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Title: FLAG REGIMEN, COMBINED WITH GEMTUZUMAB (FLAG-GO) RESULTS IN BETTER OPTIMAL MOLECULAR RESPONSE AND OUTCOMES, COMPARED TO COMBINATION WITH IDARUBICIN (FLAG-IDA) IN UNTREATED CORE BINDING FACTOR AML

Abstract Type: Poster Presentation

Topic: Acute myeloid leukemia - Clinical

Background:

Optimal molecular response (OMR), defined as reduction of quantitative polymerase chain reaction (QPCR) value for the relevant transcript of the disease defining translocation (RUNX1-RUNX1T1/CBFB-MYH11) at end of induction to ≤ 0.1 and at end of consolidation ≤ 0.01 , is the most relevant parameter impacting outcome in patients with CBF AML (1). The addition of gemtuzumab ozogamicin (GO) to a fludarabine, GCSF, cytarabine (FLAG) based regimen (FLAG-GO) in induction has resulted in improved molecular responses and clinical outcomes (1,2).

Aims:

We prospectively monitored OMR and survival outcomes in a cohort of newly diagnosed CBF-AML patients treated in a phase 2 trial of FLAG-GO

Methods:

Since 2007 we have treated our patients with CBF AML prospectively in a trial that included FLAG-GO induction, however during the period when GO was withdrawn from the US market, GO was replaced with idarubicin (i.e. FLAG-IDA) (NCT00801489). We present our most up to date analysis of the prospectively collected data that includes molecular monitoring.

Results:

One hundred seventy nine (179) patients with de novo CBF AML have been treated, with 85 patients receiving FLAG-GO induction and 94 receiving FLAG-IDA. There were 3 deaths in induction. Median age was (47 years, range: 19-79 years) and 47% (N=84) were female. Overall survival for the FLAG-GO cohort at 6 years was 80% while the same for FLAG-IDA group was 70% ($p=0.07$)(Fig.1A). Relapse free survival at 6 years was 76% for FLAG-GO and 58% for FLAG-IDA ($p=0.02$)(Fig.1B). OMR at end of induction and end of all consolidation was achieved by 61% and 83% of patients in the FLAG-GO cohort while the same for FLAG-IDA cohort was 41% and 56% respectively (Table 1).

***Can you state something about FLT3 and KIT mutations?

22 patients with therapy related CBF AML were treated (7 with FLAG-GO and 15 with FLAG-IDA) within this protocol. OMR at end of induction and end of all consolidation was achieved by 71% and 85% (5/7 and 6/7 respectively) in the FLAG-GO cohort while only 33% (5/15) and 40% (6/15) respectively with the FLAG-IDA cohort. Because of small numbers adequate statistical analysis could not be done.

Summary/Conclusion:

FLAG-GO based induction/consolidation results in higher OMR and improved outcome in patients with de novo CBF AML .

Keywords: RUNX1, Cytarabine, AML