Coverage with Evidence Development

Implantable Cardioverter Defibrillators

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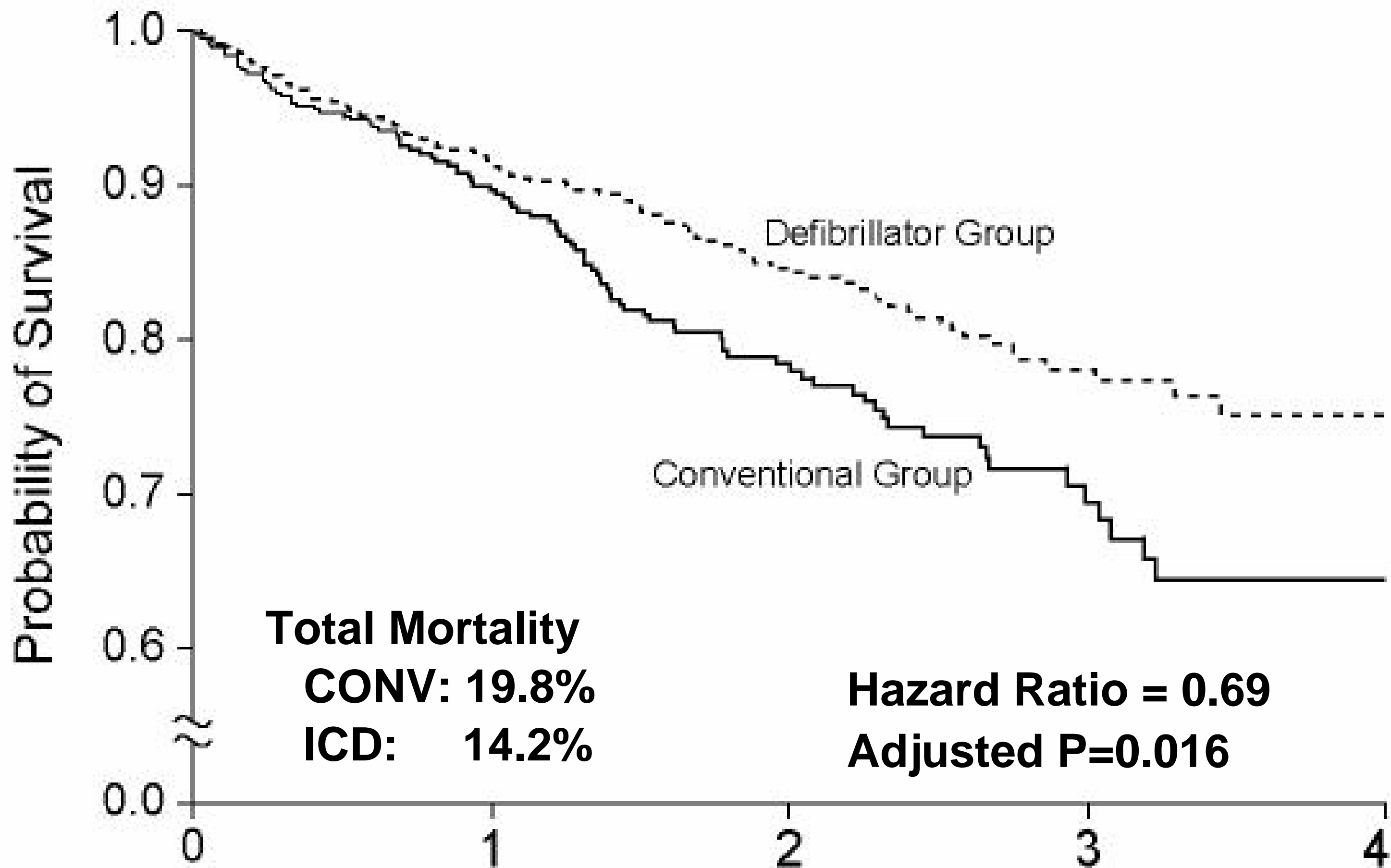
June 23, 2009

Kaplan-Meier Survival by Treatment Group



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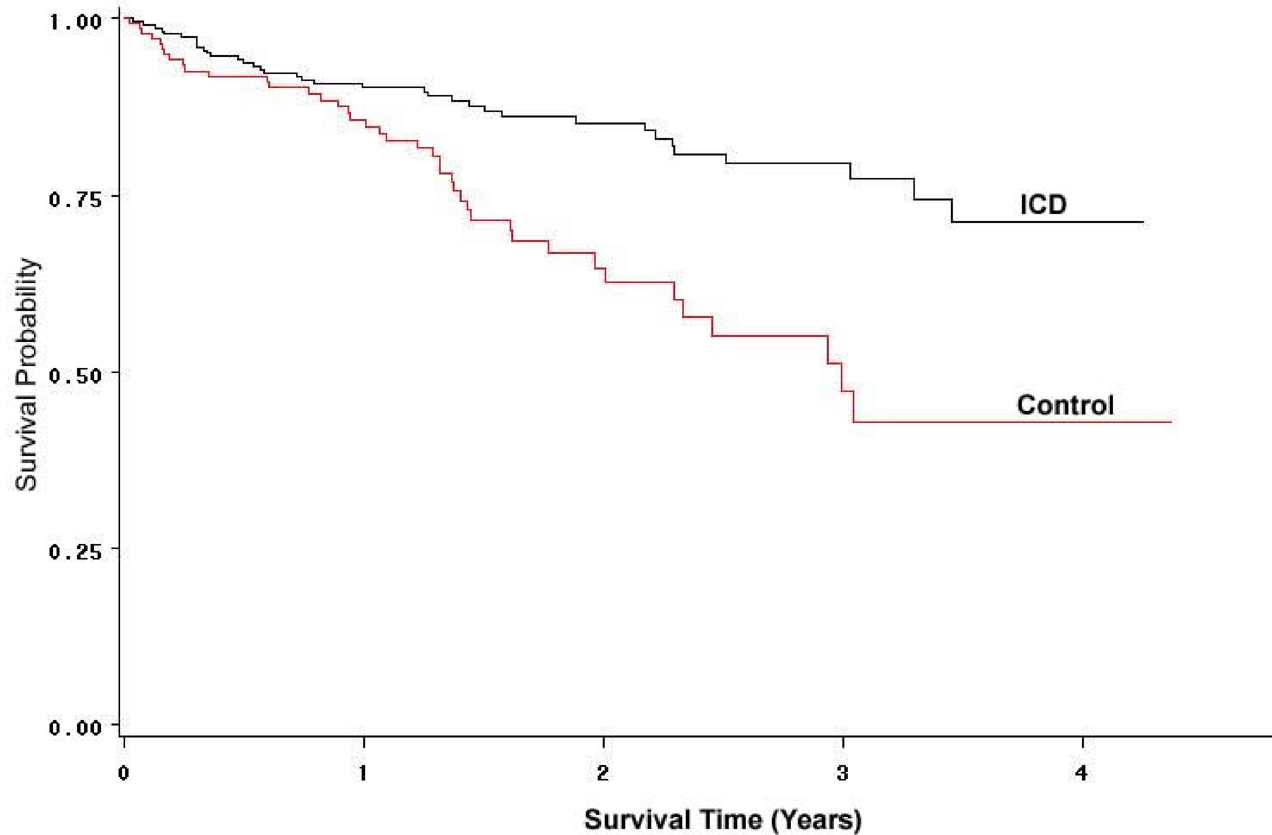
31% reduction in risk of all-cause mortality

Survival Probability for Patients with QRS > 120 ms



value=0.001

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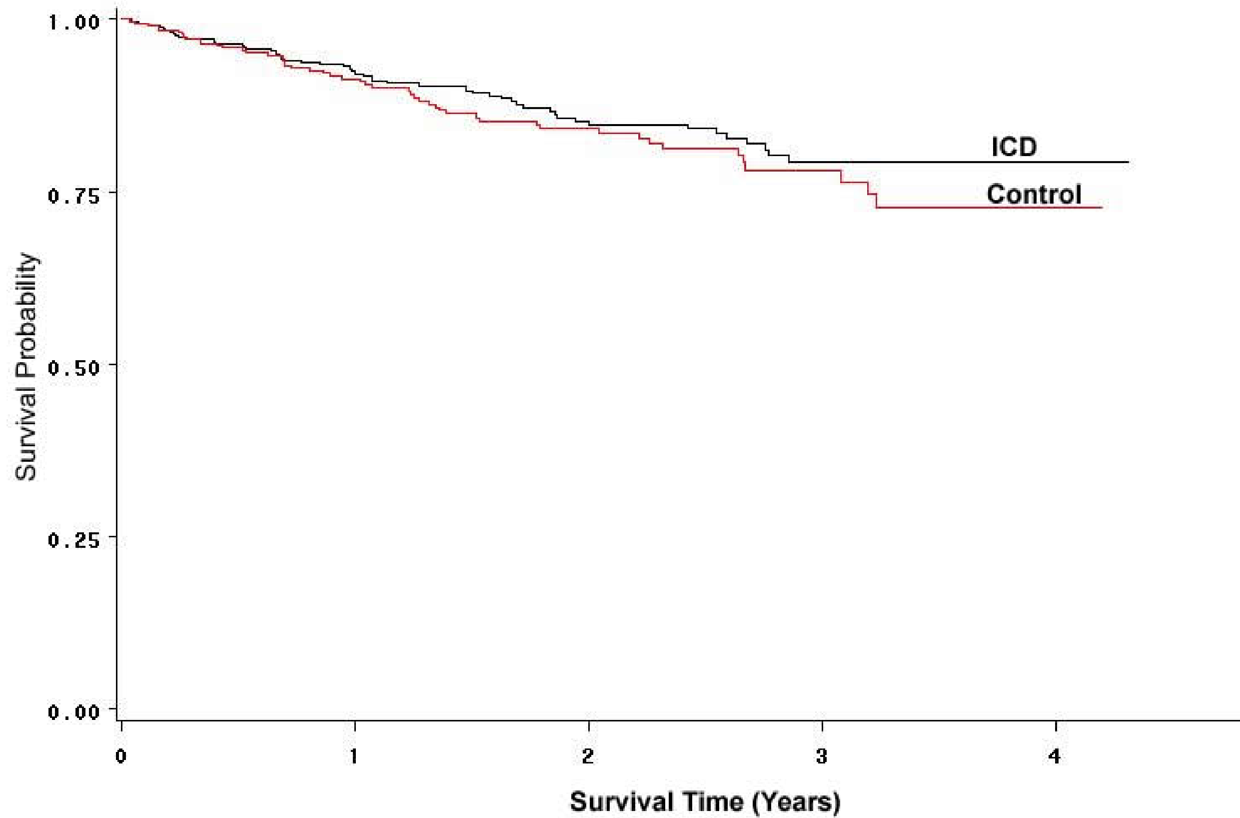
Survival Probability for Patients with QRS $\leq$ 120 ms



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Clinical experts react to Medicare ICD policy

- “The Medicare program cannot prove that this technology does not provide a benefit, and therefore is obligated to pay for it.”
- “I find it hard to believe that in a country as wealthy as the US, we cannot find the funds to pay for lifesaving technology”
- “What Hitler was unable to do, the Medicare program is trying to finish”

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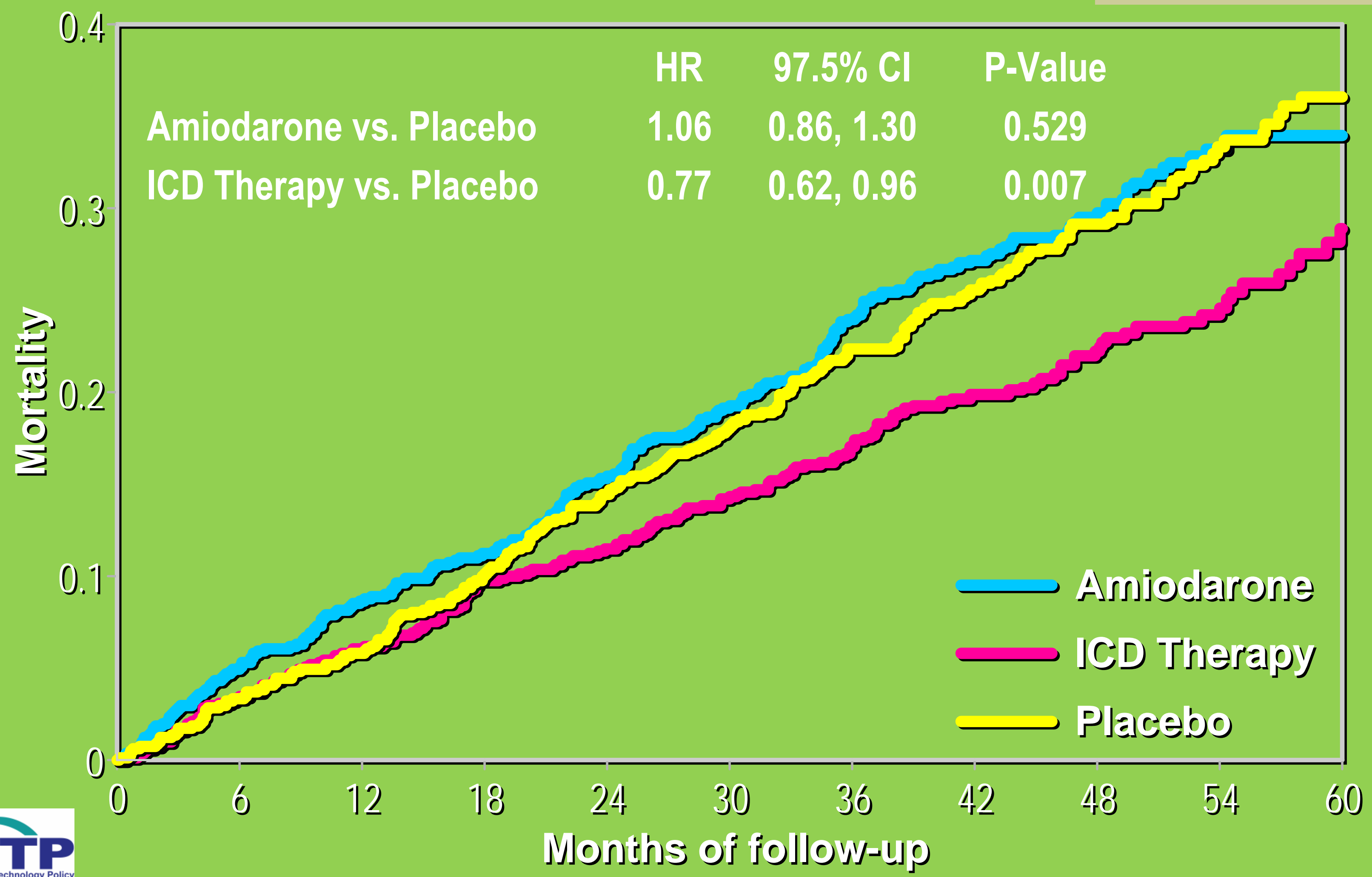
Sudden Cardiac Death
SCD-HeFT
Heart Failure
Trial

Mortality by Intention-to-treat



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Sudden Cardiac Death
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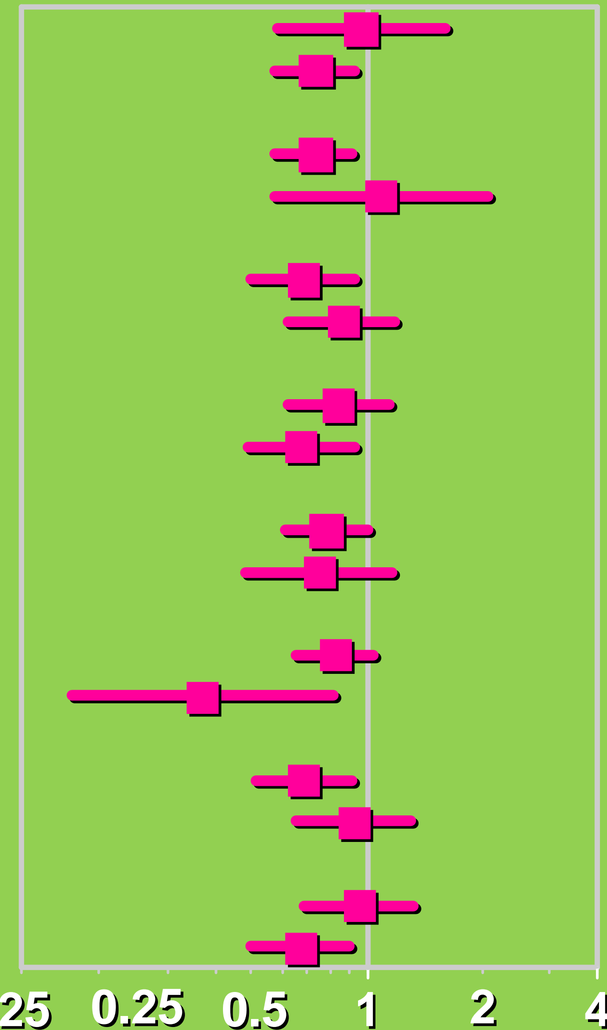
Trial

Additional Subgroups: ICD vs. Placebo

		N	HR	97.5% CI
Gender	Female	382	0.96	0.58, 1.61
	Male	1294	0.73	0.57, 0.93
LVEF	≤ 30%	1390	0.73	0.57, 0.92
	> 30%	285	1.08	0.57, 2.07
Age	< 65	1098	0.68	0.50, 0.93
	≥ 65	578	0.86	0.62, 1.18
QRS Duration	< 120 ms	977	0.84	0.62, 1.14
	≥ 120 ms	699	0.67	0.49, 0.93
Race	White	1283	0.78	0.61, 1.00
	Non-White	393	0.75	0.48, 1.17
Enrolling Country	U.S.	1512	0.82	0.65, 1.04
	Non-U.S.	164	0.37	0.17, 0.82
Beta Blocker	Yes	1157	0.68	0.51, 0.91
	No	519	0.92	0.65, 1.30
Diabetes	Yes	524	0.95	0.68, 1.33
	No	1152	0.67	0.50, 0.90



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"Never, ever, think outside the box."

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Coverage with Evidence Development

- **Links payment to requirement for prospective data collection**
- **Intent is to guide clinical research to address questions of interest to Medicare**
  - **Medicare must approve study design**
- **Goal to allow access while address research questions unlikely to be done otherwise**

Initial Working Group

- Heart Rhythm Society (Chair)
- Heart Failure Society of America
- Guidant
- Medtronic
- FDA (observer)
- American College of Cardiology
- Society for Thoracic Surgery
- St. Jude
- Biotronik
- CMS (observer)

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Registry Goals

- More effectively target interventions to subgroups who will benefit the most from therapy
- Generate evidence on patient subgroups not studies in major clinical trials
- Monitor real world clinical practice patterns
- Compare general population data with results from controlled clinical trials
- Provide a method for clinicians to satisfy quality measurement and reporting requirements

Funding Sources

- Wellpoint - $500,000 grant to establish the baseline registry
- NCDR registry now supported with $3000 per hospital annual fee
- Lengthy process required to raise $3.6 million for longitudinal study of 3500 patients
  - To begin soon with $1.5m from industry, $1m from AHIP, 1.1m from NIH (via CVRN)

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Implantable Defibrillator Registry

- 300k+ patients now in registry
- Baseline data interesting
  - Median age 74 (vs 60 in trials); LVEF higher
  - 3.6% complication rate
- No firing info, death or other outcomes data
  - Low priority for NHLBI, Industry, ACC/HRS
  - AHRQ has recently identified funds
  - Small fraction of $15B could have major ROI

ICD / CED Lesson Learned

- Timing
  - Must anticipate and start before coverage process
- Methods
  - Must be clear on questions and select appropriate methods
- Stakeholder ambivalence
  - Industry, professional societies, research funders each have reasons for concern
  - Incentives must be aligned
- Funding
  - Must be a clear funding model
- Interest in growing in US and elsewhere
  - Inevitable need to balance access and evidence

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