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A Study of Prescription Patterns of Acute Myeloid Leukaemia Patients Admitted in Clinical Hematology Ward in a Tertiary Care Hospital: A Prospective Observational Study

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ABSTRACT

Background: Prescription pattern analysis is a central tool of rational pharmacotherapy and is particularly relevant in acute myeloid leukaemia (AML), where intensive multi-agent regimens carry a high risk of toxicity, prolonged neutropenia and life-threatening infection.1 In resource- constrained settings, rising antimicrobial resistance and variable drug availability further complicate management. Published data on AML prescribing from Northeast India are scarce.
Objectives: To describe the chemotherapeutic, anti-infective and supportive prescription pattern in patients admitted with newly diagnosed AML to the clinical haematology ward of a tertiary care teaching hospital; to evaluate prescribing using the WHO/INRUD core prescribing indicators; and to compare local practice with national and international benchmarks.
Methods: This was a prospective, observational, single-centre study enrolling 120 consecutive in- patients with newly diagnosed AML over a one-year period. Patients with relapsed disease or a concurrent second malignancy were excluded. Data were collected from prescription records and case files using a structured proforma and analysed with descriptive statistics. WHO/INRUD core prescribing indicators were computed and interpreted with appropriate reference to the inpatient oncology setting.
Results: The cohort comprised adolescents and adults (age range 15–56 years; mean age 37.3 ± 12.0 years); 68 (56.7%) were male (male-to-female ratio 1.31:1). ECOG performance status ranged from 0 to 3. Parenteral routes accounted for 92% of all drug administrations. All patients received granulocyte colony-stimulating factor (G-CSF) support — pegfilgrastim in 85% and filgrastim in 60%. Febrile neutropenia occurred in 60% of patients. The most frequent first-line empirical antibiotics were cefixime (61%), piperacillin-tazobactam (20%) and cefpodoxime (19%); escalation agents were teicoplanin (65%), meropenem (40%) and colistin (8%). All patients received fluconazole prophylaxis. The mean number of drugs per encounter was 9.5, generic prescribing was 100%, and 82.1% of drugs were listed in the NLEM 2022.
Conclusion: Prescribing for supportive care and antibiotic escalation broadly resembled that of other Indian centres. However, two evidence–practice gaps were identified: the predominant first- line use of oral, non-anti-pseudomonal cephalosporins for febrile neutropenia, and exclusive reliance on fluconazole rather than mould-active antifungal prophylaxis. The frequent use of reserve antibiotics underscores an urgent need for a structured antimicrobial stewardship programme. These findings identify specific, actionable targets for improving AML pharmacotherapy in this setting.

Keywords: *Acute myeloid leukaemia; Prescription pattern; Drug utilisation; WHO/INRUD indicators; Febrile neutropenia; Granulocyte colony-stimulating factor; Antimicrobial stewardship; Antifungal prophylaxis; India.*

INTRODUCTION

Prescription pattern monitoring, a core component of drug utilisation research, evaluates whether medicines are selected, dosed and administered appropriately. The World Health Organization, together with the International Network for the Rational Use of Drugs (INRUD), has standardised this assessment through a set of core prescribing indicators that are widely used to benchmark rational drug use.[1] Such analysis is especially important in oncology, where the agents used are highly toxic and the margin for error is narrow.

Acute myeloid leukaemia (AML) is an aggressive clonal malignancy of myeloid progenitor cells in which immature blasts accumulate in the bone marrow and blood, impairing normal haematopoiesis.[2] Management is complex and typically combines cytotoxic induction chemotherapy with growth-factor support, antimicrobial and antifungal prophylaxis, antiemetics and other supportive medicines, all of which must be carefully selected and monitored.[2,3] Each component carries its own risk profile, so the overall prescription pattern has a direct bearing on patient safety and outcome.

The epidemiology of AML in India differs from that of high-income countries. Indian series consistently report a substantially younger age at presentation — a median of around 40 years — compared with approximately 65–70 years in Western populations.[2,4,5] Management is further complicated by a high burden of antimicrobial resistance; multidrug-resistant Gram- negative organisms are a major and growing cause of mortality in Indian hospitals.[6] These factors make the study of real-world prescribing in Indian centres both relevant and necessary.

Few studies have examined AML prescription patterns in tertiary centres of Northeast India. The present study was therefore undertaken to characterise prescribing practice in newly diagnosed AML patients at a large government teaching hospital, to assess this practice against the WHO/INRUD core indicators, and to compare it with national and international standards in order to identify areas for improvement.

AIMS AND OBJECTIVES

The objectives of the study were:

- To describe the prescription pattern — including chemotherapeutic, anti-infective and supportive medicines — in patients admitted with newly diagnosed AML to the Clinical Haematology Ward of GMCH.
- To evaluate prescribing using the WHO/INRUD core prescribing indicators.
- To compare local prescribing practice with that of other Indian cancer centres and with international guideline recommendations.
- To identify evidence–practice gaps and suggest targeted improvements in AML pharmacotherapy at the institution.

MATERIALS AND METHODS

Study design and setting

This was a prospective, observational, single-centre study conducted in the Clinical Haematology Ward of Gauhati Medical College and Hospital (GMCH), Guwahati — a large government teaching hospital and tertiary referral centre serving the Northeast India region. The study was carried out over a one-year period.

Study population

A total of 120 consecutive in-patients with newly diagnosed AML, admitted during the study period, were enrolled. Patients with relapsed or previously treated AML, and those with a concurrent second malignancy, were excluded. APL cases were excluded.

Data collection

For each patient, data were extracted from prescription sheets and case records using a pre- designed structured proforma capturing demographic details, Eastern Cooperative Oncology Group (ECOG) performance status, chemotherapy received, and all concomitant medicines administered during the hospital stay. For the purpose of the WHO/INRUD analysis, an "encounter" was defined as the complete inpatient prescription record of a single patient for the index admission. Written informed consent was obtained from every patient, or from a parent or guardian in the case of minors.

Prescribing indicators

The five WHO/INRUD core prescribing indicators were calculated: the mean number of drugs per encounter, the percentage of drugs prescribed by generic (International Nonproprietary) name, the percentage of encounters with an antibiotic prescribed, the percentage of encounters with an injection prescribed, and the percentage of drugs prescribed from the National List of Essential Medicines (NLEM) 2022.[1,7] It should be noted that the published WHO reference

values for these indicators were derived from primary-care, predominantly outpatient settings; they are not validated benchmarks for an inpatient oncology unit, where polypharmacy and near-universal parenteral and antimicrobial use are clinically mandated.

Statistical analysis

Data were entered into Microsoft Excel and summarised using descriptive statistics (frequencies, percentages, means with standard deviations, and medians with interquartile ranges). Given the descriptive, single-cohort design, no inferential statistical testing was performed.

Ethical approval

The study was approved by the Institutional Ethics Committee of GMCH.

RESULTS

Patient characteristics

One hundred and twenty patients with newly diagnosed AML were enrolled. Ages ranged from 15 to 56 years, with a mean of 37.3 ± 12.0 years (median 37 years; interquartile range 27–47). The most frequent age groups were 25–34 years (25.8%; n = 31) and 35–44 years (23.3%; n = 28), followed by 45–54 years (20.0%; n = 24), 15–24 years (18.3%; n = 22) and 55–56 years (12.5%; n = 15) (Table 1). Nearly half of the cohort (49.2%) was aged between 25 and 44 years, a relatively young adult profile consistent with the pattern reported from other Indian centres.

Of the 120 patients, 68 (56.7%) were male and 52 (43.3%) were female, giving a male-to- female ratio of 1.31:1. ECOG performance status at presentation was 0 in 34 patients, 1 in 20, 2 in 36 and 3 in 30 (Table 2), indicating that a substantial proportion presented with impaired functional status.

Table 1. Age distribution of AML patients (n = 120)

Age group (years)	Number of patients	Percentage (%)
15–24	22	18.3
25–34	31	25.8
35–44	28	23.3
45–54	24	20.0
55–56	15	12.5
Total	120	100

Table 2. ECOG performance status (n = 120)

ECOG status	Number of patients
ECOG 0	34
ECOG 1	20
ECOG 2	36
ECOG 3	30
Total	120

Route of administration

Parenteral routes (intravenous and subcutaneous) accounted for approximately 92% of all drug administrations, consistent with the intensive nature of induction therapy. Oral agents were used mainly for prophylaxis and symptomatic relief.

Granulocyte colony-stimulating factor support

All 120 patients (100%) received G-CSF support. Pegfilgrastim was administered to 85% (n = 102) and filgrastim to 60% (n = 72); some patients received both agents at different phases of treatment.

Febrile neutropenia and antibiotic use

Febrile neutropenia was observed in 60% of patients (n = 72). Empirical antibiotics were commenced when fever developed in the setting of neutropenia. Among first-line agents, cefixime was the most frequently prescribed (61%; n = 73), followed by piperacillin- tazobactam (20%; n = 24) and cefpodoxime (19%; n = 23). When fever persisted, antibiotics were escalated: teicoplanin was used in 65% (n = 78), meropenem in 40% (n = 48) and colistin in 8% (n = 10) of patients (Table 3).

Table 3. Antibiotic use in patients (n = 120)

Antibiotic	Number of patients (%)
First-line: Cefixime	73 (61%)

First-line: Piperacillin-tazobactam	24 (20%)
First-line: Cefpodoxime	23 (19%)
Escalation: Teicoplanin	78 (65%)
Escalation: Meropenem	48 (40%)
Escalation: Colistin	10 (8%)

Antifungal and supportive medicines

All patients received fluconazole as antifungal prophylaxis. Clotrimazole mouthwash was prescribed to 110 patients (91.6%) for the prevention and treatment of oral fungal infection and mucositis. Other supportive medicines included antiemetics (100 patients), calcium supplementation (75) and proton-pump inhibitors (PPIs; 60 patients, 50%), as summarised in Table 4.

Table 4. Supportive care medicines (n = 120)

Medicine	Number of patients
Antiemetics (for nausea/vomiting)	100
Calcium supplementation	75
Proton-pump inhibitors (PPI)	60
Clotrimazole mouthwash	110
Antifungal prophylaxis (fluconazole)	120 (100%)

WHO/INRUD core prescribing indicators

The five core indicators are summarised in Table 5. The mean number of drugs per encounter was 9.5, reflecting the high complexity of AML induction, which requires the simultaneous use of cytotoxic agents, growth factors, antimicrobial and antifungal prophylaxis, antiemetics and other supportive medicines. All drugs were prescribed by their generic (International Nonproprietary) name (100%). Every patient received at least one antibiotic (100%) and at least one injection (100% of encounters; 92% of all administrations were parenteral). Of the 1,135 drug administrations recorded, 932 (82.1%) were listed in the NLEM 2022.[7] The 203 non-NLEM administrations were accounted for entirely by three agents — pegfilgrastim (n = 102), teicoplanin (n = 78) and cefpodoxime (n = 23) — the use of which was based on disease severity and institutional infection patterns. As noted in the Methods, the WHO reference values shown derive from primary-care settings and are provided for context only.

Table 5. WHO/INRUD core prescribing indicators (n = 120)

WHO/INRUD indicator	Study value (GMCH)
1. Mean drugs per encounter	9.5
2. Drugs prescribed by generic name	100%
3. Encounters with an antibiotic	100%
4. Encounters with an injection	100%
5. Drugs from NLEM 2022	82.1% (932/1135)

DISCUSSION

This study describes the prescription pattern of newly diagnosed AML patients at a tertiary centre in Northeast India and benchmarks it against national and international practice. Several findings merit discussion.

Patient profile

The cohort was relatively young, with a mean age of 37.3 years, in contrast to Western populations, where AML predominantly affects older adults (median 65–70 years).[2] This finding is closely in keeping with Indian data: the large prospective series from Christian Medical College, Vellore, reported a median age of 40 years,[4] and a substantial adolescent- and-young-adult burden has been documented at Tata Memorial Hospital, Mumbai.[8] The biological basis for the younger presentation of AML in India remains incompletely understood and is thought to reflect a combination of demographic, genetic and environmental factors.[5]

Granulocyte colony-stimulating factor support

All patients received G-CSF, with pegfilgrastim used prophylactically in 85%. While prophylactic G-CSF is recommended by ASCO for regimens carrying a febrile-neutropenia risk above 20%,[9] the evidence for routine growth-factor support specifically during AML remission-induction is weaker and is graded lower in the same guideline. There is a long- standing theoretical concern that G-CSF may stimulate residual leukaemic blasts, and large analyses have examined the leukaemogenic potential of growth factors in other settings.[10] In addition, long-acting pegfilgrastim is not generally preferred during acute-leukaemia induction, where short-acting filgrastim allows more flexible dose titration. The high prophylactic use of pegfilgrastim observed here therefore diverges from common practice and warrants review

against current recommendations.[3,9]

Antibiotic prescribing

Febrile neutropenia occurred in 60% of patients, confirming infection as a dominant problem during AML induction. The first-line empirical choices, however, diverge markedly from guideline recommendations. The most frequently used first-line agent, cefixime (61%), together with cefpodoxime (19%), are oral, third-generation cephalosporins that lack reliable anti-pseudomonal activity and are not appropriate as empirical monotherapy for high-risk febrile neutropenia. International guidance from the IDSA recommends an intravenous anti- pseudomonal β-lactam — piperacillin-tazobactam, cefepime or a carbapenem — as first-line empirical therapy in high-risk neutropenic patients,[11] and oral regimens are reserved for selected low-risk patients only.[12] Of the first-line agents recorded here, only piperacillin-tazobactam (20%) is concordant with this standard. This pattern indicates a clear need to revise the institutional empirical-therapy protocol; the authors are encouraged to confirm whether the oral cephalosporins represented genuine empirical therapy for neutropenic fever or were instead used as step-down or low-risk oral therapy, as this distinction is central to the interpretation.

Frequent escalation to meropenem (40%) and colistin (8%) is of particular concern, as these are reserve agents that should be restricted to documented or strongly suspected resistant infection. Their frequent use reflects the heavy burden of antimicrobial-resistant organisms in the region. Indian studies of febrile neutropenia in AML from resource-constrained settings have similarly reported high rates of multidrug-resistant infection and carbapenem or colistin escalation,[8,13] and national surveillance confirms a rising prevalence of carbapenem-resistant Gram-negative organisms, for which colistin remains one of the few consistently active agents.[14,6] Colistin-sparing strategies using newer agents are increasingly advocated where available.[15] Together these findings highlight an urgent need for a structured antimicrobial stewardship programme within the haematology service.

Antifungal prophylaxis

All patients received fluconazole for antifungal prophylaxis. Current ECIL guidance, however, favours a mould-active agent such as posaconazole for patients undergoing remission-induction chemotherapy for AML, particularly where the local incidence of invasive mould disease is high.[16] The pivotal randomised controlled trial by Cornely and colleagues demonstrated that posaconazole was superior to fluconazole or itraconazole, reducing proven or probable invasive fungal disease from 8% to 2%, lowering invasive aspergillosis, and significantly improving overall survival in AML patients during induction.[17] By this standard, exclusive reliance on fluconazole is suboptimal.

Nevertheless, posaconazole is considerably more expensive than fluconazole and is not always readily available or affordable for the predominantly low-income population served by the institution. Fluconazole is therefore used as a pragmatic, cost-effective alternative — illustrating that guidelines developed in high-income settings cannot always be transplanted directly without accounting for local economic realities. The widespread use of clotrimazole mouthwash (91.6%) is consistent with good supportive-care practice. Conversely, PPIs were prescribed to half of the cohort (50%); published evidence links PPI use in haematology patients receiving chemotherapy to an increased risk of gut-derived bacteraemia and febrile- neutropenic episodes,[18,19] so the indication for PPI prophylaxis in each patient merits review.

Rational use and stewardship implications

On the WHO/INRUD indicators, generic prescribing was universal and NLEM compliance was high (82.1%), both of which are favourable. The apparently large deviations in mean drugs per encounter, antibiotic use and injection use are expected artefacts of comparing an inpatient AML unit against primary-care reference values and should not be interpreted as irrational prescribing. The clinically meaningful signals are instead the choice of first-line antibiotics and the reliance on fluconazole. A formal antimicrobial stewardship and antifungal-prophylaxis programme — in line with contemporary prophylaxis guidance[20] — would address both. As newer, better-tolerated regimens (for example, azacitidine– venetoclax) become more widely available in India,[21] periodic re-evaluation of prescribing will remain important.

Strengths and limitations

The main strengths of this study are its prospective design, complete capture of inpatient prescriptions, and the application of standardised WHO/INRUD indicators in a setting where such data are scarce. Several limitations should be acknowledged. First, it was a single-centre study, limiting generalisability. Second, the analysis was descriptive, without inferential testing or long-term outcome follow-up. Third, AML was not characterised by cytogenetic or molecular subtype, which is central to contemporary classification and risk stratification.[3]

CONCLUSION

This study provides a comprehensive picture of prescribing practice for newly diagnosed AML at a tertiary centre in

Northeast India. In terms of patient profile, G-CSF support and supportive care, practice broadly mirrors that of other large Indian centres. The analysis, however, identifies two important and actionable divergences from current evidence-based standards. First, empirical antibiotic therapy for febrile neutropenia relied predominantly on oral, non-anti-pseudomonal cephalosporins, which is discordant with guideline-recommended therapy, while escalation to reserve agents such as meropenem and colistin was frequent; together these indicate the need both to revise first-line empirical protocols and to establish a structured antimicrobial stewardship programme. Second, antifungal prophylaxis relied exclusively on fluconazole, whereas mould-active agents such as posaconazole are preferred for AML induction; this difference is driven largely by cost and availability and should be revisited as access improves.

Rather than confirming that current practice is optimal, the principal value of this study lies in identifying specific, modifiable gaps in antimicrobial and antifungal prescribing. Periodic prescription-pattern analysis of this kind is essential for translating such findings into improved care, and we hope these results will inform AML management at GMCH and at comparable centres across Northeast India.

DECLARATIONS

Funding: No funding was received for this study.

Conflict of interest: There is no conflict of interest.

Ethical approval: The study was approved by the Institutional Ethics Committee of Gauhati Medical College and Hospital, Guwahati, Assam, India (approval number:190/2007/Pt- II/march 2024/16).

Informed consent: Written informed consent was obtained from all patients, or from a parent or guardian for minors, before enrolment.

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