate of dissatisfaction was observed among those with BMI <18 (4.54%). We found a statistically significant ($p < 0.05$) relation of BMI with various issues related to body image. Similar to our study, Ganesan et al.² observed that 23% of underweight individuals were content with their BMI, and 7.4% did not wish to lose more weight. Similarly, 58.3% of those in the normal BMI category desired to lose weight, and 71% were unhappy with how they looked. This demonstrates unequivocally the propensity to favor slender body types. They observed that dissatisfied body image was significantly correlated with increased BMI.

We also found that most subjects were not taking weight control pills, but most (69.04%) exercised to control their weight. This healthy practice might be due to the fact that we targeted medical students in our study, and they were well aware of healthy weight control measures. Calzo et al.¹⁴ and Bucchianeri et al.¹⁵ implied that the effects on body image are long-lasting, with higher BMI during adolescence as a robust predictor of low body satisfaction in early adulthood.

Our study observed a dissatisfaction rate of 6.8% among late adolescents. In studies by Ganesan et al.² and Pelegrini et al.,⁹ a higher rate of dissatisfaction (67% and 71%, respectively) was observed among adolescents with their bodies. In our study, the dissatisfaction rate was quite low. This might be because we targeted subjects from medical backgrounds, and they have better anthropometric variables and perceptions of body image.

We found that males (64%) showed significantly more dissatisfaction related to body image than females (36%). Pelegrini et al.⁹ found that boys wanted their body silhouettes to be larger, while girls wanted theirs to be smaller. Biolcati et al.¹⁶ and Klimek et al.¹⁷ observed that body dissatisfaction in both girls and boys was positively and significantly linked with internalization of the thin and muscular ideals, respectively. In contrast to our study, Pollina Pocallet et al.¹⁸ found that girls had higher body dissatisfaction and concern levels than boys, and individuals with low self-esteem demonstrated a higher body dissatisfaction score. A strong correlation was found between the body dissatisfaction score and body image concern/self-esteem.

We observed a significant impact ($p < 0.05$) of social media on the rate of body dissatisfaction. In our study, most subjects watched television programs (74%), and most (50.8%) were frequent social media users checking updates hourly. We found that dissatisfaction was higher (54.55%) among those checking updates hourly. Sagrera et al.¹ stated that social media (SM) users who utilize a variety of platforms had higher body image issues (BII) than non-users ($p < 0.001$). They proposed that the detrimental relationship between SM use and BII might have an impact on teenage mental

health that goes beyond cultural and socioeconomic boundaries. Twenge and Martin¹⁹ observed that time spent on social media positively correlates with the growth and durability of BII. They discovered a direct link between enhanced body monitoring and how frequently SM accounts are checked. Additionally, they noticed that the amount of time spent on SM increased with body dissatisfaction.

We also observed a significant impact ($p < 0.05$) of social background on body image dissatisfaction. The dissatisfaction rate was higher among urban (72.73%) residents than rural residents. Similar results were obtained in a study by Mishra and Mukhopadhyay,²⁰ who found that adolescents in cities are less satisfied with their bodies than those in rural areas.

In our study, we found that body image dissatisfaction had a significant ($p < 0.05$) impact on adolescents' psychological health. Among the participants, 72.7% felt fatigued, 68.2% had difficulty concentrating, 59.1% felt reduced interest in events or activities, 54.5% thought of suicide, and 45.5% felt sadness.

Wroblewski et al.²¹ observed that adolescent mental health is impacted by body dissatisfaction, which increases risk of reporting frequent feelings of loneliness, anxiety-induced sleeplessness, and trouble interacting with others. Widasuari and Yudianto²² found that body dissatisfaction lowers one's sense of self, which can impair one's mental faculties and encourage the emergence of harmful coping mechanisms like eating disorders and unhealthy weight loss plans. Tamhane²³ stated that the likelihood of suicidal thoughts was predicted by body dissatisfaction.

LIMITATIONS

The present study was conducted on a specific group of study subjects from medical backgrounds and from self-financing and government-aided institutions, which brought together adolescents from various cultural and socioeconomic backgrounds. This affects the generalizability of the findings to the whole adolescent population. Furthermore, our study was conducted with a limited sample size. Thus, further prospective studies are needed on more diverse adolescent groups, with different age groups belonging to different communities and fields.

CONCLUSION

This study emphasizes the significance of comprehending the elements influencing the health and welfare of the susceptible adolescent population. Moreover, developing future supporting interventions may require close collaboration with the adolescent community. In order to lessen the negative effects of body image dissatisfaction on the present and future welfare of adolescents. The findings may appropriately indicate that social media platform providers should prioritize developing technologies to limit the detrimental body image content that is available to vulnerable adolescents.

ETHICS APPROVAL

The study was approved by the Institutional Ethics Committee of Punjab Institute of Medical Sciences (Approval No. PIMS/DP/Gen 167/1898–99).

INFORMED CONSENT

Written informed consent was obtained from all participants prior to enrolment in the study.

DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article.

AUTHOR CONTRIBUTIONS

AB and HSB: Conceptualization, methodology, questionnaire design, manuscript writing, review, and editing.

FP, KB, and MKS: Data collection and analysis.

All authors reviewed and approved the final version of the manuscript.

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Nil.

AI USE DECLARATION

All intellectual content was developed by the authors. Artificial intelligence (AI) was used only for minor language editing.

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A Sensitivity Showdown—Comparing the Modified Bleach Concentration Method with Conventional Ziehl–Neelsen Staining for Detection of *Mycobacterium tuberculosis* in Extrapulmonary Sites

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ABSTRACT

Background: Tuberculous lymphadenitis remains a common form of extrapulmonary tuberculosis (EPTB), particularly in resource-limited settings. Fine-needle aspiration cytology (FNAC) is a valuable diagnostic tool, though the low sensitivity of conventional Ziehl–Neelsen (ZN) staining limits its diagnostic yield.

Objectives: To evaluate and compare the diagnostic performance of the modified bleach concentration method with the conventional ZN staining technique in detecting acid-fast bacilli (AFB) from lymph node aspirates in suspected cases of TB lymphadenitis.

Materials and methods: A cross-sectional study was conducted on 68 patients with clinically suspected TB lymphadenitis. FNAC samples were stained using both conventional ZN and modified bleach concentration methods. AFB detection rates and cytomorphological patterns were analyzed and compared.

Results: AFB were detected in 14 cases (20.6%) by both methods, while the modified bleach method detected an additional 32 cases, raising the total to 46 AFB-positive cases (67.6%). No cases were positive on conventional ZN but negative on the modified method. Cytomorphological analysis revealed the following distribution of patterns: Pattern 1 being most common (45.6%), pattern 2 in 17 cases (25%), patterns 3 and 4 in 7 cases each (10.29%), pattern 5 in 4 cases (5.9%), and pattern 6 in 2 cases (2.9%).

Conclusion: The modified bleach concentration method significantly improves AFB detection compared to conventional ZN staining. It is a cost-effective, simple, and more sensitive diagnostic approach for TB lymphadenitis, particularly suitable for resource-constrained settings. Further studies are warranted to assess its specificity and rule out false-positive results.

Keywords: Acid-fast bacilli, Bleach method, Extrapulmonary tuberculous lymphadenitis, Fine-needle aspiration cytology, Lymphadenitis, Tuberculosis, Ziehl–Neelsen.

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INTRODUCTION

Tuberculosis (TB) is a highly transmissible airborne infection caused by *Mycobacterium tuberculosis*, a leading global cause of illness and mortality, surpassing human immunodeficiency virus-acquired immunodeficiency syndrome (HIV-AIDS) as the leading cause of death from a single infectious disease, excluding the coronavirus disease 2019 (COVID-19) pandemic.¹ Despite the high success rate of correctly performed directly observed treatment, short-course (DOTS), India has the world's highest burden of TB, accounting for an estimated 2.2 million cases out of a total of 9.6 million.²

TB diagnosis involves clinical evaluation and bacteriological confirmation through methods like acid-fast bacilli (AFB) staining, molecular tests, and culture, with mycobacterial culture on Lowenstein-Jensen media as the gold standard, despite its lengthy processing time.³ Extrapulmonary tuberculosis (EPTB), comprising about 15% of TB cases, involves infection outside the lungs, often spread via blood or lymph from a pulmonary source, with tuberculous lymphadenitis as the most common form.⁴ In India, fine-needle aspiration cytology (FNAC) is the preferred, minimally invasive diagnostic tool for suspected

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EPTB lymphadenitis, offering a rapid and practical evaluation of peripheral lymphadenopathy.⁵ Though FNAC aids in TB diagnosis, its limited specificity, due to overlapping features with other conditions like fungal infections and sarcoidosis, and the need for skilled interpretation, hinder its effectiveness in peripheral health care settings.^{6,7}

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In EPTB diagnosis, Ziehl–Neelsen (ZN) staining for AFB plays a crucial role but has low sensitivity, ranging from 9 to 46%.⁸ Research suggests that AFB detection with ZN staining improves by liquefying samples with chemical agents, followed by centrifugation or sedimentation.^{9,10} Sodium hypochlorite (household bleach) enhances the sensitivity of ZN staining by liquefying and concentrating samples. It was initially used for sputum processing in TB diagnosis.¹¹

If proven more sensitive than conventional ZN staining, sodium hypochlorite could be the best choice for TB detection in control programs due to its safety, affordability, and ease of use.¹² If more sensitive than conventional ZN staining, this method could be ideal for TB detection in control programs due to its safety, cost-effectiveness, and scalability without requiring extra infrastructure.¹³

MATERIALS AND METHODS

This observational, cross-sectional, and analytical study was conducted over a period of 18 months as part of postgraduate research in the Department of Pathology in Pune, Maharashtra, involving 68 patients clinically suspected of extrapulmonary tuberculosis (EPTB). Fine-needle aspiration (FNA) was performed under aseptic conditions using a 21-gauge needle and 10 cc syringe. Aspirates were categorized as caseous or purulent and processed using Leishman, Giemsa, Papanicolaou, and conventional ZN stains. The remaining sample underwent a modified bleach concentration method using 5% sodium hypochlorite, followed by centrifugation at 5000 rpm for 15 minutes after adding 1 mL of distilled water. The sediment was then smeared, air-dried, heat-fixed, and stained with ZN stain for AFB detection.¹⁴

The spectrum of cytomorphologic features observed on Leishman-, Papanicolaou-, and Giemsa-stained smears was broadly categorized into six patterns using the following criteria¹⁵:

Pattern 1: Epithelioid granulomas with Langhans giant cells and caseous necrosis. Presence of epithelioid granulomas with central caseous necrosis signifies a more active inflammatory process. Epithelioid cell granuloma with caseating necrosis is a typical pathological finding in tuberculosis.¹⁶

Pattern 2: Numerous clusters of epithelioid cells in a reactive background. These clusters signify an immune response to *M. tuberculosis*. The reactive background refers to the surrounding inflammatory environment where various immune cells, including lymphocytes and additional macrophages, interact.

Pattern 3: Mostly caseous necrotic material with few epithelioid cells. Characterized by a predominance of necrotic material with only a few scattered epithelioid cells and lymphocytes.

Pattern 4: Caseous necrotic material with few lymphocytes and histiocytes; no epithelioid cells. This usually is indicative of massive tissue destruction.

Pattern 5: Only caseous necrosis without any other cell types.

Pattern 6: Tuberculous abscess showing predominantly neutrophils along with degenerating epithelioid cells and semifluid necrotic material.

RESULTS

The study included 68 participants, with the largest age groups being 41–50 and 51–60 years (20.6% each). Males comprised 66.2% of the sample. Most participants (92.6%) had cervical involvement, with fewer cases in the axillary (4.4%) and

inguinal (2.9%) regions. Common symptoms included weight loss (67.65%) and fever with loss of appetite (88.23%), while hepatosplenomegaly and generalized lymphadenopathy were rare (2.9% each). Human immunodeficiency virus (HIV) was detected in 16.2% of participants, while 83.8% tested negative. AFB detection varied with staining methods; in HIV-positive cases, the conventional ZN stain identified 2 (18.18%) positive cases, whereas the modified ZN stain detected 9 (81.81%). Among HIV-negative participants, the modified ZN stain identified more AFB-positive cases, 37 (64.9%), compared to the conventional ZN stain, 12 (21.05%). Cytomorphological analysis in HIV cases revealed pattern 6 in 45.45%, pattern 4 in 36.36%, and pattern 1 in 18.18% of cases (Table 1 and Fig. 1).

Table and Figure 1 show the cytomorphological patterns observed among participants, which were categorized into six distinct patterns. Pattern 1 was the most common, observed in 31 participants (45.6%). Pattern 2 was observed in 17 participants (25%), while patterns 3 and 4 each appeared in 7 participants (10.29%). Pattern 5 was found in 4 participants (5.9%), and pattern 6 was the least frequent, appearing in only 2 participants (2.9%) (Table 2 and Fig. 2).

Table and Figure 2 show the comparison of the conventional ZN method with the modified ZN method for detection of AFB. Out of a total of 68 cases, 14 (20.58%) were positive for AFB by both the conventional ZN stain and the modified ZN stain. The modified ZN stain detected an additional 32 positive cases that were not identified by the conventional ZN stain, leading to a total of 46 (67.6%) positive cases by the modified ZN stain.

Table 1: Distribution of study subjects according to pattern seen on cytomorphology

Pattern on cytomorphology	Number	Percentage
Pattern 1	31	45.6%
Pattern 2	17	25%
Pattern 3	7	10.29%
Pattern 4	7	10.29%
Pattern 5	4	5.9%
Pattern 6	2	2.9%
Total	68	100%

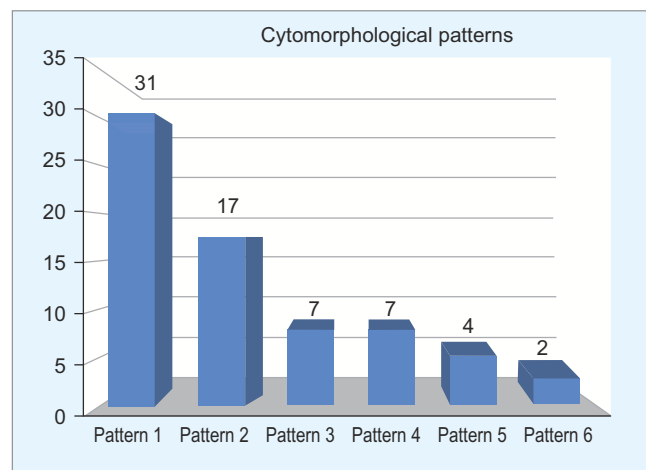


Fig. 1: Cytomorphological patterns

Modified Bleach Concentration Method with Conventional ZN Staining

Table 2: Distribution of study subjects according to comparison of conventional ZN method with modified ZN method for detection of AFB

Modified ZN stain	Conventional ZN stain		Total
	Positive for AFB	Negative for AFB	
Negative for AFB	0	22	22
Positive for AFB	14	32	46

Table 3: Distribution of AFB grading on both stain methods

Conventional ZN stain AFB grading	Modified ZN stain AFB grading			Total
	1+	2+	No grade	
1+	2	12	0	14
No grade	32	0	21	53
Total	34	12	21	67

Table 4: Diagnostic performance metrics for the modified ZN stain

Validity parameters	Value	95% CI
Sensitivity	100.00%	76.84–100.00%
Specificity	40.74%	27.57–54.97%
Positive likelihood ratio	1.69	1.35–2.11
Negative likelihood ratio	0.00	–
Disease prevalence (*)	20.59%	11.74–32.12%
Positive predictive value (*)	30.43%	25.96–35.31%
Negative predictive value (*)	100.00%	84.56–100.00%
Accuracy (*)	52.94%	40.45–65.17%

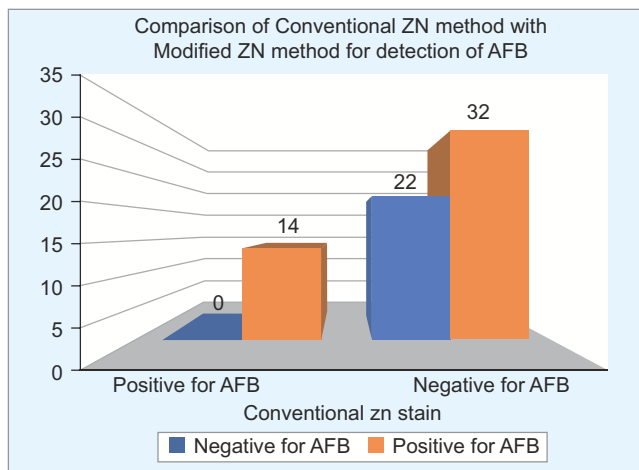


Fig. 2: Comparison of the conventional ZN method with the modified ZN method for the detection of AFB

However, there were no cases missed by the modified ZN stain that were positive by the conventional ZN stain. This indicates that the modified ZN stain detected more cases of AFB, but the 32 additional positive cases suggest that the modified ZN stain may have a higher number of false-positive results compared to the conventional ZN stain (Table 3 and Fig. 3).

Table and Figure 3 show the distribution of AFB grading by both staining methods. The conventional ZN stain detected 32 cases with no grade and 2 cases with a 1+ grade, showing limited positive identification. The modified ZN stain, in contrast, detected 21 cases with no grade, while 12 cases were graded 1+ and 2 cases

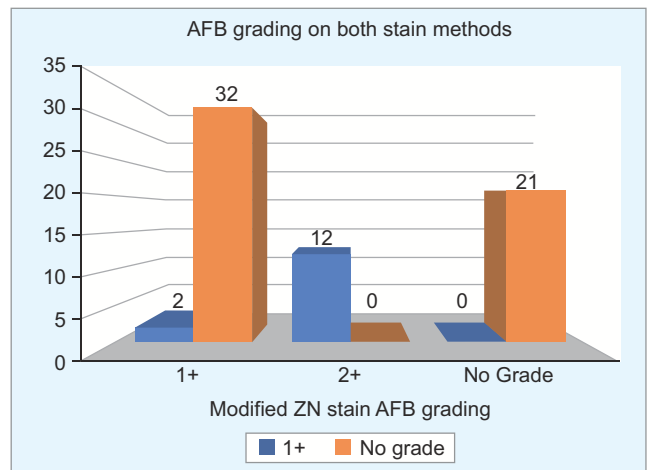


Fig. 3: AFB grading by both staining methods

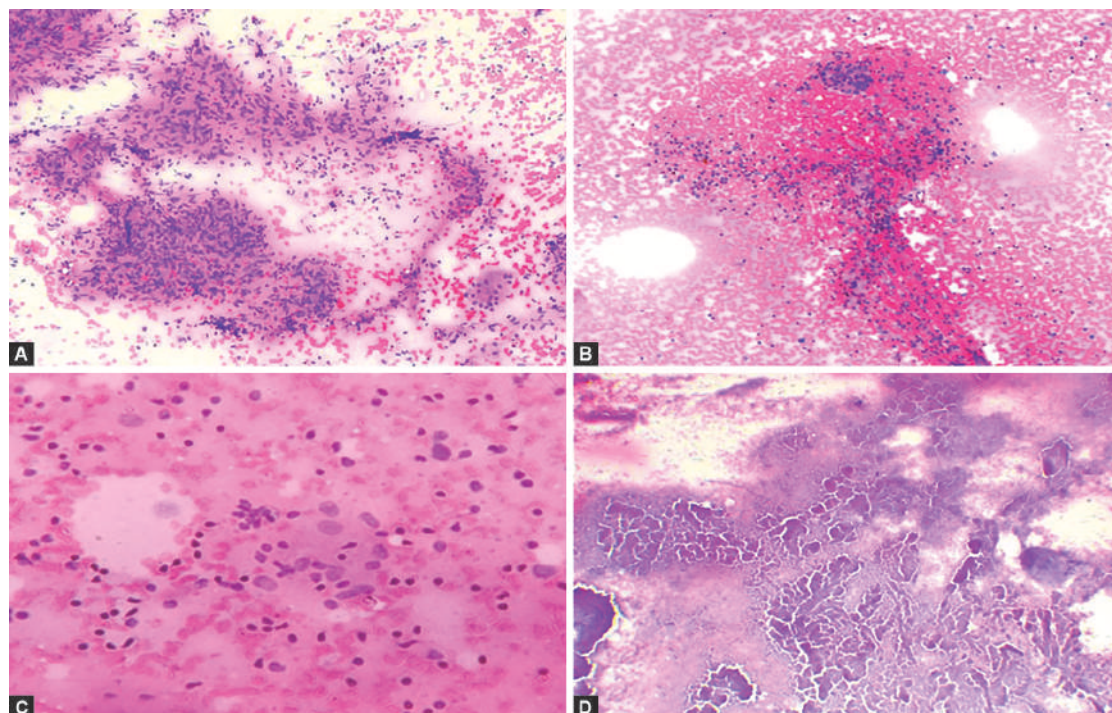
were graded 2+, suggesting that it identified more cases with higher intensity. This shows a higher degree of AFB positivity and intensity with the modified ZN stain, with an overall greater number of graded positive cases than the conventional ZN stain (Table 4 and Figs 4 and 5).

Table 4 presents the diagnostic performance metrics for the modified ZN stain. The sensitivity of the test was 100.00%, indicating no false-negative results. The specificity was 40.74%, indicating a relatively low ability to correctly identify nondiseased individuals. The positive likelihood ratio was 1.69, and the negative likelihood ratio was 0.00. The disease prevalence was 20.59%, and the positive predictive value was 30.43%, indicating that a positive test was only moderately likely to indicate disease. The negative predictive value was 100.00%, indicating that negative results were highly reliable. The accuracy of the test was 52.94%, suggesting moderate overall reliability (Figs 4 and 5).

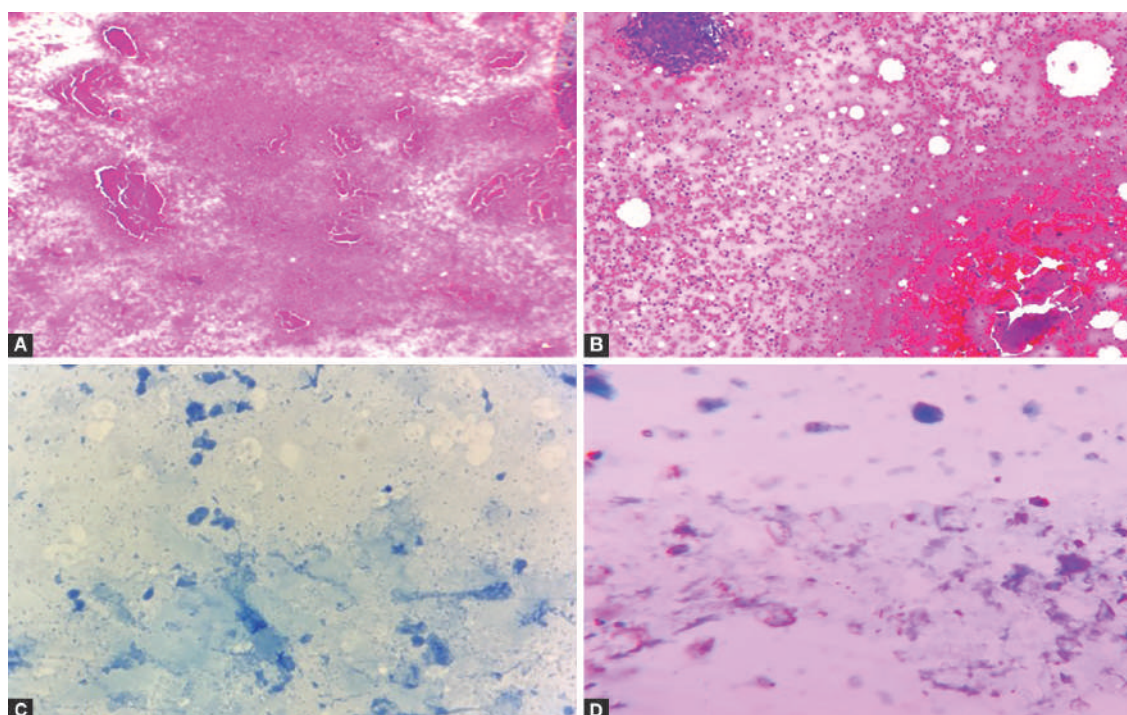
DISCUSSION

This study evaluated the demographic profile, clinical features, diagnostic accuracy, and cytomorphological patterns of suspected AFB cases, comparing conventional ZN staining with a modified bleach concentration method and analyzing correlations with human immunodeficiency virus (HIV) status.

The majority of cases fell in the 41–60-year age-group, consistent with Rekha Bansal et al.'s findings (mean age: 49.03 ± 18.51 years)¹⁷ and Rolo et al. (49.6 years).¹⁸ However, Khan et al.¹⁰ reported a younger mean



Figs 4A to D: (A) Photomicrograph from lymph node aspiration showing epithelioid granulomas with Langhans giant cells and caseous necrosis (pattern 1) (H&E, 400x); (B) Photomicrograph from lymph node aspiration showing numerous clusters of epithelioid cells in a reactive background (pattern 2) (H&E, 200x); (C) Photomicrograph from lymph node aspiration showing predominantly caseous necrotic material with few epithelioid cells (pattern 3) (H&E, 400x); (D) Photomicrograph from lymph node aspiration showing caseous necrotic material with few lymphocytes and histiocytes and no epithelioid cells (pattern 4) (H&E, 200x)



Figs 5A to D: (A) Photomicrograph from lymph node aspiration showing only caseous necrosis without any other cell types (pattern 5) (H&E, 200x); (B) Photomicrograph from lymph node aspiration showing neutrophils along with degenerating epithelioid cells and semifluid necrotic material (pattern 6) (H&E, 200x); (C) Photomicrograph from lymph node aspiration of the patient showing ZN staining (conventional method): AFB negative (ZN, 400x); (D) Photomicrograph from the same patient's lymph node showing ZN staining (modified bleach method): AFB positive (ZN, 400x)

age of 32.18 ± 15.7 years, reflecting population variation.¹⁰ A consistent male predominance was noted in our study (66.2% males), which parallels findings by Reddy et al.,¹⁹ Kassa et al.,²⁰ and Rekha Bansal et al.,¹⁷ who all reported higher male representation.

Symptomatically, fever and loss of appetite were predominant in our cohort, similar to observations by Rekha Bansal et al.,¹⁷ Dwivedi and Mathur,⁹ and Khan et al.¹⁰ Cough and weight loss were also commonly reported across these studies.

Our study also explored the relationship between HIV status and AFB detection. Similar to the findings of Tadesse et al.,³ Khan et al.,¹⁰ and Patel et al.,¹⁴ we observed AFB-positive cases in HIV-infected individuals, highlighting the diagnostic challenges in coinfecting patients. These studies emphasize the importance of appropriate testing strategies to accurately identify infections in HIV-positive populations.

In terms of anatomical site involvement, 92.6% of cases in our study showed cervical lymphadenopathy, with rare involvement of the axillary (4.4%) and inguinal (2.9%) regions, findings consistent with Chand et al.'s report.²¹ Cytomorphologically, pattern 1 (epithelioid granuloma with caseous necrosis) was the most common (45.6%) in our study, which aligns with multiple studies but contrasts with Mahajan et al.,²² who reported pattern 2 as predominant. Pattern 6 was most frequent among HIV-positive cases in our study.

Our study aligns with the findings of Habeenzu et al.,²³ demonstrating that modified or concentration-based staining methods significantly improve the sensitivity and detection of AFB compared to the conventional ZN technique. In our study, the modified ZN method detected more cases at higher grades (12 at 1+ and 2 at 2+), whereas the conventional method identified only 2 cases at 1+. Similarly, Habeenzu et al.²³ observed increased AFB grading with concentrated smears. This underscores the diagnostic advantage of improved staining protocols in enhancing the visibility and intensity of bacilli.

Furthermore, our results echo a broader pattern reported in studies by Mahajan et al.,²² Laddha et al.,²⁴ and Rani and Manazir,²⁵ who also documented increased positivity with the bleach method. For example, our modified ZN method detected an additional 32 positive cases over the conventional method, while Krishna and Gole²⁶ found 34 additional cases with bleach processing. These findings confirm the bleach method's consistent superiority in AFB detection.

Diagnostic comparisons revealed that the modified ZN method had a 100% negative predictive value but a lower positive predictive value (30.43%) and an overall accuracy of 52.94%. Our results, similar to those of Habeenzu et al.,²³ Mahajan et al.,²² and Laddha et al.,²⁴ showed that the modified or bleach method enhanced sensitivity and AFB grading. A proper TB diagnosis is required to control the emergence of medication resistance, lessen transmission, and enhance treatment.²⁷ This study aimed to determine which method is better at detecting AFB in FNA smears from suspected TB lymphadenitis cases: the modified bleach concentration method or the traditional ZN staining technique.¹⁰ These findings underscore its cost-effectiveness and diagnostic utility, particularly in resource-limited settings, and support integrating molecular methods for improved accuracy in managing AFB and HIV coinfections.

CONCLUSION

This study emphasizes the importance of early diagnosis of AFB infections, particularly in HIV-positive patients who may present with more severe symptoms. It demonstrates that the modified ZN

technique offers improved diagnostic accuracy, which can lead to prompt treatment and better outcomes, especially for coinfecting individuals.

The study aligns with existing research on demographic trends, such as male preponderance and symptom prevalence, while offering new insights into cytomorphological patterns that can help tailor treatment. It advocates the use of the modified ZN method in routine diagnostics for high-risk groups, potentially influencing new clinical recommendations to increase detection rates, particularly in HIV-positive individuals.

The study also highlights the cost-effectiveness of this method in resource-limited settings, noting that earlier detection could reduce health care costs related to advanced disease stages. Additionally, combining modern molecular diagnostic tools with the modified ZN technique could further enhance diagnostic accuracy and improve treatment strategies for AFB infections in the context of HIV coinfection.

ETHICS APPROVAL

Ethics approval was obtained from the Institutional Ethics Committee of Dr D. Y. Patil Medical College, Pimpri, Pune (Approval No. IESC/PGS/2023/194) on 22 December 2023.

INFORMED CONSENT

Written informed consent was obtained from all participants prior to enrolment.

CLINICAL TRIAL REGISTRATION

This study was not registered as a clinical trial.

DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this article.

AUTHOR CONTRIBUTIONS

Conceptualization, methodology, data collection, writing – original draft: Dr Shafali Deopa, Dr MB Iqbal.

Writing – review & editing: Dr Shafali Deopa, Dr MB Iqbal, Rutika Ghatge, Charusheela Gore.

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None.

AI USE DECLARATION

AI tools were used only for language editing; all intellectual content was developed by the authors.

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Antitubercular Treatment-induced Psychosis: A Systematic Review and Recommendations

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ABSTRACT

Introduction: India has one of the highest burdens of tuberculosis (TB). Several antitubercular agents are used in combination to treat tuberculosis; however, these agents may precipitate adverse effects, including psychosis. Therefore, a management plan for psychosis is required for patients receiving antitubercular treatment (ATT).

Aim: To review the available literature related to antitubercular-induced psychosis and its management.

Methods: A systematic search was conducted on PubMed, CENTRAL, and Google Scholar using search terms (e.g., "antitubercular agents," each of the first-line and second-line antitubercular agents, "tuberculosis," "psychotic disorders," "schizophrenia"). Relevant studies up to January 2025 were selected for the review using International Classification of Diseases-10 (ICD-10) criteria.

Results: Of 595 records, 66 were included in this review, comprising 43 case reports, 12 case series, 10 retrospective studies, and 1 cohort study. Cycloserine was the most common agent reported to cause psychotic symptoms, followed by fluoroquinolones, isoniazid, ethionamide, and, rarely, ethambutol, rifampicin, streptomycin, and para-aminosalicylic acid (PAS). Strategies, including discontinuing the precipitating agent and the use of antipsychotic drugs (e.g., phenothiazines), have been utilized for treating antitubercular-induced psychotic symptoms.

Conclusion: Current literature is limited primarily to case reports and case series. Based on available literature, the present study proposes stepwise recommendations for the management of psychosis in patients on ATT. Challenges, such as the correct diagnosis of antitubercular-induced psychosis and its management, have been discussed. Further randomized controlled trials and longitudinal studies are required to establish higher-level recommendations.

Keywords: Antitubercular agents, Drug-induced psychosis, Organic psychosis, Psychotic disorders, Tuberculosis.

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INTRODUCTION

Tuberculosis (TB) remains one of the top 10 causes of death globally,¹ with India bearing the highest burden, accounting for a quarter of global TB cases and a third of related deaths.²

While first-line antitubercular drugs (FLDs) such as isoniazid, rifampin, pyrazinamide, ethambutol, and streptomycin are used to treat drug-sensitive TB, cases of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) require second-line drugs (SLDs) such as kanamycin, levofloxacin, cycloserine, fluoroquinolones, ethionamide, capreomycin, p-aminosalicylic acid, moxifloxacin, clofazimine, linezolid, high-dose isoniazid, and amoxicillin-clavulanic acid.

Many of these agents are known to cause neuropsychiatric side effects, including psychosis, yet the literature guiding the management of antitubercular drug-induced psychosis (ATDIP) remains sparse. This review evaluates the available literature to provide practical guidance for clinicians managing ATDIP.

METHODS

Research Questions

We sought to answer the following questions related to the management of ATDIP:

- Should the antitubercular drug be discontinued, or should an antipsychotic be added?

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Source of support: Nil

Conflict of interest: None

- What is the role of combining both strategies?
- Should the offending drug be reintroduced after symptom resolution?

Eligibility Criteria

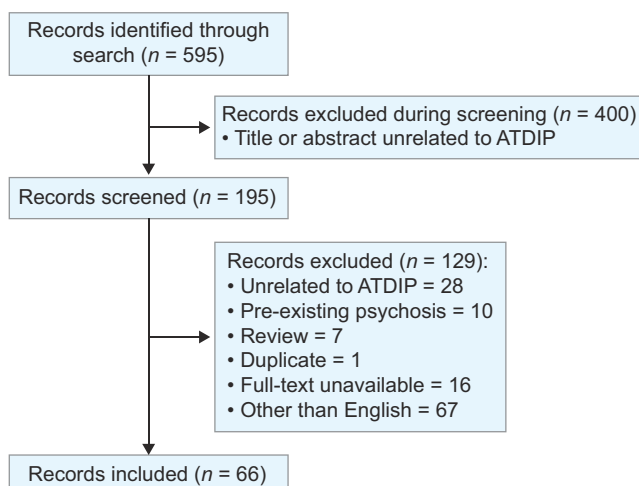
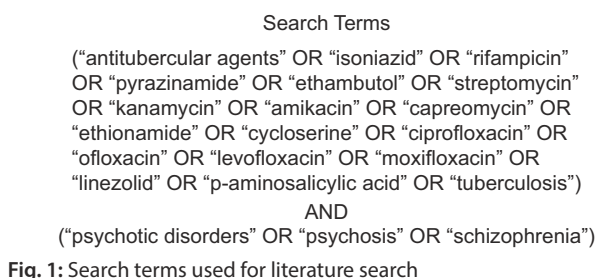
- **Inclusion criteria:** The original studies (cross-sectional, cohort, case-control), case series, and reports in English involving ATDIP as defined by ICD-10 DCR F.06.
- **Exclusion criteria:** Review articles, studies with preexisting psychosis and delirium, non-English publications, and unavailability of full text.

Information Source and Search Strategy

The literature was searched till January 2025 on PubMed, CENTRAL, and Google Scholar for search terms including antitubercular drugs and psychosis (Fig. 1). Furthermore, the references of the selected articles and the excluded review articles were also examined that might have been overlooked in the previous search.

Selection Process and Data Extraction

After the database search, titles and abstracts were screened for relevance. Full texts of eligible articles were then reviewed to confirm eligibility. Data were extracted under the following headings: study design, sample characteristics, treatment received before onset of neuropsychiatric symptoms, duration of treatment before the onset of neuropsychiatric symptoms, the neuropsychiatric symptoms, management strategy, treatment received for neuropsychiatric symptoms, results, and remarks. Two author groups (SJ, HKK, AS, and PK, VV, AK) independently performed data extraction, resolving discrepancies through consensus. The process adhered to PRISMA 2020 guidelines.



RESULTS

Out of 595 records, 66 studies were included: 43 case reports, 12 case series, 10 retrospective studies, and 1 cohort study (Fig. 2, Table 1, and Supplemental Table S1). A total of 75 cases have been reported from all case reports and series.

First-line Drugs

Isoniazid is the most frequently reported FLD and the third most common antitubercular drug causing psychosis (0.7–1.9%).^{3,6,69} Symptoms typically appear after ~2.5 months (range: 4 days–17 months). Prodromal symptoms, including anxiety, mood lability, facial twitching, headache, giddiness, and insomnia, may precede psychosis.^{12,27} Common psychosis symptoms include persecutory delusions, auditory hallucinations, aggression, suicidal or assaultive behavior, and insomnia.

Only two cases of ethambutol-induced psychosis have been reported, with onset between 4 and 14 days.¹³ Streptomycin-induced cases appeared after 3 weeks to 8 months of treatment.^{9,28,29} Rifampicin has also been implicated but was excluded due to the unavailability of the full text.⁷⁰

Second-line Drugs

Cycloserine is the most frequently reported antitubercular drug causing psychiatric side effects (9.7–50%), with psychosis occurring in up to 12% of cases.^{6,69} Onset typically occurs after ~6 months (range: 3 days–30 months) and includes persecutory or infidelity delusions, auditory hallucinations, insomnia, and aggressive or suicidal behavior. Effects are dose-dependent.⁷¹

Fluoroquinolones are the second most reported group, with ~3.7% developing psychosis—most often with ciprofloxacin and moxifloxacin.^{47,71} Symptoms appear within 2–4 days and are also dose-related.

Ethionamide causes psychiatric symptoms in 1–2% of patients.⁷² Psychosis from sodium para-aminosalicylate (PAS) typically occurs after ~2 months (range: 2 weeks–4 months).³⁷

Management of Antitubercular Drug-induced Psychosis

Should the Antitubercular Drug be Stopped or Should an Antipsychotic be Added?

The most frequent management approach was stopping the offending drug alone (44%, $n = 30$) or combined with antipsychotic therapy (32%, $n = 22$). Less common strategies included stopping all antitubercular drugs (12%, $n = 8$), stopping all drugs plus adding antipsychotic (3%, $n = 2$), using antipsychotics alone (4%, $n = 3$), dose reduction of precipitating drug along with antipsychotic (1.5%, $n = 1$), and stopping antitubercular drug along with adding electroconvulsive therapy (3%, $n = 2$).

Combined strategy (discontinuing offending drug + adding antipsychotic) led to quicker symptom resolution (mean 14 days; range 2–42 days) compared to stopping the drug alone (mean 20 days; range 1–120 days). Fluoroquinolone-induced psychosis resolved rapidly after stopping the drug (mean 4.9 days; range: 1–9 days), whereas isoniazid-induced psychosis took longer (mean 29 days; range: 2–120 days), but improved faster (mean 16 days; range 2–42 days) when antipsychotics were added (Table 2).

Should the Discontinued Drug be Reintroduced?

Rechallenge was attempted in 13 of 75 reported cases. Of these, 69% ($n = 9$) experienced relapse,^{10,15,16,24,27,28,32,34,43} 23% ($n = 3$) remained

Table 1: Summary of included studies.

<i>Antitubercular drug-induced psychosis (N = 66)</i>	<i>Case reports (n = 43)</i>	<i>Case series (n = 12)</i>	<i>Retrospective studies (n = 10)</i>	<i>Cohort study (n = 1)</i>
Any drugs (2)	0	0	2 ^{3,4}	0
Second-line drugs (4)	1 ⁵	0	2 ^{6,7}	1 ⁸
Isoniazid (3)	0	2 ^{9,10}	1 ¹¹	0
Isoniazid (27)	15 ^{12,13,14–26}	8 ^{9,27,28,29,30–33}	4 ^{10,11,34,35}	0
Ethambutol (1)	1 ¹³	0	0	0
Streptomycin (3)	0	3 ^{9,28,29}	0	0
p-Aminosalicylate (4)	1 ³⁶	3 ^{9,29,37}	0	0
Cycloserine (10)	9 ^{36,38–45}	1 ⁴⁶	0	0
Any fluoroquinolones (1)	0	0	1 ⁴⁷	0
Ciprofloxacin (9)	8 ^{48–55}	1 ⁵⁶	0	0
Ofloxacin (3)	2 ^{57,58}	1 ⁵⁹	0	0
Levofloxacin (7)	7 ^{39,60–65}	0	0	0
Moxifloxacin (2)	2 ^{66,67}	0	0	0
Ethionamide (1)	0	0	1 ⁶⁸	0

Table 2: Days required for resolution of psychotic symptoms with various management strategies.

<i>Days required for remission</i>	<i>Isoniazid (n = 26)</i>	<i>Cycloserine (n = 11)</i>	<i>Ciprofloxacin (n = 7)</i>	<i>Ofloxacin (n = 4)</i>	<i>Levofloxacin (n = 5)</i>	<i>Moxifloxacin (n = 2)</i>	<i>Streptomycin (n = 4)</i>	<i>PAS (n = 6)</i>	<i>Isoniazid (n = 1)</i>	<i>Ethambutol (n = 1)</i>
Stopping the precipitating agent only (n = 26)	29 (2–120) days	3 days	4 (1–9) days	25 days	2.5 (2–3) days	1 day	–	45 (30–60) days	60 days	–
Stopping the precipitating agent and adding an antipsychotic (n = 20)	16 (2–42) days	15 (4–30) days	9 (3–24) days	12 (3–21) days	–	–	–	–	–	–
Stopping all possible agents (n = 8)	15 (2–28) days	–	–	1 day	3 days	–	32 (14–45) days	28 (14–42) days	–	2 days
Stopping all possible agents and adding antipsychotic (n = 2)	–	9 (4–14) days	–	–	–	–	–	4 days	–	–
Adding antipsychotic only (n = 3)	40 (28–60) days	–	–	–	–	–	–	–	–	–
Dose reduction of precipitating agent and adding an antipsychotic (n = 1)	–	4 days	–	–	–	–	–	–	–	–
Stopping the precipitating agent and adding convulsive therapy (n = 1)	180 days	–	–	–	–	–	–	–	–	–

symptom-free,^{19,37,46} and 1 case (8%) tolerated reintroduction using a low-dose gradual escalation.⁴⁶ A cross-sectional study also reported a 22% relapse rate with cycloserine reintroduction.⁶

DISCUSSION

The association between tuberculosis (TB) and mental illness is bidirectional. Studies report that 19–37% of individuals with preexisting mental illness, and 14% with psychosis, test positive for TB. Conversely, 50–72% of TB patients have comorbid psychiatric conditions such as depression, psychosis, or anxiety. This overlap is attributed to shared risk factors (e.g., homelessness, migration, HIV,

substance use), direct CNS involvement by TB, or neurotoxic effects of anti-TB drugs.^{69,73} Risk factors for isoniazid-induced psychosis include higher drug doses, older age, comorbid medical conditions, alcohol use, and prior psychiatric illness.⁶⁹ Psychosis caused by one anti-TB drug may also occur with others.¹³

There are several hypotheses for the mechanism behind ATDIP. For example, the high blood–brain barrier penetrability, decreased GABA, and NMDA receptor–agonism for cycloserine, ciprofloxacin, and moxifloxacin induced psychosis. Increased catecholamines due to MAO inhibition, altered NMDA in the hippocampus, and neuropathy due to depletion of pyridoxine

(vitamin B6) for isoniazid and ethionamide-induced psychosis.^{6,23} Although pyridoxine supplementation has not been found effective in the treatment of isoniazid-induced psychosis.¹⁹ The role of copper and iron chelation, mitochondrial and lysosomal toxicity has been suggested for ethambutol-induced psychosis.⁷¹

Several mechanisms have been proposed for ATDIP. Cycloserine,⁷⁴ ciprofloxacin, and moxifloxacin⁴⁷ may cause psychosis via high blood–brain barrier penetration, decreased GABA, and NMDA receptor agonism. Isoniazid and ethionamide are associated with MAO inhibition, altered hippocampal NMDA activity, and pyridoxine depletion,^{6,23} though pyridoxine supplementation is ineffective in treating isoniazid-induced psychosis.¹⁹ Ethambutol-induced psychosis may involve copper and iron chelation, and mitochondrial or lysosomal toxicity.⁷¹

Most evidence on ATDIP comes from case reports and series, with few longitudinal studies. This limited evidence poses several clinical challenges: (1) distinguishing preexisting nonorganic psychosis from organic psychosis, (2) identifying ATDIP among other organic causes, and (3) managing ATDIP—deciding which antitubercular drugs to stop, continue, or restart, and when to initiate or discontinue antipsychotics. A stepwise management approach based on this study is outlined in Figure 3.

Step 1: Distinguishing Preexisting Psychosis from Organic Psychosis

Patients on antitubercular therapy (ATT) presenting with psychosis should be assessed for preexisting psychiatric illness. Such conditions are not a contraindication to ATT and should be treated conventionally.⁶ However, preexisting psychosis may worsen, particularly with rifampicin, which lowers plasma levels of antipsychotics via CYP1A2 induction (e.g., olanzapine, clozapine, asenapine), CYP3A4 induction (e.g., aripiprazole, quetiapine, and pimozide), and PGP Efflux Transporter induction (e.g., risperidone).⁷⁵ In such cases, adjust antipsychotic doses with close monitoring for side effects.

Step 2: Ruling Out Other Organic Causes

If psychosis persists despite adequate antipsychotic treatment, other causes—such as substance use/withdrawal, seizures, dyselectrolytemia, CNS TB, AIDS, or other psychosis-inducing drugs like corticosteroids—should be excluded before diagnosing ATDIP. Corticosteroid-induced psychosis is more common and may warrant dose reduction or withdrawal before altering ATT.⁷⁶

Step 3: Managing ATDIP

New-onset psychosis during TB treatment should only be attributed to ATT after excluding other causes.

Step 3A: Discontinue Suspected Drug

If feasible, sequentially stop suspected agents: cycloserine → fluoroquinolones → isoniazid → ethionamide → ethambutol, rifampicin, streptomycin, PAS.

Step 3B: Initiate Antipsychotic Therapy

Antipsychotics may be added depending on severity and suspected drug. Isoniazid-induced psychosis improves faster when stopped along with antipsychotics than by discontinuation alone. Fluoroquinolone-induced psychosis usually resolves within a week without antipsychotics.

Haloperidol, risperidone, and olanzapine are commonly effective. Phenothiazines (e.g., thioridazine, chlorpromazine, trifluoperazine) may offer additional antimycobacterial benefit.^{69,77} Avoid clozapine due to the risk of worsening TB, especially in combination therapy.⁷⁸ Taper antipsychotics after symptom resolution.

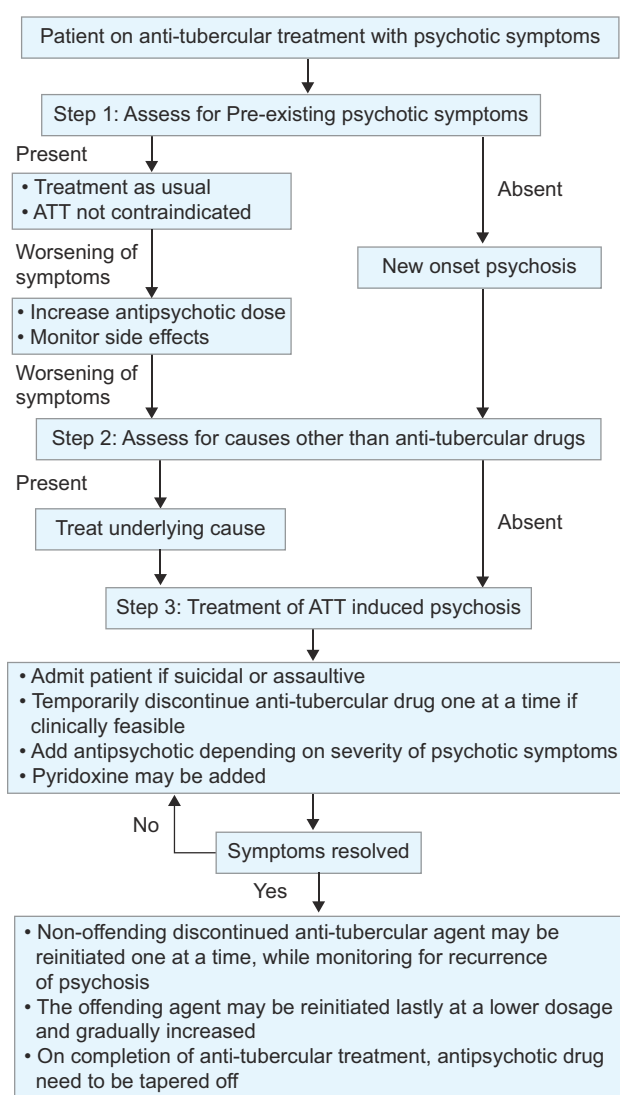


Fig. 3: Stepwise management plan for patients with anti-tubercular drug-induced psychosis

Step 3C: Stop Additional Suspected Drug

If symptoms persist, stop the next likely offending drug (per Step 3A), adjusting antipsychotic dose as needed.

Step 3D: Reintroduce ATT Gradually

Once symptoms resolve, reintroduce non-offending ATT drugs one at a time, monitoring for recurrence. If necessary, reintroduce the offending agent at a lower dose with close observation. Continue antipsychotics until TB treatment completion, then taper.

Pyridoxine (100–200 mg/day) may help with isoniazid, cycloserine, or ethionamide-induced psychosis, though its role remains unclear; however, supplementation is safe.^{2,6,19} Patients with suicidal or violent behavior should be hospitalized and closely supervised. All harmful objects and medications should be removed.

Psychosis during TB treatment can cause stigma, poor adherence, treatment failure, resistance, and mortality.⁷² Hence, healthcare providers in the DOTS program should be trained to screen for psychiatric symptoms and collaborate closely with mental health services.

Limitations

Our recommendations are primarily based on case reports and series, with few longitudinal studies, resulting in weak evidence. Only English-language literature was included, possibly missing relevant non-English articles. Due to limited access, we searched PubMed, CENTRAL, and Google Scholar, but not Scopus or Embase, which may have led to omissions. To mitigate this, we manually reviewed reference lists of selected and review articles to capture all eligible studies.

CONCLUSION

In the absence of evidence-based guidelines, our stepwise recommendations, though based on limited evidence, can assist clinicians in managing ATDIP. Randomized controlled trials are needed to develop stronger guidelines. Similar recommendations are also needed for other common psychiatric adverse effects of antitubercular drugs, such as depression and anxiety.

AUTHOR CONTRIBUTIONS

Conceptualization: SJ and AS; Literature review: Two author groups (SJ, HKK, AS, and PK, VV, AK) independently performed data extraction, resolving discrepancies through consensus; Writing – original draft: SJ and HKK; Review & editing: All authors were involved in preparation of final manuscript.

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AI USE DECLARATION

Online AI tool was used for Spelling and Grammar Check in the preparation of this manuscript.

SUPPLEMENTARY MATERIAL

The supplementary Table S1 is available online on the journal website. <https://www.onlinejima.com/journalDetails/JIMA>.

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Atypical Presentation of Chikungunya Virus Infection: More Than Meets the Eye

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ABSTRACT

Background: The recent surge in global chikungunya virus (CHIKV) outbreaks has compelled physicians and epidemiologists to concentrate on atypical symptoms because to their substantial and occasionally fatal consequences. Information regarding the unusual symptoms of CHIKV infection is scarce, with only a handful of solitary case reports and hospital-based studies accessible. A thorough assessment of the atypical symptoms is crucial for understanding the true characteristics of CHIKV infection and its effects on those afflicted.

Case descriptions: Cases 1 and 2 presented with neurological manifestations, and MRI in both cases revealed nonspecific findings, which is unusual for chikungunya. Case 3 was observed to have multiple, painful, erythematous papules with hemorrhagic crusting in the bilateral groin along with tongue erosions and oral ulcers, which is often confused for sexually transmitted infections. Similarly, cases 5 and 6 presented with a maculopapular rash. Case 4 had an unusual cardiac presentation as retrosternal pain radiating to the back and bilateral lower limb edema, and she had worsening of her leprosy symptoms.

Conclusion: Chikungunya viral infection can have a multitude of presentations, be it cutaneous, neurological, cardiac, or respiratory manifestations. Identifying the symptoms early can help provide timely management and improve overall outcomes.

Keywords: Coryza, Lepromatous leprosy, Maculopapular rash, Viral myalgia.

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INTRODUCTION

Chikungunya fever (CHIKF) is an arboviral illness induced by the chikungunya virus (CHIKV), an alphavirus belonging to the *Togaviridae* family. Transmission occurs through a human-mosquito-human cycle initiated by a mosquito bite. Symptoms manifest after 2–6 days of incubation, characterized by high fever and intense arthralgia. The condition is self-limiting and often resolves within 2 weeks.¹ Chronic illness may remain for several years, accompanied by ongoing polyarthralgia. The overlapping symptoms and shared vectors of dengue and malaria provide significant hurdles for diagnosing and treating this illness. CHIKF was initially reported in India in 1963. Following a quiescent interval of 32 years, CHIKV re-emerged in India in 2005. Every section of the nation has become endemic due to the illness, with outbreaks resulting in severe economic and production losses.¹

While chikungunya is often not deemed life-threatening, unusual clinical presentations leading to considerable morbidity have been recorded, particularly during outbreaks. CHIKV infection may lead to severe sickness requiring urgent care, accompanied by considerable death. Although some fatalities are directly linked to CHIKV infection, overall mortality also rises during outbreaks.²

Chikungunya virus (CHIKV) infection is typically regarded as a benign illness regarding mortality, as severe cases are few.^{3,4} Recent increases in CHIKV outbreaks globally have prompted doctors and epidemiologists to focus on atypical symptoms because of their significant and occasionally lethal sequelae.⁵ Information about the atypical symptoms of CHIKV infection is limited, with just a few isolated case reports and hospital-based research available.⁶ A meticulous evaluation of the unusual symptoms is essential for comprehending the actual attributes of CHIKV infection and its

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impact on affected individuals. The aims of our case series were to (1) examine the prevalence and frequency of atypical symptoms among patients and (2) ascertain demographic characteristics and concomitant diseases.

CASE DESCRIPTIONS

Case 1

A 39-year-old male patient presented to the emergency department with complaints of high-grade fever associated with chills for 4 days (103.2 °F). He had associated complaints of vomiting and headache for 4 days, followed by altered sensorium for 1 day. On examination, the patient appeared disoriented and irritable, with GCS being E4V3M6. CNS examination revealed exaggerated bilateral deep tendon reflexes and a positive Babinski reflex; the remaining systemic examination was regular. The laboratory investigation revealed HIV reactive status, with the presence of antichikungunya IgM in serum and CSF (Table 1). An MRI brain

screening was performed to confirm the diagnosis, which suggests small vessel ischemic changes (Fig. 1).

The patient was treated with IV antibiotics, steroids, and IV acyclovir 500 mg TDS with added supportive care. Due to a decline in GCS, the patient was intubated and maintained on mechanical ventilation, which was started for a drop in GCS. The patient recovered after 10 days.

Case 2

A 79-year-old male patient had chief complaints of high-grade fever and arthralgia for the past 7 days. This was associated with a history of altered sensorium and gradually progressive loss of consciousness for 2 days. On examination, the patient was febrile (temperature 102 °F), lethargic, and disoriented with a GCS of E2V4M4. The blanching rash was present all over the body. A neurological examination revealed that deep tendon reflexes were absent and that there was a mute plantar response.

The treatment was started with IV antibiotics and IV Hydration. MRI brain was suggestive of multiple small infarcts and changes of

encephalitis. Because of low GCS, the patient was intubated, and mechanical ventilation was started (Fig. 2).

Case 3

A 29-year-old male patient came to the OPD with complaints of fever, high grade (102 F), which was associated with generalized weakness, myalgia, bilateral wrist tenderness, and pruritus. On examination, the patient was observed to have multiple, painful, erythematous papules with hemorrhagic crusting in the bilateral groin and well-defined erosions present over the tongue with oral ulcers. The laboratory investigation showed a platelet count of 74,000 on admission, and serum antichikungunya IgM was positive. Sexually transmitted diseases were evaluated and ruled out. The patient was treated with supportive treatments; the patient showed significant clinical improvement with healing of the lesions. On follow-up, after 4 weeks, the patient's skin lesions were completely resolved (Fig. 3).

Case 4

A 50-year-old female patient presented to the OPD with complaints of fever and vomiting for 2 days. This was associated with chest pain, retrosternal radiating to the back, and bilateral lower limb edema. She had a known case of lepromatous leprosy with type 2 lepra reaction and systemic hypertension. On examination, the patient had multiple well-defined hyperpigmented patches to papules and nodules over the bilateral upper limb, lower limb, trunk, ears, and abdomen. She also had bilateral ulnar nerve thickening, two fluid-filled bullous lesions over her right foot, along with a tender swelling of the right knee joint. The serum antichikungunya IgM was observed to be positive and associated with thrombocytopenia (79,000/mm³). Subsequently, the patient deteriorated, suspected to be in septic shock (Procalcitonin-50 ng/mL), and was started on inotropes (noradrenaline), IV meropenem 1 gm BD with oxygen support via an NRBM. The patient recovered within 3 weeks and was discharged.

Case 5

An 18-year-old female patient came with a fever of 8 days, associated with chills (101 °F on admission), myalgia, arthralgia, and headache. A blanching rash and maculopapular rash on the trunk and back were noted during the examination. The patient

Table 1: CSF findings for case 1 and case 2

	Case 1	Case 2
CSF	Routine microscopy	
Appearance	Clear, transparent	Clear, transparent
Proteins	263.5	247.9
TLC	640	
Neutrophils-95/Lymphocytes-5	42	
Neutrophils-10%/Lymphocytes-90%		
LDH	147	145
ADA	19.2	4.8
Glucose	24	45
CSF	Culture sensitivity	
	No growth	No growth
	Antichikungunya IgM	
	Positive	Positive

CSF, Cerebrospinal fluid

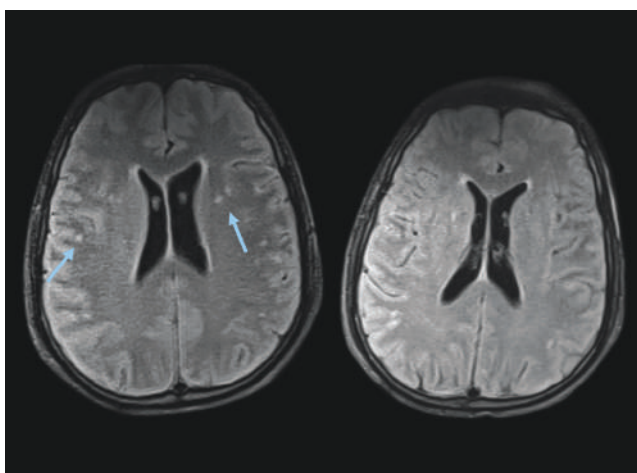


Fig. 1: Plain magnetic resonance imaging (MRI) of the brain showing multiple fluid-attenuated inversion recovery (FLAIR) hyperintensities in the bilateral corona radiata and centrum semiovale regions (blue arrow)

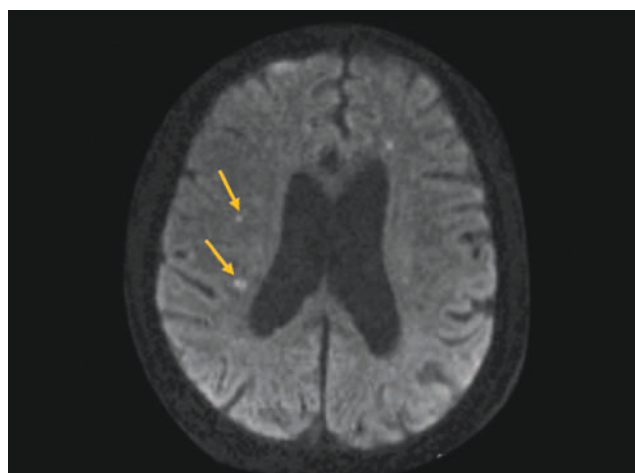


Fig. 2: Plain MRI of the brain showing multifocal tiny acute nonhemorrhagic infarcts involving the deep and periventricular white matter in the bilateral frontoparietal regions (orange arrow)



Fig. 3: Bilateral groin lesions

Table 2: Clinical manifestations and laboratory parameters

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Fever	+	+	+	+	+	+
Skin rash	–	–	+	+	+	+
Joint pain	–	–	+	+	+	+
Vomiting	+	–	–	–	–	+
Altered Sensorium	+	+	–	–	–	–
White blood cells (cells/mm ³)	9,000	9,100	3,900	2,600	3,600	3,700
Lowest platelet (cells/mm ³)	186,000	93,000	72,000	62,000	37,000	17,000
ESR	72	49	15	53	10	Not done
CRP	53.5	223.11	55	249	5.05	41.27
Ferritin		393		8,070	163	34,092
SGOT	50	94	118	143	50	2378
SGPT	29	177	176	84	21	705
ALP	98	404	146	209	62	419
Chikungunya antibody	IgM+ IgG–	IgM+ IgG–	IgM+ IgG–	IgM+ IgG–	IgM+ IgG–	IgM+
Coinfection	HIV	Absent	Absent	Absent	Dengue IgG, IgM	Dengue IgM

was started on IV antibiotics and IV fluids. Serum antichikungunya IgM and antidengue IgG IgM were detected in adequate titers. Marked thrombocytopenia was seen without any major bleeding manifestations, with a platelet count as low as 37,000. During treatment, the patient's symptoms gradually improved. Following clinical stabilization and recovery, the patient was discharged.

Case 6

A 43-year-old female came with complaints of fever, vomiting, severe abdominal pain, shortness of breath, and arthralgia for the past 2 days. On examination, a blanching rash was present with reddish discoloration in both upper limbs, lower limbs, and abdomen. Laboratory findings revealed severe thrombocytopenia, leukocytopenia, raised liver enzymes, and deranged creatinine. Ultrasound of the abdomen was suggestive of bilateral pleural effusion, mild ascites, and hepatomegaly. The serum antidengue IgM and anti-CHIKV IgM came up positive. IV hydration and IV antibiotics were started for the patient. On day 3, the patient presented with hematuria, for which four random donor platelet

(RDP) transfusions were given because of thrombocytopenia (17,000/mm³). The patient showed satisfactory clinical improvement within 1 week of treatment, with complete resolution of serositis and viral hepatitis.

DISCUSSION

This series aimed to document the unusual clinical manifestation of CHIK in India (Table 2). Atypical symptoms were seen more often in our case series than prior evidence shows. Fever was the most often reported symptom, accompanied by headache and vomiting. Only a single patient had joint discomfort. Most research indicated that the most frequently reported symptoms of CHIKV infection manifest within minutes to hours following the beginning of fever in 87–99% of patients.⁷⁹ Joint pain was recorded as the earliest symptom in the Kerala outbreak (2007), with an overall incidence of just 17%, predominantly affecting the elderly (77%) in comparison to younger age groups.¹⁰ This may signify a significant alteration in the trend of CHIKV infection and, thus, might be a focal point for future research endeavors.

The current investigation revealed that the incidence of patients exhibiting weakness and neurological symptoms was markedly lower than that observed in outbreaks in India and Singapore.⁷⁹ A study by Deeba et al.³ noted a high incidence of neurological symptoms.

A decline in blood pressure during the acute phase of CHIKV infection was noted in a lesser proportion of patients (1.6%) compared to the outbreak on Reunion Island, aligning with our case series findings, where septic shock was reported in one patient.¹¹ This unusual symptom is often described in individuals with dengue fever. However, it is hardly documented in cases of CHIKV infection. Unlike earlier outbreaks, cutaneous signs (27.1%) were less prevalent in the Dhaka epidemic, contradicting the findings of the current investigation.⁵¹²

The CHIKV virus affects the joints, resulting in tenosynovitis and enthesopathy, which manifests as arthralgia. Leprosy is linked to sensory loss, arthritis or arthralgia affecting several joints, and tenosynovitis, particularly during responses. In this case series, one patient had a deterioration of her lepromatous leprosy following the onset of chikungunya. In conjunction with joint edema, Ulnar nerve enlargement may indicate a co-infection, as shown by Nithya et al.¹³

Da Silva et al.¹⁴ conducted a systematic study and found that the predominant ocular symptoms of CHIKV infection were ocular discomfort, inflammation, and diminished visual acuity, with conjunctivitis and optic neuritis being the most prevalent manifestations of the disease. These incidents predominantly involved individuals aged 42 ± 9.5 years, primarily women. Although these symptoms have not been observed in our case series, it is crucial to diagnose them in conjunction with chikungunya.

Additionally, Chronic arthralgia in chikungunya generally involves the same joints affected during the acute phase, and the arthropathy is not usually overtly erosive.¹⁵¹⁶

CONCLUSION

A considerable body of scientific research over the past two decades indicates that CHIK should not be regarded as a benign condition, since it can cause considerable morbidity and mortality. A comprehensive understanding of this condition is essential for revising management techniques. This case series delineates the diverse atypical presentations of chikungunya infection. The information provided here would be consistently beneficial, particularly for physicians and policymakers in India, in enhancing the outcomes of future epidemics.

PATIENT CONSENT FOR PUBLICATION

Written informed consent was obtained from the patient for publication of the clinical details and images.

AUTHOR CONTRIBUTIONS

Patient Management, writing – review & editing: Dr Sachin Shivnitwar, Dr Manaswini Edara.

Data Collection, writing – original draft: Dr Sandesh Sadanand Raut.

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AI USE DECLARATION

No AI tools were used in the preparation of this manuscript.

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Multifocal Glioblastoma in a 61-year-old Woman: A Rare and Challenging Diagnosis

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ABSTRACT

Introduction: Multifocal glioblastoma is a rare and aggressive variant of glioblastoma with a poor prognosis. Management of this condition presents unique challenges in terms of diagnosis and treatment.

Case description: A 61-year-old woman presented with generalized weakness and a history of supratentorial glioblastoma following surgical resection, radiotherapy, and chemotherapy. The patient reported a gradual decline in consciousness, mild headaches, and difficulty concentrating. Magnetic resonance imaging (MRI) examination revealed multiple lesions in both frontal lobes with internal hemorrhage, compression of the left anterior cerebral artery, as well as subfalcine and uncal herniation. Positron emission tomography-computed tomography (PET-CT) did not show any systemic metastasis. Histopathological analysis confirmed glioblastoma, with immunohistochemical profiling showing a high proliferation index (Ki-67 = 94%). This indicated a highly aggressive tumor. Postchemotherapy MRI demonstrated a reduction in tumor size and edema, but a new subdural hygroma was found. The patient is currently undergoing adjuvant chemotherapy.

Conclusion: Management of multifocal glioblastoma requires an individualized and innovative therapeutic approach, given its aggressive nature and resistance to standard therapies.

Keywords: Brain tumor, Case report, Cancer therapy, Disease progression, Glioblastoma.

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INTRODUCTION

Multifocal glioblastoma is a condition with considerable implications, as it is a very rare incidence whose prevalence rates have not been specified.¹ In general, glioblastoma incidences are recorded at 3–10 cases per 1,00,000 people yearly. Among the glioblastomas, multifocal glioblastoma is one of the rarer forms compared to other forms of the disease.² It is an extremely serious condition with serious consequences; mortality rates are very high, and the average life expectancy of a person is around 14–15 months after diagnosis.³ Multifocal glioblastoma is a tumor characterized by the growth of several separate tumor lesions within the brain. Compared to solitary glioblastomas, multifocal glioblastomas have distinct presentations that create difficulties during diagnosis and treatment because of their complex nature and aggressive growth pattern.⁴ The prognosis of multifocal glioblastoma is generally worse than that of solitary glioblastomas and is usually associated with much shorter life expectancy.²

The clinical manifestations of multifocal glioblastoma are complex and can mimic other neurological disorders, complicating the diagnostic process.⁵ Modern imaging techniques such as MRI play a crucial role in detecting this condition.⁶ However, MRI results can sometimes be misinterpreted as brain metastases or other abnormalities.⁷ The complexity of diagnosing this condition underscores the need for comprehensive clinical evaluation and histopathological confirmation in order to devise an appropriate treatment strategy. In this article, we present a case of multifocal glioblastoma. This case report discusses the challenges in diagnosis, treatment options, and its impact on patient care. By discussing this multifocal glioblastoma case, we aim to contribute to the

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existing literature and further enhance understanding regarding the management of this condition in clinical practice.

CASE DESCRIPTION

A 61-year-old woman presented to the neurology department with the chief complaint of generalized weakness affecting both proximal and distal muscles, with persistent weakness not accompanied by decreased muscle tone. The patient had previously been referred from the Neurosurgery Department following resection of supratentorial cerebral glioblastoma, followed by radiotherapy and chemotherapy, and was currently undergoing adjuvant chemotherapy. The patient reported a gradual decline in consciousness and difficulty concentrating since July 2022. She also experienced mild headaches [numeric rating scale (NRS) 1–2] that occurred infrequently. The headaches occurred at any time and did not improve with rest. The patient was admitted to the hospital due to generalized weakness and has shown some improvement.

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She had undergone resection at another hospital and received concurrent chemotherapy and radiotherapy at Penang Hospital (first temozolomide treatment from 9th to 13th November 2022; currently on adjuvant temozolomide for 3 months). There was no weakness in one half of her body, no double vision, dizziness, or balance problems. There was no family history of tumors.

Neurological examination revealed a positive Brudzinsky sign in the neck, and the Karnofsky Performance Status (KPS) score indicated normal activity with some difficulties and other symptoms. Previous examinations confirmed that the brain tumor excised from the left frontal lobe was glioblastoma. Magnetic resonance imaging (MRI) scans (Fig. 1) revealed multiple lesions in both frontal lobes with internal hemorrhage, as well as compression of the left anterior cerebral artery, suggesting possible metastasis. Additionally, brain edema with a 7.2 mm rightward subfalcine herniation and uncus herniation were noted. Positron emission tomography-computed tomography (PET-CT) imaging did not detect any disease elsewhere (Fig. 2).

The patient was diagnosed with multifocal glioblastoma in August 2022 and underwent tumor resection (Fig. 3), chemoradiotherapy, and emergency ventriculoperitoneal (VP) shunt placement due to decreased consciousness. She is currently undergoing additional chemotherapy. The most recent MRI scan at our hospital (Fig. 1) shows postchemotherapy evaluation for glioblastoma. Multiple masses with hemorrhage were seen in the left frontal cortex and subcortex, as well as in the right periventricular region, consistent with glioblastoma. The

tumor size showed a reduction, resulting in reduced brain edema. The right subfalcine herniation improved, but the leftward herniation remained stable. Additionally, a new subdural hygroma was found with a thickness of about 7.8 mm in the right frontotemporal-parieto-occipital region.

Histopathological examination revealed several fragments of a high-grade malignant glial tumor. Some tumor fragments were viable

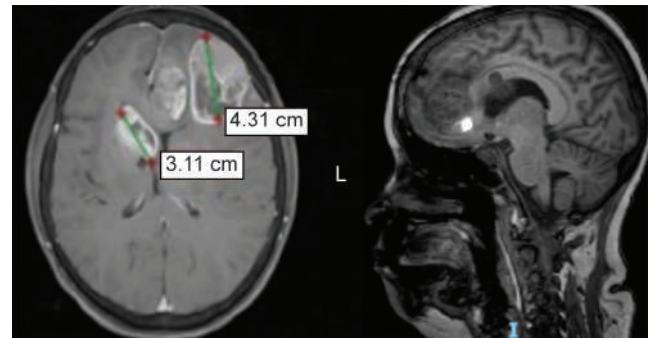
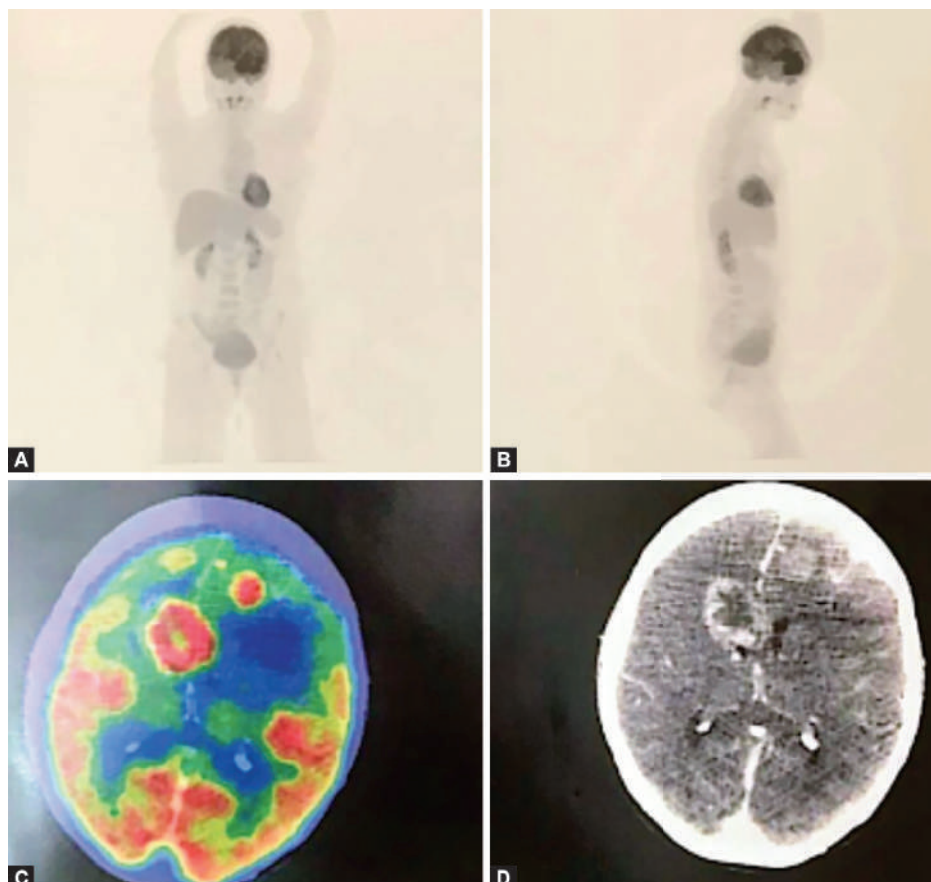


Fig. 1: Results of contrast-enhanced head MRI. The figure shows the contrast-enhanced head MRI images of the 61-year-old woman, revealing multifocal glioblastoma. Multiple enhancing lesions are observed in different regions of the brain, consistent with the diagnosis of multifocal glioblastoma



Figs 2A to D: (A) Whole-body anterior maximum intensity projection (MIP) image from the ¹⁸F-FDG PET-CT scan showing increased fluorodeoxyglucose uptake in multiple intracranial lesions; (B) Whole-body lateral maximum intensity projection (MIP) image from the ¹⁸F-FDG PET-CT scan demonstrating the distribution of metabolically active intracranial lesions; (C) Axial fused ¹⁸F-FDG PET-CT image of the brain showing marked hypermetabolism in multiple glioblastoma lesions; (D) Corresponding axial CT image of the brain demonstrating multiple glioblastoma lesions, correlating with the hypermetabolic foci observed on the fused PET-CT image

and highly cellular, while others were largely infarcted, necrotic, and hemorrhagic. The malignant cells showed significant pleomorphism and frequent mitotic activity. The cells were round or polygonal

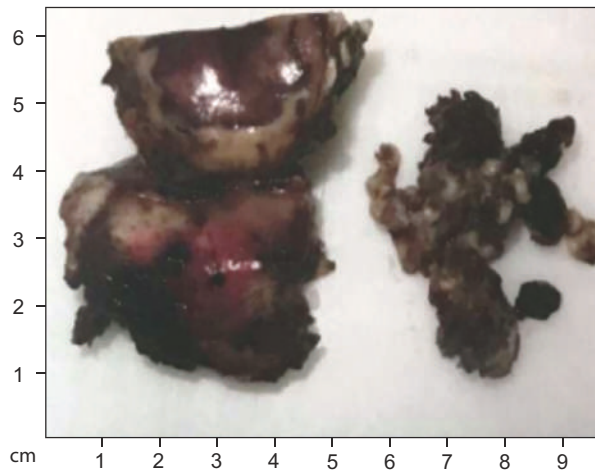


Fig. 3: Excised brain tumor mass from the left frontal region. The figure shows the excised tumor mass obtained from the left frontal region of the brain. The specimen is characterized by its irregular shape and firm consistency, consistent with the histopathologic features of glioblastoma. The tumor tissue was carefully removed during surgery for further analysis and confirmation of the diagnosis of multifocal glioblastoma

with poorly defined eosinophilic cytoplasm, and many had large, hyperchromatic nuclei. Multinucleated giant tumor cells were also observed. The specimen showed extensive thermocoagulation artifacts. Histopathological findings indicated that the excised mass from the left frontal lobe exhibited histological features highly suggestive of glioblastoma. Immunohistochemical examination showed that the neoplastic cells were strongly positive (3+) for glial fibrillary acidic protein (GFAP), S-100, alpha-thalassemia/mental retardation syndrome X-linked (ATRX), p53, and vimentin, with focal positivity for cluster of differentiation 99 (CD99) and SRY-box transcription factor 10 (SOX10). The cells were negative for synaptophysin, chromogranin, AE1/AE3, and neuron-specific enolase (NSE). The Ki-67 proliferation index was 94%. The immunohistochemical profile of the dominant tumor in the left frontal lobe indicated that the lesion was glioblastoma.

In this case, the patient underwent combination therapy consisting of chemotherapy and radiotherapy. Chemotherapy was administered using temozolomide at a dose of 75 mg/m² per day, given daily for 6 consecutive weeks. Additionally, the patient received radiotherapy with a total dose of 60 Gy, delivered in 30 fractions over a 6-week period. Following the initial treatment phase, the patient was given adjuvant chemotherapy with temozolomide at a dose of 200 mg/m² per day for 5 days in every 28-day cycle. This was followed by six cycles of maintenance chemotherapy, with temozolomide administered at a dose of 150–200 mg/m² per day for 5 days in each monthly cycle.

Postoperative MRI (Fig. 4) revealed a surgical resection cavity with no evidence of residual tumor, indicating successful gross-total resection. Considering the patient's clinical history and the

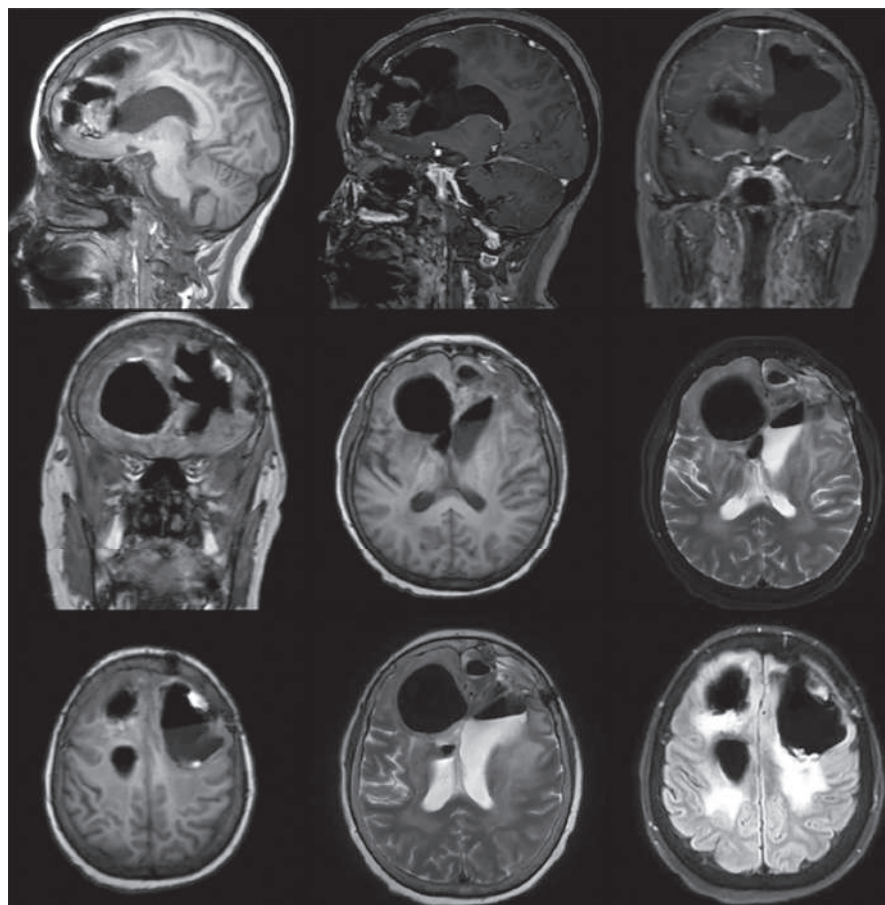


Fig. 4: Postoperative MRI of the patient showing the surgical resection cavity with no evidence of residual tumor

aggressive nature of glioblastoma, the differential diagnoses considered in this case included brain metastases from systemic malignancy, primary central nervous system lymphoma, multifocal or multicentric glioblastoma, demyelinating disease such as multiple sclerosis, and infectious or inflammatory lesions.

In the follow-up, the patient was in a stable neurological condition, with a Glasgow Coma Scale (GCS) score of 4-5-6, indicating a *compos mentis* state. Motor strength was full (5/5) in both the upper and lower extremities. Babinski reflex was negative bilaterally, no pathological reflexes were observed, and muscle tone was within normal limits. There were no motor deficits, and cranial nerve examination showed no abnormalities from the olfactory nerve (cranial nerve I) to the hypoglossal nerve (cranial nerve XII). Laboratory findings revealed a hemoglobin level of 12.5 gm/dL, a leukocyte count of 7,110/ μ L, and a platelet count of 91,000/ μ L. Liver function tests showed aspartate aminotransferase/alanine aminotransferase (AST/ALT) levels of 13/24 U/L. Renal function was within normal limits, with urea at 20.2 mg/dL and creatinine at 0.19 mg/dL. Serum albumin was slightly decreased at 3.22 gm/dL.

DISCUSSION

This article reports the case of a 61-year-old woman with multifocal glioblastoma. This case report highlights the diagnostic and therapeutic challenges of this rare variant of glioblastoma. With radiological characteristics often resembling brain metastases, accurate diagnosis is essential to ensure proper management. Multifocal glioblastoma requires an individualized approach due to its resistance to conventional therapies and the absence of standard treatment protocols.⁸ Previously, cases of glioblastoma in children,⁹ football players,¹⁰ and others have also been reported. This is the first case reported in Indonesia. It can enhance understanding of the diversity of glioblastoma characteristics in Indonesia.

The case we report is a case of glioblastoma in a 61-year-old woman. Multifocal glioblastoma is the most aggressive primary central nervous system (CNS) tumor in adults, with an average survival time of 14–15 months after conventional therapy, including surgery, radiation, and chemotherapy.¹ Although there have been advances in therapy for this condition, most patients still have a poor prognosis. Regarding treatment options for this case, the Food and Drug Administration (FDA) currently approves radiation, temozolomide (TMZ), and tumor treating fields (TTF) as standard therapies, while novel therapies such as boron neutron capture therapy (BNCT), immunotherapy, epigenetic therapy, and gene therapy show promising results but remain limited to clinical research.¹¹

In this case, imaging modalities play an important role in diagnosing glioblastoma. On imaging, multifocal glioblastoma may appear as multiple lesions with distinct patterns of spread, either multifocal with microscopic connections between lesions or multicentric without such connections.¹² This identification is crucial as it has implications for diagnostic and therapeutic approaches. Although the pathogenic mechanism of multifocality is not yet fully understood, the diffuse and invasive nature of glial cells in multifocal glioblastoma is believed to contribute to its poor prognosis and resistance to therapy.¹³

This case report has several benefits and clinical implications. First, this case report underlines the challenges in the diagnosis and management of multifocal glioblastoma, considering its poor prognosis and resistance to therapy. This report underlines the need for an individual approach for each patient. Second,

multifocal glioblastoma is a rare condition, and this case report helps enrich the literature with a detailed description of its clinical, radiological, and pathological characteristics.¹⁴ Third, this report could provide further data on treatment options, such as surgical, radiotherapy, or chemotherapy choices, especially in multifocal cases that carry a worse prognosis than solitary glioblastoma. Fourth, given the age of 61 years in this patient, this study offers more information on the presentation of glioblastoma in the elderly population and its implications for prognosis and tolerance to therapy. Fifth, understanding the multifocal pattern will further help clinicians develop therapeutic strategies that are more customized to individual patients, considering not just treatment *per se* but also quality of life. Further research needs to be carried out on the pathogenesis of multifocal glioblastoma, as well as the development of therapeutic strategies that consider its diffuse and invasive characteristics.

The following are the limitations of this case report. First, this study reports only one case; thus, our findings cannot be generalized to other patients with multifocal glioblastoma. This limitation diminishes the strength of this study in drawing universal conclusions. Second, this study lacks data on in-depth genetic or molecular analyses, such as isocitrate dehydrogenase 1/isocitrate dehydrogenase 2 (IDH1/IDH2) mutations or O-6-methylguanine-DNA methyltransferase (MGMT) promoter methylation status, which could provide deeper insights into tumor characteristics and responses to therapy. Third, long-term follow-up of the patient's condition, such as overall survival or progression-free survival, was not reported in this study.

CONCLUSION

This case report emphasizes the complexity of diagnosing and treating multifocal glioblastoma. The management of this condition requires a comprehensive approach that takes individual circumstances into account. It is crucial to innovate and modify therapies tailored to the patient. Further research is needed to better understand the pathogenesis of multifocal glioblastoma, improve diagnostic accuracy, and develop more effective treatment strategies to extend patient survival.

PATIENT CONSENT FOR PUBLICATION

Oral informed consent for publication was obtained from the patient during clinical care. The patient subsequently passed away, and written documentation of consent is no longer available. The case has been fully anonymized, and no identifiable personal information has been included to protect the patient's privacy.

AUTHOR CONTRIBUTIONS

Wahyuni Ramadhani Suaib: Conceptualization, investigation, data curation, formal analysis, resources, project administration, visualization, methodology, writing – original draft, writing – review & editing.

Dessika Rahmawati: Supervision, validation, writing – review & editing.

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The authors sincerely acknowledge the patient and the patient's family. They hope that sharing this case will contribute to improving medical knowledge and the care of patients with similar conditions.

AI Use Declaration

The authors declare that no artificial intelligence (AI) tools were used in the preparation of this manuscript.

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A Curious Case of Consciousness

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ABSTRACT

Pyrexia of unknown origin (PUO) is a grouping of myriad unrelated afflictions that share the feature of persistent unexplained fever despite basic investigations. Fever frequently affects consciousness. We present a case of an elderly female who we evaluated. She was diagnosed with scrub typhus on D (day)1 with immunological assay, and additionally diagnosed with urinary tract infection (UTI) on D3 with microbiological assay. She developed progressive hepatic encephalopathy from D3, which responded to conservative management, but even after completion of the antibiotic course for the scrub typhus and UTI, her febrile episodes failed to resolve. Her sensorium again worsened from D5. Meanwhile, her antinuclear antibody (ANA) profile suggested differentials of neuro-lupus and autoimmune hepatitis. She was put on corticosteroids and subsequently on Rituximab, required inotropic support, and although her fever resolved, she developed acute kidney injury (AKI), which required further rescue hemodialysis. She finally improved from D22 onwards and made an acceptable recovery. Her case again highlights the high likelihood of noninfective autoimmune etiology in long-standing PUO and the need for judicious clinical acumen in resource-poor settings in developing nations.

Keywords: Altered sensorium, Autoimmune hepatitis, Case report, Hepatic encephalopathy, Neuropsychiatric systemic lupus erythematosus (Neuro-lupus), Pyrexia of unknown origin (PUO), Scrub typhus.

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INTRODUCTION

Consciousness is the state or quality of being aware of one's existence, sensations, thoughts, and surroundings. It is a complex and multifaceted phenomenon that is still not fully understood by science. Altered sensorium can manifest as confusion, disorientation, dizziness, decreased alertness, including coma. It can be caused by various factors such as infection, head injury, medication side effects, metabolic imbalances, substance abuse, and neurological or other medical conditions. It may be a sign of a serious underlying issue. Medical literature focuses on the most common cause of altered sensorium with fever: infection, resulting in meningoencephalitis. Scrub typhus is one of the most common zoonotic infections causing central nervous involvement along with hepatic and renal dysfunctions in the tropics. However, it is quite challenging to rule out the exact cause of impaired consciousness after ruling out infection and correcting metabolic abnormalities. We should always keep in mind that autoimmune etiology such as systemic lupus erythematosus (SLE) can cause fever, altered sensorium, and multiorgan involvement. We report a case of scrub typhus infection complicated with probable autoimmune hepatitis and neurolupus, and our journey toward a case of impaired consciousness made us curious to reach the ultimate diagnosis and a satisfactory outcome. The principle of Occam's razor posits that physicians should focus on a single etiological cause for a given set of symptoms rather than considering multiple unrelated conditions. This principle is applicable to many medical diagnoses. However, our case aligns more closely with Hickam's dictum, which indicates that two or more unrelated etiologies may be present rather than a singular, unifying explanation.

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CASE DESCRIPTION

A 67-year-old female presented with fever, cough, and generalized weakness for the last 22 days, during which she had continued to take over-the-counter medications and herbal concoctions. Fever was high-grade, continuous, and accompanied by chills and rigors. She complained of dry cough, muscle ache, and joint pain. She denied any history of headache (unilateral or retro-orbital), vomiting, jaw claudication, night sweats, weight loss, or altered sensorium. She was a known case of type 2 diabetes mellitus, hypertension, and hypothyroidism for which she was on pharmacotherapy.



On examination, she was febrile (temp 40°C), had tachypnea and tachycardia, and normal sensorium. She had mild pallor, but no petechial rash, palpable lymphadenopathy, or eschar was found. Blood pressure was 96/50 mm Hg, pulse rate was 130 bpm, oxygen saturation was 95% in room air, respiratory rate was 24/min, and considering her raised quick sequential organ failure assessment (qSOFA) score, she was put on broad-spectrum antibiotics (Cefoperazone–Sulbactam as per departmental protocol), and a full battery of investigations was initiated.

D (day) 1 tests for malaria parasite dual antigen (MPDA), thick and thin smears, typhoid IgM and IgG, dengue NS1 and IgM assay, HBsAg, anti-HCV, VDRL, HIV (1 and 2) were negative. Scrub typhus IgM was positive in the enzyme-linked immunosorbent assay (ELISA) test, and intravenous doxycycline was added. D1 reports also revealed the first evidence of altered hematological parameters, including low hemoglobin levels and neutrophilic leukocytosis, and raised C-reactive protein (203.5). Deranged LFT (liver function test) with significantly raised transaminases and altered RFT (renal function test) with raised urea and creatinine values were distinct findings. Urine examination showed 6–8 pus cells in high-power field and trace protein. Chest X-ray (D1) showed prominent bilateral pulmonary vasculature markings, mild blunting of the left costophrenic angle and apparent cardiomegaly. Arterial blood gas analysis showed respiratory alkalosis with a lactate level of 1.98 mmol/L, which was corrected subsequently. Ultrasonography of the whole abdomen (D1) revealed hepatosplenomegaly. A straight X-ray abdomen revealed no abnormality. Normal-sized cardiac chambers and grade I diastolic dysfunction with left ventricular ejection fraction 61% were reported in echocardiography on D2. Urine culture (available on D3) showed growth of *Klebsiella* after 72 hours of incubation with colony count 142,000 CFU/mL, and based on reports injection meropenem was initiated (cefoperazone–sulbactam was stopped as the reports showed resistance and there was no clinical improvement). Contrast-enhanced computed tomography thorax (D3, the creatinine values had almost normalized by the 3rd day) revealed ill-defined areas of ground glass opacification in posterior segments of bilateral lungs, likely pulmonary edema and bilateral mild pleural effusion. The evidence of anemia, serositis, altered LFT and renal function tests, with the primary presentation of long-standing PUO, prompted us to test for ANA (full profile with Hep-2 assay).

Central venous catheterization was done, and fluid resuscitation with central venous pressure monitoring. Oxygen support was added depending on requirement from day 3. Considering the hypoalbuminemia, 5% human albumin was transfused. From day 4, she became drowsy and a nasogastric tube was inserted.

Noncontrast computed tomography of the brain was done to rule out cerebrovascular accident (CVA), which suggested chronic small vessel ischemic changes and mild cerebral volume loss.

Increased ammonia levels raised a suspicion of hepatic encephalopathy. Lactulose enema and oral lactulose and oral rifaximin were started. Patient was afebrile, but drowsiness persisted. On day 5, the report of the ANA profile was received, and the patient was diagnosed with probable autoimmune hepatitis. She was not a candidate for liver biopsy and was found negative on the comb test. ANA was found to be positive at a 1:320 titer on the immunofluorescence method. Anti-LKM1 antibody was subsequently positive. Keeping in mind autoimmune hepatitis, intravenous steroids were added. Decreased hemoglobin level and altered coagulation profile were treated with three units of packed red blood cells and 3 units of fresh frozen plasma on day

6. As there was melena, terlipressin was added for hepatorenal syndrome (HRS). 5% albumin was transfused on day 7. The patient was still drowsy with adequate urine output and no fever. On day 8, the patient was reevaluated as having completed treatment with doxycycline and optimized treatment of hepatic encephalopathy. Her serum ammonia decreased with stable vitals, but drowsiness persists. Injection rituximab was planned according to protocol, as anti-dsDNA was positive and it raised suspicion of neuro lupus in our mind as one possibility. Surprisingly, she was conscious and alert from day 9 with a GCS (Glasgow Coma Scale) of 13 out of 15. Limb physiotherapy and positioning were started from day 10. Oxygen support was tapered down and stopped.

On day 12, a swelling appeared on the right side of the neck. ENT (ear–nose–throat) opinion was taken regarding the swelling.

Ultrasonography of the neck showed a vascular space-occupying lesion (26.73 × 18.80 mm) in the right supraclavicular space with pulsatile flow in the approximately subclavian vessels. Contrast-enhanced computed tomography of the neck showed a few (3–4) well-defined hypodense-enhancing lesions in the right infraclavicular region, likely lymph nodes. Fine needle aspiration cytology from the swelling was suggestive of an organized inflammatory lesion with scattered polymorphs, histiocytes, lymphocytes, and occasional plasma cells in a fatty background mixed with blood.

On day 14, there was sudden onset respiratory distress in the morning with oxygen saturation of 72% on oxygen. Four units of fresh frozen plasma were transfused due to fresh bleeding from the mouth. Diuretics were added depending on the fluid volume status of the patient. Urine output decreased from day 20. Her consciousness status decreased again to 8 out of 15, and metabolic acidosis was noted on arterial blood gas analysis. A provisional diagnosis of uremic encephalopathy was made, and we started rescue hemodialysis. On day 24, the patient was fully conscious and alert with stable vitals. She was reasonably stable without any oxygen support.

On day 26, at last, she was discharged with oral antibiotics, oral steroids, and lactulose syrup apart from other supportive therapy.

She was followed up in medicine outpatient after seven days and found to have a reasonably acceptable outcome with stable vitals and settled inflammatory markers. Her renal and liver function tests were in an acceptable range, and she can manage 6 feet of walking with little help.

DISCUSSION

Identifying a reversible cause in critical care is of utmost importance. Following the initial stabilization of the patient, a swift investigation to determine the causative agent or to implement source reduction becomes a fundamental aspect of the treatment strategy. Nevertheless, the limited capacity for clinical examination and the patient's relative immobility often impede the identification of diagnostic cues in many critical scenarios.

Scrub typhus, a zoonotic disease prevalent in this region, is increasingly recognized as a causative factor of meningoencephalitis.^{1,2} A study indicates that altered sensorium, seizures, and signs of meningeal irritation are observed in up to 56%, 46%, and 49% of meningoencephalitis cases, respectively.³ However, swift diagnosis through immunofluorescence testing and treatment with doxycycline is effective in curing most cases.

Clouding of Consciousness

Table 1: Serial blood parameters

Parameters																	
Unit	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	D13	D15	D17	D21	D22
Hb (Hemoglobin) gm/dL	9.9		9.9		7.4	7.6		8.1	8.4				9.3	9.2		8.7	
TLC (Total leukocyte count) /cumm	10,270		10,050			6,770		7,900	7,240			11,600	6,930	9,530		12,130	
DLC (Differential leukocyte count) N/L/M/E %	84/14/ 1/1		79/19 /1/1			82/16 1/1		85/13 /1/1	90/8/ 1/1			87/11 /1/1	87/11 /1/1	81/17 /1/1		88/10 /1/1	
PLT (Platelet)	1.68								1.65					1.72			
Lac																	
ESR (Erythrocyte sedi- mentation rate) mm in 1st hour	64					52		48	28				32	46			
PT (Prothrombin time) second		20			20	19.2					18		17.3	18.2			
APTT (Activated partial thromboplastin time) second		34.2			28.7	42.7					22.5		20.4	19.2			
INR (International normalization ratio)		1.54			1.55	2.48					1.38		1.32	1.39			
–																	
Urea mg/dL	78	90.2	95.3			136.6	116	127.3	117.1	93		71	70.9	70	62	177	192
Creatinine mg/dL	2.6	2.4	1.6			1.5	1.4	1.4	1.5	0.9		0.8	1.0	1.3	1.1	4.9	5.0
Sodium mmol/L	128.6		129.8	132.2		138.2		139.6	145			150.8	151.1	152.1	145.4	144.6	
Potassium mmol/L	5.43		4.39	5.27		5.14		5.03	4.66			3.74	4.24	3.43	2.73	3.75	
Total protein gm/dL	5.4		5.7		5.7			6.6			6.7			5.8			
Albumin gm/dL	2.5		2.3		2.4			3.4			3.4			3.2			
Globulin gm/dL	2.9		3.4		3.3			3.2			3.3			2.6			
Total bilirubin mg/dL	2.5		3.9		2.4			1.7			1.6			1.7			
Direct bilirubin mg/dL	1.1		1.6		1.1			0.5			0.5			0.5			
Indirect bilirubin mg/dL	1.4		2.3		1.3			1.2			1.1			1.2			

Contd...

Clouding of Consciousness

Contd...

Parameters																	
Unit	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	D13	D15	D17	D21	D22
Alanine amino-transferase U/L	72		67		64			46			51			48			
Aspartate amino-transferase U/L	113		112		132			53			59			50			
Alkaline phosphatase U/L	313		279		256			229			140			138			
Fasting glucose mg/dL	100																
Postprandial glucose mg/dL		190															
Glycated hemoglobin %	6.4																
C-reactive protein mg/dL	203.5		169.7			32.3			28.3			20.2		79.8		163.2	
Thyroid stimulating hormone μIU/mL	2.998																
Ammonia μg/dL				126		169	366	235	205	296	157	128	116.2	88.8	127	102.4	98.9
Anti-dsDNA IU/mL						365.12										30.10	
Complement 3 mg/dL																107	
Complement 4 mg/dL																38.8	

Our patient, who presented with acute febrile illness accompanied by multiorgan involvement, tested positive for scrub typhus. Despite administering doxycycline, we were unable to improve her sensorium and vital signs, raising concerns about our initial assessment of complicated scrub typhus.

Liver dysfunction associated with systemic lupus erythematosus (SLE) can arise from various factors, including drug-induced effects, the disease itself, fatty liver, autoimmune hepatitis (AIH), primary biliary cirrhosis, cholangitis, as well as alcohol or viral hepatitis.⁴ It is important to note that lupus hepatitis and autoimmune hepatitis are two separate immunological disorders affecting the liver, both of which can exhibit similar clinical, laboratory, and systemic manifestations, thereby complicating the diagnostic process.⁵

Hepatic encephalopathy is relatively uncommon in cases of autoimmune hepatitis and typically presents as a late manifestation of liver involvement in SLE.⁶ A definitive diagnosis of autoimmune hepatitis necessitates histopathological evaluation.⁷ We established a probable diagnosis of autoimmune hepatitis based on positive autoimmune markers and negative serological results for hepatotropic viruses. Our patient exhibited altered consciousness and elevated serum ammonia levels, along with impaired liver function. A provisional diagnosis of hepatic encephalopathy alongside autoimmune hepatitis was

considered within the diagnostic framework. However, despite successfully stabilizing the liver's synthetic and metabolic functions, we were unable to achieve a significant improvement in consciousness.

The patient was diagnosed with lupus, exhibiting a high titer of antinuclear antibodies (ANA), along with symptoms such as fever, serositis, delirium, and positive anti-dsDNA results, suggesting potential hepatic and neurological involvement.⁸ A cerebrospinal fluid (CSF) analysis ruled out other infectious causes of meningoencephalitis. Following the initiation of steroid treatment for autoimmune hepatitis, we decided to administer rituximab (anti-CD20).

Remarkably, the patient demonstrated a rapid improvement in cognitive function. However, she later developed acute kidney injury accompanied by uremia, which was effectively managed through hemodialysis. Notable overall improvement was observed starting from day three post-Rituximab infusion.

After an extended stay in the intensive care unit lasting over three weeks, amid the complex etiological considerations regarding the encephalopathy, we ultimately achieved a satisfactory outcome. We faced challenges related to multiorgan involvement with multiple potential etiologies occurring simultaneously. We aim to share our experience to enhance existing knowledge within the medical literature (Table 1).

CONCLUSION

This case underscores the diagnostic complexity of prolonged pyrexia of unknown origin with altered consciousness and multiorgan dysfunction. Although scrub typhus was identified and treated, persistent fever and encephalopathy prompted further assessment, leading to recognition of concurrent autoimmune hepatitis and probable neuropsychiatric systemic lupus erythematosus. The patient's favorable outcome following prompt immunosuppressive therapy highlights the importance of considering coexisting autoimmune disorders when clinical improvement remains inadequate despite appropriate antimicrobial treatment. This report reaffirms the relevance of Hickam's dictum in complex clinical practice and stresses the need for a systematic, multidisciplinary approach to PUO in resource-limited settings.

INFORMED CONSENT

Written informed consent was obtained from the patient for publication of the clinical details.

AUTHOR CONTRIBUTIONS

KG and SDC: Patient management; review and editing.

SG: Patient management, data collection, and writing – original draft.

RG: Data collection and writing – original draft.

All authors reviewed and approved the final version of the manuscript.

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AI USE DECLARATION

The authors acknowledge the use of AI-assisted tools, including Grammarly, for language editing, structural suggestions, and proofreading during manuscript preparation. The final version of the manuscript was written, reviewed, and approved entirely by the authors, and no AI-generated content has been included as original research material.

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A Perfect Storm in a Young Male: Ischemic Stroke and Thyroid Storm Unmasking Hyperthyroidism

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ABSTRACT

Thyroid storm is a rare life-threatening presentation of Graves' disease. Ischemic stroke without atrial fibrillation coexisting with thyroid storm is even rarer and has high mortality. Early diagnosis and appropriate simultaneous management of both diseases can reduce the morbidity and mortality significantly. The authors report a case of hyperthyroidism presenting with ischemic stroke and thyroid storm in a young adult, which is the first case reported from India and the second in the world.

Keywords: Case report, Hyperthyroidism, Ischemic stroke, Thyroid storm, Young stroke.

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KEY MESSAGE

In a young stroke patient with sudden deterioration, it is imperative to rule out thyroid disorders even in the absence of atrial fibrillation, as early diagnosis and prompt aggressive simultaneous management of both diseases reduces morbidity and mortality significantly.

INTRODUCTION

Hyperthyroidism presenting as ischemic stroke with thyroid storm is very rare. Ischemic stroke can be a precipitating factor for thyroid storm, or the thyroid storm may lead to arrhythmias and cardiomyopathy, which may lead to an ischemic stroke. The prevalence of hyperthyroidism is 1.3% in India.¹ Thyroid storm is an acute severe manifestation of thyrotoxicosis which is seen in approximately 1–2% of cases. It has a mortality of 10–30% in spite of advances in treatment.^{2,3} Here we describe the case of a young gentleman presenting with ischemic stroke and thyroid storm.

CASE PRESENTATION

A 31-year-old nondiabetic, nonhypertensive gentleman presented with high-grade continuous fever, altered sensorium, left-sided paralysis, and breathlessness for 3 days. He had no history of headache, convulsions, palpitations, aura, vomiting, chest pain, dyspnea, or ear discharge. Three days earlier, he was completely healthy when he suddenly experienced dizziness followed by altered sensorium. He was previously admitted to another hospital, and his past medical history was insignificant. He did not use tobacco or alcohol. He was diagnosed with left hemiplegia, and the CT scan of his brain showed a right temporoparietal occipital infarct, for which he received thrombolysis with tenecteplase. Over the next 24 hours, his condition deteriorated, and he was transferred to our hospital under a neurosurgeon's care. Unfortunately, we had no access to his previous medical reports at the time of admission.

On admission, he appeared thin and in distress. He had a high fever (104°F), tachycardia (140/minute, regular rhythm), hypotension, hypoxia, and E2V1M1. On pulmonary examination,

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bilateral rales were noted. He was then intubated and transferred to the intensive care unit (ICU), and supportive treatment was started. Investigations revealed leukocytosis with neutrophilia, metabolic acidosis, high C-reactive protein, blood glucose, and creatinine levels (Table 1). Chest X-ray showed pulmonary congestion. Blood cultures were negative. ECG showed sinus tachycardia and left ventricular hypertrophy with a strain pattern. A repeat CT scan of the brain confirmed right temporoparietal occipital infarct with linear hyperdensity and midline shift to the left (Fig. 1).

The patient's high fever, low blood pressure, tachycardia, and hypoxemia raised concern for sepsis leading to a diagnosis of ischemic stroke with septicemia and metabolic acidosis. He was started on broad-spectrum antibiotics with supportive treatment. A neurologist was consulted, and further investigations revealed high homocysteine, positive troponin I, and low TSH. An echocardiogram showed global hypokinesia with reduced ejection fraction (40–45%), leading to a diagnosis of stress cardiomyopathy.

On the fourth day of admission, in view of the low TSH, an endocrinology opinion was sought. The patient was maintaining vital

Table 1: Laboratory values

Investigation	On admission	On the fourth day of admission	On discharge	Reference range
Hemoglobin	12.5	11.3	12.4	12–15 gm/dL
Total count	22,900	14,600	7,500	6,000–10,000 cells/mm ³
Differential count	90/5/2/3	70/25/2/3	72/25/2/2	
Platelet count	2.6	2.55	2.69	1.5–3.5 lakh/ μ L
Serum creatinine	1.98	1.09	0.89	0.6–1.2 mg/dL
Alanine aminotransferase	36		42	16–64 U/L
Random blood glucose	240	140	160	<200 mg/dL
C-reactive protein	359	110	6.9	0–5 mg/L
Serum sodium	131		137	135–145 mmol/L
Serum potassium	3.79	4.23	3.87	3.5–5.0 mmol/L
Total cholesterol	162			200–239 mg/dL
Triglyceride	117			150–199 mg/dL
LDL	65			<100 mg/dL
HDL	17			40–60 mg/dL
ABG				
pH	7.26			7.35–7.45
pO ₂	78			80–105 mm Hg
pCO ₂	36.9			35–45 mm Hg
Oxygen saturation	86			95–98%
Bicarbonate	16.7			22–26 mmol/L
Base excess	–10			–2 to 3.0 mmol/L
Urine acetone	Absent			
Homocysteine		>50		<15 μ mol/L
TSH		0.02		0.5–5.0 mIU/L
Troponin I		0.32		0–0.04 ng/mL
HbA1c		7.2%		<6%



Fig. 1: CT scan brain showed acute large right temporoparietal occipital infarct with linear hyperdensity within - could be reperfusion and mass effect in form of uncus bulging on right side, compression of right lateral and third ventricles and 7.6 mm midline shift to the left

signs with inotropic and ventilatory support. Despite treatment, he continued to have tachycardia, bilateral rales, and altered sensorium. On further evaluation, he had a firm, nontender goiter measuring 2 × 2 cm, without lymphadenopathy. On persistent questioning,

the patient's relatives confirmed that his younger brother had hypothyroidism. In view of the goiter, family history of hypothyroidism, and low TSH, he was further investigated to rule out thyrotoxicosis with thyroid storm or Hashimoto's encephalopathy. On further evaluation, free T3, free T4, anti-TPO antibodies, anti-TRAb antibodies, and anti-GAD antibodies were significantly elevated (Table 2).

As a result, the patient was diagnosed with hyperthyroidism with thyroid storm and latent autoimmune diabetes in adults (LADA). In view of the patient's poor condition, a thyroid scan was deferred, and he was started on neomercazole, glucocorticoids and a low dose of propranolol as he had hypotension. Over the next 2 days, his general condition, level of consciousness and hemiparesis (left upper limb 0/5, left lower limb 3/5) improved. Inotropic and ventilatory support was gradually withdrawn, and his vitals returned to normal. He was transferred to the ward. On the 10th day of admission, MRI of the brain showed a right temporoparietal occipital infarct with no midline shift (Fig. 2). MR angiogram showed mild to moderate narrowing of M1 and M2 segments of the right middle cerebral artery with paucity of distal flow and the need to rule out vasculitis (Fig. 3). An ANA profile and antiphospholipid antibodies were negative.

On discharge, he had hemiparesis (left upper limb 0/5, lower limb 4/5), fair glycemia, and normal routine investigations except for low TSH. Echo was also normal.

At 1-month follow-up, he had monoparesis with power of 3/5 in the left upper limb. He had normal free T3 and free T4 with

Table 2: Thyroid function tests and antibody values

Investigation	Baseline	On discharge	On follow-up	Reference range
Free T3	6.16	3.9	3.8	2.3–4.2 pg/mL
Free T4	3.36	1.6	1.3	0.8–1.7 ng/dL
TSH*	0.02	0.01	0.1	0.5–5.0 mIU/L
Anti-TPO antibodies†	>1000			0–5.6 IU/L
Anti-TRAb antibodies‡	110			<1.2 IU/L
Anti-GAD antibodies§	135			<5.0 IU/L

*Thyroid-stimulating hormone; †anti-thyroid peroxidase antibodies; ‡TSH receptor antibodies; §glutamic acid decarboxylase autoantibodies

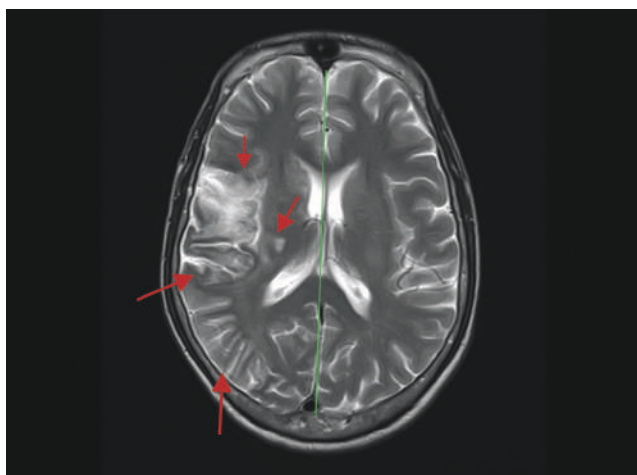


Fig. 2: MRI brain axial T2W image showed well defined hyperintense areas of subacute infarcts (Red arrows) involving cortex and white matter of parts of right insula, right frontal and right parieto-occipital lobes without significant mass effect or midline shift

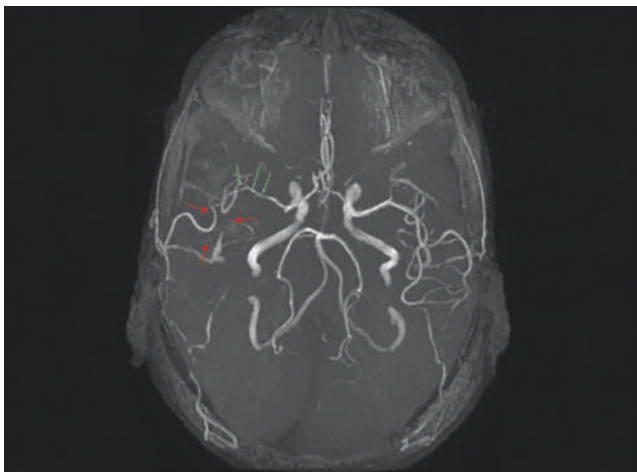


Fig. 3: Time of flight (TOF) MR angiography images of brain showed mild to moderate diffuse long segment narrowing of M1 and M2 segments of right middle cerebral artery (Green arrows) with paucity of its distal branches (Red arrows) as compared to contralateral side

borderline low TSH. A thyroid scan was suggestive of Graves' disease (Fig. 4). The glucocorticoids were tapered off and stopped, and the patient was maintained on neomercazole. The insulin was stopped, and glycemia was controlled by diet.

The final diagnosis was Graves' disease presenting as thyroid storm and ischemic stroke with LADA.

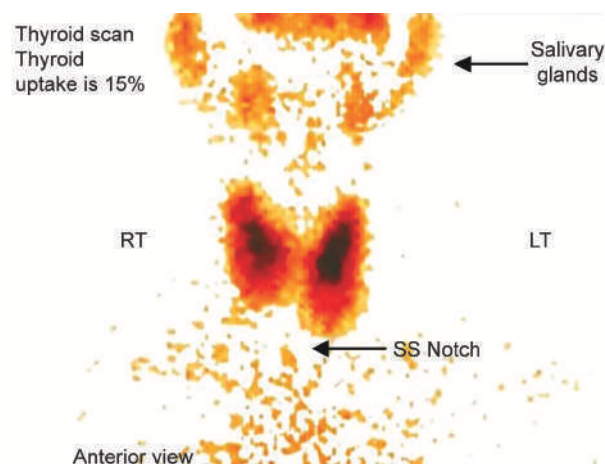


Fig. 4: Thyroid scan showed homogeneously increased tracer uptake noted throughout the gland. Thyroid uptake is 15% (normal 0.4–3.4%). The scan findings are consistent with features of an enlarged hyperfunctioning thyroid gland

DISCUSSION

Thyroid storm is a life-threatening emergency. The diagnosis is based mainly on clinical findings and thyroid function test results. Burch et al. suggested diagnostic criteria for thyroid storm, in which a score >45 is highly suggestive.³ Our patient had a score of 90. Early diagnosis and management are very rewarding. Management includes prompt initiation of high doses of thioamides, steroids, and beta-blockers, and treatment of the precipitating illness.

Graves' disease rarely presents as ischemic stroke and thyroid storm. According to Squizzato et al., it is hypothesized that hyperthyroidism can lead to atrial fibrillation or a hypercoagulable state, which can subsequently result in ischemic stroke.⁴ Our patient did not have atrial fibrillation but had homocysteinemia, which is also a known risk factor for stroke.⁵ It is possible that in our patient, the stroke led to thyroid storm, thus unmasking Graves' disease, or the patient had paroxysmal atrial fibrillation leading to stroke. In their studies, Siu et al. and Sheu et al. reported that 0.6% and 0.7% of hyperthyroid patients, respectively, had ischemic stroke with no evidence of atrial fibrillation.^{6,7}

Snyder et al. reported a similar case wherein the patient had ischemic stroke and then decompensated a few hours later, unmasking hyperthyroidism.⁸ Unlike our patient, this patient had atrial fibrillation and was treated with esmolol and apixaban apart from propylthiouracil and steroids. They preferred using clopidogrel over aspirin as it increases the peripheral conversion of T4 to T3. Also, they advocated using warfarin at a low dose due to reduced levels

of vitamin K-associated clotting factors in hyperthyroid patients. In their trial, Goldstein et al. stated that novel oral anticoagulants (NOACs), especially apixaban, are superior to warfarin in atrial fibrillation irrespective of thyroid status.⁹

Except for the case report by Snyder et al., the remaining case reports of ischemic stroke and thyroid storm are in patients already diagnosed with hyperthyroidism.^{8,10,11} Most of the data are from Japan and Asian countries. Our case is unique as stroke and thyroid storm were the presenting features of hyperthyroidism, and he also had LADA. Thyroid storm causes increased catecholamine release, which induces inhibition of insulin release and may therefore lead to unmasking of diabetes. Additionally, our patient did not have atrial fibrillation. At present, thyroid function testing is not recommended in the workup of stroke in young adults, and so we suggest a high index of suspicion for the same if the patient deteriorates suddenly or has a family history of thyroid disease.

CONCLUSION

In the appropriate clinical setting, a high index of suspicion for thyroid disorders should be maintained in young stroke patients. Early diagnosis and prompt treatment of thyroid storm reduce morbidity and mortality significantly.

AUTHOR CONTRIBUTIONS

Conceptualization: Dr Shalini Pandya, Paresh G Mody.

Patient Management: Dr Shalini Pandya, Dr Paresh G Mody.

Data Collection: Dr Shalini Pandya, Dr Paresh G Mody.

Data Interpretation: Dr Shalini Pandya.

Writing – Original Draft: Dr Shalini Pandya.

Writing – Review & Editing: Dr Shalini Pandya, Dr Paresh G Mody.

All authors have reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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AI Use Declaration

No artificial intelligence (AI) tools were used in the preparation of this manuscript.

We confirm that this manuscript is original, has not been published previously, and is not under consideration for publication elsewhere. All authors have read and approved the manuscript and consent to its submission for publication. We appreciate your time and consideration of our manuscript.

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CASE REPORT

An Unusual Case of Syncope

Supriya Barsode¹, Aryaa Rajendra Deshmukh², Shreyash Gulhane³

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ABSTRACT

Colonic diverticulitis refers to inflammation of the diverticula; it is predisposed by a variety of factors and presents with various clinical features. We present an unusual presentation of cecal diverticulitis in the form of syncope. It becomes imperative to promptly manage the case based on clinical acumen and various diagnostic tools to successfully start the treatment and provide a good prognosis.

Colonic diverticulitis is a common condition of the gastrointestinal system characterized by inflammation of a diverticulum, the pathogenesis of which is more complex and multifactorial. Per rectal bleeding owing to hemorrhage from a diverticulum is the most common presentation in the elderly population. Of these, there is an increased risk of bleeding among patients diagnosed with hypertension, who have atherosclerosis, or have a history of consumption of nonsteroidal anti-inflammatory drugs or antithrombotic medications. It is routinely observed that right-sided colonic diverticulitis is a rare presentation as compared to sigmoid or descending colon diverticulitis.

Keywords: Case report, Cecal diverticulitis, Embolization, Syncope.

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CASE DESCRIPTION

An 83-year-old female with known hypothyroidism and hypertension presented with complaints of a sudden episode of loss of consciousness lasting for 30 minutes with alleged per-rectal bleeding. The patient had a history of weight loss of 12–14 kg in 6 months, had altered bowel movements, generalized weakness, and Bell's palsy 6 years ago. The patient was admitted with the above complaints.

The patient had anemia with hemoglobin 7.4 gm/dL and was transfused with one PCV.

A gastroenterology referral was sought for the per-rectal bleeding, and sigmoidoscopy was advised. The sigmoidoscopy showed a blood collection of approximately 200–300 mL (Fig. 1). Colonoscopy was advised, and a gastrointestinal surgery referral was sought. Contrast-enhanced computed tomography (CECT) of the abdomen was suggestive of a small diverticulum in the cecum along with minimal fat stranding surrounding the diverticulum along the left lateral wall and base region, likely diverticulitis.

Active extravasation of contrast was noted in the cecum with pooling in the venous phase (Fig. 2). Mild atherosclerotic narrowing was noted at the origin of the celiac trunk.

An interventional radiology referral was sought in view of this, and embolization was advised. A cardiology referral was sought for bradycardia, and external loop recorder (ELR) monitoring was advised. Two-dimensional echocardiography showed an ejection fraction (EF) of 60%.

Magnetic resonance imaging (MRI) of the brain with angiography was suggestive of microbleeds in both cerebral hemispheres and the left cerebellar hemisphere and atherosclerotic plaques in both internal carotid arteries (ICAs) in the carotid canal not causing any luminal narrowing.

The patient had four episodes of per-rectal bleeding and went into hypotension with blood pressure 106/60 mm Hg, for which

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she was started on inotropic support. The patient also had one seizure-like episode and was transferred to the intensive care unit (ICU).

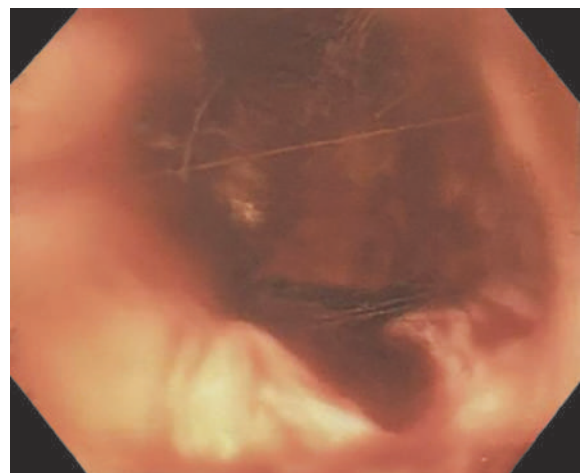


Fig. 1: Bleeding seen

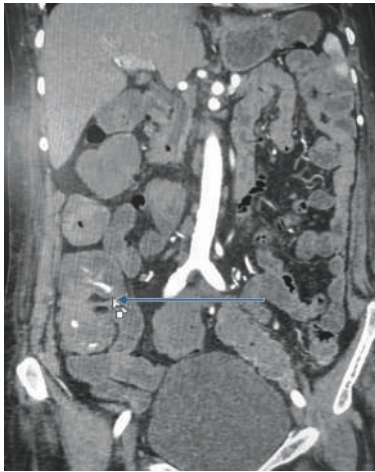


Fig. 2: Arrow indicating active extravasation of contrast

Embolization was done, and the patient was monitored for blood pressure and per-rectal bleeding. The patient was then discharged in a fair general condition and with normal vitals.

DISCUSSION

Syncope is a clinical presentation characterized by a short period of temporary loss of consciousness, which is self-limiting. The cause is attributed to reduced blood flow to the brain secondary to systemic hypotension.¹

Syncope in the context of abdominal pathology is thought to be multifactorial, which is often related to pain, hypertension, or a vasovagal response. It is also an uncommon presentation of cecal diverticulitis.² Per-rectal bleeding further complicates the clinical picture, suggesting a possible gastrointestinal source. Common complications of colonic diverticuli are rupture, perforation, and bleeding. Massive episodes of per-rectal bleeding precipitate hypotension, and inotropic support becomes essential to reverse it. Elderly patients with diverticulitis usually present with per-rectal bleeding.³ The patient's history was positive for hypertension, which is an independent risk factor for bleeding. As presented above, the patient was brought in with complaints of per-rectal bleeding and syncope.

Hematochezia, or per-rectal bleeding, is a common presentation of lower gastrointestinal bleeding. To diagnose and manage the patient appropriately, a primary diagnostic tool such as sigmoidoscopy is used. It proves beneficial to perform sigmoidoscopy in cases of complicated diverticulitis or prolonged symptoms as well as in elderly patients, since older age predisposes to malignancies.⁴

The patient was an 83-year-old female who presented to the emergency department with syncope and per-rectal bleeding suggestive of cecal diverticulitis. Owing to its uncommon

presentation, differentials must be ruled out, and a thorough history, examination, and investigation are required.

The use of CECT is imperative in the diagnosis of diverticulitis, since it is extremely important to locate the bleed for prompt treatment. Embolization is employed as the first-line treatment in cases of bleeding diverticula.⁵

CONCLUSION

We presented a case of ileocolic arterial embolization for cecal diverticulitis in a patient who presented with syncope and per-rectal bleeding. A systematic approach to diagnosis, including imaging and endoscopy, is crucial. Owing to its rare presentation as syncope, many factors are to be taken into consideration. The prognosis for cecal diverticulitis is usually favorable with prompt and conservative management.

PATIENT CONSENT FOR PUBLICATION

Written informed consent was obtained from the patient for the publication of clinical details and images.

AUTHOR CONTRIBUTIONS

Patient Management: Dr Supriya Barsode and Dr Shreyash Gulhane; Data collection: Dr Shreyash Gulhane and Aryaa Deshmukh; Writing – original draft: Dr Shreyash Gulhane and Aryaa Deshmukh; Review & editing: Dr Supriya Barsode.

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AI USE DECLARATION

No AI tools were used in the preparation of this manuscript.

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Unappreciated Work of Coauthors

Rajashri Patil¹, Sriram Kannuri², Sahjid Mukhida³, Sameena Khan⁴, Nikunja Kumar Das⁵

Journal of the Indian Medical Association (2026): 10.5005/jima-11070-0051

Dear Sir,

Academic research papers are a way to disseminate information from a few to many; they initiate a dialog with readers, which in turn leads to novel ideas for research and development. Expressing your thoughts and your research work in the form of a paper is a better way in the current digital world. Some hypotheses, diagnostic methods, or treatment plans with their experience done in one part of the world and their success or failure experience can help patients/clinicians in another part of the world. This idea exchange is possible only due to research publications.¹

Authoring an academic paper can be done by an individual, but most often it is authored by multiple individuals who have defined responsibilities regarding drafting the paper. In large-sized studies, we observe that often fieldwork is done by junior staff, but the recognition for their work is many a time understated in the final manuscript draft. Many times, some multicentric studies where centers are situated so far away from each other worked as a team on the projects. There are multiple shreds of evidence where more than 25 centers studied together and found better treatment results.²

When a manuscript is produced, it is not just the effort of the person writing it; it is the effort of the individual who has brought forth the concept and study design, the individual who has collected and analyzed data, and the person doing manuscript review and revision. As per the International guidelines of authorship, they mentioned the criteria and eligibility of the authorship in a manuscript. After publishing the research work in any reputed indexing journal, it confirms the contribution of all registered authors.³

In today's scenario, institutes encourage their research staff to write and publish research work. They also appreciate the authors for publishing their research work, which is required, though they appreciate only the first or corresponding author. As we earlier discussed, research work is not a single-person job, but it is teamwork.⁴ In published research work, when the journal approves all authors' contributions, how does an institute or their designated people not appreciate it? If only the first author or corresponding authors are responsible for credit for research work, why do other authors contribute? The first author became first because other authors stand behind him/her. If all authors stuck to having their name first, neither the work would start nor be complete, and without work, no chance of publication.⁵

Teamwork is always required for a better outcome because a single person is not able to handle all the sections at a time. Drug discoveries and vaccine trials are the best examples

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Conflict of interest: None

of multicentric teamwork. However, this type of policy is not encouraging research work, but they are discouraging teamwork.⁶

We are not against the institutional policies, but we want to say that all the coauthors of the research work are eligible for the same amount of appreciation. To give incentives or awards to authors for their research work, they can follow their institutional policies. We are against not appreciating the other coauthors because they are not first/corresponding authors in published documents.

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Nil.

AUTHOR CONTRIBUTIONS

Conceptualization: Dr Rajashri Patil.

Writing – original draft: Dr Sriram Kannuri.

Review & editing: Dr Sahjid Mukhida and Dr Sameena Khan.

Literature search: Dr Nikunja Kumar Das.

Final Approval: All authors.

AI USE DECLARATION

No AI tools were used in the preparation of this manuscript.

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Reply to “Vitamin D3 Insufficiency and Its Correlation with Disease Severity and Diagnostic Biomarkers in Rheumatoid Arthritis: A Case-control Study”

Astha Goyal¹, Nidhi Rohan Purandare²

Journal of the Indian Medical Association (2026): 10.5005/jima-11070-0062

Dear Editor,

We would like to express our profound gratitude to the authors of “Vitamin D3 Insufficiency and Its Correlation with Disease Severity and Diagnostic Biomarkers in Rheumatoid Arthritis: A Case-control Study”¹ for their important academic contribution. Their findings shed important light on the connection between rheumatoid arthritis (RA) and vitamin D3 levels.

We suggest the following ideas and clarifications to support these findings even further and increase the significance of upcoming studies in this field:

Reports indicate that between 18% and 31% of RA patients are obese.² Adipose tissue is known to have a significant impact on the inflammatory process. In addition to adipocytokines, adipocytes also create inflammatory cytokines. Consequently, obesity can raise systemic inflammation, which raises the risk of rheumatoid arthritis.³ BMI may therefore have an impact on the severity of RA; hence, providing study participants with their BMI could provide crucial context.

Evidence suggests a strong association between smoking and more pronounced joint inflammation, as indicated by a greater number of swollen joints and elevated C-reactive protein (CRP) levels.⁴ Furthermore, cigarette smoking significantly elevates the risk of various health issues, including cancers, cardiopulmonary diseases, infections, and autoimmune conditions such as systemic lupus erythematosus and RA.⁵ Therefore, accounting for the smoking status of the study participants is essential.

Hormonal risk factors for RA in women include short fertile period, lactation, progestin use, oral contraceptive use, age at menarche, and pregnancy termination.⁶ Therefore, it is essential to ascertain whether these physiological circumstances existed during the study.

In conclusion, we noticed that reference 33 is missing from the given list. It is essential to ensure that each citation is complete and precise.

We believe that addressing these points will further enrich the understanding derived from the current study and provide a more robust foundation for future investigations into the complex interplay of factors influencing rheumatoid arthritis.

ETHICAL APPROVAL/INFORMED CONSENT

Not applicable.

ACKNOWLEDGMENT

Nil.

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Conflict of interest: None

AUTHOR CONTRIBUTIONS

Astha Goyal: Conceptualization, writing – original draft.

Nidhi Rohan Purandare: Review and editing.

AI USE DECLARATION

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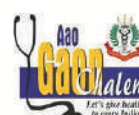


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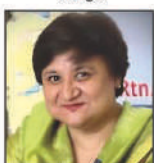
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