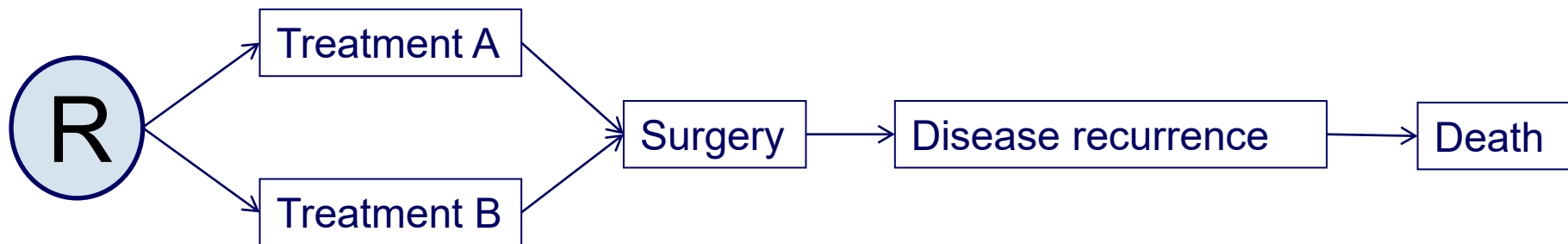


PATHOLOGICAL COMPLETE RESPONSE (pCR)

Patients with early operable breast cancer may receive neo-adjuvant treatment prior to surgery



pCR at surgery after 3 months



DFS after several years



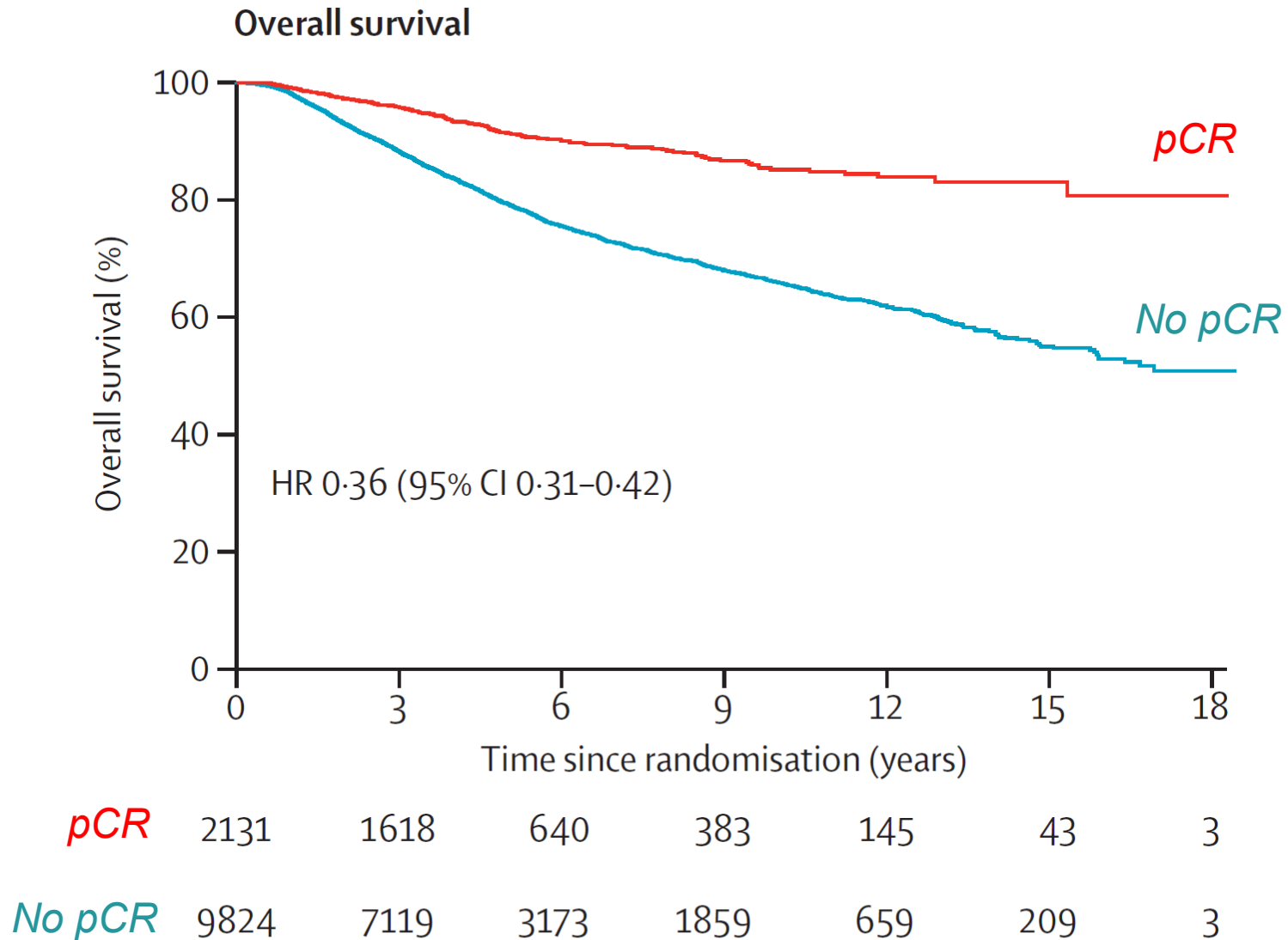
OS after several years



ASSESSMENT OF SURROGACY USING META-ANALYSIS

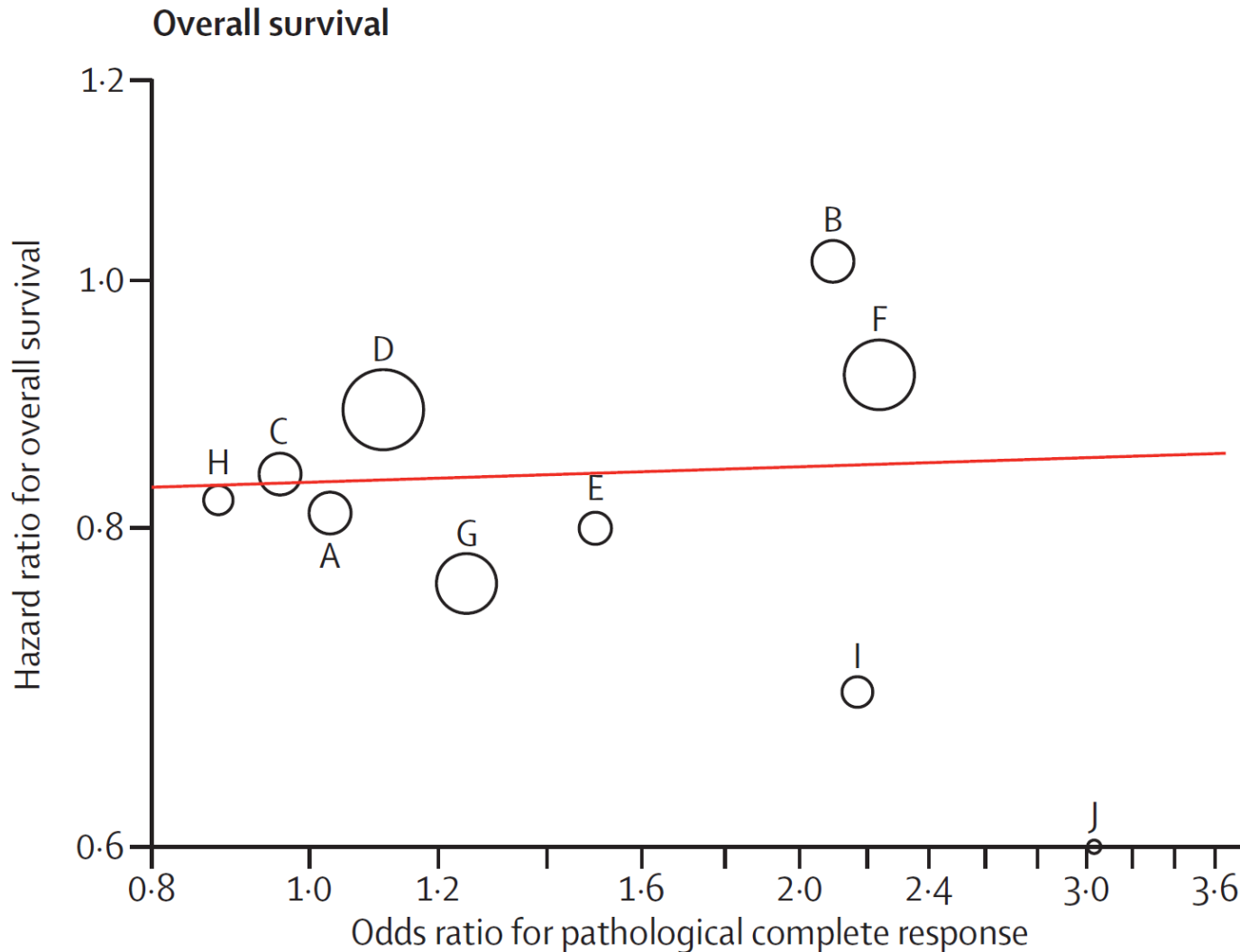
- Meta-analysis conducted by FDA
- 12 randomized trials (11,955 patients)
- pCR predicts OS
- Treatment effect on pCR does **not** predict effect on OS

pCR PREDICTS OS



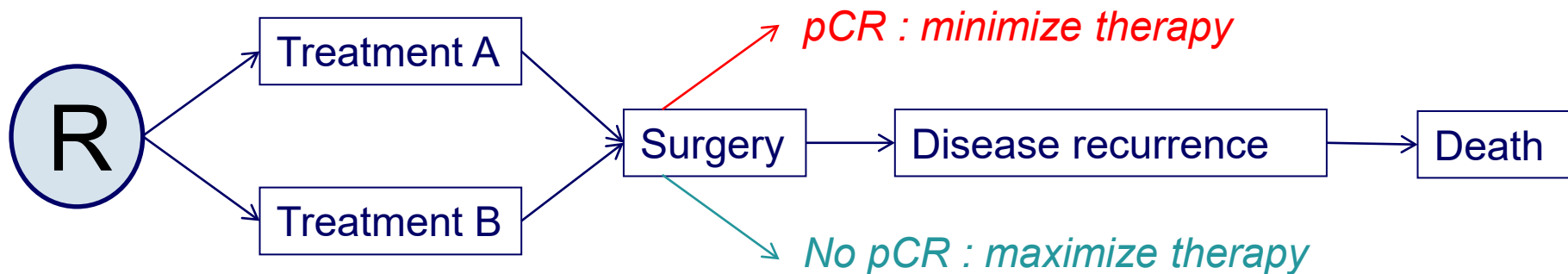
Ref: Cortazar et al., *Lancet Oncol* 2014; 384:164.

TREATMENT EFFECT ON pCR DOES **NOT** PREDICT TREATMENT EFFECT ON OS



PATHOLOGICAL COMPLETE RESPONSE (pCR)

Patients with early operable breast cancer may receive neo-adjuvant treatment prior to surgery



Therapies based on the surrogate may confound the effect of initial treatment on long-term outcomes

Confirmatory trials may well show less health care resource utilization but no difference in long-term outcomes