PET-based decisions in Hodgkin lymphoma

2014 ESMO congress
ESMO/EANM joint symposium

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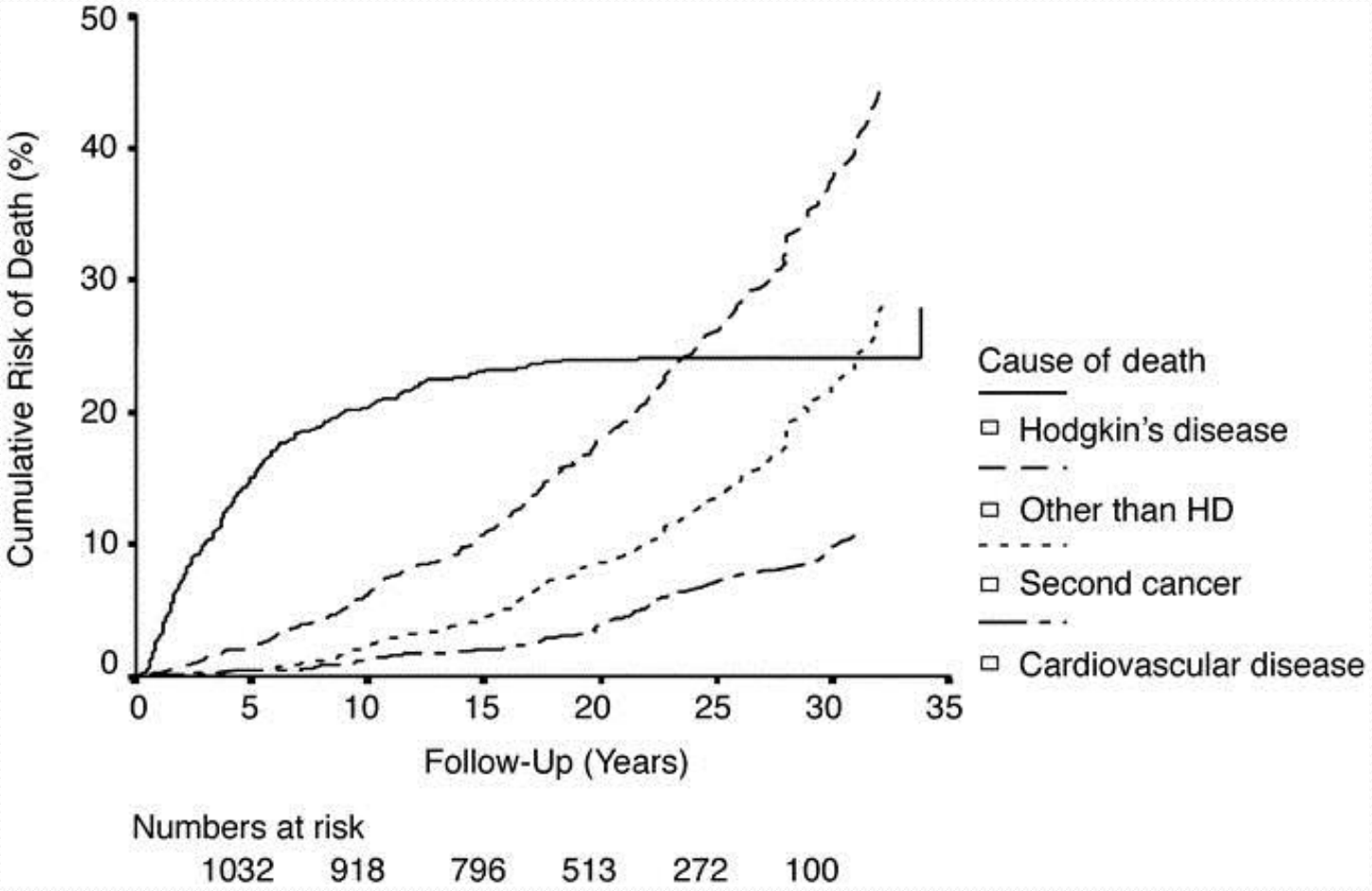
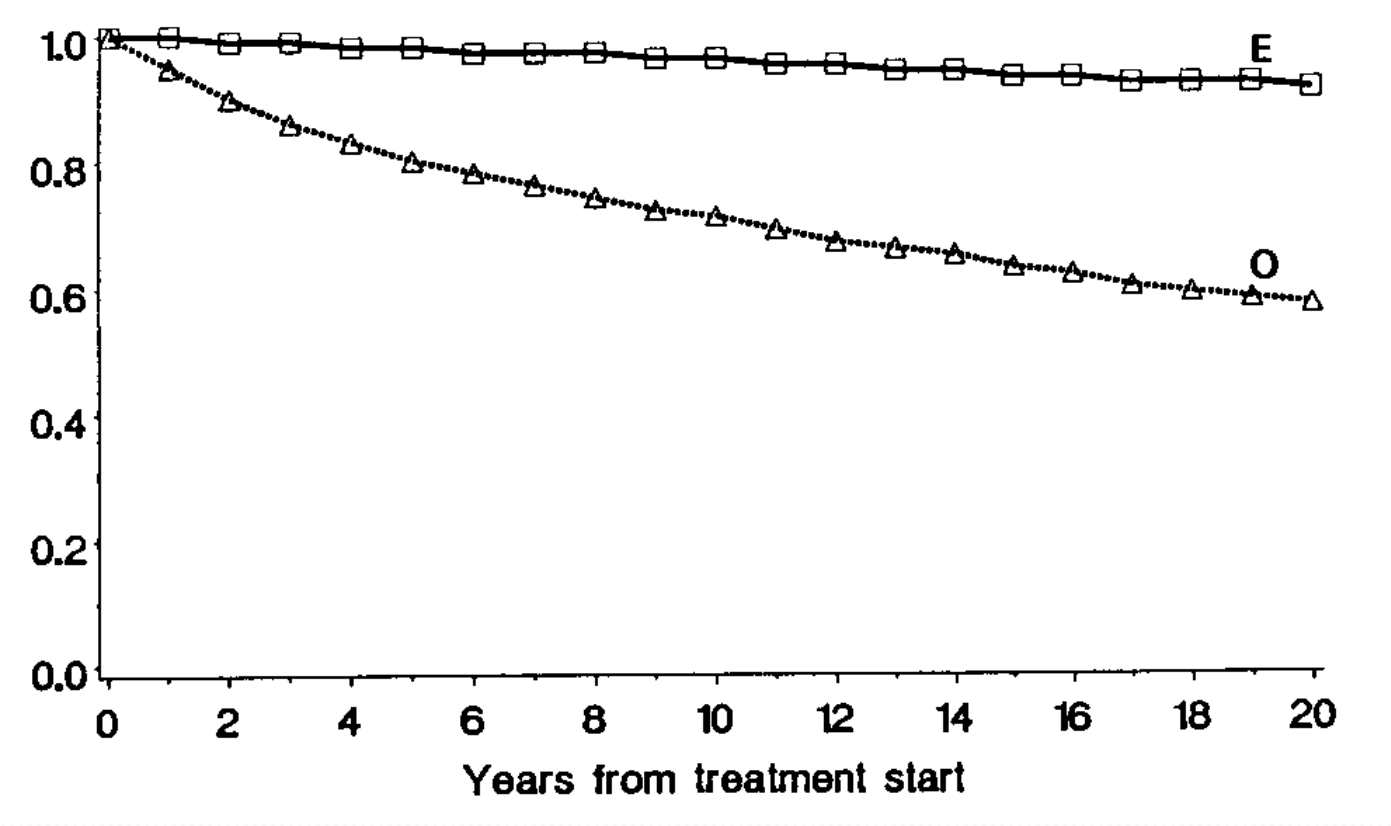
HL cure rates are very high, but



Aleman et al. J Clin Oncol 2003; 21(18): 3431-39.

Expected vs. observed survival



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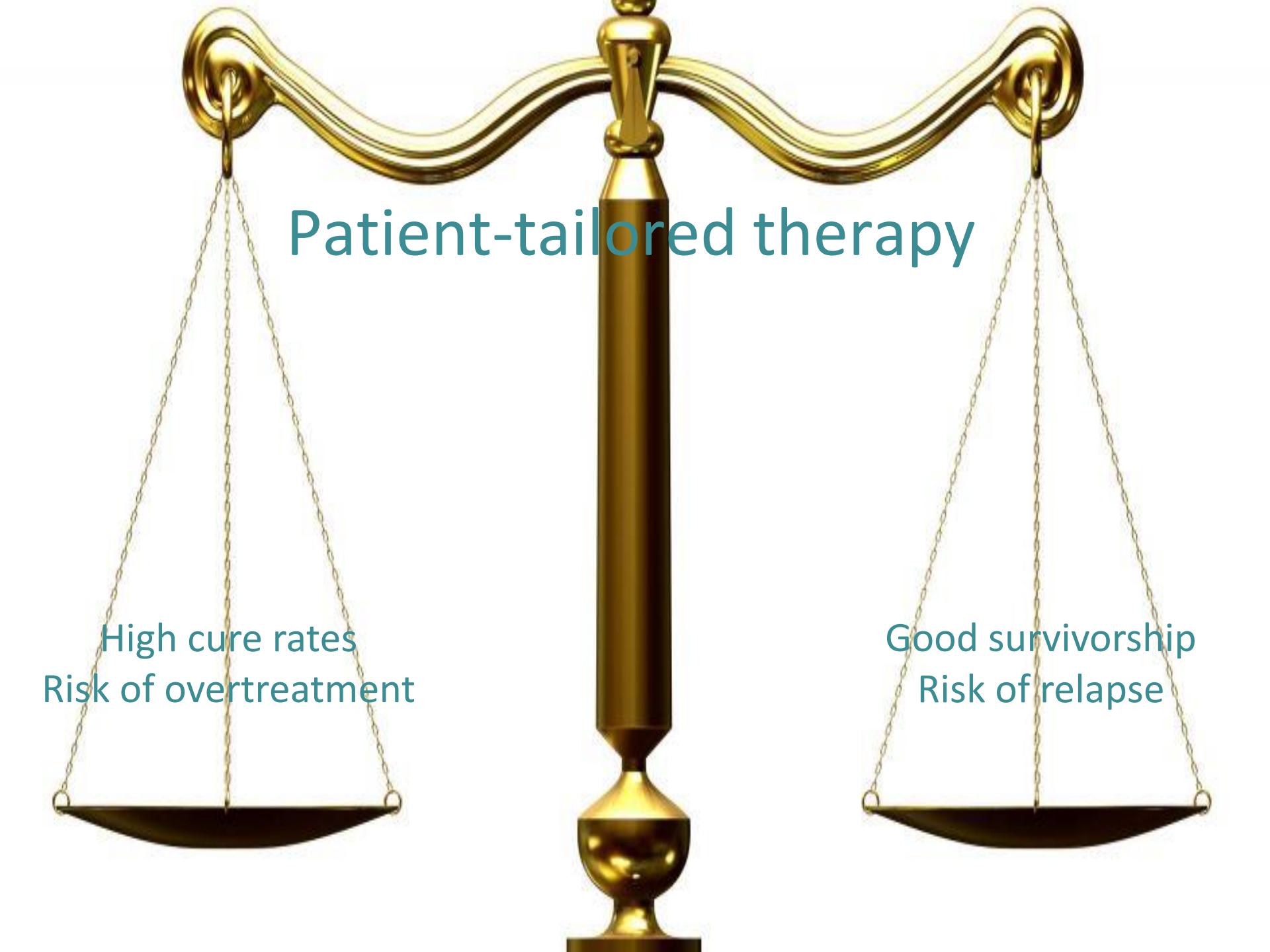
Patient-tailored therapy
High cure rates
Risk of overtreatment
Good survivorship
Risk of relapse

The therapeutic dilemma in HL

- We want to personalise treatment in order to
  - maintain or improve the cure rates
  - and still reduce toxicity
- For this purpose, among other things, we need
  - knowledge about prognostic and predictive factors
  - a precise determination of initial disease extent
  - accurate and early assessment of responsiveness to therapy

Staging

Early treatment monitoring and
PET response-adapted therapy

Post-treatment evaluation

Follow-up

Relapsed/refractory HL

Summary

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PET/CT Staging

- Clinical stage is the most important determinant for the choice of first line treatment strategy in HL
- More individualized therapy increases demand for precise determination of initial disease extent
- PET/CT is more sensitive than conventional staging methods (incl. CT), with equal specificity[1]
- PET/CT results in upstaging of 15-25% of patients, shift from early to advanced stage in 10-15% of patients[1,2]

1. Hutchings M, *et al*. Haematologica 2006;91:48–29
2. Zaucha, JM, *et al*. ASH 2012 poster #2632. Poster session 621, Sunday Dec 9, 6.00-8.00 pm.

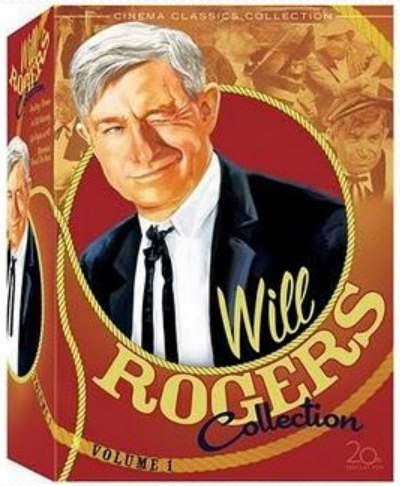
What is the consequence of this improved staging accuracy?

Better outcome for both early and advanced stages?

So why are we not happy?

Because we should be careful not to overtreat

"When the Okies left Oklahoma and moved to California, they raised the average intelligence in both states." - Will Rogers



PET/CT: Handle with care

- Upstaging means further risk of overtreatment
- PET/CT staging should be accompanied by
  - More refined and tailored treatment strategies to avoid over-treatment due to upstaging
  - Relevant modifications to the staging system to enhance the benefits obtained from improved accuracy
- Radiotherapists have shown the way:
  - Smaller treatment volumes despite detection of more involved nodes (IFRT → INRT)[1]

1. Girinsky *et al.* Radiother Oncol. 2007; 85: 178-86.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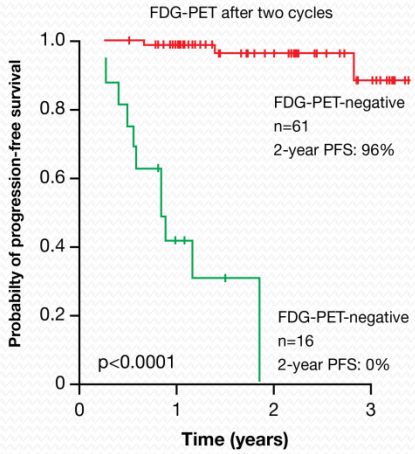
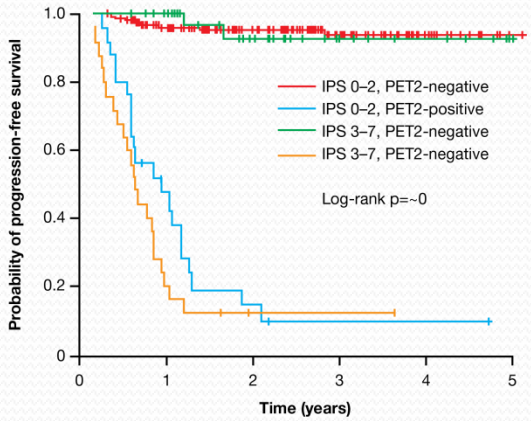
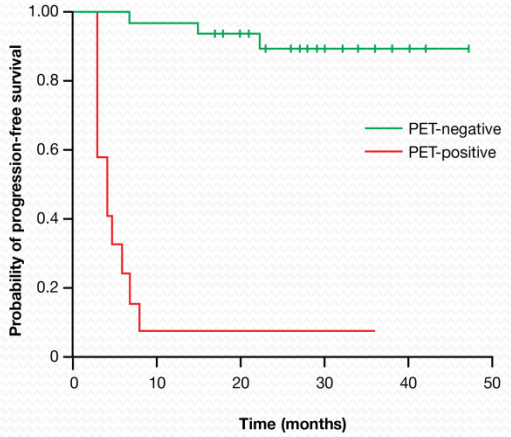
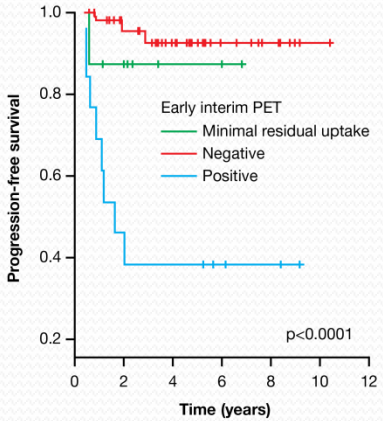
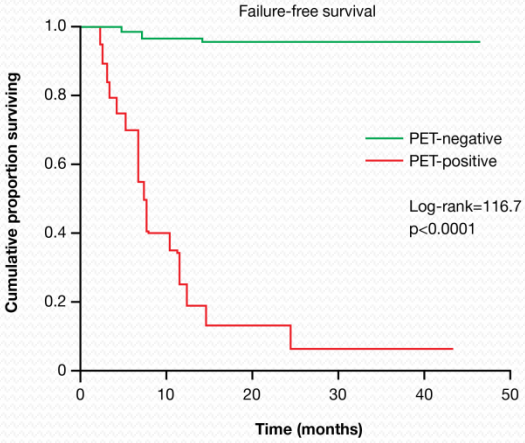
Many studies show excellent outcomes for FDG-PET-negative patients compared with those showing persistent FDG uptake[1–6]

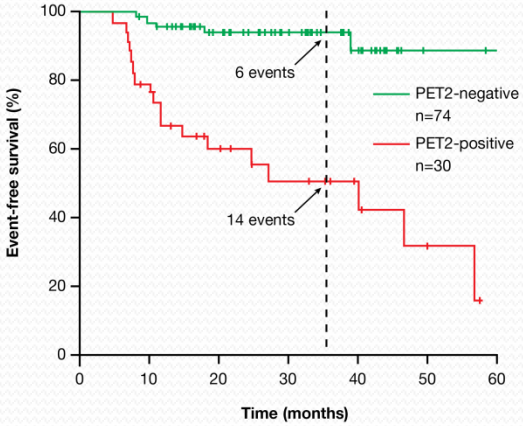












1. Hutchings M, *et al*. Blood 2006;107:52–9.
2. Gallamini A, *et al*. J Clin Oncol 2007;25:3746–52.
3. Kostakoglu L, *et al*. Cancer 2006;107:2678–87.
4. Hutchings M, et al. Ann Oncol 2005;16:1160–8.
5. Gallamini A, et al. Haematologica 2006;91:475–81.
6. Cerci JJ, et al. J Nucl Med 2010;51:1337–43.

Many studies show excellent outcomes for FDG-PET-negative patients compared with those showing persistent FDG uptake[1–6]

Study	No. of chemo-therapy cycles before FDG-PET	Number of patients	Number (%) of patients whose FDG-PET results were:				Follow- up (months)
			Positive		Negative		
			Total	Treatment failure	Total	Treatment failure	
Hutchings, *et al.* 2005[1]	2 or 3	85	13	8 (62)	72	4 (6)	6–125
Hutchings, *et al.* 2006[2*]	2	77	16	11 (69)	61	3 (5)	2–41
Zinzani, *et al.* 2006[3]	2	40	8	7 (88)	28	0 (0)	12–27
Gallamini, *et al.* 2006[4*]	2	108	20	18 (90)	88	3 (3)	2–47
Gallamini, *et al.* 2007[5*]	2	260	50	43 (86)	210	10 (5)	4–62
Cerci, *et al.* 2010[6*]	2	104	30	16 (53)	74	6 (8)	32-40
Gallamini, *et al.* 2011[7]	2	260	45	33 (73)	215	12 (6)	2-110

1. Hutchings M, *et al*. Blood 2006;107:52–9.
2. Gallamini A, *et al*. J Clin Oncol 2007;25:3746–52.
3. Kostakoglu L, *et al*. Cancer 2006;107:2678–87.
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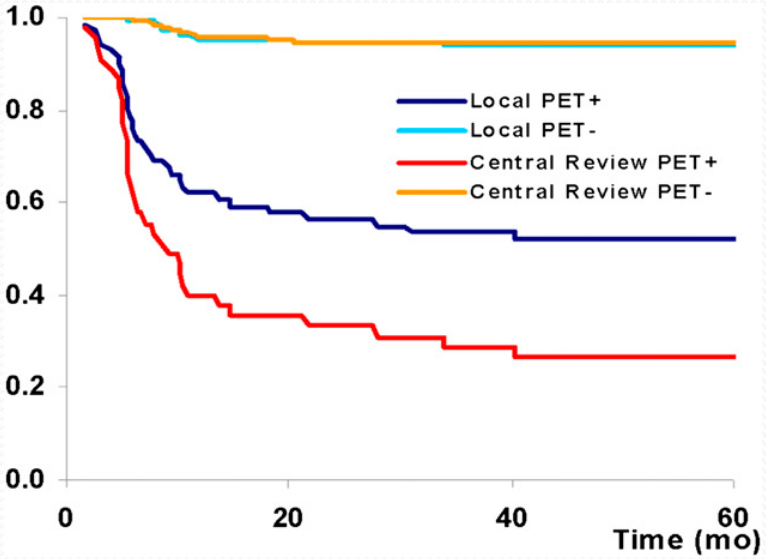
6. Cerci JJ, *et al.* J Nucl Med 2010;51:1337–43.
7. Gallamini A, *et al.* ICML Lugano 2011, abstract # 047

International validation study of the Deauville 5-point scale for interim PET in HL[1,2]

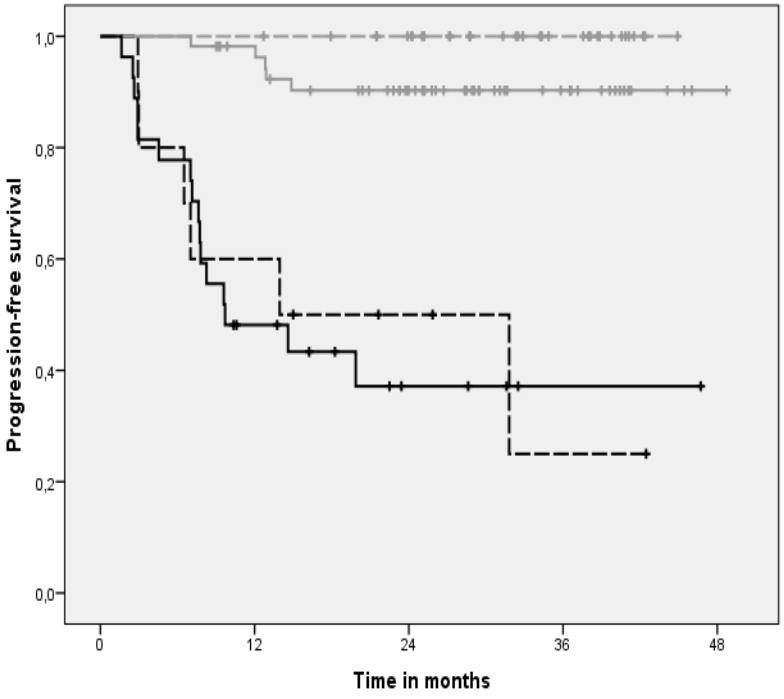
- 260 patients with advanced HL
- All baseline and interim(PET2) PET/CT scanns were independently scored by six blinded reviewers
- According to the Deauville 5-point scale
- 3-year failure free survival:
  - 95% for PET negative
  - 28% for PET positive



1. Biggi A, Gallamini A, *et al*. J Nucl Med 2013; 54:683–690
2. Gallamini A, et al. Haematologica 2014; 99(6):1107-13.

Prognostic value of **very early** treatment monitoring in HL

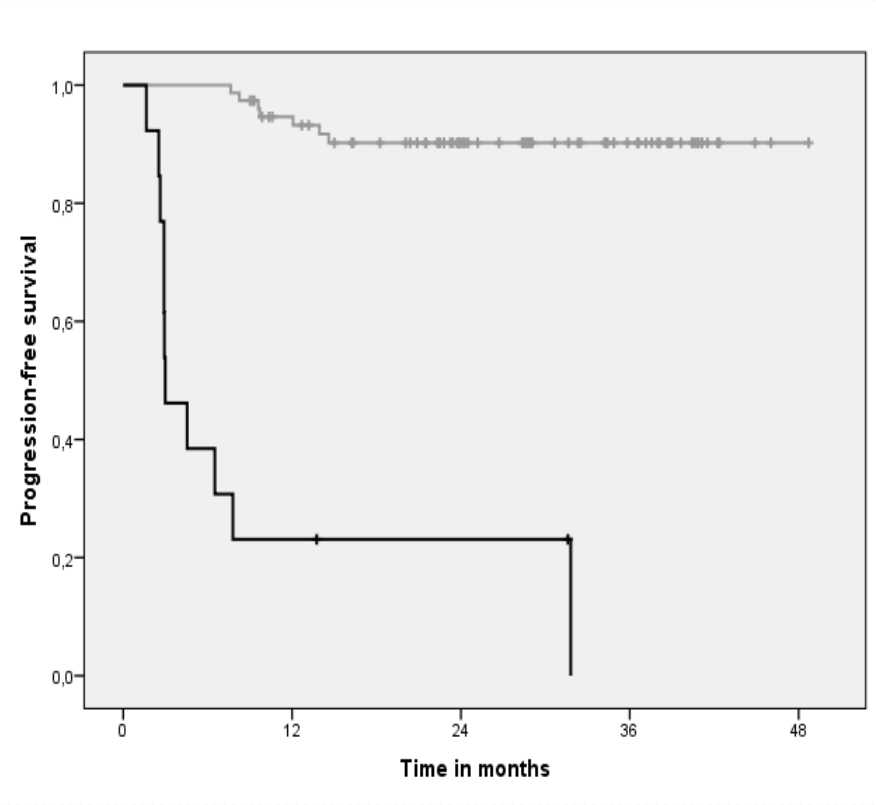
- 126 HL patients PET/CT scanned after one cycle of chemotherapy
- Prospective data
- Internationalt(US, Polen, Italien, Danmark) multicenter study with blinded central review
- 44 patients with early stage disease (dashed curves) and 82 patients with advanced disease



1. Hutchings M, Kostakoglu L, Zaucha JM, *et al*. J Clin Oncol 2014; 32(25):2705-11

Prognostisk værdi af **meget tidlig** behandlingsmonitorering ved HL

- 126 HL patients PET/CT scanned after one cycle of chemotherapy
- Prospective data
- Internationalt(US, Polen, Italien, Danmark) multicenter study with blinded central review
- 44 patients with early stage disease (dashed curves) and 82 patients with advanced disease
- 89 patients with PET1 and PET2:
  - NPV 98% for PET1 (darker curve)
  - NPV 90% for PET2 (lighter curve)



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Early stage HL: Can a negative early PET/CT select patients who do not need radiotherapy?

Study	Patients	Main PET-driven intervention	Phase
GHSG HD16	Early stage HL no risk factors	No radiotherapy in experimental arm if PET-negative after 2xABVD	III
EORTC/GELA/FIL H10 *(Completed)*	Early stage HL	Experimental arm: No radiotherapy if PET-neg after 2xABVD BEACOPPesc + radiotherapy if PET-pos after 2xABVD	III
UK NCRI RAPID (*Completed)*	Early stage HL	If PET-negative after 3xABVD randomization to RT vs. no RT	III
CALGB 50604	Early stage HL non-bulky	Additional ABVDx2 and no radiothrapy if PET-neg after 2xABVD. BEACOPPesc + radiotherapy if PET-pos after 2xABVD	II
CALGB 50801	Early stage HL bulky	Additional ABVDx4 and no radiothrapy if PET-neg after 2xABVD. BEACOPPesc + radiotherapy if PET-pos after 2xABVD	II
ECOG 2410	Early stage HL bulky	4xBEACOPPesc + RT if PET-positive after 2xABVD	II

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Preliminary results of H10 and RAPID trials

No radiotherapy in experimental arm if PET-negative after 2 ABVD or 3 ABVD

European H10 trial IA:

- 1137 patients, median FU 13 months
- Futility analysis based on 33 events
- Non-inferiority margin 10%
- PET2 negative, patients without RF:
  - 1-y PFS 94.9% if no RT
  - 1-y PFS 100% if INRT
- PET2 negative, patients with RF:
  - 1-y PFS 94.7% if no RT
  - 1-y PFS 97.3% if INRT
- No OS analysis

Trial closed early due to futility!

UK RAPID trial:

- 600 patients, median FU 46 months
- Final analysis based on 36 events
- Non-inferiority margin 7%
- PET2 negative patients:
  - 3-y PFS 90.7% if no RT
  - 3-y PFS 93.8% if IFRT
- PET2 negative patients:
  - 3-y OS 99.5% if no RT
  - 3-y OS 97.0% if IFRT

Trial considered positive!

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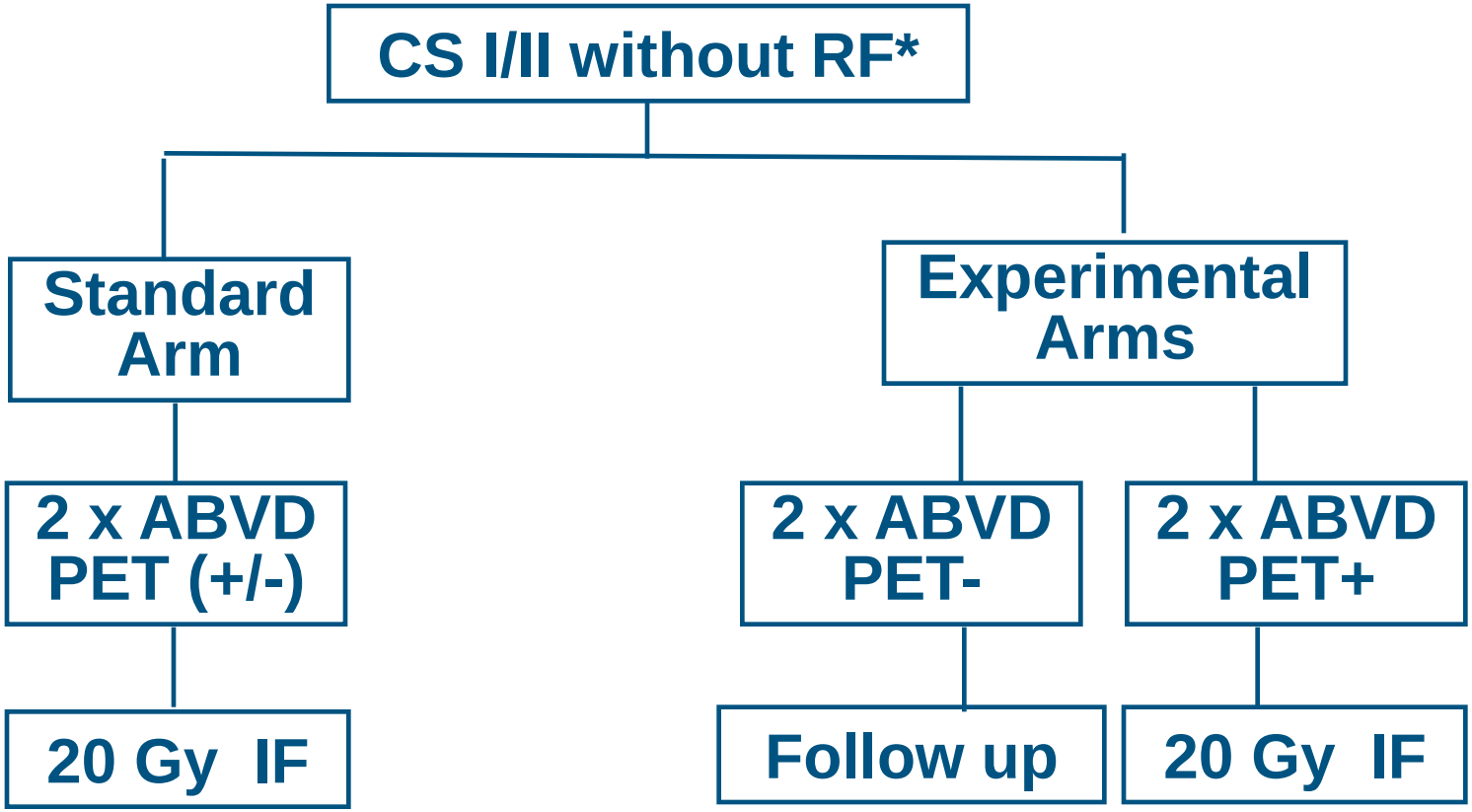
Ongoing GHSG trial (HD16)
for early favorable HL



*a) large mediastinal mass; b) extranodal disease; c) high ERS; d) 3 or more areas

Courtesy of Andreas Engert

PET response adapted treatment of advanced HL

Study	Patients	Main PET-driven intervention	Phase
GITIL HD0607 *(Completed)*	Stage IIB-IV + stage IIA with RF	Intensification to BEACOPPesc if PET-positive after 2xABVD	II
RATHL *(Completed)*	Stage IIB-IV	Intensification to BEACOPP if PET-positive after 2xABVD Randomisation between ABVD and AVD if PET-negative	III
Israel/Rambam (*Completed)*	Early stage + RF/bulk or advanced stage	PET after 2xBEACOPPbaseline or BEACOPPesc: Proceed to 4xBEACOPPesc If PET-positive or 4xBEACOPPbaseline if PET-negative	II
IIL HD0801 (*Completed)*	Stage IIB-IV	Salvage regimen if PET-positive after 2xABVD. Randomisation between radiotherapy and no further treatment after completion of 6xABVD if PET-negative after 2xABVD	III
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LYSA AHL2011	Early stage HL bulky	De-escalation from BEACOPPesc to ABVD in exper. arm in case of a negative PET after 2 and 4 cycles. Standard arm: 6 x BEACOPPesc.	III
SWOG S0816	Stage III-IV	Intensification to BEACOPPesc if PET-positive after 2xABVD	II

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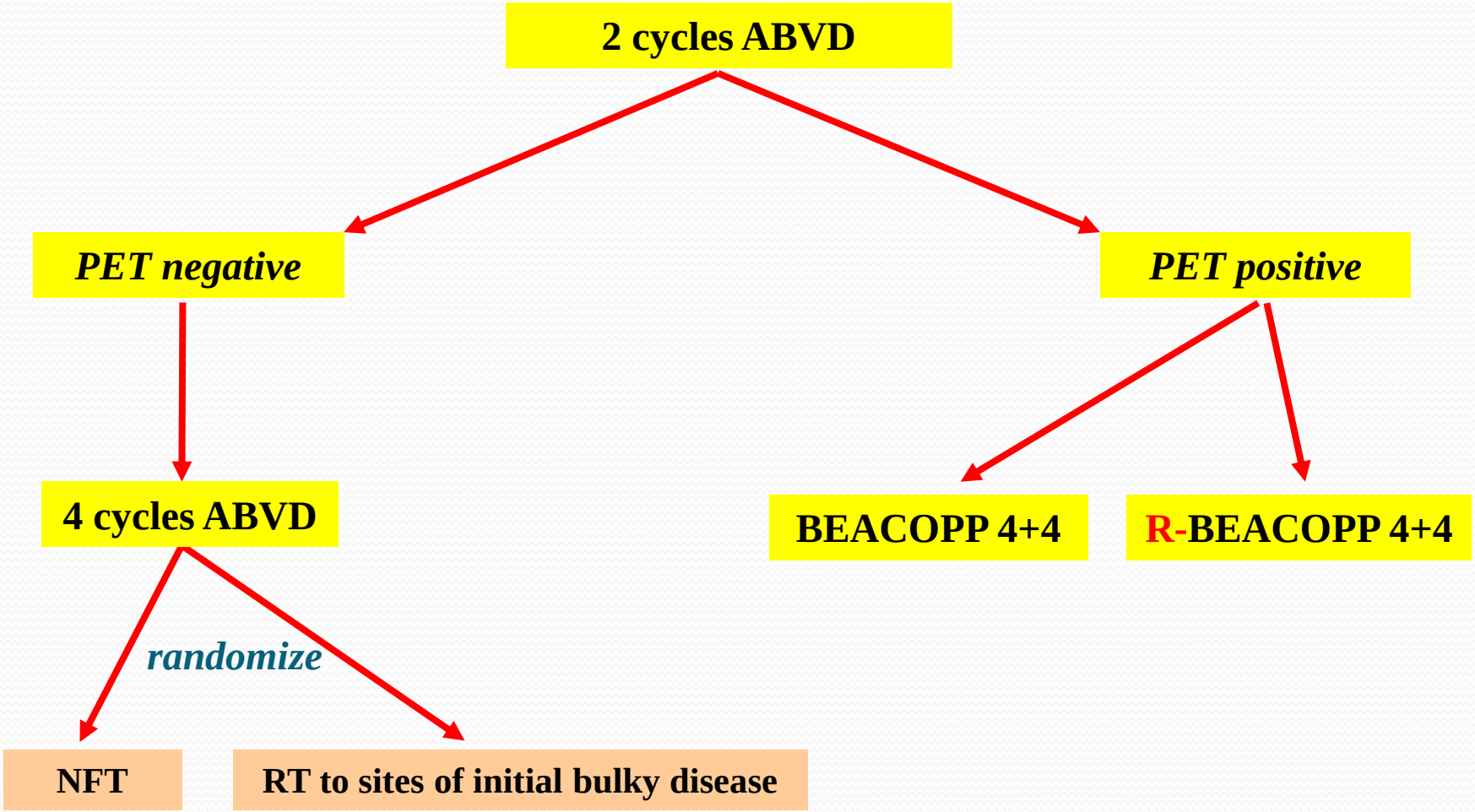
GITIL HD0607



PI: Andrea Gallamini, Cuneo IT

GITIL HD 0607 interim analysis

- 497 patients included, 263 evaluable
- 41 PET2 positive, 222 PET2 negative
- In all 263 evaluable patients:
  - PET2 positive: CR rate 73%
  - PET2 negative: CR rate 95.5%
- In 187 patients with min. Follow-up 12 months:
  - PET2 positive: 1-y PFS 80.5%
  - PET2 negative: 1-y PFS 97.3%

1. Gallamini A, et a. ASH 2012 abstract #550

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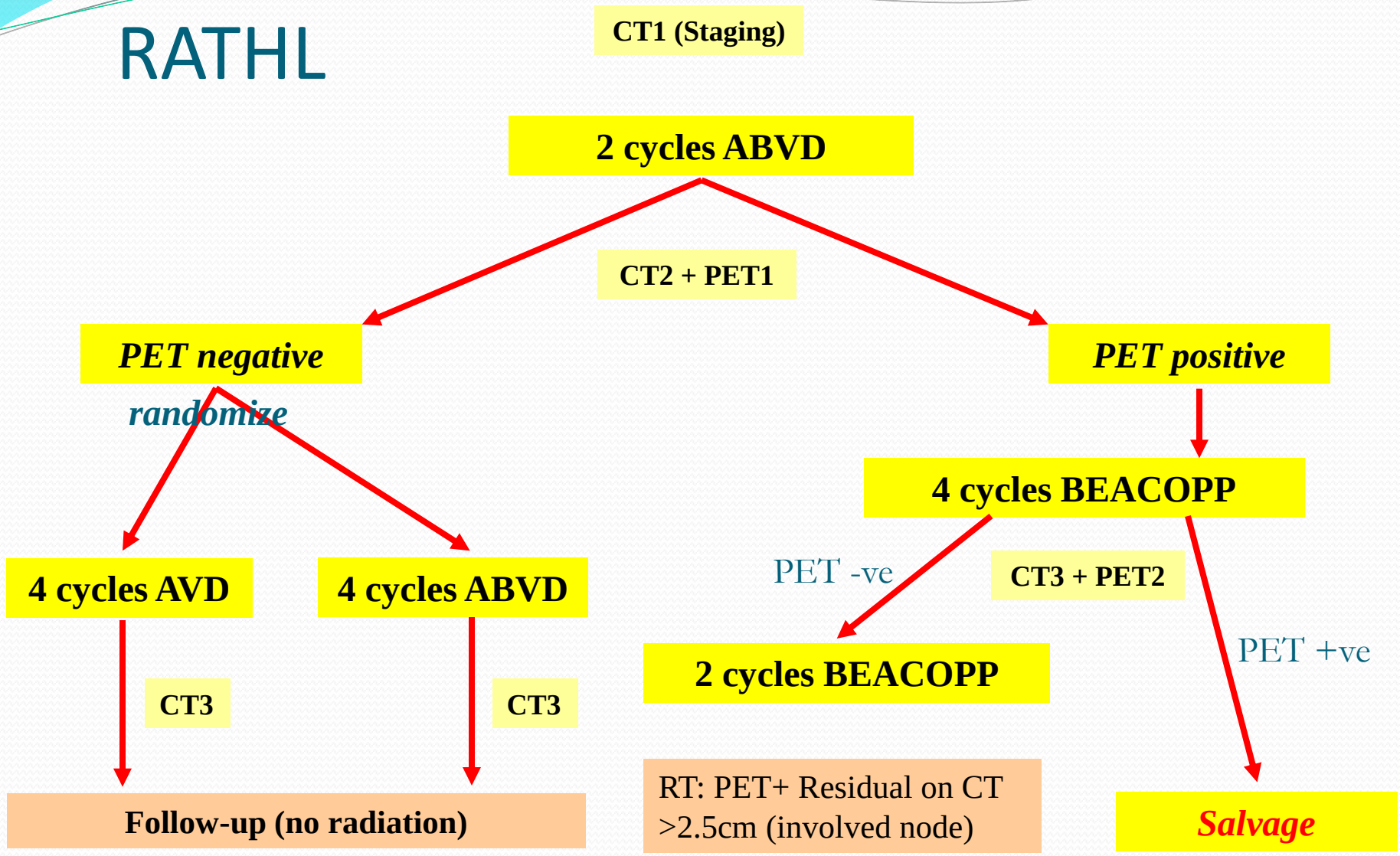
RATHL



PI: Prof. Peter Johnson, Southampton

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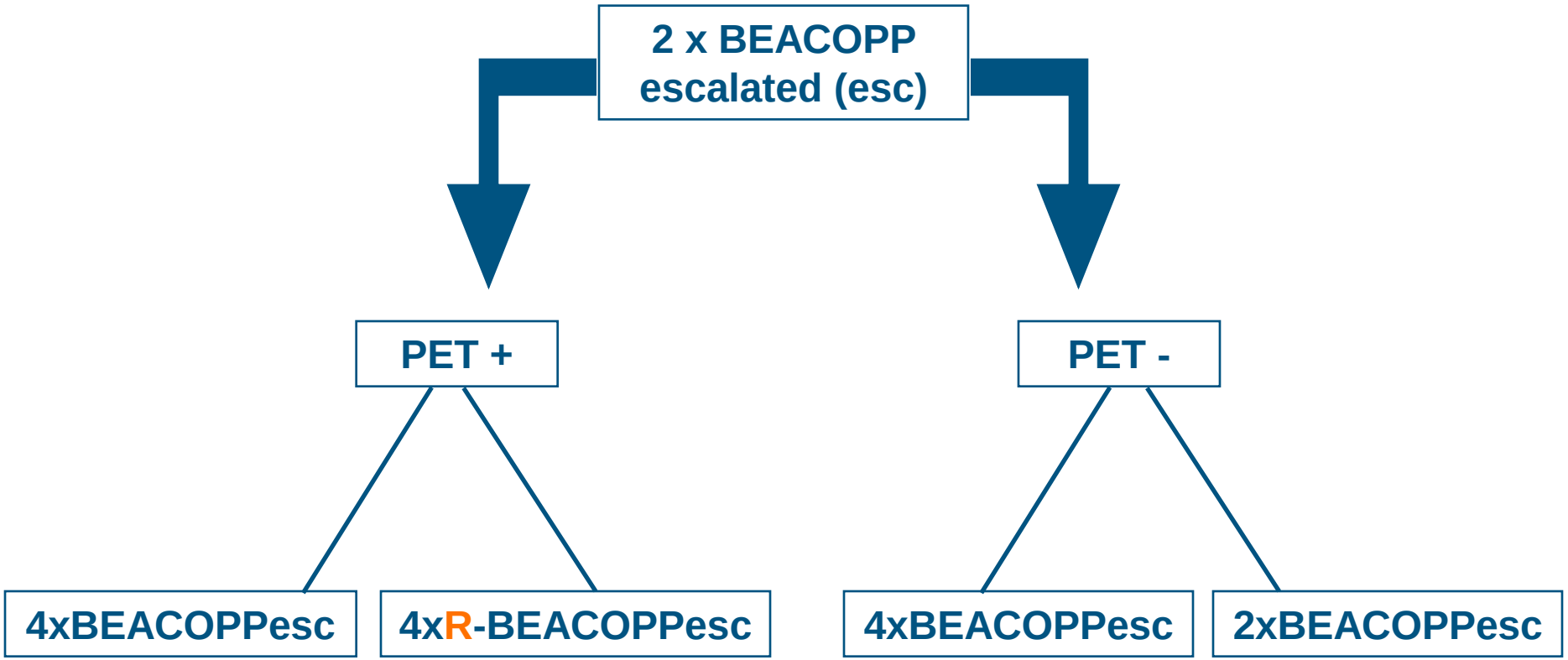
GHSG ongoing HD18 trial
for advanced stages



After chemo: PET; RX to PET+ res nodes >2.5 cm

PET-: Follow up

Courtesy of Andreas Engert

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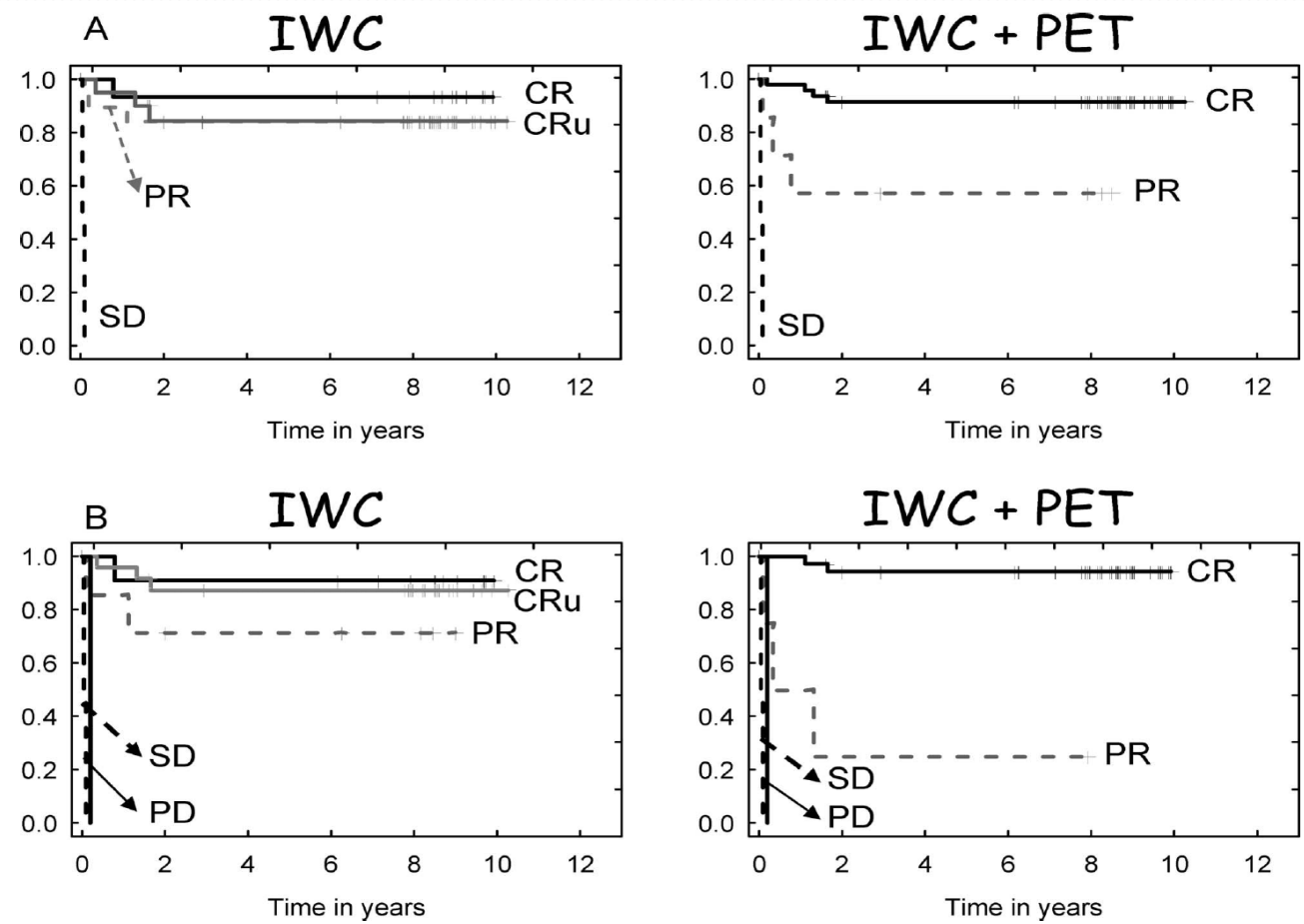
FDG-PET for post-treatment evaluation

- FDG-PET has very high negative predictive value (NPV) and variable positive predictive value (PPV) for post-treatment evaluation with conventional treatment[1]
- The 2007 International Working Group response criteria:[2]
  - If PET-negative, the patient is in complete remission
  - In HL, the new criteria are more predictive of outcome than the previous criteria[3]
- FDG-PET can be used to determine the need for additional radiotherapy in advanced HL[4,5]

1. Terasawa T, *et al*. J Nucl Med 2008;49:13–21.
2. Cheson BD, *et al*. J Clin Oncol 2007;25:579–86.
3. Brepoels L, *et al*. Leuk Lymphoma 2007;48:270–82.
4. Engert A, *et al*. Lancet 2012;379:1791-9.
5. Savage KJ, *et al*. Presented at American Society of Clinical Oncology annual meeting, Chicago, IL, USA;3–7 June 2011: Abstract #8034.

Hodgkin lymphoma



Brepoels *et al*. Leuk Lymphoma 2007;48:1522–30.

PET/CT determines the need for consolidation RT in advanced HL

GHSG HD 15 experience[1,2]

- BEACOPP chemoterapy
- Only patients with a PET-positive residual mass > 2.5 cm received RT
- 4-year PFS 91.5% in post-treatment PET-negative patients

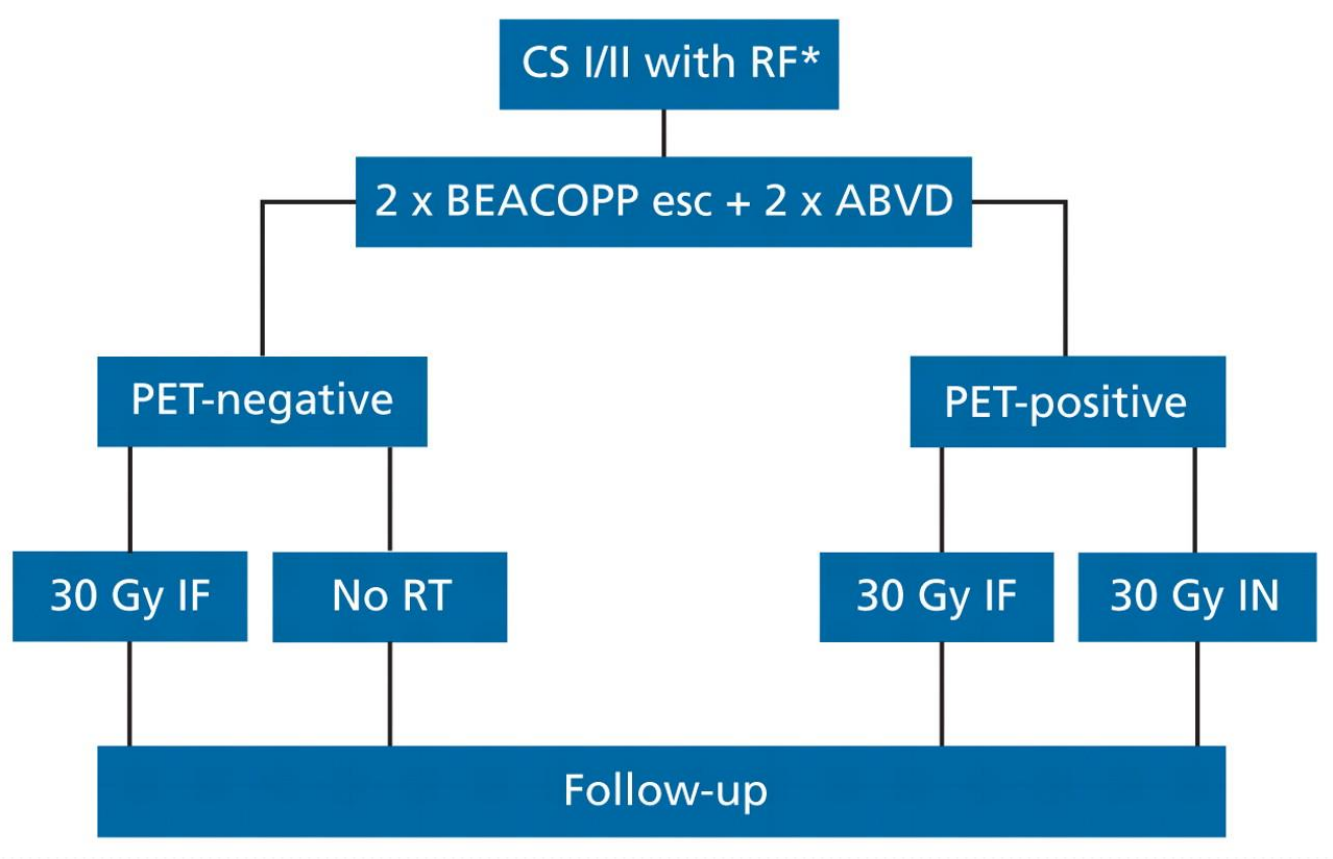
BCCA experience[3]

- ABVD chemotherapy
- Only patients with a PET-positive residual mass > 2.0 cm received RT
- 3-year PFS 89% in post-treatment PET-negative patients

1. Engert A, *et al*. Lancet 2012;379:1791-9
2. Engert A, *et al*. ASH 2012 poster #3684. Poster session 624, Monday Dec 10, 6.00-8.00 pm.
3. Savage KJ, *et al*. Presented at American Society of Clinical Oncology annual meeting, Chicago, IL, USA;3–7 June 2011: Abstract #8034.

- and perhaps in early stage HL with risk factors?

- German HD17 trial for intermediate stage HL:



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FDG-PET in HL follow-up

- At first remission, PET/CT sensitivity and negative predictive value (NPV) are close to 100%, however:[1,2]
  - significantly higher rates of false-positives than CT
  - PET/CT and CT have similarly (low) positive predictive value (PPV) for detection of recurrent HL/secondary malignancies
- It takes 50–100 FDG-PET scans to detect one relapse earlier than conventional methods (including CT)[3,4]
- Currently, no available evidence to show that patients with minimal, asymptomatic disease do better after salvage therapy than patients with low tumour burden and discrete symptoms
- The benefit of routine follow-up scanning appears to be most clear:
  - during the first 1–2 years[1,2,4,5]
  - in patients with a residual mass[2,5]
  - in patients with a positive interim PET[1]

1. Lee AI, *et al*. Cancer 2010;116:3835–42.
2. El Galaly T, *et al*. Haematologica 2012 Jun; 97: 931-6.
3. Hutchings M, Polliack A. Leuk Lymphoma 2012 Jun;53:1015-6.
4. Zinzani PL, *et al*. J Clin Oncol 2009;27:1781–7.
5. Petrausch U, *et al*. Ann Oncol 2010;21:1053–7.

Staging

Early treatment monitoring and
PET response-adapted therapy

Post-treatment evaluation

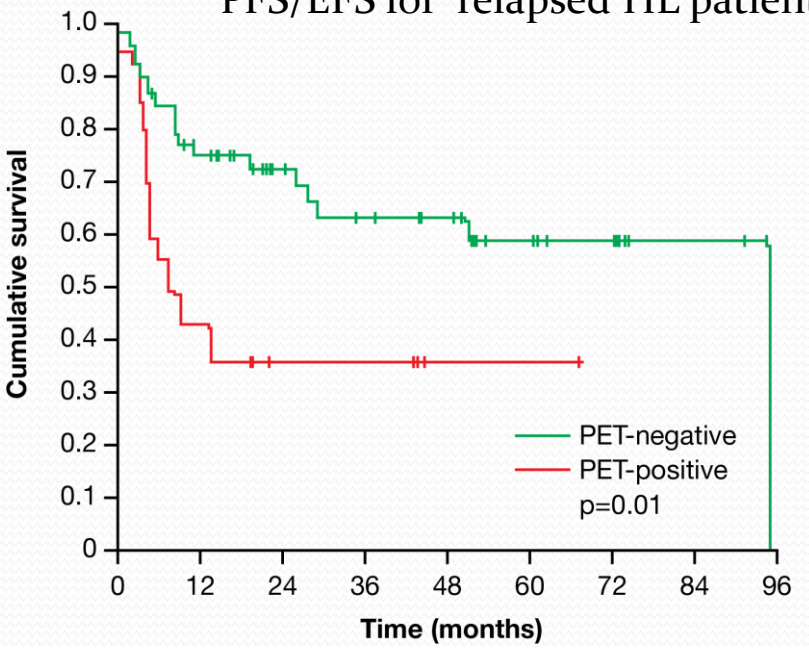
Follow-up

Relapsed/refractory HL

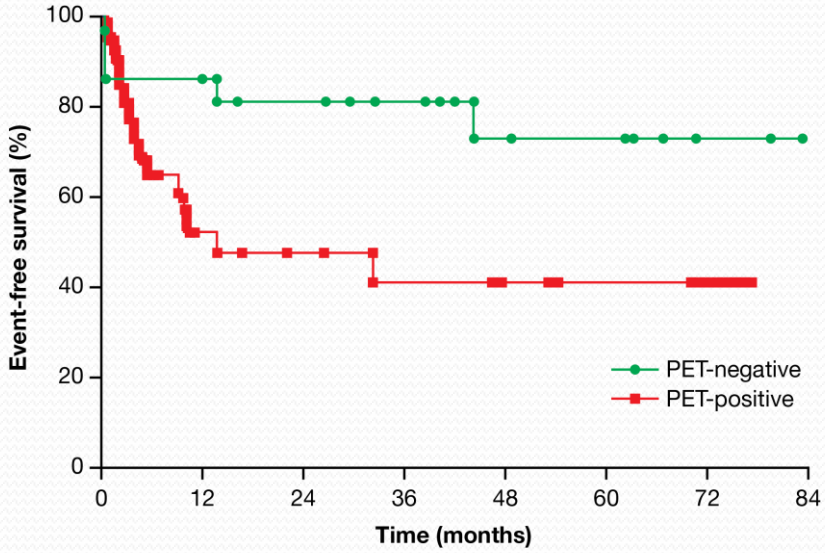
Summary

Post-induction PET/CT before HD+ASCT predicts outcome in relapsed HL patients

PFS/EFS for relapsed HL patients according to pre-transplant PET/CT



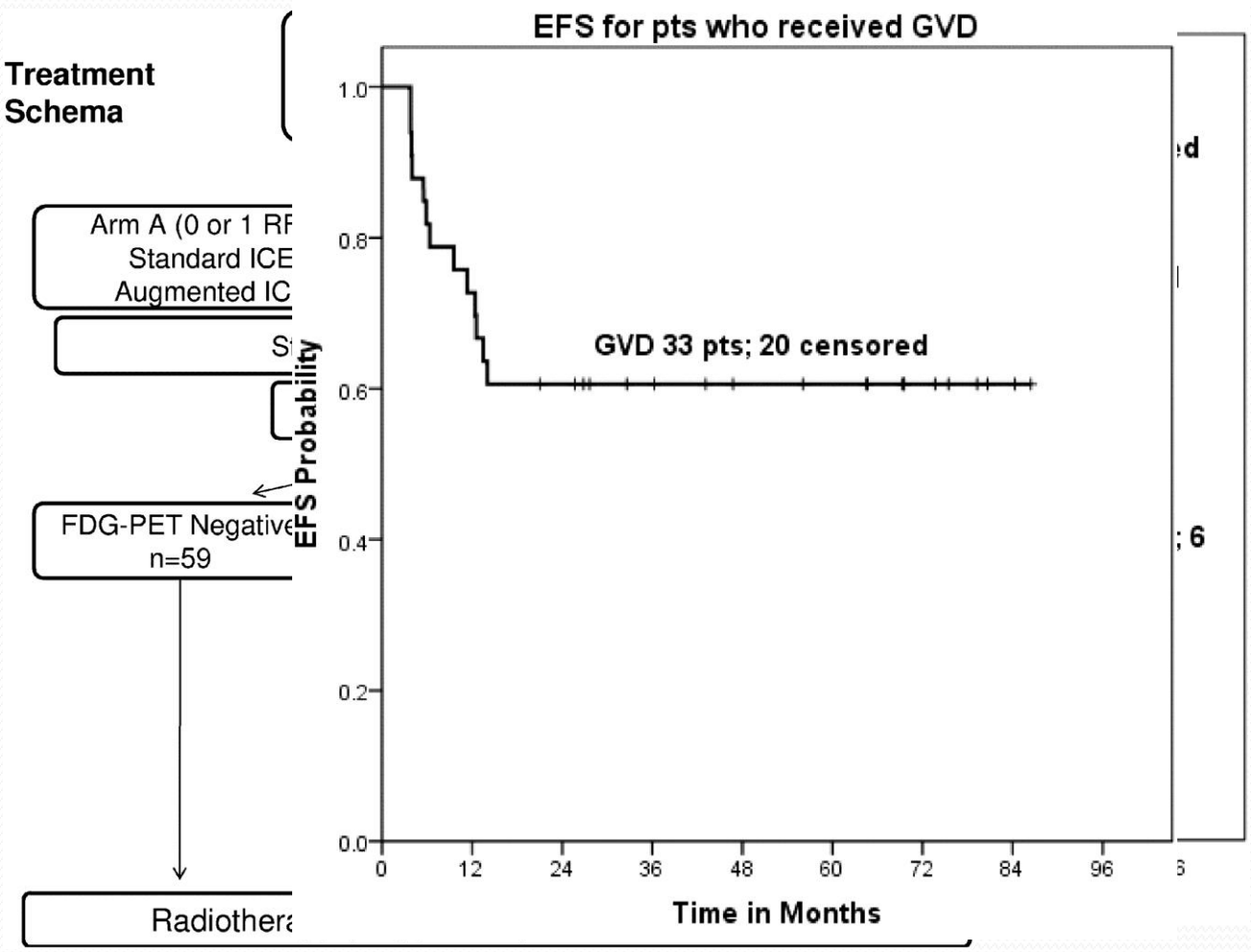
76 patients, 2-y PFS 73% vs. 36%[1]



46 patients, 3-y EFS 82% vs. 41%[2]

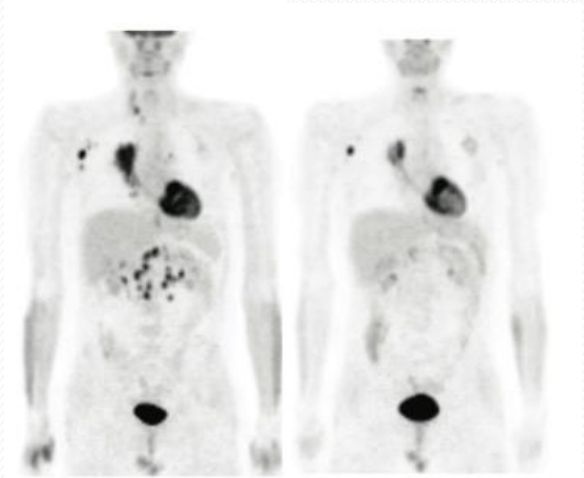
1. Mocikova H, *et al*. Leuk Lymphoma 2011;52:1668–74.
2. Smeltzer JP, *et al*. Biol Blood Marrow Transplant 2011;17:1646–52.

PET/CT may help tailor salvage treatment for relapsed HL



1. Moskowitz CH, *et al*. Blood 2012; 119:1665-1670.

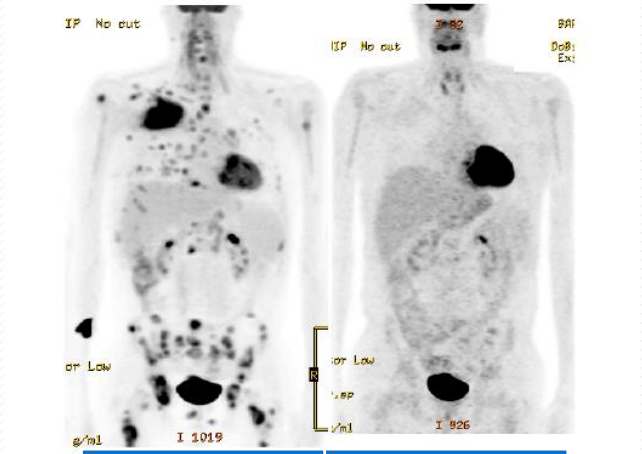
FDG-PET in clinical trials of R/R HL



Baseline | Cycle 2

Trial of lenalidomide[1]

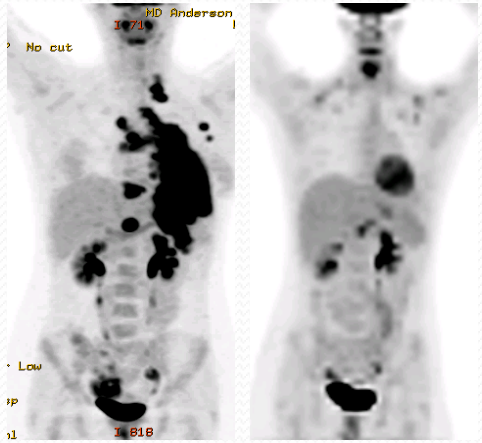
PET at baseline and after 2 cycles



Baseline | Cycle 2

Trial of brentuximab vedotin[2]

PET at baseline and after 2 cycles



Baseline | Cycle 2

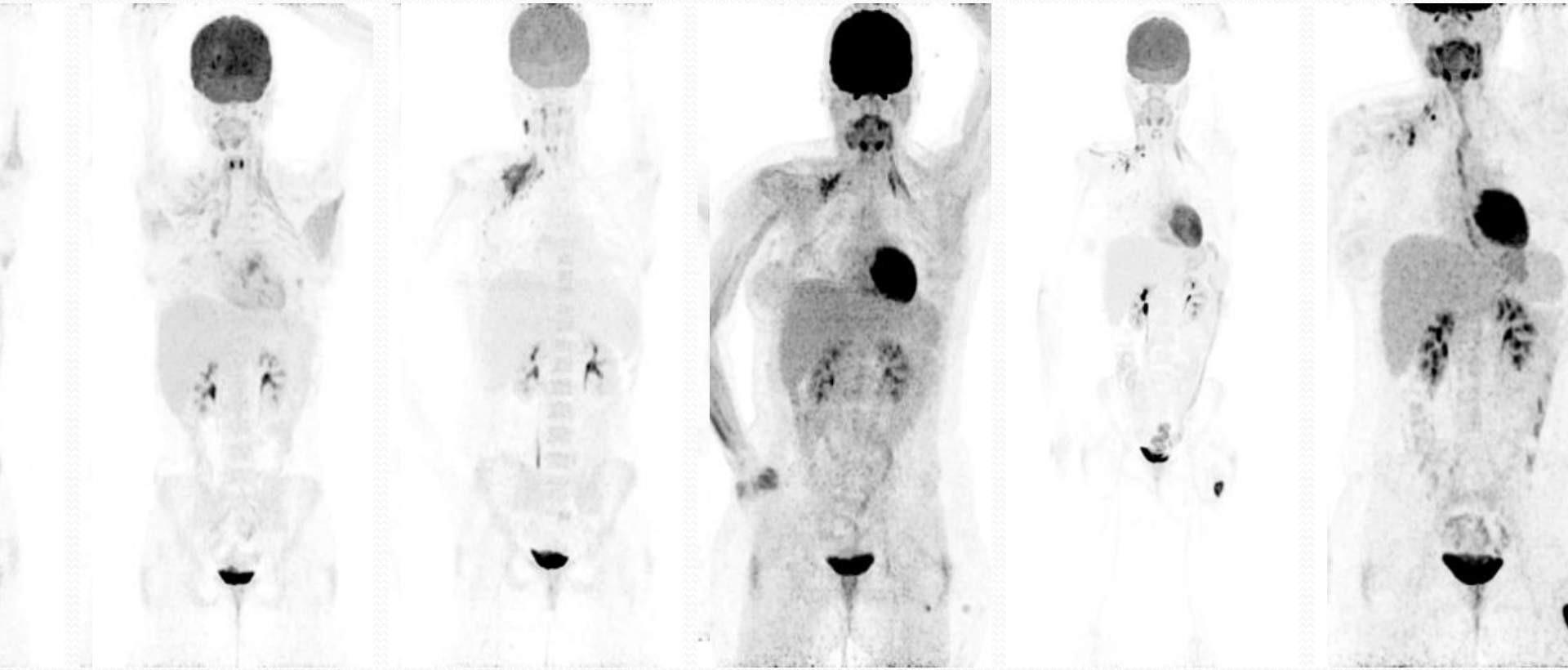
Trial of brentuximab vedotin[3]

PET at baseline and after 2 cycles

Courtesy of Andreas Engert.

1. Böll B, *et al*. Br J Haematol 2009;148:480–90.
2. Younes A, *et al*. Presented at the 50th Annual Meeting of the American Society of Hematology; San Francisco, California, USA; 6 –9 December 2008: Abstract # 1006.
3. Younes A, *et al*. Presented at the 14th Congress of the European Hematology Association; Berlin, Germany; 4–7 June, 2009: Abstract # 0503.

19 year-old female. Diagnosed with stage IIA HL summer 2010. Treated with 4 cycles ABVD. Progression immediately before IFRT Nov. 2010. HD+ASCT winter 2011. Relapse Nov 2011. PR after Lenalidomid. Short-lived CR after Everolimus. Lasting CR after GVD.



HAP After BEAM+ASCT After Relapse ABVD RT planning scan After 2 x ICE After 5 x DHAP After BEAM+ASCT

AlloSCT April 2014. Still in remission.

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Summary

Summary

- **Staging PET/CT**
  - Increased staging accuracy – better basis for risk-stratified treatment
  - More refined definition of radiotherapy volumes – less irradiation to normal tissues
  - Baseline scan essential for subsequent PET/CT monitoring
- **Early response monitoring**
  - Early PET/CT is strongly prognostic in HL
  - Early PET/CT may allow tailored treatment (improving outcomes , reducing over-treatment?)
- **Post-treatment evaluation**
  - Cornerstone in the revised response criteria
  - Offers improved selection of patients for consolidation radiotherapy
  - High NPV – suited for characterisation of a residual mass
  - Moderate PPV – treatment failure can only be safely determined with biopsy
- **Follow-up**
  - Only when clinically indicated
- **R/R disease**
  - After induction therapy and pre-transplant – good predictor of outcome after HD-ASCT
  - Better measure of activity than traditional CT response criteria, particularly for PR patients
  - Only limited data on the value of PET/CT guided therapy

Recommended reading

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The latest version is at http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2013.54.8800

JOURNAL OF CLINICAL ONCOLOGY | SPECIAL ARTICLE

Recommendations for Initial Evaluation, Staging, and Response Assessment of Hodgkin and Non-Hodgkin Lymphoma: The Lugano Classification

Bruce D. Cheson, Richard I. Fisher, Sally F. Barrington, Franco Cavalli, Lawrence H. Schwartz, Emanuele Zucca, and T. Andrew Lister

Published Ahead of Print on August 11, 2014 as 10.1200/JCO.2013.53.5229
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JOURNAL OF CLINICAL ONCOLOGY | SPECIAL ARTICLE

Role of Imaging in the Staging and Response Assessment of Lymphoma: Consensus of the International Conference on Malignant Lymphomas Imaging Working Group

Sally F. Barrington, N. George Mikhaeel, Lale Kostakoglu, Michel Meignan, Martin Hutchings, Stefan P. Müeller, Lawrence H. Schwartz, Emanuele Zucca, Richard I. Fisher, Judith Trotman, Otto S. Hoekstra, Rodney J. Hicks, Michael J. O'Doherty, Roland Hustinx, Alberto Biggi, and Bruce D. Cheson

Who is still afraid of Hodgkin lymphoma?

Symposium for 50th Anniversary of the EORTC Lymphoma Group

November 14th 2014, Hilton, Antwerp, Belgium

Invited Speakers

M. André (BE)
A. Engert (DE)
M. Federico (IT)
M. Henry-Amar (FR)
T. Girinsky (FR)
T. Illidge (UK)
J. Raemaekers (NL)
A. Sureda (ES)
A. Younes (USA)

EORTC

More information coming soon on http://www.eortc.org/research-groups/lymphoma-group