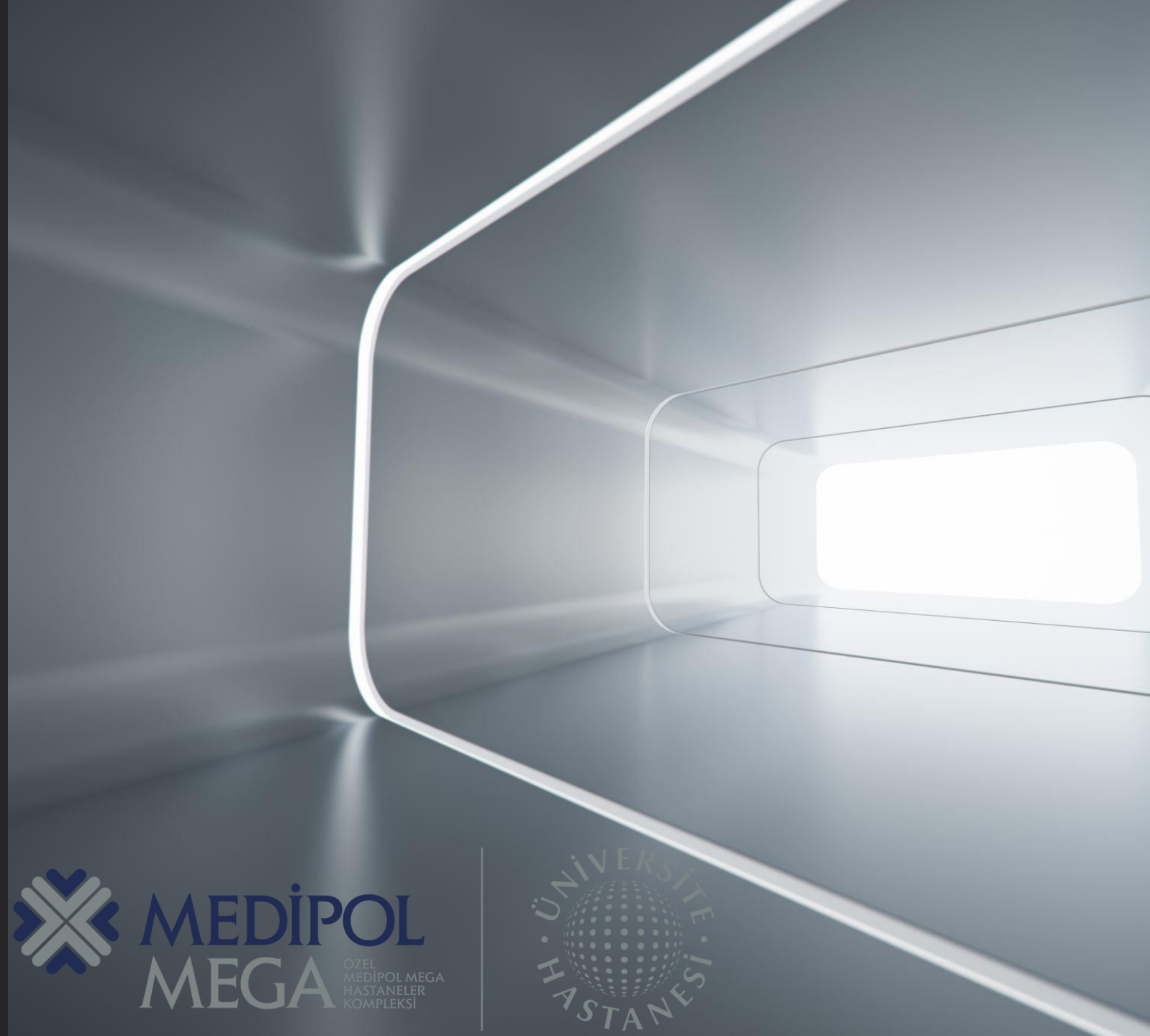
Akut Myeloid Lösemi'de İdame Tedavisinin Yeri

DOÇ. DR. ÖMÜR GÖKMEN SEVİNDİK



Kliniğinizde Akut Myeloid Lösemi Hastalarında Rutin İdame Tedavisi Uyguluyor Musunuz?

A) EVET

B) HAYIR

Kliniğinizde Hastalık veya Hasta Özelinde Akut Myeloid Lösemi’de İdame Tedavisi Uyguluyor Musunuz?

A) EVET

B) HAYIR

Kliniğinizde Hastalık veya Hasta Özelinde Akut Myeloid Lösemi’de Net Genetik Profilleme Yapabiliyor musunuz (NGS..)?

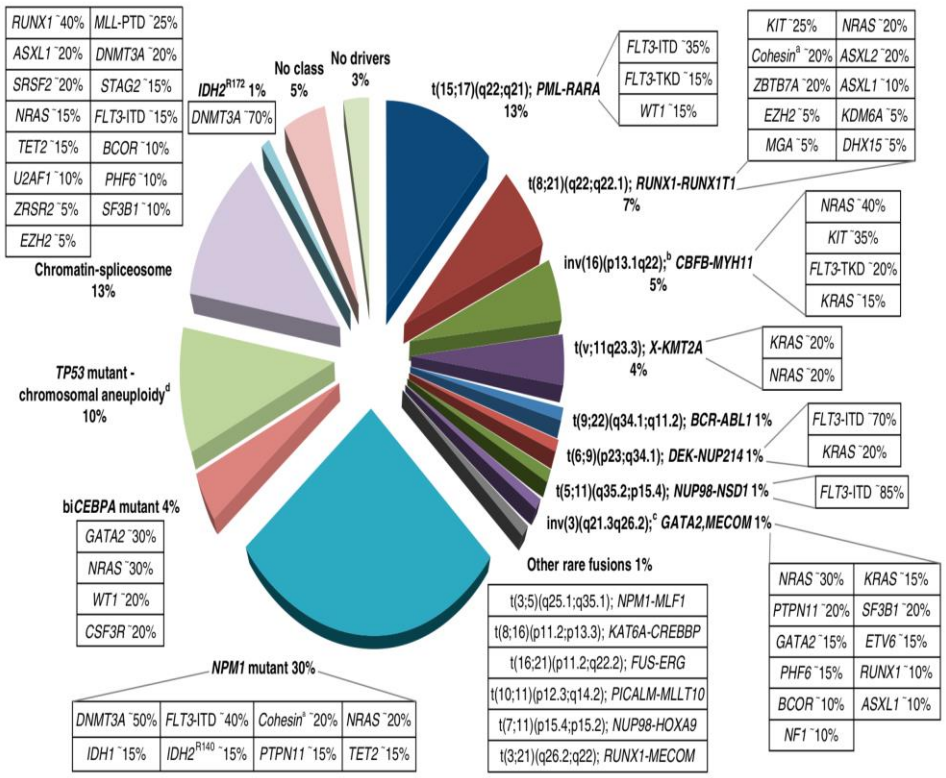
A) EVET

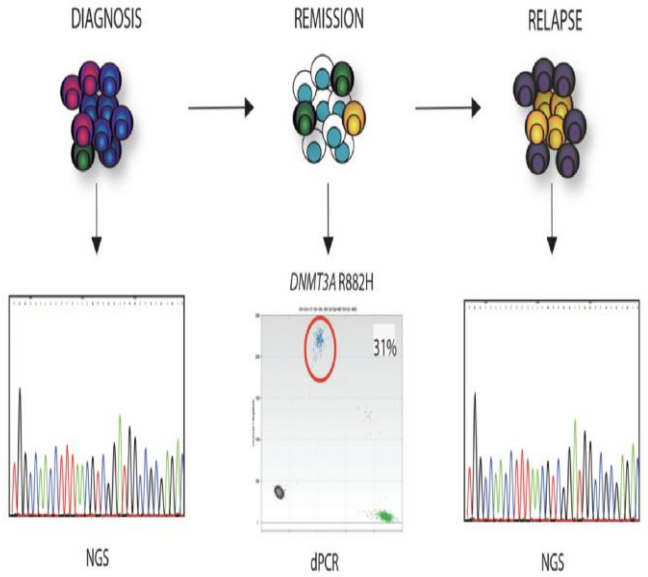
B) HAYIR

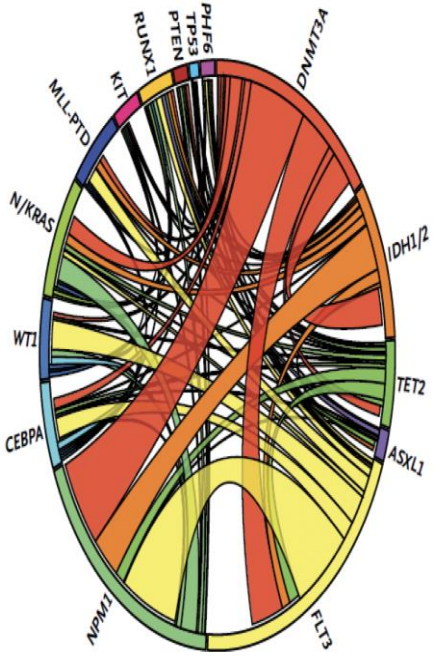
Sunum Planı

- Akut Myeloid Lösemi’de değişen kavramlar
- Akut Myeloid Lösemi’de genel tedavi yaklaşımı
- Akut Myeloid Lösemi’de idame tedavisinin rolünü irdeleyen çalışmalar
- ÖZET

AML - Kompleks Patofizyolojik Temel





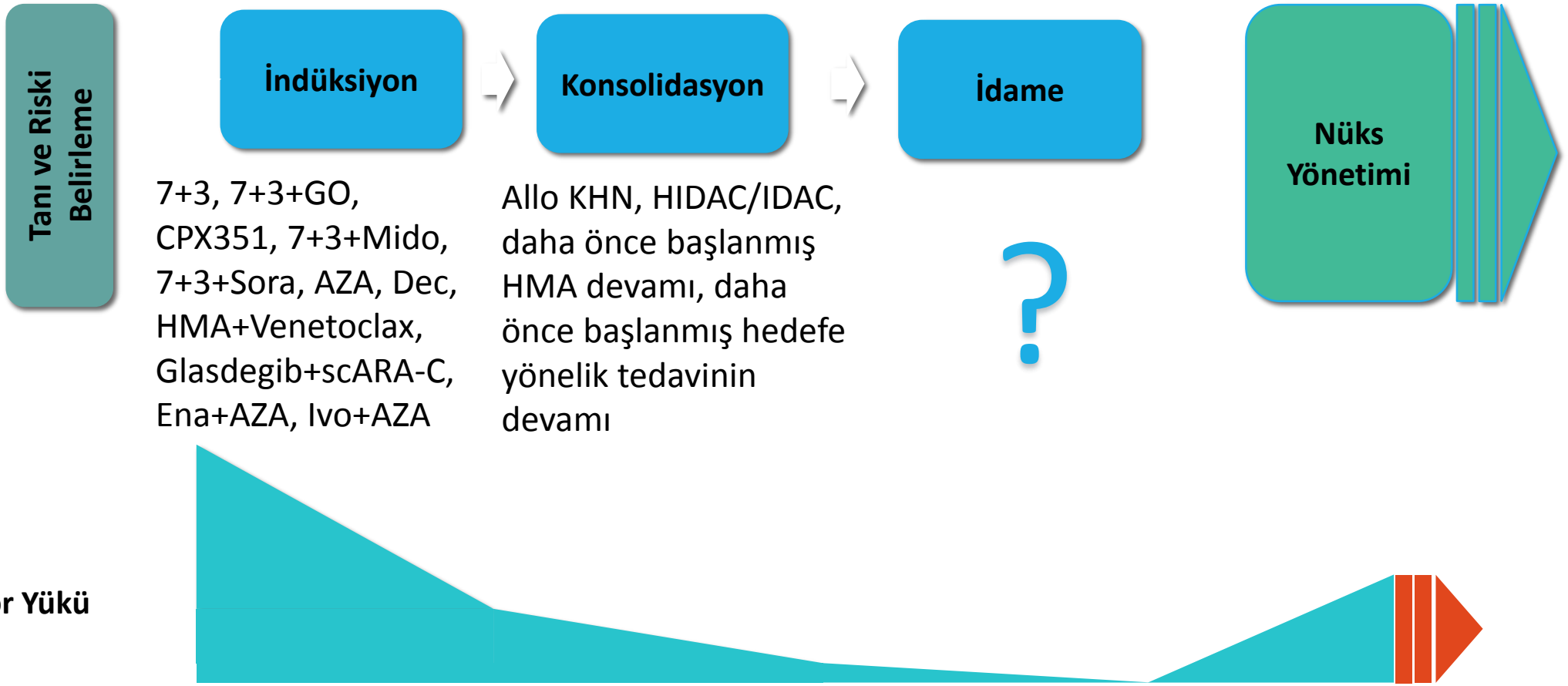


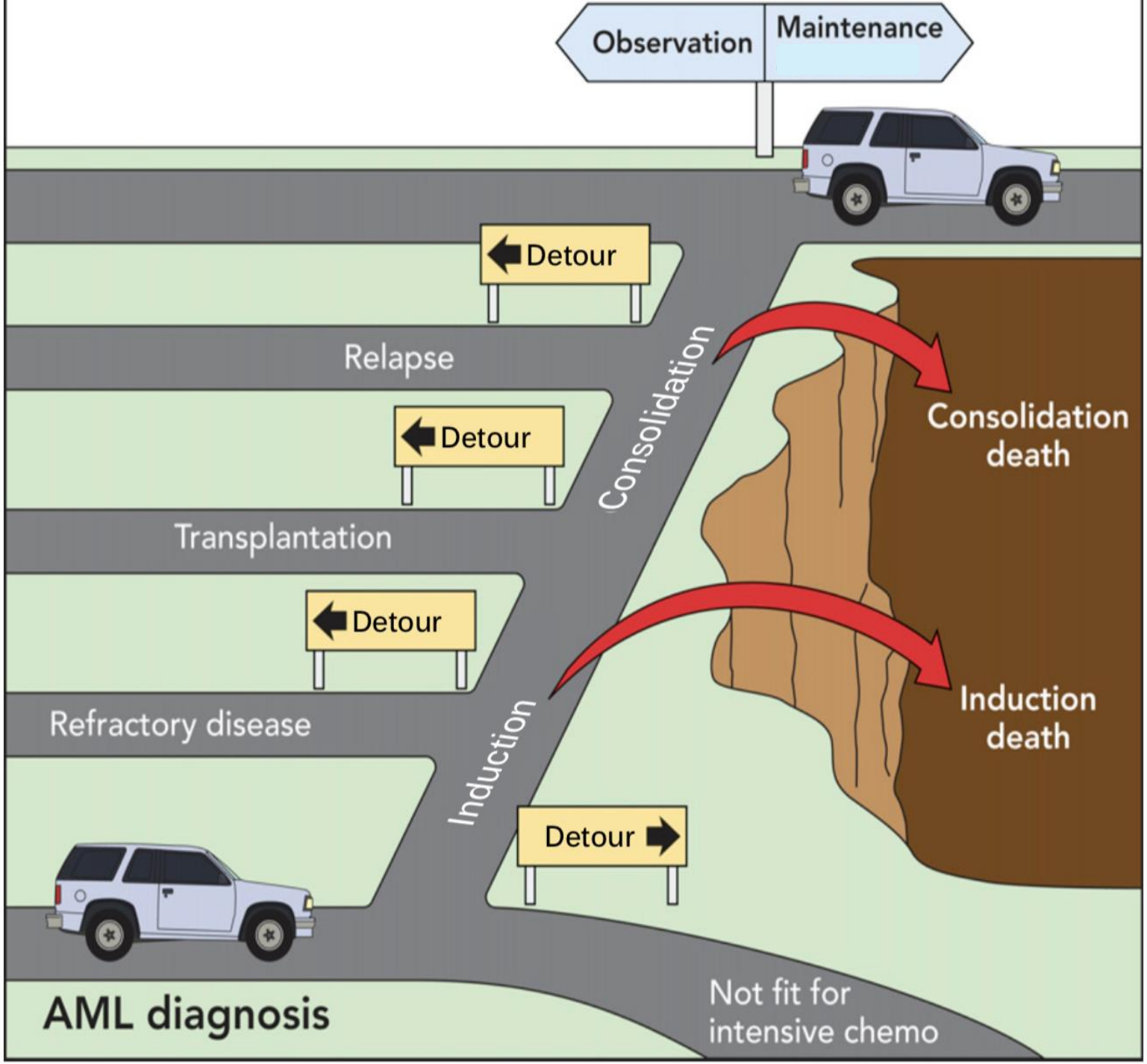
Gene	Overall Frequency, %
FLT3 (ITD, TKD)	37 (30, 7)
NPM1	29
DNMT3A	23
NRAS	10
CEBPα	9
TET2	8
WT1	8
IDH2	8
IDH1	7
KIT	6
RUNX1	5
MLL-PTD	5
ASXL1	3
PHF6	3
KRAS	2
PTEN	2
TP53	2
HRAS	0
EZH2	0

AML – Değişen Tedavi Paradigması

Midostaurin (Rydapt)	Nisan 2017
CPX-351 (Vyxeos)	Ağustos 2017
Enasidenib (Idhifa)	Ağustos 2017
Gemtuzumab Ozogamicin (Mylotarg)	Eylül 2017
Ivosidenib (Tibsovo)	Temmuz 2018
Gilteritinib (Xospata)	Kasım 2018
Glasdegib (Daurismo)	Kasım 2018
Venetoclax (Venclyxto)	Kasım 2018

AML’de Değişen Tedavi Paradigması





İdeal İdame Tedavisi

- Mümkün olan en az ek toksisite ile yanıt sürdürülebilirliğini sağlamalı hatta derinleştirebilmeli, nüksü önleyebilmeli
- Kolay uygulanmalı, uygulama şeması ağır ek mali/yatış/vizit yükü getirmemeli
- Sadece PFS, RFS, EFS değil OS'yi de uzatabilmeli
- Yaşam kalitesini kötü yönde etkilememeli
- Bütün bu şartları destekleyen en az bir randomize kontrollü faz 3 verisi olmalı

AML'de Hipometile Edici Ajanlar ile İdame Tedavisi

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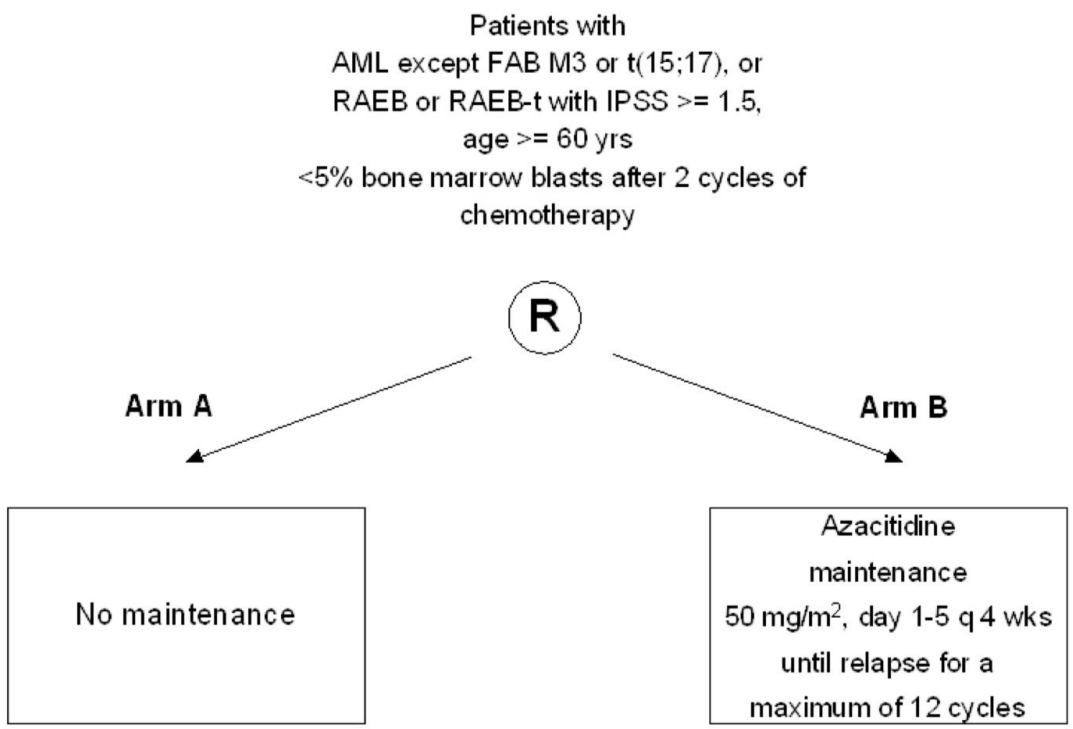
HOVON 97 çalışması

Azacitidine maintenance after intensive chemotherapy improves DFS in older AML patients

Gerwin Huls, Dana A. Chitu, Violaine Havelange, Mojca Jongen-Lavrencic, Arjan A. van de Loosdrecht, Bart J. Biemond, Harm Sinnige, Beata Hodossy, Carlos Graux, Rien van Marwijk Kooy, Okke de Weerdt, Dimitri Breems, Saskia Klein, Jürgen Kuball, Dries Deeren, Wim Terpstra, Marie-Christiane Vekemans, Gert J. Ossenkoppele, Edo Vellenga, and Bob Löwenberg

Blood 2019 :blood-2018-10-879866; doi: https://doi.org/10.1182/blood-2018-10-879866

AML'de Hipometile Edici Ajanlar ile İdame Tedavisi

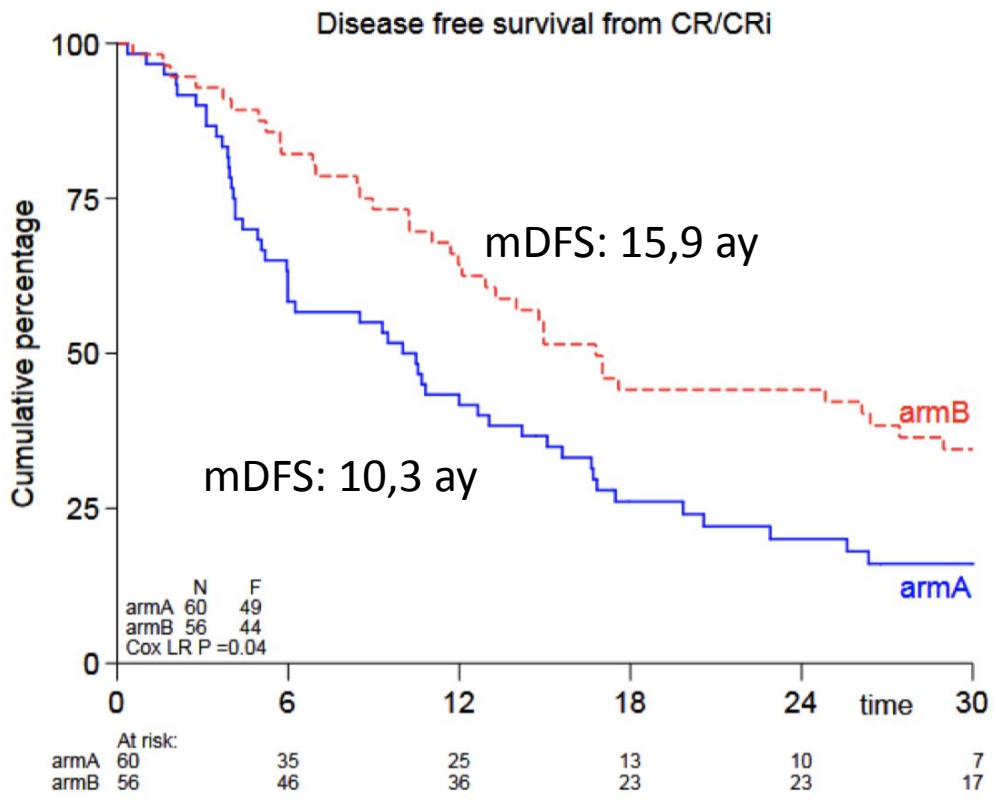


	Observation arm (N=60)	Azacitidine arm (N=56)
Gender: male/female	33 / 27 (55% / 45%)	35/21 (63% / 37%)
Age: median/range	69 / 60-79	69 / 64-81
WHO performance WHO 0 WHO 1 WHO 2 Unknown	 23 (38%) 34 (57%) - 3 (5%)	 29 (52%) 17 (30%) 5 (9%) 5 (9%)
Unfavourable risk cytogenetic abnormalities at diagnosis *	14 (23%)	9 (16%)
CR(i) obtained after: Induction cycle 1 Induction cycle 2	 45 (75%) 15 (25%)	 35 (63%) 21 (37%)
Platelet count ≥ $100x10^9$/L	45 (75%)	38 (68%)
Neutrophils ($x10^9$/L) median range	 4.1 1.5-38	 3.3 0.6-13.7
CR	45 (75%)	37 (66%)
MDS-RAEB	6 (10%)	6 (11%)

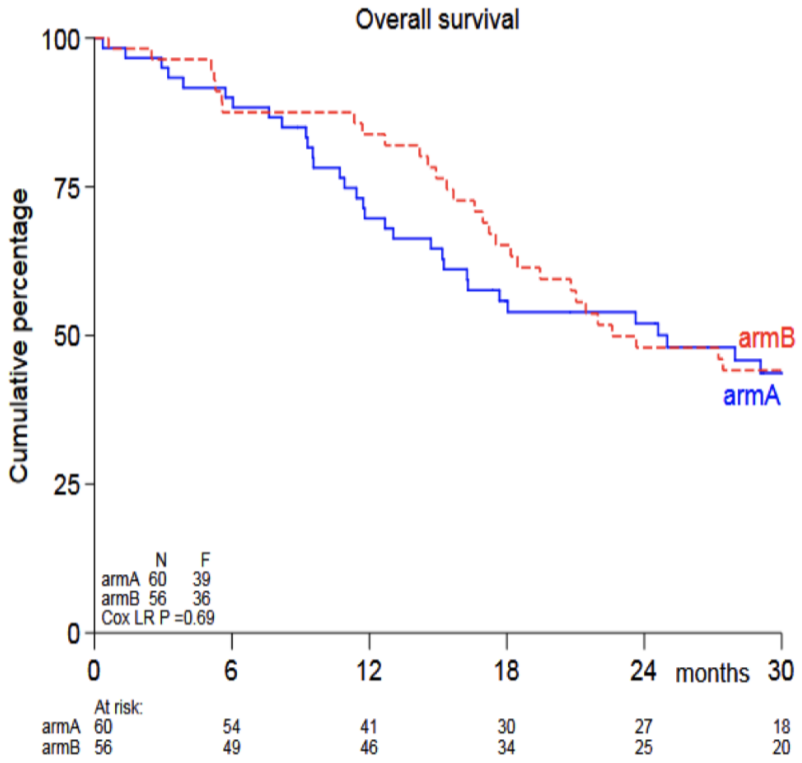
* -7, -7q, -5, -5q, abn 3q, complex ≥ 3 abnormalities

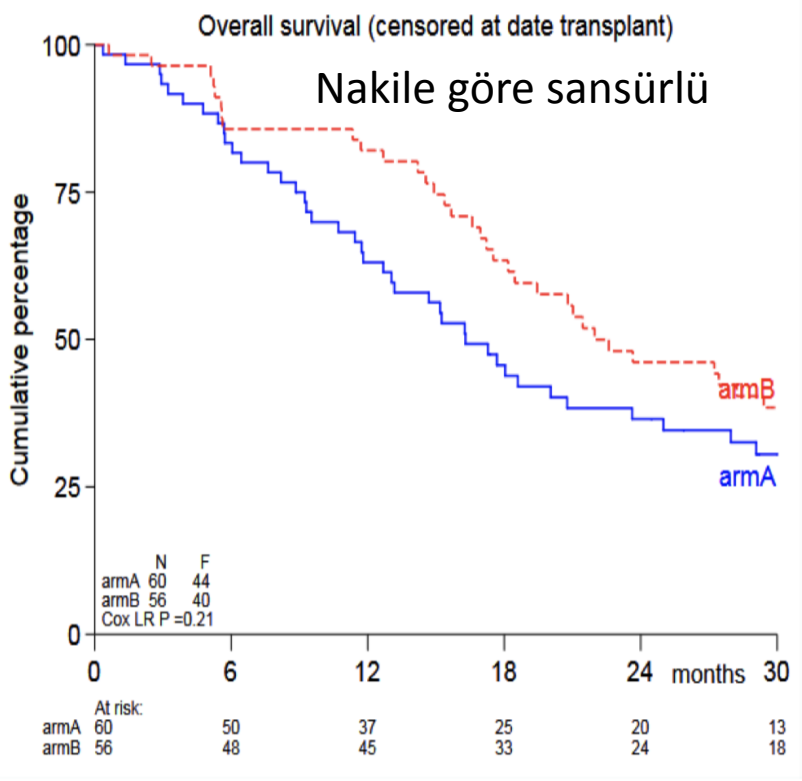
AML'de Hipometile Edici Ajanlar ile İdame Tedavisi

	Observation arm (N=60)	Azacitidine arm (N=56)
Transfusion requirements		
RBC (median / mean) (units)	0 / 1	0 / 1
# patients receiving no RBC	55 (92%)	48 (86%)
Platelets (median / mean)	0 / 1	0 / 1
# patients receiving no platelets	56 (93%)	48 (86%)
Nights in hospital		
(median / mean)	0 / 1	0 / 2
# patients without nights in hospital	55 (92%)	48 (86%)
Adverse events (AE)		
Median	1	2
# AE ≥ 2 grade (total)	449	510
Patients with serious adverse events (SAE)		
0 SAE	56 (93%)	42 (75%)
1 SAE	4 (7%)	11 (20%)
2 SAE		2 (3%)
3 SAE		1 (2%)



AML’de Hipometile Edici Ajanlar ile İdame Tedavisi





Yavaş hasta alım hızı (7,5 yıl)

Kurtarma tedavilerinin kontrol grubunda daha erken ve fazla kullanılması

MRD verilerinin yokluğu

Önemli kısıtlılıklar

AML’de Hipometile Edici Ajanlar ile İdame Tedavisi

Biol Blood Marrow Transplant. 2018 Oct;24(10):2017-2024. doi: 10.1016/j.bbmt.2018.06.016. Epub 2018 Jun 20.

CC-486 Maintenance after Stem Cell Transplantation in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndromes.

de Lima M[1], Oran B[2], Champlin RE[2], Papadopoulos EB[3], Giralt SA[3], Scott BL[4], William BM[5], Hetzer J[6], Laille E[6], Hubbell B[6], Skikne BS[6], Craddock C[7].

Allo nakile ilerlenmiş morfolojik tam remisyondaki yüksek riskli MDS ve AML hastaları,

7 hasta CC486’yı günde bir kez 200-300 mg po 7 gün süreyle, 23 hasta ise 150-200 mg po dozda 14 gün süreyle her 28 günde bir hastalık ilerlemesi, nüks veya tolere edilemez toksisiteye dek kullanmış.

AML’de Hipometile Edici Ajanlar ile İdame Tedavisi

	Age/ Gender	AML/MDS Classification	Conditioning Regimen	Source/ Donor	Reason for CC-486 Discontinuation
CC-486 200 mg x 7days	75/M	MDS-Int2	MAC	BM/Unrelated	Completed Study
	65/F	AML-NOS	RIC	PB/Sibling	Withdrew Consent
	65/M	AML-NOS	RIC	PB/Unrelated	Withdrew Consent
CC-486 300 mg x 7 days	28/M	AML-NOS	MAC	BM/Unrelated	Relapse
	43/M	AML-RGA	MAC	PB/Unrelated*	Relapse
	72/M	AML-NOS	RIC	PB/Unrelated	Other†
	48/M	AML-NOS	RIC	PB/Sibling*	Relapse
CC-486 150 mg x 14 days	71/M	T-AML	MAC	PB/Sibling	Completed Study
	50/M	AML-NOS	MAC	PB/Sibling	Completed Study
	62/M	AML-NOS	MAC	PB/Sibling	Adverse Event
	64/M	AML-MRC	RIC	BM/Unrelated	Adverse Event
CC-486 200 mg x 14 days	59/M	AML-MRC	MAC	PB/Sibling	Completed Study
	80/M	AML-NOS	RIC	BM/Unrelated	Completed Study
	53/F	MDS-HIGH	MAC	PB/Unrelated	Completed Study
	67/M	AML-NOS	MAC	PB/Sibling	Completed Study
	68/M	AML-NOS	MAC	BM/Unrelated	Completed Study
	70/M	AML-NOS	RIC	PB/Sibling	Completed Study
	32/M	AML-RGA	MAC	PB/Sibling	Completed Study
	31/M	AML-RGA	RIC	PB/Sibling	Completed Study
	69/M	AML-NOS	RIC	PB/Unrelated	Completed Study
	66/M	MDS-INT1	RIC	PB/Unrelated	Completed Study
	53/M	AML-RGA	MAC	BM/Unrelated	Adverse Event
	71/M	AML-NOS	RIC	PB/Unrelated*	Relapse
	58/F	MDS-INT2	MAC	PB/Unrelated	Adverse Event
	71/M	AML-RGA	MAC	PB/Unrelated	Withdrew Consent
	67/M	AML-NOS	RIC	PB/Unrelated	Death‡
	68/M	AML-RGA	MAC	BM/Unrelated	Relapse
	58/M	AML-RGA	MAC	BM/Unrelated	Withdrew Consent
	53/M	AML-RGA	MAC	PB/Unrelated	Withdrew Consent
	62/M	AML-MRC	MAC	PB/Unrelated	Relapse

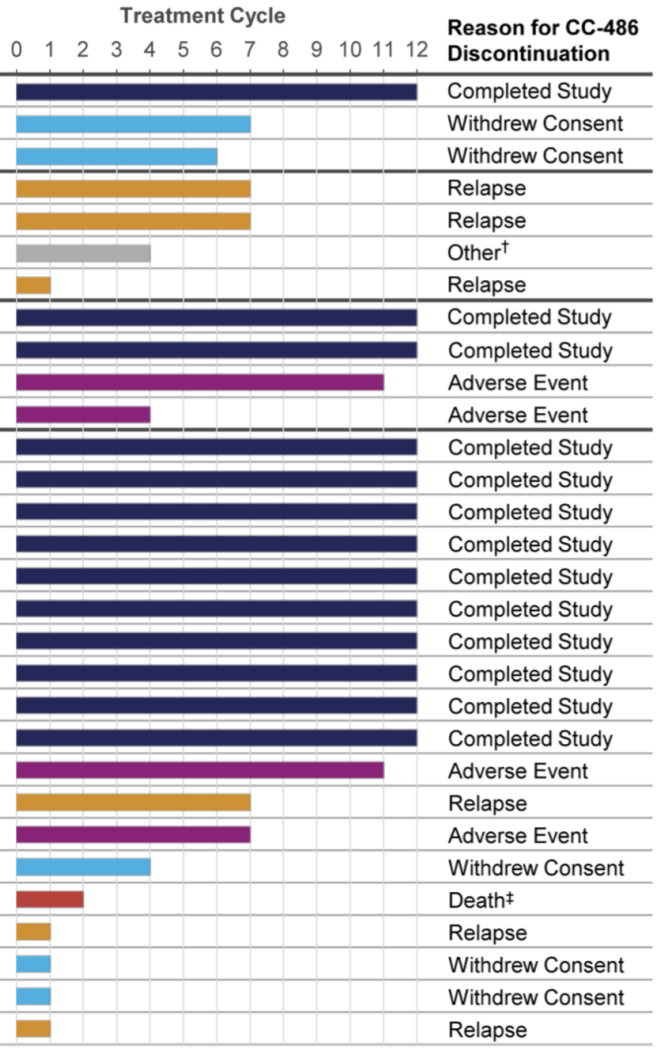
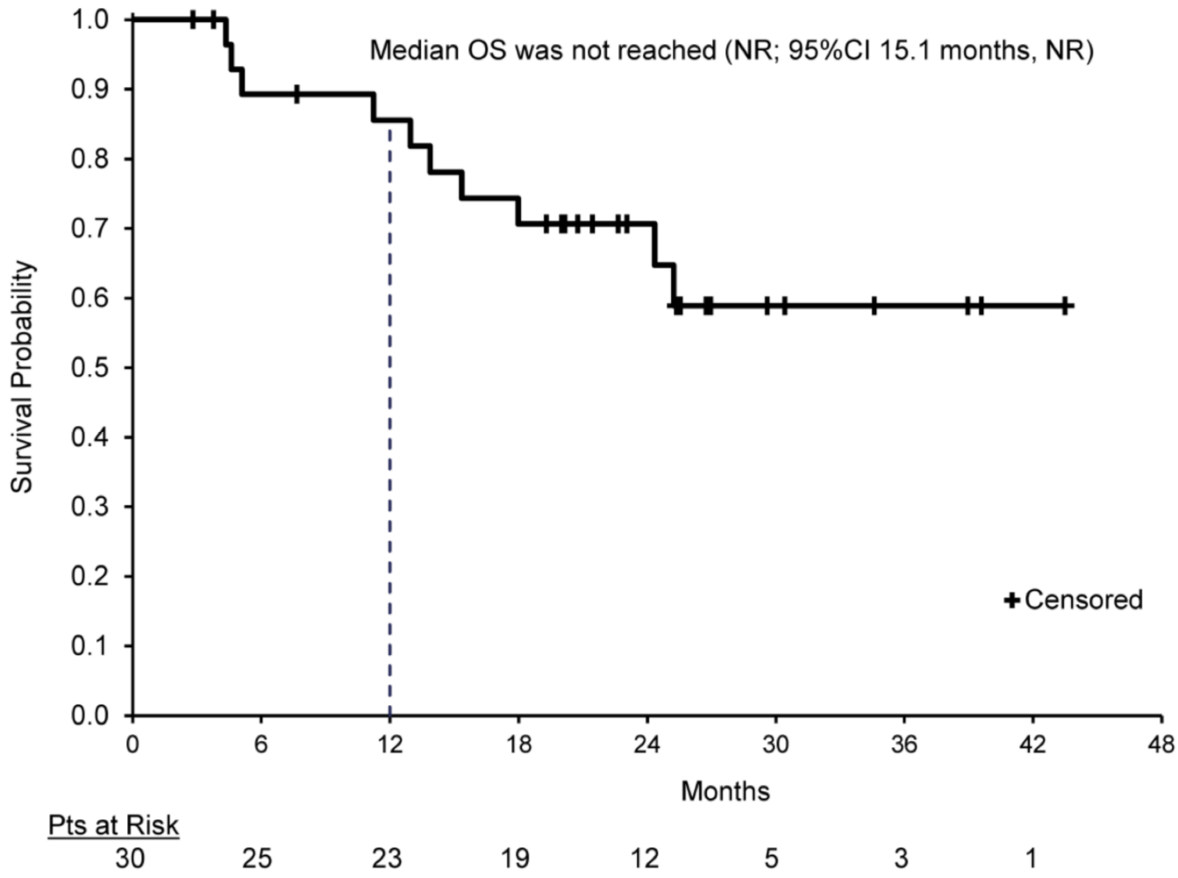


Figure 2.



AML'de Hipometile Edici Ajanlar ile İdame Tedavisi

Leukemia. 2017 January ; 31(1): 34–39. doi:10.1038/leu.2016.252.

Maintenance therapy with decitabine in younger adults with acute myeloid leukemia in first remission: a phase 2 Cancer and Leukemia Group B study (CALGB 10503)

William Blum[1], Ben L. Sanford[2], Rebecca Klisovic[1], Daniel J. DeAngelo[3], Geoffrey Uy[4], Bayard L. Powell[5], Wendy Stock[6], Maria R. Baer[7], Jonathan E. Kolitz[8], Eunice S. Wang[9], Eva Hoke[2], Krzysztof Mrózek[1], Jessica Kohlschmidt[1,2], Clara D. Bloomfield[1], Susan Geyer[10], Guido Marcucci[11], Richard M. Stone[3], and **Richard A. Larson[6] for the Alliance for Clinical Trials in Oncology**

AML'de Hipometile Edici Ajanlar ile İdame Tedavisi

TY1'de nakile ilerlenmemiş genç hastalar

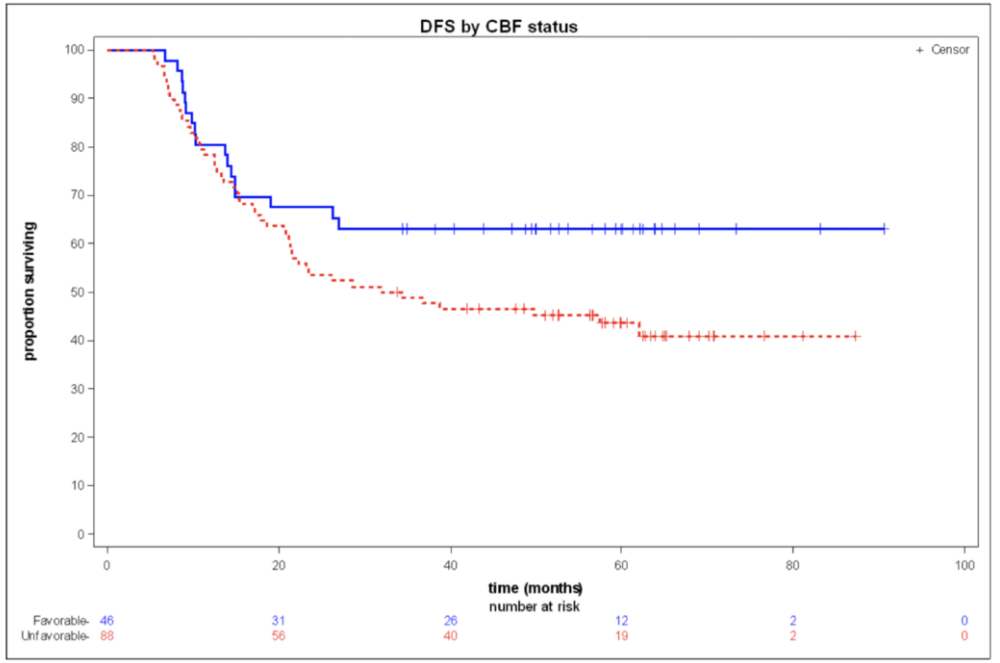
Desitabin 20 mg/m2 iv 4-5 gün her 6 haftada bir toplam 8 siklus

Geçmiş CALGB çalışma gruplarındaki hastaların verileri ile kıyaslama yapılmış

Sitogenetik riske göre de alt grup analizi uygulanmış

Treatment course	**No.**	**% of CR patients**
Achieved CR, received maintenance	134	32
Achieved CR, no maintenance	280	68
Reasons for no maintenance		
Early relapse	29	7
Withdrew for non-protocol therapy (alloHCT in CR1)	96 (86)	23 (21)
Patient refused	44	11
Unresolved toxicity after consolidation	33	8
Ineligible due to low counts (post autoHCT)	38	9
Death during consolidation	6	1
Insurance denial	4	<1
Other	30	7

AML'de Hipometile Edici Ajanlar ile İdame Tedavisi



Adverse Event[a]	Grade 3		Grade 4[b]	
	No.	%	No.	%
Neutropenia	16	12	103	79
Thrombocytopenia	43	33	52	40
Anemia	15	11	0	0
Febrile neutropenia	13	10	1	1
Infection with <Grade 3 ANC	3	2	0	0
Infection with ≥Grade 3 ANC	9	7	0	0
Fatigue[a]	9	7	0	0
Pain[a]	7	5	0	0
ALT[a]	4	3	0	0
Dyspnea*	4	3	0	0

Characteristic	CALGB 10503	CALGB 19808	*P*-value[†]
ELN Genetic Group,[‡] no. (%)			.07
Favorable	85 (63)	94 (44)	
Intermediate-I	13 (10)	28 (13)	
Intermediate-II	16 (12)	36 (17)	
Adverse	10 (7)	10 (5)	
Unknown	10 (7)	46 (21)	
3-year OS, %	68	61/68	
3-year DFS, %	54	45/56	

AML'de Hipometile Edici Ajanlar ile İdame Tedavisi

Leukemia. 2012 November ; 26(11): 2428–2431. doi:10.1038/leu.2012.153.

A Randomized Study of Decitabine Versus Conventional Care for Maintenance Therapy in Patients with Acute Myeloid Leukemia in Complete Remission

Yanis Boumber[1], **Hagop Kantarjian**[2], **Jeffrey Jorgensen**[3], **Sijin Wen**[4], **Stefan Faderl**[2], **Ryan Castoro**[2], **Jane Autry**[2], **Guillermo Garcia-Manero**[2], **Gautam Borthakur**[2], **Elias Jabbour**[2], **Zeev Estrov**[2], **Jorge Cortes**[2], **Jean-Pierre Issa**[2,5], and **Farhad Ravandi**[2]

AML'de Hipometile Edici Ajanlar ile İdame Tedavisi

45 hasta, TY1 veya TY2 sonrası Decitabine 20 mg/m2 5 gün her 4-8 haftada bir 12 siklus

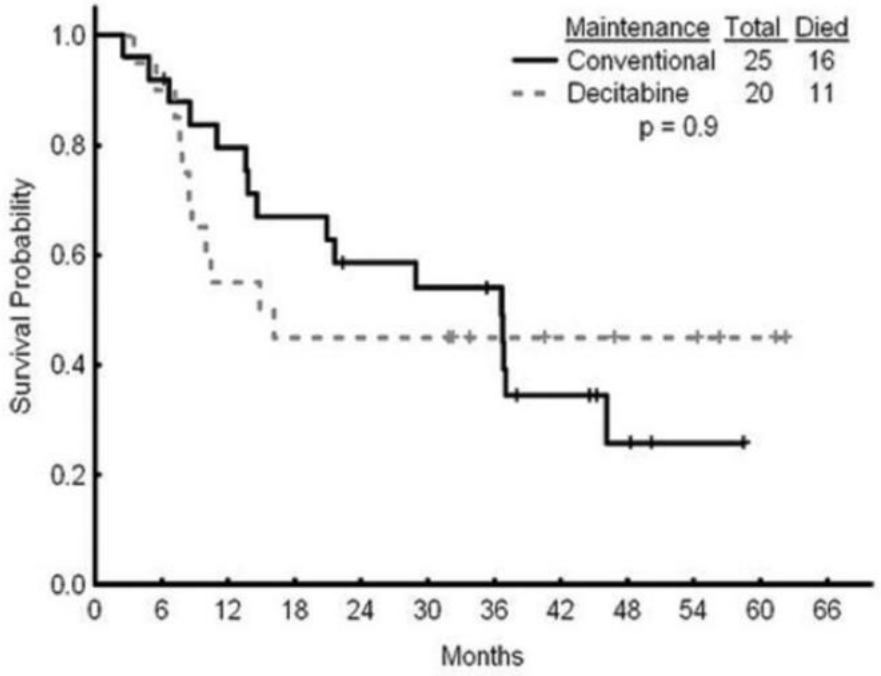
Karşılaştırma kolu konvansiyonel takip veya tedavi (sc ARA-C, yoğun KT) uygulanan 27 hasta

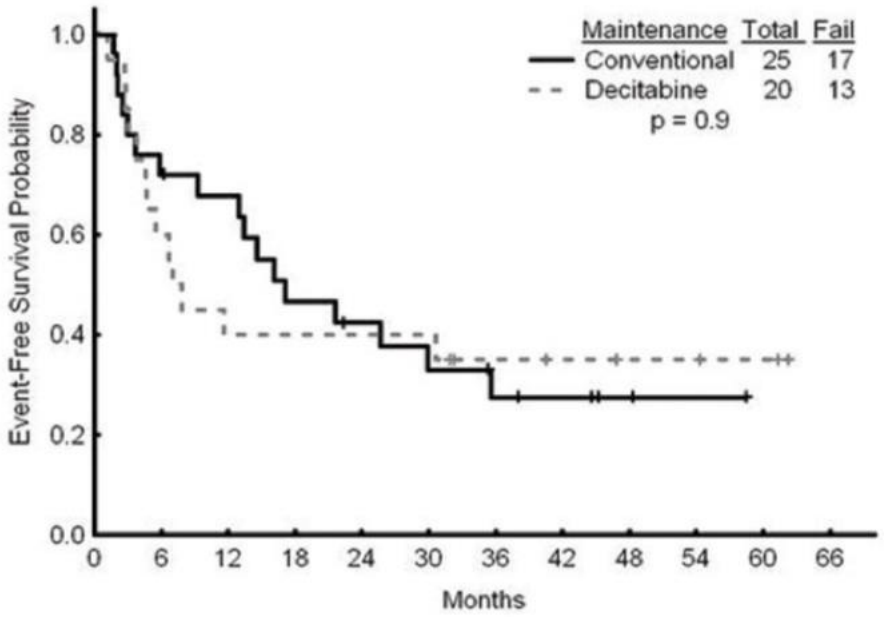
Medyan 4,5 siklus Dec uygulanabilmiş (1-12)

Medyan takip süresi 44,9 ay

Characteristics	Decitabine (n=20)	Conventional Care (n=25)	p-value
Age, median [range], years	62, [24–79]	53 [31–72]	0.10
≤ 60	9 (45)	18 (72)	0.12
> 60	11 (55)	7 (28)	
CR1	14 (70) [1CRp]	21 (83) [1CRp]	0.26
CR2	6 (30) [1CRp]	3 (12)	
CR3	0	1 (4)	
Induction regimen			0.20
SDAC + Anthracycline (3+7)	7 (35)	3 (12)	
HiDAC + Anthracycline	11 (55)	18 (72)	
Single agent (e.g. Clofarabine)	2 (10)	4 (16)	
No. of consolidation cycles			0.19
≤ 1	8 (40)	5 (20)	
> 1	12 (60)	20 (80)	
Cytogenetics			0.99
Intermediate	15 (75)	19 (76)	
Unfavorable	5 (25)	5 (20)	
Favorable (relapsed)	0	1 (4)	

AML’de Hipometile Edici Ajanlar ile İdame Tedavisi





AML'de Gemtuzumab Ozogamisin ile İdame Tedavisi

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A phase 3 study of gemtuzumab ozogamicin during induction and postconsolidation therapy in younger patients with acute myeloid leukemia

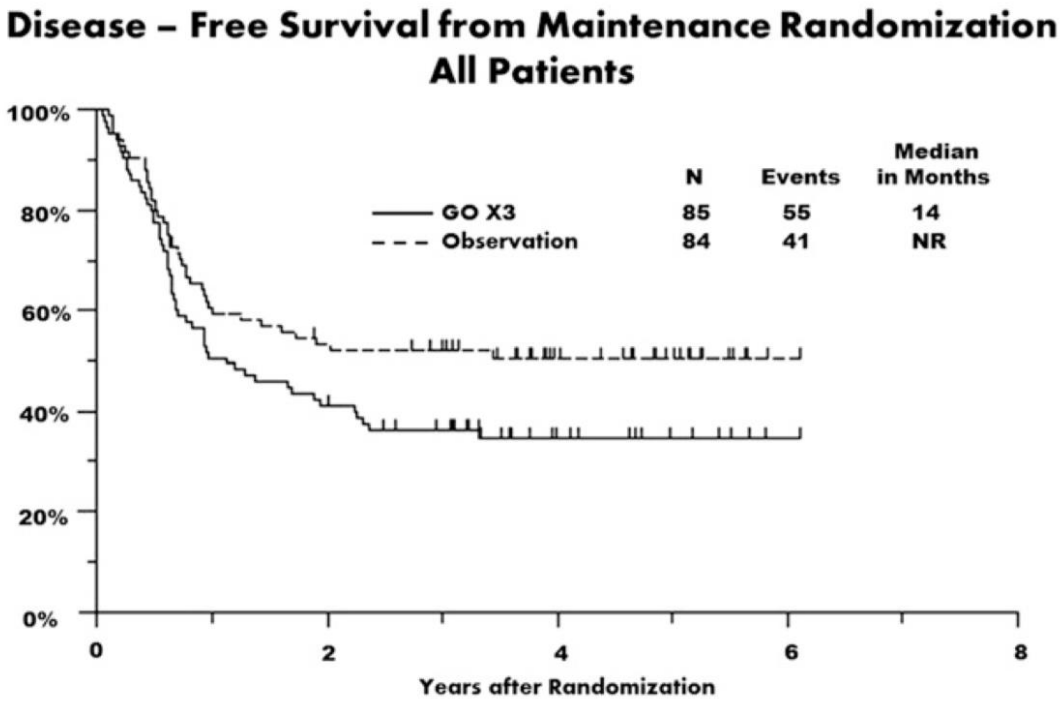
Stephen H. Petersdorf,[1] Kenneth J. Kopecky,[1,2] Marilyn Slovak,[3] Cheryl Willman,[4] Thomas Nevill,[5] Joseph Brandwein,[6] Richard A. Larson,[7] Harry P. Erba,[8] Patrick J. Stiff,[9] Robert K. Stuart,[10] Roland B. Walter,[1] Martin S. Tallman,[11] Leif Stenke,[12] and Frederick R. Appelbaum[1]

AML’de Gemtuzumab Ozogamisin ile İdame Tedavisi

GO’nin standart indüksiyon tedavisine eklenmesinin ve sonrasında da idame tedavisi olarak kullanılmasının etkinliğini irdeleyen bir faz 3 randomize çalışma

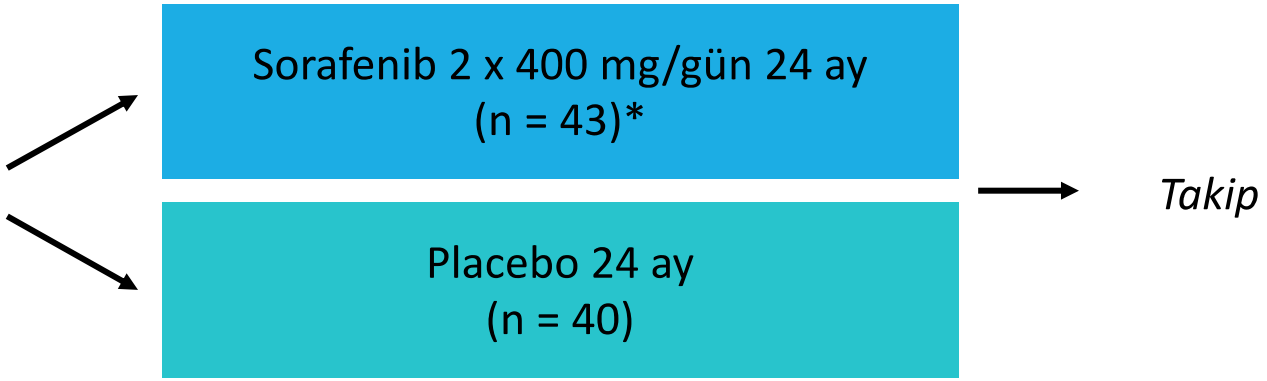
Hastalar öncelikle 7+3 ve 7+3+GO indüksiyon tedavisi gruplarına randomize edilmiş. Sonrasında 3 kür HIDAC ile konsolidasyon tedavisi uygulanmış ve bir sonraki aşamada da TY’ı koruyan hastalar ek olarak 3 siklus süren 5mg/m2 dozunda 28 günde bir uygulanan GO ve izlem gruplarına randomize edilmiş.

Toplam 147 hasta konsolidasyon sonrası GO idame veya izlem gruplarına randomize edilmiş



AML’de FLT İnhibitörleri ile İdame Tedavisi – SORMAIN çalışması

Nakilden sonraki 60-100. gün kontrollerinde Tam Hematolojik Yanıtı olan FLT3ITD mutasyonu pozitif hastalar, ECOG PS 0/1, 2-4.derece GvHD’si olmayan (N = 83*)



* Başlangıç dozu 2*200 mg 14 gün içerisinde tolere edilir ise 2*400 mg

Birincil Sonlanım Noktası: Relapssız Sağkalım, İkincil Sonlanım Noktası: Genel Sağkalım

AML'de FLT İnhibitörleri ile İdame Tedavisi – SORMAIN çalışması

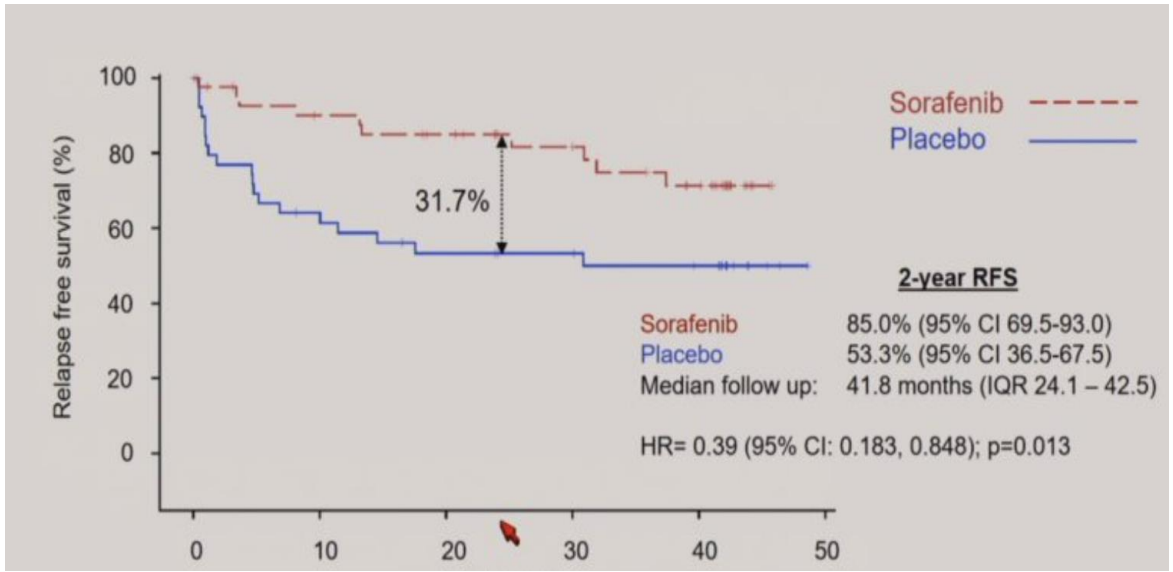
Characteristic	Sorafenib (n = 43)	Placebo (n = 40)
Median age, yrs (range)	54.17 (23.6-74.6)	53.59 (18.6-75.6)
Female, n (%)	25 (58.1)	17 (42.5)
ECOG PS 0/1, n (%)	13 (30.2)/29 (67.4)*	18 (45)/22 (55)
Median white cell count, 10^3/mL (range)	4.62 (1.88-12.75)	5.60 (1.98-11.22)
Median platelet count, 10^3/mL (range)	143 (70-408)	141 (56-353.0)
FLT3-ITD detectable, n (%)		
▪ Positive	4 (9.3)	3 (7.5)
▪ Negative	35 (81.4)	33 (82.5)
▪ Missing	4 (9.3)	4 (10.0)
NPM1 detectable, n (%)	NPM1 mutated: n = 29	NPM1 mutated: n = 23
▪ Positive	8 (27.6)	7 (30.4)
▪ Negative	17 (58.6)	14 (60.9)
▪ Missing	4 (13.8)	2 (8.7)

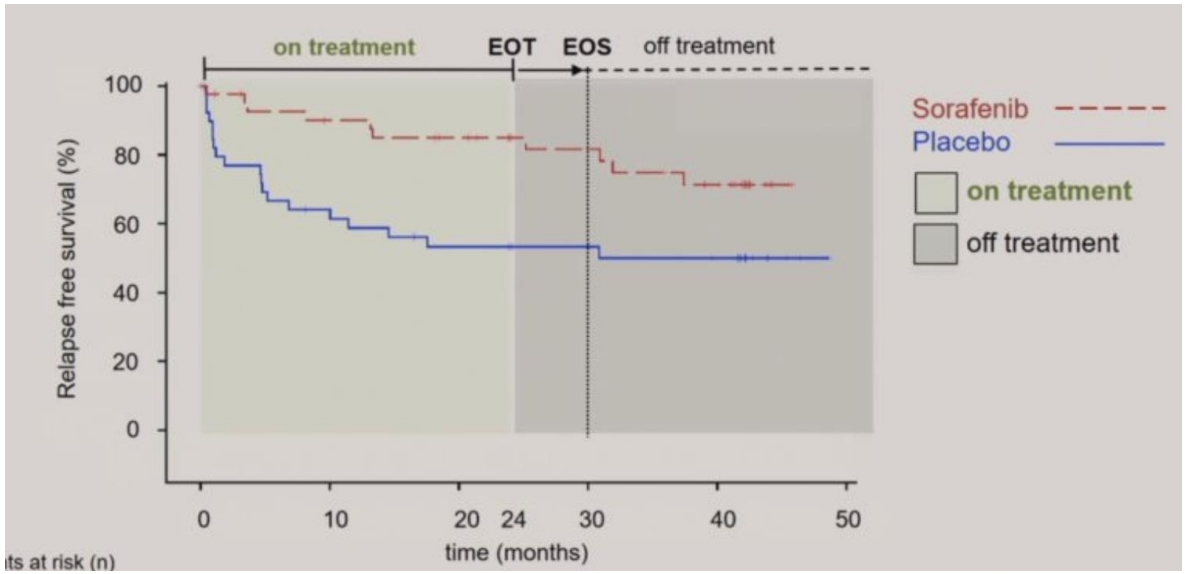
AML'de FLT İnhibitörleri ile İdame Tedavisi – SORMAIN çalışması

Characteristic, n (%)	Sorafenib (n = 43)	Placebo (n = 40)
Cytogenetic risk		
▪ Intermediate	40 (93)	36 (90)
▪ High	1 (2.3)	3 (7.5)
▪ Unknown	2 (4.7)	1 (2.5)
No. of intensive CT cycles before alloSCT		
▪ 1	6 (14)	6 (15)
▪ 2	21 (48.8)	24 (60)
▪ 3	11 (25.6)	3 (7.5)
▪ > 3	5 (11.6)	7 (17.5)
Transplant in CHR1	32 (74.4)	27 (67.5)
Transplant outside CHR1	11 (25.6)	13 (32.5)
Remission status at transplant		
▪ CHR/no CHR	27 (62.8)/7 (16.3)	19 (47.5)/9 (22.5)
• Molecular CR	9 (20.9)	12 (30)
Conditioning therapy intensity: full/reduced	18 (41.9)/25 (58.1)	19 (47.5)/21 (52.5)
Donor: Matched unrelated donor*/family	35 (81.4)/8 (18.6)	28 (70)/12 (30)
Donor lymphocyte infusion	6 (14)	6 (15)

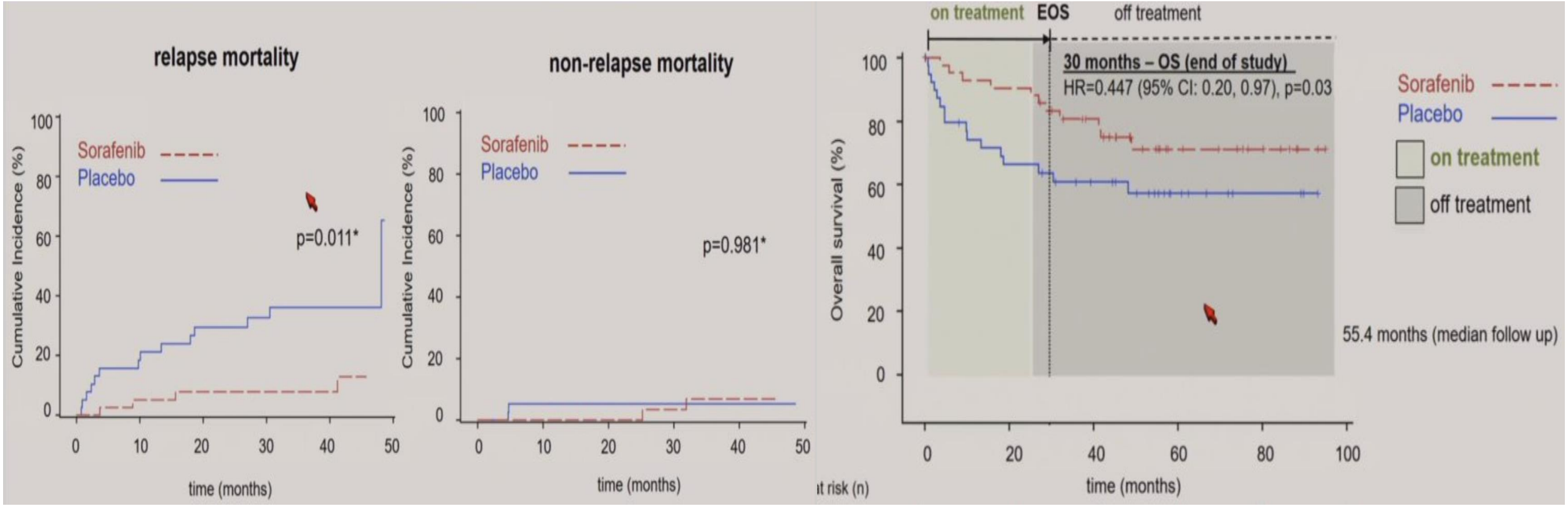
AML’de FLT İnhibitörleri ile İdame Tedavisi – SORMAIN çalışması

RFS Rate, %	Sorafenib (n = 43)	Placebo (n = 40)	Difference	HR
At 2 yrs	85.0	53.3	31.7	0.39 (95% CI: 0.183-0.848); P = .013





AML’de FLT İnhibitörleri ile İdame Tedavisi – SORMAIN çalışması



AML'de FLT İnhibitörleri ile İdame Tedavisi – SORMAIN çalışması

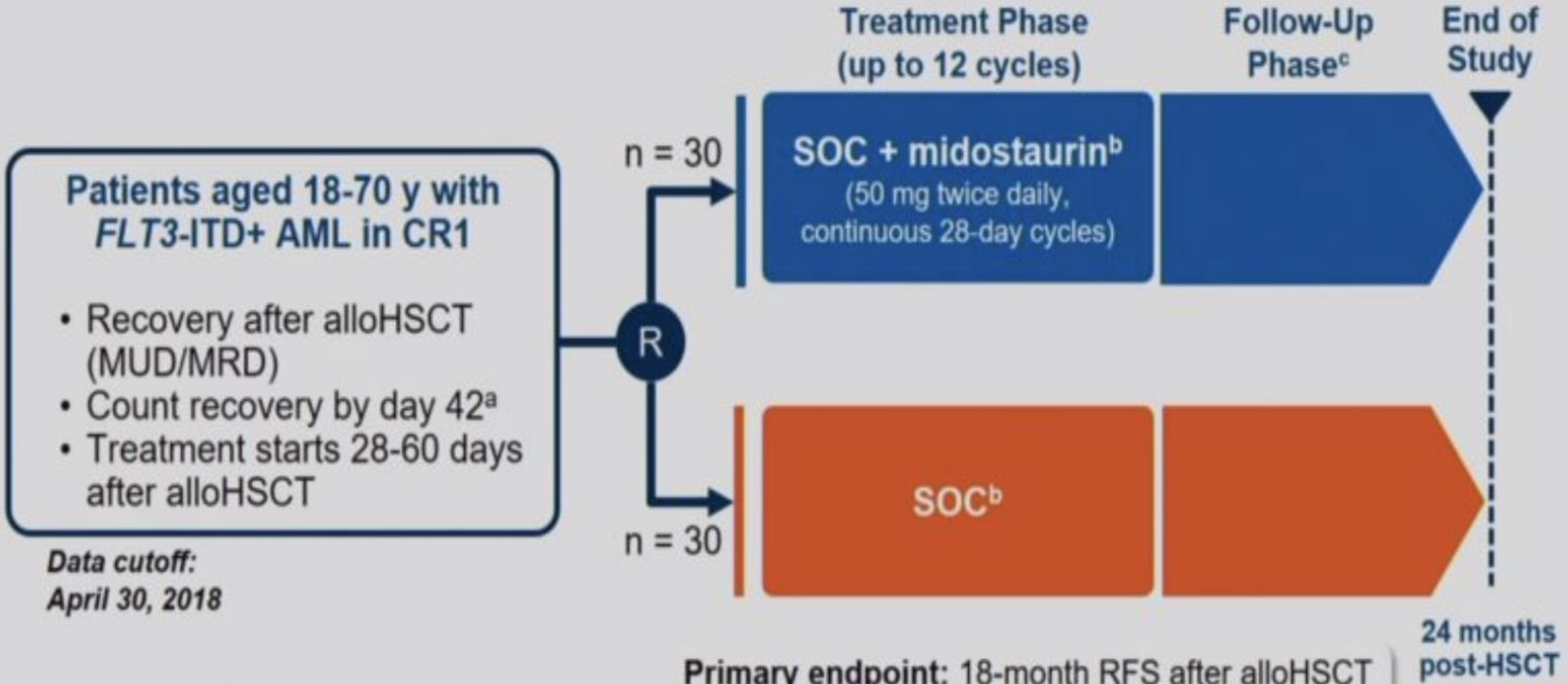
Grade 3/4 AEs, n (%)	Sorafenib (n = 42)		Placebo (n = 39)	
	All	Drug Related	All	Drug Related
GvHD	32 (76.8)	--	23 (59.8)	--
▪ Acute GvHD (grade ≥ 2)	10 (23.8)		7 (18.2)	
▪ Chronic GvHD: mild or moderate/severe	14 (33.6)/8 (19.2)	--	12 (31.2)/4 (10.4)	--
Infections	11 (26.2)	1 (2.4)	9 (23.1)	2 (5.1)
Electrolyte alterations	6 (14.3)	3 (7.1)	1 (2.6)	0
GI toxicity (vomiting, nausea, diarrhea)	6 (14.3)	2 (4.8)	6 (15.4)	3 (7.7)
Skin toxicity	5 (11.9)	2 (4.8)	1 (2.6)	1 (2.6)
Cardiotoxicity and renal insufficiency	4 (9.5)	1 (2.4)	1 (2.6)	0
Liver toxicity (ALT/AST increased)	2 (4.8)	0	2 (5.1)	2 (5.1)
Thrombocytopenia	2 (4.8)	0	1 (2.6)	0
Neutropenia	1 (2.4)	1 (2.4)	1 (2.6)	1 (2.6)
Other	33 (78.6)	8 (19.1)	22 (56.4)	4 (10.3)

AML'de FLT İnhibitörleri ile İdame Tedavisi – RADIUS çalışması

Grade 3/4 AEs, n (%)	Sorafenib (n = 42)		Placebo (n = 39)	
	All	Drug Related	All	Drug Related
GvHD	32 (76.8)	--	23 (59.8)	--
▪ Acute GvHD (grade ≥ 2)	10 (23.8)		7 (18.2)	
▪ Chronic GvHD: mild or moderate/severe	14 (33.6)/8 (19.2)	--	12 (31.2)/4 (10.4)	--
Infections	11 (26.2)	1 (2.4)	9 (23.1)	2 (5.1)
Electrolyte alterations	6 (14.3)	3 (7.1)	1 (2.6)	0
GI toxicity (vomiting, nausea, diarrhea)	6 (14.3)	2 (4.8)	6 (15.4)	3 (7.7)
Skin toxicity	5 (11.9)	2 (4.8)	1 (2.6)	1 (2.6)
Cardiotoxicity and renal insufficiency	4 (9.5)	1 (2.4)	1 (2.6)	0
Liver toxicity (ALT/AST increased)	2 (4.8)	0	2 (5.1)	2 (5.1)
Thrombocytopenia	2 (4.8)	0	1 (2.6)	0
Neutropenia	1 (2.4)	1 (2.4)	1 (2.6)	1 (2.6)
Other	33 (78.6)	8 (19.1)	22 (56.4)	4 (10.3)

RADIUS Study Schema

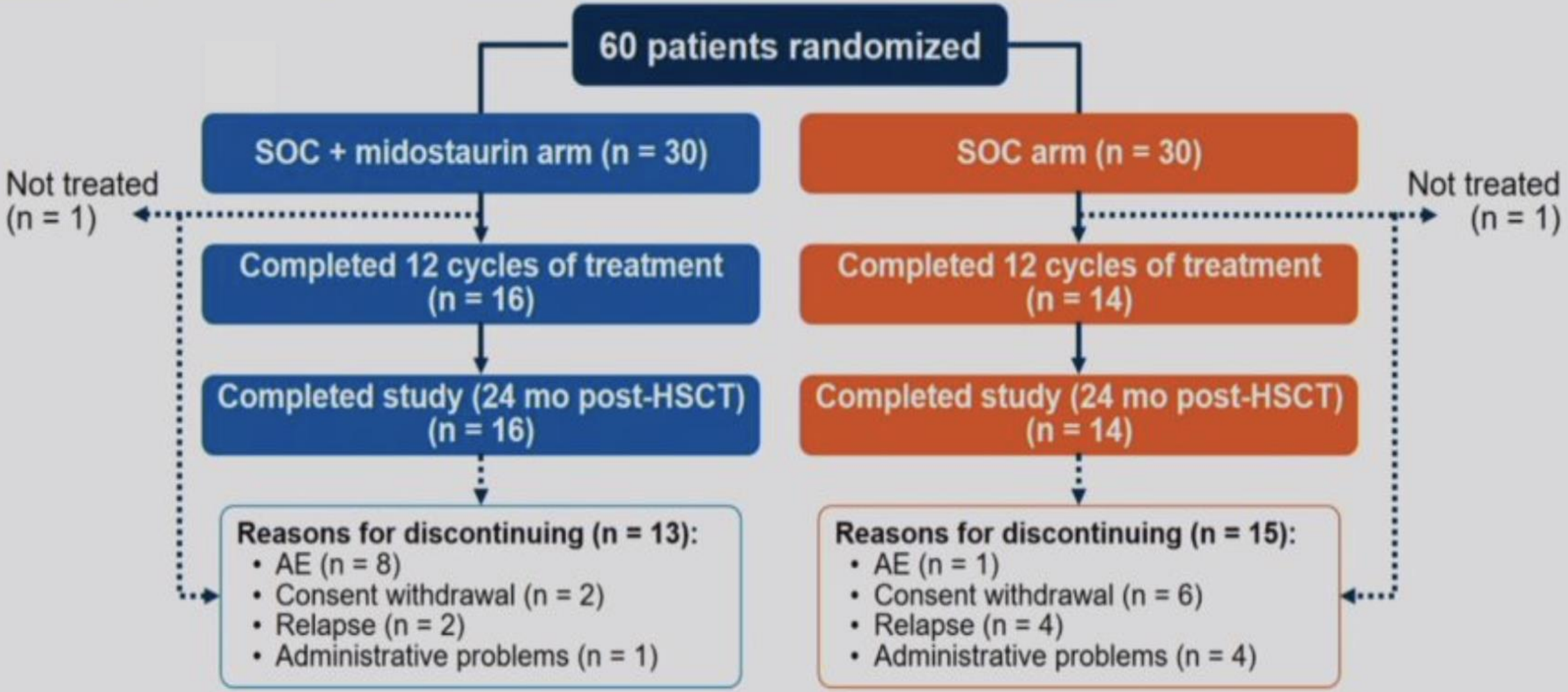
Randomized, phase 2, open-label study comparing midostaurin + SOC vs SOC after alloHSCT



Data cutoff:
April 30, 2018

Primary endpoint: 18-month RFS after alloHSCT
Selected secondary endpoints: safety, OS, 24-month RFS after alloHSCT

CONSORT Diagram

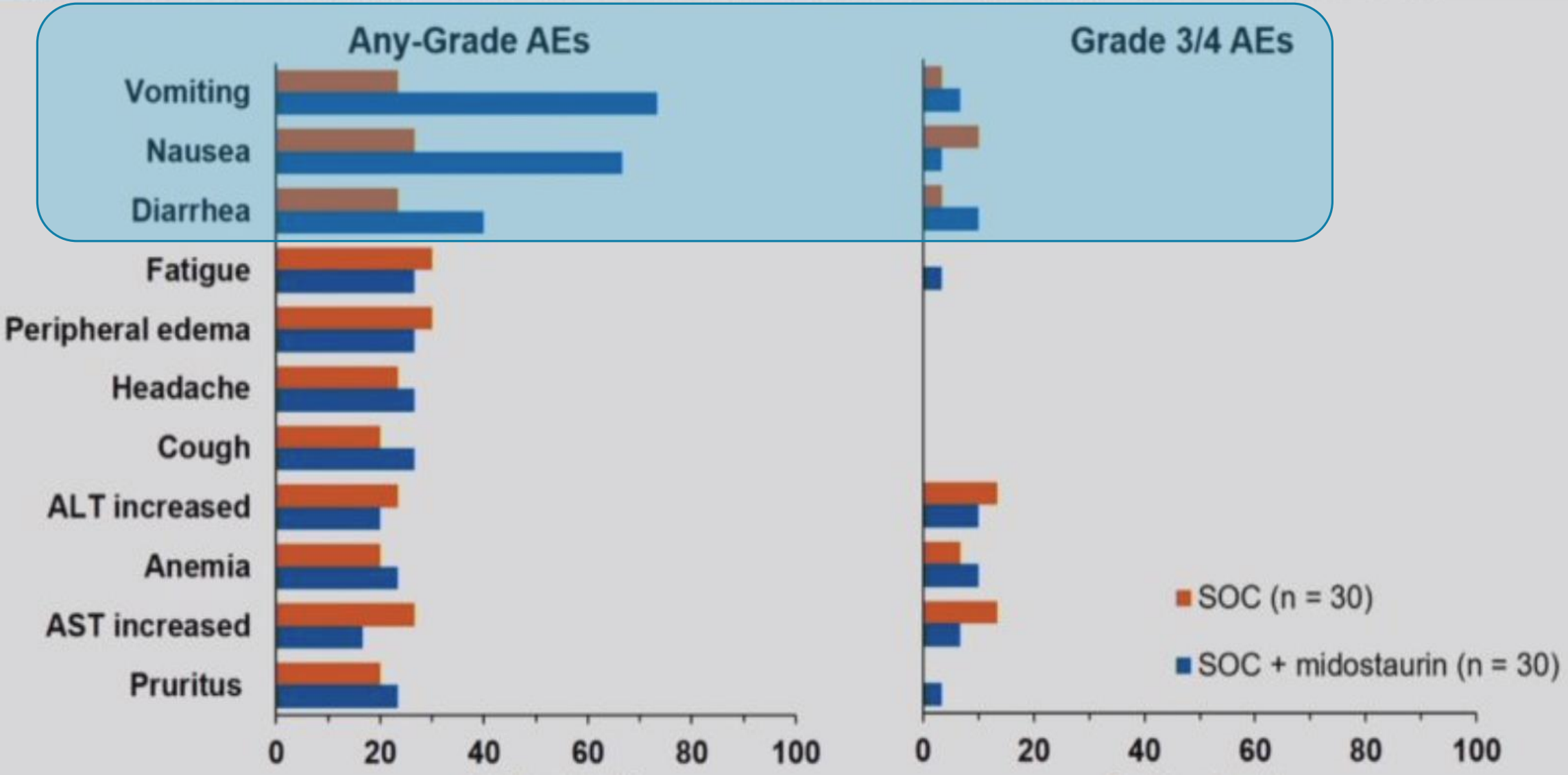


Baseline Patient Characteristics

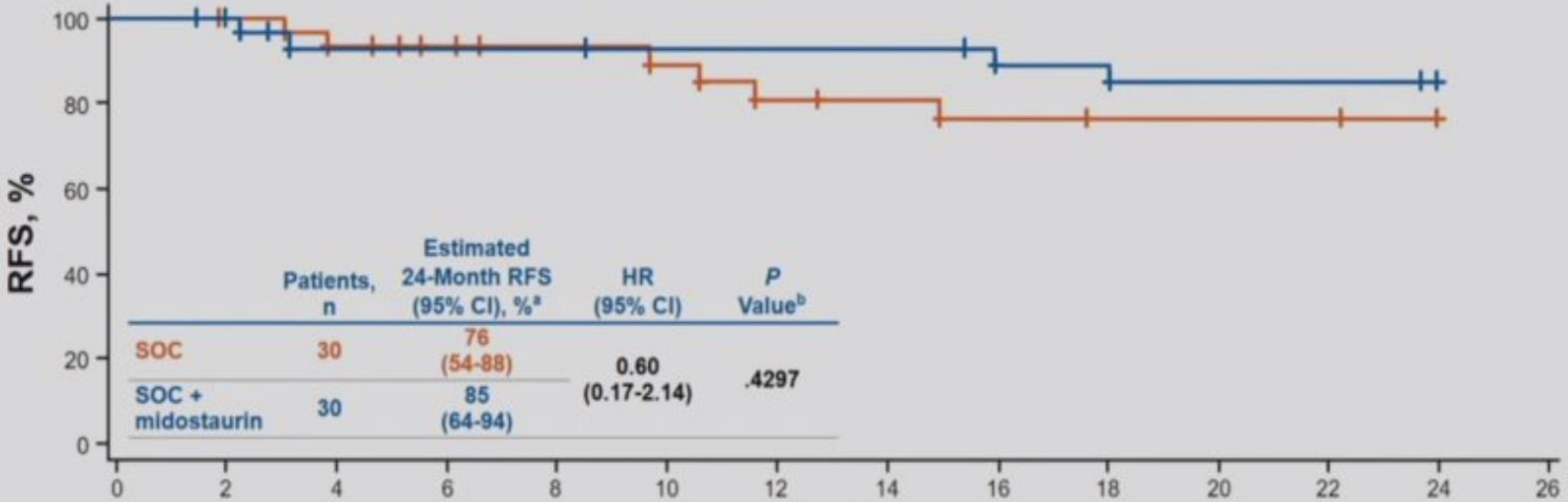
Full Analysis Set		SOC (n = 30)	SOC + Midostaurin (n = 30)
Median age (range), years		56 (20-68)	48 (20-61)
Sex, n (%)	Male	16 (53)	18 (60)
	Female	14 (47)	12 (40)
Race, n (%)	White	27 (90)	27 (90)
	Other	3 (10)	3 (10)
AML status at initial diagnosis, n (%)	De novo	27 (90)	30 (100)
	Secondary to AHD	1 (3)	0
	Therapy related	2 (7)	0
Purpose of pre-HSCT treatment, n (%)	Induction	30 (100)	30 (100)
	Consolidation	22 (73)	20 (67)
	Maintenance	2 (7)	1 (3)

Adverse Events (occurring in ≥ 20% of patients)

The most common any-grade AEs with midostaurin were low-grade gastrointestinal events



Relapse-Free Survival: 24 Months After HSCT

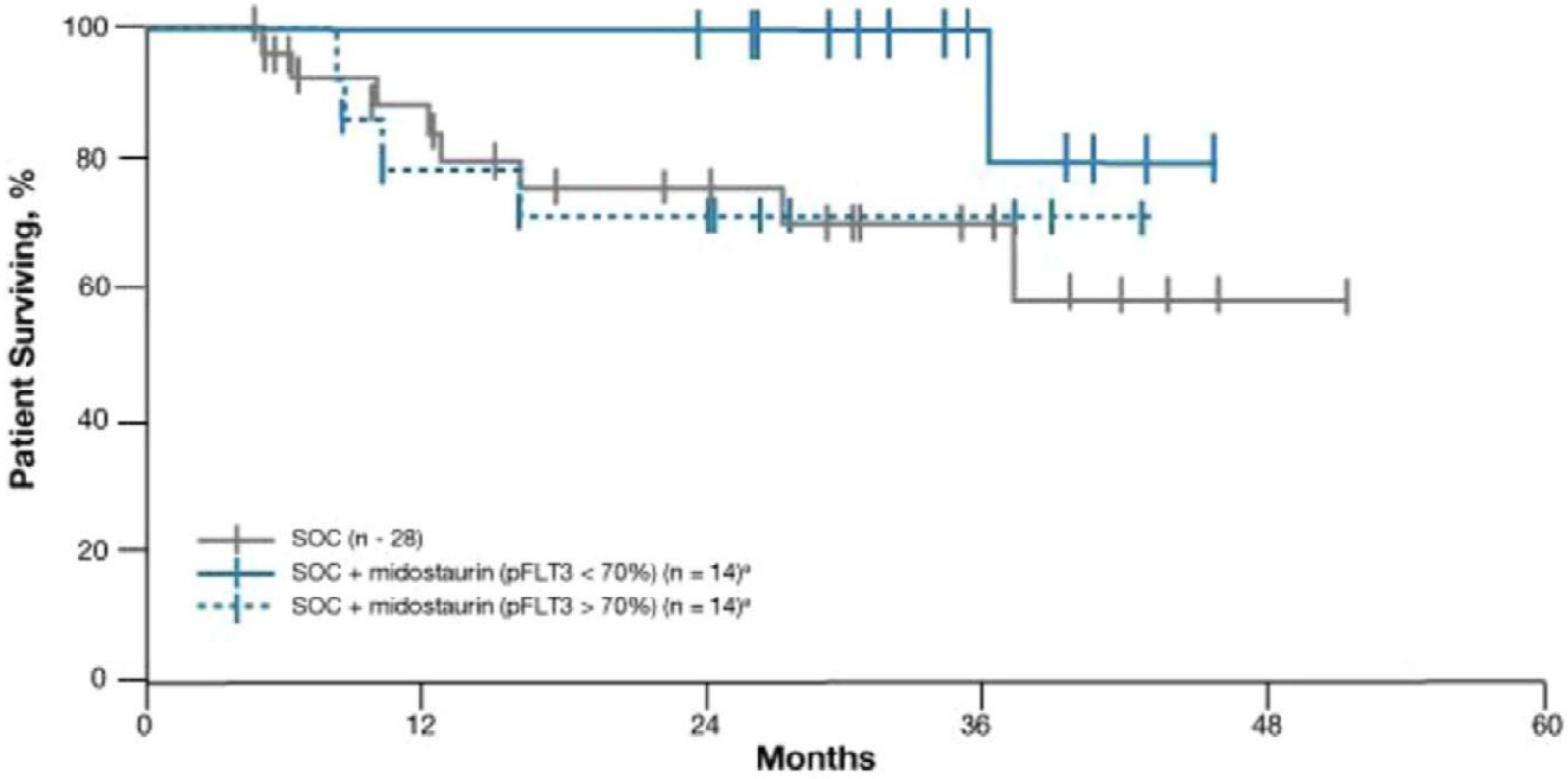


	Patients, n	Estimated 24-Month RFS (95% CI), %[a]	HR (95% CI)	*P* Value[b]
SOC	30	76 (54-88)	0.60 (0.17-2.14)	.4297
SOC + midostaurin	30	85 (64-94)		

No. of Patients at Risk

SOC	30	29	27	24	22	21	19	18	17	16	16	16	15
SOC + midostaurin	30	29	25	25	25	24	24	24	22	22	21	21	20

AML’de FLT İnhibitörleri ile İdame Tedavisi – RADIUS çalışması



[a] Median pFLT3 was 70% of baseline among all patients in the SOC + midostaurin arm. Patients were grouped by the degree of FLT3 inhibition, above (>70%) or below (<70%) of the median. FLT3 inhibition was higher in patients with pFLT3 <70% of baseline.

ÖZET

Tüm Akut Myeloid lösemi hastalarına konsolidasyon tedavisi sonrası idame tedavi önermek elimizdeki veriler ışığında mümkün değildir.

AML'de idame tedavisi çalışmaları genellikle oldukça sınırlı sayıda hastanın oldukça uzun sürelerde dahil edilebildiği, genellikle tek kollu çalışmalardır.

Randomize kontrollü çalışmalar ile idamede rüştünü ispatlayabilmiş ve hatta genel sağkalıma katkıda bulunabilmiş yegane ajanlar FLT3 inhibitörleridir. Özellikle gilteritinib, quizartinib gibi FLT3 inhibitörlerinin idame verilerini mevcut süregiden faz 2/3 çalışmaları ışığında yakın gelecekte görebileceğiz.

Oral Azasitidin'in oldukça iyi bir dizayna sahip faz 3 idame çalışması(Quazar) sürmektedir ve

Newsroom – Published on: September 17, 2019

Celgene Announces Topline Results for Maintenance Therapy in Acute Myeloid Leukemia

Mary Caffrey

Acute myeloid leukemia is the most common acute adult cancer diagnosed in the United States; 61,000 Americans are living with this disease and more than 10,000 will die of it this year.

Celgene Corporation has announced achievement of primary and secondary end points in a phase 3 study of an investigational therapy for maintenance of patients with newly diagnosed acute myeloid leukemia (AML) who achieve a complete response or a complete response with incomplete blood count recovery with induction chemotherapy.

The study, QUAZAR AML-001, of the therapy CC-486, showed that the maintenance therapy resulted in highly statistically significant and clinically meaningful improvement in overall survival compared with placebo. In addition, the study met the key secondary end point of relapse-free survival and also showed statistically significant improvement, according to a statement from the company.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