

**CER in prostate cancer:
the view of the radiation oncology
community**

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***Big* questions require RCTs**

Questions that evolve slowly:

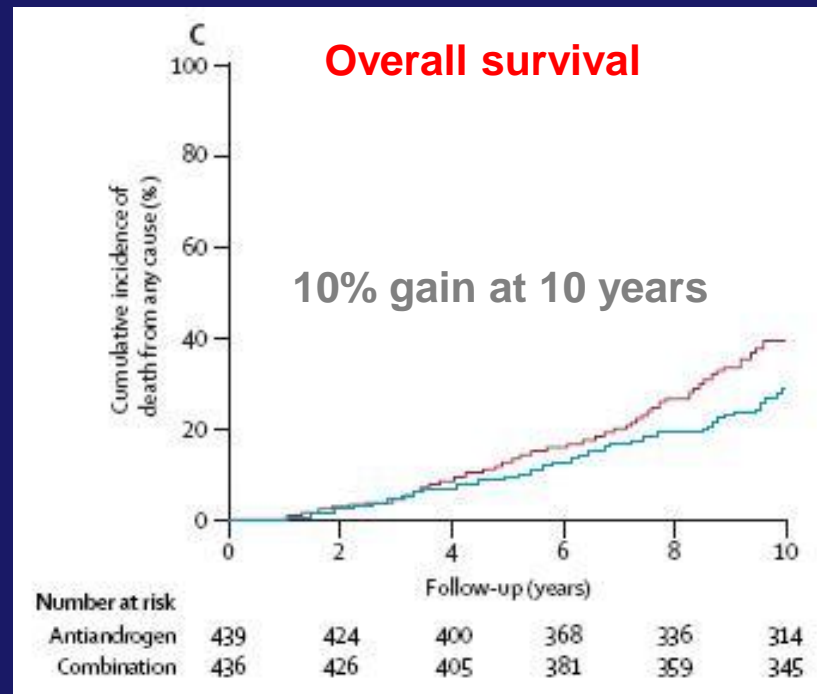
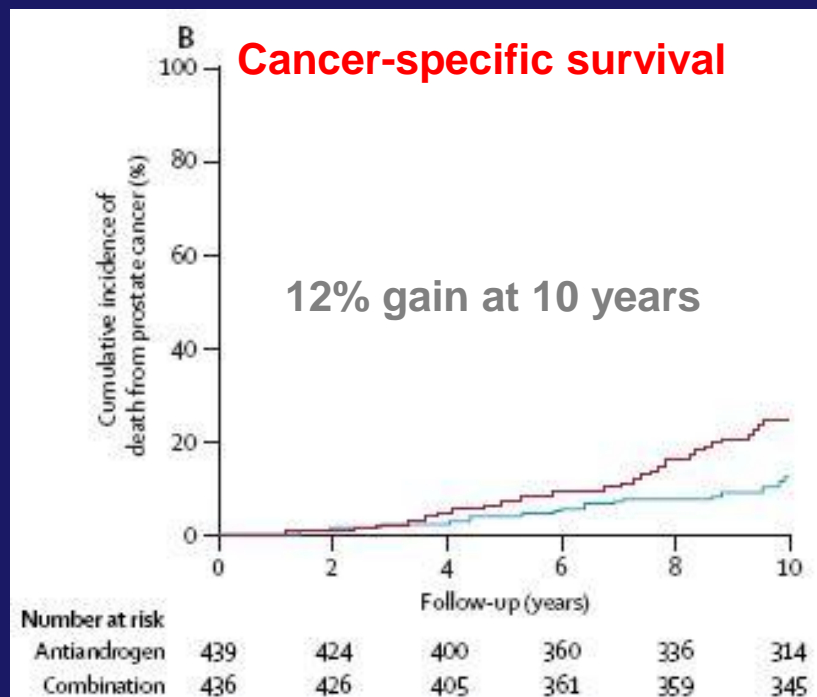
- **Curative treatment or active surveillance ?**
- **Which broad curative treatment ?**
- **With or without systemic therapy ?**

***Big* questions require RCTs**

- RCTs prove principle
- Observational studies give real-world relevance

Does radiation improve survival of men with localized prostate cancer?

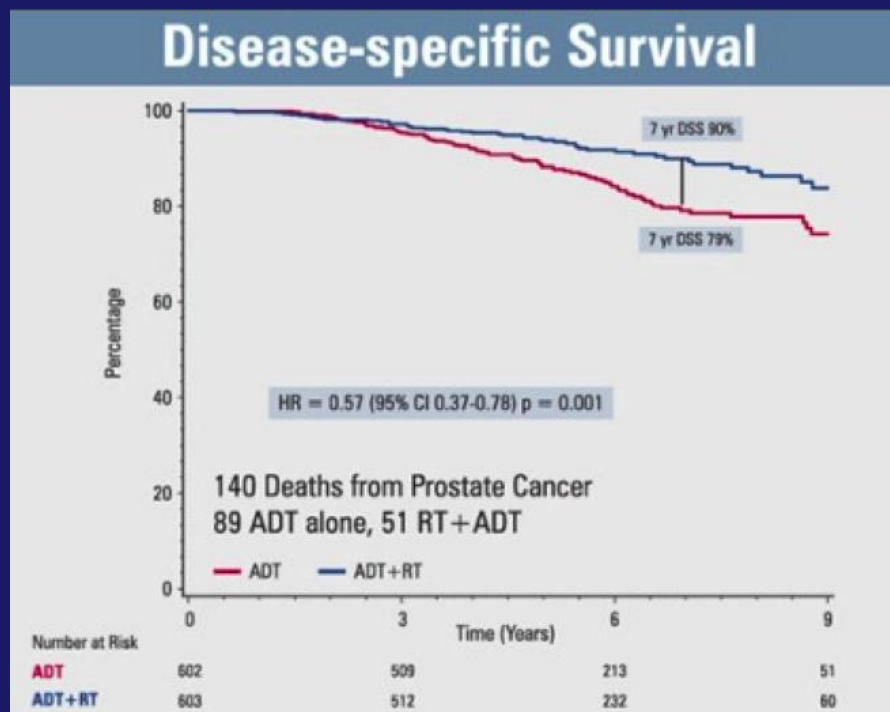
Results of Scandinavian randomized trial SPCG-7 *Widmark et al Lancet 2009*



- Clear and significant survival gains
- No QoL disadvantage

Does radiation improve survival of men with localized prostate cancer?

Results of UK Canada randomized trial P07 *Warde et al ASCO 2010*



- Clear and significant survival gains

Does radiation improve survival of men with localized prostate cancer?

Results of SEER/Medicare observational study 2011

Lu Yao (unpublished data)

	<u>10- year DSM</u>		
	<u>RT</u>	<u>No RT</u>	
Low-risk cancer	4.5%	6.1%	not sig
Intermediate-risk cancer	9.7%	13.0%	sig
High-risk cancer	16.1%	19.6%	sig

- Significant but smaller survival gains

Problem #1: spectrum of disease

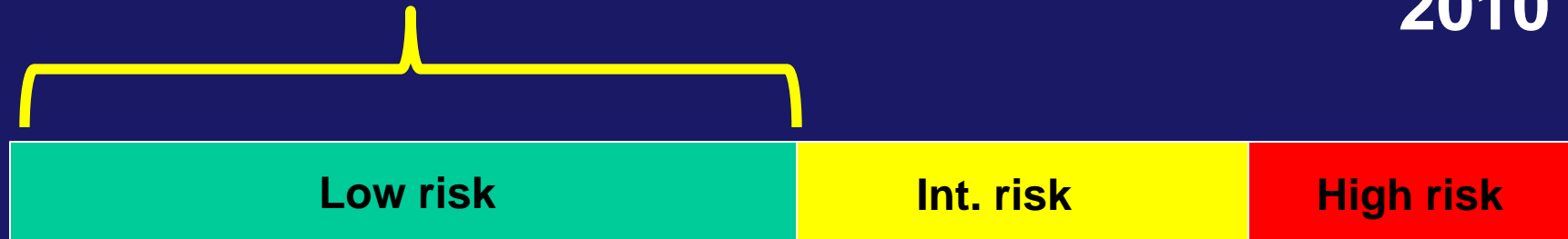
“Off-label use”

1990



“Off-label use”

2010



ProTECT Trial UK

Accrued: 2002-8

225,000 men

Randomized by family practice

PSA
screening

No
screening

Case detection

Surgery

700

External
beam

700

Active
surveillance

800

Endpoints:

- PCa death
- Metastases

***Detail* questions do not require RCTs**

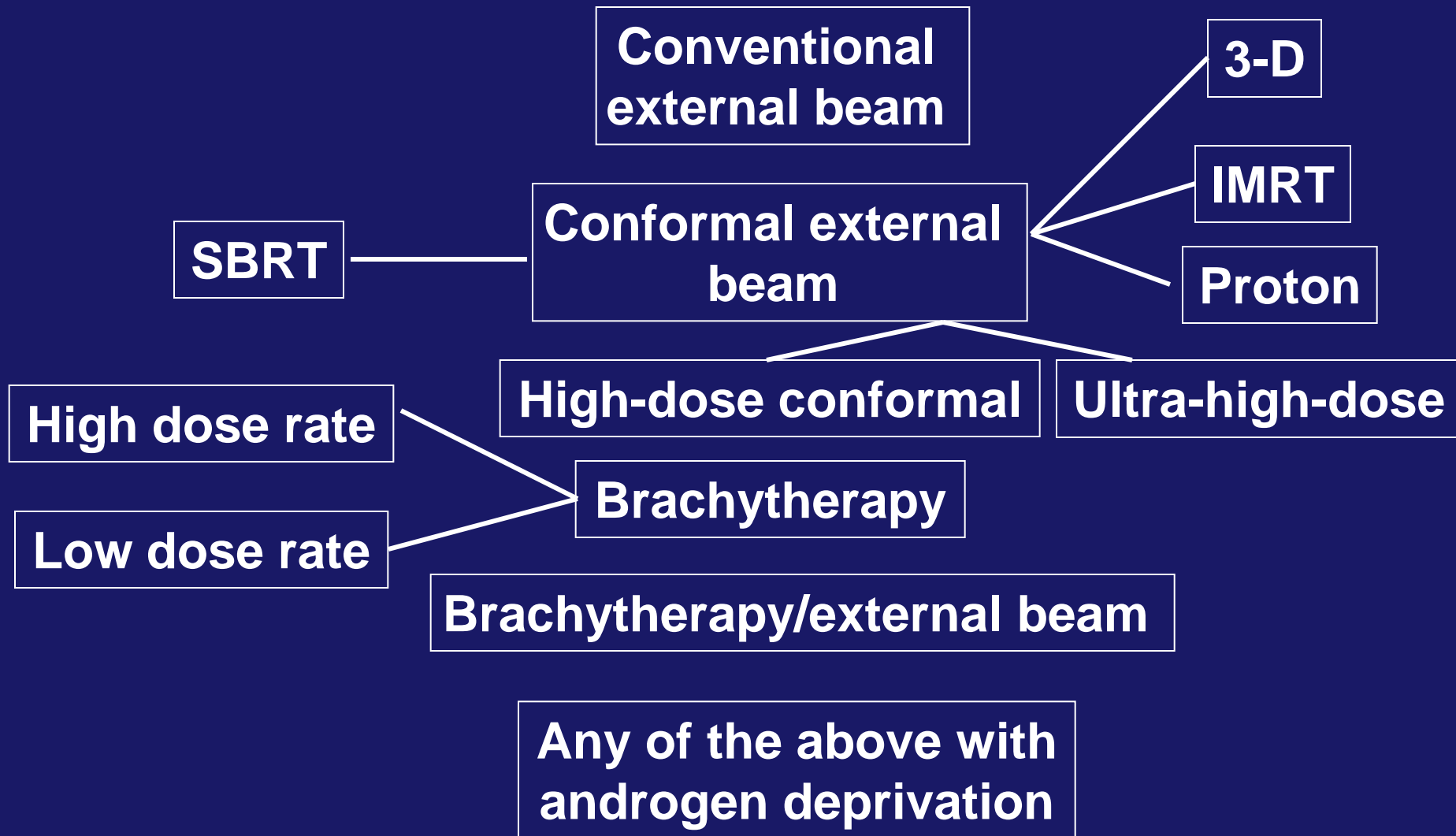
Questions that evolve quickly:

- **Radiation device A vs B vs C ?**
- **Surgical approach A vs B vs C ?**

Problem #2: Radiation oncologists love their gizmos

Conventional
external beam

Problem #2: Radiation oncologists love their gizmos

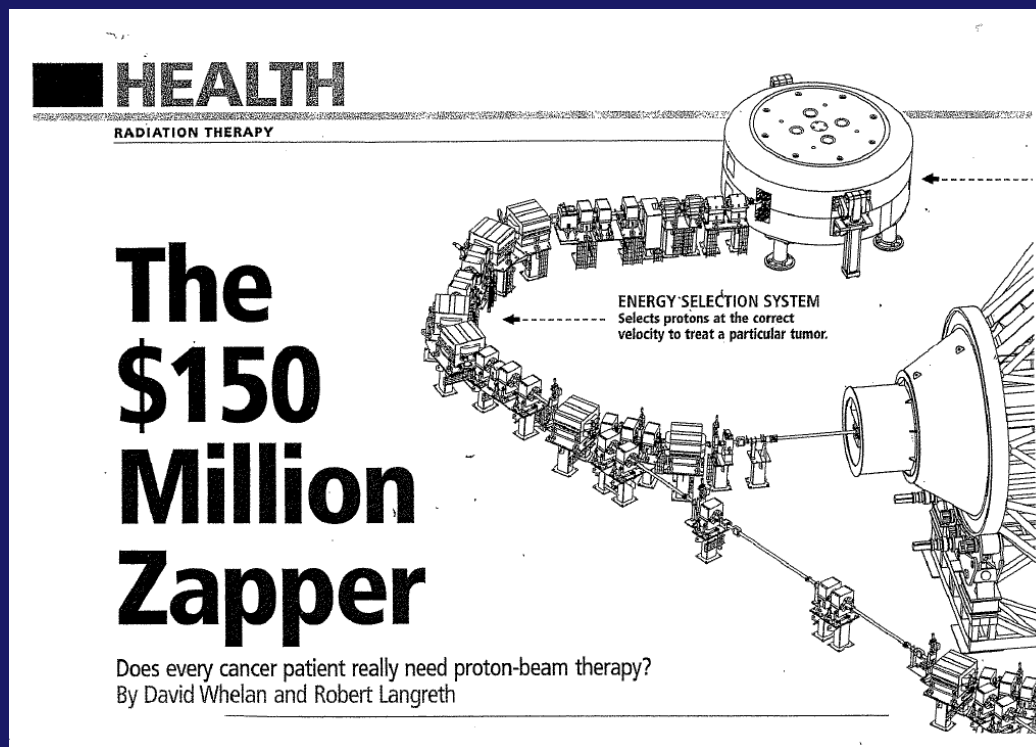
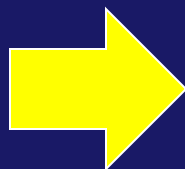
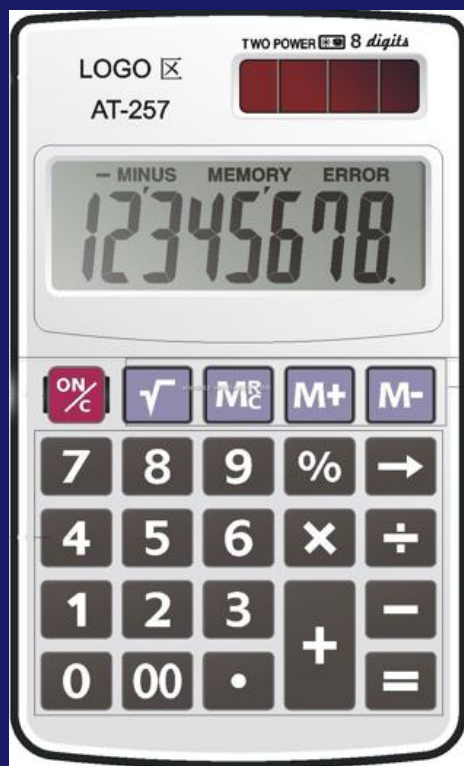


The radiation oncologists fear about CER

- **Slow the engine of technological discovery**
- **Tested technologies obsolete by time of reporting**
- **Never be able to recoup significant investments**

Is medical technology ever a big question or always a small detail question ?

Depends upon the definition of a medical device



Is medical technology ever a big question or always a small detail question ?

Significant innovations need RCTs

1. Need for re-training/re-credentialing of physicians
2. Provide a treatment for a condition for which none previously existed
3. An innovation, although directed toward improving the health of a sick individual, could also cause harm
4. When the price of an innovation is so high to the health care system that major opportunity costs are engendered

Practical CER in prostate cancer

- “Big questions” still need RCTs to test principle supplemented by observational studies to test applicability
- “Smaller questions” need a melange of rapid answer observational studies (with RCTs if possible)
- Some “small” questions are so big that RCTs remain desirable