

**3762 A Good Adherence to ELN 09 Recommendations in Chronic Myeloid Leukemia (CML) Treatment with Imatinib, Is Associated with Better Outcomes in Patients Treated Outside Clinical Trials** 

**Program:** Oral and Poster Abstracts

**Session:** 632. Chronic Myeloid Leukemia - Therapy: Poster III

Monday, December 10, 2012, 6:00 PM-8:00 PM

Hall B1-B2, Level 1, Building B (Georgia World Congress Center)

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**Introduction:** In late 2009 it was published the second version of the international recommendations for CML monitoring and treatment with Imatinib and other tyrosine kinase inhibitors(TKI) (Bacarrani M et al JCO 2009). Although widely distributed and discussed, there has not been any report describing the adherence of hematologists to those guidelines, or analyzing the differential outcomes in the setting outside clinical trials

**Objectives:** To study the association between the compliance to ELN 09 recommendations in every timepoint, and the response to TKI treatment

**Methods and patients:** CML patients in first chronic phase, treated upfront with imatinib, outside clinical trials. The adherence to ELN 09 in the given timepoint was classified, as orthodox if, monitoring and treatment were done accordingly, and heterodox, if monitoring or treatment were done disaccordingly. Study variables: Best complete cytogenetic response (CCyR) and major molecular response (MMR) with Imatinib and second line TKI, and progression rates. Besides, we analyzed the association between response grades considering the value obtained in the precedent timepoint.

**Results:** 374 patients (229 men, 145 women) were included. The Sokal risk distribution was: low (L): 138(39%), intermediate (I): 172 (48%) , and high (H): 44(12%). Correspondent values for Euro score were 170(48%), 165(47%) y 19(5%). EUTOS score: L: 294(91%), H: 30(9%). Median age: 52 years (15-88). Median follow-up 59.3 months (0,6-131,9). A summary of the results is shown in Table 1. Most of the patients were evaluated on time (73-90%), and 2/3 of the patients were monitored and managed in an orthodox way in the specific timepoints. The rate of CCyR and MMR were significantly higher in patients managed in an orthodox way. In contrast, progression rates were significantly higher only in those patients whose management was heterodox at 3 months. Besides, a better response at any given timepoint was associated with better ulterior responses.

**Conclusions:** Our results reinforce the use of ELN 09 recommendations, showing that those patients whose monitoring and treatment is done according to these recommendations have a higher probability of response. An orthodox management in the first trimester of treatment is specially important, because it is associated with a lower progression rate.

Timepoint	3 m	Response at 6 m			Best CCyR with Imatinib	Best CCyR with TKI's	Best MMR with Imatinib	Best MMR with TKI's	Progression to AP or BC
		Optimal	suboptimal	failure					
N at 3 months	374	Evaluated 281(75,1%)			Evaluable by ELN 09 35(62,8%)				
Orthodox Management	193(61%)	118/124 (95%)	3/124 (2,4%)	3/124(2,4%)	171/190 (90%)	176/191 (89,5%)	159/181(83,2%)	167/190 (87,9%)	3/193 (1,6%)
Heterodox Management	125(39%)	56/85 (79%)	6/85 (7%)	25/85(29,4%)	92/115 (80%)	99/117 (84,6%)	90/117 (76,9%)	100/120 (83,3%)	8/125 (6,4%)
		P<0,0001			P=0,014	P=0,038	P=0,116	P=0,3	P=0,02

								73	1
Timepoint	6 m	Response at 12 m			Best CCyR with Imatinib	Best CCyR with TKI's	Best MMR with Imatinib	Best MMR with TKI's	Progression to AP or BC
N at 6 m	352 (94% initial) Evaluated 270 (76,7%) Evaluable by ELN 09 244 (69,3%)								
Orthodox M.	249(71%)	162/184(88%)	16/184(8,7%)	6/184(3%)	217/245(88,6%)	227/246(92,3%)	203/244(83,2%)	216/246(87,8%)	9/249(3,6%)
Heterodox M.	103(29%)	56/71(78,8%)	11/71(15,5%)	4/71(5,6%)	82/102(74,7%)	87/102(85,2%)	77/102(75%)	82/103(79,6%)	2/103(1,9%)
		P=0,132			P=0,044	P=0,046	P=0,096	P=0,096	P=0,412
Timepoint	12 m	Response at 18 m			Best CCyR with Imatinib	Best CCyR with TKI's	Best MMR with Imatinib	Best MMR with TKI's	Progression to AP or BC
N at 12 m	334 (90% initial) Evaluated 302(90%) Evaluable by ELN 09 257 (77%)								
Orthodox M.	207/289(72%)	115/164(70%)	39/164(24%)	10/164(6%)	188/207(90,8%)	195/207(94,2%)	190/206(92%)	195/207(94%)	3/207(1,5%)
Heterodox M.	82/289(28%)	24/42(57%)	9/42(21%)	9/42(21%)	68/81(84%)	75/81(92,7%)	57/79(72%)	63/80(79%)	3/103(2,9%)
		P=0,009			P=0,095	P=0,221	P<0,0001	P<0,0001	P=0,235
Timepoint	18 m				Best CCyR with Imatinib	Best CCyR with TKI's	Best MMR with Imatinib	Best MMR with TKI's	Progression to AP or BC
N at 18 m	290 (77% initial) Evaluated 244 (84%) Evaluable by ELN 09 232 (80%)								
Orthodox M.	205/277(74%)				199/205(97%)	200/205(97,5%)	190/205(92,7%)	192/205(93,6%)	4/205(3,6%)
Heterodox M.	72/277(26%)				55/72(76,4%)	63/72(73,7%)	55/71(77,4%)	61/72(84,7%)	2/72(1,9%)

						%)	
			P=0,001	P=0,001	P<0,0001	P=0,02	P=0,679

Disclosures: Casado: *Novartis*: Consultancy, Speakers Bureau; *BMS*: Consultancy, Speakers Bureau; *Pfizer*: Consultancy, Speakers Bureau. Martínez-López: *Celgene*: Honoraria. Steegmann: *Novartis*: Consultancy, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *BMS*: Consultancy, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *Pfizer*: Consultancy, Speakers Bureau.

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