8th Annual Emirates Cardiac Society Conference

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How Applicable Valvular Guidelines to our Practice

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ACC Middle East Conference 2017

WHAT ARE GUIDELINES?

- "… a general rule, principle or piece of advice."
- "… how something should be done."

- Wikipedia… "a guideline is a statement by which to determine a course of action. It is aimed to streamline particular processes according to a set of routine or sound practice."

- Institute of Medicine identifies clinical guidelines, "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances."

WHAT ARE GUIDELINES?

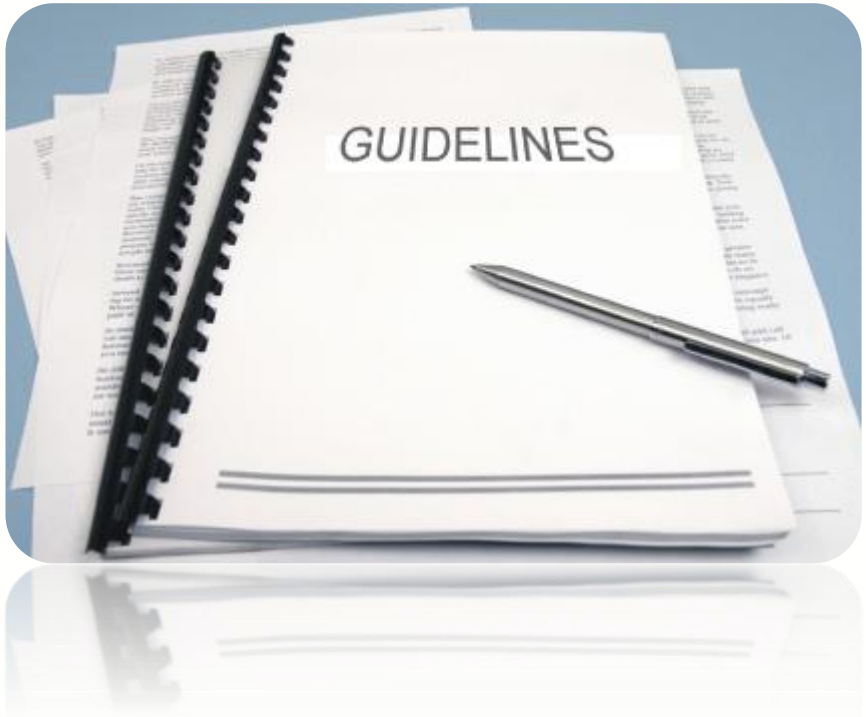
- By definition, following guidelines is never mandatory. Guidelines are not binding and are not enforced.
- Guidelines are suggestions not rules but they descend from peer-reviews.

How Applicable Valvular Guidelines to our Practice

- In Asia, a significant number of patients of various ages present with valvular heart disease requiring intervention.
- The prevalence of rheumatic fever remains very high in Asia ranging from 1.2 – 21 per 1000. This results in a high number of patients relatively young with RHD.

- Considering the population of Asia, this number will be much greater as compared to the West.
- It is estimated that there is a cardiac center for each 16 million people.
- There is a huge variation and diversity in social status, education and culture.

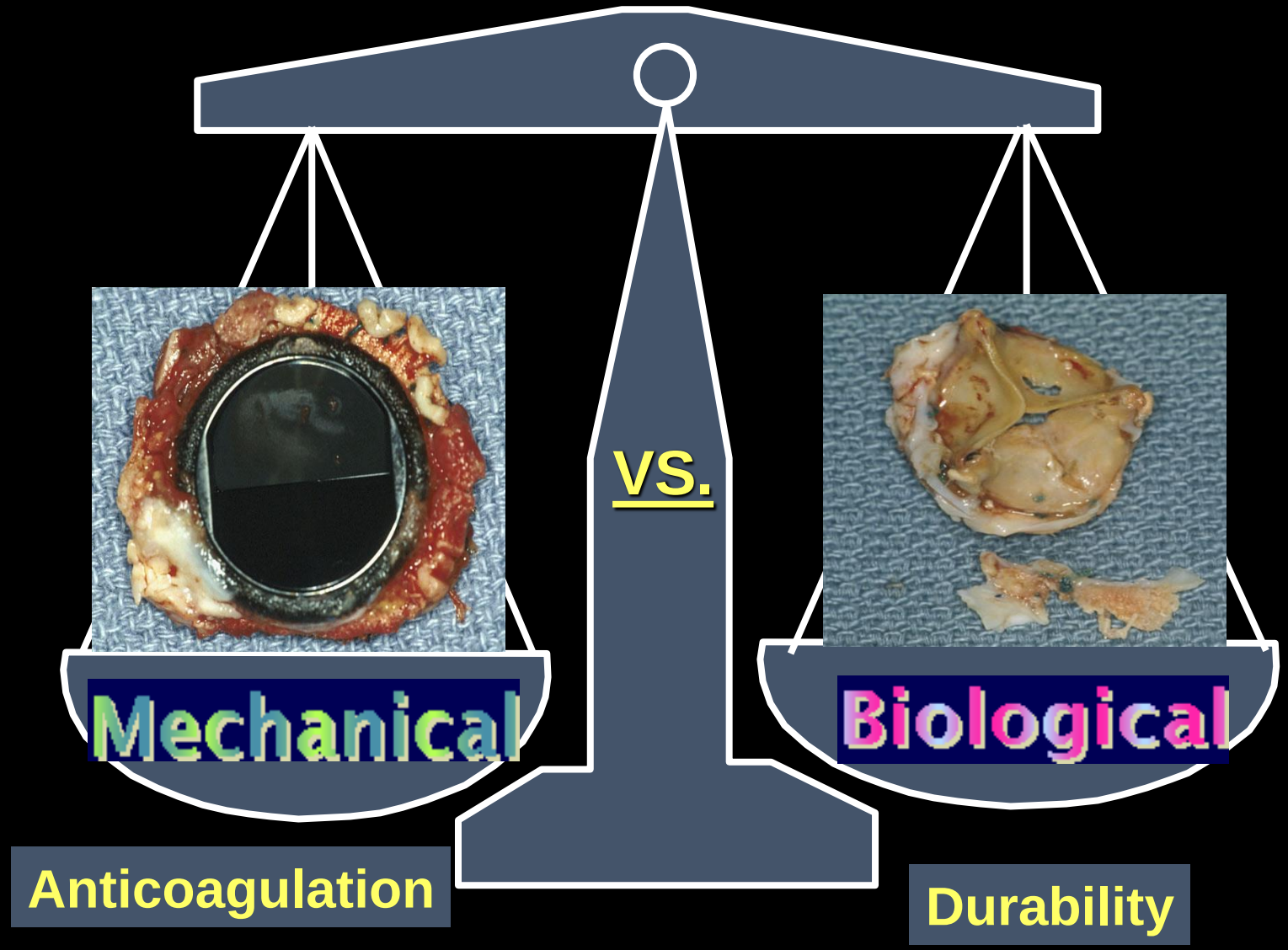
- Published valvular guidelines aim at guiding physician in decision making for the indications of intervention, medical therapy versus percutaneous intervention versus surgery!



- The guidelines are mostly based on studies, observation from the Western Hemisphere where facilities and infrastructures are excellent, education is widespread and culture is fairly homogenous, unlike Asian population.

PROSTHETIC VALVE CHOICE

- Shared decision making is a Class I indication in selecting a mechanical versus a bioprosthesis.
- Among patients undergoing aortic or mitral valve replacement the age range was expanded from age 60-70 to age 50-70 for Class IIa indications for either a mechanical or bioprosthetic valve choice.


VS.
Mechanical
Biological
Anticoagulation
Durability

- Mechanical valve require life long anticoagulation with its major drawbacks
  - Exercise and sports
  - Pregnancy
  - Therapeutic range control

Effect of Study Setting on Anticoagulation Control*

A Systematic Review and Metaregression

Carl van Walraven, MD; Alison Jennings, MA; Natalie Oake, BA; Dean Fergusson, PhD; and Alan J. Forster, MD

Background: For patients receiving therapy with oral anticoagulants (OACs), the proportion of time spent in the therapeutic range (*ie*, anticoagulation control) is strongly associated with bleeding and thromboembolic risk. The effect of study-level factors, especially study setting, on anticoagulation control is unknown.

practices having significantly lower control than either anticoagulation clinics or clinical trials (−12.2%; 95% CI, −19.5 to −4.8; p < 0.0001). Self-management was associated with a significant improvement of time spent in the therapeutic range (+7.0%; 95% CI, 0.7 to 13.3; p = 0.03).

Conclusions: Patients who have received anticoagulation therapy spend a significant proportion of their time with an INR out of the therapeutic range. Patients from community practices showed significantly worse anticoagulation control than those from anticoagulation clinics or clinical trials. This should be considered when interpreting the results of, and generalizing from, studies involving OACs. *(CHEST 2006; 129:1155–1166)*

Key words: anticoagulation; deep venous thrombosis; pulmonary embolism

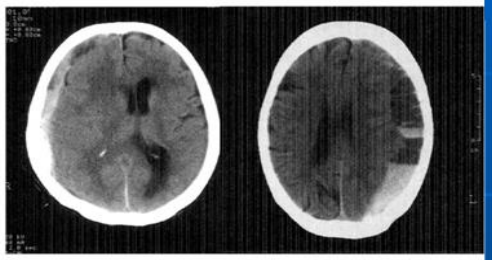
Abbreviations: CI = confidence interval; INR = international normalized ratio; OAC = oral anticoagulant

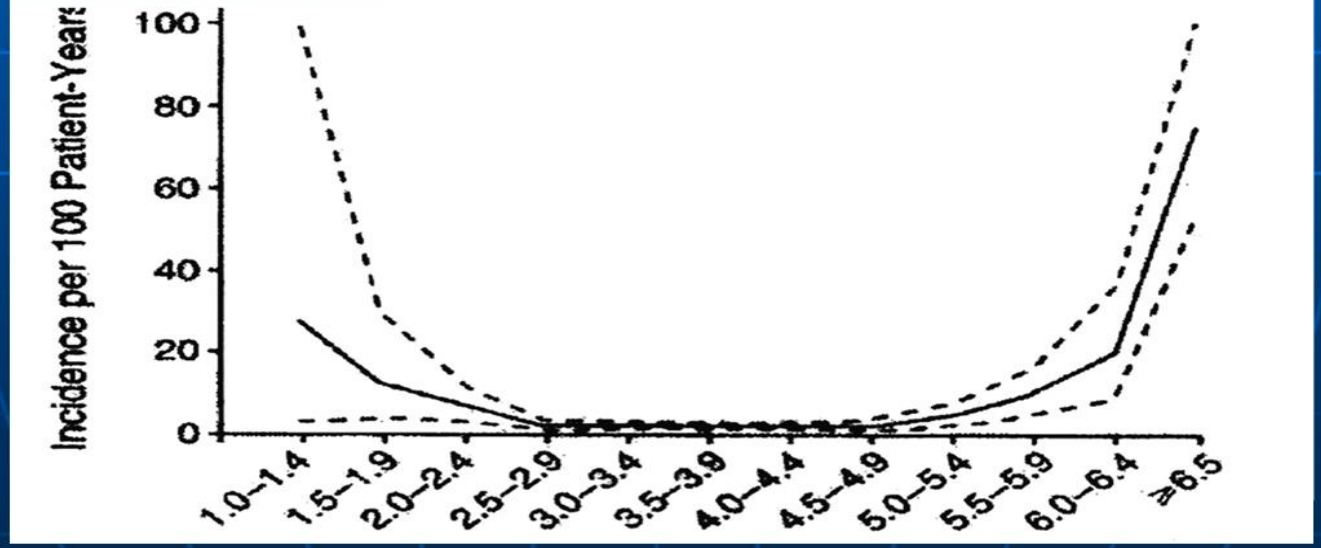
Patients who have received anticoagulation therapy spend a significant proportion of their time with an INR out of the therapeutic range.

Warfarin is the second most likely drug, after Insulin to send Americans to the ER.

Adverse Events Are Common with Mechanical Valves

INR-Specific Incidence Of All Adverse Events





Cannegieter et al. N Engl J Med 1995;333:11

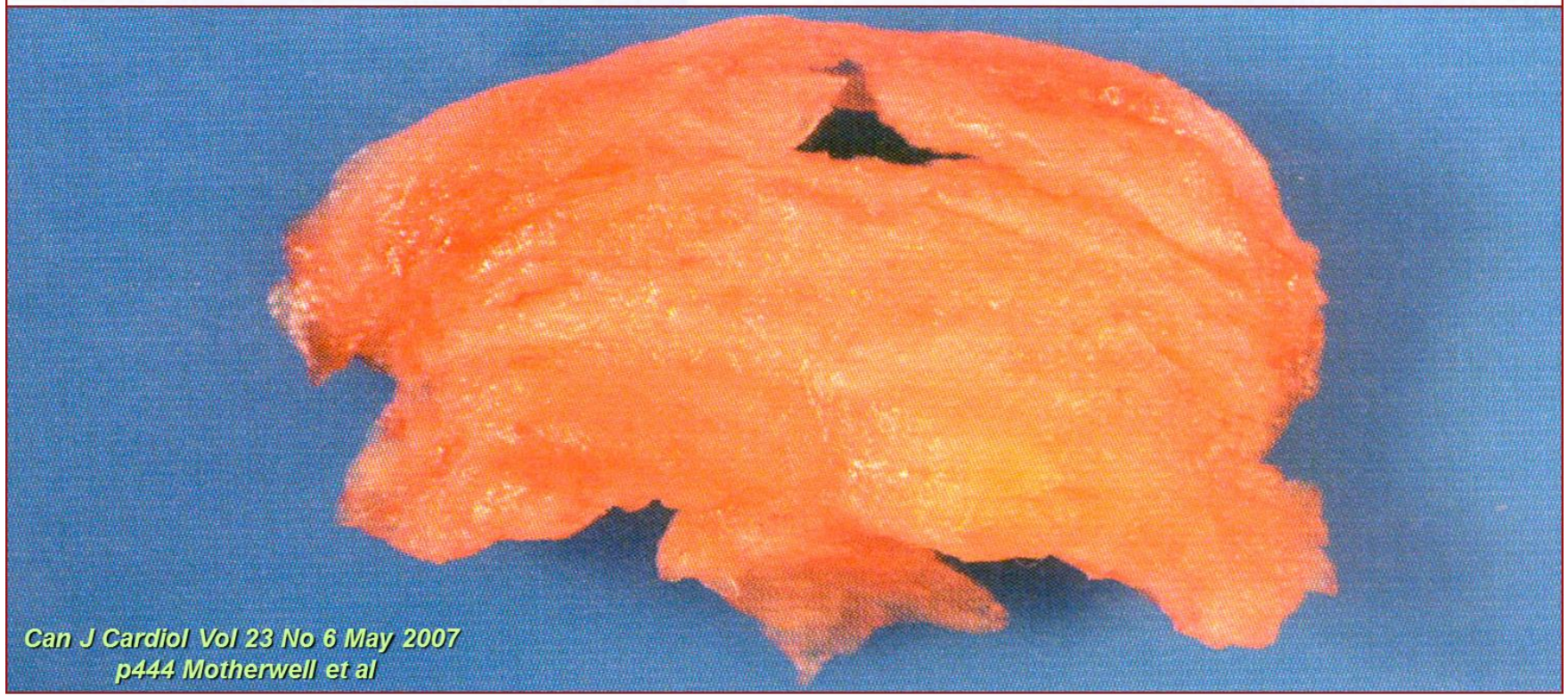
- For a female in child-bearing age with a mechanical prosthesis who wishes to become pregnant, no method of anticoagulation is risk-free whether continued use of Coumodin or any form of anticoagulation.

How Applicable Valvular Guidelines to our Practice

IMAGES IN CARDIOLOGY

Thrombosed prosthetic valve in a 32-week pregnant 20-year-old woman

Duncan W Motherwell BSc (Hons) MB ChB MRCP[1], Jane E Ramsay MB ChB MD MRCOG[2], Stewart R Craig MB ChB FRCS[3], Adrian JB Brady BSc (Hons) MD FRCP (Glasg) FRCPE FAHA[1]



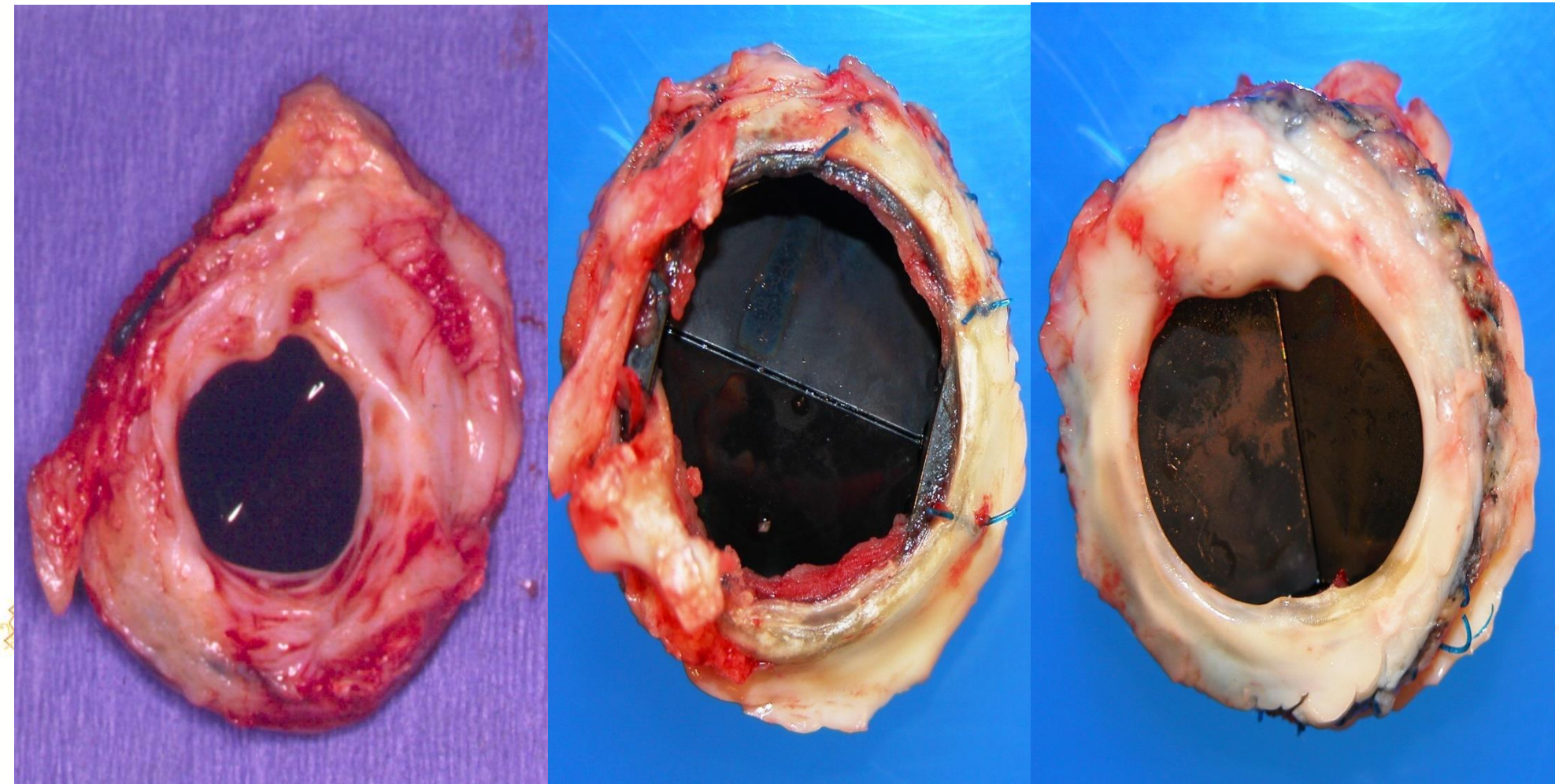
Can J Cardiol Vol 23 No 6 May 2007
p444 Motherwell et al

- Coumodin administration can be associated with an increased risk of fetal wastage and birth defects particularly of the required dose exceeds 5 mg per day.

- Direct Oral anticoagulant (DOAC) 2017 guidelines?!!

There are unchanged recommendations for use of vit K antagonists for mechanical prosthesis.

… mechanical valves are not a permanent solution…



Glutaraldehyde fixed porcine bioprosthesis became commercially available in 1970.

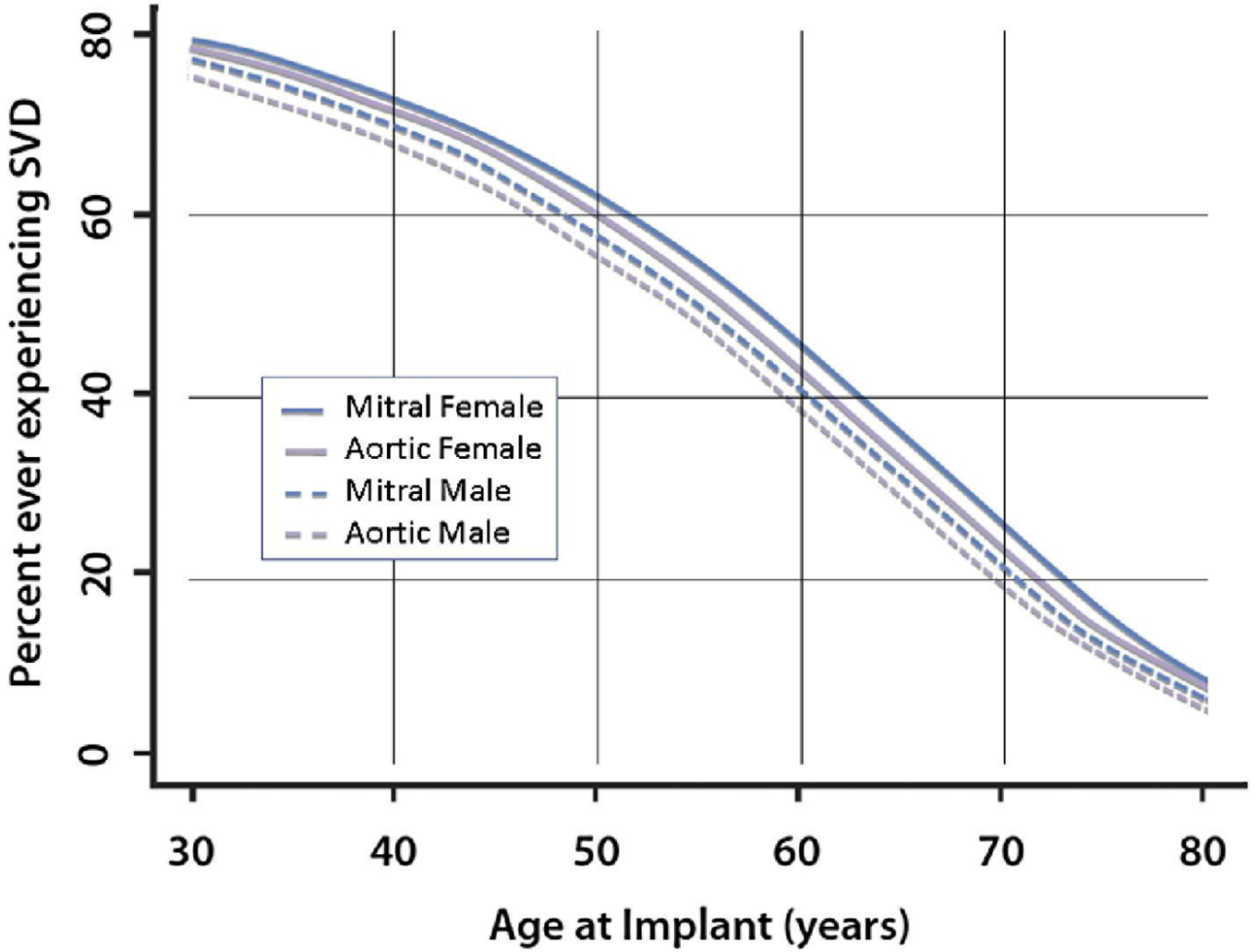
Bioprosthesis were expected to provide the answer because of not requiring anticoagulation.

HOWEVER,

- experience demonstrated that bioprosthesis ultimately fail.

- a direct relationship exists between age and structural deterioration of the bioprosthesis.

How Applicable Valvular Guidelines to our Practice



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Quattro Mitral Valve

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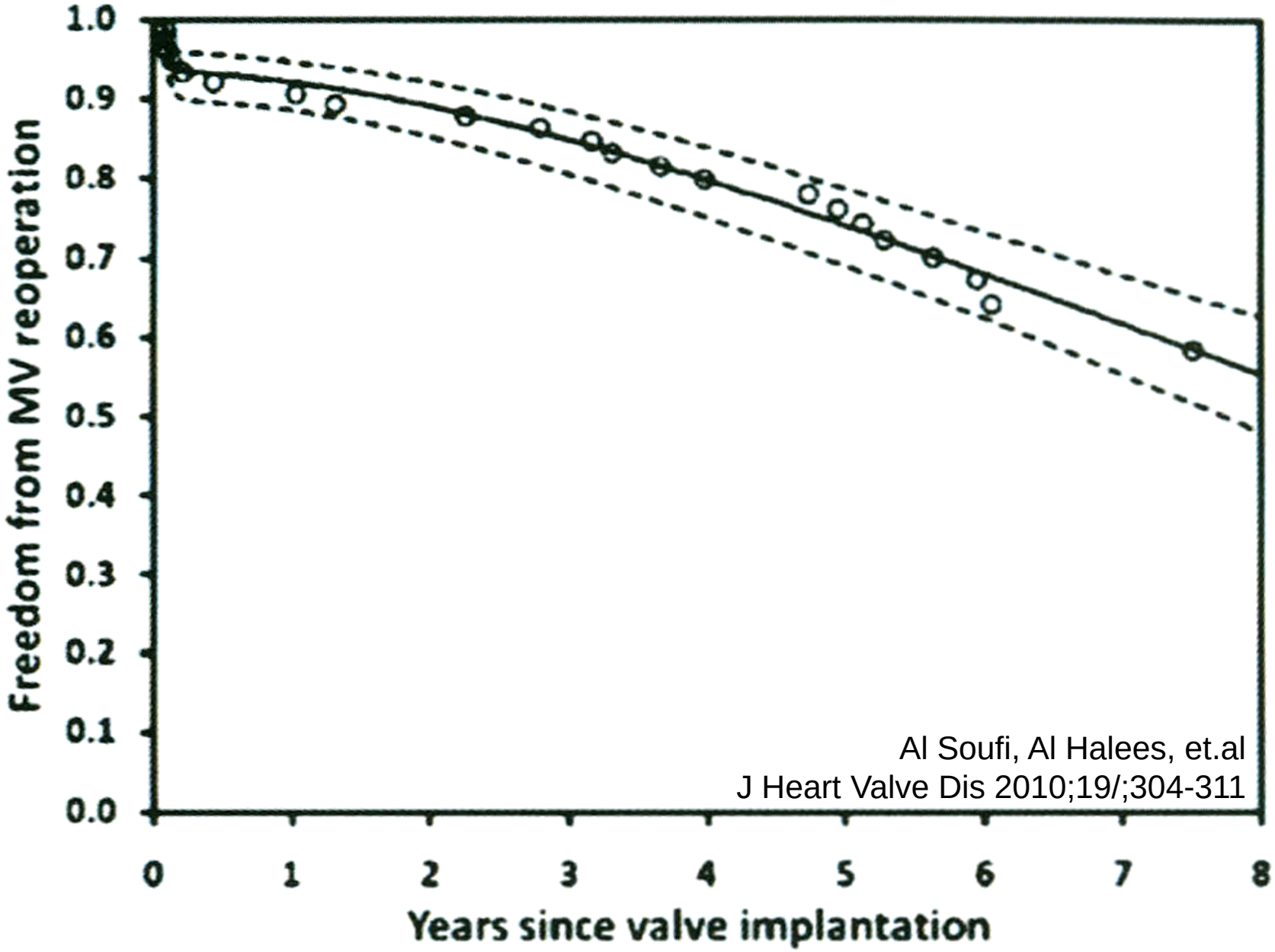
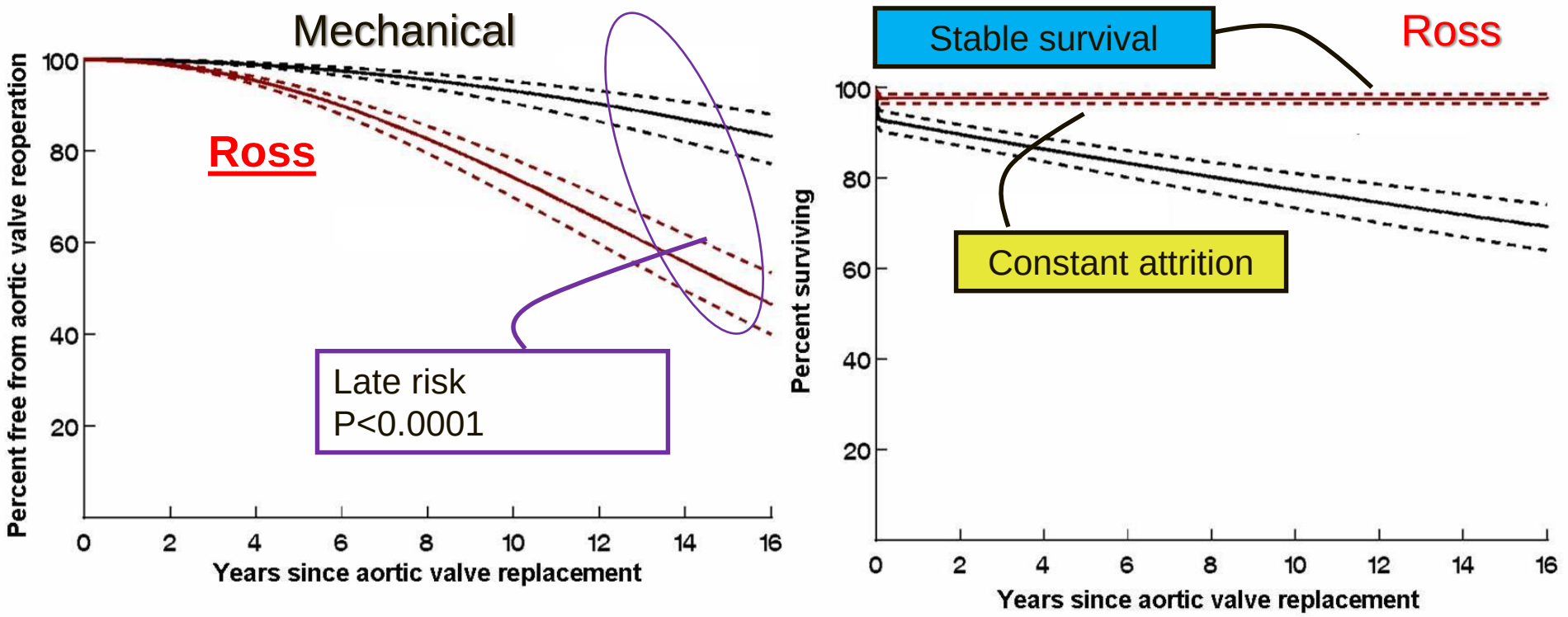


Al Soufi, Al Halees, et.al
J Heart Valve Dis 2010;19/;304-311

SURVIVAL ADVANTAGE



Al Soufi, Al Halees et al - J Thorac Cardiovasc Surg 2009;137:362-70

- In general use of bioprosthesis in the young has been controversial and their use below age 40 years is generally and according to guidelines is not recommended…!

And this same situation exists in many other Asian countries.

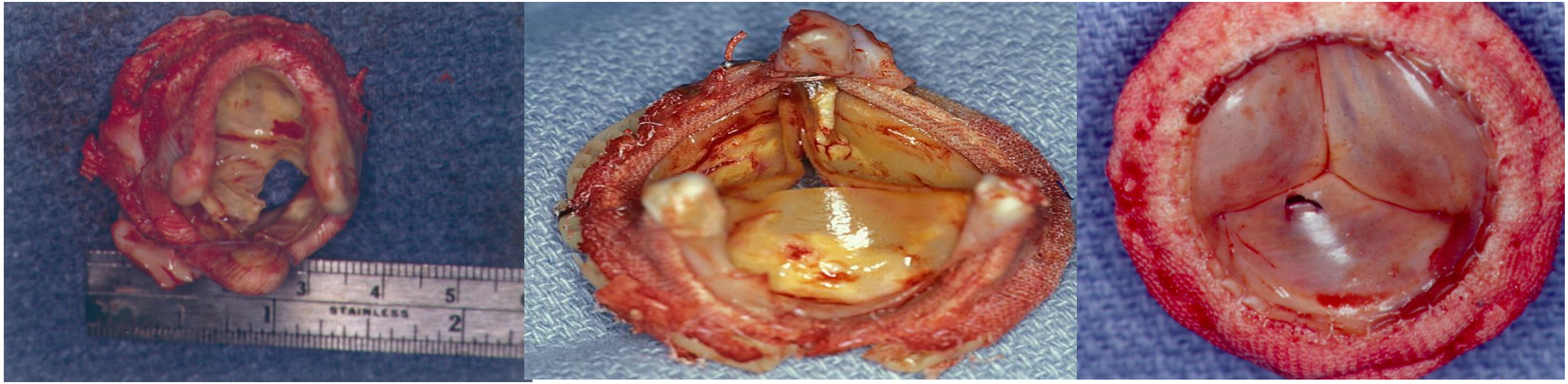
In our area, we have been implanting bioprosthesis in young patients because of the difficulty encountered in controlling anticoagulation and because of pregnancy in young females.

317 patients with Hancock II Bioprosthesis (344)

- ISOLATED MVR 190
- ISOLATED AVR 15
- MVR + AVR 28
- HANCOCK II + REPAIR 111

Age 11-40 yrs Mean 27 ± 7.5
Hospital Mortality 1%

None of the valves deteriorated before 5 years even in the youngest.



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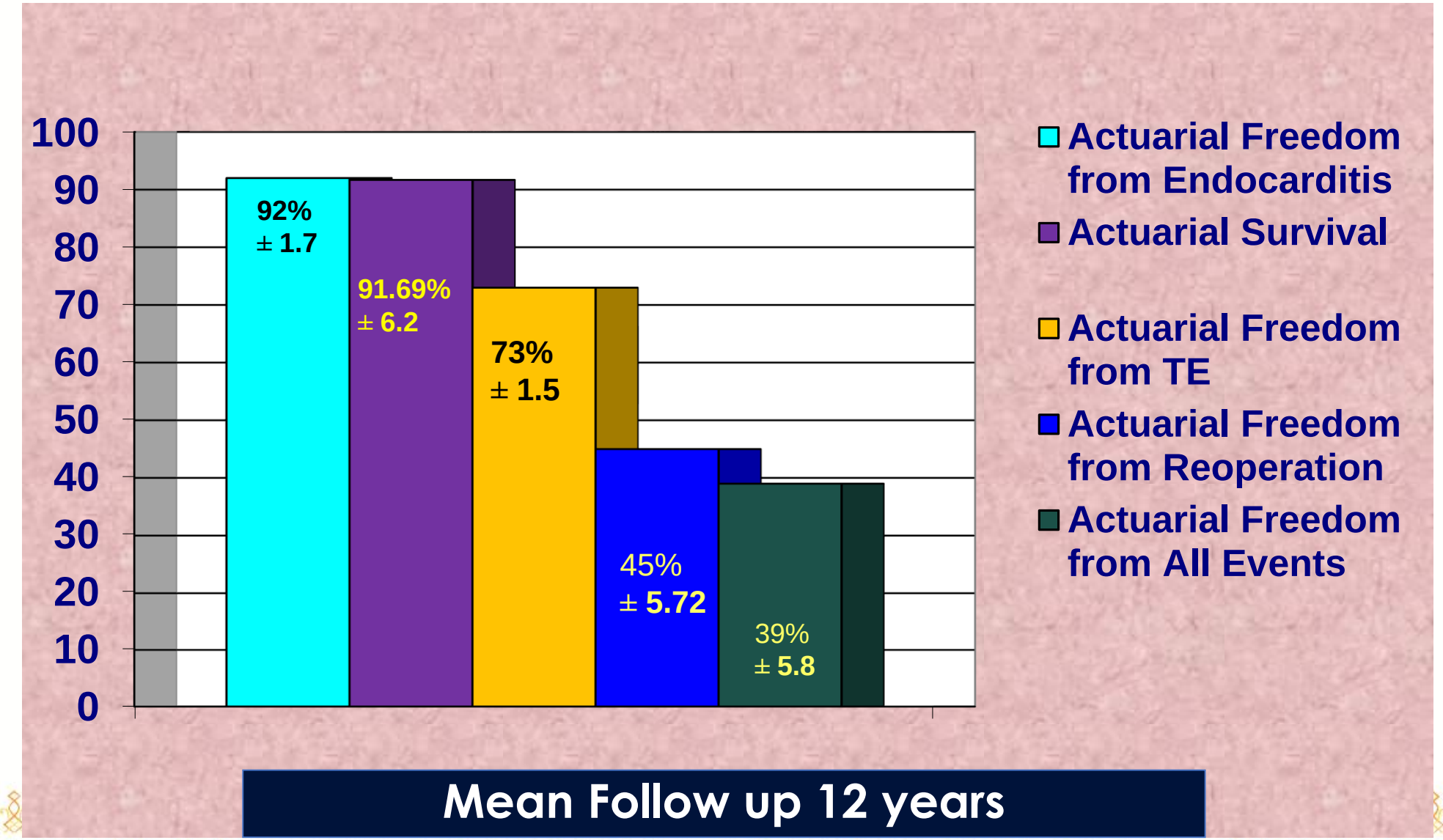

Mean Follow up 12 years

ELSEVIER

European Journal of Cardio-thoracic Surgery 36 (2009) 84–90

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

www.elsevier.com/locate/ejcts

Aortic and mitral valve replacement in children: is there any role for biologic and bioprosthetic substitutes?☆

Bahaaldin Alsoufi [a,*], Cedric Manlhiot [b], Brian W. McCrindle [b], Charles C. Canver [a], Ahmed Sallehuddin [a], Saud Al-Oufi [a], Mansour Joufan [a], Zohair Al-Halees [a]

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Received 1 September 2008; received in revised form 20 February 2009; accepted 24 February 2009; Available online 14 April 2009

Conclusion: While valve reoperation is inevitable following AVR and MVR with biologic and bioprosthetic substitutes; favorable results such as low valve-related morbidity rate, good long-term survival and functional status encourage their consideration as valid replacement alternatives in selected children especially females. Valve durability is higher in the mitral position and longevity of bioprosthetic valves is greater than that of homografts especially in the mitral position.

Valve durability is higher in the mitral position and longevity of bioprosthetic valves is greater than that of homografts especially in the mitral position.

110 children with mean age 15.6 ± 2.6 years with biological MVR and/or AVR replacement [123 valves, mostly Hancock II]

♣15 years after valve replacement

- 6% died without subsequent surgery
- 72% underwent reoperation
- 23% remained alive with no further replacement
- 95% are in NYHA-FC I-II
- No bleeding episodes
- No thromboembolic episodes

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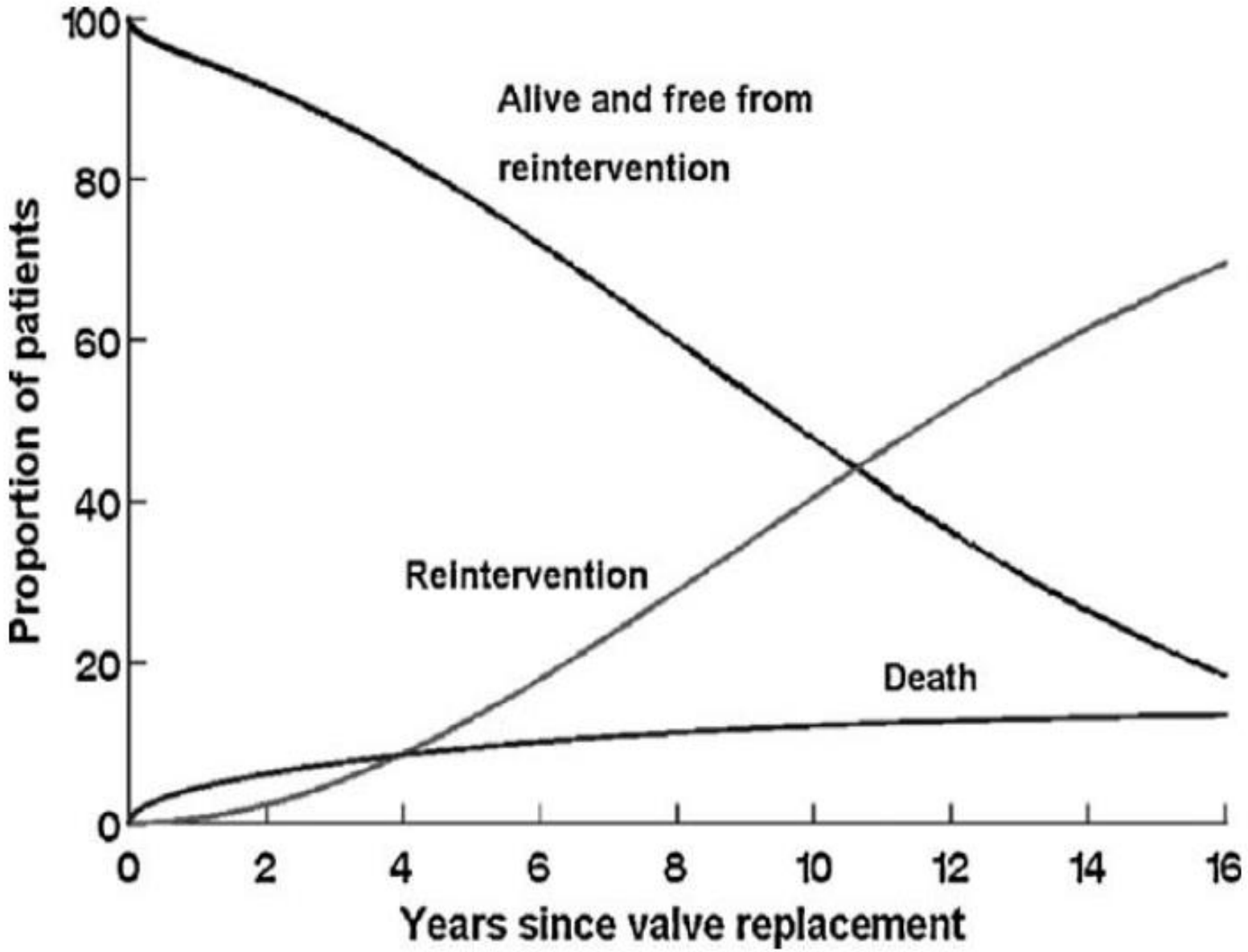

AlSoufi, Al Halees et al
Eur J Cardiothorac Surg
2009;36:84-90

Pregnancy?

Several previous reports suggested that pregnancy accelerates bioprosthesis degeneration.

Few data are available on long term follow up.

Pregnancy Has No Effect on the Rate of Structural Deterioration of Bioprosthetic Valves: Long-term 18-year Follow Up Results

Fayez El Shaer[1], Walid Hassan[1], Bendehiba Latroche[1], Sumaya Helaly[1], Hesham Hegazy[1], Maie Shahid[1], Gamal Mohamed[2], Zohair Al-Halees[1]

[1]*King Faisal Heart Institute,* [2]*Department of Biostatistics, Epidemiology and Scientific Computing, King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia*

Up to 18 years follow up of patients with a BPV and repeated pregnancy showed there to be no pregnancy-related accelerated degeneration of BPVs. In addition. Fetal loss rates were most likely lower with the use of BPVs.

age who underwent BPV replacement between 1986 and 2000 were allocated to two groups: group P (n = 49; mean age 25 ± 6 years) who became pregnant (144 pregnancies), and group NP (n = 36; mean age 27 ± 7 years) who never became pregnant. The general characteristics of both groups were comparable. Clinical and echocardiographic data were obtained annually for all subjects; the mean follow up for all patients was 8.5 ± 3.8 years (range: 4.6-18.4 years). Group P received 59 (68% mitral) BPVs, while group NP received 45 (60% mitral). The majority of BPVs were Hancock II® porcine bioprostheses. The end-point

demonstrated no significant differences between the P and NP groups (RR 1.8; 95% CI = 0.761-4.256; p = 0.18). Further analysis testing the potential effect of increased number of pregnancies on the duration to redo surgery among P group showed no effect.

Conclusion: Up to 18 years' follow up of patients with a BPV and repeated pregnancy showed there to be no pregnancy-related accelerated degeneration of BPVs. In addition, fetal loss rates were most likely lower with the use of BPVs.

Journal of Heart Valve Disease 2005; 14:481-485

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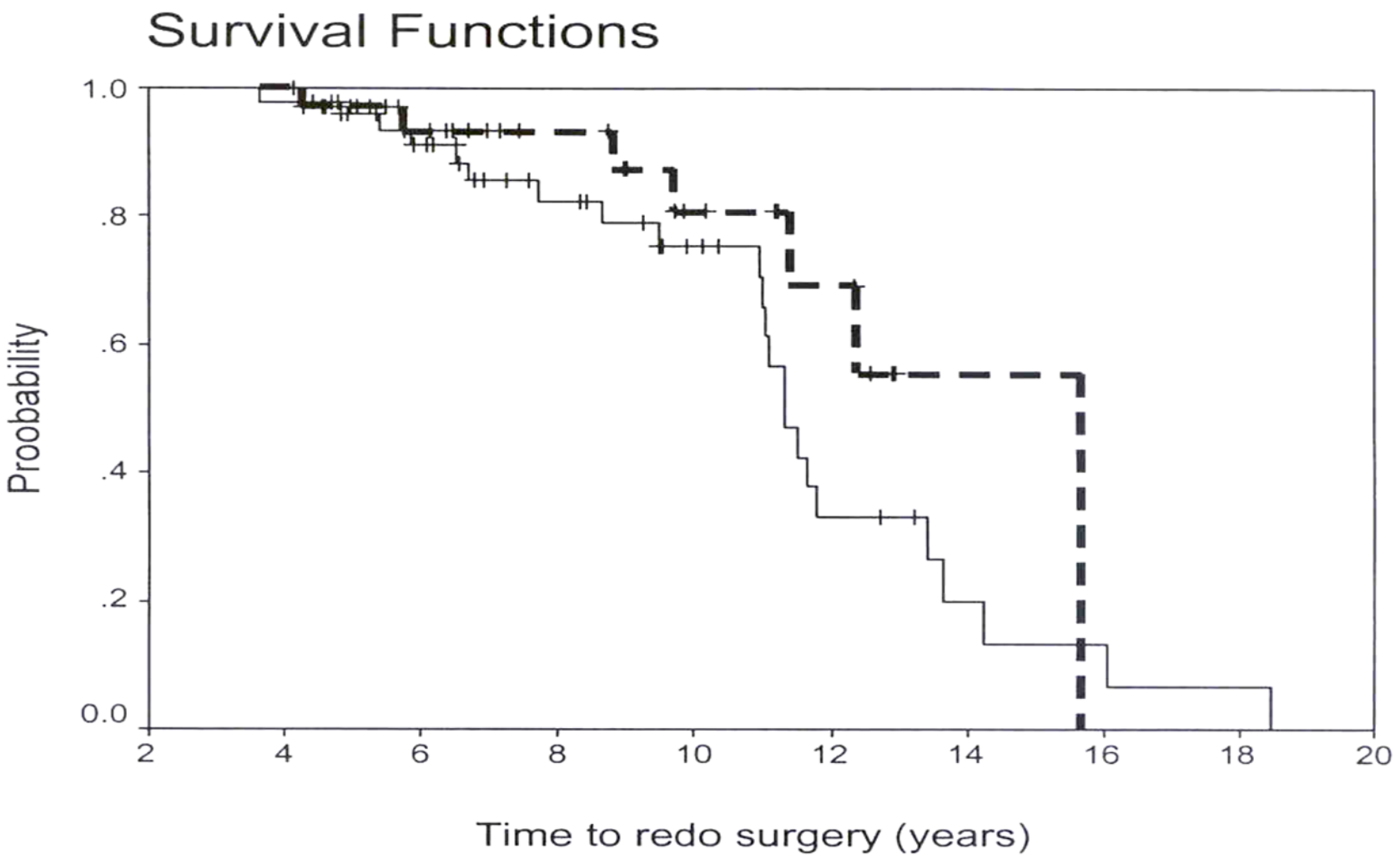
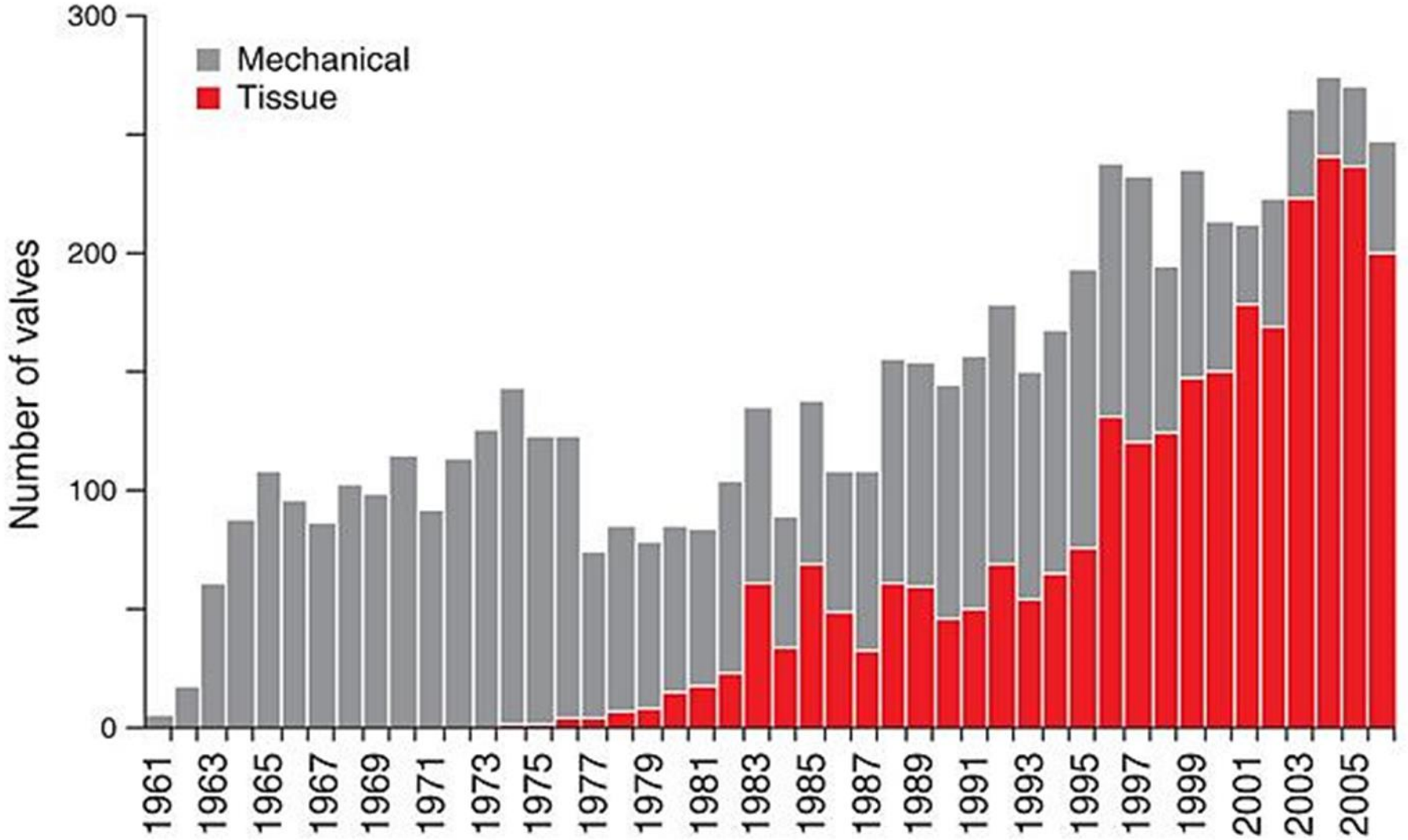


Non-pregnant------
Pregnant ---------


Mechanical
Tissue
Number of valves
300
200
100
0
1961
1963
1965
1967
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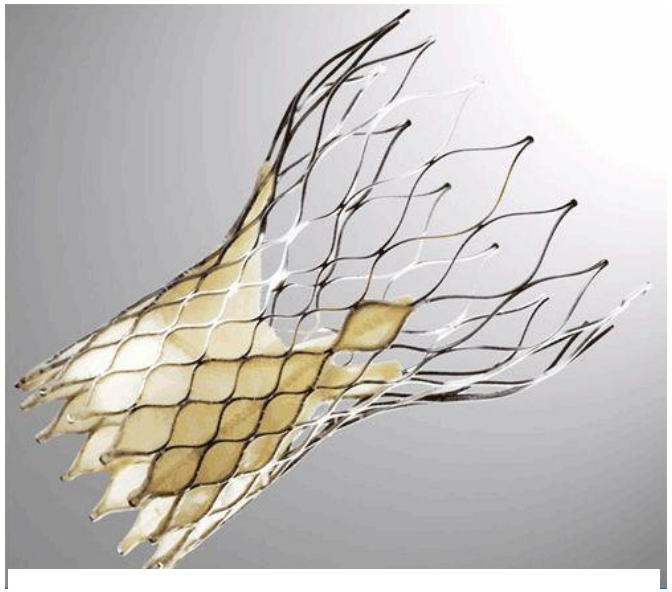

The Story of TAVI

Transcatheter aortic valve implantation (TAVI) was introduced to treat high risk patients with aortic stenosis.

Transcatheter aortic valve in valve for failed aortic bioprosthesis also took off….

- It is technically demanding.
- It has high rate of initial device malposition 11%
- Risk of coronary obstruction 2%
- Need for emergency surgery 2%
- Stroke rate 2%

This concept was expanded into valve in valve MVR through transapical approach.

It is becoming a viable option for selected high risk patients.

Guidelines that are inflexible can harm by not leaving enough room for the clinicians to tailor care to patient's specific circumstances and medical history.

What is best for patients overall, as recommended in guidelines, may be inappropriate for an individual. Blanket recommendations, rather than a menu of options or recommendations for shared decision-making, ignore patients'prereferences.

Algorithms that reduce patient care into a sequence of binary (yes/no) decisions often do injustice to the complexity of medicine and the thought processes inherent to clinical judgment.

- Guidelines are guides not rules.
- Read them carefully with a critical eye. If you don't agree with a certain aspect; check references.
- Look at your own practice again with a critical eye and see how it fits with guidelines. Your aim will always be to improve outcomes.
- If your practice is different and your outcomes are excellent; study this and publish results. Your work may contribute to the next "update" of guidelines.

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