Value-Based Reimbursement: Conceptual and Policy Issues

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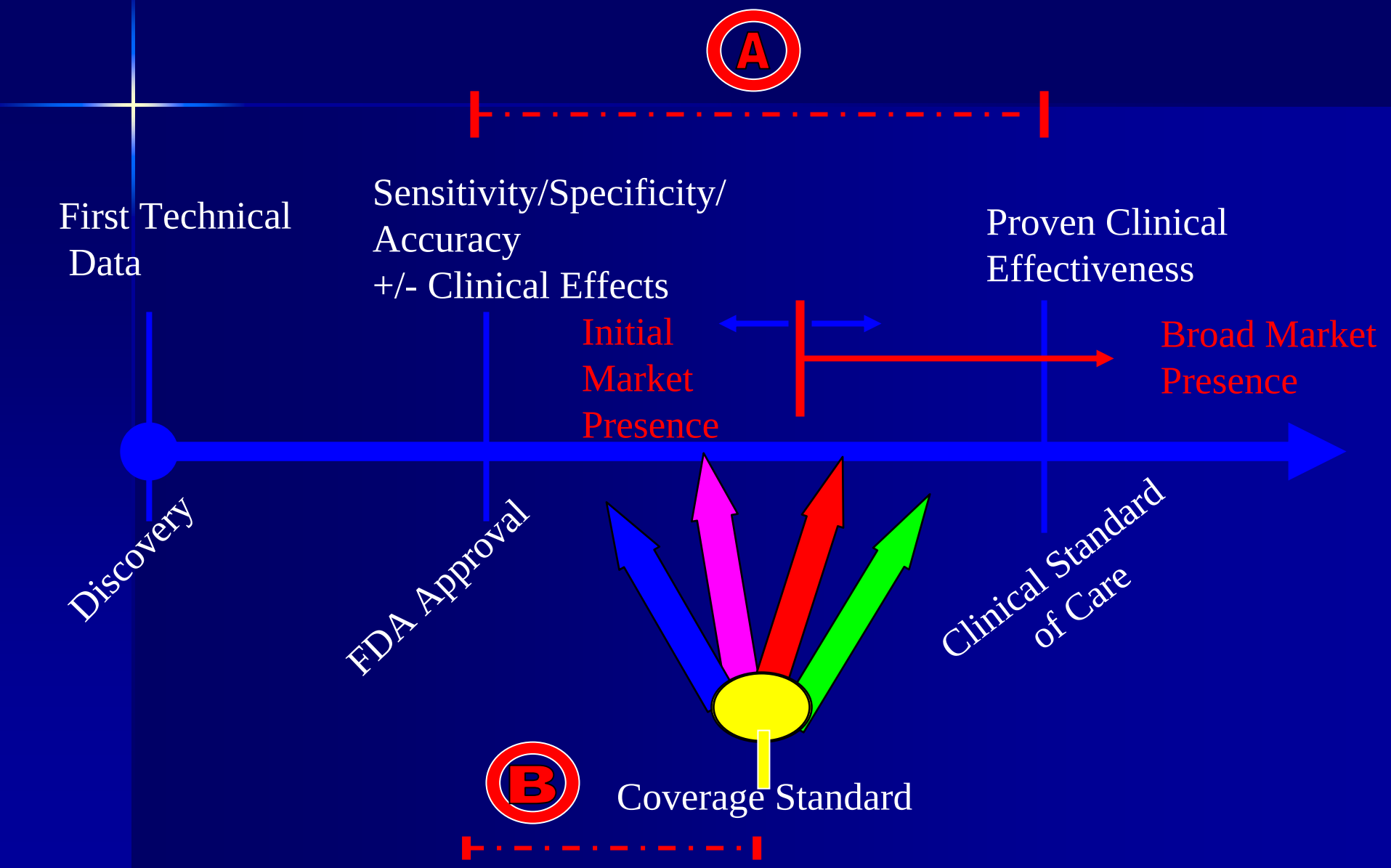
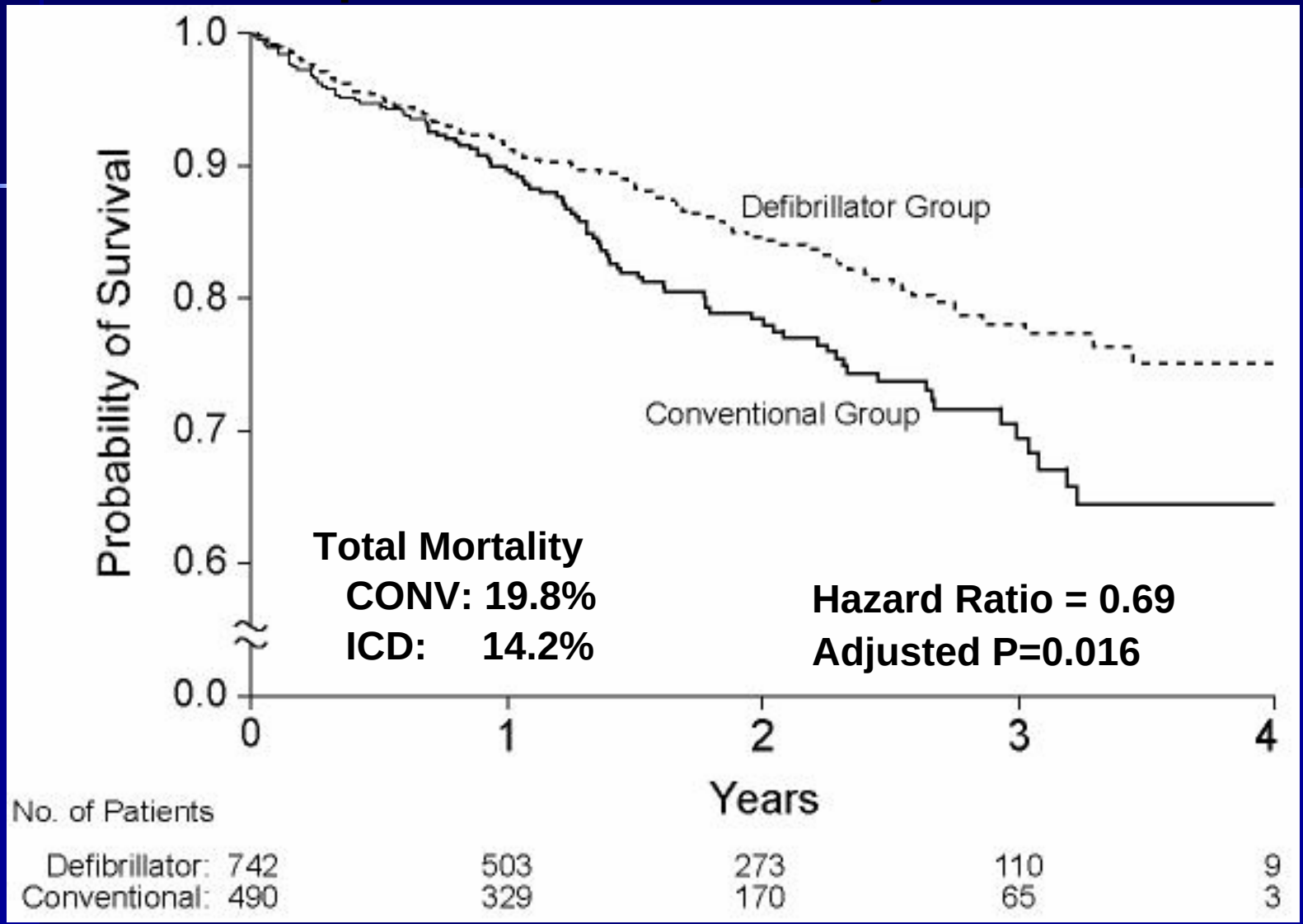
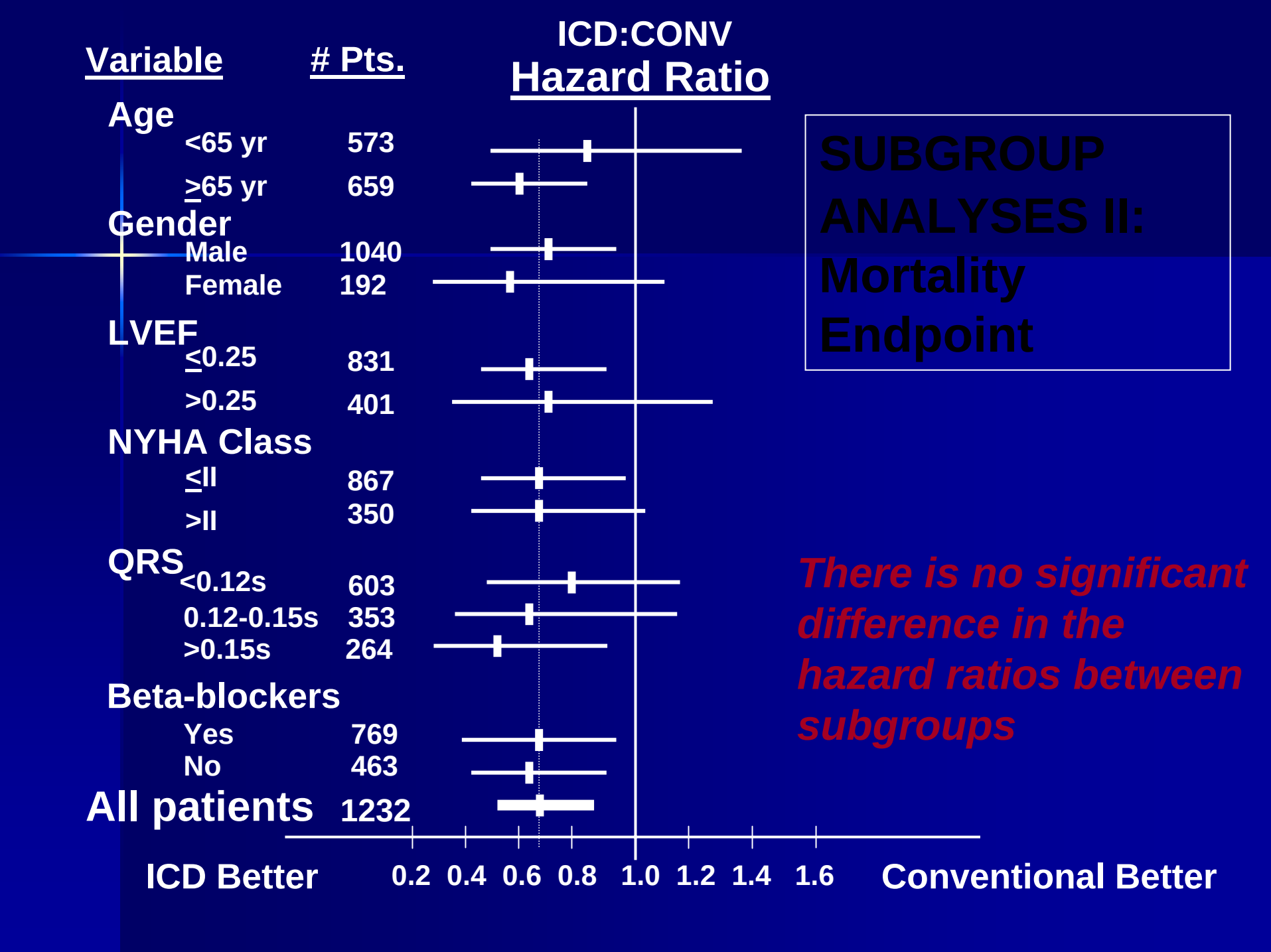
Natural History of Technology



Kaplan-Meier Survival by Treatment Group



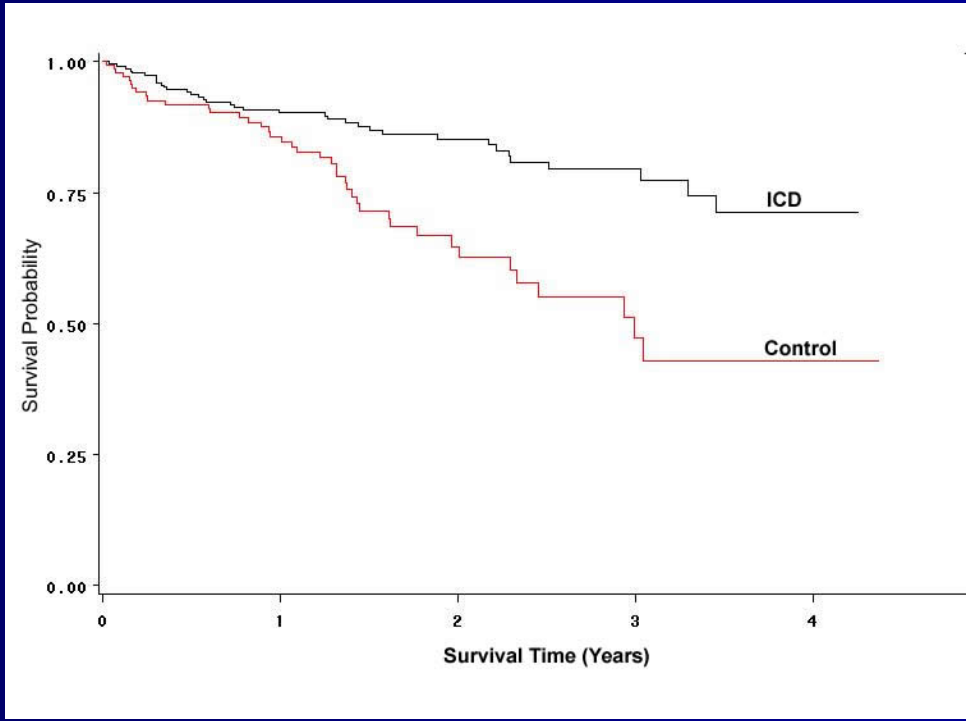
31% reduction in risk of all-cause mortality



SUBGROUP ANALYSES II: Mortality Endpoint

There is no significant difference in the hazard ratios between subgroups

Kaplan-Meier Estimates of the Survival for Patients with QRS > 120 ms



p-value=0.001

Patients with pacemakers were excluded.
CMS analysis of the MADIT II dataset supplied by Guidant.

CMS
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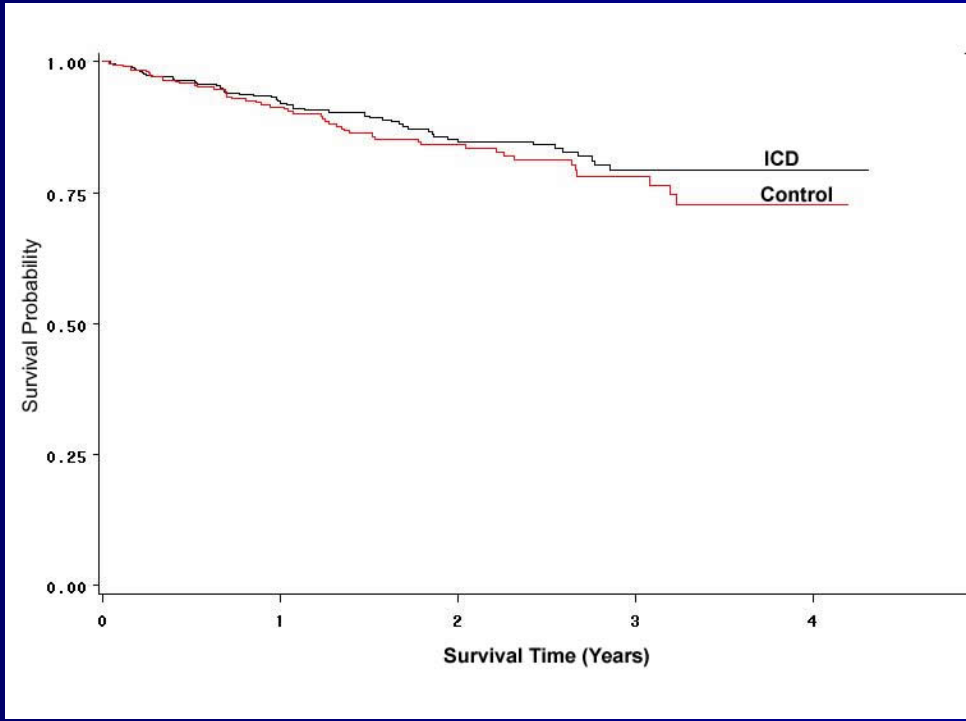
Kaplan-Meier Estimates of the Survival for Patients with QRS ≤ 120 ms



p-value=0.25

Patients with pacemakers were excluded.
CMS analysis of the MADIT II dataset supplied by Guidant.

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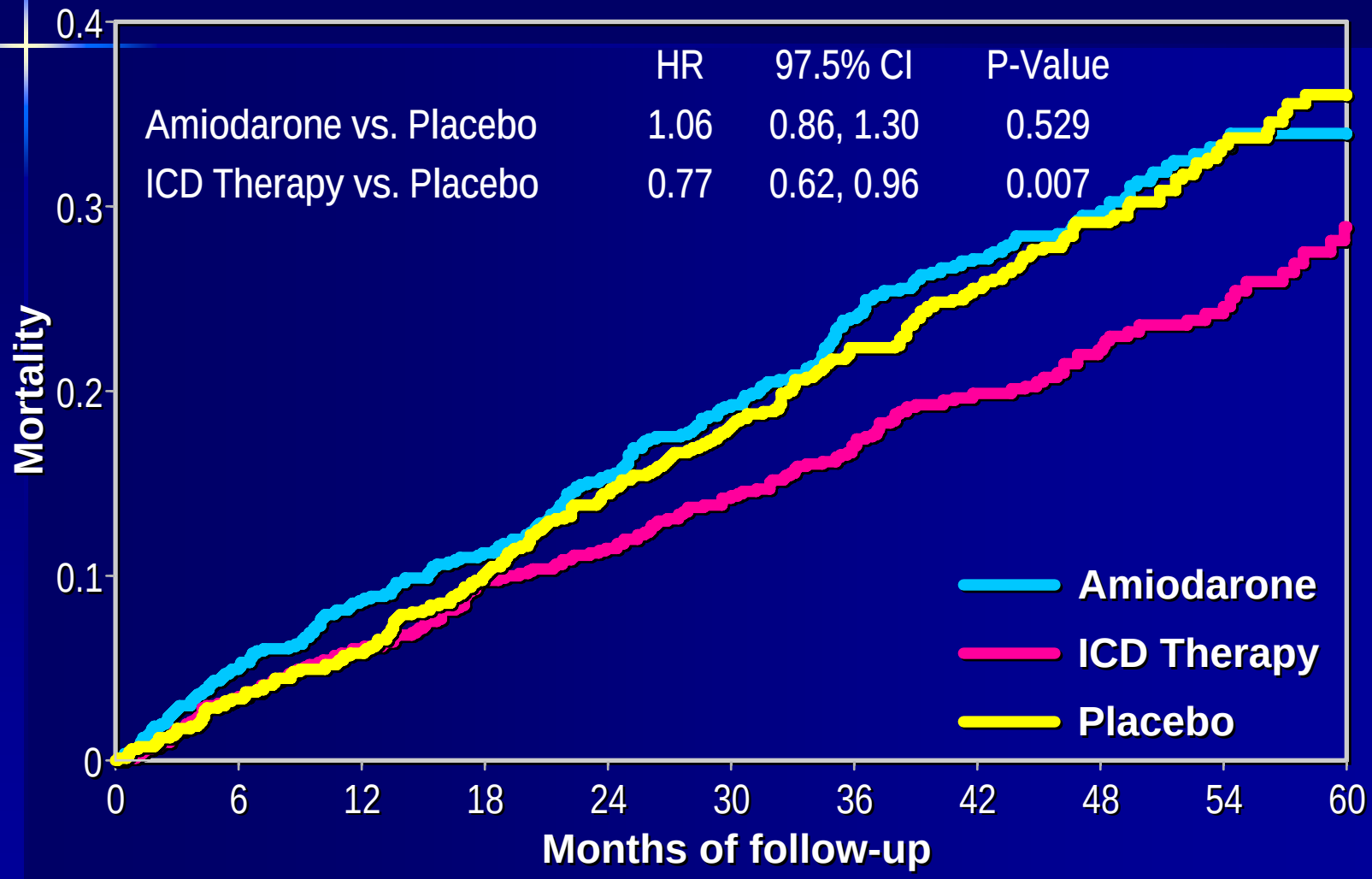
CMS June 2003 ICD policy

- CMS covers MADIT-I patients and wide-QRS subgroup of MADIT-II
  - Single trial
  - Possible selection bias
  - IIa recommendation by ACC/AHA/NASPE
- Announced that NCD would be reconsidered following SCD-HeFT

Sudden Cardiac Death
SCD-HeFT
Heart Failure
Trial

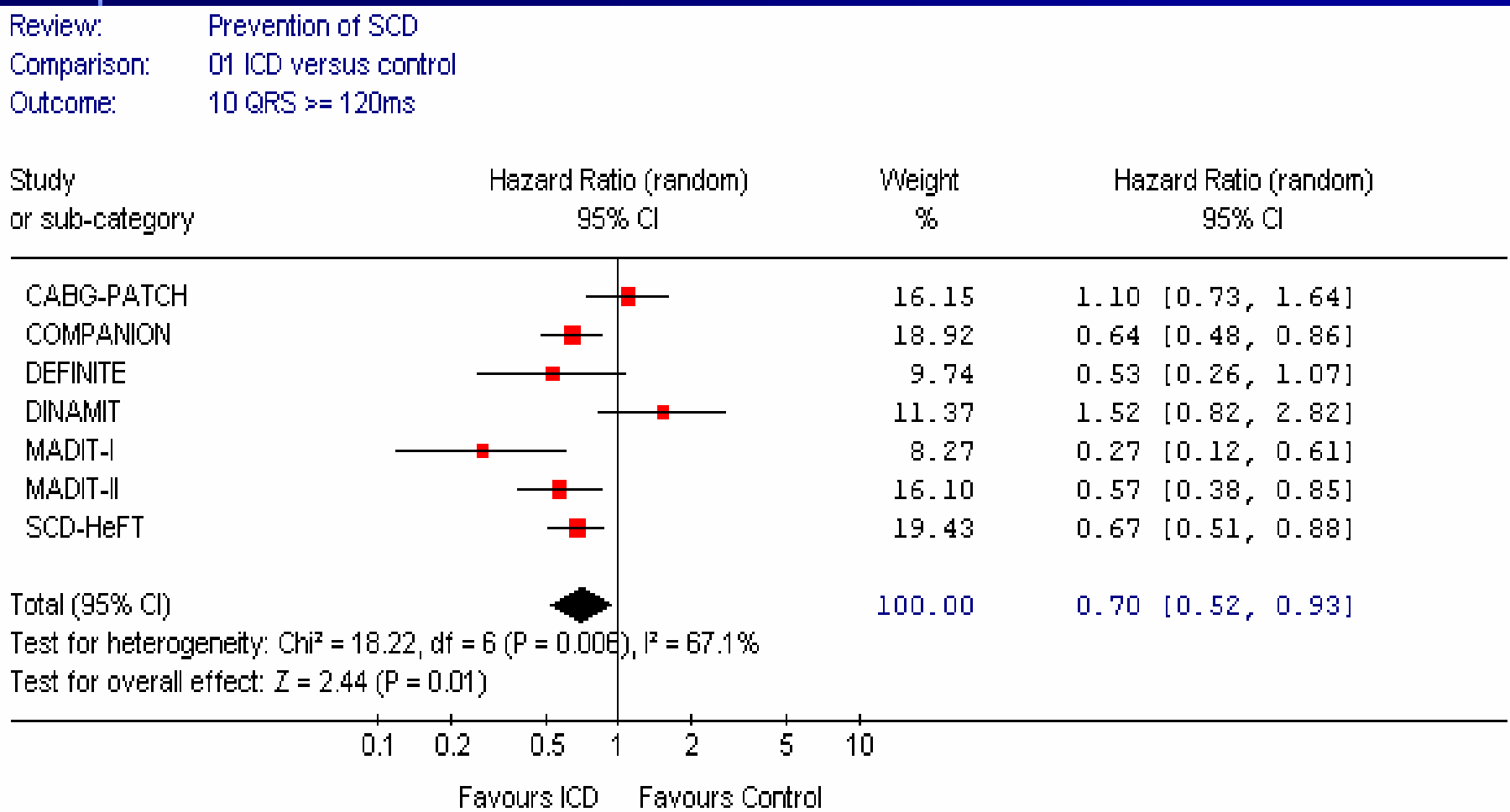
Mortality by Intention-to-treat



Meta-Analysis Results: ICD Therapy for Primary Prevention of SCD

(DCRI, 2004)

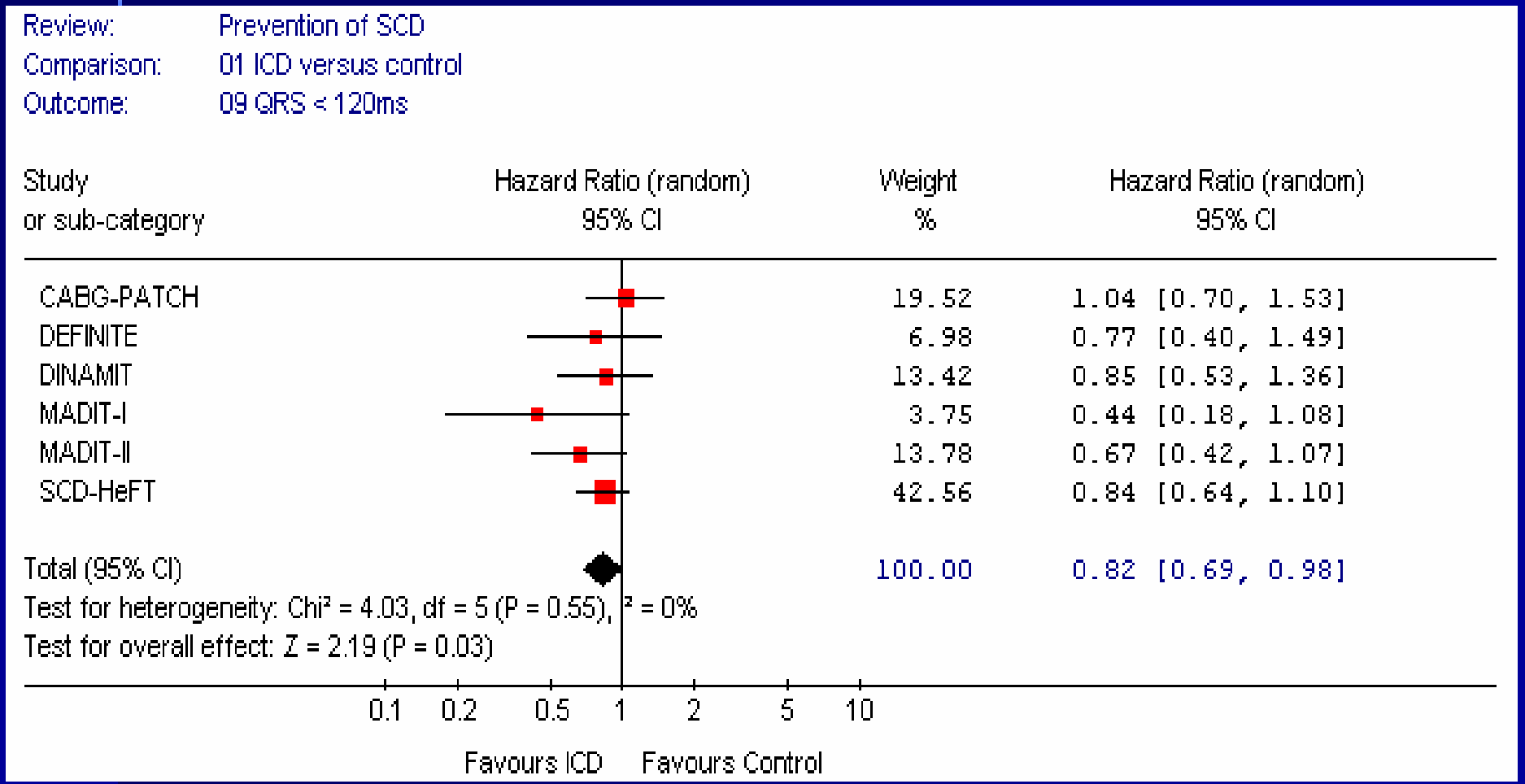
QRS >= 120



Meta-Analysis Results: ICD Therapy for Primary Prevention of SCD

(DCRI, 2004)

QRS < 120ms

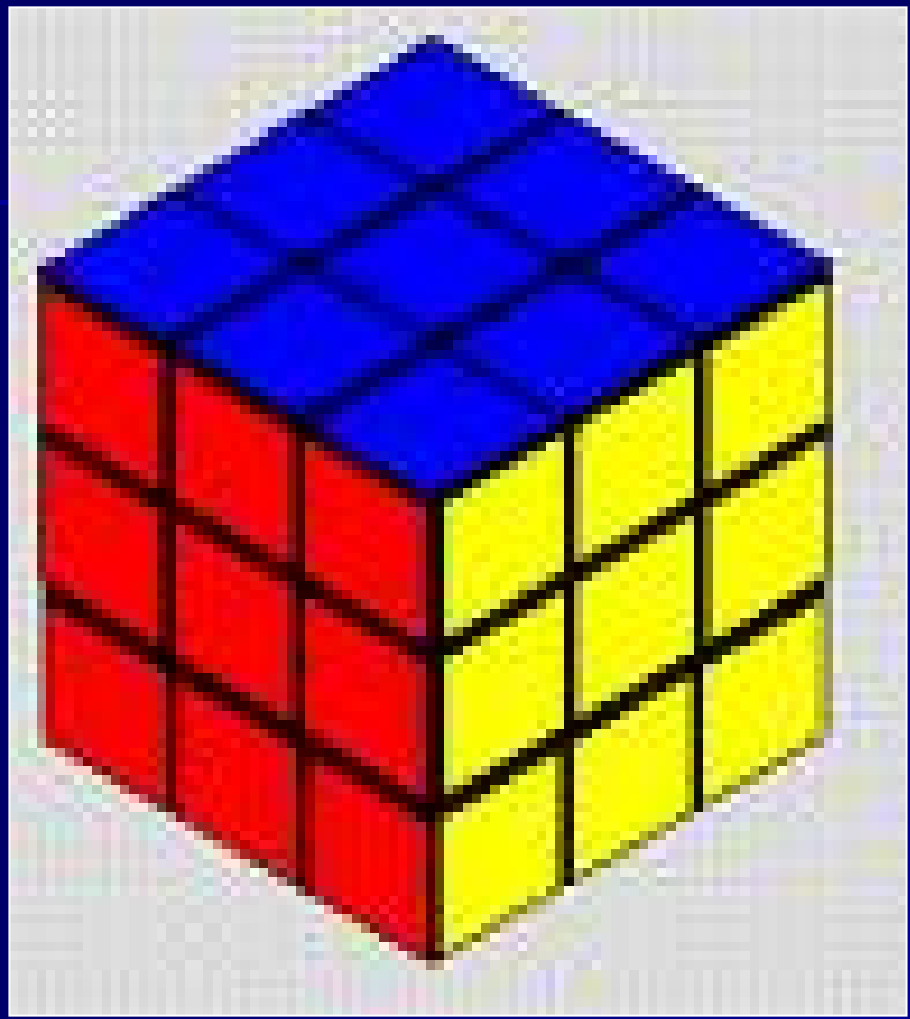


CMS ICD policy Jan 2005

- Medicare proposed decision to cover most pts with EF<35%
- SCD-HeFT make eligible pool 1M+
- Linked to submission of data to national ICD registry (CED)
- Intended goal of registry to get better information on patterns of use, real world event rates, risk stratification

CEA for ICDs

- NEJM Oct 6, 2005
  - Sanders, Hlatky, Owens,
- Markov model
  - based on meta-analysis of 8 trials
- 34K to 70.2K per life year saved
  - All sensitivity analyses below 100k/life-year
- Incremental cost $3-5B per year
- Called for better risk stratification
- Cheaper ICDs might also be worthwhile



Contact Information

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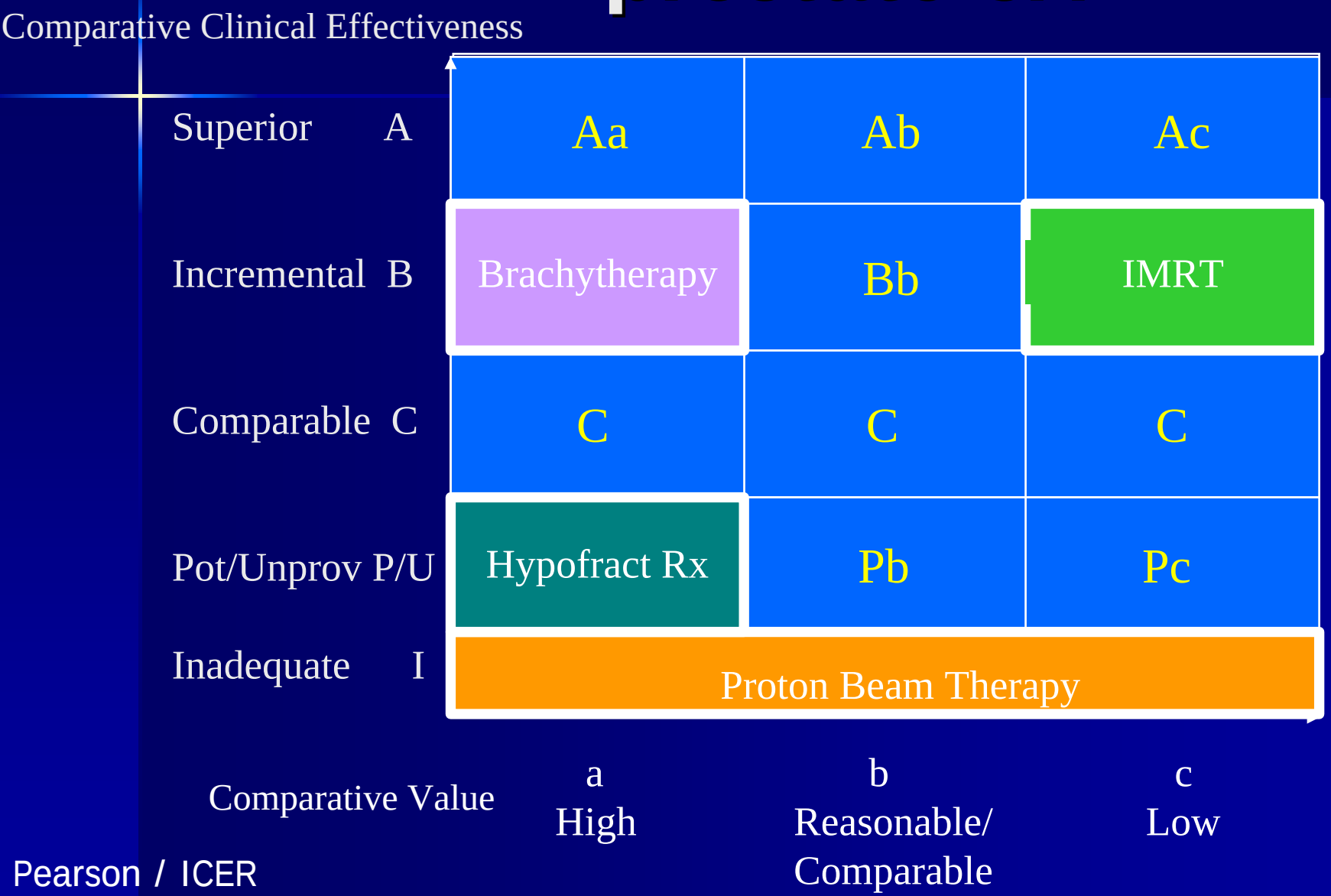
Value-based options

- QOE high, MOB high, relative cost low
  - Covered without limitations
- QOE mod, MOB mod, relative cost mod
  - Differential co-pay
- QOE low, MOB high, relative cost high
  - Coverage with evidence development
- etc

Impact on Innovation

- Current pricing
  - Cost and risk of R&D
  - Resource use in delivering service
  - Reinvestment in innovation
- Value-based pricing
  - Amount of health benefit produced
  - Insensitive to risk, resources, innovation

Radiation for low-risk prostate CA



Pearson / ICER

Albuterol / Xopenex

- Levalbuterol is S-enantiomer of albuterol
- Good pharmacologic rationale for improved effectiveness with fewer side effects
- Initial clinical studies showed better FEV-1, reduced beta adrenergic effects
- Large RCTs suggested lower hospitalization, but unclear impact on FEV-1
- CMS process: LCA, NCD, 1847(a)(1)
- What would have made sense?

Evidence of Effectiveness

- Key limiting factor in determining value
- Use of observational data
  - Nurse's Health / WHI, COURAGE, CATIE
- Pathophysiologic rationale
- Pragmatic trials, observational studies

Evidence-based Medicine (EBM): Original definition

"…Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and patho-physiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research."

Evidence-Based Medicine Working Group, JAMA (1992)

Quality of evidence

- prospective studies vs retrospective studies
- randomized vs observational studies
- concurrent vs. non-concurrent comparisons
- large studies vs. small studies
- blinded vs. unblinded observers
- effectiveness vs. efficacy
- hard outcomes / functional outcomes vs. intermediate outcomes