Rete Ematologica Pugliese

Real World Evidence
Nuovi target terapeutici in ematologia

San Giovanni Rotondo
8 - 9 Novembre 2018

DECITABINA E LAM : ESPERIENZA REAL WORLD DELLA REP

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DECITABINE AS SINGLE AGENT FOR TREATMENT OF NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) IN ELDERLY PATIENTS: A RETROSPECTIVE, MULTICENTER REAL LIFE STUDY OF THE "RETE EMATOLOGICA PUGLIESE" (REP)

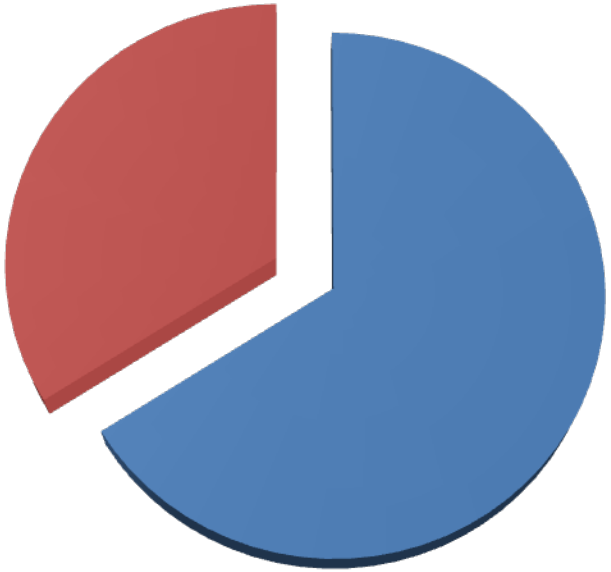
Since Settember 2013 to January 2018

- **135 pts in seven hematological departments of the "REP".**
- **≥ 60 ys**
- **Diagnosis of de novo or secondary/therapy-related AML**
- **Patients previously treated with HMA were not included**
- **Decitabine in a schedule of 20 mg/m2 for five days every 4 weeks**

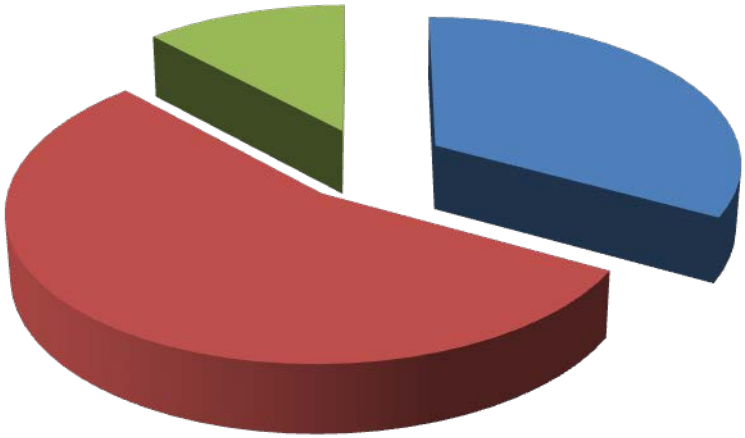
Baseline charateristics of the patients (N = 135)

Characteristics	N (%)
Age (median, range)	76 (63-89)
Male/Female, n (%)	84 (62)/51 (38)
AML De novo	62(46%)
Secondary/therapy-related	73(54%) 35 %
BM blast %, median (range)	52 (20-90)
Hemoglobin (g/dL) , med. (range)	7.4 (5.3-12.0)
WBC (mL) , median (range)	12.8 (0.8-248)
Platelet (mL), median (range)	47.000 (2.000-380.000)
Baseline ECOG PS 0-1	(90) 66 %
2	(45) 34 % 23 %

Cytogenetic Analysis (n=90)



done 66% not done 34 %

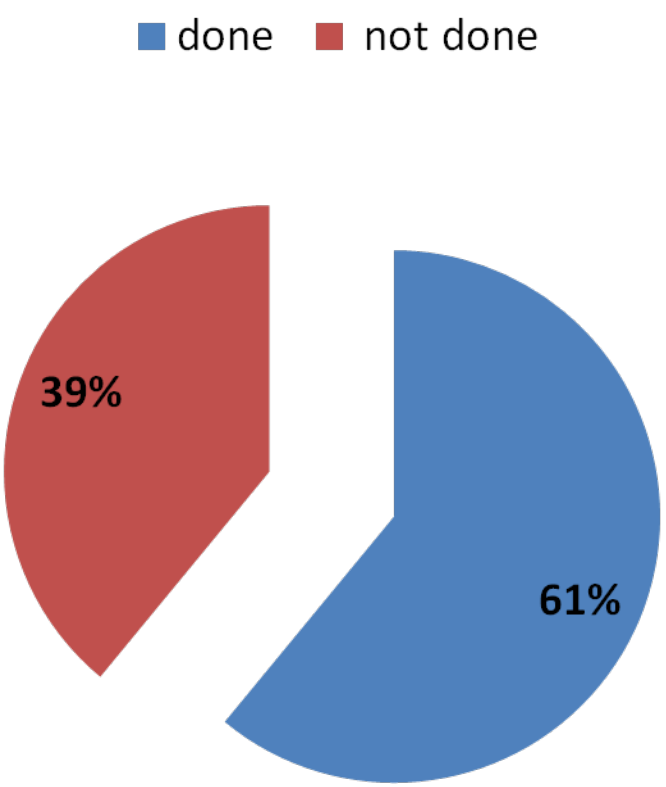


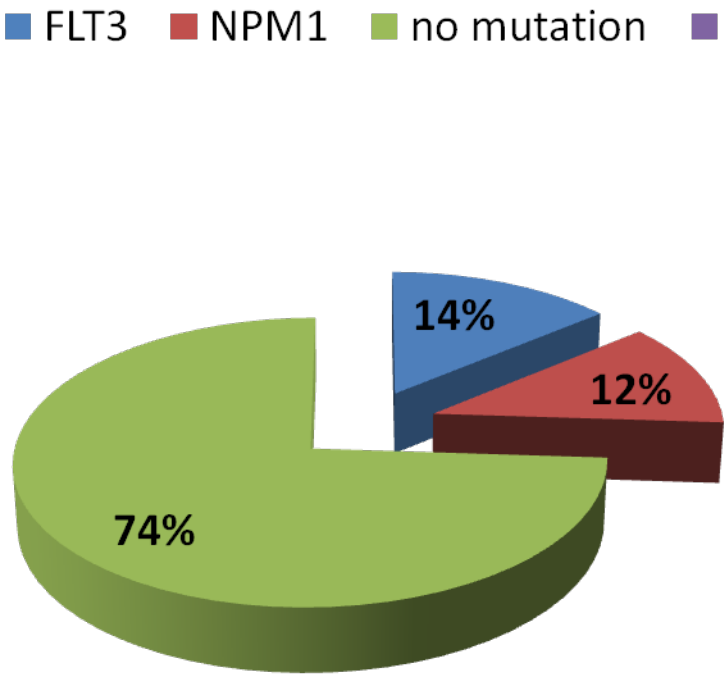
high 33%

intermediate 55%

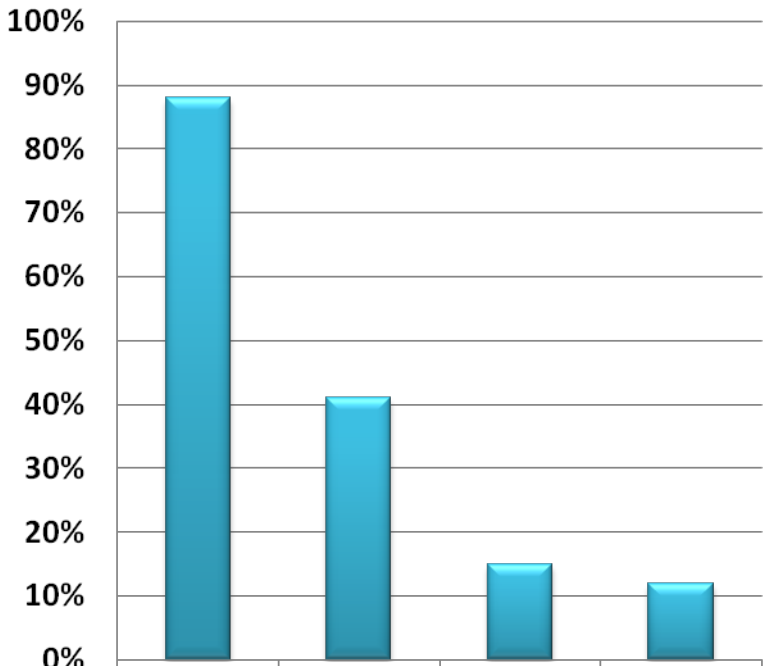
favorable 12%

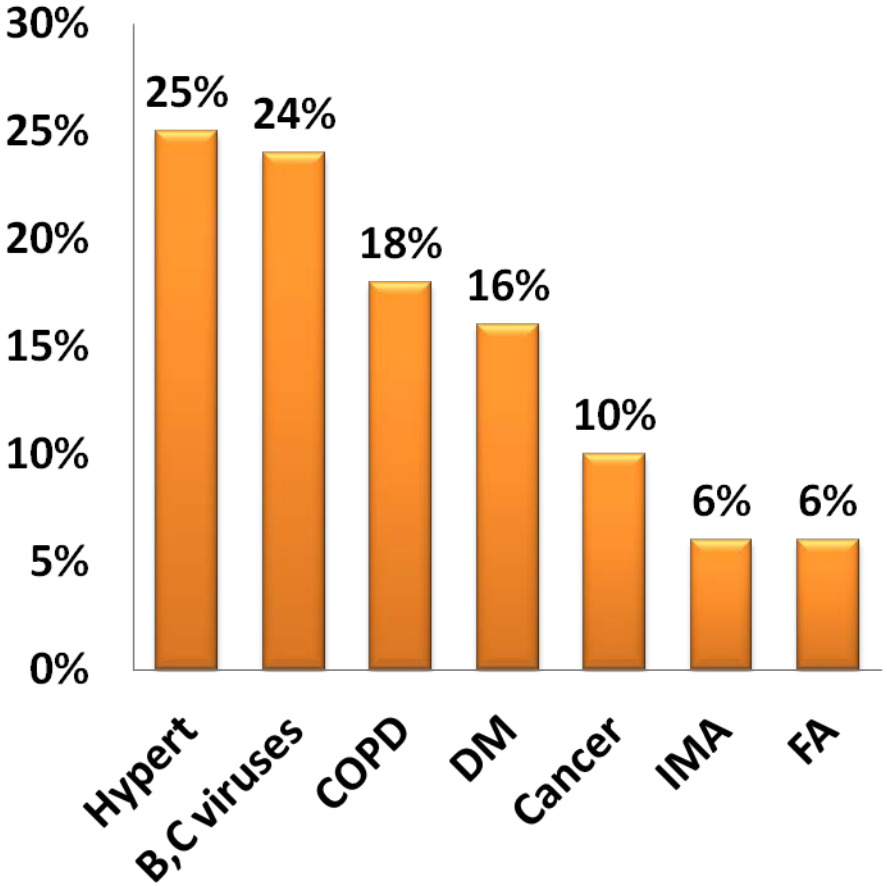
Molecular biology (n=83)





Comorbidity (n=120)

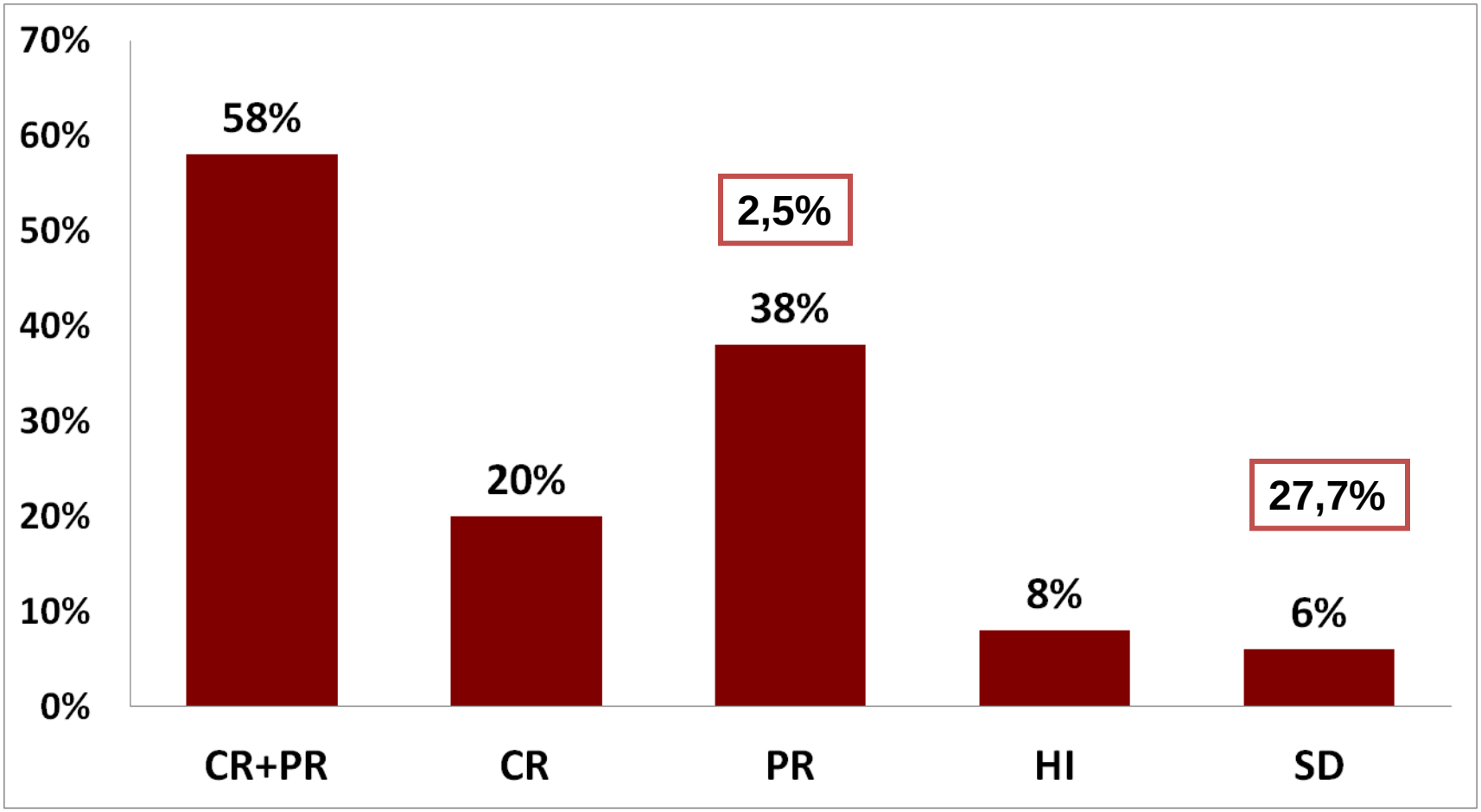




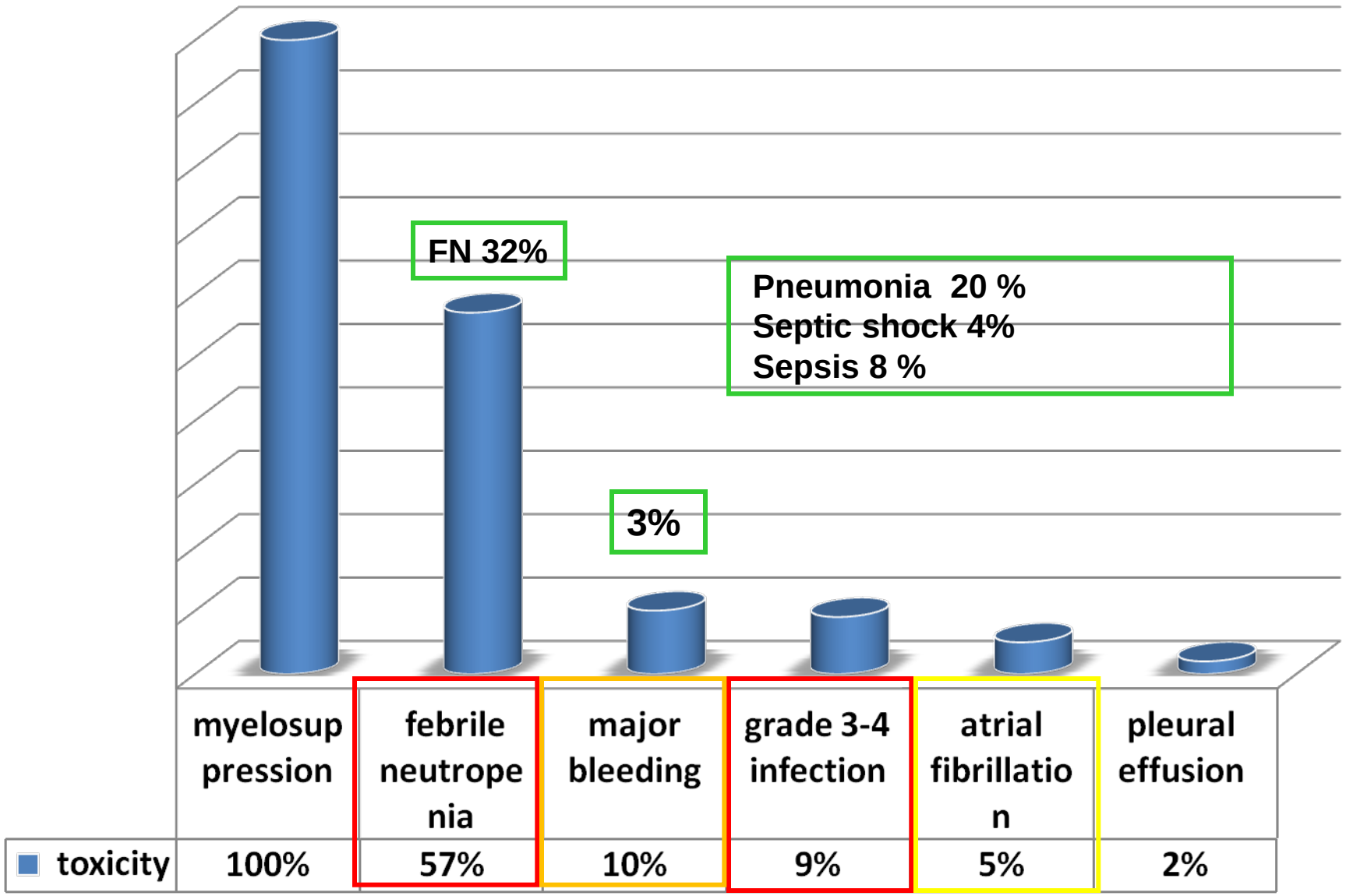
RESULTS

- The median number of cycles delivered was 4 (range, 1-23).
- Seventy-five (55%) patients that received a minimum of four cycles were evaluated for response.
- Response was evaluated in according to AML response criteria.
- One hundred and two (75%) patients were admitted to the hospital to start treatment or for treatment related toxicity.
- The median duration of hospitalization was 15 days (range, 5-92 days)

Results

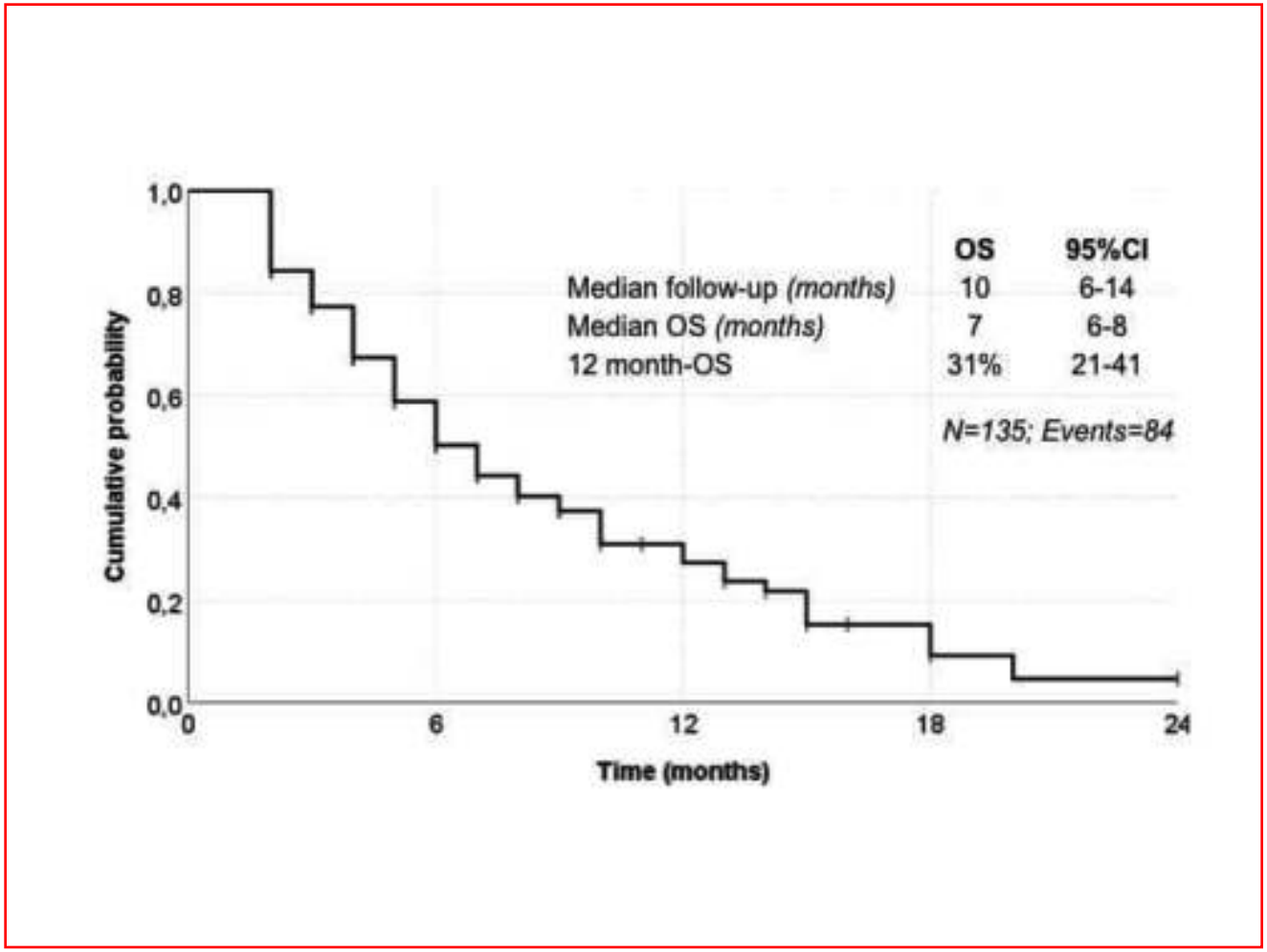


Toxicity



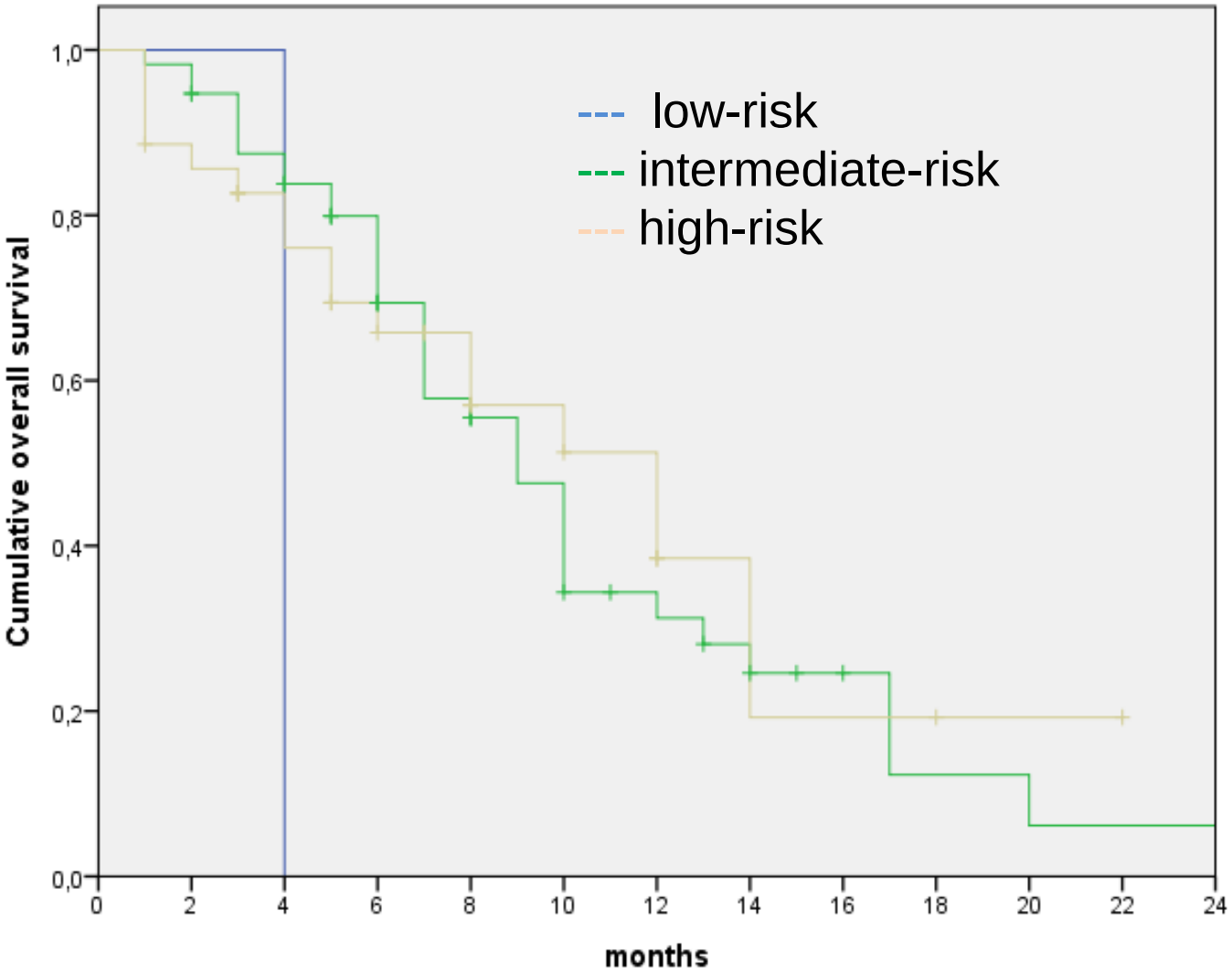
	myelosuppression	febrile neutropenia	major bleeding	grade 3-4 infection	atrial fibrillation	pleural effusion
toxicity	100%	57%	10%	9%	5%	2%

Results



- **After a median follow-up of 10 months (95% CI, 6-14 months) the median overall survival in the intent to treat population was 7.0 months (95% CI, 6-8 months) from the start of decitabine treatment .**
- **At 12-months 31% (95% CI, 21-41%) of patients included in the analysis are alive.**

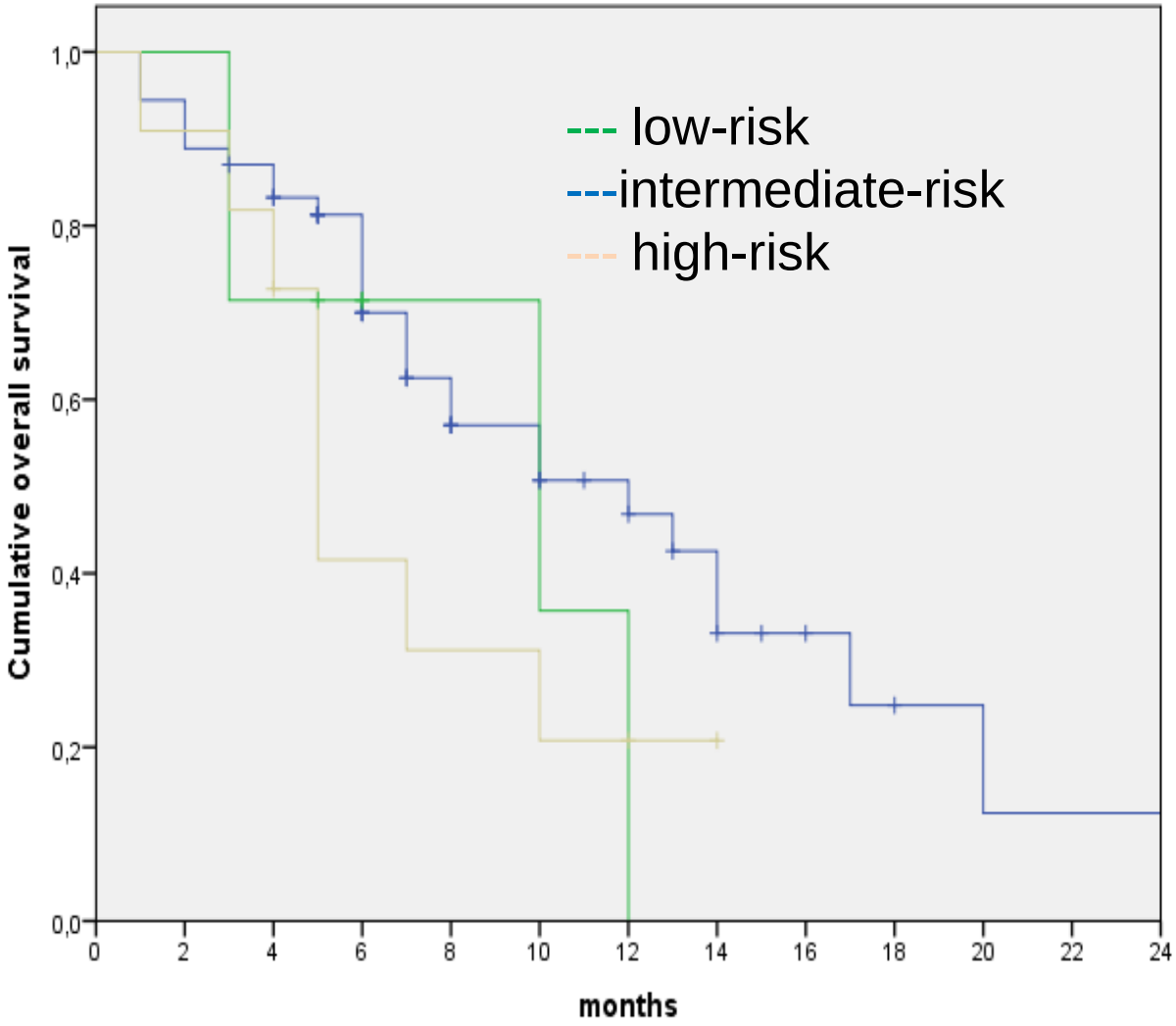
Overall Survival according cytogenetic risk categories



P = 0.212

Low-risk: not evaluable (only 1 pts in this subset)
Intermediate-risk: median survival 9 months (95%CI 7.6 – 10.3)
High-risk: median survival 12 months (95%CI 7.4 – 16.5)

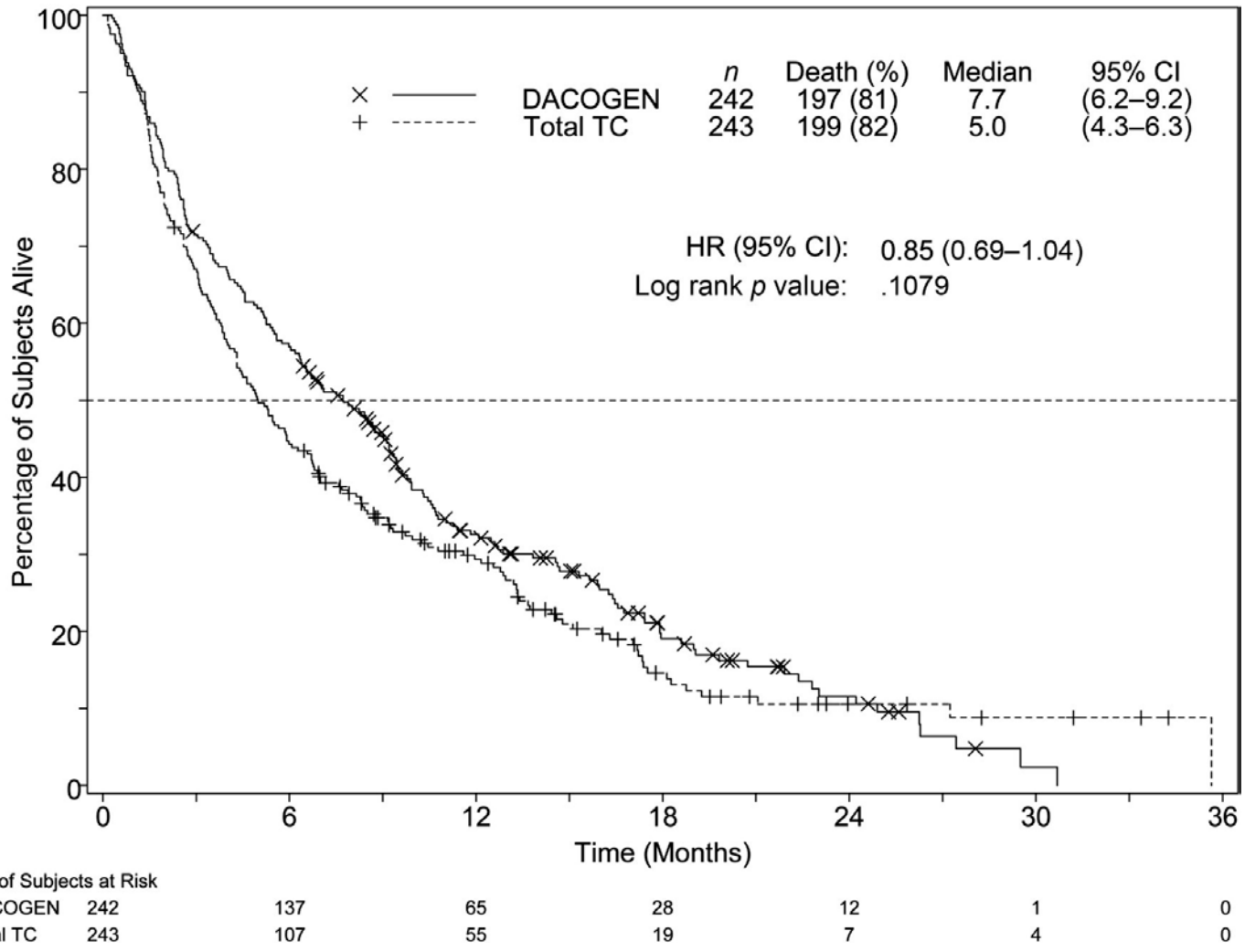
Overall Survival according molecular risk categories



P* = *0.205

Low-risk: median survival 12 months (95%CI 6.4 – 17.5)
Intermediate-risk: median survival 10 months (95%CI 2.0 – 20.2)
High-risk: median survival 5 months (95%CI 4.0 – 5.9)

Overall survival data (DACO-016 study: intent-to-treat population; clinical cutoff date, 2009).



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Multicenter, Randomized, Open-Label, Phase III Trial of Decitabine Versus Patient Choice, With Physician Advice, of Either Supportive Care or Low-Dose Cytarabine for the Treatment of Older Patients With Newly Diagnosed Acute Myeloid Leukemia

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Purpose

This multicenter, randomized, open-label, phase III trial compared the efficacy and safety of decitabine with treatment choice (TC) in older patients with newly diagnosed acute myeloid leukemia (AML) and poor- or intermediate-risk cytogenetics.

Patients and methods

Exclusion criteria included acute promyelocytic leukemia, t(8;21) or inv(16) karyotype abnormalities, CNSleukemia, active systemic malignancies, unstable angina or New York Heart Association class 3/4 congestive heart failure, inaspirable bone marrow, **comorbidities** or organ dysfunction, uncontrolled active infection, or HIV.

CONCLUSIONS

Even in the real life setting, the reported ORR and OS rate of decitabine given as single agent for the treatment of elderly patients with AML ineligible for conventional chemotherapy it should be emphasized that results were obtained in a population of patients with different comorbidities.

Thanks