UNIVERSITÄT DUISBURG ESSEN

# Complementary and Alternative Medicine – Innovation and added Value for European Healthcare“

## European Parliament, Brussels 9. Oct. 2012

# Evidence-base and effectiveness of Complementary and Alternative Medicine

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Kliniken Essen-Mitte, Germany



KLINIKEN ESSEN-MITTE,
Department for Internal and Integrative Medicine

# The basic principles of Complelentary and Alternative Medicine (CAM)

The basic principles of CAM is the stimulation of the *self-healing-ability* of the body.

Beside the personal constitution also the bio-psycho-social situation of the patient is taken into consideration.

# CAM Methods in Europe

- **I. Naturopathy acc. to *Kneipp***

  - healthy Nutrition
  - Physical Exercise
  - Herbal Medicine
  - Hydrotherapy
  - Mind/Body Medicine

**II. Traditional Naturopathic Medicine**

Fasting, Neuraltherapy, Massage, Reflexology

**III other whole system approaches**

Homeopathy, Antroposophic Medicine

Traditional Chinese Medicine, Ayurveda and Shiatsu

# CAM Methods in Europe

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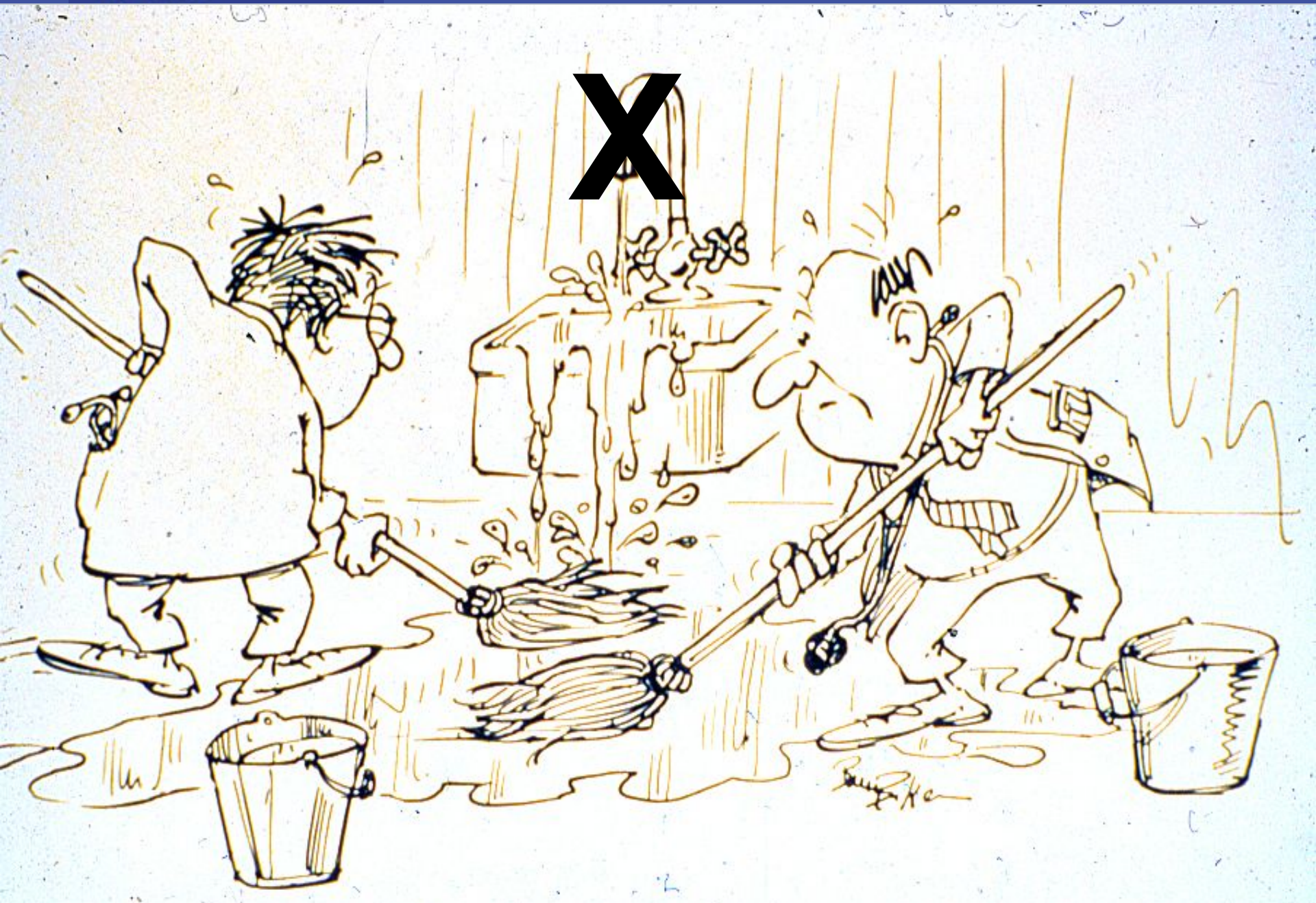
# Whole system approach to treat the root cause …



# Complementary and Alternative Medicine (CAM)

- Mostly traditional healing methods
- long clinical experience
- mostly safe
- often beneficial to patients

# Mainstream medicine

**The current prevailing paradigm within the medical community is**

***evidence-based medicine (EBM).***

# Definition of *evidence-based medicine* (EBM) acc. *David Sackett 1996*

I. External evidence (based on randomized-controlled trials, RCTs)

II. Internal evidence (experience of the phycisian)

III. Patients preferences

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# Randomized-controlled trials, RCTs

RCTs are typically designed to provide ***evidence of „efficacy“*** **of a new agent**, where „*efficacy*“ is defined as proof that the agent has a therapeutic effect.

**The highest level of evidence is the positive meta-analysis from RCTs.**

**Level of evidence 1A!**

# Definitions:

- **'Efficacy'** refers to the extent to which a specific intervention is beneficial under ***'ideal' conditions***.

- **'Effectiveness'** is a 'measure of the extent to which a specific intervention when deployed ***in the field in routine care*** does what it is intended to do for a specific population.

Last J, Spasoff, RA, Harris S: A dictionary of epidemiology. Oxford University Press, 2001

# Purpose of my talk

- … to show that the **evidence-base of major mainstream medicine** treatments is **weaker than generally tought**.
- … there is some scientific **evidence-base and effectiveness of CAM therapies** in the field of illnesses that are responsible for a majority of medical costs in Europa.
- … CAM might be relevant for **important EU health.**

# Relevant health condition and illnesses

**Cancer**

**Heart disease**

**Chronic pain condition**

# Focus on: CAM-based *Mind-Body Medicine* and *Lifestyle Change*

**Health**

**maintanance**

**promotion**

**literacy**

**prevention**

# How is the level of evidence in Oncology?

**Level of Scientific Evidence Underlying Recomandations Arising From the *National Comprehensive Cancer Network* (NCCN) clinical practice guidelines.**

***Poonacha and Go, J Clin Oncol 2011***

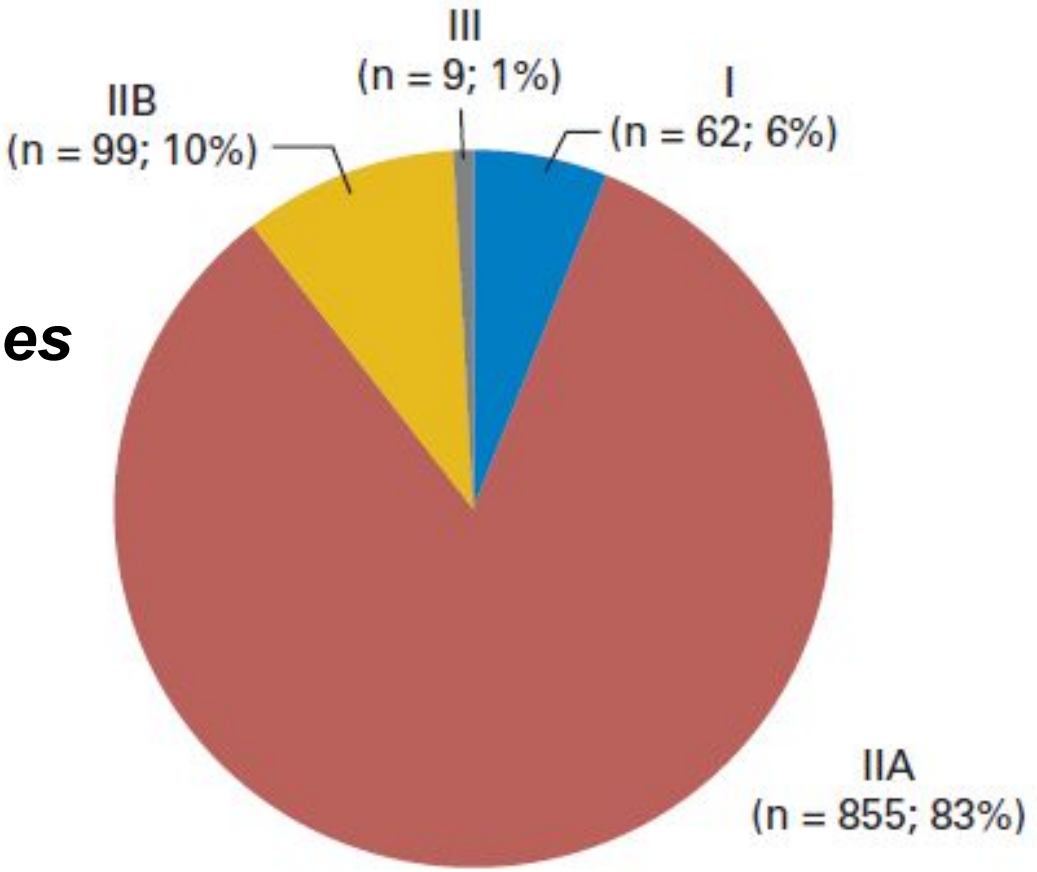


**KLINIKEN ESSEN-MITTE,**
**Department for Internal and Integrative Medicine**

# Distribution of categories of *evidence and consensus* for all guidelines

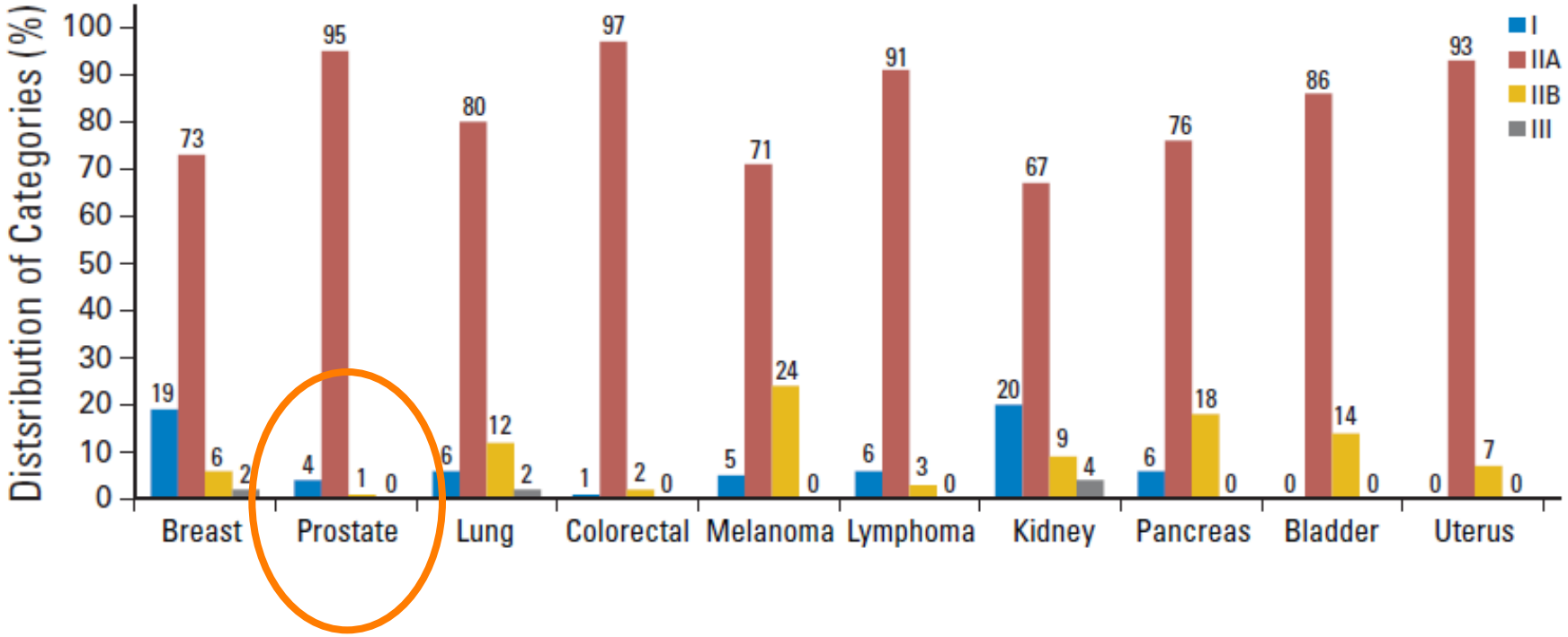
***Evidence of all guidelines***

***6%***




*J Clin Oncol 29:186-191. © 2010*

# Distribution of categories of *evidence and consensus* according to type of guideline




*J Clin Oncol 29:186-191. © 2010*

# The NCCN definitions for various evidence and consensus categories

- I, **high level of evidence such as RCTs** with uniform consensus
- II A, lower level of evidence (not RCT, no control group) **with uniform consensus**
- II B, lower level of evidence **without uniform consensus but no major disagreement**
- III, any level of evidence but with major disagreement

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# Radical Prostatectomy versus Observation for Localized Prostate Cancer

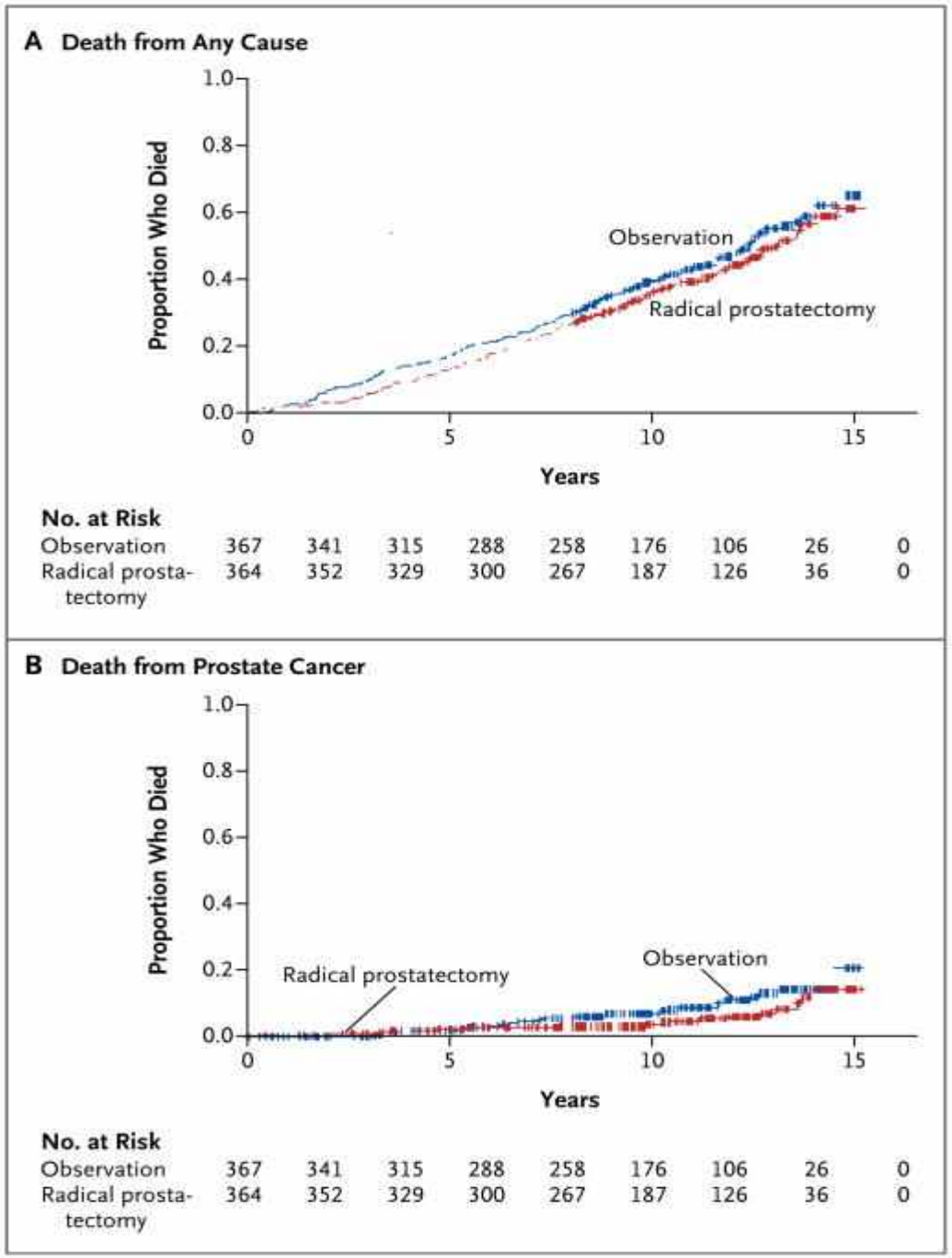
Timothy J. Wilt, M.D., M.P.H., Michael K. Brawer, M.D., Karen M. Jones, M.S., Michael J. Barry, M.D., William J. Aronson, M.D., Steven Fox, M.D., M.P.H., Jeffrey R. Gingrich, M.D., John T. Wei, M.D., Patricia Gilhooly, M.D., B. Mayer Grob, M.D., Imad Nsouli, M.D., Padmini Iyer, M.D., Ruben Cartagena, M.D., Glenn Snider, M.D., Claus Roehrborn, M.D., Ph.D., Roohollah Sharifi, M.D., William Blank, M.D., Parikshit Pandya, M.D., Gerald L. Andriole, M.D., Daniel Culkin, M.D., and Thomas Wheeler, M.D., for the Prostate Cancer Intervention versus Observation Trial (PIVOT) Study Group

# Radical prostatectomy versus observation for localized prostate cancer.

*Wilt et al. N Engl J Med. 2012*

## CONCLUSIONS

**… did not significantly reduce all-cause or prostate-cancer mortality**, as compared with observation, through **at least 12 years of follow-up**.



# Side effects:

Table 2. Patient-Reported Urinary, Erectile, and Bowel Dysfunction at 2 Years, According to Study Group.*

| Dysfunction | Radical Prostatectomy | Observation | P Value |
|---|---|---|---|
| | *no./total no. (%)* | | |
| Urinary incontinence† | 49/287 (17.1) | 18/284 (6.3) | <0.001 |
| Erectile dysfunction‡ | 231/285 (81.1) | 124/281 (44.1) | <0.001 |
| Bowel dysfunction§ | 35/286 (12.2) | 32/282 (11.3) | 0.74 |

# What is the consequence?

***„wait and see“***

seems to be the best therapy!

# Intensive lifestyle changes may affect the progression of prostate cancer.

*Ornish et al. 2005, J Urol*

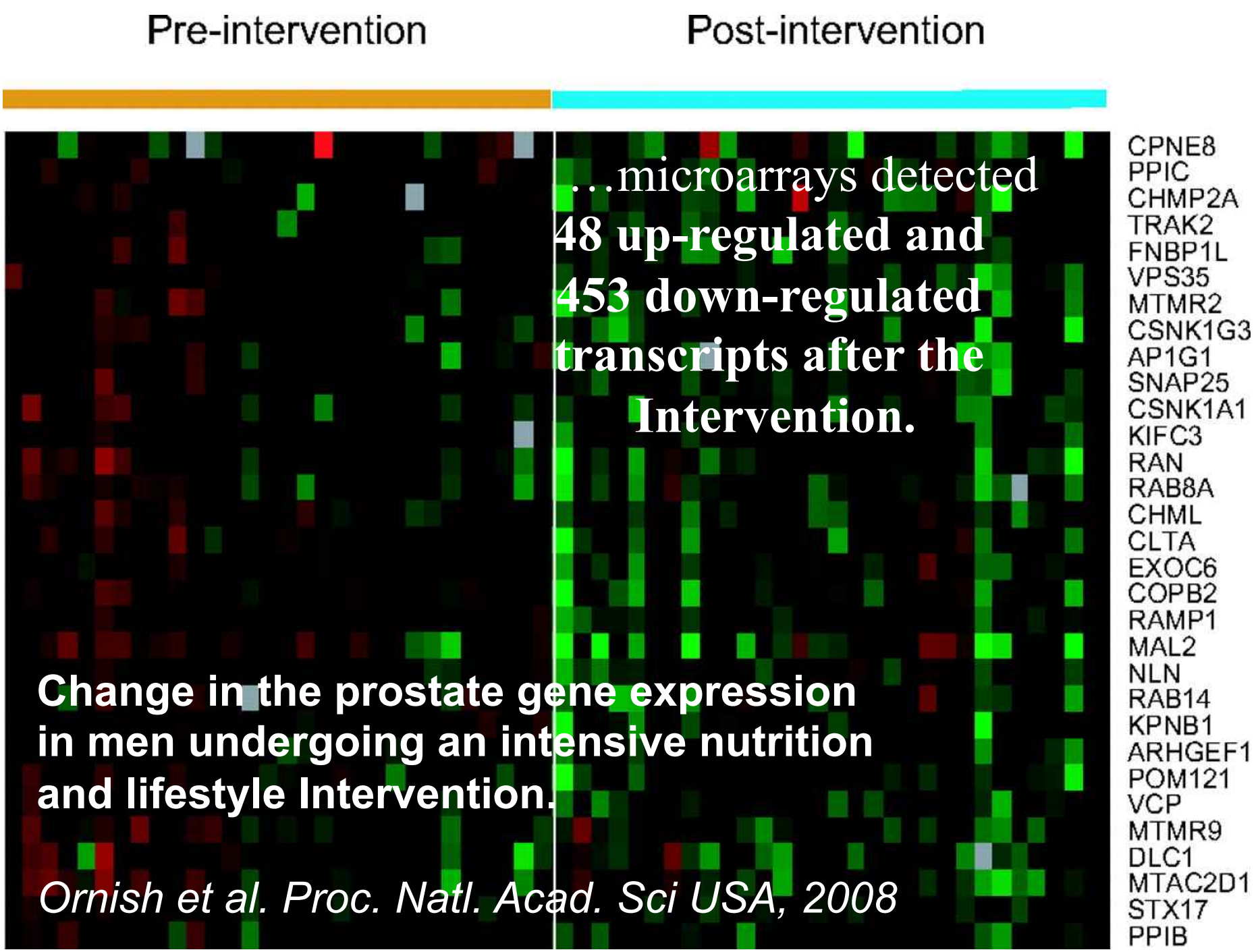
Mind-Body-oriented lifestyle change combining fat-free diet, regular exercise (6x 30 walking/week) and stress reducing procedures (Yoga, meditation) significantly **reduced PSA-level** in men with prostate carcer.

**Even after two years the number of necessary operations and radiotherapy was significantly reduced.**

# Changes in prostate gene expression in men undergoing an intensive nutrition and lifestyle intervention.

*Ornish D, Proc Natl Acad Sci U S A. 2008*

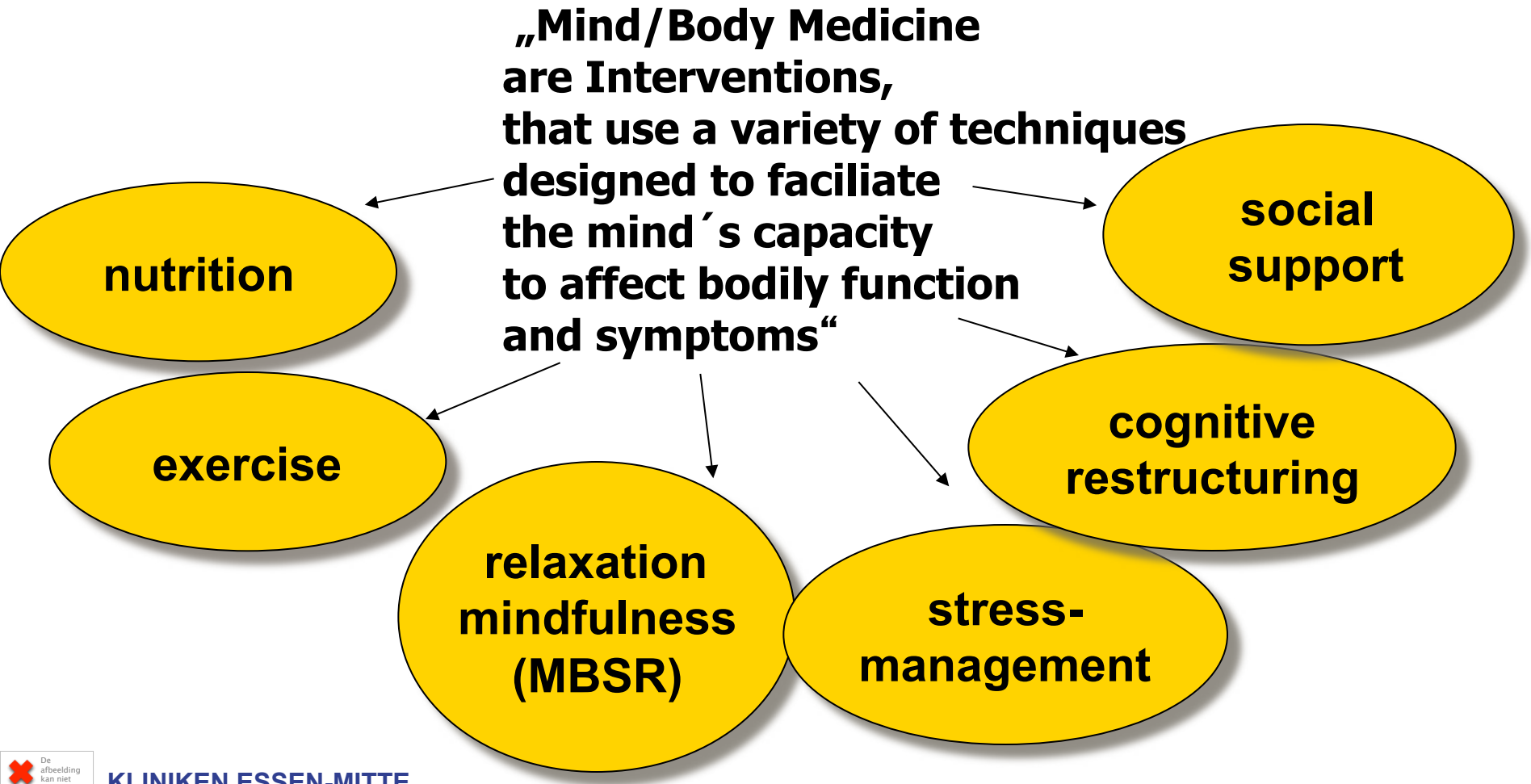
**Mind-Body Medicine and Lifestyle change even had impact on the genes!**




**Change in the prostate gene expression in men undergoing an intensive nutrition and lifestyle Intervention.**

*Ornish et al. Proc. Natl. Acad. Sci USA, 2008*

# Mind/Body Medicine NIH



# How is the level of evidence in Cardiology?

**Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines.**

**Tricoci et al. JAMA 2009**



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**Department for Internal and Integrative Medicine**

# Scientific Evidence Underlying the ACC/ AHA Clinical Practice Guidelines

**Tricoci et al. *JAMA*. 2009**

## Conclusions:

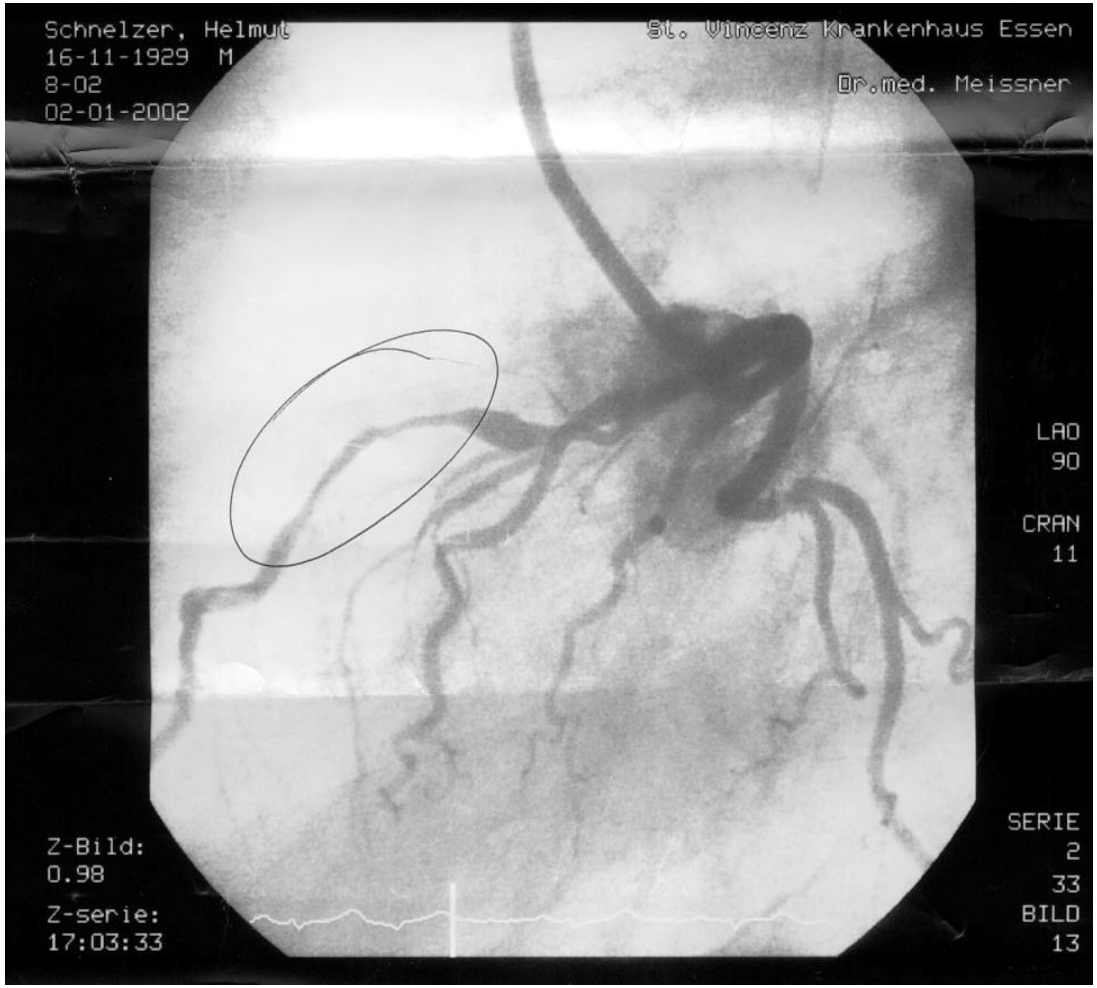
Recommendations issued in current ACC/AHA clinical practice guidelines **are largely developed from lower levels of evidence** …

# „Level of Evidence in Current Guidelines“
## *Summary of guidelines (median)*

*Tricoci et al. JAMA 2009*

**11.4%**

# Stenosis of the coronary artery



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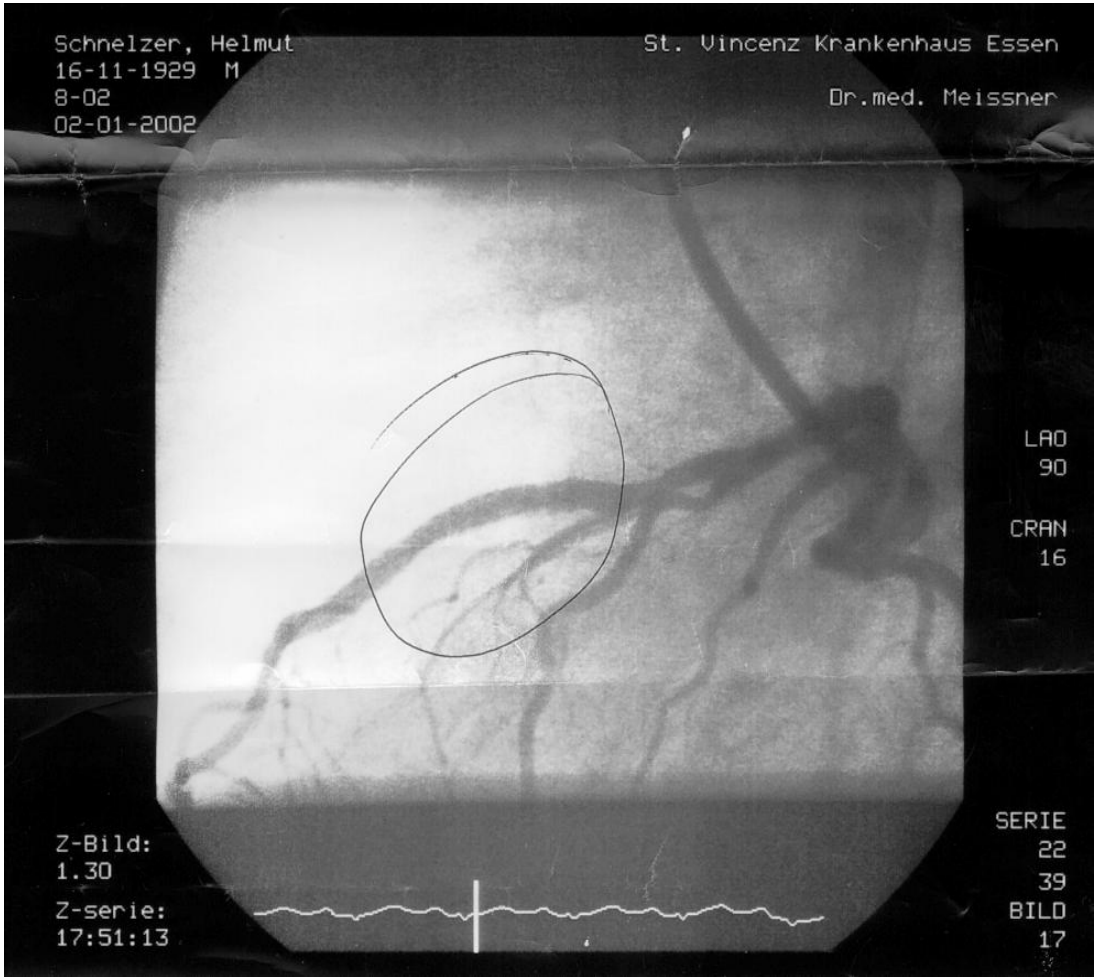
# Stenosis of the coronary artery, after stent implantation



# How is the evidence of coronary stent implantation for ***stable coronary artery disease***?

**Initial coronary stent implantation with medical therapy vs. medical therapy alone for stable coronary artery disease:**

**Meta-analysis of randomized controlled trials.**

**Stergiopoulos and Brown,**
**Arch Intern Med. 2012 .**

# Initial coronary stent implantation with medical therapy vs. medical therapy alone for stable coronary artery disease:

## Meta-analysis of randomized controlled trials.

**Stergiopoulos and Brown,**
**Arch Intern Med. 2012 .**

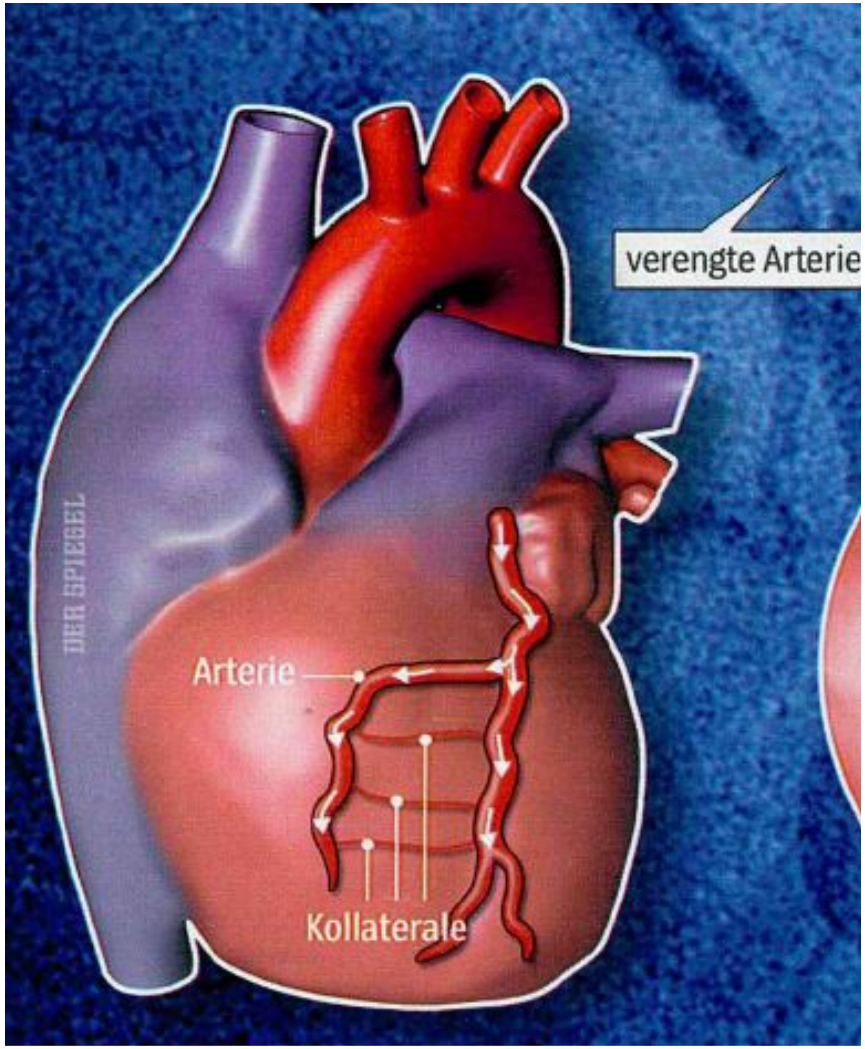
**CONCLUSION:**

Initial **stent implantation** for **stable CAD shows no evidence of benefit** compared with initial medical therapy for prevention of death, nonfatal MI, unplanned revascularization, or angina.

# „Level of Evidence in Current Guidelines“
## *Stabile Angina*

**Tricoci et al. JAMA 2009**

**6.4%**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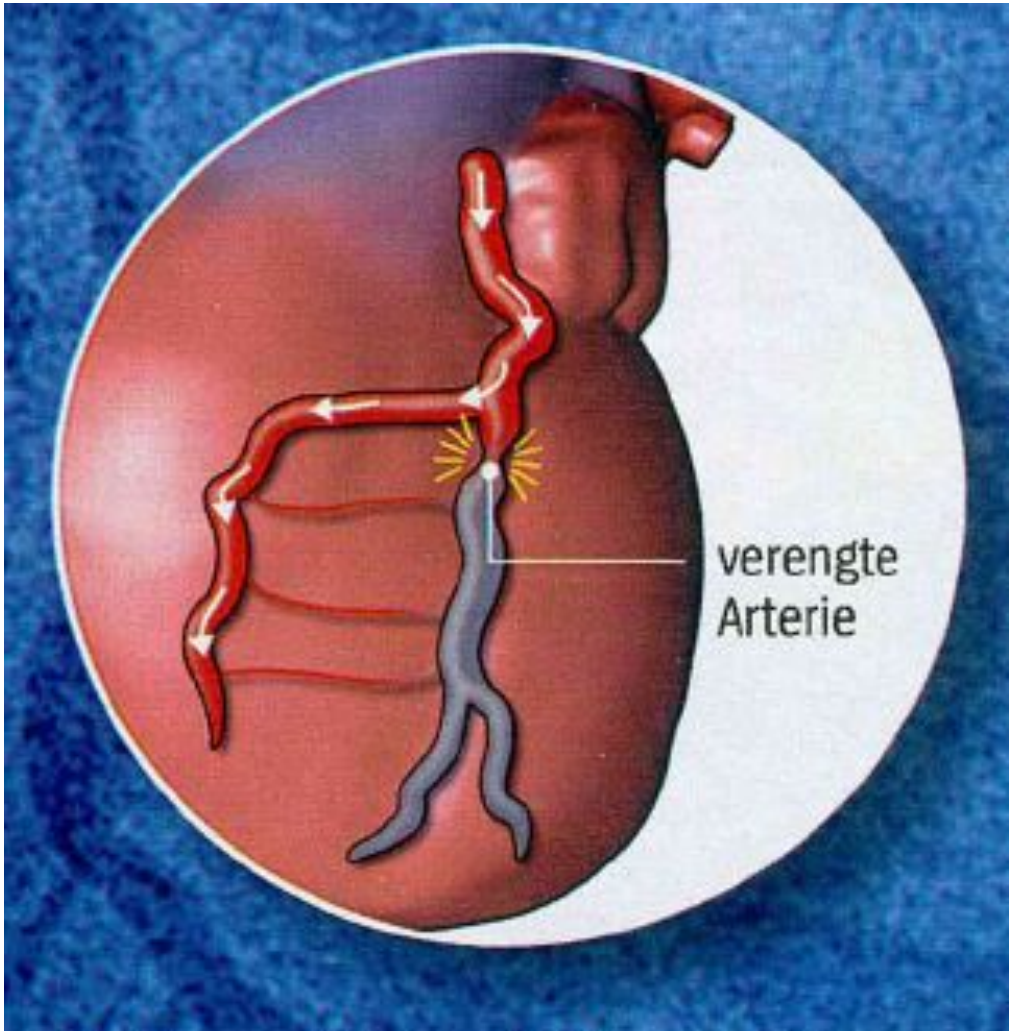
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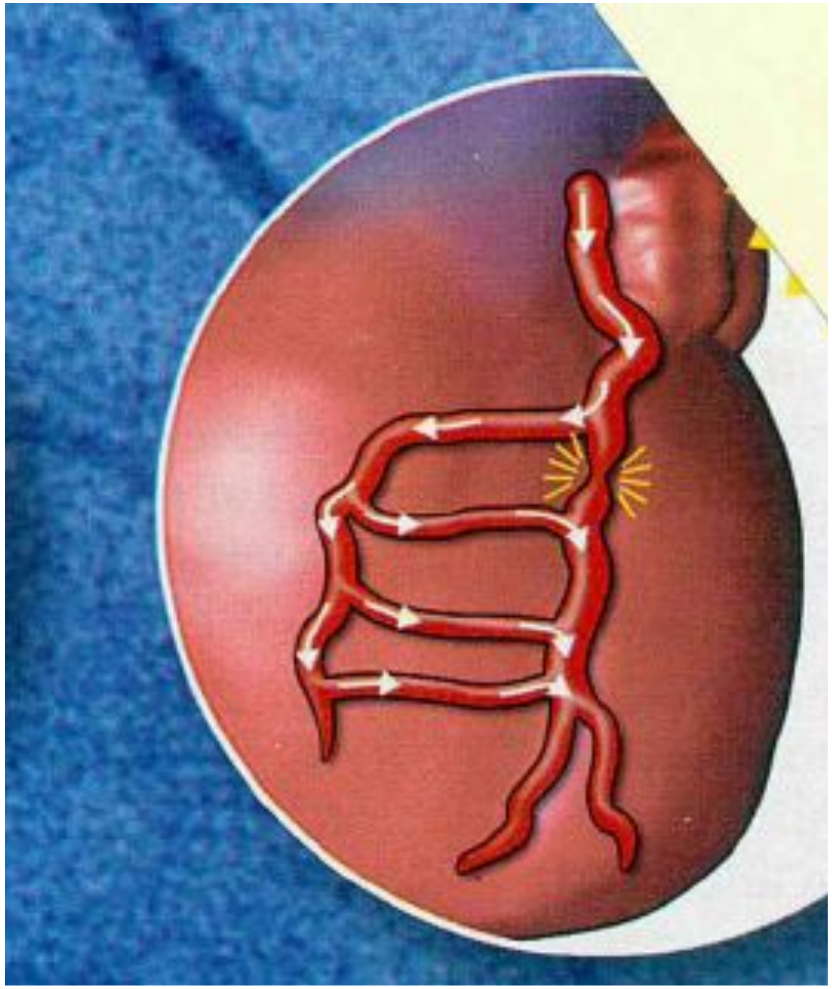
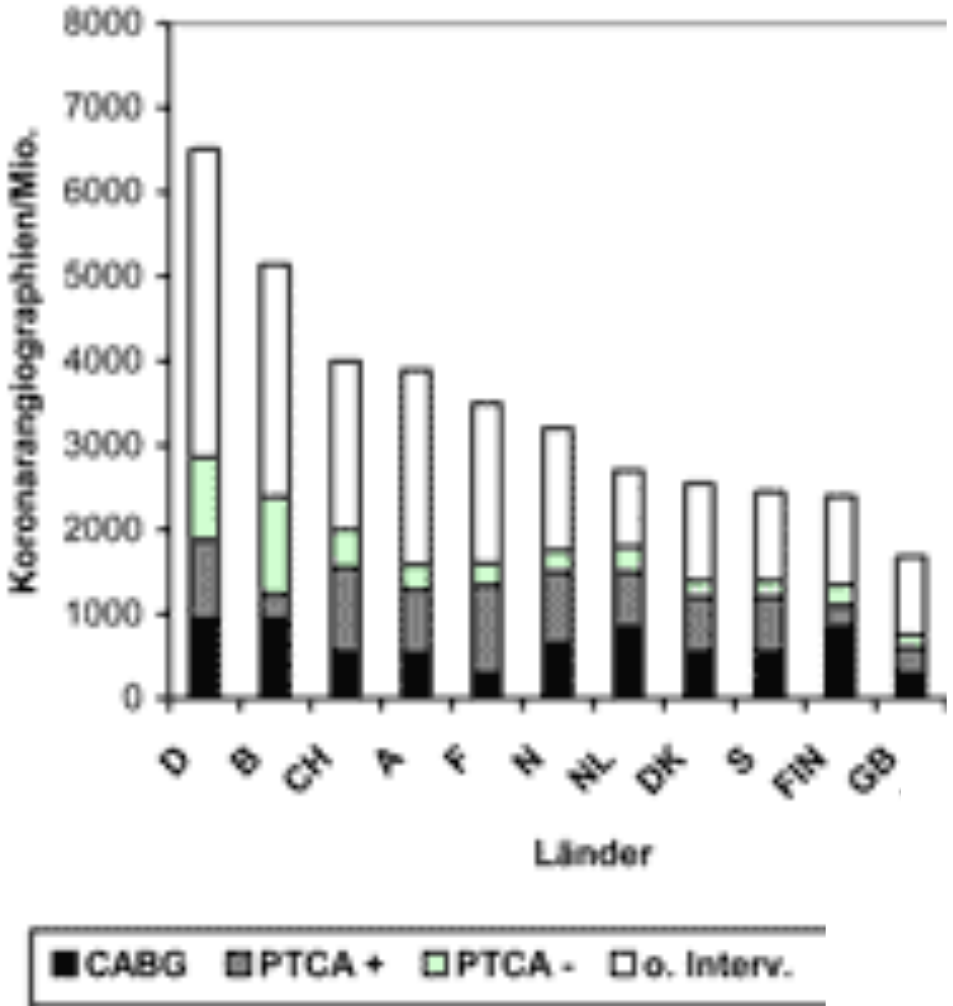


***self healing ability* of the heart!**

# Coronary angiopraphy and stent implantation per 1 million inhabitants in European countries



# Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study.

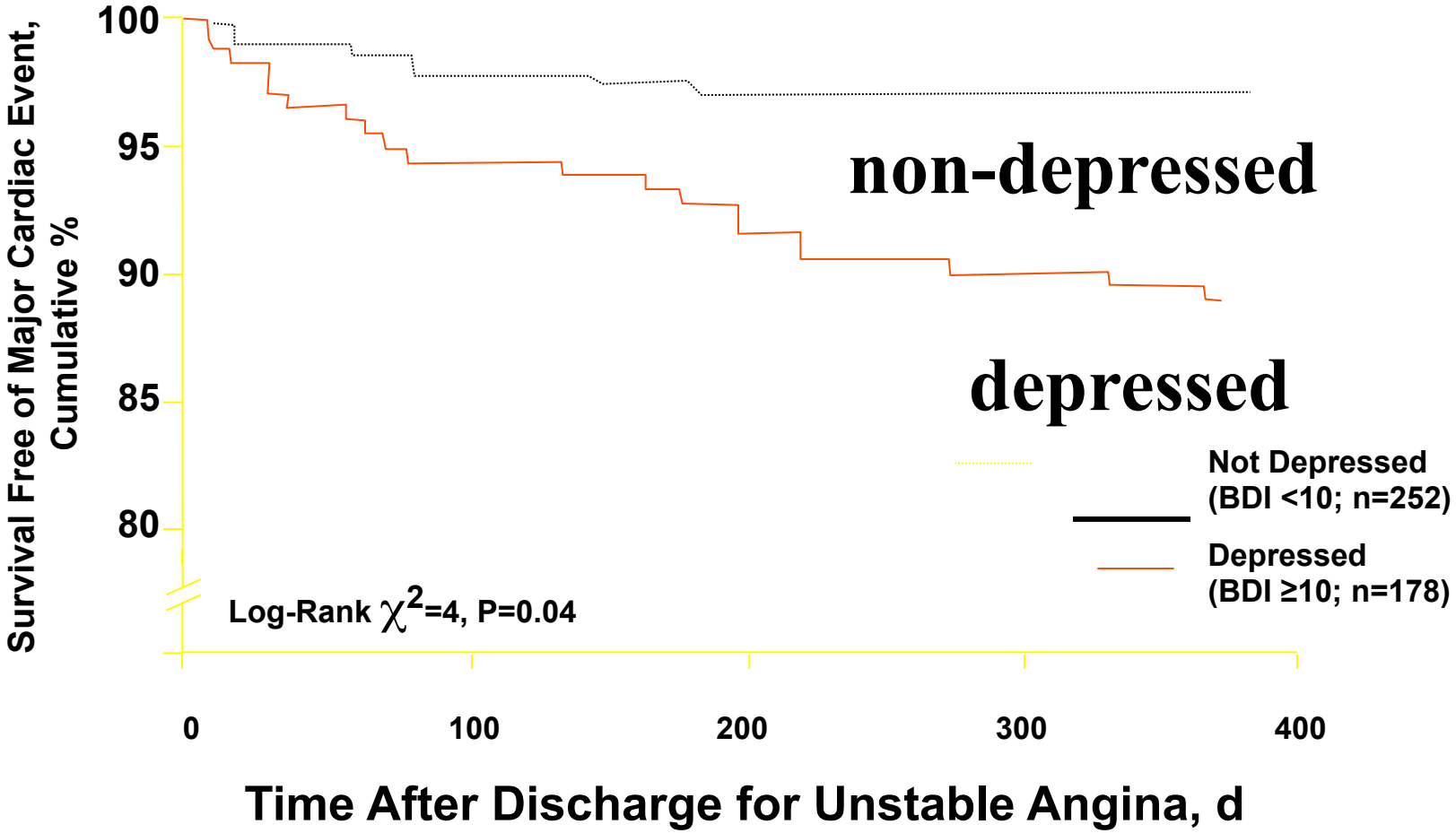
Yusuf S, et al., Lancet. 2004

**Stress and factors of lifestyle explain up to 90% (men) and 94% (women) of risk factors for myocardial infarction.**

# CAM in heart disease

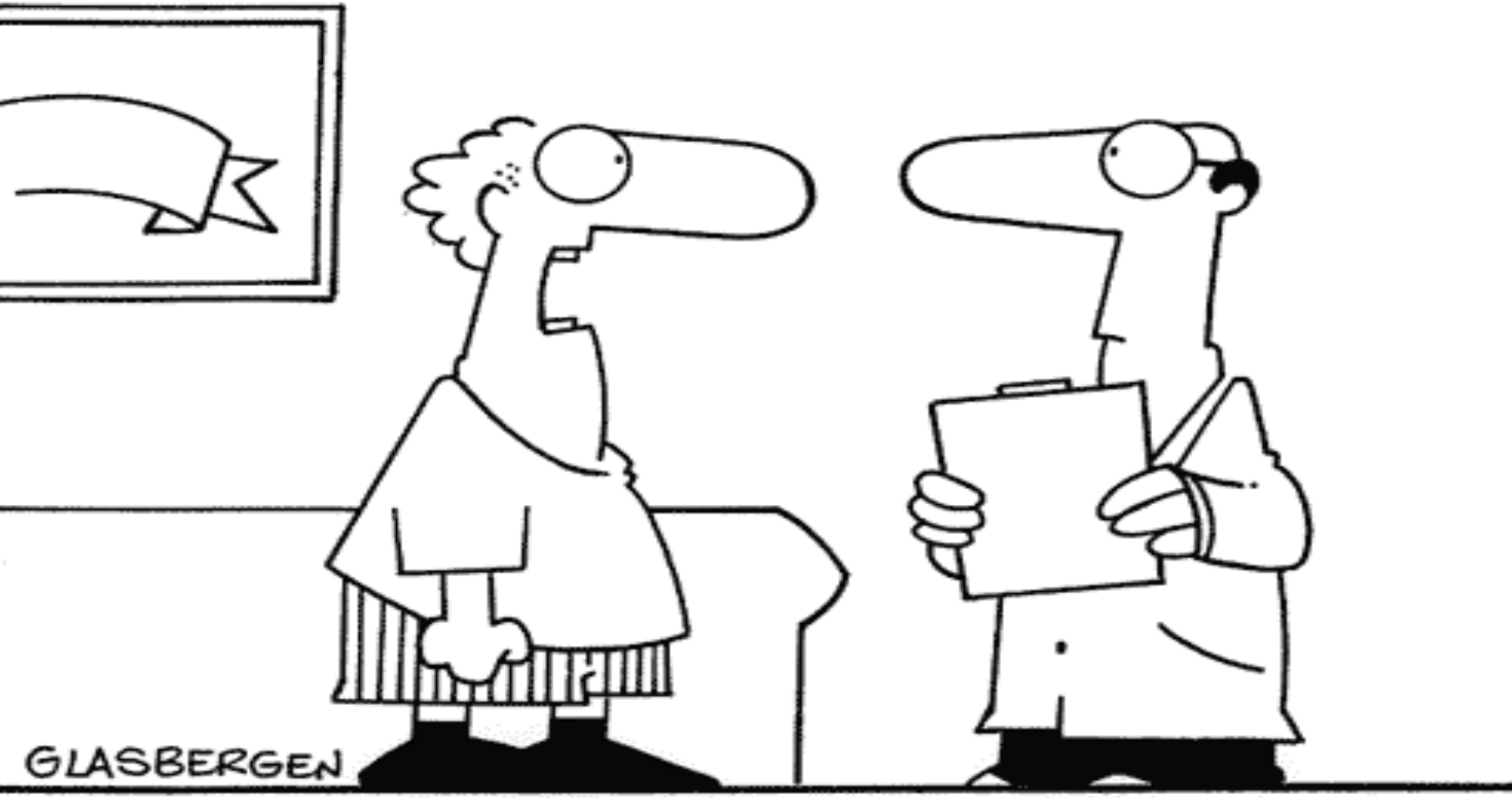
- Fasting
- Mediterranean diet
- Exercise
- Mind/Body medicine and lifestyle change

# Survival free of major cardiac events 1 year following discharge for depressed and nondepressed patients with unstable angina.



# Methods to elicitate the „*Relaxation Response*“

- **Mindfulness-based therapies**
  - Meditation (MBSR)
  - Yoga
  - Qigong
- Visualisation
- Progr. Muscel Relaxation
- Autogenic Training
- Prayer
- ...




**„I´m learning how to meditate, doctor - but I want to meditate better and faster! I want to be on the cutting edge of meditation!“**

De afbeelding kan niet worden weergegeven. Mogelijk is er onvoldoende geheugen beschikbaar

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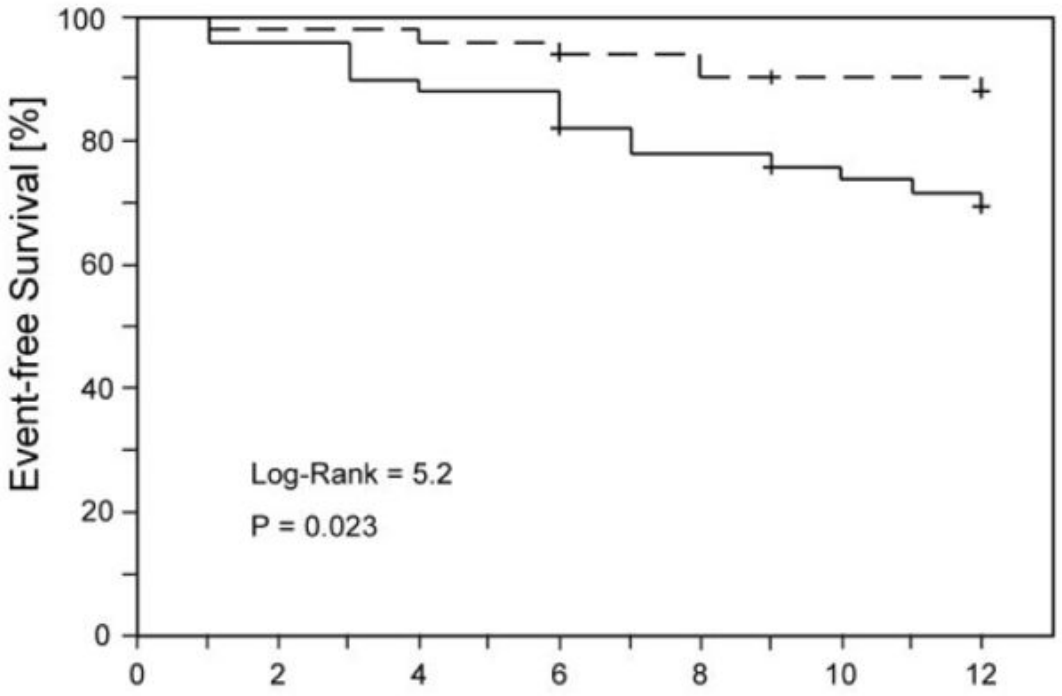
# Sport vs. Stent in stable coronary artery disease: a randomized trial.

*Hambrecht et al 2004, Circulation*




Sport

Stent

| *Patients at Risk* | | | |
|---|---|---|---|
| PTCA/Stent Group | 50 | 41 | 35 |
| Exercise Training Group | 51 | 48 | 45 |

# The Lyon-Heart Study

*- mediterranean diet after myocardial infarction -*

**n = 605 pat. after infarction**

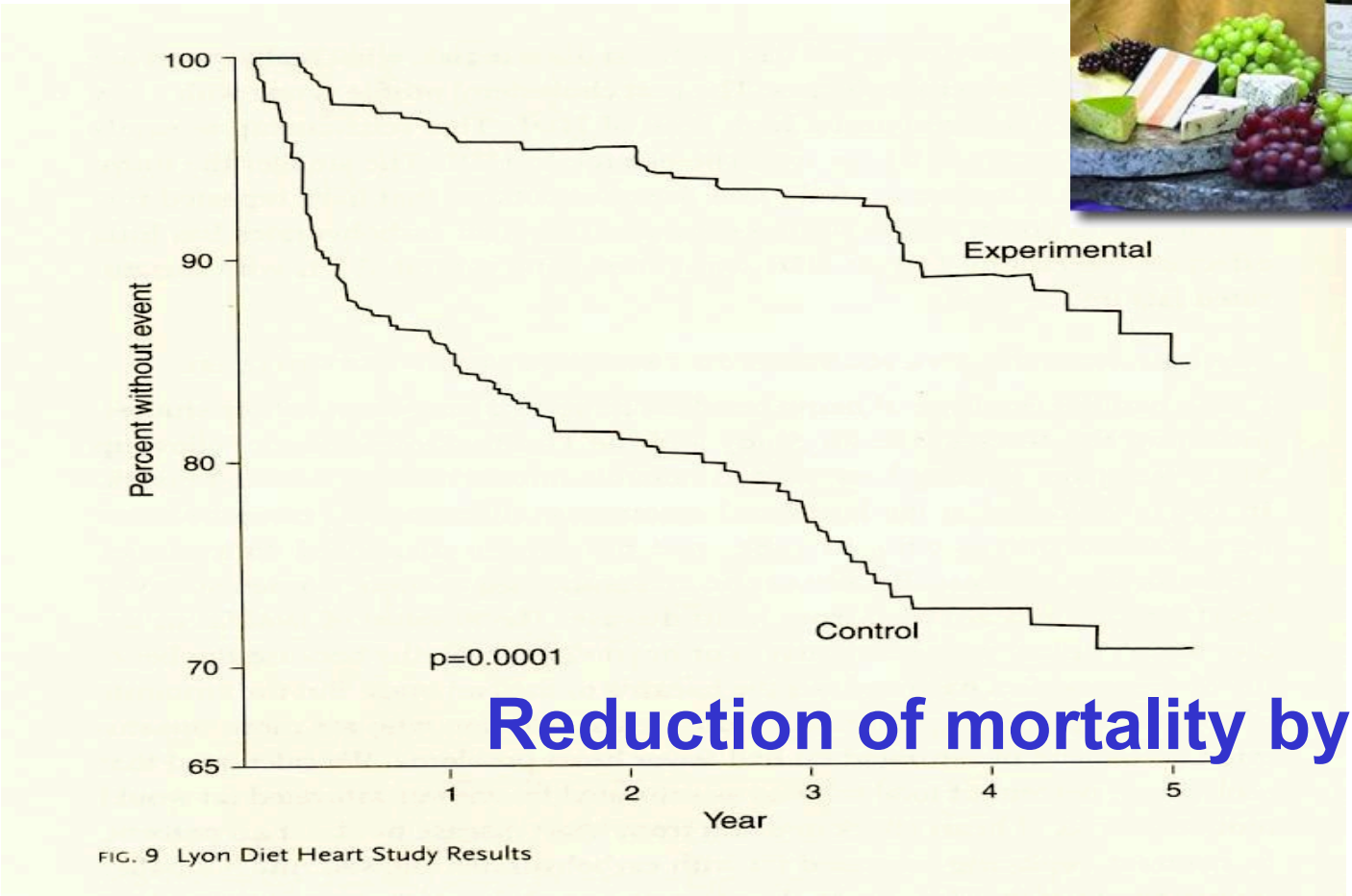



FIG. 9 Lyon Diet Heart Study Results

**Reduction of mortality by 70%**

# Usefulness of Routine Periodic Fasting to Lower Risk of Cor. Artery Disease in Patients Undergoing Cor. Angiography

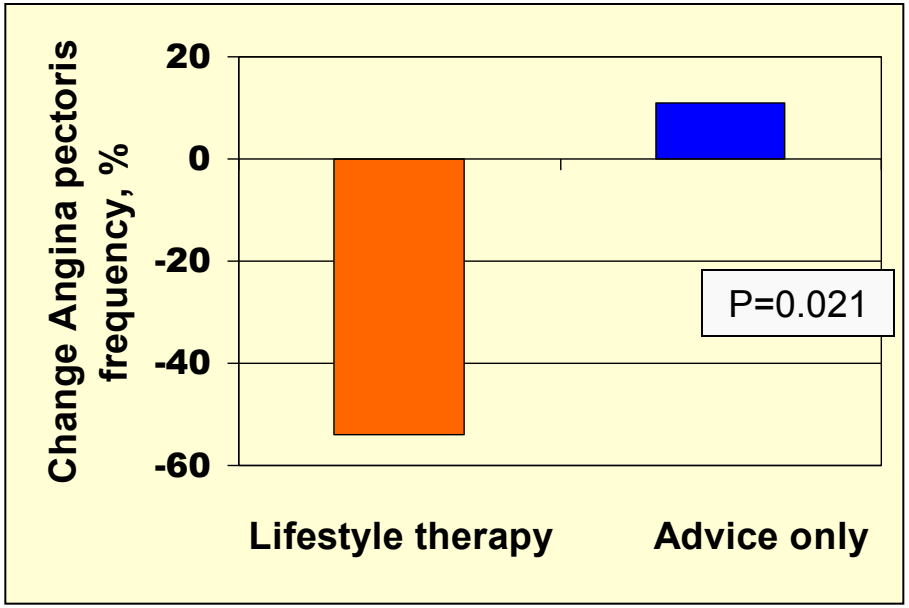
**Horne et al. Am J Cardiol 2008**

## Fasting

**Fasting (2 days per month) significantly reduce the risk of myocardial infarction.**

# *SAFE-LIFE Study*
# Universität Duisburg-Essen

## 50% reduction in angina by CAM-based lifestyle change!




Michalsen A et al: Am Heart J 2005;
Michalsen et al: Psychother Psychosom 2005

# How effective is arthroscopic surgery for osteoarthritis of the knee?

A controlled trial of arthroscopic surgery for osteoarthritis of the knee.

*Moseley et al. 2002, N Engl J Med*

# A controlled trial of arthroscopic surgery for osteoarthritis of the knee.

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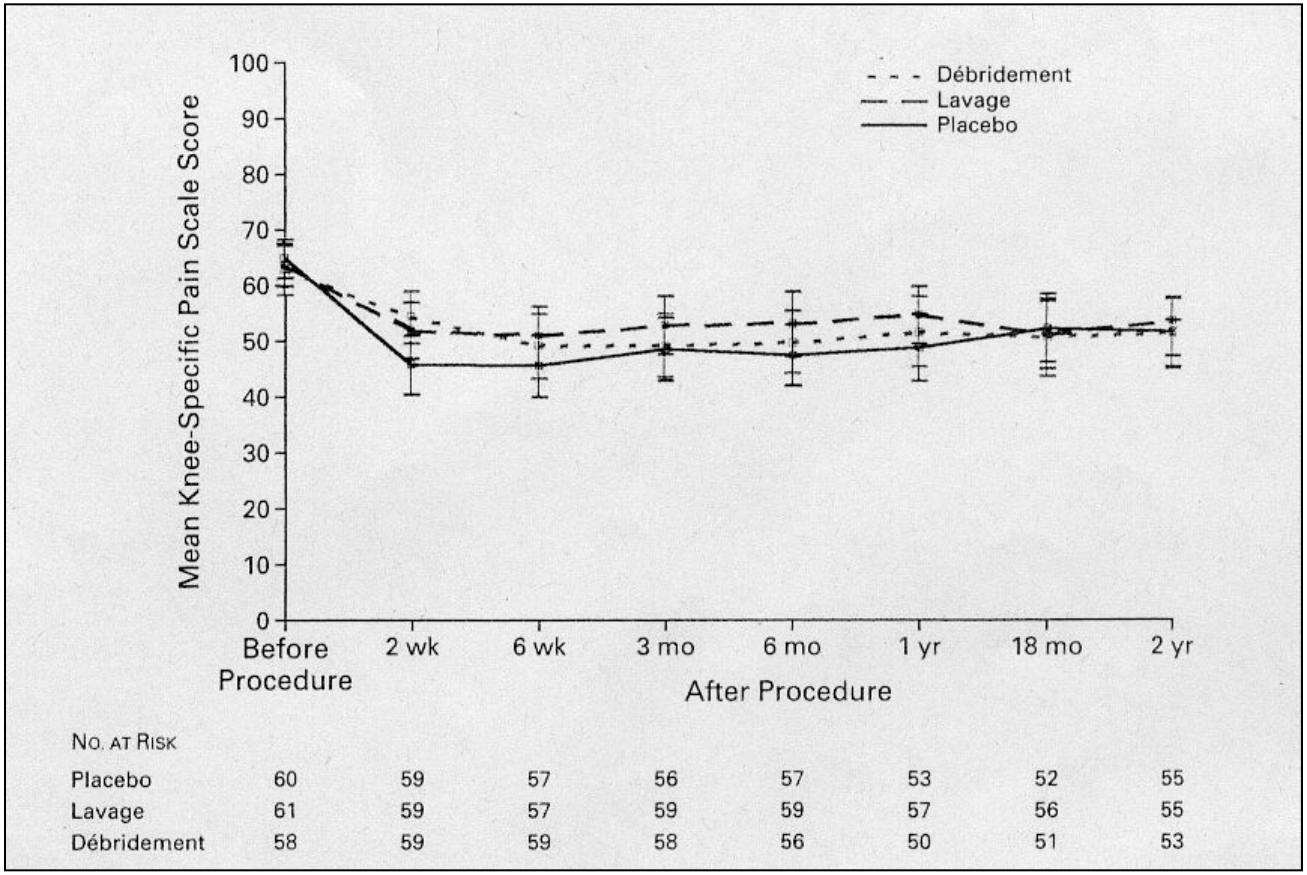


| No. at Risk | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Placebo | 60 | 59 | 57 | 56 | 57 | 53 | 52 | 55 |
| Lavage | 61 | 59 | 57 | 59 | 59 | 57 | 56 | 55 |
| Débridement | 58 | 59 | 59 | 58 | 56 | 50 | 51 | 53 |

# A controlled trial of arthroscopic surgery for osteoarthritis of the knee.

*Moseley et al. 2002, N Engl J Med*

In this controlled trial involving patients with osteoarthritis of the knee, the **outcomes after arthroscopic lavage or arthroscopic débridement were no better than those after a placebo procedure**.

# How is the level of evidence for arthroscopic surgery of knee osteoarthritis?

Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C: **Arthroscopic debridement for knee osteoarthritis**. Cochrane Database Syst Rev 2008;23:CD005118.

There is 'gold' level evidence that **AD has no benefit for undiscriminated osteoarthritis** (mechanical or inflammatory causes).

# How is the level of evidence for arthroscopic surgery of knee osteoarthritis?

Reichenbach S, Rutjes AW, Nüesch E, Trelle S, Jüni P. **Joint lavage for osteoarthritis of the knee**. Cochrane Database Syst Rev. 2010;12:CD007320.

Joint **lavage does not result in a relevant benefit for patients with knee osteoarthritis** in terms of pain relief or improvement of function.

# Evidence of CAM therapies in osteoarthritis

**Meta-Analyse**

| | |
|---|---|
| • Tai Chi | pos |
| • Acupuncture | pos |
| • Leech therapy | pos |
| • Exercise | pos |

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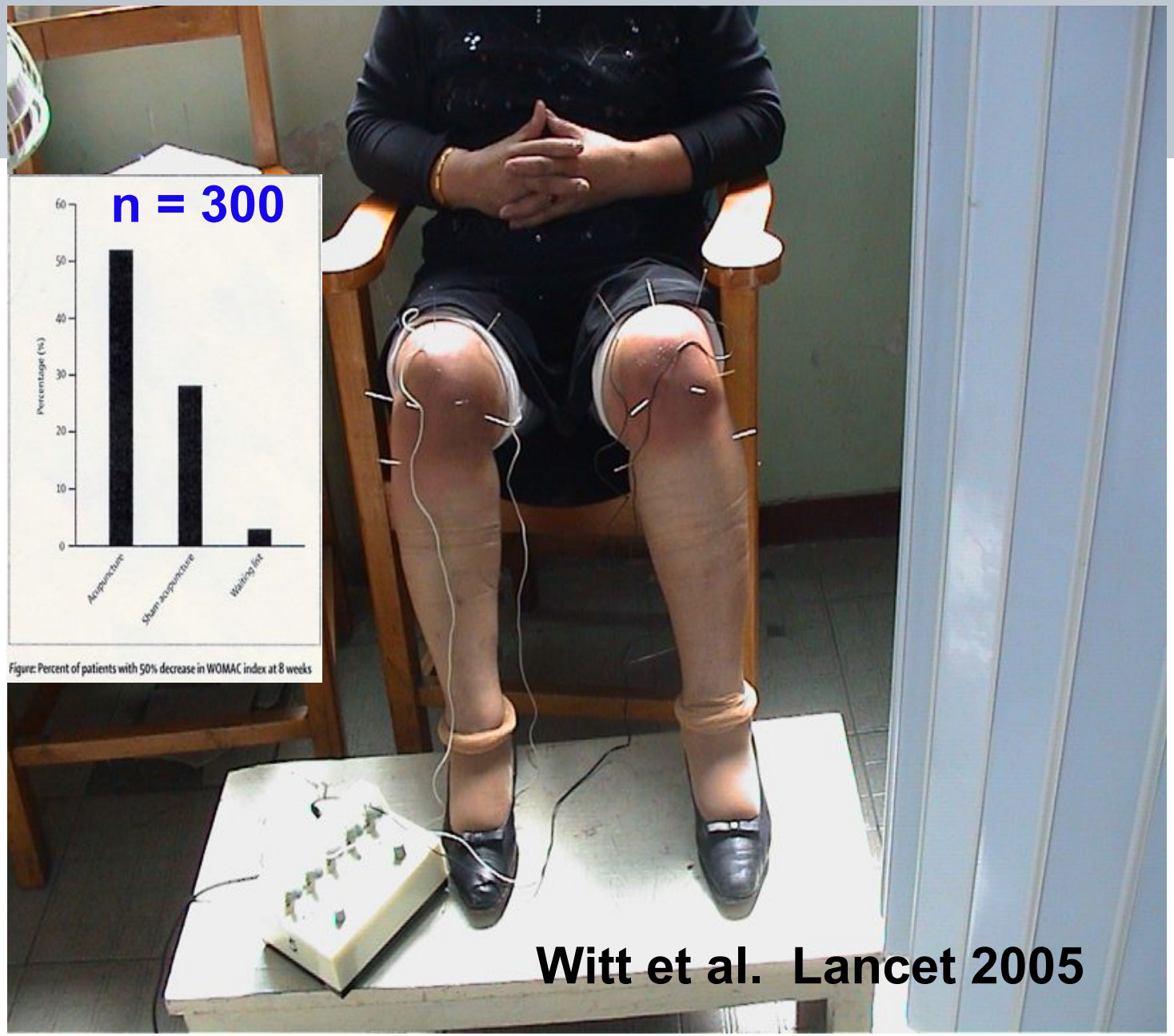
# Evidence of acupuncture




De afbeelding kan niet worden weergegeven. Mogelijk is er onvoldoende geheugen beschikbaar


Leech therapy in
osteoarthritis

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# … this therapy …

… is **safe** and **inexpensive,**

… from the **clinical aspect of experience - effective**

… and from the ***evidence of efficacy*** at least as efficient as one of the gold standard in orthopedics, **the arthroscopic surgery**


cabbage

# Summary

- The **evidence-base of major mainstream medicine** treatments is **weaker than generally thought**.

- There is some scientific **evidence-base and effectiveness of CAM** therapies in the field of

  **oncology, cardiology and chronic pain condition**

  that are responsible for the majority of medical costs in Europe.

- CAM might be relevant for **important EU health issues** like health maintanance, promotion, literacy and illness prevention.