

## **“Real World Evidence”**

### **Nuovi target terapeutici in ematologia**

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Auditorium “Fra Agostino Daniele”

San Giovanni Rotondo

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U.O.: Ematologia con Trapianto

Azienda Ospedaliero-Universitaria

Policlinico di Bari

Azacitidina e LMA:

Esperienza REAL WORLD della REP



Contents lists available at [ScienceDirect](#)

## Leukemia Research

journal homepage: [www.elsevier.com/locate/leukres](http://www.elsevier.com/locate/leukres)



Leukemia article

### Azacitidine in the treatment of older patients affected by acute myeloid leukemia: A report by the Rete Ematologica Pugliese (REP)

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## Caratteristiche dei pazienti

	N-90	(%)
Sex: M/F	48/42	53/47
Median age (range (r))	75 (65-89)	
ECOG Performance status $\geq 2$	43	48
FAB diagnosis		
LAM0/1/2/4/5/6	12/42/17/6/9/4	13/47/19/7/10/4
Hemoglobin g/dL (r)	8.4 (5.4-9.3)	
White blood cells $\times 10^9/uL$ (r)	2.6 (0.6-72.4)	
Platelets $\times 10^9/uL$ (r)	61 (3-585)	
% Bone marrow blast cells, (r)	35 (20-90)	
% Peripheral blood blast cells, (r)	10 (0-80)	
Cytogenetic risk group <sup>a</sup>		
Favorable	0	0
t(8,21)	0	0
inv 16 or t(16,16)	0	0
t(15,17)	0	0
Intermediate	40	44
+8	7	7
+11	6	7
Normal Karyotype	27	30
Adverse	35	39
-7,add(7q)/del(7q)	6	7
-5, add(5q),del(5q)	5	6
inv3 or t(3,3)	3	3
Complex	13	14
Monosomal karyotype	8	9
Not performed	15	17

### unfitness

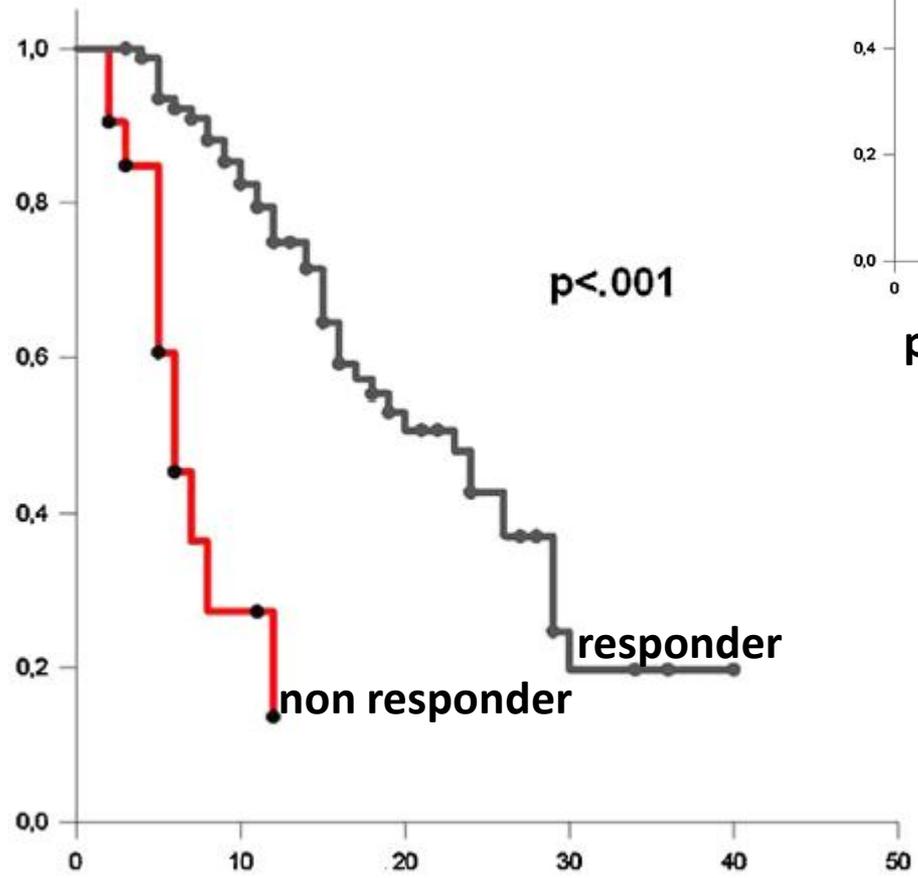
	N	(%)
Advanced age >75 yy	45	50
ECOG PS $\geq 3$ not related to leukemia	11	12
High-risk cytogenetics	35	39
Cardiac comorbidity	18	20
<45% FEV	12	13
congestive heart failure	1	1
ischemic cardiomyopathy	5	6
Hepatic comorbidity HBV/HCV related	6	7
On dialysis	3	3
Pulmonary disease requiring oxygen	7	8
Other neoplasia	6	7

**Almeno 4 cicli di trattamento, anche se nessun tipo di risposta ai primi 2**  
**Rivalutazione dopo 4 cicli**

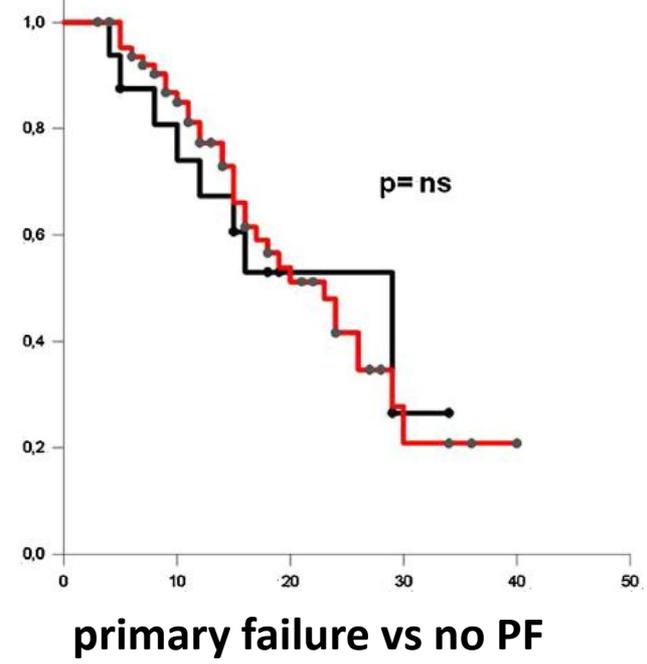
	N	(%)
Best overall response	41	46
CR	16	18
CR with incomplete blood count recovery	3	3
PR	22	25
Hematological improvement <sup>b</sup>	15	17
Transfusion independence	13	14
Median N of AZA treatment	9 (2–36)	
Time to best response, months, m (r) <sup>a</sup>	4 (1–13)	
Duration of response, m (r) <sup>a</sup>	6 (0–28)	
Time to progression, m (r) <sup>a</sup>	5 (1–7)	
Primary failure		
Yes/no	19/71	21/79

**Almeno 4 cicli di trattamento, anche se nessun tipo di risposta ai primi 2; Rivalutazione dopo 4 cicli**

OS mediana intero gruppo: 12mesi



OS mediana: 23 vs 6 mesi



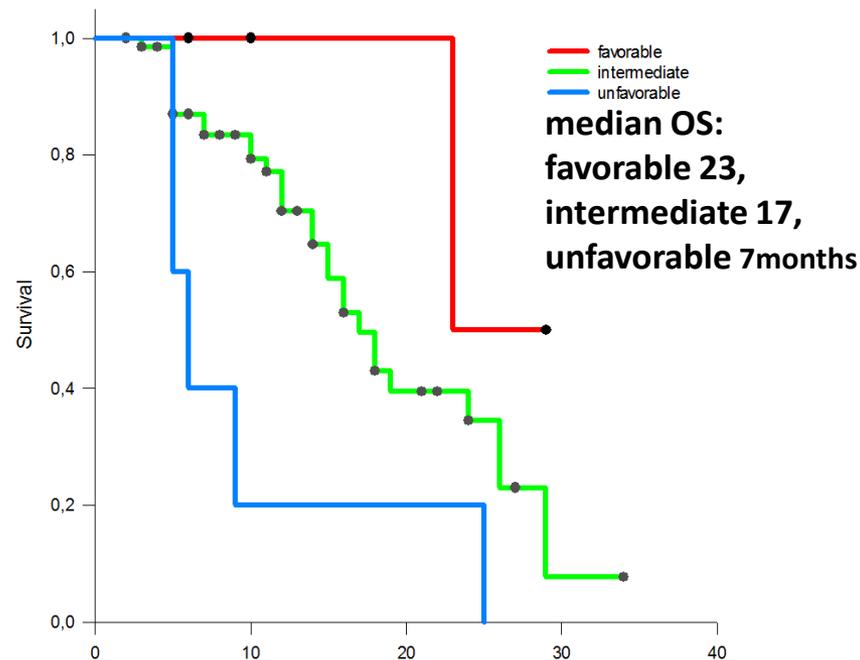
## Variabili con impatto in multivariata

	Risposta	OS
Cariotipo	si	no
BM blasts	no	no
PS ECOG>2	si	si
Esordio >10000/gb	no	no

**ALMA score:**

**PS, GB esordio, citogenetica si conferma valido!**

OS - European ALMA score



**Grazie per  
l'attenzione**