

Consensus on graft-versus-host disease

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ABSTRACT

Graft-versus-host disease (GVHD) remains the mainly cause of late non-relapse mortality following allogeneic hematopoietic cell transplantation. Advancements in novel immunosuppressive therapies and prophylactic regimens necessitate an update to current clinical guidance. This consensus provides updated evidence-based recommendations for GVHD prophylaxis, alongside the treatment of acute and chronic disease.

Keywords: Graft vs Host Disease. Therapeutics. Consensus.

INTRODUCTION

The 2025 updates to the 2022 Consensus Guidelines of the Brazilian Society of Cellular Therapy and Bone Marrow Transplantation on Graft-versus-Host-Disease (GVHD) include:

- Table 1: GVHD prophylaxis regimens used, with levels of evidence and grades of recommendation:
- GVHD prophylaxis with calcineurin inhibitor and sirolimus in myeloablative (MA) allogeneic hematopoietic cell transplantation (allo-HCT) from matched related and matched and mismatched unrelated donors;
- GVHD prophylaxis with post-transplantation cyclophosphamide (PTCy) alone or associated with mycophenolate mofetil (MMF)/calcineurin inhibitor (adults) in MA allo-HCT from matched related and matched and mismatched unrelated donors;
- GVHD prophylaxis with PTCy/MMF/sirolimus in myeloablative MA allo-HCT from matched related and matched and mismatched unrelated donors;

- GVHD prophylaxis with Abatacept in mismatched unrelated donors;
- GVHD prophylaxis with PTCy in reduced intensive conditioning (RIC) and non-myeloablative (NMA) allo-HCT;
- PTCy/MMF/sirolimus in RIC and NMA allo-HCT;
- GVHD prophylaxis with sirolimus/cyclosporine/MMF in RIC and NMA allo-HCT;
- GVHD prophylaxis with PTCy/MMF/sirolimus in haploidentical HCT;
- GVHD prophylaxis with Rabbit Antithymocyte Globulin (rATG) in HLA-identical allo-HCT from related and unrelated donors using peripheral blood stem cells (PBSC) as stem cell source;
- Table 7: Second-line therapy of chronic GVHD (cGVHD), with levels of evidence and grades of recommendation:
- Axatilimab.

Graft-versus-host disease (GVHD) is a common complication of allogeneic hematopoietic cell transplantation (allo-HCT). It occurs when immune cells from a non-identical donor (the graft) react against a transplant recipient (the host). Acute and chronic GVHD are multisystem disorders that differ in several respects, with the most widely accepted distinctions being those defined by the consensus criteria proposed by the National Institutes of Health (NIH)¹.

Despite appropriate immunoprophylaxis, 20–80% of recipients develop some degree of acute GVHD after allo-HCT². The main risk factors for acute GVHD are donor-recipient human leukocyte antigen (HLA)-mismatch; donor-patient gender disparity; conditioning regimen intensity; prophylactic regimen used; and stem cell source (peripheral blood > bone marrow > umbilical blood cord)³.

To a better standardization of the criteria for classification and data reporting of acute GVHD, the Mount Sinai Acute GVHD International Consortium (MAGIC)⁴ is currently considered the most appropriate method for the diagnosis, staging, and grading of acute GVHD^{4,5}. The application for grading can be accessed at <https://www.uzleuven.be/egvhd>.

As the leading cause of long-term morbidity and mortality after hematopoietic cell transplantation (HCT) in this population, chronic GVHD occurs in 30–70% of allo-HCT recipients^{6–8}, with a two-year cumulative incidence of 34% among recipients of related or unrelated donor HCT using bone marrow or peripheral blood stem cells (PBSC) grafts, as defined by the NIH criteria³. The main risk factors for this complication include HLA-matched unrelated, HLA-mismatched related, or HLA-mismatched unrelated donors; female-to-male donor-recipient sex mismatch; mobilized peripheral blood grafts; and older donor and recipient age³. The NIH consensus criteria are widely used for the classification and severity grading of cGVHD¹. The application for grading can be accessed at <https://www.uzleuven.be/egvhd>.

Table 1 shows GVHD prophylaxis regimens:

Table 1. Graft-versus-host disease prophylaxis regimens, with levels of evidence and grades of recommendation.

Type of allo-HCT	Prophylaxis regimen	Level of evidence
MA allo-HCT using matched related and matched/mismatched unrelated donors	Calcineurin inhibitor and methotrexate (MTX) ^{9–15}	Level 1a, grade of recommendation A
	Calcineurin inhibitor and mycophenolate mofetil (MMF) ^{14–22}	Level 1a, grade of recommendation B; level 1b, grade of recommendation A; level 2b, grade of recommendation B
	Calcineurin inhibitor and sirolimus ^{23–26}	Level 1b, grade of recommendation A
	PTCy alone (50 mg/kg on D+3 and D+4) or combined with MMF/calcineurin inhibitor (adults) ^{27–43}	Level 1b, grade of recommendation A; level 2b, grade of recommendation C; level 3b, grade of recommendation B; level 2b, grade of recommendation B
	PTCy (50 mg/kg on D+3 and D+4)/MMF/sirolimus ⁴⁴	Level 2b, grade of recommendation B
	Abatacept ⁴⁵	Level 2b, grade of recommendation B

Continue...

Continuation.

Type of allo-HCT	Prophylaxis regimen	Level of evidence
RIC and NMA allo-HCT	Calcineurin inhibitor and MMF ^{19,46–49}	Level 4, grade of recommendation C; level 2b, grade of recommendation B; level 1b, grade of recommendation A
	PTCy (50 mg/kg on D+3 and D+4) ^{43,50–54} (for adults)	Level 1b, grade of recommendation A; level 2b, grade of recommendation B; level 3b, grade of recommendation B
	PTCy (50 mg/kg on D+3 and D+4)/MMF/sirolimus ⁵⁵	Level 2b, grade of recommendation B
	Sirolimus/cyclosporine/MMF ^{56–58}	Level 2b, grade of recommendation B; level 1b, grade of recommendation A
HLA-identical allo-HCT using related and unrelated PBSC donors	Rabbit antithymocyte globulin (rATG) < 6 mg/kg ^{59–73}	Level 1a, grade of recommendation A; level 1b, grade of recommendation A
Haploidentical allo-HCT	PTCy (50 mg/kg on D+3 and D+4) plus a calcineurin inhibitor and MMF ^{74–76}	Level 2b, grade of recommendation B
	PTCy/MMF/Sirolimus ^{77–80}	Level 2b, grade of recommendation B
Haploidentical allo-HCT — Beijing protocol	High-dose rATG (10 mg/kg), MMF, calcineurin inhibitor, and MTX ⁸¹	Level 2b, grade of recommendation B

HCT: hematopoietic cell transplant; MA: myeloablative; allo-HCT: allogeneic hematopoietic cell transplant; RIC: reduced-intensity conditioning; NMA: non-myeloablative; HLA: human leukocyte antigen; PBSC: peripheral blood stem cells; PTCy: post-transplant cyclophosphamide; *consider decreasing the PTCy dose in elderly patients or with cardiac morbidity (level of evidence 1b, grade of recommendation B)^{82–84}. Source: Elaborated by the authors.

Table 2 shows first-line therapy for grade I-IV acute GVHD:

Table 2. First-line therapy for grade I-IV acute graft-versus-host disease, with levels of evidence and grades of recommendation.

Grade	Treatment	Level of evidence
I	Optimize prophylactic regimen, adjust calcineurin inhibitor through levels, add topical corticosteroids or tacrolimus. No systemic immunosuppression is recommended ⁸⁵	Level of evidence 1b, grade of recommendation A
IIa* (less severe forms)	Start MP 0.5–1 mg/kg/day, escalating up to 2 mg/kg if worsening occurs after 72 hours ⁸⁶ . Do not withdraw concomitant calcineurin inhibitor (cyclosporine or tacrolimus) prophylaxis. Add non-absorbable glucocorticoids (beclomethasone and budesonide) as an adjuvant to systemic corticosteroids for mild upper or lower GI acute graft-versus-host disease (500–1,000 mL/stool output/day) ^{87,88}	Level of evidence 1b, grade of recommendation A; level of evidence 1b, grade of recommendation A
II-IV	Start MP 2 mg/kg/day or its prednisone equivalent ⁸⁵ . Do not withdraw concomitant calcineurin inhibitor (cyclosporine or tacrolimus) prophylaxis	Level of evidence 1a, grade of recommendation A

*Any combination comprising a rash involving < 50% of the body surface area without rapid progression within the first 6–24 hours, anorexia, nausea, emesis, or diarrhea < 1 L/day (children < 20 mL/kg/day), in the absence of liver involvement (bilirubin < 2 mg/dL in the absence of either hepatic complications or < 3 mg/dL if hepatic complications other than graft-versus-host disease are present); mild graft-versus-host disease confined to the skin and covering < 50% of the total body surface area not rapidly progressing does not usually require treatment with prednisone⁸⁹; MP: methylprednisolone; GI: gastrointestinal. Source: Elaborated by the authors.

Table 3 shows chronic GVHD indication for systemic treatment:

Table 3. Chronic graft-versus-host disease indication for systemic treatment¹: level of evidence 2b, grade of recommendation B.

Global severity	High risk for mortality*	Systemic treatment
Mild	No	No
Mild	Yes	Yes [#]
Moderate	No/Yes	Yes
Severe	No/Yes	Yes

*Platelets < 100,000/mm³ or receiving steroids at the time of chronic graft-versus-host disease diagnosis; [#]the risk of chronic graft-versus-host disease should be weighed against the benefits of the graft-versus-tumor effect. Source: Elaborated by the authors.

Table 4 shows first-line therapy of chronic GVHD:

Table 4. First-line therapy of chronic graft-versus-host disease, with levels of evidence and grades of recommendation*.

Treatment	Level of evidence
Standard treatment comprises prednisone 1 mg/kg/day and cyclosporine ^{2,90}	Level of evidence 1c, grade of recommendation A

*Criteria for starting systemic treatment for chronic graft-versus-host disease: score > 2 in at least one organ, involvement of ≥ three organs with a score of 1, lung score of 1 or 2, and mild chronic graft-versus-host disease with high-risk features (thrombocytopenia < 100,000/mm³ and immunosuppressive therapy at the time of chronic graft-versus-host disease diagnosis)⁹¹. Source: Elaborated by the authors.

Table 5 shows the definition of steroid refractoriness or resistance, steroid dependence, and steroid intolerance for acute and chronic GVHD:

Table 5. Definition of steroid refractoriness or resistance, steroid dependence, and steroid intolerance for acute and chronic graft-versus-host disease⁵: level of evidence 5, grade of recommendation D.

	aGVHD	cGVHD
Refractoriness or resistance	aGVHD progressing within three to five days after initiation of therapy with ≥ 2 mg/kg/day of prednisone OR failure to improve within five to seven days after initiation of treatment OR incomplete response after > 28 days on immunosuppressants including steroids	cGVHD progressing while on prednisone at ≥ 1 mg/kg/day for one or two weeks OR stable GVHD while on ≥ 0.5 mg/kg/day of prednisone for one or two months
Dependence	Inability to taper prednisone below 2 mg/kg/day OR recurrence of aGVHD while tapering steroids	Inability to taper prednisone below 0.25 mg/kg/day in at least two unsuccessful attempts at least eight weeks apart
Intolerance	Unacceptable toxicity emerging while on steroids	

aGVHD: acute graft-versus-host disease; cGVHD: chronic graft-versus-host disease. Source: Elaborated by the authors.

Table 6 shows second-line therapy for grade II-IV acute GVHD:

Table 6. Second-line therapy for grade II-IV acute graft-versus-host disease, with levels of evidence and grades of recommendation.

MMF	Level of evidence 2b, grade of recommendation C ⁹²⁻⁹⁵	Six-month complete response (CR) and partial response (PR) rates of up to 77%
Extracorporeal Photopheresis	Level of evidence 2a, grade of recommendation B ⁹⁶⁻¹⁰⁷	Overall response rates (ORR) of 84 and 65% in skin and gut aGVHD, respectively
ATG	Level of evidence 2b, grade of recommendation C ^{108,109}	ORR between 20 and 50%, particularly in skin aGVHD
Basiliximab	Level of evidence 2b, grade of recommendation B ^{110,111} Response rates of approximately 80%, with a five-year overall survival of 30%	
Infliximab and etanercept	Level of evidence 2b, grade of recommendation C ¹¹²	ORR around 70%, particularly in gut aGVHD
Ruxolitinib	Level of evidence 1b, grade of recommendation A ¹¹³⁻¹¹⁷	The REACH2* phase III study showed a 28-day ORR of 62%, compared to an ORR of 39% in the control group
Mesenchymal Stromal cell infusion	Level of evidence 2c, grade of recommendation B ¹¹⁸	50% ORR; two-year estimated probability of survival of 17.4%

MMF: mycophenolate mofetil; ATG: antithymocyte globulin; aGVHD: acute graft-versus-host disease. Source: Elaborated by the authors.

Table 7 shows second-line therapy of chronic GVHD:

Table 7. Second-line therapy of chronic graft-versus-host disease, with levels of evidence and grades of recommendation.

Extracorporeal photopheresis	Level of evidence 1b, grade of recommendation A ^{106,119–123}	Mucocutaneous manifestations, with complete response (CR) rates > 80% and significant improvement in sclerotic cGVHD
MMF	Level of evidence 4, grade of recommendation B ^{124,125}	Overall response rates (ORR) from 23 to 79% in several case series
Sirolimus	Level of evidence 4, grade of recommendation B ^{126–128}	ORR varying between 63 and 81% in several case series
Rituximab	Level of evidence 2b, grade of recommendation B ^{129–131}	Mucocutaneous and musculoskeletal manifestations, with an ORR around 70%
Imatinib	Level of evidence 2b, grade of recommendation B ^{131,132}	Cutaneous, ocular, and gut cGVHD, with an ORR of 50 to 80%
Methotrexate	Level of evidence 4, grade of recommendation B ^{133,134}	ORR varying between 58.8 and 71% in most case series
Ibrutinib	Level of evidence 2b, grade of recommendation B ^{135,136}	ORR of 67%, with a CR rate of 21%
Ruxolitinib	Level of evidence 1b, grade of recommendation A ¹³⁷	ORR of 49.7% for ruxolitinib versus 25.6% for controls (odds ratio = 2.99; $p < 0.001$); median failure-free survival > 18.6 months for ruxolitinib versus 5.7 months for controls (hazard ratio = 0.37; $p < 0.001$), and higher symptom response (24.2 versus 11%) in the ruxolitinib arm (odds ratio = 2.62; $p = 0.001$)
Belumosudil	Level of evidence 2b, grade of recommendation B ¹³⁸	ORR of 74% (95%CI, 62–84%) and 77% (95%CI, 65–87%) for belumosudil 200 mg daily × 200 mg twice daily, respectively; symptom reduction of 59 and 62% with belumosudil 200 mg daily and 200 mg twice daily, respectively
Axatilimab	Level of evidence 1b, grade of recommendation A ¹³⁹	In a pivotal, multinational, randomized phase II study, patients with recurrent or refractory cGVHD were assigned to receive axatilimab 0.3 mg/kg every two weeks (0.3 mg dose group), 1 mg/kg every two weeks (1 mg dose group), or 3 mg/kg every four weeks (3 mg dose group). ORR was 74% (95%CI 63–83) in the 0.3 mg dose group, 67% (95%CI 55–77) in the 1 mg dose group, and 50% (95%CI 39–61) in the 3 mg dose group

cGVHD: chronic graft-versus-host disease; MMF: mycophenolate mofetil; 95%CI: 95% confidence interval. Source: Elaborated by the authors.

CONCLUSION

The 2025 updates to the Brazilian Society of Cellular Therapy and Bone Marrow Transplantation Consensus Guidelines mark a pivotal advancement in standardizing the prophylaxis and therapeutic management of acute and chronic GVHD in Brazil. By incorporating precise conditioning regimens and innovative targeted platforms—such as post-transplantation cyclophosphamide combinations, sirolimus, and abatacept—, these updated guidelines optimize patient safety and clinical outcomes.

This comprehensive document serves as an essential framework for transplant physicians to unify clinical practices, while simultaneously providing public and private healthcare managers with an objective, evidence-based benchmark to guide sustainable resource allocation and ensure equitable access to high-value care.

CONFLICT OF INTEREST

Nothing to declare.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable.

AUTHORS' CONTRIBUTION

Conception and design: Funke VAM and Vigorito AC. **Acquisition of data:** Macedo AV, Feliciano JVP, Fatobene G, Moreira MCR. **Analysis and interpretation of data:** Macedo AV, Feliciano JVP, Fatobene G, Moreira MCR. **Manuscript writing:** Vigorito AC, Feliciano JVP and Macedo AV. **Critical revision:** Tavares RCBS, Silva MM, Colella MP, Rodrigues M and Bouzas LFS. **Final approval of the version to be published:** Vigorito AC.

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DECLARATION OF USE OF ARTIFICIAL INTELLIGENCE TOOLS

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