

An abstract background image featuring a complex, overlapping pattern of blue and white lines and shapes, resembling a crystalline or molecular structure. The lines are sharp and intersect at various angles, creating a sense of depth and movement. The overall color palette is dominated by shades of blue, from deep navy to bright cyan, with white highlights that define the edges of the geometric forms.

**Use of  
screening  
research to  
boost  
overdiagnosis:  
the MyPeBS  
trial**

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Conflicts of interest: None*

# Remember

In France, sept 2016,  
an independant **Civil and Scientific Inquiry into  
Mammographic Screening** recommanded:

- \* Complete stopping of the screening program
- Or
- \* Stopping the screening as existing and undergo  
complete revision

The French National Institute of Cancer (INCa) replied  
"abandoning screening programme  
would be a complete nonsense"  
Instead, it would propose  
"a screening based on the risk level"

# The MyPeBS trial

MyPeBS for "My Personal Breast Screening"  
is an international randomized study which compares

- a personalized Risk Stratified BCS
- to standard BCS
- in women aged 40-70

MyPeBS should involve 85000 women  
in France, Belgium, Italy,  
Israël, the UK  
During 6 years

The protocol is not public.  
We had to trick in order to read it.

Seems similar to the US **Wisdom Study**  
<https://clinicaltrials.gov/ct2/show/NCT02620852>

# Objectives

The study **primary objective** is to show the **non-inferiority**

- of the risk-stratified screening strategy vs standard screening
- in terms of **incidence of Breast Cancer of stage 2 and higher**

The study **secondary objective** is to show its **superiority**

# Methods

## “Personalized” arm:

4 subgroups according to their risk of Breast Cancer.

- \* Low risk → no screening
- \* Moderate risk → Mammogram +/- US every 2 years
- \* High risk → Mammogram +/- US every year
- \* Very high risk → idem + MRI scan every year

“standard” arm: usual screening program in the concerned geographical areas: every 1 to 3 years, from age 45 or 50.

After 4 years, every woman will undergo a mammography screening.

# Problem with overall design

There is no “no screening” arm

Promoters consider breast cancer screening benefits as firmly established

Controversy on efficacy is not addressed

# Risk levels issue

## “Personalized” arm:

The risk of Breast Cancer is computed from age, personal and family history, breast density and genetic testing.

However this risk assessment method has not been fully validated.

The low risk group (risk < 1%) might be very small, leading to a sharp increase of screening under age 50.

# Homogeneity issues

“Standard” arm: considered homogenous despite differences between countries

“Standard” arm: includes women over age 50 (or age 45 in a few Italian regions)

“Personalized” arm: includes women age 40 to 70

Women under age 50 will have more screening

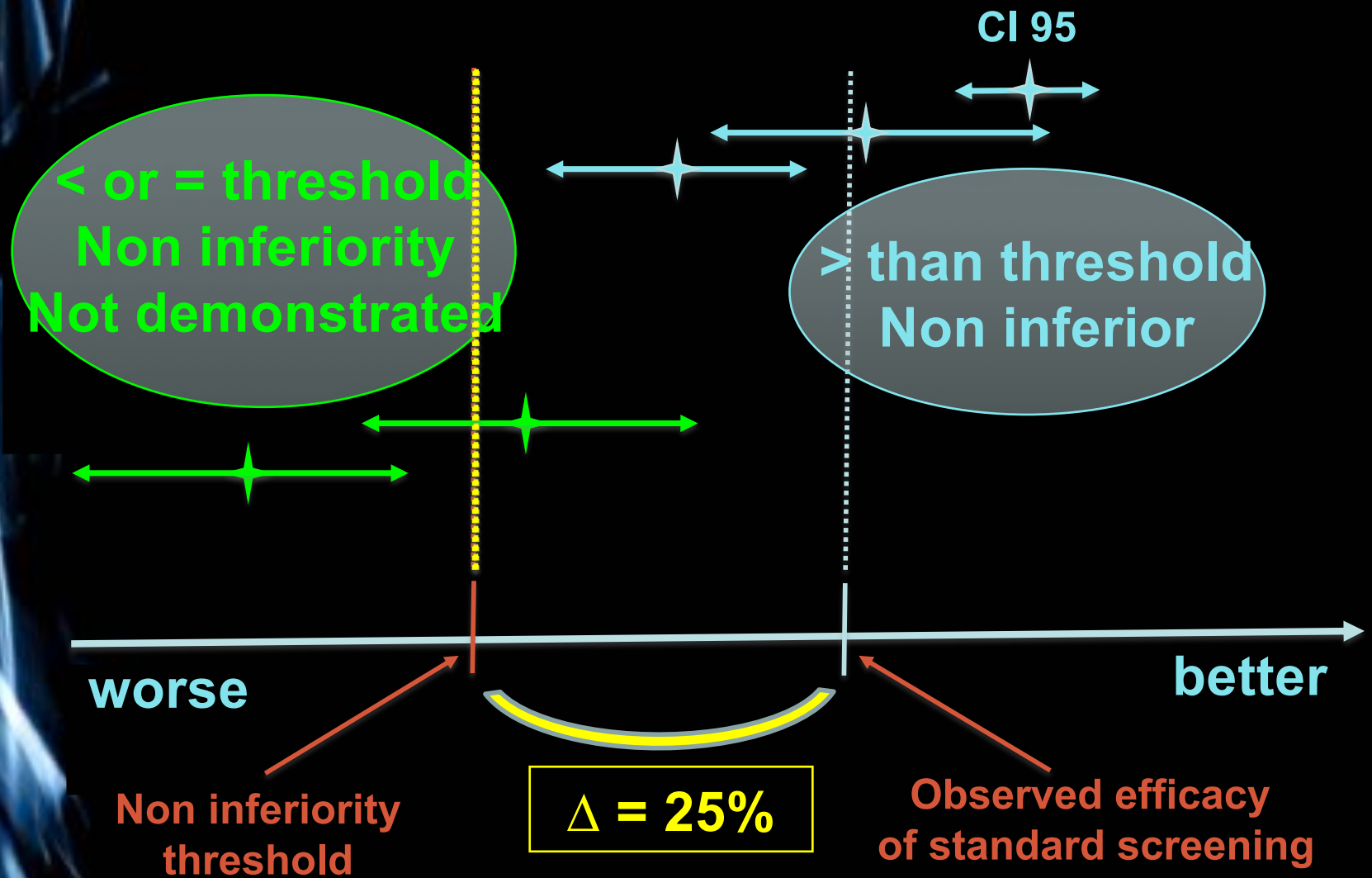
Women over age 50 should have less screening

Reasons for accepting inclusion will be opposite before and after age 50

This will lead to many statistical post hoc corrections, making the results hardly convincing

# Non inferiority trial

J. Doubovetzky, Cancer-Rose, Sydney, 7 dec 2019



# Non inferiority issue

- \* With a **threshold as low as 25%** one can predict that personalized screening will be "non inferior" to Standard screening.
- \* Promoters of MyPeBS expect about **400 new cases** of advanced cancers in the **Standard group**.  
If there is **less than 510 cases** in the Personalized screening group, the result will be considered "non inferior" to Standard
- \* Indeed, **Personalized screening might be** "non inferior" to Standard screening, and, at the same time, **not different from no screening at all**.
- \* **But you will never know !**

# Ethical issues

The accepted lowering of the decrease of  
Advanced Breast Cancer Incidence  
has no demonstrated positive counterpart

The MyPeBS trial may lead to consider a Personalized  
screening "equivalent to" or "as effective as"  
Standard screening,  
even if it doesn't lower Breast Cancer Mortality.

**DO WOMEN LIVES MATTER?**

# Information issues

The consent booklet information is untrue  
and misled women.

There is no explanation about  
**overdiagnosis**  
**overtreatment**  
and even  
**non inferiority**

None of these terms appear in the booklet

# A marketing trial ?

**Warning : this is an opinion**

If this trial is not a scientific one,  
It must be a marketing trial.

So **what does it market ?**

- Beginning at age 40
- Using genetic testing
- Using MRI for "high risk" women

**MyPeBS markets  
technological development and  
OVERDIAGNOSIS**

# Thank you for listening

You want the pdf : [ask\\_jvdoubov@gmail.com](mailto:ask_jvdoubov@gmail.com)

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