

The Management of the Menopause in the light of EBM

by

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Evidence Based Medicine

and / or

Medicine Based Evidence ?

MNC

“Without clinical expertise, practice risks becoming tyrannized by evidence.”

“Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients.”

Sackett DL et al., 1996

**“Evidence alone does not make
decisions”**

**“The new look of EBM should be research
enhanced health care”**

Haynes RB et al. Clinical expertise in the era of evidence based medicine and patient choice (Editorial) ACP Journal Club 2002,Mar-Apr;136(2):A11

“Clinicians must apply their expertise to assess the patients problem and must also incorporate the research evidence and the patient’s preferences or values before making a management recommendation”

Haynes RB et al. Evidence-Based Medicine. 1996;1:196-8

How should we read

Epidemiology

and follow

Evidence Based Medicine ?

Information is based on

- . Observational studies
(*retrospective*)
- . Clinical trials (*prospective*)
and
- . Experimental studies
 - “in vitro”
 - “in vivo” animals
 - women

Epidemiological studies

- How were they performed?
- What similarities do they have with our clinical practice?
- How to interpret them?

Epidemiological Studies

PLEASE!

Do not read only the titles

Do not read only the abstracts

Do read the full paper

Be critical!

Make up your own mind!

The “language” of the results

- . Absolute risks
- . Relative risks
- . Number needed to treat (NNT)
- . Number needed to harm (NNH)
- . Number needed to screen (NNS)
- . Events per woman / years
- . Events per total number of women

What is

a woman /year ?!

100 woman/years = 100 women treated during 12 months

is it the same as

100 woman/years = 400 women treated during 3 months

?

Do not confuse...

Relative Risk

with

Absolute Risk!

Do not confuse...

Morbidity

with

Mortality

**“Not everything that can
be counted *counts*;**

**and not everything that
counts can be counted”**

Albert Einstein

**Women
are not statistics!**

**They must be treated
individually.**

. What **do** we know?

Researchers from the University of California, at Davis, claim **clinical trials are reported with misleading statistics**

Mayor S, *BMJ* 2002;321:1353

“Most randomised trials of new treatments published in leading medical journals (*Ann Intern Med; BMJ; JAMA; Lancet*) are reported in a potentially misleading way”.

Mayor S, *BMJ* 2002;321:1353

“Most of the trials report results based on relative risk reduction”!

“Only 18 of the papers reviewed considered absolute risk reduction”!

“Only 8 of the 359 trials reported the number needed to treat (N.N.T)”!

Mayor S, *BMJ* 2002;321:1353

Lessons from the WHI

“...most articles and broadcast segments tended to focus exclusively on either the *small absolute risks* or the *larger relative risks*, neglecting the more even-handed picture that presented both.

Since the **sharply increased *relative risks* got the most play**, news coverage about the trial's findings had an alarming cast.”

Denzer S. Editorial. *Ann Intern Med.*2003;138:352-353

“The media often failed to understand the complexities and limitations of such trials and came to its own simplified conclusions.”

“The nurse’s study and ones like it could be right and the Women’s Health Initiative could be wrong, or vice-versa”

Rossouw J, 2003

“If each is right it may be because the women in the two types of studies are different in a way that researchers have not yet figured out”.

Rossouw J, 2003

***“May be each study is wrong.
May be estrogen, in pills, is not
the chemical to focus on”***

Rossouw J, 2003

“It is quite possible that both are correct. The different results may hinge on the differences between the women who joined the studies”

Grodstein F, 2003

Effect on the risk of CHD

WHI Significant increased risk

RR 1.29 (CI 1.02-1.63); 29 % increased risk

AR 0.37% vs 0.30% (ie, **37** vs **30** events annually per **10.000** women)

HERS Nonsignificant decreased risk

RR 0,99 (CI 0.84-1.17); 1% decreased risk

AR 3.66% vs 3.68% (ie, 366 vs 368 events annually per **10.000** women)

“Unlike HERS which showed no benefit or harm after 6.8 years of hormone use, WHI found more heart disease in women taking the combined therapy after 5.2 years.”

“This is a key finding because **WHI** **results apply to** healthy women while **HERS** involve **women** with **heart disease**”

Roussouw J. Release of the Results of the Estrogen Plus Progestin Trial of the Women's Health Initiative: Findings and Implication. Press Conference Remarks July 9, 2002. <http://www.nhlbi.nih.gov/whi/hrtupd/roussouw.htm>

EBM

can be used **to do...**

and **not** **to do...**

“Annual Physical Checkup May Be an Empty Ritual”...

“Many tests that are useful, like cholesterol and blood pressure checks, need not be done every year, is said in reports to doctors, policy makers and the public”.

The New York Times; August 2003; U.S. Federal Agency for Healthcare Research and Quality..

“Annual Physical Checkup May Be an Empty Ritual “ (?!...)

“No evidence, for example, that routine pelvic, rectal and testicular exams made any difference in overall survival rates for those with no symptoms of illness.” (!?...)

The New York Times; August 2003; U.S. Federal Agency for Healthcare Research and Quality.

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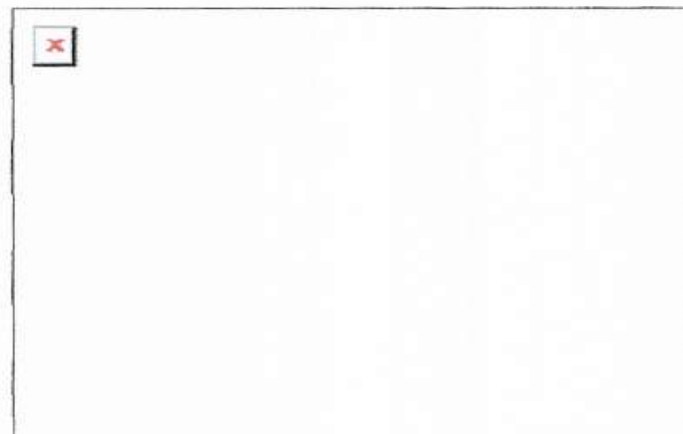
CNN To Go

Study: Fellatio may significantly decrease the risk of breast cancer in women

Thursday, October 2, 2003 Posted: 9:19 AM EDT (1319 GMT)

(AP) -- Women who perform the act of fellatio on a regular basis, one to two times a week, may reduce their risk of breast cancer by up to 40 percent, a North Carolina State University study found.

Doctors had never suspected a link between the act of fellatio and breast cancer, but new research being performed at North Carolina State University is starting to suggest that there could be an important link between the two.



Story Tools

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Study: *”Fellatio may significantly decrease the risk of breast cancer in women” !...*

(AP) – “Women who perform the act of fellatio on a regular basis, one to two times a week, may reduce their risk of breast cancer by up to 40 percent, a North Carolina State University study found”

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“CNN.com./HEALTH”

therefore ...

***When this was read and heard
all over the World...***

**Most likely, some people
started thinking that the
seminal plasma might contain
an *orally active* protective
molecule ...**

however...

It was soon found out that **it had been a joke** sent to the Web by one **ironical** N.C. University student ,who wanted to have fun with some epidemiologists! ...

The Truth?

*“The objective of both basic and clinical science is **to know the truth**”.*

*“Every epidemiologic study, no matter how good or how large, **gives only one view of the truth**”.*

“It takes many views to come close to seeing the truth”

Bush TL. *Int J Fertil.*2001;46:56-59