SPECIAL EDITION:

Highlights from ASH 2021

63rd Annual Meeting and Exposition of the American Society of Hematology
11-14th December 2021
The Belgian Journal of Hematology (BJH) is the official journal of the Belgian Hematology Society (BHS), the Belgian Society on Thrombosis and Haemostasis (BETH), the Belgian Society of Paediatric Haematology and Oncology (BSPHO) and the Belgian Society for Advancement of Cytometry (BSAC). The BJH aims to be a peer-reviewed hematology journal covering all aspects of the diagnostic and clinical management of hematology patients, reflecting a multidisciplinary approach to therapy. It aims at informing clinicians active in the field of hematology in Belgium and Luxembourg, thereby giving clinicians a solid support for daily practice.

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FIRST LINE THERAPY FOR NEWLY DIAGNOSED TRANSPLANT-ELIGIBLE PATIENTS

Updates were presented on important clinical trials including anti-CD38 antibodies as part of induction, consolidation or maintenance. In the phase II GRIFFIN trial, an updated analysis was presented after 24 months of maintenance therapy and a median follow-up of 38.6 months.1 Patients were randomised to receive either Daratumumab (D)-Revlimid-Velcade-dexamethasone (D-RVD) or RVD (four cycles in induction and two cycles in consolidation), autologous stem cell transplantation (ASCT) and maintenance with either daratumumab-Revlimid or Revlimid alone. The estimated 36-months progression-free-survival (PFS) was 88.9% for D-RVD and 81.2% for RVD. MRD negativity (10^-5) (determined by next-generation sequencing (NGS)) was higher (50% vs. 10.6%) at the end of consolidation after D-RVD and this difference persisted (64.4% vs. 35.6%) after 24 months of maintenance. For the phase III German GMMG-HD7 trial including 662 patients and comparing VRD with or without isatuximab (Isa), MRD negativity (10^-5) was higher in patients treated upfront with D-VTD and was of little benefit to improve MRD-negativity in patients who started treatment with VTD alone. Taken these three datasets together, it is clear that the addition of anti-CD38 in all phases of the transplant trajectory improves MRD-negativity. This will ultimately translate into prolonged PFS and probably overall survival (OS), in accordance with a recent meta-analysis on the prognostic value of MRD-negativity with respect to PFS and OS.4 Another IFM phase II study (45 patients included) showed that the combination of daratumumab-ixazomib (IXA)-lenalidomide-dexamethasone (D-IRD) in extended induction (six cycles) and consolidation (four cycles) was safe and led to a PFS of 95.2% at two years (Figure 1) and MRD-negativity of 51.4% after consolidation which is however somewhat lower as compared to D-VTD (64%) in the Cassiopeia study.5,6 The Spanish Myeloma Group (GEM) compared the combination of lenalidomide-dexamethasone with or without ixazomib as maintenance therapy after ASCT. After two years patients becoming MRD negative discontinued and in case of positive MRD, maintenance was continued for an additional three years.7 The addition of ixazomib did not improve PFS, which was 63% at five years from the start of maintenance in both arms. But again interesting data on MRD-negativity emerged from this trial: i) standard-risk patients being MRD-negative after consolidation had PFS/OS of 78%/90% at five years, ii) patients with high-risk disease and MRD-positive after consolidation had a dismal prognosis (PFS = 37 months) and iii) MRD-negativity at two years of maintenance was associated with a high relapse rate despite continuation of maintenance.

SUMMARY

This paper reports on selected oral abstracts presented at ASH 2021 on the treatment of newly diagnosed and relapsed/refractory multiple myeloma (MM) patients.

Department of Haematology, UZ Brussel, Brussels, Belgium.

Please send all correspondence to: R. Schots, MD, PhD, Department of Haematology, UZ Brussel, Av. du Laerbeek 101, 1090 Jette, Belgium, tel: +32 2 477 41 11, email: Rik.Schots@uzbrussel.be.

Conflict of interest: Advisory boards: BMS, Amgen, AstraZeneca and Sanofi.
Highlights in chronic lymphocytic leukaemia

T. Feys, MSc, MBA

SUMMARY
The research landscape in chronic lymphocytic leukaemia (CLL) anno 2022 puts a strong focus on the optimal treatment choice in the frontline setting. In this setting, targeted therapy options have largely replaced chemoimmunotherapy as standard of care. However, with this evolution comes a new question: which patient is best treated with a continuous treatment option and who benefits most from a time-limited treatment approach? During ASH 2021, results of several studies looking at both treatment strategies have been presented, further fuelling this debate. Despite the impressive improvements in the frontline setting, a large proportion of patients will eventually relapse or develop refractoriness to the available therapies. To address this medical need, researchers continue to develop new treatment modalities. In this light, ASH 2021 featured promising results with the novel BTK-inhibitor pirtobrutinib and provided a reassuring update of the ASCEN trial evaluating acalabrutinib in the relapsed/refractory setting.

FIRST-LINE TREATMENT
In recent years, the choice between continuous or time limited treatment regimens has been the focus of many discussions on the optimal first-line treatment for patients with CLL. During ASH 2021, new data were presented for both these treatment strategies and the choice between continuous therapy or fixed duration treatments formed the topic of an interesting educational session.

CLINICAL TRIAL DATA WITH CONTINUOUS FIRST-LINE TREATMENT
When talking about continuous treatment in the first-line treatment we are actually discussing the use of Bruton’s tyrosine kinase inhibition (BTKi). The first study demonstrating the therapeutic potential of BTKi in the CLL setting consists of the PCYC 1102 trial, a phase Ib/II trial evaluating ibrutinib in first-line or relapsed/refractory (R/R) CLL.1 Recently, the final analysis of this trial revealed an impressive seven-year progression-free survival (PFS) rate with ibrutinib of 83% and 34% for patients with newly-diagnosed and R/R disease, respectively.1 Subsequently, three large phase III trial established ibrutinib as a standard of care first-line regimen for CLL patients. In RESONATE-2, ibrutinib proved to be associated with a significantly better PFS and OS than chlorambucil in unfit CLL patients.2 Similarly, the ALLIANCE study showed a superior PFS with ibrutinib (with or without rituximab) compared to chemo-immunotherapy (CIT) with bendamustine and rituximab (BR) in the treatment of newly-diagnosed CLL patients who were deemed unfit for more intensive CIT with the combination of fludarabine, cyclophosphamide and rituximab (FCR).3 Finally, the ECOG1912 study also demonstrated superiority of ibrutinib over FCR in the first-line treatment of CLL patients with a significantly better PFS and OS.4 Despite being a very effective first-line treatment for patients with CLL, a treatment with ibrutinib does come with some troublesome toxicity, including the risk for atrial fibrillation (AF), hypertension, bleeding and rash. As these toxicities are mainly attributable to the off-target effects of ibrutinib, more selective next-generation BTK inhibitors were developed.
CHRONIC MYELOID LEUKAEMIA

With currently available Tyrosine Kinase Inhibitors (TKIs), the lifespan of CML patients is near normal. The focus in CML treatment has thus broadened from giving an effective treatment to also striving for a good quality of life. Therefore, it is of the utmost importance to choose the correct treatment for each patient. In his educational session, Dr. Mauro focused on the toxicity of TKIs. Knowledge of the side effects of each available TKI is the first step in making the correct choice. Dasatinib can cause pleural effusion in up to 30-40% of patients, with a dose- and age-dependent risk that remains present over time. Pulmonary hypertension is less frequent following dasatinib treatment, yet this is not always reversible with cessation of the drug. Nilotinib and ponatinib carry a risk of arterial occlusive events, especially in patients over 60 years of age and with a high Systematic Coronary Risk Evaluation (SCORE) risk profile. The cumulative incidence of arterial occlusive events on ponatinib can be as high as 74% at three years if the SCORE-risk exceeds 5%. Furthermore, comorbidity is still the most important predictor of survival, also in CML patients. Mapping of comorbidity and cardiovascular risk is thus the second step in selecting a front-line TKI treatment. Once the TKI has been chosen adequate follow-up of cardiovascular risk factors and status is mandatory, in collaboration with the general practitioner or the cardiologist.

Estimating response on different TKIs would be helpful, therefore Zhang and colleagues presented an Imatinib Therapy Failure Model. Based on leukocyte count, haemoglobin, blood basophils and ELTS risk patients were stratified in five subgroups with a 7-year probability of failure-free survival ranging from 89% (very low risk) to 28% (very high risk) if treated with Imatinib. More than 50% of patients were classified as very low and low risk, and one could argue that for (very) high-risk patients (16 and 8%) second-generation TKIs would be the preferred front-line therapy.

Dose-reduction is a strategy to improve toxicity. The group from MD Anderson made a propensity score analysis of newly diagnosed CML patients treated with 50 mg dasatinib versus 100 mg dasatinib. Each cohort had 77 patients; median follow-up was 60 months. The rate of pleural effusion was significantly lower in the 50 mg group (6% vs. 21%, p=0.016). Improved tolerability resulted in higher response rates (MMR 82% vs. 75%, p=0.229 and MR4 63% vs. 43%, p=0.009) and similar 4-year event-free and overall survival (95% vs. 92% and 97% vs. 96%). Dose-reduction to optimise cardiovascular toxicity on ponatinib was discussed in the OPTIC-trial. This trial enrolled 283 highly pre-treated patients with virtually all patients resistant to previous TKI and about 25% of patients carrying T315I mutation. Patients were randomised to start treatment at three different doses (15 mg,
Highlights in myelodysplastic syndromes

B. Heyrman, MD

SUMMARY
The first hybrid ASH meeting lived up to the expectation of bringing new data forward that will change the life of MDS patients. Implementation of NGS in daily practice has unveiled intimate information of the disease and is moving forward into risk scores. A new and better standard risk score will change our treatment approach thereby changing the outcome of our patients. For now, we are watching new molecules grow through different trial phases and becoming impatient to install them into daily practice in the near future. A summary of the most appealing data in the field of MDS is presented here.

(BELG J HEMATOL 2022;13(1):25-8)

Fine-tuned risk scores cannot be overvalued for patients suffering from myelodysplastic syndromes. More than anything else, they guide our treatment. We have seen important changes and re-stratification of risk profile at the time the International prognostic scoring system (IPSS) was revised. The same can be said now with the implementation of gene mutations into a new risk score. The presentation of the IPSS-M (Molecular International Prognosis System) was the most ground-breaking oral in the field of MDS this year. This new risk score was developed and validated in 3,675 MDS patients. In 90% of patients, at least one gene mutation was found and in 71%, two or more mutations were found. The IPSS-M is a continuous index and implements four important aspects of the disease: i) cell-counts (haemoglobin, platelets and bone marrow blasts), ii) IPSS-R cytogenetic category iii) 22 binary features derived from the presence of mutations in 21 predictive genes and iv) one feature representing the number of mutations from a group of seventeen additional genes. The IPSS-M resulted in improved discrimination compared to the IPSS-R score in terms of leukaemia-free survival (LFS), overall survival (OS) and leukemic transformation (Figure 1). Compared to the IPSS-R, the IPSS-M resulted in re-stratification of 46% (n=1,246) of patients. In this group, 74% were upstaged and 26% were down staged. Most remarkable was that 6% of patients form the IPSS-R very-low/low shifted to IPSS-M very high/high (Figure 2). On top of this, the IPSS-M clearly stratified patients with secondary or therapy-related disease. This score will become the standard in the near future and should be implemented in every clinical trial that opens in the future.

LOW-RISK MDS
The MEDALIST trial was further updated at this meeting. This trial has led to approval and reimbursement of Luspatercept in lower risk MDS patients with ring sideroblasts who were refractory to ESA or unlikely to respond to ESA. A previous update taught us that extending treatment beyond the initial period of 24 weeks, at which the primary endpoint was calculated, could be beneficial. At ASH focus was on duration of response (median time on treatment of 51 weeks vs. 24 weeks in the placebo group) and safety (fatigue and diarrhoea in about 30%. Over all 53% had at least one grade 3 or 4 adverse event, equal to the placebo arm with 54,5%).
The use of lenalidomide (LEN) in non del5q-MDS patients reduced transfusion need in roughly one-quarter of patients but can lead to significant thrombocytopenia. Preclinical data suggested that Eltrombopag (ELT) could

Department of Haematology, Ziekenhuis Netwerk Antwerpen, Antwerp, Belgium.

Please send all correspondence to: B. Heyrman, MD, Department of Haematology, Ziekenhuis Netwerk Antwerpen, Lindendreef 1, 2020 Antwerp, Belgium. tel: +32 3 280 34 59, email: bert.heyrman@zna.be.

Conflict of interest: The author has nothing to disclose and indicates no potential conflict of interest.
Highlights in aggressive and indolent lymphoma

J. Blokken, PharmD, PhD, T. Feys, MSc, MBA

SUMMARY
During the 63rd annual meeting of ASH, again hundreds of interesting oral abstracts and poster presentations in the field of aggressive and indolent lymphoma were discussed. In this article, we will highlight some of the most promising data in the field of diffuse large B-cell lymphoma, classic Hodgkin lymphoma, enteropathy-associated T-cell lymphoma, mantle cell lymphoma and follicular lymphoma.

DIFFUSE LARGE B-CELL LYMPHOMA
FIRST-LINE TREATMENT OF DLBCL
To date, the standard of care for patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL) consists of R-CHOP. The antibody drug-conjugate polatuzumab vedotin previously demonstrated promising safety and activity when combined with rituximab, cyclophosphamide, doxorubicin and prednisone (pola-R-CHP) in a phase IB/II study. The phase III POLARIX study now compared pola-R-CHP with R-CHOP in patients with previously untreated DLBCL and an IPI score of 2-5. After a median follow-up of 28.2 months, progression-free survival (PFS) was superior with pola-R-CHP vs. R-CHOP (HR[95%CI]: 0.73 [0.57–0.95], p<0.02) with two-year PFS rates of 76.7% and 70.2%, respectively. In addition, a slight increase was seen in the level of complete remissions (CR) with pola-R-CHP (86.6% vs. 82.7%). At this point, there was no difference in overall survival (OS) (HR[95%CI]: 0.94[0.65–1.37], p=0.79). Furthermore, fewer patients in the pola-R-CHP than the R-CHOP arm received subsequent anti-lymphoma treatments. The safety profile was comparable for pola-R-CHP vs. R-CHOP, including rates of grade 3–4 adverse events (AEs), serious AEs, grade 5 AEs, and AEs leading to dose reduction. Interestingly, subgroup analyses of investigator-assessed PFS revealed that the benefit observed with pola-R-CHP was predominantly observed in patients with an IPI-score of 3-5 (62% of patients). Therefore, pola-R-CHP might become a new standard of care in patients with newly diagnosed DLBCL and an IPI-score of 3-5.3

CNS PROPHYLAXIS IN FIRST-LINE
Although high-dose methotrexate (HD-MTX) is widely used to mitigate the risk of secondary central nervous system lymphoma (SCNS), data supporting this practice are limited. Lewis et al. conducted a multicentre, retrospective study of 2,300 high-risk DLBCL patients with a CNS-IPI 4-6 or high-grade B-cell lymphoma (HGBL) with rearrangements of MYC+BCL2 and/or BCL6 or primary breast/testicular DLBCL irrespective of CNS-IPI. Except for a predominance of males, patients ≤60 years and patients with ECOG 0–1 in the HD-MTX vs. no HD-MTX groups, the demographics and treatments were well balanced. Overall, authors concluded that HD-MTX was not associated with a reduction in CNS relapse overall, in patients with a complete remission (CR) at completion of frontline treatment or in any high-risk group.4

SECOND-LINE DLBCL
To date, patients with aggressive non-Hodgkin’s lymphoma relapsed or refractory within twelve months of first-line
BLOCKING ANTITHROMBIN PRODUCTION TO TREAT HAEMOPHILIA - NEW RESULTS FROM ATLAS PHASE 3 PROGRAM WITH FITUSIRAN

Fitusiran is a small interfering RNA molecule that blocks antithrombin production in liver cells (Figure 1). Instead of taking the traditional approach in haemophilia treatment of boosting the coagulation cascade by replacing missing clotting factor VIII or IX, the concept of fitusiran is to short circuit the body’s anticoagulation system by targeting antithrombin.

Two phase III trials investigated fitusiran; a subcutaneous investigational siRNA targeting antithrombin, as once-monthly 80 mg prophylaxis in patients with haemophilia A or B. The ATLAS-INH trial was presented by Guy Young (Children's Hospital Los Angeles and University of Southern California, Los Angeles, CA, USA). Eligible patients were male, aged twelve or more years, had developed antibodies formed against exogenous clotting factors (inhibitors), and were receiving on-demand bypassing agents (BPA). Fifty-seven patients were randomly assigned 2:1 to fitusiran prophylaxis (n=38) or continuation of BPA (n=19). The annualised bleeding rate (ABR; primary endpoint) was 1.67 (95% CI 1.0–2.7) in the fitusiran group and 18.07 (10.6–30.8) in the BPA group (HR 0.09, 95% CI 0.04–0.19; p<0.0001). Twenty-five (66%) patients in fitusiran group had zero treated bleeding events. Reported treatment-emergent serious adverse events (TESAEs) were generally consistent with what is anticipated in an adult and adolescent population with severe haemophilia A or B with inhibitors, or with the previously identified risks of fitusiran. All TESAEs were reported in one patient each; in the fitusiran prophylaxis arm these included events of device related infection, haematuria, spinal vascular disorder, subclavian vein thrombosis, thrombosis, acute cholecystitis, chronic cholecystitis and asymptomatic COVID-19. There were no fatal TEAEs reported.

Alok Srivastava (Christian Medical College, Vellore, India)
In the educational program, ample time was given to discuss ways to improve access to stem cell transplantation for all patients. On the one hand, this includes discussions on starting up transplant programs in developing countries. However, on the old continent not all patients might be referred for alloHCT either. Older (not always elderly) patients might not be referred for alloHCT although we know that blood cancers are more frequent in this age group. Moreover, they more frequently present with high-risk disease, or fare worse compared to younger patients with similar disease characteristics. Nonetheless, patients might not be referred due to a fear of excess toxicity after alloHCT. Data from the Center for International Blood and Marrow Transplant Research (CIBMTR) registry show that the number of transplants in patients over 60 and 70 years of age is increasing. In 2000, they accounted for only 6% of all alloHCT performed, in 2019 this number has increased to 41% and patients over 70 now account for 10% of all transplants and even transplants over 75 years are registered.1

The ECOG-ACRIN trial investigates treatment of acute myeloid leukaemia in older patients (60-86 years); patients are randomised between 3+7 induction or clofarabine. Patients can go to alloHCT in first complete remission (CR) and investigators analyse outcome after alloHCT in this patient group. Of 727 patients included, 166 underwent alloHCT and data were analysed for 105 patients transplanted in CR or leukaemia free state (LFS). The median age was 66 years, ranging between 60 and 73. Most patients had an excellent performance status (88% ECOG 0-1) and 26% had unfavourable cytogenetics, 76% received one or two consolidation cycles. Disease free survival (DFS) at two years amounts to 53.6% with 56.4% overall survival (OS). At four years after alloHCT, DFS is still 39% and OS 42.9% (Figure 1). Non-relapse mortality (NRM) is low at six months at 4.4% for patients ≤65 years and 8.4% for patients >65 years. However, this increases significantly to 15.6% and 24% at two years for patients ≤65 years and >65 years, respectively. These data show that alloHCT is feasible and efficacious in an older patient group with AML.2

The advent of the post-transplant cyclophosphamide (PTCy) platform has revolutionised haplo-identical HCT bringing its outcome up to the level of standard MUD transplantation. In 2021, Goptuu et al. published in Blood that in myeloid disease a matched unrelated donor (MUD) is superior to a haplo-identical donor if the PTCy is used in both cases for GvHD prophylaxis.3 At ASH 2021 CIBMTR and the European group for Blood and Marrow Transplantation (EBMT) presented data of a similar analysis for lymphoid disease. Two thousand one hundred and fifty
INTRODUCTION
AML is a highly heterogeneous disease, presenting as either de novo or secondary disease. Incidence of onset increases with age, with age being associated with a higher frequency of adverse-risk cytogenetic and molecular abnormalities. Until recently, AML patients used to have limited treatment options, solely depending on intensive chemotherapy (IC), hypomethylating agents (HMAs) and stem cell transplantation (SCT) in selected patients. Over-all, the prognosis for AML patients is poor with a 5-year overall survival (OS) rate of approximately 40%, which is rapidly declining with increasing age at diagnosis. Unfortunately, approximately 50% of younger (≤60 years) and about 80–90% of older patients relapse after achieving their first complete remission (CR). Despite intensive consolidation therapy, most relapsed patients succumb to their disease. Recent developments with new treatment regimens and the application of certain agents in other settings aim to improve survival and quality of life for AML patients. Daver, et al. give a good overview of new directions for emerging therapies in AML with an insightful flow diagram of current treatment pathways in newly diagnosed AML (Figure 1).}

FIRST LINE
INTENSIVE CHEMOTHERAPY
Promising results were presented at ASH 2021 by Dr. Lachowiez with an induction and consolidation regimen comprising venetoclax (VEN) plus fludarabine, cytarabine, granulocyte colony-stimulating factor, and idarubicin (FLAG-IDA) for the treatment of newly diagnosed AML. The phase II study investigated the overall activity of the FLAG-IDA plus VEN regimen in 41 patients. The median age of the overall cohort was 44 years, at time of diagnosis, TP53 mutations were identified in 10% of patients, while KMT2A rearrangements were reported in 12% of patients. The overall response rate (ORR) was 98%, including a complete remission (CR) rate of 73%, CR with partial recovery of peripheral blood counts (CRh) rate of 12%, CR with incomplete count recovery (CRi) rate of 2%, and morphologic leukaemia-free state (MLFS) rate of 10%. Measurable residual disease negativity (MRD-) was achieved in 92% of patients with CR, CRh, and CRi. After a median of 3.8 months, 27 patients moved on to receive an allogeneic hematopoietic cell transplantation (HCT). After a median follow-up of 16 months, the median OS and EFS rates were not yet reached. The estimated one-year OS rate
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