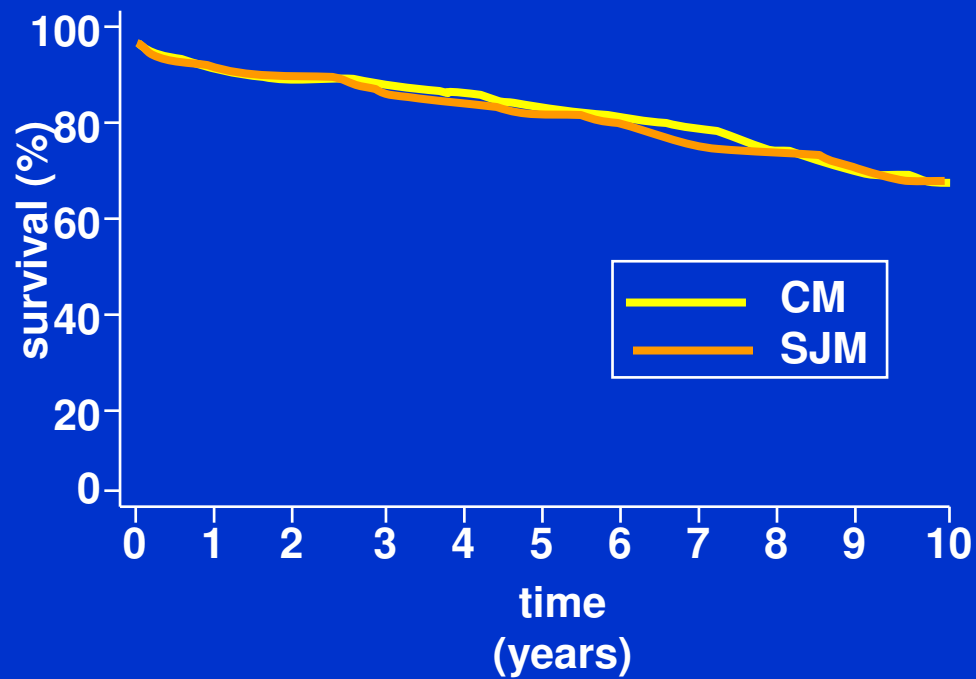


PROSTHETIC HEART VALVES, ANTITHROMBOTICS 2007

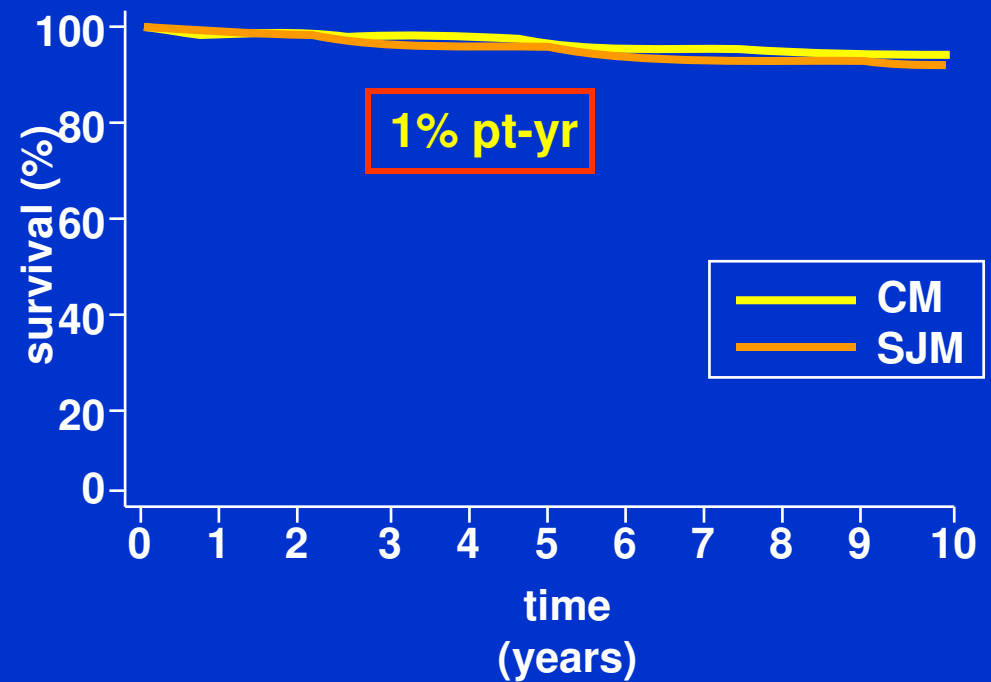
- **Survivorship, Thromboembolism, Hemorrhage**
- **Thromboembolism, Risk Factors, Compliance (PSM)**
- **Hemorrhage, Age, Bioprostheses**
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PROSPECTIVE RANDOMIZED BILEAFLET MECHANICAL PROSTHESES (10 YEAR FU, N=485)

Overall Survival



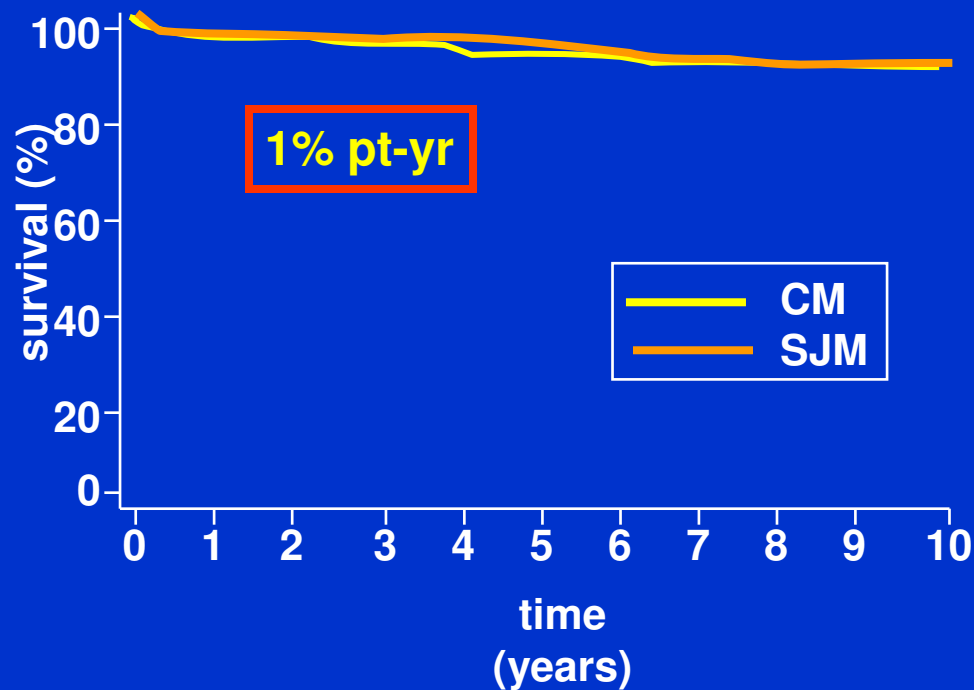
Survival Free From Valve-Death



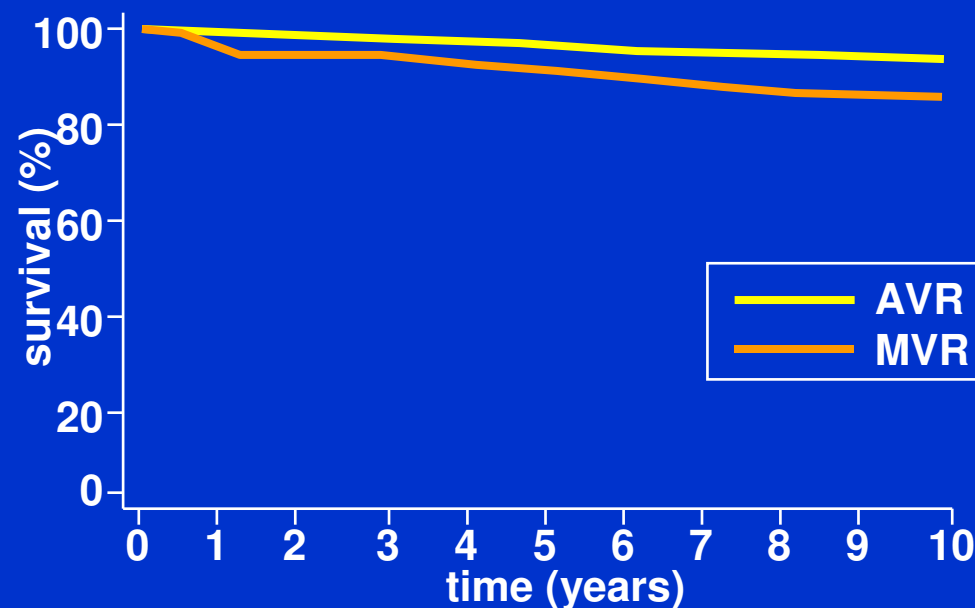
A Bryan et al., JTCS 2007; 133:617 (Bristol, UK)

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

Freedom From TE For All Study Patients

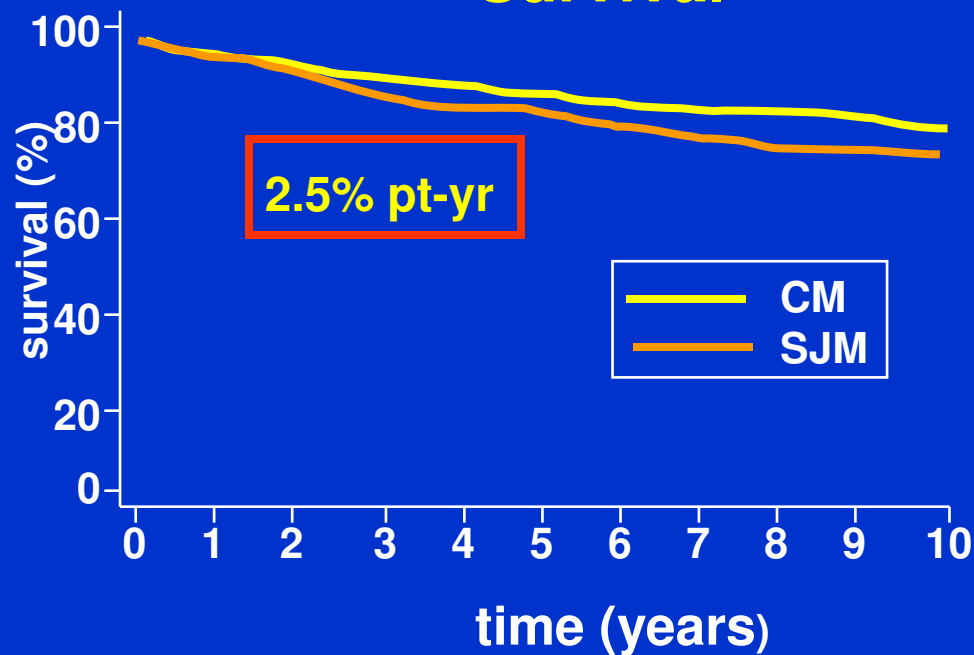


Freedom By Position of Valve Replacement

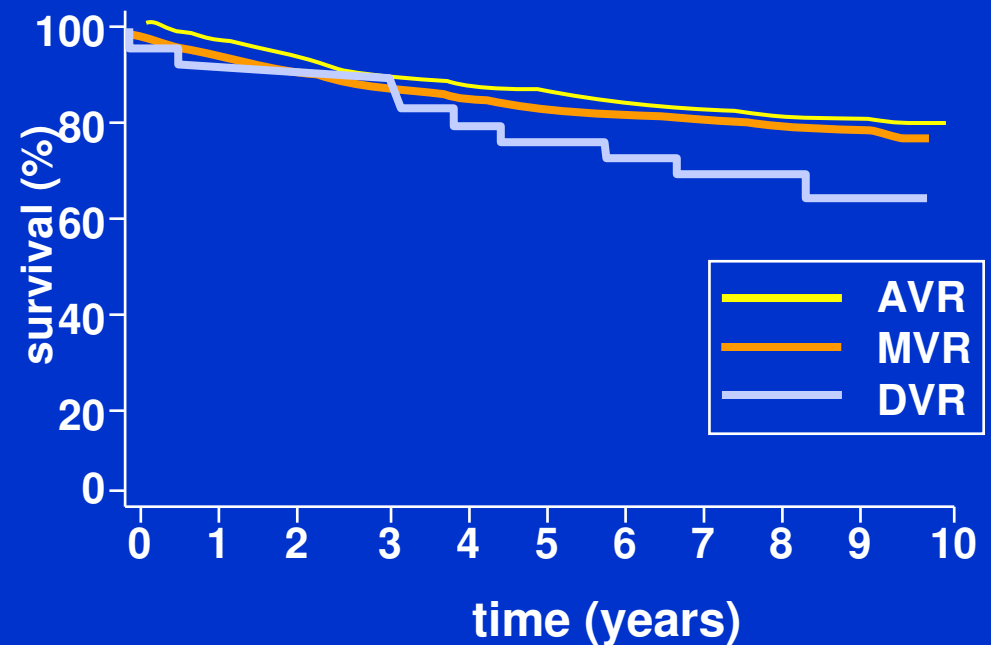


PROSPECTIVE RANDOMIZED BILEAFLET MECHANICAL PROSTHESES (10 YEAR FU, N=485)

Bleeding Event-Free Survival

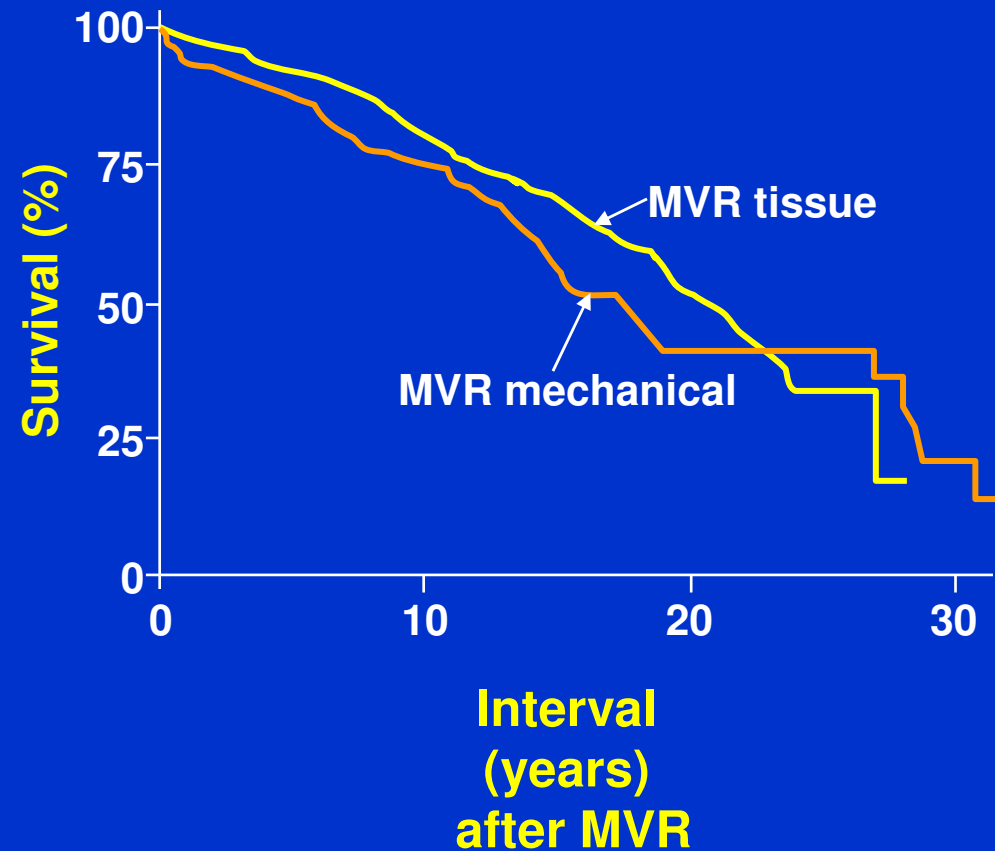
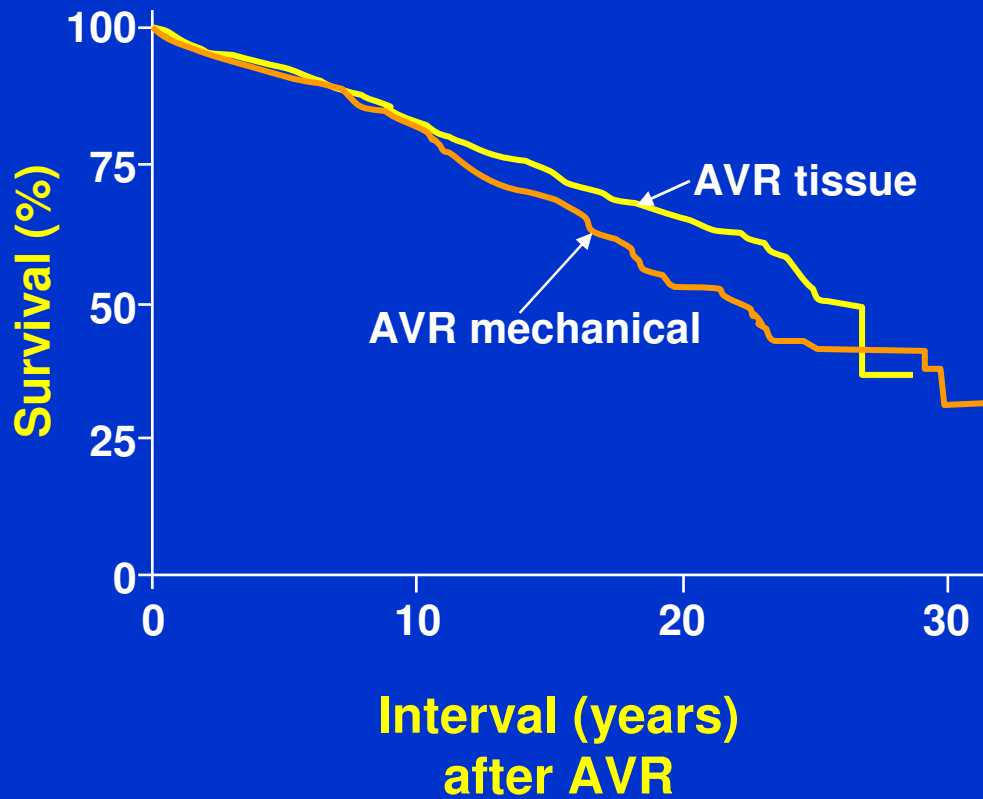


By Position of Valve Replacement



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

2-3% pt-yr



M Ruel et al., Circ 2007; 116(Suppl I):I-294 (Ottawa Heart Inter)

PROSTHETIC HEART VALVES, ANTITHROMBOTICS 2007

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PROSTHETIC HEART VALVES - ANTITHROMBOTICS 2007

RISK FACTORS FOR THROMBOEMBOLISM ¹⁻³

Atrial Fibrillation

LV Dysfunction

Previous Thromboembolism

Hypercoagulable, LA Thrombus at Operation

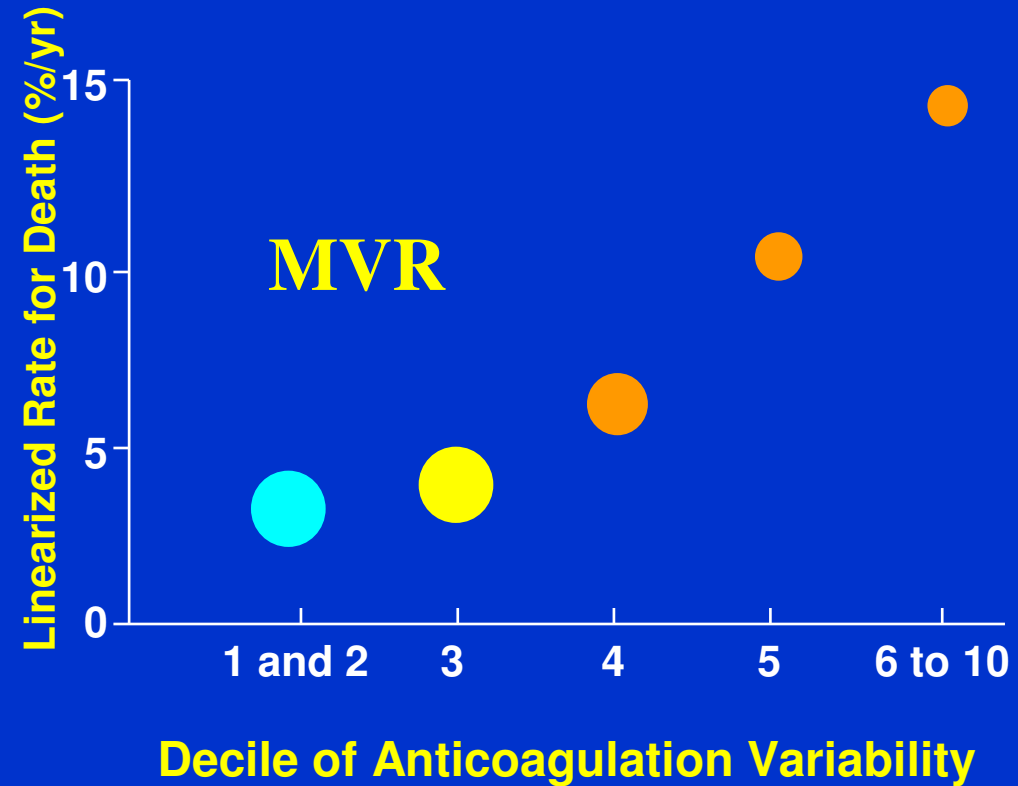
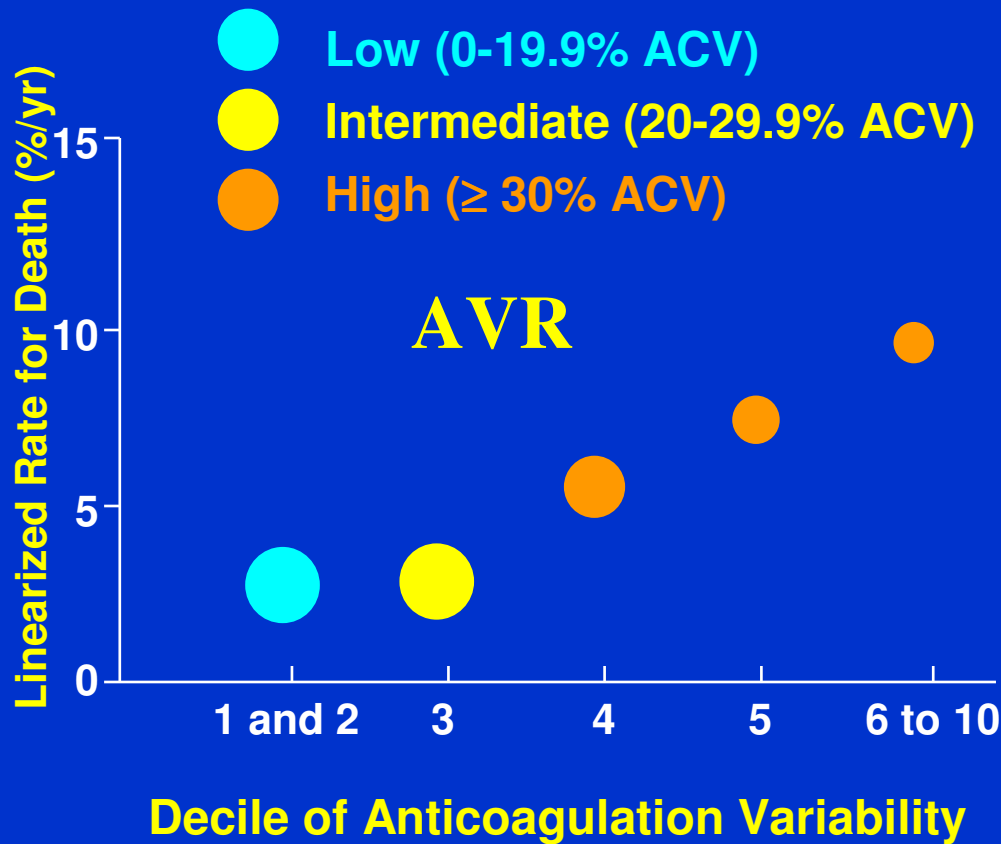
Poor and Variability of Anticoagulation

ACCP (PD Stein et al) Chest **2004**;119:220S

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

ACC/AHA (R.O. Bonow et al) Circ **2006**;114:e84

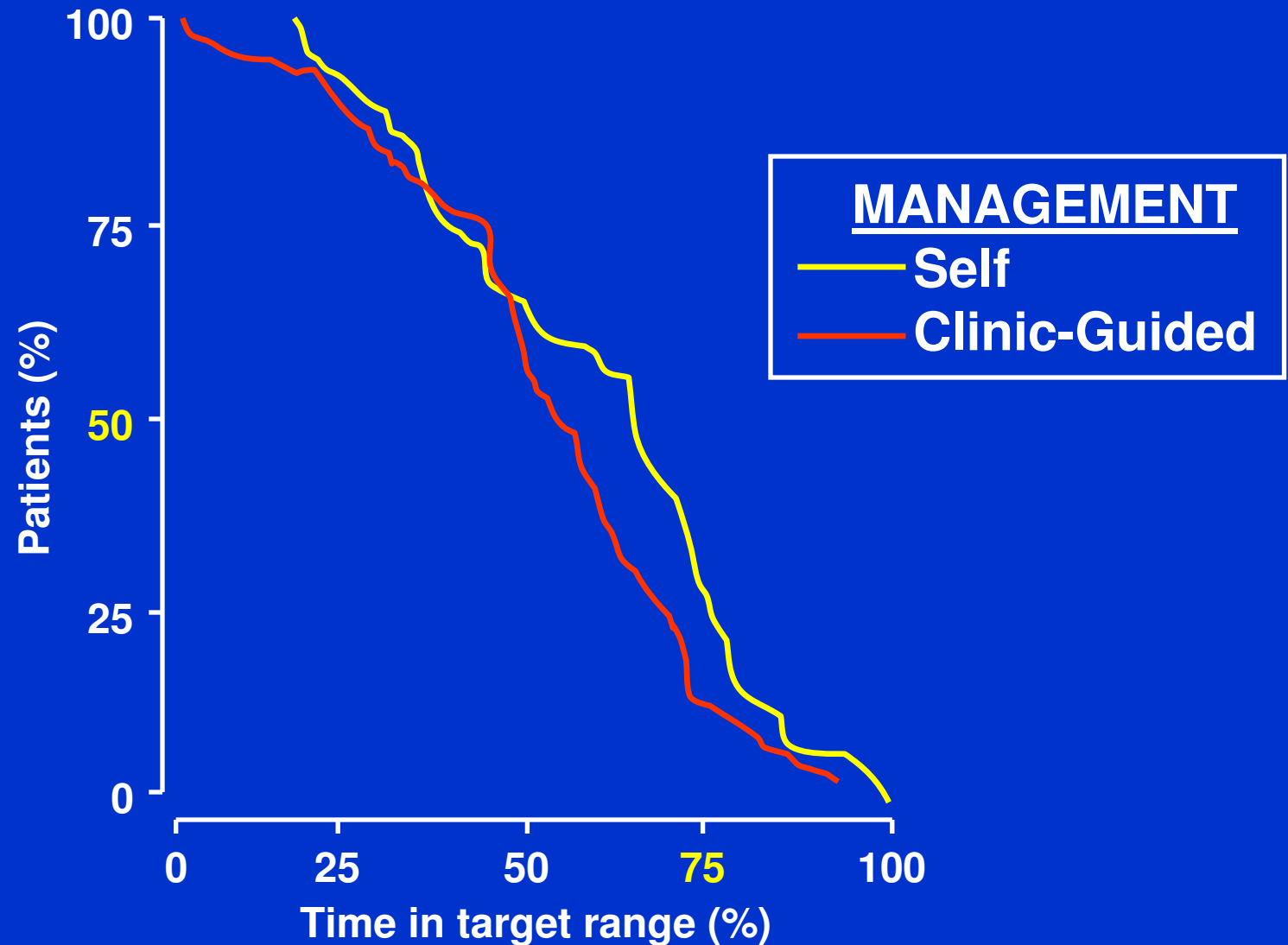
VARIABILITY OF ANTICOAGULATION AND MORTALITY¹ (% INR OUTSIDE 2 TO 4) - - MEDTRONIC VALVE – UK (N=1476 Pts – INR=82297)



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**

COMPARISON OF CONTROL OF ANTICOAGULATION IN PATIENTS DURING SELF-MANAGEMENT AND CLINIC-GUIDED MANAGEMENT



ME Crombeecke et al., Lancet 2000; 356:97 - Netherlands

PROSTHETIC HEART VALVES, ANTITHROMBOTICS 2007

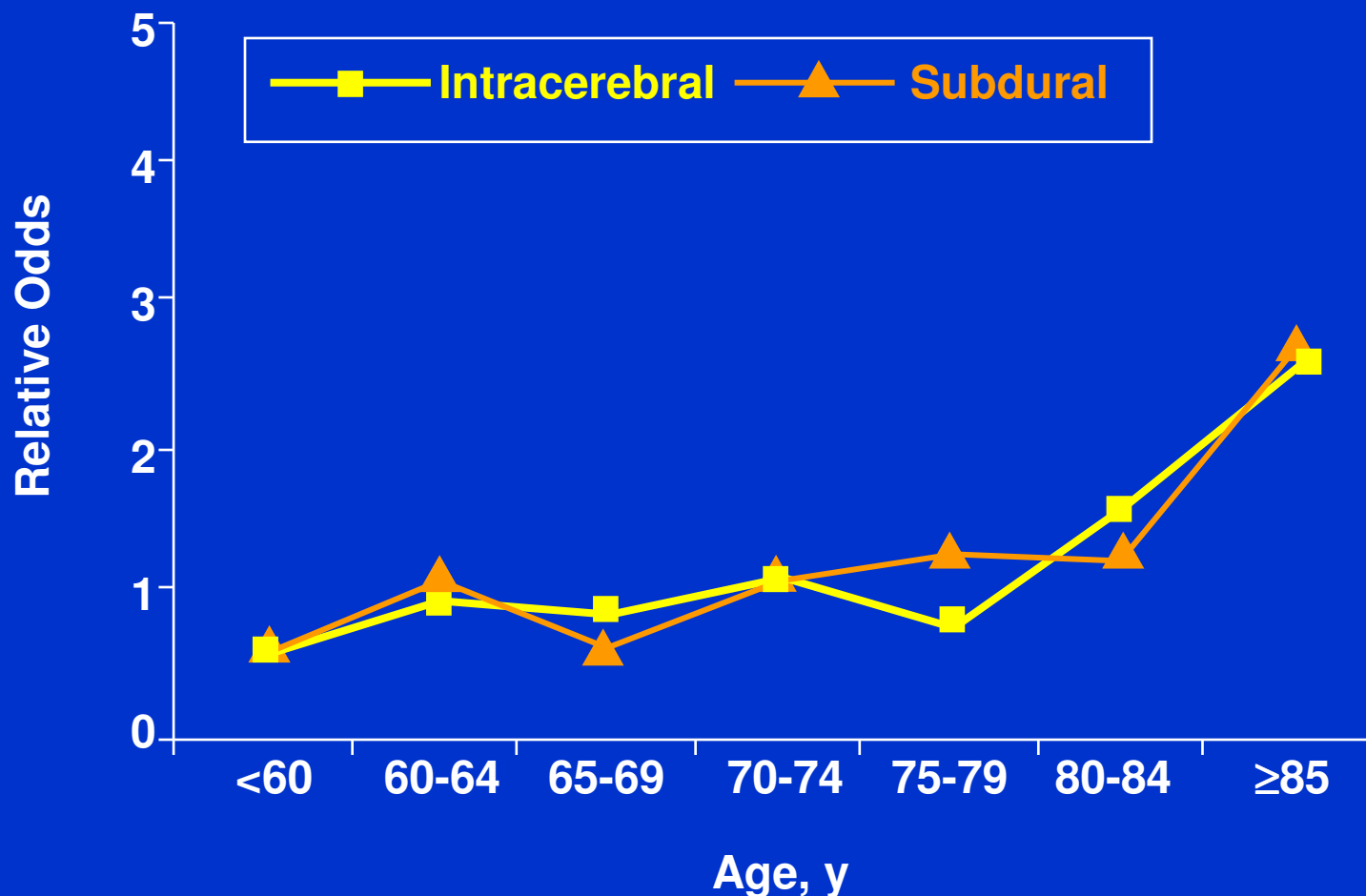
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BLEEDING AND THROMBOEMBOLIC EVENTS BY INDICATION FOR TREATMENT

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

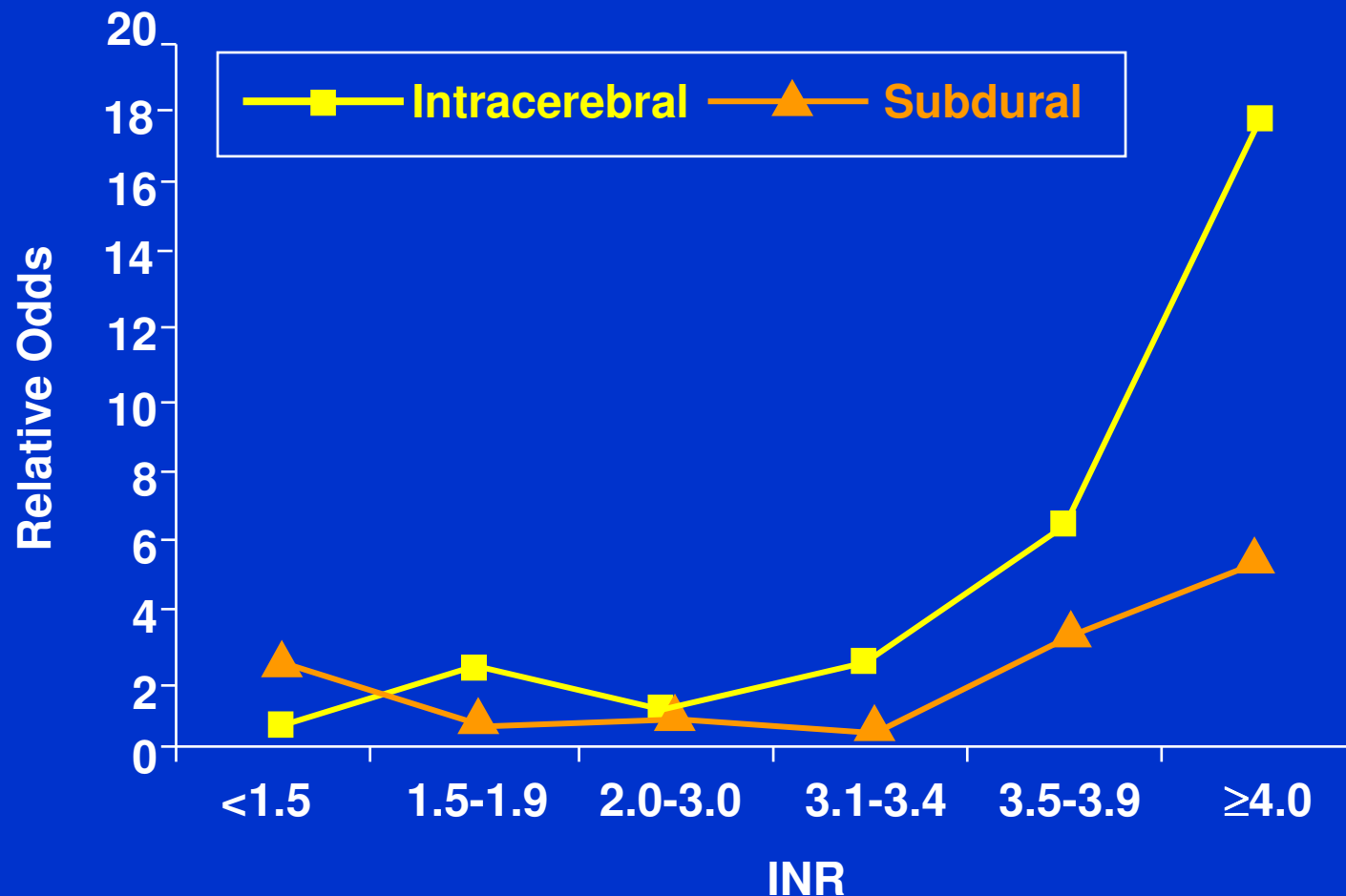
LEIDEN ANTIC. CLINIC (M Torn et al.,) Ach Int Med 2005; 165:152

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



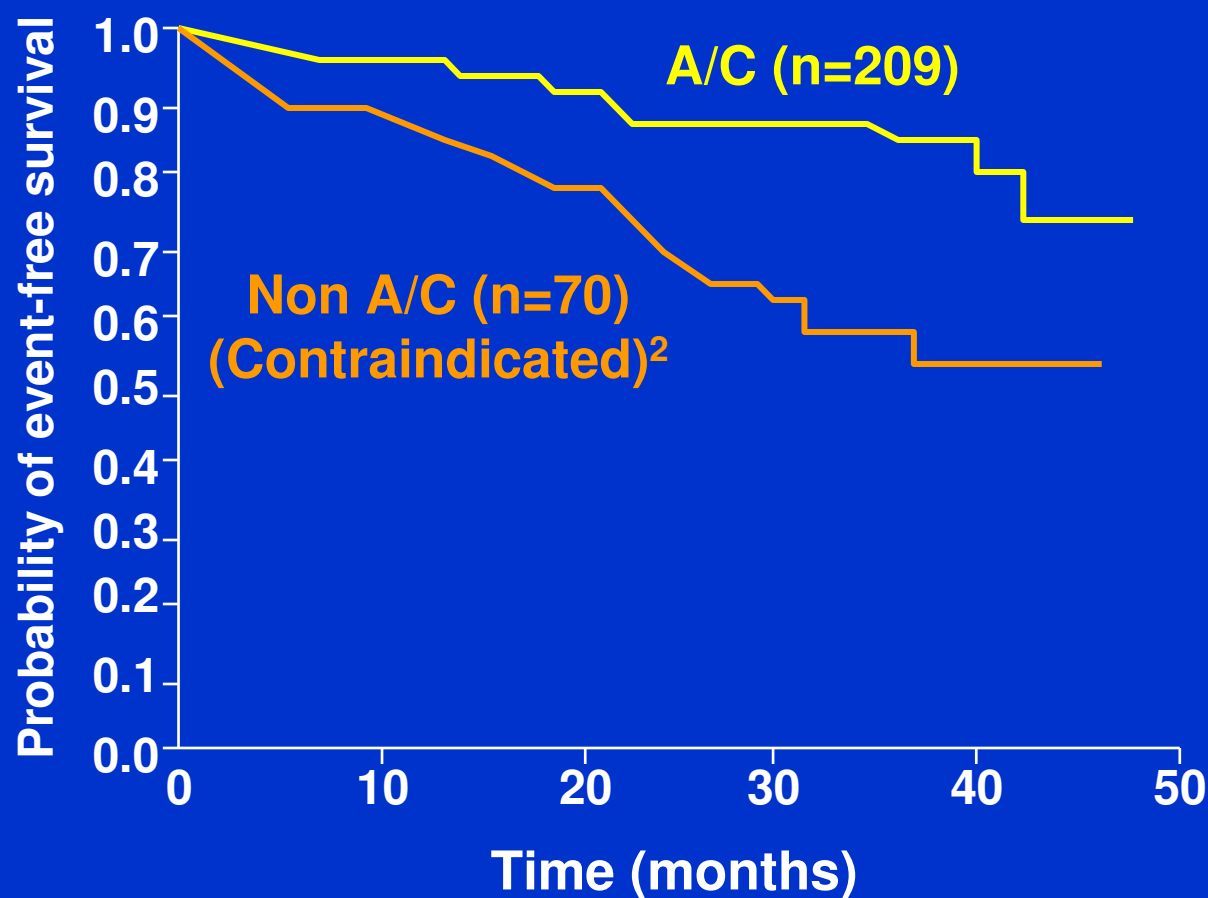
MC Fang et al., Ann Intern Med 2004; 141:745 (UCSF, Boston, Oakland)

RELATIVE ODDS OF INTRACRANIAL HEMORRHAGE & INR 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)

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 ?

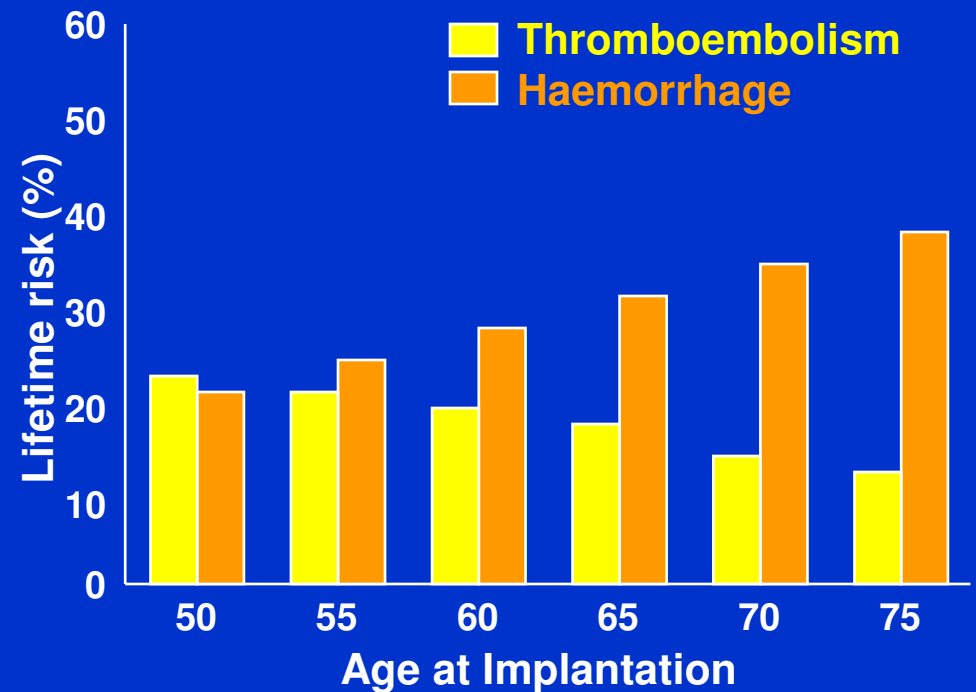
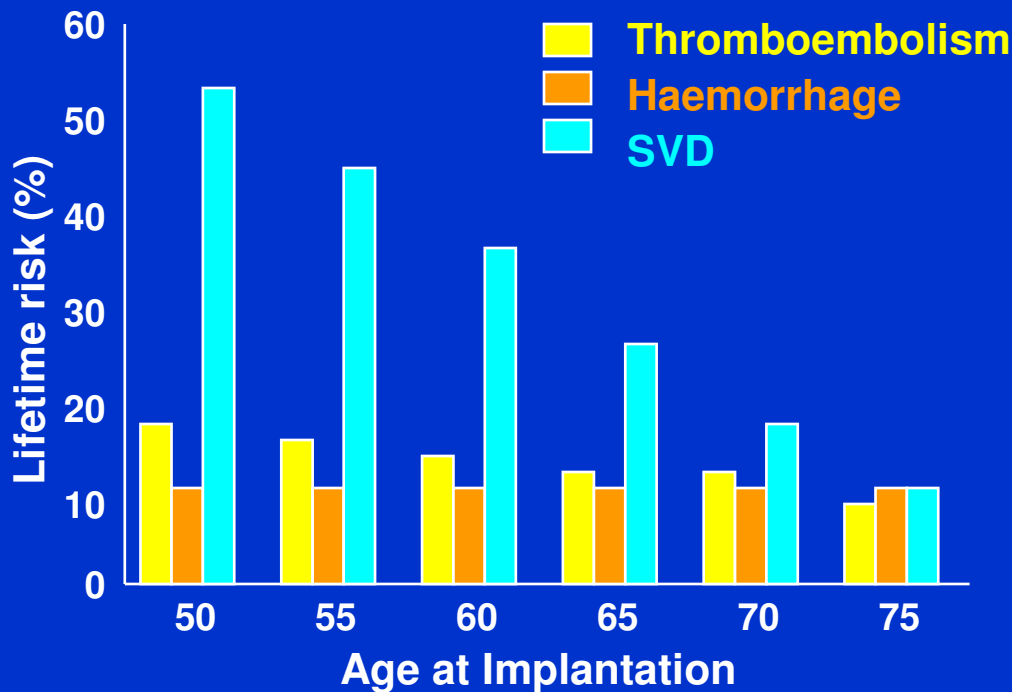
²ASA or platelet inhibitor

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

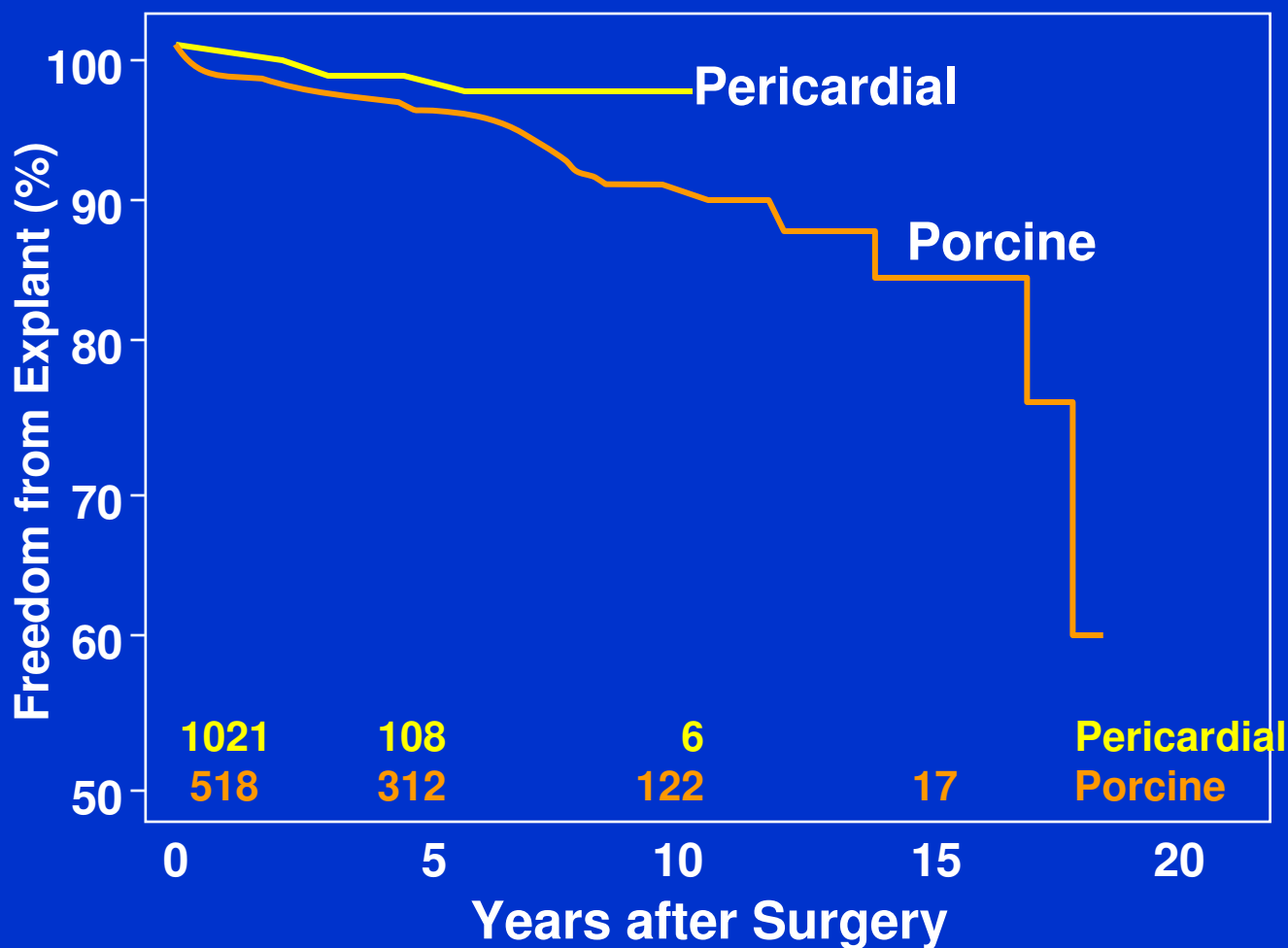
LIFETIME RISK OF THROMBOEMBOLISM, HAEMORRHAGE & SVD FOLLOWING AVR IN MEN OF DIFFERENT AGES

**PORCINE BIOPROSTHESIS
(N=9007)**

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



FREEDOM FROM EXPLANT (SVD) FOR PORCINE AND PERICARDIAL AORTIC VALVE REPLACEMENT PATIENTS



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

PROSTHETIC HEART VALVES, ANTITHROMBOTICS 2007

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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 (RO Bonow et al.) Circ **2006**; 114:e84
ESC (Butchard, EG et al) Eur Heart J **2005**;26:2463
ACCP (PD Stein et all) Chest **2004**;119:220S

ATRIAL FIBRILLATION - RISK OF STROKE BY CHAD* SCORE

CHAD Index

Antithrombotics

High Risk:

Hx TE, MS, **PHV**

Warfarin INR 2.0-3.5

2 RF

Warfarin INR 2-3

Moderate Risk: 1 RF

ASA 81-325mg

or Warfarin INR 2-3

Low Risk: 0 RF

ASA 81-325 mg

* RF: C.Fail./ EF <35% 1, Hypert. 1, Age >75 1, Diabetes 1,
ACC/AHA/ESC (Fuster V et al) Circ 2006; 114:700

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 (3,2)	Yes / No	Yes	Yes
Long-term therapy (2)	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

PROSTHETIC HEART VALVES, ANTITHROMBOTICS 2007

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PROSTHETIC HEART VALVES - ANTITHROMBOTICS 2007

The First Two Weeks

- **^{1,2}High incidence of stroke** in the first two weeks
- **¹Probably 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. Y Shapira, A Sapie, A Battles et al., Clin Card **2002**; 25:323
6. G Montalescot et al., **2000**; 101:1083

CLINICAL TRIALS EVALUATING USE OF SHORT TERM LMWH IN PATIENTS WITH PROSTHETIC HEART VALVES

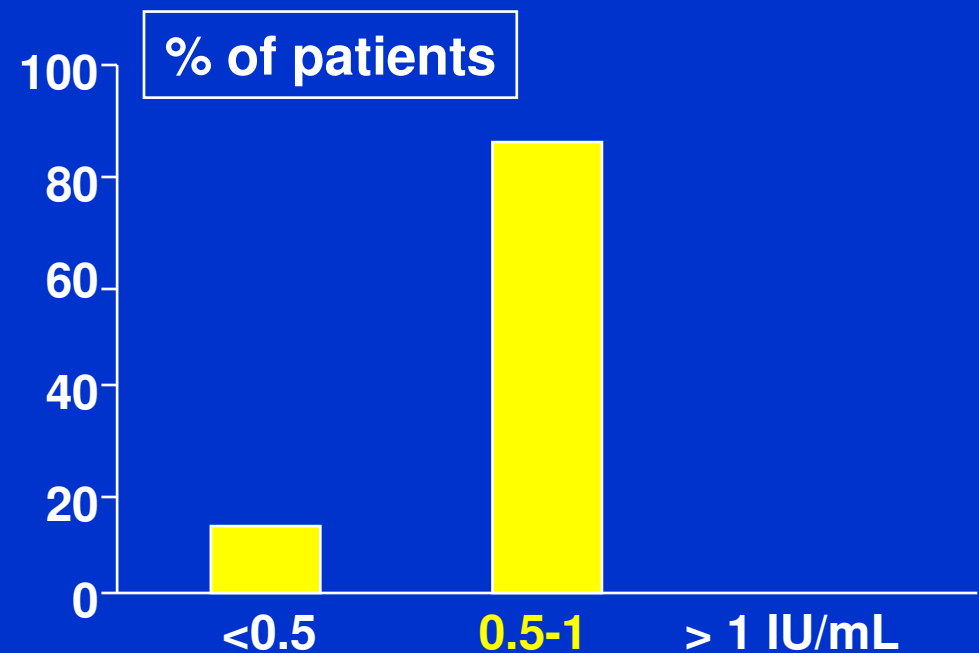
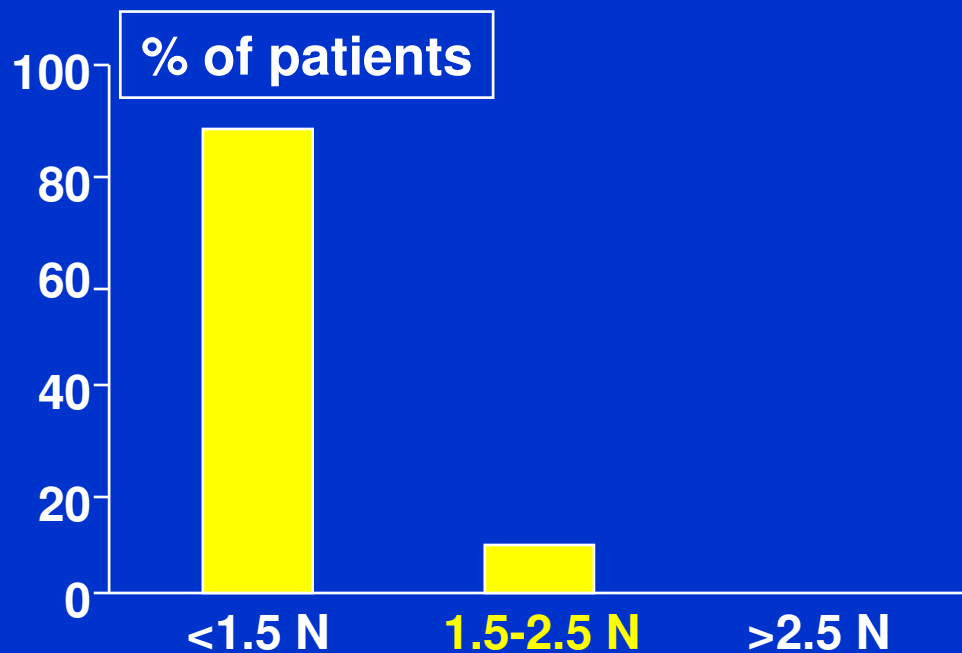
Reference	Patient description	Enoxaparin	
		Dosing	Outcome
Spandorder et al., (1999)	12 valve patients	1 mg/kg SC BID, 10 ± 7 d	No TE
Berdague et al., (1999)	15 valve patients	1 mg/kg SC BID, 10 ± 6 d	One TE
Monalescot et al., (2001)	73 valve treated	14d	No TE
Johnson et al., (2001)	209 valve patients	1 mg/kg SC BID, 10 ± 7 d	No TE
Ferreira et al., (2003)	82 valve patients	1 mg/kg SC BID, 10 ± 7 d	No TE

N Seshadri et al., AHJ 2005; 150:27 (Canada)

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

aPTT in patients treated With SC UH after 2-days

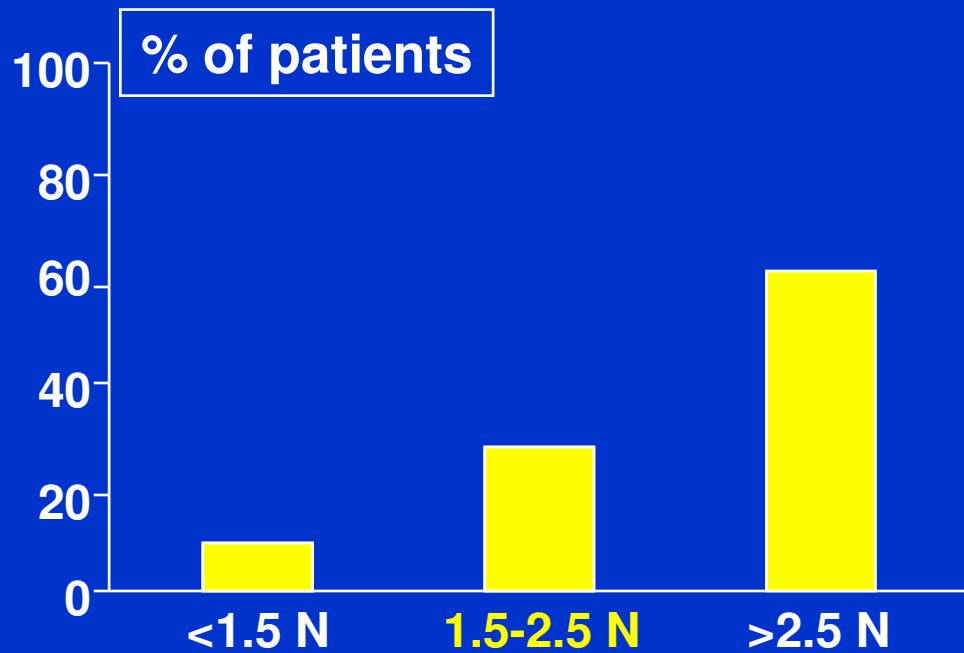
Anti-Xa activity in patients treated With SC LMWH after 2 days



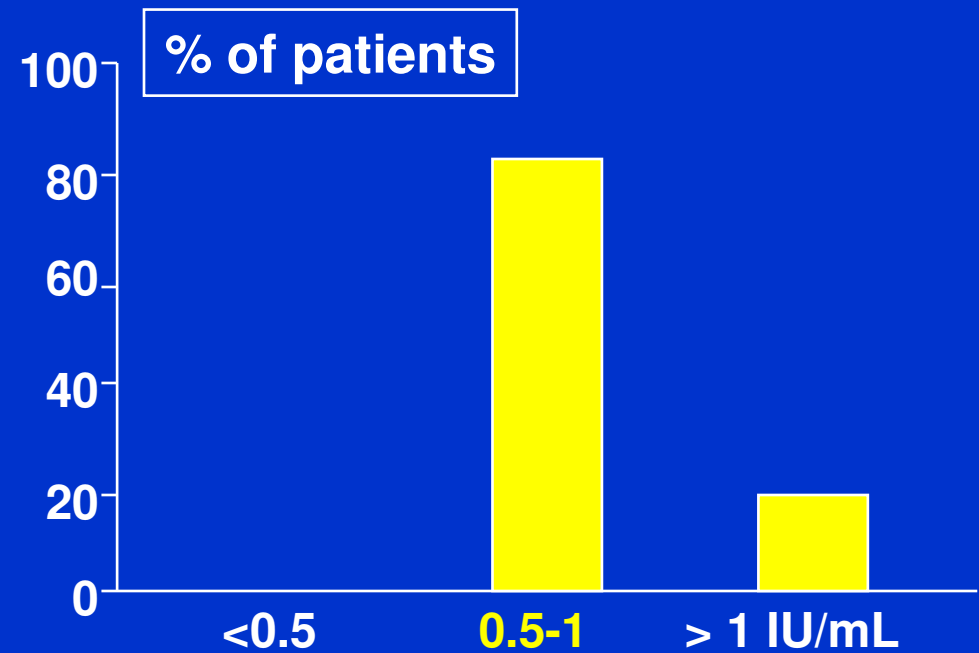
Day 2 IV UH, Day 3 SC H + Coumadin (Modified)
G Montalescot et al., Circ 2000; 101:1083 (Paris)

SC LMWH SUPERIOR TO SC UH - PROSTHETIC VALVE PATIENTS 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)

“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 **2007** (In Press)

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

PROSTHETIC HEART VALVES, ANTITHROMBOTICS 2007

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***BRIDGING THERAPY
NONCARDIAC SURGERY, INVASIVE PROCEDURES,***

Class I

Patients who are at low risk for thrombosis, which is defined as a bileaflet aortic valve with no RFs.*

- 1. Warfarin** should be withheld **48 to 72 hours** before the procedure to allow the INR below 1.5.
- 2. Warfarin** is restarted **24 hours** after procedure.
- 3. Heparin** is usually not necessary.

***Risk factors: AF, previous TE, LV dysfunction, & hypercoagulability
ACC/AHA (RO Bonow et al.) Circ 2006; 114:84**

***BRIDGING THERAPY – CLASS 1
NONCARDIAC SURGERY, INVASIVE PROCEDURES,***

Patients at high risk for thrombosis, defined as a mechanical aortic valve with any RFs* or any mechanical mitral valve.

- 1. Warfarin should be withheld > than 72 hours before the procedure.**
- 2. Therapeutic doses of intravenous unfractionated heparin should be started when the INR falls below 2.0, usually 48 hours before the procedure.**
- 3. Heparin is stopped four to six hours before the procedure.**
- 4. Heparin and warfarin are restarted as soon after surgery as bleeding stability permits.**
- 5. Heparin is discontinued when the INR reaches therapeutic levels.**

***Risk factors include AF, previous TE, LV dysfunction, and hypercoagulability
ACC/AHA (RO Bonow et al.) Circ 2006; 114:84**

BRIDGING THERAPY

NONCARDIAC SURGERY, INVASIVE PROCEDURES,

Class IIa

Fresh frozen plasma when an emergency procedure is necessary.

Class IIb

Among patients at **high risk for thrombosis** as defined above, therapeutic doses of **sc unfractionated heparin (15,000 units every 12 hours)** or **low molecular weight heparin (100 U/kg every 12 hours)** during the period when the **INR is subtherapeutic**.

Class III

Routine high dose **vit. K1**, which can cause a hypercoagulable state.

***Risk factors include AF, previous TE, LV dysfunction, and hypercoagulability**
ACC/AHA (RO Bonow et al.) Circ 2006; 114:84

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ANTICOAGULATION DURING PREGNANCY (N=1234) IN WOMEN (N=976), MECHANICAL HEART VALVE PROSTHESIS

Anticoagulation regimen	Embryopathy (%)	Abortion (%)	TE (%)	Maternal death (%)
Vitamin K antag throughout	6.4	25	3.9	1.8
Heparin (UH) throughout	0	24	33	15
Low dose	0	20	60	40
Adjusted dose	0	25	25	6.7
Heparin first trimester, then vitamin K antagonists	3.4	25	9.2	4.2

Chan WS et al Arch Intern Med **2000**;160:191

ESC.EHJ 2003; 24:761 - **ACCP** (SM Bates et al) Chest **2004**;126:627S

***RECOMMENDATIONS FOR
ANTICOAGULATION DURING PREGNANCY:
WEEKS 1 THROUGH 35 IN PATIENTS WITH
MECHANICAL PROSTHETIC VALVES***

The decision whether to use **heparin** during the first trimester (ACCP 6-12 weeks) or to continue **oral anticoagulation** throughout pregnancy should be made after **full discussion with the patient and her partner.**

ACC/AHA. Circ 1998; 98:1975 – **ESC.** EHJ 2003; 24: 761
ACCP (SM Bates et al) Chest 2004;126:627S

ANTICOAGULATION PROPHYLAXIS IN PREGNANT WOMEN WHO HAVE A PROSTHETIC HEART VALVE

Higher risk

Warfarin (INR 2.5-3.5) for 35 wk
IV UFH (aPTT of 2.5-3.5)
+ ASA 80-100 mg qd),

Lower risk

SC UFH (midinterval aPTT 2.0-3.0)
or LMWH (predose anti-Xa ~0.6) 12wk,
Warfarin (INR 2.5-3.0) to 35th w,
SC UFH (midinterval aPTT 2.0-3.0),
or LMWH (predose anti-Xa ~0.6)

SC UFH (aPTT > 2.5)
or LMWH (predose anti-Xa ~0.7) 12 wk
Warfarin (2.5-3.5) to 35 wk
IV UFH (aPTT > 2.5)
or LMWH (predose anti-Xa ~0.7)
+ ASA 80-100 mg qd

SC UFH (midinterval aPTT 2.0-3.0)
or LMWH (predose anti-Xa level ~0.6
throughout pregnancy

Modified by S Danik, V Fuster. Obst and Gynec Clin of North Am **2006**; 33:481
(V Elkayam et al. J Cardiovasc Pharm Ther 2004; 9:107)

PROSTHETIC HEART VALVES, ANTITHROMBOTICS 2007

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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%

Echo - Doppler*

Transthoracic for severe obstruction
Transesophageal for mild or no obstruction

* Guidelines — JACC 1997; 30:1521

THROMBOSIS OF PROSTHETIC HEART VALVES

Class I

1. **TTE-Doppler** in patients with suspected prosthetic valve thrombosis to assess **hemodynamic severity**
2. **TEE and/or fluoroscopy** in patients with suspected valve thrombosis to assess **valve motion and clot burden.**

Class IIa

1. **Emergency operation** for patients with a thrombosed **left-sided** prosthetic valve and **NYHA class III-IV.**
2. **Emergency operation** for patients with a thrombosed **left-sided** prosthetic valve and **a large clot burden.**
3. **Fibrinolytic therapy** for thrombosed **right-sided** prosthetic heart valves with **NYHA class III-IV symptoms or a large clot burden.**

***Risk factors include AF, previous TE, LV dysfunction, and hypercoagulability
ACC/AHA (RO Bonow et al.) Circ 2006; 114:84**

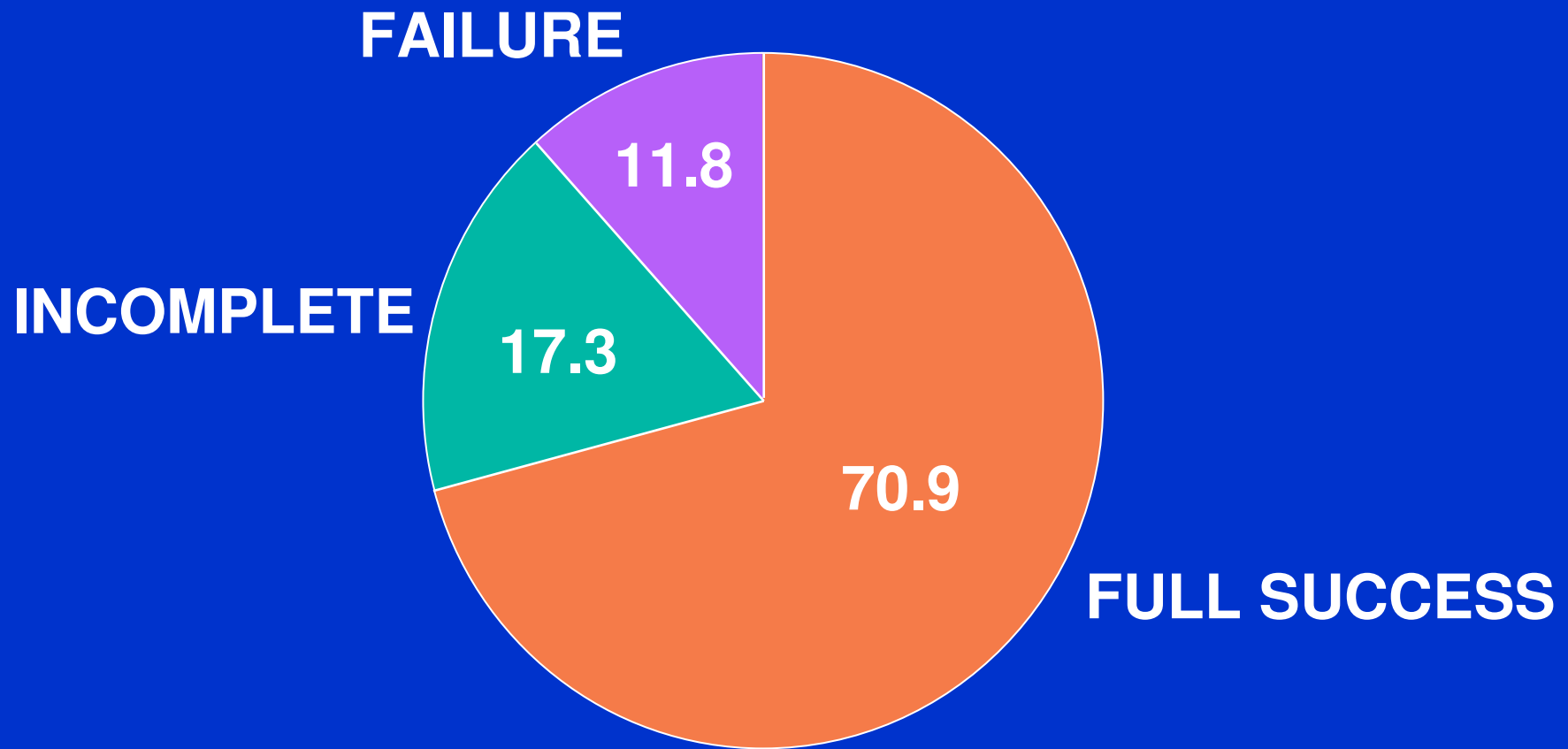
THROMBOSIS OF PROSTHETIC HEART VALVES

Class IIb

1. **Fibrinolytic therapy** for patients with a thrombosed **left-sided** prosthetic valve, **NYHA class I-II** and a **small clot burden**.
2. **Fibrinolytic therapy** for patients with a thrombosed left-sided prosthetic valve, **NYHA class III-IV**, and **small clot** burden if **surgery is high risk or not available**.
3. **Fibrinolytic therapy** may be considered for patients with an obstructed, thrombosed left-sided prosthetic valve who have **NYHA class II-IV** symptoms and a **large clot** burden if emergency **surgery is high risk or not available**.
4. **Intravenous UFH** as an alternative to fibrinolytic therapy may be considered for patients with a thrombosed valve who are in **NYHA functional class I-II** and have a **small clot burden**.

*Risk factors include AF, previous TE, LV dysfunction, and hypercoagulability
ACC/AHA (RO Bonow et al.) Circ 2006; 114:84

FIBRINOLYSIS OF PROSTHETIC VALVE THROMBOSIS (N=127)



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

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

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- **Approach to Special Conditions**
 - Very Early Antithrombotic Therapy – Heparins**
 - Bridging – Surgery, Invasive**
 - Young Women and Pregnancy**
 - Valve Thrombosis**









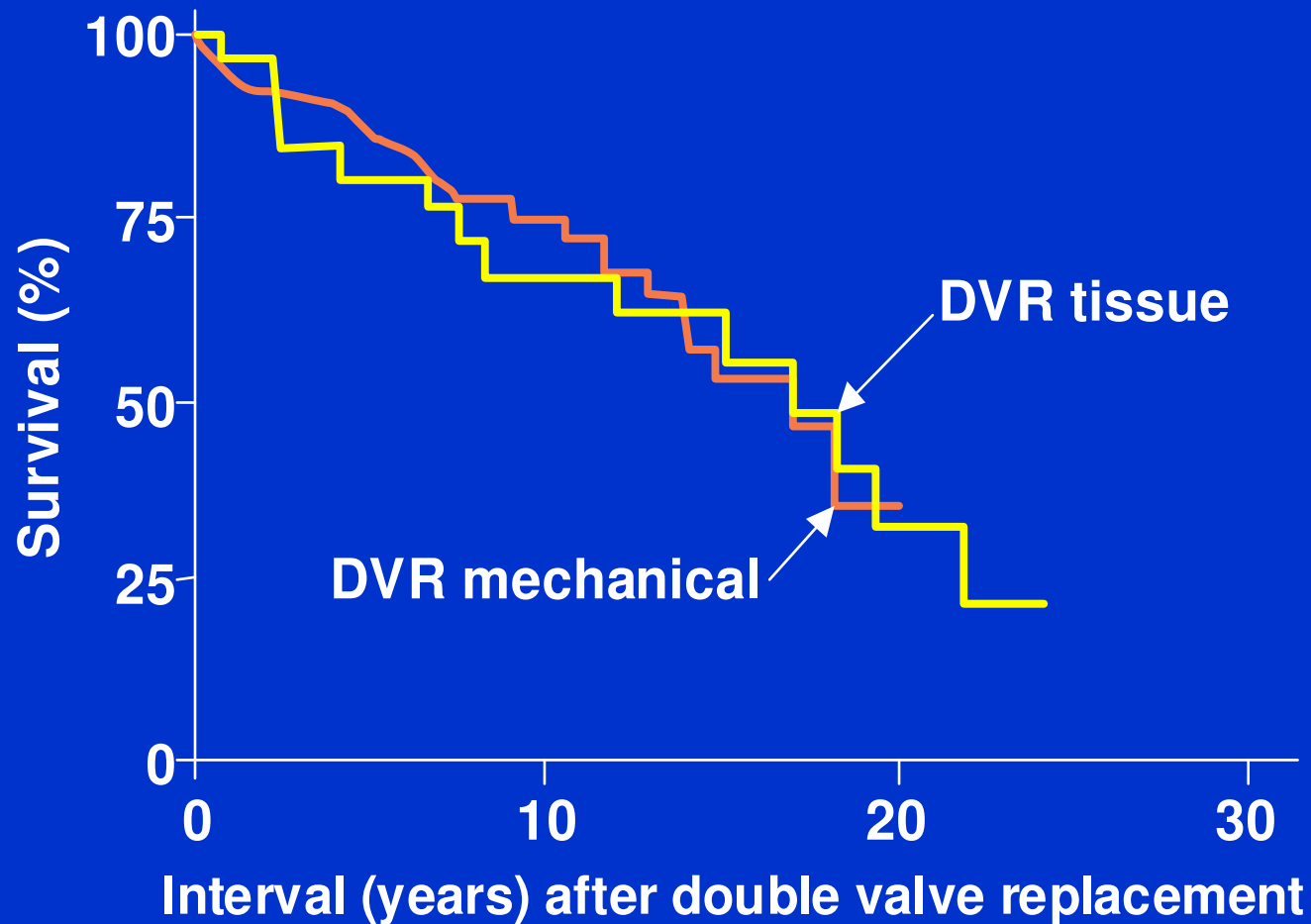
PROSTHESES AT THE INITIAL VALVE REPLACEMENT OPERATION

	AVR (n=314)		MVR (n=214)		DVR (n=39)	
	Tissue (n=170)	Mechanical (n=144)	Tissue (n=121)	Mechanical (n=93)	Tissue (n=15)	Mechanical (n=24)
Bjork-Shiley		2		1		1
Carbomedics*		5		7		
Carpentier Edwards*	2		1			
Harken		67		40		9
Homograft*	8					
Ionescu-Shiley	136		86		13	
Lellehei Kaster		31		8		3
Medtronic Hall*		22		22		9
Medtronic Hancock*	24		34		2	
Starr Edwards				1		
St. Jude Medical*		17		14		2

*Denotes prostheses that are still commercially available

M Ruel et al., Circ **2007**; 116(Suppl I):I-294 (Ottawa HeartInter)

CRUDE SURVIVAL AFTER DVR ACCORDING TO THE TYPE OF PROSTHESIS USED AT INITIAL VALVE REPLACEMENT



M Ruel et al., Circ 2007; 116(Suppl I):I-294 (Ottawa Heart Inter)

PATTERNS OF VALVE REOPERATION

	T Repl. With M	T Repl. With T	M Repl With T	M Repl With M	Repl. Other Left-Heart Valve
1st reop. after AVR (n=136)	82	23	9	12	9
2nd reop. after AVR (n=25)	11	0	1	4	9
1st reop. after MVR (n=87)	63	8	9	5	2
2nd reop. after MVR (n=11)	5	2	0	2	2
1st reop. after AVR (n=13)	8	1	2	2	n/a
2nd reop. after AVR (n=2)	1	0	0	1	n/a

T = Tissue; M = Mechanical

M Ruel et al., Circ 2007; 116(Suppl I):I-294 (Ottawa Heart Inter)