Bendamustine-Rituximab (BR) Replaces R-CHOP as “Standard of Care” in the Treatment of Indolent Non-Hodgkin‘s Lymphoma in German Haematology Outpatient Centres.

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1. Introduction

With the FDA and EMA approval of bendamustine a new treatment option has recently become available to patients with indolent (low-grade) non-Hodgkin‘s lymphoma (iNHL). Clinical registries provide insight into real-life treatment. They can help to answer the question whether patients may benefit from new research findings.

2. Methods

The clinical registry on lymphoid neoplasms (TLN Registry) prospectively collects data of treated patients with lymphoid B-cell neoplasms in haematology outpatient centres in Germany. Conducted by iOMEDICO in collaboration with the Arbeitskreis Klinische Studien (AKS) and the Kompetenznetz Maligne Lymphome (KML), it aims at recruiting 3500 patients with aggressive or indolent non-Hodgkin‘s lymphoma, chronic lymphocytic leukaemia or multiple myeloma. Patients older than 18 years are eligible for enrolment at the start of their 1st-line or 2nd-line treatment. At time of enrolment data on patients’ demography, tumour history and characteristics, clinical and medical parameters and concomitant disorders and diseases are documented. During the course of therapy patients are treated according to physician’s choice, their individual needs and schedules. No specifications are imposed to the physicians’ assessment for treatment at any time. All systemic antineoplastic treatments, as well as radiotherapies and/or surgeries are documented. Treatment outcome parameters including best tumour response(s), time of progression(s) and time of death are documented. Patients are followed for 5 years.

Since May 2009, 106 sites (accounting for approx. 30-40% of all outpatient centre-based specialists within the field of Haematology and Oncology in Germany) have recruited a total of 2579 pts.

3. Results

From the overall sample, 645 patients received systemic 1st-line treatment for indolent non-Hodgkin‘s lymphoma (iNHL). The majority of patients have been diagnosed with follicular lymphoma (Figure 1). 53% of patients are male, mean age at time of primary diagnosis was 65 years and at start of therapy 66 years.

	iNHL, total	BR	R-CHOP
Patients (N)	645 [100%]	428 [66,4%]	105 [16,3%]
Male (%)	52,9	53,0	55,2
Age at start of treatment (n)[a]	645	428	105
Median (years)	68,5	69,7	61,6
Median ± StD (years)	65,9 ± 12,7	67,2 ± 12,1	60,8 ± 12,4
Presence of B-Symptoms (n)[a]	614	411	102
Present (%)	23,5	23,4	25,5
Tumor stage (Ann Arbor) (n)[a]	502	339	80
Stage I (%)	7,0	3,8	12,5
Stage II (%)	14,7	16,2	10,0
Stage III (%)	24,7	23,3	38,8
Stage IV (%)	53,6	56,6	38,8
Charlson-Score [0-34] (n)[a]	640	423	105
Mean ± StD	0,6 ± 1,0	0,6 ± 1,0	0,4 ± 0,9

Table 1:
Patient characteristics - 1st-line treatment of iNHL

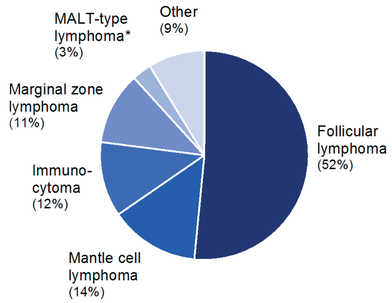

Figure 1:
Frequency of iNHL subgroups

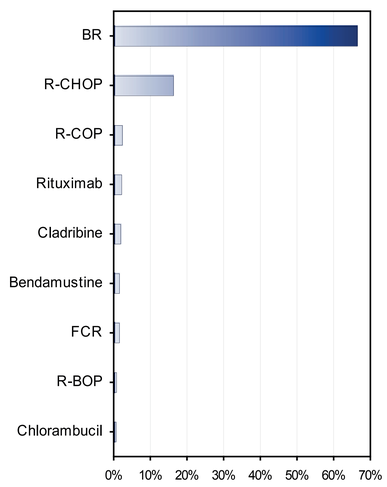

Figure 2:
Frequency of 1st-line treatment of iNHL (n=645)

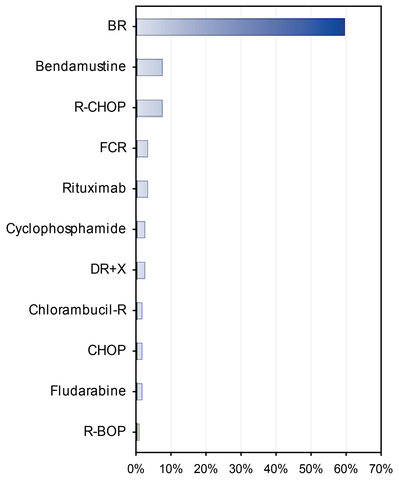

Figure 3:
Frequency of 2nd-line treatment of iNHL (n=121)

Tumour stage was 7% Stage I, 15% Stage II, 25% Stage III and 54% Stage IV (Table 1). 61% of patients (n=387) were diagnosed with at least one comorbidity, mainly hypertension (33%) or diabetes (12%); the average Charlson Comorbity Index of 0.6 indicates that patients have few comorbities.

Rituximab is part of the 1st-line treatment in 94% (n=606) of patients with iNHL. Bendamustine is part of the 1st-line treatment in 71% (n=455) of patients with iNHL. It is mostly applied in combination with rituximab (BR, 66%, n=428). Further 2% (n=10) receive bendamustine as monotherapy (Figure 2). Rituximab / cyclophosphamide / doxorubicin / vincristine / prednisone (R-CHOP) as 1st-line treatment is applied in 16% (n=105) of patients with iNHL (Figure 2).

Patients receiving BR or R-CHOP differ. Patients characteristics indicate that BR is applied preferably in elderly patients (mean 67.2 vs. 60.8 years). However, BR is the preferred treatment also in patients younger than 66 years (60% vs. 23%).
The use of BR has increased from 62% in 2009 to 68% in 2011, whereas the rate of R-CHOP has decreased from 19% in 2009 to 15% in 2011.

Of all patients with iNHL, 121 have received 2nd-line treatment. Rituximab is part of the 2nd-line treatment in 84% (n=102) of patients with iNHL. Bendamustine is part of the 2nd-line treatment in 68% (n=82) of patients with iNHL. It is mostly applied in combination with rituximab (BR, 60%, n=72). Further 7% (n=9) receive bendamustine as monotherapy (Figure 3). R-CHOP as 2nd-line treatment is applied in 7% (n=9) of patients with iNHL (Figure 3).

4. Conclusion

BR is the most frequently used systemic treatment for patients with iNHL in German haematology outpatient centres. The use of BR has continuously increased since 2009. In contrast, the use of R-CHOP has decreased. This indicates that in Germany R-CHOP can no longer be considered as “standard of care” for patients with iNHL. These data also show that results from clinical trials are quickly implemented into daily practice. The impact of BR on quality of life and survival remains to be of central interest in the future.

In collaboration with:

AKS Arbeitskreis klinische Studien e.V.

Kompetenznetz Maligne Lymphome

Bendamustine: Bendamustine (mono) ± Prednisone | BR: Bendamustine + Rituximab ± Prednisone | CHOP: Cyclophosphamide + Doxorubicin + Vincristine ± Prednisone | Chlorambucil-R: Chlorambucil + Rituximab | Cladribine: Cladribine (mono) | Cyclophosphamide: Cyclophosphamide (mono) | DR-X: Dexamethasone + Rituximab + other | Fludarabine: Fludarabine (mono) | FCR: Fludarabine + Cyclophosphamide + Rituximab ± Prednisone | R-BOP: Rituximab + Bendamustine+ Vincristine | R-CHOP: Rituximab + Cyclophosphamide + Doxorubicin + Vincristine ± Prednisone | R-COP: Rituximab + Cyclophosphamide + Vincristine | Rituximab: Rituximab (mono)

* MALT: Mucosa-associated lymphoide tissue

Disclosures: Knauf: Mundipharma: Membership in Advisory Board; Honoraria

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