

HIGHER EARLY POST-TRANSPLANT TACROLIMUS LEVELS ARE ASSOCIATED WITH INFERIOR SURVIVAL OUTCOMES AFTER MATCHED UNRELATED DONOR ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION

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INTRODUCTION

- Tacrolimus is widely used for graft-versus-host disease (GVHD) prophylaxis following matched unrelated donor (MUD) allogeneic hematopoietic stem cell transplantation (HSCT).
- However, the prognostic impact of higher early post-transplant tacrolimus exposure remains uncertain.

AIM

- We evaluated the association between higher tacrolimus exposure during the first 30 days after MUD allogeneic HSCT and survival outcomes.

METHOD

- This single-center, retrospective study included 46 adults who underwent MUD allogeneic HSCT between January 2024 and May 2025.
- Mean tacrolimus levels within the first 30 days post-transplant were calculated and assessed for associations with survival outcomes.

CONCLUSIONS

- Higher early tacrolimus levels were independently associated with inferior OS after MUD allogeneic HSCT.
- Patients with mean tacrolimus levels >10.5 ng/mL experienced significantly worse 1-year overall survival, suggesting that excessive early exposure adversely impacts survival and supporting further investigation into optimal tacrolimus target ranges after MUD allogeneic HSCT.

RESULTS

Variables	n (% , range)
Median age (years)	64 (19-74)
Age	
Age < 65 years	25 (54.3)
Age ≥ 65 years	21 (45.7)
Sex	
Male	21 (45.7)
Female	25 (54.3)
Race	
White	39 (84.8)
Other	7 (15.2)
Numbers of antigen mismatch	
0	34 (77.3)
1	9 (20.5)
>1	1 (2.3)
Conditioning intensity	
Myeloablative	29 (63.0)
Reduced-intensity	17 (37.0)
HCT-CI score	
0	17 (36.9)
1-2	19 (41.3)
≥3	10 (21.7)
Mean ± SEM	1.43 ± 0.23
Acute graft-versus-host disease	
Yes	21 (45.7)
No	25 (54.3)
Chronic graft-versus-host disease	
Yes	4 (9.1)
No	40 (90.9)
Infection	
Yes	24 (52.2)
No	22 (47.8)

Table 1. Clinical characteristics

Survival outcomes	n (% , range)
Median follow-up (months)	18 (1-27)
100-day survival	43 (93.5)
6-month survival	42 (91.3)
1-year survival	41 (84.8)
Incidence of relapse	5 (10.9)
Non-relapse mortality	5 (10.9)
Median OS (months)	Not reached
Estimated OS rates	
1-year (%)	89.1
2-year (%)	86.6

Variables	Multivariate regression results HR (95% CI)	p-value
# of antigen mismatch		
0		
1	0.00 (0.00)	0.98
>1	10.42 (0.44-245.62)	0.15
Conditioning intensity		
Myelo ablative		
Reduced-intensity	0.69 (0.068-6.92)	0.75
HCT-CI score		
0		
1-2	1.29 (0.097-16.97)	0.85
≥3	1.32 (0.088-19.84)	0.84
Acute graft-versus-host disease		
No		
Yes	0.21 (0.016-2.75)	0.23
Chronic graft-versus-host disease		
No		
Yes	0.00 (0.00)	0.99
Infection		
No		
Yes	7.18 (0.73-70.57)	0.091
Mean tacrolimus levels	2.75 (1.36-5.55)	0.005

Table 3. Multivariate Cox regression analysis of tacrolimus levels within 30 days post-transplant and other clinical variables with overall survival

Variables	Multivariate regression results HR (95% CI)	p-value
# of antigen mismatch		
0		
1	0.00 (0.00-1.01*10 ²³⁵)	0.96
>1	3.61 (0.25-51.85)	0.35
Conditioning intensity		
Myelo ablative		
Reduced-intensity	0.69 (0.064-7.60)	0.77
HCT-CI score		
0		
1-2	0.62 (0.049-7.75)	0.71
≥3	1.02 (0.085-12.30)	0.99
Acute graft-versus-host disease		
No		
Yes	0.59 (0.065-5.50)	0.65
Chronic graft-versus-host disease		
No		
Yes	0.00 (0.00)	0.99
Infection		
No		
Yes	2.99 (0.41-21.65)	0.28
Mean tacrolimus levels		
≤10.5 ng/mL		
>10.5 ng/mL	16.43 (1.60-168.51)	0.018

Table 4. Multivariate Cox regression analysis of mean tacrolimus levels >10.5 ng/mL within 30 days post-transplant and other clinical variables with overall survival

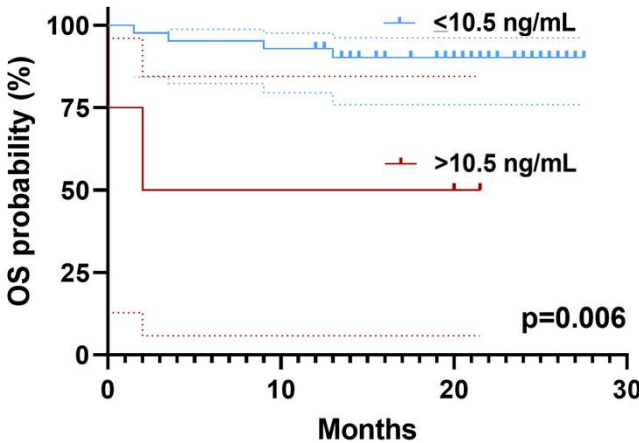


Figure 1. Overall survival (OS) of patients with mean tacrolimus levels <10.5 ng/mL compared to >10.5 ng/mL within 30 days post-transplant