



DLBCL

ASH 2018 | Secondary analysis of the phase III GOYA trial: CHOP6 *versus* CHOP8 for first-line DLBCL

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On Monday 3 December 2018, during the [60th Annual Meeting of the American Society of Hematology \(ASH\)](#), San Diego, CA, [Laurie Sehn](#) from [British Columbia Cancer Agency](#), Vancouver, CA, presented the results of the phase III trial GOYA ([Abstract #783; Oral Session #626](#)).

GOYA ([NCT01287741](#)) was an international, open-label, randomized, phase III trial that compared the efficacy and safety of rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) to obinutuzumab (G) plus CHOP in previously untreated patients diffuse large B-cell lymphoma (DLBCL) patients. In the [primary analysis](#) of the GOYA trial, there was no significant difference in the three-year PFS of patients receiving R-CHOP to those receiving G-CHOP. In this current secondary analysis, the assessed endpoints were investigator-assessed (INV) progression-free survival (PFS), and overall survival (OS) in patients receiving six cycles of CHOP (CHOP6) *versus* eight cycles of CHOP (CHOP8). Secondary endpoint was safety of CHOP6 *versus* CHOP8.

Study design

- N = 1418 previously untreated DLBCL patients, aged ≥ 18 with International Prognostic Index (IPI) ≥ 2 or IPI = 1 due to age alone or IPI = 0 with bulky disease (one lesion ≥ 7.5 cm), Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 , and ≥ 1 bi-dimensionally measurable lesion
- These patients were 1:1 randomized according to planned number of CHOP cycles, IPI, and geographic region to either:
 - G-CHOP (n = 706) or;
 - R-CHOP (n = 712)
- Dosing:
 - G-CHOP: 1000 mg of G on Day 1,8, and 15 of cycle 1 and on Day 1 of cycles 2–8. CHOP for 6 or 8 cycles every 21 days
 - R-CHOP: 375 mg/m² of R on Day 1 on cycles 1–8. CHOP for 6 or 8 cycles every 21 days
 - The number of CHOP cycles (6 or 8) was pre-selected at each site prior to trial opening
 - CHOP6: n = 526 patients
 - CHOP8: n = 186 patients
 - Data cut-off: January 31, 2018
 - Median follow-up: 3.9 years

Results

- Median follow-up: 29 months

- GOYA primary analysis results:
 - INV PFS (R-CHOP [n = 712] vs G-CHOP [n = 706]):
 - One-year PFS: 79.8% vs 6%
 - Two-year PFS: 71.3% vs 4%
 - Three-year PFS: 66.9% vs 6%
 - Comparison: HR = 0.92; 95% CI (0.76–1.11); *P* = 0.3868
- Current exploratory analysis results:
 - INV PFS (CHOP6 [n = 526] vs CHOP8 [n = 186]):
 - Three-year PFS: 68.7% vs 8%
 - Comparison: HR = 0.92; 95% CI (0.69–1.23)
 - INV OS (CHOP6 [n = 526] vs CHOP8 [n = 186]):
 - Three-year OS: 83.2% vs 2%
 - Comparison: HR = 0.65; 95% CI (0.46–0.91)
 - Subgroup analysis according to initial bulky disease, high IPI, ABC subtype, or partial response on interim computerized tomography did not identify any group that benefits (PFS) from 8 *versus* 6 CHOP cycles

Safety

- Total adverse events (AEs) were lower in the CHOP6 (42.7%; n = 461) arm than the CHOP8 (65.3%; n = 144)
- Grade 3–5 AEs were lower in the CHOP6 (17.8%; n = 461) arm than the CHOP8 (38.9%; n = 144)
- Serious AEs were lower in the CHOP6 (12.2%; n = 461) arm than the CHOP8 (20.1%; n = 144)

Conclusions

- No additional clinical benefit was observed with 8 versus 6 cycles of CHOP in combination with rituximab
- Subgroup analysis did not identify any clinical or biological subgroup that benefited from 8 CHOP cycles
- Grade 3–5 AEs and all grade infections were markedly higher in patients receiving 8 CHOP cycles, compared to those receiving 6 CHOP cycles
- According to the investigators, six cycles of CHOP (3-weekly) in combination with rituximab should be considered standard of care for patients with advanced-stage DLBCL

References

1. [Laurie S. et al.](#) No Added Benefit of Eight Versus Six Cycles of CHOP When Combined with Rituximab in Previously Untreated Diffuse Large B-Cell Lymphoma Patients: Results from the International Phase III GOYA Study. [Oral Abstract #783: ASH 60th Annual Meeting and Exposition](#), December 2018, San Diego, CA.

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