

REVIEW ARTICLE

Allogeneic haematopoietic cell transplant in cutaneous T-cell lymphomas: Recommendations from the EBMT PH&G Committee

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Abstract

This manuscript provides expert recommendations on the role of allogeneic haematopoietic cell transplantation (allo-HCT) for cutaneous T-cell lymphoma (CTCL), specifically mycosis fungoides (MF) and Sezary syndrome (SS). Critical aspects such as patient selection, timing, and bridging therapy are addressed, as well as donor source, conditioning regimens and post-transplant management. These consensus guidelines are based on a thorough literature review and discussions among leading dermatologists and haematologists. These recommendations aim to harmonize clinical practice towards improving patient outcomes in these rare but aggressive lymphomas. It is of critical importance to consider allo-HCT early in the management of eligible patients with high-risk disease. Advanced stage, large-cell transformation, relapsed or refractory disease following systemic treatment, and N3-stage lymph node involvement are indicators that should trigger consultation with a transplant haematologist in parallel with a donor search. Early interaction between dermatologists and transplant haematologists is vital to avoiding delays, which can significantly impact post-transplant outcomes and survival.

KEY WORDS

allogeneic transplantation, cutaneous T-cell, lymphomas, mycosis fungoides, Sézary syndrome, skin cancer

INTRODUCTION

Cutaneous T-cell lymphomas (CTCL) are rare cancers, with an estimated incidence of about 6–10 cases per million per

year,¹ although rates may vary based on geographical location² and ethnicity. The most prevalent subtype is mycosis fungoides (MF), accounting for approximately 50–60% of cases.³ MF presents in early stage with cutaneous patches

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and/or plaques and may have low level blood involvement and lymph node enlargement. Advanced stages may present with tumours or erythroderma and may have neoplastic involvement of blood, lymph nodes or rarely internal organs. Around a third of early-stage MF patients progress to advanced stages.⁴ Sézary syndrome (SS) is an aggressive leukaemic variant of CTCL which is traditionally defined by the triad of erythroderma, generalized lymphadenopathy and the presence of neoplastic T-cells in skin, lymph nodes and blood. The neoplastic cells, known as Sézary cells, exhibit distinctive cerebriform nuclei, expressing CD4 often with loss of CD7 and/or CD26. Of note, in HTLV-1 endemic areas, HTLV-1 serology is mandatory to rule out smouldering or aggressive cutaneous adult T cell leukaemia/lymphoma, which may have a clinical presentation similar to MF.⁵

Definitions of advanced-stage CTCL and high-risk advanced-stage CTCL are reported in Table 1.

While early stages of MF are treated by external (skin-directed) therapies as first-line treatment, later stages need systemic therapies including cytotoxic agents^{6–9} and targeted therapies.^{10,11}

Advanced-stage MF and SS are associated with a poor prognosis¹² with most patients not surviving beyond 5 years from diagnosis, and nowadays allo-HCT remains the only curative option.^{13–18} Historical data from the EBMT registry show 5-year progression-free (PFS) and overall (OS) survival rates after allo-HCT of 26% and 38%, respectively, underscoring its curative potential but also the challenges associated with the high relapse incidence (RI) observed post-transplant.^{14–17}

A recent meta-analysis on allo-HCT reported 1-year and 3-year OS rates of 51% and 40%, respectively, with PFS rates of 42% at 1 year and 33% at 3 years.¹⁸

In a recent, controlled, prospective study,¹⁴ 99 patients were stratified by disease severity and matched for confounding factors using propensity scores. Patients allocated to allo-HCT demonstrated a significantly improved PFS (9.0 months) compared to patients offered conventional

Why was this consensus process undertaken?

Although a growing body of data on allo-HCT in CTCL is being reported, there remains a notable lack of comprehensive European guidelines specifically addressing the role of allo-HCT in the treatment algorithm of CTCL and consented to by dermatologists and transplant physicians. In the absence of detailed guidelines, inconsistent referral practices can result in delayed lack of access to this potentially life-saving treatment. Standardized guidelines are needed to ensure timely referral and optimal use of allo-HCT in clinical practice.

What do these recommendations add?

The following questions are addressed:

1. Which CTCL patients are candidates for allo-HCT?
2. What is the optimal timing for allo-HCT?
3. How should allo-HCT be performed in CTCL patients?
4. How should CTCL patients be managed post-allo-HCT?

What are the implications of these recommendations for disease understanding and/or clinical care?

These recommendations provide clear guidance to dermatologists and haematologists managing patients with CTCL. By addressing the critical aspects of patient selection, optimal timing, transplantation methodology and post-transplant management, they aim to standardize clinical practices and improve patient outcomes. This guidance underscores the importance of early identification of transplant candidates and outlines strategies for effective management of the disease.

TABLE 1 Definition of advanced-stage CTCL and high-risk advanced-stage CTCL.

Disease category	Definition
Advanced-stage CTCL	• Mycosis fungoides (MF) Stages IIB to IVB (according to ISCL/EORTC staging) • Sézary syndrome
High-risk advanced-stage CTCL	Presence of one or more poor prognostic features: • Large-cell transformation (LCT) • Significant nodal involvement (N3) • Visceral involvement (M1) • Relapsed or refractory disease after first-line systemic therapy (excluding methotrexate, retinoids and interferon) • Elevated serum LDH at diagnosis • CLIC high-risk group: Stage IV disease, age > 60, LCT, elevated LDH (≥2 risk factors)

Abbreviations: CLIC, Cutaneous Lymphoma International Consortium; EORTC, European Organisation for Research and Treatment of Cancer; ISCL, International Society for Cutaneous Lymphomas; LDH, lactate dehydrogenase.

therapies (3.0 months), with a hazard ratio of 0.38 (95% CI 0.21–0.69; $p < 0.0001$) reflecting a 62% relative reduction in the risk of disease progression or death, therefore favouring allo-HCT in intention-to-treat and per-protocol analyses. Subgroup analyses revealed that the benefit of allo-HCT was consistent across MF and SS subtypes.

Although allo-HCT is mentioned in European guidelines and position statements for MF/SS, there is little detailed guidance on indications, optimal timing, and disease status for allo-HCT, as well as about the specific modalities on how to best perform transplantation.^{19,20}

In this project, a multidisciplinary panel of expert haematologists and dermatologists was convened to elaborate joint guidelines for allo-HCT in patients with advanced CTCL. These guidelines aim to address key clinical questions,

specifically identifying which CTCL patients are suitable candidates for allo-HCT, determining the optimal timing for transplantation and establishing best practices for performing allo-HCT in this patient population. Additionally, the guidelines provide recommendations on the post-transplant management of CTCL patients, emphasizing the importance of a collaborative approach between dermatologists and transplant physicians to ensure seamless counselling and care throughout the disease trajectory.

While these recommendations were developed through a European collaborative process, the underlying principles may be adapted to different health care systems and transplant practices. Regional variations exist—for example, in the availability of donor registries, conditioning protocols, and access to novel therapies—particularly between Europe, North America and Asia. Contextual adaptation is encouraged to enhance global applicability.

METHODOLOGY

The workshop preceding this report adhered to the methodology outlined by the EBMT Practice Harmonisation and Guidelines (PH&G) Committee.²¹ The chairs (GD and NS) selected a list of European ‘CTCL and allo-HCT experts’ based on their professional expertise and willingness to actively participate in elaborating these recommendations.

Key methodological elements and topics to be addressed were identified during a series of discussions prior to the meeting. Preparation for the workshop included a thorough literature review.

Two primary work packages (WP) were established. WP1 focused on the general treatment algorithm for CTCL entities, including the role of allo-HCT, and WP2 addressed the specifics of allo-HCT, from preparatory phases to transplantation, post-transplant maintenance and follow-up. Insights from internationally renowned reviewers further enriched these recommendations.

STATE OF THE ART

First-line therapy

First-line treatments for advanced-stage CTCL are outlined in recent EORTC consensus guidelines by Latzka et al., which recommend tailoring therapy based on the disease type (MF or SS), presence of large-cell transformation, disease burden, progression rate and patient-related factors such as comorbidities and performance status.^{19,22}

Treatment options include extracorporeal photopheresis, systemic therapies such as interferon-alpha, bexarotene and other oral retinoids, or low-dose methotrexate. In patients with limited disease and slow evolution, skin-directed therapies may also be useful, alone or in combination, such as phototherapy (UVB/PUVA) or low-dose RT. Total-skin electron-beam therapy is also an option in patients with

widespread skin disease²³ but may be best followed by a systemic treatment such as maintenance or allo-HCT. Patients with widespread disease may benefit from brentuximab-vedotin (BV)¹¹ or mogamulizumab,¹⁰ (both off-label in first-line treatment in Europe), romidepsin (off-label in Europe)²⁴ or chemotherapy.^{6–9} Allo-HCT may be considered in first remission for younger patients less than 65 years old with SS or selected high-risk patients with MF who are eligible.^{13–15,17,20,25}

Treatment of refractory/relapsed patients

Second-line treatment of advanced MF includes **brentuximab vedotin (BV)** and **mogamulizumab**, which are preferred due to their favourable efficacy and safety profiles. Chemotherapy (mostly single agent) remains an option, and multi-agent chemotherapy may be used as a bridge to allo-HCT in patients with refractory and/or bulky disease. In Sézary syndrome, first-line systemic treatment frequently consists of combination approaches such as extracorporeal photopheresis (ECP) plus pegylated interferon-alpha, with early switching to mogamulizumab in the case of insufficient response. Indeed, the extent of blood involvement, particularly B2, is considered a surrogate marker for response to mogamulizumab. Recently, Bozonnet et al. published real-world data confirming the efficacy of mogamulizumab in reducing leukaemic disease burden for the first time mogamulizumab, thereby supporting its early integration into the treatment algorithm.²⁶

Although not approved in Europe, the histone deacetylase (HDAC) inhibitor romidepsin has shown some efficacy in the treatment of advanced-stage CTCL and is a therapeutic option.²⁴ Mogamulizumab is approved and can be used in patients with advanced-stage MF as second-line treatment.¹⁰ Because the drug target, CCR4, is also expressed on normal regulatory T cells, its use before allo-HCT has been associated with an increased risk of acute graft-versus-host disease (GVHD), as observed in studies on adult T-cell leukaemia/lymphoma. Therefore, a 6-week wash-out period between the last administration of mogamulizumab and allo-HCT is recommended.^{27,28}

WORKSHOP RECOMMENDATIONS

Role of allo-HCT in CTCL

The prognosis of patients with advanced-stage CTCL remains poor, with a median OS often below 40 months.¹² For these patients, immunotherapy with allo-HCT, based on its inherent graft-versus-lymphoma (GvL) effect, is the only curative option.

Evidence from retrospective and matched controlled trials demonstrated that allo-HCT significantly improved PFS compared to non-HCT therapies in patients with advanced-stage CTCL.¹⁴ (Table 2) However, this potential benefit must

TABLE 2 Allo-HCT in CTCL.

Ref	Subtype N° of patients	Prospective/retrospective/ phase	Treatment/conditioning	NRM	PFS	OS
Duarte et al. 2010	36 MF 24 SS	Retrospective	44 RIC 25 TCD	1 y; 20% 2 y; 22%	1 y; 42% 3 y; 34%	1 y; 66% 3 y; 54%
Duvic et al. 2010	19	Prospective	RIC	NA	NA	Median not reached at 19 mo
Delioukina et al. 2012	11	Prospective	RIC	2 y; 22%	2 y; 47%	2 y; 55%
Lechowicz et al. 2014	SS 129	Retrospective	83 RIC 46 MAC	1 y; 19% 5 y; 22%	1 y; 31% 5 y; 17%	1 y; 54% 5 y; 32%
De Masson et al. 2014	37	Retrospective	25 RIC 12 MAC	2 y; 18%	2 y; 31%	2 y; 57%
Hosing et al. 2015	MF 30 SS 17	Prospective	RIC	3 y; 17%	4 y; 26%	4 y; 51%
Weng et al. 2020	MF 13 SS 22	Prospective Phase II	TSEB/TLI/ ATG	2 y; 14%	3 y; 41%	3 y; 26%
Ritchie et al. 2020	SS:4 MF:11 ALCL:2	Retrospective	TSEB/ TLI/ATG	2 y; 7%	-	1 y; 87% 2 y; 79%
Domingo-Domenech et al. 2021	113	Prospective	76% RIC	5 y; 28%	5 y; 26%	5 y; 38%
Stamouli et al. 2021	MF 8 SS 2	Retrospective	Low-dose TBI fludarabine-Cy	12% (mFU 20 mo)	51 mo	51 mo
Elliott et al. 2021	MF 17 SS 9	Retrospective	2 MAC 24 RIC	17%	-	-
De Masson et al. 2023	55	Prospective	RIC	10%	Median 9 mo	Median not reached at 12 mo
Onida et al. 2024 (abstr)	MF 40 SS 23	Retrospective	Low-dose TBI, fludarabine, melphalan	5 y 14%	5 y DFS 33%	5 y 53%

Abbreviations: ALCL, anaplastic large-cell lymphoma; ATG, antithymocyte globulin; Cy, cyclophosphamide; DFS, disease-free survival; FU, follow-up; MAC, myeloablative conditioning; MF, mycosis fungoides; mo, months; NA, not available; NRM, non-relapse mortality; OS, overall survival; PFS, progression-free survival; RIC, reduced intensity conditioning; SS, Sézary syndrome; TBI, total body irradiation; TCD, T-cell depletion; TLI, total lymphoid irradiation; TSEB, total-skin electron beam therapy; y, year.

be carefully weighed against the substantial morbidity associated with allo-HCT, which carries a not negligible risk of treatment-related mortality, along with a high risk of relapse. Moreover, the long-term survival outcomes remain modest and, in some reports, comparable to those achieved with conventional therapies^{12,29,30} raising important questions about the optimal timing and indication for allo-HCT. In this context, careful patient selection is paramount. High-risk advanced-stage disease includes patients with Stages IIB to IVB MF or SS who present with at least one poor-prognostic factor: large-cell transformation,^{31,32} significant nodal (N3) or visceral (M1) involvement,²² previous relapse or refractoriness after first-line systemic treatment (excluding methotrexate, retinoids and interferon).¹⁴ Notably, the subgroup of patients with LCT-MF appears to derive the greatest benefit from allo-HCT, with the CUTALLO trial showing more favourable outcomes in this population, supporting its prioritization for transplant evaluation. For rare entities, such as primary subcutaneous gamma-delta T-cell lymphoma or CD8⁺ aggressive epidermotropic primary CTCL, only case reports and small series have been published to date. Some of these publications reported long-term remissions after allo-HCT, which strongly suggest a clinically relevant GvL effect also in these entities.^{33–35}

Although not included as ‘poor-prognosis factor’ in the CUTALLO trial, elevated serum lactate dehydrogenase (LDH) level at diagnosis has been identified as an independent pejorative criterion for patients with advanced-stage CTCL in the Cutaneous Lymphoma International Consortium (CLIC) analysis,¹² and such patients should also be considered for allo-HCT. In the CLIC analysis, three groups of advanced-stage MF/SS patients could be defined, respectively low (0–1 risk factor), intermediate (2 risk factors) and high risk (3–4 factors), based on the four following risk factors: Stage IV disease, age greater than 60 years, large-cell transformation in the skin and elevated serum LDH. High-risk patients as well as younger individuals in the intermediate-risk group according to CLIC should be considered for allo-HCT.¹²

Regarding Sézary syndrome, the emergence of novel therapies—particularly mogamulizumab, which has shown the ability to prolong progression-free survival while maintaining quality of life (QoL) and demonstrating a favourable toxicity profile—may allow deferral of allo-HCT in patients with risk factors for transplant-related mortality (TRM), particularly in those achieving durable responses.

In general, early transplant referral remains advisable for high-risk CTCL patients; however, the decision should

be individualized, taking into account disease trajectory, comorbidities and patient preference, as preservation of quality of life with less intensive therapies may be preferable in selected cases.

Recommendations:

- For patients with early-stage MF (IA–IIA), allo-HCT is generally not indicated.
- For patients with Stage IB/IIA MF who have relapsed or are refractory after multiple lines of systemic therapy, allo-HCT may be considered on an individual basis.
- Patients with large cell transformation, Stage IV MF and patients with SS should be considered for allo-HCT regardless of the treatment line.
- Eligible patients with relapsed or refractory Stages IIB and III should be considered for allo-HCT as soon as a response is achieved.
- For rare entities such as primary subcutaneous gamma-delta T-cell lymphoma, or CD8 aggressive epidermotropic primary CTCL:
 - A donor search should be initiated upon diagnosis.
 - Allo-HCT can be considered as consolidation in patients achieving complete response (CR) or partial response (PR) following first-line treatment.

Timing and disease status at allo-HCT

CR, PR, very good PR (VGPR), stable disease (SD) and progressive disease (PD) are defined according to ISCL/USCLC/EORTC response criteria.²²

Disease status at allo-HCT is a critical prognostic factor significantly influencing outcomes. Patients undergoing allo-HCT in CR or VGPR before disease became refractory to conventional therapies and/or organ involvement have better PFS and OS, with much lower relapse rates as compared to patients with advanced, uncontrolled skin and organ involvement.^{15,17,18,25,36} In a study by the London group on 41 patients,³⁷ those who achieved CR before allo-HCT experienced significantly lower rates of progression or relapse compared to patients not in CR (20.8% compared to 70.6%, $p=0.006$). The median OS and PFS were 4.88 versus 1.53 years and 4.88 versus 0.62 years, respectively. Furthermore, patients with measurable residual disease (mRD) in blood or skin had a higher probability of disease progression or relapse than patients who achieved molecular remission in both blood and skin, with incidences of progression or relapse of 87% and 9%, respectively.^{36,38}

Salvage therapy or response induction before allo-HCT

Salvage therapy aims not only at reducing tumour burden in order to create the most favourable conditions for the subsequent allo-HCT, but also at managing symptoms and improving quality of life.

Patients with significant residual disease (i.e. mSWAT [modified Severity Weighted Assessment Tool] >10 or persistent extracutaneous disease) should not directly undergo transplantation if there remains a realistic option to achieve CR or VGPR. The mSWAT is an internationally recognized skin scoring system that evaluates the tumour burden in skin by multiplying the percentage of body surface area involved by a weighting factor of 1 (for patches), 2 (for plaques) or 4 (for tumours).²² Beyond chemotherapy, mogamulizumab for SS without large-cell transformation,¹⁰ total-skin electron-beam therapy,²³ BV in CD30-positive disease, alone or in combination with chemotherapy^{39,40} may be effective. For patients with transformed MF, multi-agent chemotherapy should be considered as a reasonable option.⁴¹

Total skin electron beam therapy (TSEB) targets cutaneous manifestations of CTCL and can be used to reduce tumour load and possibly achieve remission prior to allo-HCT. TSEB is generally well-tolerated and effective in reducing the cutaneous tumour burden, thereby helping to bring the disease into remission prior to transplant.^{23,38,42} The total dose varies between 12 and 36 Gy depending on disease extent, type of lesions and degree of skin infiltration.^{23,43}

Although randomized trials are lacking, expert consensus suggests tailoring pre-transplant therapy based on disease characteristics and treatment goals.

- In Stage IIB disease with large-cell transformation (LCT), aggressive behaviour justifies an attempt to achieve the deepest possible remission before allo-HCT. CHOP or CHOEP-based regimens are reasonable options, and brentuximab vedotin, particularly in CD30+ disease, may be preferred due to its favourable toxicity profile and efficacy in inducing remission. When CD30 expression is present, BV alone or in combination with chemotherapy may be used as a bridge to transplant.
- In Stage III/IV disease, treatment selection should balance the urgency of disease control, patient fitness, and toxicity risk. In frail patients or slow-progressing SS, ECP alone or with low-dose interferon may be suitable, particularly when rapid disease control is not essential. However, when the goal is to achieve CR or VGPR before transplant, more intensive strategies like mogamulizumab followed by total-skin electron beam irradiation (TSEBI) should be considered.

In the absence of validated prospective algorithms, multidisciplinary discussions between dermatologists and transplant physicians remain essential to adapt the treatment approach to the individual patient.

Recommendations:

Figure 1 illustrates treatment strategies and the transplant algorithm.

- Patients with high-risk advanced CTCL (both MF and SS) meeting the indication for allo-HCT should undergo transplantation as soon as they reach CR.

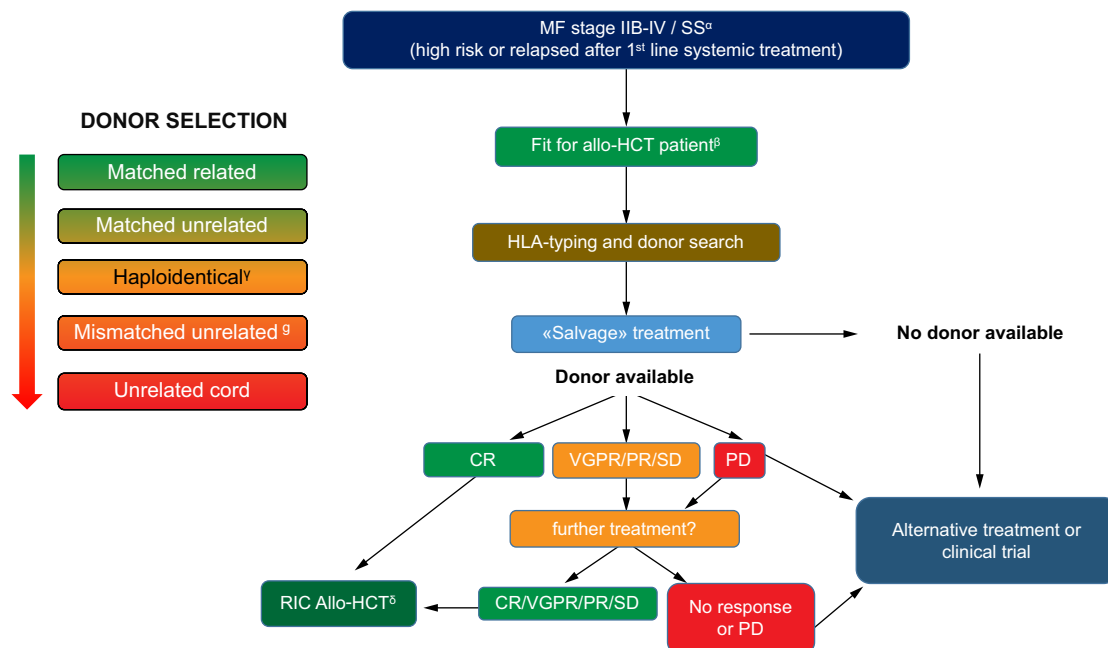


FIGURE 1 Proposed algorithm for the management of high-risk and/or relapsed/refractory CTCL. allo-HCT, allogeneic haematopoietic cell transplantation; CR, complete remission; MF, mycosis fungoid; PD, progressive disease; PR, partial remission; RIC, reduced intensity conditioning; SD, stable disease; SS, Sezary syndrome; VGPR, very good PR. α : patients with SS, rare entities or large cell transformation should be considered for allo-HCT regardless of the line of treatment, in CR or PR; β : according to age, PS, comorbidities; γ : According to centre preference; δ : GVHD prophylaxis should follow general guidelines for allo-HCT.

- For patients not reaching CR after salvage therapy, PR or VGPR or SD with limited residual disease (i.e. mSWAT <10) is also considered an acceptable condition.
- There are no specific recommendations regarding the optimal number and modalities of prior therapies before allo-HCT.
- For refractory cases, including those post-TSEB, allo-HCT is not recommended.

Prerequisites for allo-HCT in CTCL

Age, comorbidities and performance status

While allo-HCT is a potentially curative option, its success is also influenced by age, performance status and comorbidities. Advanced age is generally associated with a higher risk of transplant-related complications and non-relapse mortality (NRM), although reduced-intensity conditioning (RIC) has made allo-HCT feasible in older patients. Patients with a good performance status and a low comorbidity index can anticipate more favourable outcomes (HCT-comorbidity index [CI], 0–2).

Recommendations:

- There are no data supporting specific limits for age, comorbidities and performance status of patients with MF and SS who are considered candidates for allo-HCT.
- Age, HCT-CI, performance status and comorbidities must be weighed against disease status to determine the overall risks of allo-HCT.

- General principles for allo-HCT in lymphomas should be followed.⁴¹

Donor choice

In the study by the London group,³⁷ the median OS for 41 patients with MF ($n=34$) or SS ($n=7$) was 4.84 years for matched unrelated donors (MUD), 3.55 years for matched related donors (MRD) and only 0.66 years for haploidentical transplantation. However, it is important to note that only 3 patients underwent haploidentical transplantation in this series, limiting the interpretation and practical consequences of these results. In general, published studies on haploidentical transplants in CTCL remain scarce.⁴⁴

A recent meta-analysis included data on only 12 patients who underwent haploidentical transplantation⁴⁵; this small sample size makes it difficult to draw definitive conclusions.

A study by the Milan group⁴⁶ analysed 63 patients with MF ($n=40$) or SS ($n=23$) transplanted using HLA-identical sibling donors ($n=22$), unrelated donors ($n=28$; 15 HLA-matched and 13 HLA-mismatched) and haploidentical donors ($n=13$). MRD demonstrated better survival outcomes and lower transplant-related mortality (TRM) compared to both unrelated and haploidentical donors. While survival outcomes for haploidentical transplants were slightly inferior to MRD, they were comparable to MUD. TRM for haploidentical donors was relatively low, but the cumulative incidence of relapse or progression was notably higher than in MRD, indicating a need for enhanced disease control strategies in this cohort. Larger studies on haploidentical

transplantation in T-cell lymphomas have reported outcomes comparable to those of MRD and MUD.^{47–49}

In most diseases, MRD is the preferred choice. However, transplantation from an HLA-MUD has been shown to achieve comparable outcomes.⁵⁰ Therefore, MRD is preferred over mismatched MUD and haploidentical donors. The use of unrelated cord blood transplantation is declining and should be reserved for specific cases where no living donor is available.⁵¹

Recommendations:

- The selection of a suitable donor should align with established guidelines for all lymphomas, including T-cell lymphomas, following a hierarchical preference: MRD, MUD, haploidentical donor or 1-antigen-MMUD (Figure 1).

What is the recommended conditioning regimen and the strategy for GVHD prevention?

Available literature supports the use of RIC as the preferred approach for most patients, especially older individuals or those with significant comorbidities.^{17,20,52}

A recent systematic review and meta-analysis comparing outcomes of myeloablative conditioning (MAC) and RIC for MF and SS revealed that cumulative OS was significantly better after RIC (58% [95% CI, 47%–68%]) compared to MAC (30% [95% CI, 7%–42%]; $p < 0.001$).⁴⁵ These findings underscore the role of RIC in optimizing outcomes by balancing efficacy and toxicity, considering the patient's age, overall health, disease burden, and risk of relapse. Low-dose total body irradiation (LdTBI) has also been used for conditioning; however, there is no evidence to suggest that LdTBI should be preferred over non-LdTBI regimens.

Weng et al. from Stanford University School of Medicine reported on a chemo-free reduced-intensity regimen in a series of 35 patients, the majority of whom had Sézary syndrome ($n = 22$), while 13 had MF.³⁶ The conditioning regimen included TSEB, total nodal irradiation and anti-thymocyte globulin. The 1- and 2-year NRM were 3% and 14%, respectively, and the 2-, 3- and 5-year OS rates were 68%, 62% and 56%, with a significantly lower incidence of disease progression or relapse in patients achieving a molecular remission (9% vs. 87%; $p = 0.02$). The same conditioning regimen was initially analysed in a small cohort of 17 patients from the United Kingdom. The 2-year OS was 79% and TRM was low, suggesting that chemo-free conditioning could be a good and effective alternative before allo-HCT.¹³ Long-term outcomes of the Stanford chemo-free regimen were recently reported by Morris et al.,³⁷ with a cumulative incidence of NRM of 12.6% at 2 years and a 5-year OS rate of 37.7% (MF 36.7%, SS 57.1%).

Outside of haploidentical transplantation, GVHD prophylaxis in allo-HCT typically includes a combination of a calcineurin inhibitor (CNI) with either methotrexate (MTX) or mycophenolate mofetil (MMF).⁵³ Data on GVHD prophylaxis, specifically in PTCL patients, remain limited. The

addition of anti-thymoglobulin to the conditioning regimen has been shown to reduce GVHD incidence in patients with acute lymphoblastic lymphoma or T-cell lymphoma.⁵⁴ T-cell depletion by alemtuzumab is not generally recommended because high relapse rates after allo-HCT were repeatedly observed.⁵⁵ While post-transplant cyclophosphamide is primarily used in haploidentical settings,⁵⁶ its application is expanding to other donor–recipient scenarios.

Recommendations:

- RIC should be the preferred regimen.
- With no data supporting a specific RIC regimen, centres should stay with the locally established RIC regimens.
- GVHD prophylaxis should follow general guidelines for allo-HCT.⁵⁷

What is the role of post-transplant measurable residual disease monitoring, maintenance therapy and immunomodulation strategies?

Although the achievement of post-transplantation molecular remission has been reported to associate with significantly better survival outcomes,^{36,37} there are no available data supporting the recommendation of post-allo HCT mRD monitoring nor the use of maintenance strategies for CTCL (e.g. bexarotene, interferon alfa or extracorporeal photopheresis),^{55,58,59} even in mRD-positive patients.

While no standardized approach currently exists for post-allo-HCT MRD monitoring in CTCL, future clinical trials should incorporate sensitive and disease-specific tools. Flow cytometry (FACS) can be used for monitoring residual circulating Sézary cells in the blood. In parallel, T-cell receptor (TCR) rearrangement studies—including clonality assessment and quantification—may offer a more precise evaluation of minimal disease burden and should be considered for inclusion in prospective protocols.

Recommendations:

- There is no evidence supporting mRD monitoring in routine practice for CTCL
- Post-transplant maintenance or preemptive therapies in mRD-positive patients is not standard of care and should be restricted to clinical trials.

How should post-transplant relapse in CTCL be managed?

Management of post-transplant relapse requires a multidisciplinary approach, emphasizing close collaboration with dermatologists and radiotherapists. Relapses with early stage MF lesions may be managed with skin-directed therapy or possibly donor-lymphocyte infusion (DLI) and must therefore be differentiated from GVHD or skin infections.^{14,37}

Dermatologists and dermato-pathologists play a crucial role in accurately evaluating and diagnosing any skin disease occurring after allo-HCT. Biopsies of affected skin are often necessary.

Unfortunately, post-transplant relapses, predominantly in the skin, are common but may be low grade and frequently managed with skin-directed treatment. Relapse in other compartments such as blood, lymph nodes or internal organs may also occur. A significant number of patients achieve a second remission post-transplant with prolonged disease control after tapering of immunosuppressive drugs, local radiotherapy (RT) or TSEB, and disease-specific treatments.¹⁴ Management of post-transplant relapse typically involves tapering of immunosuppressive therapy and/or DLI to elicit or enhance a GVL effect. DLI have shown efficacy in inducing durable remissions, especially in cases where measurable residual disease or early signs of relapse are detected.¹⁴ As with other disorders, DLI requires careful monitoring due to the significant risk of GVHD.

These immunological approaches should be combined with disease-specific treatments, tailored to the patient's condition and disease stage. Localized skin lesions may be managed with radiation therapy, while patch-stage disease could be treated with skin-directed topical therapies. Systemic or widespread skin relapses may require systemic treatment, such as BV or IFN- α , particularly in case of relapse with large-cell transformation.³⁹

Recommendations:

- Conventional therapy combined with immune tapering is recommended.
- DLI is recommended as the primary immunomodulatory strategy for relapse after allo-HCT.
- Localized RT or skin-directed therapy is a suitable option in patients with limited skin relapse.
- When feasible, TSEB is a recommended option for patients with diffuse skin relapse.
- There is no recommendation for a second allo-HCT, but it may be considered if appropriate, possibly from a different donor.

AREAS FOR INVESTIGATION IN ALLO-HCT FOR CTCL

- Given the rarity of the disease and the heterogeneity of its clinical presentations, much of the current evidence on allo-HCT is derived from retrospective analyses, registry data and small single-centre studies. Prospective, randomized trials remain exceedingly difficult to conduct in this setting. Limitations such as small sample sizes, lack of standardized treatment protocols and selection bias are inherent to most available studies, particularly those evaluating donor source, optimal timing, the number of lines of salvage treatment prior to allo-HCT, conditioning regimens and post-transplant interventions. In particular, the impact of modern GVHD prophylaxis, including

post-transplantation cyclophosphamide (PTCy), on outcomes remains unclear at this time. These data limitations must be acknowledged when interpreting existing literature and applying it to clinical decision-making.

- As with other details of the transplant procedure, there is insufficient evidence regarding the role and methodologies for mRD monitoring, as well as the utility of maintenance therapy following allo-HCT in CTCL. Ongoing research into CAR T-cell therapy⁶⁰ as a potential alternative to allo-HCT in CTCL, or as a bridge to transplant, highlights a promising avenue for future investigation.

CONCLUSIONS

This expert consensus involving dermatologists and haematologists taking care of CTCL patients to receive allo-HCT underscores the critical importance of careful patient selection, optimal disease control before transplant and post-transplant management. Most importantly, early consultation and discussions between the treating dermatologist/haematologist and the transplant team are crucial to allow for timely transplantation for patients in whom allo-HCT is indicated.

Further studies are necessary to refine patient selection, evaluate maintenance and relapse therapies, and explore innovative approaches such as immune intervention including monoclonal and bispecific antibodies, antibody-drug conjugates, checkpoint inhibitors and CAR T-cell therapy. Although these novel therapies are still under investigation in CTCL, early-phase trials suggest promising activity, particularly for relapsed or refractory disease. CAR-T cell constructs targeting CD4 or CD30, as well as bispecific antibodies (e.g. CD30 $\times$ CD16 or CD3 $\times$ CD4), are currently in development, though clinical availability remains limited outside of trials. These strategies may eventually serve as adjuncts or alternatives to allo-HCT in selected patients.

AUTHOR CONTRIBUTIONS

GD, PD and NS conceived and designed the manuscript topics to be covered. GD and NS were the leaders of the workshop. IYA, FO, ALR and IOS proposed the methodology. GD, AdM, PB, AB, SF, RD, CPF, EG, OH, CK, OT, WJ, EG, POR, EP, JS, IEK, SNQ, YS, GW, AS, EP, PLOR, ALR, ISO, JS, IYA, FO and NS undertook literature research, interpretation of data and formulated the recommendations. All co-authors played an important role in interpreting results, revised the manuscript, approved the final version and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved.

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