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EHA25 VIRTUAL

25th Congress of the European Hematology Association

VIRTUAL EDITION

Role of Radiotherapy and Dose-Densification of R-CHOP in Primary Mediastinal B-Cell Lymphoma: A Subgroup Analysis of the UNFOLDER Trial of the German Lymphoma Alliance (GLA).

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Honoraria:

Held: Roche

Disclosure

Consulting or Advisory Role:

Held: BMS; MSD; Roche

Research Funding:

Held: BMS; Amgen; Roche; Spectrum Pharmaceuticals

Travel, Accommodations, Expenses:

Held: BMS; Roche

Funding of the UNFOLDER trial:





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Background:

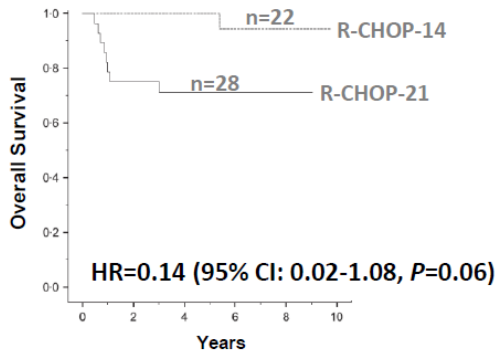
- **PMBCL is a distinct entity of aggressive lymphoma**
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PMBCL subgroup analysis of
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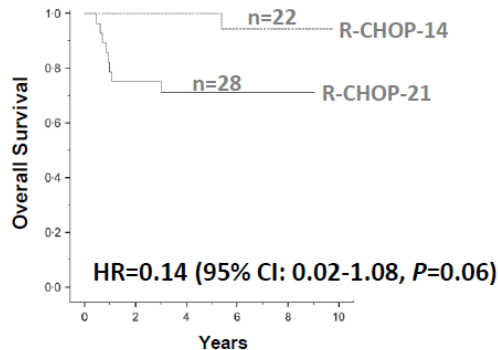


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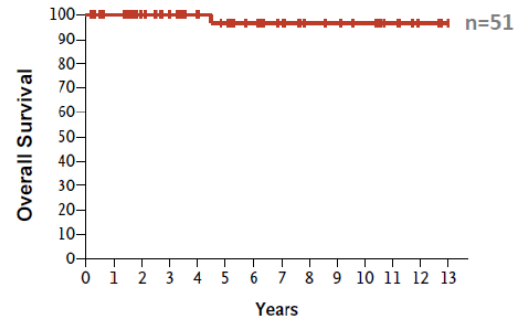
PMBCL subgroup analysis of
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Gleeson; BJH 175(4); 2016

Role of radiotherapy?

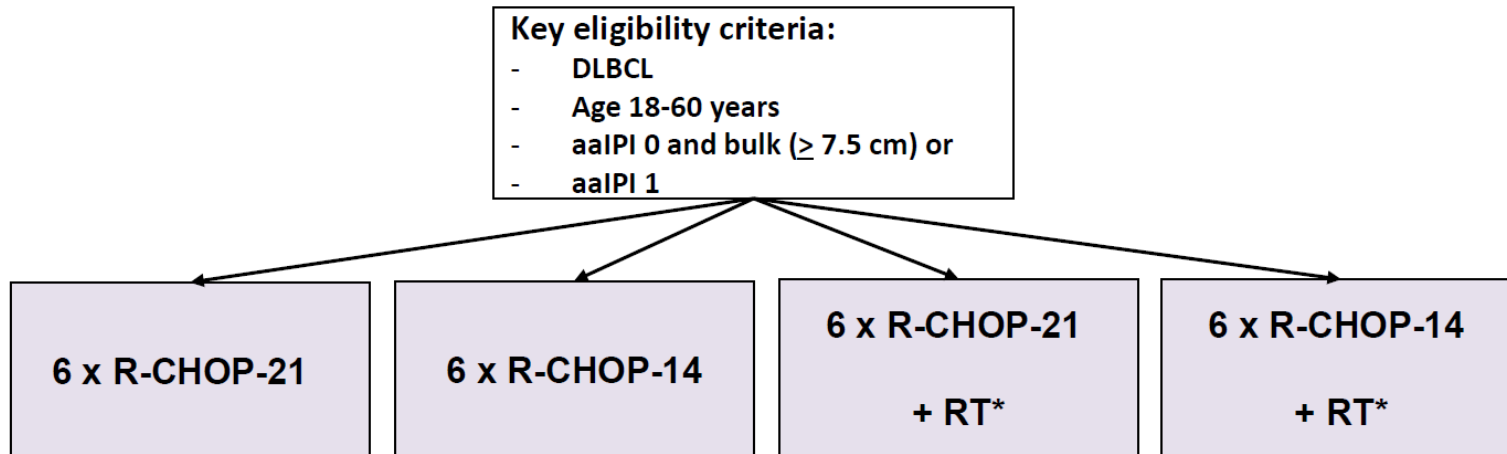
DA-EPOCH-R without radiotherapy
NCI phase-II trial



Dunleavy; NEJM 3682(15); 2013

UNFOLDER - Study Design:

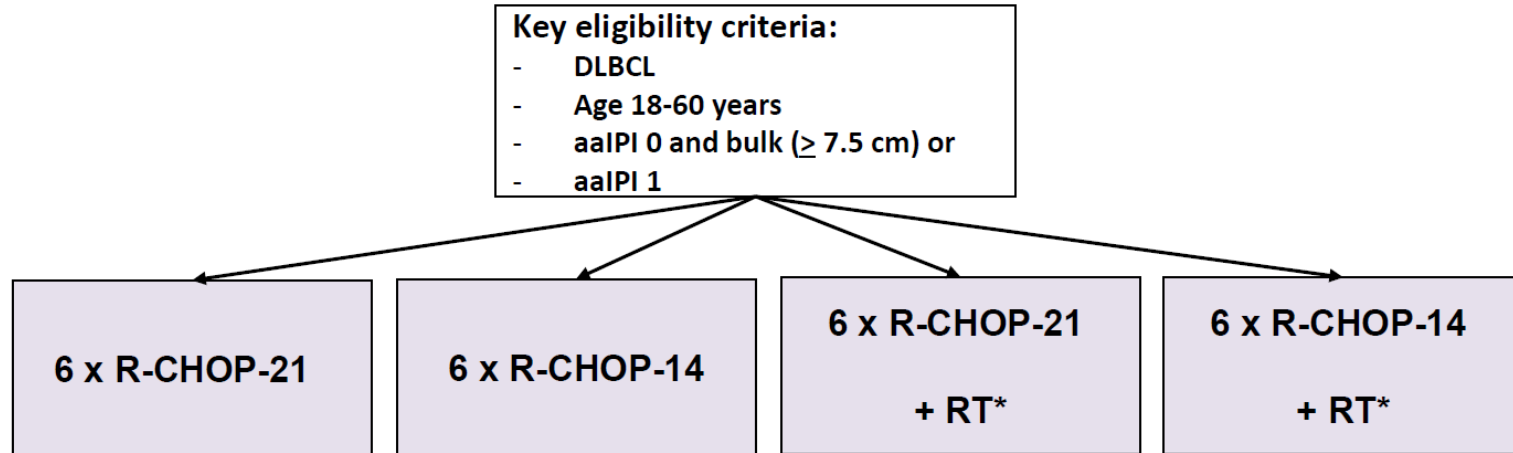
2 x 2 factorial Design



* Only pts. with bulky disease and extralymphatic involvement have been randomized to these arms

UNFOLDER - Study Design:

2 x 2 factorial Design



➔ 131 pts. with PMBCL with bulky mediastinal mass included.

Radiotherapy (RT):

- Involved-field technique to:
 - Bulky disease ($\geq 7.5\text{cm}$),
 - Extralymphatic involvement accessible to RT .
- Cumulative dose 39.6 Gy (1.8 Gy, 5x /week)
- Start 2-6 weeks after 6. cycle of R-CHOP

Endpoints

- **Event-free Survival*:**
 - PR, NC, PD, unknown
- - Relapse after CR/ CRu
- - CR/ CRu and additional treatment
- - Death of any cause

- **Progression-free Survival:**
 - PD at the end of study therapy,
 - Progression after PR, NC,
 - Relapse after CR/ CRu
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- **Overall Survival:**
 - Death of any cause

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Residual masses:

- CRu: $\geq 75\%$ decrease of SPD or
no viable lymphoma in biopsy

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- **No PET-Scan mandatory**

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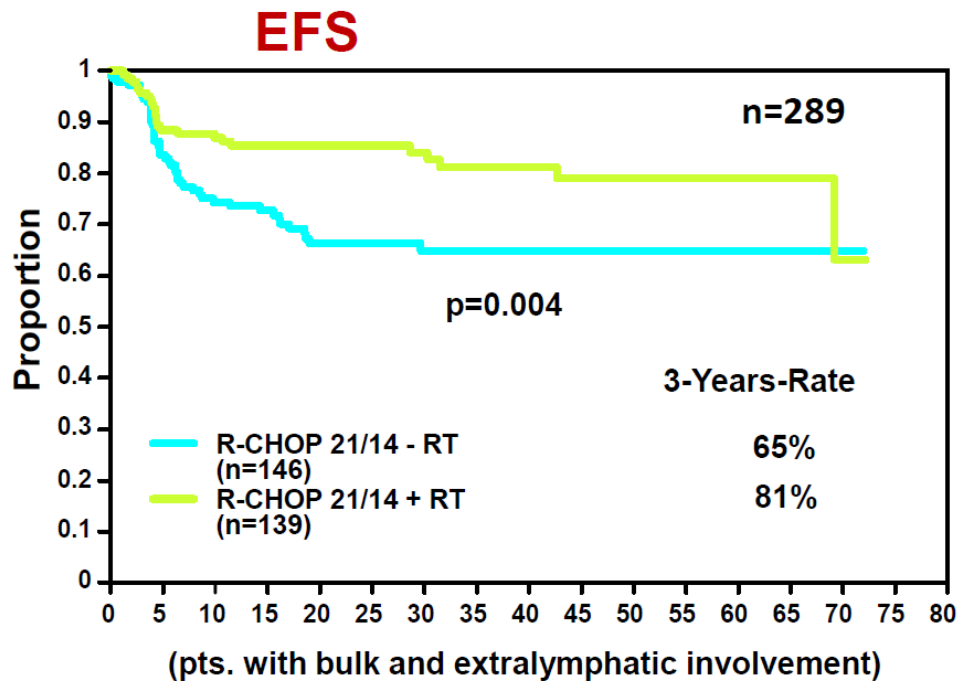
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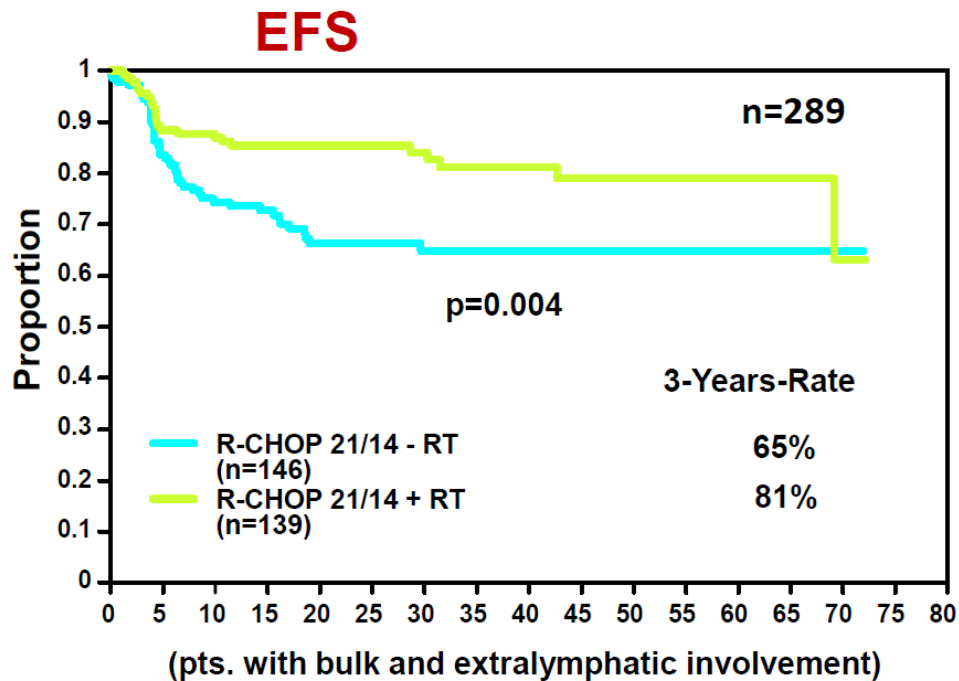
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Interim Analysis:



June 2012;

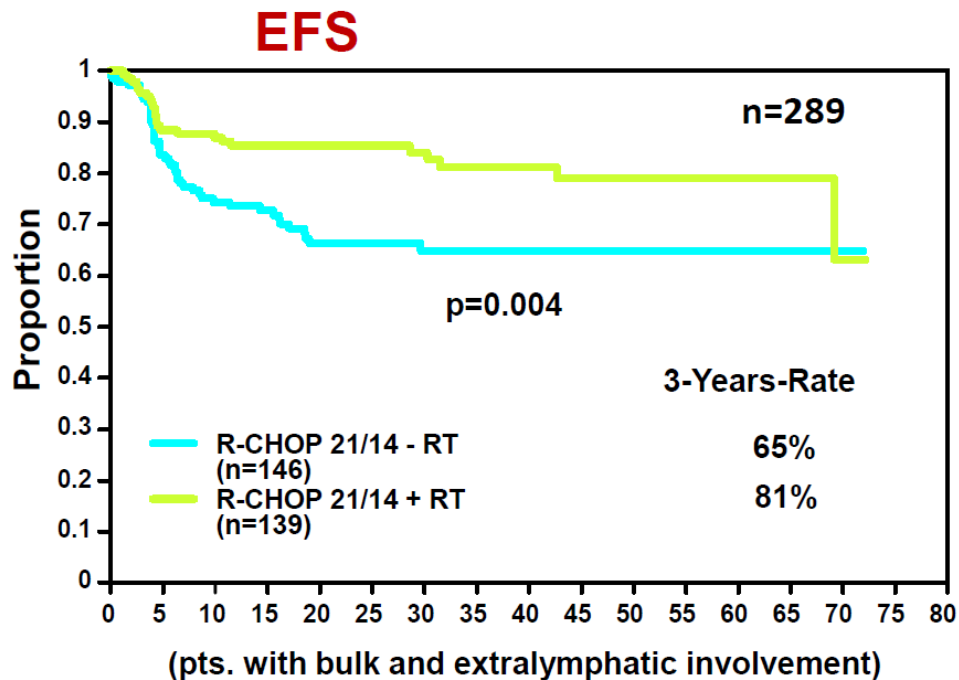
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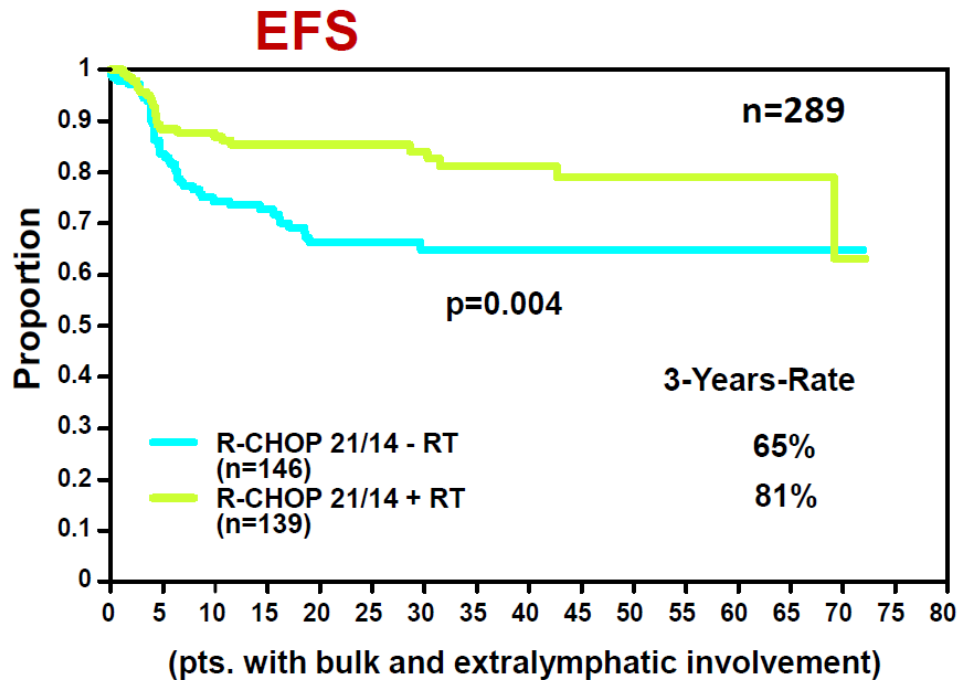


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DSMC recommendation:
Closure of arms without radiotherapy for pts. with bulk or extralymphatic involvement

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-> 3rd. Amendment

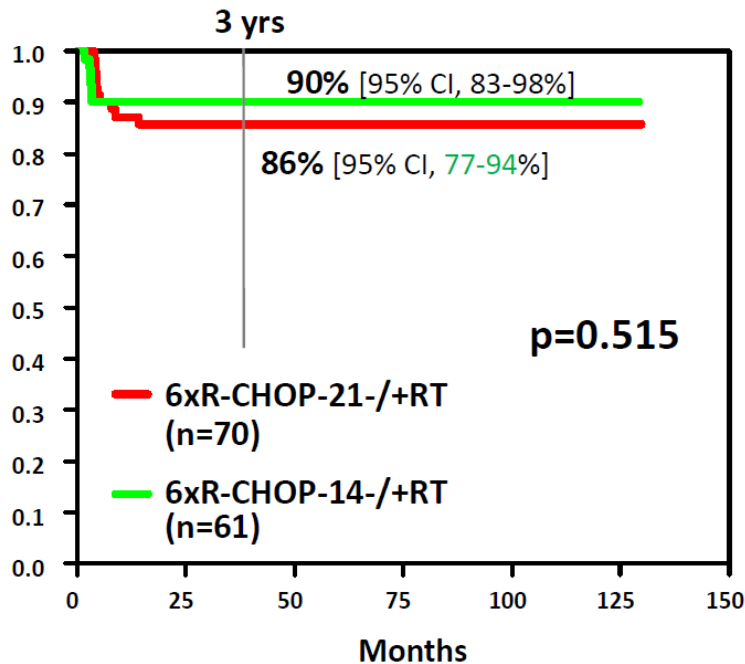
Demographics:

	R-CHOP-21 (n=27)		R-CHOP-14 (n=22)		R-CHOP-21 + RT (n=43)		R-CHOP-14 + RT (n=39)		all PMBCL (n=131)		
Male	14	52%	11	50%	19	44%	16	41%	60	46%	
Female	13	48%	11	50%	24	56%	23	59%	71	54%	
Age, median (range)	38	(22, 60)	32	(20, 51)	33	(19, 55)	34	(18, 60)	34	(18, 60)	
LDH > UNV	22	82%	20	91%	32	74%	29	74%	103	79%	
ECOG > 1	0	0%	0	0%	0	0%	0	0%	0	0%	
Stage III/IV	1	4%	0	0%	5	12%	4	10%	10	8%	
aaIPI	0	4	15%	2	9%	8	19%	6	15%	20	15%
	1	23	85%	20	91%	33	77%	33	85%	109	83%
	2	0	0%	0	0%	2	5%	0	0%	2	2%
Stage III/IV	I	17	63%	10	46%	19	44%	13	33%	59	45%
	II	9	33%	12	54%	19	44%	22	56%	62	47%
	III	0	0%	0	0%	0	0%	2	5%	2	2%
	IV	1	4%	0	0%	5	12%	2	5%	8	6%
Extralymph. Involv.	4	15%	4	18%	12	28%	11	28%	31	24%	
Bulk ≥ 7.5 cm	27	100%	21	96%	43	100%	39	100%	130	99%	

EFS, primary endpoint:

R-CHOP-21 vs. R-CHOP-14

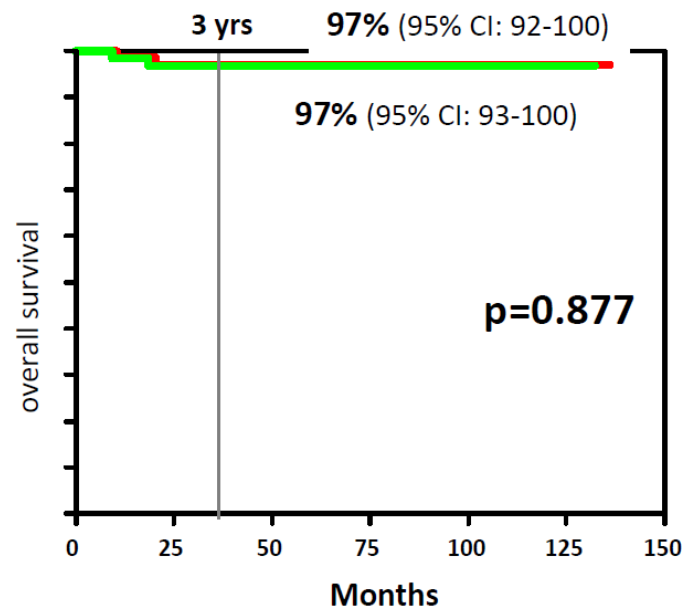
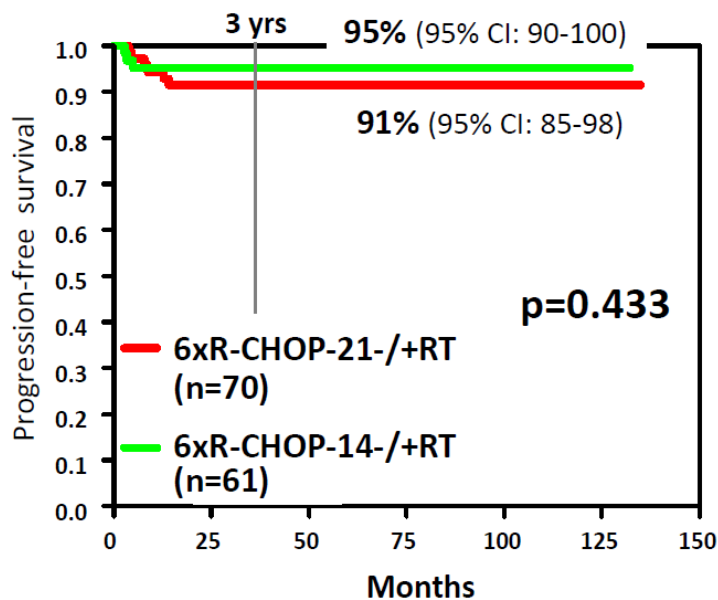
2 x 2 factorial
analysis



PFS and OS:

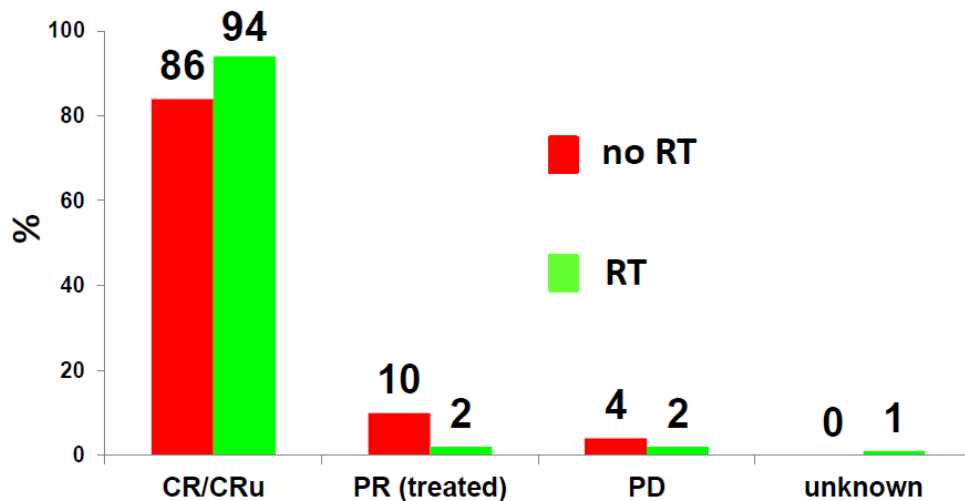
R-CHOP-21 vs. R-CHOP-14

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Response rates:

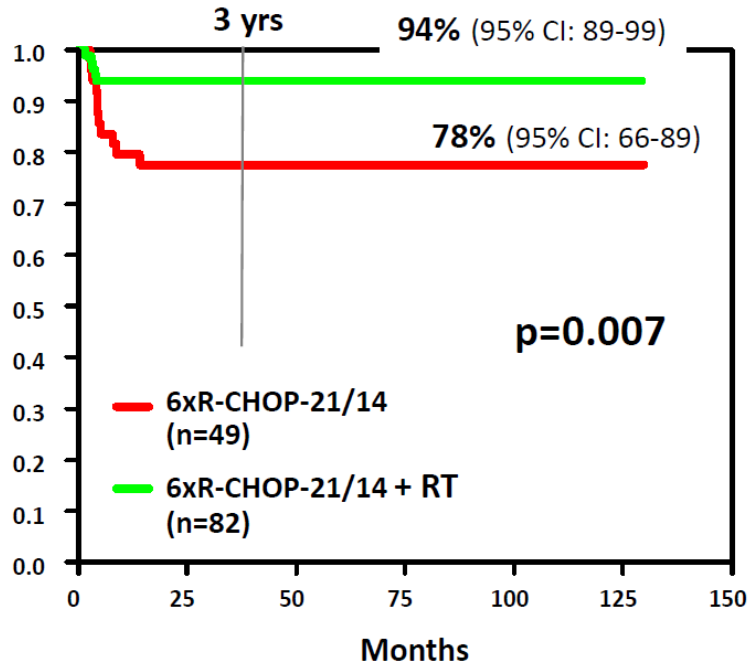
Radiotherapy vs. observation



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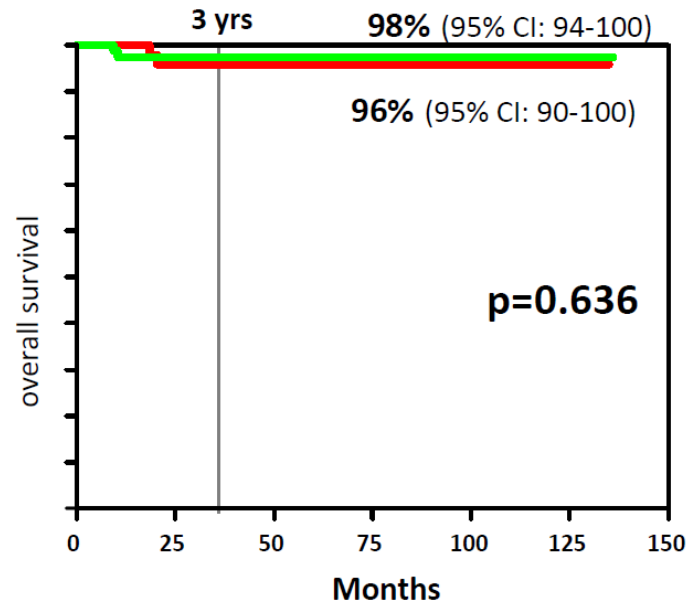
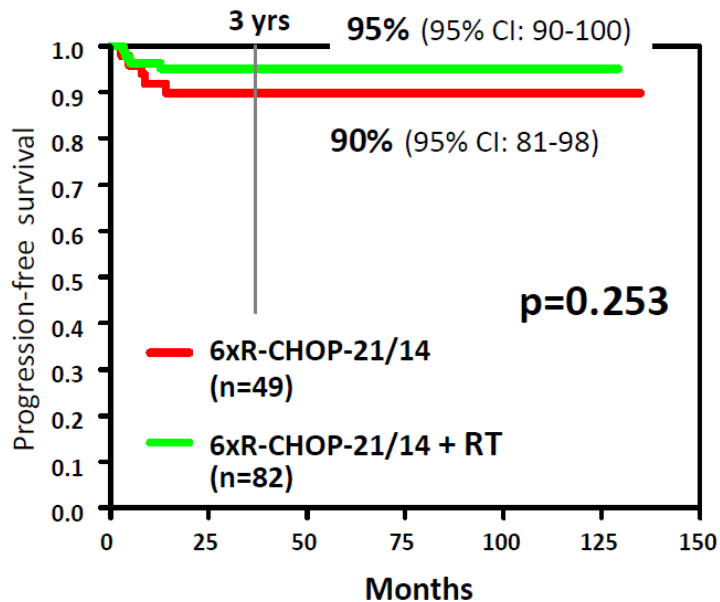
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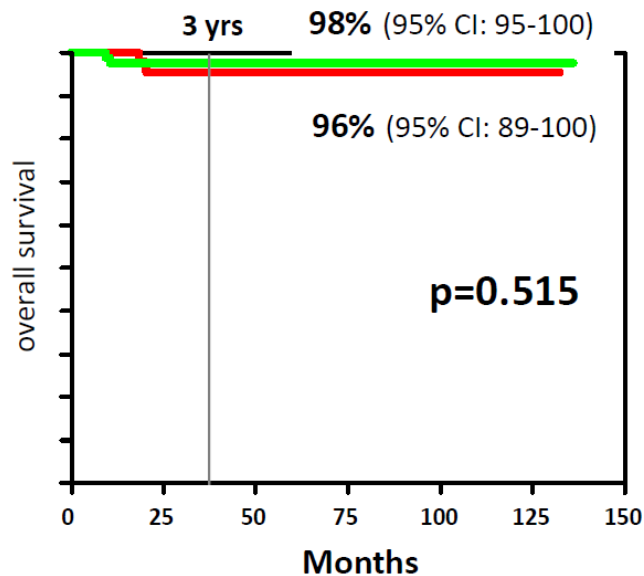
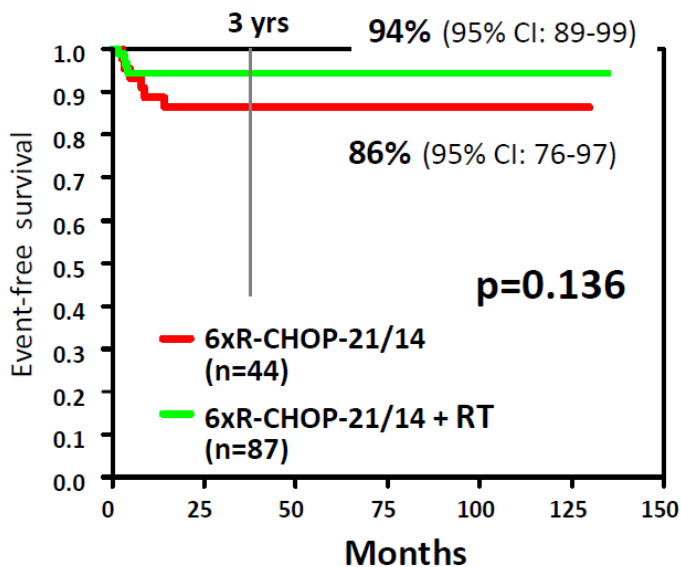
EFS Events:

	R-CHOP-21/14 n=49 (%)	R-CHOP-21/14 + RT n=82 (%)
Progressive disease	2 (4)	2 (2)
PR requiring therapy [Radiotherapy]	5 (10) [4]	2 (2) [-]
Relapse after CR/CRu	3 (6)	0
CR/CRu and addition. therapy [radiotherapy]	1 (2) [1]	0
unknown		1 (1)

EFS and OS (post-hoc, as treated analysis).

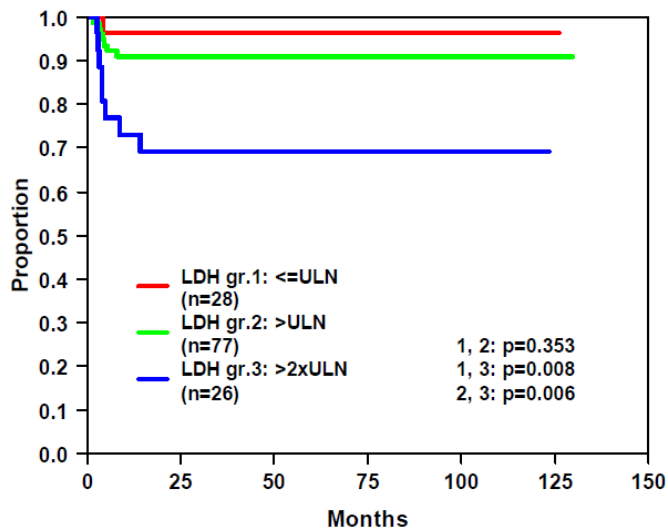
Radiotherapy vs. observation

* Five patients in the observation arm received radiotherapy and were not counted as event but analysed within the RT arm

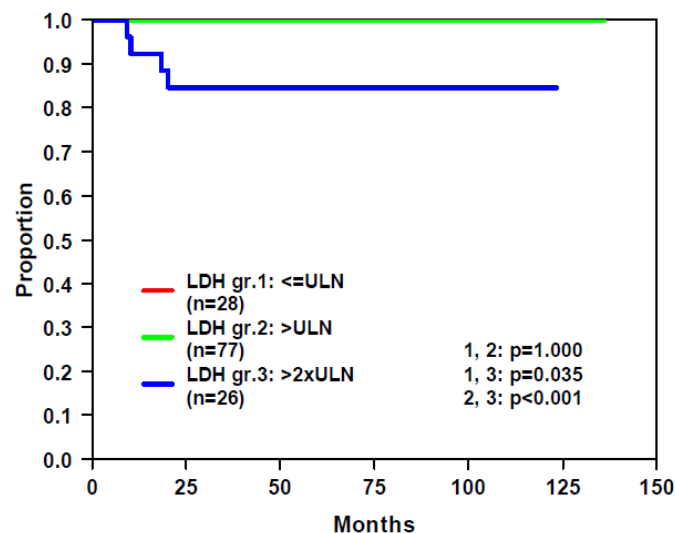


Prognostic factors – LDH > 2x UNV:

Event-free survival



Overall survival



Prognostic factors – multivariate analysis

	EFS		PFS	
	HR (95% CI)	p	HR (95% CI)	p
6xR-CHOP-21/14+RT vs. 6xR-CHOP-21/14	0.2 (0.1; 0.7)	0.012	0.4 (0.1; 1.9)	0.255
6xR-CHOP-14-/±RT vs. 6xR-CHOP-21-/±RT	0.8 (0.3; 2.3)	0.708	0.6 (0.1; 2.6)	0.506
Extralymp. involvement	4.2 (1.3; 13.4)	0.015	3.0 (0.6; 15.3)	0.185
Bulk > 10 cm	1.2 (0.4; 3.7)	0.752	1.6 (0.4; 7.5)	0.533
LDH > 2xULN	4.8 (1.6; 13.8)	0.004	12.4 (2.6; 59.4)	0.002
Stage III/IV	1.9 (0.3; 10.9)	0.495	6.0 (0.7; 51.1)	0.102



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- **No differences in outcome between R-CHOP-14 and R-CHOP-21.**



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UNFOLDER trial Team:



Coordinating Investigators:

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M. Pfreundschuh (Germany)

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Reference Radiology– Homburg/Germany:

Günther Schneider

Reference Pathology:

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