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A pilot study to evaluate the efficacy and safety of prophylactic Romiplostim in preventing Grade 4 thrombocytopenia in multiple myeloma and lymphoma patients undergoing Autologous stem cell transplant

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ABSTRACT

Background and Introduction: During Autologous stem cell transplant, one of the dreaded complications is Grade 4 thrombocytopenia, which leads to prolonged hospitalization and increased transfusion requirement. This pilot study aims to evaluate the efficacy and safety of prophylactic romiplostim in preventing grade 4 thrombocytopenia in this patient population.

Methods: From January 2024 to march 2025, an open label pilot study was conducted with 26 eligible adult patients undergoing Autologous stem cell transplant in a tertiary care oncology center. Beginning from day +1 post-transplant Romiplostim (250 mcg SC) was administered weekly until platelet engraftment. Results were compared with historical controls who did not receive romiplostim. Complete blood counts, transfusion requirements, adverse events and engraftment timelines were assessed on daily basis and documented. Statistical analysis was performed using appropriate comparative methods; $p<0.05$ was considered significant.

Results: Use of romiplostim reduced the incidence of grade 4 thrombocytopenia in multiple myeloma patients who received melphalan-200mg/m^2 as conditioning regimen (27.3% reduction, $p=0.04$). Also, there was a significant reduction in single donor platelet transfusion requirement in this group($p=0.03$). Platelet engraftment was faster across all conditioning regimens in the intervention group. Neutrophil engraftment and duration of hospital stay were comparable. There were no major bleeding or thrombotic adverse events reported. An exploratory cost benefit analysis showed potential economic advantages due to decreased transfusion requirements.

Conclusion: Prophylactic romiplostim administration during Autologous stem cell transplant is a safe, effective intervention in reducing grade 4 thrombocytopenia and platelet transfusion requirements. Larger studies are warranted to confirm these findings.

Introduction

Autologous stem cell transplantation (ASCT) remains a cornerstone therapeutic strategy for eligible patients with hematologic malignancies such as multiple myeloma and lymphoma[1]. With advances in supportive care, ASCT has become increasingly safe and effective, offering durable disease control. However, the use of high-dose conditioning regimens is inevitably associated with profound cytopenias, among which thrombocytopenia is particularly concerning[2]. Grade 4 thrombocytopenia, defined as a platelet count $<25 \times 10^9$/L, is almost universal after ASCT and is associated with significant morbidity, including spontaneous bleeding, need for intensive transfusion support, and prolonged hospitalization[3].

Platelet transfusion remains the mainstay of supportive care. While effective in preventing hemorrhage, transfusions carry risks such as alloimmunization, febrile and allergic reactions, and transmission of infections[4,5]. Moreover, repeated transfusion episodes contribute substantially to the cost of ASCT, particularly in low- and middle-income countries where blood product availability is often limited[6]. Thus, there is a growing clinical and economic interest in strategies that can mitigate the severity of thrombocytopenia and reduce transfusion burden[7].

Romiplostim is a thrombopoietin receptor agonist (TPO-RA) that stimulates megakaryocyte proliferation and differentiation through activation of the MPL receptor[8]. Initially approved for the treatment of chronic immune thrombocytopenia (ITP)[9,10], romiplostim has demonstrated sustained efficacy in raising platelet counts and reducing bleeding risk in both clinical trial and real-world settings[11,12]. Its role has since expanded to chemotherapy-induced thrombocytopenia (CIT), where it has been shown to accelerate platelet recovery, reduce transfusion requirements, and allow continuation of chemotherapy without dose delays[13-15].

In the setting of hematopoietic stem cell transplantation, the use of TPO-RAs is gaining increasing attention. Recent meta-analyses and observational studies have reported encouraging response rates of up to 70–80% in post-transplant thrombocytopenia, with generally favorable safety profiles[16,18]. Early pilot studies specifically evaluating romiplostim following ASCT suggest faster platelet engraftment and reduced platelet transfusion needs without an excess in thrombotic events[19,20]. These data, however, are still limited, especially in resource-constrained environments where supportive transfusion services may be stretched.

Another important consideration is the economic impact of romiplostim use in ASCT. While the upfront drug cost is not negligible, studies in ITP and CIT have suggested that reductions in transfusion needs and hospital stay may lead to overall cost savings[21,22]. Including pharmacoeconomic outcomes alongside clinical endpoints is therefore essential, particularly in LMIC settings where treatment affordability plays a central role in therapy adoption.

Given these gaps in evidence, we conducted a prospective, open-label pilot study to evaluate the efficacy, safety, and cost-effectiveness of prophylactic romiplostim in preventing grade 4 thrombocytopenia in multiple myeloma and lymphoma patients undergoing ASCT at a tertiary care oncology center in India.

2. Materials and Methods

2.1 STUDY DESIGN AND SETTING

This was a prospective, open-label, single-center pilot study conducted at a tertiary care oncology center in South India. The study period extended from January 2024 to March 2025. Institutional ethical approval was obtained prior to study initiation.

2.2 STUDY POPULATION

Patients aged 18 years and older with a confirmed diagnosis of multiple myeloma or lymphoma scheduled to undergo autologous stem cell transplantation (ASCT) were considered eligible. Inclusion criteria included adequate organ function and successful peripheral blood stem cell mobilization. Patients were excluded if they had ongoing bleeding, prior exposure to thrombopoietin receptor agonists, or contraindications to romiplostim.

The intervention cohort (romiplostim group) was prospectively enrolled, while the control group comprised historical patients matched for age, diagnosis, and conditioning regimen, who underwent ASCT at the same center without receiving romiplostim.

2.3 TREATMENT AND INTERVENTION PROTOCOL

All patients received disease-appropriate high-dose chemotherapy followed by ASCT. Conditioning regimens included Melphalan 200 mg/m² (M200), Melphalan 140 mg/m² (M140), or BEAM (carmustine, etoposide, cytarabine, and melphalan), selected based on underlying diagnosis and institutional protocol.

The romiplostim group received 250 mcg of romiplostim via subcutaneous injection beginning on Day +1 following stem cell infusion, repeated weekly until platelet engraftment was achieved. Platelet engraftment was defined as a platelet count exceeding 20,000/µL for seven consecutive days without the need for transfusion.

All patients received standard supportive care, including granulocyte-colony stimulating factor (G-CSF), prophylactic antimicrobials, and transfusions per institutional guidelines. Single-donor platelet (SDP) transfusions were administered as indicated, based on platelet counts (<20000/µL) and clinical status (bleeding tendencies).

2.4 MONITORING AND OUTCOME MEASURES

Complete blood counts were performed daily from the day of transplantation until engraftment. Neutrophil engraftment was defined as an absolute neutrophil count (ANC) ≥500/µL sustained for three consecutive days.

Primary Endpoint:

- Incidence of Grade 4 thrombocytopenia (platelet count <25,000/µL) following ASCT.

Secondary Endpoints:

- Number of SDP transfusions administered per patient.
- Time to platelet engraftment.
- Length of post-transplant hospitalization.
- Frequency and severity of adverse events attributed to romiplostim.
- Economic analysis incorporating hospitalization, transfusion needs, and drug costs.

2.5 COST ANALYSIS

A cost-minimization approach was adopted using fixed institutional rates:

- Daily inpatient charge: ₹10,000
- Cost per unit of SDP: ₹14,000
- Cost per romiplostim dose (250mcg): ₹2,500

Costs were aggregated for each patient based on conditioning regimen and clinical course.

2.6 STATISTICAL ANALYSIS

Data were analyzed using SPSS version 26. Baseline characteristics were summarized using descriptive statistics. Continuous variables were compared using the independent t-test or Mann–Whitney U test, and categorical variables were analyzed using chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant.

3. Results

3.1 BASELINE CHARACTERISTICS

A total of **66 patients** were included in the study:

- **Control group**: 40 patients
- **Romiplostim group**: 26 patients

The distribution of disease was similar across both groups:

- **Multiple myeloma**: 21 controls, 13 romiplostim
- **Lymphoma**: 19 controls, 13 romiplostim

Table 1: Summary of Baseline Characteristics by Disease and Treatment Group

Variable	Multiple Myeloma (Control)	Multiple Myeloma (Romiplostim)	Lymphoma (Control)	Lymphoma (Romiplostim)
Age (years)				
18–35	1	2	13	10
36–65	19	10	5	3
>65	1	1	1	0
Gender				
Male	14	6	13	5
Female	7	7	6	8
Prior Lines of Treatment				
1	6	7	2	3
≥2	15	6	17	10
Conditioning Regimen				
Melphalan 200 (M200)	17	11	0	0
Melphalan 140 (M140)	4	2	2	0
BEAM	0	0	17	13

Note: The average romiplostim dose was **2 doses of 250 mcg** per patient.

3.2 INCIDENCE OF GRADE 4 THROMBOCYTOPENIA

The incidence of Grade 4 thrombocytopenia was 100% in all control groups across conditioning regimens. In the romiplostim group, significant reduction was observed only in the M200 regimen.

Table 2: Incidence of Grade 4 Thrombocytopenia by Conditioning Regimen

Regimen	Control n/N (%)	Romiplostim n/N (%)	p-value (Fisher's exact test)
M200	17/17 (100%)	8/11 (72.7%)	0.04
M140	6/6 (100%)	2/2 (100%)	1.00
BEAM	17/17 (100%)	12/13 (92.3%)	0.433

Interpretation: Prophylactic romiplostim significantly reduced Grade 4 thrombocytopenia in patients receiving M200 ($p = 0.04$).

3.3 MEAN SINGLE DONOR PLATELET (SDP) REQUIREMENT

Romiplostim resulted in lower mean SDP use across all regimens. Statistical significance was achieved only in the M200 group.

Table 3: Mean SDP Requirement per Patient

Regimen	Group	Mean ± SD	Mean Reduction	p-value (independent t-test)
M200	Control	3.76 ± 1.52	↓ 1.31	0.035
	Romiplostim	2.45 ± 1.69		
M140	Control	3.33 ± 1.75	↓ 0.33	0.697
	Romiplostim	3.00 ± 1.41		
BEAM	Control	5.82 ± 3.99	↓ 0.90	0.373
	Romiplostim	4.92 ± 2.53		

Interpretation: A statistically significant reduction in SDP transfusion requirement was seen in patients receiving M200 with romiplostim ($p = 0.035$). Non-significant reductions were observed in M140 and BEAM groups.

3.4 ENGRAFTMENT AND HOSPITALIZATION OUTCOMES

Neutrophil Engraftment

There was **no statistically significant difference** in neutrophil engraftment between groups across any conditioning regimen.

Table 4: Median Neutrophil Engraftment (days)

Regimen	Control (Median, IQR)	Romiplostim (Median, IQR)	p-value
M200	10 (1.5)	10 (3)	0.83
M140	9.5 (3)	10.5 (1)	0.34
BEAM	9 (2.5)	10 (5)	0.45

Platelet Engraftment

Romiplostim significantly improved platelet engraftment time in all regimens.

Table 5: Median Platelet Engraftment (days)

Regimen	Control (Median, IQR)	Romiplostim (Median, IQR)	p-value
M200	11 (2.5)	9 (2)	0.046
M140	10 (2)	8.5 (1)	0.049
BEAM	12 (3)	10 (2)	0.01

Interpretation: Romiplostim significantly reduced time to platelet engraftment in M200, M140, and BEAM regimens.

Duration of Hospital Stay

No statistically significant reduction in hospital stay was observed.

Table 6: Median Hospital Stay Duration (days)

Regimen	Control (Median, IQR)	Romiplostim (Median, IQR)	p-value
M200	19 (2.5)	18 (4)	0.45
M140	19.5 (3)	18.5 (3)	0.56
BEAM	22 (4)	22 (4)	1.00

3.5 SAFETY AND ADVERSE EVENTS

Table 7: Adverse Events

Event	Control Group	Romiplostim Group
Thrombosis	1 (Grade 2)	0
Bleeding	0	0

Interpretation: Romiplostim was well tolerated. No thrombotic or bleeding events were reported in the romiplostim group

3.6 COST-BENEFIT ANALYSIS

Cost-minimization analysis was performed using institutional rates (₹10,000/day hospital stay, ₹14,000 per single-donor platelet [SDP] unit, and ₹2,500 per romiplostim dose). Median hospital stay was comparable between groups across regimens, but the romiplostim group required fewer SDP transfusions.

- **M200:** Control total cost ₹2,42,706 vs. Romiplostim ₹2,19,363 → savings **₹23,343**
- **M140:** Control total cost ₹2,41,666 vs. Romiplostim ₹2,32,000 → savings **₹9,666**
- **BEAM:** Control total cost ₹3,01,529 vs. Romiplostim ₹2,93,922 → savings **₹7,607**

Overall, prophylactic romiplostim demonstrated modest but consistent cost savings across regimens, largely attributable to reduced transfusion requirements.

4. Discussion

4.1 PRINCIPAL FINDINGS AND INTERPRETATION

In this pilot study of ASCT recipients with multiple myeloma or lymphoma, prophylactic romiplostim significantly reduced the incidence of Grade 4 thrombocytopenia in patients receiving the M200 conditioning regimen (72.7% vs. 100%, $p = 0.04$), alongside a statistically significant reduction in mean single-donor platelet (SDP) transfusion requirements (3.76 ± 1.52 vs. 2.45 ± 1.69 units, $p = 0.035$). Importantly, romiplostim also accelerated platelet

engraftment across all conditioning regimens—M200 (11 vs. 9 days, $p = 0.046$), M140 (10 vs. 8.5 days, $p = 0.049$), and BEAM (12 vs. 10 days, $p = 0.01$). There were no differences in neutrophil engraftment ($p > 0.3$ for all) or length of hospitalization ($p > 0.4$ for all), and no thrombotic or bleeding adverse events were observed. Also, prophylactic romiplostim showed consistent cost savings across all regimens, mainly due to fewer transfusions. These findings suggest that romiplostim safely enhances platelet recovery and reduces transfusion dependence in select ASCT patients, particularly those conditioned with M200.

These findings align with those of Scordo et al.,[10] who conducted an open-label pilot study of romiplostim for thrombocytopenia after autologous hematopoietic cell transplantation. Their study reported that romiplostim administration led to earlier platelet recovery and reduced the need for platelet transfusions in patients undergoing ASCT. However, the study did not find a significant difference in the incidence of grade 4 thrombocytopenia between the romiplostim and control groups.[10] This discrepancy may be attributed to differences in study design, patient populations, and conditioning regimens used.

Similarly, Vadlamani et al. observed that romiplostim reduced platelet transfusion needs and shortened the time to platelet engraftment in multiple myeloma patients undergoing ASCT. Their study reported a lower average number of 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 cohort compared to the control group.[11] These results are consistent with our findings and further support the efficacy of romiplostim in enhancing platelet recovery post-ASCT.

Collectively, these studies suggest that prophylactic romiplostim may offer clinically meaningful benefits in select ASCT populations, particularly those receiving M200-based conditioning regimens. By enhancing platelet recovery and reducing transfusion dependence without introducing safety concerns, romiplostim could serve as a valuable supportive care strategy in high-risk transplant recipients. Moreover, the observed cost savings reinforce its potential utility in resource-constrained settings. However, larger, randomized controlled trials are warranted to confirm these findings and to further refine patient selection criteria for maximal benefit.

4.2 BIOLOGICAL RATIONALE AND CLINICAL SIGNIFICANCE

Romiplostim's mechanism as a thrombopoietin receptor agonist stimulating megakaryopoiesis and platelet production provides a biologically plausible explanation for the observed improvements in platelet engraftment time and transfusion rates[8]. By administering romiplostim preemptively, the therapy may bridge the vulnerable post-chemotherapy period, when endogenous thrombopoietin spikes may lag behind platelet recovery[9,12]. Faster platelet recovery can lower bleeding risk and transfusion burden, ultimately reducing resource utilization[21]. The absence of significant delays in neutrophil engraftment or adverse events supports thespecificity and safety of this intervention[3,5].

4.3 CHEMOTHERAPY-INDUCED THROMBOCYTOPENIA (CIT)

Romiplostim use beyond ITP extends into managing CIT. A retrospective series from Memorial Sloan Kettering involving 20 patients with protracted CIT showed effective platelet recovery ($\geq 100 \times 10^9$/L in 19/20 cases) and chemotherapy resumption with minimal toxicity, apart from three thromboses attributed to baseline risks[13]. A larger quality improvement cohort of 239 patients echoed these findings, showing robust platelet doubling by day 14 and chemotherapy continuation in most, with VTE rates comparable to oncology norms[14]. A randomized phase II trial further demonstrated normalization of platelet counts in 85% of patients, enabling uninterrupted chemotherapy[15]. In contrast, a systematic meta-analysis of thrombopoietic agents in CIT showed heterogeneous results, likely reflecting differences in study design, dosing, and patient selection[16].

4.4 POST-TRANSPLANT THROMBOCYTOPENIA

Meta-analyses focused on TPO-RA efficacy after hematopoietic stem cell transplantation (HSCT) present compelling evidence. Across 19 studies including 378 patients, pooled response rates were ~73%, substantially higher than recombinant human thrombopoietin at ~28%, with a median survival of ~66% and a low adverse event rate (~3%)[17]. Broader reviews of >1,700 post-HSCT patients reported response rates near 70–80%, supporting the role of TPO-RAs in engraftment failures and post-transplant thrombocytopenia[18]. Early ASCT-specific data are limited, but pilot studies have shown favorable platelet recovery trends with romiplostim, mirroring our findings[19,20].

4.5 ALTERNATIVE AGENTS

Other TPO-RAs, such as eltrombopag and avatrombopag, are oral agents with proven activity but dietary and hepatic limitations not observed with romiplostim[23,24]. Comparative trials remain limited, and romiplostim's parenteral dosing may provide more predictable pharmacokinetics in the immediate post-transplant setting.

4.6 ECONOMIC IMPLICATIONS

Our exploratory cost–benefit analysis indicates that romiplostim, despite its upfront drug cost, can yield net savings during ASCT by lowering transfusion requirements. Cost reductions ranged from ~₹7,000 to ₹23,000 across regimens, with the greatest benefit in patients receiving M200. These results align with pharmacoeconomic studies in ITP and CIT, where reduced transfusion burden and shorter hospital stays offset drug costs[21,22,25-27]. Recent multicenter reviews have also highlighted the potential financial advantages of TPO-RAs in transplant-associated thrombocytopenia[28]. While our sample size was small, these findings emphasize the need for prospective cost-effectiveness studies, particularly in LMICs where transfusion and hospitalization costs are major drivers of healthcare expenditure.

4.7 STRENGTHS, LIMITATIONS, AND INTERPRETATION
Strengths of our study include regimen-specific reporting of outcomes, prospective collection in the intervention cohort, and incorporation of cost-effectiveness data. Limitations include small sample size, use of historical controls, and single-center design, which may affect generalizability. Longer follow-up is needed to assess potential late toxicities such as marrow fibrosis or thrombosis.

4.8 CLINICAL IMPLICATIONS AND FUTURE DIRECTIONS
Romiplostim's use in ASCT to prevent severe thrombocytopenia warrants larger randomized trials, stratified by conditioning regimen and incorporating patient-centered and economic outcomes. Comparative studies of TPO-RAs, long-term safety evaluations, and pharmacoeconomic modeling across healthcare systems are essential. Integration of such agents into guidelines, such as those of the NCCN[29], will depend on confirmation of both clinical and financial benefit.

5. Conclusion

This pilot study reinforces the therapeutic promise of prophylactic romiplostim in ASCT patients: reducing Grade 4 thrombocytopenia, enhancing platelet recovery, and curbing platelet transfusion needs, all with a favorable safety profile. Supported by meaningful literature in both CIT and post-transplant thrombocytopenia realms, these findings provide strong rationale for comprehensive RCTs aiming to establish romiplostim—or potentially other TPO-RAs—as standard adjunct therapy in selected ASCT protocols.

DECLARATIONS
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Conflict of interest: none

Ethical approval: Yes

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