EFFICACY AND SAFETY ANALYSIS OF ROMIPLOSTIM IN ACUTE MYELOID LEUKEMIA PATIENTS UNDERGOING CONSOLIDATION CHEMOTHERAPY

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Introduction

Chemotherapy Induced Thrombocytopenia (CIT) contributes significantly to morbidity and mortality secondary to hemorrhagic complications in AML patients treated with intensive chemotherapy. Romiplostim is a TPO receptor agonist approved for the treatment of chronic ITP and is useful in managing CIT.

Aim

To evaluate the duration of thrombocytopenia after Romiplostim administration in patients of Acute myeloid Leukemia undergoing consolidation chemotherapy

Objectives

PRIMARY OBJECTIVE:

To study the time to platelet recovery, defined as **unsupported Total platelet count ≥ 20,000/mm3 for 3 consecutive days** from the start of consolidation chemotherapy

SECONDARY OBJECTIVE:

- To study the platelet transfusion requirement
- To assess the adverse effect profile of Romiplostim
- To study the number of clinically significant bleeding events (CSBEs)

Methods

Sample size: A total of **31 patients** were enrolled and **90 cycles of consolidation** were analysed in **Romiplostim arm.** Retrospective cohort comprised of 30 patients with 90 cycles of consolidation.

Study Duration: March 2023 to December 2024 (prospective arm)

Inclusion Criteria

- **AML patients aged ≥18 years**
- **Patients in morphological remission post induction chemotherapy**
- Patients who had received or were scheduled to receive romiplostim during consolidation chemotherapy

Exclusion Criteria

- Patients diagnosed with Acute Promyelocytic Leukemia (APML)
- Patients with a clinically relevant thrombotic disorder (e.g., venous thromboembolism, stroke, myocardial infarction, or unstable angina) within the 6 months prior to enrolment

Study Intervention

- All patients in the study population received intensive cytarabine consolidation.

Timing of Romiplostim Administration

Day +5 or later during consolidation chemotherapy cycles when **platelet counts fell below 75,000/mm³**, and **weekly thereafter** until the achievement of an **unsupported platelet count of ≥20,000/mm³ for 3 consecutive days**, defined as **time to platelet recovery (TTPR)**.

Schedule of Administration Dosage

A fixed dose of **500 mcg/week** was administered subcutaneously until the TTPR criterion was met.

Characteristic	Value
Median no of Romiplostim dose (n, Range)	2 (1 - 3)
Day of administration of 1st dose, IQR	8 (6 - 9)
Median platelet count at 1st dose of Romiplostim, IQR (per microL)	60000 (50000 – 70000)
Day of administration of 2nd dose, IQR	14 (13 - 15)
Median platelet count at 2nd dose of Romiplostim, IQR (per microL)	12000 (8000 – 15000)
Day of administration of 3rd dose, IQR	20 (19 - 21)
Median platelet at 3rd dose, IQR (per microL)	11000 (10000 - 15000)
Adverse effect of Romiplostim	None

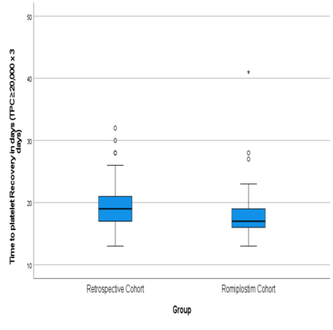
Data analysis:

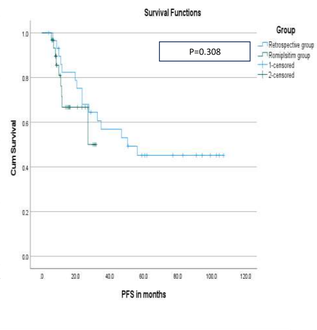
- Data from EMRs were de-identified and recorded in Excel, capturing baseline demographics and risk profile, treatment details, hematologic outcomes, infectious complications, and relapse/survival data.
- All analyses were performed using SPSS version 27. Statistical significance was set at $p < 0.05$.

Results

Baseline characteristics		Romiplostim group (N=31)	Retrospective group (N=30)	P value
Age in years (Median, Range)		51 (19-72)	46 (19-66)	0.201
Gender (n,%)	Male	17 (54.8)	16 (53.3)	0.906
	Female	14 (45.2)	14 (46.7)	
Presence of comorbidities (%)		11 (36.6)	17 (54.8)	0.202
Performance Status (ECOG)	1	20	24	0.229
	2	9	6	
	3	2	0	
Cytogenetics (n,%)	Favourable	10 (32.3)	9 (30)	0.588
	Intermediate	21 (67.7)	20 (66.7)	
	Adverse	0	1 (3.3)	
ELN 2022 Risk	Favourable	22 (71)	17 (56.7)	0.508
	Intermediate	7 (22.6)	10 (33.3)	
	Adverse	2 (6.4)	3 (10)	
Type of Induction chemotherapy	3+7 (Daunorubicin+ Cytarabine)	17 (54.8)	28 (93.3)	<0.001
	HMA +Ven	14 (45.2)	2 (6.7%)	
HMA + Venetoclax cycles (median)		4	2.5	
Flowcytometric MRD post Induction	Positive	7 (22.6%)	Not done	
	Negative	24 (77.4%)		

Characteristic	Romiplostim group (n=90 cycles)	Retrospective Control group (n=90 cycles)	P value
Cumulative Cytarabine Dose per cycle (g/sqm), Median, Range	9 (6-18)	9 (3-18)	0.03
Time to platelet recovery (Unsupported TPC ≥20,000/µL x 3 days) (Median in days, Range)	17 (13- 41)	19 (13-32)	<0.001
Total RDP (Random donor platelet) requirement, Median, IQR	7 (4-13)	7 (4-12)	0.901
Total SDP (Single donor platelet) requirement, Median, Range	0.25 (0-3)	0 (0 - 12)	0.374
Time to Neutrophil Recovery (ANC ≥500/µL x 3 days), Median in days, Range	15 (10-25)	16 (12-26)	0.001
Total number of GCSF doses	11 (7-22)	13 (7-21)	0.005
Incidence of Febrile Neutropenia (n, %)	78 (86.6)	78 (86.6)	1
Severe Sepsis and Septic shock (n, %)	6 (0.06%)	6 (0.06%)	1
Clinically significant bleeding events	0	0	





Discussion

- Romiplostim shortened platelet and neutrophil recovery
- No impact on transfusion needs, infection rates, or PFS
- Multivariable analysis showed G-CSF doses, consolidation cycle, and baseline platelet count as significant predictors of recovery time
- **Romiplostim not independently significant in multivariable analysis**
- Supportive benefits possible without increased relapse risk

References

Kantarjian et al. *Lancet Haematol*. 2018;5(3):e117-e126.

Soff GA, Miao Y, Devlin SM, et al. *J Clin Oncol*. 2019;37(31):2892-2898.

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