



# Patient information and informed consent

Maarten Witsenburg

# Interventional/diagnostic catheterization

Shift from diagnostic to interventional since Rashkind in '70s

Invasive study/treatment has inherent risks

Complications may be serious and even fatal

Balance the advantages and risks (including ionizing radiation risk)

Patient/legal representative has to agree after appropriate information

The cardiologist has the duty to inform

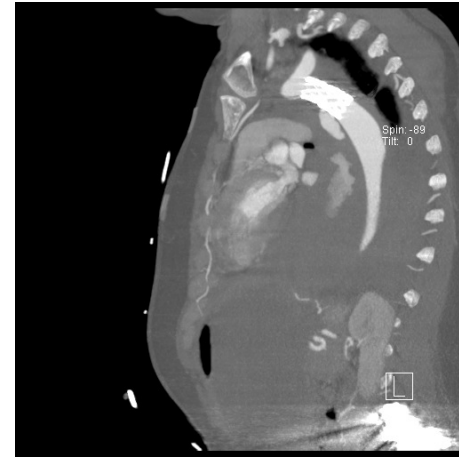
## Some unexpected problems

Covered stent for re-coarctation,  
fatal bleeding after 6 hours

Embolization of ASD device to  
PA, surgical removal

Fatal bleeding from femoral  
artery, 2 days after thrombolysis

Femoral artery tear necessitating  
vascular surgery



# Informed consent

**Informed consent = Duty to inform + Agreement of the patient**

*Essential step in any diagnostic or interventional catheterization*



# Healthcare ethics

## Moral concepts

- Benevolence, autonomy, absence of malice, equity and responsibility

## Autonomy

- Patient can only consent after provision of adequate information

## Valid consent process

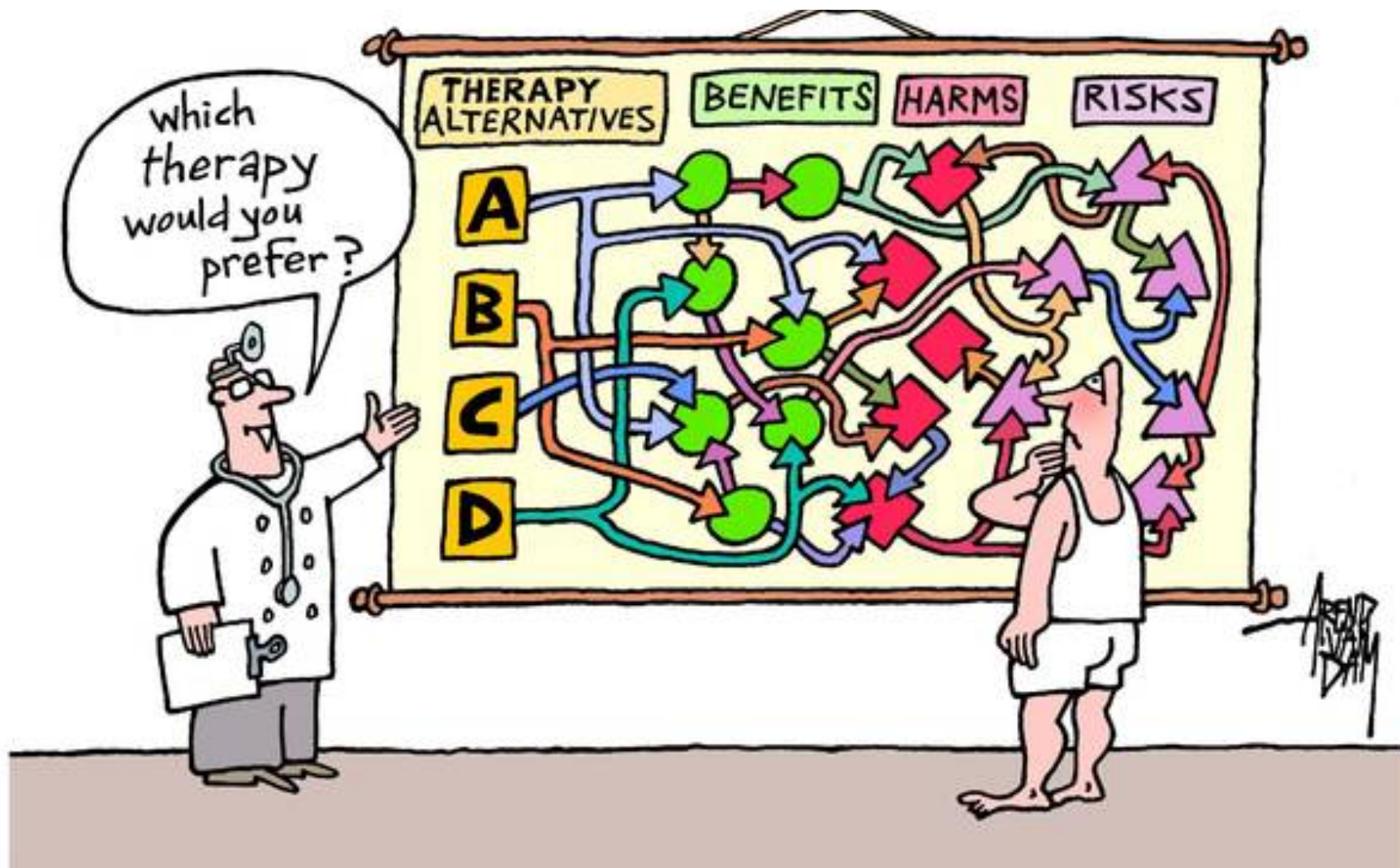
- Sufficient understanding
- Sufficient information
- Freeness from duress

# ESC-EACTS guidelines for myocardial revascularization

“Information should be objective, patient oriented, evidence based, up-to-date, reliable, understandable, accessible, relevant, and consistent with legal requirements”

Eur Heart J 2010 31:2501-55

Now everything is completely clear for the patient



# Information and consent in clinical practice

## Non-emergent setting:

- Indication for study/treatment is discussed in Multi Disciplinary Team
- MDT includes at least (paediatric) cardiologist, interventionalist, cardiac surgeon
- Alternative for MDT for non-complex cases: written and locally approved protocol
- Team decision is written down (inc names of MDT members)
- Patient/legal representative is informed



# Information and consent in clinical practice

- Take enough time for discussion with patient
- Discuss treatment indication, timing, risks, possible complications
- A lay person will always have a major lack of knowledge

Sometimes getting  
"informed" consent  
can be a  
futile task



*Handwritten signature*

# Information and consent in clinical practice

- Take enough time for discussion with patient
- Discuss treatment indication, timing, risks, possible complications
- A lay person will always have a major lack of knowledge
- Consent given orally or in writing
- Patient consent is documented in the record

# Information and consent in clinical practice

**Emergency setting (i.e. urgent balloon septostomy in TGA):**

- Give information after the procedure

# Treatment in congenital heart disease

- Rarely higher than 1C level of evidence
- Expert opinion plays a major role
- Low frequency major complications may become clear only after years
  - erosion issue in ASO occluders
- Beware of the device looking for a disease



# Final thoughts

## **Act responsible**

- before, during and after the intervention

## **In case of complications**

- explain the problem to both patient and colleagues
- describe how the complication was handled and what steps were taken to minimize any further harm
- document the complication and how it was managed in the record
- report it to authorities according to local rules

Thanks!



*Handwritten signature*