A pilot study to evaluate the efficacy and safety of prophylactic administration of romiplostim to prevent grade 4 thrombocytopenia in myeloma and lymphoma patients undergoing Autologous stem cell transplant

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INTRODUCTION

- In autologous stem cell transplantation (ASCT), grade 4 thrombocytopenia is one of the most dreaded adverse event.
- A platelet count of less than 25 X 10^9/L is considered Grade 4 thrombocytopenia according to CTCAE Ver. 5.
- This results in extended hospital stays and an increased demand for transfusions.

AIM

- To evaluate the efficacy and safety of prophylactic romiplostim in preventing grade 4 thrombocytopenia in this patient population.

OBJECTIVES

Primary objective:

- To study the efficacy of prophylactic romiplostim to prevent grade 4 thrombocytopenia in myeloma and lymphoma patients undergoing ASCT

Secondary objectives-

- To study the safety profile of romiplostim in this setting.
- To study the effect of romiplostim on-

1. Single Donor Platelet transfusions(SDP)
2. Platelet engraftment
3. Duration of hospital stay

- To perform a cost-benefit analysis

METHODS

- Open label Pilot study
- Sample size -26
- Study period – January 2024 – March 2025
- Venue: Bone marrow transplant unit , KMIO

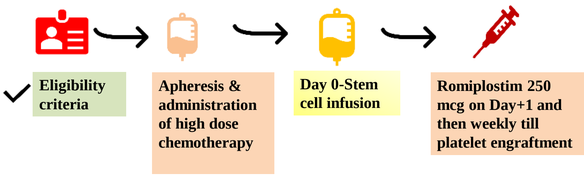
ELIGIBILITY CRITERIA

INCLUSION CRITERIA

- Multiple myeloma and lymphoma patients aged ≥18 years, wiling to give written informed consent.

EXCLUSION CRITERIA

- Age < 18 years
- Not willing for consent
- Hypersensitivity to TPO agonists
- History of thrombosis.
- SIRS/MODS
- Pregnancy and breast feeding



Eligibility criteria → **Apheresis & administration of high dose chemotherapy** → **Day 0-Stem cell infusion** → **Romiplostim 250 mcg on Day+1 and then weekly till platelet engraftment**

- Baseline characteristics were recorded
- Daily CBC monitoring till neutrophil / platelet engraftment.
- SDP transfusion according to institutional protocol.
- Adverse events- monitored throughout transplant.

Neutrophil engraftment- ANC ≥ 500 X10^9/L for 3 consecutive days.
Platelet engraftment- Platelet count >20000 X 10^9/L without transfusion support for 7 days.

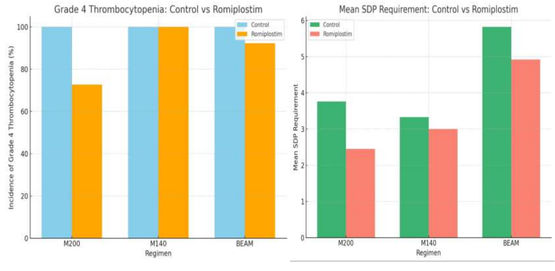
- Results obtained from the intervention was compared to historical control group(not received Romiplostim).

OBSERVATIONS

- **Control group-** 40 patients (21-Multiple myeloma,19 lymphoma patients).
- **Romiplostim group-** 26 patients (13 each -Multiple myeloma and lymphoma).
- Baseline characteristics including Age, gender, Conditioning regimen were well matched.
- Average doses of Romiplostim required was 2.

RESULTS

- In comparison to the control group, **there was a tendency** for both lymphoma patients receiving BEAM (↓7.7%, p-value 0.433) and multiple myeloma patients receiving Melphalan 200mg/m^2 (M-200,↓27.3%, p-value 0.04) to **have a lower incidence of Grade 4 thrombocytopenia** .
- There was an **overall trend toward lower Mean SDP needs** (M-200-- ↓1.31, p-value 0.035).
- Regardless of the conditioning protocol, the **romiplostim group showed a trend toward quicker platelet engraftment**.
- There was **no discernible impact on length of hospital stay or neutrophil engraftment** .
- The romiplostim group **did not experience any thrombosis or bleeding.**
- In comparison to control group, Cost-benefit analysis showed that **using Romiplostim significantly reduced costs regardless of the conditioning regimen used**.



DISCUSSION

- In comparison to Scordo et al. (N=59), who reported similar outcomes between romiplostim and control groups, our study demonstrates a trend toward reduced grade 4 thrombocytopenia with M200/BEAM, lower mean SDP requirements, and faster platelet engraftment across all regimens, without safety concerns.[1]
- Our findings in the multiple myeloma cohort mirror those of Vadlamani Surya Prakash et al., showing fewer SDP transfusions (1.39 vs. 3.40; *p*=0.0001) and faster platelet engraftment (9.72 vs. 12.57 days; *p*=0.0018) in the romiplostim group.[2]

CONCLUSION

- Prophylactic romiplostim administration during ASCT is a safe, effective intervention in reducing grade 4 thrombocytopenia and platelet transfusion requirements.
- Larger studies are warranted to confirm these findings.

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