Randomized trial of vaginal brachytherapy vs observation for high-intermediate risk endometrial carcinoma

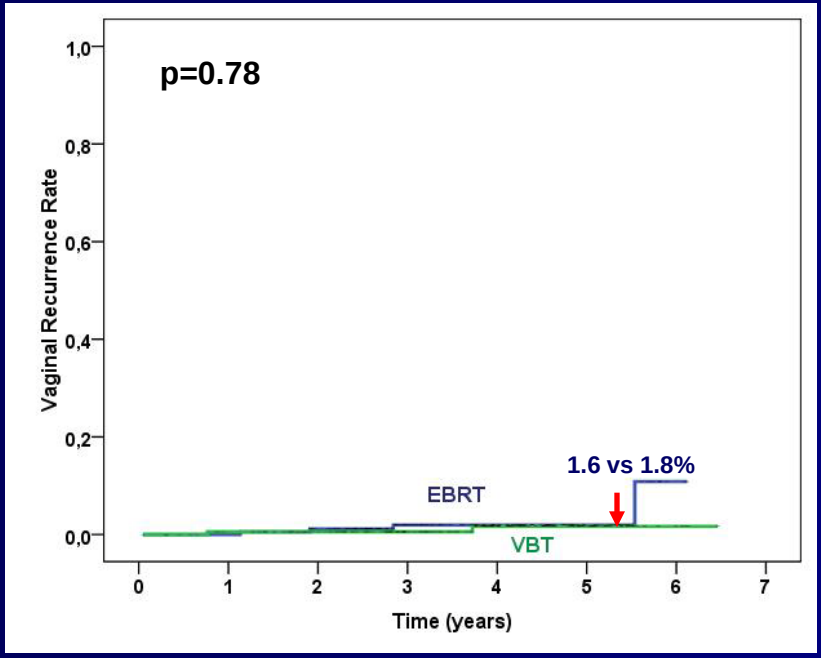
PORTEC - 4

DUTCH GYNAECOLOGICAL ONCOLOGY GROUP

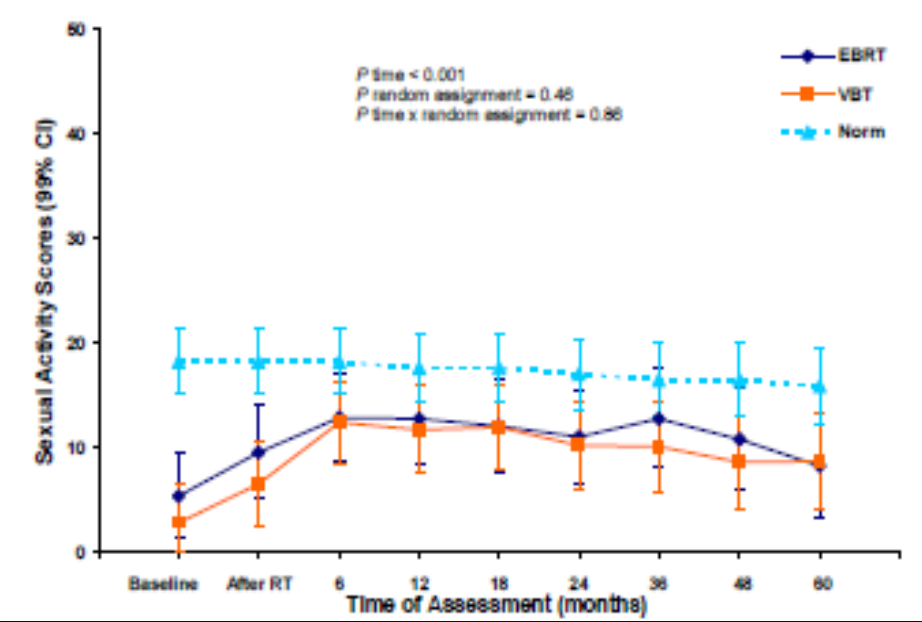
DUTCH CANCER SOCIETY

PORTEC-2: results

Vaginal Recurrence



Sexual activity



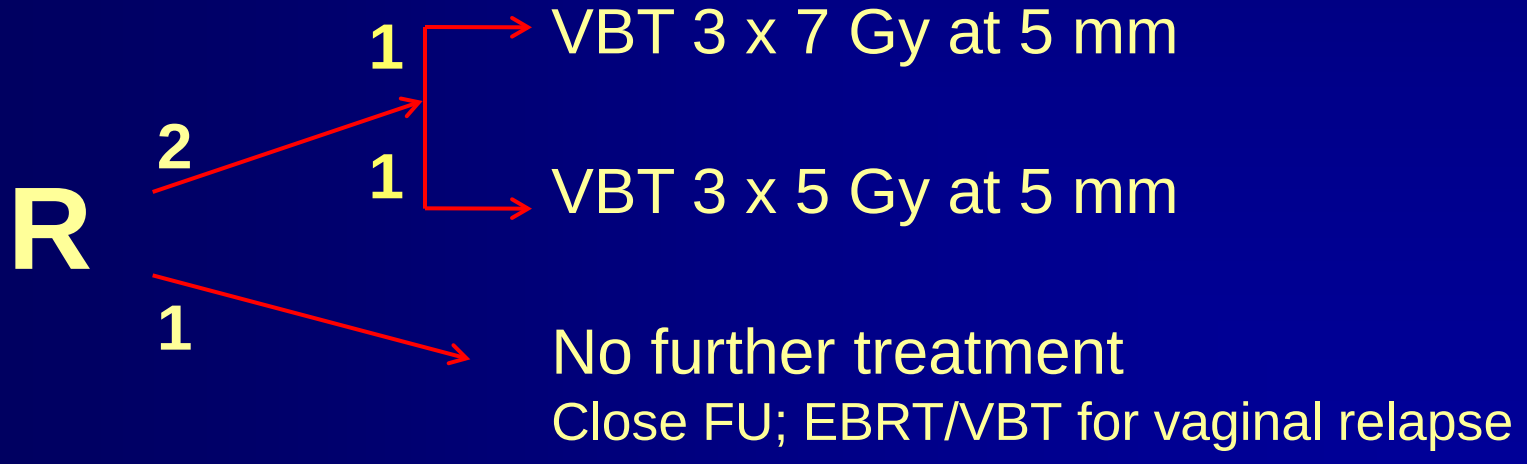
Nout et al, Lancet 2010; ESTRO 2010

Questions after PORTEC-2

- More atrophy in patients who had vaginal brachytherapy
  - Is 21 Gy in 3 fractions at 5 mm the optimal dose?
  - Many other schedules with lower doses seem equally effective
- Should we treat all HIR patients or treat only for relapse? No survival difference!

PORTEC-4 design

- *HIR endometrial carcinoma*
- *21 Gy in 3 fractions vs 15 Gy in 3 fractions*
- *Vaginal brachytherapy vs no further treatment*



PORTEC 4

PORTEC-4 eligibility

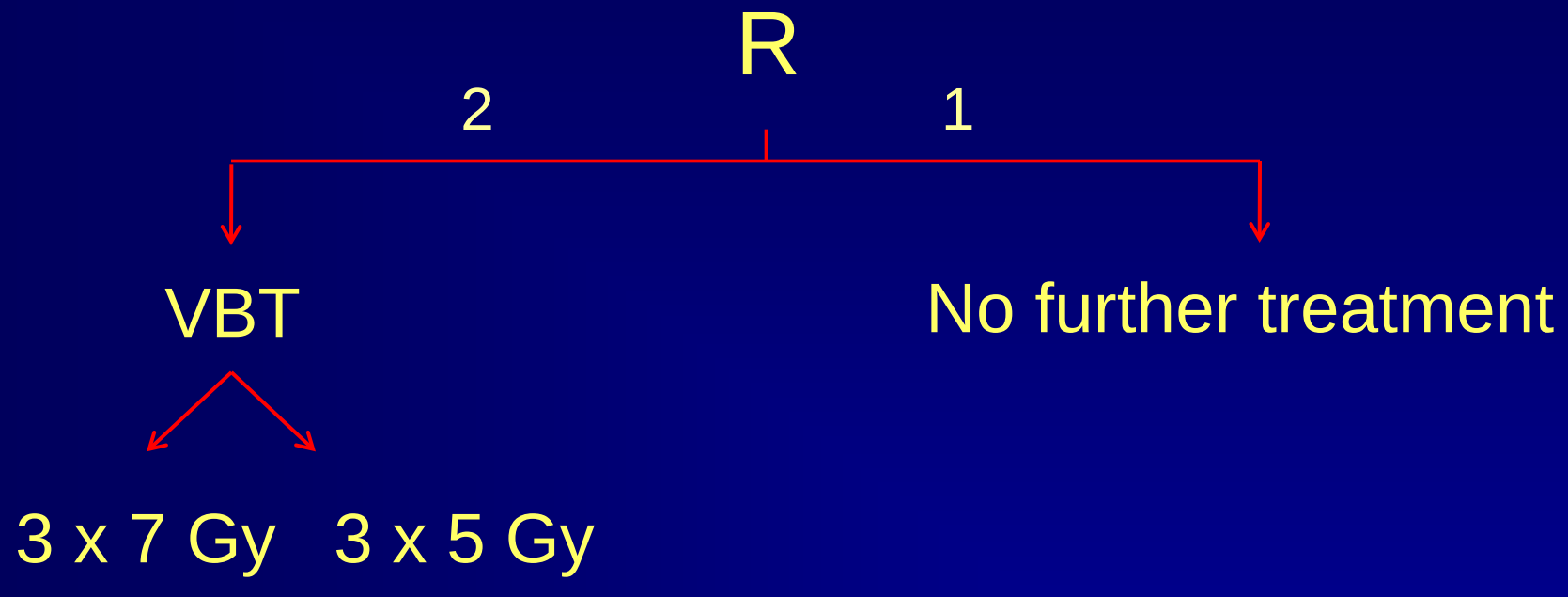
Inclusion (FIGO 2009):

- Stage IA, any age, grade 3 without LVSI
- Stage IB, age ≥ 60 years, grade 1 or 2
- Stage IB, any age, grade 1 or 2 with LVSI

Endpoints:

- Vaginal recurrence / 5-year vaginal control
- Survival and relapse
- Vaginal mucosal toxicity, Quality of life

Statistics



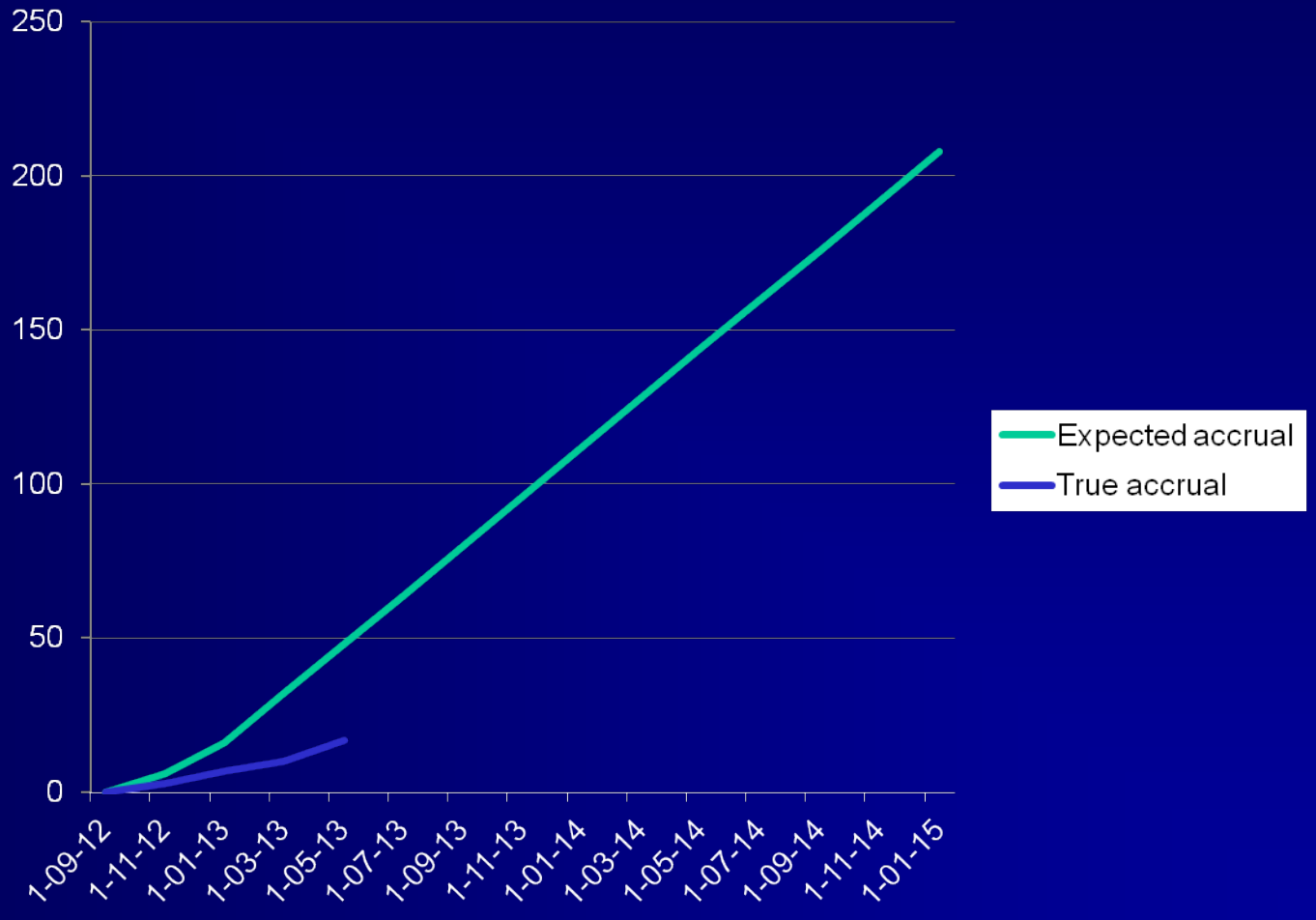
- 10% vs 2.5%; power 90%
- 3x5 Gy: estimate of VRR (se<2.5%)
- N = 500

PORTEC-4

- *Upfront pathology review:*
  - *Regional gynecologic pathologist*
- *Funding by Dutch Cancer Society*
- *Central Ethics approval*
- *Local approval and dummy run procedures ongoing for some centres*

  - *Study activated 1 September 2012*

PORTEC-4 accrual



PORTEC-4