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# Exploring the metabolic adverse effects induced by Nilotinib in adult patients diagnosed with Chronic Myeloid Leukaemia – A Scoping Review

**Student[a]:** Nikita Kaur | **Supervisor(s)[b]:** Dr Soban Sadiq

## Abstract

**Background:** Chronic myeloid leukaemia (CML), characterised by the BCR-ABL1 gene mutation, is a myeloproliferative condition primarily managed with tyrosine kinase inhibitors (TKIs), such as 2nd generation Nilotinib. However, the wide range of therapies available, alongside the generally favourable outcomes, may lead to the misconception that CML is a straightforward disease to manage. This attitude can expose high-risk patients to delayed treatment responses, insufficient attention to toxicity concerns and poor outcomes. Thus, a scoping review was conducted to address these concerns, particularly the metabolic safety profile of Nilotinib.

**Methods:** This review utilised the PRISMA Extension for Scoping Review (PRISMA-ScR) checklist as a foundation for research. A systematic literature search was conducted across multiple databases, and these studies were inputted into Rayyan software. Fifteen studies met the inclusion criteria following a comprehensive review process and data were synthesised through thematic analysis. The papers consisted primarily of observational cohort studies, however there was also 1 randomised controlled trial (RCT) and 1 case report.

**Results:** All the studies observed adverse Nilotinib-induced metabolic changes, and most commented on the long-term cardiovascular implications of these adverse effects. One of the most prevalent adverse effects was hyperglycaemia; according to several studies, up to 11% of patients experienced grade 3/4 hyperglycaemic episodes and elevated fasting glucose levels. Significant rises in HbA1c, however, were rare. Within three to six months of starting medication, lipid abnormalities such as increased LDL, HDL, and total cholesterol were noted, indicating the necessity of proactive lipid monitoring. Although no clear connection to pancreatitis was found, elevated pancreatic enzymes were also reported. Cardiovascular implications, including increased risk of diabetes, dyslipidaemia, and peripheral arterial disease, were evident, with higher cumulative CV events in patients on prolonged Nilotinib therapy, particularly at higher doses.

**Conclusions:** Findings highlight the need for robust cardiovascular risk assessment and careful monitoring of Nilotinib's metabolic effects to reduce long-term risks.

**Keywords:** cardiovascular disease | chronic myeloid leukaemia | diabetes | dyslipidaemia | hyperglycaemia | monitoring | nilotinib | pancreatitis | pancreatitis | risk assessment |

[a] Nikita Kaur 4th Year Medical Student, Kent and Medway Medical School, Canterbury, United Kingdom.

[b] Dr Soban Sadiq, Senior Lecturer, Kent and Medway Medical School, Canterbury, United Kingdom.

**Main contact email:** N.kaur467@kmms.ac.uk