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POSTER ABSTRACTS

627.AGGRESSIVE LYMPHOMAS: CLINICAL AND EPIDEMIOLOGICAL

Efficacy and Safety of Polatuzumab-Vedotin Plus Rituximab, Cyclophosphamide, Doxorubicin and Prednisone (Pola-R-CHP) for Diffuse Large B-Cell Lymphoma in the Real-World Setting: A Single Institute Retrospective Study

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Background In the POLARIX study, Pola-R-CHP showed significant improvement in progression free survival (PFS) in previously untreated diffuse large B-cell lymphoma (DLBCL) compared to R-CHOP. Pola-R-CHP was approved in September 2022 in Japan ahead of the the world. However, there are still few reports about the safety and efficacy of Pola-R-CHP in real-world setting, leaving some questions about the optimal patient population for Pola-R-CHP. So, we conducted this single institute retrospective observational study in clinical practice.

Methods The Pola-R-CHP group included untreated DLBCL patients who received Pola-R-CHP therapy from September 2022 to January 2023 at Kansai Medical University Hospital. The control group included untreated DLBCL patients treated with R-CHOP or R-THP-COP from January 2020 to June 2022 at our hospital. The primary endpoint was the complete remission rate (CRR) at the end of treatment, and secondary endpoints were 6-month PFS, 6-month overall survival (OS) survival, and severity and frequency of adverse events.

Results In the Pola-R-CHP group, 30 patients (median age 74 [range;42-88] years) were enrolled. 8 patients over 80 years old were included. 46.7% (14/30) of the cases were Ann Arbor Stage III-IV, and 73.3% (22/30) of the cases had IPI(International Prognostic Index) of 2 or more points. 60.0% (18/30) of patients were GCB (germinal center B-cell) type and 33.3% (10/30) were non-GCB type, and 36.7% (11/30) of patients were DEL (Double expressor lymphoma).In the control group, 100 patients (median age 75 [range;39-88] years) were enrolled. 23 patients over 80 years old were included. 54% (54/100) of the cases were Stage III-IV, and 74%(74/100) of the cases had IPI of 2 or more points. 44%(44/100) of patients were GCB type and 47% (47/100) were non-GCB type (nine were not classified), and 40% (40/100) of patients were DEL. 65% (65/100) of patients were treated with R-CHOP and 35% (35/100) patients were treated with R-THP-COP. There were no significant differences in the patient backgrounds between the respective groups.In Pola-R-CHP cohort, the median follow-up was 282 days (range, 181-348 days). The median number of Pola-R-CHP cycles performed 6 (range; 2-6), with a 6-cycles completion rate of 86.7% (26/30). In patients over 80 years old, the doses of CHP were reduced to 50%.

In the Pola-R-CHP group at end of treatment (EOT), the overall response rate was 93.3% (n=28), CRR was 86.7% (n=26), partial response was 6.7% (n=2), and progressive disease was 6.7% (n=2)(Fig.1). In the control group, CRR at EOT was 76.0% but the difference between each group was not significant (p=0.321). The PFS at 6 months was 93.3% (95% confidence interval (CI),75.9%-98.3%) in the Pola-R-CHP group and 80.0% (95%CI,70.7%-86.6%) in the control group, with significantly improvement in the Pola-R-CHP group (p=0.017). Notably, in patients with IPI of 4 to 5, CRR was 88.9 % in the Pola-R-CHP group and 51.5% in the control group (p=0.060), and the PFS at 6 months was significantly higher in the Pola-R-CHP group (88.9% [95%CI,43.4%-98.4%] vs. 60.6%[95%CI,42.0%-74.9%]; p=0.034) In the patients with high metabolic tumor volume (MTV) measured based on PET-CT (cut off value; 166 cm^3 in the top quartile of MTV), PFS at 6 months was significantly higher in the Pola-R-CHP group than the control group (100% vs 73.7% [95% CI,47.9%-88.1%]; p=0.045). OS at 6 months was 89% (95%CI,81%-93.8%) in the control group, while all patients in the Pola-R-CHP group were alive.

The most common AE was hematological toxicity: neutropenia, anemia, and thrombocytopenia at grade 3-4 was observed in 43.3%, 16.7%, and 20.0%, respectively (Fig. 2). 14 cases of infection were observed. Peripheral neuropathy was found in 23.3% of the patients, and one of the patients reached grade 3-4. Many cases were complicated with constipation, but only a few cases were grade 3-4. Diarrhea was present in 20%, but all were mild and transient. No deaths due to AE were observed. One patient had to discontinue treatment due to heart failure. Unexpected adverse events were not observed.

Conclusion In this study, Pola-R-CHP showed a treatment response and PFS benefit compared to historical control in patients with previously untreated DLBCL in the real-world setting.The incidence of diarrhea and peripheral neuropathy was lower,

while AE profiles were similar to POLARIX study. Pola-R-CHP is well tolerated and the efficacy can be promising compared to R-CHOP.

Disclosures Ito: *CSL Behring:* Honoraria; *Eisai:* Honoraria; *Nippon Shinyaku:* Honoraria; *AbbVie GK.:* Honoraria; *Takeda Pharmaceutical Company Limited:* Honoraria; *Novartis:* Honoraria; *Mundipharma:* Honoraria; *Kyowa Kirin:* Research Funding; *Chugai Pharmaceutical Co., Ltd.:* Honoraria, Research Funding; *Asahi Kasei Pharma Corporation:* Research Funding; *Bristol-Myers Squibb Company:* Honoraria, Research Funding; *Sanofi:* Honoraria.

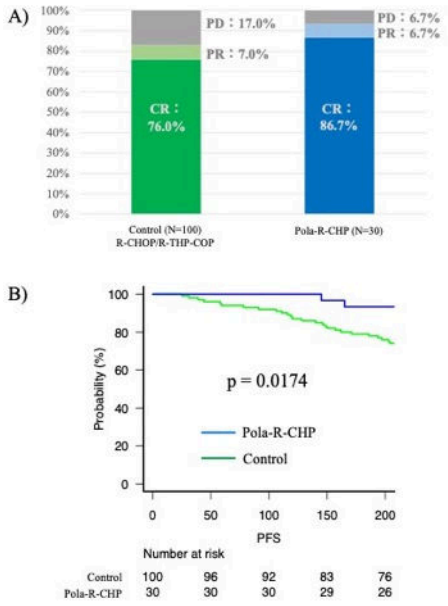

Figure 1 A) Overall response rate of all patients
B) Progression-free survival at 6 months of all patients

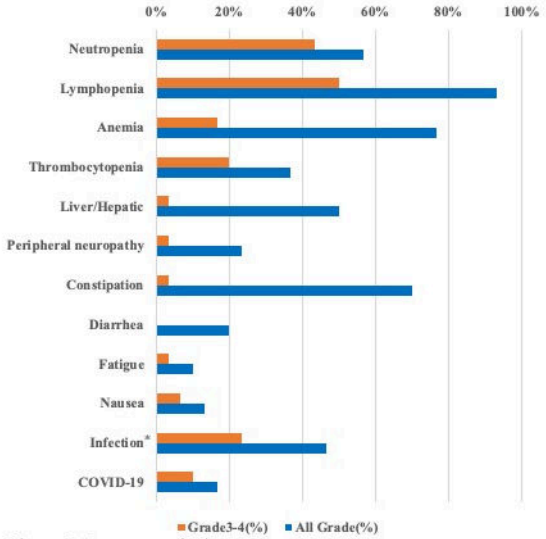

Figure 2 Summary of adverse events.
*: including COVID-19

Figure 1

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