



Brentuximab vedotin monotherapy is a feasible and effective treatment for older patients with classical Hodgkin lymphoma unsuitable for curative chemotherapy: Results from the prospective GHSG–NLG phase II BVB trial

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Despite progress over the last decades, the treatment of patients with classical Hodgkin lymphoma (cHL) over the age of 60 years remains challenging.¹ Biological age, degree of frailty, and severity of underlying diseases may hamper the administration of curative chemotherapy-based approaches developed for younger patients.^{2,3} Furthermore, older patients more often have B-symptoms, advanced-stage disease, or other factors known to affect prognosis negatively.³ To improve outcomes for elderly patients with cHL, treatment approaches need to accommodate greater heterogeneity of patients.

In aggressive non-Hodgkin lymphoma (NHL), progress has been made in identifying older patients with impaired health who may need adapted treatment approaches.⁴ Efforts to identify vulnerable older patients are currently also underway for elderly patients with cHL.^{1,3} Meanwhile, novel drugs hold promise as effective and better-tolerated options compared to traditional chemotherapy in older individuals.^{1,5} The antibody-drug conjugate brentuximab vedotin (BV) contains the tubulin-acting drug monomethyl auristatin E and targets CD30 expressing malignant Hodgkin and Reed–Sternberg cell characteristic of cHL. Single-agent BV has relatively low toxicity with neuropathy being a common dose-limiting adverse effect, and is also tolerated by relapsed or refractory cHL patients over the age of 60 years.⁶

We started a prospective phase II trial in 2015, evaluating single-agent BV in patients considered unsuitable for available curative

combination chemotherapy. The BVB trial (BV or BV with cyclophosphamide, doxorubicin, and prednisolone in the treatment of older patients with newly diagnosed cHL) was an international two-armed open-label intergroup multicentre phase II trial by the German Hodgkin Study Group (GHSG) and the Nordic Lymphoma Group (NLG) (NCT02191930). The main inclusion criteria were histologically proven cHL, no previous treatment, and age ≥ 60 years. Patients at any stage were eligible for BV monotherapy if scored ≥ 7 by the cumulative illness rating scale for geriatrics (CIRS-G) or not considered candidates for curative combination chemotherapy at the investigator's judgment irrespective of performance status. Patients with pre-existing peripheral neuropathy grade ≥ 1 were excluded. Staging of cHL was done with contrast-enhanced computed tomography (CT) from neck to pelvis and bone marrow biopsy (Supporting Methods). All patients gave written informed consent.

BV was administered intravenously every 3 weeks at 1.8 mg/kg (maximum 180 mg) for up to 16 cycles. The response was assessed with CT after two and six cycles and at the end of therapy. Fluorodeoxyglucose positron emission tomography with CT (PET-CT) was not mandatory at diagnosis or response evaluation. The primary endpoint was objective response rate (ORR) including complete response (CR), complete undetermined response (CRu), and partial response (PR) by central assessment using radiological criteria.

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TABLE 1 Patient characteristics for the prospective phase II trial and retrospective real-world cohort.

Characteristic	Prospective BV monotherapy group, N = 19 n (%)	Retrospective real-world cohort, N = 49 n (%)
Median age (range) (y)	82 (62–88)	81 (65–92)
Male/female	12 (63)/7 (37)	32 (65)/17 (35)
Ann Arbor stage		
I	1 (5)	5 (10)
II	5 (26)	16 (33)
III	5 (26)	10 (20)
IV	8 (42)	18 (37)
B-symptoms present	13 (68)	31 (63)
Risk stratification ^a		
Early favorable	2 (11)	4 (8)
Early unfavorable	4 (21)	7 (14)
Advanced	13 (68)	38 (78)
International prognostic score		
1–3	13 (68)	22 (45)
4–7	6 (32)	26 (53)
Missing		1 (2)
ECOG status		
0	4 (21)	4 (8)
1	7 (37)	11 (22)
2	4 (21)	15 (31)
3	4 (21)	13 (29)
4	0	5 (10)
Histology subtype		
Nodular sclerosis	5 (26)	20 (41)
Mixed cellularity	4 (21)	7 (14)
Lymphocyte rich	0	3 (6)
Lymphocyte depleted	0	7 (14)
cHL, not otherwise specified	10 (52)	12 (25)
CIRS-G score		
0–3		3 (6)
4–7	6 (32)	12 (24)
8–14	13 (68)	24 (49)
15–25		10 (20)
CIRS-G highest single score		
Mild	1 (5)	
Moderate	8 (42)	
Severe	8 (42)	34 (69)
Extreme	2 (11)	17 (35)
CIRS-G ≥ moderate organ dysfunction		
Heart	10 (53)	
Vascular	9 (47)	
Endocrine	5 (26)	

TABLE 1 (Continued)

Characteristic	Prospective BV monotherapy group, N = 19 n (%)	Retrospective real-world cohort, N = 49 n (%)
Musculoskeletal	5 (26)	
Respiratory	4 (21)	

Abbreviations: BV, brentuximab vedotin; cHL, classical Hodgkin lymphoma; CIRS-G, cumulative illness rating scale for geriatrics; ECOG, Eastern Cooperative Oncology Group; GHSG, German Hodgkin Study Group.

^aRisk stratification according to the German Hodgkin Study Group (prospective trial cohort) or the Norwegian Lymphoma Group (retrospective real-world cohort).

Secondary endpoints included toxicities during treatment, relative dose intensity, progression-free survival (PFS), and overall survival (OS) at 3 years (Supporting Methods).

Between December 2015 and October 2018, we enrolled 20 patients in the BV monotherapy arm (Figure S1). Recruitment was slightly faster than anticipated in the protocol but slower than for patients included in the combination chemotherapy arm of the trial, reflecting the rarity of these patients and possibly also the difficulty of recruiting frail patients into trials at academic centres. The diagnosis of cHL was not verified in one patient, resulting in an intention-to-treat (ITT) population of 19 patients (Table 1). The median age was 82 (range 62–88) years, 68% had advanced disease, 42% had Eastern Cooperative Oncology Group performance status 2–3, and 68% had CIRS-G scores 8–14. All 19 patients received at least two cycles of BV, but one patient terminated early without response assessment. Six additional patients stopped treatment before cycle 6 (three due to toxicity, one progression of cHL, and one each due to the patient's or doctor's decision). The median number of cycles administered was 6 (range 2–16). Of 79 applied cycles, 13 (17%) were delayed and 2 (3%) by 2 weeks or more for a median relative dose intensity of 81.1% (range 24.6–99.2). One patient received additional radiotherapy after the final response assessment.

Toxicities were evaluated in the ITT population (Table S1 and Figure S2). With optional granulocyte colony-stimulating factor (G-CSF) applied in 15 patients, hematological toxicity grade 3 was seen in three patients. Neutropenic fever occurred in one patient and infections grade ≥3 in four (two bacterial infections and two with unknown pathogen). Non-hematological toxicity of grade ≥3 occurred in 10 patients, including grade 4 gastrointestinal adverse events (AE) in two (pangastritis with ascites in one and abdominal angina in another). One patient reported sensory neuropathy grade 3. Neuropathy was otherwise moderate, with grades 1 and 2 reported by nine patients and was numerically more severe in patients with a higher number of cycles (Table S2). During follow-up, eight patients still reported neuropathy grade 1 (four patients) or grade 2 (four patients).

Eighteen patients were evaluated for the primary endpoint after completing between two and six cycles of therapy (Figure S3). CR or CRu was reported in four (22%), PR in seven (39%), stable disease in one, and progression in four patients. Central response assessment was unavailable in two patients (both with PR per investigator's assessment). ORR by radiological assessment was 61% with a lower one-sided 95% confidence interval (CI) limit of 39.2%, meeting the primary endpoint definition for efficacy (two-sided 95% CI: 31–100). PET-CT was available for response assessment in 14 patients, showing complete metabolic response (Deauville score ≤3) in seven patients (50%).

At the median observation time from the start of treatment of 30 months, four patients progressed during or within 3 months after

treatment, three patients relapsed between 3 and 12 months, and two suffered relapse after more than 12 months. Seven patients died: two from toxicities related to subsequent treatments (both pneumonia), two from cHL, and three from other causes (atherosclerotic heart disease, sepsis, and unknown cause in one each). Median PFS was 19 months (95% CI: 5–30), and median OS was not reached (Figure 1). Three-year PFS and OS were 27% (95% CI: 6–48) and 56% (31–81), respectively.

Two phase II studies with BV monotherapy as first-line treatment for elderly cHL patients have been reported previously.^{7,8} In similar cohorts (median age 78 and 77 years and considerable comorbidity), both found higher ORR based on PET-CT (84 and 93%, respectively) but the different imaging modality used hampers direct comparison of ORR between these trials. Compared to our trial, the median duration of response in the two other studies was shorter, 7 and 9 months, respectively. In the BREVITY trial, the 2-year PFS and OS rates were 7%, and 42%, respectively; to our knowledge, 2- or 3-year outcomes are not available from the study reported by Forero-Torres et al.⁸ All three trials are relatively small and therefore difficult to compare at a detailed level, but the encouraging 3-year PFS rate of 27% observed in our trial suggests that BV may even provide sustained benefit for a subset of patients. Both previous studies found BV monotherapy to

have low-to-moderate toxicities, allowing administration of a median number of cycles between 4 and 8, in line with our observations. The three studies combined indicate that BV monotherapy is feasible in older cHL patients with significant comorbidities.

All three trials on BV monotherapy in older cHL patients included patients who were not candidates for curative combination chemotherapy but no uniform definition or systematic analysis of patients receiving palliative treatment is available. Treatment in elderly patients with cHL varies considerably and depends on age and level of comorbidities (4). Similarly, treatment intensity, age, comorbidity, and other determinants of biological age and frailty seem important for outcome.^{1–3} As the use of traditional palliative treatment and the outcome in old and frail cHL patients are not systematically reported, we analysed for comparison similar patients from a retrospective national register-based study from 2000 to 2015, before the introduction of BV in front-line treatment.⁹ Out of 492 patients, 49 with cHL (NLPHL and composite lymphomas excluded) and palliative treatment—defined as dose-attenuated combination chemotherapy (<50% of doxorubicin and/or alkylating agents of standard regimens), single-agent chemotherapy, or localized radiotherapy—were identified (Supporting Methods and Figure S1). Overall, these patients had similar baseline characteristics as the BV monotherapy trial population, except possibly

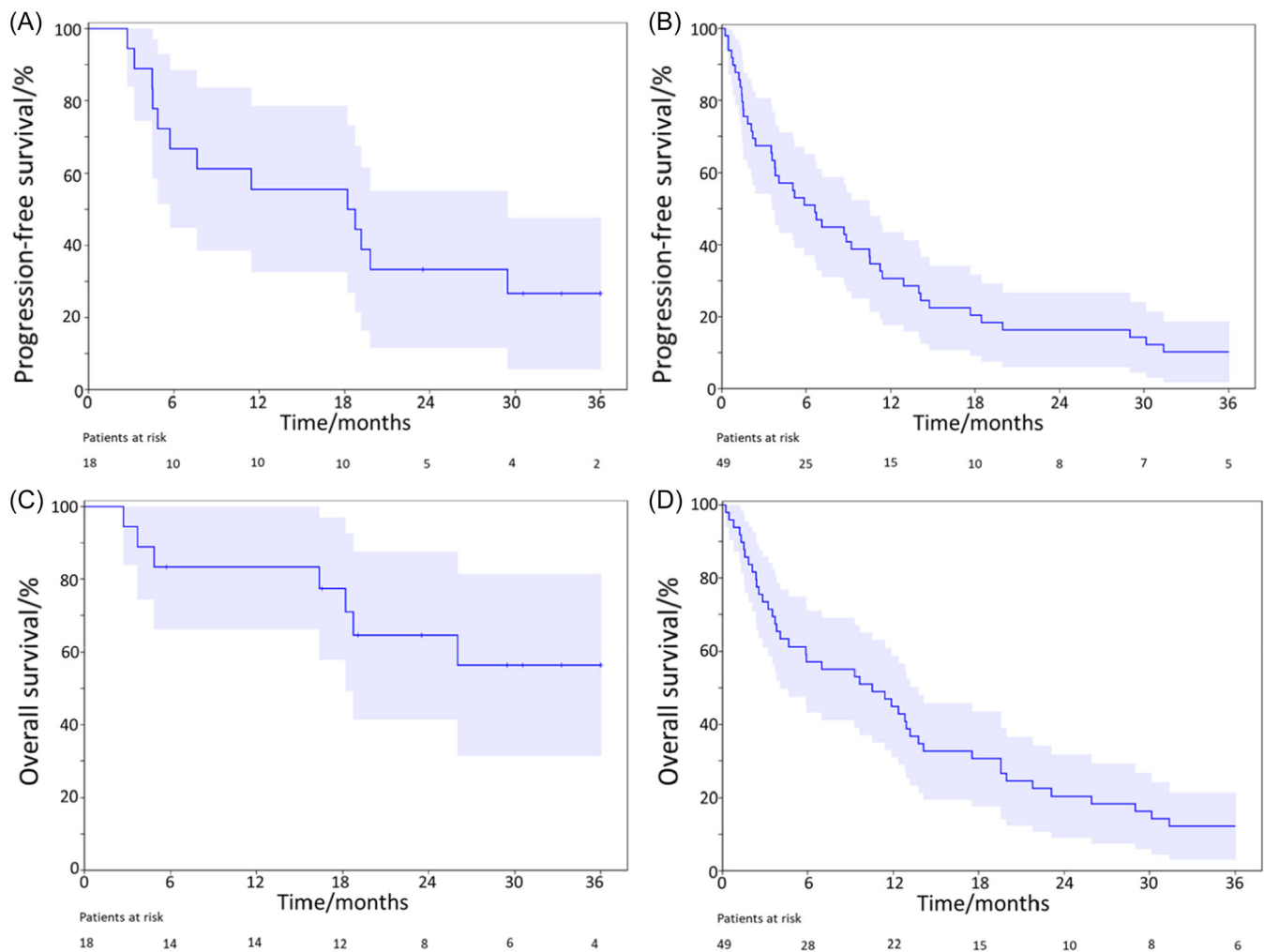


FIGURE 1 Progression-free and overall survival in the prospective trial and retrospective real-world cohorts. (A, C) Progression-free and overall survival in prospective trial patients treated with brentuximab vedotin and (B, D) retrospective cohort of real-world patients treated with palliative intent. Shaded areas represent 95% confidence intervals.

higher IPS and CIRS-G scores, the latter associated with a higher proportion of patients with severe or extreme organ impairments (Table 1). Twelve received attenuated cyclophosphamide, doxorubicin, vincristine, and prednisolone (CHOP); eight received cyclophosphamide, vincristine, and prednisolone (CVP); six received oral trofosfamide; and six received bleomycin, vincristine, and prednisone (Table S3). The median number of cycles for intermittent schedules was 2 (range 1–8). Six patients received additional radiotherapy as part of primary treatment and seven received local radiotherapy alone. Response to therapy by radiological criteria was unknown in 11 patients: 10 of whom had short follow-up and died within 4 months of starting therapy, and one died after 12 months of unknown cause (Figure S3). For 38 patients who underwent response evaluation, CR was documented in 8 (16%) and PR in 15 (31%), resulting in an ORR in all 49 patients of 47% (95% CI 30–70).

Median PFS and OS in the historical cohort were 6.6 months (95% CI 3.8–9.5) and 10.5 months (3.8–17.2), respectively (Figure 1). The rates of PFS and OS at 3 years were 10% (95% CI 2–19) and 12% (4–21), respectively. Patients who received anthracyclines had similar outcomes as those who were treated with either radiotherapy only or chemotherapy without anthracyclines (Figure S4).

Although comparisons to retrospective cohorts must be interpreted with caution, our findings point to a possible role of BV as a single agent in this setting. The two cohorts are similar in terms of age and CIRS-G, which are validated components of geriatric assessment in elderly NHL patients.⁴ No patient in the historical cohort received immune checkpoint inhibition in later lines which may help explain the shorter OS compared to BV-treated patients in recent trials.^{7,8} The real-world experience reported herein highlights difficulties in treating older cHL patients with conventional treatment (53% of patients received only 1–2 cycles of intermittent chemotherapy) and keeping them in follow-up (22% were lost before any documented assessment of response or clinical benefit). These palliatively treated patients made up only approximately 10% of the whole population of older cHL patients in Norway, and may help explain the slow recruitment of this population into academic trials.

The effect of single-agent BV has prompted trials combining BV with other agents in older cHL patients. Combinations with either dacarbazine or nivolumab appear well tolerated and induce remission in over 90% of patients^{10–12} with long-term durability of remissions in a subset of patients.¹³ To our knowledge, these not yet approved combination regimens provide the most promising results for frail elderly cHL patients published to date. However, the patients recruited in these trials tend to be younger, with median ages of 69 and 72 years.^{10–12} Thus, they possibly represent slightly different and potentially fitter cohorts compared to the studies of BV monotherapy or the real-world population described herein. The combination of BV and bendamustine, though active, resulted in excessive toxicities in older cHL patients.¹⁰

The results of BV monotherapy compare favourably also with single-agent nivolumab in elderly and frail patients with cHL.¹⁴ In the Niviniho trial, complete or partial metabolic responses were seen in 48% of patients and those with less than a complete metabolic response went on with a combination of nivolumab and vinblastine. Toxicity was high, with 50% experiencing grade 3 or 4 AE, and 30% of patients discontinuing treatment due to AE attributed to nivolumab. The median PFS was 10 months, which is in line with preliminary results for pembrolizumab in elderly cHL patients.¹⁵ Despite the activity, single-agent checkpoint inhibition may not represent a “one-size-fits-all” solution for the growing population of frail elderly cHL patients.

Novel drugs, including BV, have also been tested in older fit patients with cHL considered eligible for intensive combination chemotherapy. An interim analysis of the other arm of the BVB trial, designed for fit patients with advanced-stage cHL tested BV in combination with

cyclophosphamide, doxorubicin, and prednisolone. This analysis has reported considerable activity previously,¹⁶ and a final analysis is awaited. A sequential regimen of BV followed by doxorubicin, vinblastine, and dacarbazine (AVD) was highly successful in a phase II trial of elderly patients.¹⁷ However, adding BV simultaneously to AVD (BV-AVD) did not benefit elderly advanced-stage cHL patients when compared to ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine) in the randomized ECHOLON-1 trial.¹⁸ Recently, subgroup analyses of the randomized S1826 trial showed improved tolerability and promising efficacy of nivolumab with AVD (N-AVD) compared to BV-AVD in elderly advanced-stage cHL patients.¹⁹ Importantly, neither ECHOLON-1 nor S1826 was specifically designed for individuals over ≥60 years and included patients likely represent a carefully selected relatively fit subgroup of elderly patients.

With the emergence of new treatment options for both fit and frail elderly patients, there is an urgent need for clearer criteria to identify those who can tolerate and benefit from these treatments. These criteria will likely encompass geriatric assessments, as has been shown in aggressive NHL.⁴ To this end, we recently developed and validated simplified geriatric score consisting of CIRS-G, age and ECOG status for older cHL patients.²⁰

In conclusion, our results show that BV monotherapy can induce remission in the majority of old and frail cHL patients and a smaller fraction of patients remain without PFS events with mature follow-up. In light of the manageable tolerability profile, BV monotherapy constitutes a first-line treatment option for this patient group. Although our retrospective data for conventional palliative treatments cannot be directly compared to prospective trial results, they support the clinical relevance of BV monotherapy as a palliative treatment of older and frail patients with cHL, which has not been subject to systematic investigations outside of a few clinical trials thus far.

ACKNOWLEDGMENTS

This study was supported by Millennium Pharmaceutical and Takeda. The authors would like to thank all patients and their families for participating in the prospective trial or for allowing their data to be used for the retrospective real-world data analysis. The authors also thank the staff at each of the study sites and the Norwegian Cancer Registry for their contributions to the study.

Nordic Lymphoma Group (NLG): A. F., D. M., P. M. H. K., and S. M. L.

German Hodgkin Study Group (GHSG): P. J. B., G. S., M. F., P. B., and B. B.

AUTHOR CONTRIBUTIONS

Alexander Fosså, Daniel Molin, Peter Borchmann, and Boris Böll designed the prospective study. Alexander Fosså designed the retrospective data analysis. All authors participated in the conduct of the prospective trial, recruited and treated patients, and provided and collected data. Alexander Fosså, Gundolf Schneider, and Boris Böll performed the data analysis. Alexander Fosså, Paul J. Bröckelmann, Peter Borchmann, and Boris Böll wrote the manuscript. All authors have read, provided input, and approved the final manuscript.

CLINICAL TRIAL REGISTRATION

The trial was registered on [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT 02191930).

CONFLICT OF INTEREST STATEMENT

A. F. received honoraria from Johnson & Johnson, Roche, Takeda, Merck Sharp & Dohme, BMS, Eusapharma, Kite Gilead, Kyowa Kirin, and SOBI; research support from Takeda (the submitted work) and

Roche; and served as a consultant for Takeda, Kite Gilead, and SOBI. D. M. received honoraria from Roche. P. J. B. served as a consultant for Merck Sharp & Dohme, Need Inc., Stemline, and Takeda; held stock options in Need Inc.; received honoraria from BeiGene, BMS/Celgene, Merck Sharp & Dohme, Need Inc., Stemline, and Takeda; and received research support from BeiGene (Inst), BMS (Inst), Merck Sharp & Dohme (Inst), and Takeda (Inst), all outside the submitted work. U. S. received honoraria from Kite Gilead, Novartis, BMS, SOBI, Takeda, and Beigene; and served as a consultant for Kite Gilead, Beigene, BMS, and SOBI. P. M. H. K. received travel support from Roche Pharmaceuticals and Takeda. S. M. L. served as a consultant for AbbVie, Genmab, Gilead Incyte, Novartis, Roche, and SOBI, all outside the submitted work; received honoraria from Gilead, Incyte, Novartis, and SOBI; and received research grants from Bayer, Celgene/BMS Hutchmed, Genmab, Novartis, and Roche, all outside the submitted work. J. M. received honoraria from Merck Sharp & Dohme. M. F. received honoraria from Celgene, BMS, Takeda, and Janssen. P. B. has advisory/expert roles for Takeda Oncology, Merck Sharp & Dohme, Roche, and Miltenyi Biotech; received honoraria from Takeda Oncology, BMS, Roche, Merck Sharp & Dohme, Miltenyi Biotech, Gilead, AbbVie, Beigene, and Incyte; and received research funding from Takeda Oncology, Amgen, Merck Sharp & Dohme, and Incyte. B. B. received honoraria from Roche. G. S., J. L., V. S., and K. L. declare no conflicts of interest.

CONSENT

All patients gave written informed consent.

DATA AVAILABILITY STATEMENT

Anonymized patient data may be shared upon reasonable request to the corresponding author subject to ethical and other regulatory approval.

ETHICS STATEMENT

The trial was conducted according to the guidelines for good clinical practice and approved by both the sponsor's and the other participating countries' national ethics and medicinal agencies.

FUNDING

The prospective trial was supported financially by Takeda and with supply of brentuximab vedotin. The retrospective part was supported financially by Takeda. P. J. B. was supported by an excellence scholarship from the Else-Kröner Fresenius Foundation (EKFS). K. L. received a grant from Vestre Viken Health Trust.

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SUPPORTING INFORMATION

Additional supporting information can be found in the online version of this article.

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