Devices and Other Non-Pharmacologic Therapy in CHF

Angel R. Leon, MD FACC
Division of Cardiology
Emory University School of Medicine
Disclosure

None
University of Miami vs. OSU

Renegade Miami football booster spells out illicit benefits to players

Tattoo scandal leads embattled Ohio State coach to quit post

One man’s Perrier-Jouet is another’s tattoo!
Non-Pharmacologic Therapy in CHF

ICDs to prevent sudden cardiac death
CRT for symptoms and LV function
Reduction of atrial arrhythmia burden
  CRT and atrial tachycardia and Afib
  Catheter ablation for rate control in Afib
  Primary catheter ablation of Afib
Implanted devices for CHF management
Prevention of Sudden Cardiac Death

ICD in CHF pts with VT, VF, or syncope

Primary prevention of SCD in CHF
Survival in AVID Patients

“Secondary Prevention” of sudden cardiac death

LVEF < 0.20 (Group 1)

LVEF 0.20 - 0.34 (Group 2)

LVEF > 0.34 (Group 3)

Patients with VF, symptomatic VT, asymptomatic VT, and syncope of unknown cause with significant heart disease and LV dysfunction

MADIT-II Survival Results

P = 0.007

<table>
<thead>
<tr>
<th>Year</th>
<th>No. At Risk</th>
<th>Probability</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>742</td>
<td>1.0</td>
</tr>
<tr>
<td>1</td>
<td>502 (0.91)</td>
<td>0.9</td>
</tr>
<tr>
<td>2</td>
<td>274 (0.94)</td>
<td>0.80</td>
</tr>
<tr>
<td>3</td>
<td>110 (0.78)</td>
<td>0.78</td>
</tr>
<tr>
<td>4</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>490</td>
<td>1.0</td>
</tr>
<tr>
<td>1</td>
<td>329 (0.90)</td>
<td>0.9</td>
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<tr>
<td>2</td>
<td>170 (0.78)</td>
<td>0.80</td>
</tr>
<tr>
<td>3</td>
<td>65 (0.69)</td>
<td>0.78</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
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</tbody>
</table>

SCD-HeFT: Prophylactic ICD in CHF

Ishemic and Non-ischemic LV Dysfunction
LVEF < 35%, NYHA Class II or III CHF
N=2,521

Randomization

Conventional CHF Rx & placebo

Conventional CHF Rx & amiodarone (double blind)
*Bardy, et. al. NEJM 2005*

Conventional CHF Rx & ICD
SCD-HeFT Treatment Group Mortality

Intention-to-Treat

<table>
<thead>
<tr>
<th>Treatment Comparison</th>
<th>HR</th>
<th>97.5% CI</th>
<th>P-Value</th>
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<tbody>
<tr>
<td>Amiodarone vs. Placebo</td>
<td>1.06</td>
<td>0.86, 1.30</td>
<td>0.529</td>
</tr>
<tr>
<td>ICD Therapy vs. Placebo</td>
<td>0.77</td>
<td>0.62, 0.96</td>
<td>0.007</td>
</tr>
</tbody>
</table>

Adapted from Bardy, et. al. NEJM 2005
ICD Impact by NYHA Class

NYHA Class II
- ICD Therapy
- Placebo

NYHA Class III

HR 97.5% CI
0.54 0.4-0.74
1.16 0.84-1.61

Bardy, et. al. NEJM 2005
Impact of ICD According to LVEF

- **LVEF ≤ 30%**
  - ICD Therapy
  - Placebo
  - HR: 0.73, 97.5% CI: 0.57-0.92

- **LVEF > 30%**
  - HR: 1.08, 97.5% CI: 0.57-2.07

Adapted from Bardy, et. al. NEJM 2005
Cardiac Resynchronization

Biventricular Pacing
Biventricular Pacing with ICD
CRT
Effect on Exercise Capacity

Average Change in 6 Minute Walk Distance

-40 -20 0 20 40 60
m

MIRACLE (1) MUSTIC SR (2) CONTAK CD (3) MIRACLE ICD (4)

Control CRT * P < 0.05

Average Change in Peak VO2

0 1 2 3
ml/kg/min

MIRACLE (1) MUSTIC SR (2) CONTAK CD (3) MIRACLE ICD (4)

Control CRT *

1. NEJM 2002;346:1845-53
2. NEJM 2001;344:873-80
4. JAMA 2003; 289:2685-94
CRT
QoL and NYHA Functional Class

Average Change in QoL Score (MLWHF)

NYHA: Proportion Improving 1 or More Class

Control CRT

* P < 0.05

1. NEJM 2002;346:1845-53
2. NEJM 2001;344:873-80
3. Eur Heart J 2002;23:1780-1787
5. JAMA 2003; 289:2685-94
CRT

Effect on LV Size and Function

MIRACLE

Paired, Median Changes from Baseline

CARE-HF: CRT without ICD

What is the isolated effect of CRT on all-cause mortality in pts with LV dysfunction and CHF?

NYHA Class III-IV, QRSd > 120ms, EF < 0.35

CRT-P vs optimal medical therapy: NO ICD

Extend follow-up to allow time for the therapy to demonstrate significant differences

Cleland, et al NEJM 2005;352(15)
Effect of CRT alone on all-cause mortality without the use of an ICD

Cleland, et al NEJM 2005;352(15)
CRT in mild to moderate CHF may prevent the progression of LV dysfunction: MIRACLE ICD II

CRT in mild CHF (Class I and II) improves LV function and decreases hospitalization for CHF: MADIT CRT and RAFT

Will ventricular pre-excitation in a segment adjacent to an acute MI prevent adverse post-infarct remodeling and improve LV function: PROMPT
CRT and Atrial Fibrillation

CRT reduced the frequency of AF/AFL
  Effect began within three months
  Continued reduction at one year
  Improved LV function

Data obtained from implanted devices pre- and post-upgrade to CRT

D. Yannopoulos, et al JACC Volume 50, Issue 13, Pages 1246 - 1251
Tachycardia Induced LV Dysfunction

Excessive ventricular rates over time impact ventricular systolic function.
Rate control reverses LV dysfunction in some patients.
Duration and rate threshold difficult to gauge in humans (experimental models exist).
Tachycardia Mediated LV Dysfunction

Improvement in EF post AVJ ablation:

- 18% (n=22): Twidale, PACE 1998 (21)
- 29% (n=17): Morady, JACC 1997 (29)
- 25% (n=12): Rodriguez, AJC 1993
- 25% (n=63): Kay, JICE 1998 (2)

Following either complete AVJ ablation or modification to control ventricular rates
Ablate-Pace Trial: LV Dysfunction

63/156 pts with baseline LVEF ± 0.45:
• 1yr survival 0.73 vs 0.88 in those with EF > 0.45 (p = 0.03)
• 9 died; 2 CHF, 2 SCD, 2 CVA (EF 0.30)

Response to ablation in the lowest EF group:
• Baseline EF 0.31 ± 0.2 improved to 0.41± 0.2 (3mo) and remained at 0.41 ± 0.3 (1yr) p= 0.0001

Kay GN, J Inter Card Electrophys 1998,(2)2
Catheter ablation improves LV function in patients with refractory Afib
A large proportion of patients with AF and CHF may have reversible LV dysfunction
Patients with reduced EF remain at risk for death after an ablate-pace strategy
Patients with AF, CHF, and AVJ ablation underwent upgrade to CRT after >6mo of RV pacing:

(Mean duration of RV pacing 24mo)

Upgrade to CRT in CHF with AV block and RV pacing improves symptoms, EF, hospital use

(León, JACC 4/2002)
1. Will LV function recover, and if so, how long after achieving rate control?

- LVEF may improve in up to 25% of patients with good rate control, usually within three months.
2. Should one implant an ICD in all patients with LVEF \( \leq 0.35 \) and AF scheduled for AVJ ablation?

- Pts with a low baseline EF in Ablate-Pace had an increased risk of SCD. Re-assess EF at 3mo in those receiving PPMs.
- Poor rate control during AF represents a potentially reversible cause of LV dysfunction.
Suggestion: Relegate AVJ ablation as a last resort in managing AF:

1. Attempt to maintain SR with AADs
2. Increasing use of AF ablation in CHF
3. AVJ ablation still valuable in specific patient populations and in those with CRT devices that develop AF.
Hybrid AF ablation: PVI + WACA

RF delivery at sites in the circumlinear pattern coincide with the site of pulmonary vein potentials.
Catheter ablation in patients with CHF:
- Preservation of SR improves LVEF
- Eliminates a need for AVJ ablation
- Reduces use of antiarrhythmic drugs
- Initial experience encouraging but patient selection remains a major consideration

Hsu, Jais, et al NEJM Volume 351:2373-2383 December 2004
Afib Ablation: PVI in CHF

Multi-center RCT (n=81) in symptomatic AF, LVEF < 40%, NYHA II-III
PVI vs HIS ablation & BiV pacing
Primary endpoint: 6-min walk, LVEF, QoL
Secondary endpoints: AF, LA size
Follow period of 1 year

Khan MN, NEJM 359(17):1778-1785
PVI in CHF

PVI LVEF
Mean increase 8.8%
70% had an increase
EF 35% vs 27% (p < 0.001)

6 min walk
340m vs 297m (p < 0.001)

Quality of Life
MLWHF 60 vs 82 (p < 0.001)

Khan MN, NEJM 359(17):1778-1785