

# EBM in der Praxis

Harald Kamps

Facharzt für Allgemeinmedizin

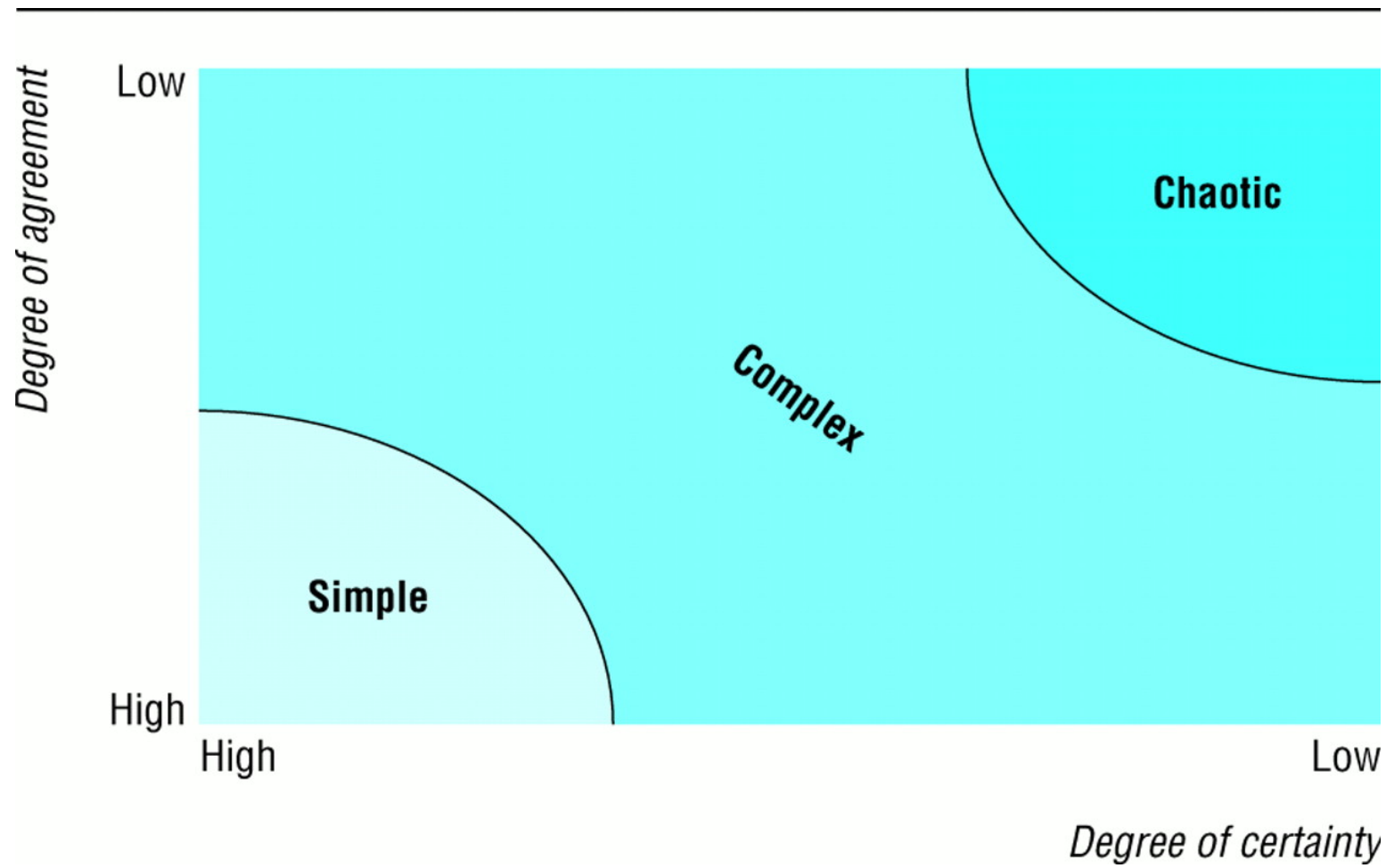
FA für Öffentliches Gesundheitswesen

[www.praxis-kamps.de](http://www.praxis-kamps.de)

Kurs Sozialmedizin, März 2008

# Du sollst keine anderen Patienten haben als mich!

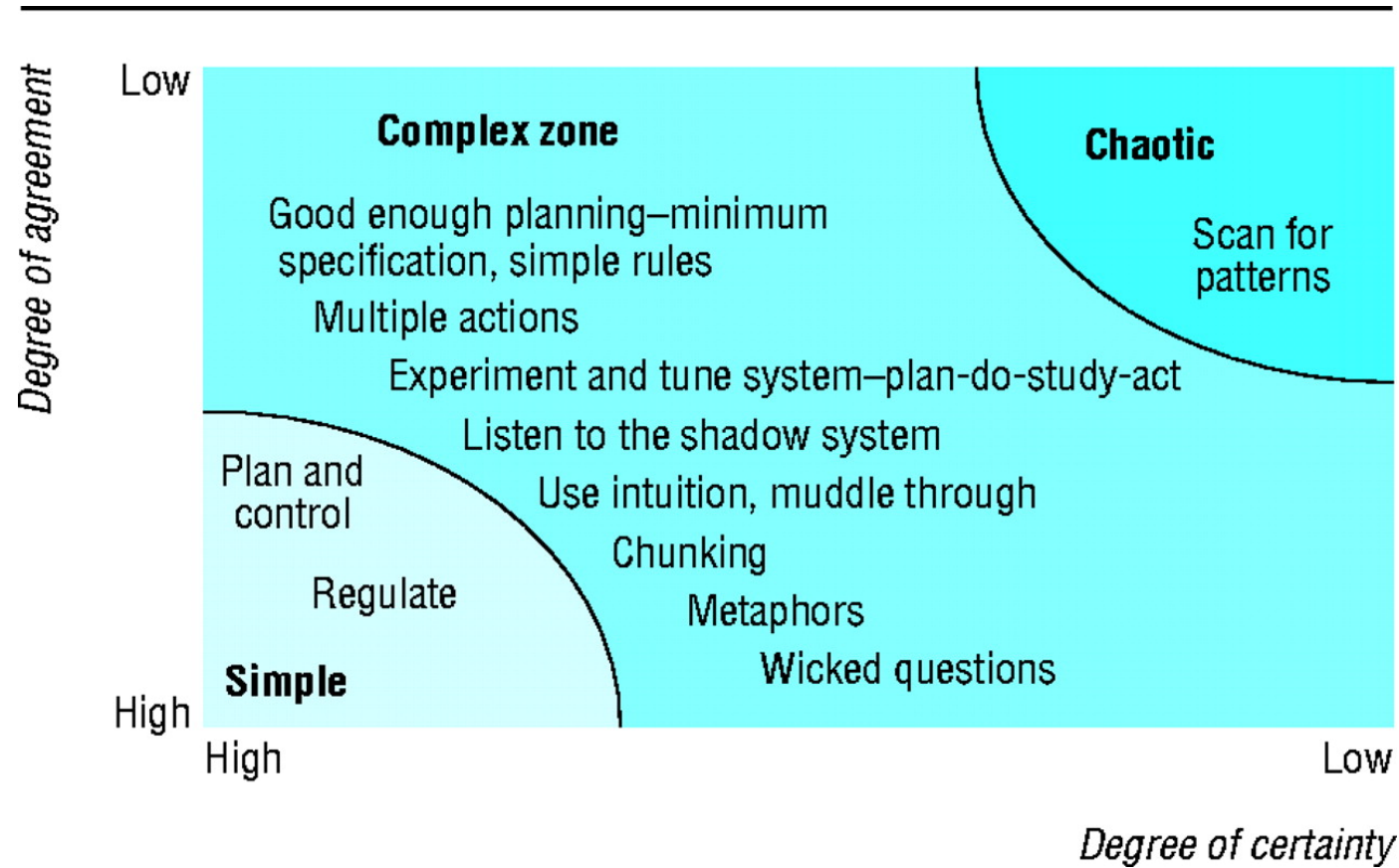
- Allgemeinmediziner - Sozialmediziner
- Entscheidungshilfen – wie soll ich mit Unsicherheit umgehen?
- Komplexe Welt
- RCT, N-of-1, statistische Begriffe wie ARR, RRR, NNT
- Risikokommunikation am Beispiel ARRIBA



Plsek, P. E et al. BMJ 2001;323:625-628



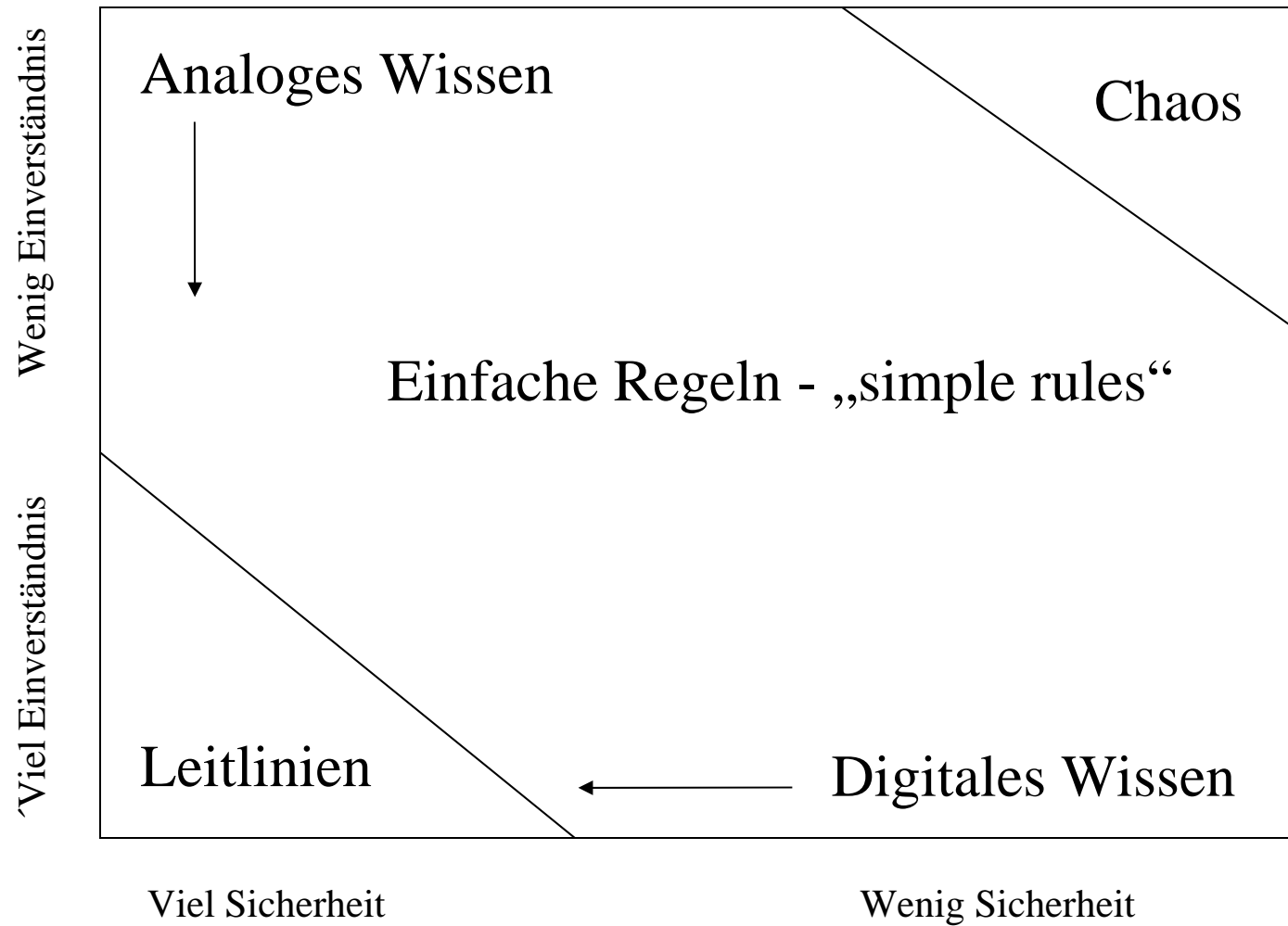
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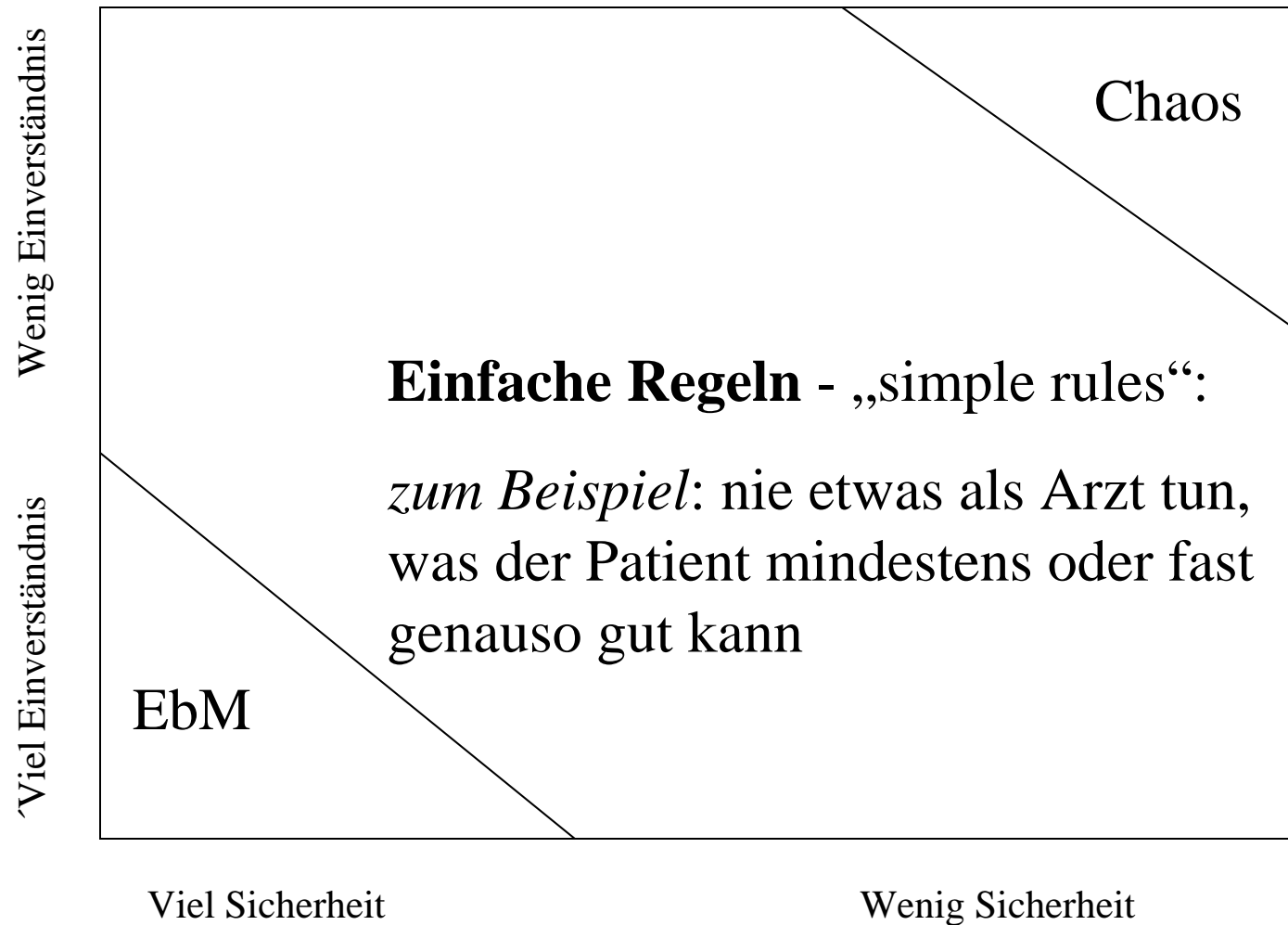
Wilson, T. et al. *BMJ* 2001;323:685-688

BMJ

# Komplexität



# Komplexität



# Hierarchie der Evidenz



Centre for Health Evidence: [Home](#) » [Users' Guides to EBP](#)

## EBM: Principles of Applying Users' Guides to Patient Care

*Gordon H Guyatt MD, Brian Haynes, Roman Z. Jaeschke, Deborah J Cook, Lee Green, C. David Naylor, Mark C. Wilson, W. Scott Richardson for the Evidence Based Medicine Working Group*

*Based on the Users' Guides to Evidence-based Medicine and reproduced with permission from JAMA. (2000;284(10):1290-1296). Copyright 2000, American Medical Association.*

**Table 1**

### **A hierarchy of strength of evidence for treatment decisions**

- N of 1 randomized trial
- Systematic reviews of randomized trial
- Single randomized trial
- Systematic review of observational studies addressing patient-important outcomes
- Single observational study addressing patient-important outcomes
- Physiologic studies
- Unsystematic clinical observations

# Auch ein „N-of-1“

## DRUG POINTS

### Atorvastatin may cause nightmares

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BMJ 2006;332:950

Atorvastatin (Lipitor; Pfizer, Walton-on-the-Hill) is a 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitor, prescribed for the treatment of hypercholesterolaemia in many patients worldwide. This case report relates atorvastatin to the occurrence of nightmares.

A 72 year old woman with a history of longstanding hypertension, treated hypothyroidism, heart failure, and chronic renal failure started taking 10 mg atorvastatin once a day because of hypercholesterolaemia. Concurrent drugs were 75 µg levothyroxine once a day, 5 mg amlodipine once a day, 100 mg atenolol once a day, and 50 mg losartan once a day. Five days after starting atorvastatin, she had extreme nightmares each night for two and a half weeks. Because of a presumed connection with her recently started statin, I discontinued this treatment for five days. No nightmares occurred. Although reluctant for a rechallenge, she agreed to take the atorvastatin again, which promptly resulted in nightmares; these dreams disappeared after discontinuation.

Several studies have looked at sleep disturbance or abnormal dreams related to HMG-CoA reductase inhibitors. The phenomena seem comparable within several groups of statins with different lipophilic properties and compared with placebo.<sup>1</sup> These studies

found side effects only between groups of patients treated with different statins or placebo, without rechallenges to relate these events to the use of these drugs.

A possible relation between nightmares and statins has previously been reported with the use of simvastatin and atorvastatin.<sup>2</sup> To our knowledge,

A 72 year old woman with a history of longstanding hypertension, treated hypothyroidism, heart failure, and chronic renal failure started taking 10 mg atorvastatin once a day because of hypercholesterolaemia. Concurrent drugs were 75 µg levothyroxine once a day, 5 mg amlodipine once a day, 100 mg atenolol once a day, and 50 mg losartan once a day. Five days after starting atorvastatin, she had extreme nightmares each night for two and a half weeks. Because of a presumed connection with her recently started statin, I discontinued this treatment for five days. No nightmares occurred. Although reluctant for a rechallenge, she agreed to take the atorvastatin again, which promptly resulted in nightmares; these dreams disappeared after discontinuation.

# Ein RCT in der Allgemeinarztpraxis

## Can sutures get wet? Prospective randomised controlled trial of wound management in general practice

Clare Heal, Petra Buettnner, Beverly Raasch, Sheldon Browning, David Graham, Rachel Bidgood, Margaret Campbell, Robert Cruikshank

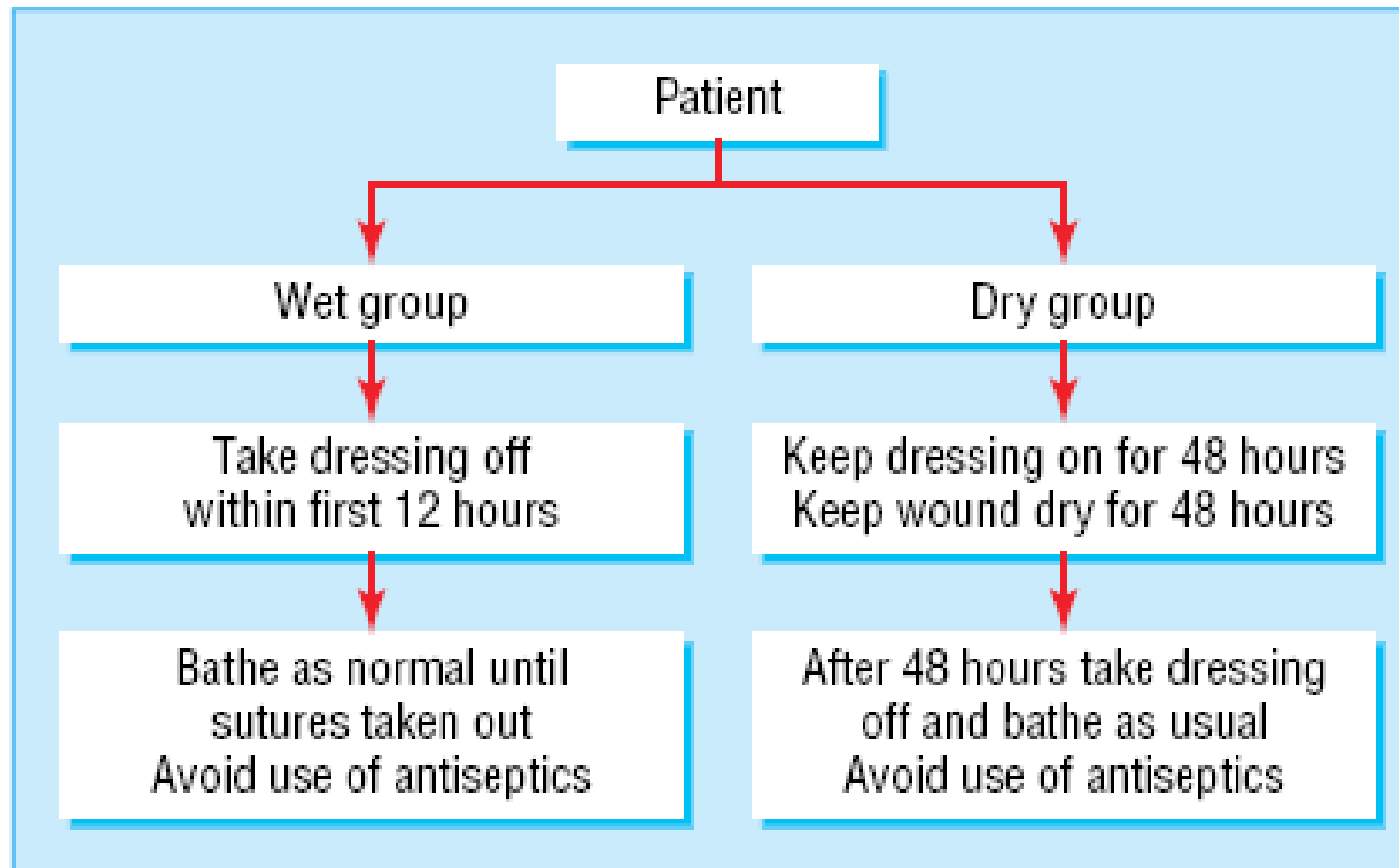
### Abstract

**Objective** To compare standard management of keeping wounds dry and covered with allowing wounds to be uncovered and wet in the first 48 hours after minor skin excision.

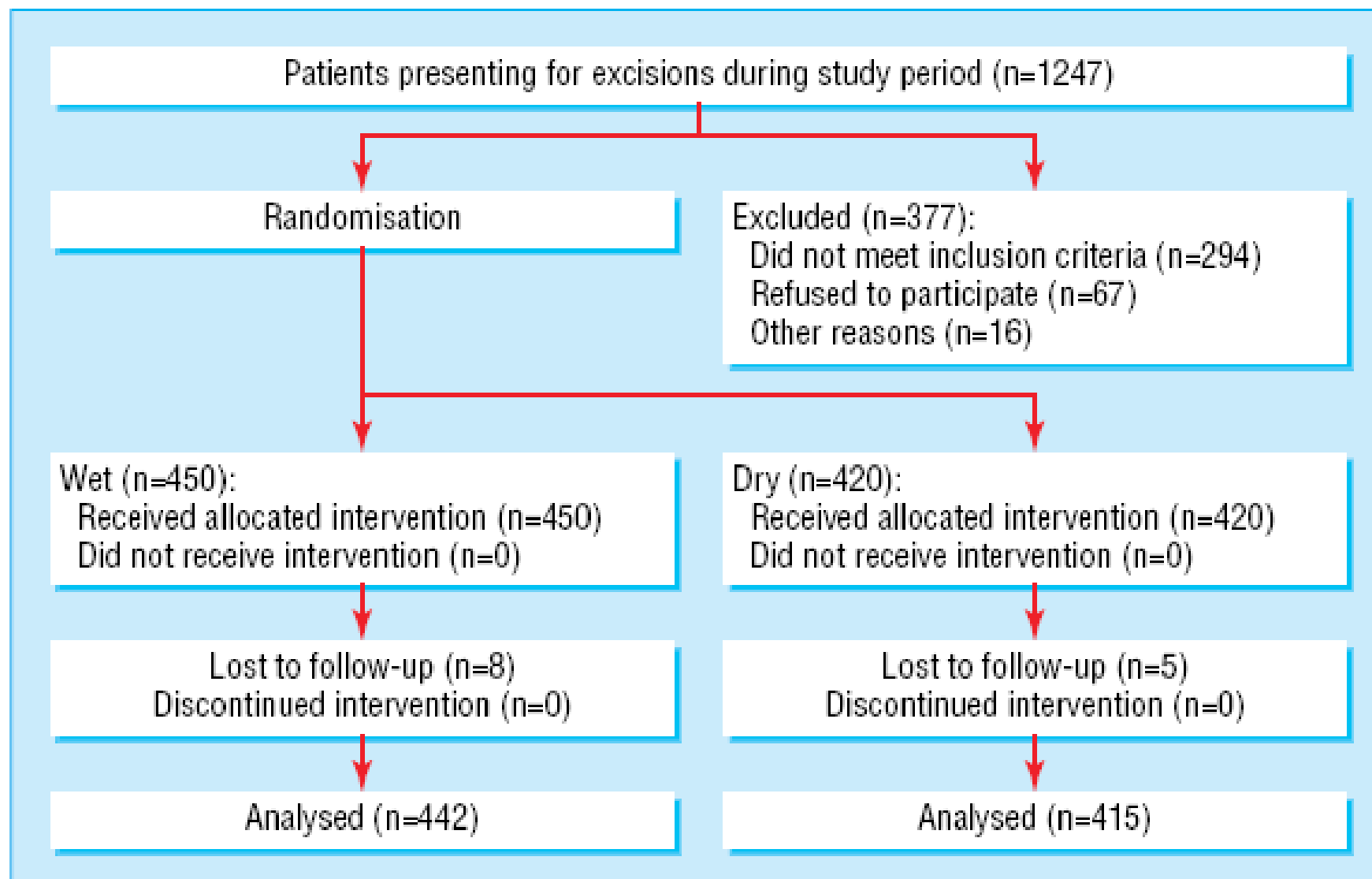
**Design** Prospective, randomised controlled, multicentre trial testing for equivalence of infection rates.

**Setting** Primary care in regional centre, Queensland, Australia.

**Participants** 857 patients randomised to either keep their wound dry and covered (n = 442) or remove the dressing and wet the wound (n = 415).



**Fig 1** Wound management protocol in wet (intervention) and dry (control) groups



## und das Ergebnis...

**Results** The incidence of infection in the intervention group (8.4%) was not inferior to the incidence in the control group (8.9%) ( $P < 0.05$ ). The one sided 95% confidence interval for the difference of infection rates was  $\infty$  to 0.028.

**Conclusion** These results indicate that wounds can be uncovered and allowed to get wet in the first 48 hours after minor skin excision without increasing the incidence of infection.

Cite this article as: BMJ, doi:10.1136/bmj.38800.628704.AE (published 28 April 2006)

# What sort of evidence do we need in primary care?

Sharon Mickan and Deborah Askew

BMJ 2006;332:619-620  
doi:10.1136/bmj.332.7542.619

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## What sort of evidence do we need in primary care?

*General practitioners need evidence from and about the patients they see*

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Research p 685

In this week's *BMJ* (p 685), Mant and colleagues raise again the question of whether large scale randomised controlled trials provide evidence relevant to primary care.<sup>1</sup> In a cross sectional study they question whether the UK national clinical guidelines for stroke are applicable to primary care patients. These guidelines, largely based on the PROGRESS trial,<sup>1</sup> recommend a target blood pressure of 140/85 mm Hg, with further lowering beyond this target desirable through use of a thiazide diuretic and an angiotensin converting enzyme inhibitor.<sup>2</sup>

Mant and colleagues critiqued the applicability of these guidelines to primary care patients by comparing the characteristics of patients in English general

widespread use of the guidelines. Patients with stroke in English primary care were generally older, equally comprised men and women, and had had their cerebral events less recently than the trial participants.

widespread use of the guidelines. Patients with stroke in English primary care were generally older, equally comprised men and women, and had had their cerebral events less recently than the trial participants. They may not necessarily benefit from the relatively aggressive treatment recommended in the national guidelines. Given that most chronic stroke patients are managed by general practitioners, Mant and colleagues are calling for more appropriate research to provide evidence applicable to primary care.<sup>2</sup>

# Was bedeuten die Ergebnisse eines RCTs?

- Die Studienpopulation muss vergleichbar sein.
- Wie vermittele ich dann die Ergebnisse?
  - ARR (absolute Risikoreduktion): *der Vorsichtige?*
  - RRR (relative Risikoreduktion): *der Verkäufer?*
  - NNT (Number needed to treat): *der Wissenschaftler?*

# NNT, RRR, ARR

- Beispiel:
- RCT Studie zur Wiederbelebung
  - Intervention Herzmassage vor Elektroschock
  - Kontrolle: zuerst Elektroschock
- Effekt: **nicht** erreichte spontane Herzaktion
  - Intervention: 42% (D-i) Kontrolle: 62% (D-k)

# ARR, RRR, NNT

- **ARR** =  $D_k - D_i = 62\% - 42\% = 20\%$
- **RRR** =  $(D_k - D_i) / D_k = 20\% / 62\% = 32\%$
- **NNT** =  $1 / ARR = 1 / 0,2 = 5$
- Einer von 5 Patienten hat Nutzen von der Behandlung: nämlich mit der kardiopulmonalen Rettung vor dem Elektroschock zu beginnen.

# NNT bei chronischen Krankheiten

- In den meisten Fällen kann eine Krankheit nicht verhindert werden, der Tod kann in keinem Fall verhindert werden - nur der Zeitpunkt kann verschoben werden.
- Es kommt also auf den Zeitpunkt an, an dem der Effekt gemessen wird.
- Was bedeutet **NNT = 20** bei der Beurteilung von Interventionen bei chronischen Erkrankungen?

## Antall som må behandles (NNT) - misvisende, misforstått, misbrukt?

Torbjørn Wisløff Peder A. Halvorsen Ivar Sønbo Kristiansen

Tidsskr Nor Lægeforen 2004; 124: 1926-9

Utskriftsvennlig (PDF) 

[English summary](#)

## Tidsskrift for Den norske lægeforening

Tidsskriftet

Stillinger

Kurs og møter

Tema

Spesialist

Manusnett

Legel

► Siste utgave

[Tidligere utgaver](#)

[Søk/Arkiv](#)

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Tidsskriftet](#)

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[Nyhetsarkiv](#)

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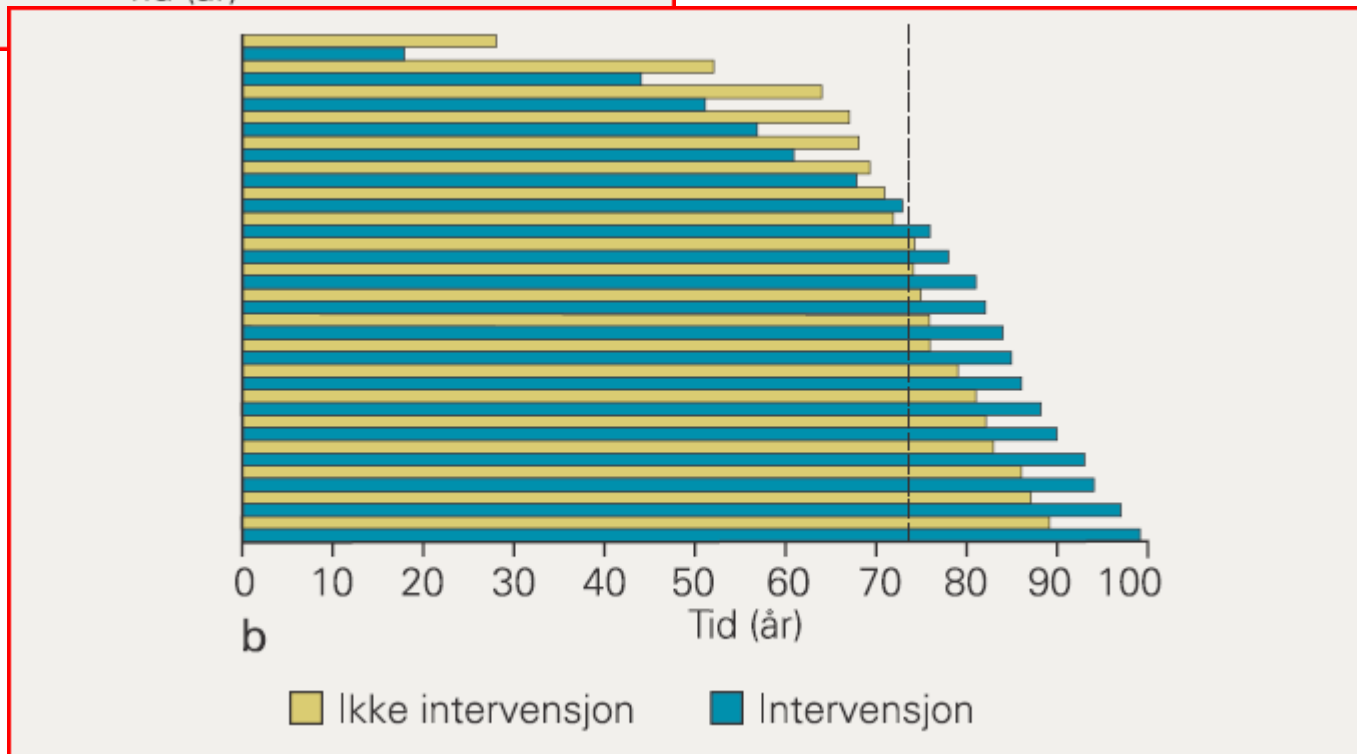
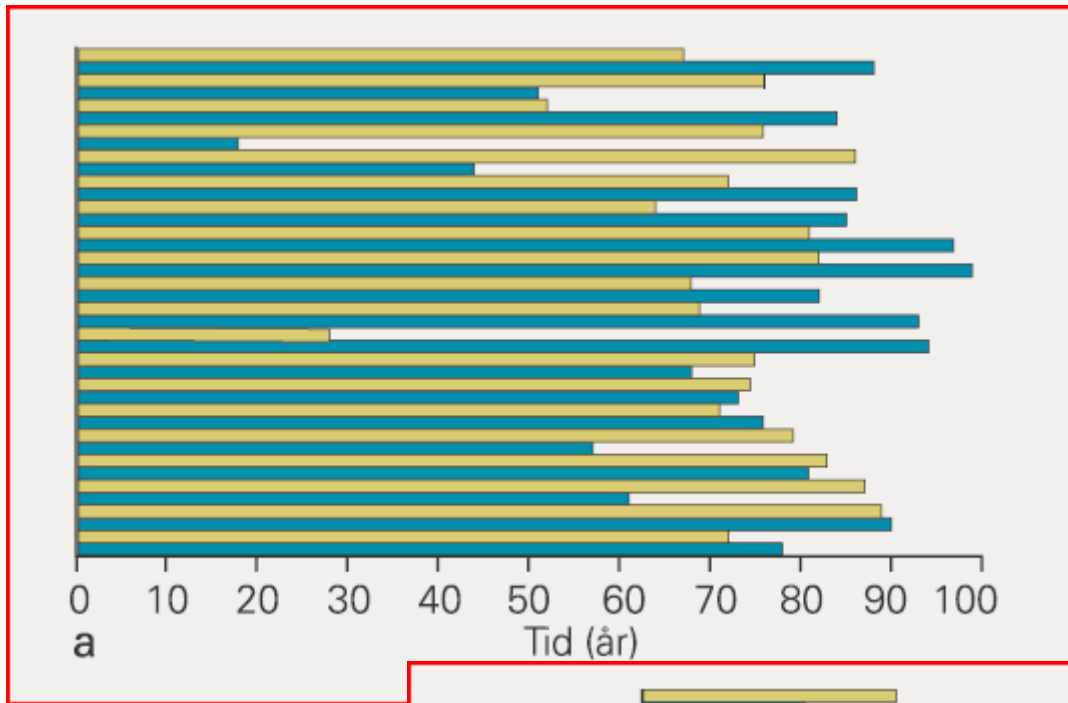
[Annonser](#)

### Number needed to treat: misleading, misunderstood, misused?

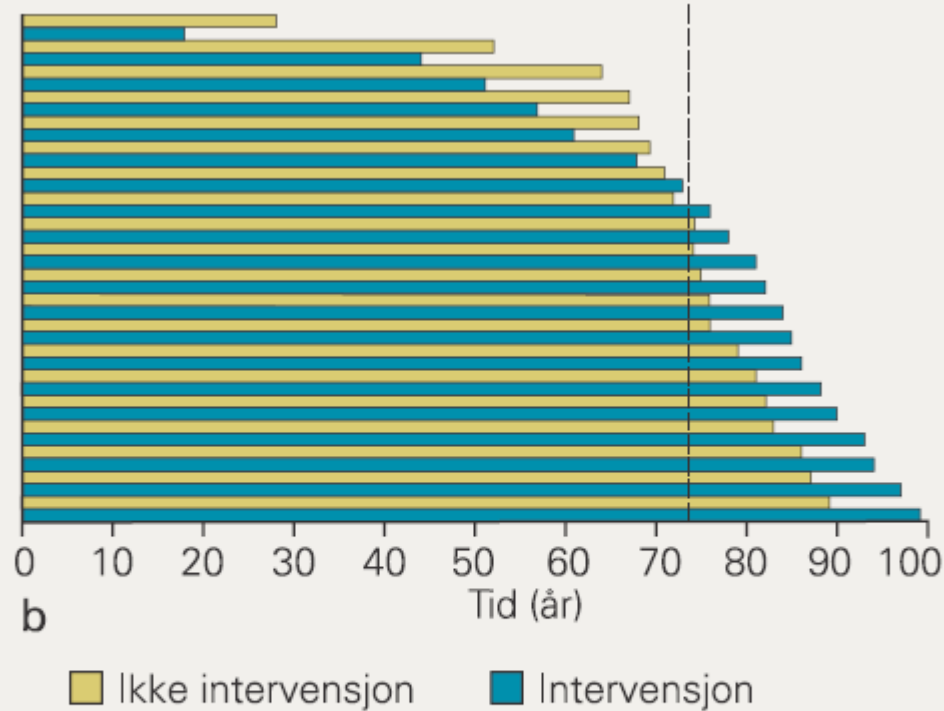
Torbjørn Wisløff, Peder A. Halvorsen, Ivar Sønbo Kristiansen

Number needed to treat (NNT) is one of several effect measures that does not capture the time dimension because it is based on observations at a given, random point in time. This aspect makes NNT a problematical measure of the effect of interventions against chronic disease processes in which time to event is an essential issue.

Additionally, the statistical properties of NNT are not favorable. It may leave the impression that adverse disease events are completely avoided by intervention when in fact they are postponed. We suggest that NNT should be used and interpreted with caution.

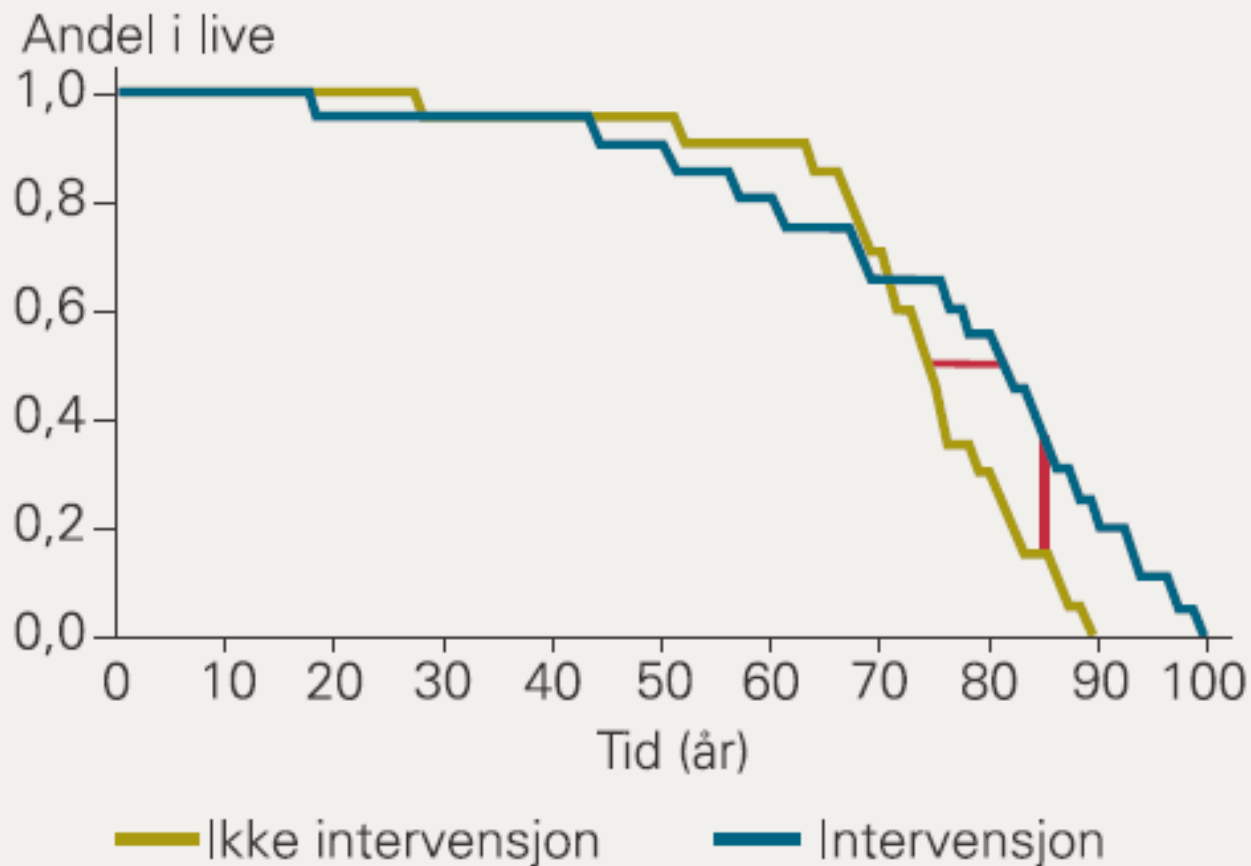


Ikke intervensjon    Intervensjon



a) Levetid for 20 pasienter som fikk behandling (intervensjon) for en dødelig tilstand og 20 identiske kontrollpasienter. b) Samme pasienter som figur 1a, men ordnet etter levetid. Den stiplede linjen angir et tidspunkt der det er ett dødsfall mindre i intervensjonsgruppen enn i kontrollgruppen

Die vertikale Linie ist eingezeichnet zu einem Zeitpunkt, wo es in der Interventionsgruppe einen Todesfall weniger gibt als in der Kontrollgruppe: ARR 1/20. NNT=20. Aber 14 weitere scheinen im weiteren Verlauf positiven Effekt der Intervention zu haben. „Vertikale“ Endpunktbeschreibungen geben also nur den durchschnittlichen Effekt zu diesem Zeitpunkt wieder.



Dieselben Daten, jetzt als Analyse der Überlebenszeit mit der Lebenszeit auf der x-Achse und dem Anteil der Überlebenden auf der y-Achse.  $D_i - D_k$  ist als vertikale rote Linie eingezeichnet (vermittelt einen visuellen Eindruck von ARR/RRR und NNT). Die horizontale rote Linie ist bei 50% eingezeichnet und beschreibt den Unterschied in der medianen Überlebenszeit.

# Risikointervention

- Am Beispiel ARRIBA

## Sechs Schritte

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**A**bsolute und  
**R**elatives  
**R**isiko -  
**I**ndividuelle  
**B**eratung in der  
**A**llgemeinpraxis

ARRIBA-Herz ☺

# Oder interaktiv mit e-arriba <http://www.arriba-hausarzt.de/>

# Information über Möglichkeiten

Maßnahme	Rel. Risiko ↓	Ind. Plan
Rauchstopp	ca. 35%	
Bewegung	ca. 35%	
Med. BDr ↓	ca. 25%	
ASS	ca. 20%	
Statine	ca. 20-25%	

4

ARRIBA-Herz ☺

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