

第25回内科 MGR CRT-D vs ICD:両室ペーシングの効果

Cardiac-Resynchronization Therapy (CRT) for the Prevention of Heart-Failure Events

AJ Moss, et al.

N Eng J Med 2009 Oct 1

心不全治療のための心臓再同期療法

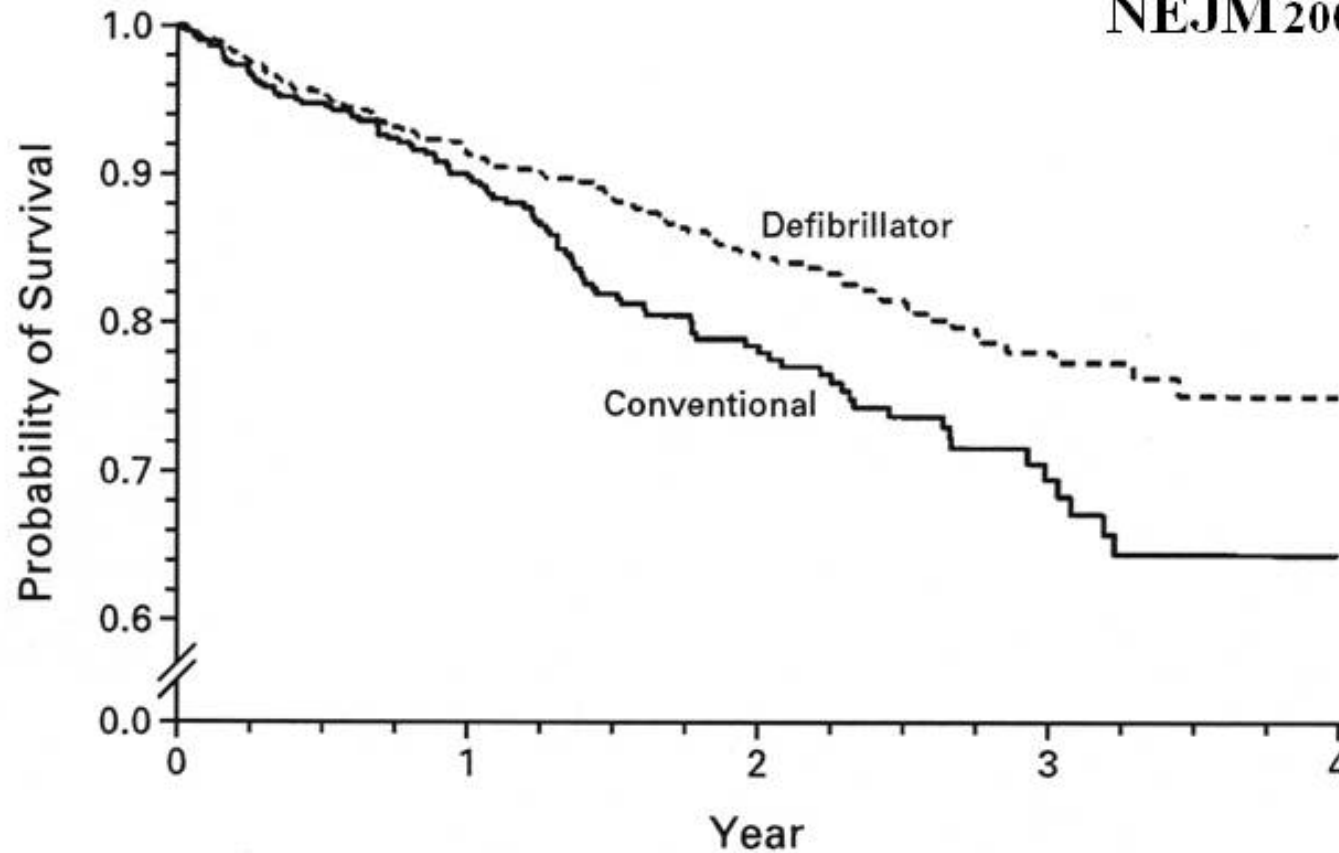
心不全の非薬物治療：
早期からの介入は予後を改善するか。

心筋梗塞後の左室機能低下例において植え込み型除細動器治療は生命予後を改善する

対象: 1ヶ月以上前に発症した心筋梗塞

左室駆出率 (LVEF < 30%)

NEJM 2002; 346: 877-883



No. AT RISK

Defibrillator	742	503 (0.91)	274 (0.84)	110 (0.78)	9
Conventional	490	329 (0.90)	170 (0.78)	65 (0.69)	3

Figure 2. Kaplan-Meier Estimates of the Probability of Survival in the Group Assigned to Receive an Implantable Defibrillator and the Group Assigned to Receive Conventional Medical Therapy.

The difference in survival between the two groups was significant (nominal $P=0.007$, by the log-rank test).

低心機能症例:

QRS > 120 ms

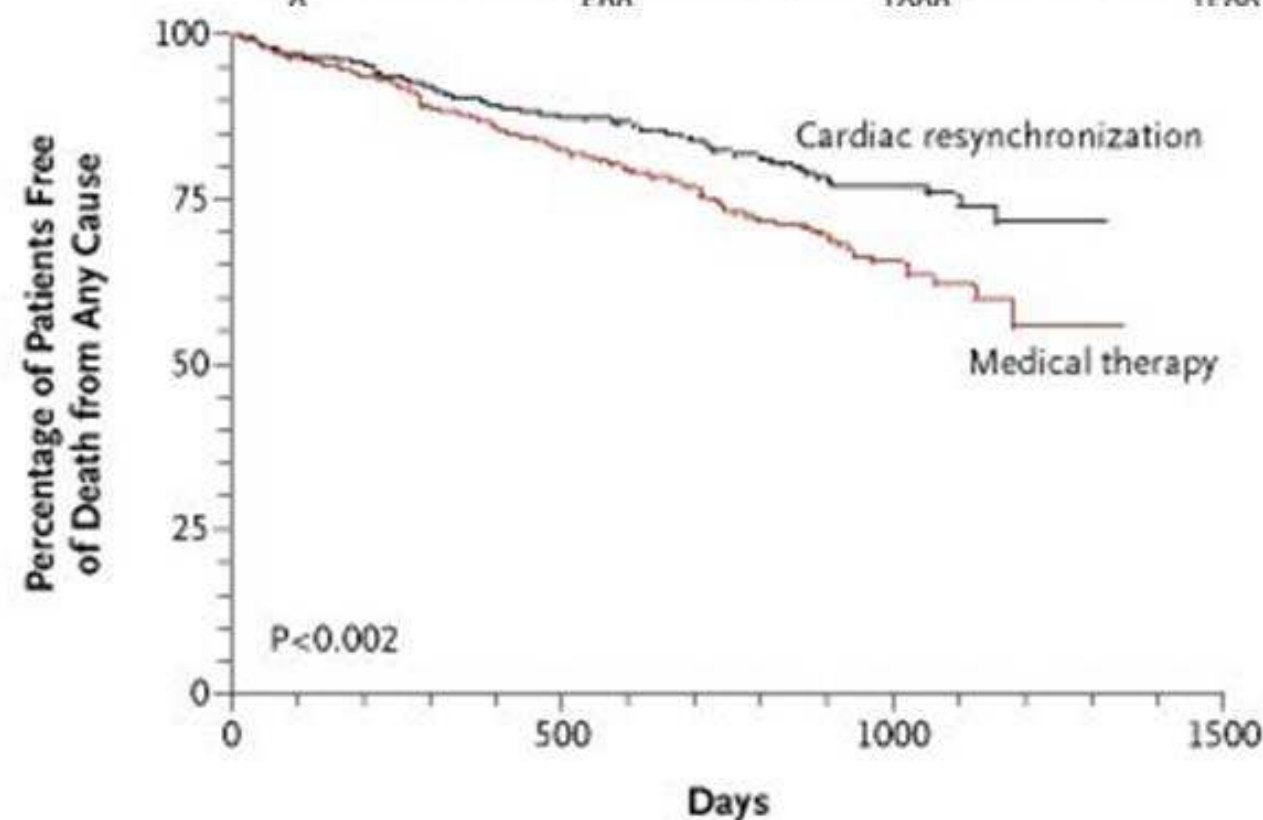
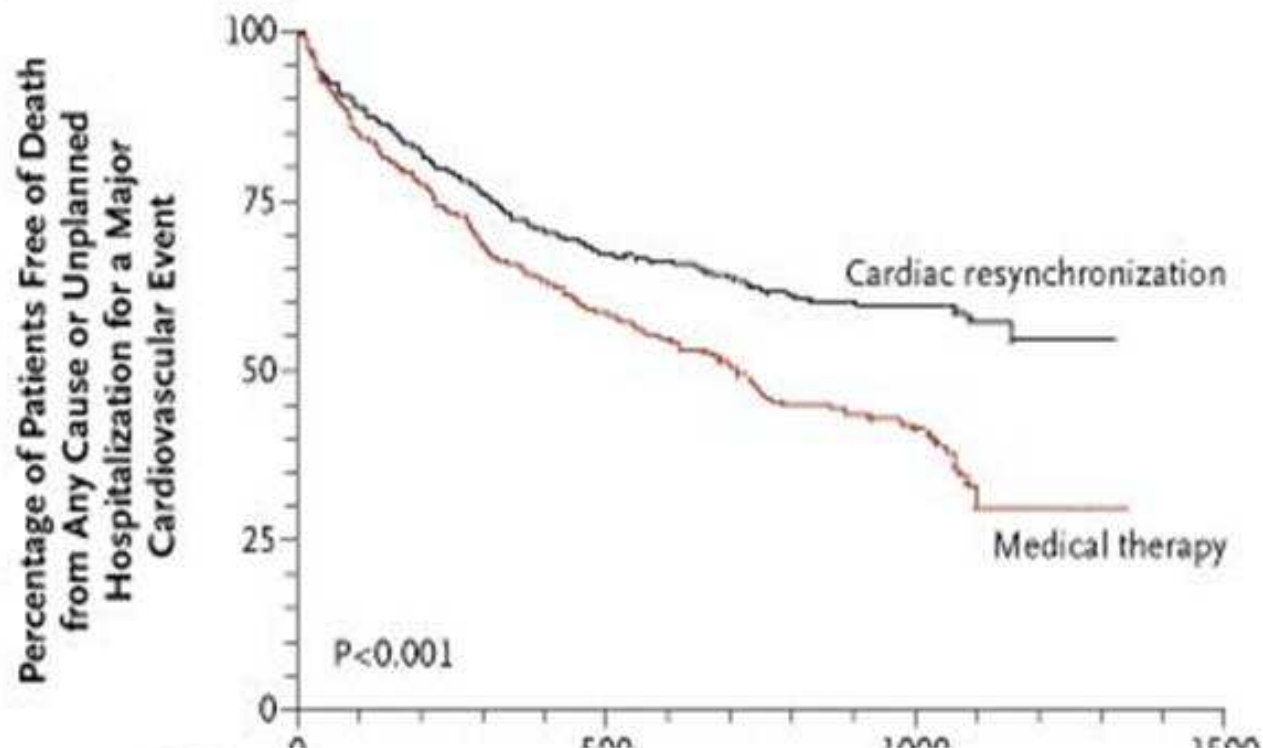
LVEF < 35%

NYHA III-IV

ACE-I 95%、B-blocker 70%での
十分な内科治療を行っている

において、両心室ペーシング治療
は予後を改善する
(29ヶ月の観察
GARE-HF Study)

N Engl J Med 2005; 352: 1539



BACKGROUND

This trial was designed to determine whether cardiac-resynchronization therapy (CRT) with biventricular pacing would reduce the risk of death or heart-failure events in patients with mild cardiac symptoms, a reduced ejection fraction, and a wide QRS complex.

METHODS

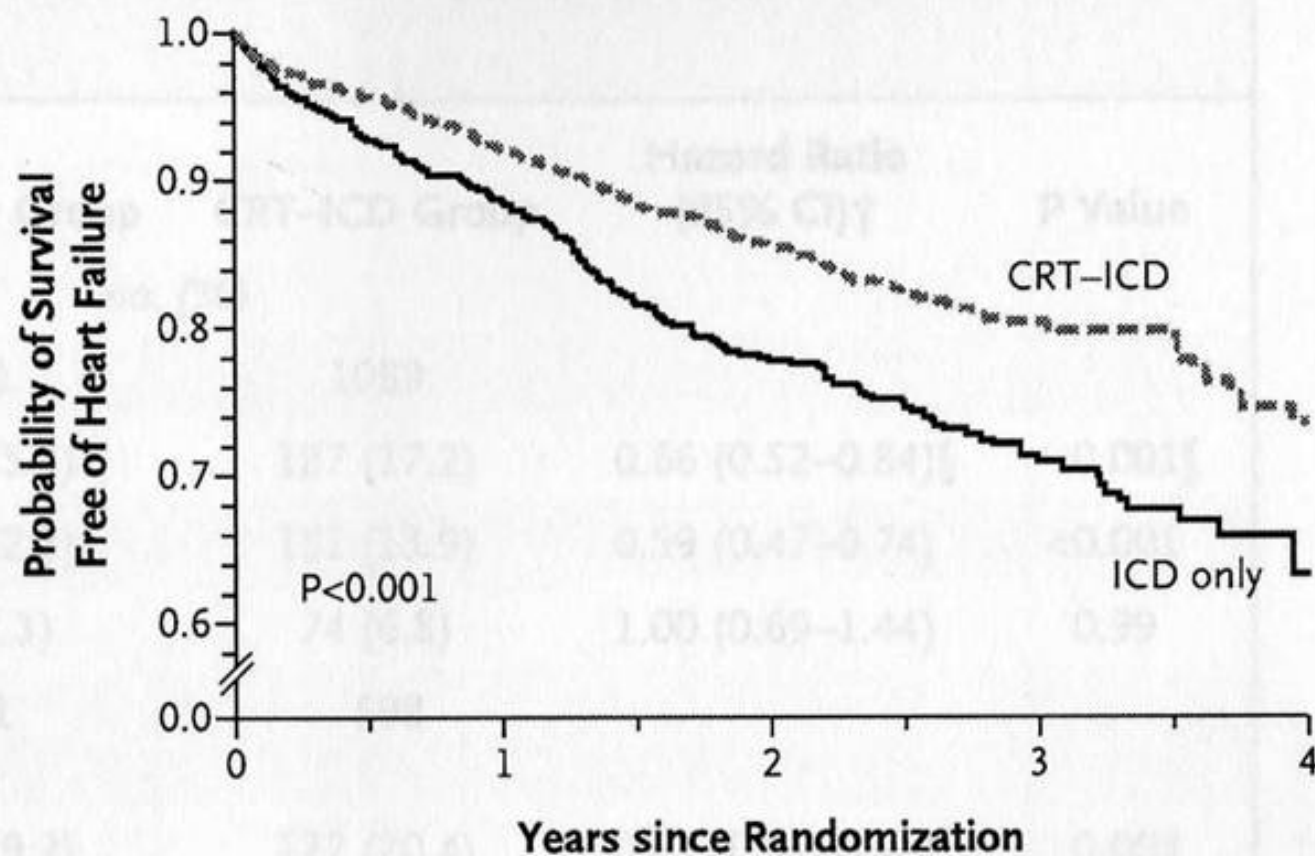
During a 4.5-year period, we enrolled and followed 1820 patients with ischemic or nonischemic cardiomyopathy, an ejection fraction of 30% or less, a QRS duration of 130 msec or more, and New York Heart Association class I or II symptoms. Patients were randomly assigned in a 3:2 ratio to receive CRT plus an implantable cardioverter-defibrillator (ICD) (1089 patients) or an ICD alone (731 patients). The primary end point was death from any cause or a nonfatal heart-failure event (whichever came first). Heart-failure events were diagnosed by physicians who were aware of the treatment assignments, but they were adjudicated by a committee that was unaware of assignments.

RESULTS

During an average follow-up of 2.4 years, the primary end point occurred in 187 of 1089 patients in the CRT-ICD group (17.2%) and 185 of 731 patients in the ICD-only group (25.3%) (hazard ratio in the CRT-ICD group, 0.66; 95% confidence interval [CI], 0.52 to 0.84; $P=0.001$). The benefit did not differ significantly between patients with ischemic cardiomyopathy and those with nonischemic cardiomyopathy. The superiority of CRT was driven by a 41% reduction in the risk of heart-failure events, a finding that was evident primarily in a prespecified subgroup of patients with a QRS duration of 150 msec or more. CRT was associated with a significant reduction in left ventricular volumes and improvement in the ejection fraction. There was no significant difference between the two groups in the overall risk of death, with a 3% annual mortality rate in each treatment group. Serious adverse events were infrequent in the two groups.

CONCLUSIONS

CRT combined with ICD decreased the risk of heart-failure events in relatively asymptomatic patients with a low ejection fraction and wide QRS complex. (ClinicalTrials.gov number, NCT00180271.)



No. at Risk (Probability of Survival)

ICD only	731	621 (0.89)	379 (0.78)	173 (0.71)	43 (0.63)
CRT-ICD	1089	985 (0.92)	651 (0.86)	279 (0.80)	58 (0.73)

Figure 2. Kaplan–Meier Estimates of the Probability of Survival Free of Heart Failure.

There was a significant difference in the estimate of survival free of heart failure between the group that received cardiac-resynchronization therapy plus an implantable cardioverter–defibrillator (CRT–ICD) and the group that received an ICD only (unadjusted $P < 0.001$ by the log-rank test).

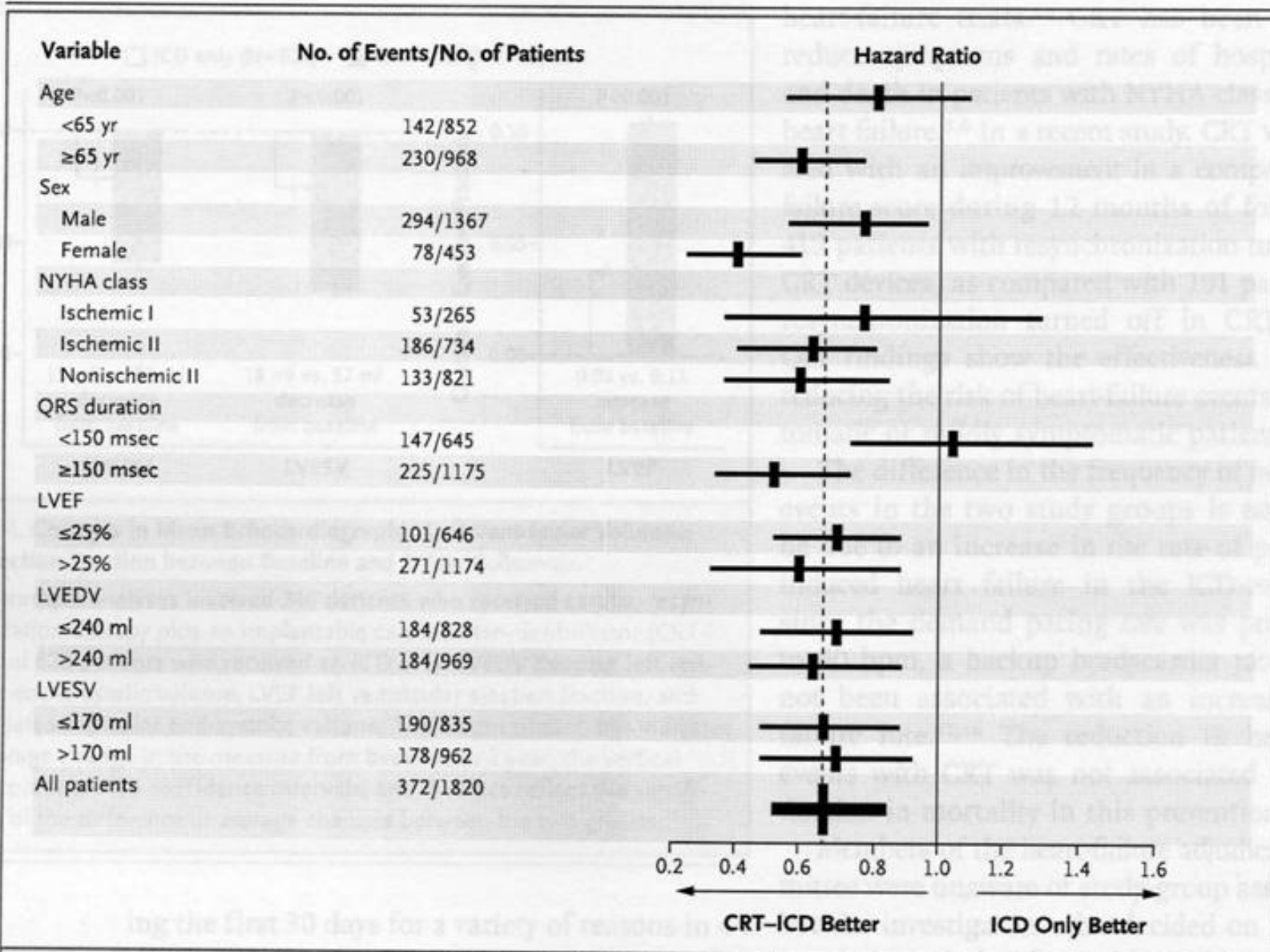


Figure 3. Risk of Death or Heart Failure, According to Selected Clinical Characteristics.

The hazard ratios for death or nonfatal heart failure (whichever came first) are shown for various subgroups among patients who received cardiac-resynchronization therapy plus an implantable cardioverter-defibrillator (CRT-ICD) and those who received an ICD only. The dashed vertical line represents the results for the entire study (hazard ratio in the CRT-ICD group, 0.66), and the horizontal lines indicate 95% confidence intervals. LVEDV denotes left ventricular end-diastolic volume, LVEF left ventricular ejection fraction, LVESV left ventricular end-systolic volume, and NYHA New York Heart Association. Two subgroup treatment interactions were identified, for sex ($P=0.01$) and QRS duration ($P=0.001$). All other interaction P values exceeded 0.10.

左室収縮能の低下した症例での左脚ブロックの頻度



1. Masoudi, et al. JACC 2003;41:217-23

2. Aaronson, et al. Circ 1997;95:2660-7

ACC/AHA/NASPEによる両室ペーシングの適応基準

1. 薬剤抵抗性の心不全
2. 左室駆出率(LVEF) < 35 %
3. 左室拡張終期径(LVDd) > 55 mm
4. 左脚ブロック、QRS > 130 ms
5. NYHA IIIまたはIV度

Pre

Post

QRS 198 ms

QRS 158 ms

I



II



III



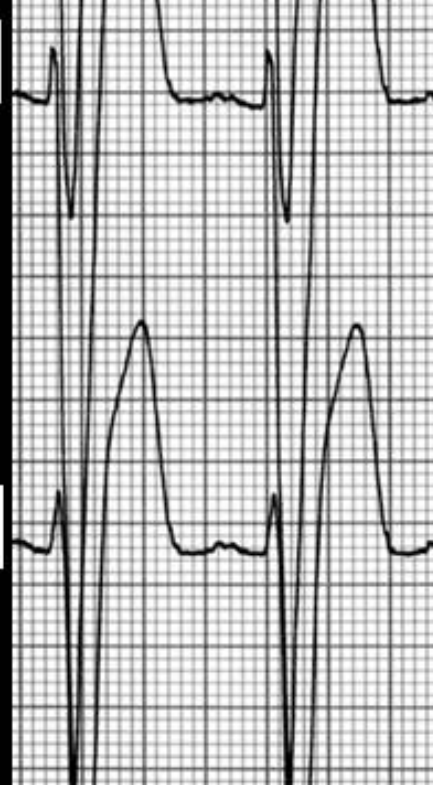
Pre

Post

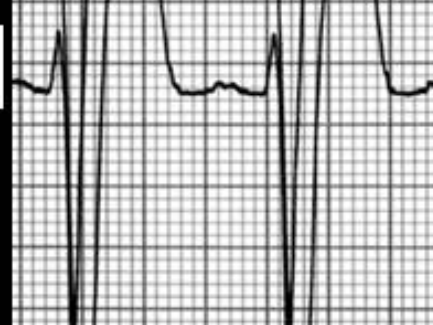
V1



V2

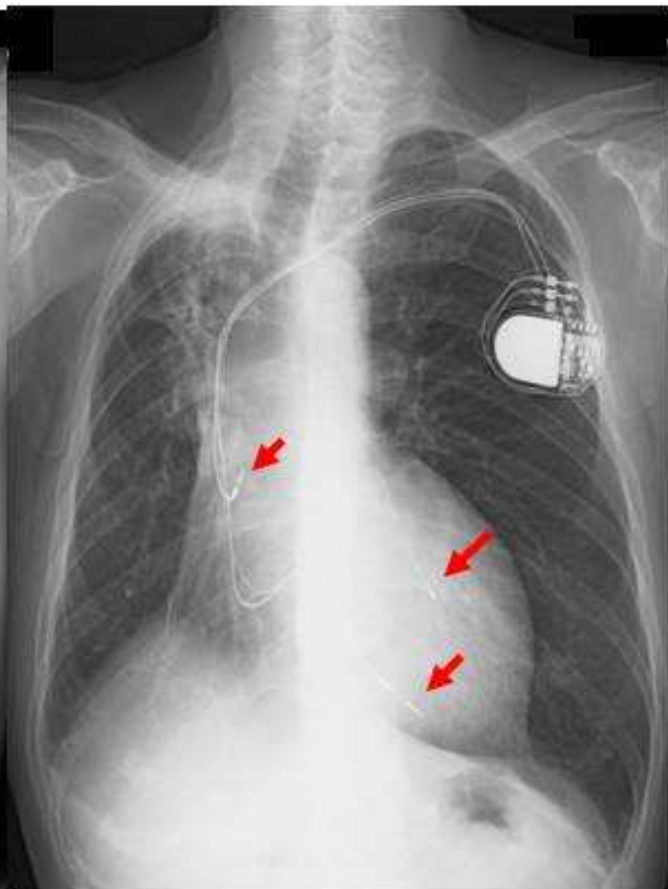


V3

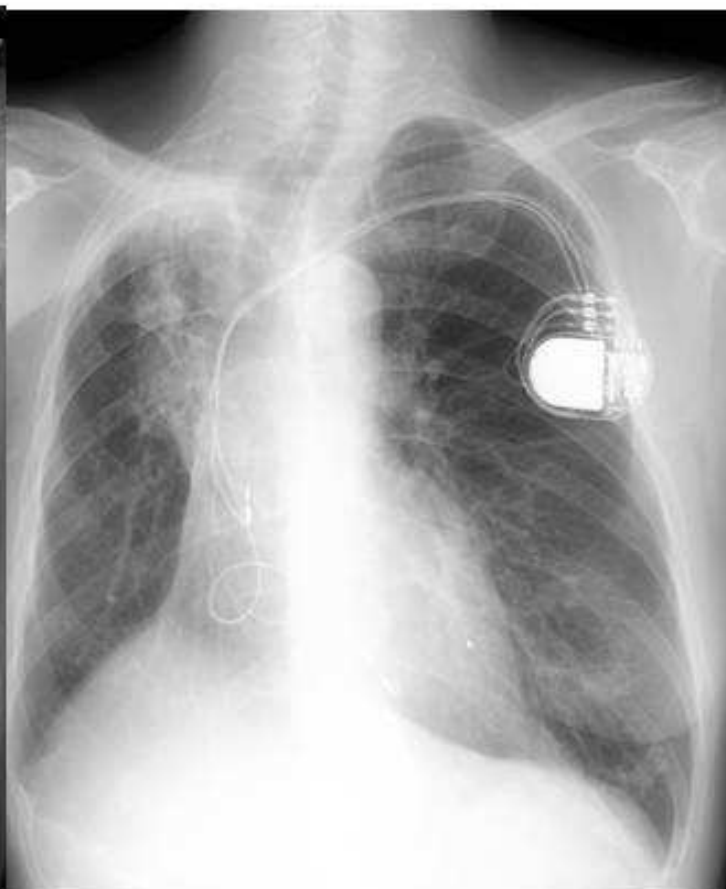




植え込み前
NYHA III



植え込み直後
2005/9

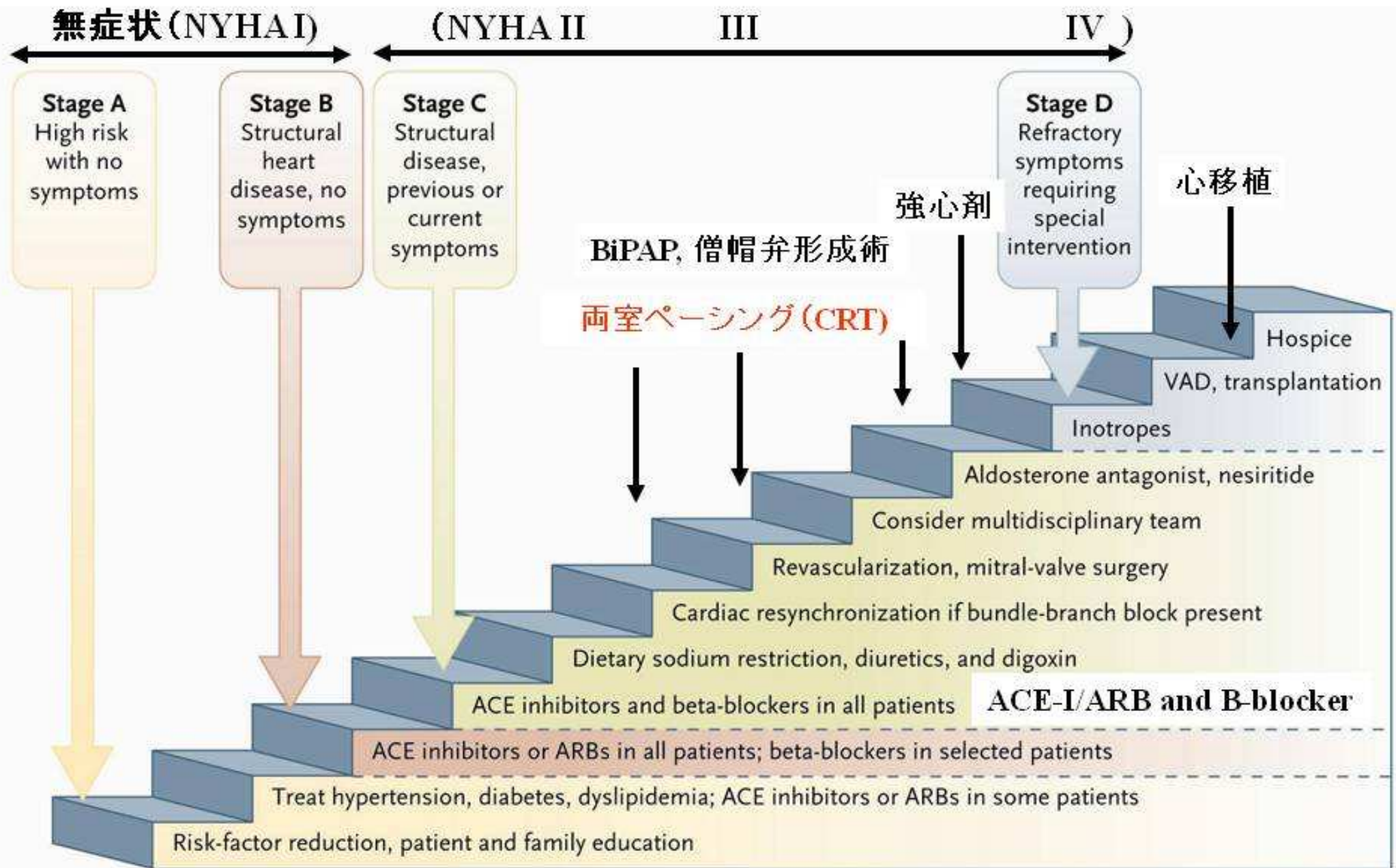


2011/6
NYHA I

ACC/AHA/NASPEによる両室ペーシング の適応基準

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4. 左脚ブロック、QRS > 130 ms
5. NYHA IIIまたはIV度

ACC/AHA ガイドライン: 心不全の段階的治療



当院の治療成績(2007/9-施設基準を満たす)

両室pacing機能付き植え込み型除細動器(ICD): CRT-D 14例

両室pacing機能付きpacemaker: CRT-P 7例

3例は通常のpacemakerに左室リードを追加

2例は高齢者で小柄体型で、2例は希望でCRT-Pとした

植え込み型除細動器(ICD) 36例

* 3例 左室リード挿入できず(左室リード挿入:88%)

まとめ

- 1: 治療抵抗性心不全症例に対して、両室pacingは有用な治療法である。
- 2: NYHA I-IIの軽症症例に対しては、予後改善効果は明らかではないが、入院を減少させる(MADIT-CRT study)
- 3: 当院ではNYHA III以上の治療抵抗性心不全症例が主な対象である。心室頻拍が出現した症例に対しての植え込み型除細動器(ICD)植え込み時には、積極的に両室pacing機能付ICD植え込みを行っている
- 4: 今後はLVEF < 30%症例での一次予防症例への適応拡大が臨床的問題点である