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1639 Rituximab, Bendamustine, Mitoxantrone, Dexamethasone (R-BMD) in Patients with Follicular Lymphoma in Relapse or Refractory to First-Line Treatment with Immunochemotherapy. R-BMD Geltamo 08 Trial

Program: Oral and Poster Abstracts
Session: 624. Lymphoma - Therapy with Biologic Agents, excluding Pre-Clinical Models: Poster I

Saturday, December 8, 2012, 5:30 PM-7:30 PM
Hall B1-B2, Level 1, Building B (Georgia World Congress Center)

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Objectives

To evaluate the efficacy and safety of rituximab-bendamustine-mitoxantrone-dexamethasone (R-BMD) in patients with relapsed or refractory follicular lymphoma, (R/R FL) to first-line therapy with R-chemotherapy (R-ChemoT), followed by maintenance with R.

Methods

Phase II trial including 61 patients with R/R LF, after a 1st R-ChemoT line. Induction treatment: Rituximab 375 mg/m^2 iv, day 1; bendamustine 90 mg/m^2 iv, days 1 and 2; mitoxantrone 6 mg/m^2/day iv, day 1; oral dexamethasone 20 mg / day, days 1 to 5. Cycles of 28 days. Evaluation of response after 3rd cycle. If stable disease or progression: withdrawal from the study. If complete response (CR) or complete response unconfirmed (CRu): administration of a 4th cycle. If partial response (PR): administration up to 6 cycles. If CR, CRu or PR at the end of induction: patients receive maintenance with R 375 mg/m^2/day every 12 weeks for 2 years. Primary objective: Complete responses (CR + CRu). Results are presented as valid % and median [range].

Results

Results from 46 patients who completed induction period. 52.2% women, age 63 [32-76] years. Ann Arbor stage III / IV 75.6% (31/41) and III / IV-B 22.6% (7/31). FLIPI: intermediate risk 28.9% (11/38); high-risk 23.7% (9/38). Number of administered cycles: 4 [1-6]. Overall response 93.5% (43/46); CR: see Table 1. Progression Free Survival –median (CI95%)-: 14.5 (11.6-NA) months. The most relevant grade 3/4 toxicity: neutropenia 52% (n = 24; 17 patients received G-CSF) and thrombocytopenia 4.3% (n = 2). Infections grade 3/4: 6.5% (n = 3). One patient died due to CMV reactivation. No skin reactions were reported. There are maintenance available data from 15 patients: 3 patients sustained CR at the end of this period, and 2 patients progressed.

Conclusions

R-BMD is a treatment schedule effective and a safe alternative for patients with R/R FL, after a 1st line with R-ChemoT. No skin reactions were reported, possibly due to the inclusion of dexamethasone in the treatment scheme. Additional follow up is required to achieve more conclusive findings.

Table 1

Response after R-BMD induction in patients with R/R FL after 1st line with R-ChemoT

	Response after 3rd cycle			*Better response after induction*	
	N (%)	*CI 95%*		*N (%)*	*CI 95%*
CR/CRu	27 (60,0)	[44,3 -74,3]	CR/CRnc	33 (73,3)	[58,1 - 85,4]
PR	15 (33,3)	[20,0 - 49,0]	PR	10 (22,2)	[11,2 - 37,1]
SD	2 (4,4)	[0,5 - 15,2]	SD	2 (4,4)	[0,5 - 15,2]
Unknown*	1 (2,2)	[0,1 - 11,8]			
Total^	45 (100)		Total^	45 (100)	

* *Patients without evaluation after the 3rd cycle. He received an additional cycle and was evaluated after end of induction.*
^ One non evaluable patient

Disclosures: No relevant conflicts of interest to declare.

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