

# Optimal dose horse antithymocyte globulin for the treatment of adult patients with aplastic anemia: a prospective randomized comparative study

Zalina Fidarova, Elena Mikhailova, Hunan Julhakyany, Vera Troitskaya, Anastasia Abramova, Anton Luchkin, Elena Parovichnikova, Valeriy Savchenko

It is generally known that horse antithymocytic globulin (ATGAM) are more effective for treatment of pts with acquired AA than rabbit ATG. There is no doubt, that dose regime 160 mg/kg ATGAM Improves response for young pts after 1<sup>st</sup> course. Optimal ATGAM dose is important unsettled issue to achieve as soon as possible remission in adult pts and reduce time to allo-BMT in refractory cases

## Aim

**Aim** of this study is to evaluate effectiveness and response rate on ATGAM\*20 and ATGAM\*40 dose in adult pts with aplastic anemia

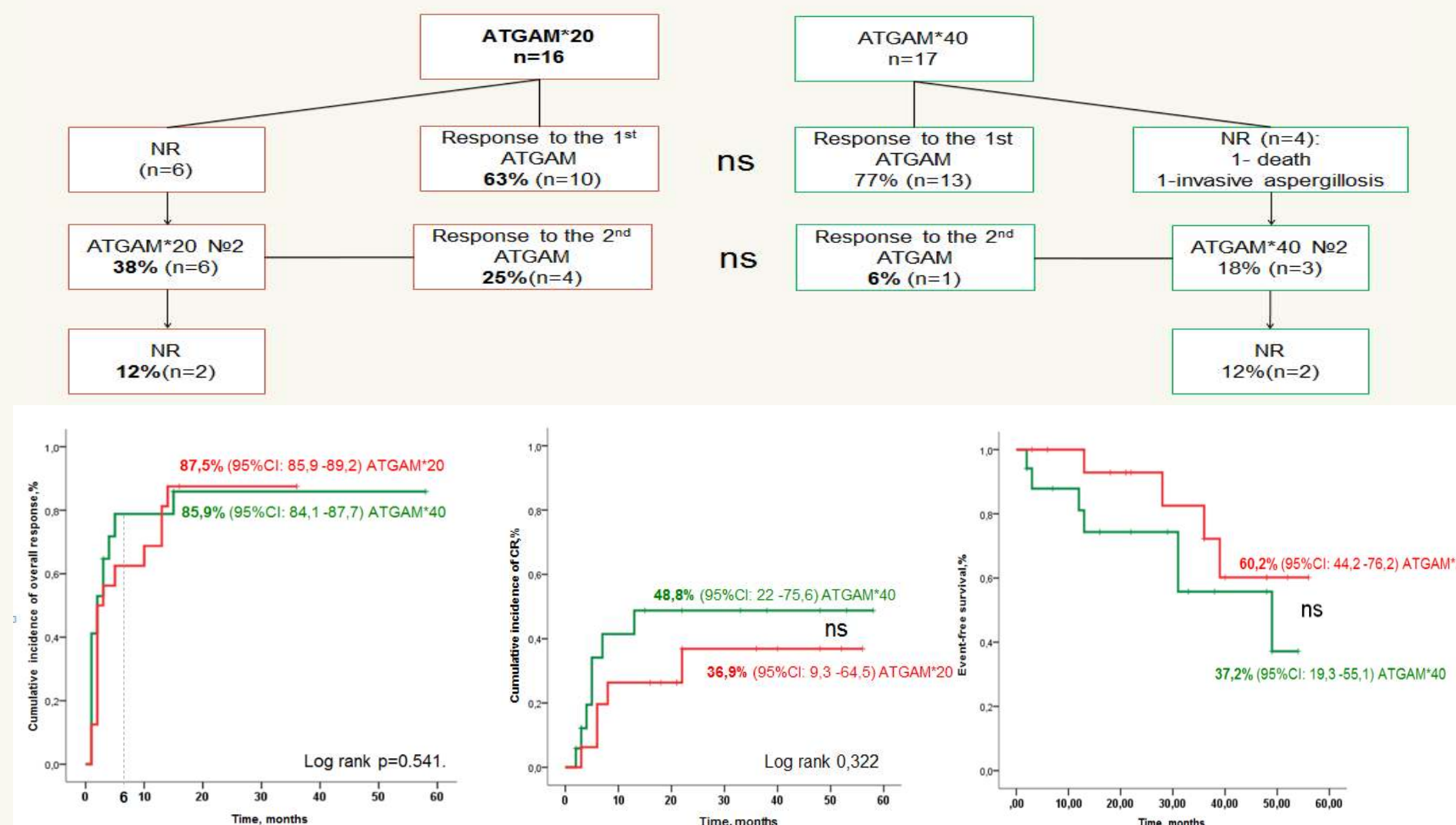
## Design

Thirty-three patients with acquired AA (NSAA/SAA) required in combined IST with ATGAM and cyclosporin A were included into the prospective study since 2013 year

## Material and methods

We are presenting a single-center experience. The median of observation time was 30 (3-58) months. All pts were randomized before IST into 2 groups: ATGAM\*20 (ATGAM 20 mg/kg/day 1-5 days, n=16) and ATGAM\*40 (ATGAM 40 mg/kg/day 1-4 days, n=17). There were no significant differences between two groups in such parameters as: median age (26vs25 years); gender (M/W: 9/7 vs 10/7); severity (NSAA/SAA: 10/6 vs 10/7); median of Grans (0,62vs0,58x10<sup>9</sup>/l) and Ret (30,1 vs 13,04x10<sup>9</sup>/l); presence of PNH-clone (11vs15 pts); median time to the start of IST after diagnosis were 3 months in both groups

## Overall response



## Results

The frequency of reaction to drug administration, serum sickness and infections complications were comparable in both groups. Cumulative rate of overall response was higher in ATGAM\*20 group (87,5% (95%CI: 85,9 -89,2)) vs ATGAM\*40 group (85,9% (95%CI: 84,1 -87,7)). The second course of ATGAM\*20 were effective in 4 of 6 pts who did not achieve response after 1<sup>st</sup> course, however, the second course of ATGAM\*160 were not effective in 2 of 3 pts. Complete response rate after IST of ATGAM\*40 was 48,8% (95%CI: 22 -75,6), but in group ATGAM\*20 it was 36,9% (95%CI: 9,3 -64,5) (p>0,05) even after 2nd course. It is important to note, that median time to achieve response was less in ATGAM\*40 (2,7vs6,2 months respectively)

## Conclusion

In conclusion we propose that Low-dose of ATGAM for treatment of adult AA patients were effective but not sufficient to reduce timing before allo-BMT.

	ATGAM*20	ATGAM*40	p
Pts, n	16	17	
Age, median, years	26(20-34)	25(19-35)	0,423
M\F, n	9/7	10/7	0,699
Severity of AA			
SAA/NSAA, n	6/10	7/10	0,445
Hemogram			
ANC, x10 <sup>9</sup> /l, median (min-max)	0,68 (0,01-2,26)	0,51 (0,09-1,34)	0,423
ARC, x10 <sup>9</sup> /l, median (min-max)	30,9 (5,2-72,5)	17,04 (1,87-35,2)	0,182
SF, ngr/ml, median (min-max)	663 (15,9-1549)	627 (78-1988)	0,181
PNH-clone, n	11/16 (69%)	15/17(88%)	0,56
LDH, E/l	407 (213-711)	344,8 (321-481)	0,773
Interval diagnosis - IST, months, median (min-max)	3 (1-45)	3 (1-15)	0,58
Observation time, months, median (min-max)	29 (5-45)	33 (3-58)	0,789