Insuficiência Cardíaca e a Utilização de Marcapassos, Ressincronizadores e Desfibriladores:

Evidências que Respaldam a Prática

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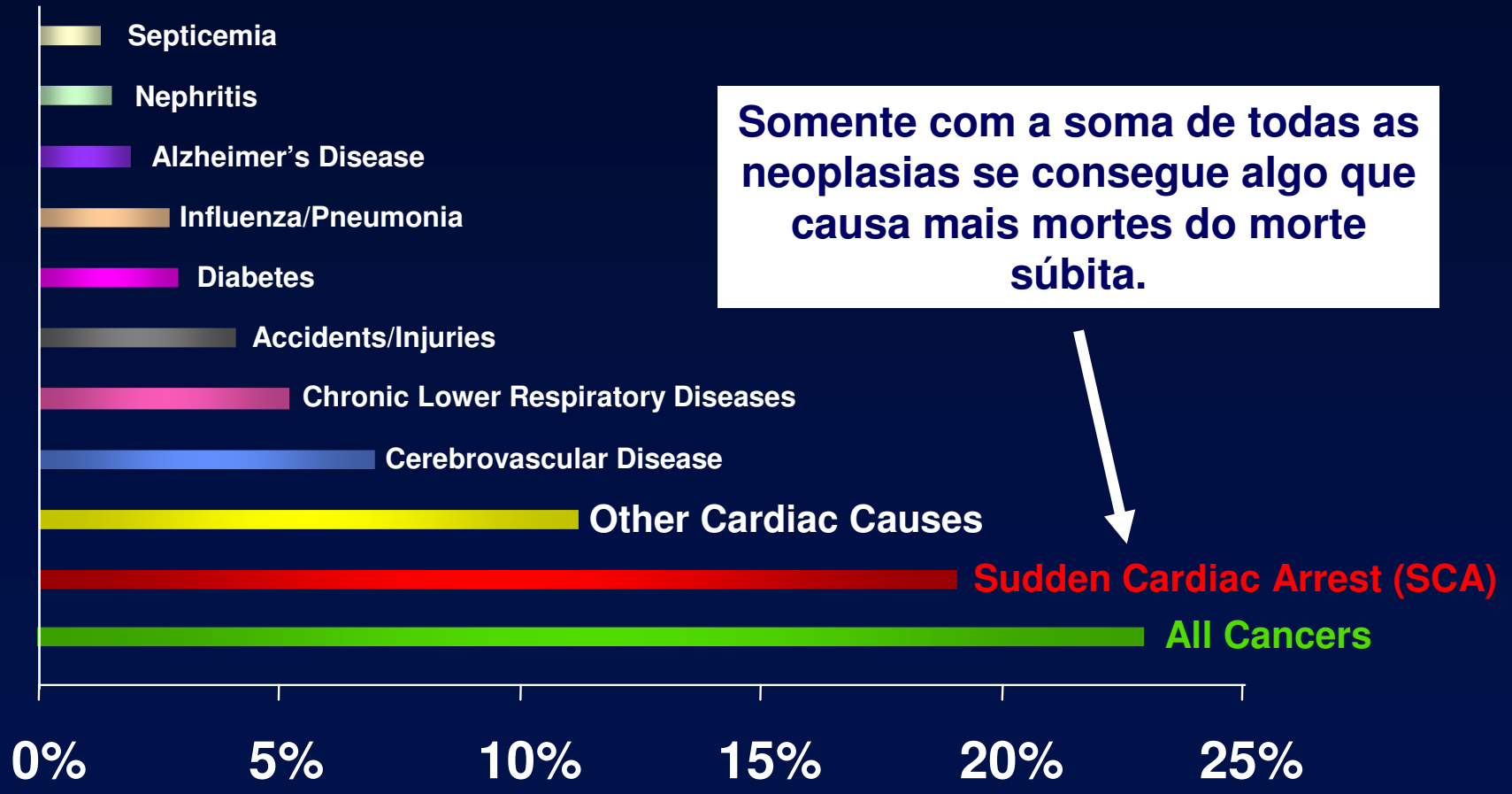
INC 30 Anos

O seu coração é o nosso compromisso

pró cardíaco

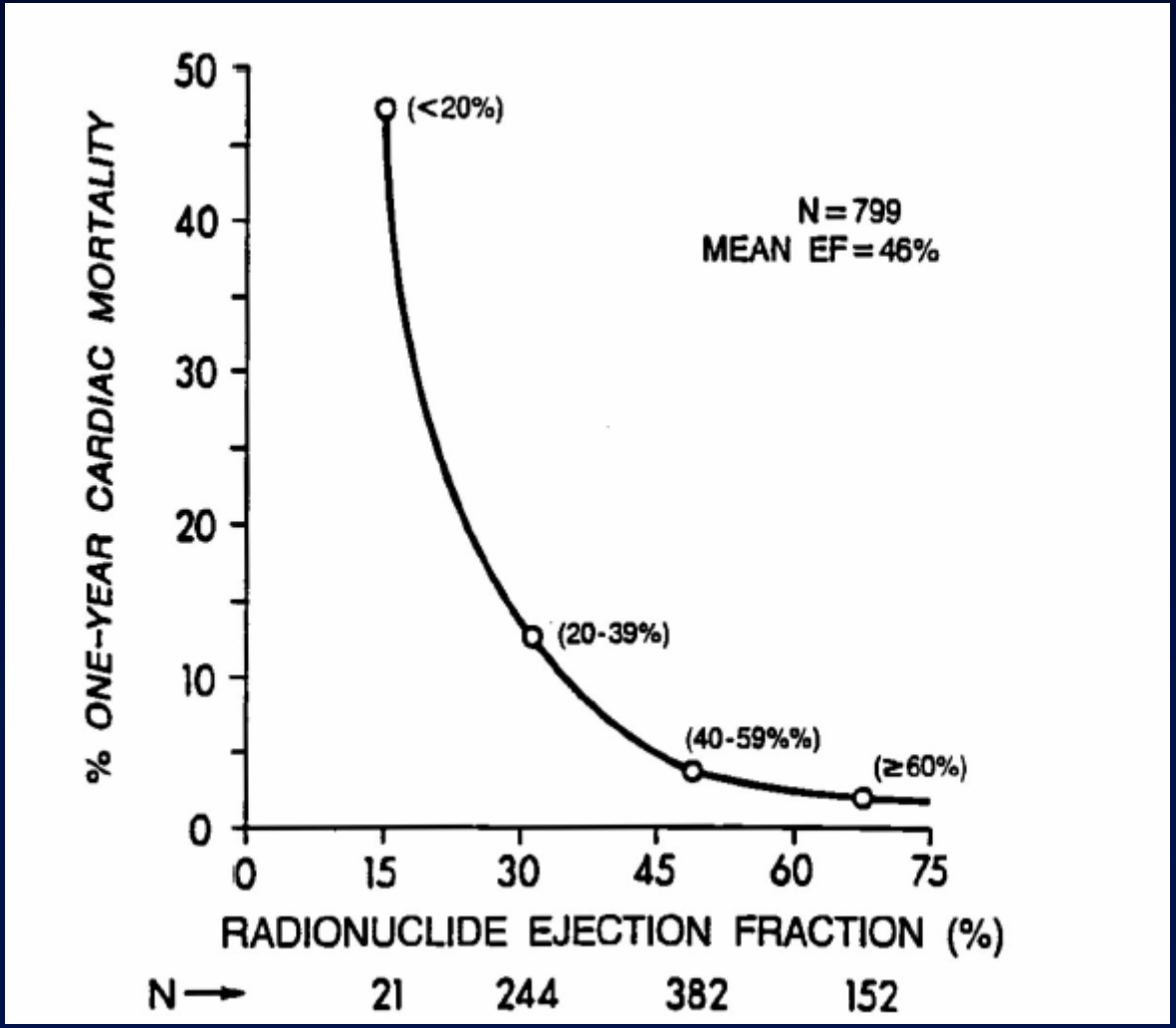
Maior Causa de Morte nos EUA



Somente com a soma de todas as neoplasias se consegue algo que causa mais mortes do morte súbita.

National Vital Statistics Report, Vol 49 (11), Oct. 12, 2001.
State-specific mortality from sudden cardiac death – United States 1999. *MMWR*. 2002;51:123-126.

IC - Importância da FE



Circulation 2005; 111: 2537-49

CDI - Evolução (1989-2004)

209 cc

113 cc

80 cc

80 cc

72 cc

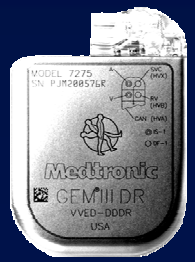
54 cc

62 cc

49 cc

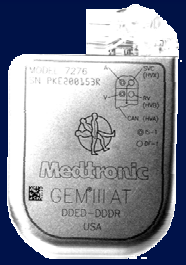
39.5 cc

39 cc



39.5 cc

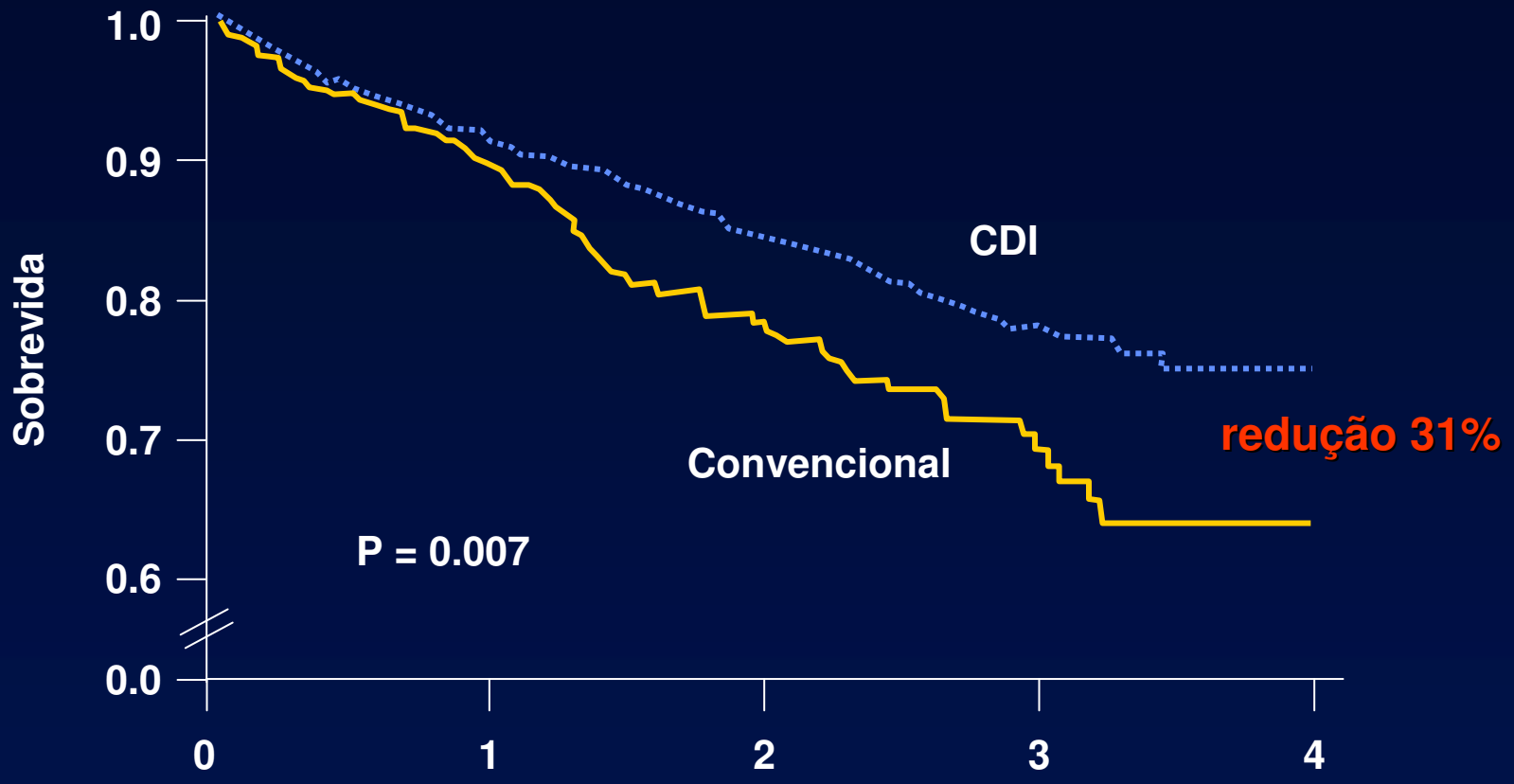
39 cc



39.5 cc

36 cc

MADIT II - Sobrevida



n - 1.232 pt

No. Sob risco					
CDI	742	502 (0.91)	274 (0.94)	110 (0.78)	9
Convencional	490	329 (0.90)	170 (0.78)	65 (0.69)	3

Moss AJ. *N Engl J Med*. 2002;346:877-83.

Sudden Cardiac Death
SCD-HeFT
Heart Failure
Trial

SCD-HeFT

CMD ± DAC e ICC

↓

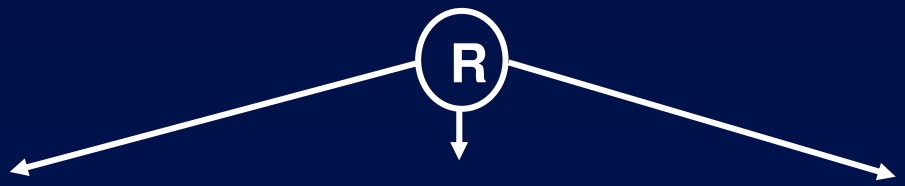
FE ≤ 35%

↓

NYHA Classe II ou III

↓

Teste 6 minutos, Holter



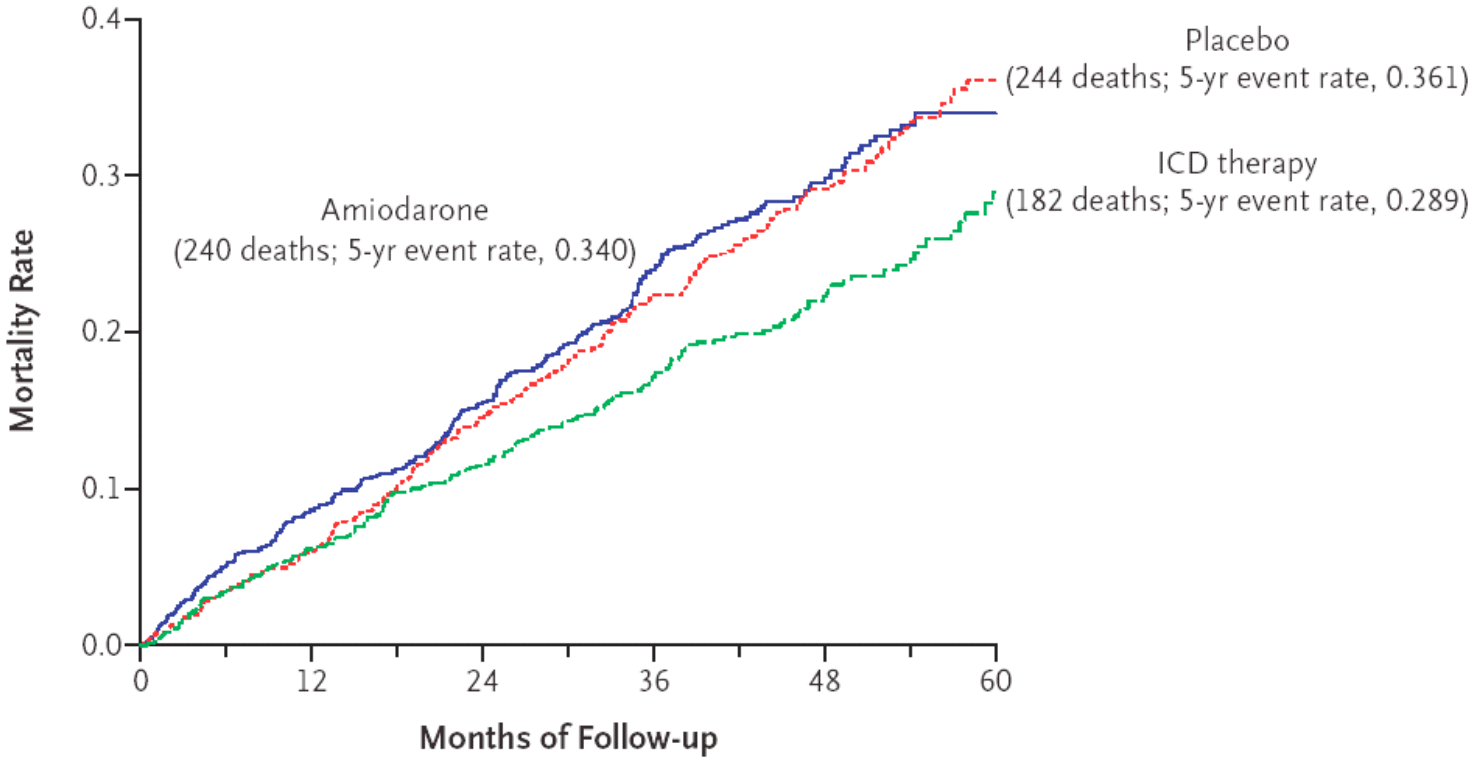
Placebo Amiodarona CDI

Bardy G et al.
NEJM 2005; 352:3

Sudden Cardiac Death
SCD-HeFT
Heart Failure Trial

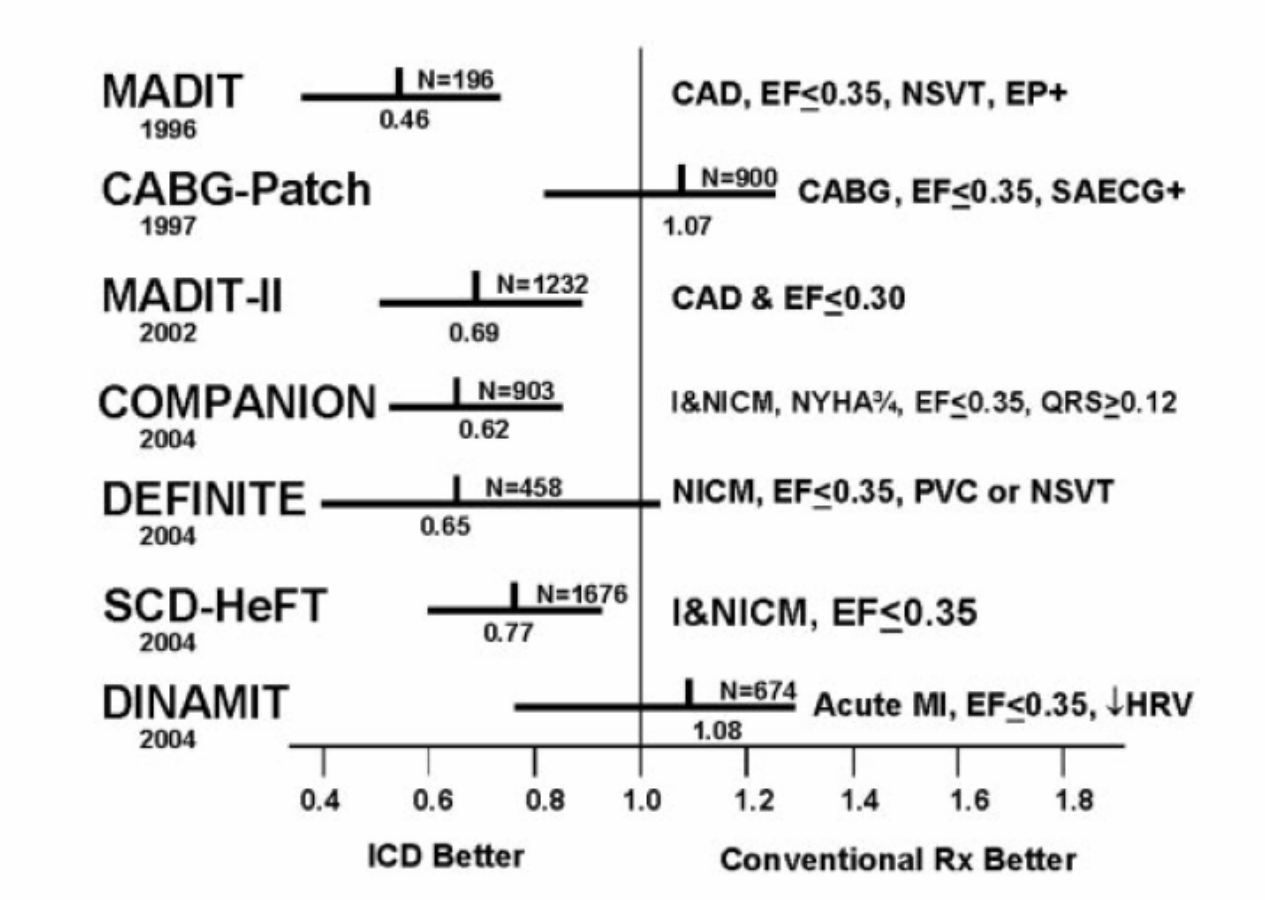
Mortalidade por Todas as Causas

	Hazard Ratio (97.5% CI)	P Value
Amiodarone vs. placebo	1.06 (0.86–1.30)	0.53
ICD therapy vs. placebo	0.77 (0.62–0.96)	0.007



No. at Risk						
Amiodarone	845	772	715	484	280	97
Placebo	847	797	724	505	304	89
ICD therapy	829	778	733	501	304	103

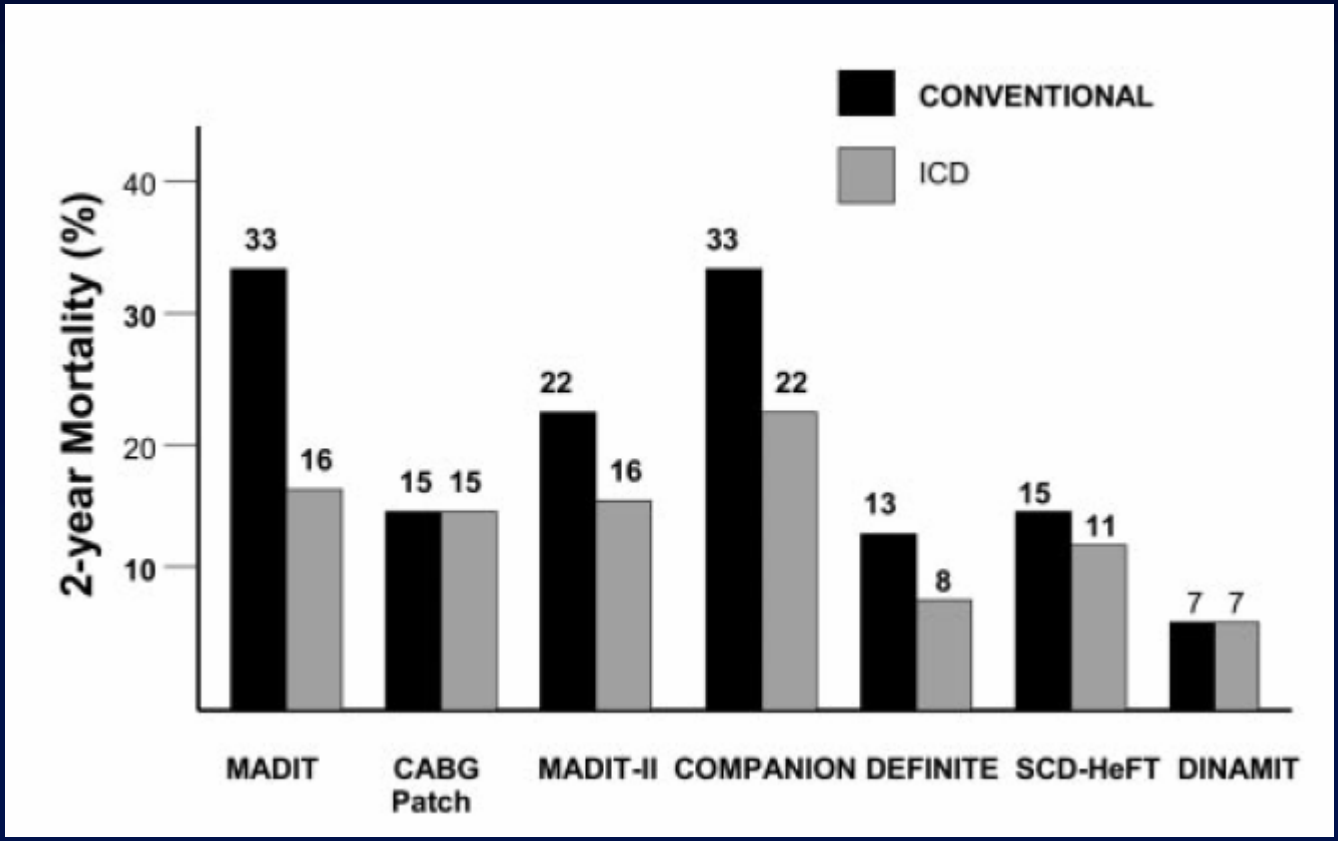
Redução de Risco - Profilaxia Primária



- Redução do risco relativo = 28%

Circulation 2005; 111: 2537-49

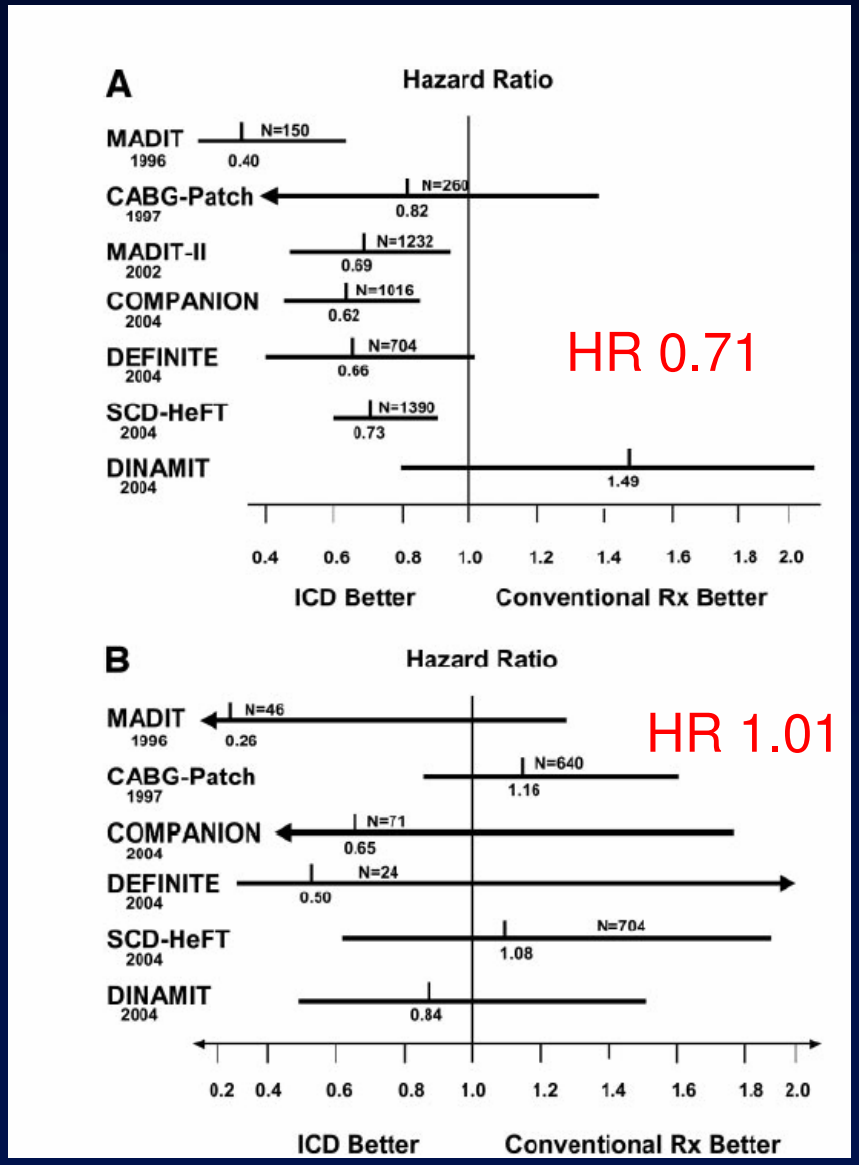
Redução de Risco - Profilaxia Primária



- Redução do risco absoluto = 3%

Circulation 2005; 111: 2537-49

Preditores de Benefício - Fração de Ejeção



HR 0.71

HR 1.01

FE < 30%

Este é o parâmetro ideal? Não!

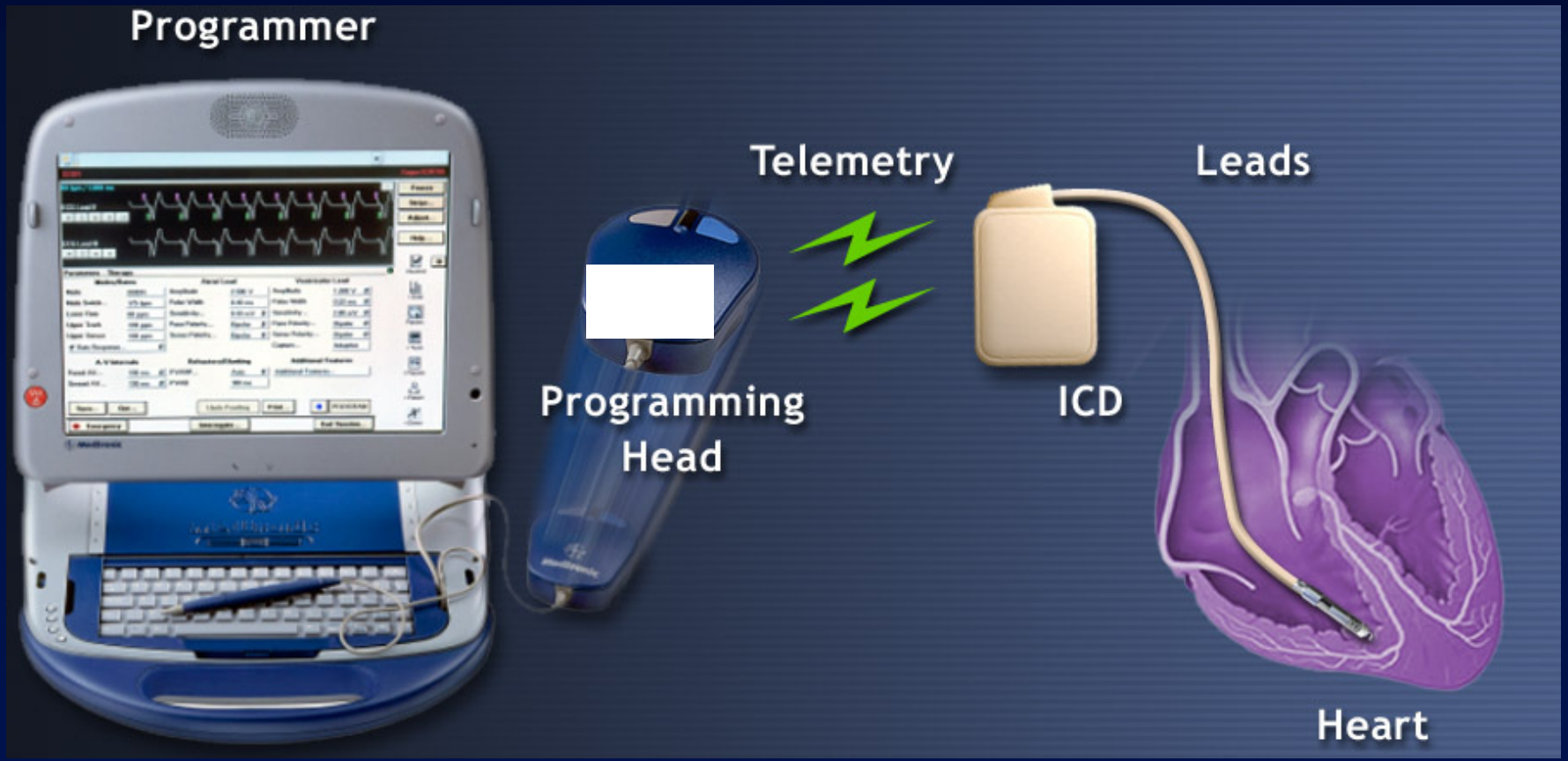
Existe algo melhor? Não!

É o que temos comprovado!

FE > 30%

Circulation 2005; 111: 2537-49

Programabilidade



O que dizem as diretrizes?

ACC/AHA/ESC Practice Guidelines

ACC/A
Ventri

atients With
en Cardiac

A Report o
the Europea
Develop

Developed

Task Force and
ing Committee to
hmias and the

urt Rhythm Society

XVI. HEART FAILURE

Recommendations

Class I

1. ICD therapy is recommended for secondary prevention of SCD in patients who survived VF or hemodynamically unstable VT, or VT with syncope and who have an LVEF less than or equal to 40%, who are receiving chronic optimal medical therapy and who have a reasonable expectation of survival with a good functional status for more than 1 y. *(Level of Evidence: A)*
2. ICD therapy is recommended for primary prevention to reduce total mortality by a reduction in SCD in patients with LV dysfunction due to prior MI who are at least 40 d post-MI, have an LVEF less than or equal to 30% to 40%, are NYHA functional class II or III, are receiving chronic optimal medical therapy, and who have reasonable expectation of survival with a good functional status for more than 1 y. *(Level of Evidence: A)* (See Section IA.)
3. ICD therapy is recommended for primary prevention to reduce total mortality by a reduction in SCD in patients with nonischemic heart disease who have an LVEF less than or equal to 30% to 35%, are NYHA functional class II or III receiving chronic optimal medical therapy, and who have reasonable expectation of survival with a good functional status for more than 1 y. *(Level of Evidence: B)* (See Section IA.)

MADIT II

SCD-HeFT

Definite

Circulation 2006; 114: 1088-1132

ACC/AH
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Revise the

Developed in

-Based Therapy
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American Heart
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for Implantation of
Devices)
ic Surgery and Society of

Class I

1. ICD therapy is indicated in patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes. *(Level of Evidence: A)*[4,133–138]
2. ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. *(Level of Evidence: B)*[4,133–138]
3. ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study. *(Level of Evidence: B)*[4,136]
4. ICD therapy is indicated in patients with LVEF less than 35% due to prior myocardial infarction who are at least 40 days post–myocardial infarction and are in NYHA functional Class II or III. *(Level of Evidence: A)*[4,139]
5. ICD therapy is indicated in patients with nonischemic dilated cardiomyopathy who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. *(Level of Evidence: B)*[4,139–141]
6. ICD therapy is indicated in patients with LV dysfunction due to prior myocardial infarction who are at least 40 days post–myocardial infarction, have an LVEF less than 30%, and are in NYHA functional Class I. *(Level of Evidence: A)*[4,132]
7. ICD therapy is indicated in patients with nonsustained VT due to prior myocardial infarction, LVEF less than 40%, and inducible ventricular fibrillation or sustained VT at electrophysiological study. *(Level of Evidence: B)*[4,131,142]

Circulation 2008; 117: 2820-40

Diretrizes Brasileiras de Dispositivos Cardíacos Eletrônicos Im

SBC-AMB
SOCIEDADE BRASILEIRA DE ARRITMIAS
DEPARTAMENTO DE ESTIMULAÇÃO CARDÍA

Recomendações para Implante de CDI na Prevenção Primária de MSC em pacientes com cardiopatia estrutural

Classe I

Sobreviventes de IAM há pelo menos 40 dias ou com cardiopatia isquêmica crônica, sob tratamento farmacológico ótimo, sem isquemia miocárdica passível de tratamento por revascularização cirúrgica ou percutânea e expectativa de vida de pelo menos 1 ano com:

1. FEVE ≤ 35% e CF II-III, ou FEVE ≤ 30% e CF I, II ou III *(NE A);* Madit II

2. FEVE ≤40%, TVNS espontânea e TVS indutível ao EEF *(NE B).* Madit

Classe IIa

1. Pacientes com cardiomiopatia dilatada não isquêmica, CF II-III, com FEVE ≤ 35% e expectativa de vida de pelo menos 1 ano *(NE A);* SCD-HeFT

2. Pacientes com cardiopatia isquêmica ou não-isquêmica, CF III-IV, FEVE ≤ 35%, QRS ≥ 120ms, para os quais tenha sido indicada TRC e expectativa de vida de pelo menos 1 ano *(NE B);*

Classe III

1. Pacientes com cardiopatia passível de correção cirúrgica ou percutânea *(NE B);*

2. Pacientes com cardiopatia isquêmica e FEVE ≥ 35% *(NE B).*

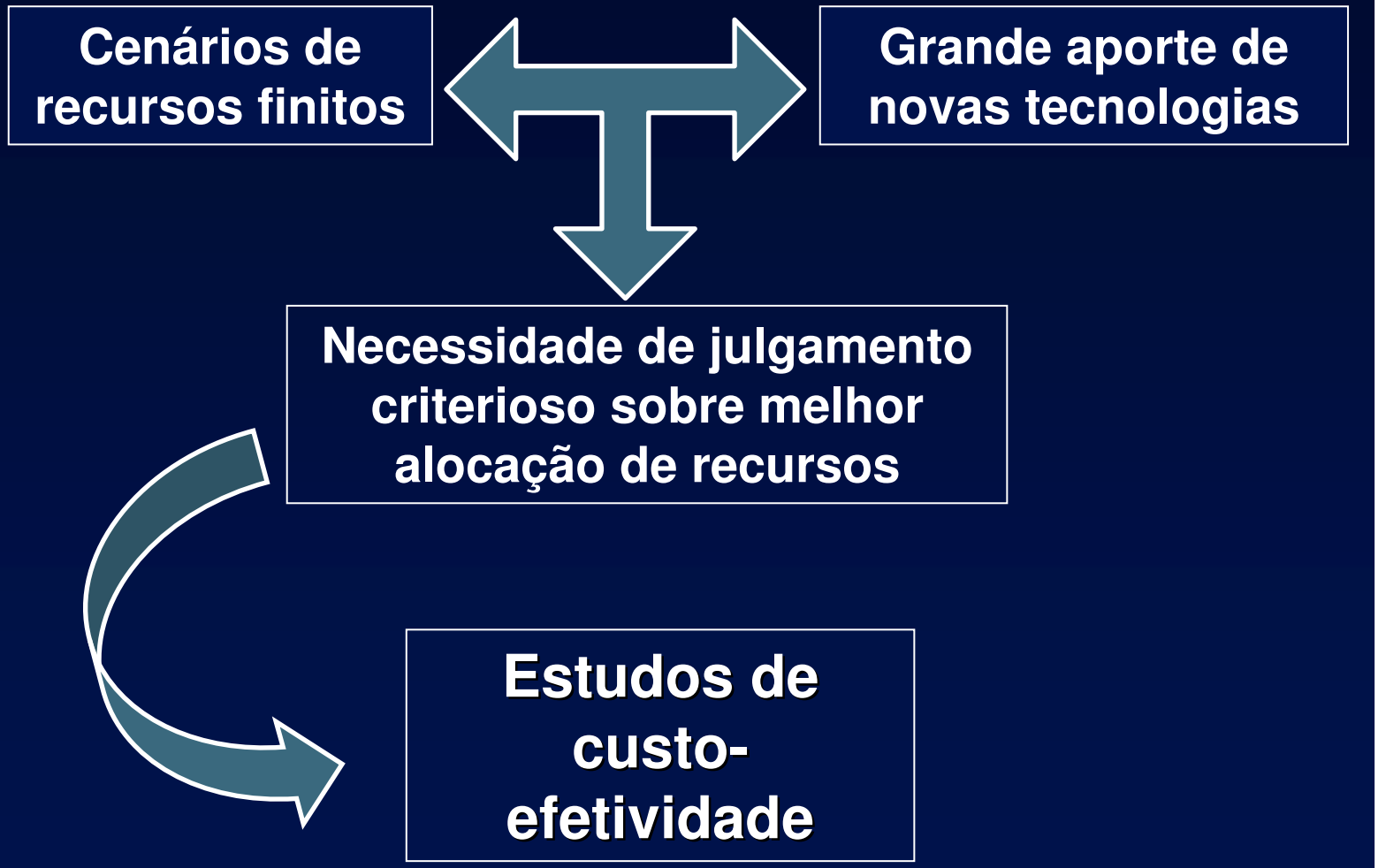
Arq Bras Cardiol 2007; 89: e210-e238

Mito

CDIs são muito caros se usados em todos os pacientes com indicação

Não deixe de ser curioso ...

Estudos de Custo-Efetividade



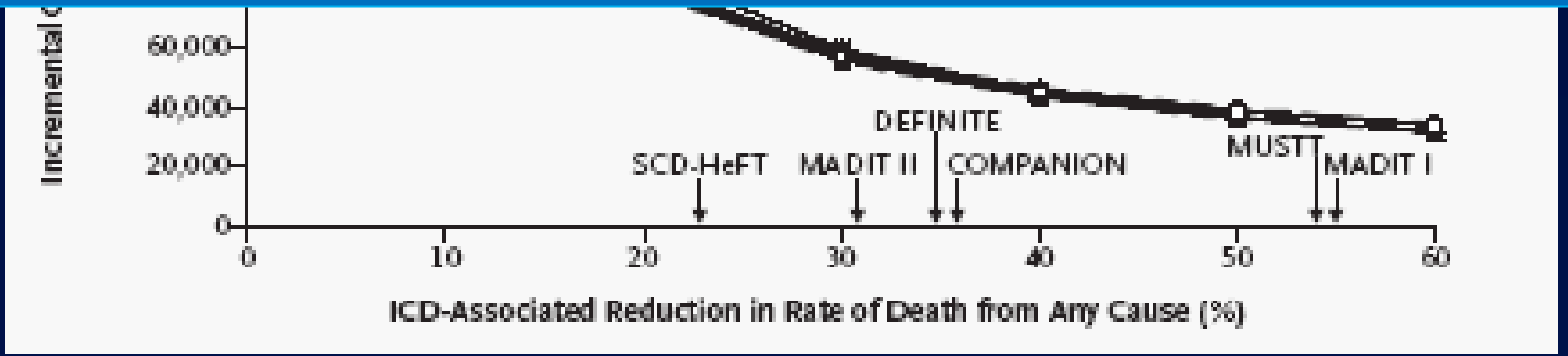
Qual a Custo-efetividade?

CDI reduz mortalidade

Acréscimo de 2,12 a 6,21 anos

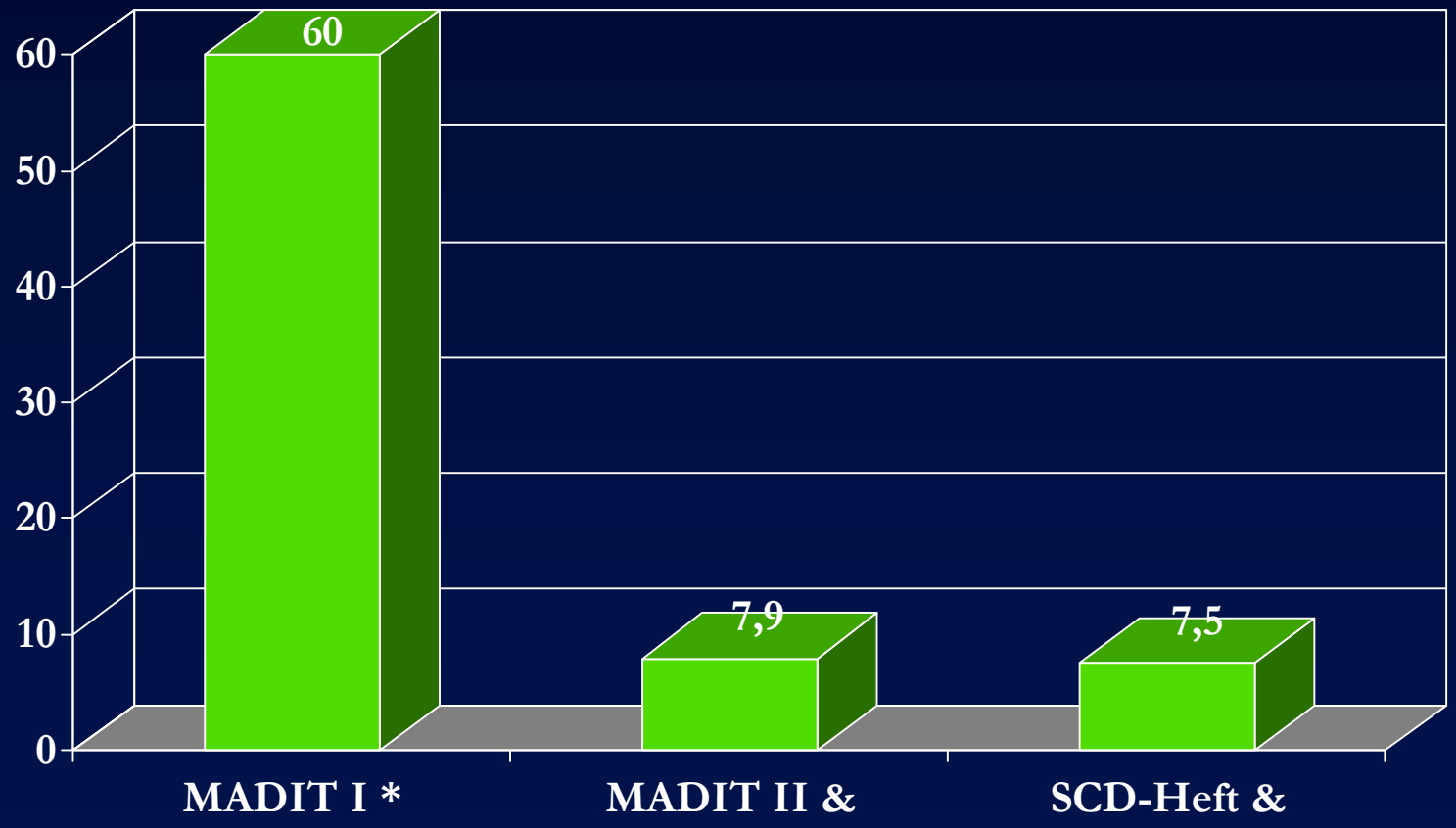
Custo-efetividade aceitável

<$51.000 por ano de vida adicional



Sanders G et al. N Eng J Med 2005; 353: 1471

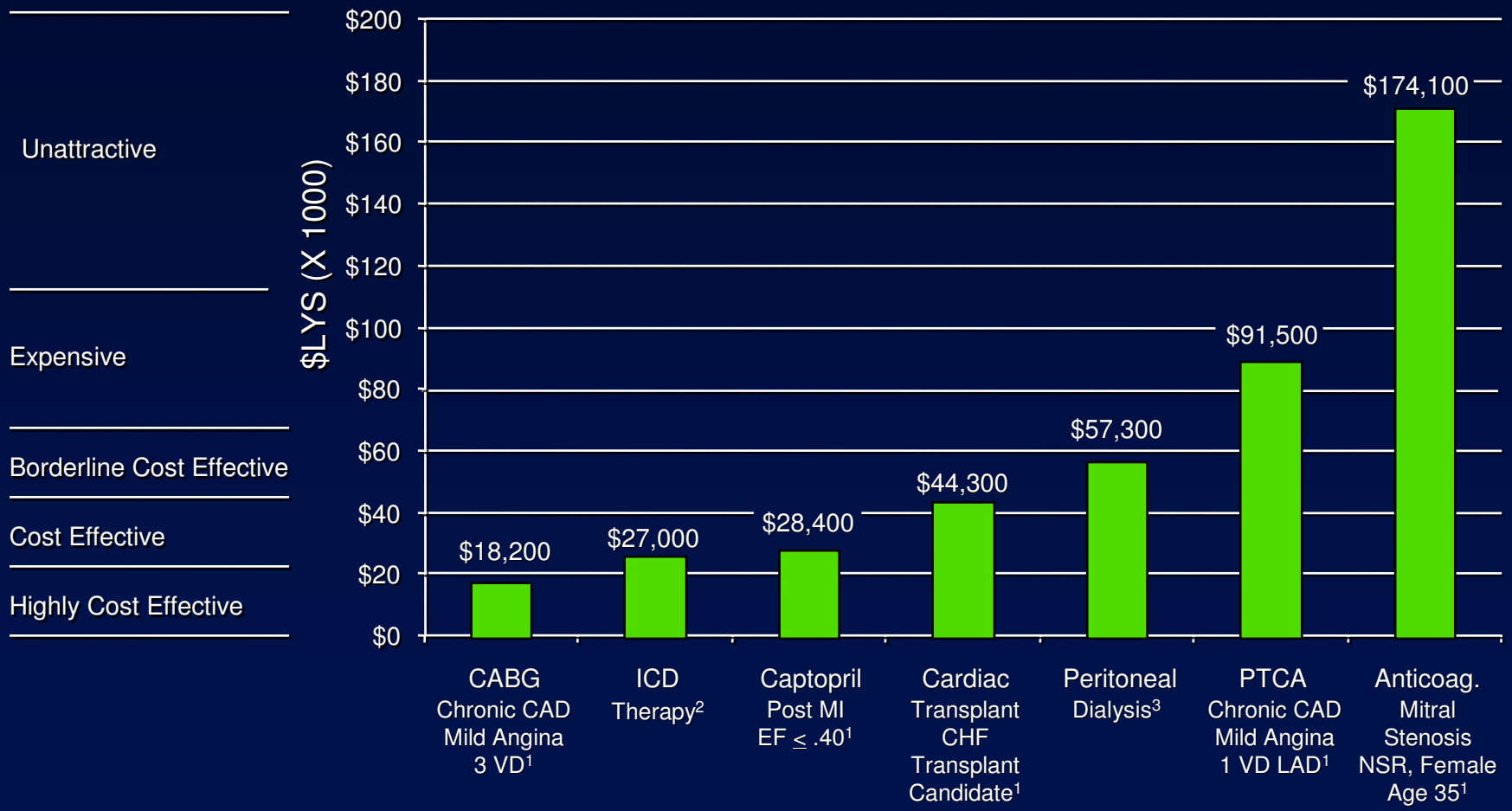
Na Prevenção Primária, o CDI é Usado?



*: em 2 anos
&: por ano

Epstein A et at. Circulation 2007;115

Custo Efetividade - CDI ($LYS)*



*Versus Conventional Therapy

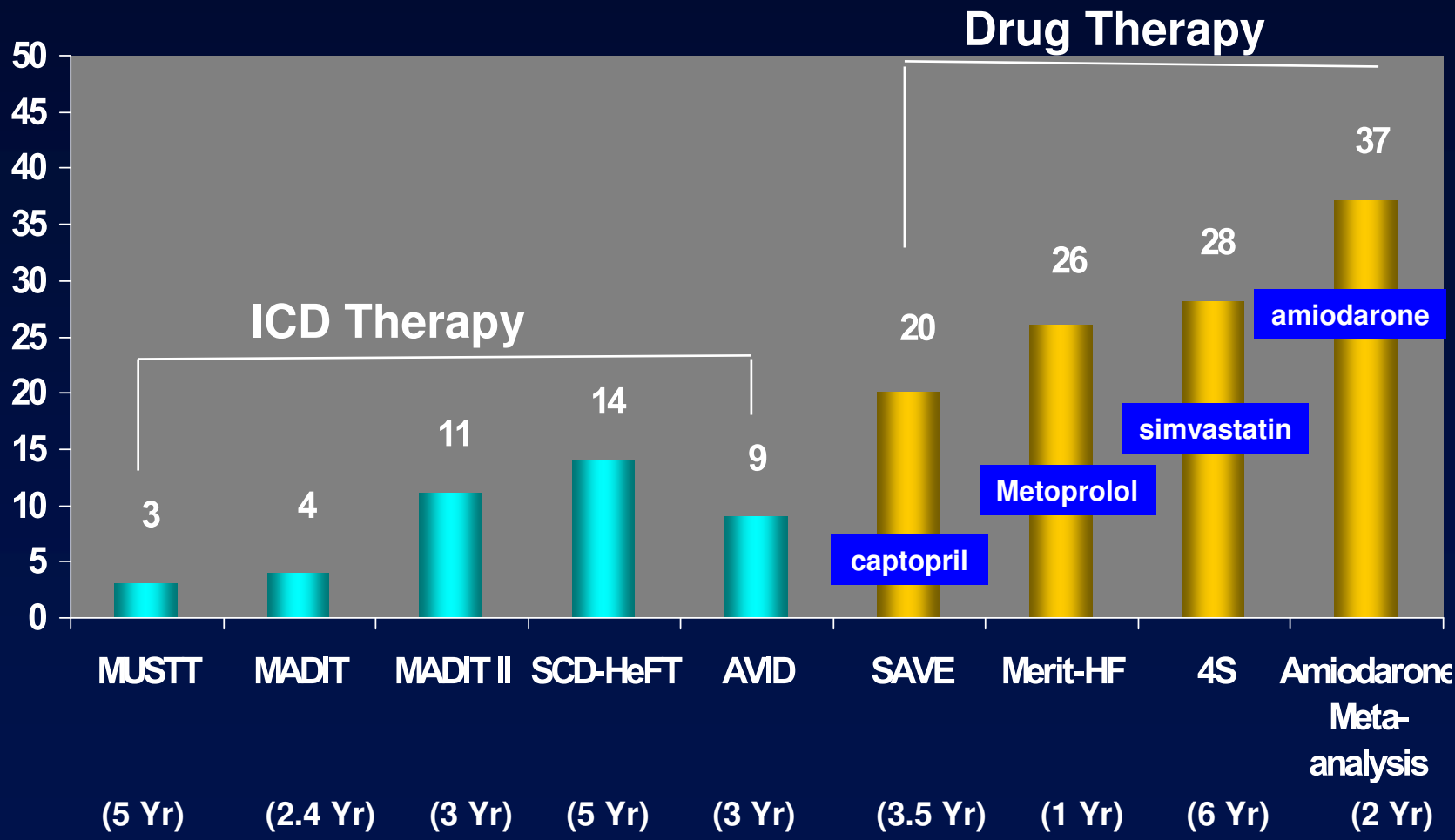
[1] Kupersmith. Progress in Cardiovascular Disease. 1995. [2] Owens. Annals of Internal Medicine. 1997. [3] Kupperman. Circulation. 1990

Análise da Custo-Efetividade - CDIs

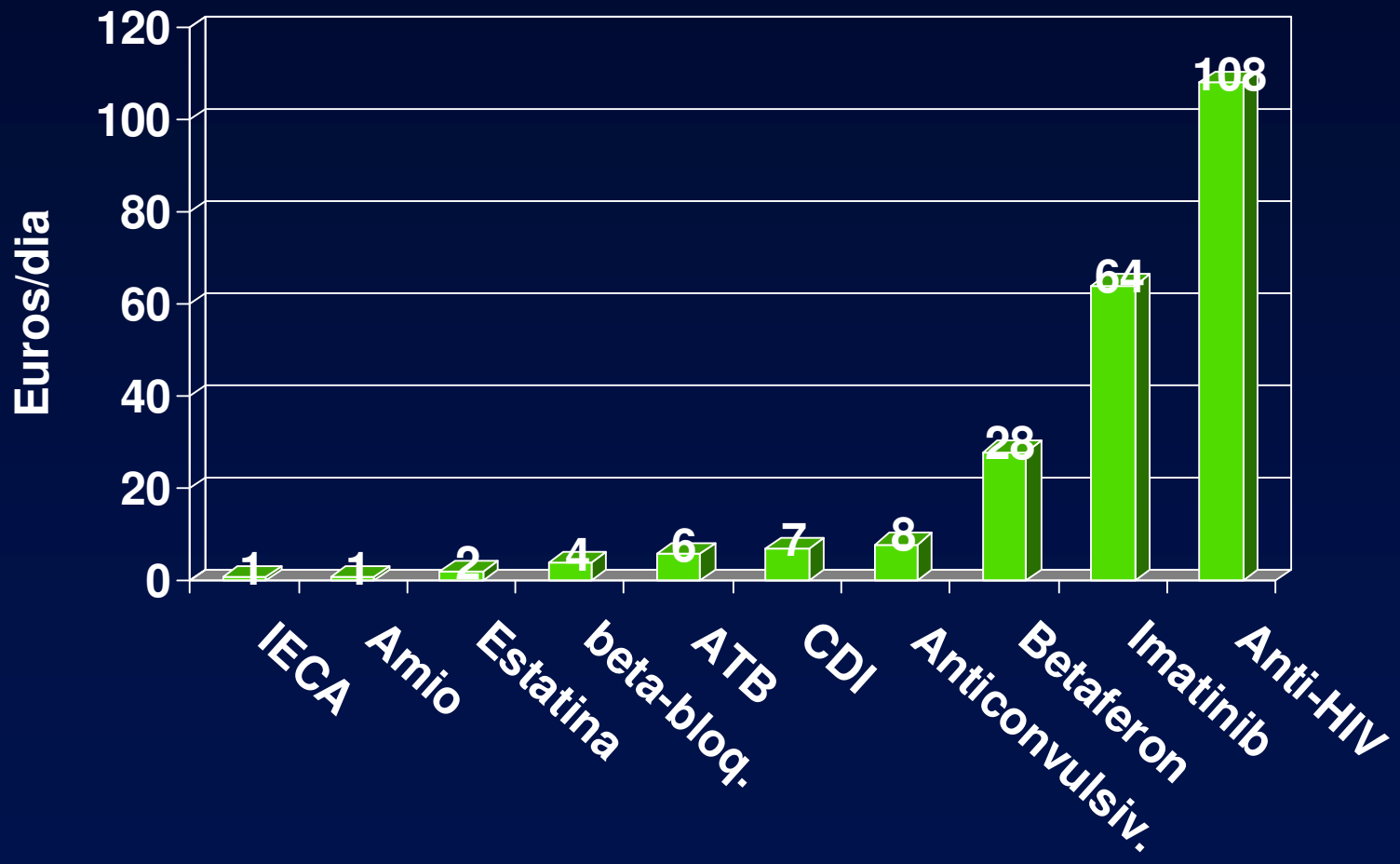
[1] Feldman AM. www.theheart.org. ACC News. March 16, 2005.
[2] Mark DB. www.theheart.org. AHA News. November 11, 2004.
[3] Ak-Khatib S. *Ann Intern Med.* 2005;142:593-600.
[4] Larsen G. *Circulation.* 2002;105:2049-2057.

NNT - número de implantes por vida salva

$NNT_{x\ years}$ = 100 / (% Mortality in Control Group – % Mortality in Treatment Group)



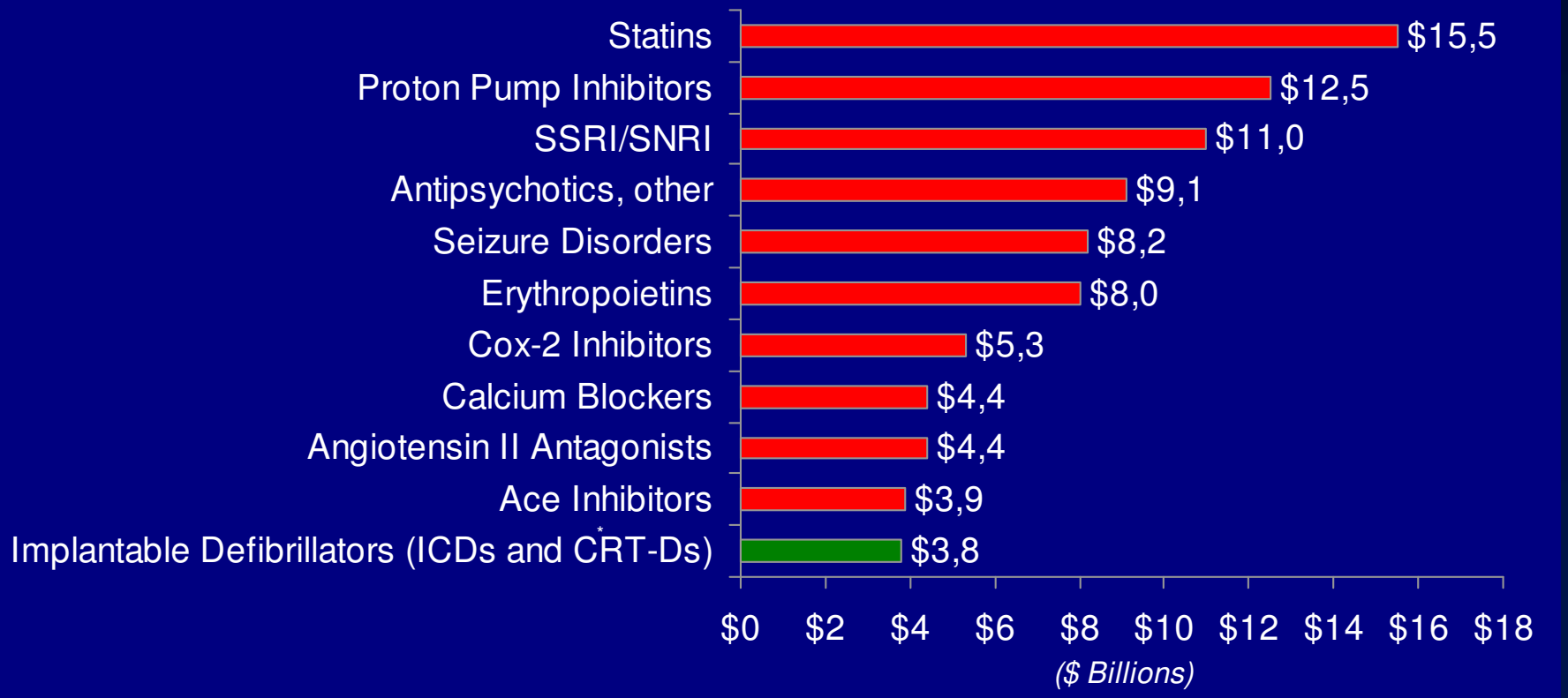
Custo é Muito Alto?



Camm J et al. Eur Heart J 2007; 28: 392

Mais Gastos com Remédios

Total United States Sales, 2004



* Implantable defibrillator sales estimates include initial implants and replacements

[1] IMS Health, IMS National Sales PerspectivesTM, 2005. Leading 20 Therapeutic Classes by U.S. Sales, 2004. http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891394,00.html. Accessed March 7, 2005.

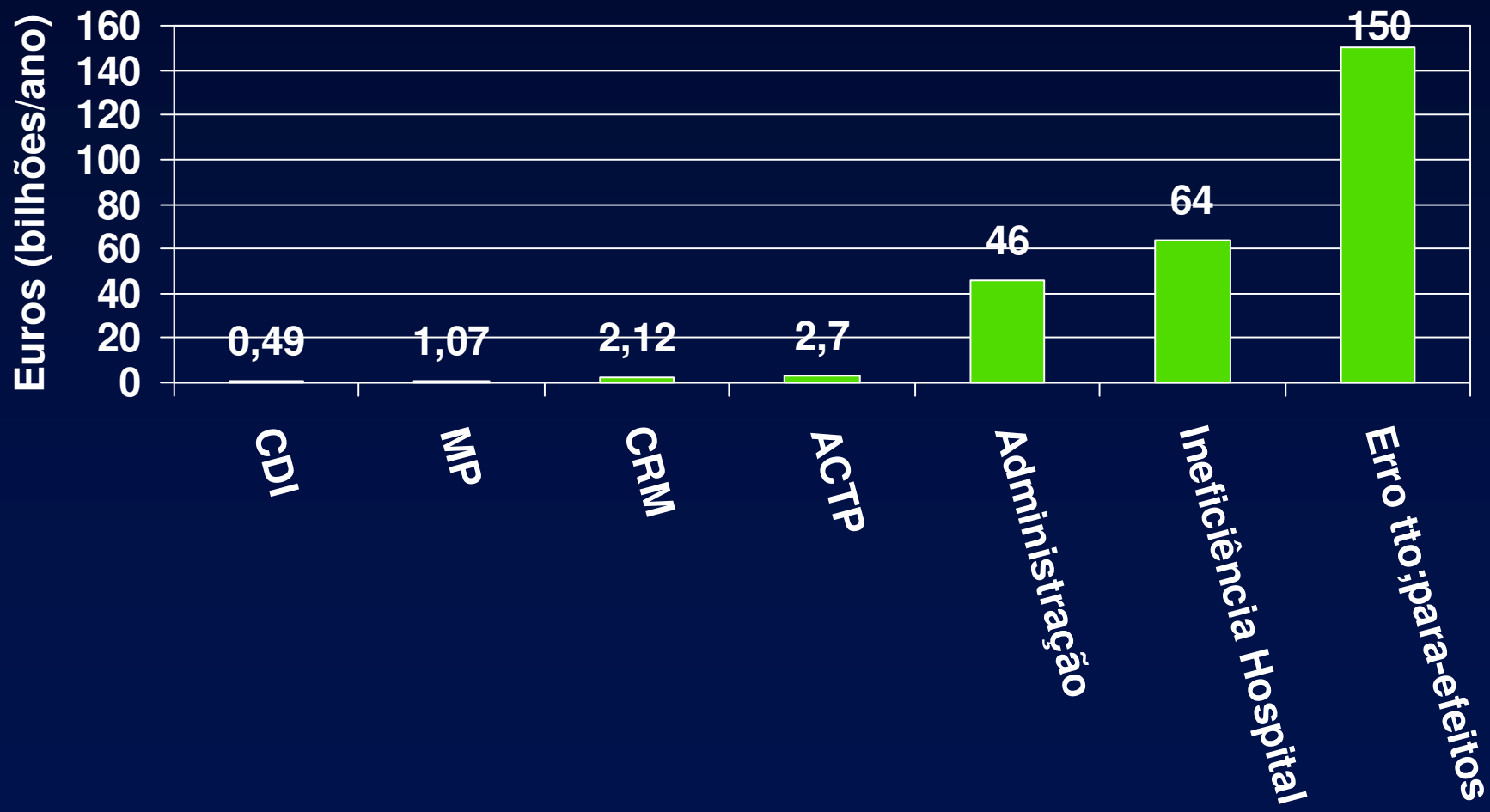
[2] JP Morgan Annual Market Model for Implantable Cardioverter Defibrillators. The MedTech Monitor. JP Morgan; New York: January 6, 2004.

Gastos da Sociedade em Outras Intervenções que Salvam Vidas

Intervention	Cost/Life-Year Saved in 1993
Flashing lights at railroad crossings	$42,000
Flammability standard for upholstered furniture	$68,000
Airbags (vs. manual lap belts) in cars	$120,000
Annual mammography for women age 40-49	$190,000
Smoke detectors in homes	$210,000
Front disk (vs. drum) brakes in cars	$240,000
Strengthen buildings in earthquake-prone areas	$18,000,000
Ground fault circuit interrupters	$1,200,000

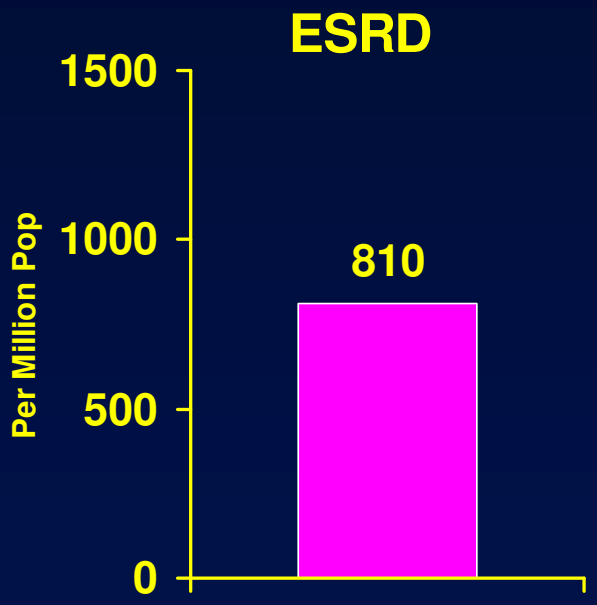
[1]Tengs TO, et al. Five-Hundred Life-Saving Interventions and Their Cost-Effectivenss. *Risk Analysis*, Vol. 15, No. 3, 1995.

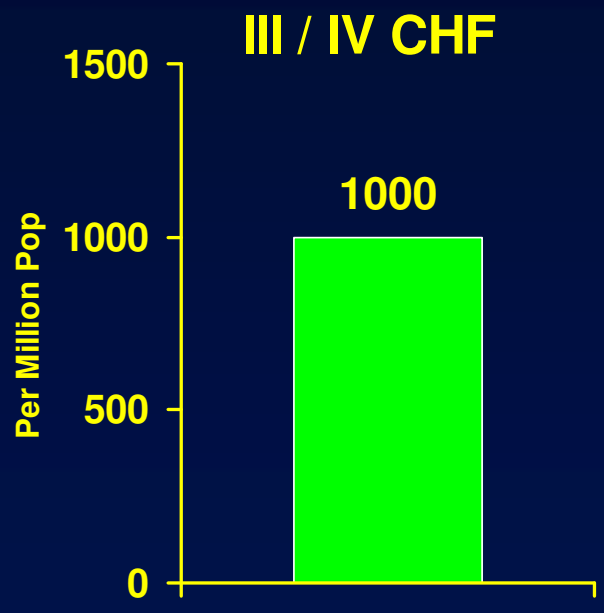
O Sistema de Saúde não Suporta?



Camm J et al. Eur Heart J 2007; 28: 392

Prevalence

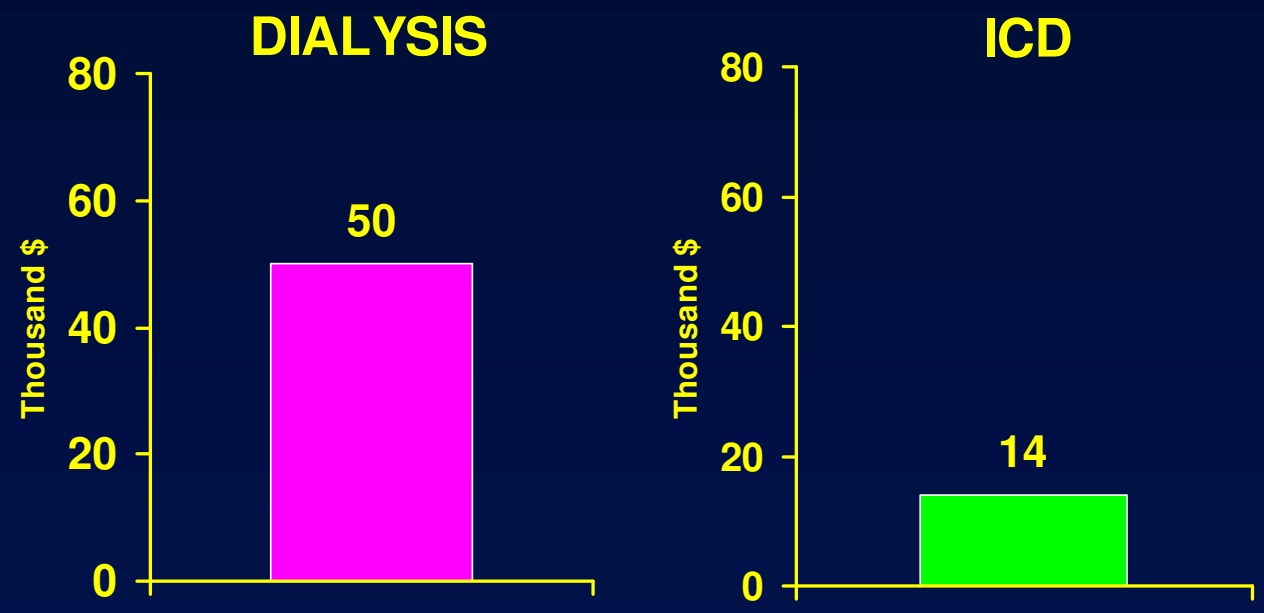




Ratio

1 : 1.2

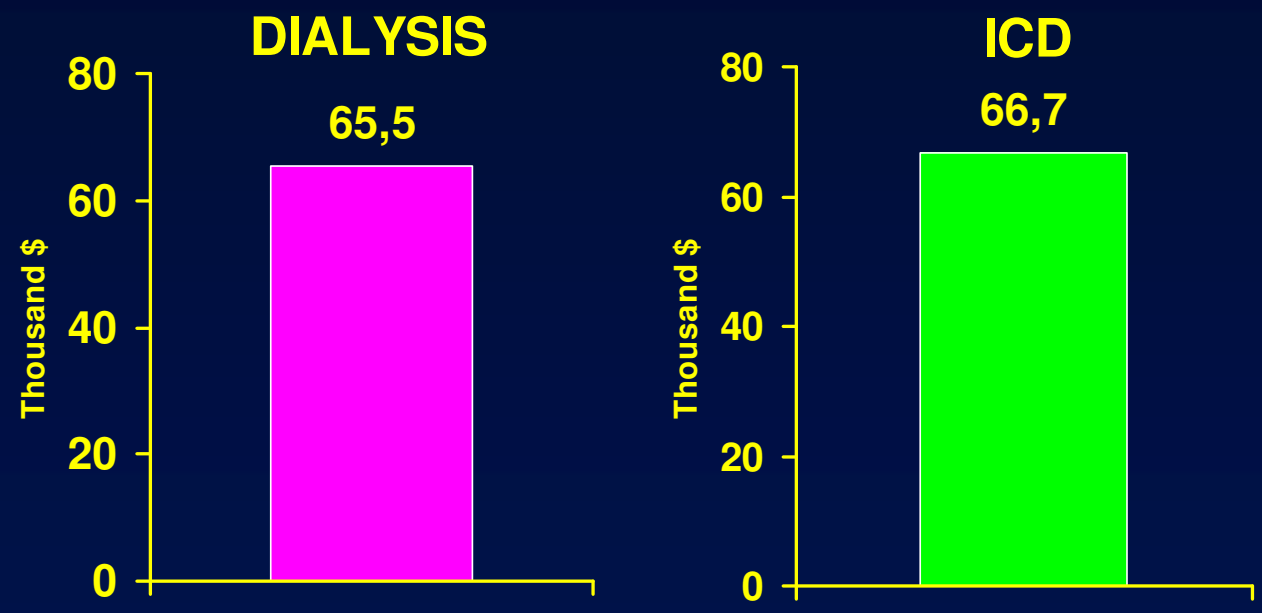
Annual Cost of Therapy



Ratio

3.6 : 1

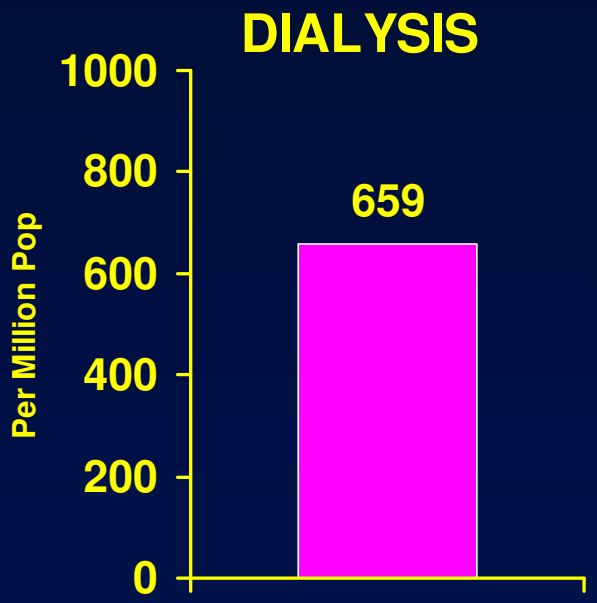
Cost Per Year of Life Saved

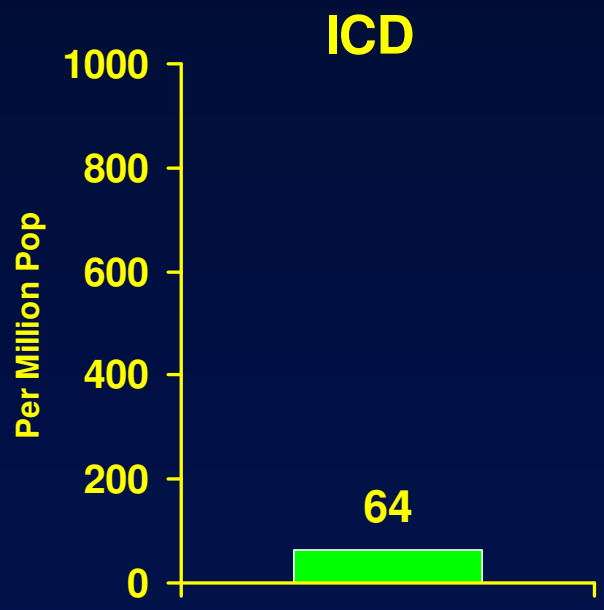


Ratio

1 : 1

Treatment Usage

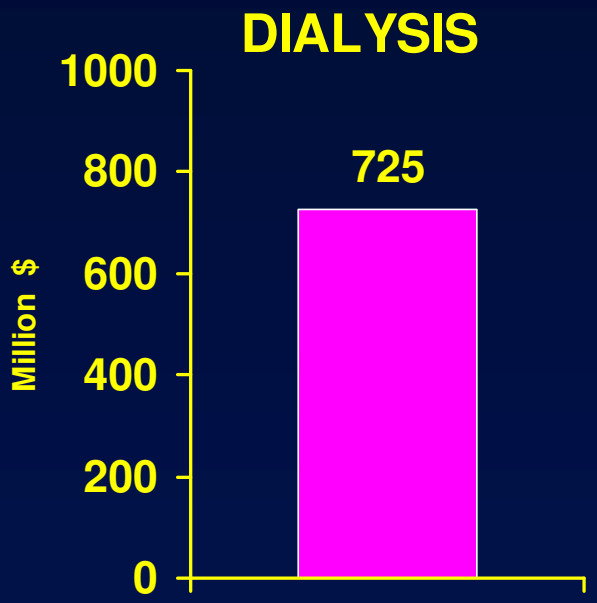


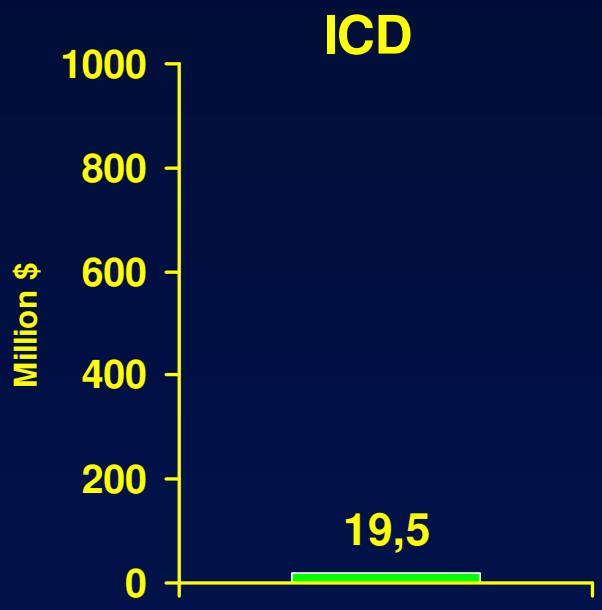


Ratio

10 : 1

Usage x Annualized Therapy Cost = Total Spending



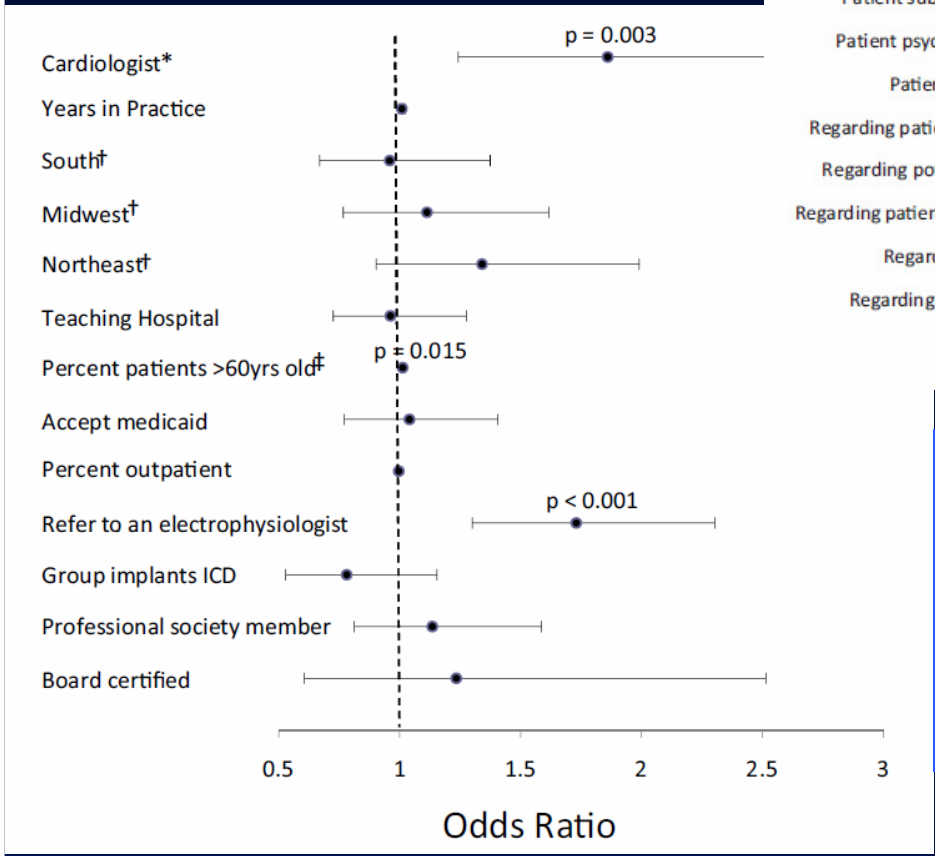


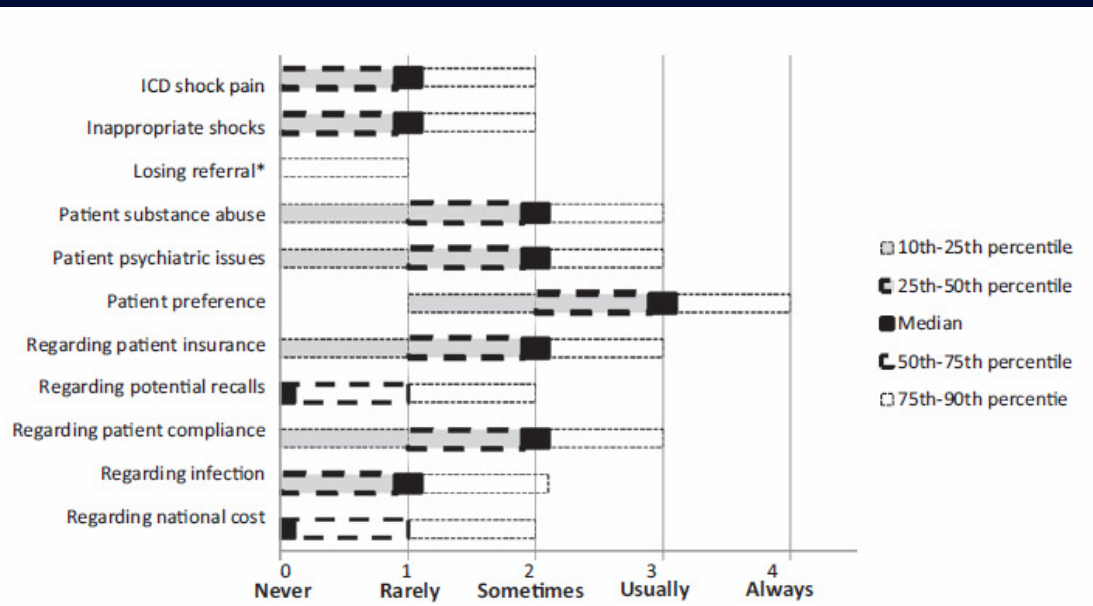
Ratio

37 : 1

Referring physicians' discordance with the primary prevention implantable cardioverter-defibrillator guidelines: A national survey

3.000 médicos - EUA





28% - não indica CDI para prevenção primária
15% - acredita que só indicado na presença de arritmias documentadas
36% - indica com FE > 40%

Heart Rhythm 2012; 9: 874-881

CDI para Profilaxia Primária: há viabilidade no Brasil?

Dados Brasileiros?

Volume ** • Number ** • **
VALUE IN HEALTH

Cost-Effectiveness of Implantable Cardioverter-Defibrillators in Brazil: Primary Prevention Analysis in the Public Sector

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[1]Graduate Program in Epidemiology of Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil; [2]Graduate Program in Cardiology of Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil and National Institute for Health Technology Assessment (IATS)—CNPq/Brazil; [3]Cardiology Division, Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil

ABSTRACT

Background: Several studies have demonstrated the effectiveness and cost-effectiveness of implantable cardioverter-defibrillators (ICDs) in chronic heart failure (CHF) patients. Despite its widespread use in developing countries, limited data exist on its cost-effectiveness in these settings.
Objective: To evaluate the cost-effectiveness of ICD in CHF patients under the perspective of the Brazilian Public Healthcare System (PHS).
Methods: We developed a Markov model to evaluate the incremental cost-effectiveness ratio (ICER) of ICD compared with conventional therapy in patients with CHF and New York Heart Association class II and III. Effectiveness was evaluated in quality-adjusted life years (QALYs) and time horizon was 20 years. We searched MEDLINE for clinical trials and cohort studies to estimate data from effectiveness, complications, mortality, and utilities. Costs from the PHS were retrieved from national administrative databases. The model's robustness was assessed through Monte Carlo simulation and one-way sensitivity analysis. Costs were expressed as international dollars, applying the purchasing power parity conversion rate (PPP US$).
Results: ICD therapy was more costly and more effective, with incremental cost-effectiveness estimates of PPP US$ 50,345/QALY. Results were more sensitive to costs related to the device, generator replacement frequency and ICD effectiveness. In a simulation resembling the MADIT-I population survival and ICD benefit, the ICER was PPP US$ 17,494/QALY and PPP US$ 15,394/life years.
Conclusions: In a Brazilian scenario, where ICD cost is proportionally more elevated than in developed countries, ICD therapy was associated with a high cost-effectiveness ratio. The results were more favorable for a patient subgroup at increased risk of sudden death.
Keywords: chronic heart failure, cost-effectiveness, implantable cardioverter-defibrillators, primary prevention.

Medidas de Efetividade

- Avaliação em anos de vida salvos (AVS) e os mesmos ajustados para qualidade (QALYs)
- Parâmetro de efetividade → metanálise dos ECRs
- Parâmetros de complicações → metanálises publicadas na literatura, coortes e registros

Ezekowitz et al. Ann Intern Med 2007;147:251

Kleemann et al. Circulation 2007;115:2474

Avaliação de Custos

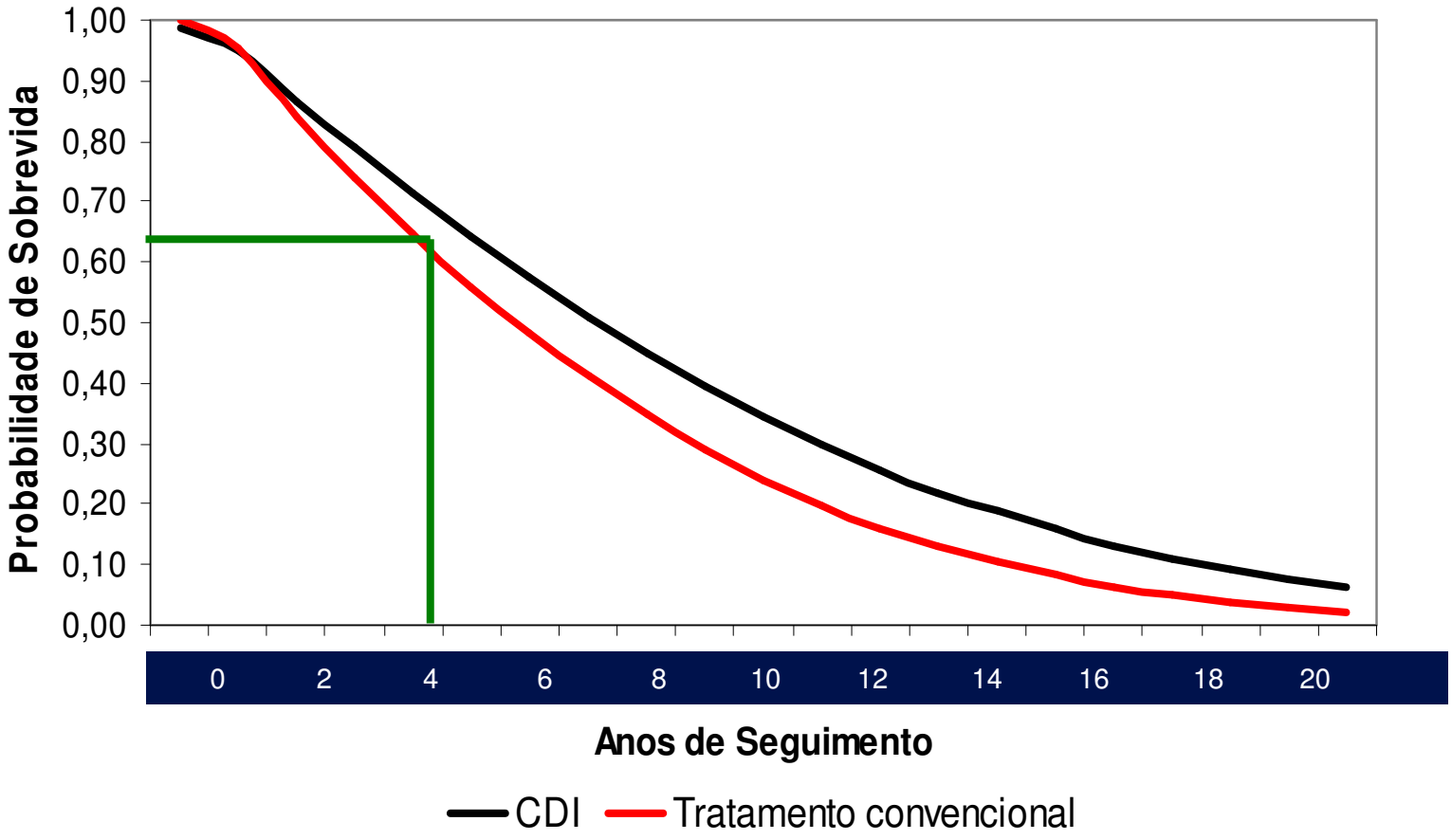
- Custos do implante de CDI, troca da bateria e tratamento de possíveis complicações → tabela SUS
- Valores de internações por ICC da tabela SUS
- Obtenção do custo anual do manejo da ICC de coorte nacional

Araujo DV et al Arq Bras Cardiol 2005;84:422

Parâmetros Adotados

Parâmetro	Valor	Variação na análise de sensibilidade
Redução de mortalidade com CDI	26%	17% - 33%
Morte operatória	1,3%	1,2 - 1,4%
Falha de implantação	1,1%	0,9 - 1,3%
Taxa de quebra de cabos: 1º ano	2,36%	2,36% - 2,93%
Taxa de quebra de cabos: último ano	6,72%	6,72% - 8,33%
Taxa anual de infecção	0,60%	0,50% - 0,80%
Morte por infecção	21%	0 - 50%
Deslocamento de cabos (1º ano)	3,48%	1,92% - 5,23%
Tempo de troca do gerador	5 anos	3 - 7 anos
Custo do CDI	R$ 30.460	R$ 15.230 - 45.690
Custo da troca do gerador	R$ 29.408	R$ 14.704 - 44.112
Custo do reposicionamento dos cabos	R$ 393	R$ 196 - 589
Custo da troca dos cabos	R$ 7.594	R$ 3.797 - 11.391
Custo anual do manejo da ICC	R$ 3.160	R$ 1.580 - 4.741
Utilidade de um paciente com ICC	0,88	0,71 - 0,88
Taxa de desconto	3%	0 - 7%

Predição de sobrevida



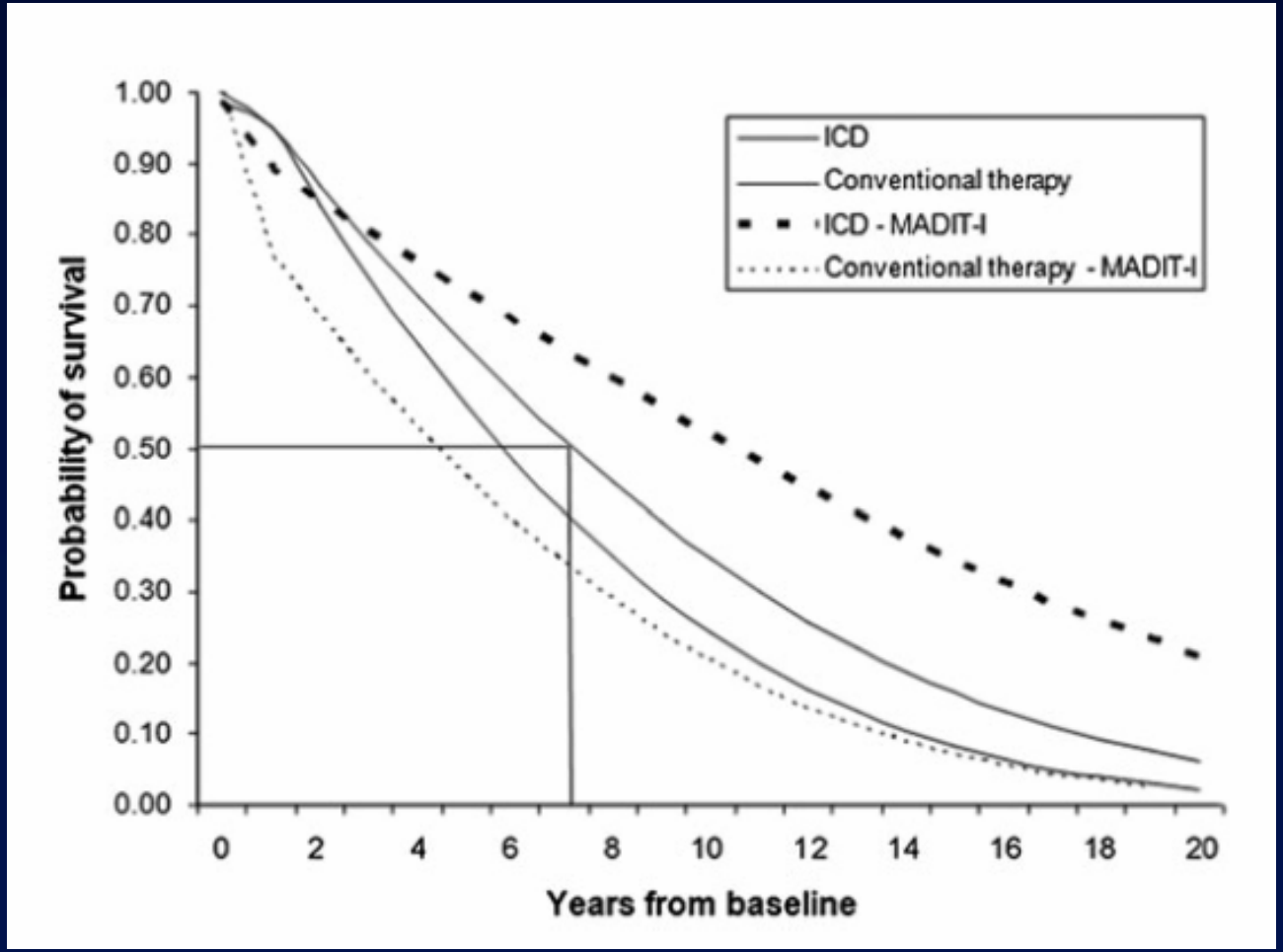
4º ano: sobrevida de 65% no controle –

MADIT-II = 64%, SCD – HeFT = 71%

Custo e Efetividade das Estratégias

	Custo Total (R$)	Efetividade		Custo-Efetividade Incremental	
		Anos de Vida	QALYs	R$ / AVS	R$ / QALY
Tratamento convencional	33.408	5,95	5,23	-	-
Tratamento convencional + CDI	96.131	6,99	6,15	60.120	68.318
	62.723	1,04	0,92		

Critérios MADIT

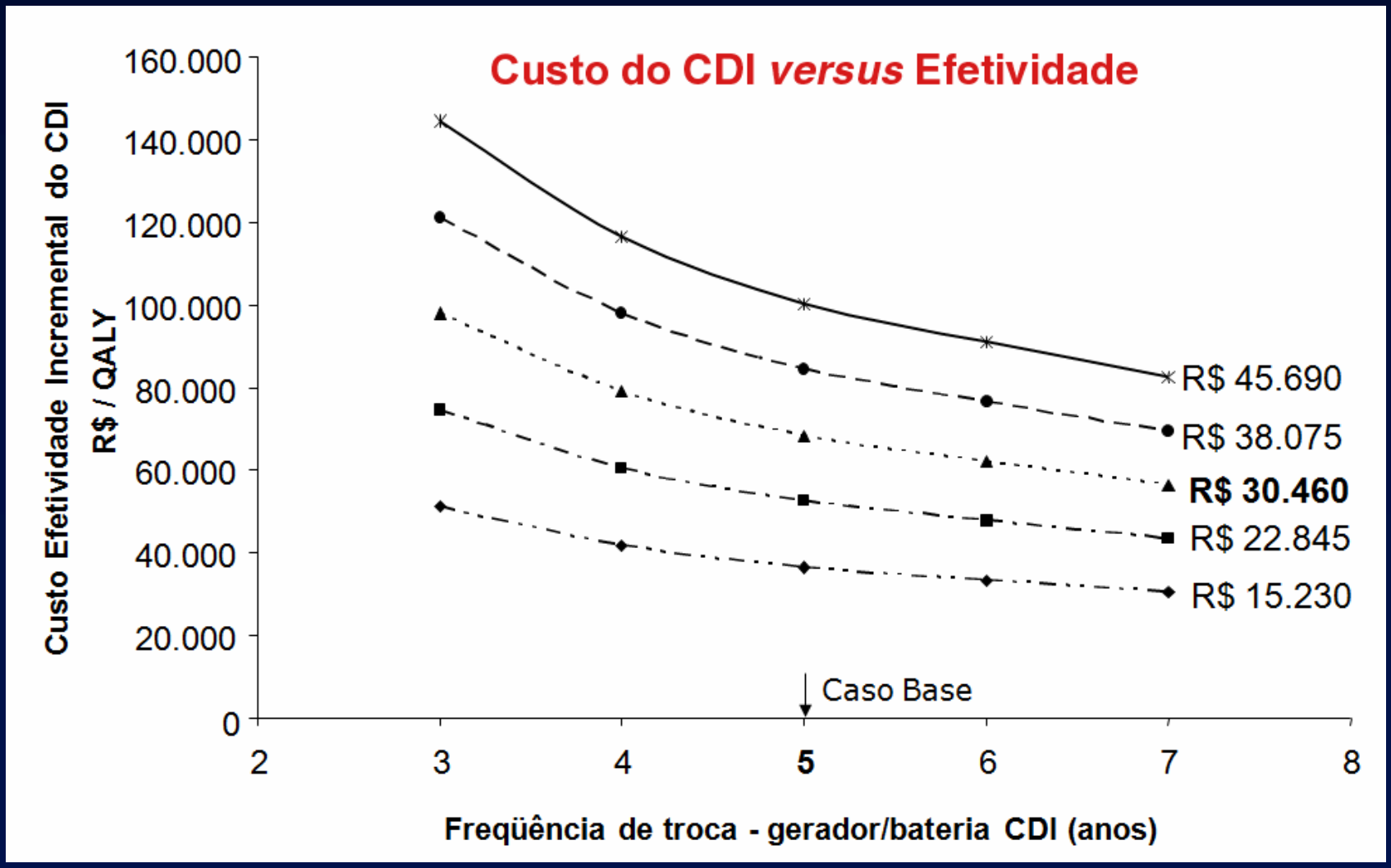


Custo e Efetividade das Estratégias – Cenário MADIT

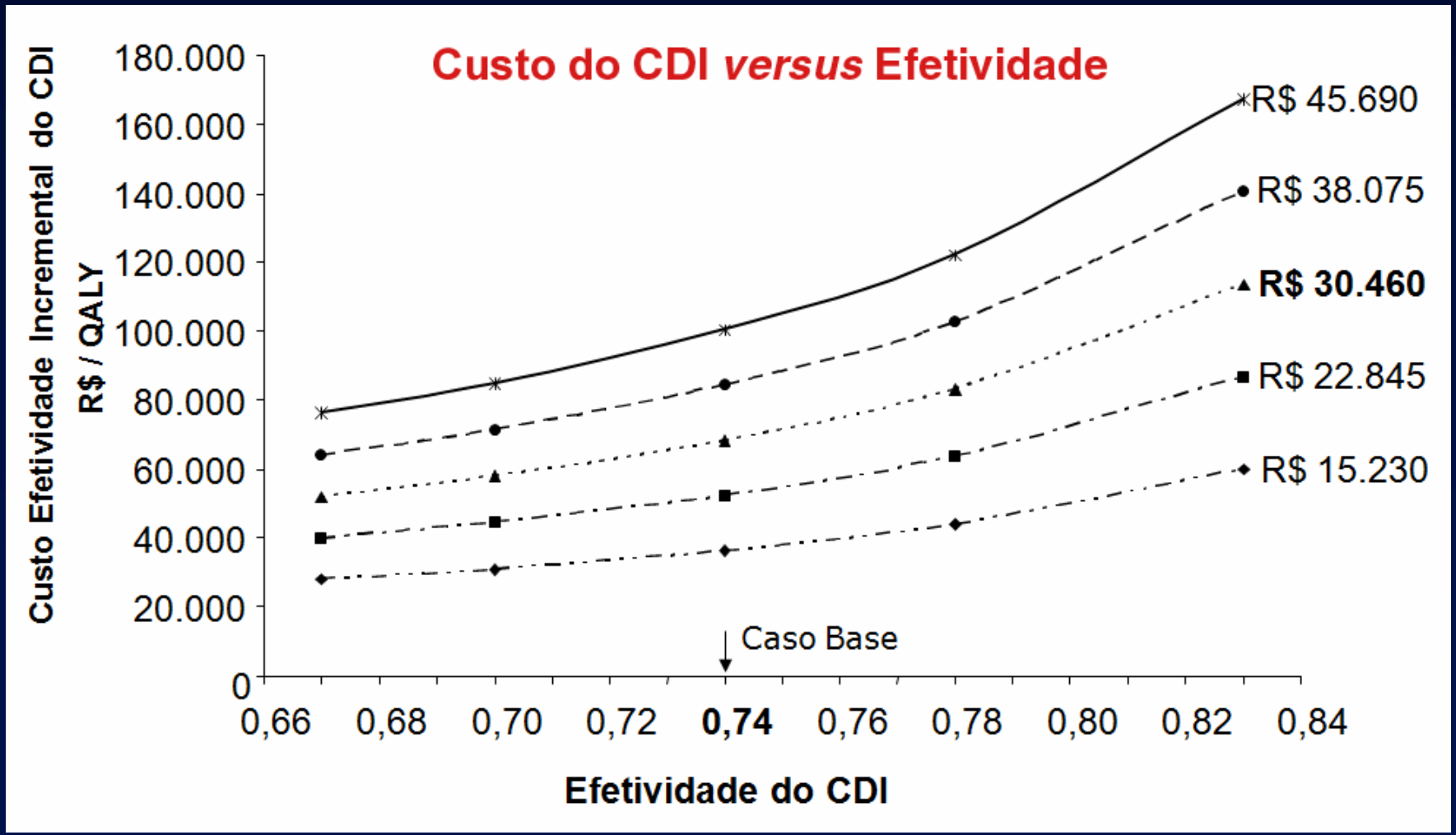
	Custo Total	Efetividade		Custo-Efetividade Incremental	
		Anos de Vida	QALYs	R$ / AVS	R$ / QALY
Tratamento convencional	31.874	4,97	4,37	-	-
Tratamento convencional + CDI	109.141	8,67	7,63	20.890	23.739
	77.267	3,70	3,26		

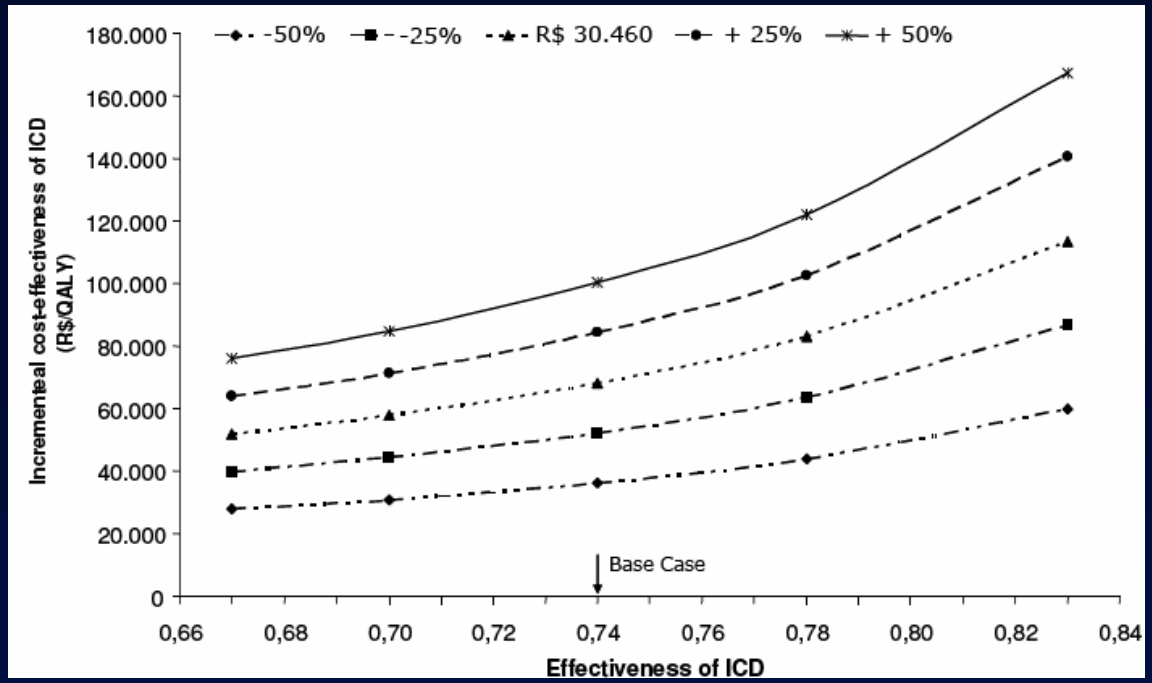
- 84% das simulações no Monte Carlo ficaram abaixo do ponto de coorte de 3 x o PIB per capita

Análise de Sensibilidade
Frequência de Troca



Análise de Sensibilidade
Efetividade





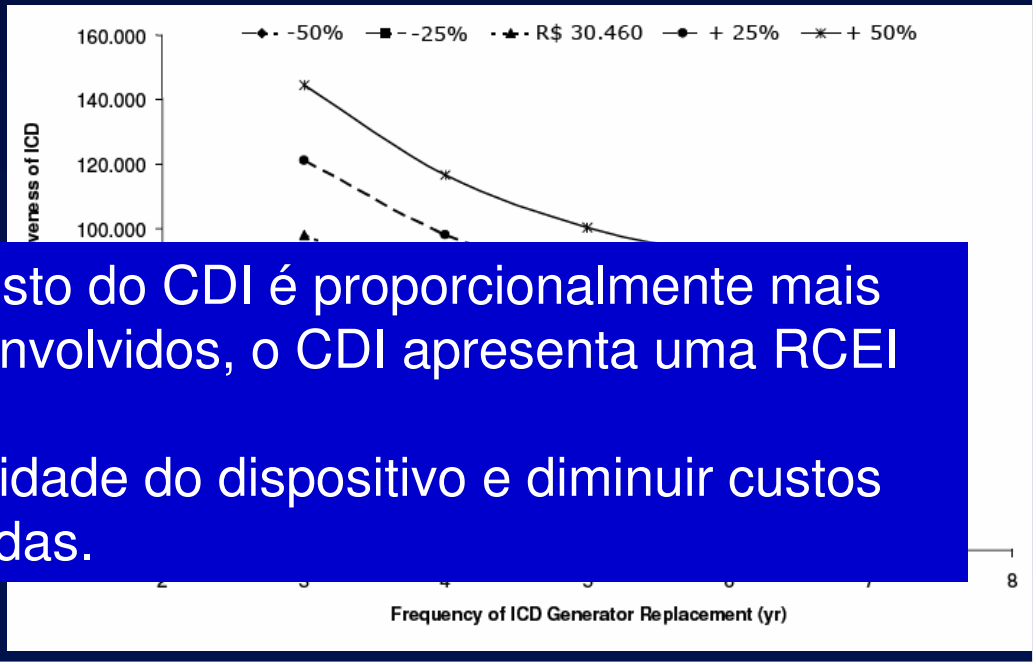
CDI - R$ 68.318/AVAQ

3xPIB = R$ 37.311/AVAQ

(<2% das simulações)

Análise simulando MADIT I:

- R$ 23.739/AVAQ



No cenário Brasileiro, onde o custo do CDI é proporcionalmente mais elevado do que em países desenvolvidos, o CDI apresenta uma RCEI elevada.
Estratégias para melhorar efetividade do dispositivo e diminuir custos associados devem ser perseguidas.

Conclusões

- Em ICC e FE <35%, a custo-efetividade do CDI apresenta valor limítrofe (R$ 68.318 / QALY), mas elevado na perspectiva do SUS.
- Para tornar mais favorável:
  - maior efetividade
  - redução custos e maior duração do dispositivo
- Em uma população com maior risco de mortalidade arrítmica, o valor é reduzido para R$ 23.739 / QALY.

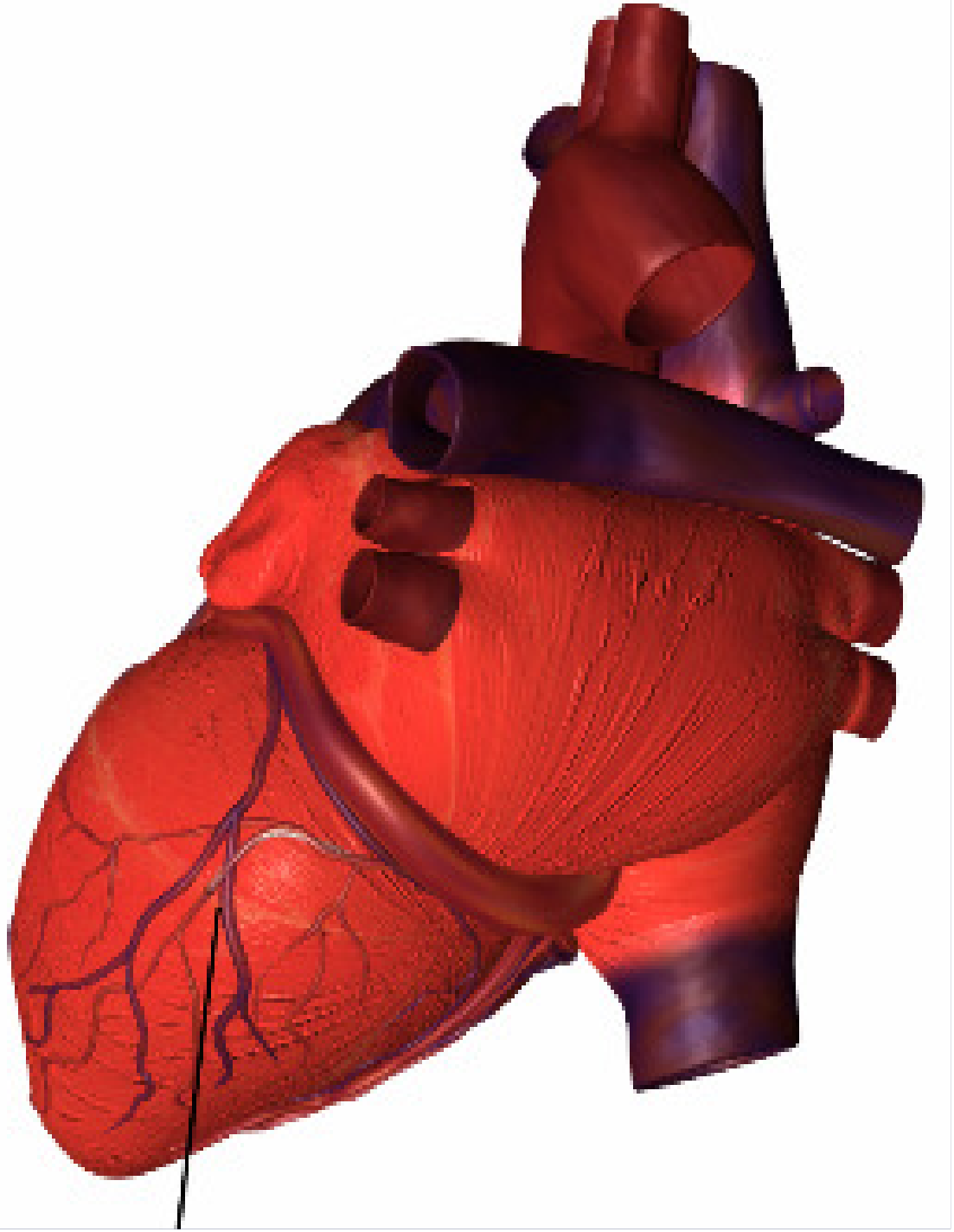
A melhor maneira de melhorar o padrão de vida está em melhorar o padrão de pensamento.

U. S. Andersen

Atingindo a TRC

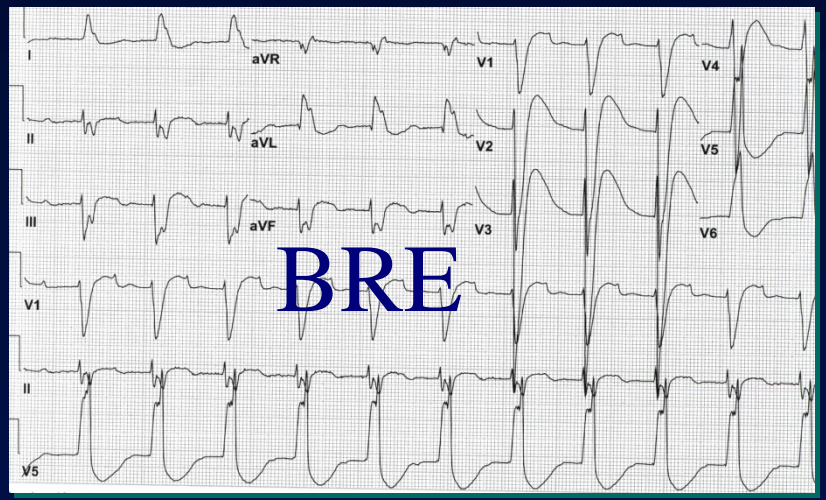
- Approach Transvenoso
  - Cabo eletrodo de MP convencional no AD
  - Cabo eletrodo convencional de MP/CDI no VD
  - Cabo eletrodo específico no VE através de um ramo venoso do seio coronário

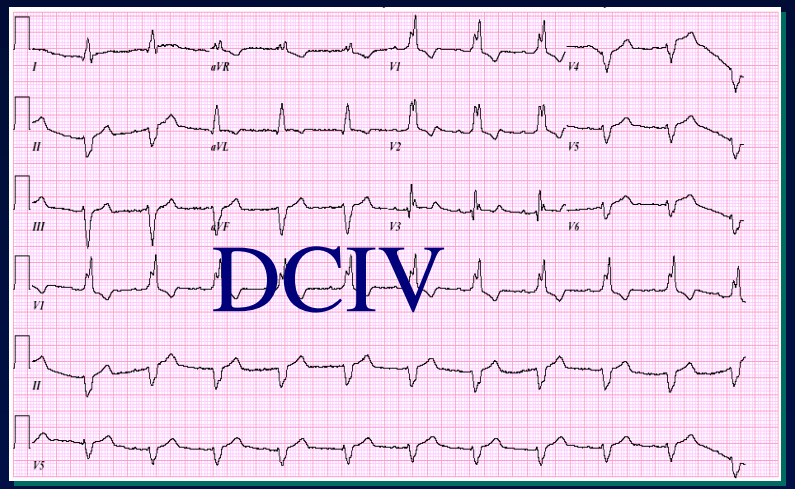
Veia Cardíaca Lateral

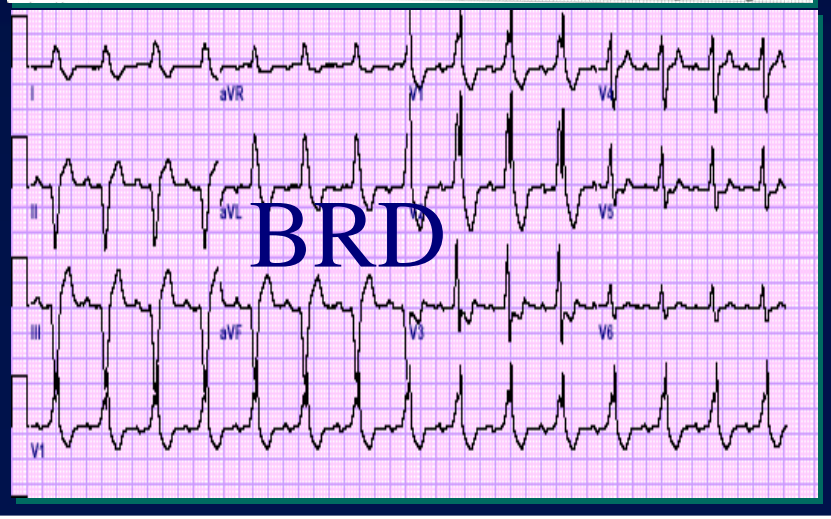


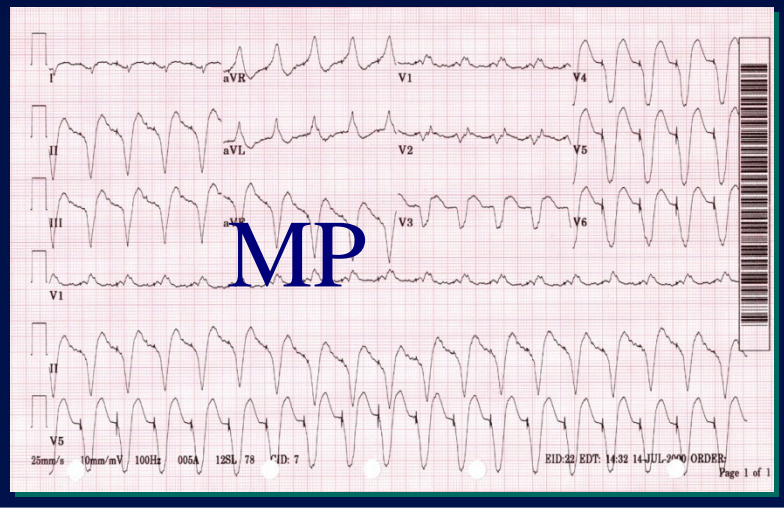
Dissincronia : Como Definir

- ECG - QRS Largo
  - Facil, rápido e barato

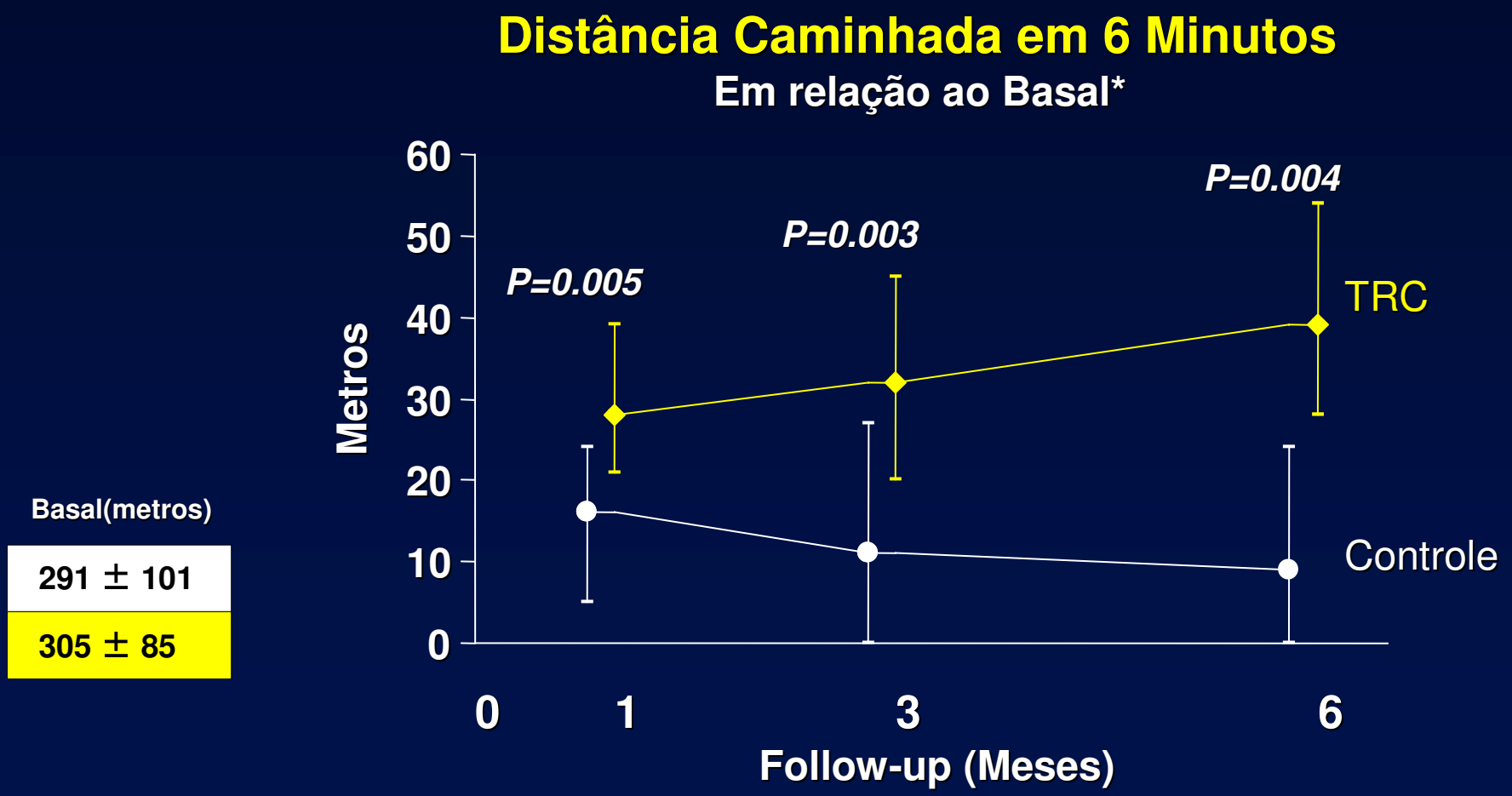






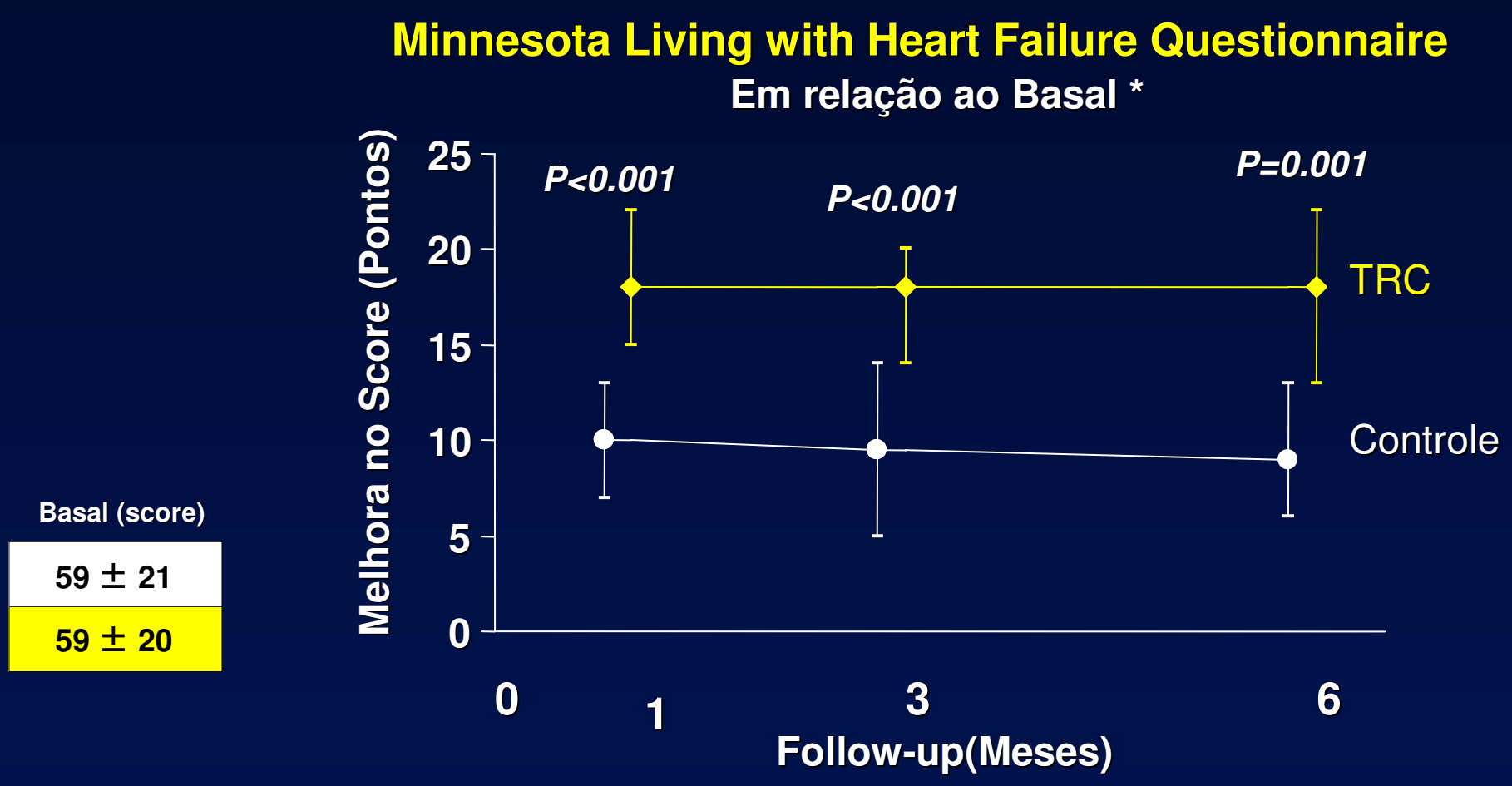


TRC Melhora a Capacidade Funcional



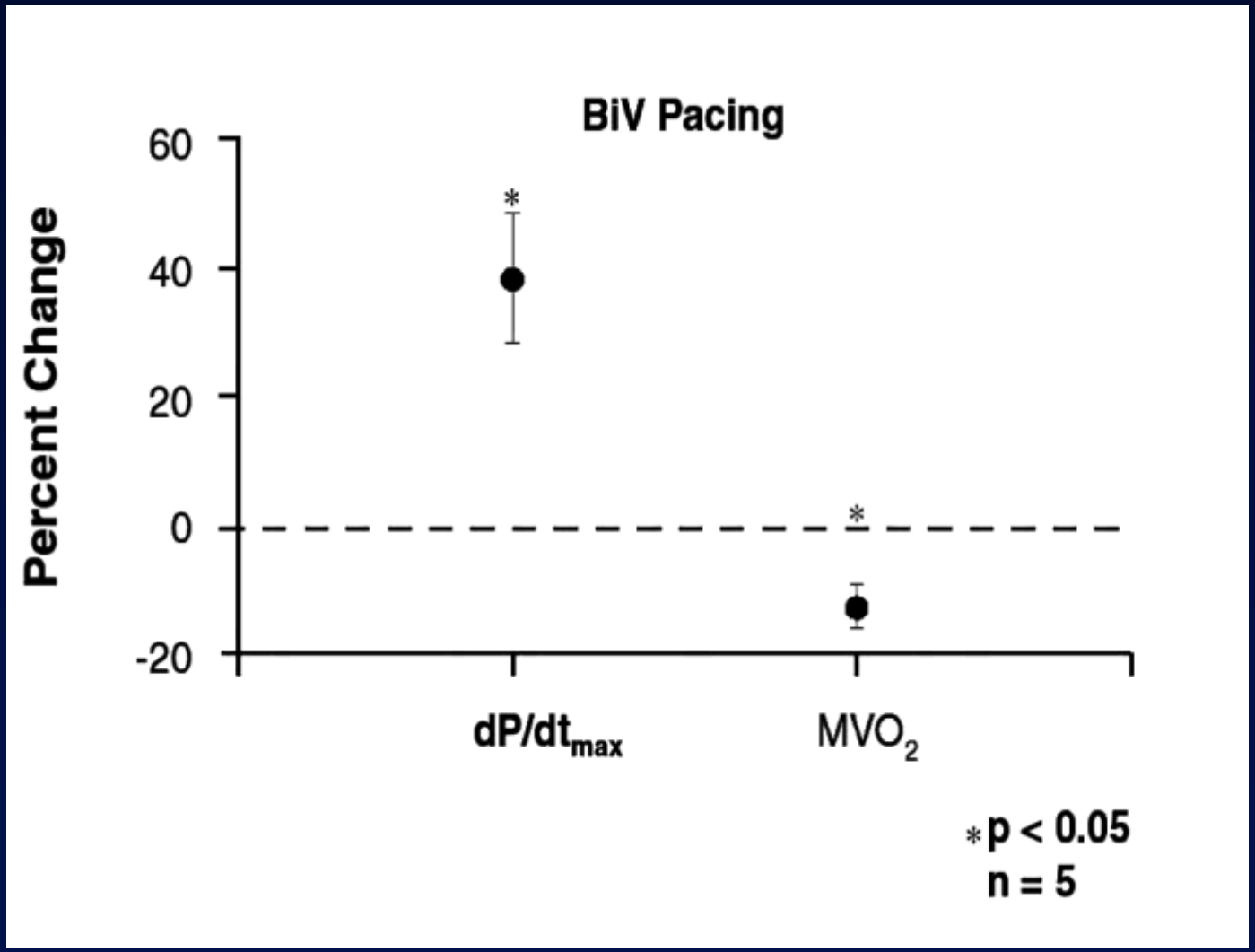
Abraham WT, Fisher WG, Smith AL, et al. *N Engl J Med* 2002;346:1845-1853

TRC Melhora a Qualidade de Vida



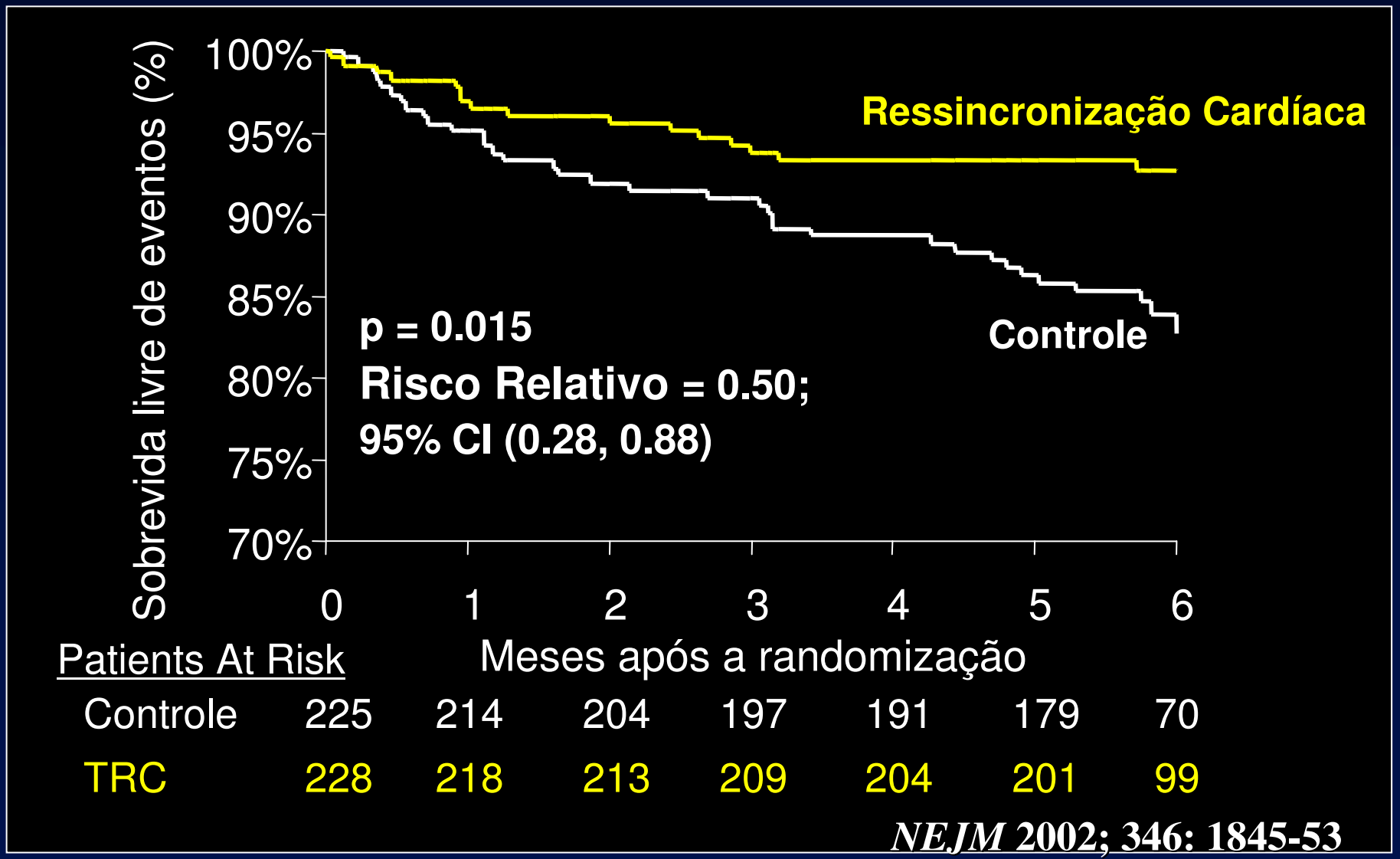
Abraham WT, Fisher WG, Smith AL, et al. *N Engl J Med* 2002;346:1845-1853

A TRC Não Aumenta o Consumo de Oxigênio Miocárdico



Adapted from: Nelson G, Berger R, Fetics B, et al. *Circulation*. 2000; 102:3053-3059.

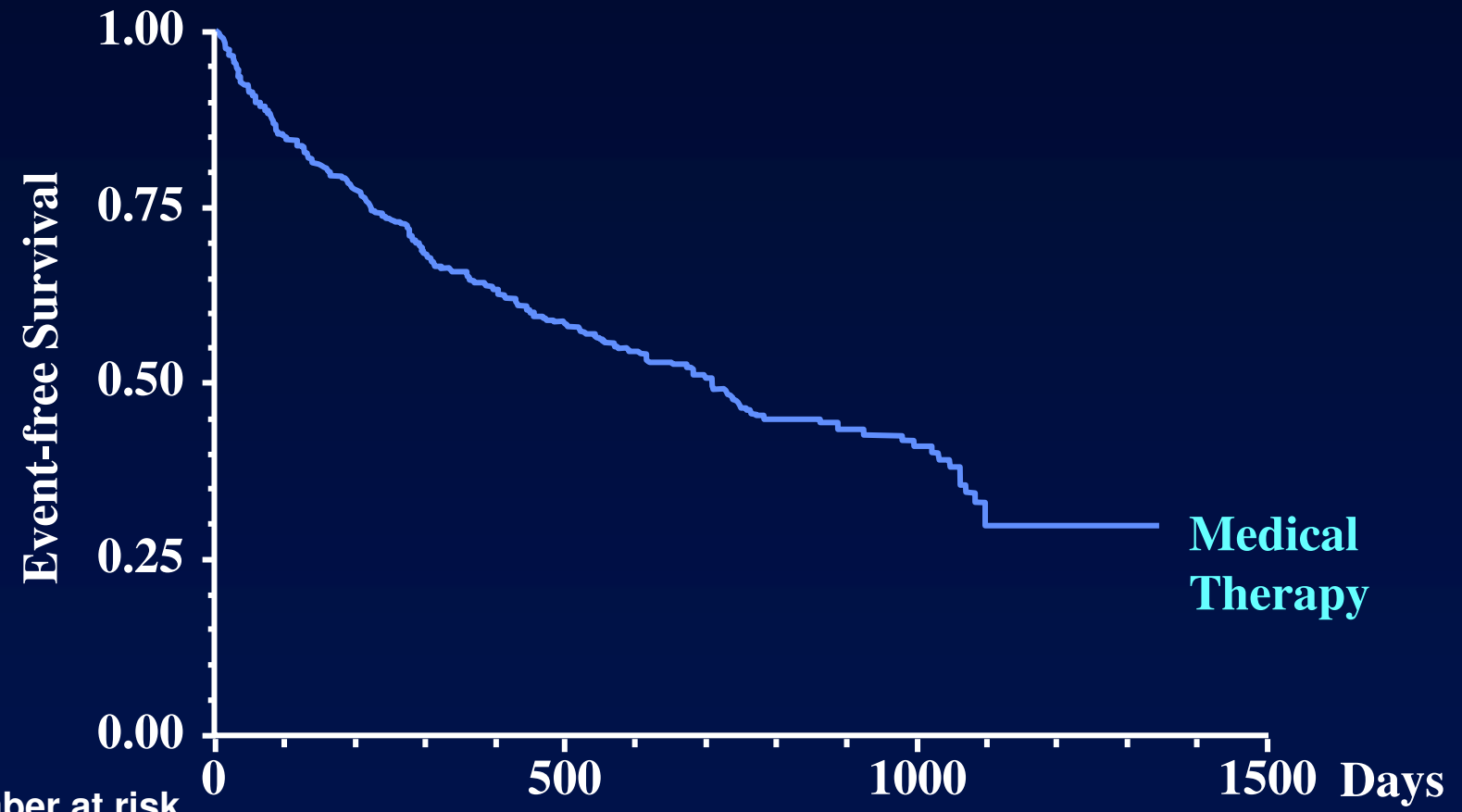
Hospitalizações para IC Descompensada



NEJM 2002; 346: 1845-53

“Endpoint”primário

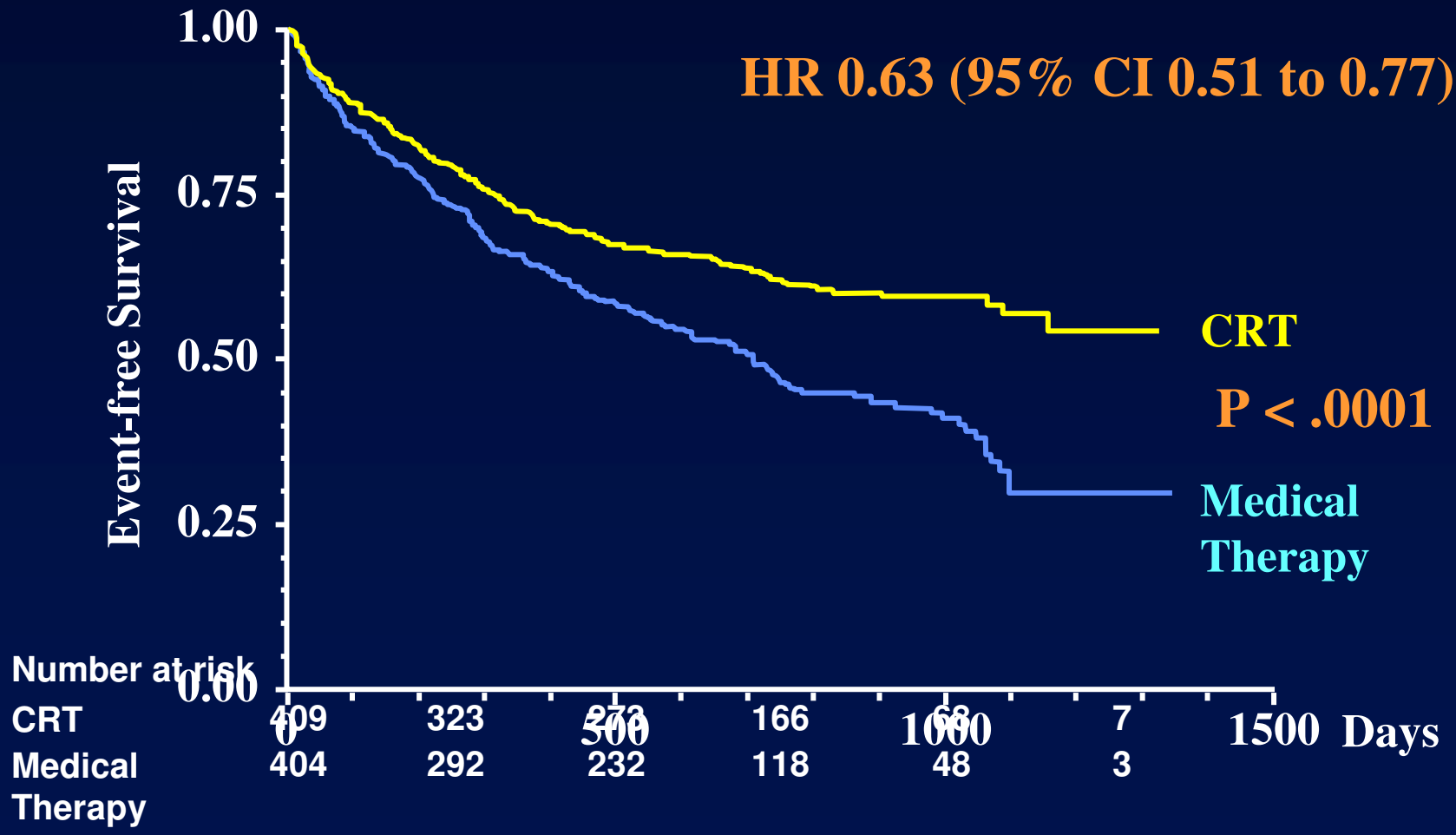
(mortalidade por todas as causas ou hospitalização não planejada por evento CV)



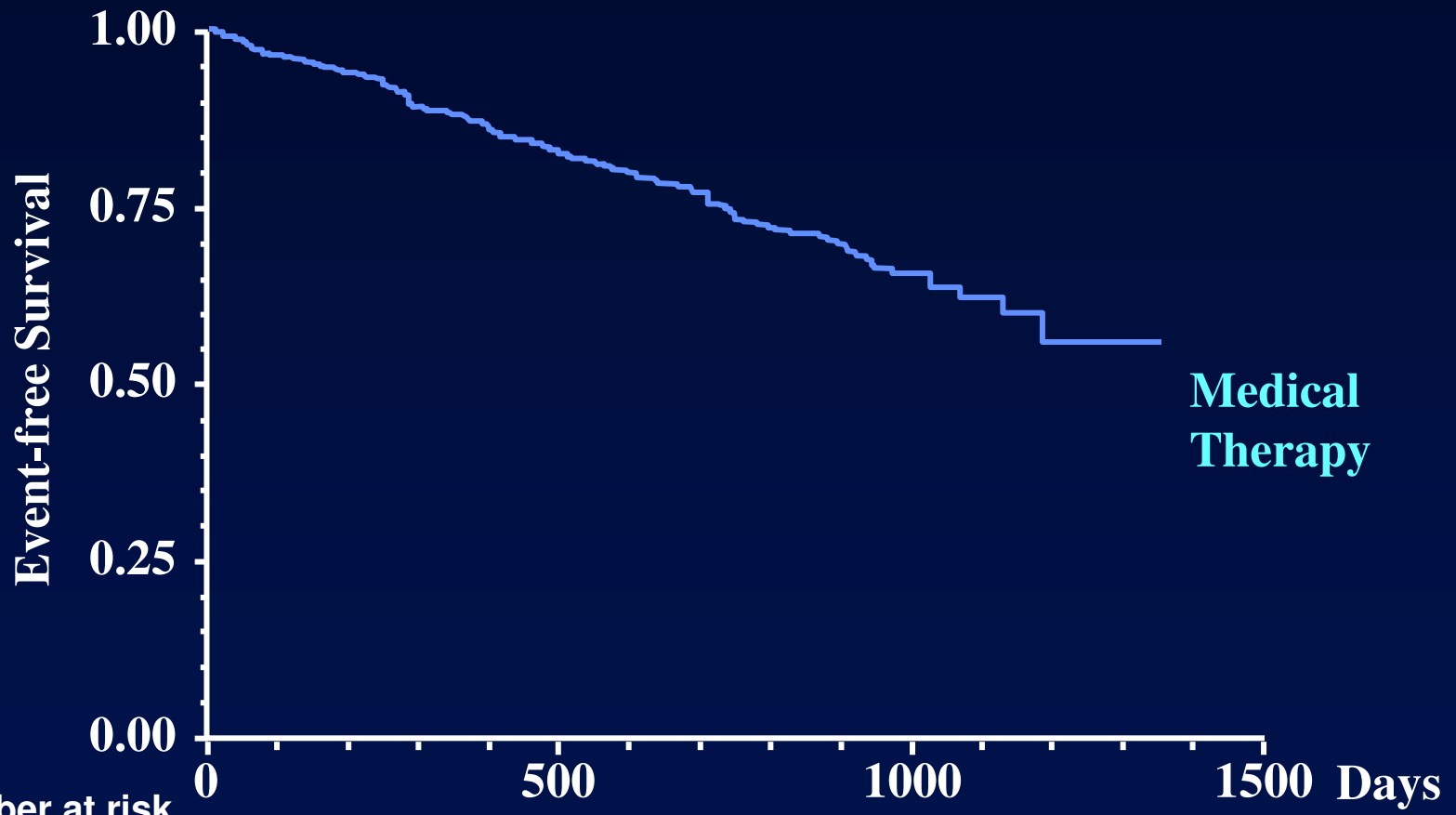
Number at risk						
CRT	409	323	273	166	68	7
Medical Therapy	404	292	232	118	48	3

“Endpoint”primário

(mortalidade por todas as causas ou hospitalização não planejada por evento CV)

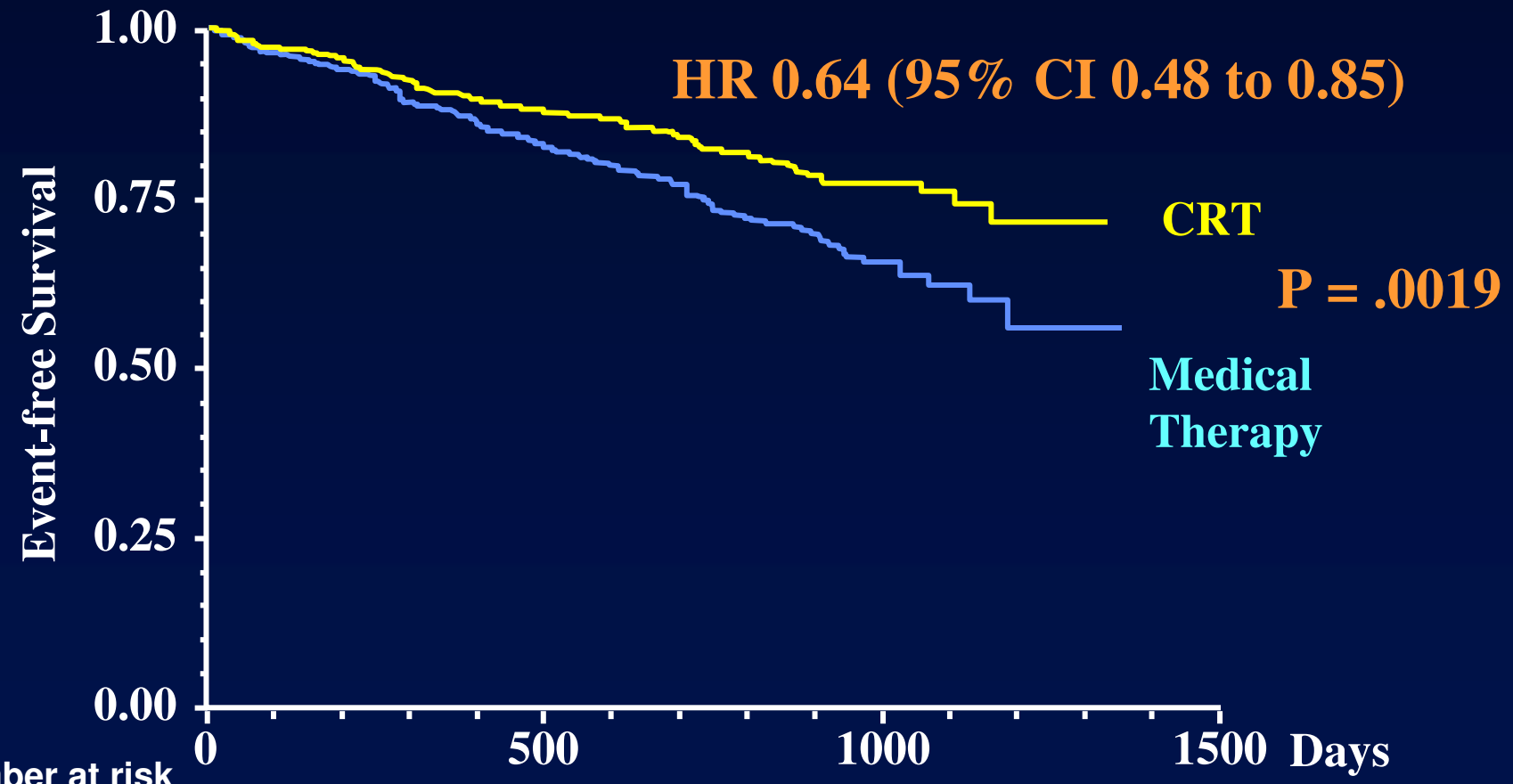


Mortalidade por todas as causas



Number at risk						
CRT	409	376	351	213	89	8
Medical Therapy	404	365	321	192	71	5

Mortalildade por todas as causas



Number at risk						
CRT	409	376	351	213	89	8
Medical Therapy	404	365	321	192	71	5

Quem se Beneficia?

NYHA Classe III/IV

Tratamento Clinico otimizado

FE<35%

Eletrocardiograma

- QRS ≥ 130 ms

Ecocardiograma

Dissincronia Mecânica?

Results of the Predictors of Response to CRT (PROSPECT) Trial

Eugene S. Chung, MD; Angel R. Leon, MD; Luigi Tavazzi, MD; Jing-Ping Sun, MD; Petros Nihoyannopoulos, MD; John Merlino, MD; William T. Abraham, MD; Stefano Ghio, MD; Christophe Leclercq, MD; Jeroen J. Bax, MD; Cheuk-Man Yu, MD, FRCP; John Gorcsan III, MD; Martin St John Sutton, FRCP; Johan De Sutter, MD, PhD; Jaime Murillo, MD

Table 1. Summary of Echocardiographic Predictors of Response to CRT

Echocardiographic Predictor	Description of Method	Echocardiography Method	Cutoff
SPWMD[10]	Septal-posterior wall motion delay; M mode measured by parasternal short-axis view	M mode	≥130 ms
IVMD[14]	Interventricular mechanical delay defined as the difference between left and right ventricular preejection intervals	Pulsed Doppler	≥40 ms
LVFT/RR[14]	Left ventricular filling time (LVFT) in relation to cardiac cycle length (RR) as measured by transmitral Doppler echo expressed as percentage	Pulsed Doppler	≤40%
LPEI[14]	Left ventricular preejection interval defined as the time interval between the beginning of QRS and beginning of left ventricular ejection by Doppler	Pulsed Doppler	≥140 ms
LLWC[14]	Intraventricular dyssynchrony left lateral wall contraction defined as the presence of overlap between the end of lateral wall contraction (via M mode) and onset of LV filling (by Doppler echocardiography)	M mode and pulsed Doppler	Any overlap
Ts-(lateral-septal)[15]	Delay between time to peak systolic velocity in ejection phase at basal septal and basal lateral segments	TDI	≥60 ms
	ventricular segments with a systolic contraction component in early diastole by TDI and confirmed with strain rate imaging		
Ts-peak displacement	Maximum difference of time to peak systolic displacement for 4 segments	TDI	≥Median
Ts-peak (basal)	Maximum difference of time to peak systolic velocity for 6 segments at basal level	TDI	≥Median
Ts-onset (basal)	Maximum difference of time to onset of systolic velocity for 6 segments at basal level	TDI	≥Median

Endpoint – redução de 15% em escore clínico ou no volume sistólico final VE

498 pt

FE < 35%

QRS > 130ms

53 centros

3 Core Labs

Circulation 2008; 117: 2608-16

Heart Failure

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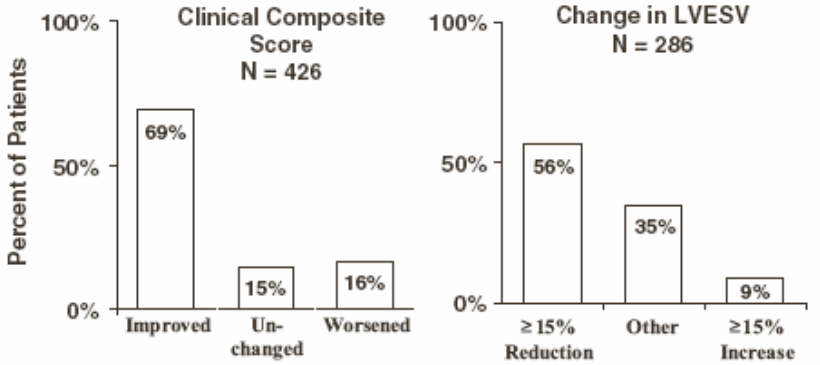
			CCS				LVESV			
				Improved				Reduced ≥15%		
Echocardiography Type	Dyssynchrony Method/Cutoff	Cutoff Met?	Total	n	%	*P*	Total	n	%	*P*
None	QRS ≥130 ms		426	294	69		286	161	56	
M mode	SPWMD ≥30 ms	Yes	157	113	72	0.44	130	84	65	0.021
		No	135	91	67		98	48	49	
Pulsed Doppler	IVMD ≥40 ms	Yes	194	143	74	0.045	148	92	62	0.029
		No	182	116	64		128	62	48	
	↓VFT/RR ≤40%	Yes	112	87	78	0.018	88	59	67	0.012
		No	235	153	65		168	85	51	
	LPEI ≥140 ms	Yes	239	175	73	0.013	185	113	61	0.016
		No	146	89	61		97	44	45	
M mode+Doppler	LLWC any overlap	Yes	17	11	65	0.58	16	10	63	0.61
		No	230	164	71		174	95	55	
TDI, published	Ts Lat-Sep ≥60 ms	Yes	95	64	67	1.00	74	50	68	0.005
		No	128	87	68		99	45	45	
	Ts-SD ≥32 ms	Yes	119	86	72	0.27	98	55	56	0.33
		No	48	30	63		35	16	46	
	PVD ≥110 ms	Yes	179	123	69	0.42	143	80	56	0.77
		No	93	59	63		71	38	54	
TDI+SRI, published	DLC ≥2 segments	Yes	111	75	68	0.79	90	51	57	0.68
		No	160	105	66		123	66	54	
TDI, median value used as cutoff	Ts peak displacement ≥120 ms	Yes	64	46	72	0.34	49	29	59	0.30
		No	61	38	62		45	21	47	
	Ts peak basal ≥83 ms	Yes	137	95	69	0.44	105	62	59	0.28
							111	57	51	
						0.029	110	63	57	0.58
							106	56	53	

Grande variabilidade intra e interobservador nos parâmetros de doppler tecidual



Sensibilidade – 6-74%

Especificidade – 35-91%

Circulation 2008; 117: 2608-16

Heart Failure

Results of the Predictors of Response to CRT (PROSPECT) Trial

Eugene S. Chung, MD; Angel R. Leon, MD; Luigi Tavazzi, MD; Jing-Ping Sun, MD; Petros Nihoyannopoulos, MD; John Merlino, MD; William T. Abraham, MD; Stefano Ghio, MD; Christophe Leclercq, MD; Jeroen J. Bax, MD; Cheuk-Man Yu, MD, FRCP; John Gorcsan III, MD; Martin St John Sutton, FRCP; Johan De Sutter, MD, PhD; Jaime Murillo, MD

Conclusion—Given the modest sensitivity and specificity in this multicenter setting despite training and central analysis, no single echocardiographic measure of dyssynchrony may be recommended to improve patient selection for CRT beyond current guidelines. Efforts aimed at reducing variability arising from technical and interpretative factors may improve the predictive power of these echocardiographic parameters in a broad clinical setting. (*Circulation*. **2008;117: 2608-2616.**)

- Índices ecocardiográficos de dissincronia mecânica são inadequados para seleção de pacientes para ressincronização na prática clínica.

- Medidas apresentam alta variabilidade e baixa sensibilidade para detecção de não-respondedores e para expandir as indicações atuais (QRS estreito)

Circulation 2008; 117: 2608-16

European Heart Journal (2005) 26, 2681–2688
doi:10.1093/eurheartj/ehi662

Clinical research

FASTTRACK Cost-effectiveness of cardiac resynchronization therapy: results from the CARE-HF trial

Melanie J. Calvert[1], Nick Freemantle[1*], Guiqing Yao[1], John G.F. Cleland[2], Lucinda Billingham[1], Jean-Claude Daubert[3], and Stirling Bryan[1] on behalf of the CARE-HF Investigators

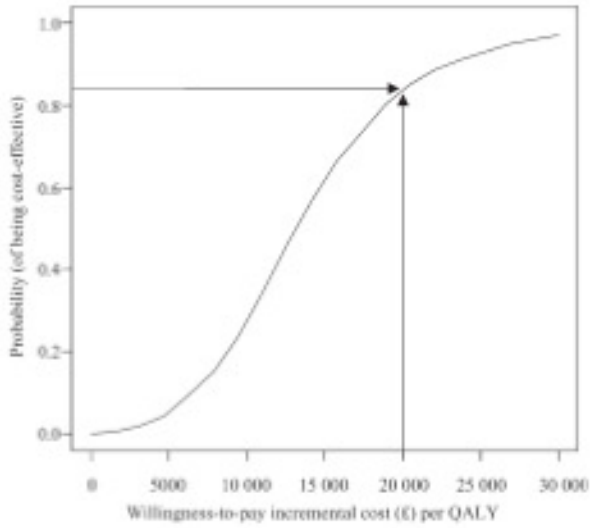


Figure 2 Cost-effectiveness acceptability curve. £20 000 = €29 400.

estimated device battery longevity of 6 years.

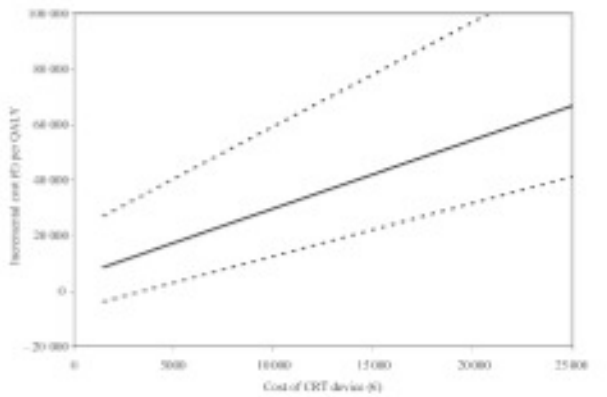


Figure 3 Sensitivity analysis: the effect of varying CRT device cost on cost/QALY estimates. Mean cost/QALY by CRT device is shown with 95% bootstrapped CI. CRT device cost includes cost of the device and leads. LV lead and procedure cost were kept constant.

European Heart Journal 2005; 26: 2681-88

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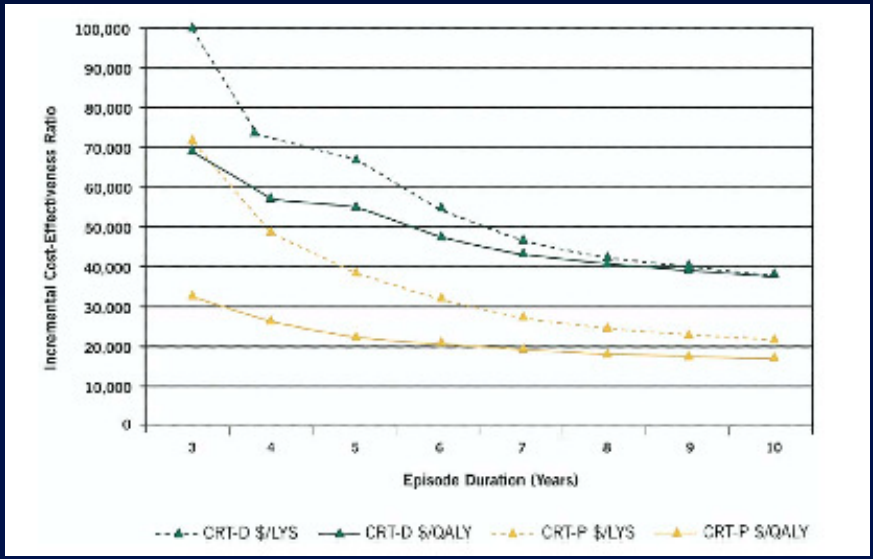
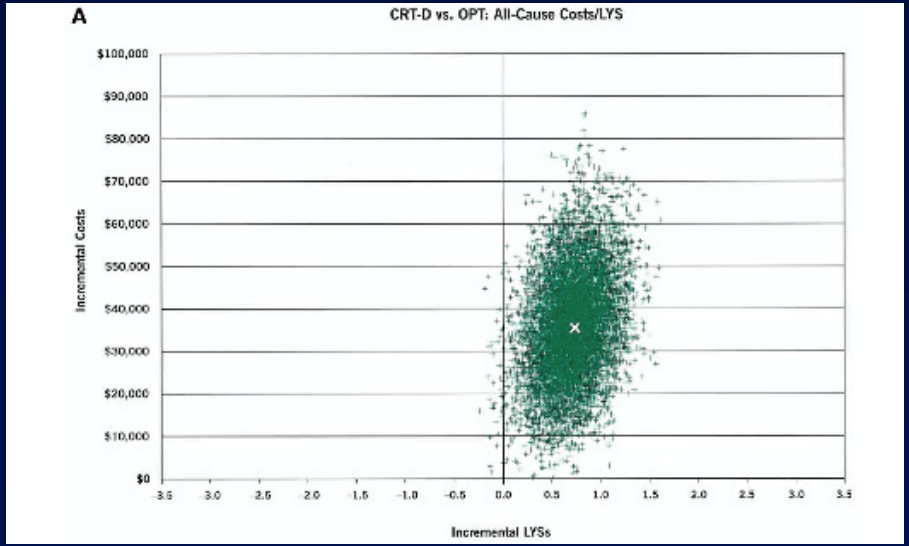
FOCUS ISSUE: CARDIAC RESYNCHRONIZATION THERAPY

Cost Effectiveness and Regulatory Considerations

Cost Effectiveness of Cardiac Resynchronization Therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial

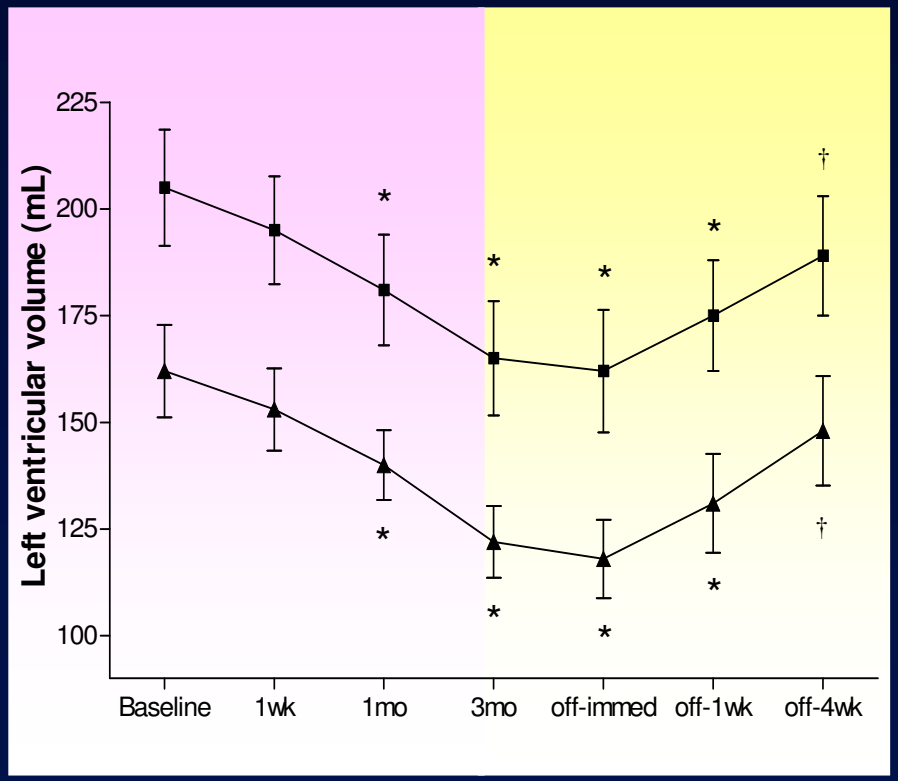




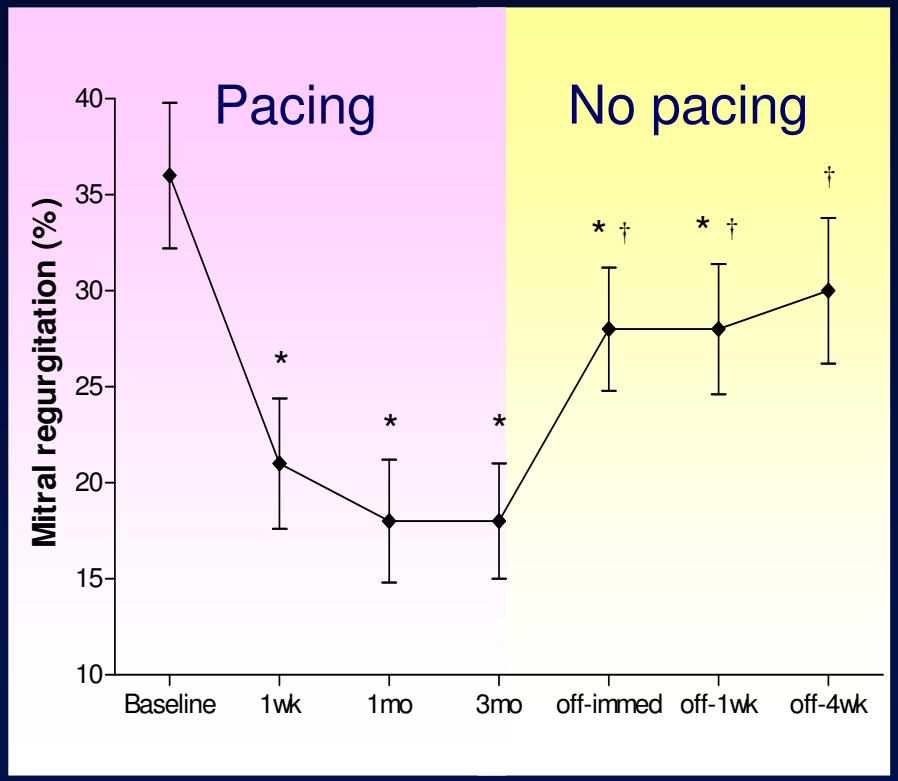
JACC 2005; 12: 2311-21

Remodelamento Reverso do VE

LV End Systolic and Diastolic Volumes



MR area



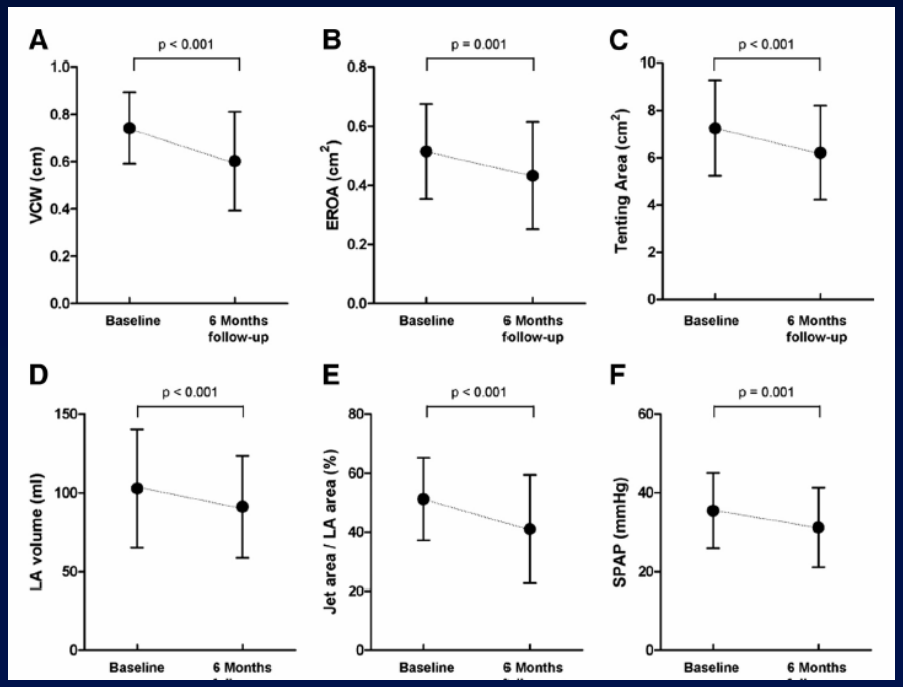
N = 25

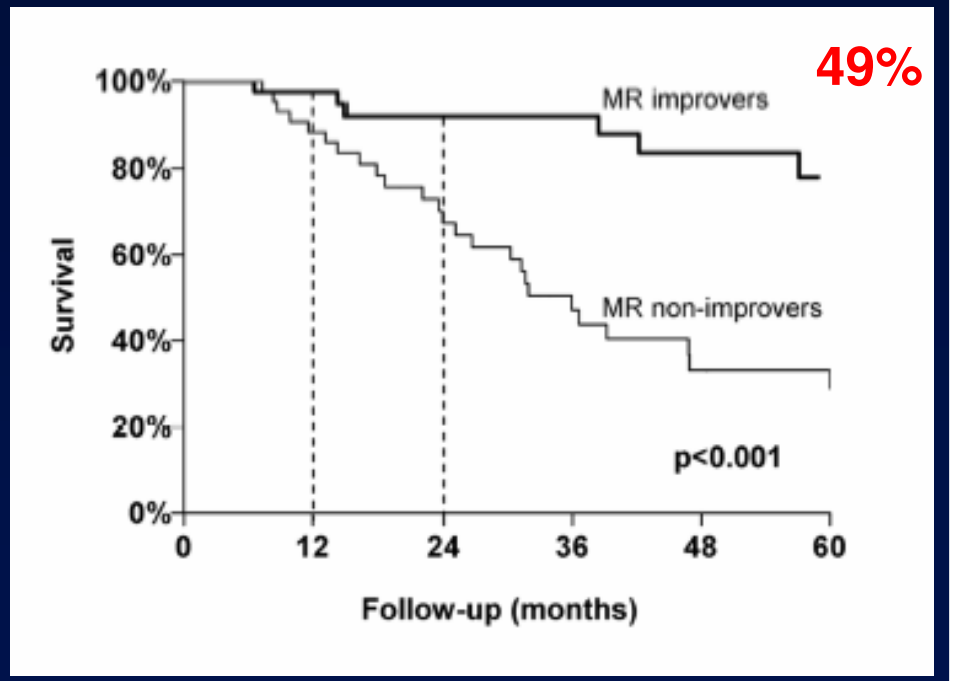
Yu CM, et al, *Circulation* 2002;105:438-445

Valvular Heart Disease

Cardiac Resynchronization Therapy as a Therapeutic Option in Patients With Moderate-Severe Functional Mitral Regurgitation and High Operative Risk

Rutger J. van Bommel, MD; Nina Ajmone Marsan, MD; Victoria Delgado, MD, PhD; C. Jan Willem Borleffs, MD, PhD; Eva P.M. van Rijnsoever, MSc; Martin J. Schalij, MD, PhD; Jeroen J. Bax, MD, PhD

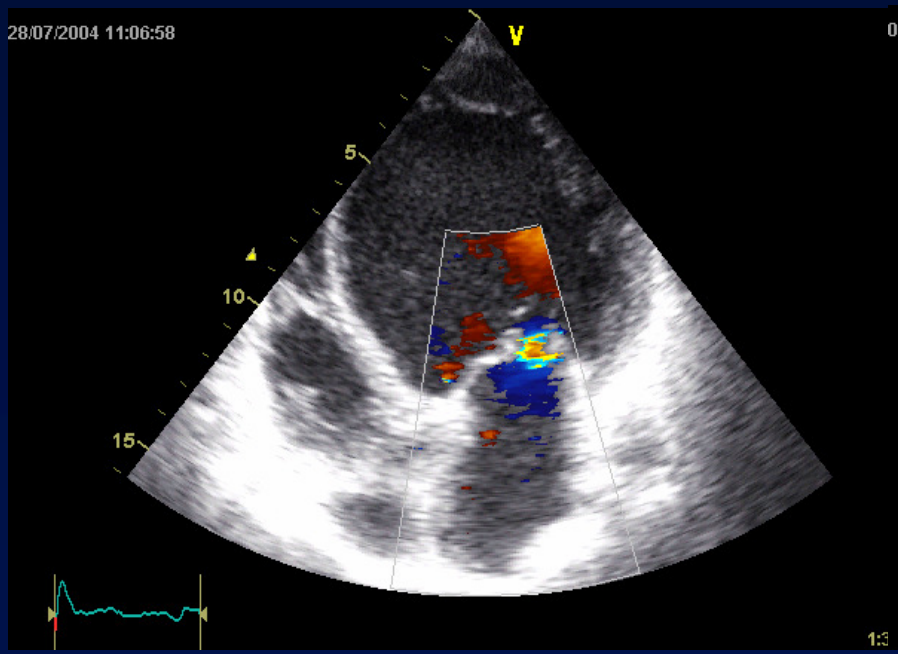




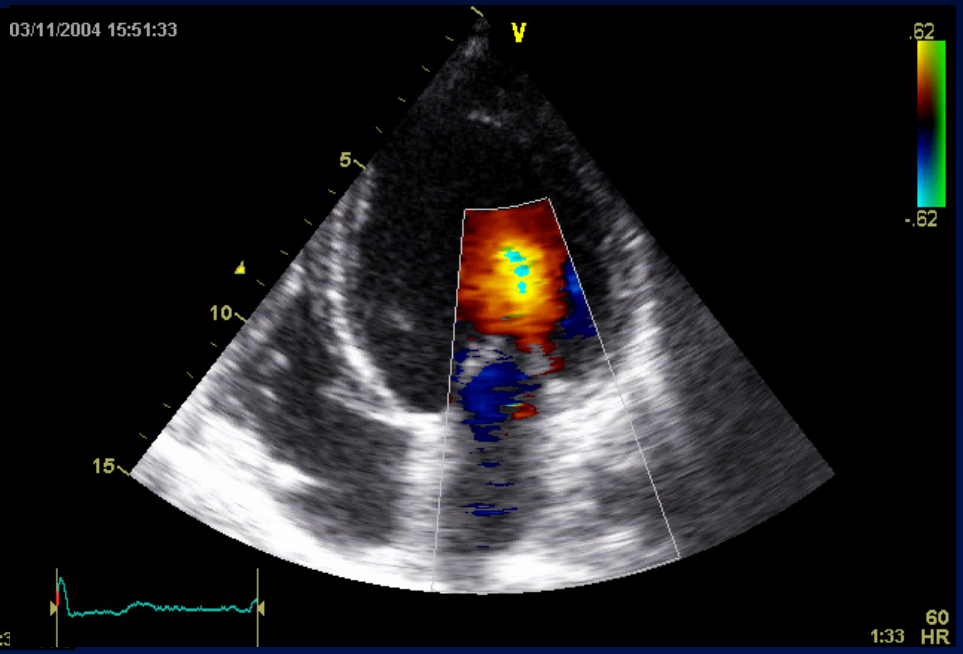
Circulation 2011; 124: 912-919

Regurgitação Mitral

Pré- Ressincronização



Pós- Ressincronização



Cardiac-Resynchronization Therapy for the Prevention of Heart-Failure Events

Arthur J. Moss, M.D., W. Jackson Hall, Ph.D., David S. Cannom, M.D., Helmut Klein, M.D., Mary W. Brown, M.S., James P. Daubert, M.D., N.A. Mark Estes III, M.D., Elyse Foster, M.D., Henry Greenberg, M.D., Steven L. Higgins, M.D., Marc A. Pfeffer, M.D., Ph.D., Scott D. Solomon, M.D., David Wilber, M.D., and Wojciech Zareba, M.D., Ph.D., for the MADIT-CRT Trial Investigators*

1820 pt, FE < 30%, QRS ⩾ 130 ms

Cardiopatia isquêmica – NYHA I e II

Cardiopatia não-isquêmica – NYHA II

F-up = 2,4 anos

3:2

CDI

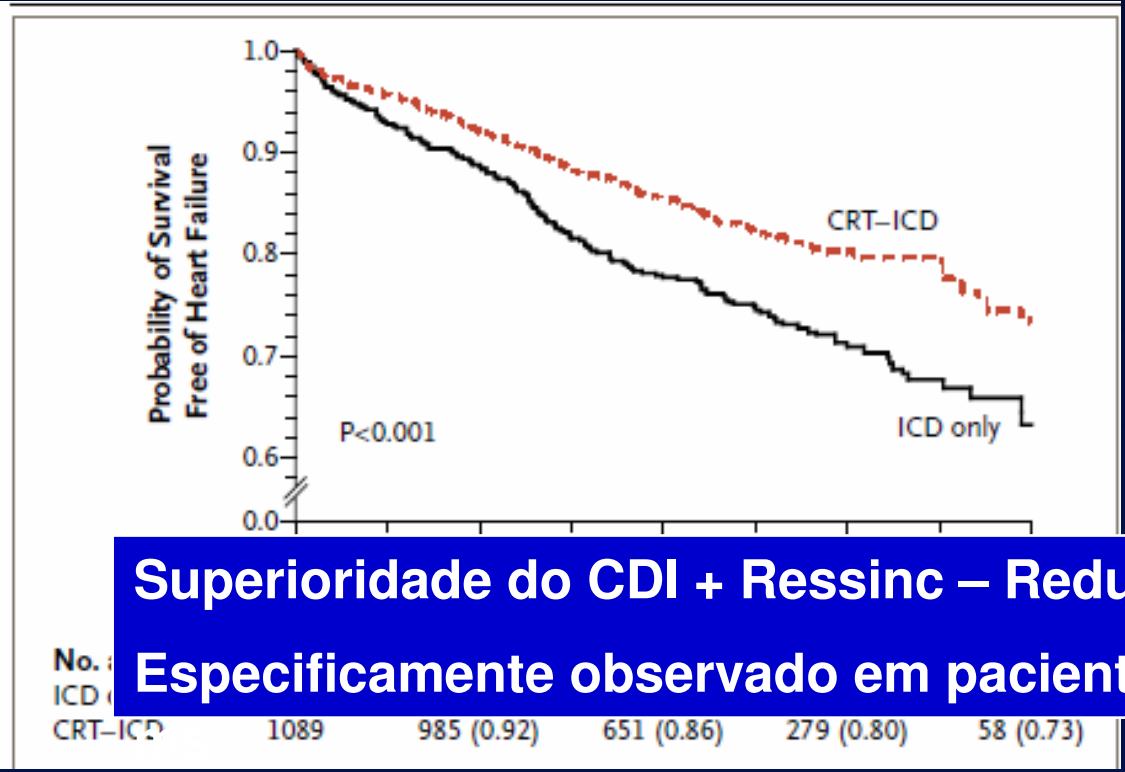
CDI + Ressinc

End point – Morte ou IC não-fatal

NEJM 2009; 361: 1329-38

Cardiac-Resynchronization Therapy for the Prevention of Heart-Failure Events

Arthur J. Moss, M.D., W. Jackson Hall, Ph.D., David S. Cannom, M.D., Helmut Klein, M.D., Mary W. Brown, M.S., James P. Daubert, M.D., N.A. Mark Estes III, M.D., Elyse Foster, M.D., Henry Greenberg, M.D., Steven L. Higgins, M.D., Marc A. Pfeffer, M.D., Ph.D., Scott D. Solomon, M.D., David Wilber, M.D., and Wojciech Zareba, M.D., Ph.D., for the MADIT-CRT Trial Investigators*



HR – 0,66

NNT = 12

Sem diferença entre isquêmicos e não-isquêmicos

Superioridade do CDI + Ressinc – Redução de 41% em IC

Especificamente observado em pacientes com QRS ≥ 150

NEJM 2009; 361: 1329-38

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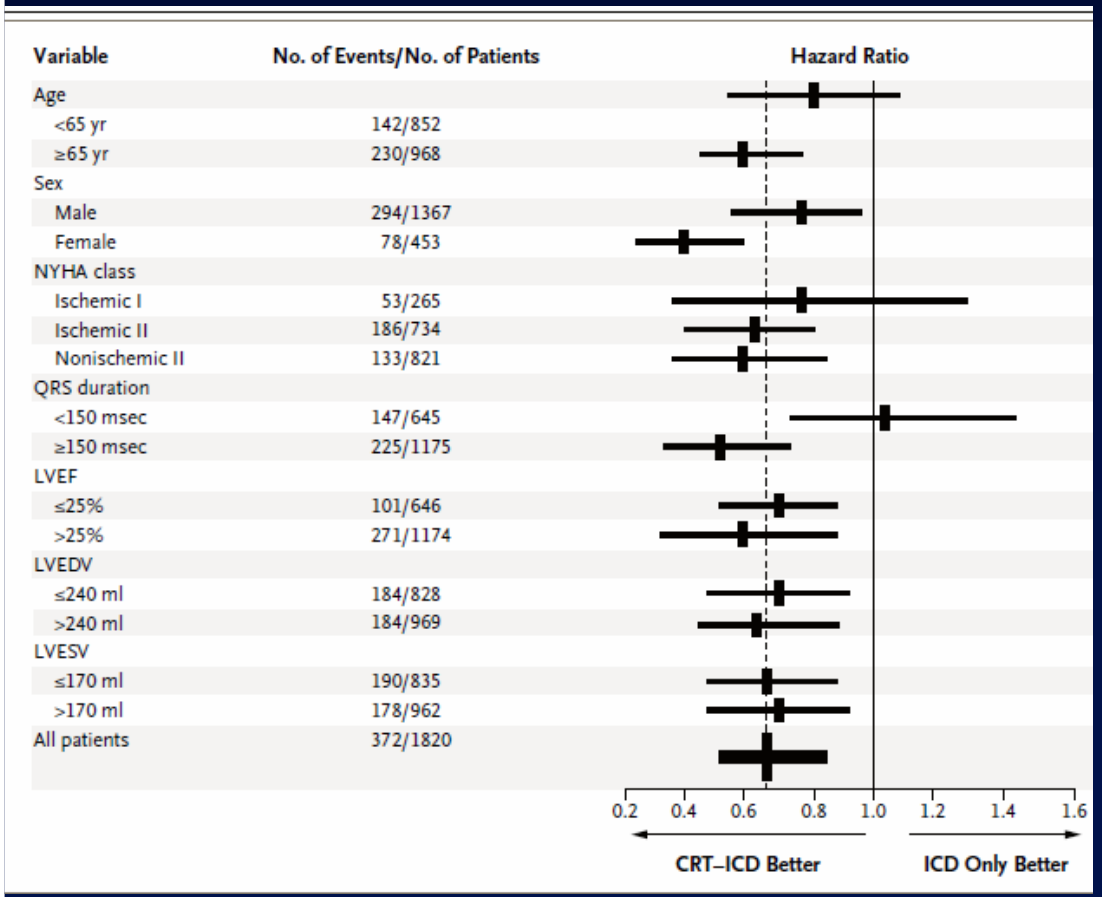

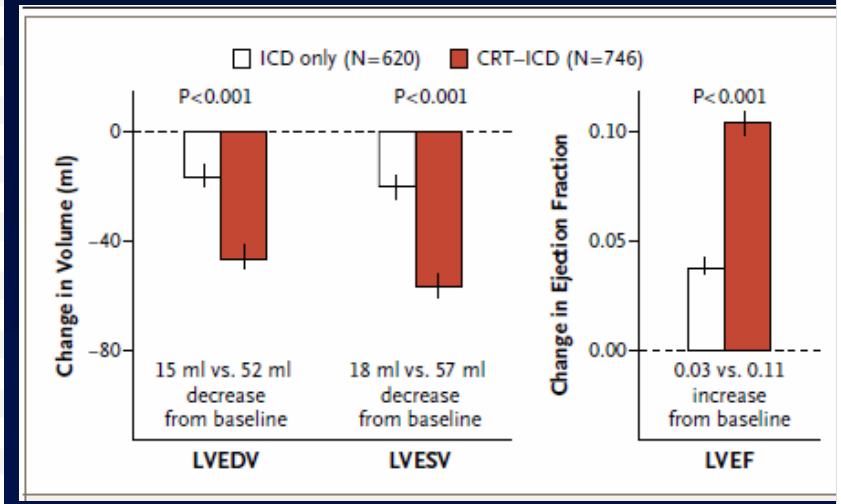

NEJM 2009; 361: 1329-38

Prevention of Disease Progression by Cardiac Resynchronization Therapy in Patients With Asymptomatic or Mildly Symptomatic Left Ventricular Dysfunction

Insights From the European Cohort of the REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) Trial

262 pt, FE < 40%, QRS ⩾ 120 ms

NYHA I e II

F-up = 2 anos

CRT ON

CRT OFF

End point – Piora dos parâmetros de IC

JACC 2009; 54: 000-000

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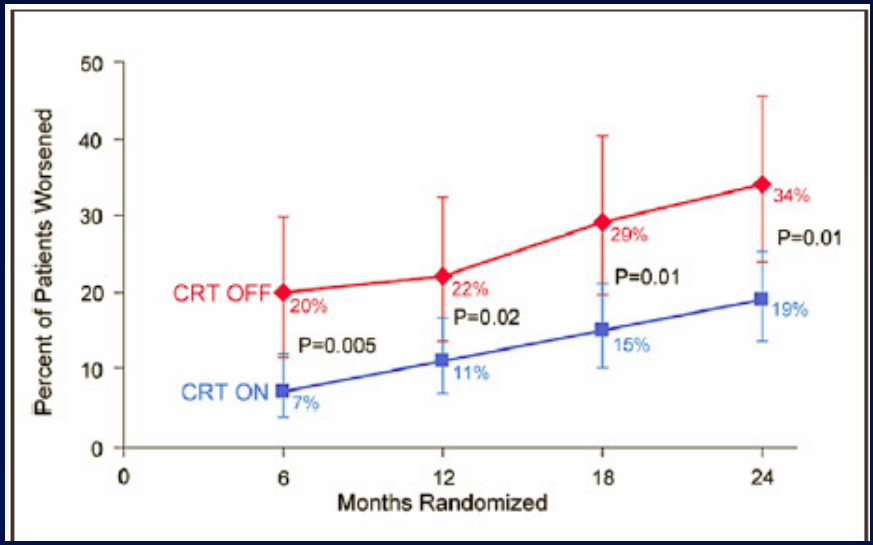

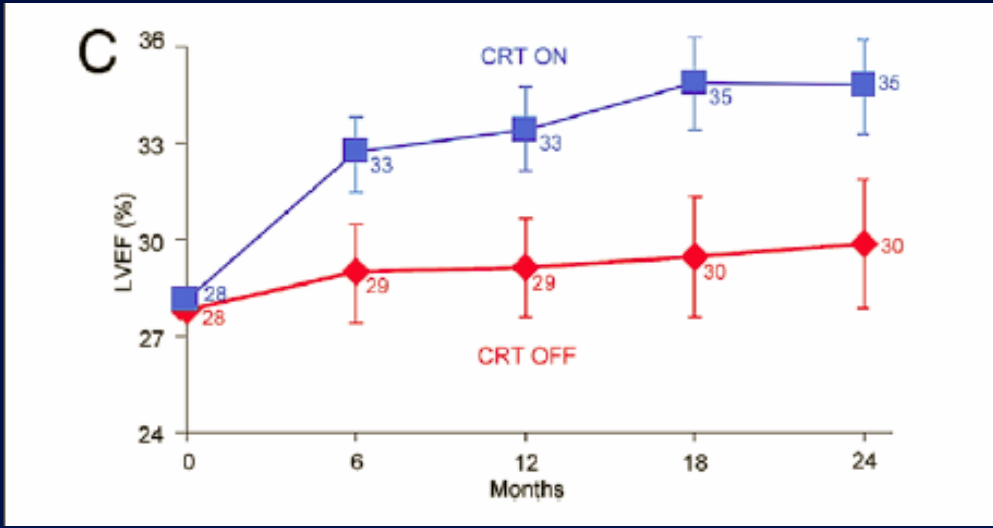

JACC 2009; 54: 000-000

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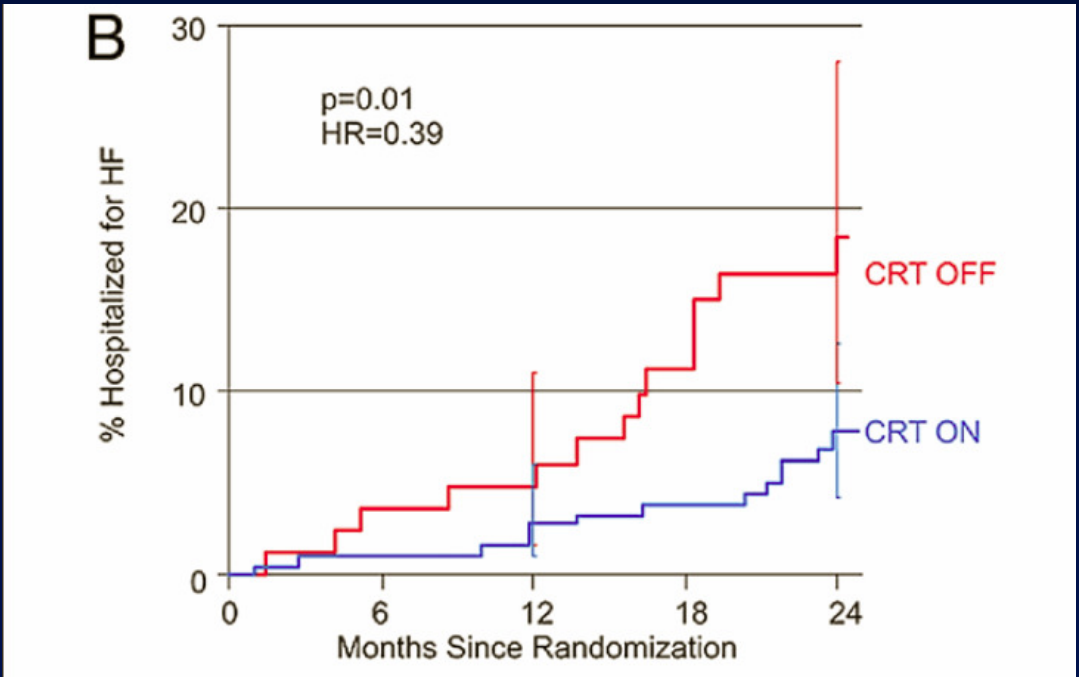
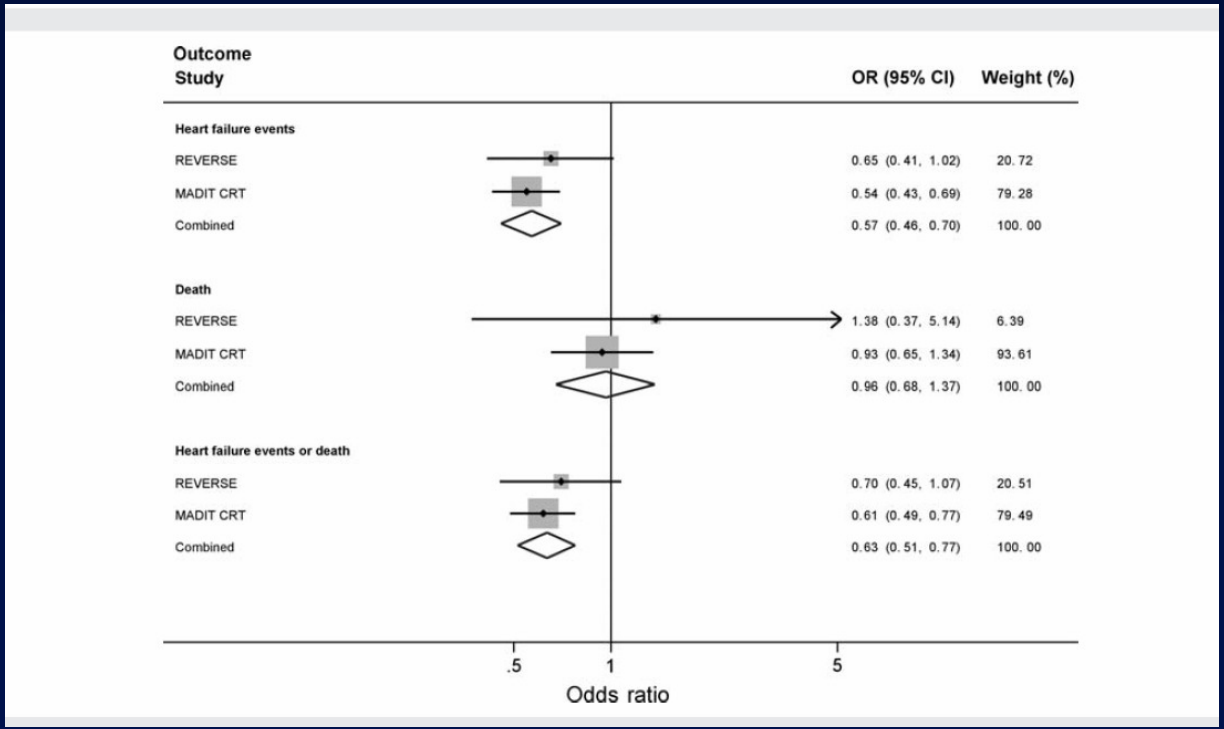


JACC 2009; 54: 000-000

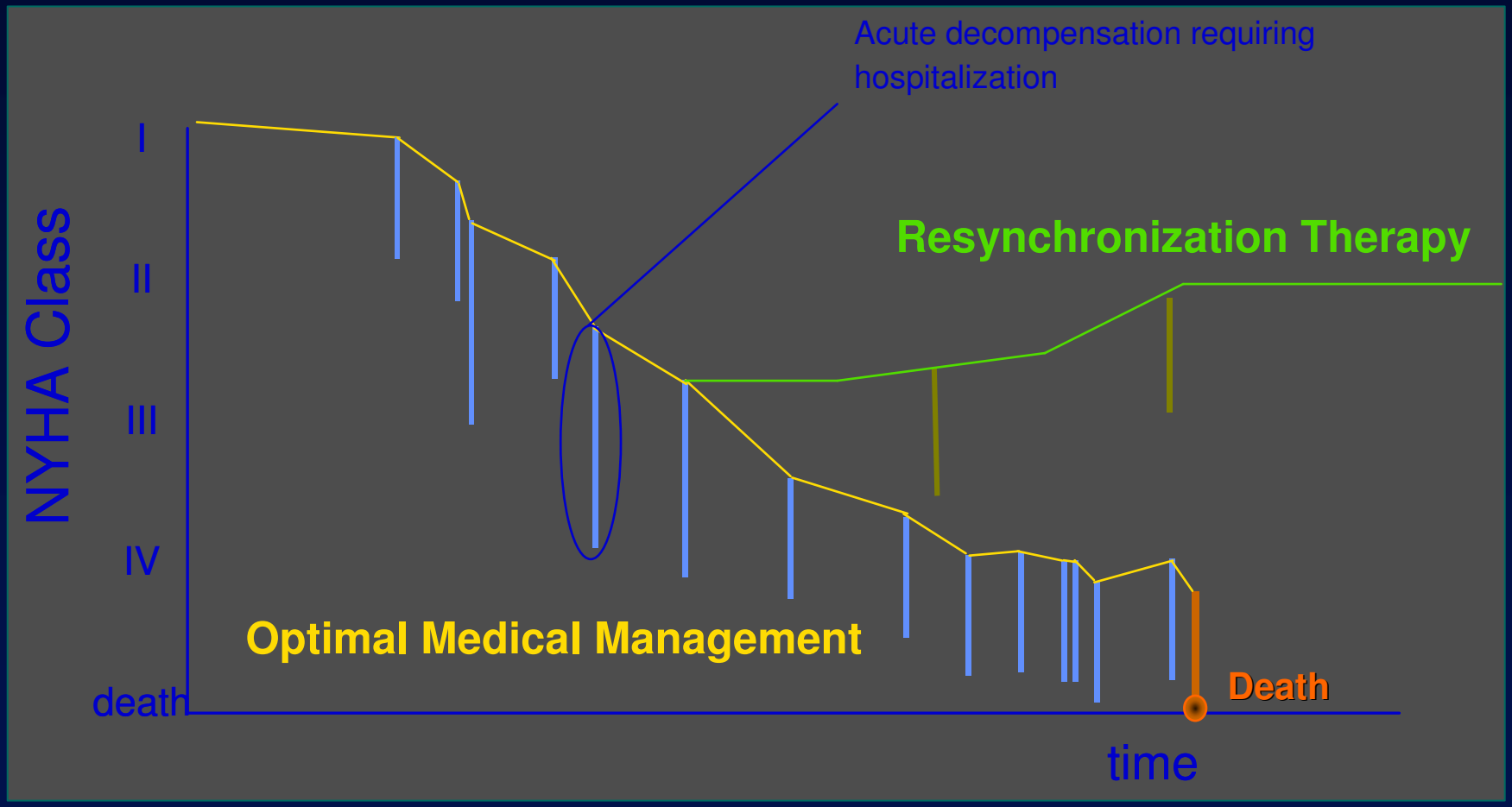
Effectiveness of cardiac resynchronization therapy in mild congestive heart failure: systematic review and meta-analysis of randomized trials

Steven A. Lubitz[1,2†], Peter Leong-Sit[3†], Nowell Fine[3†], Daniel B. Kramer[4,5†], Jagmeet Singh[6], and Patrick T. Ellinor[1,6*]



European Journal of Heart Failure 2010; 12: 360-366

Impacto Esperado da CRT na História Natural da Insuficiência Cardíaca




lorrylorry

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices)

Developed in Collaboration With the American Association for Thoracic Surgery and Society of Thoracic Surgeons

11. Recommendations for Cardiac Resynchronization Therapy in Patients With Severe Systolic Heart Failure

Class I

1. For patients who have LV ejection fraction (LVEF) less than or equal to 35%, a QRS duration greater than or equal to 0.12 seconds, and sinus rhythm, CRT with or without an ICD is indicated for the treatment of New York Heart Association (NYHA) functional Class III or ambulatory Class IV heart failure symptoms with optimal recommended medical therapy. *(Level of Evidence: A)*[101,101a–101c]

Class IIa

1. For patients who have LVEF less than or equal to 35%, a QRS duration greater than or equal to 0.12 seconds, and atrial fibrillation, CRT with or without an ICD is reasonable for the treatment of NYHA functional Class III or ambulatory Class IV heart failure symptoms on optimal recommended medical therapy. *(Level of Evidence: B)*[101,102]
2. For patients with LVEF less than or equal to 35% with NYHA functional Class III or ambulatory Class IV symptoms who are receiving optimal recommended medical therapy and who have frequent dependence on ventricular pacing, CRT is reasonable. *(Level of Evidence: C)*[101]

Circulation 2008; 117: 2820-40

European Heart Journal
doi:10.1093/eurheartj/ehq337

ESC GUIDELINES

2010 Focused Update of ESC guidelines on device therapy in heart failure

An update of the 2008 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure and the 2007 ESC guidelines for cardiac and resynchronization therapy

Recommendation in patients with heart failure in New York Heart Association function class III/IV

Recommendation	Patient population	Class[a]	Level[b]	Ref.[c]
CRT-P/CRT-D is recommended to reduce morbidity and mortality[d]	NYHA function class III/IV LVEF ≤35%, QRS ≥120 ms, SR Optimal medical therapy Class IV patients should be ambulatory[e]	I	A	5–19

European Heart Journal
doi:10.1093/eurheartj/ehq337

ESC GUIDELINES

2010 Focused Update of ESC guidelines on device therapy in heart failure

Recommendation in patients with heart failure in New York Heart Association function class II

Recommendation	Patient population	Class[a]	Level[b]	Ref.[c]
CRT preferentially by CRT-D is recommended to reduce morbidity or to prevent disease progression[d]	NYHA function class II LVEF ≤35%, QRS ≥150 ms, SR Optimal medical therapy	I	A	9, 20–22

Diretrizes Brasileiras de Dispositivos Cardíacos Eletrônicos Implantáveis (DCEI)

SBC-AMB
SOCIEDADE BRASILEIRA DE ARRITMIAS CARDÍACAS - SOBRAC/SBC
DEPARTAMENTO DE ESTIMULAÇÃO CARDÍACA ARTIFICIAL – DECA/SBCCV

Recomendações para implante de Ressincronizador Cardíaco

Classe I

1. Pacientes com FE ≤ 35%, ritmo sinusal, IC com CF III ou IV, apesar de tratamento farmacológico otimizado e com QRS > 150ms *(NE A)*

2. Pacientes com FE ≤ 35%, ritmo sinusal, IC com CF III ou IV, apesar de tratamento farmacológico otimizado, com QRS de 120 a 150ms e comprovação de dissincronismo por método de imagem - *(NE A)*.

Classe IIa

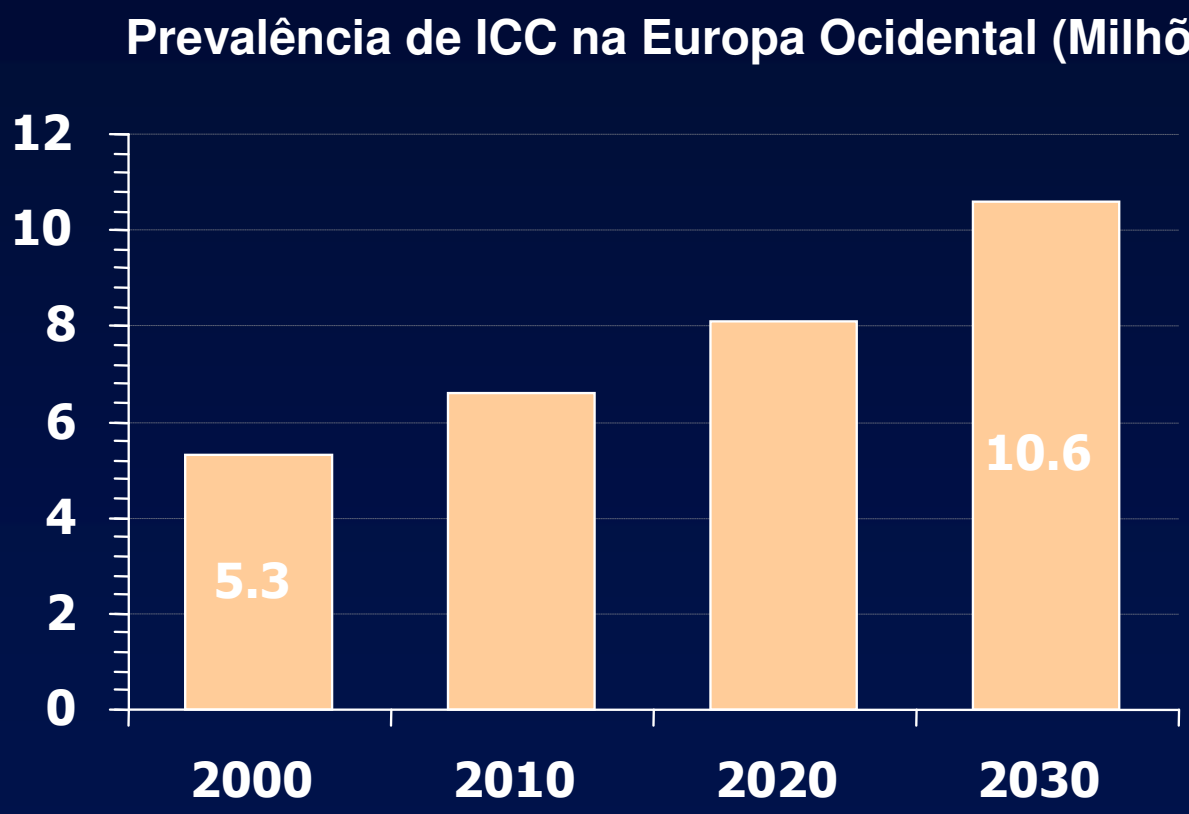
1. Pacientes com IC em CF III ou IV, sob tratamento medicamentoso otimizado, com FE ≤ 35%, dependentes de marcapasso convencional, quando a duração do QRS for superior a 150ms ou quando houver dissincronismo documentado por método de imagem *(NE B)*.

2. Pacientes com FE ≤ 35%, com FA permanente, IC com CF III ou IV, apesar de tratamento farmacológico otimizado e com QRS > 150ms *(NE C)*.

3. Pacientes com FE ≤ 35%, FA permanente, IC com CF III ou IV apesar de tratamento farmacológico otimizado e com QRS de 120 a 150ms com comprovação de dissincronismo por método de imagem *(NE C)*.

Arq Bras Cardiol 2007; 89: e210-e238

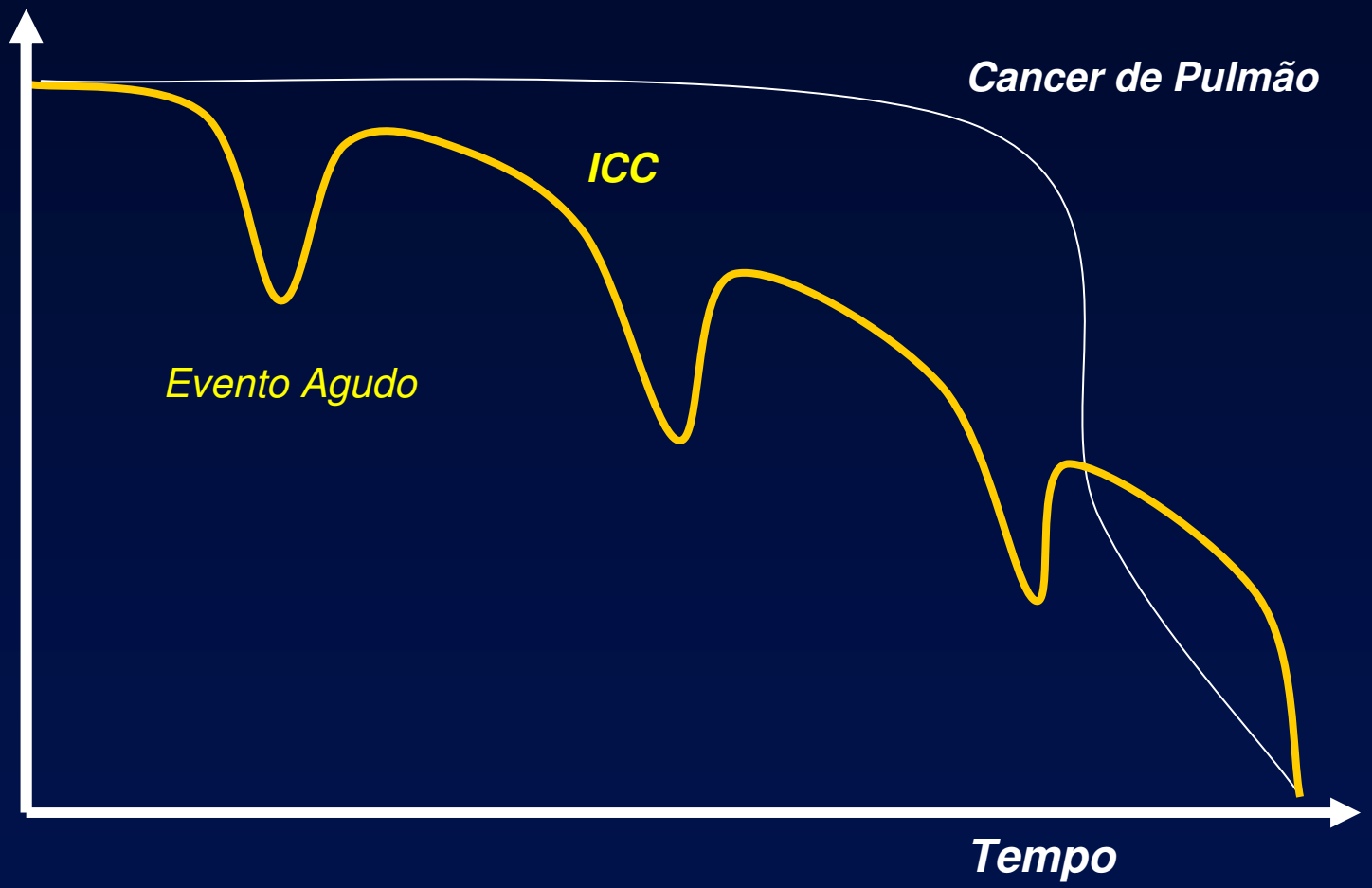
A Prevalência de ICC Deve Dobrar em 30 anos



- População idosa
- Manejo da doença coronaria

Source: New Medicine Reports 1997 ; 1999 Heart and Stroke Statistical Update, AHA

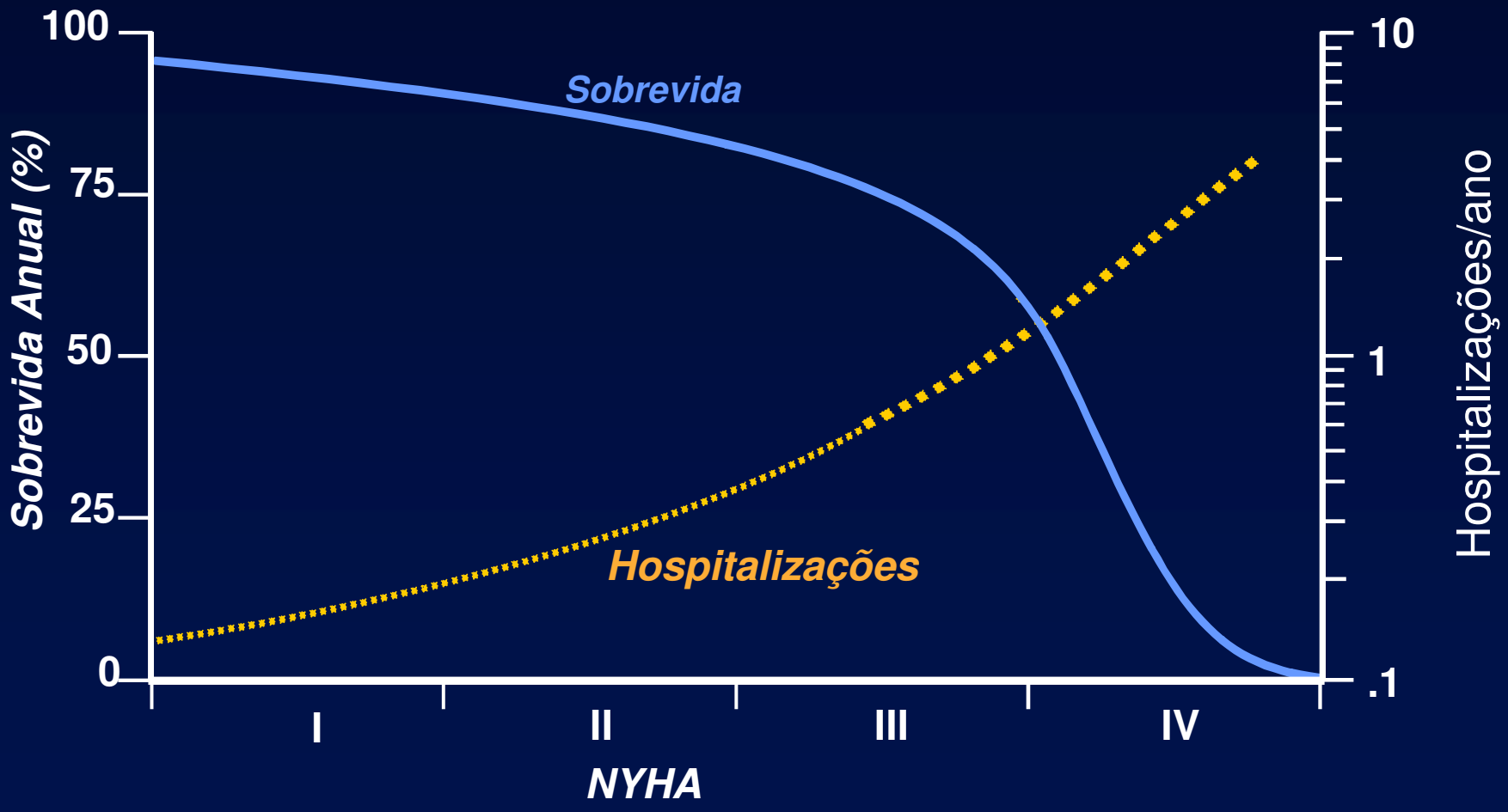
ICC - Tratamento Atual...



- Quase todas as formas de cancer tem melhor prognóstico que ICC

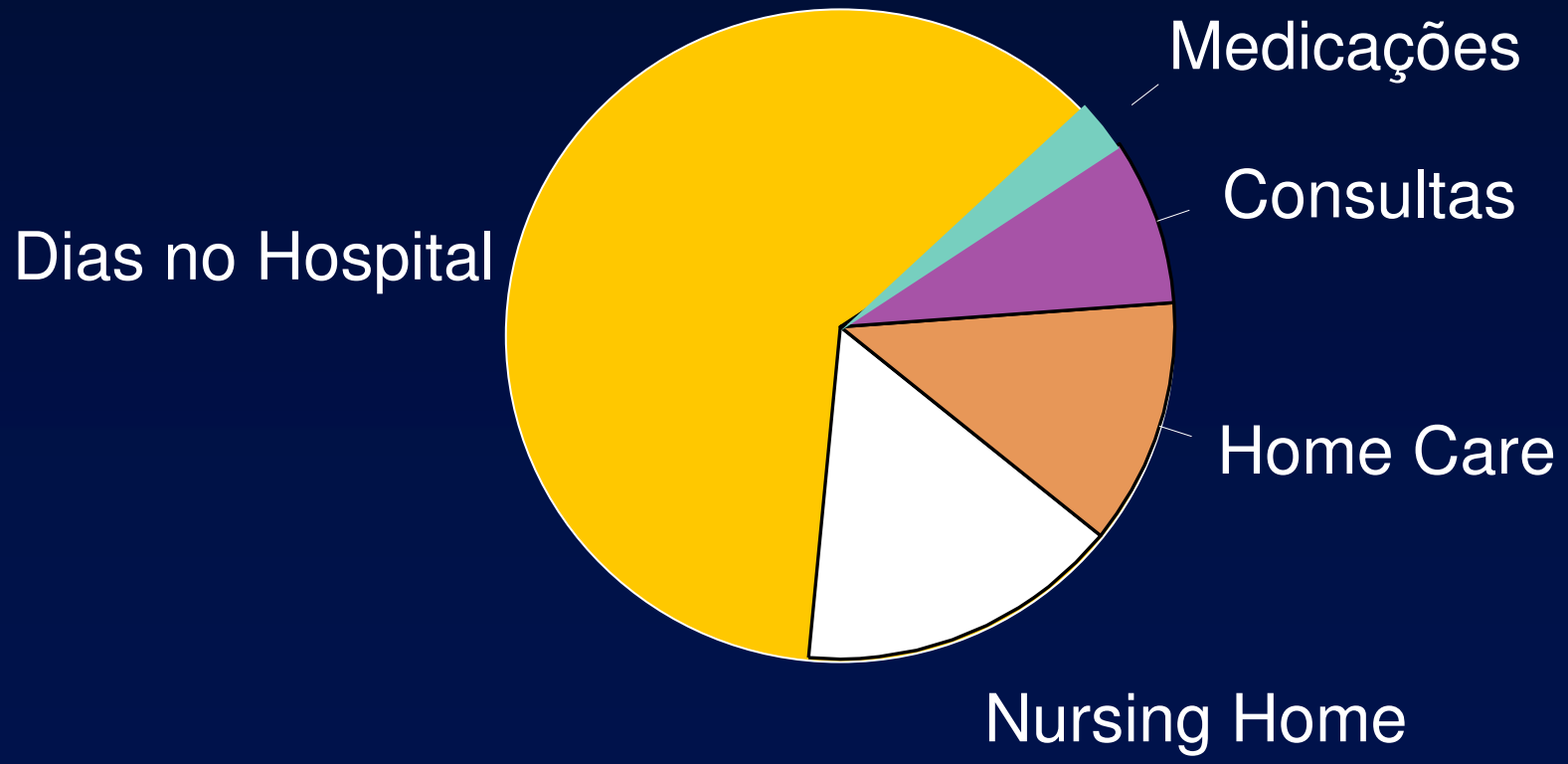
Source: More 'malignant" than cancer? Five-year survival following a first admission for heart failure. Eur J Heart Failure 2001; 3:315-22

ICC - Tratamento Atual...



Hospitalizações - Maior Parte do Custo

Custos diretos nos USA ($19.4 bilhões)



AHA Heart and Stroke Statistical Update 2001

Mais especificamente ...

- Admissões por ICC devem aumentar em 50% nos próximos 25 anos.
- 2/3 dos pacientes com ICC tem ao menos duas admissões por ano.
- Pacientes usam média de 6 medicamentos.
  - 35% dos novos casos de ICC são hospitalizados no primeiro ano após o diagnóstico.
  - Taxa de readmissão por ICC de 20-30% em 3 meses.

Petersen S et al. Coronary heart disease statistics: heart failure supplement. London, British Heart Foundation, 2002
English et al. Crit Care Nurse Q. 1995;18:1-6
Young et al. Clinical Management of Heart Failure. Professional Communications Inc.,2001:xiii,24

CRT: Impact

- Heart failure (USA) → 5.0 million
- 1/3 NYHC 3-4 → 1.7 million
- 70% in sinus rhythm → 1.2 million
- 30 to 40% QRS (>120msec)

What about pts Class 1-2 ?

What about pts in AF ?

What about pts with QRS < 120 ?

~10%

→ 350.000 to 450.000 patients in the US possible candidates to CRT according to the most recently published AHA/ACC/NASPE guidelines .

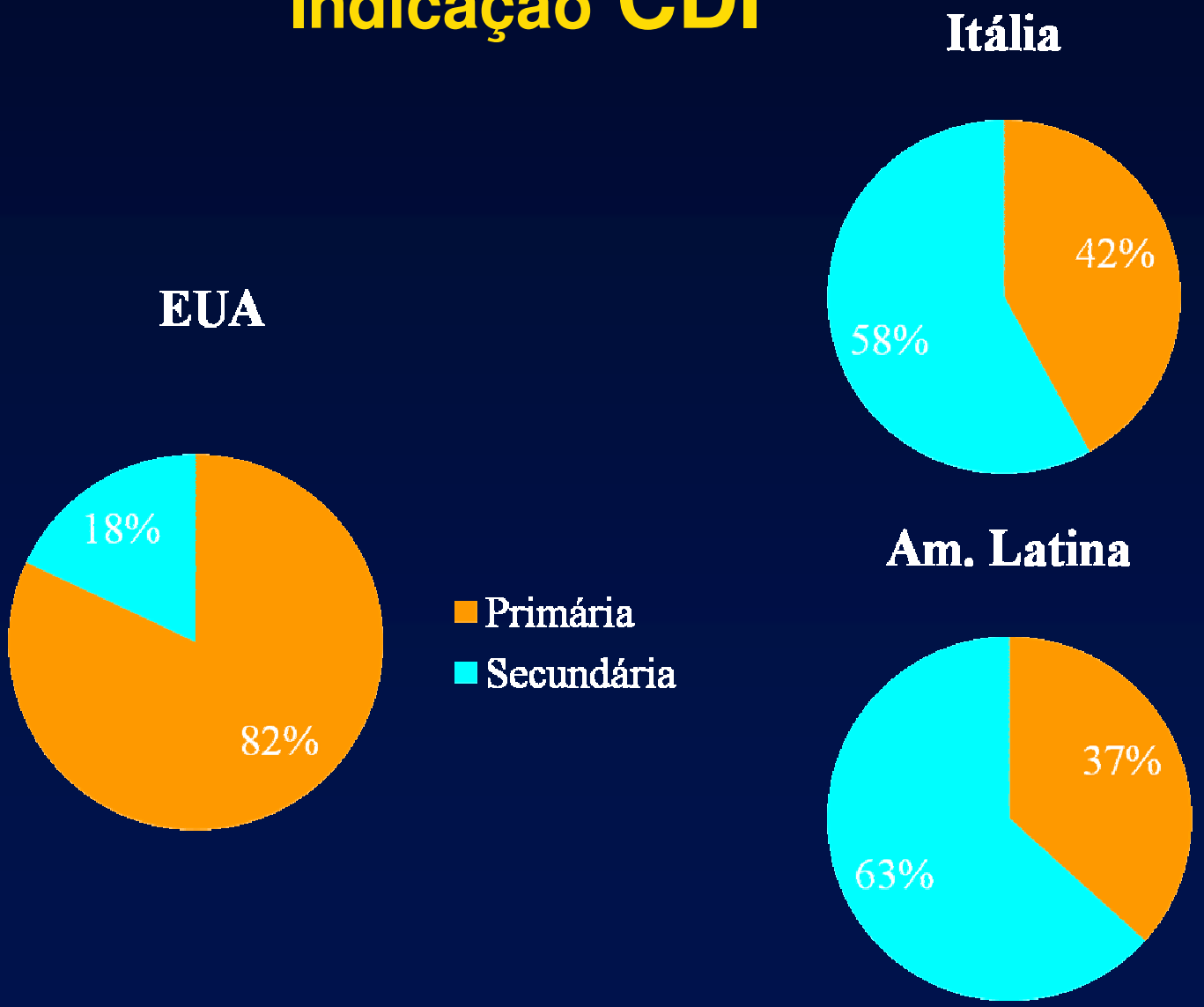
~70%

7%

Can we improve responder rate?

No mundo real...

Indicação CDI

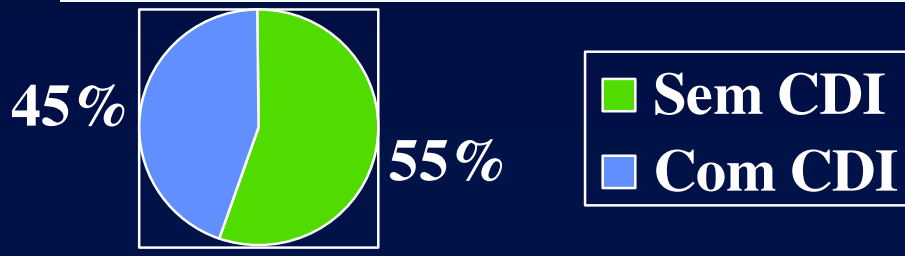


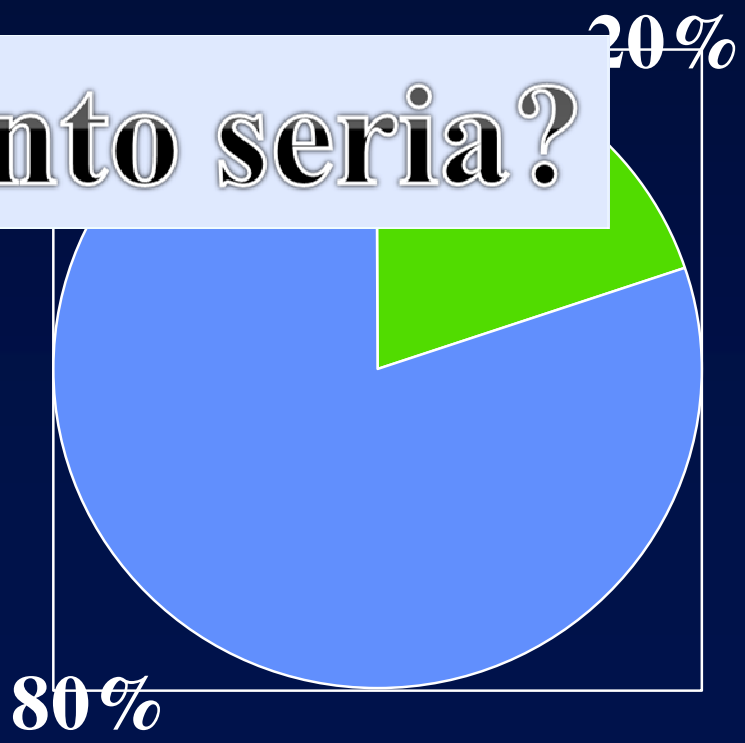
Uso do RC sem e com CDI

Europa

EUA

No Brasil, quanto seria?





O que Esperamos, Enfim...

- Perspectivas futuras:
  - Melhor extratificação de risco
  - Desenvolvimento tecnológico
    - menos choques
    - longevidade e confiabilidade
    - redução de complicações
  - Redução de custos
- Enquanto isso não vem:
  - Bom senso!
  - “Open-mind”!

Obrigado!!!