

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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The basic principles of Complementary 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

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- **Mind/Body Medicine**

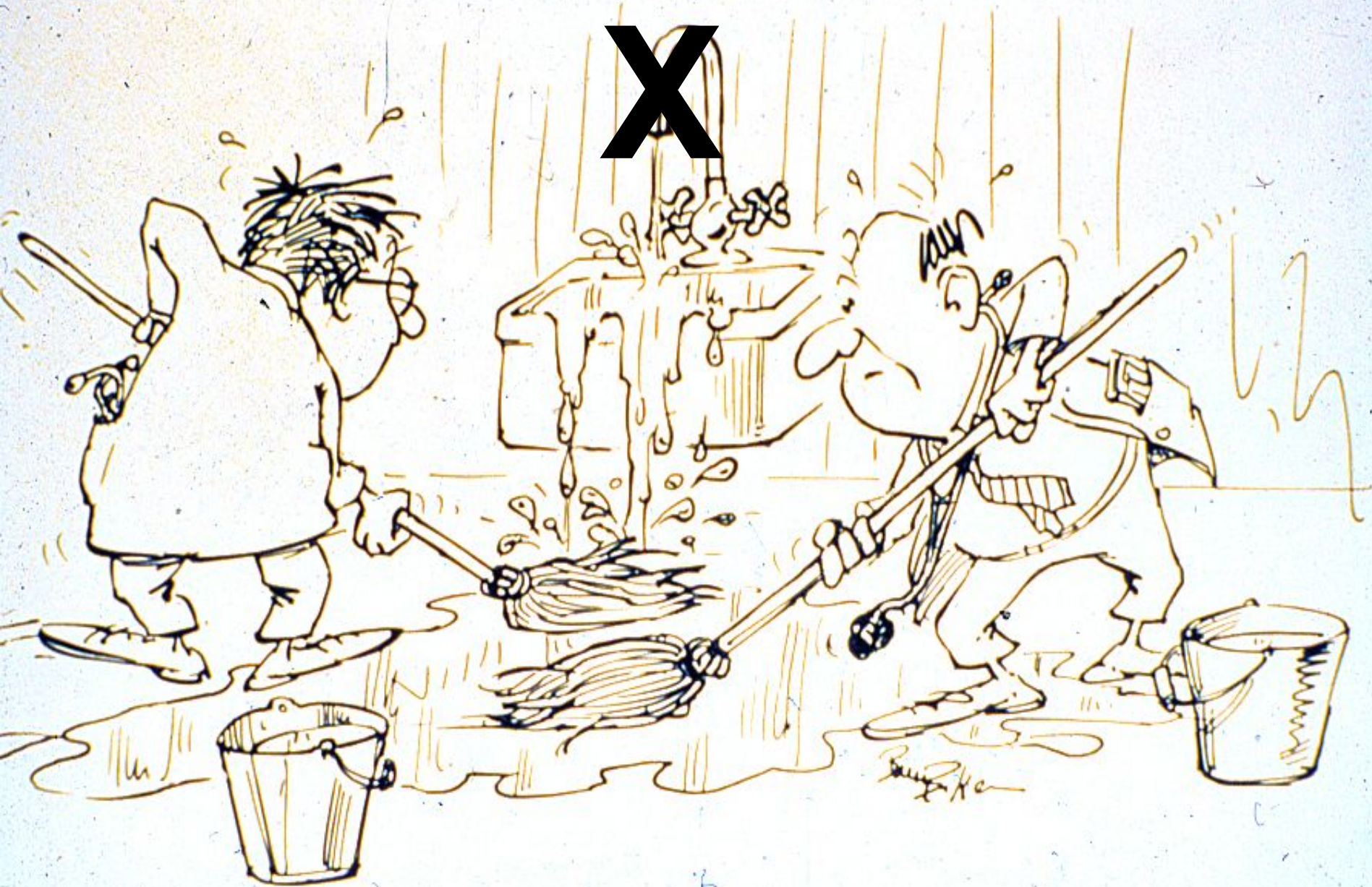
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Complementary and Alternative Medicine (CAM)

- **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 physician)**
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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 thought**.
- ... 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?

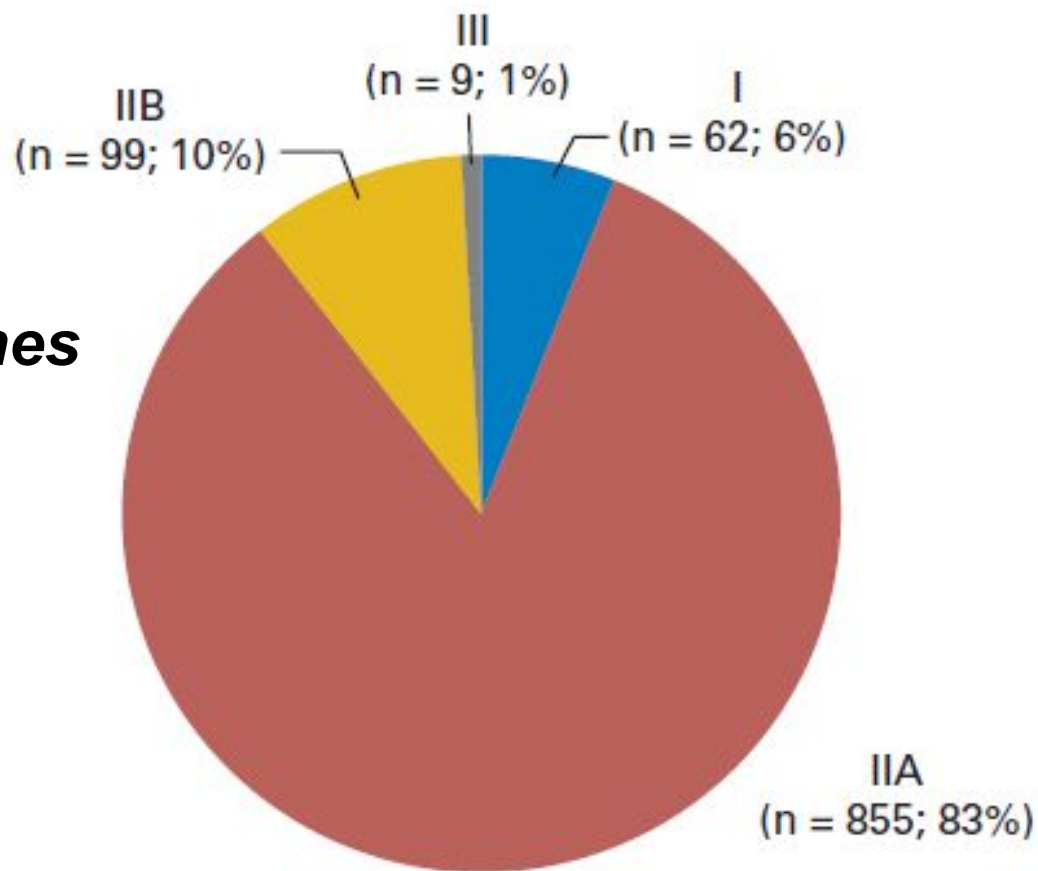
**Level of Scientific Evidence Underlying
Recomandations Arising From the *National
Comprehensive Cancer Network* (NCCN)
clinical practice guidelines.**

Poonacha and Go, J Clin Oncol 2011

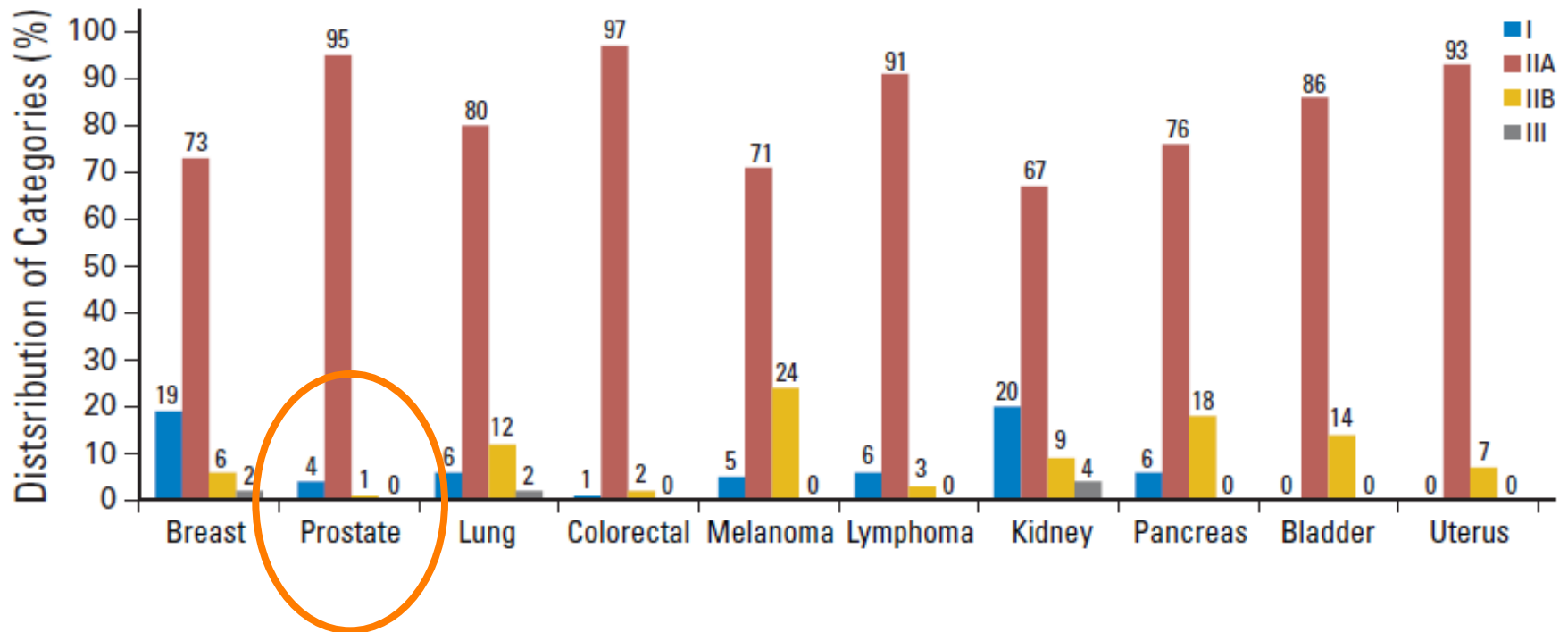
Distribution of categories of *evidence and consensus* for all guidelines

Evidence of all guidelines

6%



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



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

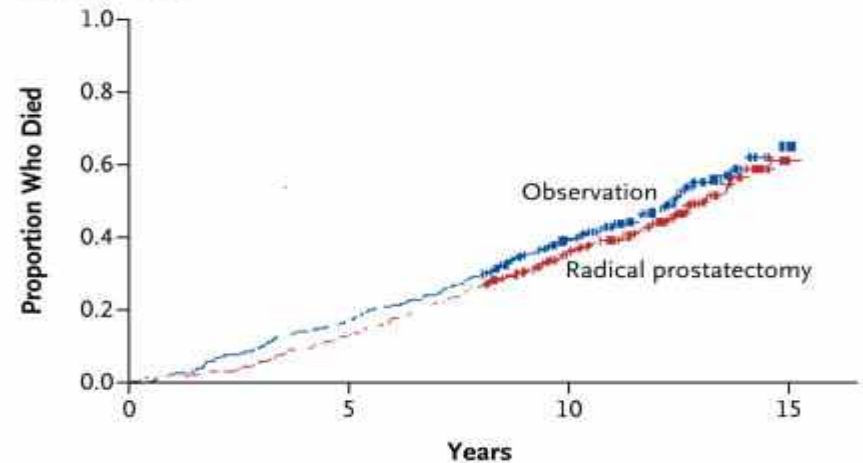
Radical prostatectomy versus observation for localized prostate cancer.

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.**

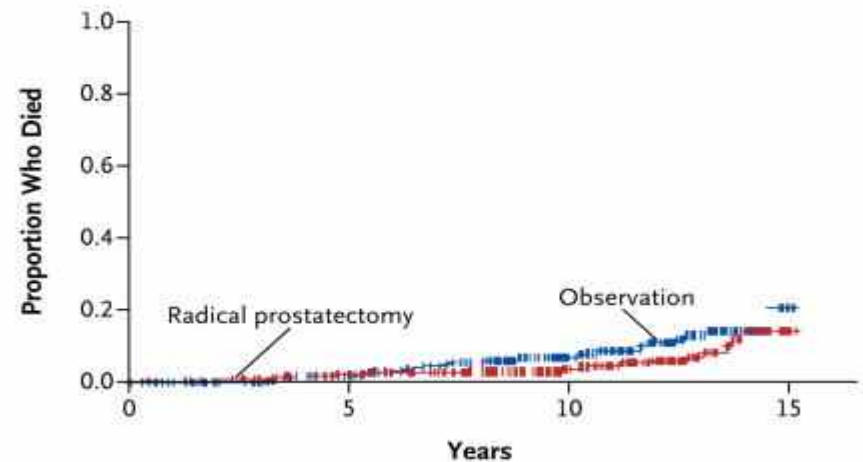
A Death from Any Cause



No. at Risk

Observation	367	341	315	288	258	176	106	26	0
Radical prostatectomy	364	352	329	300	267	187	126	36	0

B Death from Prostate Cancer



No. at Risk

Observation	367	341	315	288	258	176	106	26	0
Radical prostatectomy	364	352	329	300	267	187	126	36	0

Side effects:

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

Dysfunction	Radical Prostatectomy	Observation	P Value
	<i>no./total no. (%)</i>		
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 cancer.

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!**

Pre-intervention

Post-intervention

...microarrays detected
**48 up-regulated and
453 down-regulated
transcripts after the
Intervention.**

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

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

CPNE8
PPIC
CHMP2A
TRAK2
FNBP1L
VPS35
MTMR2
CSNK1G3
AP1G1
SNAP25
CSNK1A1
KIFC3
RAN
RAB8A
CHML
CLTA
EXOC6
COPB2
RAMP1
MAL2
NLN
RAB14
KPNB1
ARHGEF1
POM121
VCP
MTMR9
DLC1
MTAC2D1
STX17
PPIB

Mind/Body Medicine

NIH

**„Mind/Body Medicine
are Interventions,
that use a variety of techniques
designed to facilitate
the mind's capacity
to affect bodily function
and symptoms“**

nutrition

**social
support**

exercise

**cognitive
restructuring**

**relaxation
mindfulness
(MBSR)**

**stress-
management**

How is the level of evidence in Cardiology?

Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines.

Tricoci et al. JAMA 2009

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)*

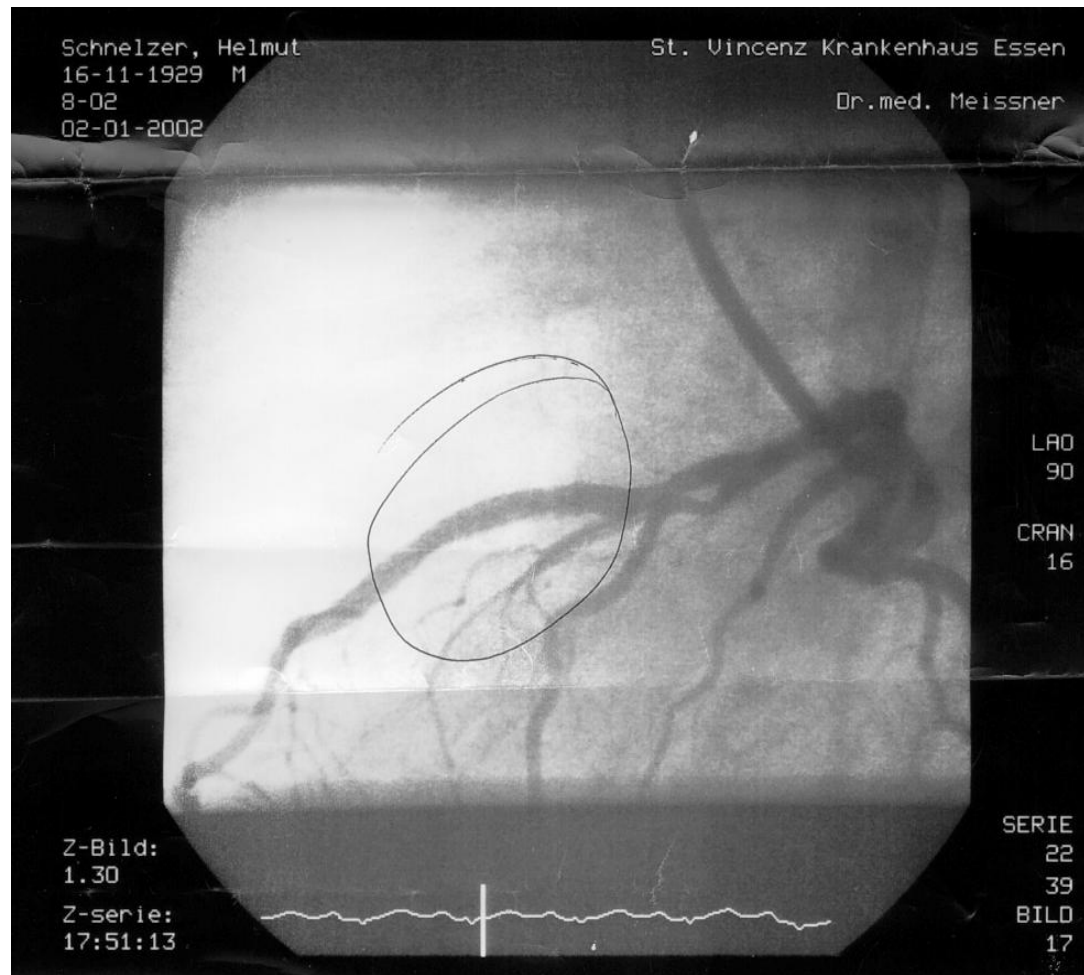
Tricoci et al. JAMA 2009

11.4%

Stenosis of the coronary artery



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.

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Arch Intern Med. 2012 .**

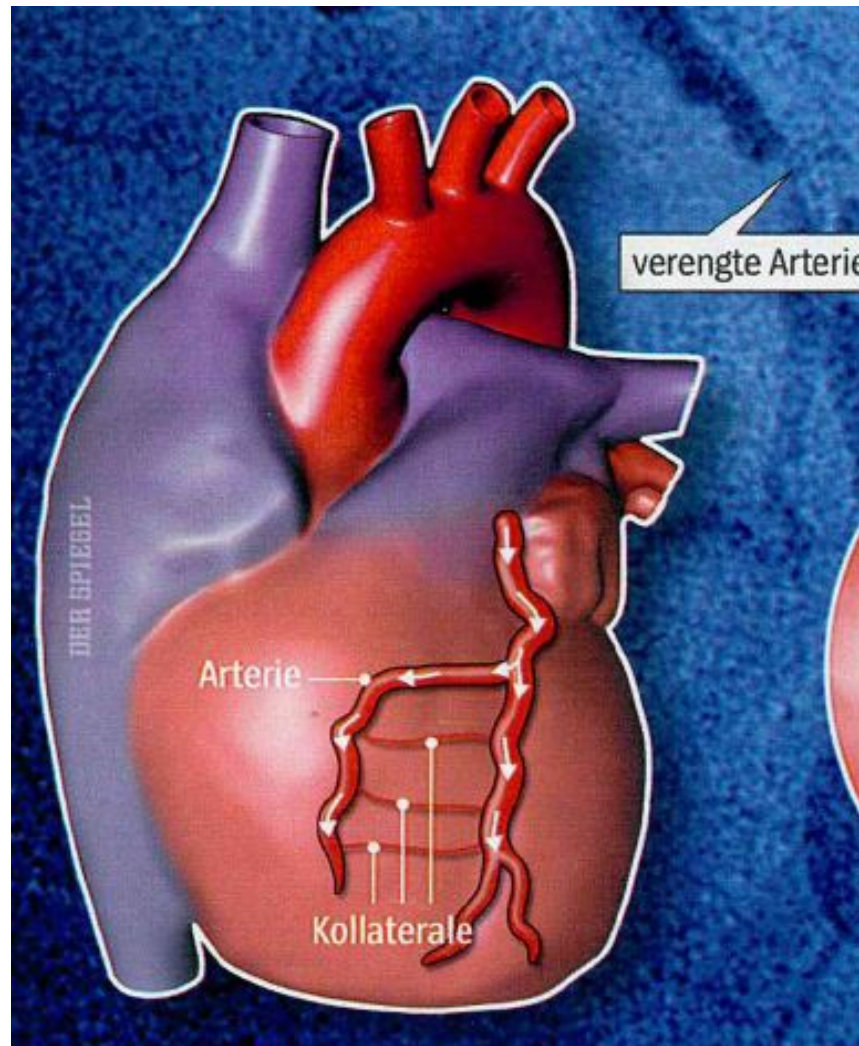
CONCLUSION:

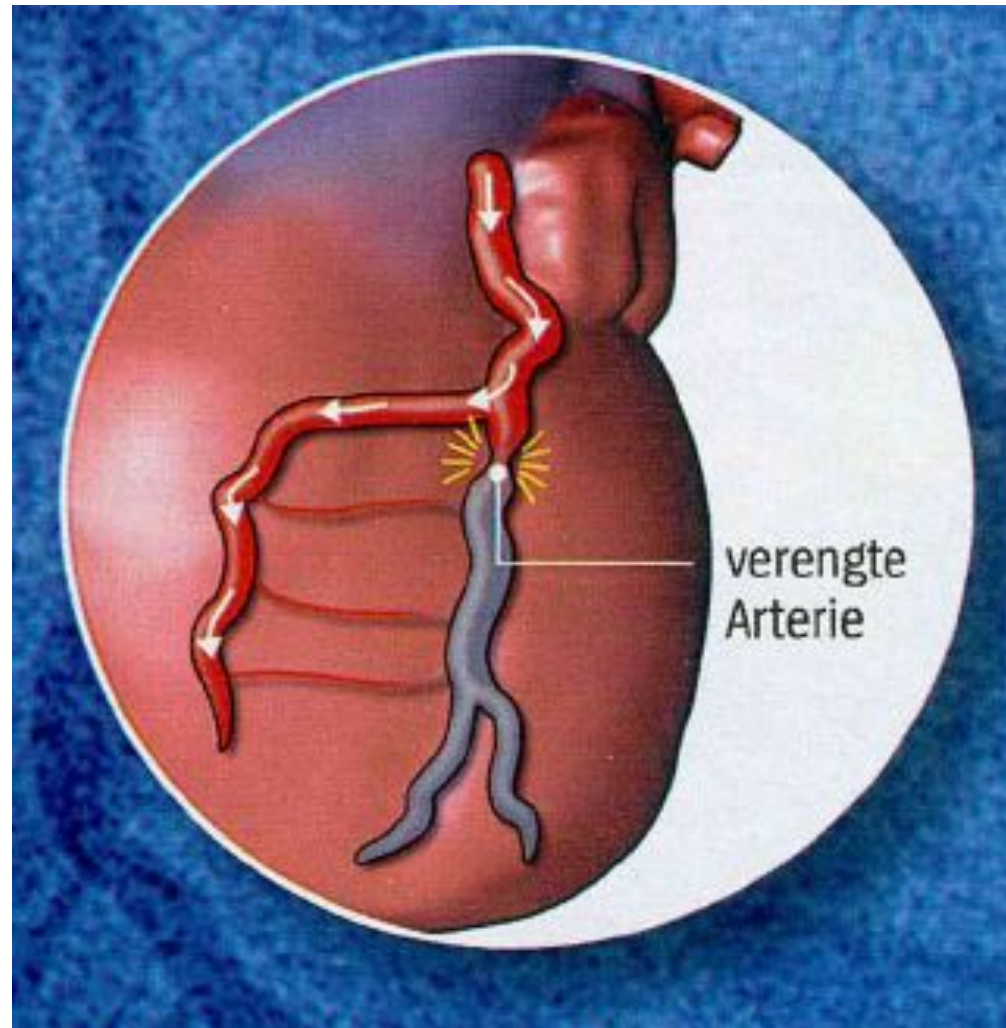
Initial stent implantation for stable CAD shows no evidence of benefit compared with initial medical therapy for prevention of death, nonfatal MI, unplanned revascularization, or angina.

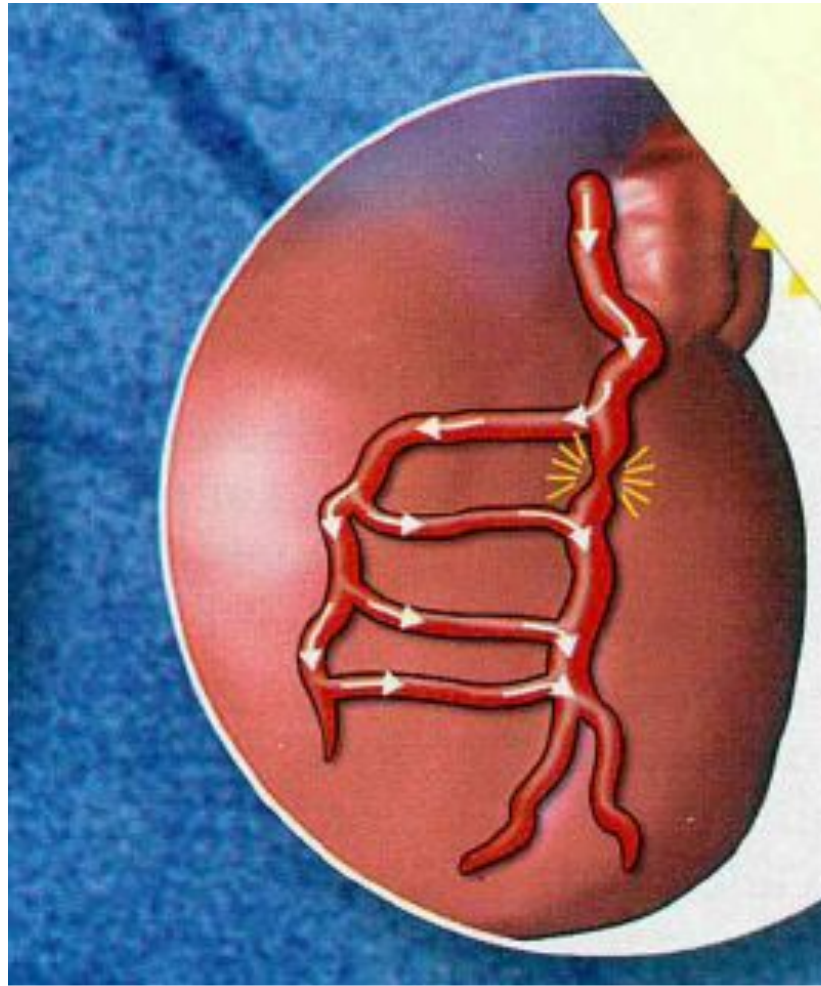
„Level of Evidence in Current Guidelines“ *Stabile Angina*

Tricoci et al. JAMA 2009

6.4%

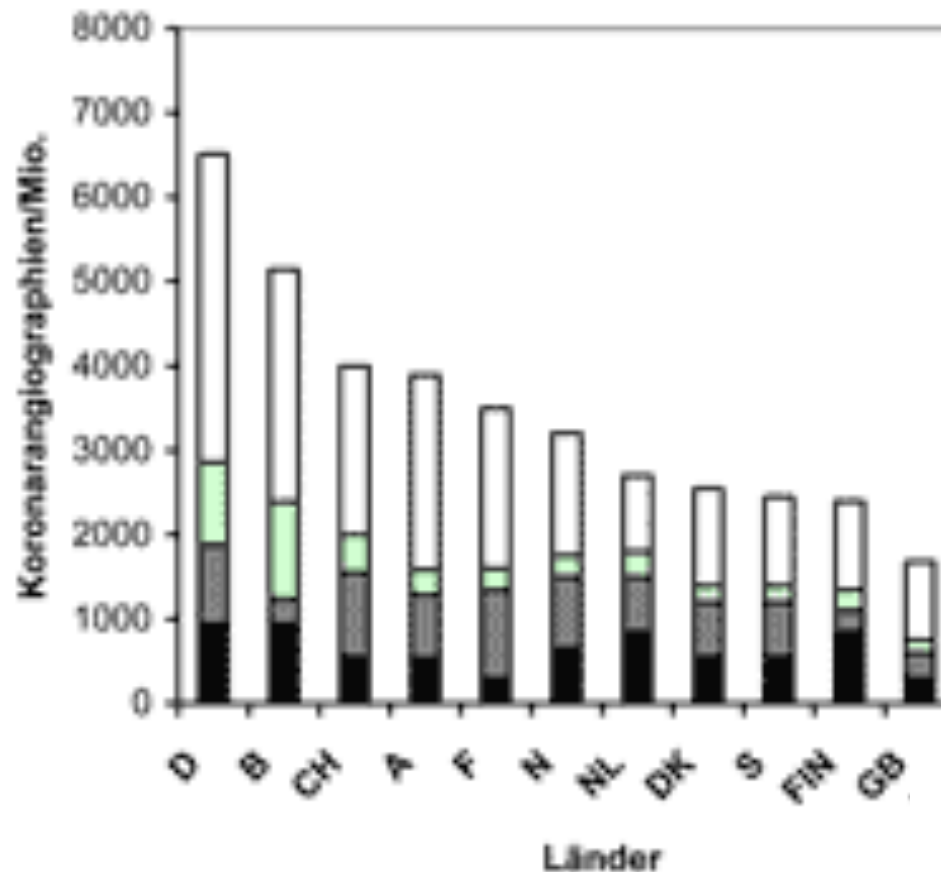






self healing ability of the heart!

Coronary angiography and stent implantation per 1 million inhabitants in European countries



■ CABG ■ PTCA+ ■ PTCA- □ o. Interv.

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

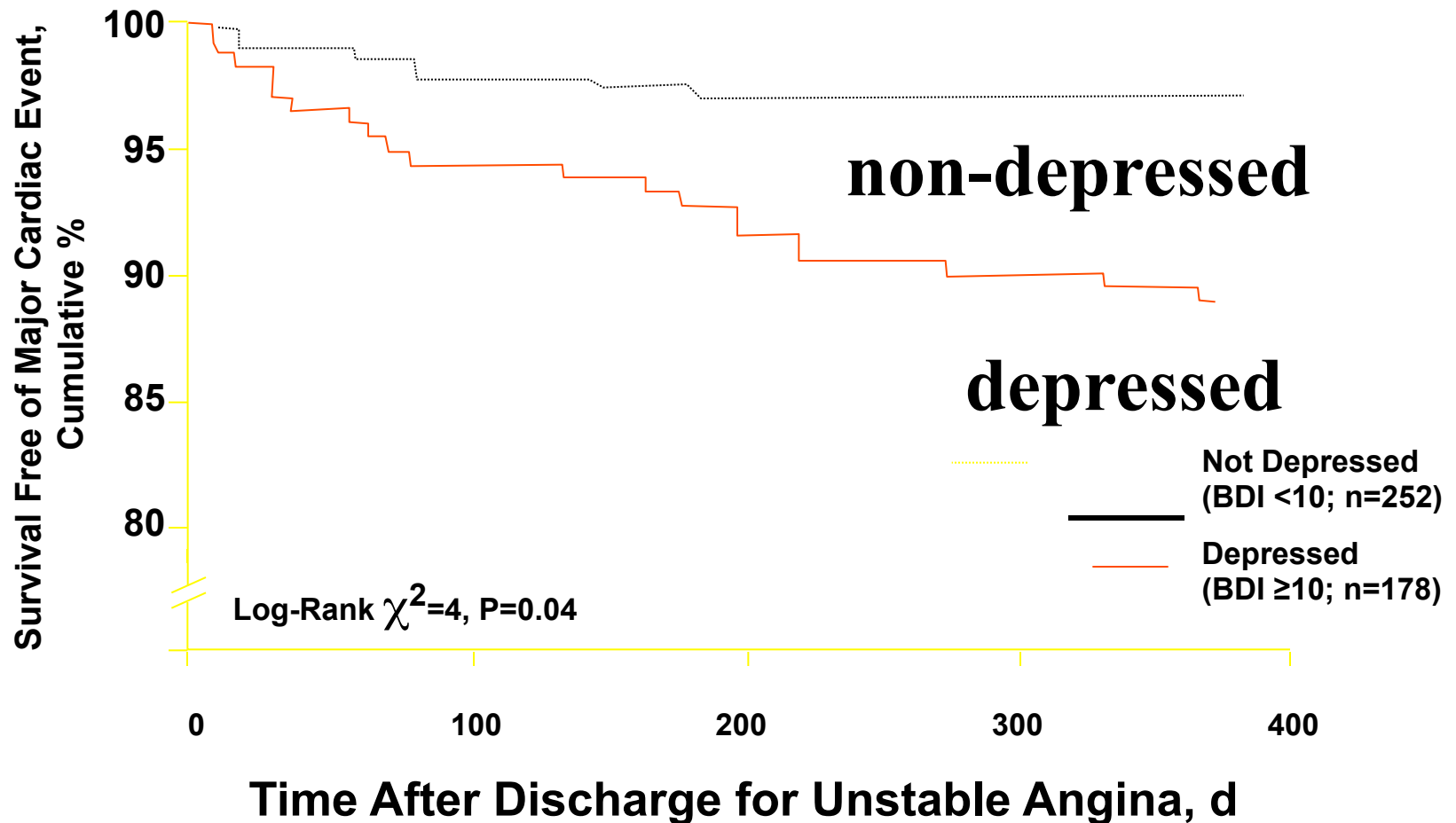
Yusuf S, et al., Lancet. 2004

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**

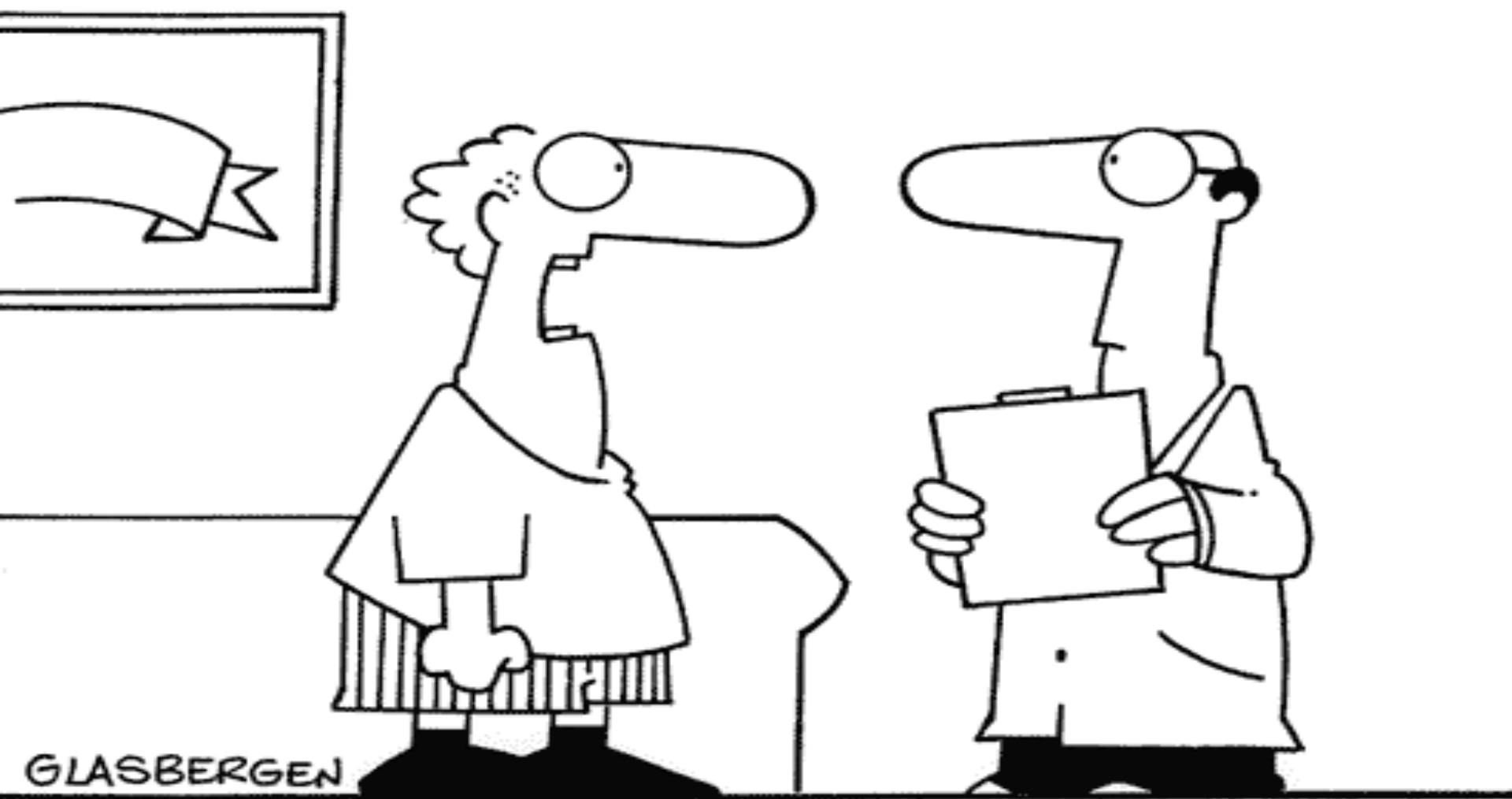
Meditation (MBSR)

Yoga

Qigong

- Visualisation
- Progr. Muscel Relaxation
- Autogenic Training
- Prayer
- ...



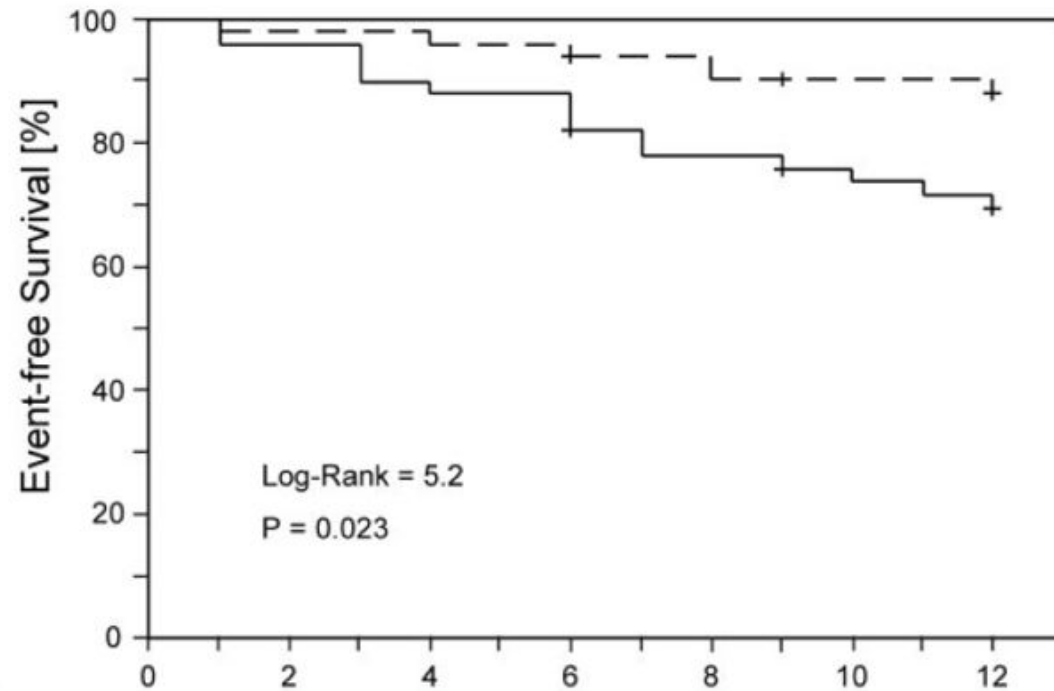


„I’m learning how to meditate, doctor - but I want to meditate better and faster! I want to be on the cutting edge of meditation!“

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

Follow up [Months]

The Lyon-Heart Study

- *mediterranean diet after myocardial infarction* -

n = 605 pat. after infarction

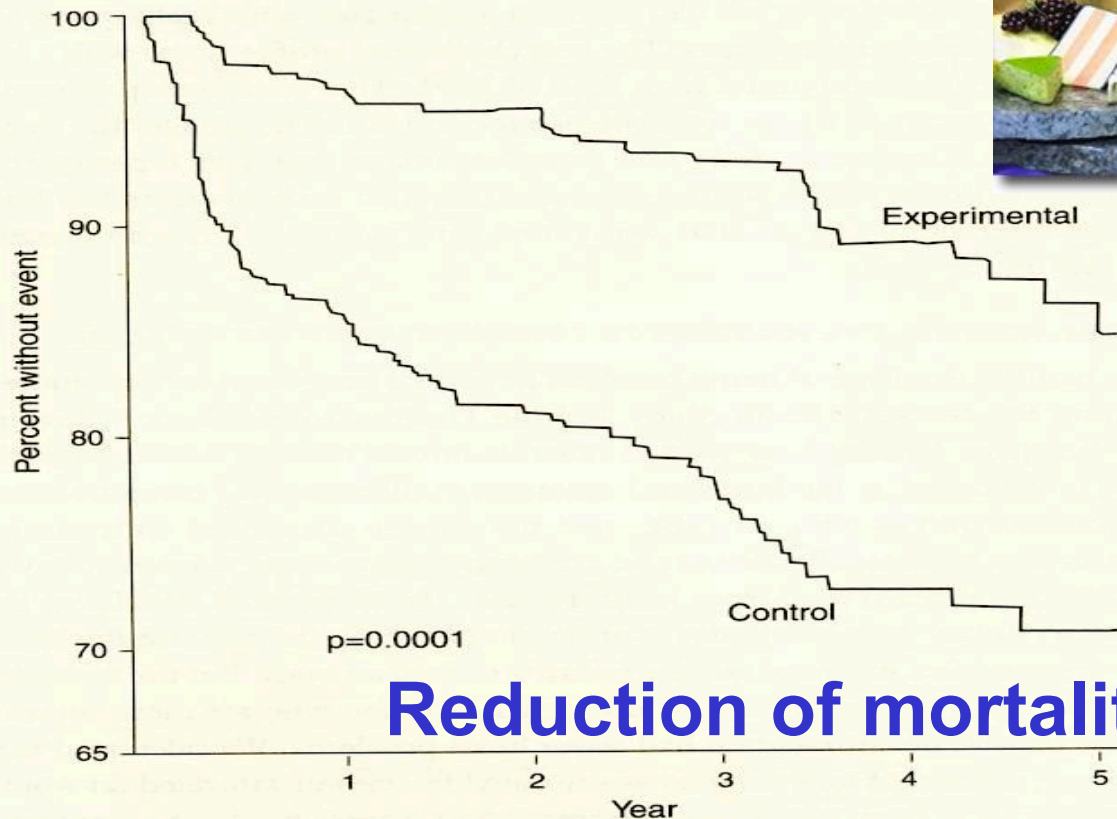


FIG. 9 Lyon Diet Heart Study Results

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

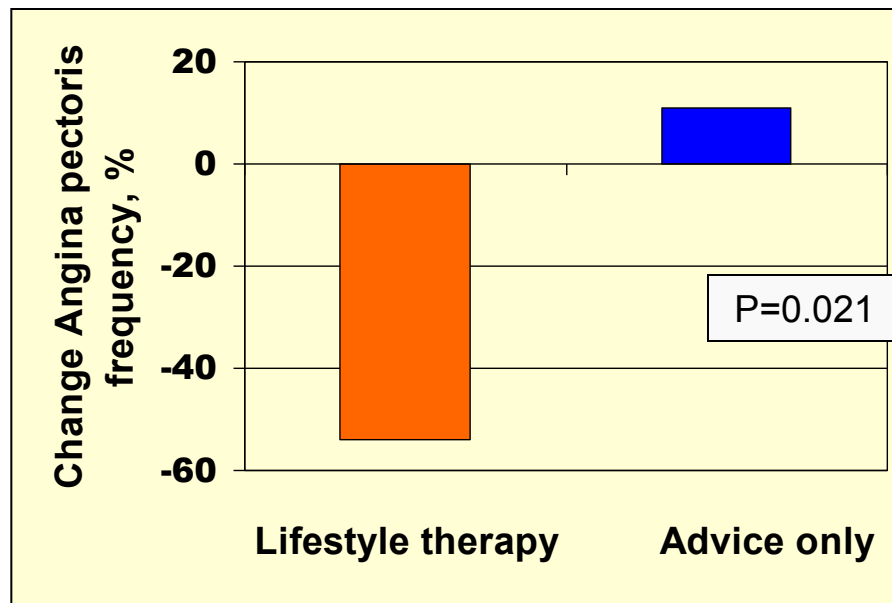
Fasting

**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

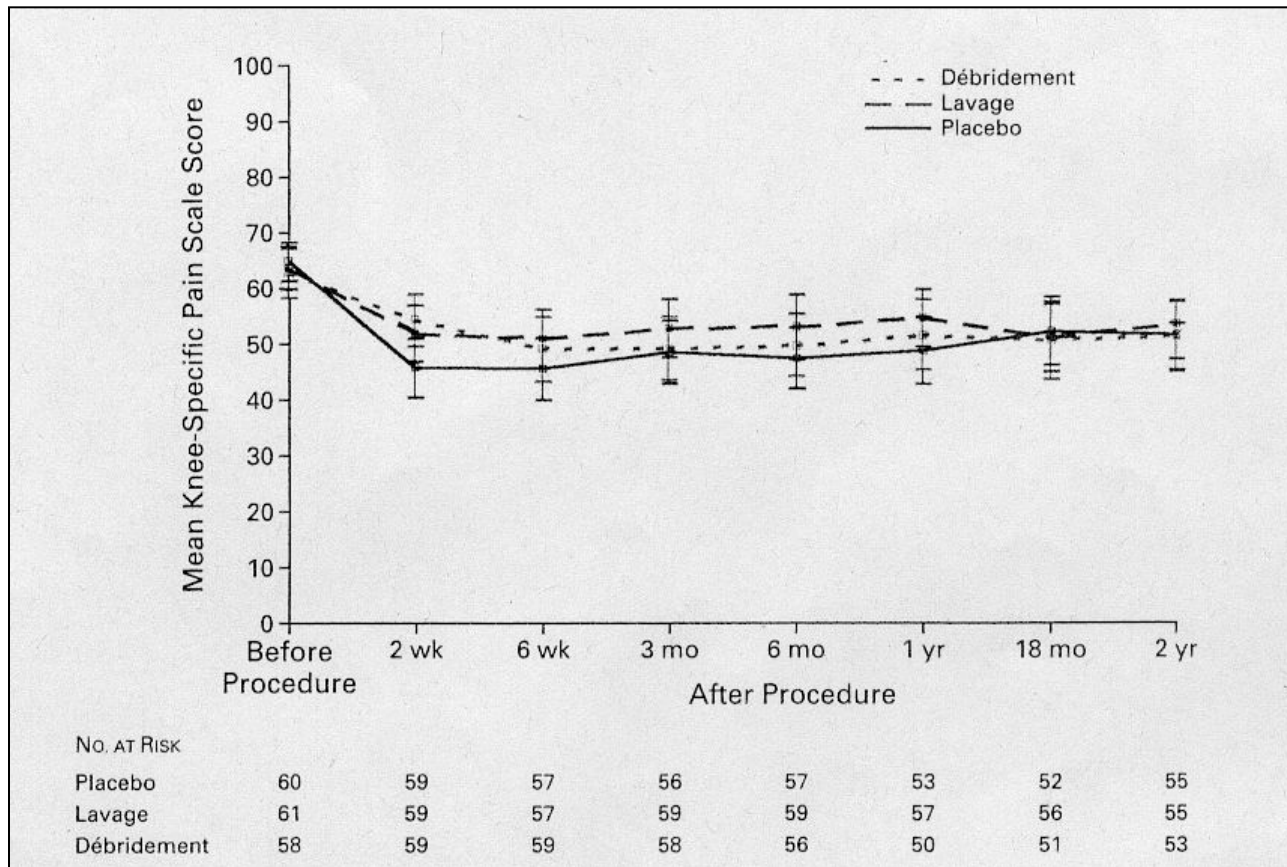
How effective is arthroscopic surgery for osteoarthritis of the knee? _

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.

Moseley et al. 2002, N Engl J Med



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.

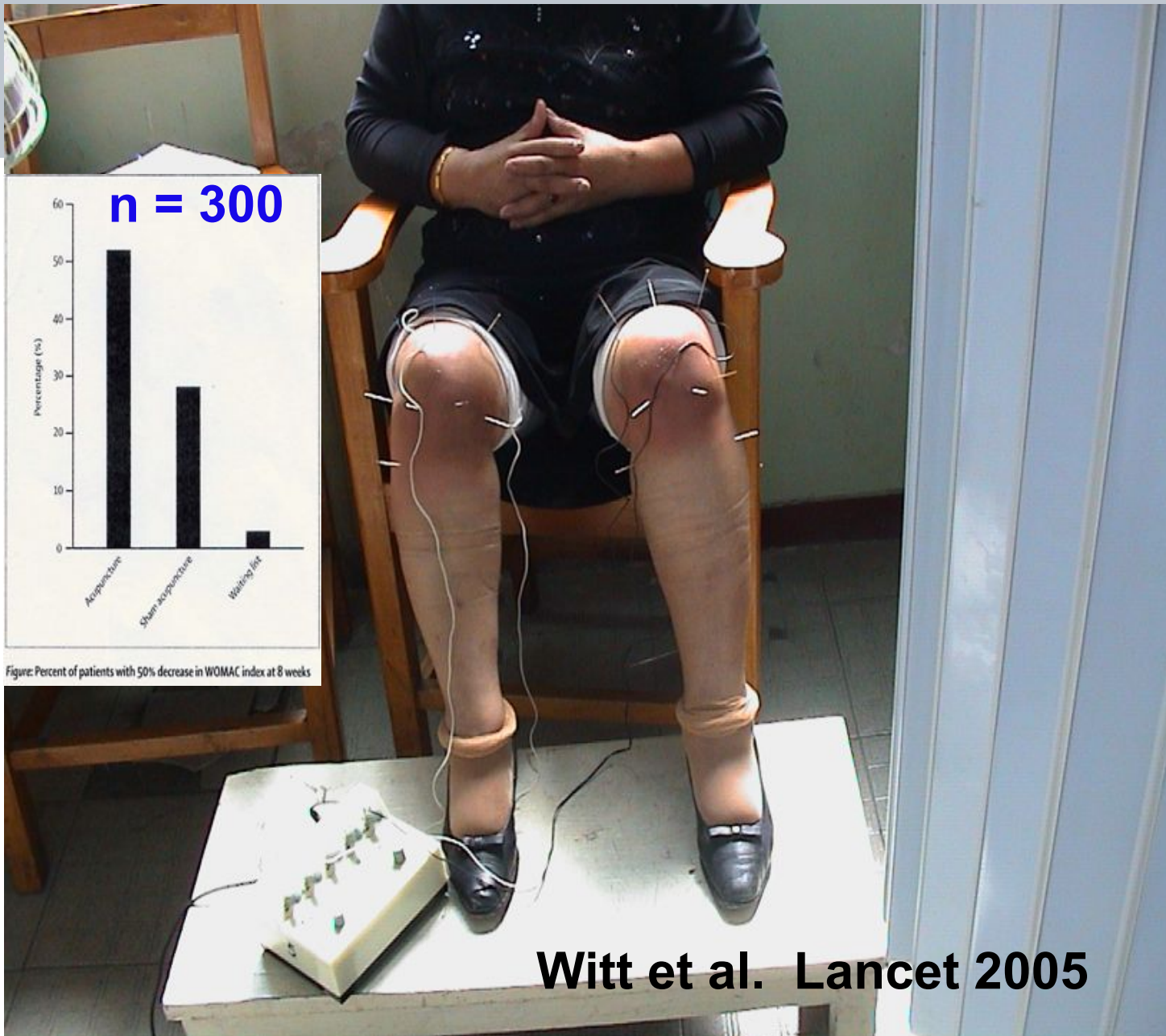
Joint lavage does not result in a relevant benefit for patients with knee osteoarthritis in terms of pain relief or improvement of function.

Evidence of CAM therapies in osteoarthritis

Meta-Analyse

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

Evidence of acupuncture



Witt et al. Lancet 2005



**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 maintenance, promotion, literacy and illness prevention.