Received: 7 June 2024 | Accepted: 10 June 2024

DOI: 10.1002/jha2.970

eJHaem

British Society for Haematology

SHORT REPORT

Real-world outcomes of patients with relapsed/refractory large B-cell lymphoma receiving second-line therapy in England

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Funding information
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Abstract

Autologous stem-cell transplantation (ASCT) is standard therapy for relapsed/refractory large B-cell lymphoma (R/R LBCL), but many patients are either ineligible or unable to receive it. This retrospective study characterized outcomes in R/R LBCL, delineated by eligibility for, and receipt of, ASCT. Median progression-free survival (PFS) and event-free survival (EFS) for patients undergoing ASCT were 35.2 and 31.6 months (overall survival [OS] not reached). Median PFS, EFS, and OS were 4.3, 4.3, and 6.9 months for ineligible patients, and 2.7, 2.6, and 9.4 months for those eligible for but unable to receive ASCT. This highlights an unmet need for alternative therapies in patients unable to receive ASCT.

KEYWORDS
ASCT, LBCL, outcomes, real-world evidence

1 | INTRODUCTION

Although first-line (1L) chemoimmunotherapy in large B-cell lymphoma (LBCL) is curative in approximately two-thirds of cases, 20–50% of cases are refractory to treatment or relapse (R/R) [1]. Standard of care (SoC) for second-line (2L) therapy includes platinum-based chemotherapy, followed by high-dose chemotherapy (re-induction therapy) with autologous stem-cell transplant (ASCT) [2]; however, less than half of R/R patients are eligible for ASCT [1], and of those, 30–50% will not proceed to ASCT due to inadequate response to re-induction therapy [3, 4].

Recent advances in chimeric antigen receptor (CAR) T-cell therapies may lead to improved outcomes [5], with one such therapy having been recommended as an alternative to SoC for the treatment of R/R

LBCL in ASCT-eligible patients. Real-world studies in the pre-cellular therapy era have demonstrated that non-receipt of ASCT is associated with poorer outcomes [6, 7], and whilst chemoimmunotherapy for R/R LBCL is rapidly evolving, real-world survival in this cohort remains poor [8, 9]. Furthermore, there are no data directly comparing outcomes between patients receiving ASCT, ASCT-ineligible patients, and ASCT-eligible patients who do not proceed to ASCT.

This study aims to compare outcomes in these three clinically distinct subgroups: for patients with R/R LBCL receiving 2L therapy in England from 2003 to 2018.

2 | MATERIALS AND METHODS

This retrospective, observational study included patients with histologically confirmed, aggressive B-cell non-Hodgkin lymphoma with R/R disease after 1L therapy, treated at one of six regional referral centers in England from Jan 1, 2003, to Sep 30, 2018. (See Supporting Information Methods for CONSORT diagram).

Patients who met the selection criteria were stratified by receipt of ASCT; those who did not receive ASCT were stratified further by ASCT-eligibility. Since it was not directly reported, eligibility was determined based on the 2L chemotherapy regimen received and an estimation of physiological fitness. Assessment criteria were validated by expert opinion.

Patients who were ASCT-eligible but did not receive ASCT (TE non-ASCT) received one of 12 chemotherapy regimens at 2L: cisplatin, cytarabine, dexamethasone (DHAP); carboplatin, cisplatin, dexamethasone, gemcitabine (GDP); carboplatin, etoposide, ifosfamide (ICE); epirubicin, etoposide, ifosfamide (IVE); cisplatin, cytarabine, etoposide, methylprednisolone (ESHAP); cytarabine, dexamethasone, oxiplatin (DHAX); dexamethasone, cytarabine, carboplatin (DHAC); methotrexate, cytarabine, rituximab, thiotepa (MATRIx); mesna, ifosfamide, mitoxantrone, etoposide (MINE); ifosfamide, etoposide, cytarabine (IVAC); ifosfamide, gemcitabine, vinorelbine (IGEV); or carmustine, etoposide, cytarabine, melphalan (BEAM).

Patients who were ASCT-ineligible and did not receive ASCT (TNE non-ASCT) did not receive DHAP, GDP, ICE, IVE, ESHAP, or DHAX at 2L. They also met at least one of the following criteria: age $\geq$ 70 years; Eastern Cooperative Oncology Group propensity score (ECOG PS) $\geq$ 2; diffusing capacity of the lung for carbon monoxide $\leq$ 60%; left ventricular ejection fraction $\leq$ 50%; creatine clearance $<$ 60 mL/min; alanine aminotransferase/aspartate aminotransferase $>$ 2 x upper limit of normal.

Patients who could not be grouped according to these criteria, due to lack of data regarding treatment history and/or clinical characteristics, were considered unclassified and excluded from analysis.

Key endpoints were event-free, progression-free, and overall survival (EFS, PFS, and OS). See Supporting Information Methods for further information.

This study was conducted in accordance with applicable regulatory and good practice guidelines and approved by the Health Research Authority (254220) and the National Research Ethics Committee (19/NE/0021). The study did not require informed consent.

3 | RESULTS

Overall, 299 patients met eligibility criteria, of whom 98 (32.8%) underwent ASCT, 125 (41.8%) were ASCT-eligible but did not proceed to ASCT (TE non-ASCT) and 49 (16.4%) were ASCT-ineligible (TNE non-ASCT). A further 27 patients (9.0%) who did not receive ASCT could not be appropriately classified as eligible/ineligible based on treatment history and/or clinical characteristics and were excluded from the analysis (Table 1).

Most patients in the ASCT subgroup received 2L multi-agent chemotherapy and ASCT, with (n = 64, 65.3%) or without (n = 26, 26.5%) anti-CD20 mAb. A minority of patients received 2L chemotherapy and an allogeneic stem-cell transplant, either with (n = 6, 6.1%) or without (n = 2, 2.0%) anti-CD-20 mAb. The overall response rate (ORR) in the ASCT subgroup was 86.2% [95% confidence interval [CI]: 77.5, 92.4] with 64.9% [95% CI 54.4, 74.5] achieving a complete response (CR) following ASCT.

Most TE non-ASCT patients received 2L chemotherapy, with (n = 90, 72.0%) or without (n = 35, 28.0%) anti-CD20 mAb. In the TNE non-ASCT subgroup, 17 patients (34.7%) received chemotherapy with, and 29 patients (59.2%) without, anti-CD20 mAb. Three received other treatments (6.1%). ORR in the TE non-ASCT and TNE non-ASCT subgroups was 44.7% [95% CI: 35.4, 54.3] and 25.7% [95% CI: 12.5, 43.3] respectively, with 12.3% [95% CI: 6.9, 19.7] and 20.0% [95% CI: 8.4, 36.9] achieving CR.

Median OS for TE non-ASCT and TNE non-ASCT subgroups were 9.44 months [95% CI: 8.29, 11.05] and 6.94 months [95% CI: 4.77, 9.11], respectively, while median OS for the ASCT subgroup was not reached (NR) [95% CI: 38.33, NR] (Figure 1A). With ASCT as a reference, hazard ratios (HRs) for OS for the TE non-ASCT and TNE non-ASCT subgroups were 3.24 [95% CI: 2.22, 4.72] and 4.81 [95% CI: 3.11, 7.45], respectively.

Median PFS for the ASCT, TE non-ASCT, and TNE non-ASCT subgroups were 35.21 months [95% CI: 21.21, NE], 2.70 months [95% CI: 2.40, 3.49] and 4.27 months [95% CI: 2.40, 6.35] respectively; median EFS was 31.59 months [95% CI: 18.77, NE], 2.60 months [95% CI: 2.17, 3.12] and 4.27 months [95% CI: 2.40, 6.35] (Figure 1B,C), where non-overlapping CIs indicate a significantly improved PFS and EFS for the ASCT subgroup compared with TE non-ASCT and TNE non-ASCT subgroups. With ASCT as a reference, HRs for progression were 3.36 [95% CI: 2.23, 5.07] and 3.90 [95% CI: 2.76, 5.49] for TNE non-ASCT and TE non-ASCT subgroups respectively, and 3.44 [95% CI: 2.29, 5.17] and 4.95 [95% CI: 3.52, 6.95] for EFS.

4 | DISCUSSION

The proportion of the cohort defined as TNE non-ASCT was lower than would be expected in clinical practice, perhaps due to the

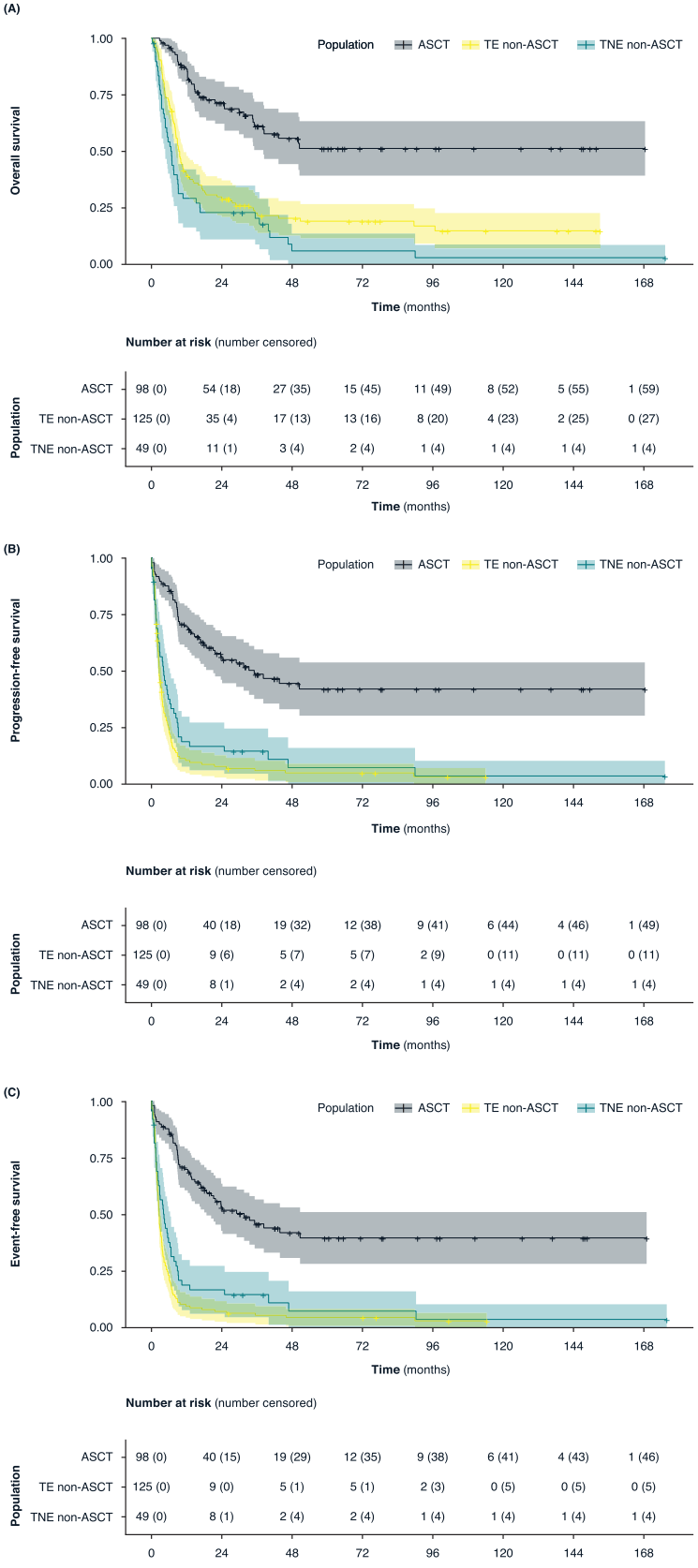

FIGURE 1 (A) Overall survival from the start of 2L treatment, (B) progression-free survival, and (C) event-free survival. ASCT, autologous stem cell transplant; TE, transplant eligible; TNE, transplant non-eligible. Unclassified patients were not considered for the analyses of overall, progression-free, and event-free survival (OS, PFS, and EFS).

TABLE 1 Baseline patient characteristics.

Patient characteristics	Overall* (*N* = 299)	ASCT (*N* = 98)	TE Non-ASCT (*N* = 125)	TNE Non-ASCT (*N* = 49)
Months from initial diagnosis to index date, median (IQR)	10.75 [6.94, 23.06]	12.36 [7.99, 30.19]	8.81 [5.98, 14.79]	17.29 [8.65, 41.03]
Age (years), mean (SD)	59.76 (13.40)	56.85 (11.18)	56.17 (12.36)	74.68 (12.16)
Age (years), *n* (%)				
< 70	235 (78.6)	93 (94.9)	108 (86.4)	7 (14.3)
≥ 70	64 (21.4)	5 (5.1)	17 (13.6)	42 (85.7)
Sex, *n* (%)				
Male	187 (62.5)	58 (59.2)	79 (63.2)	29 (59.2)
ECOG PS, *n* (%)				
0	94 (31.4)	38 (38.8)	41 (32.8)	8 (16.3)
1	79 (26.4)	19 (19.4)	36 (28.8)	13 (26.5)
2	25 (8.4)	4 (4.1)	11 (8.8)	10 (20.4)
3	10 (3.3)	1 (1.0)	3 (2.4)	6 (12.2)
4	1 (0.3)	0 (0)	1 (0.8)	0 (0)
Unknown	90 (30.1)	36 (36.7)	33 (26.4)	12 (24.5)
IPI score, *n* (%)†				
0–2	138 (46.2)	50 (51.0)	61 (48.8)	13 (26.5)
3–5	29 (9.7)	3 (3.1)	18 (14.4)	6 (12.2)
Unknown	132 (44.1)	45 (45.9)	46 (36.8)	30 (61.2)
Disease histology‡, *n* (%)				
DLBCL NOS	203 (67.9)	56 (57.1)	90 (72.0)	39 (79.6)
DLBCL NOS (tFL)	19 (6.4)	3 (3.1)	10 (8.0)	5 (10.2)
FL3B	5 (1.7)	0 (0)	3 (2.4)	0 (0)
HGBCL	14 (4.7)	5 (5.1)	6 (4.8)	1 (2.0)
Not verified¥	58 (19.4)	34 (34.7)	16 (12.8)	4 (8.2)
Extranodal disease, *n* (%)				
Yes	156 (52.2)	42 (42.9)	76 (60.8)	27 (55.1)
No	119 (39.8)	48 (49.0)	38 (30.4)	19 (38.8)
Missing	24 (8.0)	8 (8.2)	11 (8.8)	3 (6.1)
Refractory§ or relapsed to last therapy, *n* (%)				
Refractory	164 (54.8)	41 (41.8)	79 (63.2)	26 (53.1)
Relapsed	117 (39.1)	51 (52.0)	40 (32.0)	20 (40.8)
Missing¶	18 (6.0)	6 (6.1)	6 (4.8)	3 (6.1)
Best response to prior therapy, *n* (%)				
CR	117 (39.1)	51 (52.0)	40 (32.0)	20 (40.8)
PD	46 (15.4)	8 (8.2)	26 (20.8)	7 (14.3)
PR	103 (34.4)	28 (28.6)	44 (35.2)	18 (36.7)
SD	15 (5.0)	5 (5.1)	9 (7.2)	1 (2.0)
Missing	18 (6.0)	6 (6.1)	6 (4.8)	3 (6.1)
Prior receipt of rituximab, *n* (%)	298 (99.7)	97 (99.0)	125 (100.0)	49 (100.0)

Abbreviations: ASCT, autologous stem-cell transplant; CR, complete response; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Subgroup performance status; FL3B, follicular lymphoma grade 3B; HGBCL, high-grade B-cell lymphoma; IPI, inventory performance index; IQR, interquartile range; NHL, non-Hodgkin lymphoma; NOS, not otherwise specified; PD, progressive disease; PR, partial response; SD, stable disease or standard deviation; TE, transplant eligible; tFL, transformed follicular lymphoma; TNE, transplant non-eligible.

*Unclassified patients were included in the patient characteristics for the overall patient cohort, but were not included in later analyses.

†If missing, the IPI score was calculated based on the constituent parts, starting at 0 and adding one for each of the following that is true: Age > 60, ECOG PS ≥ 2, Ann Arbor disease stage, n(%) III–IV, Serum lactate dehydrogenase (LDH, n(%)) ≥ 500 U/L, Extranodal sites, n(%) > 1.

‡Eligible patients had an initial diagnosis of aggressive B-cell NHL of the following confirmed histology (diffuse large B cell lymphoma (DLBCL), not otherwise specified (NOS), high-grade B-cell lymphoma with *MYC* and *BCL2* and/or *BCL6* rearrangement with DLBCL histology, PMBCL, and FL3B).

§Status was defined as relapsed if a patient achieved a complete response after the start date of the last prior therapy and had clinical outcome records with stable disease, progressive disease, or no response after CR but before the 2L start date, otherwise status was refractory.

¶Status was missing for all patients with no response data recorded between 1 and 2L.

¥High grade B-cell NHL subtype not verified.

lower-than-expected average age compared with other real-world LBCL populations [7, 10]. This may represent a selection bias, given that participating study sites were tertiary referral centers; nevertheless, other clinical characteristics in our study were consistent with other real-world cohorts [6, 7]. The age of the TNE non-ASCT group was numerically higher than for other subgroups; this was expected, as centers typically excluded patients aged ≥ 70 years for ASCT. In a recent Japanese retrospective study describing outcomes in ASCT-eligible patients with R/R DLBCL, the average age was 55, similar to the ASCT-eligible population in our study [11] (Table 1).

The ASCT subgroup had improved survival outcomes compared with subgroups who did not proceed to ASCT. The OS curve for the ASCT subgroup plateaus at 48 months, indicating that ~50% of patients receiving ASCT could be considered long-term survivors. These data align with data from the CORAL and LY.12 studies, two phase 3 randomized studies investigating re-induction regimens in DLBCL; in a post-hoc conditional survival analysis, OS approached that of the general population for those patients with R/R-DLBCL who were disease-free at 2 years [12] Additionally, both CORAL and the ORCHARRD study, another phase 3 study investigating re-induction therapies in DLBCL, described a 2-year post-transplant OS of > 50% [13, 14]. The Japanese retrospective study found that OS for ASCT-eligible patients who did not proceed to curative treatment was 5.6 months, compared with 9.44 months in our TE non-ASCT group [11].

The EFS findings from our cohort (median EFS ~32 months) also align with observations from CORAL and LY.12, in which EFS at 36 months for transplanted patients were 53.3% [95% CI: 46.9, 59.3] and 51.1% [95% CI: 44.3, 57.5], respectively [12].

Routinely collected clinical data are a potentially valuable resource, allowing retrospective studies of real-world demographic, clinical, and outcomes data that are complementary to clinical trials. With the recent approval of CAR-T and immunotherapies expected to improve outcomes in those who do not receive ASCT, this study may serve as a benchmark for future real-world studies.

Limitations include those intrinsic to retrospective studies, including the potential for erroneous or incomplete data entry, and variation in investigational and reporting practices over the study period. Most data in our study were from patients treated between 2010–2015. As anticipated, there was a degree of missingness for some variables, which may introduce a risk of bias. Analyses and comparisons did not adjust for patient characteristics. However, we do not feel that this impacts the key study conclusions. Eligibility for ASCT was partially defined based on the 2L treatment regimen received, which, although widely accepted clinically, potentially introduces definition bias; this definition may also introduce age as a confounding variable. Analyses included data from patients treated at six treatment centers, which although geographically dispersed, may not be fully representative of the wider LBCL population across England or internationally.

5 | CONCLUSION

Data from this R/R-LBCL cohort treated at English University hospitals showed that receipt of ASCT at 2L conferred significantly improved survival outcomes, whilst patients who did not receive ASCT experienced poor outcomes irrespective of eligibility status. Considering the large proportion of patients who were eligible for ASCT yet unable to receive it, this represents a significant unmet need. Future analyses exploring determinants of ASCT receipt and risk factors for relapse post-ASCT would also be valuable.

AUTHOR CONTRIBUTIONS

All authors conceptualized and designed the study. Christopher P. Fox, Nagesh Kalakonda, John G. Gribben, William Townsend, Tobias Menne, and John Radford led data collection at respective study sites. Emma Tyas, Miranda Cooper, and Joshua Rickards were responsible for data analysis. All authors contributed to the interpretation of the results, preparation, and review of the manuscript, and approval of the final manuscript for publication.

ACKNOWLEDGMENTS

The authors thank Alice Bedwell and Daniel Sugrue of Health Economics and Outcomes Research Ltd. for providing medical writing support/editorial support, which was funded by Bristol Myers Squibb in accordance with Good Publication Practice guidelines. Data analysis support was also received from Lumanity and funded by Bristol Myers Squibb. William Townsend acknowledges research support and funding from the University College London Hospitals Biomedical Research Centre.

CONFLICT OF INTEREST STATEMENT

Farah Toron and Paula Williams are employees of Bristol Myers Squibb. Emma Tyas is an employee of Lumanity, which received fees from Bristol Meyers Squibb in relation to this study. Miranda Cooper and Joshua Rickards were employees of Lumanity at the time of this study.

Christopher P. Fox has received remuneration for consultancy and/or participation in advisory boards from Abbvie, AstraZeneca, Atarabio, BMS/Celgene, GenMab, Gilead/Kite, Incyte, Janssen, Lilly, Morphosys, Ono, Roche, SERB, SOBI, and Takeda. Christopher P. Fox also received research funding from BeiGene.

William Townsend has received remuneration for consulting from Roche and Gilead and has received remuneration for speaking at educational events from Roche, and for participating in advisory boards from BMS and Takeda.

John G. Gribben has received honoraria from Abbvie, Amgen, AstraZeneca, BMS, Gilead/Kite, and Janssen. John G. Gribben also received gratin fusing from AstraZeneca, Celgene, and Janssen. Tobias Menne has received travel grants from Amgen, Jazz, Pfizer, Bayer, Kyowa Kirin, BMS/Celgene, Gilead/Kite, Janssen, and Takeda and also received honoraria for advisory board meetings from Gilead/Kite,

Amgen, Novartis, Pfizer, BMS/Celgene, Daiichi Sankyo, Atara, Roche, and Janssen.

Tobias Menne has received honoraria for lectures from Gilead/Kite, Takeda, Janssen, Roche, Servier, Novartis, BMS/Celgene, Pfizer, and Incyte, and received research funding from Janssen, AstraZeneca, and Novartis

Nagesh Kalakonda received remuneration for lectures. presentations, manuscript writing, and/or educational events from BMS/Celgene, Takeda, Morphosys, Incyte, Janssen, Karyopharm, Roche, and Gilead, and received support for attending meetings from Janssen, Morphosys, and Takeda.

John Radford has received remuneration for consultancy from Takeda and ADC Therapeutics. JR's spouse is a shareholder in AstraZeneca.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

The authors have confirmed ethical approval statement is not needed for this submission.

PATIENT CONSENT STATEMENT

The authors have confirmed patient consent statement is not needed for this submission.

CLINICAL TRIAL REGISTRATION

The authors have confirmed clinical trial registration is not needed for this submission.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Fox CP, Townsend W, Gribben JG, Menne T, Kalakonda N, Williams P, et al. Real-world outcomes of patients with relapsed/refractory large B-cell lymphoma receiving second-line therapy in England. eJHaem. 2024;5:992–97. https://doi.org/10.1002/jha2.970