

Aktuelle Therapiestrategien beim peripheren T-NHL

16.1.2009, Hannover

Bertram Glass
Asklepios Klinik St.Georg, Hamburg
Abteilung Hämatologie und Stammzelltransplantation



B. Glass

Mature (peripheral) T-NHL

Histologic Subtypes

Adult T-cell lymphoma/leukemia (HTLV1+)

Aggressive NK-cell leukemia

T-cell granular lymphocytic leukemia

Anaplastic large cell lymphoma, T/null cell primary systemic type (ALCL)

Anaplastic large cell lymphoma, T/null cell primary cutaneous type

Angioimmunoblastic T-cell lymphoma

Peripheral T-cell lymphoma, not otherwise characterised (PTL)

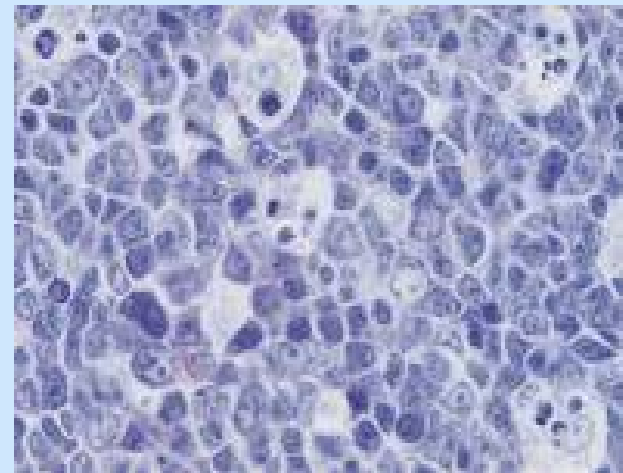
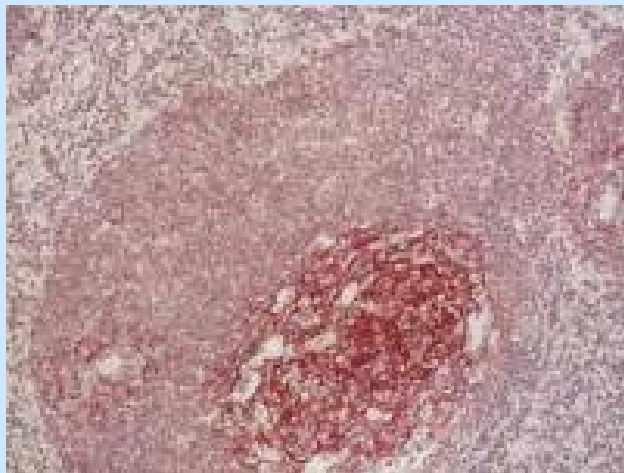
Mycosis fungoides / Sezary syndrome

Subcutaneous panniculitis-like T-cell lymphoma

Hepatosplenic gamma-delta T-cell lymphoma

Enteropathy-type T-cell lymphoma

Extranodal NK/T-cell lymphoma



Prognostic factors in aggressive N HL

Histology: T-N HL

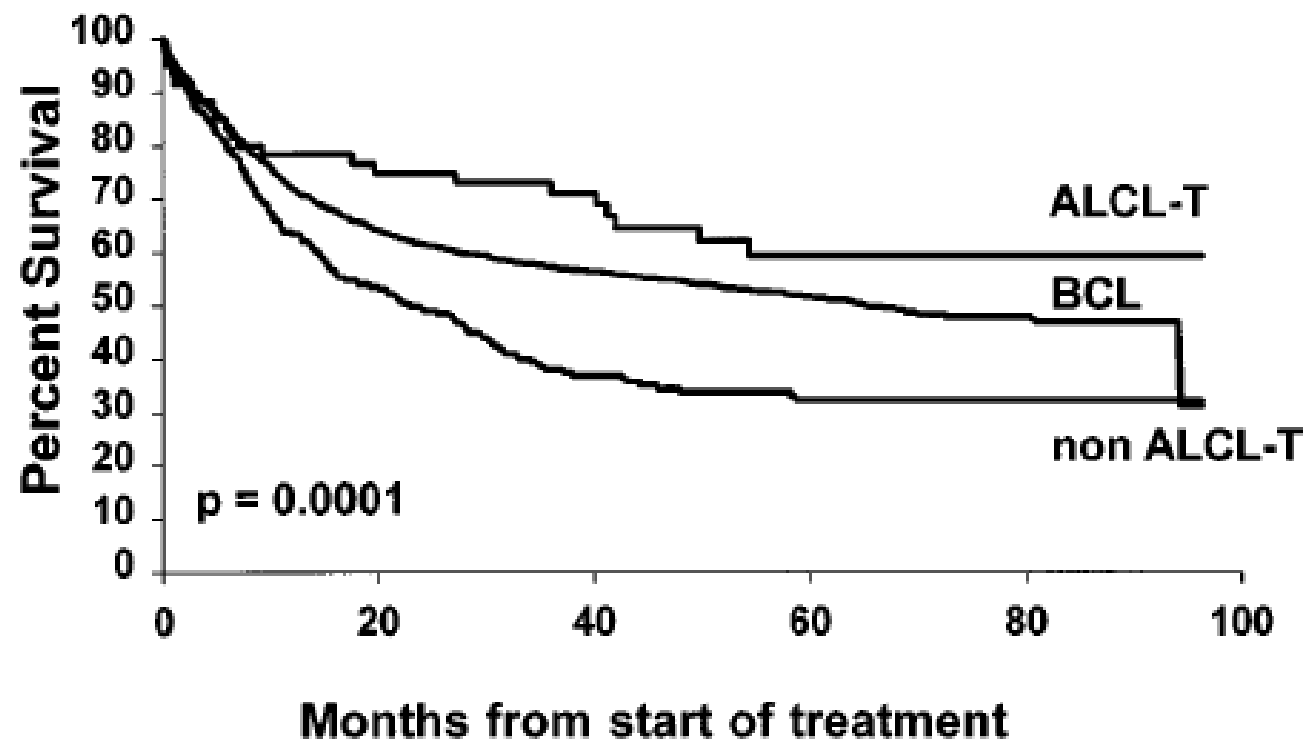
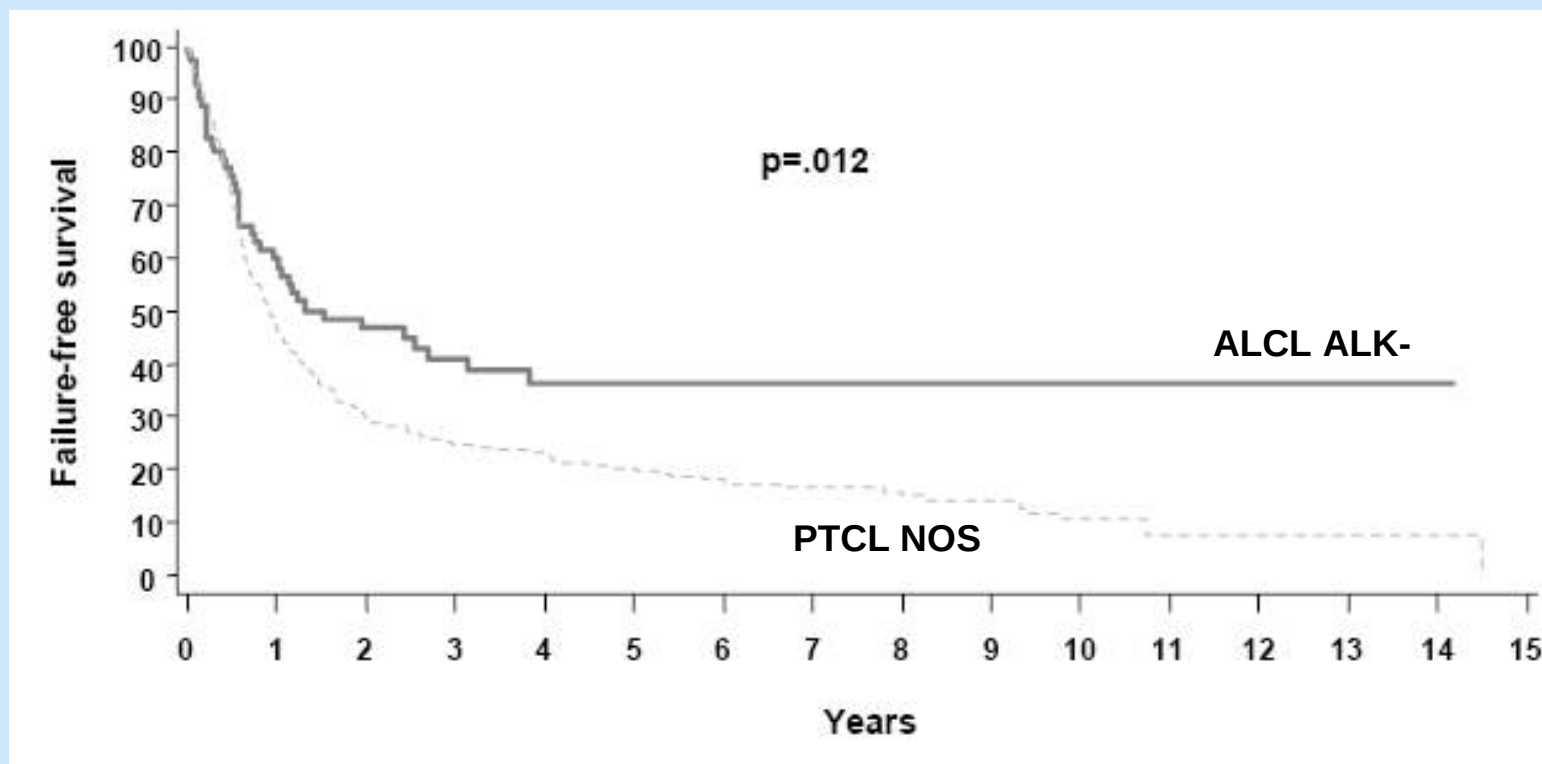


Fig 2. Overall survival of 228 non-ALCL cell and 60 T-ALCL lymphoma patients compared with 1,595 diffuse BCL patients.

Prognostic factors in aggressive T-N HL

Is ALCL ALK- better than PTCL-NOS ?



Savage et al., Blood online (2008)
doi:10.1182/blood-2008-01-134270



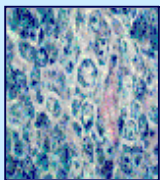
B. Class

9.1.2009

T-CELL LYMPHOMAS

in Studies of the German High-Grade Lymphoma Study Group

**N. Schmitz, M. Ziepert, M. Nickelsen,
L. Trümper, B. Glass,
M. Löffler, A. Ho, B. Metzner, N. Peter,
M. Pfreundschuh**

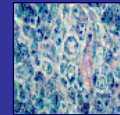


December 5, 2008
GERMAN HIGH-GRADE NHL STUDY GROUP (DSHNHL)

T-cell lymphomas in DSH NHL trials

Histologic subtypes by reference pathology (n=329)

DSHNHL



	n	%	
ALC/ALK+	73	22.2	} 58.3%
ALC/ALK-	108	32.8	
ALC/ALK unknown	11	3.3	
PTCL	68	20.7	
AITL	28	8.5	
T/NK	18	5.5	
Lymphoblastic	7	2.1	
Intestinal T/NK	2	0.6	
Hepatosplenic $\gamma\delta$	2	0.6	
Subcutaneous panniculitis-like	1	0.3	
T-cell, NOS	8	2.4	
T-cell, subtype technically not possible	3	0.9	

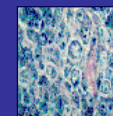


B. Class

T-cell lymphomas in DSH NHL trials

Which patient from which trial? (n=329)

DSH NHL



trial	n	age	LDH	IPI	treatment
NHL-B1	98	18-60	= N	all aalPI	CHO(E)P-14 or -21
NHL-B2	40	61-75	all	all IPI > 0	CHO(E)P-14 or -21
High/CHOEP phase II	13	18-60	all*	all aalPI	hi-CHOEP-21 vs. hi-CHOEP-14
High/CHOEP phase III	61	18-60	all	aalPI 0,1	hi-CHOEP-21 vs. CHOEP-21
Mega/CHOEP phase II	33	18-60	> N	all aalPI > 0	MegaCHOEP dose escalation
Mega/CHOEP phase III	25	18-60	all	aa IPI 2,3	MegaCHOEP vs. CHOEP-14
RICOVER-60	59	61-80	all	all IPI > 0	6 x CHOP-14 vs. 8 x CHOP-14

* LDH > N, any LDH after amendement

recruitment period: Oct 1993 - Feb 2006
 median observation time: 43 months

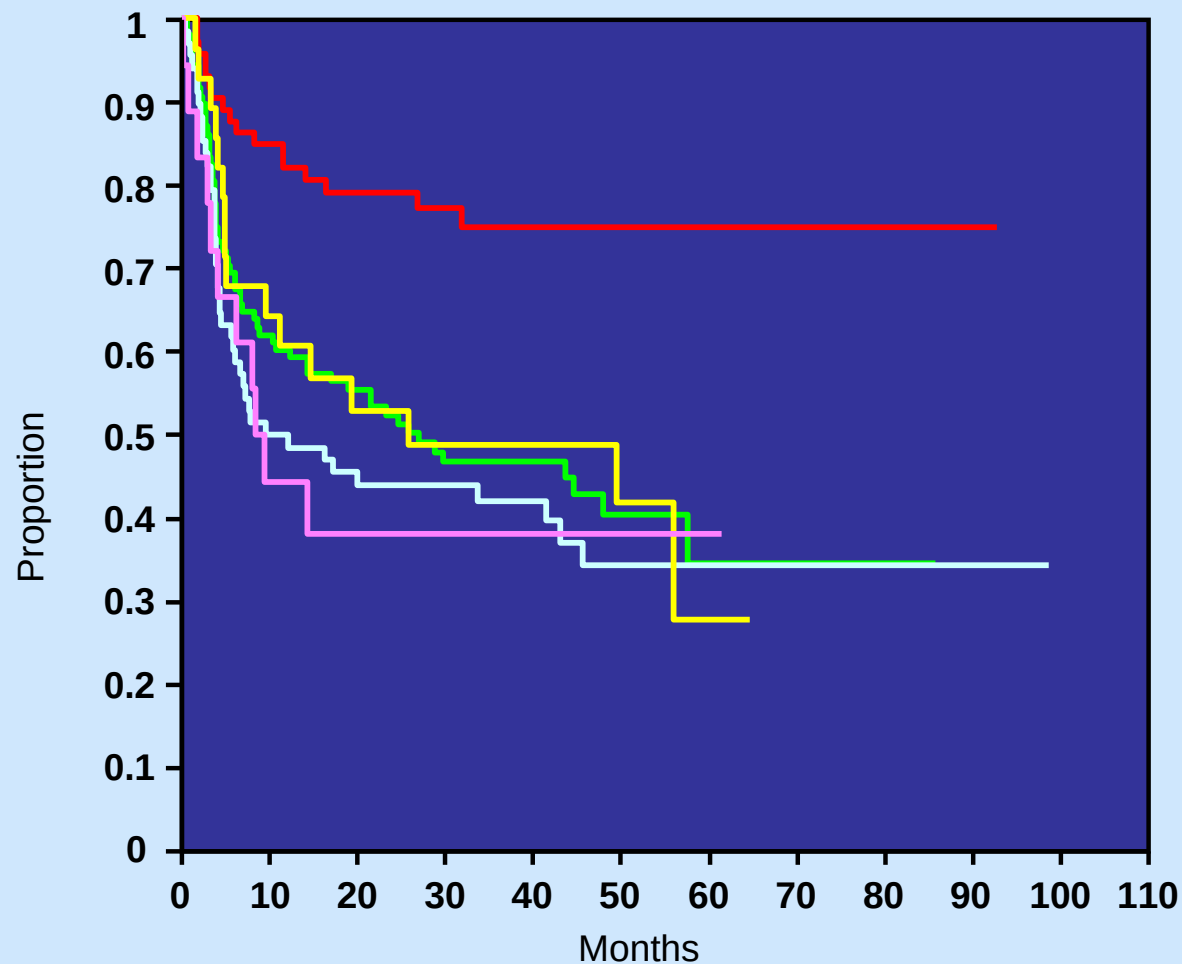
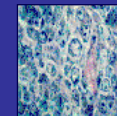


B. Class

T-cell lymphomas in DSH NHL trials

Event-free survival - histological subtypes (n=295)

DSHNHL



- 1: ALK+ (n= 73)
- 2: ALK- (n= 108)
- 3: PTCL (n= 68)
- 4: AILT (n= 28)
- 5: T/NK (n= 18)

p-values:

	2	3	4	5
1	<0.001	<0.001	0.001	<0.001
2		0.361	0.897	0.468
3			0.468	0.947
4				0.494

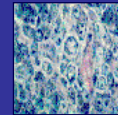


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ALK-negative and other T-cell lymphomas

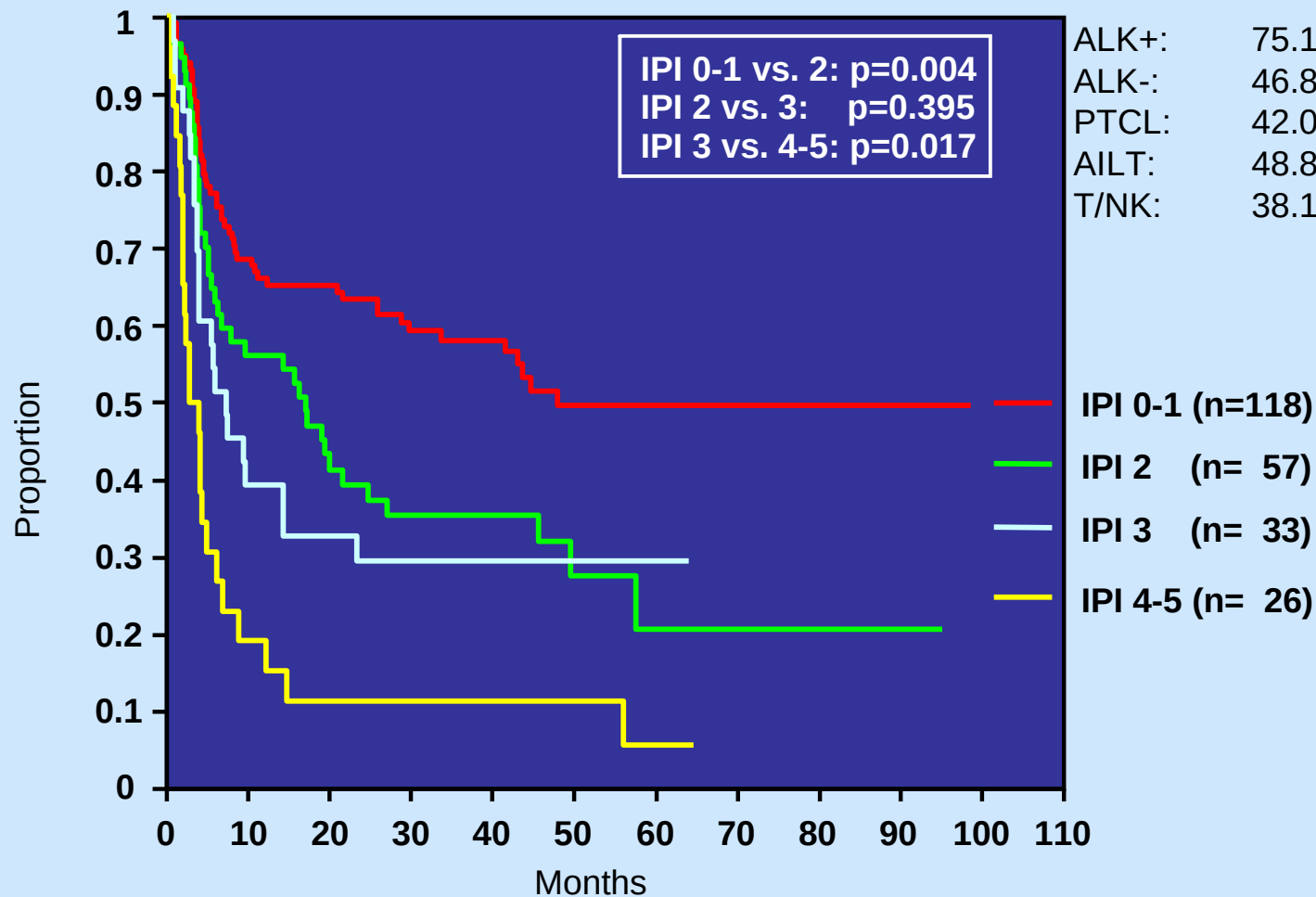
Event-free survival according to IPI score (n=234)

DSHNHL



EFS 3y

ALK+: 75.1% (95% CI: 64.5%-85.7%)
ALK-: 46.8% (95% CI: 37.2%-56.4%)
PTCL: 42.0% (95% CI: 30.0%-54.0%)
AITL: 48.8% (95% CI: 29.8%-67.8%)
T/NK: 38.1% (95% CI: 15.4%-60.8%)

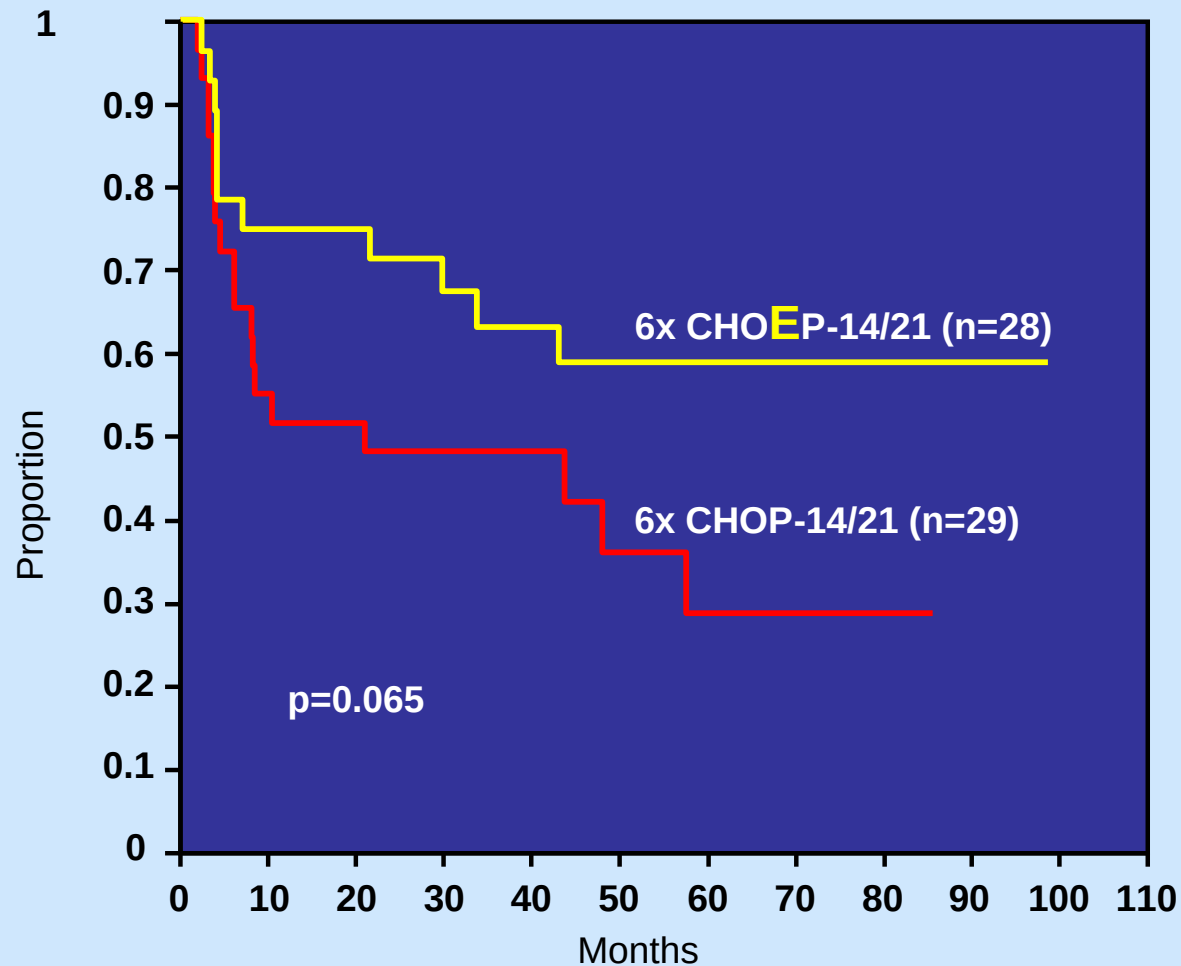
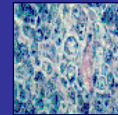


B. Class

ALK-negative and other T-cell lymphomas

NHL-B1 trial (= 60 years, LDH = N, n=57), EFS: role of etoposide

DSHNHL

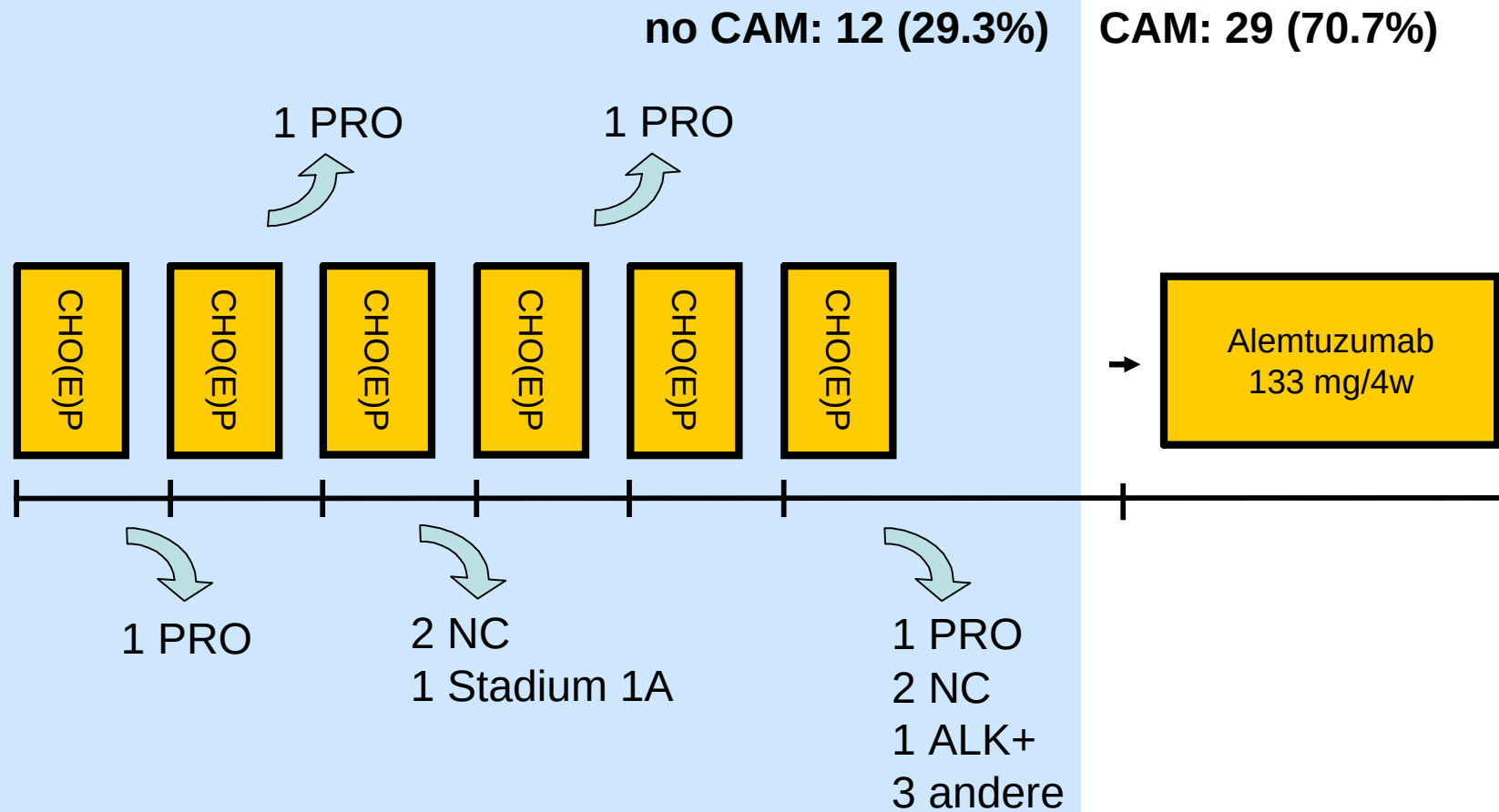


3 years EFS rate: with Etoposide: 63.2% (95% CI: 45.0%-81.4%)
without Etoposide: 48.3% (95% CI: 30.1%-66.5%)



B. Class

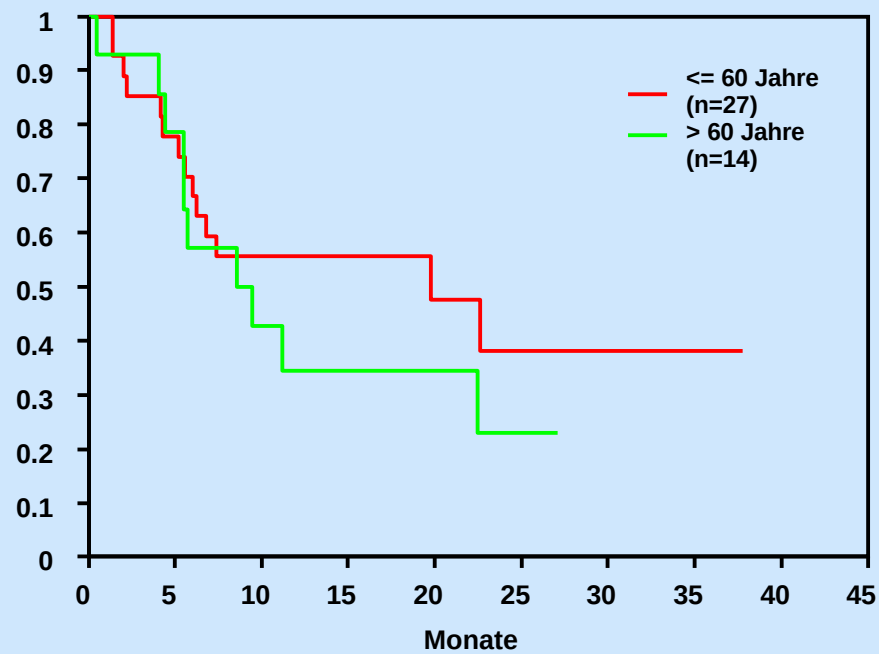
CHO(E)P + Alemtuzumab-Konsolidierung DSH NHL 2003-1: Ergebnisse



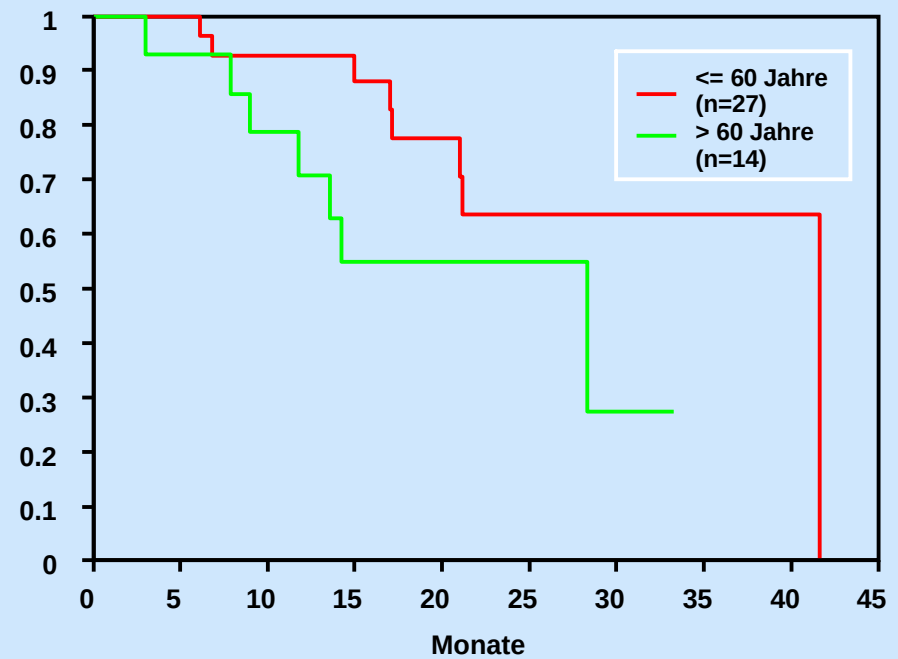
CH O(E)P + Alemtuzumab-Konsolidierung

DSH NHL 2003-1: Ergebnisse

EFS



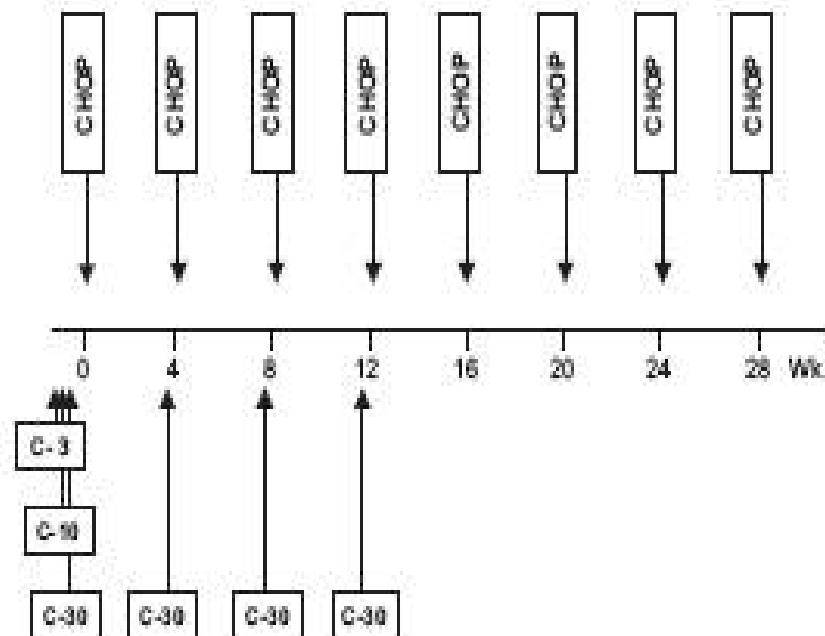
OS



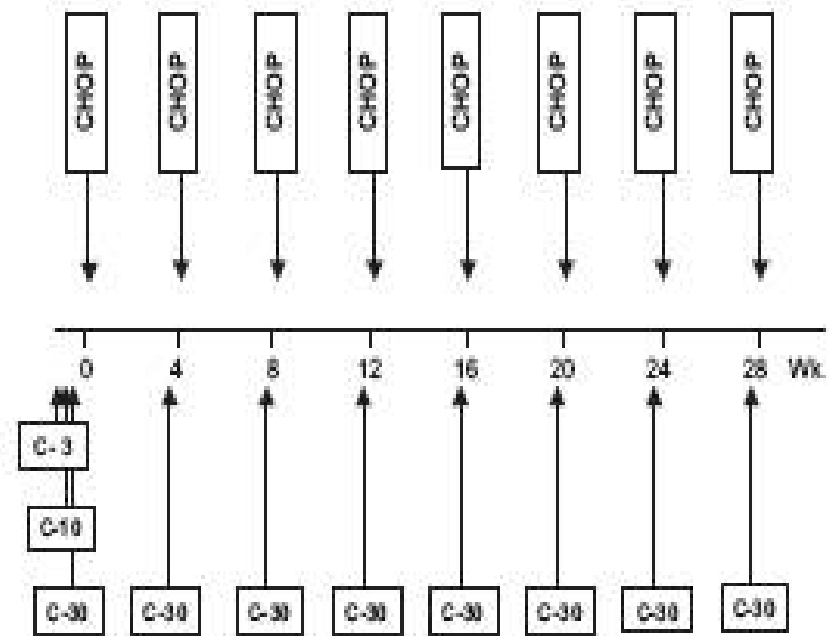
Alemtuzumab + CHOP

Design: Phase II Studie – 24 konsekutive Patienten mit PTL

CHOP-C: 1st phase (pt. 1 – 4)



CHOP-C: 2nd phase (pt. 5 - >5)



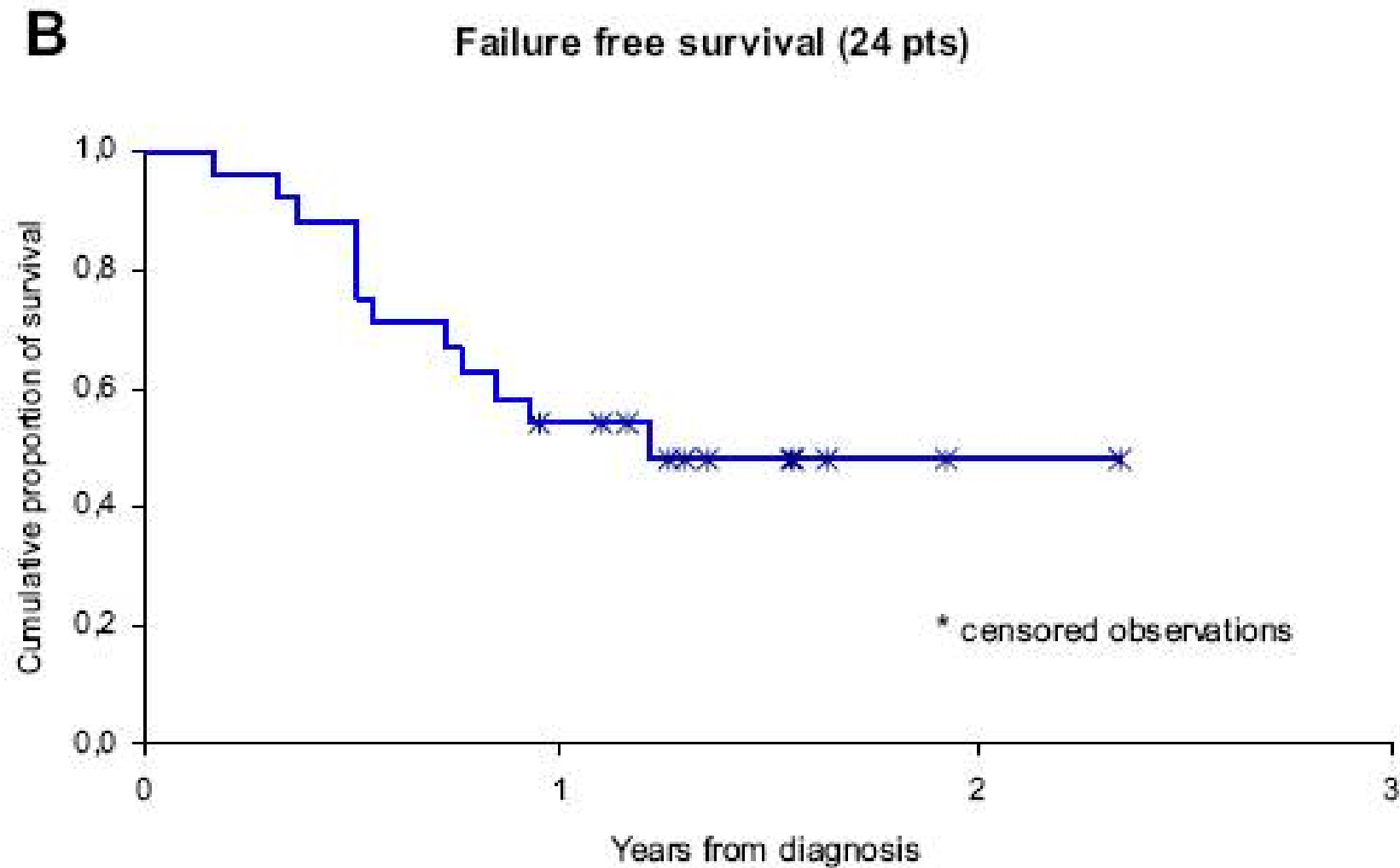
Gallamini et al, Blood 2007; 110(7): 2316-2323



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Alemtuzumab + CHOP

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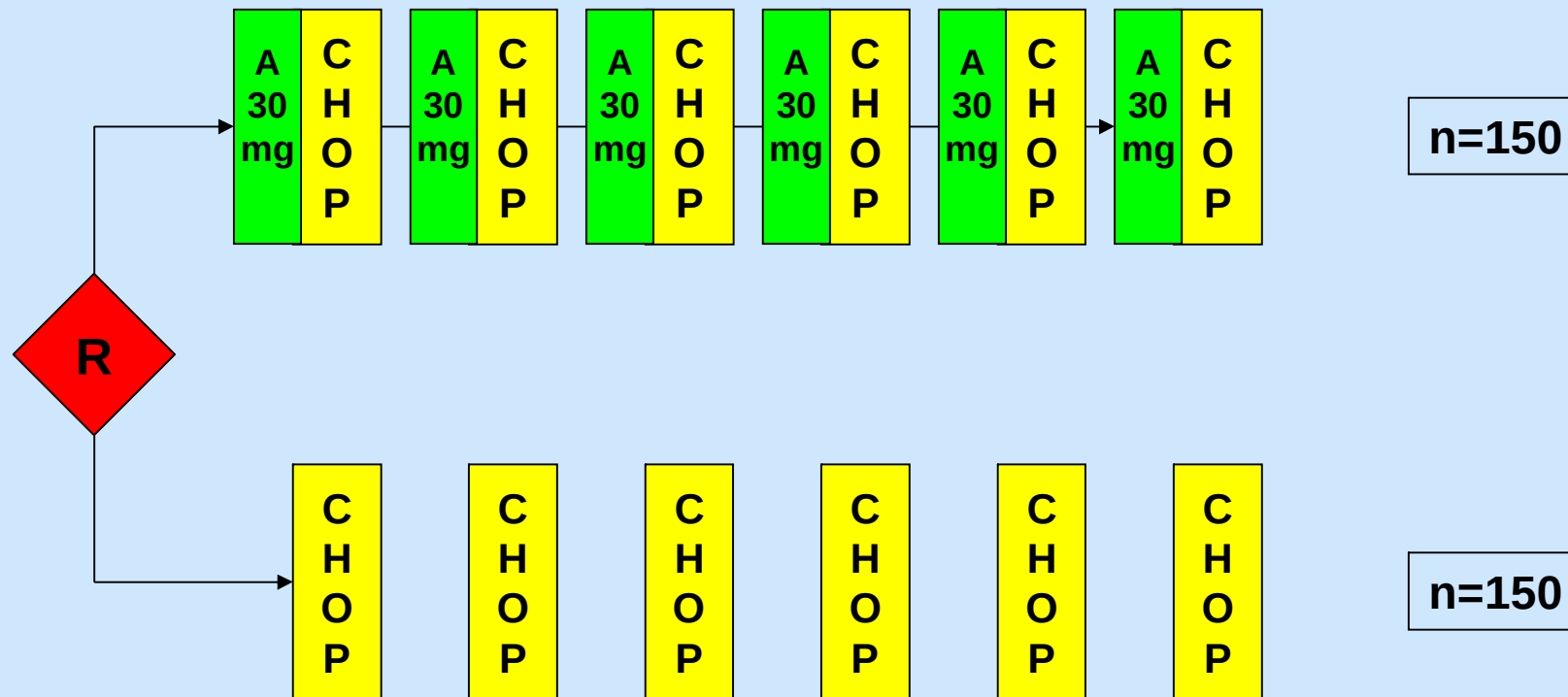
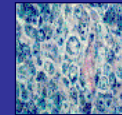


Gallamini et al, Blood 2007; 110(7): 2316-2323



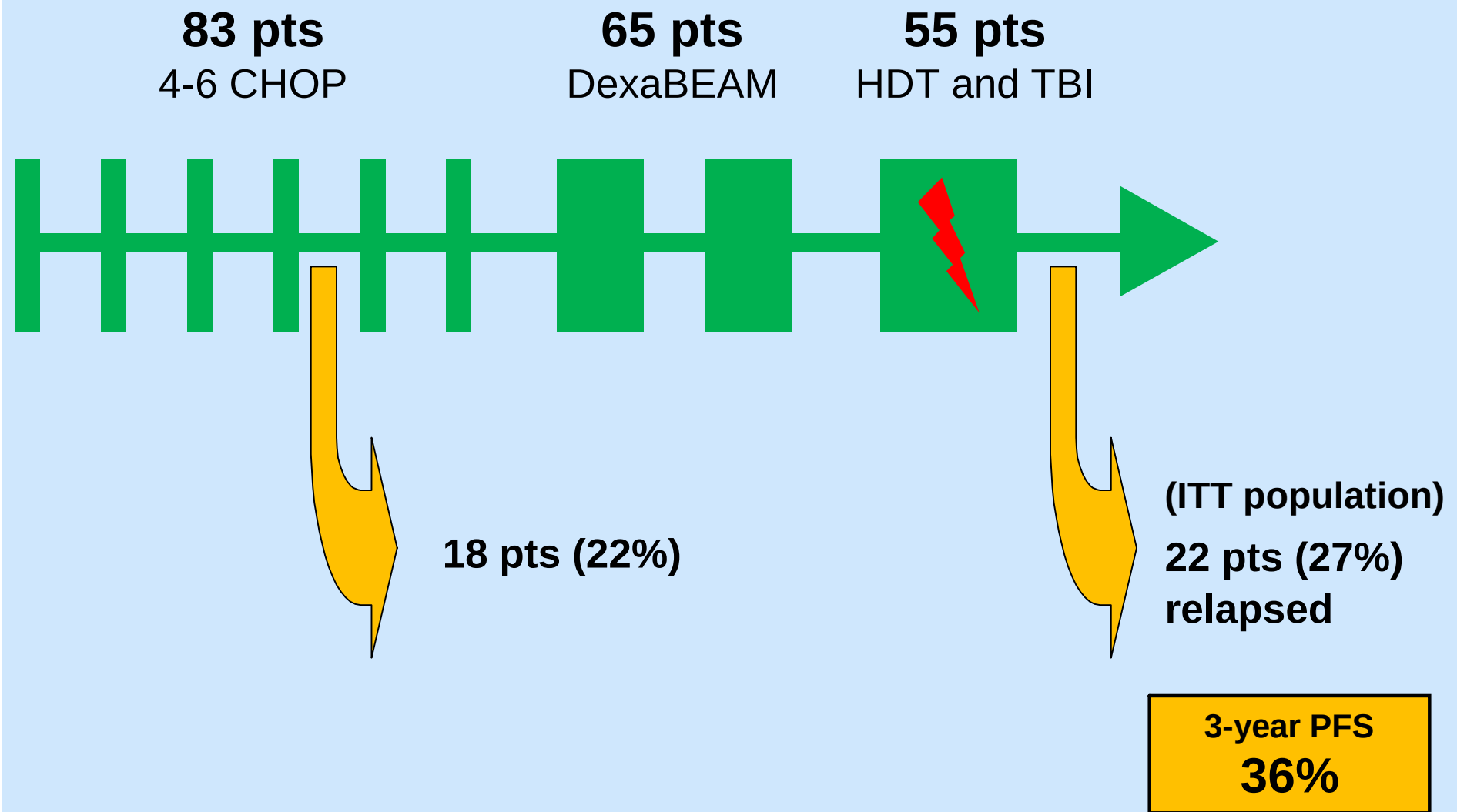
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Primärtherapie für PTCL bei älteren Patienten (>60 J.)



A = Alemtuzumab

Autologous Stem Cell Transplantation as First-line Therapy in T-cell lymphoma

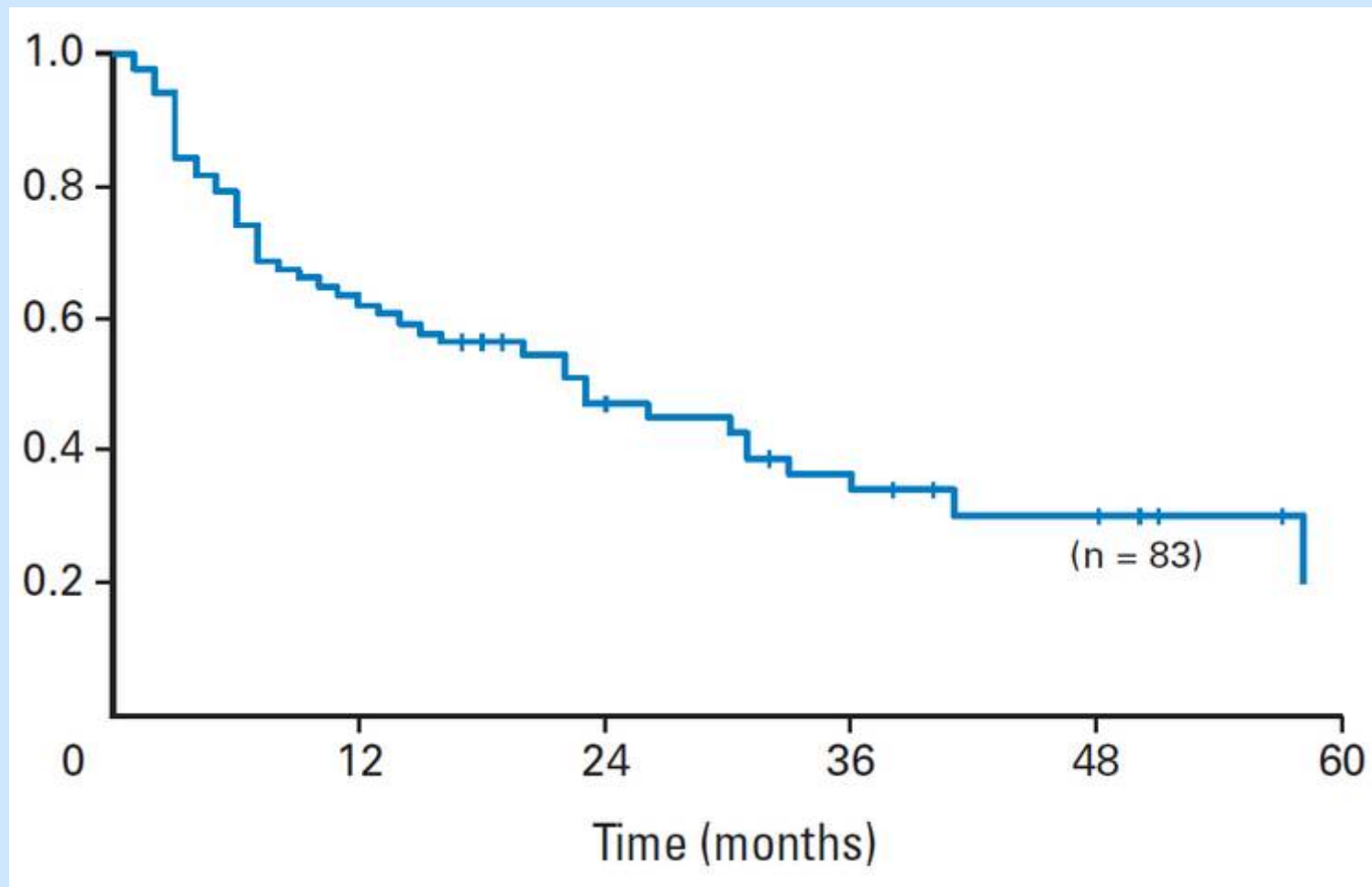


Reimer et al., JCO 2009; 27:106



B. Class

Autologous Stem Cell Transplantation as First-line Therapy in T-cell lymphoma Ergebnisse: Progression Free Survival, ITT



Reimer et al., JCO 2009; 27:106

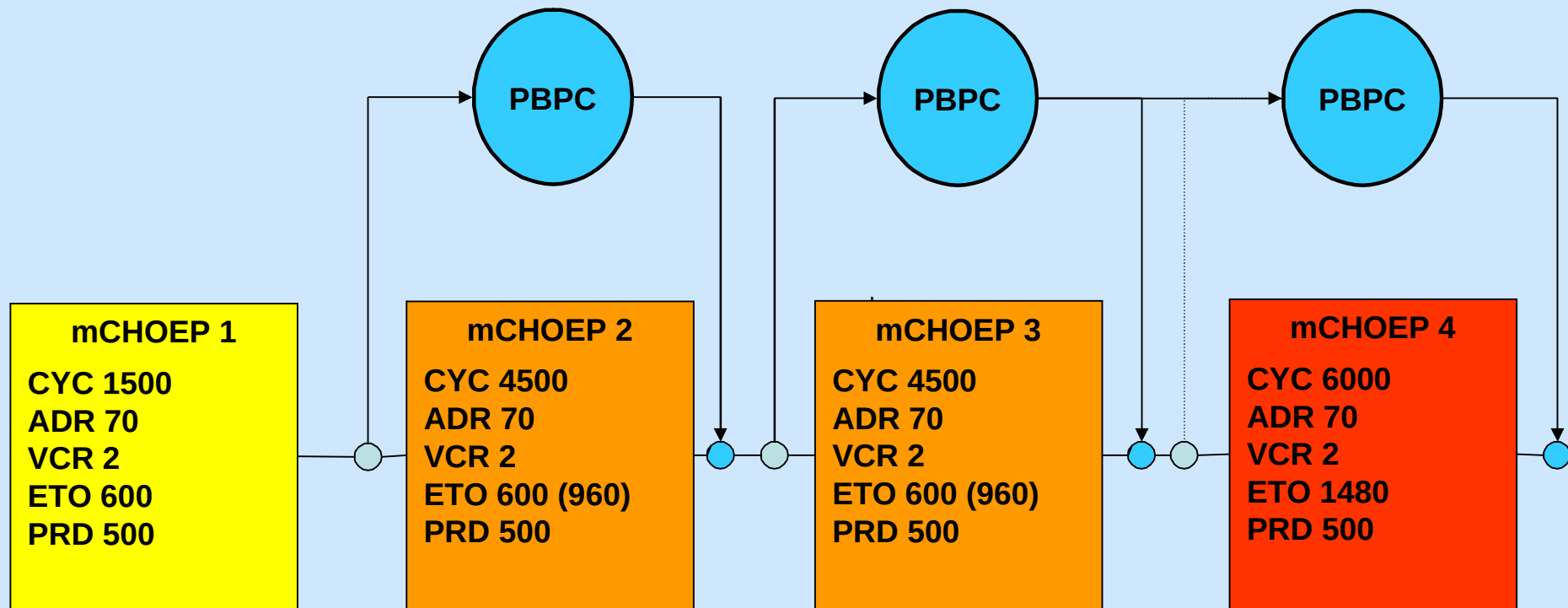
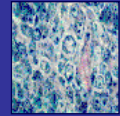


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Phase II / III study in aggressive B- and T-cell lymphoma

MegaCHOEP

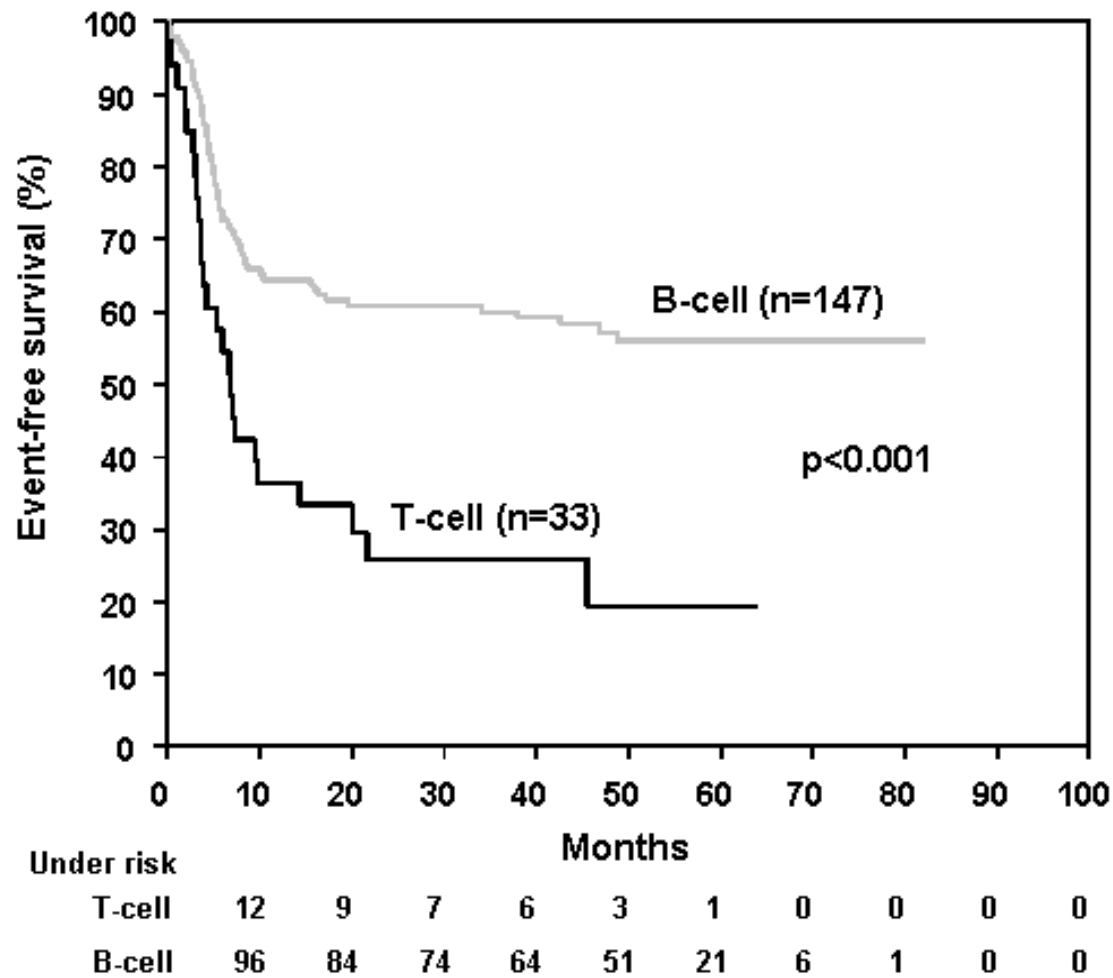
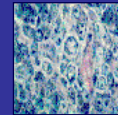
DSHNHL



B. Class

Phase II / III study in aggressive B- and T-cell lymphoma MegaCHOEP Event-free survival according to histology

DSHNHL



Nickelsen et al., manuscript in preparation



B. Class

Patients with Mature T-Cell Lymphoma Show High Relapse Rates after High Dose Therapy and Autologous Stem Cell Transplantation



M Nickelsen, C Canals, C Kyriakou, N Schmitz, M Engelhardt, T Relander, W Linkesch, V Koza, G Meloni, D Caballero, A López-Guillermo, K Indrac, H Wandt, N Theorin, B Glaß, A Sureda on behalf of the Lymphoma Working Party of EBMT

ASH Annual Meeting San Francisco December 2008

The European Group for Blood and Marrow Transplantation

ASCT in pTCL: Study design

- Retrospective EBMT study
- Mature T-cell lymphoma (PTCL NOS, AILT, ALCL)
- High dose therapy and autologous SCT in EBMT centres between 2000 and 2005
- n = 394 patients

ASCT in pTCL: histologic subtypes

Peripheral T-cell lymphoma NOS	176
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(45%)

Anaplastic large cell lymphoma	98 (25%)
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ALK pos	19 (5%)
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ALK neg	42 (10%)
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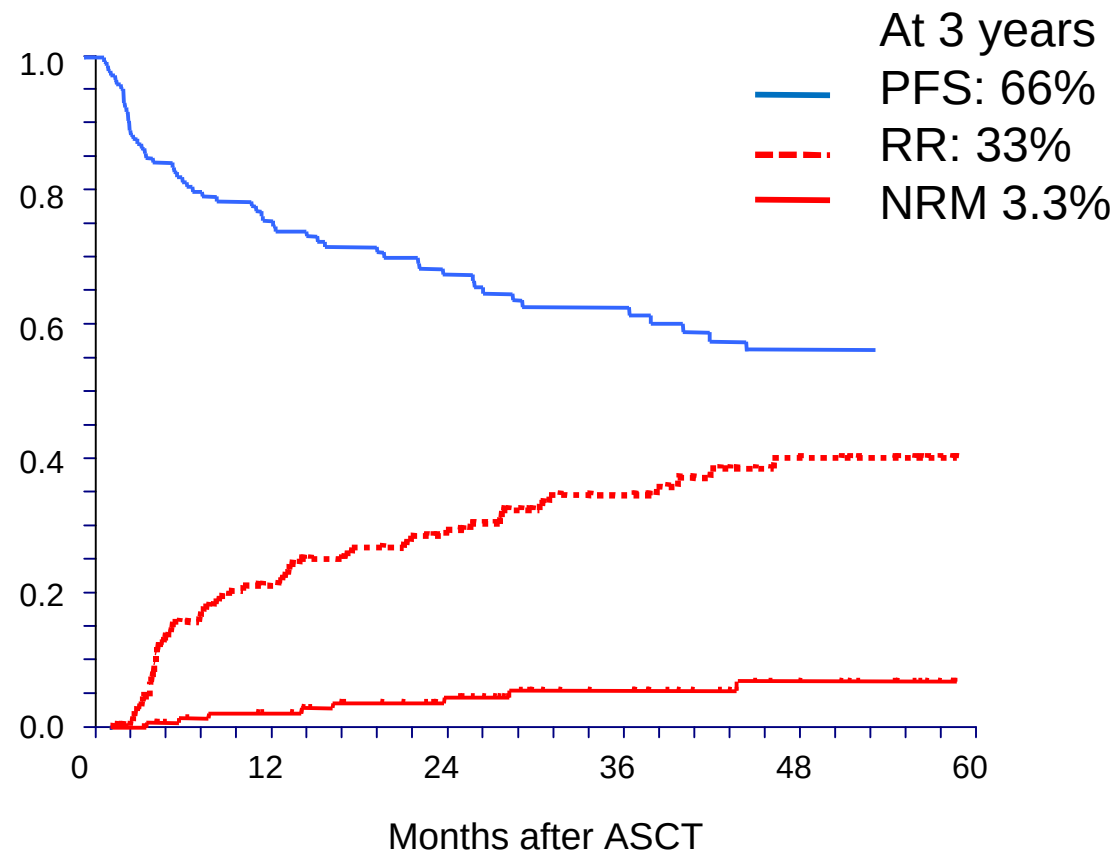
ALK unknown	37 (9%)
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Angioimmunoblastic T-cell lymphoma	120 (30%)
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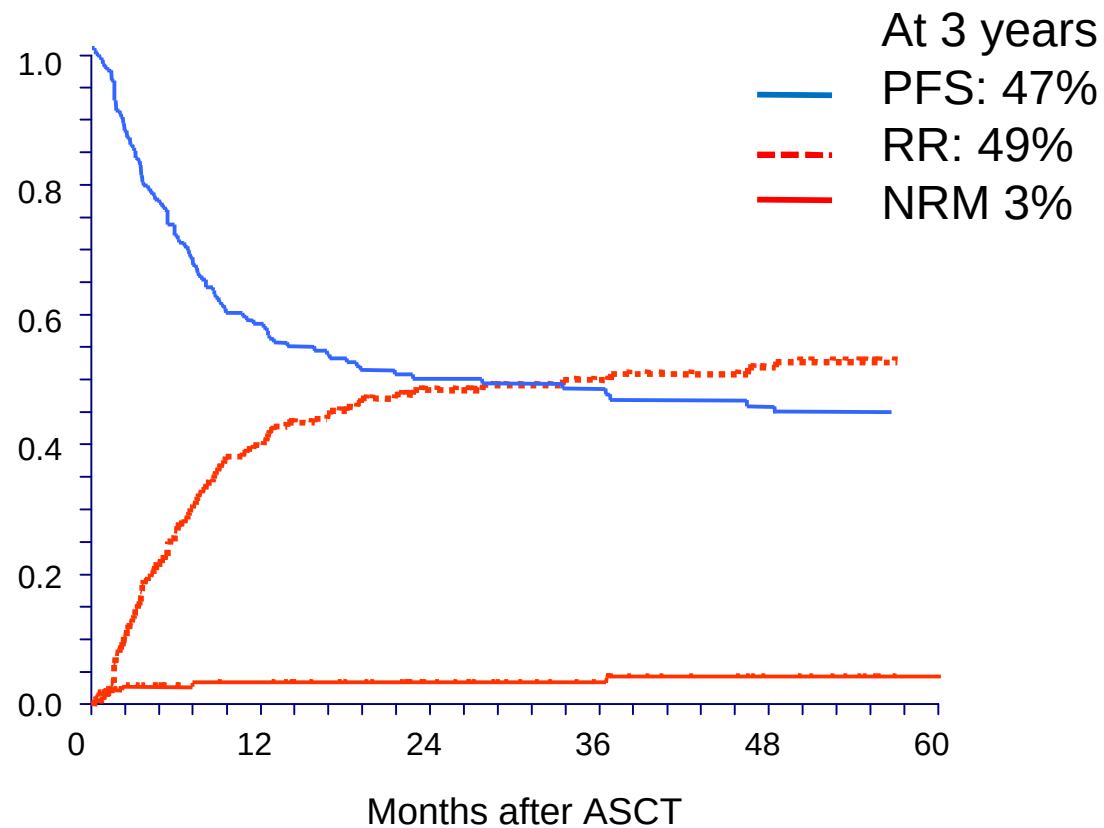
ASCT in pTCL: patient characteristics n = 394

Male (%)	62.9
Age at diagn. (years)	49.7 (14-72)
Stage III/IV (%)	71.6
LDH > N (%)	57.8
IPI high / high-intermediate (%)	36.2
≥ 2 previous treatment lines (%)	67
ECOG > 2 at SCT (%)	3
Transplanted within 1 year (%)	65
BEAM-like conditioning (%)	77
TBI-based conditioning (%)	9

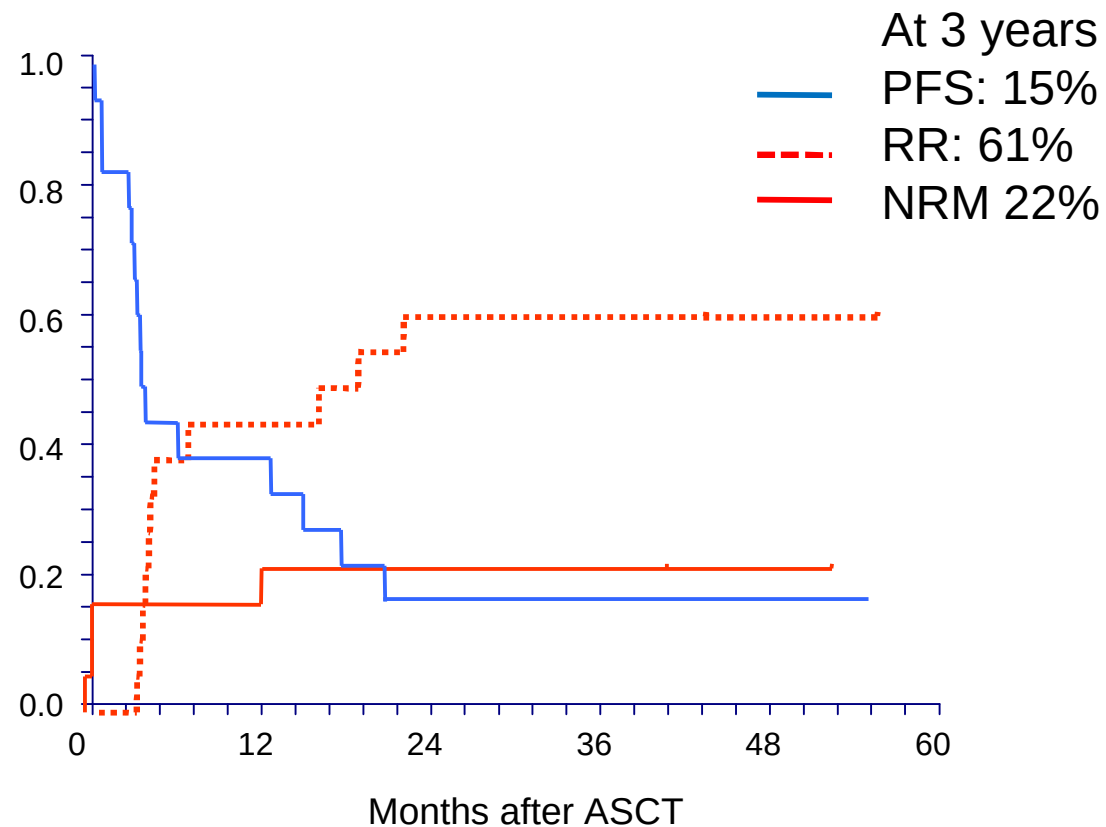
ASCT in pTCL: Patients transplanted in CR 1 (n=145)



ASCT in pTCL: Patients transplanted with chemosensitive disease (n=199)



ASCT in pTCL: Patients transplanted with chemorefractory disease (n=18)



ASCT in pTCL: Multivariate Cox analysis for NRM and Relapse Rate

Risk factors for non-relapse mortality

	p-value	relative risk (95% CI)
Poor Performance status	0.2	3.2 (1.2-9.1)
Refractory disease at ASCT	<0.001	6.7 (3.0-14.9)

Trend: male gender

Risk factors for relapse rate

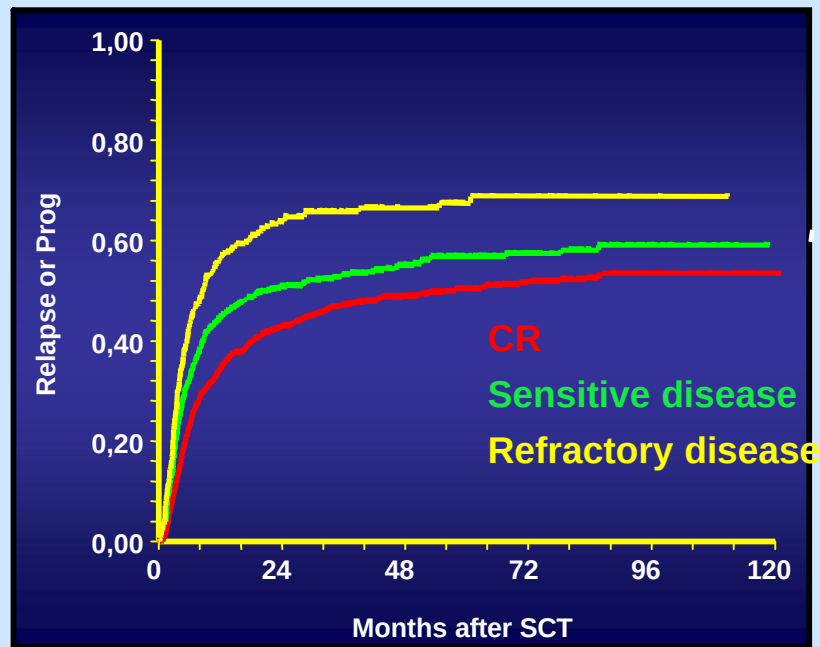
	p-value	relative risk (95%CI)
Sensitive disease vs CR1	0.001	1.9 (1.3-2.7)
Refractory disease vs CR1	0.001	3.3 (1.7-6.3)
PTCL NOS	0.02	1.4 (1.1-2)

Trends: age > 60 years, IPI high/ high intermediate

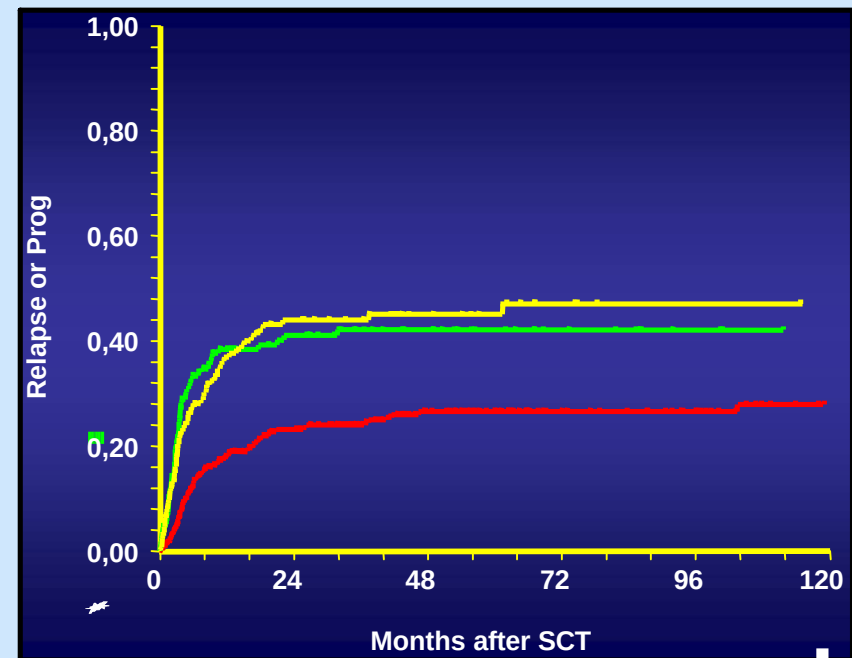
T-NHL

Allogeneic SCT : Relapse rates by type of transplant: EBMT data 1990-2006

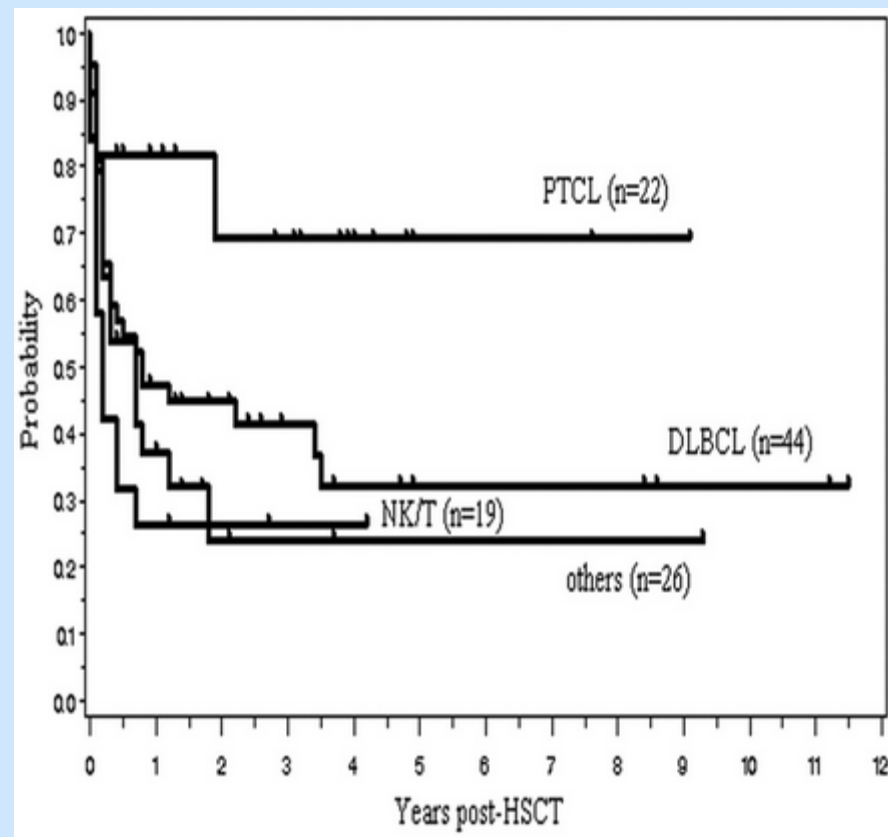
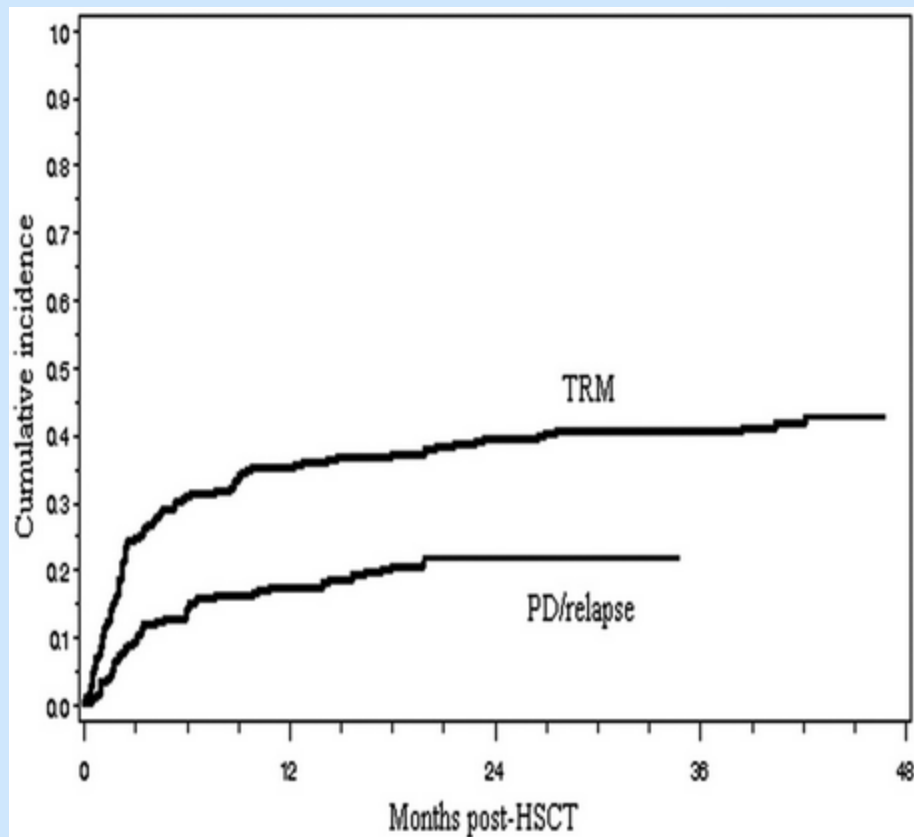
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allo

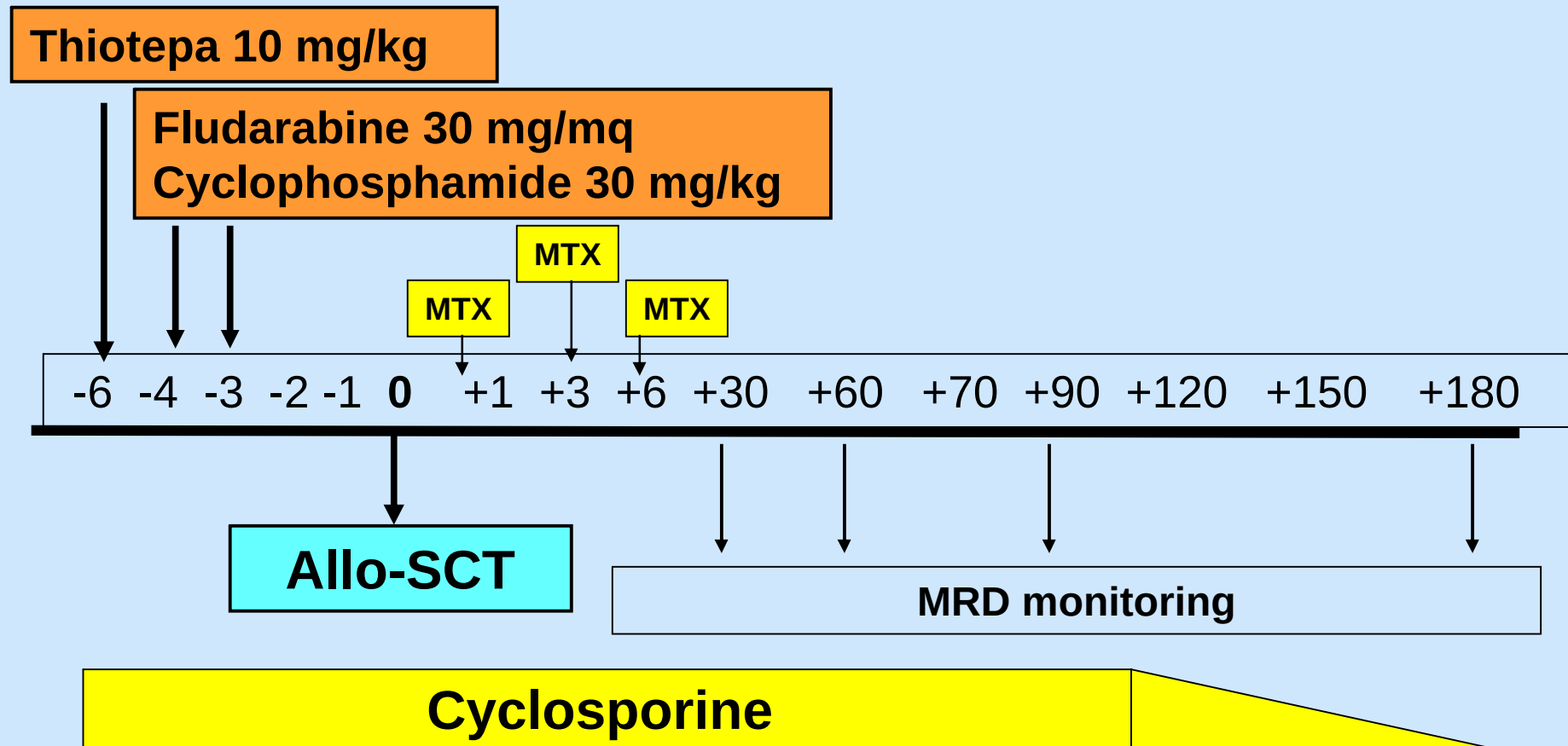


Aggressive NHL (n= 111)
Myeloablative allogeneic SCT from related and unrelated donor



Kim et al., Blood 2006; 108: 382-9

T-NHL
RIC allogeneic SCT

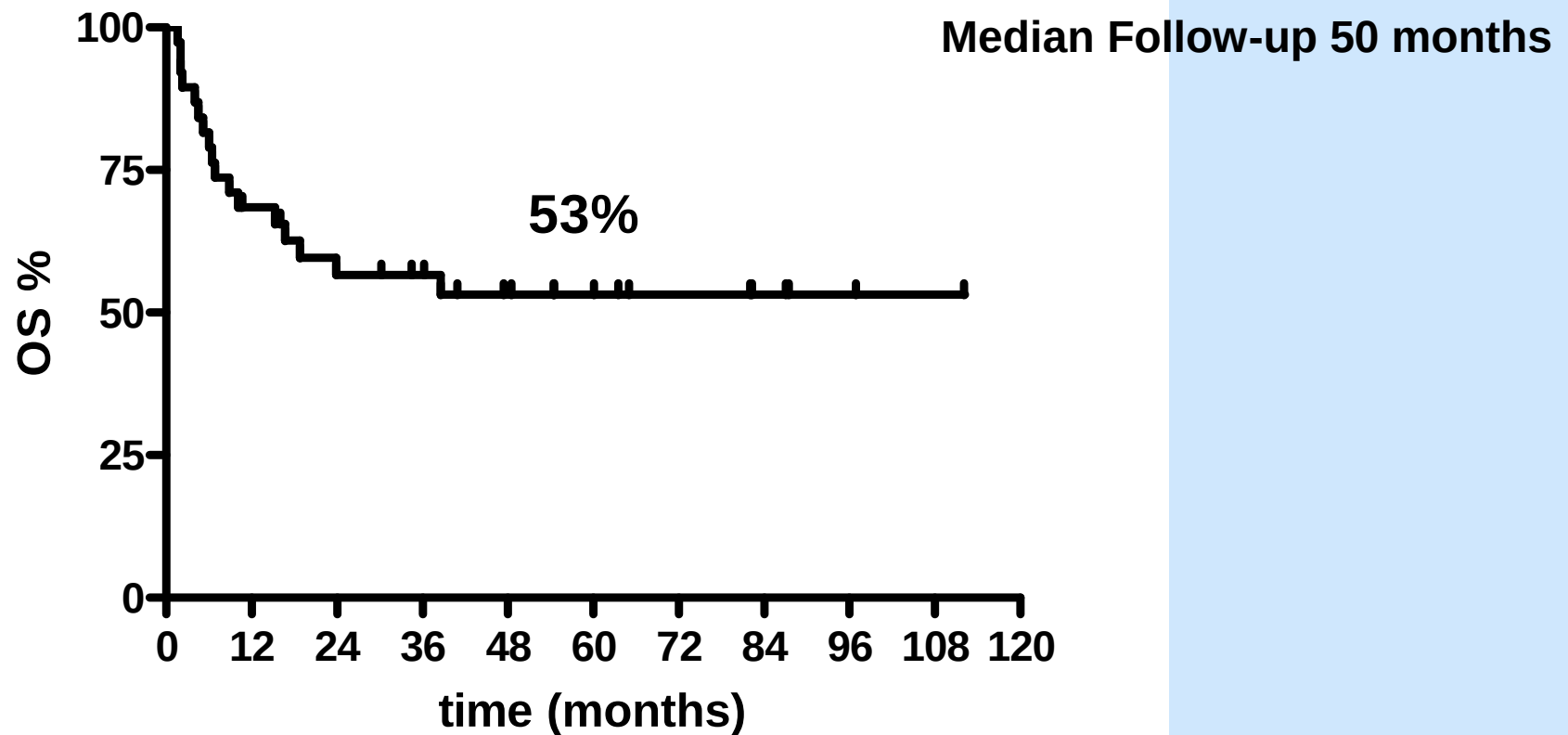


Update in relapsed PTCL

Patients Characteristics n= 38

Age	44 (15-64)
No. lines (range)	2 (1-4)
Previous autologous SCT	54%
CR pre-allogeneic SCT	35%
PR pre-allogeneic SCT	40%
Median time diagnosis to allo-SCT	15 months (6-99 months)

Update in relapsed PTCL Results, Overall survival



21 of 38 patients are alive (n=19 in CR, n=2 with disease)

12 death of disease

5 death of NRM

P. Corradini – personal communication

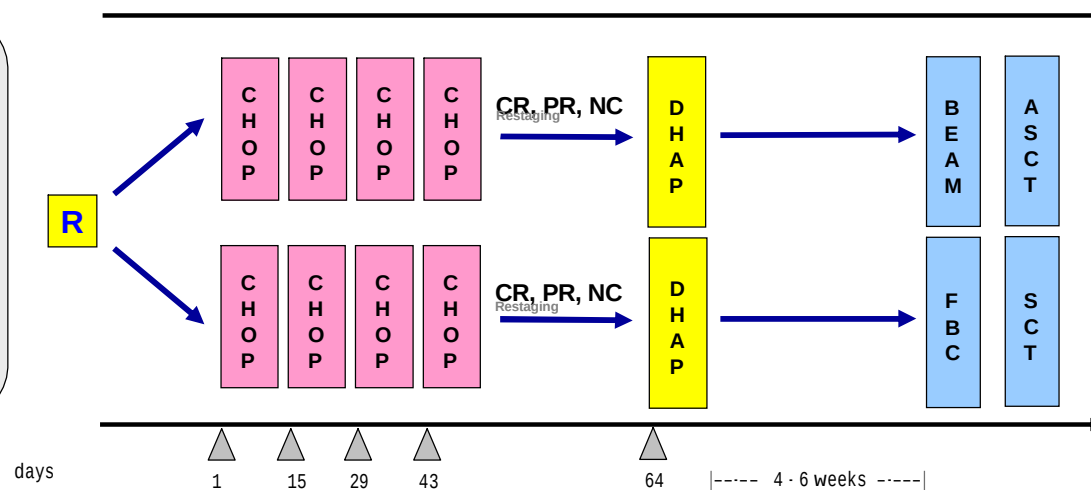


B. Glass

first-line treatment of mature (peripheral) T-cell lymphoma (PTCL), patients ≤60 years

inclusion criteria

- Peripheral T-cell lymphoma, unspec'd (PTCLu)
- Angioimmunoblastic T-cell lymphoma (AIL)
- Anaplastic large cell lymphoma, ALK negative
- Extranodal NK/T-cell lymphoma, nasal type
- Enteropathy type T-cell lymphoma
- Hepatosplenic T-cell lymphoma
- Subcutaneous panniculitis type T-cell lymphoma
- all stages and IPI except stage I with aalPI 0



R = At diagnosis, patients are randomized to allogeneic or autologous transplantation. Donor search (family or unrelated) will be initiated only in patients randomized to allogeneic transplantation. Patients randomized to allogeneic tx but without a donor will receive autologous tx. Peripheral blood stem cells are harvested after DHAP in patients who are to receive autologous tx (randomized or crossed over from the allogeneic transplant arm because no donor is available).

ASCT = autologous stem cell transplantation, SCT = allogeneic stem cell transplantation

T-NHL

Zusammenfassung

- ❖ Unter vergleichbarer Therapie haben ALCL ALK- und andere mature T-NHL eine erhebliche schlechtere Prognose als aggressive B-NHL. Bei mehr als 1 IPI Risikofaktor liegt das EFS bei $\leq 30\%$
- ❖ Ohne IPI-Risikofaktoren werden mit konventioneller Chemotherapie akzeptable Ergebnisse erzielt. CHOEP dem CHOP vermutlich überlegen.
- ❖ Alemtuzumab verbessert potentiell die Ergebnisse einer Chemotherapie. Entsprechende Phase III-Studie für Patienten > 60 Jahre überprüft die Wirksamkeit.
- ❖ HHDT und autologe SZT sinnvolle konsolidierende Therapie für Patienten mit chemosensiblen T-NHL. Rate primär chemo-refraktärer T-NHL ist hoch (ca. 30%). Nach HDT und SZT ist die Rezidivrate bedeutsam. PFS (Intent to treat) zwischen 30% und 40% nach 3 Jahren
- ❖ Periphere T-NHL sind empfindlich für den GVL-Effekt der allogenen Stammzelltransplantation. Bei Rezidivpatienten EFS zwischen 40 % und 70% nach 3 Jahren.
- ❖ Der Stellenwert der allogenen SZT in der primären Behandlung der T-NHL wird in einer Phase III – Studie überprüft.

Studententreffen der DSH NHL 2009

24. und 25. April 2009

Anmeldung:

dshnhl@uks.eu



❖ ANHANG

T-cell lymphomas in DSHNHL trials

Histologic subtypes by reference pathology (n=329)

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T-cell lymphomas in DSHNHL trials

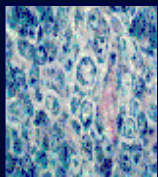
Which patient from which trial? (n=329)

trial	n	age	LDH	IPI	treatment
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Mega/CHOEP phase II	33	18-60	> N	all aalPI > 0	Mega CHOEP dose escalation
Mega/CHOEP phase III	25	18-60	all	aa IPI 2,3	Mega CHOEP vs. CHOEP-14
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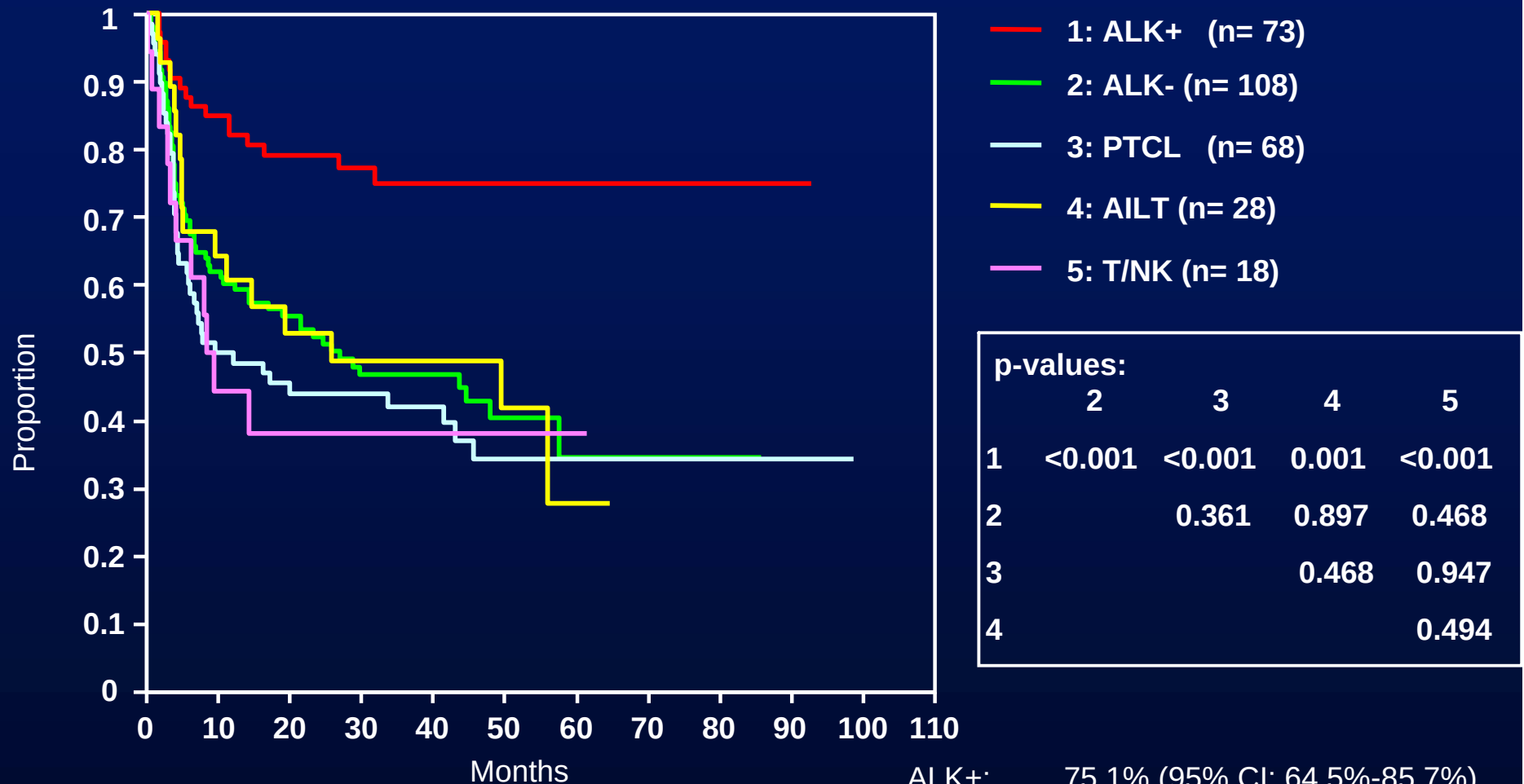
recruitment period: Oct 1993 - Feb 2006

median observation time: 43 months



T-cell lymphomas in DSHNHL trials

Event-free survival - histological subtypes (n=295)



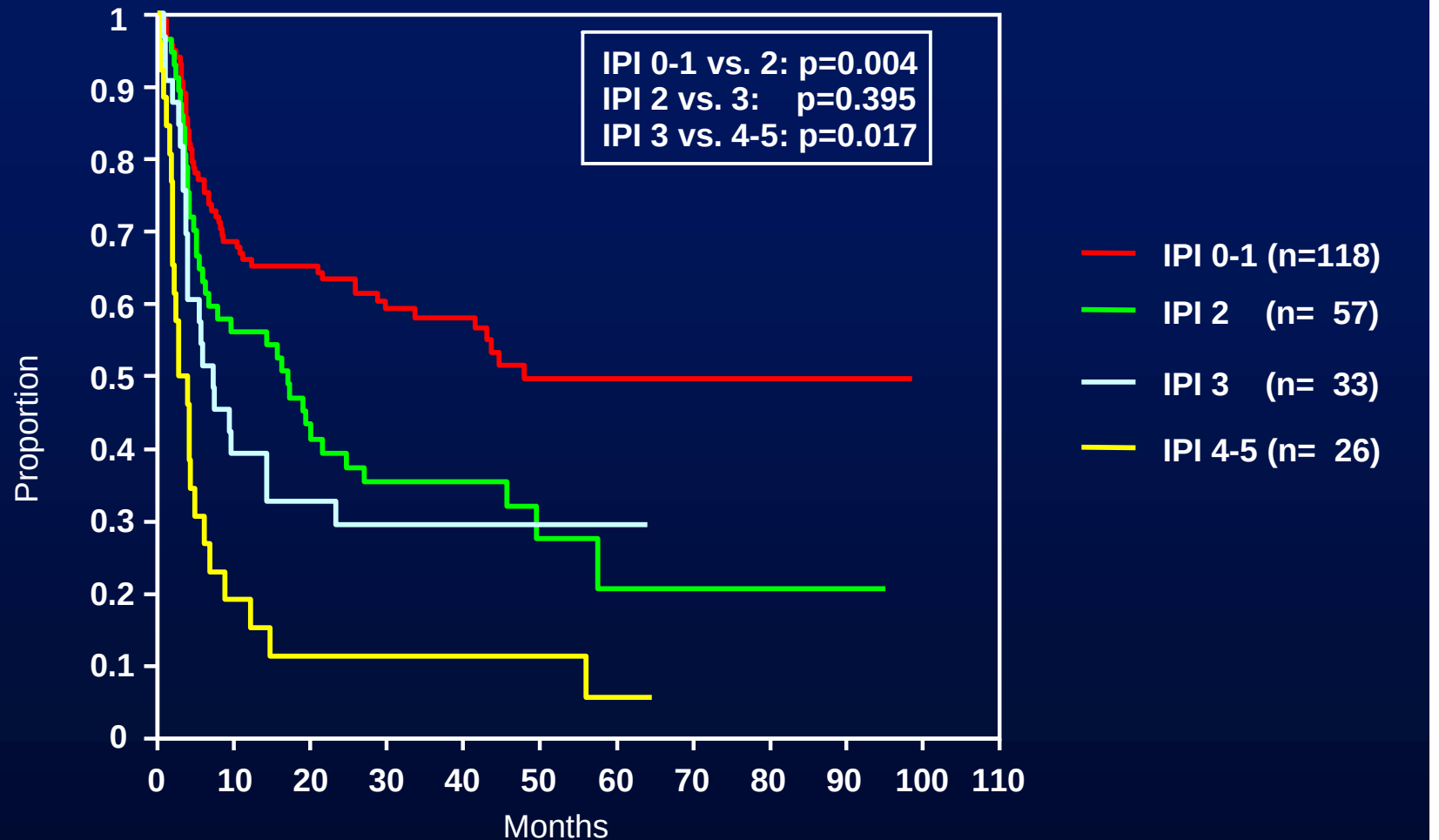
DSHNHL 05.12.2008

3-years EFS-rate:

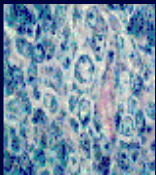
ALK+: 75.1% (95% CI: 64.5%-85.7%)
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T-cell lymphomas in DSHNHL trials

ALK-negative and other T-cell lymphomas Event-free survival according to IPI score (n=234)

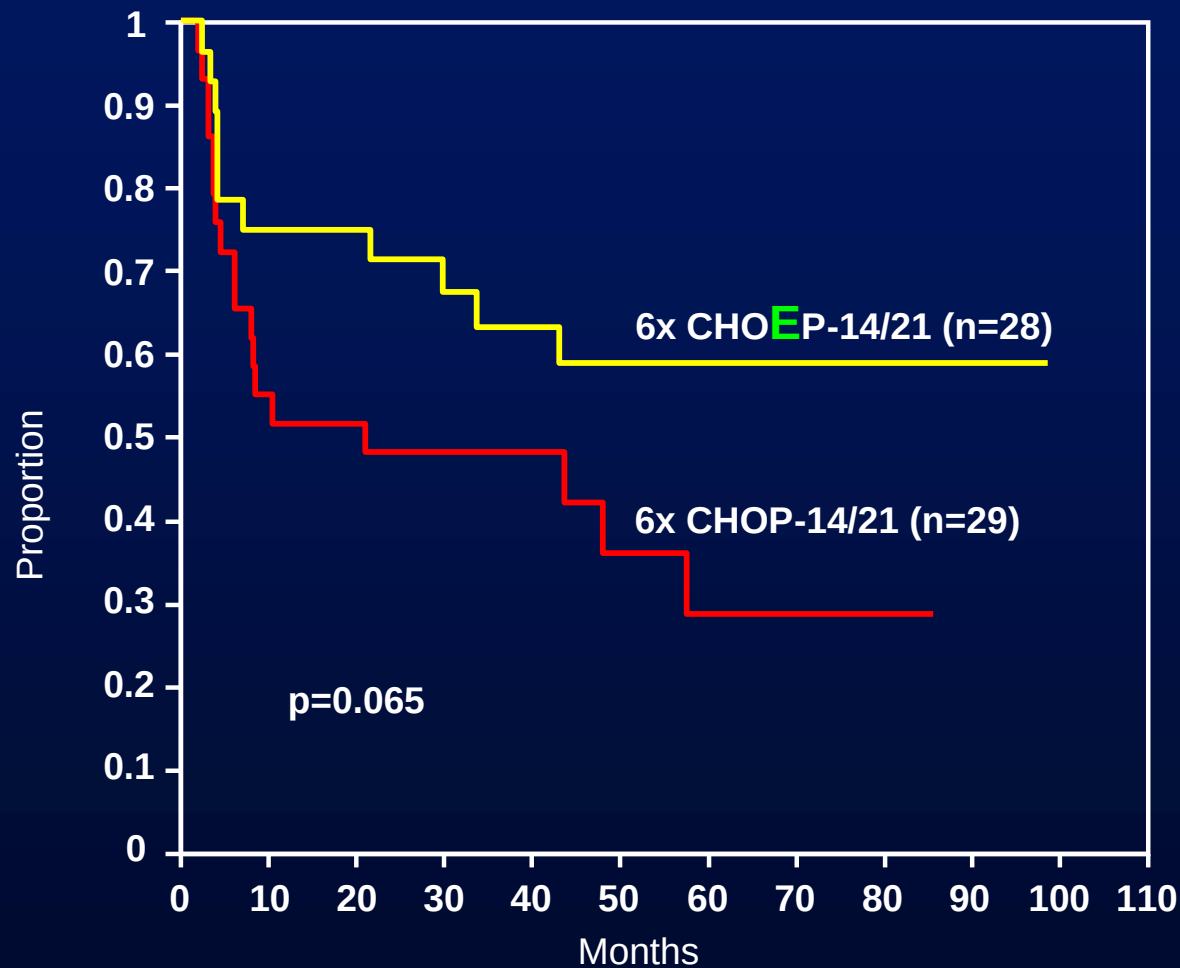


3-years EFS-rate:	IPI 0-1:	58.2% (95% CI: 49.0%-67.4%)
	IPI 2:	35.4% (95% CI: 22.7%-48.1%)
	IPI 3:	29.5% (95% CI: 13.6%-45.4%)
	IPI 4-5:	11.5% (95% CI: 0.0%-23.8%)



T-cell lymphomas in DSHNHL trials

ALK-negative ALCL and other T-cell lymphomas
NHL-B1 trial (= 60 years, LDH = N, n=57), EFS: role of etoposide

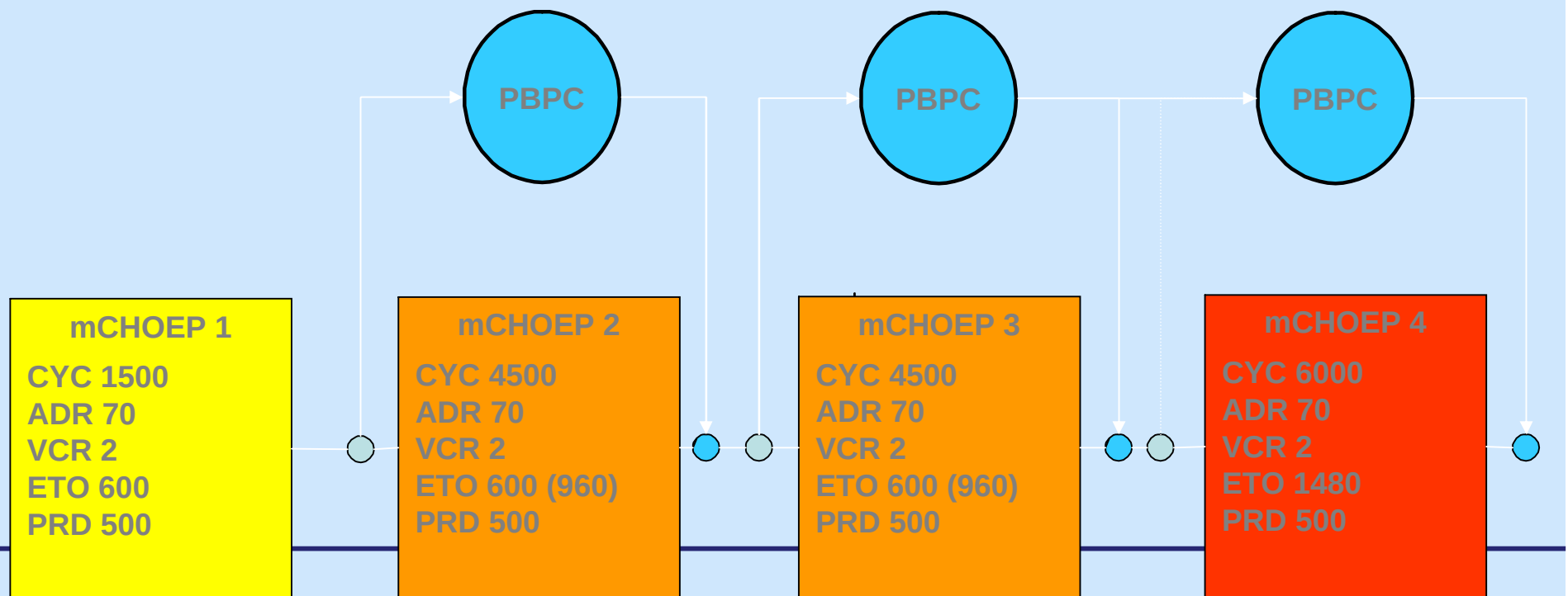


DSHNHL 05.12.2008

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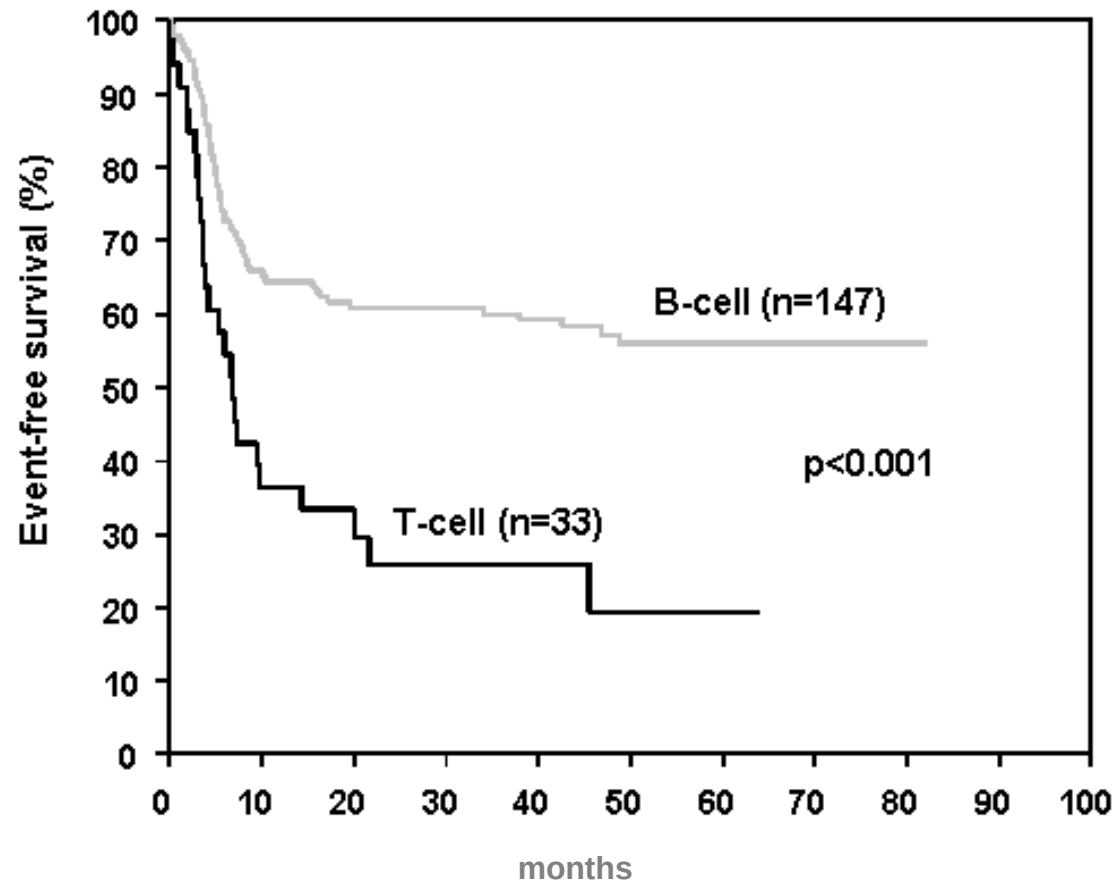


Phase II / III study in aggressive B- and T-cell lymphoma MegaCHOEP



Mega-CHOEP study (Phase I/ II)

event-free survival

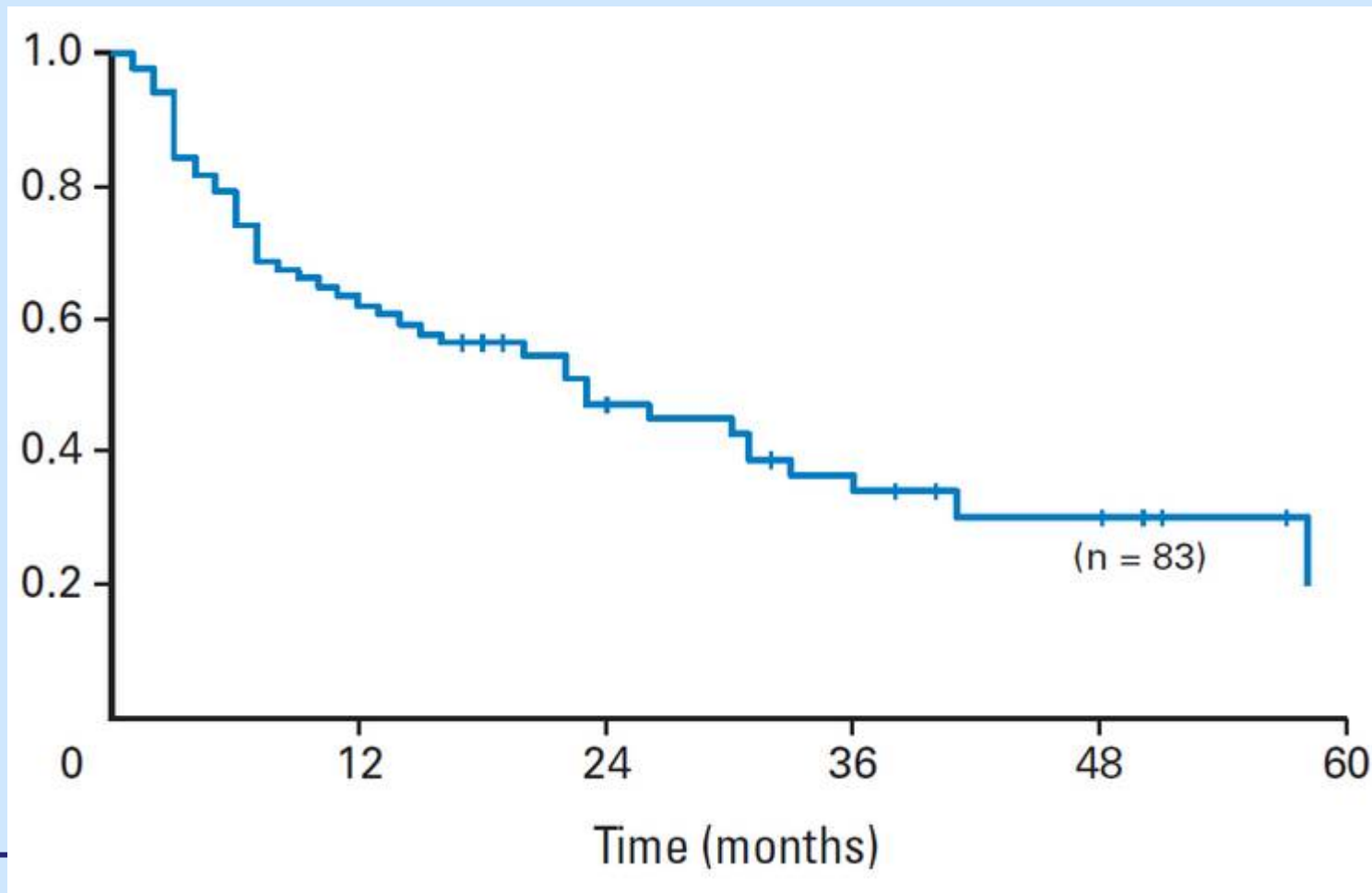


T-cell lymphomas except ALK-positive ALCL

Nickelsen et al., submitted

Autologous Stem Cell Transplantation as First-line Therapy in T-cell lymphoma

PFS

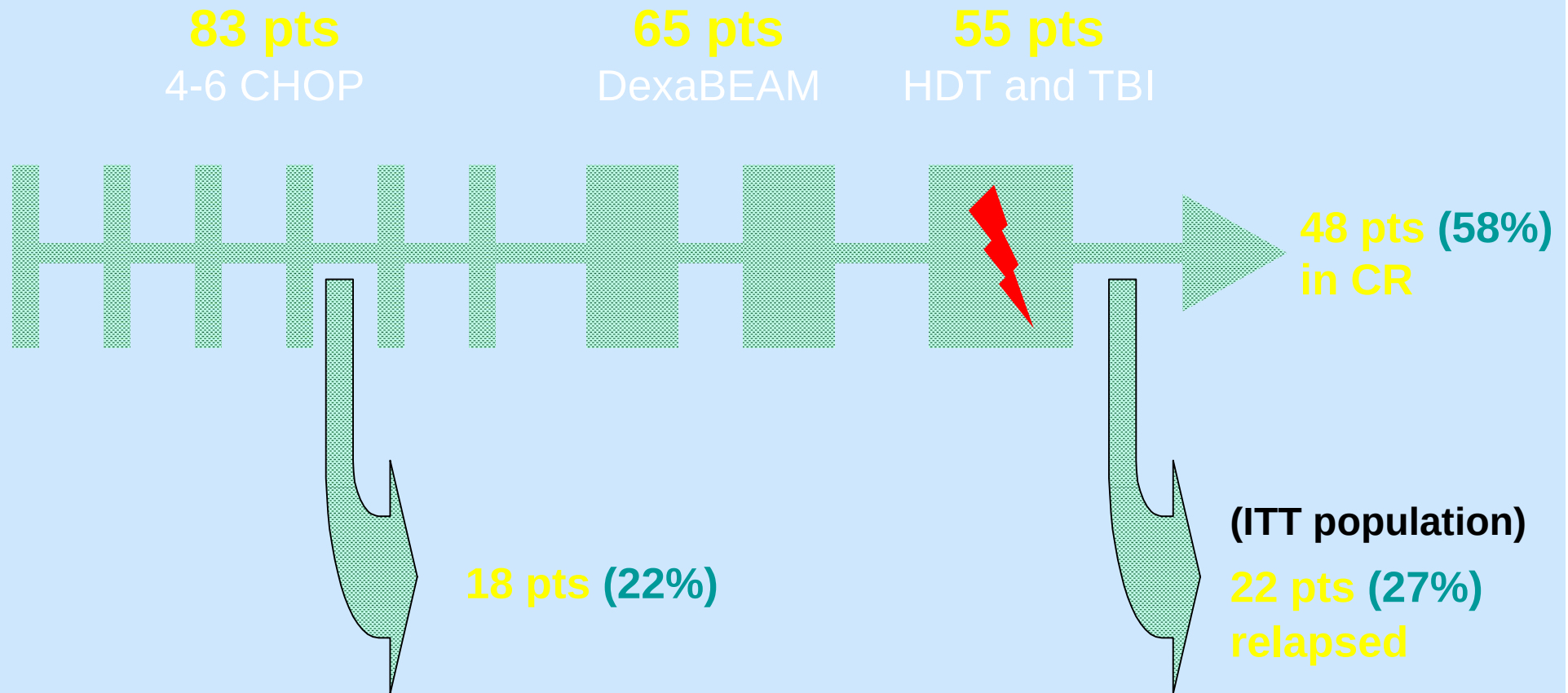


Reimer et al., JCO 2009; 27:106



Dr. G. G. G.

Autologous Stem Cell Transplantation as First-line Therapy in T-cell lymphoma

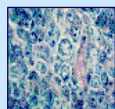
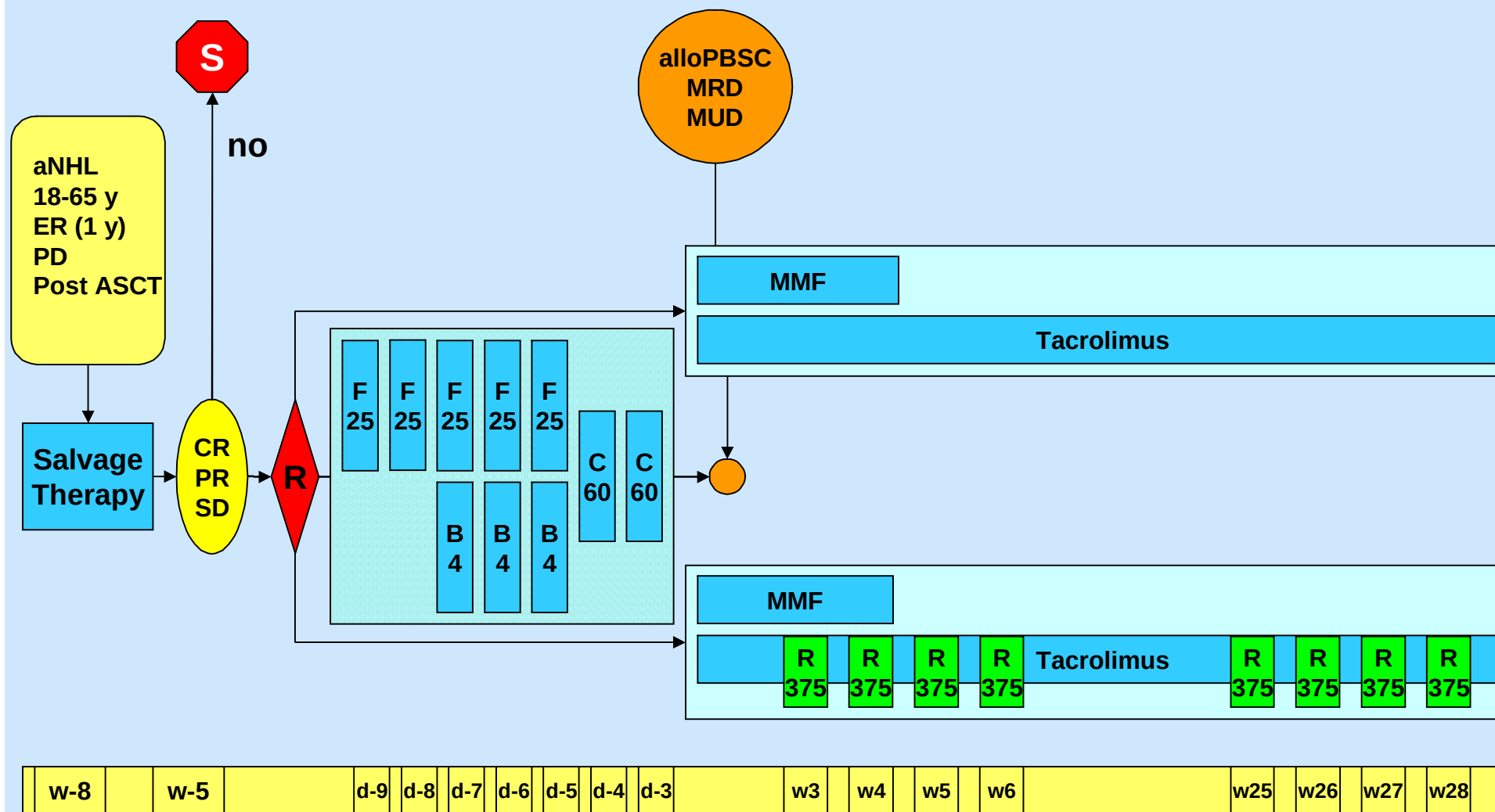


3-year PFS

36%

High-risk Relapse of aggressive NHL

Intermediate Conditioning, GVHD-Prophylaxis by Rituximab



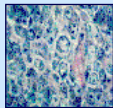
DSHNHL 2004-R3

Patient characteristics

Age (median, years)	range
49,6	21 - 65
Gender	%
male	73.3
female	26.7

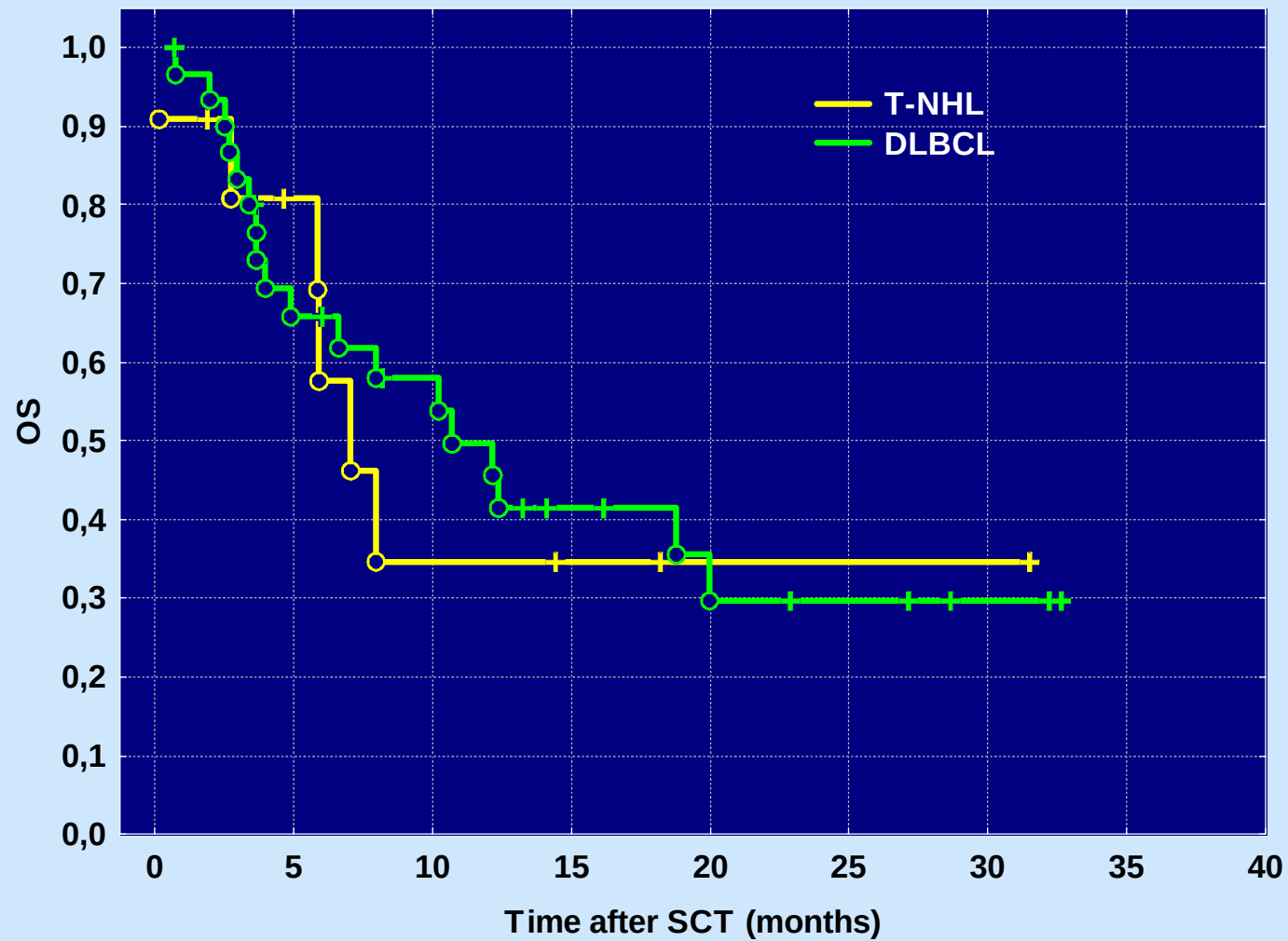
Prior transplant	%
none	28.3
1	38.3
2	23.3
Duration of last remission	
< 12 months	79.3
> 12 months	20.7

Stage at Tx	%
CR	7.2
I / II	32.7
III / IV	60.0
LDH at Tx	%
elevated	51.9
normal	48.1
a-IPI at Tx	%
0 / 1	48.1
2 / 3	51.9

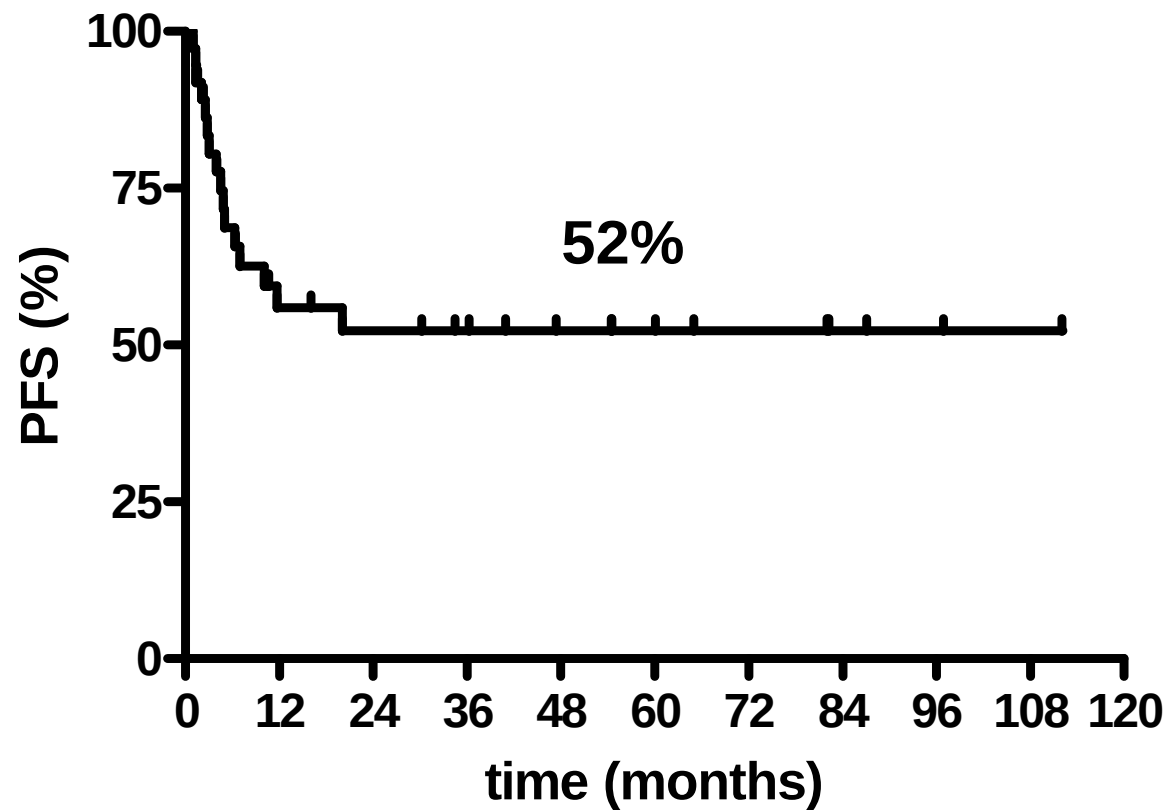


DSHNHL 2004-R3

Overall Survival and Histology



Progression Free Survival



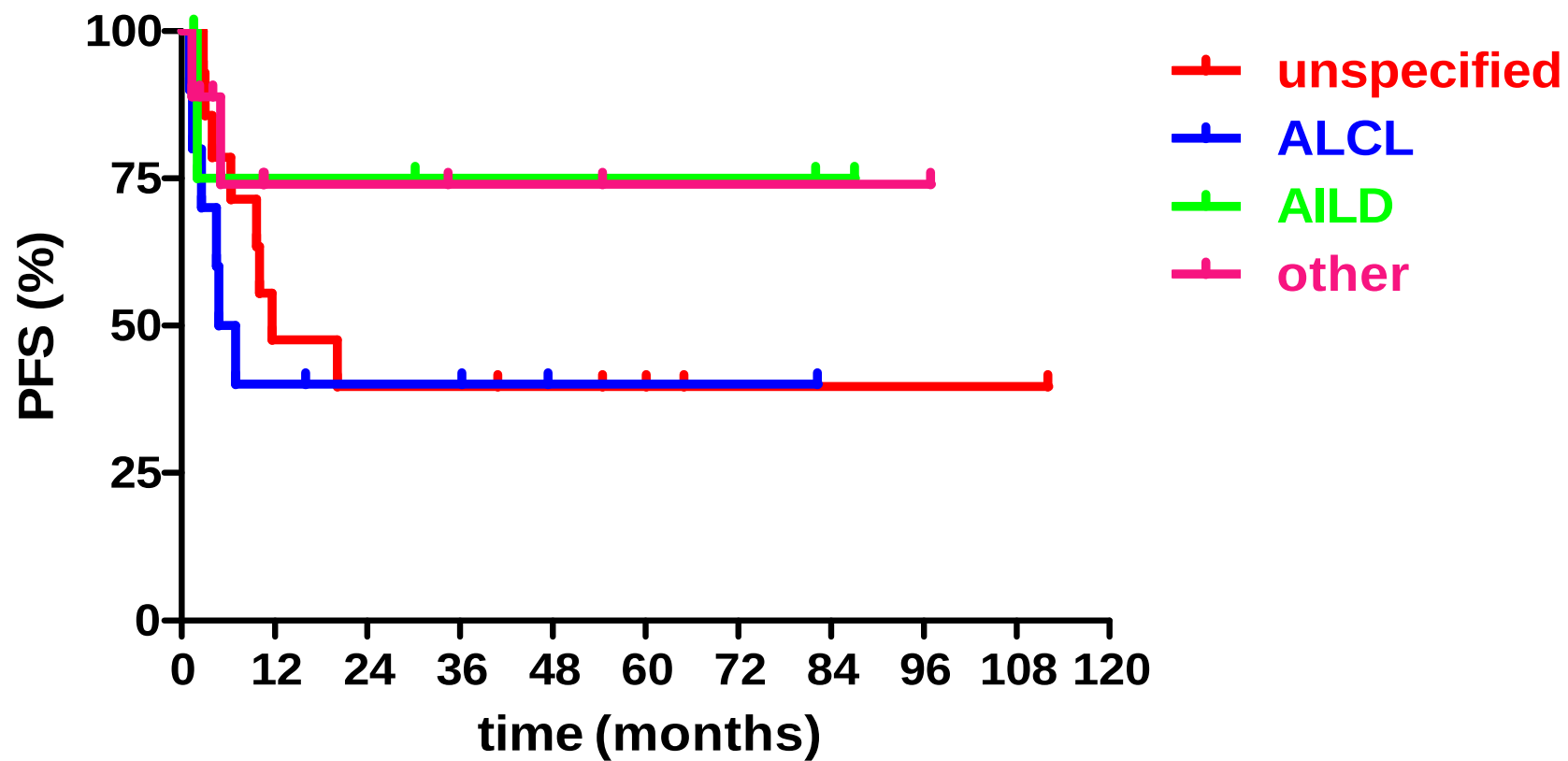
Median time to Relapse 140 days (range, 38-603 days)

Median Follow-up 50 months



B. Class

Outcome according to different subtypes



T-NHL

HDT and autologous SCT (retrospective)

Relapsed/Refractory

Author	Year	n	HDT	CR	OS
Vose	1990	17	diverse	59%	35% (2y)
Jagasia	2001	25 (8 allo)	diverse	-	74% (3y)
Rodriguez	2001	29	diverse	79%	39% (3y)
Song	2003	36	Melph/Eto	42%	48% (3y)

Relapsed/First-line

Haider	1999	14 (6 ALCL)	Cyc/Eto (Thio)	50%	30m (med OS)
Kingreen	1999	27 (only AIL)	diverse	68%	10.8m (med OS)
Blystad	2001	40 (14 ALCL)	diverse	80%	58% (3y)
Rodriguez	2003	115 (24 ALCL)	diverse	68%	56% (5y)
Jantunen	2004	37 (14 ALCL)	BEAC/BEAM	76%	54% (5y) 35% Non-ALCL

ASCT in pTCL: Conclusion

High dose therapy and ASCT are feasible and safe for patients with chemosensitive T-cell lymphoma

Even for patients transplanted in first CR, relapse rate is relatively high

Patients with chemorefractory disease do not benefit from high dose therapy and ASCT

Further studies are necessary to identify patients who can be cured by ASCT

HDT / ASCT in T cell lymphoma as part of primary treatment

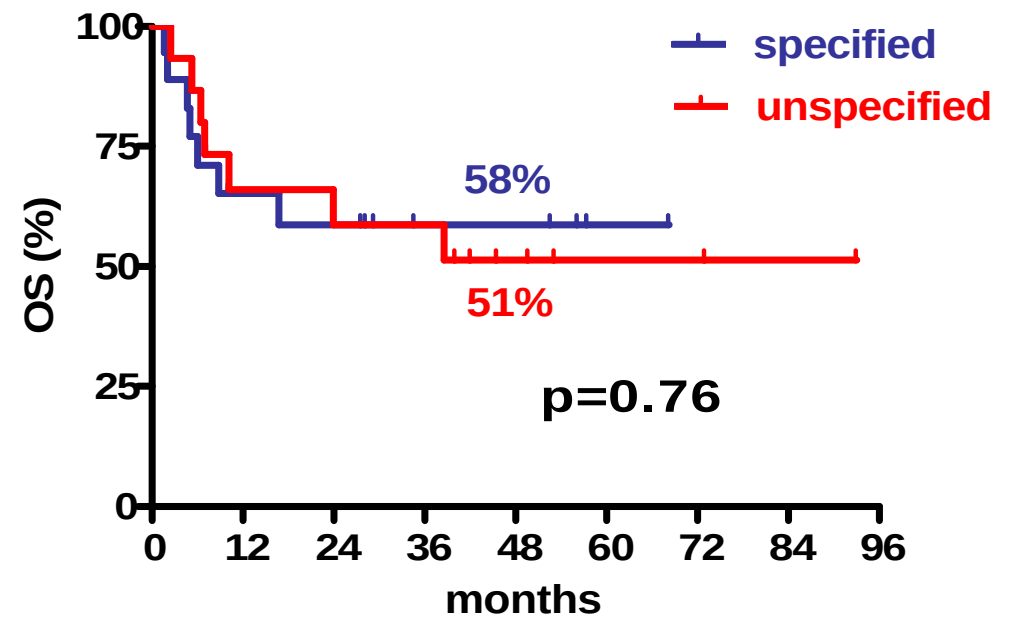
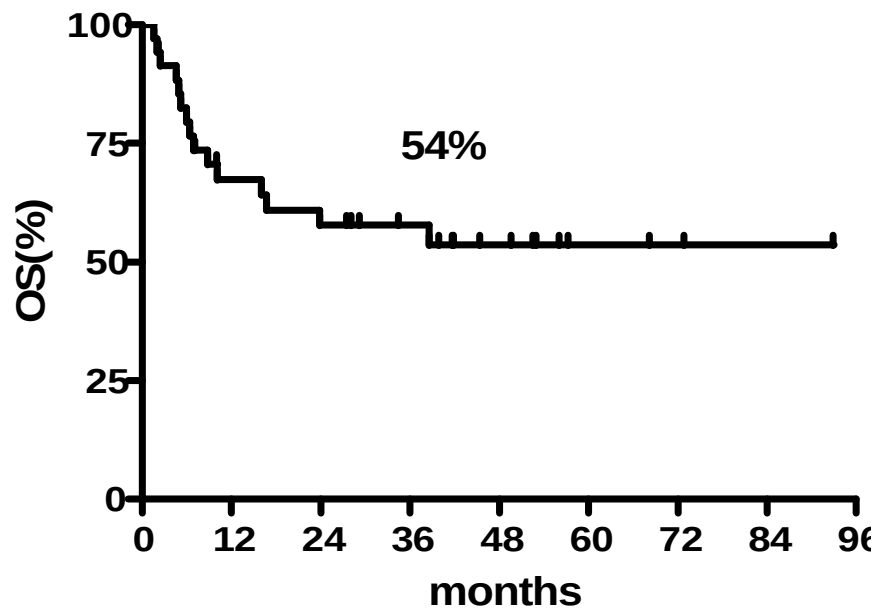
Prospective Phase II Trials

	Corradini (Leukemia 2006)	Lopez-Guillermo (ASH 2006, #3070)	Reimer (ASH 2005, #2074)	D`Amore (ASH 2006, #401)
n	62 (incl.19 ALK+ ALCL)	41 (no ALK+ ALCL)	65 (no ALK+ ALCL)	121 (no ALK+ ALCL)
Median age	43y	47y	49y	55y
Regimen	1) 2xAPO>2xDHAP ▶ HD Mito./Mel 2) MACOP-B>HD AraC/Mito ▶ BEAM	3xmaxiCHOP + 3xESHAP altern.	4-6xCHOP-21 + DexaBEAM ▶ HD Cy + TBI	6xCHOEP-14 ▶ BEAM
ASCT (%)	74%	41%	65%	73%
CR/PR pre Tx	56%/16%	49%/10%	47%/26%	50%/35%
TRM	4,8%	3%	3%	4%
OS	34% (12y) [21%*]	39% (4y)	50% (3y)	67% (3y)
EFS / FFS/PFS	30% (12y) 18%*	30% (4y)	n.d.	n.d.
Follow-up	76mo	3,9yrs (survivors)	10mo after Tx	med. 24mo

[* Non ALK+ ALCL]

T-NHL RIC allogeneic SCT

median follow-up 44 months



N = 20 alive (n= 18 CR, n= 2 relapse)

N= 15 death (n= 12 disease, n= 3 TRM)

P. Corradini



B. Class

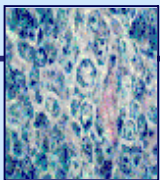
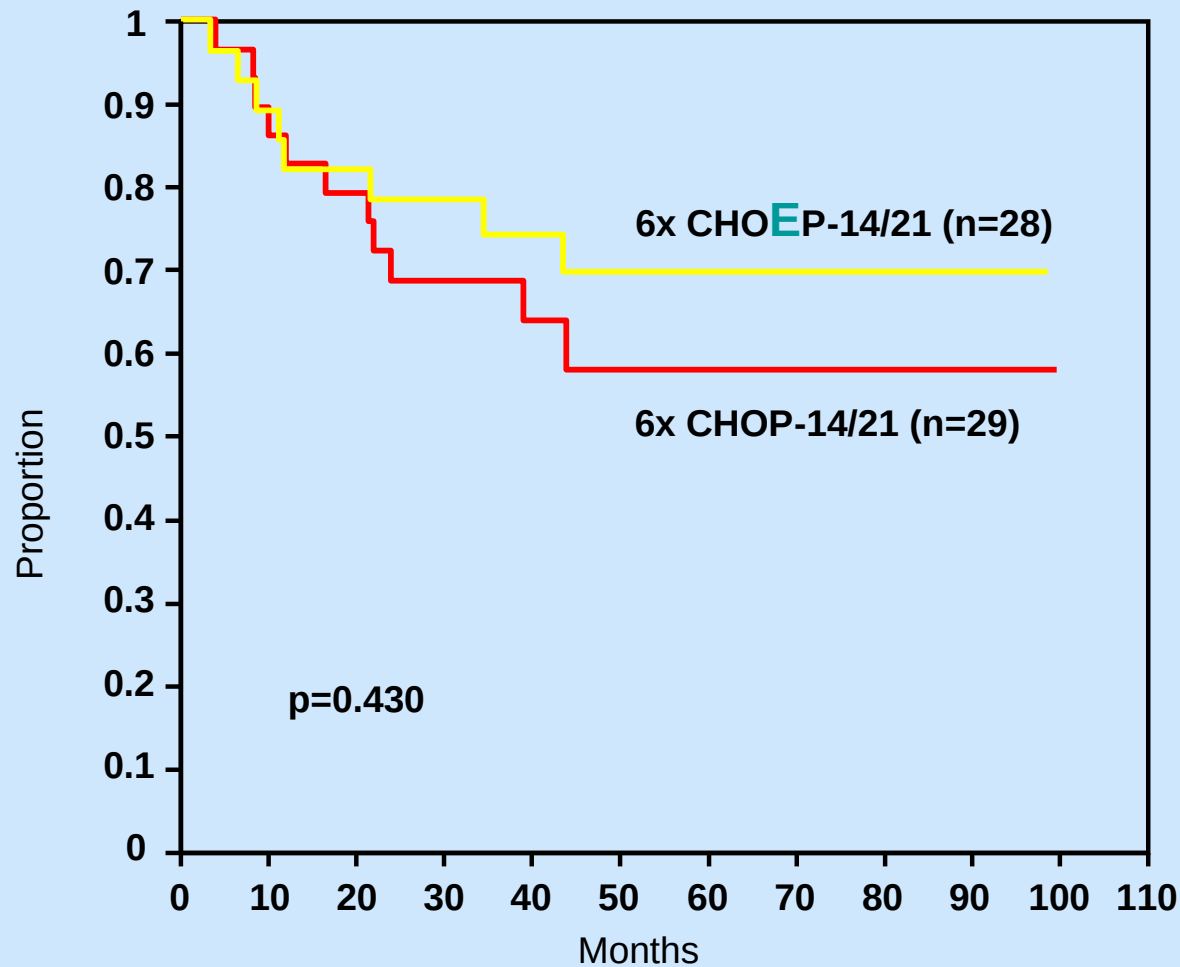
9.1.2009

54

T-cell lymphomas in DSHNHL trials

ALK-negative ALCL and other T-cell lymphomas

NHL-B1 trial (= 60 years, LDH = N, n=57), OS: role of etoposide



DSHNHL 05.12.2003

3-years OS-rate:

with Etoposide:

74.2% (95% CI: 57.5-90.9%)

without Etoposide:

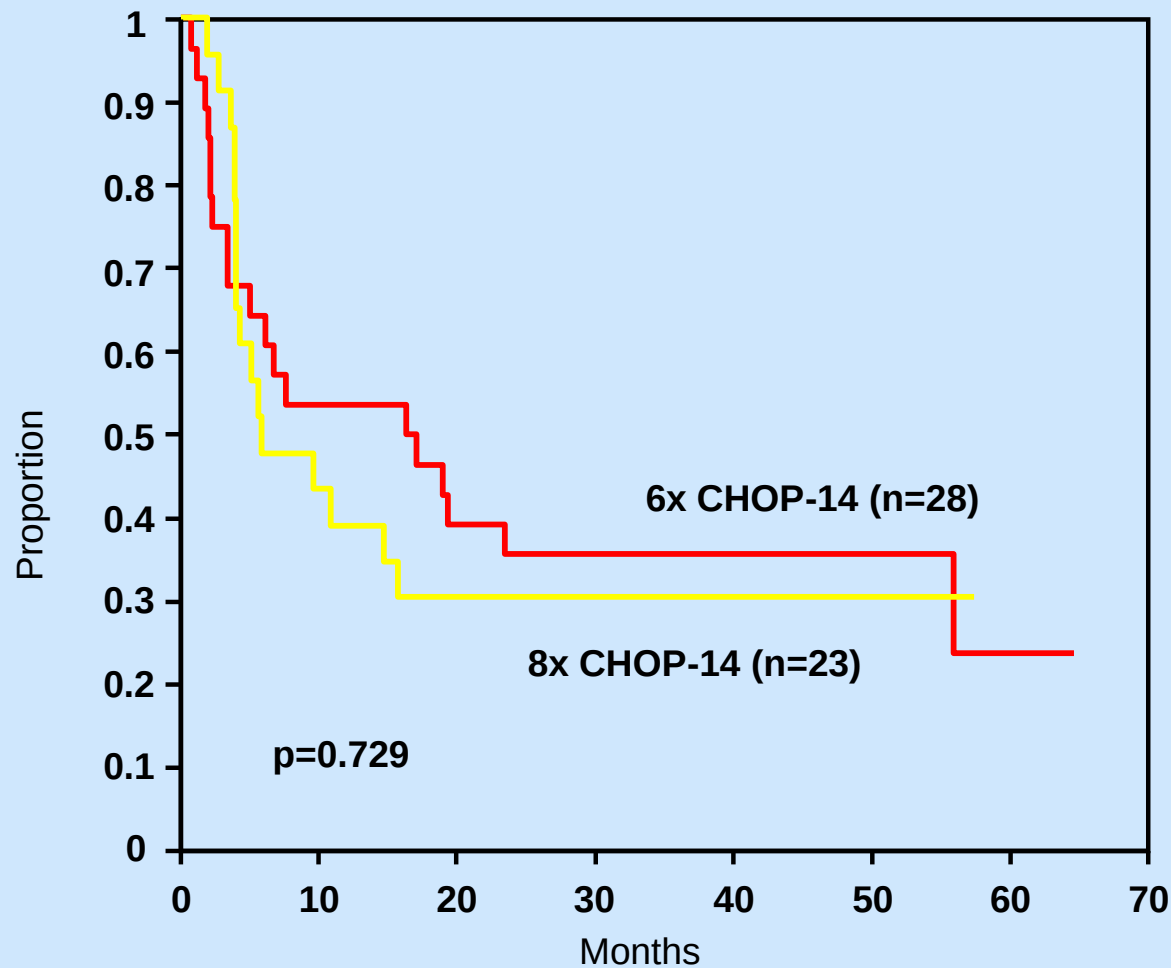
68.8% (95% CI: 51.9-85.6%)



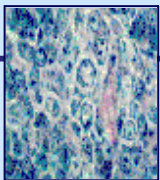
T-cell lymphomas in DSHNHL trials

ALK-negative ALCL and other T-cell lymphomas

RICOVER60 trial (60-80 years, n=51), EFS according to number of cycles



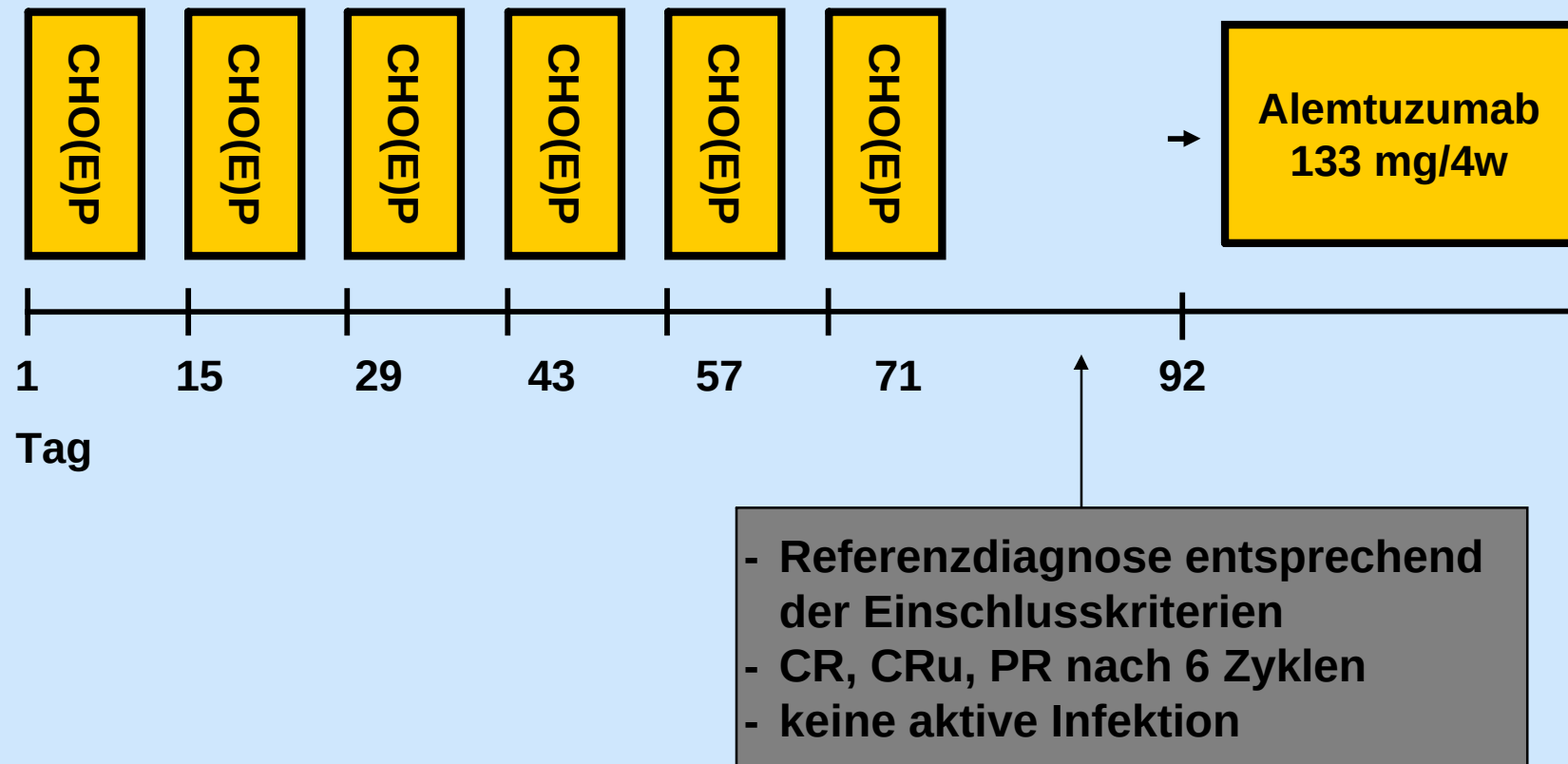
3-years EFS-rate: 6x CHOP-14: 35.7% (95% CI: 17.9-53.5%)
8x CHOP-14: 30.4% (95% CI: 11.6-49.2%)



DSHNHL 05.12.2003



DSHNHL 2003-1: Studiendesign



Binder et al., Blood (ASH Annual Meeting Abstracts) 2007; 110: 3431a

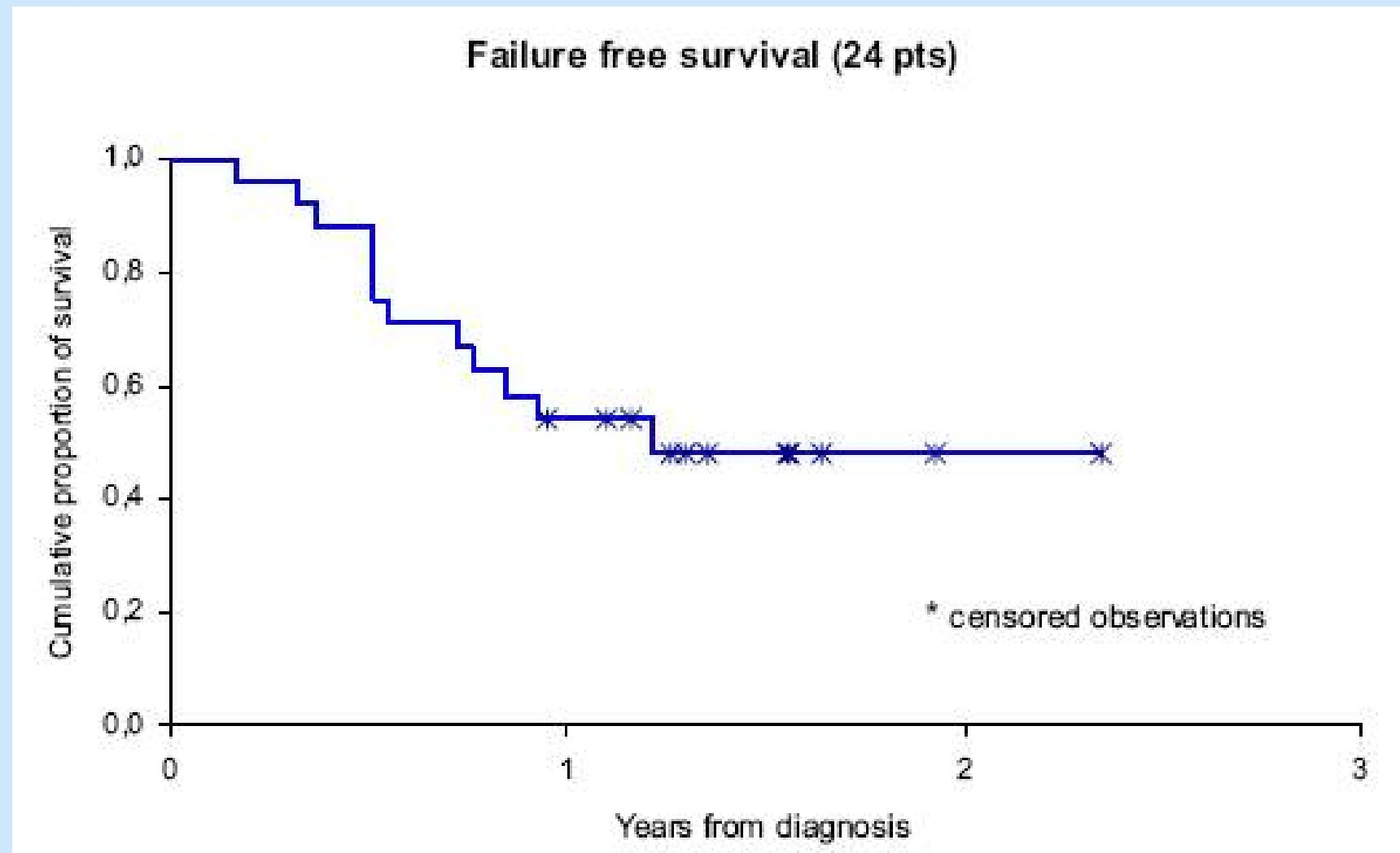


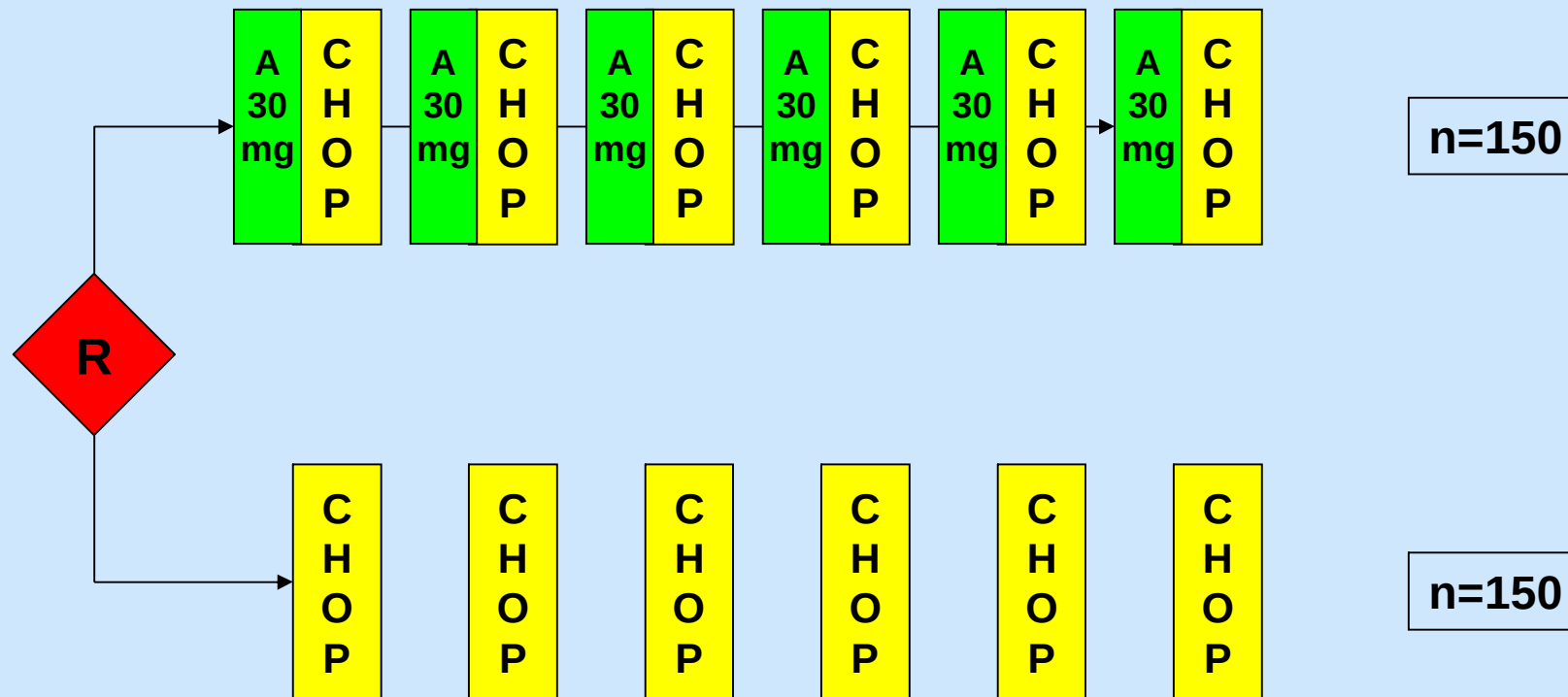
B. Class

UMG

T-NHL
RIC allogeneic SCT

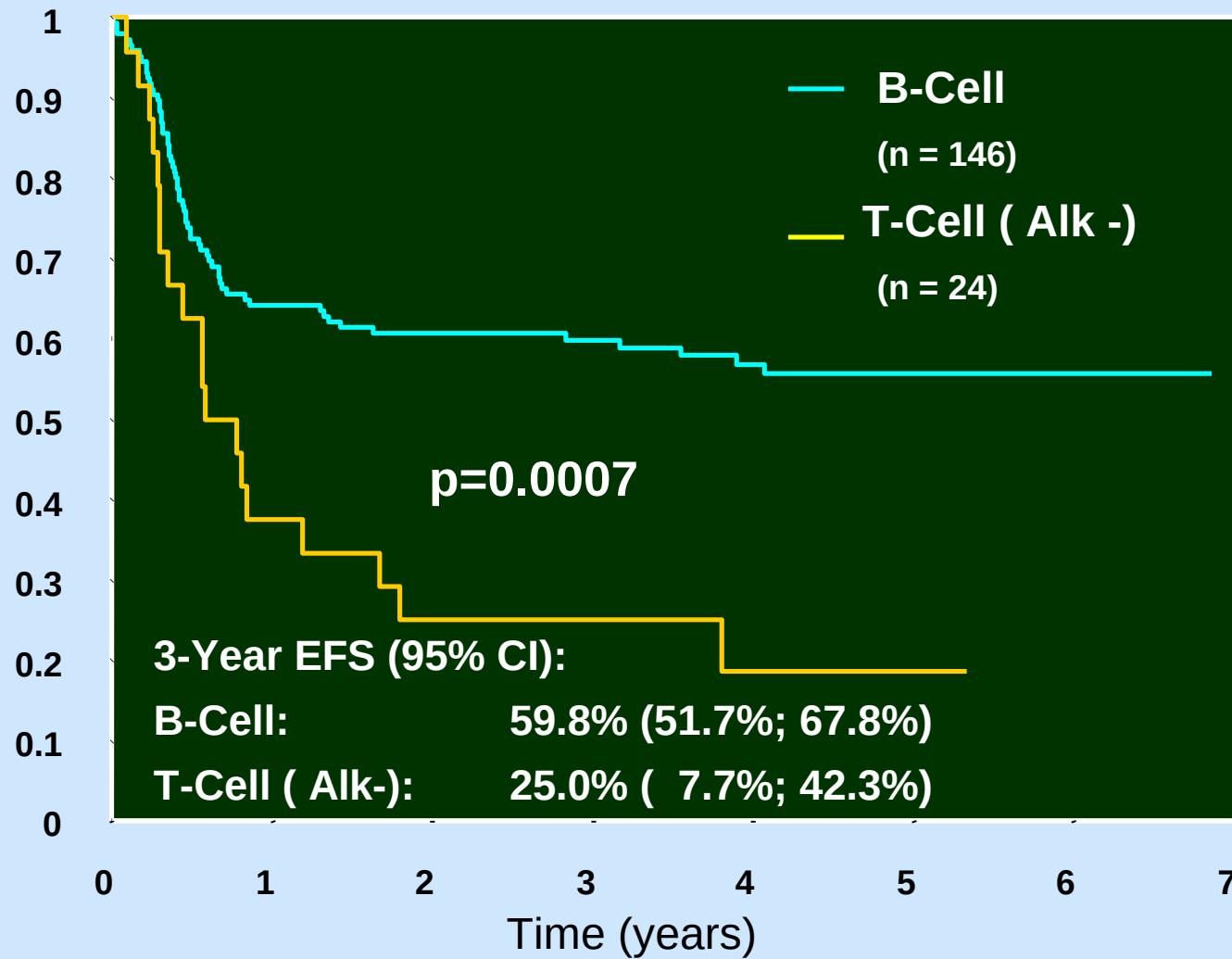
Age	43 (15-64)
No. lines (range)	2 (1-4)
Previous autologous SCT	57%
CR pre-allogeneic SCT	29%
PR pre-allogeneic SCT	42%
Median time diagnosis to allo-SCT	17 months (6-99 months)

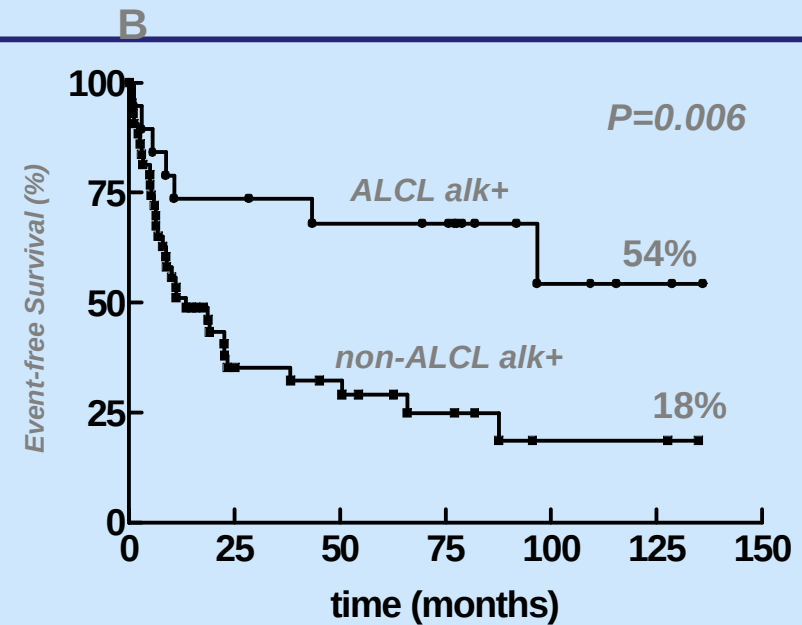
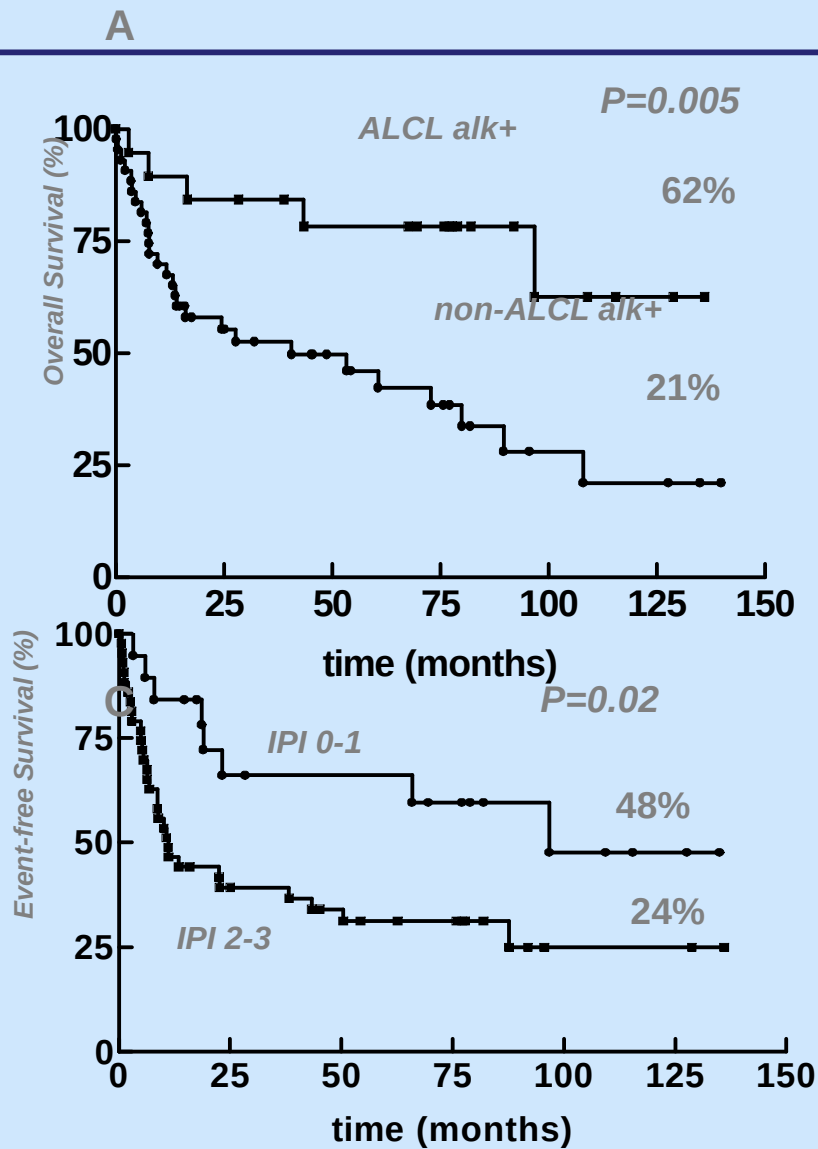




A = Alemtuzumab

MegaCHOEP Phase II T vs B: EFS

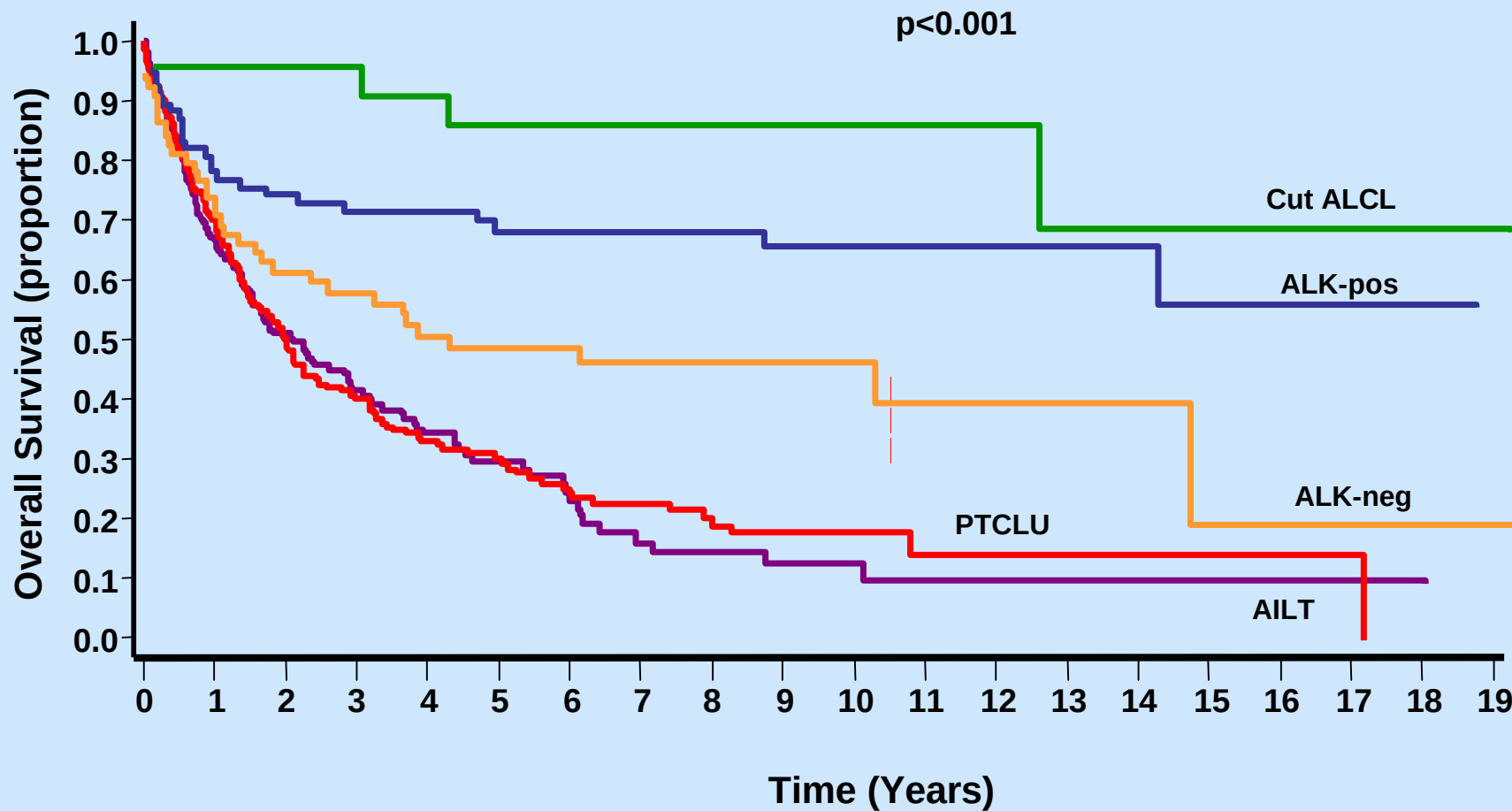




**prognostic factors for
auto-SCT in PTCL:**
aaIPI
ALK-positivity
pre-transplant CR

T-NHL

Histologischer Subtyp und Langzeitprognose



(Vose ASH 2005 811a)



B. Class

9.1.2009

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T-NHL

Resultate der konventionellen Therapie

- Anthracycline-based (CHOP-like) regimen
- Treatment analog to aggressive B-NHL
- Poor outcome

Author	Year	n	5y OS	Comment
Lippman	1988	20	15%	Non-ALCL
Coiffier	1990	108	med OS 42m	
Ascani	1997	168	(8y OS) 38%	ALCL incl
Melnyk	1997	68	39%	ALCL incl
López-G.	1998	174	(4y OS) 38%	ALCL incl
Kim	2002	78	36%	ALCL incl
Rüdiger	2002	96	26%	Non-ALCL
Huang	2004	106	22%	Only NOS

Aggressive B-Zell Non-Hodgkin-Lymphome

Histologische Einteilung

Follicular lymphoma	9690/3	
grade 1-2		
grade 3A / 3B		
Diffuse large B cell Lymphoma, NOS	9680/3	
T-cell/histiocyte rich large B-cell lymphoma	9688/3	
Primary DLBCL of the CNS		9680/3
Primary cutaneous DLBCL, leg, type		9680/3
EBV positive DLBCL of the elderly		9680/3
DLBCL associated with chronic inflammation	9680/3	
B cell lymphoma unclassifiable DLBCL / Burkitt	9680/3	
Primary mediastinal (thymic) B-cell lymphoma	9679/3	
Intravascular large B-cell lymphoma	9712/3	
ALK positive large B-cell lymphoma	9737/3	
Plasmablastic lymphoma	9735/3	
Large B-cell lymphoma in HHV8+ Castelman	9738/3	
Primary effusion lymphoma	9678/3	
B cell lymphoma unclassifiable HD / Burkitt	9596/3	
Burkitt lymphoma	9687/3	

DLBCL, NOS

Histologische Varianten

Diffuse large B cell Lymphoma, NOS

9680/3

Common morphologic variants

- centroblastic
- immunoblastic
- anaplastic

Rare morphologic variants

Molecular subgroups

- Germinal centre B-cell like (GCB)
- Activated B-cell-like (ABC)

Immunohistochemical subgroups

- CD5-positive DLBCL
- Germinal centre B-cell-like (GCB)
- Non- Germinal centre B-cell-like (GCB)

B-Zell Non-Hodgkin-Lymphome

Häufigkeitsverteilung

