Cardiologia bazata pe dovezi

Dr C Baicus
Medicina Interna Colentina
www.baicus.ro

cardiologia

- **Specialitatea in care MBD s-a dezvoltat cel mai mult**
- **Studii**
- **BANI!!!**

RCT sponsorizate de industrie

- **Profitul – foarte mare**
  - **Numar mare de utilizatori**
- **Studiile – mai ieftine**
  - **Boli frecvente, pacienti usor de gasit**
  - **Boli cu mortalitate crescuta, rapida**

RAR, NNT depind de riscul bazal

*Table 2. Coronary heart disease (CHD) event prevention for statins v placebo**

Individual trials (combined trials)†	Patient group	Mean or median follow up	RRR (95% CI)	NNT (CI)	NNT/year (CI)
a) AFCAPS/TexCAPS	No CHD, normal cholesterol	5.4 years	37% (21 to 50)	49 (33 to 99)	256 (170 to 514)
b) WOSCOPS	No CHD, high cholesterol	4.9 years	31% (17 to 43)	44 (29 to 95)	217 (141 to 463)
c) CARE	CHD, normal cholesterol	5.0 years	24% (9 to 36)	33 (20 to 99)	167 (100 to 496)
d) LIPID	CHD, normal cholesterol	6.1 years	24% (12 to 35)	28 (20 to 48)	172 (122 to 294)
e) 4S	CHD, high cholesterol	5.2 years	34% (25 to 41)	12 (9 to 17)	63 (49 to 89)

Riscul bazal

NNT

*AFCAPS/TexCAPS = AirForce/Texas Coronary Atherosclerosis Prevention Study; WOSCOPS = West of Scotland Coronary Prevention Study; CARE = Cholesterol and Recurrent Events; LIPID = Long-term Intervention with Pravastatin in Ischaemic Disease trial; 4S = Scandinavian Simvastatin Survival Study. Abbreviations defined in glossary. Data adapted from Kumana *et al*,[1] which contains references for these trials. The combined NNT/year for secondary prevention trials was lower than that for primary prevention and for individual trials only that for 4S was lower than the others ($p<0.05$).

†Results are weighted for combined trials.

Statine preventie BIC: RRR 33%

Risc BIC 3%/an
(30% /10ani)

- Tratament:
  - 8,2% populatia adulta MB

Risc BIC 0,6%/an
(6% /10ani)

- Tratament:
  - 40% populatia adulta MB
- Cost anual:
  - 6 mld £ = 10% buget

Extinderea indicatiei de tratament de la risc **3**% → risc de **1,5**%, ar costa **7500** £ → **12.500** £/an de viata salvat,

Raithatha & Smith, BMJ 2004

Extinderea pietei

- La pacienti cu risc mai mic
  - Date despre prevalenta
  - Diagnosticarea activa
- Inventarea de boli

Nivelul dovezii (EBM)

buna

Studii N-of-1

SR si metaanaliza

I. Studii clinice randomizate

II. Studii de cohortă

III. Studii caz-martor

IV. Serii de cazuri (fara grup martor)

V. Opinia expertului, fizio-patologie

slaba

VALIDITATE

Concurenta specialitatilor

- Pneumologie (astm, BPOC)
- Reumatologie (PR, osteoporoza)
- Gastroenterologie (hepatite virale)
- Neurologie (dementa)
- Psihiatrie (depresie)
- Oncologie
- Diabetologie
- Nefrologie (dializa, eritropoietina)

Au aproape 20% din piață

Top 20 al medicamentelor cu cele mai mari vânzări

Loc	Produs	Valoare (mil. euro)	Cotă de piață (%)
1	Neorecormon	37,5	2,1
2	Pegasys	28,3	1,6
3	Preductal	22,9	1,3
4	Augmentin	21,2	1,2
5	Nurofen	20,9	1,2
6	Zyprexa	20,7	1,1
7	Prestarium	19,6	1,1
8	Tertensif	17,8	1,0
9	Algocalmin	15,1	0,8
10	Detralex	14,7	0,8
11	Sermion	14,7	0,8
12	Glivec	13,2	0,7
13	Seretide	13,1	0,7
14	Plavix	12,7	0,7
15	Ampicilină	11,8	0,7
16	Simvacard	11,4	0,6
17	Sortis	11,3	0,6
18	Clexane	11	0,6
19	Bilobil	10,7	0,6
20	Taxotere	10,7	0,6

SURSA: **Cegedim**

NOTĂ: Aceste date estimează vânzările de produse din farmacii către pacienți

Ziarul Financiar, 2008

Studii fara grup martor

- **RELIEF - detralex**
- **TRUE - preductal MR**

Previne acetilcisteina efectul toxic al doxorubicinei asupra miocardului?

Dovezi non-RCT

- Un experiment pe soareci a sugerat ca acetilcisteina administrata cu 1 h inaintea doxorubicinei scade semnificativ mortalitatea pe termen scurt si lung si scaderea in greutate corporala si miocardica

Dovezi din RCT

- Afectarea miocardica acuta indusa de doxorubicina a fost similara la pacientii care au primit acetilcisteina sau placebo

Ce impact au encainidul si flecainidul asupra mortalitatii la pacientii cu aritmii ventriculare post-IMA?

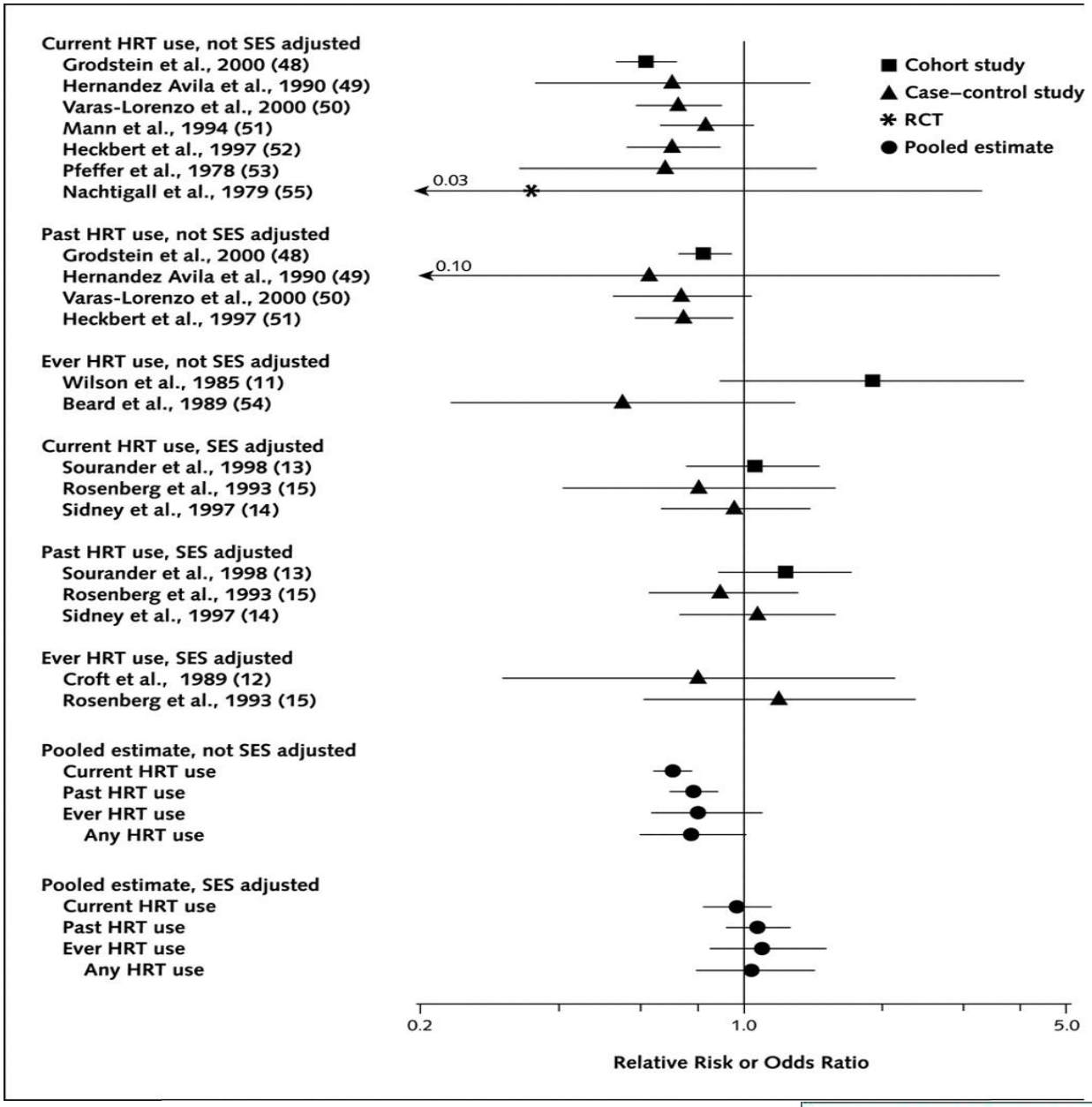
Dovezi non-RCT

- Un studiu inainte/dupa la pacientii cu TV simptomatica, recurenta, anterior refractara la antiaritmice a aratat ca encainidul a eliminat complet recurenta TV la 54% dintre pacienti dupa 6 luni de tratament. "Encainidul este un antiaritmic sigur, bine tolerat”

Dovezi din RCT

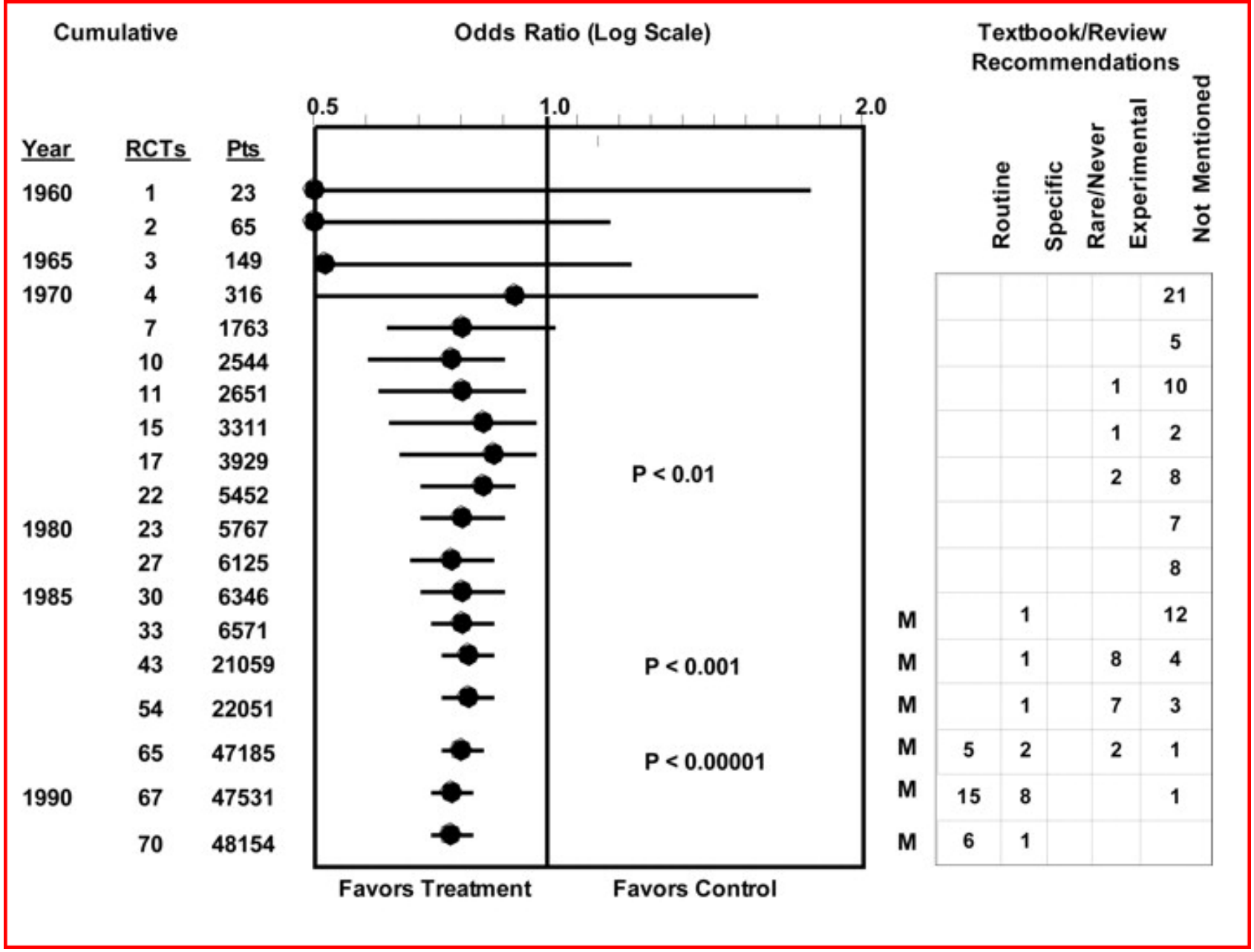
- Patientii tratati cu encainid sau flecainid au avut un risc > 2 ori (RR, 2.64; 95% CI, 1.60–4.36) de moarte cardiaca si stop cardiac fata de cei tratati cu placebo

Relative risk or odds ratio for coronary artery disease incidence

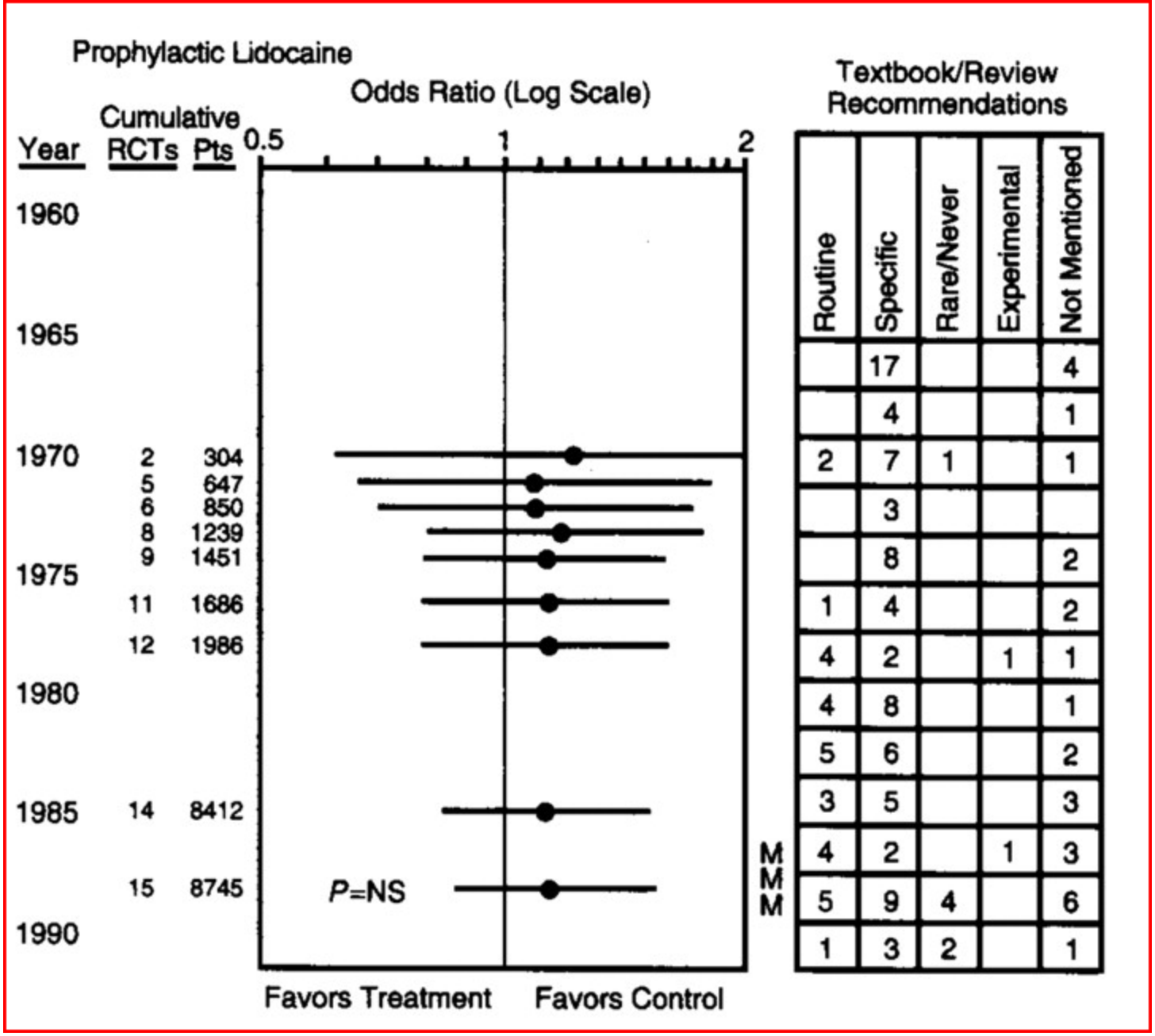


Humphrey, L. L. et. al. Ann Intern Med 2002;137:273-284

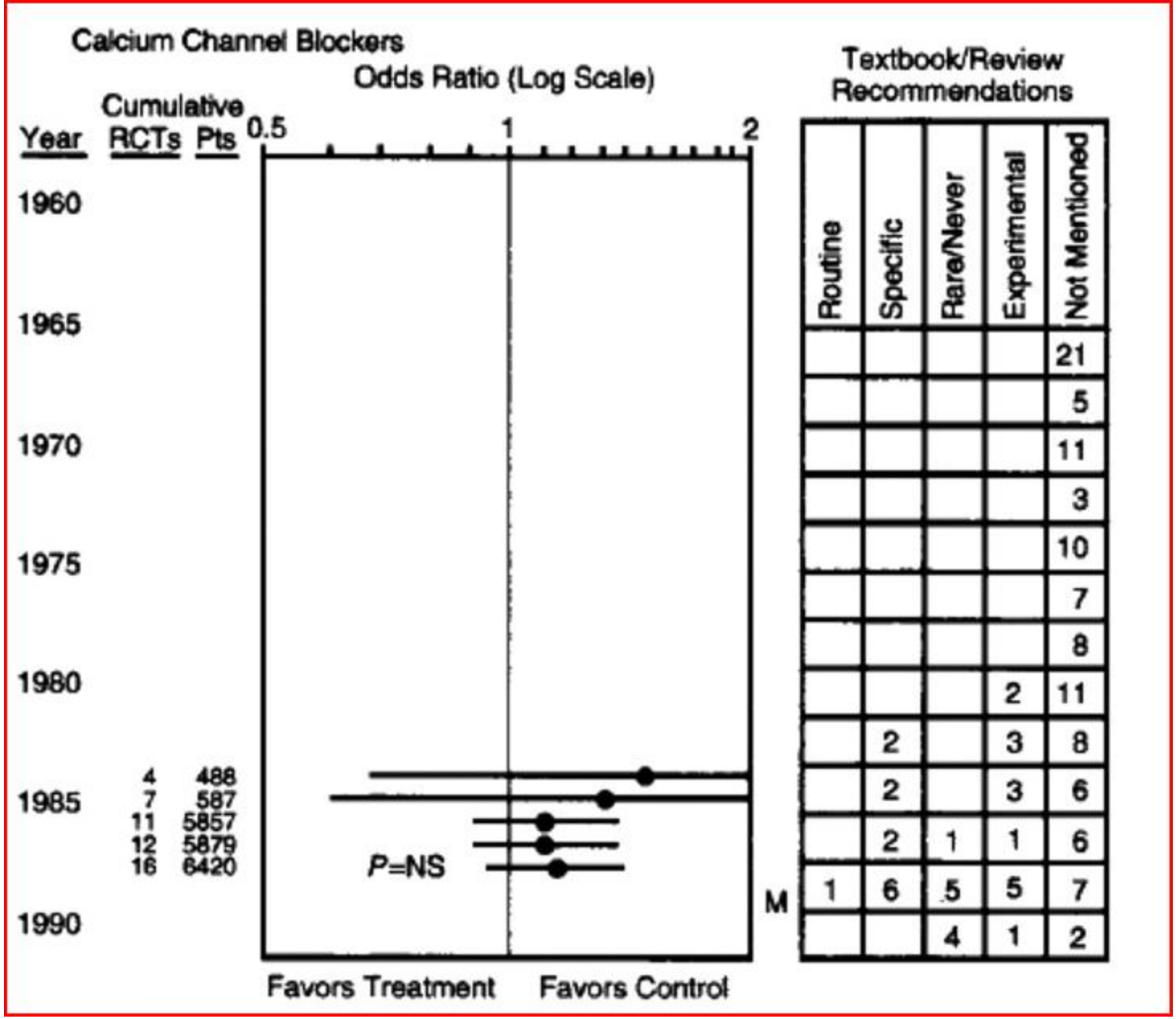
Annals of Internal Medicine



Trombolíza in IMA



Xilina la pacienti cu IMA



BCC la pacientii cu IMA

↓ calitatea RCT

I. Limite metodologice

- **Randomizare incorecta (neascunsa)**
- **Lipsa orbirii**
- **Pierderi din vedere importante (>20%)**
- **Oprirea precoce pentru eficacitate**

pot introduce erori sistematice

Guyatt (GRADE), 2006

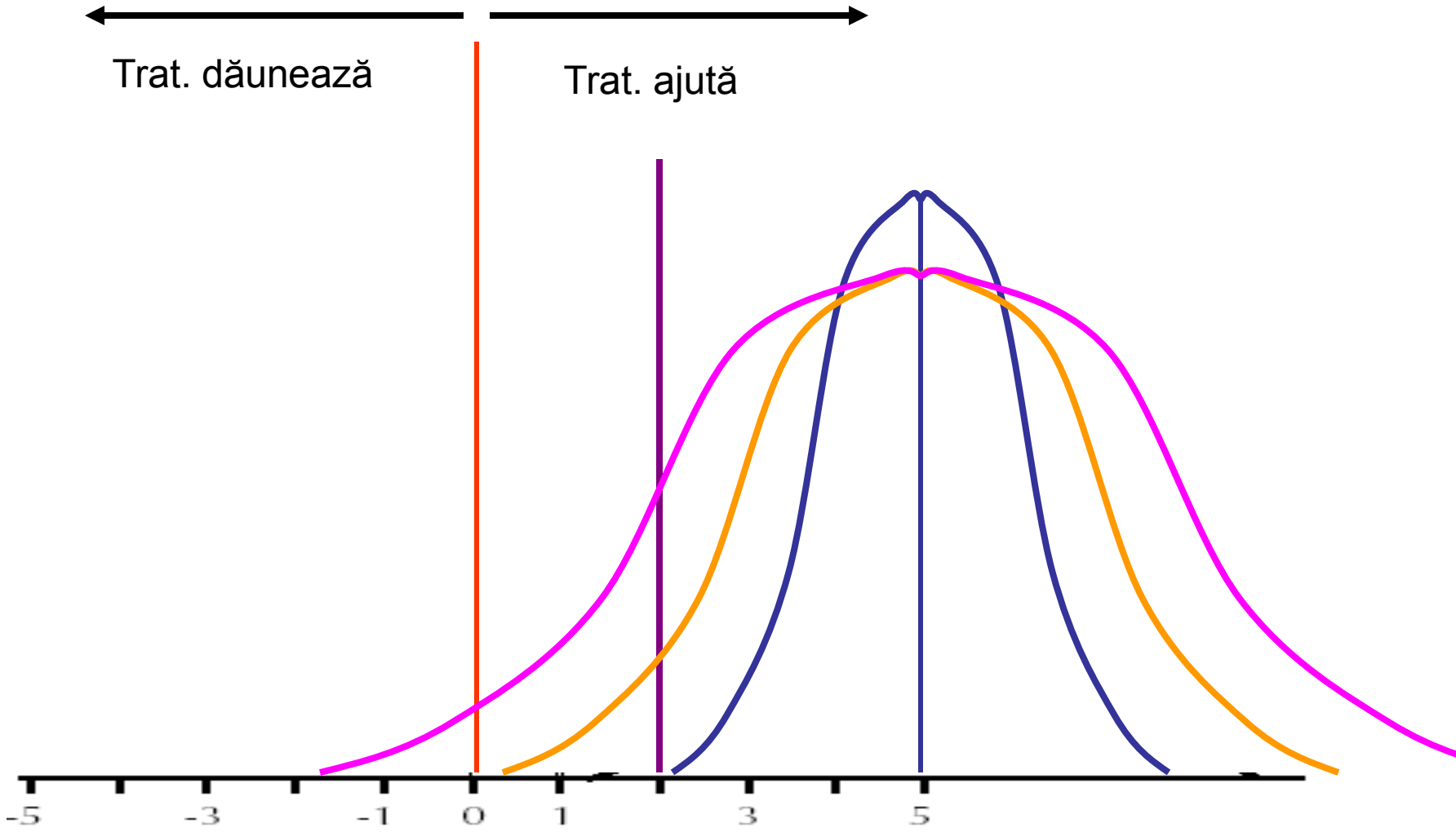
↓ calitatea RCT

II. Esantioanele mici care duc la intervale de incredere largi (nesiguranta)

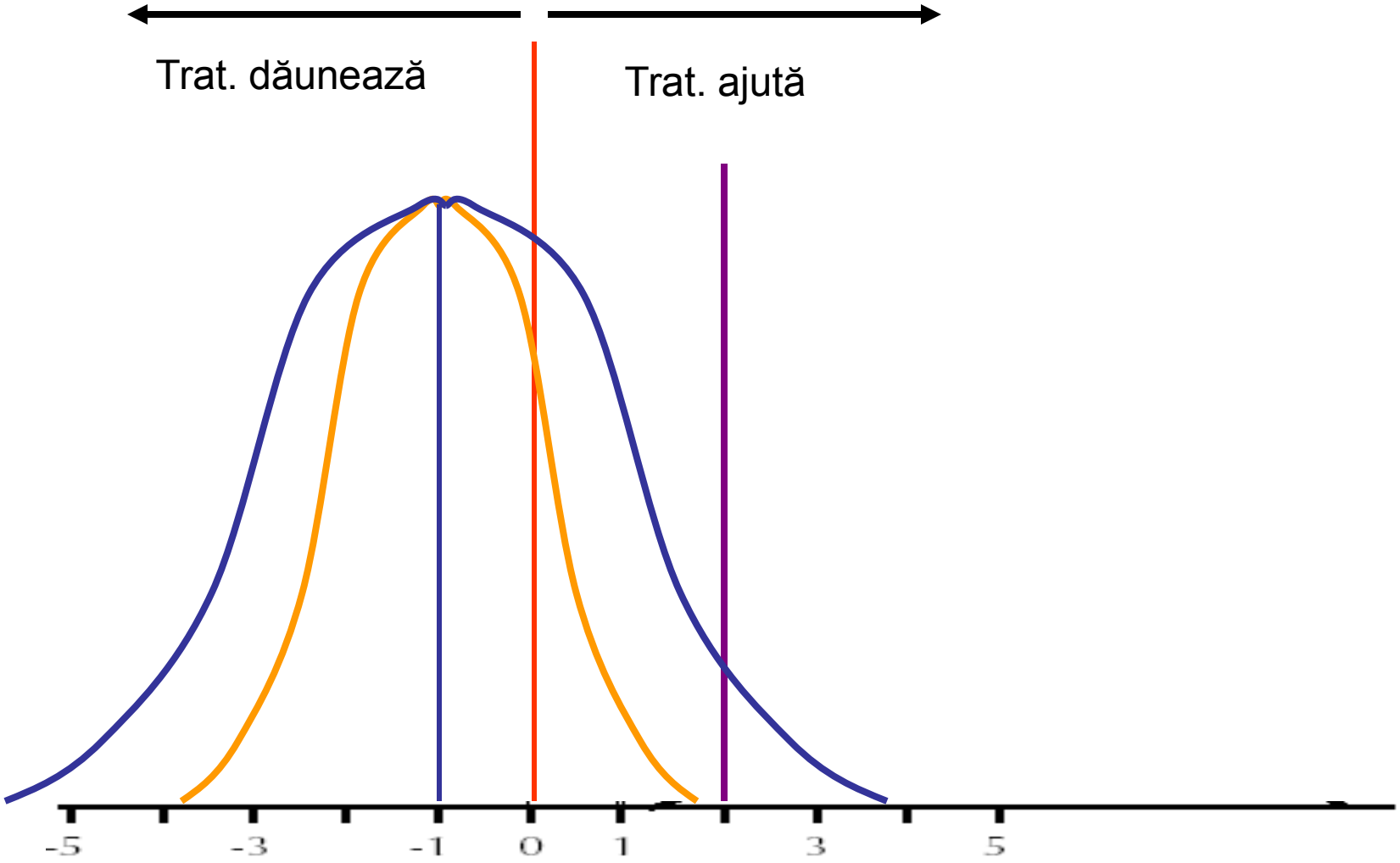
III. Efecte neorientate catre pacient (surogat)

....etc

Guyatt (GRADE), 2006



RRA

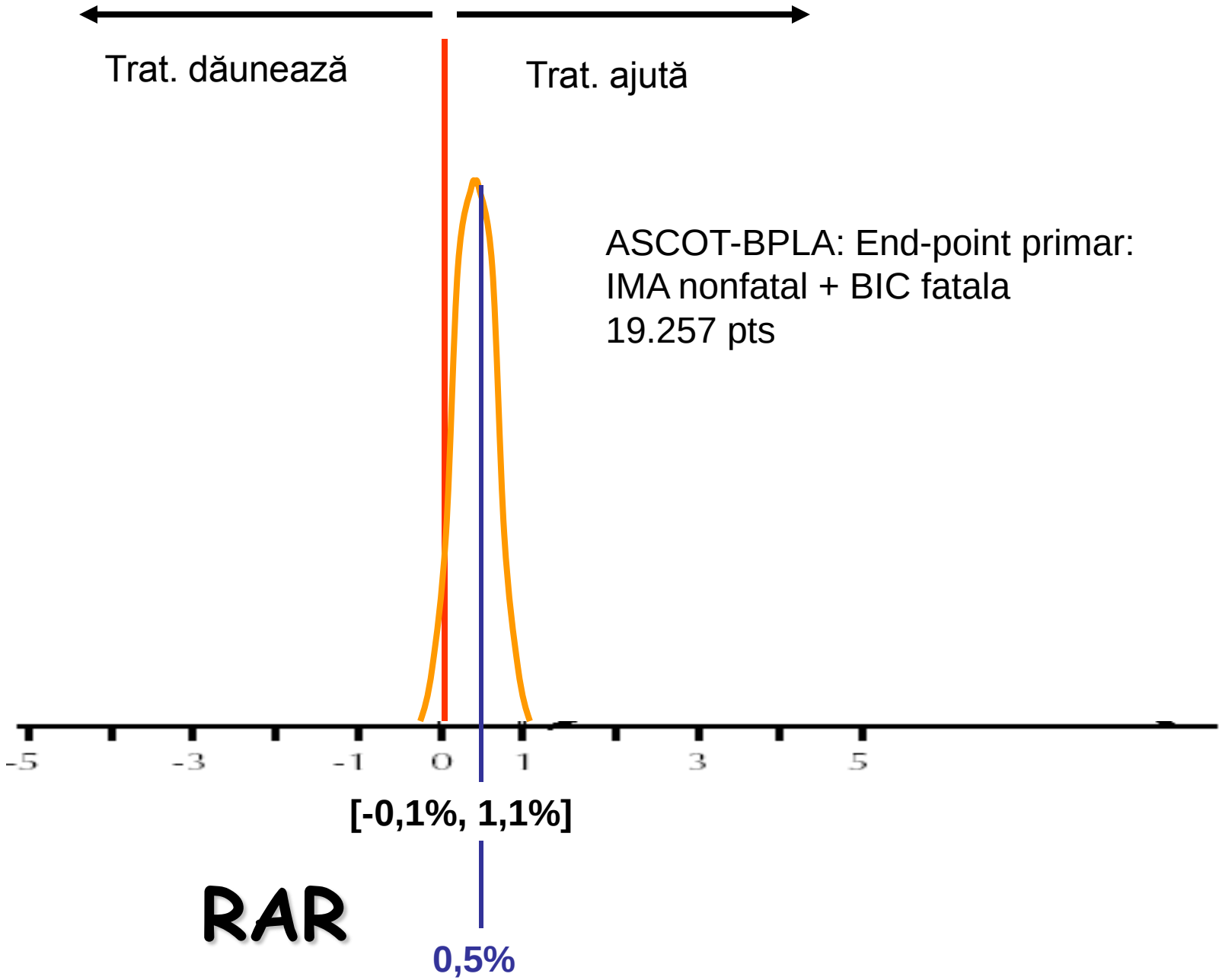


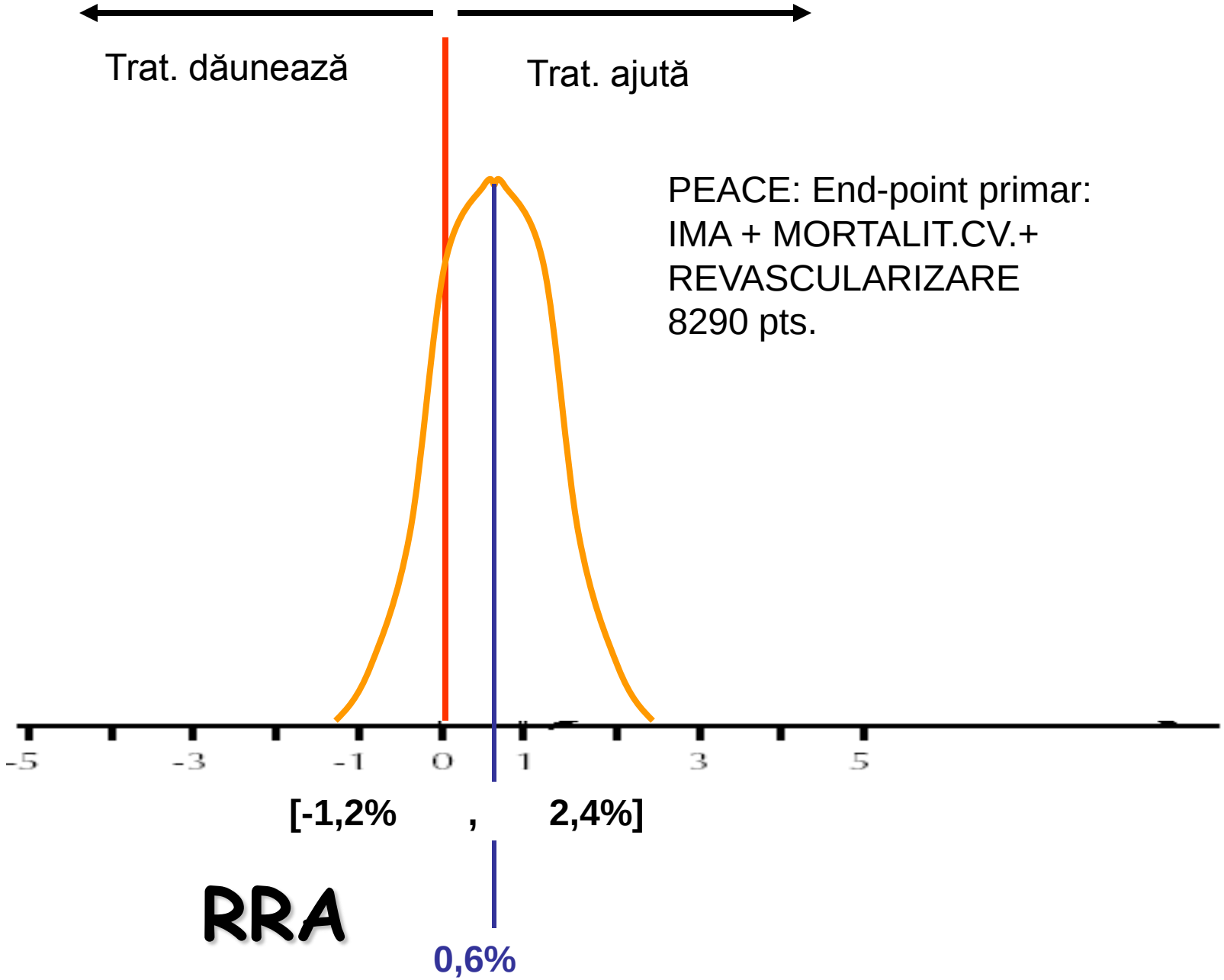
RRA

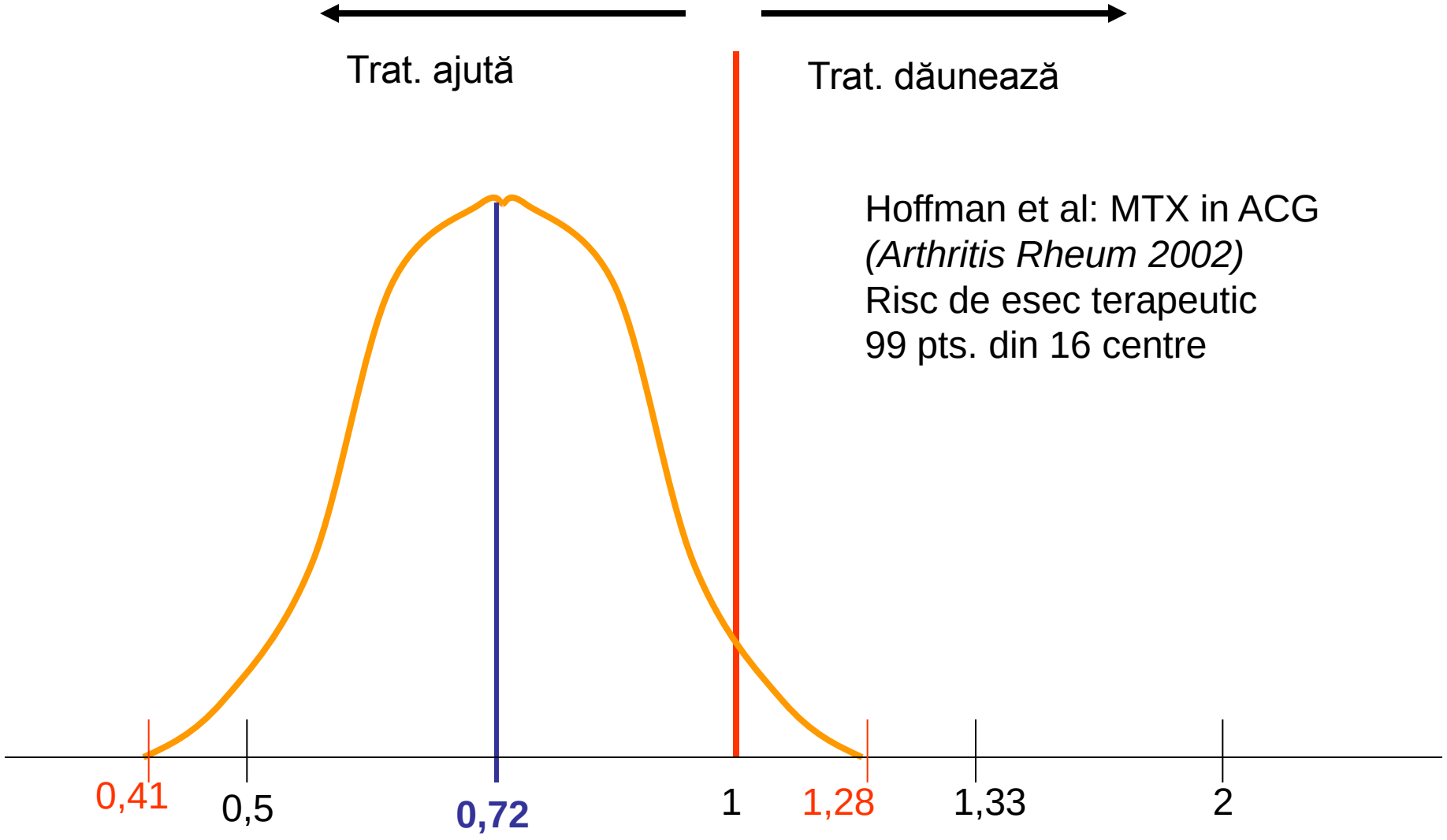
End point-uri		Rezultate[1]	
End point combinat	IM nonfatal (inclusiv silenţios) şi boală cardiacă ischemică fatală	-10%	0,5%
End point-uri secundare	IM nonfatal (exclusiv silenţios) şi boală cardiacă ischemică fatală	-13%	
	Evenimente coronariene totale	-13%	2.5%
	Mortalitate cardiovasculară	-24%	≈0,8%
	Mortalitate totală	-11%	0.9%
	AVC fatal şi nonfatal	-23%	1%
	IC fatală şi nonfatală	-16%	
	Cazuri noi de diabet	-30%	
		RRR	RRA

Tabelul 2. End point-urile evaluate în studiul ASCOTşi rezultatele finale comunicate la ESC 2005.

ASCOT - BPLA


Trat. dăunează
Trat. ajută
ASCOT-BPLA: End-point primar:
IMA nonfatal + BIC fatala
19.257 pts
-5
-3
-1
0
1
3
5
[-0,1%, 1,1%]
RAR
0,5%


Trat. dăunează
Trat. ajută
PEACE: End-point primar:
IMA + MORTALIT.CV.+
REVASCULARIZARE
8290 pts.
-5
-3
-1
0
1
3
5
[-1,2%
,
2,4%]
RRA
0,6%


Trat. ajută
Trat. dăunează
Hoffman et al: MTX in ACG
(Arthritis Rheum 2002)
Risc de esec terapeutic
99 pts. din 16 centre
0,41
0,5
0,72
1
1,28
1,33
2

RR

- D Altman - **The scandal of poor medical research** (*BMJ 1994*)
- E von Elm, M Egger – **The scandal of poor epidemiologic research** (*BMJ 2004*)

- J Freiman et al – The importance of beta, the type II error, and **sample size** in the design and interpretation of the randomized controlled trial: survey of two sets of “negative” trials (*Medical uses of statistics, Mosteller&Baillar, NEJM Books 1991)*

Table 1 Clinical characteristics of the congestive heart failure outpatient cohort (n = 175)

Age (years)	71.1 (11.2)
Men	135 (77%)
NYHA	2.7 (0.53)
LVEF (%)	36.1 (12.1%)
Hyperlipidaemia	99 (55%)
Smoking	65 (37%)
Hypertension	101 (58%)
Diabetes mellitus	62 (35%)
Ischaemic heart disease	130 (74%)
Chronic atrial fibrillation	52 (30%)
TIA/CVA	20 (11%)
PTCA or CABG	92 (53%)
ACE inhibitors/ARBs	140 (80%)
Spironolactone	77 (44%)
β blockers	128 (73%)

Data are mean (SD) or number (%).
ACE, angiotensin-converting enzyme; ARB, angiotensinogen receptor blockers; CABG, coronary artery bypass surgery; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PTCA, percutaneous transluminal coronary angioplasty; TIA, transient ischaemic attack.

George J et al.
Heart 2006;92:1420–1424.

1: Am J Kidney Dis. 2004 Apr;43(4):617-23.

Related Articles, Links

Am J Kidney Dis

Influence of antiviral therapy in hepatitis C virus-associated cryoglobulinemic MPGN.

Alric L, Plaisier E, Thébault S, Péron JM, Rostaing L, Pourrat J, Ronco P, Piette JC, Cacoub P.

Service de Médecine Interne, Pavillon Dieulafoy, CHU Purpan, Toulouse, France. alric.l@chu-toulouse.fr

BACKGROUND: The influence of hepatitis C virus (HCV) treatment on the course of HCV cryoglobulinemic membranoproliferative glomerulonephritis (MPGN) is controversial. METHODS: Twenty-five patients with nephrotic-range proteinuria, mixed cryoglobulinemia, MPGN proved by renal biopsy, and HCV infection were studied for their response to antiviral treatment. RESULTS: After first-line treatment with prednisone, furosemide, or plasmapheresis, antiviral therapy with standard or pegylated interferon alfa and ribavirin was introduced in 18 patients. These patients were compared with 7 patients who did not receive antiviral treatment. Mean duration of antiviral treatment was 18 +/- 10 months, with a follow-up of at least 6 months after treatment withdrawal. HCV RNA clearance (sustained virological response) was achieved in 12 of 18 patients. Compared with values before antiviral therapy, a decrease in proteinuria was observed in sustained virological responders at the end of combination therapy, as well as at the end of follow-up (mean, 2.85 +/- 2.2 [SD] versus 1 +/- 1.4 and 0.4 +/- 0.8 g/d, respectively; $P < 0.05$). In sustained virological responders, cryoglobulin levels at the end of treatment (0.29 +/- 0.4 g/L) and end of follow-up (0.25 +/- 0.4 g/L) were decreased ($P < 0.05$) compared with pretreatment values (1.38 +/- 2.2 g/L). Conversely, no changes in serum cryoglobulinemia levels were observed in nonresponders or controls. Serum creatinine levels remained stable in the 18 patients with antiviral therapy, regardless of response to treatment. CONCLUSION: Anti-HCV treatment improved HCV-associated cryoglobulinemic glomerulonephritis.

Publication Types:

- Clinical Trial

Puterea statistica

- EUROPA
- HYVET

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Piaggesi A, et al. ***An off-the-shelf instant contact casting device for the management of diabetic foot ulcers: a randomized prospective trial versus traditional fiberglass cast.*** Diabetes Care. 2007 Mar;30(3):586-90. PMID: 17327325

Read the Abstract (PubMed) ... Free Full Text ...

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Endocrine	5 of 7	5 of 7	
Surgery - General	4 of 7	3 of 7	
Surgery - Vascular	5 of 7	6 of 7	

< 0.001). Practicability was more favorable in group B, with a reduction of 77 and 58% of the time required for application and removal of the devices, respectively (P < 0.001). Patients` satisfaction with the treatment was higher in group B (P < 0.01). CONCLUSIONS: The Optima Diab walker is as safe and effective as TCC in the management of DFU, but its lower costs and better applicability may be of help in spreading the practice of off-loading among the centers that manage the diabetic foot.

Comments For: Internal Medicine

Comment 1:
There is a minor deficiency in that there is no conflict of interest statement.

Comment 2:
Good information. This is probably most useful to the orthopedic or podiatric practitioners we would consult for diabetic foot ulcers of this extent, requiring non-weight bearing.

Comment 3:
The difference of 10% (ARR) at 12 weeks might have not been statistically significant due to the low power of the study (40 patients) - only p, and not the confidence intervals, are given to judge this situation; probably the CI are very large, covering a clinically important difference, too. Indeed, computed with EBM Calculator ver.1.0, the ARR confidence interval was [-0.08 , 0,283], where an ARR of 28% is very important!

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Saab S, et al. ***TIPS versus paracentesis for cirrhotic patients with refractory ascites.*** Cochrane Database Syst Rev. 2006 Oct 18;(4):CD004889. PMID: 17054221

Read the Abstract (PubMed) ...

RATED BY DOCTORS IN	RELEVANCE	NEWSWORTHINESS	COMMENTS
IM/Referred Care/Hospitalists	5 of 7	5 of 7	View
Gastroenterology	6 of 7	5 of 7	
Surgery - General	6 of 7	4 of 7	

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Abstract

BACKGROUND: Refractory ascites (ie, ascites that cannot be mobilized despite sodium restriction and diuretic treatment) occurs in 10 per cent of patients with cirrhosis. It is associated with substantial morbidity and mortality with a one-year survival rate of less than 50 per cent. Few therapeutic options currently exist for the management of refractory ascites. OBJECTIVES: To compare transjugular intrahepatic portosystemic stent-shunts (TIPS) versus paracentesis for the treatment of refractory ascites in

between the two groups. AUTHORS`
CONCLUSIONS: The meta-analysis supports that TIPS was more effective at removing ascites as compared with paracentesis without a significant difference in mortality, gastrointestinal bleeding, infection, and acute renal failure. However, TIPS patients develop hepatic encephalopathy significantly more often.

Comments For: IM/Referred Care/Hospitalists

Comment 1:
The metaanalysis didn`t have enough power, the confidence intervals are still too large (for example: mortality at 30 days - from decreased with 90% by TIPS compared to paracentesis, to decreased with 90% by paracentesis compared to TIPS).

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Shibata MC, et al. ***The effects of angiotensin-receptor blockers on mortality and morbidity in heart failure: a systematic review.*** Int J Clin Pract. 2008 September;62(9):1397-1402.

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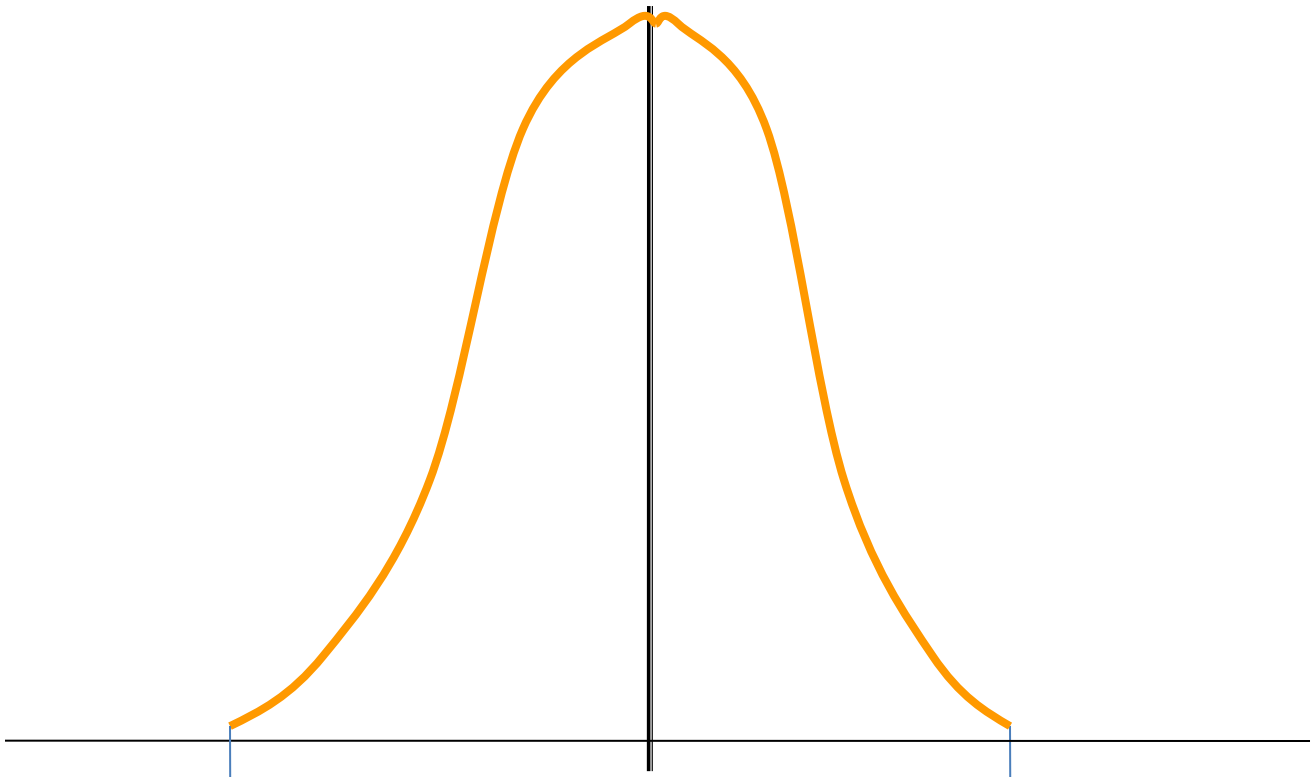
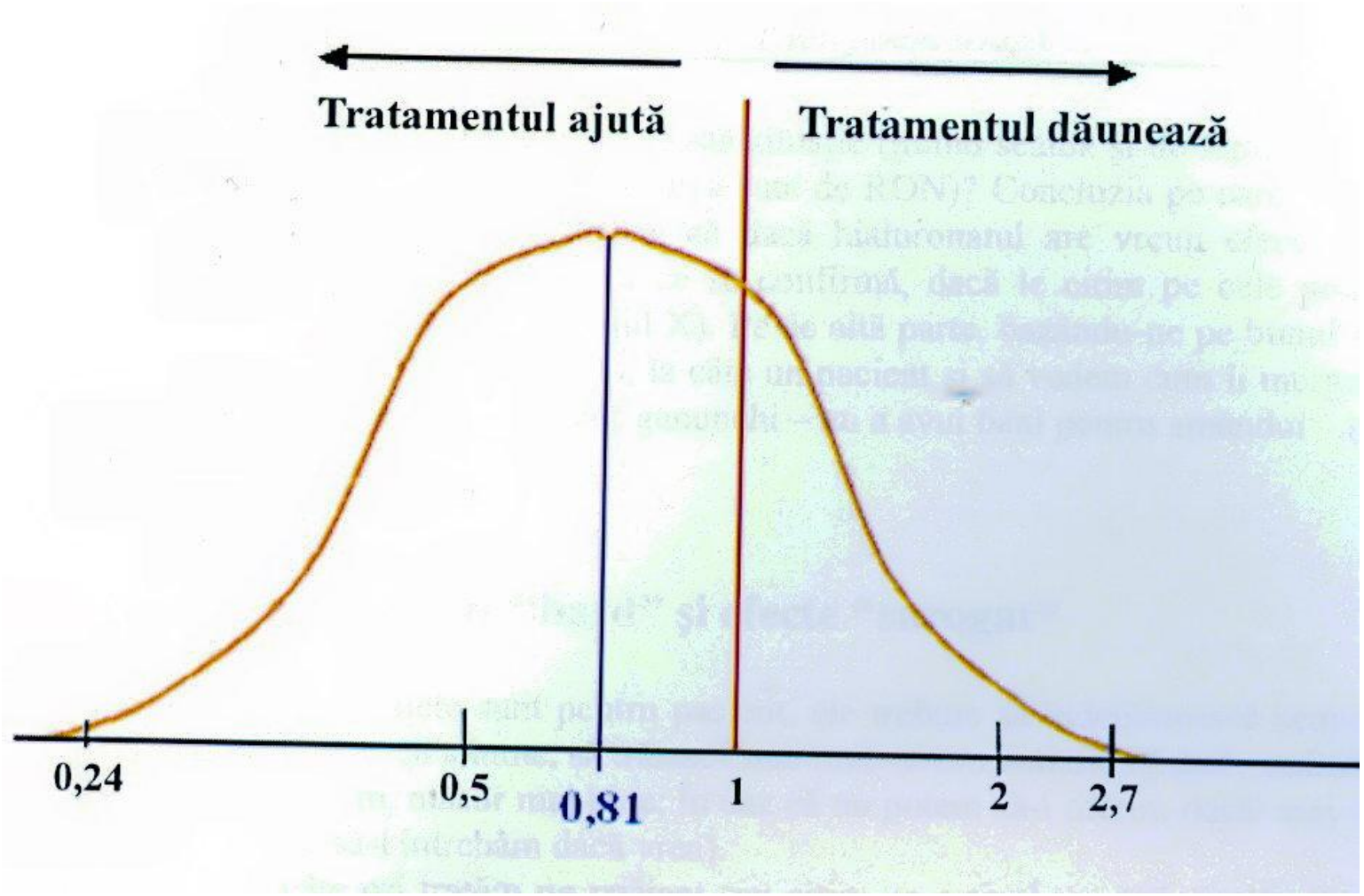
Abstract

27.495 pts, 2002-2007

Deces, ARB / ACEi: RR = **1,06** (95%CI: 0,56 – 1,62)

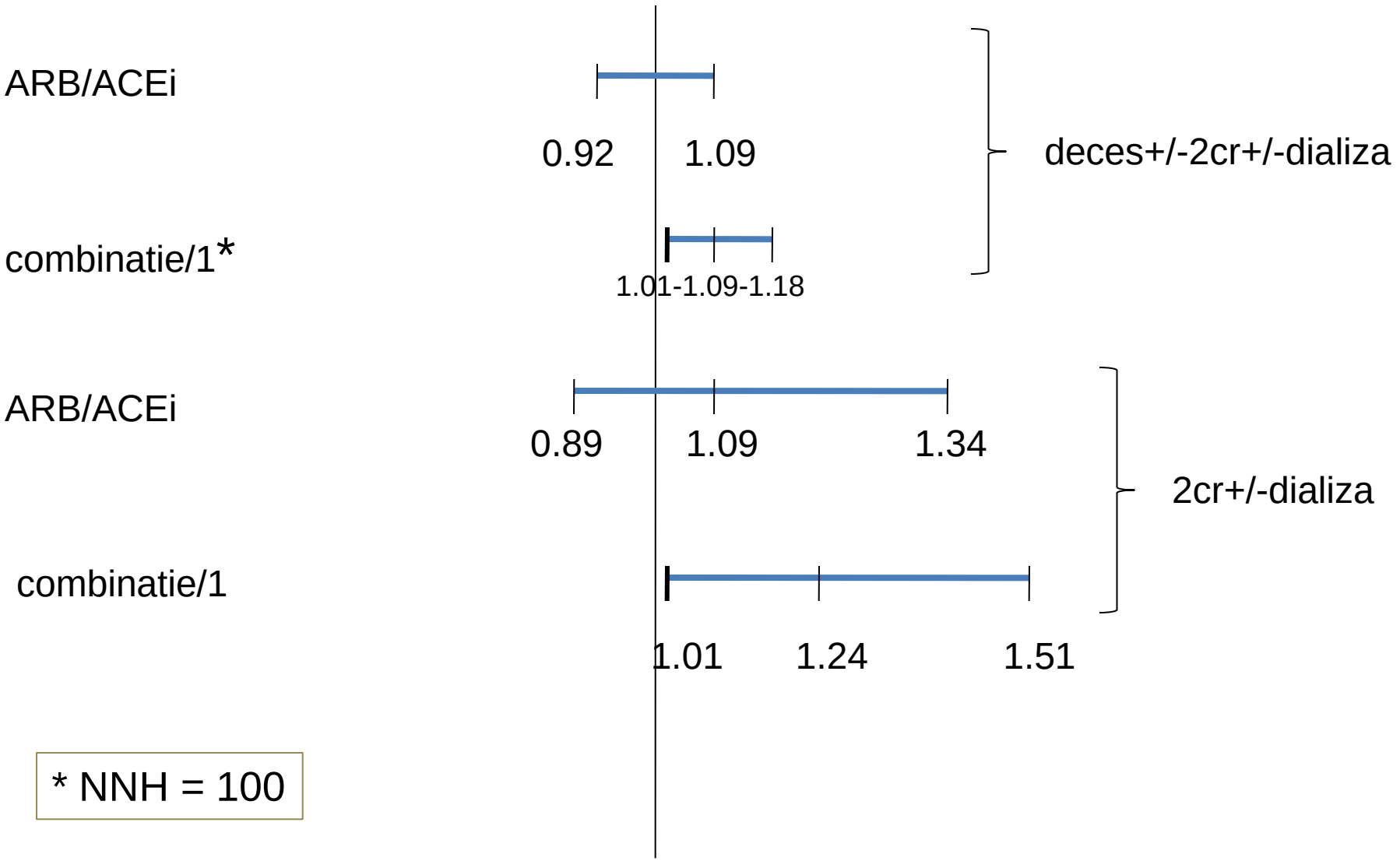




Diabet fara nefropatie: efectul ACEi in raport cu placebo (riscul de dublare a creatininei) (metaanaliza Strippoli et al, Cochrane Library 2005)

3 studii, 2683 pts.

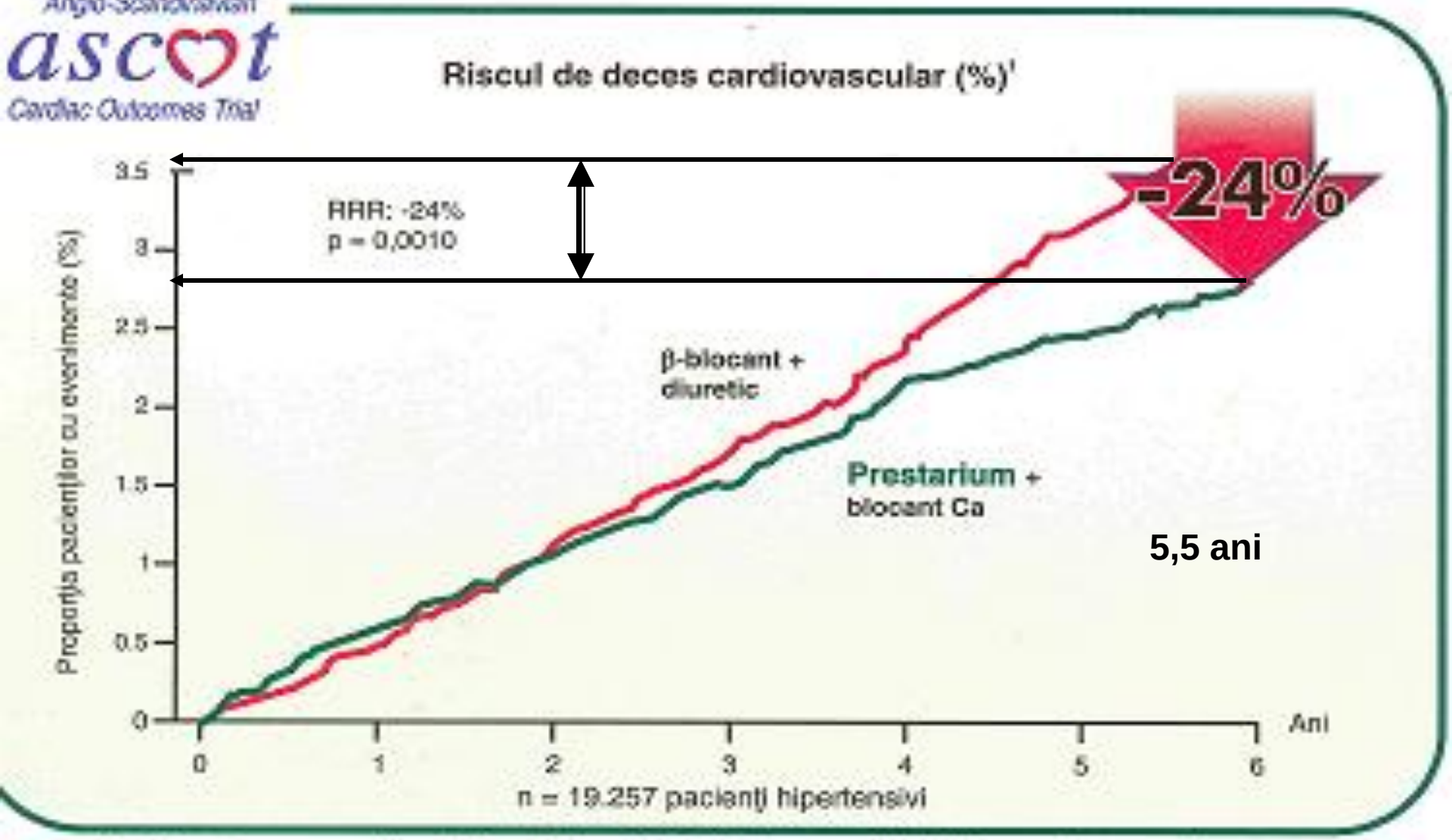
ONTARGET (>25.000 pts)



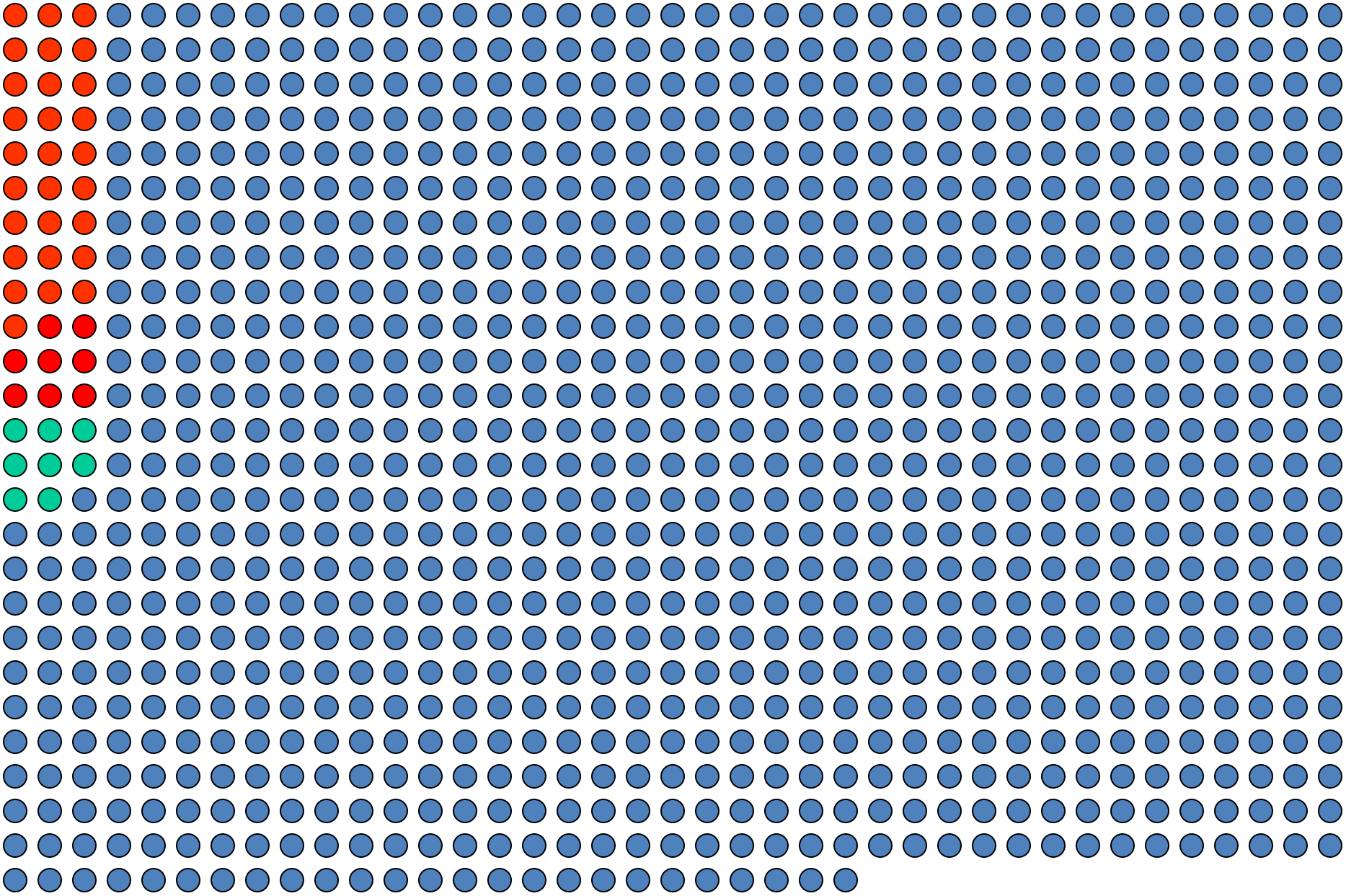
* NNH = 100

- p publicate sunt mai optimiste
- CI sunt optimiste (mai înguste decât în realitate)

Anglo-Scandinavian ascot Cardiac Outcomes Trial



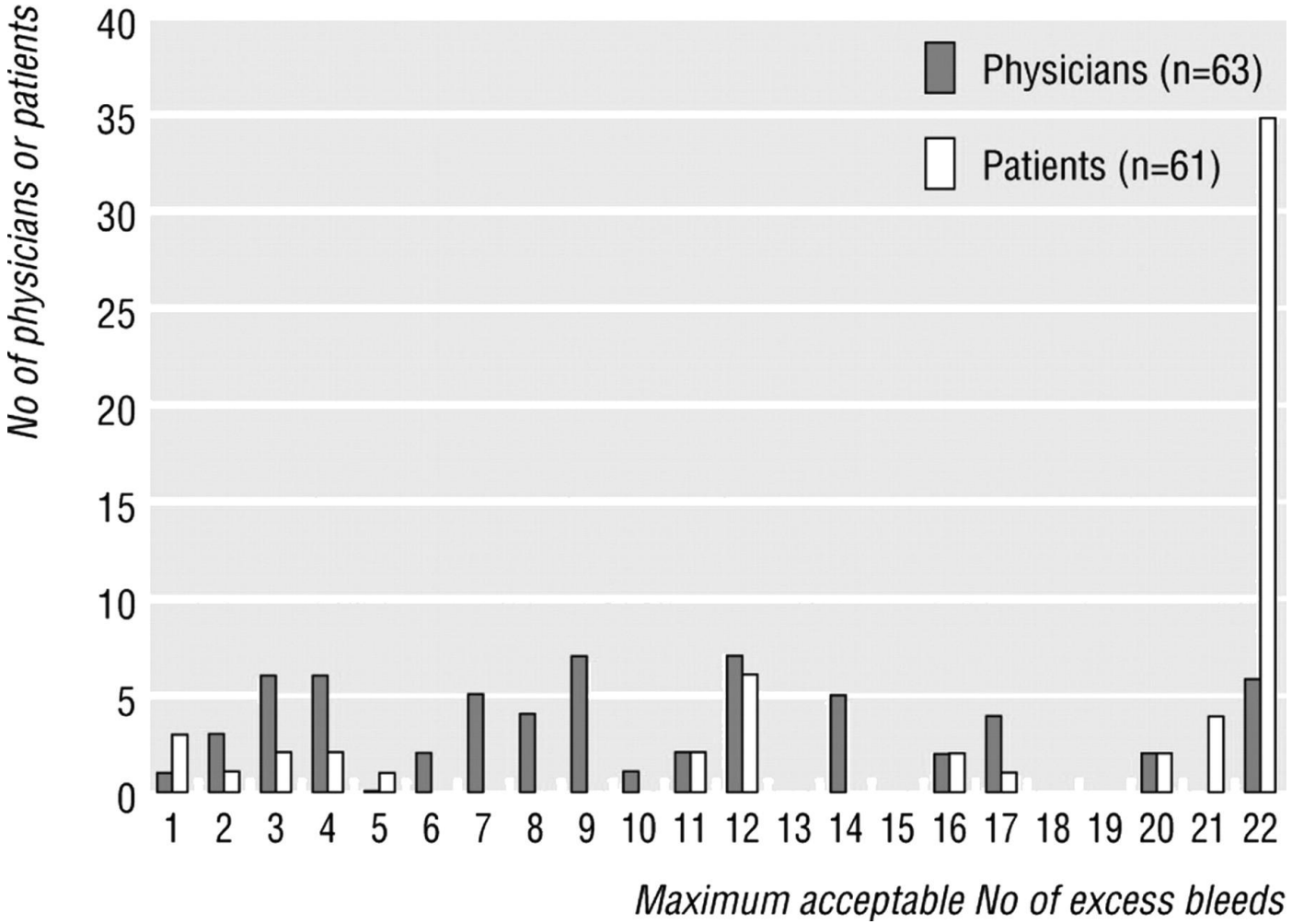
RRA=3,6-2,8 = 0,8% **NNT=100:0,8 = 125**



ASCOT-BPLA: mortalit. cv.

RAR = 0,8% 5,5 ani

Varying thresholds of major GI bleeding in 100 patients found acceptable by patients and physicians when strokes are reduced by 8 in 100 patients



Karanicolas, P. J. et al. Chest 2008;133:1067-1071

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Original Contribution

Comparison of Fixed-Dose Weight-Adjusted Unfractionated Heparin and Low-Molecular-Weight Heparin for Acute Treatment of Venous Thromboembolism

Clive Kearon, MB, PhD; Jeffrey S. Ginsberg, MD; Jim A. Julian, MMath; James Douketis, MD; Susan Solymoss, MD; Paul Ockelford, MD; Sharon Jackson, MD; Alexander G. Turpie, MB; Betsy MacKinnon, MSc; Jack Hirsh, MD; Michael Gent, DSc; for the Fixed-Dose Heparin (FIDO) Investigators

JAMA. 2006;296:935-942.

ABSTRACT

- d.a. 333 u/kg, urmata de 250u/kg, sc/12h

1: Chest. 2008 Jun;133(6 Suppl):454S-545S.

Antithrombotic therapy for venous thromboembolic disease: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition).

Kearon C, Kahn SR, Agnelli G, Goldhaber S, Raskob GE, Comerota AJ; American College of Chest Physicians.

Hamilton Health Sciences, Henderson Division, 711 Concession Street, Hamilton, Ontario, Canada. kearonc@mcmaster.ca