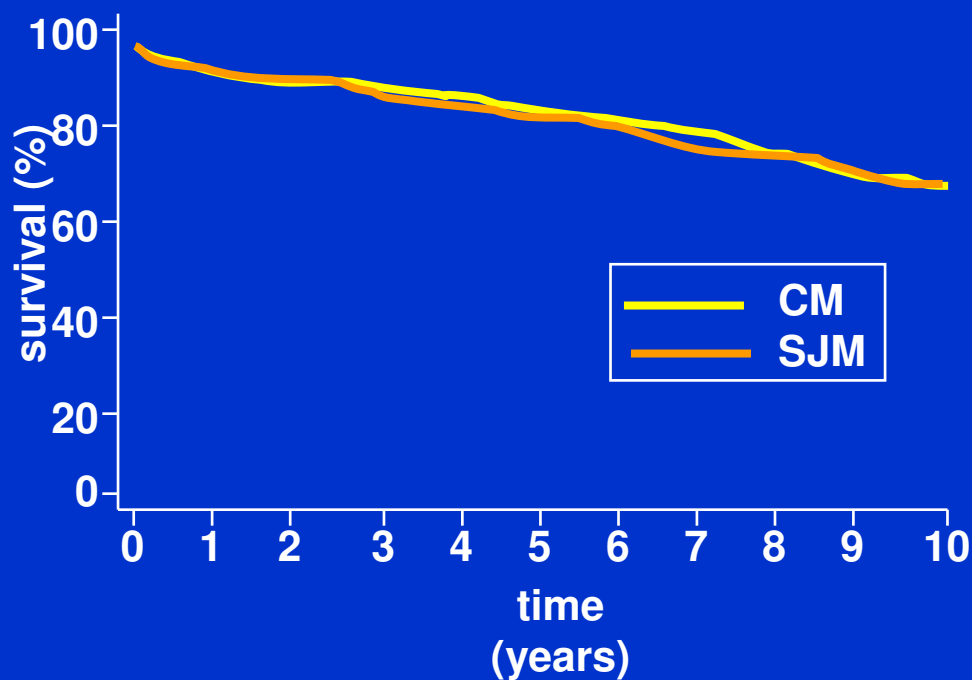


VALVULAR INTERVENTION, ANTITHROMBOTICS 2009

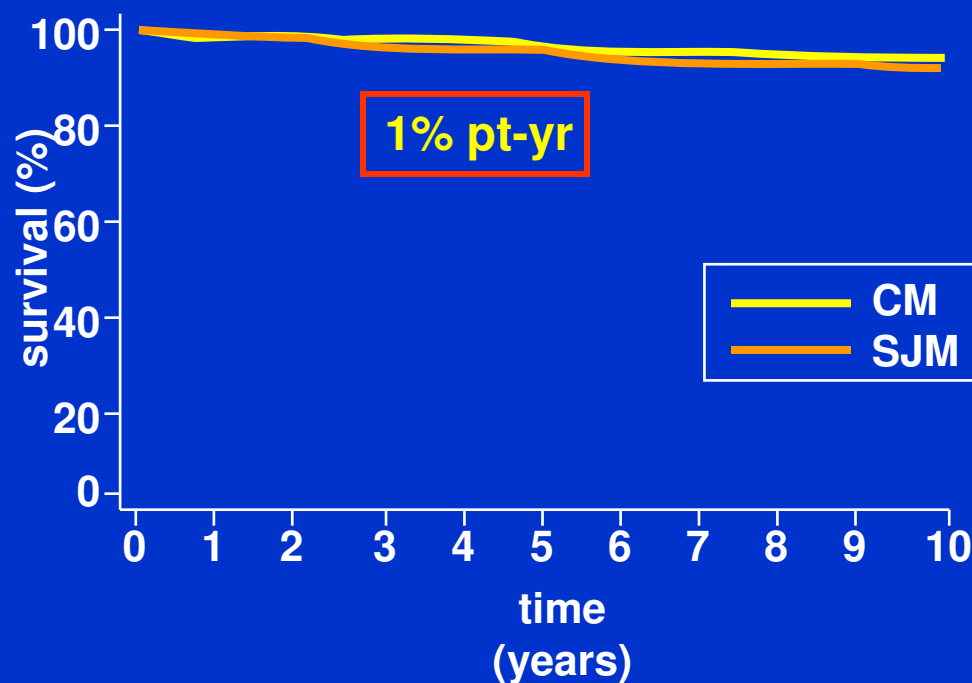
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1) RANDOMIZED BILEAFLET MECHANICAL PROSTHESES (10 YEAR FU, N=485)

Overall Survival

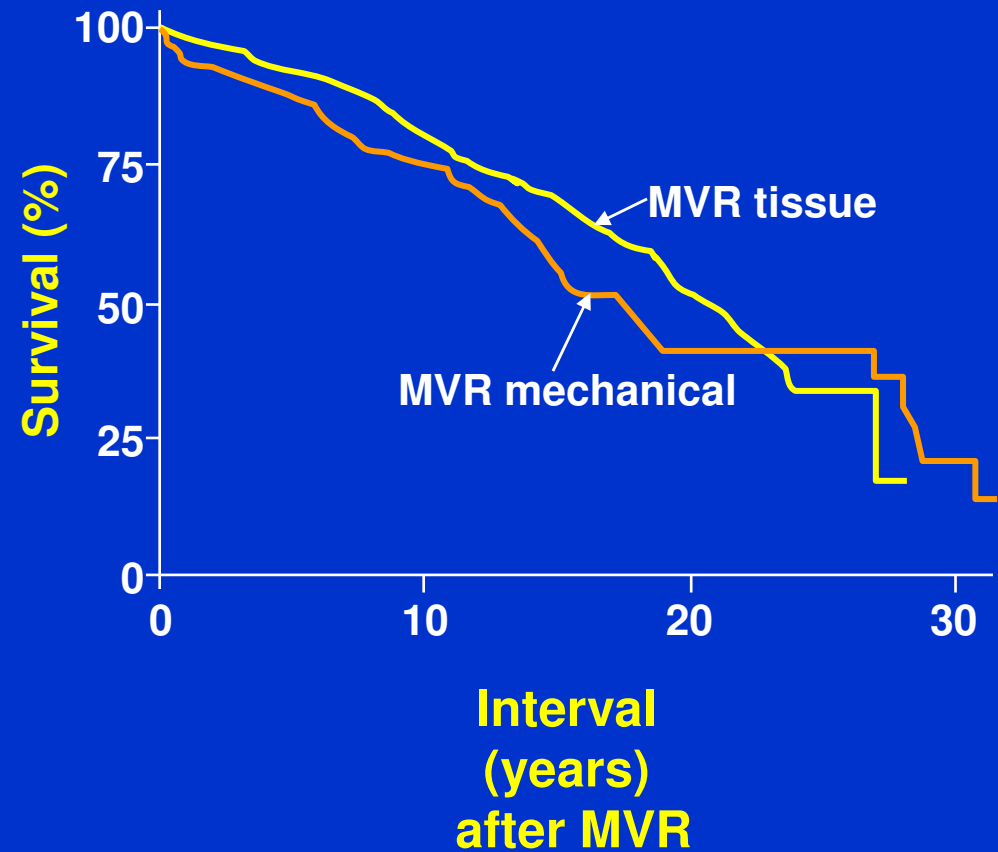
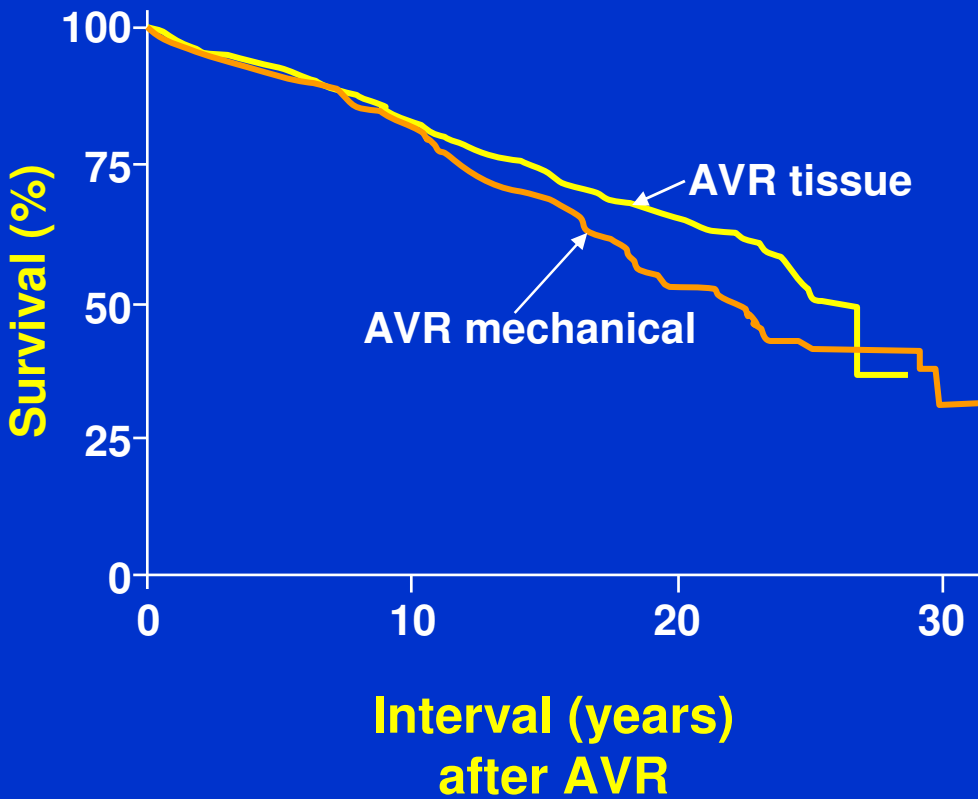


Survival Free From Valve-Death



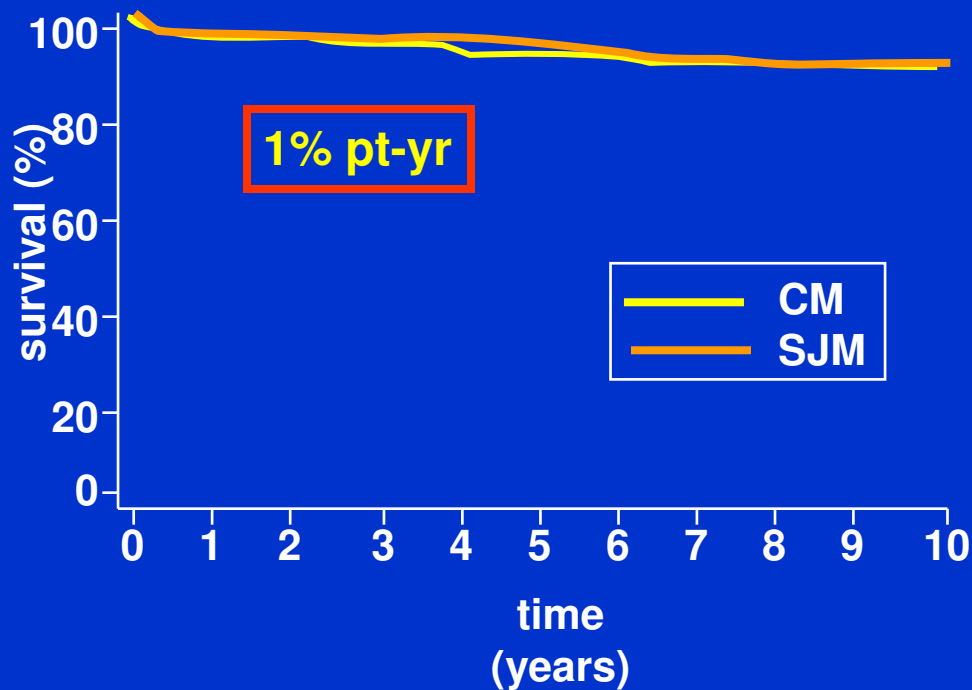
1) SIMILAR SURVIVAL AFTER FIRST AVR OR MVR, ACCORDING TO THE TYPE OF PROSTHESIS USED AT INITIAL VALVE REPLACEMENT

2-3% pt-yr

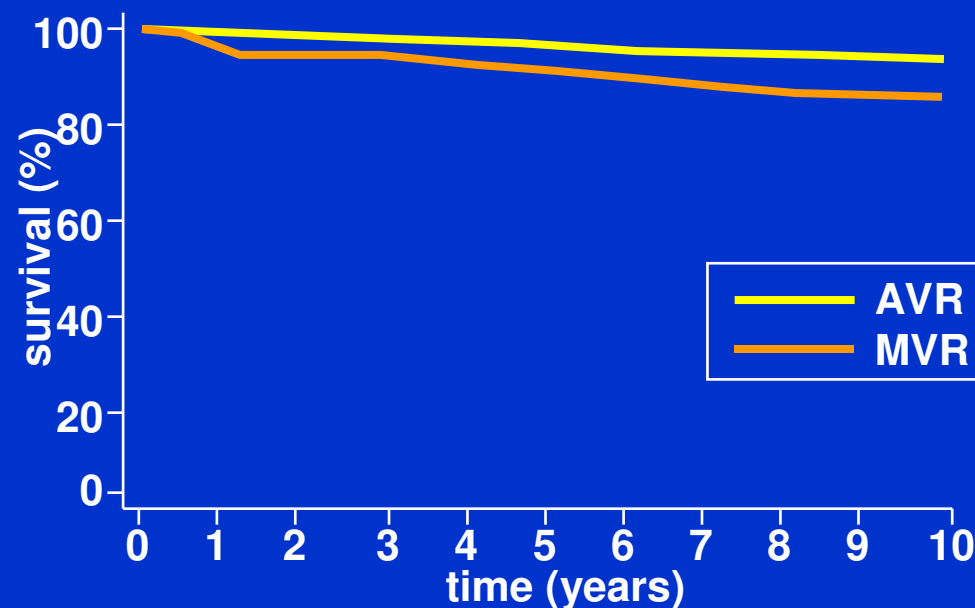


2) RANDOMIZED BILEAFLET MECHANICAL PROSTHESES (10 YEAR FU, N=485)

**Freedom From TE
For All Study Patients**

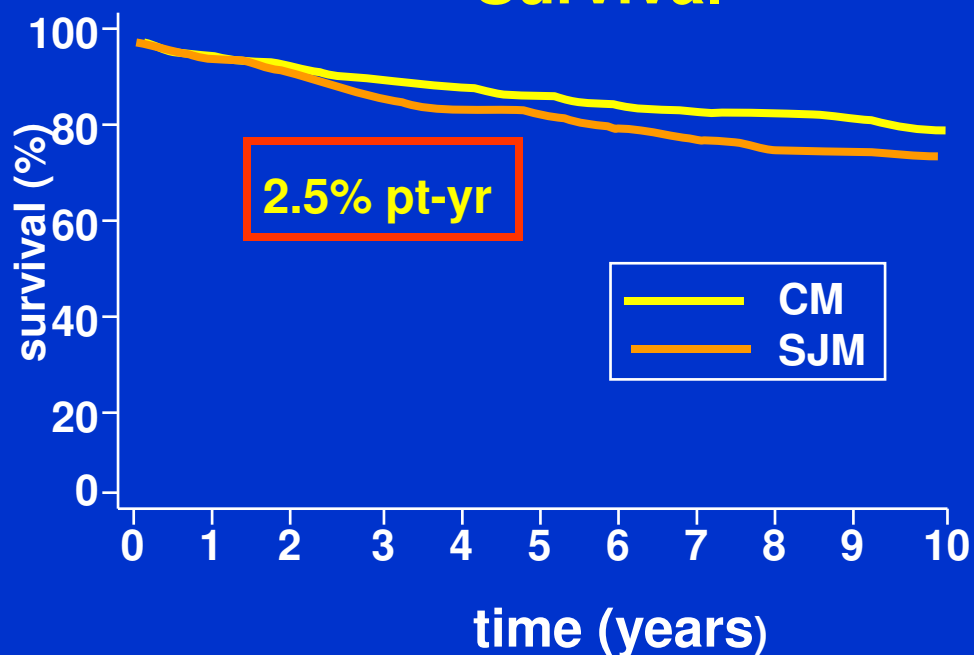


**Freedom By Position
of Valve Replacement**

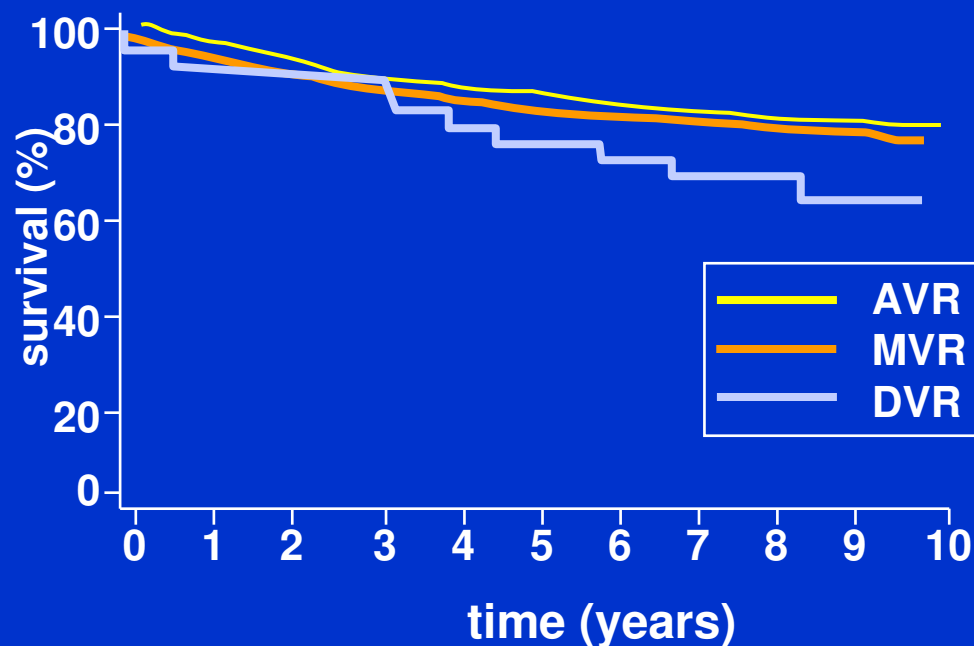


3) RANDOMIZED BILEAFLET MECHANICAL PROSTHESES (10 YEAR FU, N=485)

Bleeding Event-Free Survival



By Position of Valve Replacement



VALVULAR INTERVENTION ANTITHROMBOTICS 2009

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1) PROSTHETIC HEART VALVES

RISK FACTORS FOR THROMBOEMBOLISM ¹⁻³

Atrial Fibrillation

LV Dysfunction

Previous Thromboembolism

Hypercoagulable, LA Thrombus at Operation

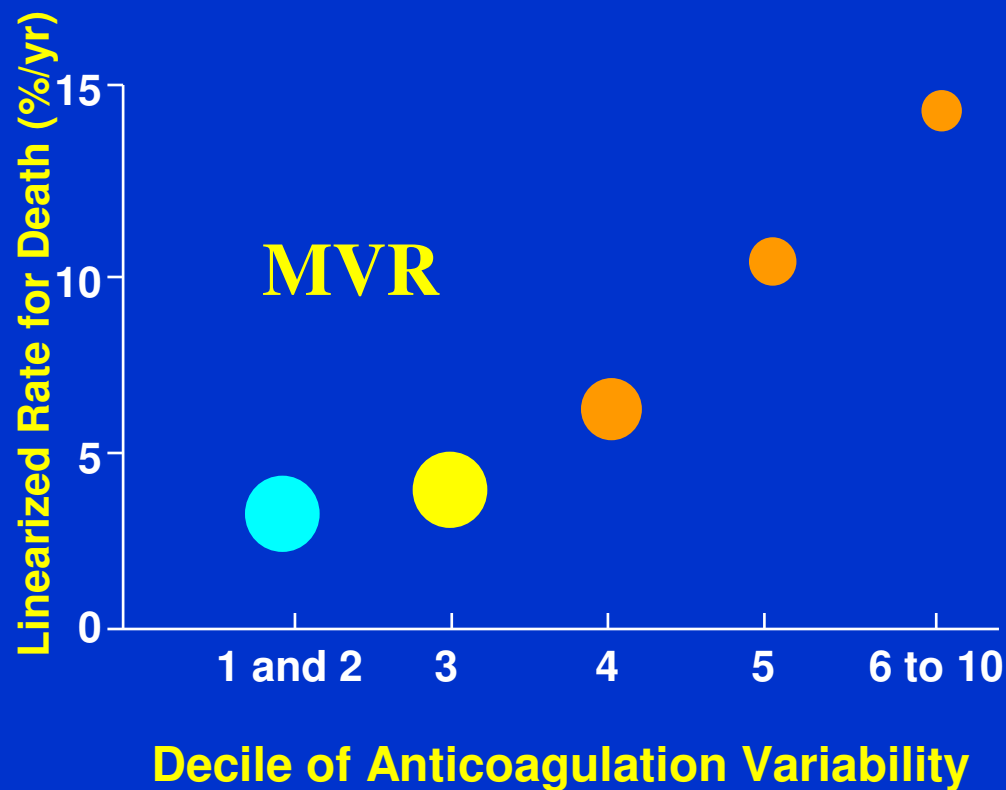
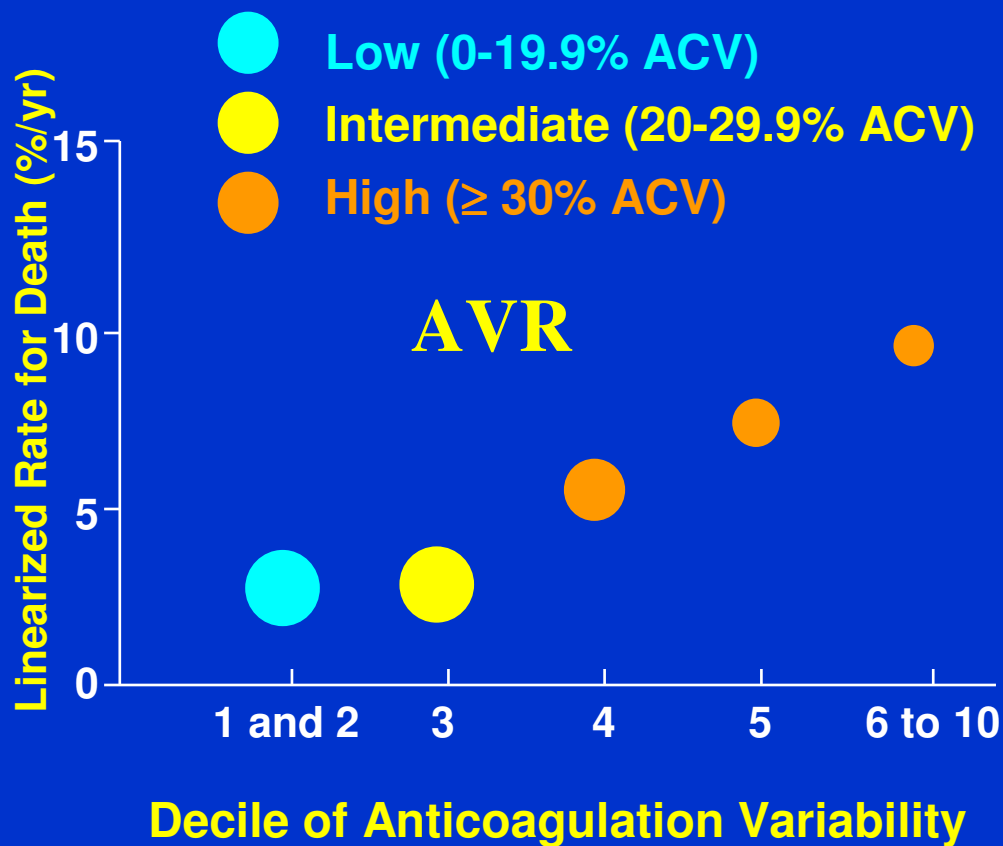
Poor and Variability of Anticoagulation

ACC/AHA VHD (RO Bonow et al.) Circ **2008**; e626

ACCP Chest **2008**; 133: 92S

ESC (Butchard, EG et al) Eur Heart J **2005**;26:2463

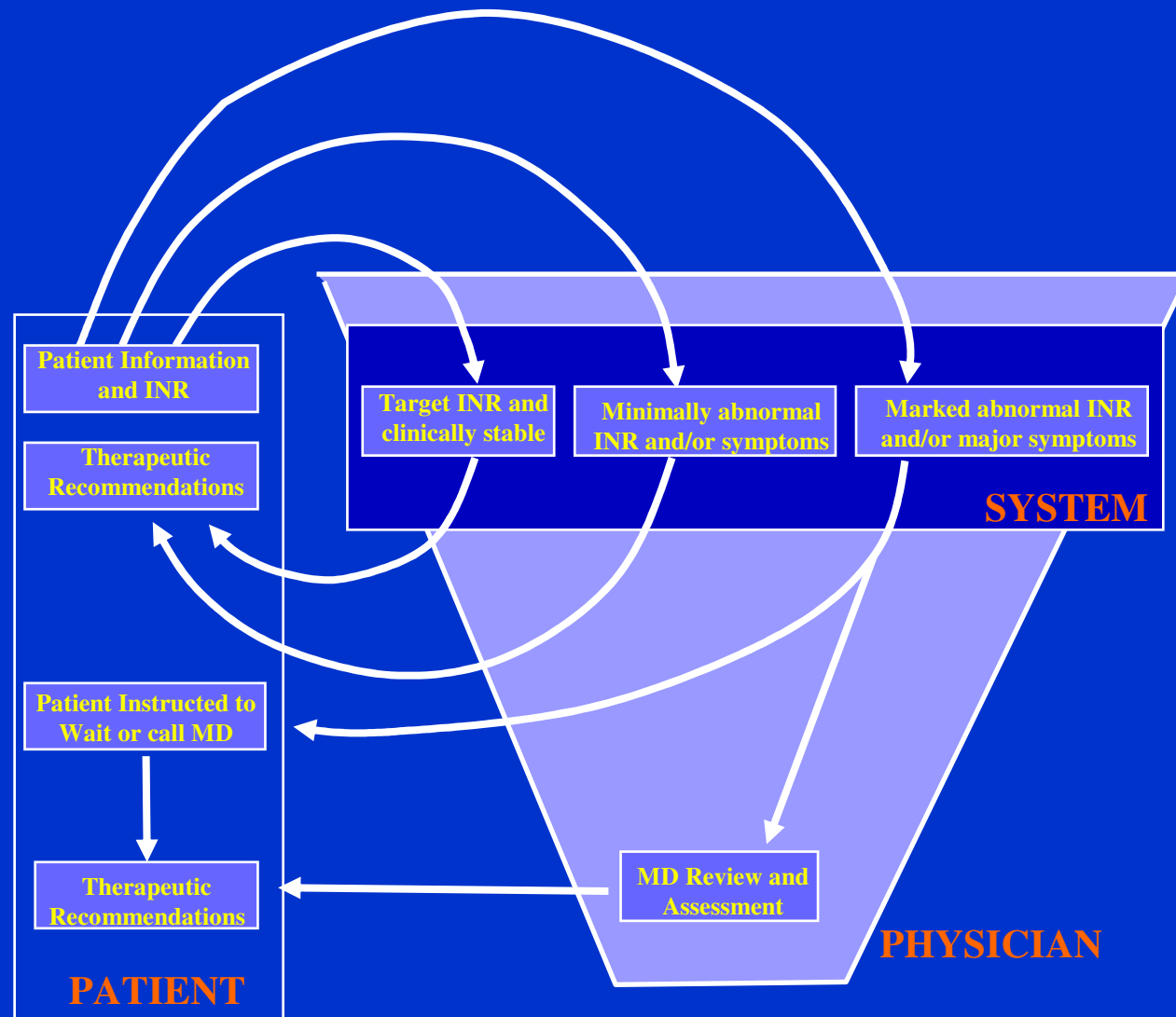
2) VARIABILITY OF ANTICOAGULATION AND MORTALITY ¹ % INR OUTSIDE 2 TO 4 - - MEDTRONIC VALVE – UK (N=1476 Pts – INR=82297)



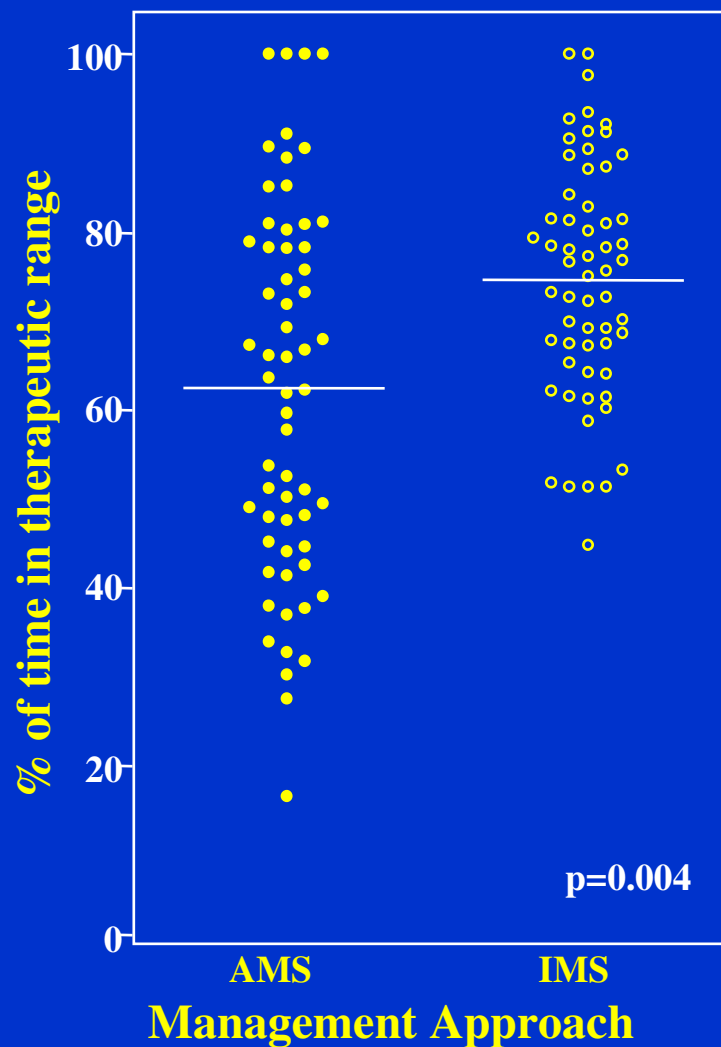
¹ Stroke, Bleeding, Endocarditis (Fibrin, Non Compliant, Antibiotics)

UK Registry (EB Butchant et al.), JTCS 2002; 123:715
OASIS (S Yusuf et al.) JACC 2002; 37:475 - **CAD**

3) SCHEMATIC MODEL OF THE INTERNET-SUPERVISED PATIENT SELF-MANAGEMENT SYSTEM



3) PERCENT TIME IN THERAPEUTIC RANGE IN ANTICOAGULATION MANAGEMENT SERVICE AMS VERSUS INTERNET-MANAGEMENT SUPERVISED OR IMS



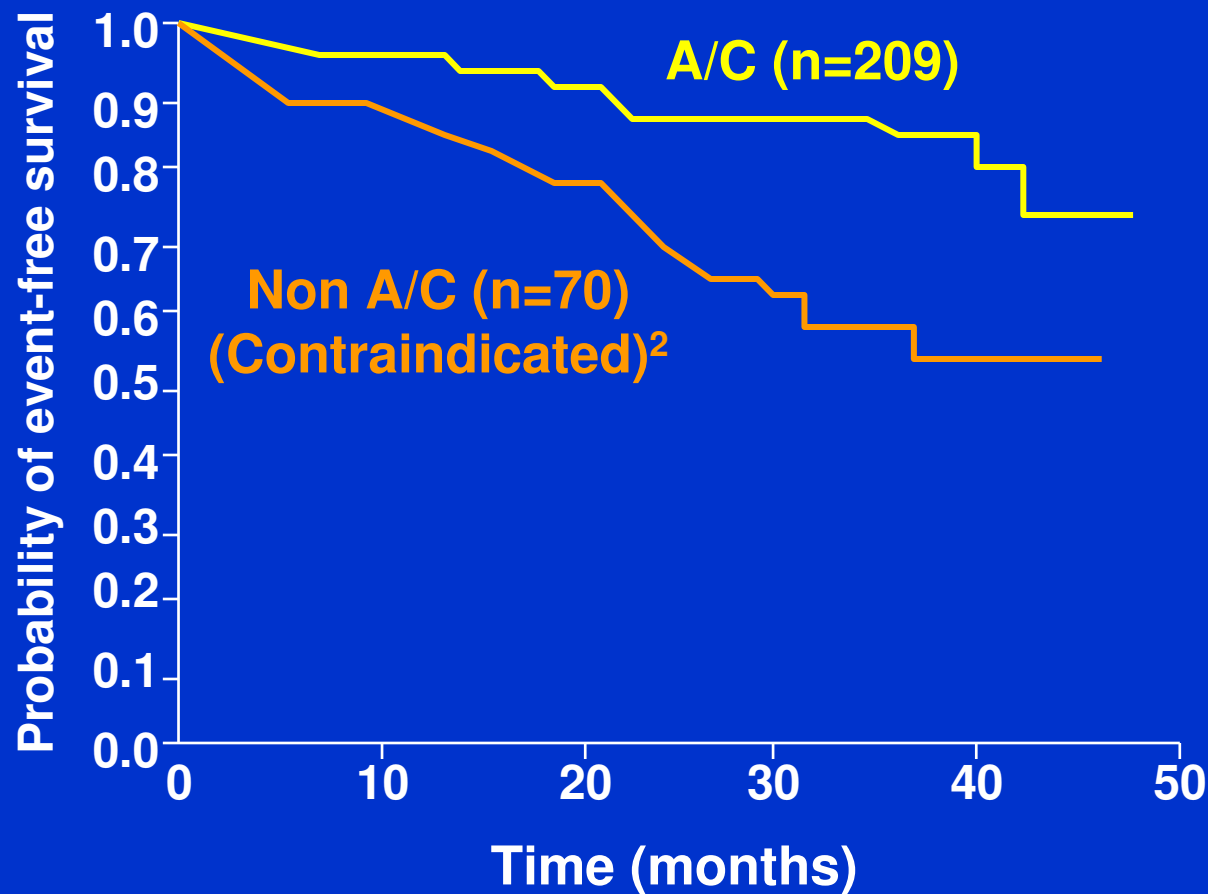
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1) BLEEDING & THROMBOEMBOLIC EVENTS BY INDICATION FOR TREATMENT

Indication/Age, y	Hemorrhage		Thromboembolism	
	No. of Events	Incidence	No. of Events	Incidence
Mechanical heart valve				
< 60	15	3.9	2	0.5
60-70	14	3.5	3	0.7
71-80	6	1.9	2	0.6
> 80	3	4.2	2	2.8
Atrial fibrillation				
< 60	2	0.5	1	0.3
60-70	17	1.9	14	1.6
71-80	44	3.0	20	1.4
> 80	32	4.5	13	1.8
Myocardial infarction				
< 60	7	0.9	13	1.6
60-70	18	1.7	15	1.4
71-80	18	1.9	21	2.2
> 80	12	3.6	12	3.6

1) NVAF ≥ 75 Y (n=279), PROBABILITY OF SURVIVAL FREE FROM EMBOLISM OR SEVERE BLEEDING BY TREATMENT GROUP

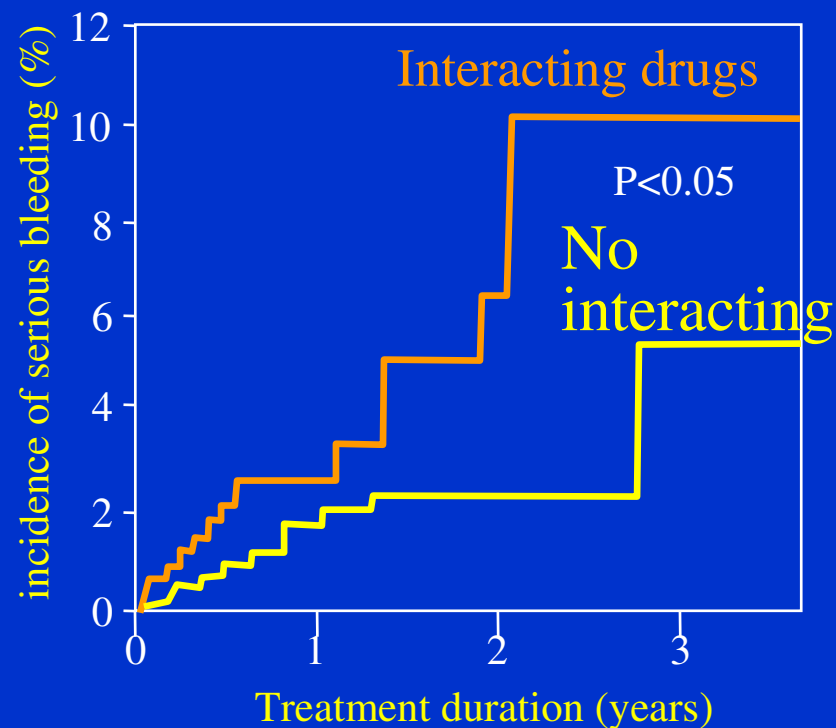
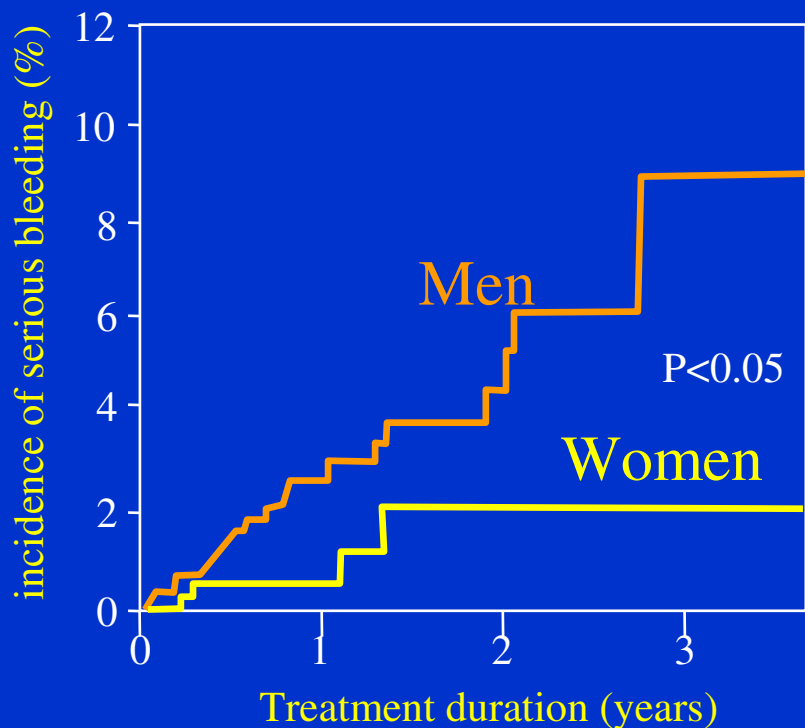


¹Mortality Non A/C > A/C (p=0.023); Bleeding Non A/C 4.1%, A/C 2.6% (p=0.25)
INR 1.6 – 2.5, Ideal 2.0 ?

²ASA or platelet inhibitor

M Ruiz Ortiz et al., Heart 2005; 91:1225 (Cordoba, Spain)

1) *INCIDENCE OF SERIOUS BLEEDING¹ (WHO)² MEN AND INTERACTING DRUGS*

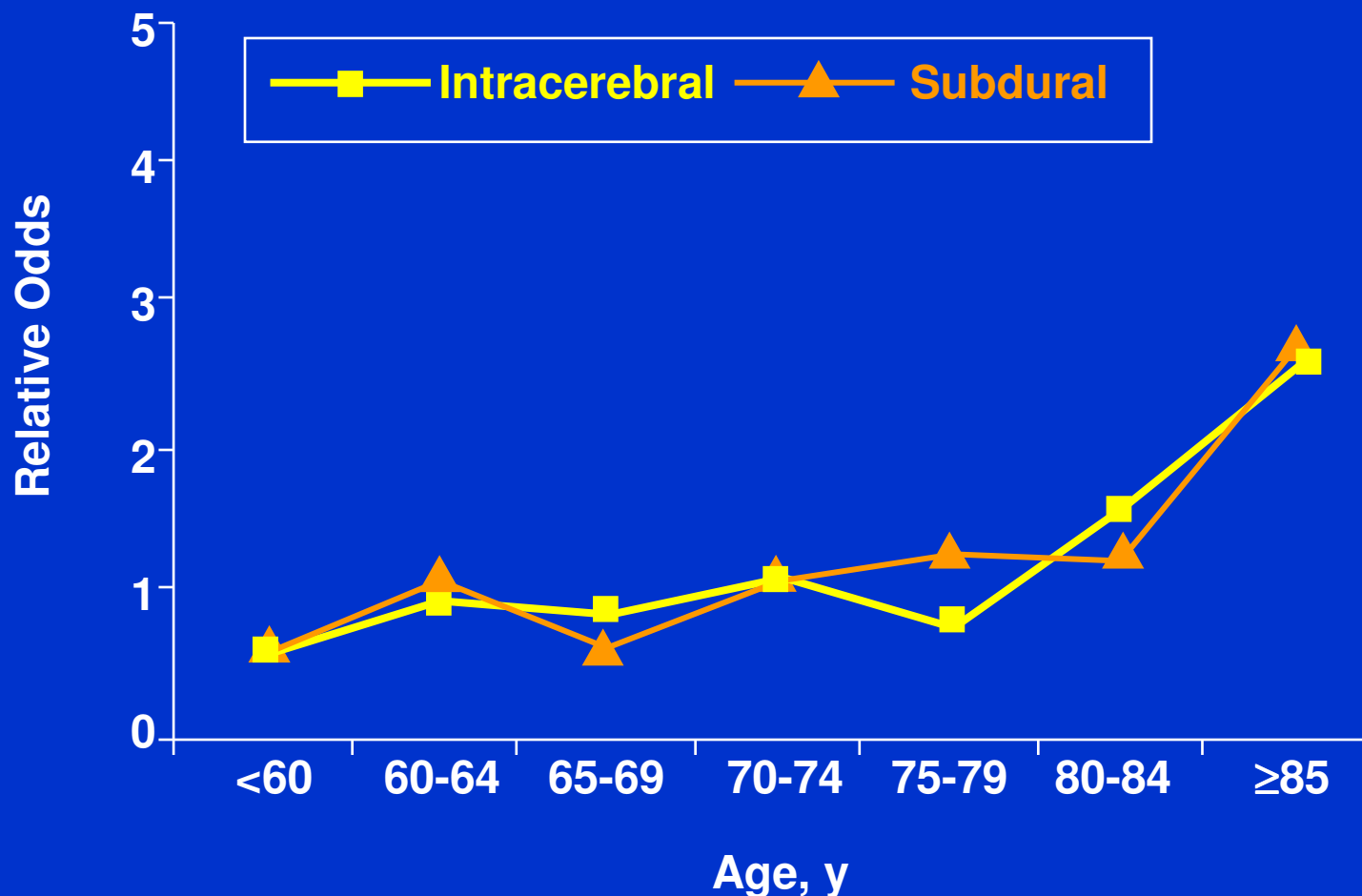


¹Incid. 2.3 per 100 pt yrs (low) – n=1523 pts – 40 centers

²Lethal, life-threatening, permanently disabling, hospitalization

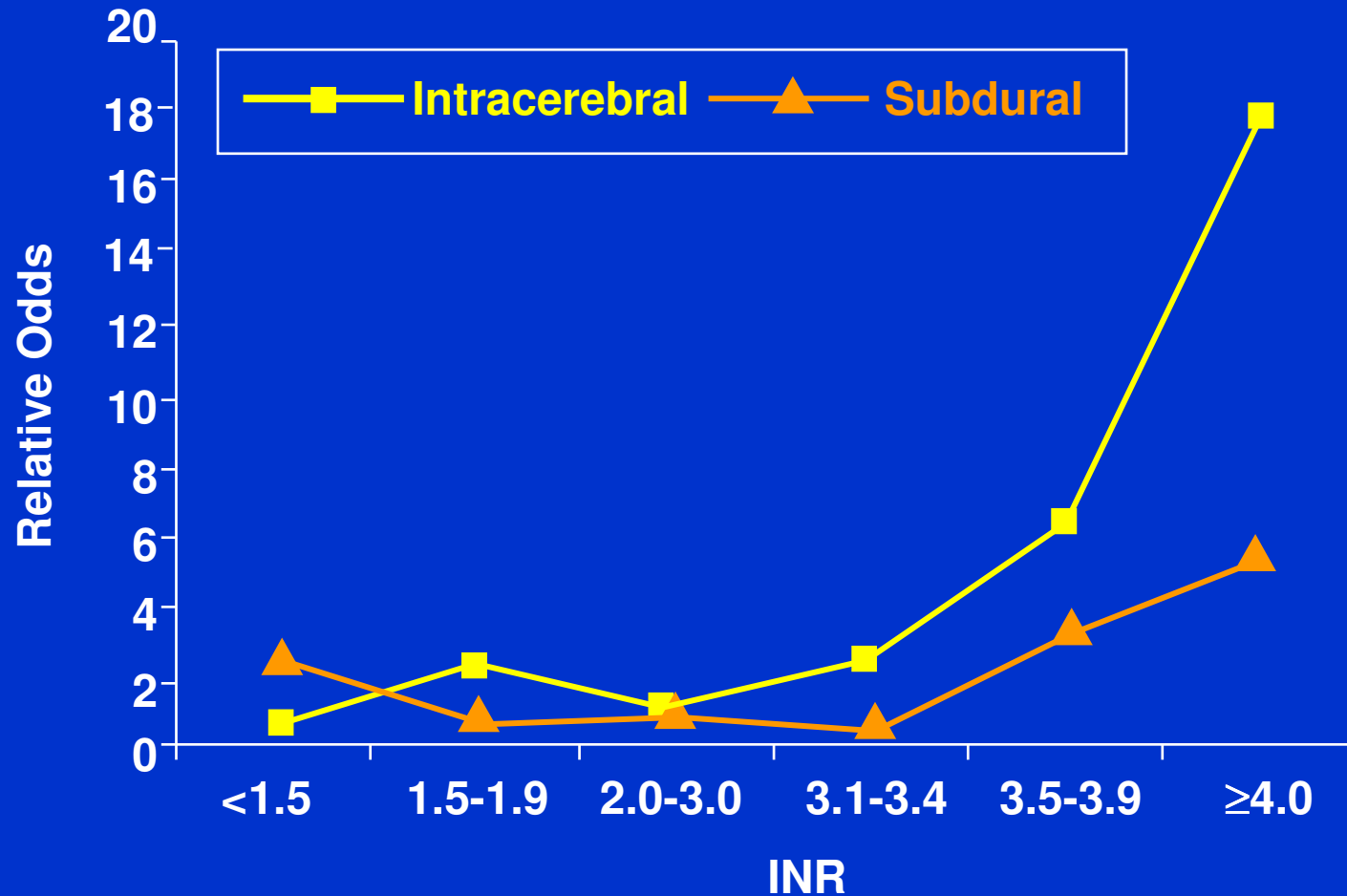
WARG (JD Lindh et al.) J Thromb Thrombol 2008; 25:151 (Sweden)

1) RELATIVE ODDS OF INTRACRANIAL HEMORRHAGE & AGE IN 145 CASE-PATIENTS (AF - INR 2.0-3.0) AND 870 CONTROLS



MC Fang et al., Ann Intern Med 2004; 141:745 (UCSF, Boston, Oakland)

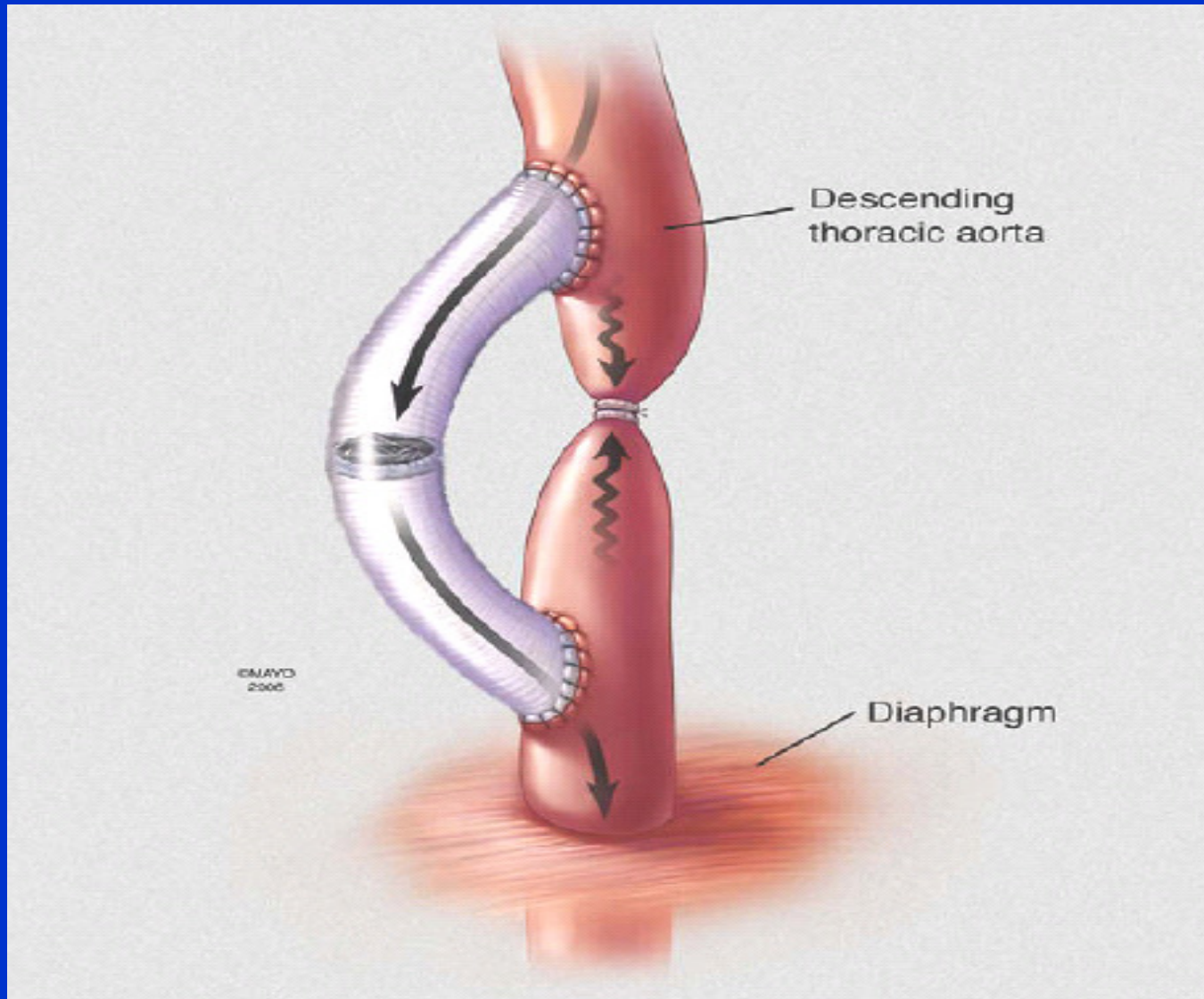
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MC Fang et al., Ann Intern Med 2004; 141:745 (UCSF, Boston, Oakland)

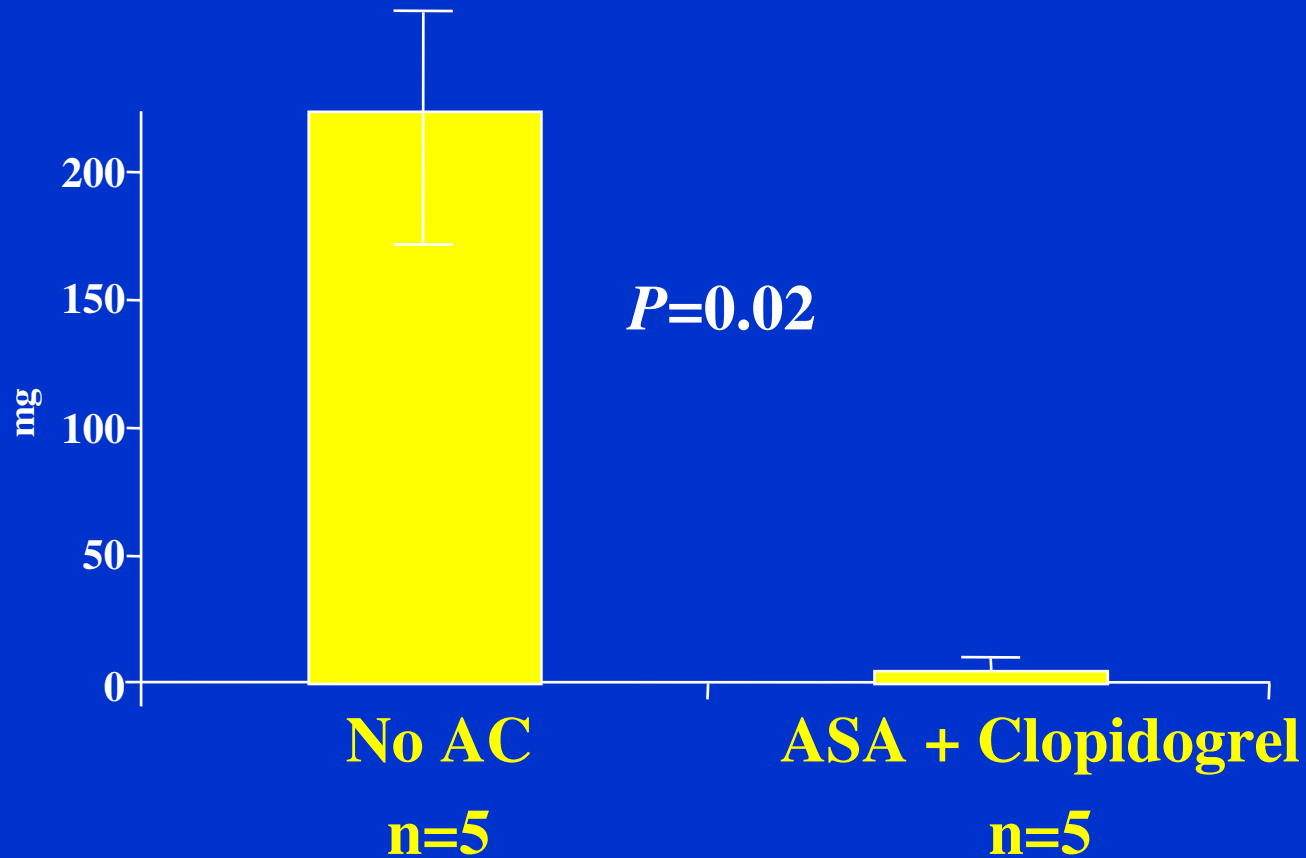
1) Swine aortic valve model & Platelet Inhibitors

(St. Jude Masters Series, St. Jude Medical)



SH McKellar et. al. *J Thorac Cardiovasc Surg* 2008;136:908. (Mayo)

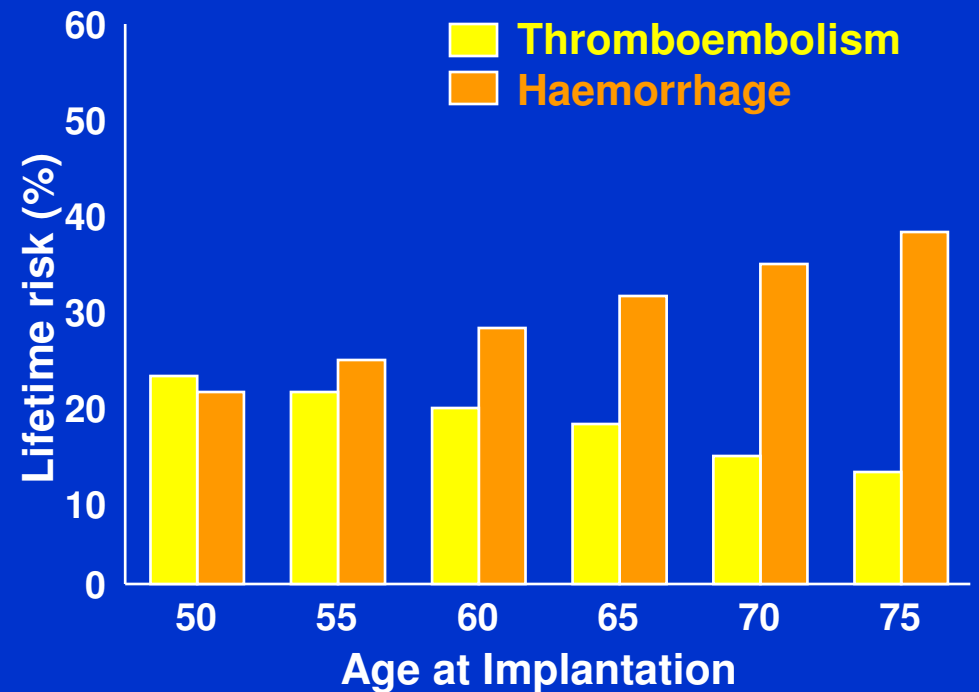
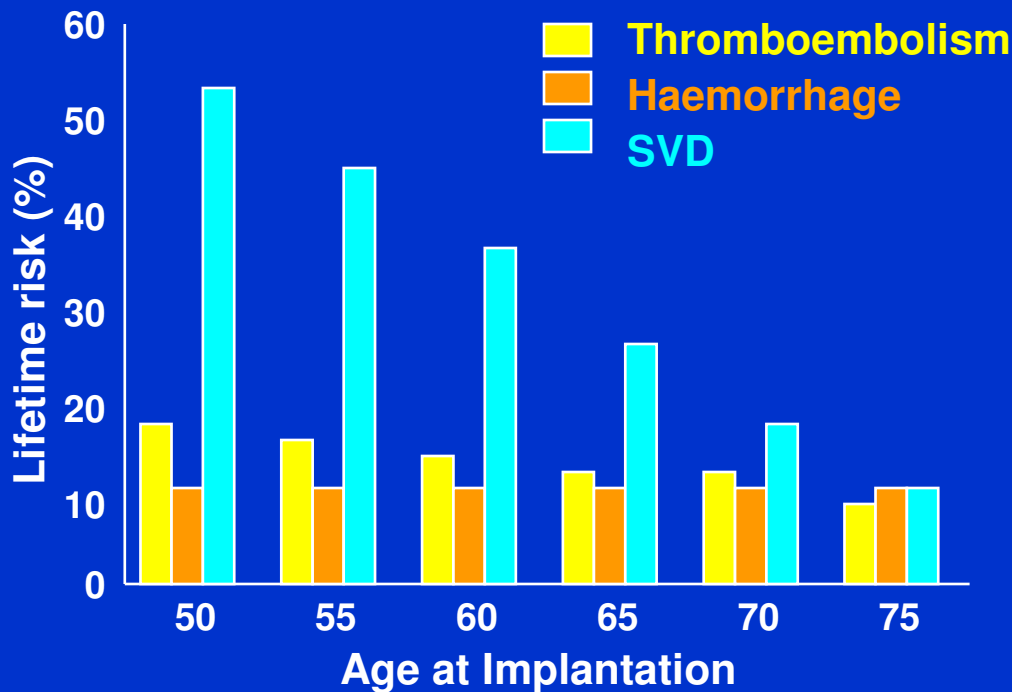
1) MEAN VALVE THROMBUS (IN MG± SE OF THE MEAN) FOR TWO 150-DAY SURVIVOR GROUPS



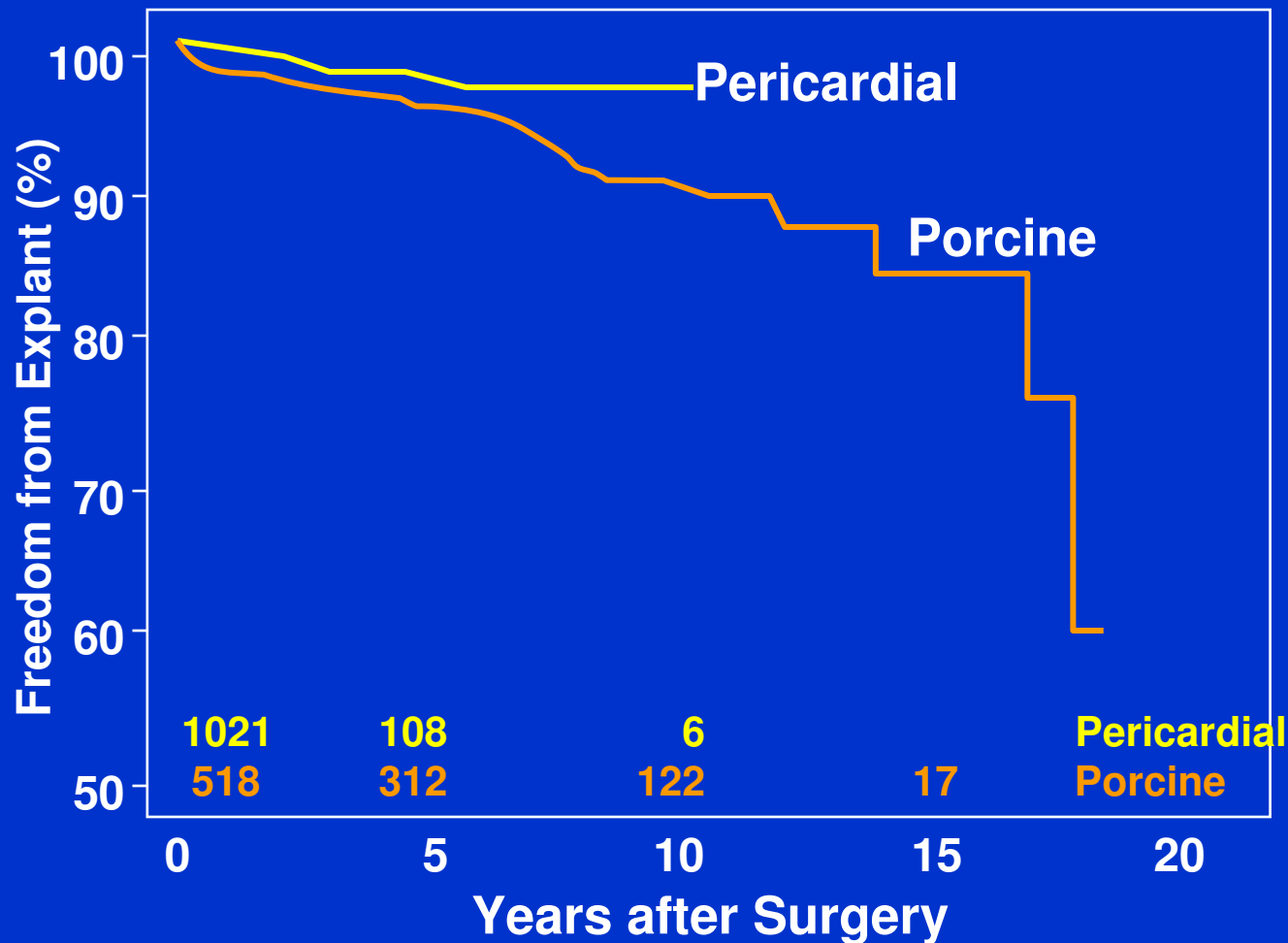
2) LIFETIME RISK EMBOLISM, HAEMORRHAGE & SVD FOLLOWING AVR IN MEN OF DIFFERENT AGES

**PORCINE BIOPROSTHESIS
(N=9007)**

**BILEAFLET MECHANICAL PROSTHESIS
(N=4274)**



2) FREEDOM FROM EXPLANT FOR PORCINE & PERICARDIAL AORTIC VALVE REPLACEMENT PATIENTS



G Gao et al., JACC 2004; 44:384 (Portland) - SVD

3) The Surprising Rise of Nonthrombogenic Valvular Surgery

It is not surprising that **patients choose valvular bioprosthesis for a better quality of life.** What surprises me is that, after almost 30 years, glutaraldehyde remains as the unsurpassed element in animal-tissue processing. **The introduction of valve reconstruction, with a proven durability of up to 25 years, allows 50-90% of diseased valves to be reconstructed, rather than replaced with a bioprosthesis or a mechanical valve.** For the first time in the history of valvular diseases, patients could be cured for the rest of their lives *and avoid anticoagulant therapy by earlier operation on sinus rhythm.*

A Carpentier. Nature Medicine **2007**; 13:1165 (*Modified*)

3) AF - Role of Oral Anticoagulation Therapy (OAT) After Pulmonary Vein Isolation



The role of OAT in preventing cerebrovascular accidents (CVA) after intracardiac echo-guided pulmonary vein antrum isolation (ICE-PVAI) is still unclear. 85 consecutive patients underwent ICE-PVAI for symptomatic drug-refractory AF. **OAT 3 months after ICE-PVAI seems to be safe in patients without AF recurrences after the first 3 months following ablation.**

A Rossillo et al. J Cardiovasc Med **2008**;9:51 (Mestre-

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1,2) RECOMMENDATIONS FOR ANTITHROMBOTIC THERAPY IN PATIENTS WITH PROSTHETIC HEART VALVES



ASA (75-100 mg)

Warfarin
(INR 2.0-3.0)

Warfarin
(INR 2.5-3.5)

No Warfarin

Mech. prosthetic valves

AVR—low risk

< 3 mo

Class I

Class I

Class IIa

> 3 mo

Class I

Class I

AVR—high risk

Class I

Class I

MVR

Class I

Class I

Biol. prosthetic valves (Repair)

AVR—low risk

< 3 mo

Class I

Class IIa

Class IIb

> 3 mo

Class I

Class IIa

AVR—high risk

Class I

Class I

MVR—low risk

< 3 mo

Class I

Class IIa

> 3 mo

Class I

Class IIa

MVR—high risk

Class I

Class I

ACC/AHA VHD (RO Bonow et al.) Circ **2008**; e626 - **ACCP** Chest **2008**; 133: 92S
ESC (Butchard, EG et al) Eur Heart J **2005**;26:2463

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1) Incidence, Imaging Analysis, and Early and Late Outcomes of Stroke After Valve Operation

We collected data from **2,808 patients** who underwent valve surgery with or without concomitant coronary artery bypass grafting from January 1998 to December 2006. Stroke was defined as any **new permanent focal neurologic deficit**. **Overall incidence of stroke was 2.2%**. Multivariate analysis revealed **calcified ascending aorta and cardiopulmonary bypass time > 120 minutes (OR 3.7)** as the highest predictors of stroke. **Intraoperative epiaortic scanning** may contribute in decreasing the incidence of this complication and **may be warranted in all patients undergoing valvular surgery**.

F Filsoufi, JG Castillo, DH Adams et al., AJ C **2008**; 101:1472

1) PROSTHETIC HEART VALVES - ANTITHROMBOTICS 2008

The First Two Weeks

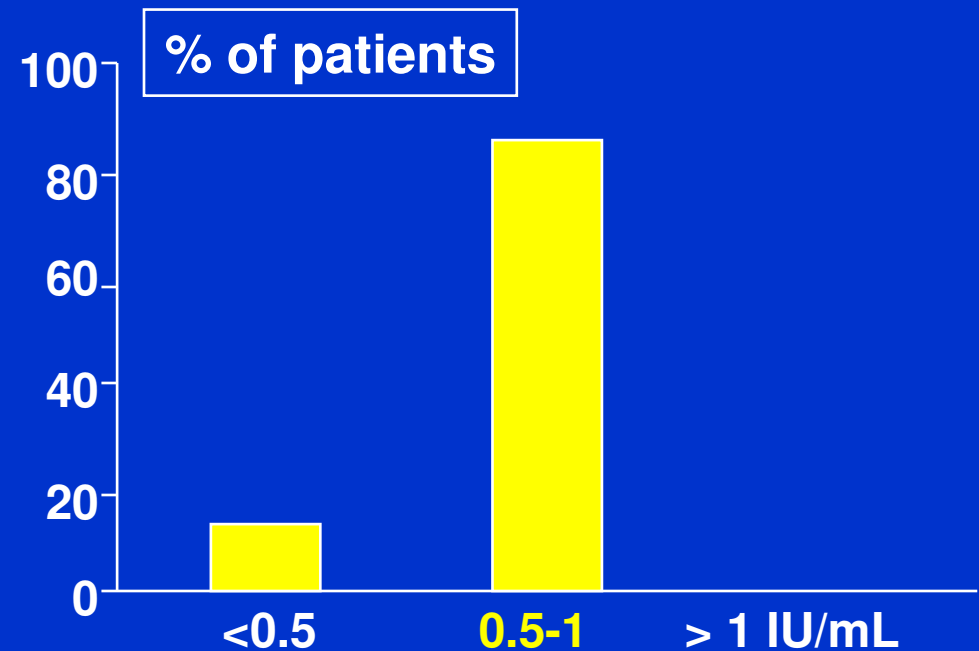
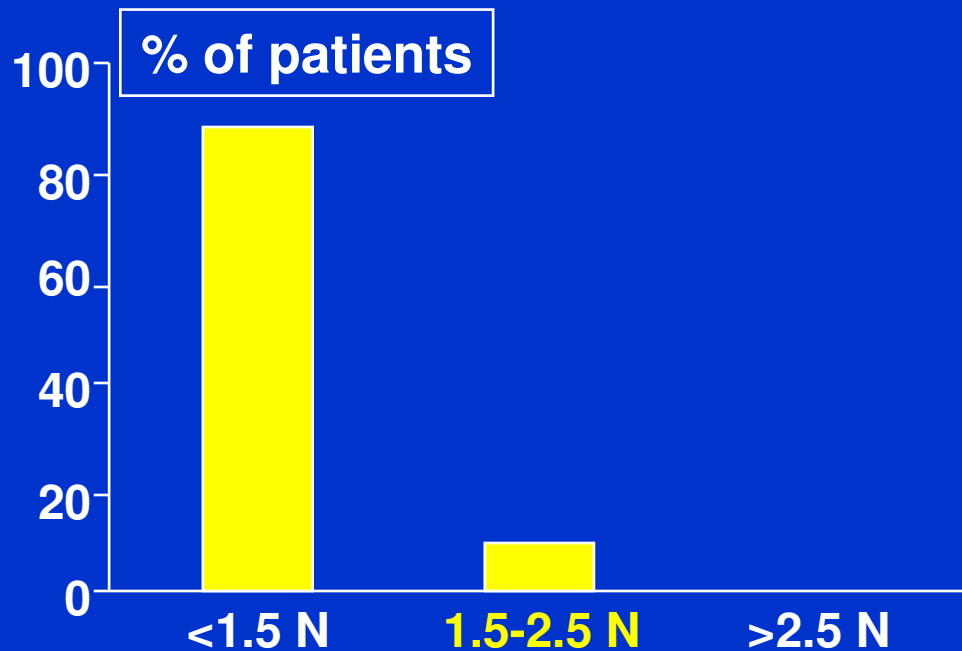
- ^{1,2}High incidence of stroke in the first two weeks
- ¹In part related to delay in achieving therapeutic INR
- ³Advantage with early aggressive antithrombotic approach
- ⁴Questionable approach
- ⁵Sc LMWH may be of benefit (thromboemboli / hemorrhage)
- ⁶Sc LMWH superior to Sc Unfractionated heparin

1. Heras M, Chesebro JH, Fuster V et al., JACC **1995**; 25:1111
2. Orzulak TA. Ann Thorac Surg **1995**; 59:462
3. Babin-Ebell J et al., Thorac Cardiovasc Surg **1995**; 43:212
4. Moinuddeen K et al., Circ **1998**; 98(suppl 19):II-95
5. N Seshadri et al., AHJ **2005**; 150:27 (Canada)
6. G Montalescot et al., **2000**; 101:1083

1) SC LMWH SUPERIOR TO SC UH - PROSTHETIC VALVES ABOUT DAY 6 TO 18 (N=208)

aPTT in patients treated With SC UH after 2-days

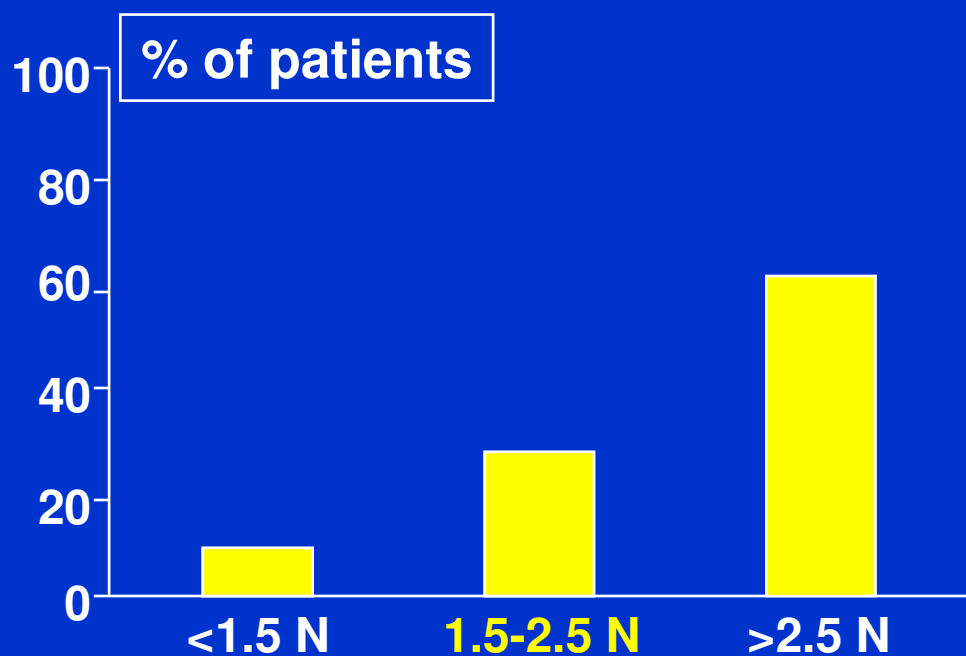
Anti-Xa activity in patients treated With SC LMWH after 2 days



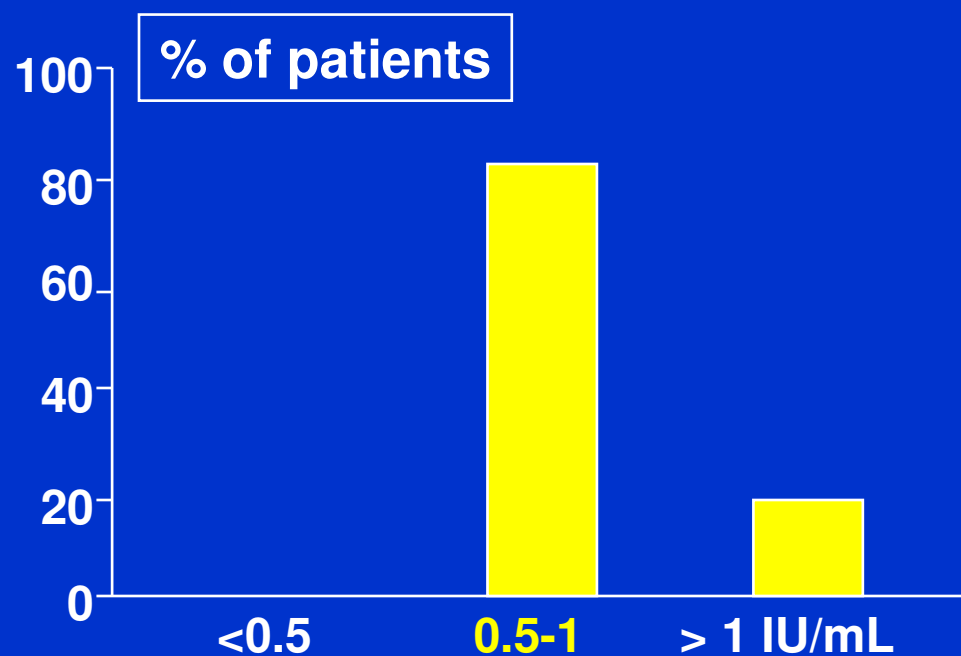
Day 2 IV UH, Day 3 SC H + Coumadin (Modified)
G Montalescot et al., Circ 2000; 101:1083 (Paris)

1) SC LMWH SUPERIOR TO SC UH - PROSTHETIC VALVES ABOUT DAY 6 TO 18 (N=208)

aPTT on the Day of SC UH Interruption



Anti-Xa activity on the Day of SC LMWH Interruption



Thromboemb 0.5% (UH) - Major Bleed 2% (UH and LMWH)
G Montalescot et al., Circ 2000; 101:1083 (Paris)

1) "THERAPEUTIC EFFECT" OF SC-BID HEPARIN

Unfract.heparin aPTT of **1.5 to 2.5**, at **8 h** after dose, or
heparin level of **0.35 to 0.70 anti-Xa u**

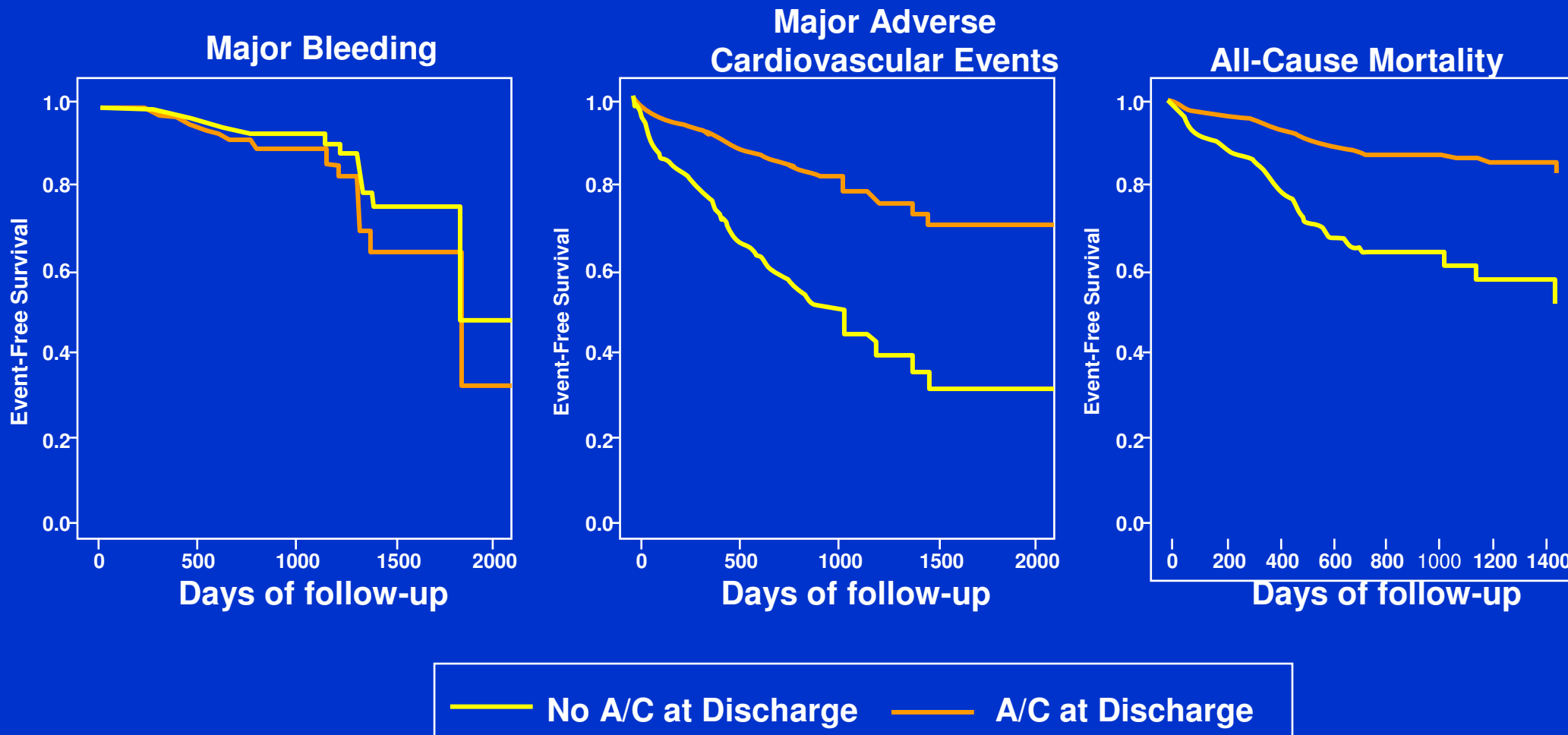
LMW heparin aPTT at **8 h** after a dose of **100 u/Kg (Dalteparin)**
to a heparin level of **0.7 to 1.1 anti-Xa units**

During **pregnancy**, aPTT levels do not accurately reflect heparin levels. Factor anti-XA levels should be **0.4 to 0.7** eight hours after a dose of unfractionated heparin and **0.7 to 1.1 ten hours after LMW heparin.**

JH McAnulty, SH Rahimtoola **2008** (In Press)

Danik S, Fuster V, Obst. Gynec Clin North Am, **2006**;33:481

2) A/C IN AF PATIENTS UNDERGOING STENTING (N=426) A/C + ASA + C (41%) - ASA + C (50%)



JM Ruiz-Nodar et al., JACC 2008; 51:818 (Spain, UK)

2) RECOMMENDATIONS FOR ANTITHROMBOTIC PRACTICE PCI REVASCULARIZATION – NEED FOR AC –

Indication	Type of antithrombotic therapy		
	Aspirin	Clopidogrel	Oral AC
Low-risk patients	Yes	Yes	No
Short-term therapy (3mo)	Yes / No	Yes	Yes
Long-term therapy	Yes Only ¹	Yes Only ²	Yes



¹ If No DES or if DES after 1 yr . ² If DES at least 1 yr

V Fuster - Modified of G Helft et al., Nature Cardio Med 2006;3:673

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1) BRIDGING THERAPY IN PATIENTS WITH MECHANICAL VALVES WHO REQUIRE INTERRUPTION OF WARFARIN THERAPY FOR NONCARDIAC SURGERY, INVASIVE PROCEDURES, OR DENTAL CARE

Class I

1. In patients at low risk of thrombosis, defined as those with a bileaflet mechanical AVR with no risk factors, it is recommended that warfarin be stopped 48 to 72 h before the procedure (so the INR falls to less than 1.5) and restarted within 24 h after the procedure. Heparin is usually unnecessary.

2. In patients at high risk of thrombosis, defined as those with any mechanical MV replacement or a mechanical AVR with any risk factor, therapeutic doses of intravenous UFH should be started when the INR falls below 2.0 (typically 48 h before surgery), stopped 4 to 6 h before the procedure, restarted as early after surgery as bleeding stability allows, and continued until the INR is again therapeutic with warfarin therapy.

1) BRIDGING THERAPY IN PATIENTS WITH MECHANICAL VALVES WHO REQUIRE INTERRUPTION OF WARFARIN THERAPY FOR NONCARDIAC SURGERY, INVASIVE PROCEDURES, OR DENTAL CARE

Class IIa

1. It is reasonable to give fresh frozen plasma to patients with mechanical valves who require interruption of warfarin therapy for emergency noncardiac surgery, invasive procedures, or dental care. **Fresh frozen plasma is preferable to high-dose vitamin K1.**

Class IIb

1. In patients at high risk of thrombosis, therapeutic doses of subcutaneous UFH (15,000 U every 12 h) or LMWH (100 U per kg every 12 h) may be considered during the period of a subtherapeutic INR.

Class III

1. In patients with mechanical valves who require emergency interruption of warfarin therapy for noncardiac surgery, invasive procedures, or dental care, **high-dose vitamin K1 should not be given routinely, because this may create a hypercoagulable condition.**

2) Periprocedural A/C Management Nonvalvular Atrial Fibrillation

345 patients eligible for inclusion. **Warfarin** was stopped 4 to 5 days before and was restarted after surgery as soon as hemostasis was assured. Bridging therapy with heparin was individual and based on the estimated risks of TE and bleeding. Periprocedural heparin was provided for 204 procedures. **Patients receiving heparin were more likely to have prior TE and a higher CHADS.** TE rate, 1.1%; Major bleeding rate, 2.7%. There were no deaths.

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SELECTION OF ANTICOAGULATION REGIMEN IN PREGNANT PATIENTS WITH MECHANICAL PROSTHETIC VALVES

Class I

1. All pregnant patients with mechanical prosthetic valves must receive **continuous therapeutic anticoagulation** with frequent monitoring.
2. Pregnant patients with mechanical prosthetic valves **who elect to stop warfarin between weeks 6 and 12 of gestation should receive continuous intravenous UFH dose-adjusted (APTT \geq 2 control), or dose-adjusted twice daily subcutaneous LMWH (anti-K level of 0.7-1.2 u per ml at 6 h).**
3. In pregnant patients with mechanical prosthetic valves, **warfarin should be discontinued and continuous intravenous UFH given starting 2 to 3 weeks before planned delivery.**

ACC/AHA VHD (RO Bonow et al.) Circ 2008; e602

SELECTION OF ANTICOAGULATION REGIMEN IN PREGNANT PATIENTS WITH MECHANICAL PROSTHETIC VALVES

Class IIa

- 1. It is reasonable to avoid warfarin between weeks 6 and 12 of gestation owing to the high risk of fetal defects.**
- 2. It is reasonable to resume UFH 4 to 6 h after delivery and begin oral warfarin in the absence of significant bleeding.**
- 3. It is reasonable to give low-dose aspirin (75 to 100 mg per day) in the second and third trimesters of pregnancy in addition to anticoagulation with warfarin or heparin.**

Class III

- 1. LMWH should not be administered to pregnant patients with mechanical prosthetic valves unless anti-Xa levels are monitored 4 to 6 h after administration.**

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1) VALVE CALCIFICATION & ANTITHROMBOTICS

1. In patients with mitral annular calcification or isolated calcific aortic valve disease complicated by systemic embolism, ischemic stroke, or transient ischemic attack, who do not have AF, we recommend aspirin (50 to 100 mg/d). For recurrent events despite aspirin therapy, we suggest treatment with VKA therapy (target INR, 2.5; range, 2.0 to 3.0).

ACCP Guidelines Chest 2008; 133:92S (Modified)

2) PERCUTANEOUS MITRAL BALLOON VALVOTOMY (PMBV) ANTITHROMBOTIC THERAPY

1. For patients being considered for PMBV, we recommend a **preprocedural TEE to exclude left atrial thrombus.**
2. For patients being considered for PMBV with **preprocedural TEE showing left atrial thrombus, we recommend postponement of PMBV and VKA therapy (target INR 3.0; range, 2.5 to 3.5) until thrombus resolution is documented by repeat TEE. If left atrial thrombus does not resolve with VKA therapy, we recommend that PMBV not be performed.**

3) AORTIC ATHEROSCLEROTIC LESIONS ANTITHROMBOTIC THERAPY

- 1. In patients with ischemic stroke associated with aortic atherosclerotic lesions, we recommend low-dose aspirin (50 to 100 mg/d) over no therapy.**
- 2. For patients with ischemic stroke associated with mobile aortic arch thrombi, we suggest therapy with either VKAs (target INR, 2.5; range, 2.0 to 3.0) or low-dose aspirin (50 to 100 mg/d).**

4) INFECTIVE ENDOCARDITIS ANTITHROMBOTIC THERAPY

1. In patients with infective endocarditis, we recommend **against routine antithrombotic therapy**, unless an indication exists.
2. In the patient **treated with VKA therapy who has infective endocarditis, we suggest VKA be discontinued at the time of initial presentation and UFH substituted**, until it is clear that invasive procedures will not be required and the patient has stabilized **without signs of CNS involvement**. When the patient is deemed stable without contraindications or neurologic complications, **we suggest reinstitution of long-term VKA therapy**.

5) PROSTHETIC HEART VALVE THROMBOSIS

Type

Usually **mechanical** (any time post-op)
Uncommonly bioprosthetic (early post-op)

Etiology

Inadequate anticoagulation in > 57-70%

Symptoms

Dyspnea and other Sx CHF usually > 1 wk,
Angina of new onset in half,
Acute pulmonary edema often present

Examination

Rales and other signs of **CHF** in > 90%
New **murmur** in 90%
Abnormal opening or closing **clicks** (absent or ↓) in 60%

5) THROMBOSIS OF PROSTHETIC HEART VALVES

Class I

1. Transthoracic and Doppler echocardiography is indicated in patients with suspected prosthetic valve thrombosis to assess **hemodynamic severity**.

2. Transesophageal echocardiography and/or fluoroscopy is indicated in patients with suspected valve thrombosis to assess **valve motion and clot burden**.

5) THROMBOSIS OF PROSTHETIC HEART VALVES

Class IIa

1. Emergency operation is reasonable for patients with a thrombosed left-sided prosthetic valve and NYHA functional class III-IV symptoms and / or a large clot burden.

2. Fibrinolytic therapy is reasonable for thrombosed right-sided prosthetic heart valves with NYHA functional class III-IV symptoms or a large clot burden.

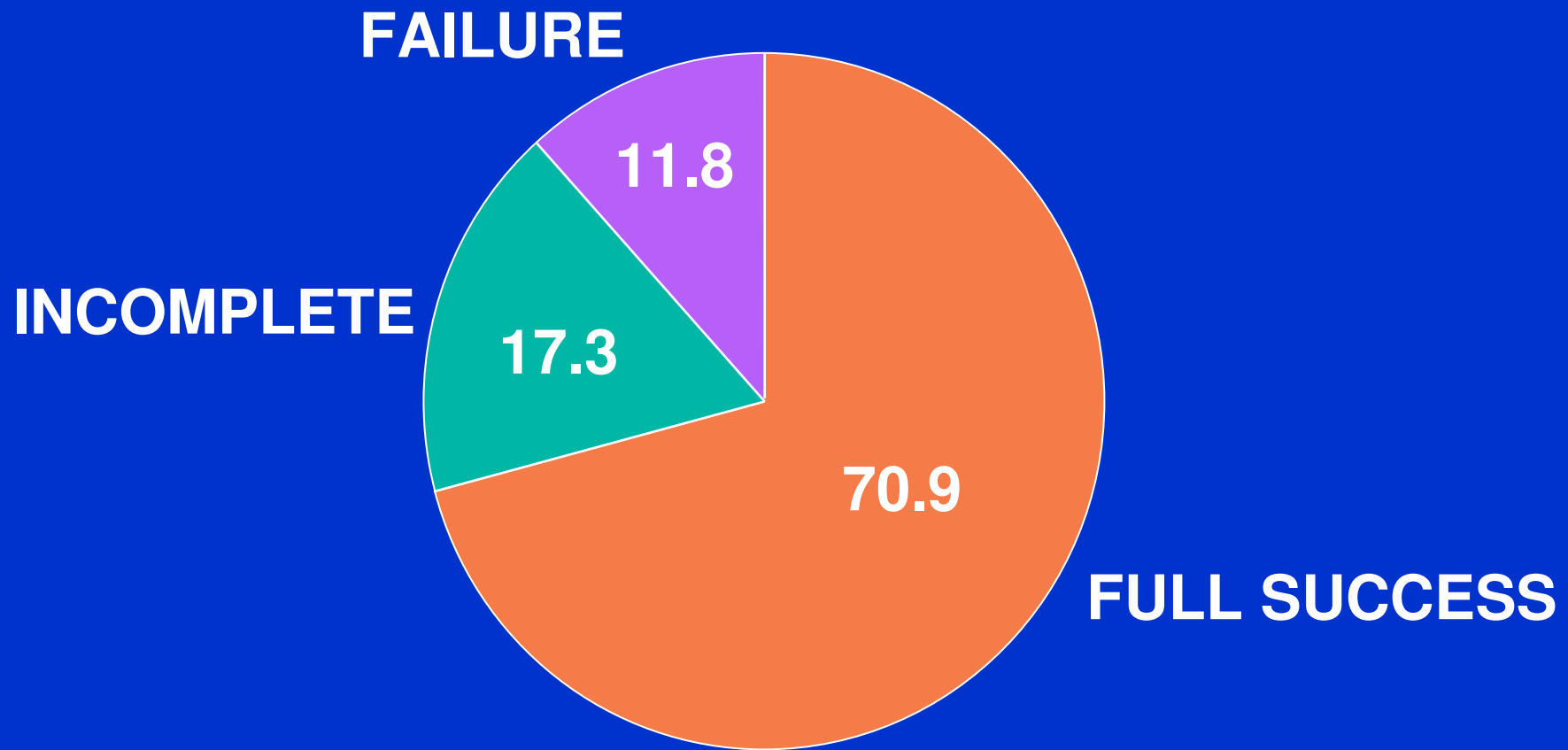
5) THROMBOSIS OF PROSTHETIC HEART VALVES

Class IIb

1. Fibrinolytic therapy or Intravenous UFH as an alternative may be considered as a first-line therapy for patients with a **thrombosed left-sided prosthetic valve, NYHA functional class I-II symptoms, and a small clot burden.**

2. Fibrinolytic therapy may be considered for patients with an **obstructed, thrombosed left-sided prosthetic valve who have NYHA functional class II-IV symptoms and a large clot burden if emergency surgery is high risk or not available.**

5) FIBRINOLYSIS OF PROSTHETIC VALVE THROMBOSIS (N=127)



Mortality 12% - Hemorrhage 5% - Emboli 15% - Recurrence 19%

R Roudaut et al., JACC 2003; 41:653

VALVULAR INTERVENTION, ANTITHROMBOTICS 2009

- PHV - Survivorship, Thromboemboli, Hemorrhage
- PHV - Emboli Risk Factors, Compliance, INR-SM
- VHD - Hemorrhage, Age, Bioprostheses, Valve Repair
- PHV - Approach to Long Term Antithrombotic Therapy
 - Mechanical Prostheses
 - Bioprostheses
- Approach to Special Conditions
 - Very Early Antithrombotic Therapy – Stenting
 - Bridging at Elective Intervention – PHV, AF
 - Young Women and Pregnancy
 - Valve Calcium, PMBV, Aorta, SBE, Valve Thrombosis

ATRIAL FIBRILLATION - 2009 CHALLENGES AND NEW OBSERVATIONS

- 1. Prevalence of AF (2)**
- 2. Classification & Patterns (5)**
- 3. Pathophysiology (7)**
- 4. Approach to Management (3)**
- 5. Heart Rate Control (1)**
- 6. Rhythm Control (4)**
- 7. Consider Ablation (6)**
- 8. Antithrombotic Therapy (8)**

ACC/AHA/ESC (Fuster V et al) Circ 2006; 114:700
AHA Guidelines Handbook – Ed. V Fuster 2009