Evidence-base and effectiveness of Complementary and Alternative Medicine

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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 physician)

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.

Purpose of my talk

• … to show that the evidence-base of major mainstream medicine treatments is weaker than generally taught.

• … 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*

- maintainance
- promotion
- literacy
- prevention
How is the level of evidence in Oncology?

Level of Scientific Evidence Underlying Recommendations 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
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.


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>
<thead>
<tr>
<th>Dysfunction</th>
<th>Radical Prostatectomy</th>
<th>Observation</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary incontinence†</td>
<td>49/287 (17.1%)</td>
<td>18/284 (6.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Erectile dysfunction‡</td>
<td>231/285 (81.1%)</td>
<td>124/281 (44.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bowel dysfunction§</td>
<td>35/286 (12.2%)</td>
<td>32/282 (11.3%)</td>
<td>0.74</td>
</tr>
</tbody>
</table>
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!
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.

Mind/Body Medicine

„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
- exercise
- relaxation
- mindfulness (MBSR)
- cognitive restructuring
- stress-management
- social support
How is the level of evidence in Cardiology?

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 \textit{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%
verengte Arterie

Arterie
Kollaterale
self healing ability of the heart!
Coronary angiography 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.

Survival Free of Major Cardiac Event, Cumulative %

- **Depressed** (BDI ≥10; n=178)
- **Not Depressed** (BDI <10; n=252)

Log-Rank \( \chi^2 = 4, P=0.04 \)

Time After Discharge for Unstable Angina, d
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

Event-free Survival [%]

Log-Rank = 5.2
P = 0.023

Patients at Risk

<table>
<thead>
<tr>
<th>PTCA/Stent Group</th>
<th>50</th>
<th>41</th>
<th>35</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise Training Group</td>
<td>51</td>
<td>48</td>
<td>45</td>
</tr>
</tbody>
</table>

Follow up [Months]
The Lyon-Heart Study
- Mediterranean diet after myocardial infarction -

n = 605 pat. after infarction

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

How effective is arthroscopic surgery for osteoarthritis of the knee?

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

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

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


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?


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?


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**
De afbeelding kan niet worden weergegeven. Mogelijk is er onvoldoende geheugen beschikbaar om de afbeelding te openen of is de afbeelding beschadigd.

KLINIKEN ESSEN-MITTE, Department for Internal and Integrative Medicine

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.