

is associated with a poor prognosis and most often a fatal outcome. The incidence of CNS relapse can vary from <1% in younger, good-risk patients, to around 30% in patients with multiple risk factors, however, the relapse risk was reported to be lower in the rituximab era in some studies. Moreover, optimal modality of CNS prophylaxis remains to be defined, with both systemic and intrathecal (IT) chemotherapy being widely used. As the incidence of CNS relapse and type of prophylaxis used varies in different reports, it is important to study this risk in different populations to implement optimal prophylaxis strategies. The Objectives of this study was to evaluate the incidence of CNS relapse in DLBCL patients at our institution and to study risk factors and the type and role of CNS prophylaxis. **Methodology:** We retrospectively analyzed patients diagnosed with DLBCL at King Khalid University Hospital, Riyadh, from January 2011 to June 2019. Data were collected from computerized hospital information system and from the files of the patients. Variables studied included age at diagnosis, stage at diagnosis, international prognostic index (IPI) and CNS-IPI score, site(s) of extra-nodal involvement, type of chemotherapy received, CNS prophylaxis and CNS relapse. CNS prophylaxis was administered on the basis of presence of high-risk features like presence of ≥ 2 extranodal sites, involvement of bone marrow, bone, testes, nasopharynx and paranasal sinuses. Patients with presence of CNS involvement at diagnosis and primary CNS lymphoma were excluded. **Results:** A total of 101 patients were diagnosed with DLBCL during the study period. There were 58 males and 43 females with a median age of 56 (range: 16-87) years. Ann Arbor stage of I-IV was assigned in 9, 21, 17 and 50 patients, respectively. The lung was the most common extranodal site involved in 27 (26.7%) patients, and liver and bone marrow involved in 20 (19.8%) patients each. Gastrointestinal tract was involved in 9 (8.9%) patients, kidneys in 5 (4.95%), breast in 4 (4%), and testis and adrenal in 2 (2%) patients each. Twenty-five (24.75%) patients had high risk CNS-IPI score, 44 (43.5%) had intermediate risk score and 32 (31.7%) had low risk score. Ninety-four (93%) patients received R-CHOP chemotherapy while rest of the patients received other types of chemotherapy, mostly a milder regimen (R-CVP), because of comorbidities and poor performance status. Sixteen patients received CNS prophylaxis, which was IT methotrexate (MTX) \pm cytarabine/hydrocortisone in all patients. Nine of 25 (36%) patients with high-risk CNS-IPI score did not receive CNS prophylaxis. After a median follow up of 36 months (range 4-114), 2 (2%) patients developed CNS relapse and died shortly after this diagnosis. Both the patients with CNS relapse had high risk CNS-IPI score and did not receive CNS prophylaxis. **Conclusion:** CNS relapse of DLBCL was uncommon in this patient population despite limited use of IT CNS prophylaxis in high-risk patients. Low incidence of CNS relapse in many high-risk patients despite limited use of IT prophylaxis may be related to rituximab use and/or other factors. Our data indicate that IT CNS prophylaxis may be adequate for DLBCL patients at high risk of CNS relapse.

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OP 03

AN UPDATED OF PIONEER PROJECT TO COLLECT DATA OF T-CELL NHL PATIENTS AMONG FIVE REGIONS OF BRAZIL. T-CELL BRAZIL PROJECT

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Objective: T-cell Brazil project started in April 2017 an ambispective study focusing to collecting epidemiological and clinical data from the most frequent subtypes of PTCL. Our goals are to obtain the frequency of subtypes by the five Brazilian macro regions; to investigate the clinical and biology characteristic; to create a routine pathological revision and to evaluate the OS, EFS in 5 years of follow-up. **Methodology:** Thirteen nine centers had approved by their Ethical Committee and using REDcap Platform by Vanderbilt are registering their cases. Descriptive and bivariate analyses, then it was applied Kaplan-Meier method and log-rank test to obtain survival estimates, using IBM-SPSS v.24 **Results:** The median age was 55 years (19-95); 56% male; Almost 72% had advanced stages, 28% ECOG ≥ 2 ; the distribution of main subtypes was: 31% PTCL-NOS; 18% ALCL, ALK-; 16% ATL; 13% ENKTL nasal and nasal type; 11% AITL; 7% ALCL, ALK+; 6% others (Table 1). 50% of patients were alive and the 24-month PFS and OS was 36% and 50%, respectively. OS by main subtypes was 48% PTCL-NOS; 61% ALCL, ALK-; 33% ATL; 46% ENKTL nasal/nasal type; 48% AITL; 80% ALCL, ALK+. **Conclusion:** This is the first experience cover all over the country, focusing also an educational and of interchanging experience network among the multidisciplinary health team in Brazil. The target of 500 was exceeded; however, the registry will go on until December as planned. All cases have been reviewed both in the registry and by pathologist Committee, and we esteem some cases

will be excluded for different reasons and anyway it will help for future analyses if the number of registers is higher.

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MYELOMA

OP 04

UPDATED PROGRESSION-FREE SURVIVAL (PFS) AND DEPTH OF RESPONSE IN IKEMA, A RANDOMIZED PHASE 3 TRIAL OF ISATUXIMAB, CARFILZOMIB AND DEXAMETHASONE (ISA-KD) VS KD IN RELAPSED MULTIPLE MYELOMA (MM)

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Objective: The anti-CD38 antibody Isa in combination with Kd is approved in various countries for patients (pts) with relapsed MM after ≥ 1 prior therapy, based on primary interim analysis (IA) of the Phase 3 IKEMA study (NCT03275285). Here we report updated efficacy and safety Results from IKEMA. **Methodology:** This prespecified final analysis (Isa-Kd 179, Kd 123 pts) evaluated updated PFS (primary endpoint), PFS2, CR rate, MRD- rate,

and MRD- and CR rate in ITT population, and safety with 2 additional years of follow-up. Isa 10mg/kg was given IV qw for 4 wks and then q2w; Kd 20/56mg/m² biw, 3/4 weeks. Hydrashift Isa IF assay was used to rule out potential Isa interference in CR determination. At cutoff (14Jan2022; median follow-up 44 mo), 49 (27.4%) Isa-Kd, 11 (8.9%) Kd pts were still on treatment. **Results:** Updated PFS was consistent with primary IA Results, showing significant benefit of Isa-Kd (vs Kd): PFS HR 0.58; PFS2 HR 0.68. Final CR rate (Isa-Kd vs Kd) was 44.1% vs 28.5%, MRD- rate 33.5% vs 15.4%, MRD- and CR rate 26.3% vs 12.2% (Table). Serious TEAEs were reported in 70.1% Isa-Kd vs 59.8% Kd pts. The most common, any-grade non-hematologic TEAEs in Isa-Kd were infusion reactions (45.8%), diarrhea (39.5%), hypertension (37.9%) and upper respiratory tract infection (37.3%). **Conclusion:** These Results show unprecedented mPFS, CR rate, MRD- and MRD- CR rates in a non-lenalidomide containing regimen with benefit maintained through subsequent therapies and a manageable safety profile. Safety profiles and efficacy Results in both arms were consistent with prior IKEMA findings. Our findings support Isa-Kd as a standard of care treatment for pts with relapsed MM.

	Isa-Kd n=179	Kd	
Median PFS, months	35.7 (28.8-44.0)	19.2 (15.8-25.0)	HR (95.4% CI) 0.58 (0.42-0.79)
Median, PFS2, months	47.2 (38.1-NC)	35.6 (34.0-40.5)	HR (95% CI) 0.68 (0.50-0.94)
	n (%) 95% CI	n (%) 95% CI	odds ratio 95% CI
ORR	155 (86.6) 0.81-0.91	103 (83.7) 0.76-0.90	-
CR	79 (44.1) 0.37-0.52	35 (28.5) 0.21-0.37	2.09 1.26-3.48
MRD-rate	60 (33.5) 0.27-0.41	19 (15.4) 0.10-0.23	2.78 1.55-4.99
MRD and CR rate	47 (26.3) 0.20-0.33	15 (12.2) 0.07-0.19	2.57 1.35-4.88

Table: Efficacy (ITT)

CI confidence Interval, HR hazard ratio, ITT intent to treat, NC not calculable, ORR overall response rate

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STEM CELL TRANSPLANT

OP 05

PEDIATRIC ACUTE MYELOID LEUKEMIA (AML): NOTCH1 ACTIVATION INFLUENCING PROGNOSIS THROUGH TRANSFORMING GROWTH FACTOR-B (TGF-BETA) / SETBP1; REPORT OF A PILOT STUDY FROM SAUDI ARABIA

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