Polska a Europa – w drodze do nowoczesnych standardów

Sytuacja chorych na białaczki

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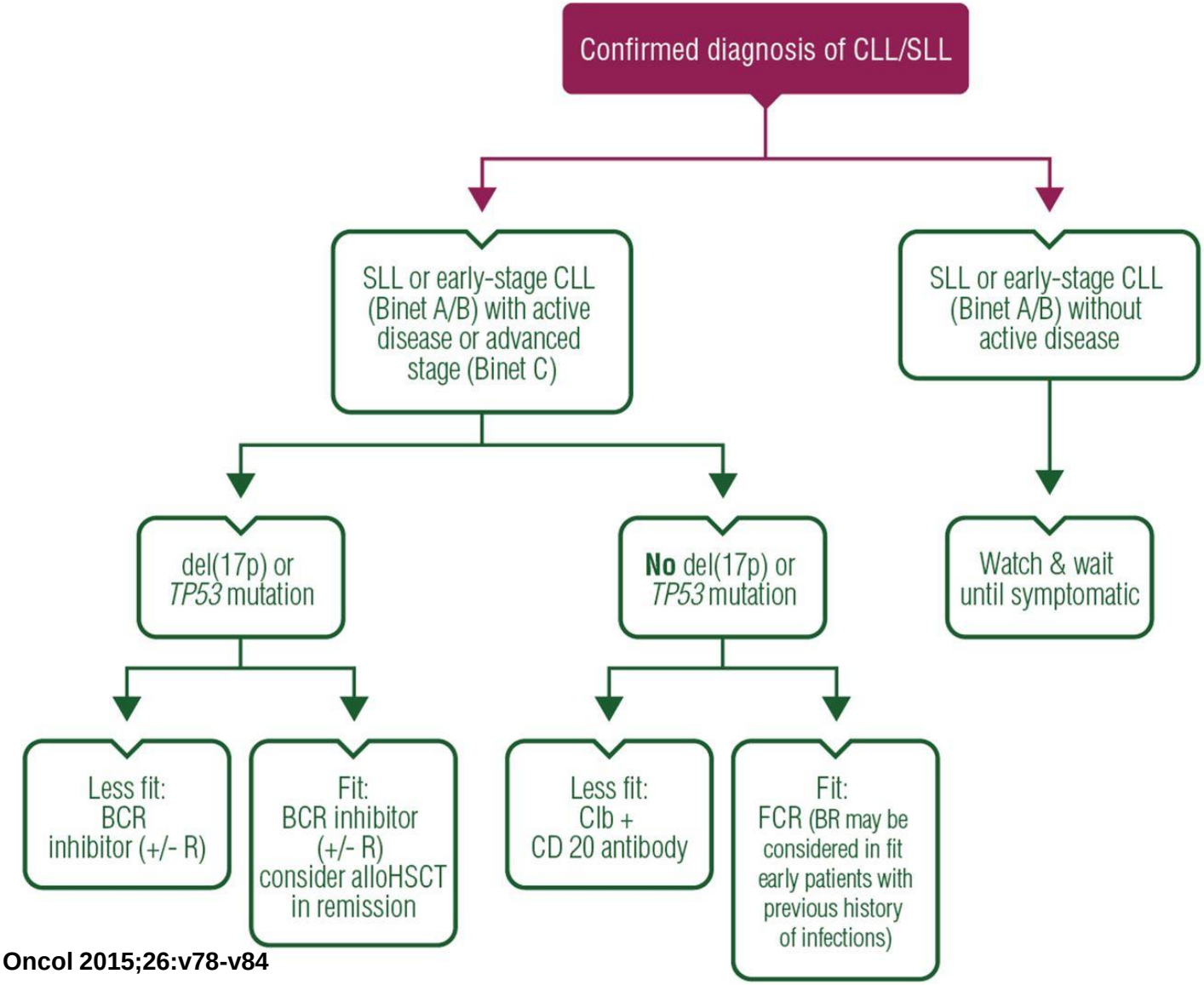
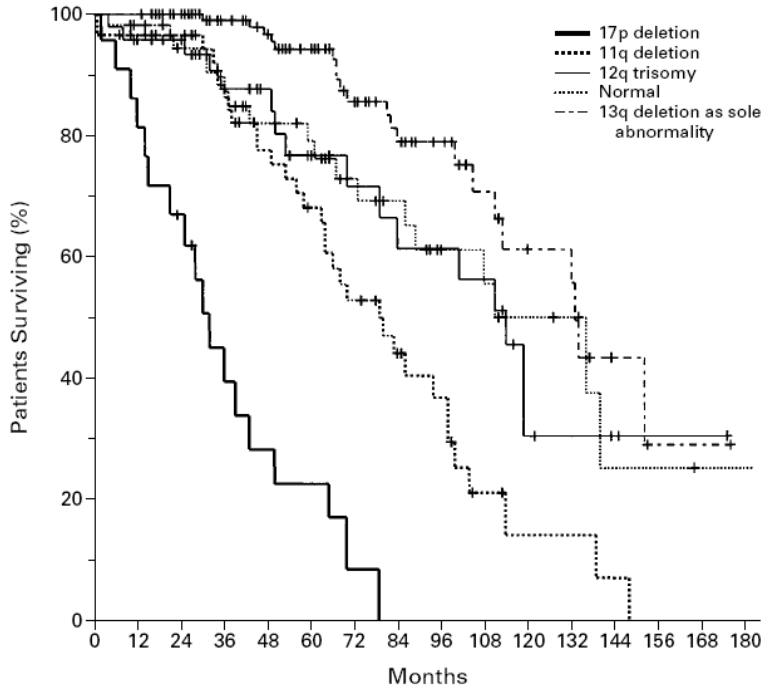
Oddział Hematologiczny COZL

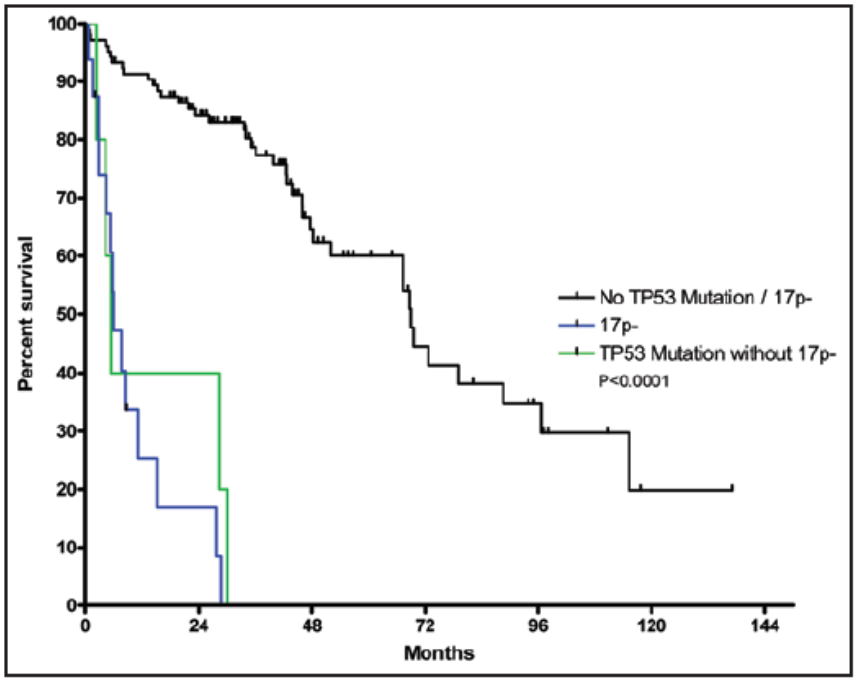
Leczenie pierwszej linii – wytyczne ESMO 2015



B. Eichhorst et al. Ann Oncol 2015;26:v78-v84

Delecja 17p i mutacja *TP53* charakteryzuje grupę chorych PBL o najgorszym rokowaniu

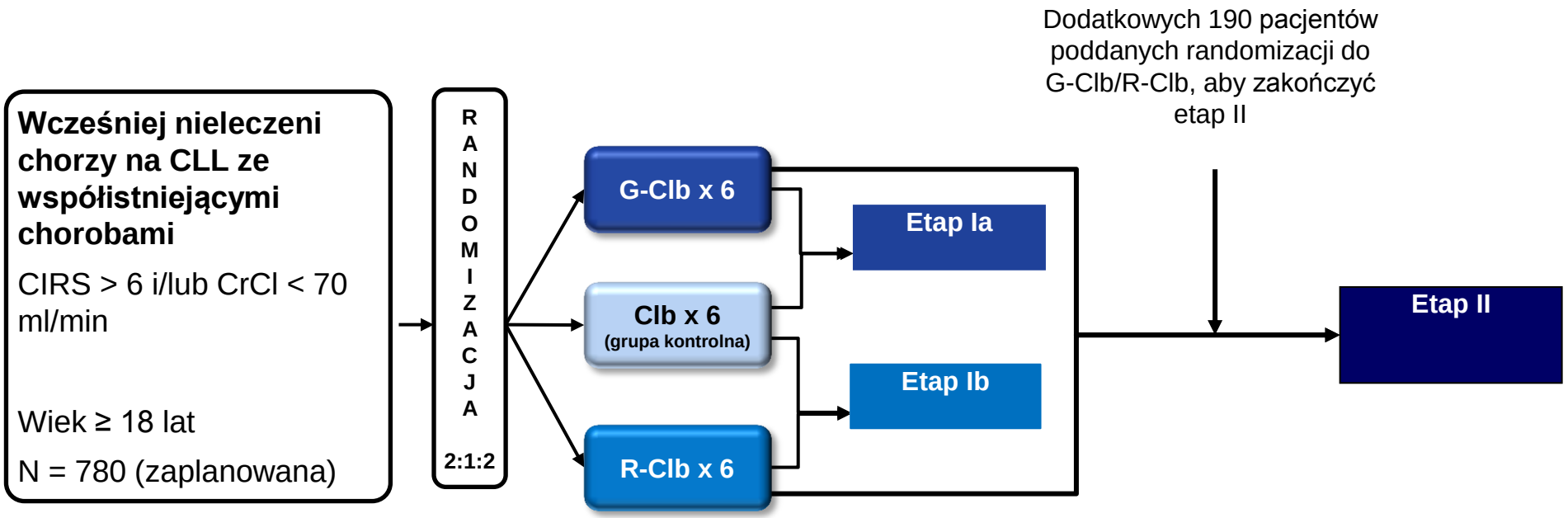




Dohner et al. NEJM 2000

Zenz i wsp. *Cell Cycle* 2008

Schemat badania CLL11

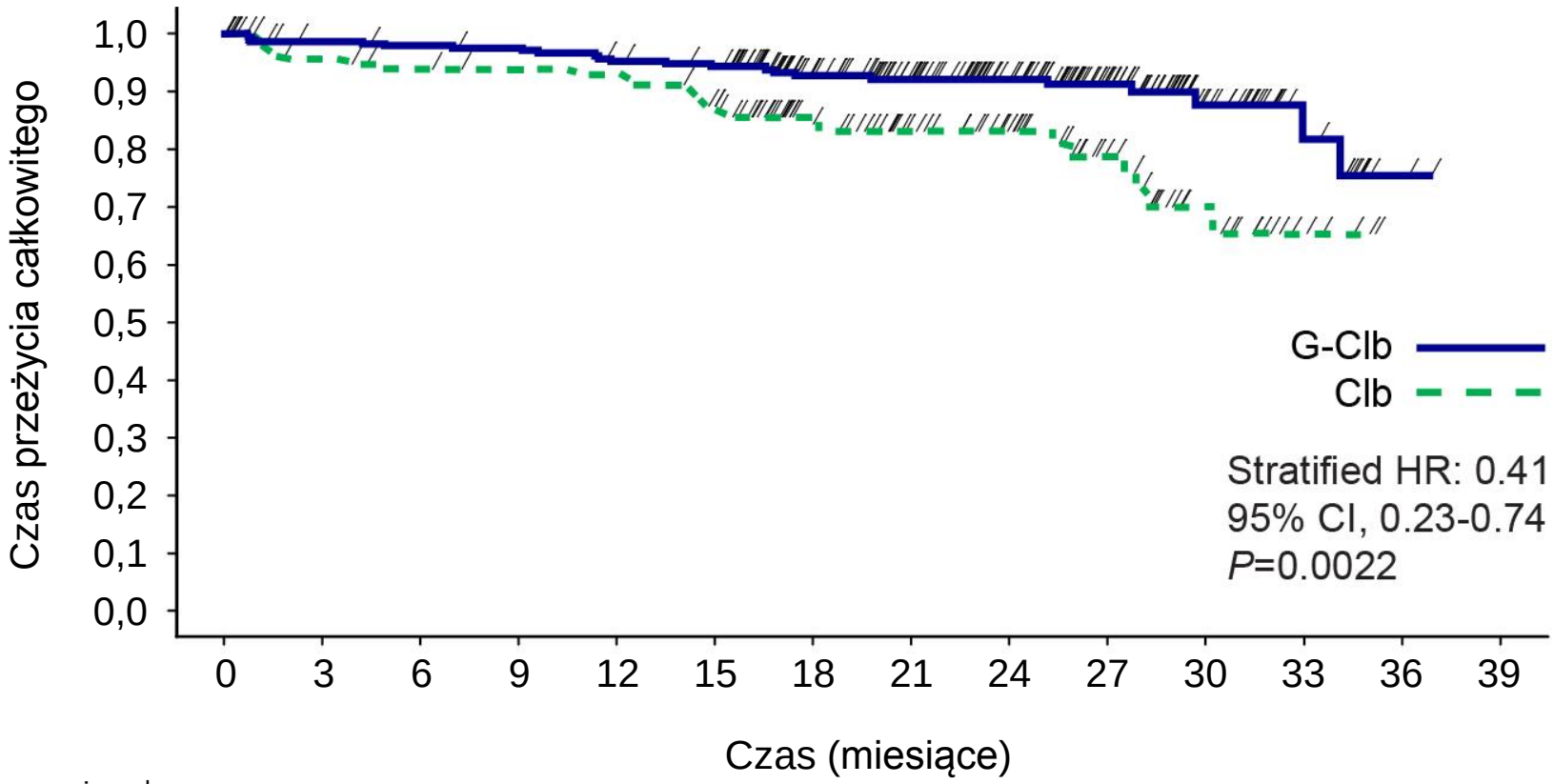


Pacjenci z CrCl < 30 ml/min lub niewystarczającą czynnością wątroby byli wykluczeni

Pacjenci z PD w grupie Clb mogli przejść do grupy G-Clb

Goede V i wsp. N Engl J Med; 2014; 12; 1101-1110

Czas przeżycia całkowitego jest istotnie dłuższy w grupie G-Clb vs Clb



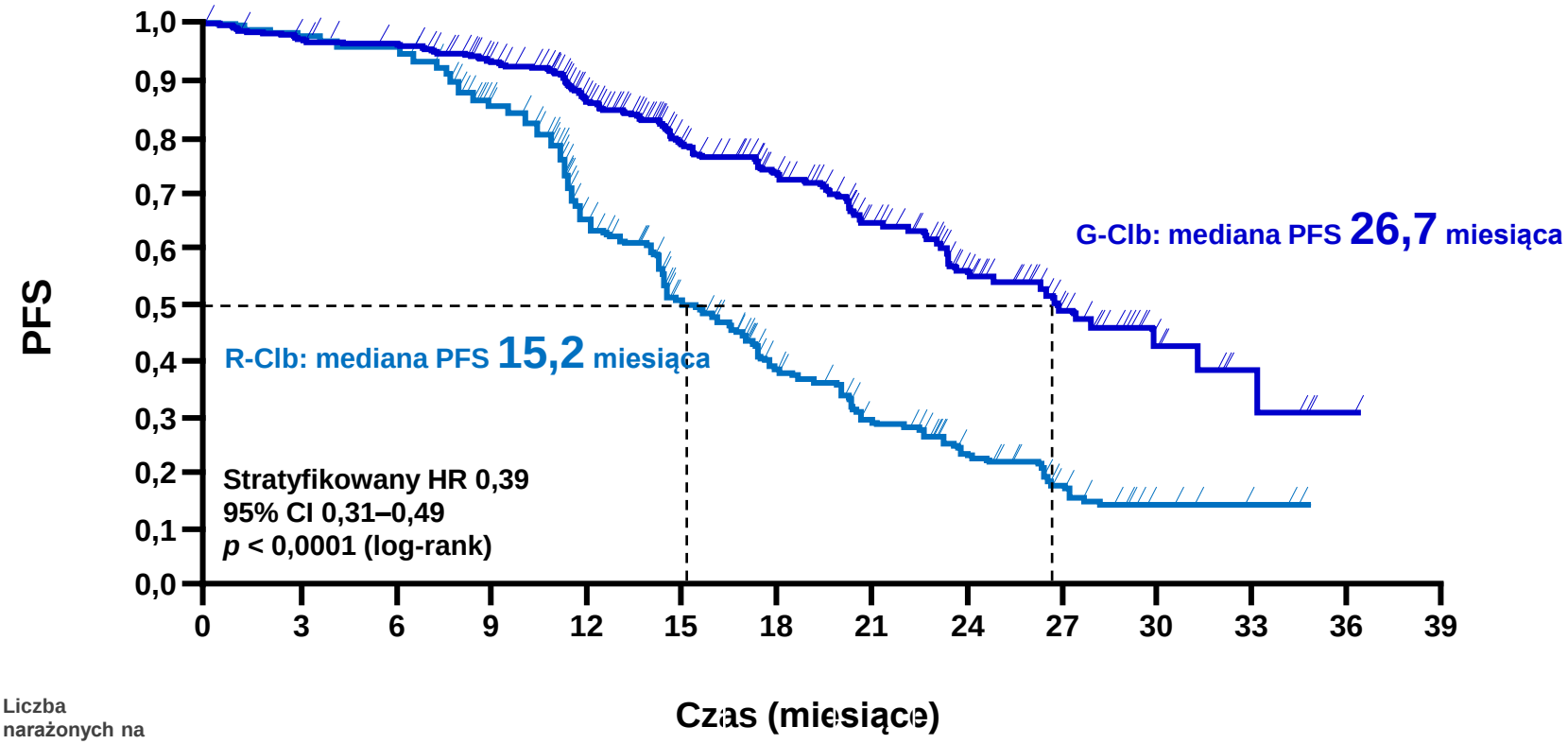
Liczba narażonych na ryzyko

G-Clb:	238	226	223	221	215	211	170	144	115	71	34	14	2	0
Clb:	118	109	105	103	102	94	70	56	44	29	15	5	0	0

Całkowita liczba zgonów: G-Clb, 22 (9%); R-Clb, 24 (20%)

Goede V i wsp. N Engl J Med; 2014; 12; 1101-1110

Redukcja ryzyka progresji w grupie G-Clb o 61% w porównaniu do R-Clb

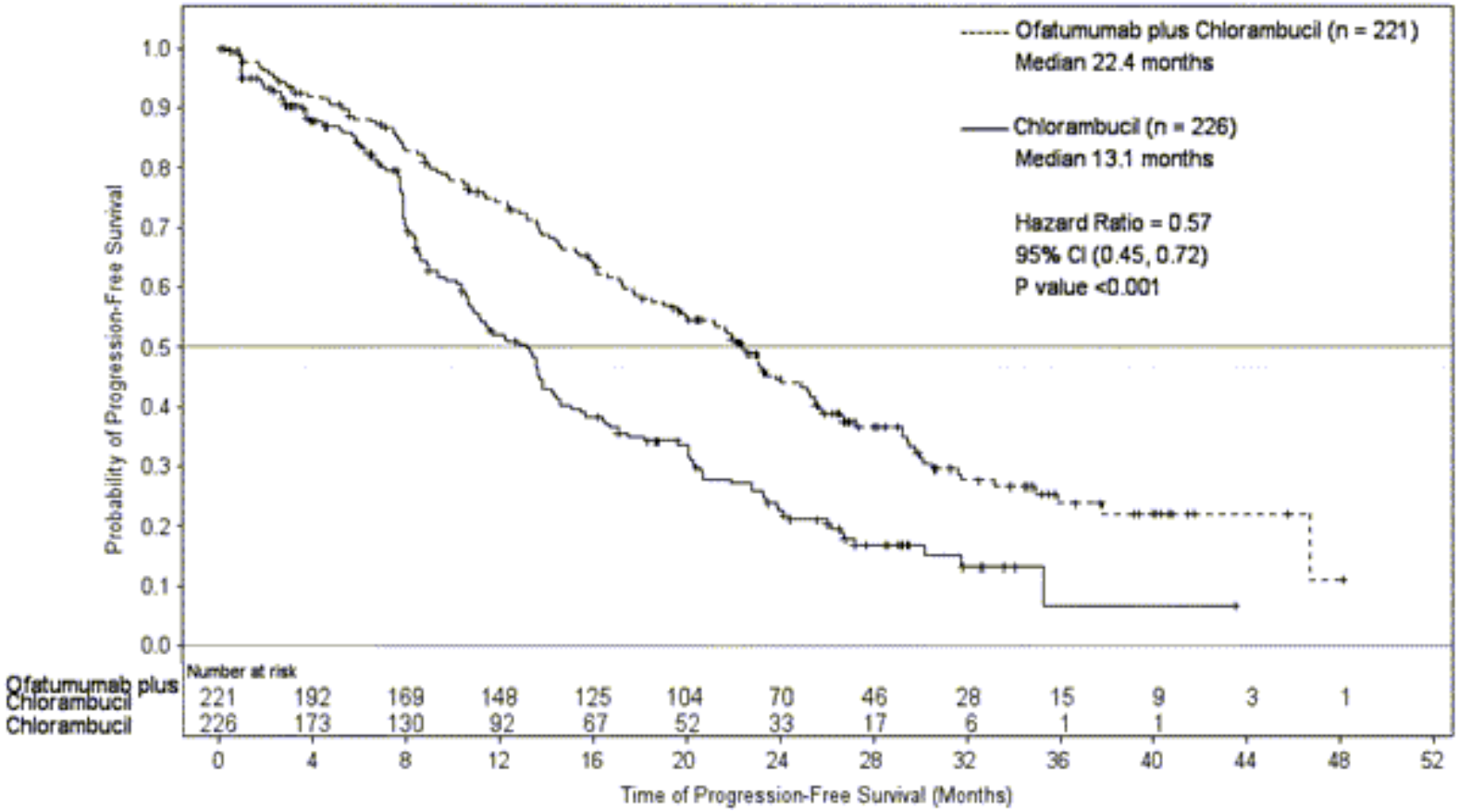


Liczba narażonych na ryzyko														
R-Clb	330	317	309	259	163	114	72	49	31	14	5	2	0	0
G-Clb	333	307	302	278	213	156	122	93	60	34	12	4	1	0

HR (ang. hazard ratio) = iloraz hazardu

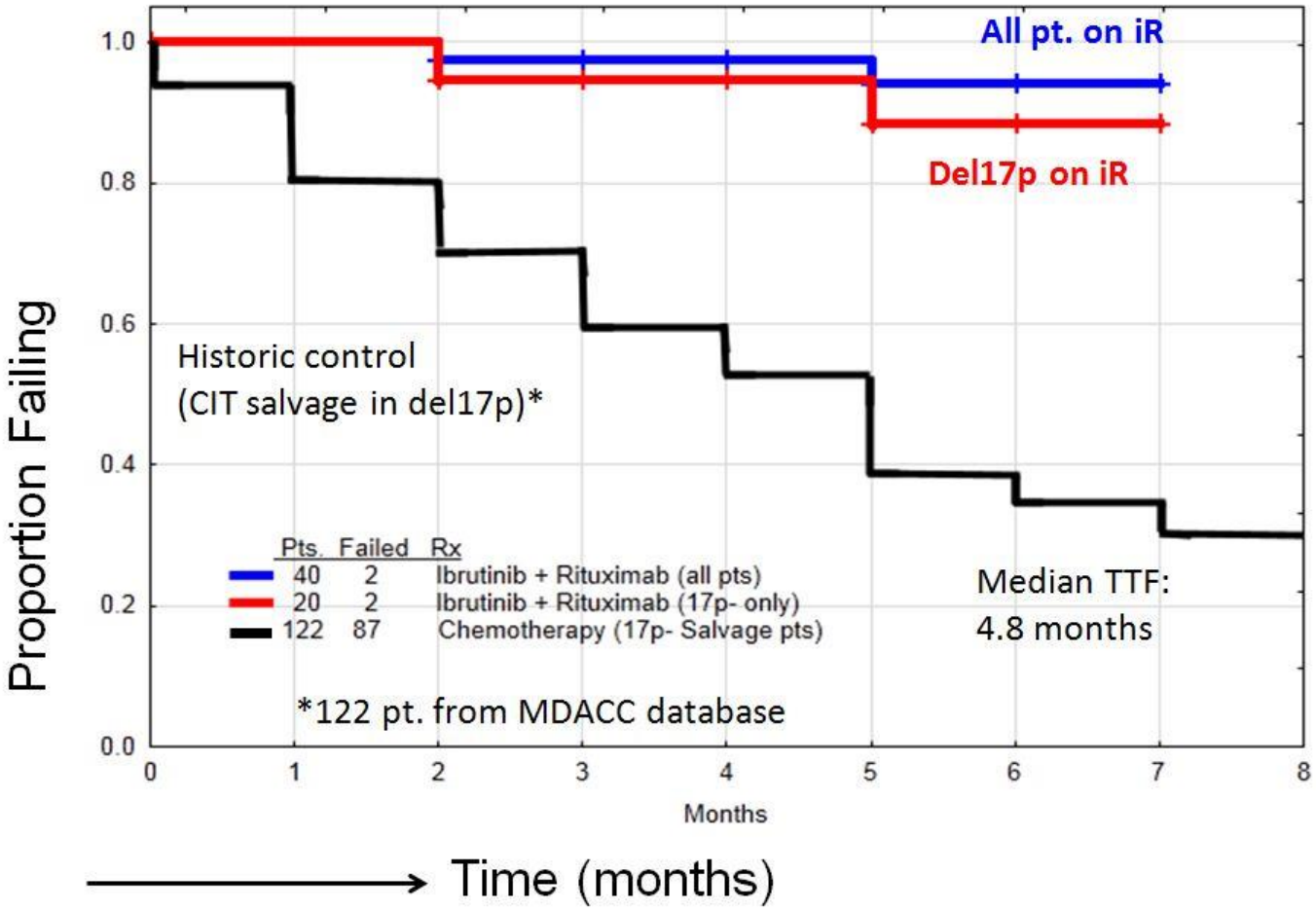
Goede V i wsp. N Engl J Med; 2014; 12; 1101-1110

Ofatumumab + chlorambucil jako skuteczna opcja terapeutyczna dla chorych PBL



Hillmen P i wsp. Lancet 2015

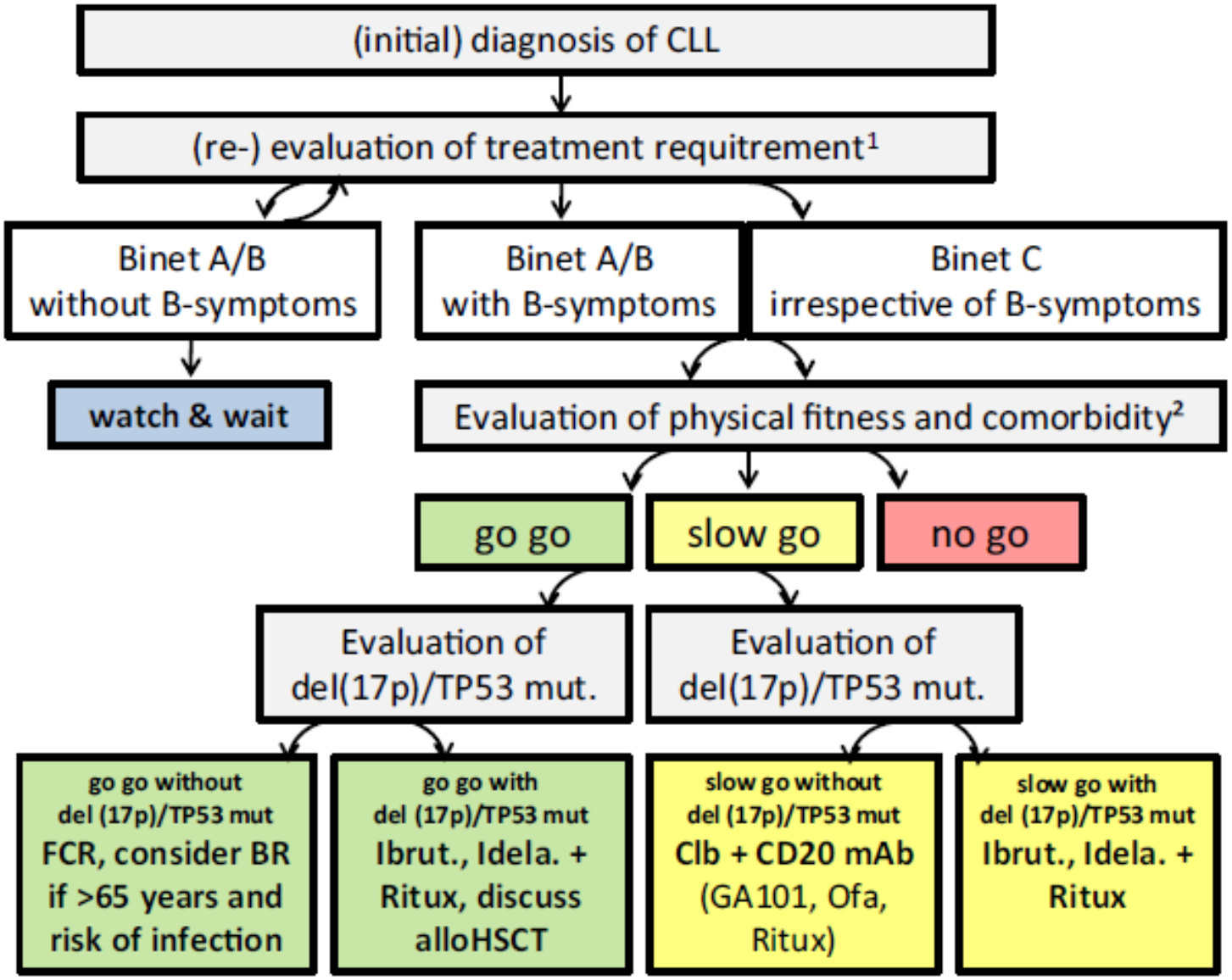
Badanie fazy II zmieniające standard leczenia



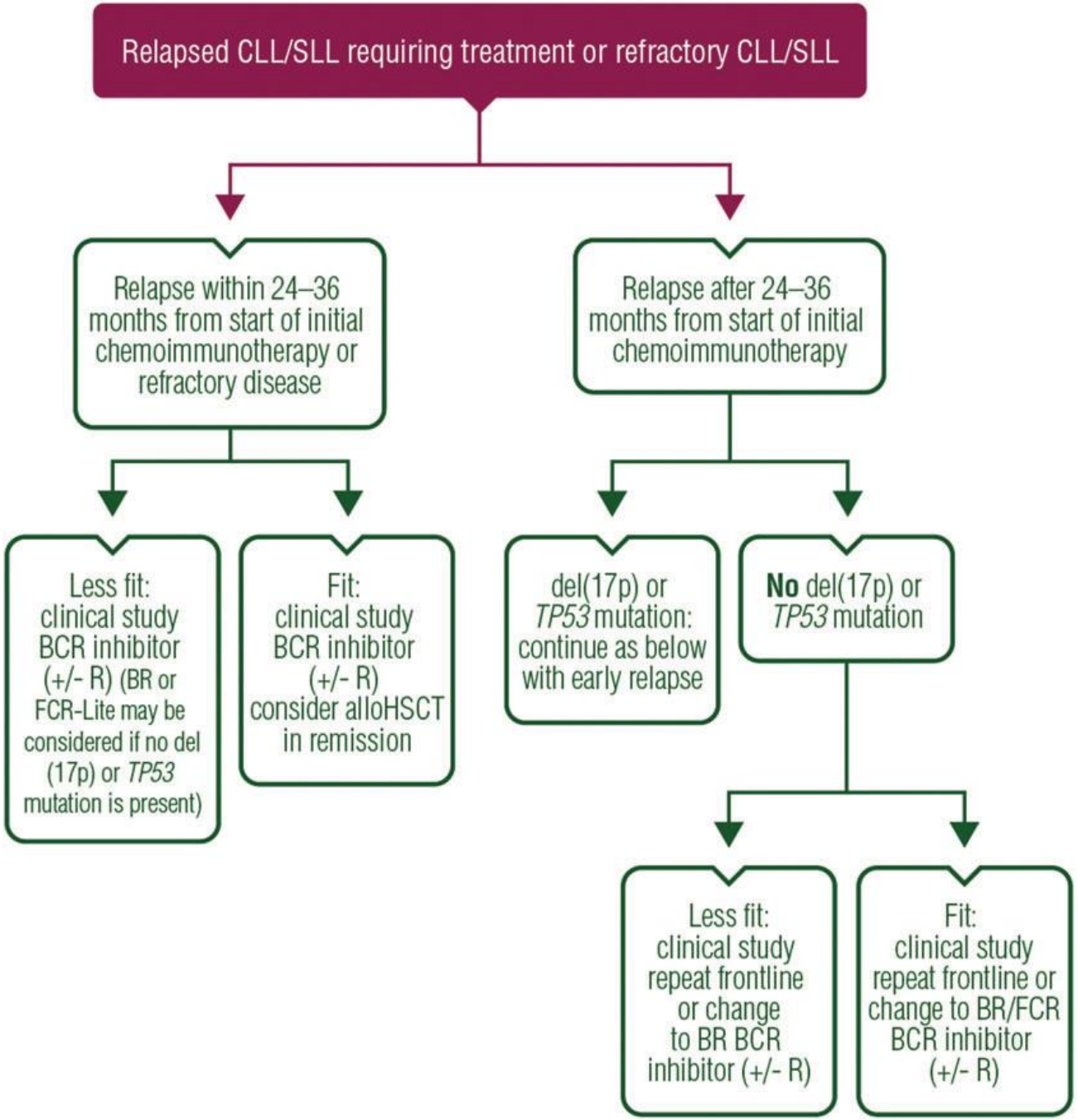
Therapeutic algorithm of the GCLLSG

(August 2015)

DEUTSCHE STUDIENGRUPPE

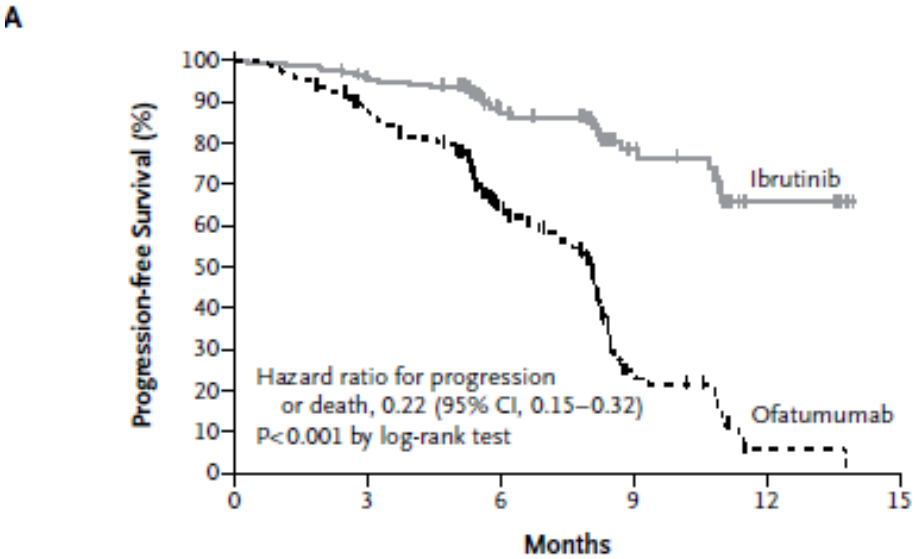


References: [1]) Hallek et al., Blood 2008
[2]) Gribben, Blood 2009

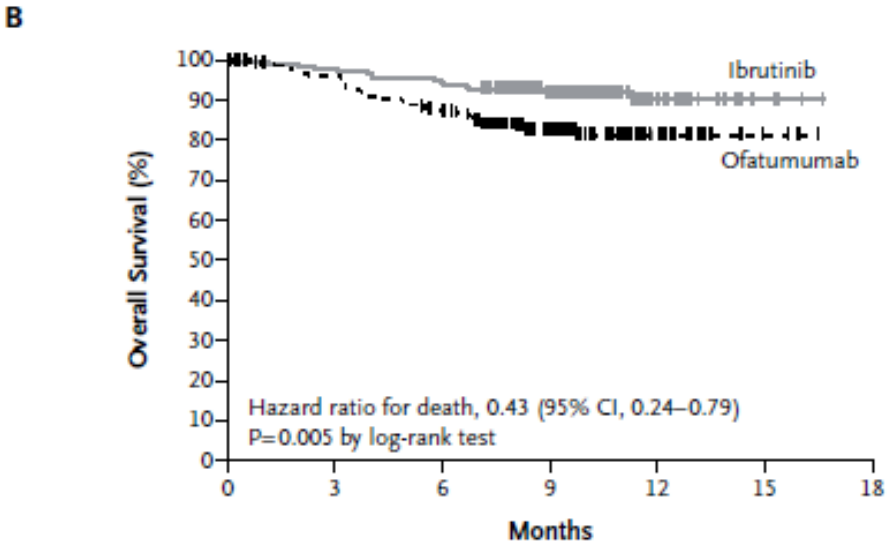


B. Eichhorst et al. Ann Oncol 2015;26:v78-v84

Ibrutinib przedłuża życie chorym w nawrocie przewlekłej białaczki limfocytowej



No. at Risk						
Ibrutinib	195	183	116	38	7	
Ofatumumab	196	161	83	15	1	0



No. at Risk						
Ibrutinib	195	191	184	115	32	5
Ofatumumab	196	183	164	88	21	3

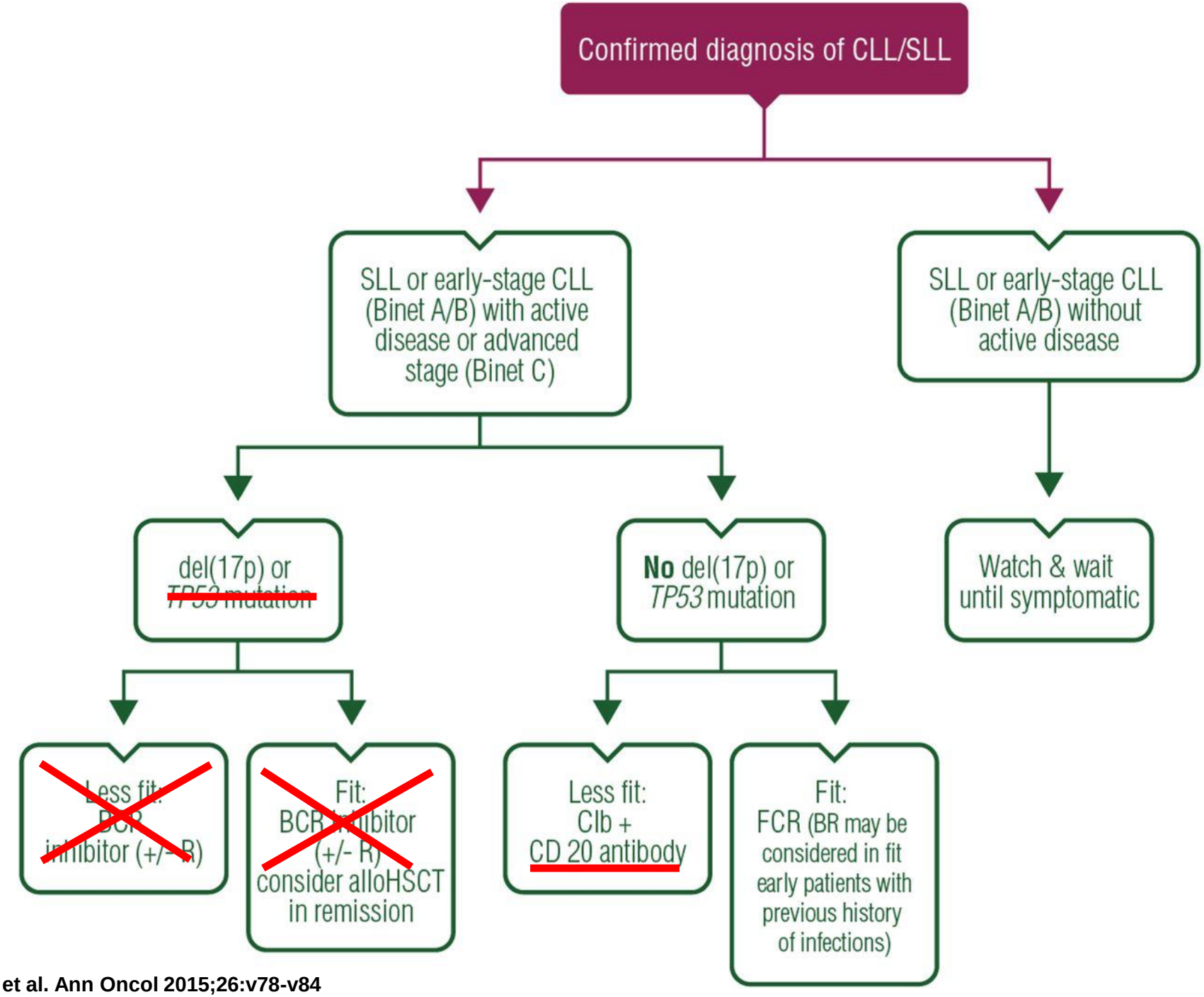
Byrd J i wsp. NEJM 2014

Idelalizyb + Rytuksymab jako skuteczne leczenie nawrotu PBL

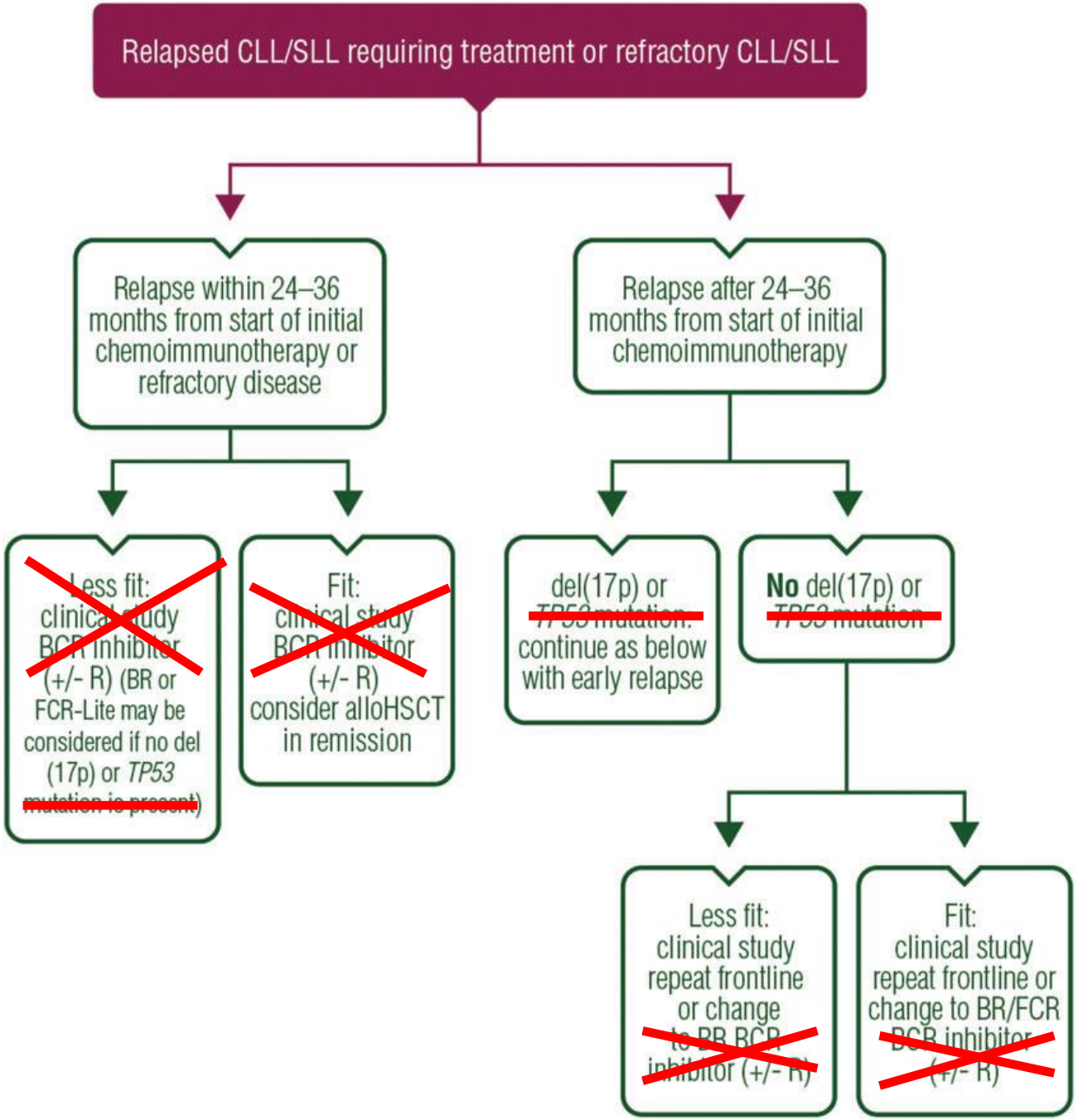
	Idelalisib + R (n = 110)	Placebo + R (n = 110)	Hazard ratio (HR)	*p*-value
Median PFS	Not reached	5.5 mo	0.15	<0.001
24-week PFS	93%	46%	—	—
Median OS	Not reached	Not reached	0.28	0.02
12-month OS	92%	80%	—	—

- Disease progression occurred in 12 patients in the idelalisib group and 53 patients in the placebo group.

Furman RR et al. *N Engl J Med* 2014;[Epub ahead of print].



B. Eichhorst et al. Ann Oncol 2015;26:v78-v84



B. Eichhorst et al. Ann Oncol 2015;26:v78-v84

Przewlekła białaczka szpikowa – leczenie rekomendacje European Leukemia Net

First line

Imatinib ~~or nilotinib or dasatinib~~

HLA type patients and siblings only in case of baseline warnings (high risk, major route CCA/Ph+)

Second line, intolerance to the first TKI

Anyone of the other TKIs approved first line (imatinib, nilotinib, dasatinib)

Second line, failure of imatinib first line

Dasatinib or nilotinib or ~~bosutinib or ponatinib~~

HLA type patients and siblings

Second line, failure of nilotinib first line

Dasatinib or ~~bosutinib or ponatinib~~

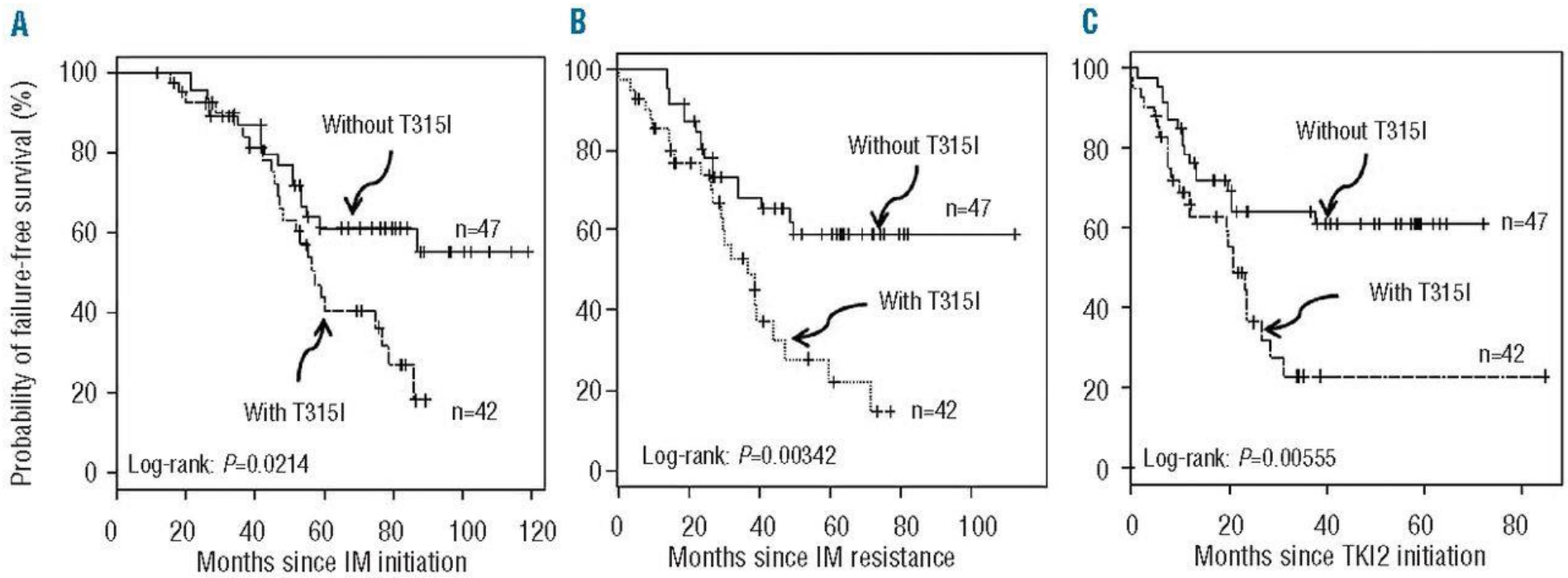
HLA type patients and siblings; search for an unrelated stem cell donor; consider alloSCT

Second line, failure of dasatinib first line

Nilotinib or ~~bosutinib or ponatinib~~

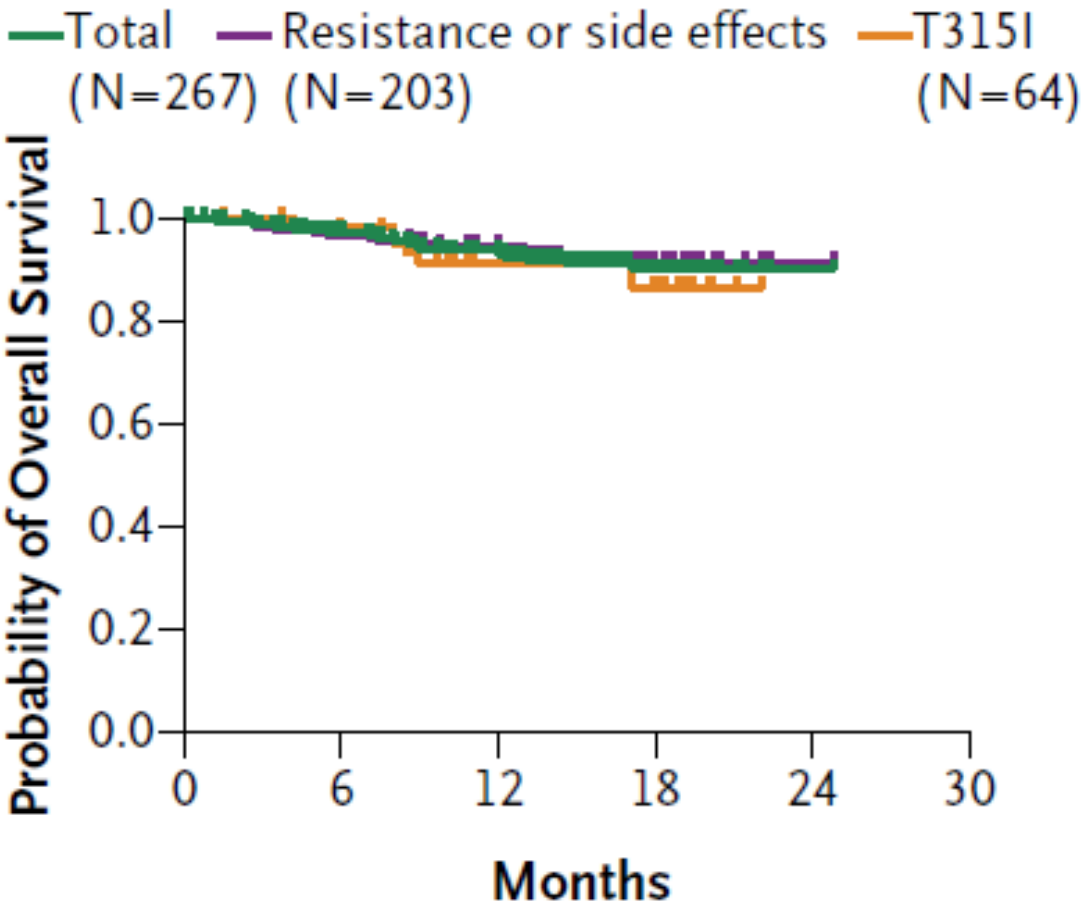
HLA type patients and siblings; search for an unrelated stem cell donor; consider alloSCT

Mutacja T315I wskazuje na oporność na inhibitory kinaz tyrozynowych



Nicolini F i wsp. Haematologica 2013

Ponatynib jest jedynym lekiem aktywnym u chorych PBSz z mutacją T315I



Cortes J i wsp. NEJM 2013

Przewlekła białaczka szpikowa – leczenie rekomendacje European Leukemia Net

Third line, failure of and/or intolerance to 2 TKIs

Anyone of the remaining TKIs; alloSCT recommended in all eligible patients

Any line, T315I mutation

~~Ponatinib~~

HLA type patients and siblings; search for an unrelated stem cell donor; consider alloSCT