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Bridging the treatment gap in chronic myeloid leukemia in low-resource settings through precision medicine

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Abstract:

Chronic myeloid leukemia (CML) is a type of blood cancer caused by an abnormal chromosome which produces a gene that drives the uncontrolled growth of white blood cells. The objectives of the current article are to ascertain the role of precision medicine in CML, identify the potential challenges in low-resource settings, and propose public health recommendations to overcome the identified challenges. The introduction of precision medicine has transformed care among patients with CML, where treatment is tailored to a specific molecular abnormality. Precision medicine ensures that the administered treatment-tyrosine kinase inhibitors (TKIs) – functions as a targeted therapeutic modality and has remarkably improved survival rates, turning CML into a predominantly chronic condition. Acknowledging the high prevalence of CML and the role of precision medicine through TKIs in improving patient outcomes, there is an urgent need to implement targeted interventions to bridge the existing challenges in low-resource settings so that the utility of precision medicine can be optimized. In conclusion, precision medicine has transformed CML care, but inequities in access to TKIs and diagnostics persist in low-resource settings. By adapting precision strategies to local contexts, equitable outcomes can be accomplished, we can move closer to making treatment-free remission a possibility for all patients, regardless of geography or availability of resources.

Keywords:

Chronic myeloid leukaemia, imatinib, precision medicine, treatment, tyrosine kinase inhibitors

Introduction

Chronic myeloid leukemia (CML) is a type of blood cancer caused by an abnormal chromosome (Philadelphia chromosome), which produces a Breakpoint Cluster Region (BCR) gene fused with the Abelson murine leukemia viral oncogene homolog 1 (ABL1) gene that drives the uncontrolled growth of white blood cells.[1] Globally, approximately five million people are living with CML.[1] Despite a decline in incidence in high sociodemographic nations, the number of cases and reported deaths continues to rise in low-sociodemographic index nations.[1,2] The results from a cross-sectional study done in a tertiary hospital in Ethiopia reported a median age of 36 years at the time of diagnosis.[3] However, the systematic analysis of estimates revealed that children <20 years account for a small share of overall cases, although these estimates were higher in low- and middle-income nations.[2] Moreover, with the introduction of tyrosine kinase inhibitors (TKI) in the therapeutic regimen, the 4-year survival rates in recent cohorts have increased to an average of 92%.[4] The objectives of the current article are to ascertain the role of precision medicine in CML, identify the potential challenges in low-resource settings, and propose public

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health recommendations to overcome the identified challenges.

Precision Medicine in Chronic Myeloid Leukaemia

The introduction of precision medicine has transformed care among patients with CML by customizing the treatment to a specific molecular abnormality (BCR-ABL1 fusion gene).[5] Precision medicine ensures that treatment with TKIs (such as imatinib or dasatinib) remains targeted and improves survival rates.[6] In other words, this individualized approach through precision medicine has shifted CML from a once-fatal leukemia into a manageable chronic disease with near-normal life expectancy.[7] Further, molecular monitoring of the BCR-ABL1 gene aids in deciding on whether to continue, switch, or discontinue therapy (in eligible patients).[6] Even on the diagnostic front, advances in molecular monitoring tools (like digital polymerase chain reaction) and next-generation sequencing have enabled risk stratification, resistance detection, and individualized treatment adjustment.[8] At the same time, the results of a meta-analysis reported that precision medicine has ensured that, beyond molecular features, parameters such as age of the patient, risk of side effects, and stage of disease are also duly acknowledged to decide which TKI is the best for a specific patient.[9]

Potential Challenges in Low-resource Settings

The management of CML in low-resource settings faces multiple challenges related to diagnostics, treatment delivery, and health system administration [Figure 1].[10-18] To begin with, patients in low-resource settings are more likely to get diagnosed at the advanced stages of disease, reducing the likelihood of achieving optimal responses to first-line TKI.[10] Most low-and middle-income nations lack capacity or accreditation for standardized molecular diagnostics, which is essential for diagnosis, response assessment, and treatment decisions.[11] The results of a cohort study done in Malaysia highlighted the insufficient access to diagnostic tools which can detect resistance mutations, either in terms of unavailability or unaffordability.[12] In addition, many such nations face shortages of trained hematology, oncology, and laboratory personnel, which directly interferes with diagnosis and management.[13] The results of a review highlighted the improvement in access in some regions to generic imatinib; nevertheless, access to patented TKIs is limited due to their high cost and uneven distribution.[14] In continuation, frequent drug-supply interruptions and shortages due to problems with manufacturing and quality concerns can compromise the continuation of therapy.[15]

The optimal management of the condition is further jeopardized by the inadequate and irregular frequency monitoring resulting from high costs and logistics barriers, including travel, which eventually impedes timely detection of treatment failure or eligibility for treatment-free remission.[16] A single-center study done in North India reported that most CML patients with poor adherence are due to high out-of-pocket expenditures, low health literacy, and social attributes (such as transport and work loss), which bring about a reduction in adherence to TKIs and worsen treatment outcomes.[16] In a study done in the United States by analyzing secondary data, it was revealed that owing to the scarcity of clinical trials and research sites in low-resource settings, there is a limited opportunity for patients to access newer agents and for locally relevant evidence to be generated.[17] At the administrative level, the presence of weak national policies, outdated procurement models, and the absence of sustainable financing mechanisms interfere with the long-term access to affordable diagnostics and therapies.[18]

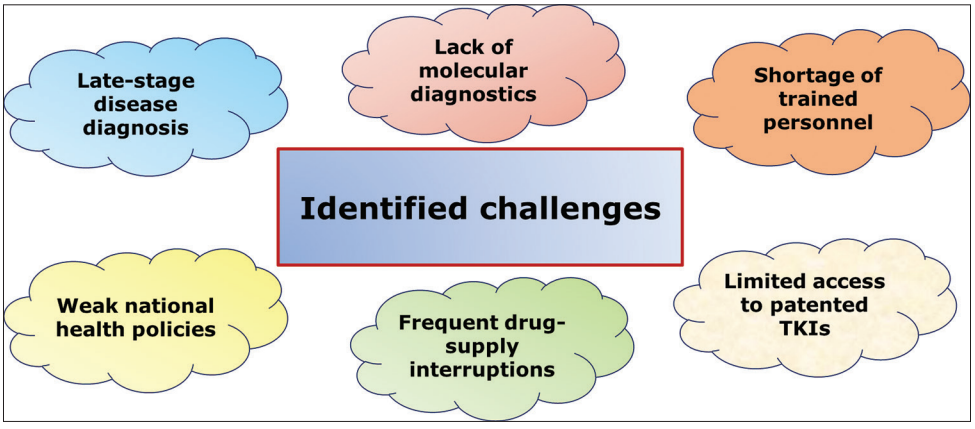

Figure 1: Identified challenges. TKIs = Tyrosine kinase inhibitors

Public Health Interventions

Acknowledging the high prevalence of CML and the role of precision medicine through TKIs in improving patient outcomes, there is an urgent need to implement targeted interventions to bridge the existing challenges in low-resource settings so that the utility of precision medicine can be optimized [Table 1].[10,19-29] At the policy level, government or partner-facilitated guaranteed access programs to ensure free provision or drug coverage for TKIs can be implemented.[19] This was evident in an observational study done in Mexico, wherein guaranteed access to Imatinib in CML patients brought about a significant difference in 20-year survival probability versus those who did not have access to the drug.[19] Another approach to support patients can be through developing partnerships with non-governmental organizations, which help in multiple activities (such as drug donation, referral networks, and patient support).[20]

The diagnostics and laboratory capacity can be strengthened by investing in regional reference labs and quality assurance for standardization and expansion of molecular monitoring, which is crucial for guiding treatment, including treatment-free remission.[21] Another way could be to deploy low-cost and feasible methods (like capillary dried blood) for facilitating remote sample collection, especially in areas where centralized venous testing is not possible.[22] Further, mutation testing hubs can be established at the regional level to facilitate the early detection of resistance mutations and guide treating physicians in selecting second or third-line TKIs.[23] For improving therapeutics, supply chain, and safety of drugs, a pharmacovigilance system can be established in low- and middle-income nations, and this delivered encouraging results in a study where the government and a nongovernmental organization had a partnership.[24] In addition, the strategy to provide quality-assured generic imatinib at affordable prices can improve clinical outcomes.[25]

To overcome staff shortage in low-resource settings, nonspecialist clinicians, nurses, and community health workers can be trained (namely, task shifting or decentralization) for routine TKI dispensation, toxicity monitoring, and teleconsultation referral. At the same time, specialists can be reserved for complex cases.[26] The results of a scoping review highlighted the role of telemedicine for specialist consultations, remote review of results, and providing support for adherence, as this can prove to be crucial in areas with a specialist shortage.[27] To ensure treatment adherence, reduce late presentation, and facilitate the delivery of patient-centred care, there is a need to organize targeted community awareness activities, including referral mechanisms.[28] Furthermore, low-cost adherence strategies, such as counseling, message reminders, and peer navigators can be employed to target financial/knowledge barriers and improve outcomes.[10] Finally, registries can be established to track incidence, treatment patterns, molecular responses, and supply issues, as all these data can aid in planning and evaluation of programs.[29]

Table 1: Identified challenges and recommended interventions

Challenges	Recommended interventions
Late-stage disease diagnosis	Conduct community awareness and screening programs
	Strengthen referral mechanisms for early diagnosis
Lack of molecular diagnostic capacity	Invest in regional reference laboratories and ensure quality assurance for standardized molecular testing
Limited access to resistance mutation testing	Establish regional mutation testing hubs and use low-cost remote collection methods like dried-blood sampling
Shortage of trained personnel	Implement task shifting - train nurses, nonspecialist clinicians, and community health workers for basic care and monitoring
Limited access to patented TKIs	Implement government or partner-facilitated guaranteed access programs
	Encourage availability of quality-assured generic Imatinib
Frequent drug-supply interruptions	Develop strong supply chain systems and pharmacovigilance mechanisms to ensure consistent drug availability and safety
High monitoring costs and logistical barriers	Use telemedicine for remote result review and follow-up; Promote decentralized monitoring systems
Poor treatment adherence due to socioeconomic barriers	Introduce low-cost adherence strategies (counselling, SMS reminders, peer navigators) and financial support programs
Limited clinical research and evidence generation	Expand research networks and clinical trial participation in low-resource settings
Weak national policies and unsustainable financing	Strengthen policy frameworks, and procurement models
	Establish sustainable financing mechanisms for diagnostics and therapy
Lack of patient awareness and health literacy	Conduct community-based education campaigns on CML management and treatment adherence
Ineffective data tracking and planning	Develop national or regional registries to monitor incidence, treatment outcomes, and supply issues for program evaluation

TKIs=Tyrosine kinase inhibitors, CML=Chronic myeloid leukaemia, SMS=Short message service

Conclusion

Precision medicine has transformed CML care, but inequities in access to TKIs and diagnostics persist in low-resource settings. By adapting precision strategies to local contexts, equitable outcomes can be accomplished, and we can move closer to making treatment-free remission a possibility for all patients, regardless of geography or availability of resources. Development of national precision oncology frameworks could reduce inequities in CML management.

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Conflicts of interest
There are no conflicts of interest.

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