Consensus in stem cell transplantation for pediatric lymphomas

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ABSTRACT

Lymphomas are the third most common childhood cancer in Brazil. Management is predicated on precise diagnosis and staging through clinical, pathological, molecular, and radiological evaluation. Although the prognosis for pediatric non-Hodgkin and Hodgkin lymphoma has improved markedly, relapsed or refractory cases remain a clinical challenge. For these patients, aggressive chemotherapy followed by autologous or allogeneic hematopoietic cell transplantation serves as a vital salvage strategy. The Pediatric Group of the Brazilian Society of Bone Marrow Transplantation and Cellular Therapy has revised its current consensus, providing updated recommendations for indications and conditioning protocols. This revision also includes the assessment of new therapeutic strategies, including immunotherapy and CAR-T cell therapy, for eligible patients.

Keywords: Pediatrics. Stem Cell Transplantation. Lymphoma.

INTRODUCTION

Lymphomas are the third most common cancer of childhood in Brazil[1]. The diagnosis and staging are based on clinical presentation, pathology findings with immunohistochemistry, molecular biology, and radiological imaging. The treatment with multiagent chemotherapy and/or radiotherapy is defined according to the lymphoma subtype, risk stratification, and institutional protocol[2].

The prognosis of children and adolescents with non-Hodgkin lymphomas (NHL) and Hodgkin's lymphomas (HL) has markedly improved in the last decades. However, relapsed or refractory disease is still associated with an inferior outcome. Aggressive chemotherapy followed by either autologous (auto) or allogeneic hematopoietic cell transplantation (allo-HCT) is a salvage treatment strategy described in the literature, with particularities according to lymphoma subtype and to the available source of stem cells[3], as summarized in Table 1.

NON-HODGKIN LYMPHOMA

Pediatric NHL generally has a favorable prognosis with conventional chemotherapy, achieving over 80% survival rates in common subtypes. While prognosis has improved, relapsed or refractory (R/R) disease remains challenging, often requiring aggressive chemotherapy and hematopoietic cell transplantation (HCT)[3].

Table 1. Type of transplant.

	Disease Phase	Autologous	Allogenic
Non-Hodgkin lymphomas (BL, DLBL, anaplastic large-cell lymphoma)	First remission	No	No
	Second remission/refractory	Yes	Yes
Lymphoblastic lymphoma	First remission	No	No
	Second remission/refractory	No	Yes
Hodgkin lymphomas	First remission	No	No
	Second remission/refractory	Yes	Yes*

BL DLBL; *it should be used for relapse after auto-hematopoietic cell transplantation or failure to mobilization. Source: Elaborated by the authors.

MATURE B-CELL LYMPHOMAS

Burkitt lymphoma (BL) and diffuse large B-cell lymphoma (DLBCL) are the most common NHL subtypes, with event-free survival rates reaching 90%. The use of rituximab in first-line therapy has significantly improved outcomes in high-risk B-cell NHL by increasing remission rates, reducing R/R disease, and consequently decreasing the need for intensive salvage therapies. In high-risk disease, it should be considered the standard of care[4,5].

Prognostic factors for R/R disease include initial treatment intensity (*e.g.*, rituximab use), lactate dehydrogenase levels, early relapse, and bone marrow involvement[4]. DLBCL generally has better survival outcomes than BL[5]. HCT is recommended for chemo-sensitive patients, while those refractory to reinduction ones or first-line therapy derive no survival benefit.

Salvage therapies and transplantation

Salvage regimens include high-risk Berlin-Frankfurt-Münster (BFM) blocks, rituximab, ifosfamide, carboplatin and etoposide (R-ICE), ifosfamide, carboplatin, idarubicin/mitoxantrone, paclitaxel, and rituximab (R-ICI/ICN), and rituximab, vincristine, idarubicin, ifosfamide, carboplatin and dexamethasone (R-VICI), with R-VICI demonstrating the best results[6]. Even in patients who have received rituximab in first-line treatment, reinduction regimens typically include anti-CD20. It is important to remember that remissions are transient, making transplantation an urgent need.

Allo-HCT is a viable alternative to auto-HCT, offering comparable outcomes, especially in cases with mobilization failure or when chemotherapy delays for stem cell collection pose a challenge due to disease progression[7].

A study by Woessmann et al.[6] reported that reinduction with intensive continuous chemotherapy using R-VICI before reduced intensity conditioning (RIC) allo-HCT resulted in the highest survival outcomes documented for relapsed/refractory BL, with a four-year overall survival rate of 67%.

There are no prospective randomized trials comparing HCT modalities, but an auto-HCT is preferred for DLBCL, while both approaches can be used for BL (46 ± 5% *versus* 44 ± 6%)[5].

A tandem transplant strategy has also been explored, in which a myeloablative (MAC) auto-HCT maximizes response, followed by RIC allo-HCT to lower toxicity while maintaining the graft-*versus*-lymphoma effect[7].

Emerging therapies: CAR-T and targeted agents

CAR-T cell therapy has emerged as a promising option for pediatric patients with relapsed/refractory DLBCL. While its use is well-established in adults, research in children is still evolving, and ongoing studies will help better define its role and long-term outcomes in the pediatric population. Although experience in pediatric BL is limited, early data suggest that CAR-T therapy could be an alternative for select patients with persistent disease following salvage chemotherapy[8,9]. However, challenges such as immune escape, relapse, and CAR-T cell persistence remain key areas of investigation.

ANAPLASTIC LARGE-CELL LYMPHOMA

Anaplastic large-cell lymphoma (ALCL) accounts for 10 to 15% of NHL in children, with more than 95% of pediatric patients having anaplastic lymphoma kinase (ALK)–positive disease[10,11]. Second remission is often consolidated with either high-dose chemotherapy and auto-HCT or allo-HCT, yielding an overall survival rate of 50 to 60%[12].

ALK-positive ALCL is often resistant to conventional chemotherapy. Therefore, salvage therapy is required. In recent years, targeted therapies, such as ALK inhibitors and brentuximab vedotin (BV) have been developed, and they have demonstrated dramatic responses in chemoresistant ALK-positive ALCL[13–15]. HCT may not be necessary for all R/R patients to achieve durable remission, but questions persist about how best to identify patients who may benefit from HCT, the optimal duration of targeted therapy, and the use of combination therapy necessary to achieve a cure[16]. In contrast to these intensive therapies, some patients with late relapses have responded to single-agent vinblastine therapy with durable remissions[17].

Knörr et al.[18] have recently reported the results of the ALCL-relapse trial, and auto-HCT was less effective for pediatric patients who experienced early relapse within one year after initial diagnosis when compared to allo-HCT. The five-year event-free survival for CD3-positive ALCL patients was 25% with auto-HCT, compared to 65% with allo-HCT—auto-HCT with BEAM and allo-HCT using TBI or Bu + thiotepa and VP). BFM group reported allo-HCT with MAC (with TBI or busulfan) and ranged event-free survival 75%[11].

In cases for whom therapeutic toxicity is a concern, using RIC has the potential to reduce the incidence of treatment-related death, like demonstrated in the Japanese group in a small cohort but with good results, conditioning with low-dose TBI, fludarabine, and melphalan[19].

Lymphoblastic lymphoma

Lymphoblastic lymphoma (LBL) is the second most common type of NHL in childhood and adolescence, accounting for 25–35% of all cases[20]. With current therapy, the event-free and overall survival for pediatric LBL patients exceeds 80%[21].

R/R LBL are commonly treated with an ALL-type treatment strategy, allo-HCT with a TBI-based conditioning regimen is recommended. The event-free survival for patients treated with allo-HCT was 40% compared with 4% in the patients who underwent auto-HCT[5,12,22].

B-lymphoblastic lymphoma patients were included in the humanized anti-CD19 CAR-T cell trial, with promising anti-tumor efficacy despite the small sample size[23].

The recommended conditioning regimens and salvage treatment strategies for NHL are summarized in Table 2.

Table 2. Suggested strategies according to B-non-Hodgkin lymphoma subtype.

Subtype	Salvage treatment	Conditioning regimen	References
BL	R-ICE or R-VICI	Auto-HCT: Bu 130 mg/m²/d–D-7 to D-4 (AUC 5,000 µM-min) + Mel 140 mg/m²/D-2 to D-1; Allo-HCT: rituximab 375 mg/m² D-10 and D-7, Flu 40 mg/m² D-9 to D-6, paclitaxel 175 mg/m² (3h) D-9, mitoxantrone 10 mg/m² (0.5 h) D-9 and D-8, carboplatin 300 mg/m² (96 h) D-7 to D-4, thiotepa 250 mg/m² (1h) D-6 to D-4 *or* TBI-based	5,6,24
DLBL	R-ICE	BEAM: BCNU 300 mg/m² (single dose) D-6 + VP 800 mg/m² (D-5 to D-2) + cytarabine 1,600 mg/m² twice daily (D-5 to D-2) + Mel 140 mg/m² (D-1)	5,25
ALCL	Vinblastin-based. BV Crizotinib	TBI 12 Gy D-8 to D-6 + VP 40 mg/kg D-5 + Cy 120 mg/kg D-4 and D-3	26
LBL	ALL protocol	ALL conditioning regimen Total body radiation 1,200 Gy + VP 60 mg/kg D-3	

HCT: hematopoietic cell transplantation; R-ICE: rituximab, ifosfamide, carboplatin and etoposide; R-VICI: rituximab, vincristine, idarubicin, ifosfamide, carboplatin and dexamethasone; BL: Burkitt lymphoma; DLBL: diffuse large cell lymphoma; ALCL: anaplasic large cell lymphoma; LBL: lymphoblastic lymphoma; ALL: acute lymphoblastic leukemia. Source: Elaborated by the authors.

HODGKIN LYMPHOMAS

Due to the high-response rates to conventional treatment, auto-HCT is not indicated as first-line therapy in pediatric HL patients, and it is generally reserved for relapse or primary refractory diseases[27]. These patients can use a risk stratification to guide rescue treatment plans, as shown in Table 3[28].

Table 3. Risk stratification for relapsed and refractory classical Hodgkin lymphoma and proposed treatment.

Risk stratification	Criteria	Proposed treatment
Low risk	- Early relapse (< four cycles of first-line chemo); - Late relapse (< six cycles of first-line chemo); - Relapse in stages I–III, without radiotherapy or radiotherapy at a site distinct from the relapse	- Chemotherapy and radiotherapy; - After two cycles, complete response on positron emission tomography–computed tomography; - No response, move to the "Standard" group
Standard	- Primarily progressive; - Early relapse (> four cycles of first-line chemotherapy); - Stage IV; - Relapse at a previously irradiated site; - If radiotherapy is considered too toxic.	- Chemotherapy Remission after the first or second line, proceed to auto-HCT. No remission, move to high-risk group
High risk	- Patients from the "Standard" group with no response to two lines of salvage therapy	- Therapeutic options to achieve remission before HCT; - Auto-HCT; - Tandem; - Allo-HCT/haplo

HCT: hematopoietic cell transplantation. Source: Daw et al.[28].

The goal of rescue chemotherapy is to achieve complete metabolic remission, with pre-auto-HCT positron emission tomography–computed tomography (PET-CT) being a key marker to determine the success of treatment. Even after a partial response, transplantation may still be considered. Special attention must be paid in PET-CT after immune checkpoint inhibitors (anti-PD1) that can present pseudoprogression of HL[29–31].

There is no standard salvage regimen for pediatric and adolescent patients with R/R HL. Recent trials have sought to optimize response while trying to minimize additional toxicity before auto-HCT. Regimens such as gemcitabine/vinorelbine/ifosfamide/prednisone (IGEV), GV or IV with or without bortezomib demonstrated comparable responses to the more toxic regimens, such as ICE, and are preferred among pediatric oncologists[28,32]. Conjugated antibody therapy, BV, or immunotherapy with anti-PD1, nivolumab or pembrolizumab can be used as rescue treatment for refractory or relapsed patients after second-line therapy[33–35]. Subsequent studies have sought to combine BV with traditional cytotoxic chemotherapy, like bendamustine (Benda) or gemcitabine (Gem), to improve responses[32,36]. PD-1 blockade may augment chemosensitivity in patients with R/R HL, and auto-HCT was associated with excellent outcomes, even among heavily pretreated, previously chemorefractory patients[37].

High-dose chemotherapy and autologous hematopoietic cell transplantation

There is no standard conditioning in the pediatric HL. The optimal conditioning regimen should be based on clinical status, known efficacy of previous drugs utilized, tumor localization, financial cost, and regulatory approval by local authorities. The most used conditioning regimens are the BEAM regimen or the alternative LEAM, which appears to have equivalent toxicity and efficacy. Benda, a very active drug in HL, may also be used in a conditioning regimen. Studies comparing BEAM and benda-EAM (with bendamustine replacing BCNU) have shown similar four-year progression free-survival (PFS) and overall survival[28]. Nieto et al.[38–40] present gemcitabine/busulfan/melphalan as a feasible regimen with substantial activity against a range of lymphoid malignancies with improved outcomes. The consensus suggestion is shown in Table 4.

Maintenance therapy after auto-hematopoietic cell transplantation

BV therapy as consolidation after auto-HCT can offer benefits for patients with R/R HL and higher risk of relapse (primary refractory disease, early relapse < 12 months after initial therapy, partial response to rescue therapy,

Table 4. Conditioning regimens for autologous transplant Hodgkin lymphoma.

Name	Description	References
BEAM	- BCNU 300 mg/m² (single dose) D-6 + VP 800 mg/m² (D-5 to D-2) + cytarabine 1,600 mg/m² twice daily (D-5 to D-2) + Mel 140 mg/m² (D-1)	56,57
BU/Mel/Gem - High risk	- Gem 2,000 mg/m² D-8 + Bu 16 mg/kg D-8 to D-5 + Mel 140 mg/m² D-3 to D-2	38
Bu/Mel - Standard risk	9	
Other options		
LEAM Benda-EAM	Using CCNU 200 mg/m² D-6 *or* Benda 200 mg/m² D-7 to D-6 (in the place of BCNU); - VP 800 mg/m² (D-5 to D-2) + cytarabine 1,600 mg/m² twice daily (D-5 to D-2) + Mel 140 mg/m² (D-1)	57,58
BuCy	- Bu (dose according to body weight* or adjustment based on pharmacokinetic studies, if available): D-8 to D-5 + Cy 120 mg/kg (D-4 and D-3) w/wo VP 45–60 mg/kg D-5	59–61

*Intravenous daily dose = < 9 kg: 4 mg/kg; 9 to < 16 kg: 4.8 mg/kg; 16–23 kg: 4.4 mg/kg; > 23 to 34 kg: 3.8 mg/kg; > 34 kg: 3.2 mg/kg; carmustine; CCNU: lomustine; VP: etoposide. Source: Elaborated by the authors.

B symptoms or extranodal disease at relapse, and two or more rescue therapies prior to transplantation). The use of 16 cycles of BV (1.8 mg/kg every three weeks) after auto-HCT has shown to improve PFS, although with limited impact on overall survival. Studies have not proven the benefit of other maintenance regimens yet[41–44].

Radiotherapy

The role of radiotherapy in the treatment of R/R HL in combination with HCT is not fully established yet. However, it remains a viable therapeutic option, especially considering that many pediatric patients with relapsed HL did not receive irradiation as part of their first-line treatment. Some studies suggest that post-transplant local radiotherapy may improve PFS, though with no significant impact on overall survival. Patients with limited-stage relapses, bulky disease, B symptoms, refractory disease, or partial response to pre-transplant treatment could be candidates for post-transplant local irradiation. Patients who do not achieve complete remission after transplantation may also benefit from local radiotherapy[28].

Allogenic hematopoietic cell transplantation

TANDEM transplantation is an alternative for patients considered at high risk for relapses after auto-HCT. This approach consists of a MAC auto-HCT followed by a non-myeloablative conditioning allo-HCT, which could be a safety and efficacy strategy for refractory patients, using matched or haplo-donors[45,46].

Allo-HCT can be considered for relapses post-auto-HCT, failure to harvest stem cells from the bone marrow or the peripheral blood or after several relapses. The conditioning regimens are either MAC or RIC, with an expected graft *versus* lymphoma effect to reduce the risk of relapse. The overall survival is comparable in both approaches, with relapses more like after a RIC transplant, whereas toxicity is more common following MAC strategy. The choice between RIC and MAC should consider the patient's individual treatment strategy, clinical status, number of previous treatments, and the perspective of adjuvant therapy[47]. With modern transplant practices, the non-relapse mortality (NRM) associated with MAC for HL has strongly decreased, resulting in non-significant improvement of event-free survival, because of a somewhat better disease control compared with RIC transplants[48]. Conditioning regimens are in Table 5 and GVHD prophylaxis in Table 6.

The use of T-cell-replete haploidentical HCT (haplo-HCT) with post-infusion cyclophosphamide (PTCy) in advanced hematological malignancies showed a good toxicity profile. It appears that haplo-HCT acts effectively against HL cells (immunological effect) and it is a good choice in the treatment of poor prognosis HL without a HLA donor[49]. Comparative studies demonstrated that allo-HCT from full-matched and haplo-donors have similar outcomes, with a reduced relapse rate and better overall survival with PTCy haplo-HCT[50–52].

Table 5. Conditioning regimens for allogeneic transplant Hodgkin lymphoma.

Donor	Conditioning regimens	References
Matched donor	RIC: Flu 150 mg/m² D-8 to D-4 + Mel 140 mg/m² D-3 to D-2	47,48,62
	BEAM or LEAM (w/wo intravenous alemtuzumab 10 mg D-5 to D-1)	63
	MAC: Bu (dose according to body weight* or adjustment based on pharmacokinetic studies, if available) (D-8 to D-5) + Cy 120 mg/kg (D-4 and D-3) w/wo VP 30 mg/kg D-5	60,61
Haplo	Cy 29 mg/kg D-6 and D-5 + Flu 150 mg/m² D-6 to D-2 + TBI (2 Gy) on D-1	50

*Intravenous daily dose = < 9 kg: 4 mg/kg; 9 to < 16 kg: 4.8 mg/kg; 16–23 kg: 4.4 mg/kg; > 23 to 34 kg: 3.8 mg/kg; > 34 kg: 3.2 mg/kg; RIC: reduced intensity conditioning; MAC: myeloablative; VP: etoposide; TBI: total body irradiation. Source: Elaborated by the authors.

Table 6. Graft-*versus*-host disease prophylaxis.[50,60-63]

Donor	Immunosuppression
Matched	CYS D-2 to D+180 (tapering from D+90) + MTX 10 mg/m² D+1, +3, +6 (+–D+11) (ATG 5 mg/kg D-4 to D-2 if MUD)
Haplo	CYS D-2 to D+180 (tapering from D+90) + MTX 10 mg/m² D+1, +3, +6 (+–D+11) (ATG 5 mg/kg D-4 to D-2 if MUD)

CYS: cyclosporine; MTX: methotrexate; ATG: rabbit antithymocitic globulin; MUD: matched unrelated donor. Source: Elaborated by the authors.

Allo-HCT after PD-1 blockade may be associated with increased toxicity and risk for developing severe acute graft-*versus*-host disease (GVHD), and it needs a minimal six-week interval between them. The use of PTCy-based GVHD prophylaxis was associated with significant improvements in PFS and GVHD-free relapse-free survival in this condition[53].

CAR-T cell

CAR-T cell therapy is a promising approach in oncology hematology. Patients with refractory HL treated with autologous T cells carrying a chimeric antigen receptor targeted against CD30, combined with lymphodepleting conditioning regimens, have achieved good response rates. However, these results are still preliminary, given the short follow-up time[54,55].

CONFLICT OF INTEREST

Nothing to declare.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable.

AUTHORS' CONTRIBUTIONS

Substantive scientific and intellectual contributions to the study: Kuwahara C, Breviglieri CNM, Milaré L and Menezes Neto OA. **Conception and design:** Kuwahara C, Breviglieri CNM, Milaré L and Menezes Neto OA. **Analysis and interpretation of data:** Kuwahara C, Breviglieri CNM, Milaré L and Menezes Neto OA. **Technical procedures:** Kuwahara C, Breviglieri CNM, Milaré L and Menezes Neto OA. **Manuscript writing:** Kuwahara C, Breviglieri CNM, Milaré L and Menezes Neto OA. **Final approval:** Kuwahara C.

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DECLARATION OF USE OF ARTIFICIAL INTELLIGENCE TOOLS

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