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Uptake of FLT3 inhibitors and impact on overall survival in patients with acute myeloid leukaemia in Sweden

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INTRODUCTION

Acute myeloid leukaemia (AML) is an aggressive haematological malignancy, with FLT3 mutations representing an important therapeutic target present in approximately one third of newly diagnosed AML patients [1].

In the past decade, targeted treatments have been introduced to routine management of patients with AML. Importantly, FLT3 inhibitors (FLT3i) significantly improved outcomes in both the first-line and relapsed/refractory settings for patients with FLT3-mutated AML [2,3], which historically have been associated with an unfavourable prognosis.

However, the uptake and real-world effectiveness of FLT3 inhibitors may vary across healthcare systems [4-7], reflecting differences in access, molecular testing, and treatment practices. In Sweden, FLT3 inhibitors first received reimbursement approval in 2018 (Midostaurin in Jan 2018 and Gilteritinib in Mar 2021).

OBJECTIVE

The aim of this study was to understand the uptake of FLT3 inhibitors in Sweden and to evaluate the overall survival benefits of patients with AML who were treated with FLT3 inhibitors.

METHODS

Study Design

- Retrospective, population-based observational study based on secondary use of nationwide health registry data from Sweden

Data Sources

- National Patient Register (NPR), Swedish Cancer Register (CR), Prescribed Drug Register (PDR), Cause of Death Register (COD)
- Linked via Swedish unique personal identifier

Study Population

- Inclusion criteria (both need to be fulfilled):
  1) ≥1 AML record (ICD-10-SE C92.0) in NPR or CR between 01/01/2018 and 31/12/2022
  2) Being ≥18 years of age at time of first AML record
  3) ≥1 dispensation record of an FLT3i (ATC: L01EX03, L01EX13) in PDR
- Exclusion criteria:
  1) Prior history of AML diagnosis before 01/01/2018
  2) Prior history of FLT3i dispensations before 01/01/2018
- Follow-up until 31/12/2022

Study Outcomes

- Overall survival was analysed using Cox proportional hazard regression with FLT3i exposure as a time-varying covariate

RESULTS

1 Study Population

A total of 2891 patients diagnosed with AML 2018-2022 were included in this study, with a median follow-up time of 189 days. Among these, 149 received FLT3 inhibitor therapy.

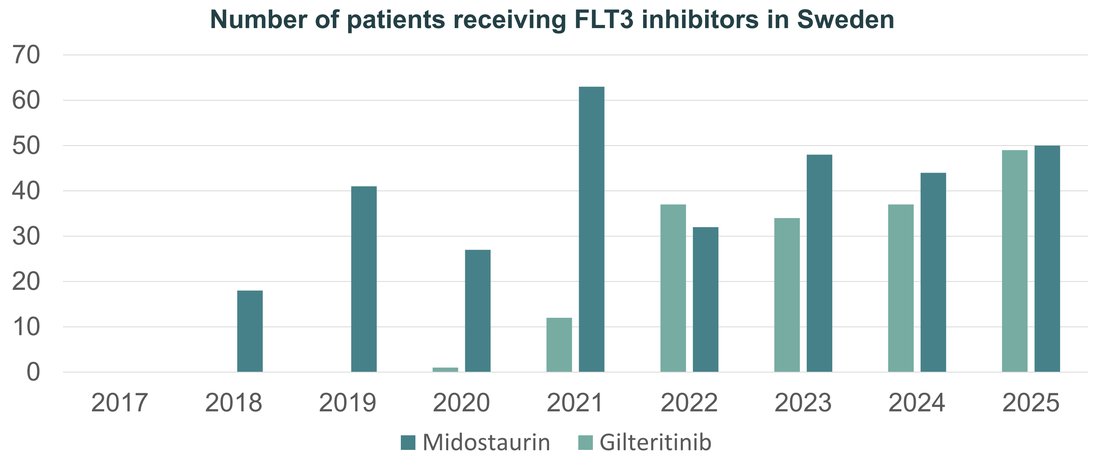
Table 1. Baseline Characteristics (n=2891; 2018-2022)

	Total AML Cohort	FLT3i-treated AML Cohort	Non-FLT3i-treated AML Cohort
Number of patients, n (%)	**2891 (100%)**	149 (5%)	2742 (95%)
Age at AML diagnosis, mean (SD)	**70.0 (15.1)**	58.7 (14.8)	70.6 (14.9)
Female, n (%)	**1298 (45%)**	74 (50%)	1224 (45%)

2 FLT3 Inhibitor Uptake

FLT3 inhibitor uptake FLT3 inhibitor uptake increased following introduction into clinical practice.

Figure 1. FLT3 inhibitor uptake in Sweden over time (2017-2025)



* Note: This study's cohort covers the years 2018-2022. However, for this chart on drug uptake data for additional years (beyond 2018-2022) was obtained from Socialstyrelsens statistikdatabas – Läkemedel. Accessed 20 May 2026.

Table 2. Details on FLT3 inhibitor treatment (n=149; 2018-2022)

	Total FLT3i-treated AML Cohort	Midostaurin*	Gilteritinib*	Both (Midostaurin & Gilteritinib)**
Number of treated patients, n (%)	**149 (100%)**	113 (76%)	22 (15%)	14 (9%)
Number of FLT3i dispensations per patient per year, mean	**2.7**	2.6	3.1	n.a.
Median days from first AML diagnosis to first FLT3i dispensation	**49**	46	115.5	n.a.

* Includes patients who had ≥1 dispensation record for one of the FLT3is (but not the other) during the follow-up period.
** Includes patients who had ≥1 dispensation record for each of the two FLT3is during the follow-up period.

3 Survival Analysis

After adjusting for sex, age, and year of diagnosis, FLT3 inhibitor treatment was associated with a reduced risk of death compared with the non-FLT3-inhibitor-treated reference group (hazard ratio: 0.70; 95% confidence interval: 0.52-0.94; p = 0.02).

Table 3. Overall survival model adjusted for sex, age, and index year (n=2891; 2018-2022)

	Hazard Ratio [95% Confidence Interval]	*p*-value
FLT3 inhibitor exposure	**0.70 [0.52-0.94]**	**0.02**
How factors adjusted for affect overall survival		
Gender		
Male	1.00	
Female	0.90 [0.82-0.99]	0.03
Age	1.06 [1.05-1.06]	0.00
Index year		
2018	1.00	
2019	0.96 [0.84-1.10]	0.07
2020	1.05 [0.92-1.20]	0.07
2021	0.98 [0.85-1.13]	0.07
2022	0.90 [0.76-1.06]	0.08

Limitations

- Data on confounding factors including FLT3 mutation status was not available in this dataset. Further analyses are warranted to understand their impact on patient survival.

Key messages

- Out of 2,891 patients diagnosed with AML 2018-2022 in Sweden, 149 (5%) received FLT3 inhibitor treatment.
- FLT3 inhibitor uptake increased following introduction into clinical practice.
- FLT3 inhibitor treatment was associated with significantly improved survival, corresponding to a ~30% reduction in the hazard of death.
- These findings support the effectiveness of FLT3 inhibitors in routine clinical care of patients with AML.

Acknowledgment: We would like to acknowledge the National Board of Health and Welfare (Socialstyrelsen) for excellent support with data extraction.
Disclosures: A. Dun, K. Kwok and T. Jacob are employees of Ciencia Research AB.
References: [1] Lewis et al. 2025 (doi: 10.1002/cam4.71205), [2] Stone et al. 2017 (doi: 10.1056/NEJMoa1614359), [3] Perl et al. 2019 (doi: 10.1056/NEJMoa1902688), [4] Shimony et al. 2022 (doi: 10.1007/s00277-022-04895-8), [5] Vives et al. 2024 (doi: 10.3390/cancers16234028), [6] Messina et al. 2024 (doi: 10.1002/jha2.1045), [7] Romero Riquelme et al. 2026 (doi: 10.1002/ajh.70488)
Presented at ISPOR Europe 2026 | Vienna, Austria | 8-11 November 2026

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