HIGH TUMOR BURDEN FOLLICULAR LYMPHOMA

IMPACT OF [18F]-FDG POSITRON EMISSION TOMOGRAPHY (PET) IN THE ASSESSMENT OF TREATMENT RESPONSE

NCT00915096

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Rationale

- FDG uptake in 95% of FL whatever the histological grade.

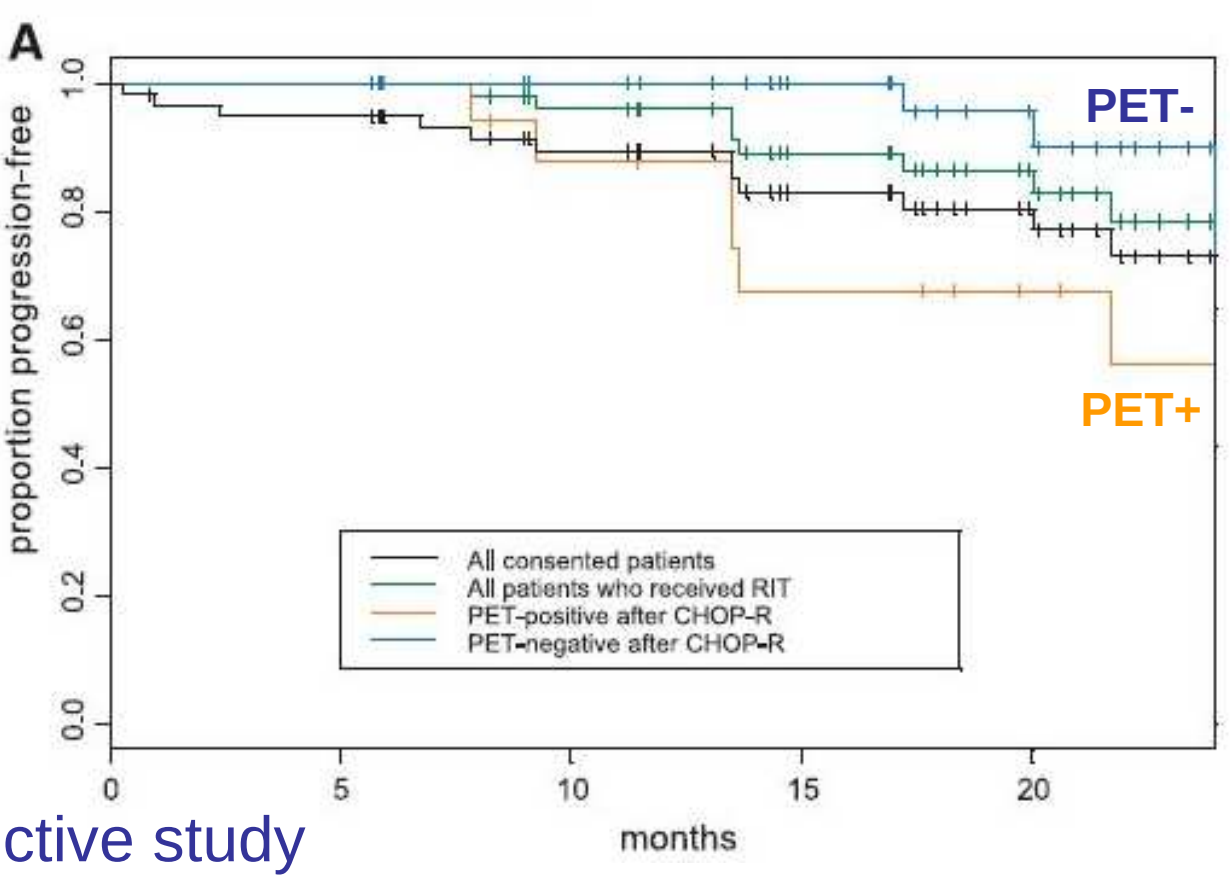
  Weiler-Sagie, *J Nucl Med* 2010

- PET could identify the site of transformation.

  Bodet-Milin, *Haematologica* 2008

- PET prognostic value (interim & end-treatment) should be prospectively evaluated in the context of new immuno chemotherapy regimens

PET after 3 CHOP-R is predicting of PFS



Prospective study

60 patients untreated by Chemo or R (advanced stage FL)

3 CHOP-R + ^{90}Y RIT + 4 R

Median follow up: 19.7months Jacobs, Swerdlow, *Clin Cancer Res* 2008

Main purpose of the study

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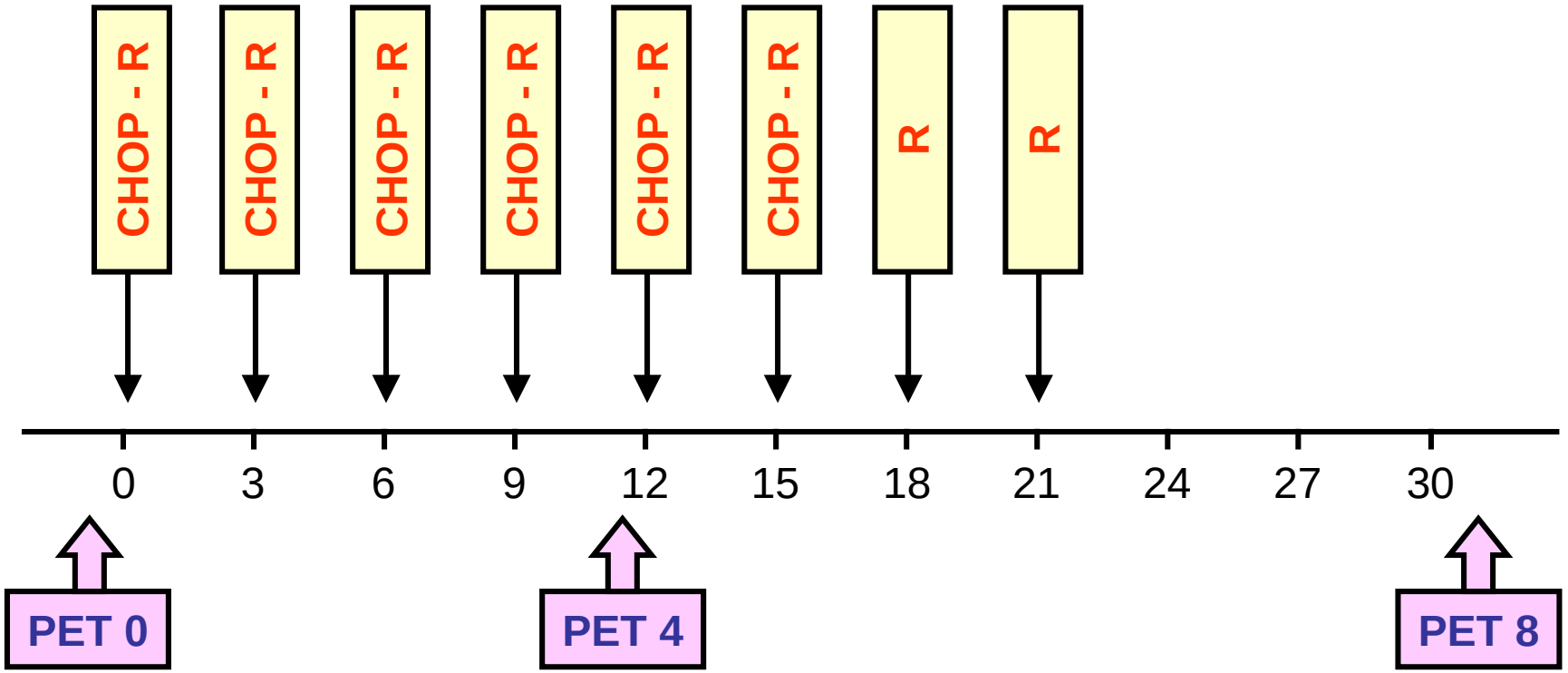
To assess in a prospective series of 120 patients with high tumor burden follicular lymphoma treated with R-CHOP, the predictive value of ^{18}FDG PET performed over (after 4 cycles), and at the end of first-line treatment on progression-free survival at 2 years.

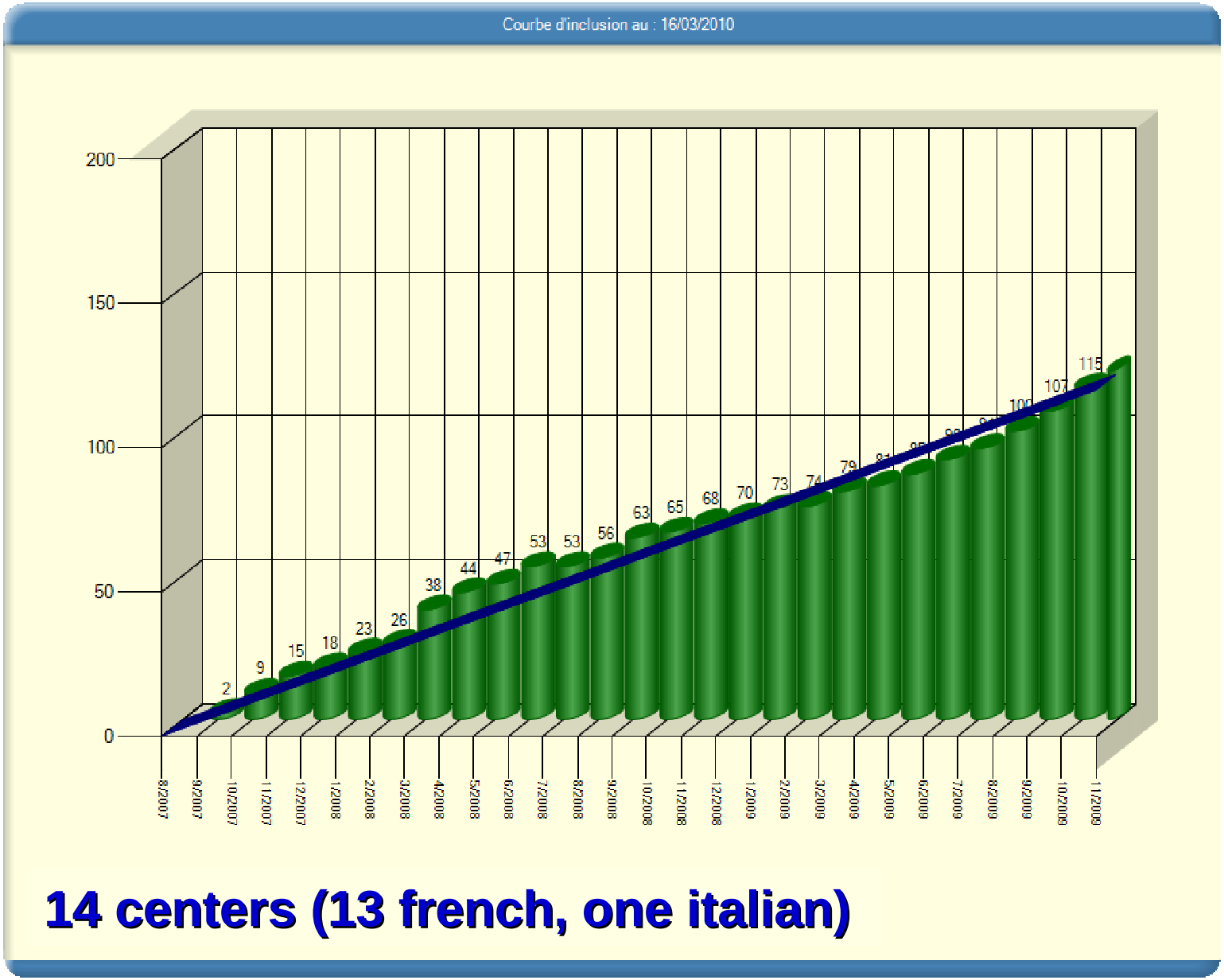
Inclusion criteria

- Patients aged 18-80 years
- Follicular lymphoma, histological grade 1-3
- Not previously treated
- With at least one of the GELF criteria

Protocol timeline



Accrual curve (8/2007 to 11/2009): 120 patients included



14 centers (13 french, one italian)

Preliminary analysis

- 60 first patients having completed PET8
- Limited to PET analysis, inclusion criteria and FLIPI
- Read only by one expert but on the same workstation (5PS)
- No follow-up analysis

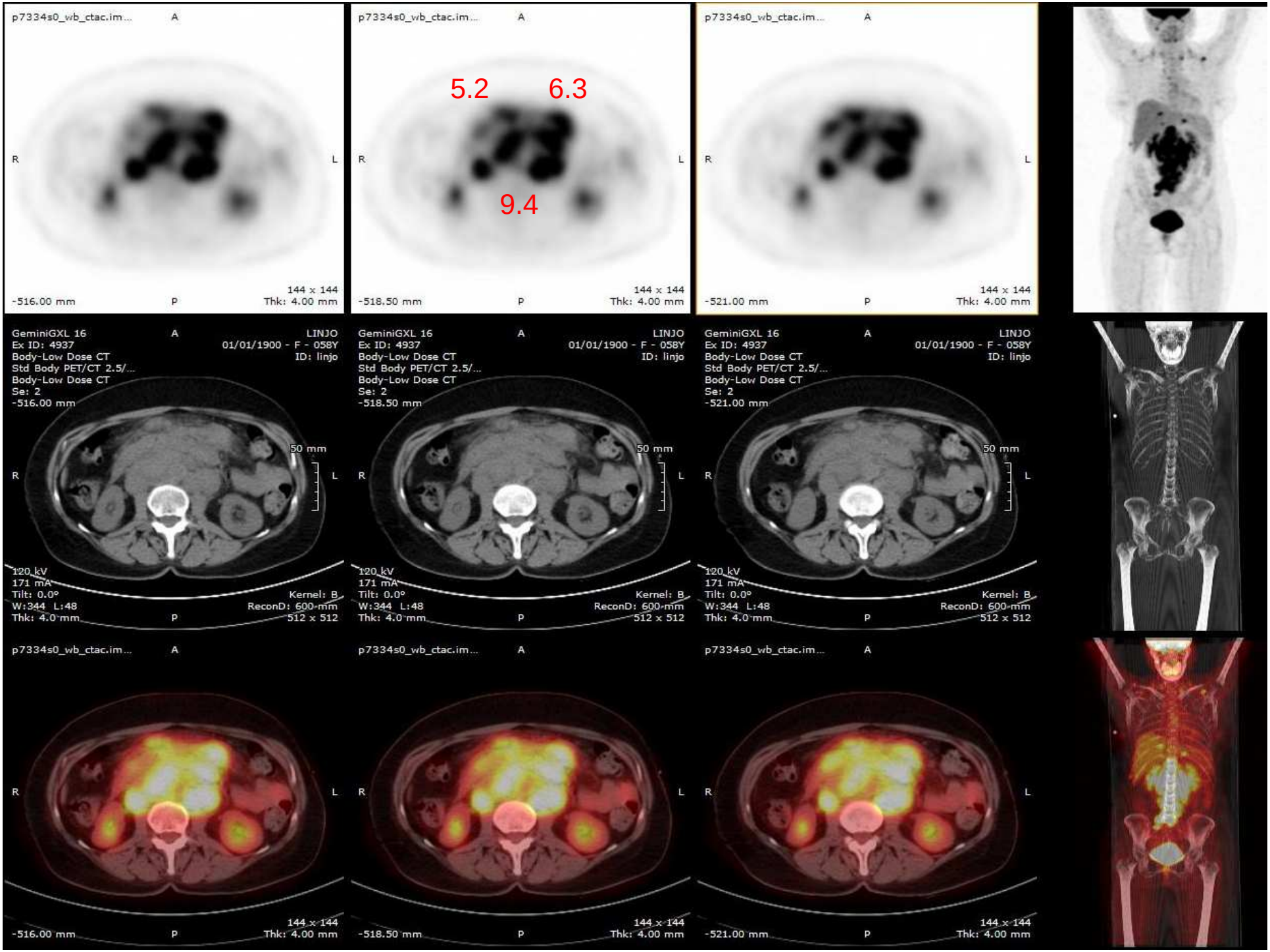
Patients characteristics (60 patients)

Age	
<60	38 (63%)
≥60	22 (37%)
FLIPI risk	
Low (0,1)	10 (17%)
Intermediate (2)	30 (50%)
High (≥ 3)	20 (33%)
Tumor burden	
Bulky (>7cm) alone	16 (27%)
3 nodes > 3cm	20 (33%)
Bulky + 3 nodes	10 (17%)
No Bulky/no 3 nodes	14 (23%)

Patients characteristics (60 patients)

Nodal localization	SUV_{max}
Cervical	5.9 (2.3-20.1)
Axillary	7.1 (1.8-26.1)
Mediastinal	7.5 (1.8-27.3)
Abdominal	9.7 (1.8-34.6)
Inguinal	6.6 (2.8-13.5)

Bone marrow foci : 20% patients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Tilt: 0.0°
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Thk: 4.0 mm
Kernel: B
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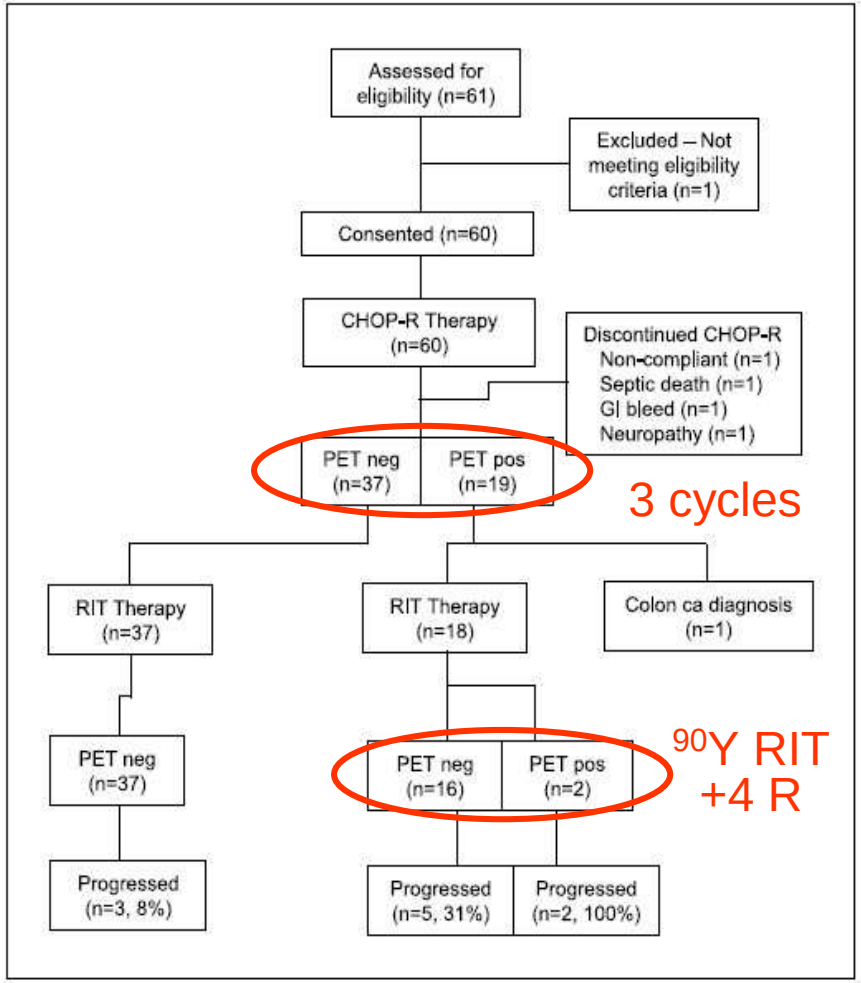
Interim/End treatment PET

Cut-off ≥ 3 (5PS)

	PET8-	PET8+
PET4 -	40	0
PET4+	6	14



Jacobs, Swerdlow, *Clin Cancer Res* 2008

CR rate by patient characteristic

Cut-off ≥ 3 (5PS)

	CR by PET4	CR by PET8
FLIPI risk		
Low (0,1)	8/10 (80%)	8/10 (80%)
Intermediate (2)	17/30 (57%)	22/30 (73%)
High (≥ 3)	15/20 (75%)	16/20 (80%)
Tumor burden		
Bulky (>7cm) alone	11/16 (69%)	13/16 (81%)
3 nodes > 3cm	13/20 (65%)	14/20 (70%)
Bulky + 3 nodes	3/10 (30%)*	6/10 (60%)
No bulky/no 3 nodes	13/14 (93%)*	13/14 (93%)

* = Fischer exact test P<0.05

Conclusion: Preliminary results

- Analysis for primary endpoint scheduled on September 2011
  - Clinical baseline characteristics
  - Histological review
  - Pet review (3 experts)