Hjerteklapper

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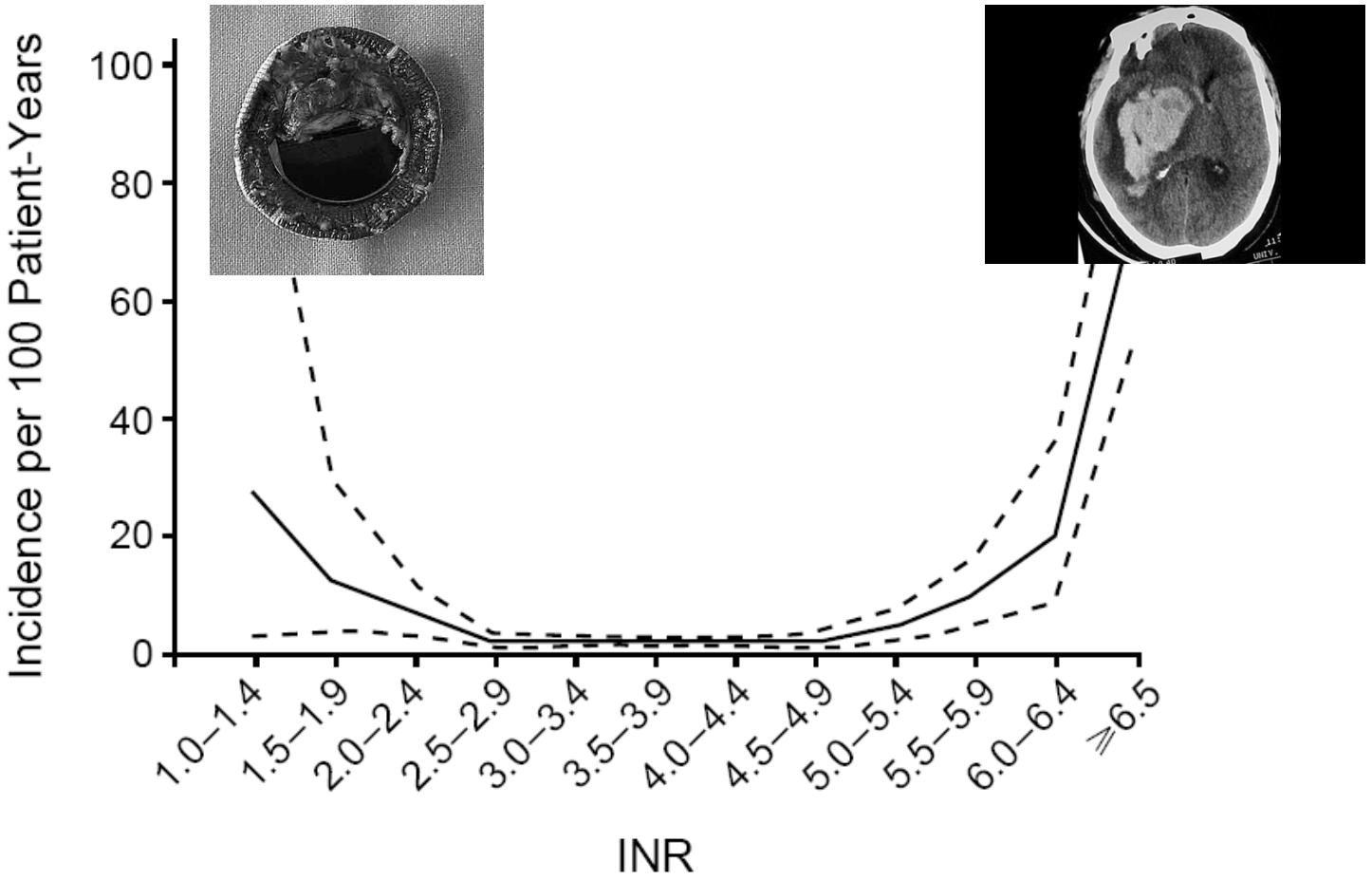
Disposition

- Typer af hjerteklapper
- Typer af operationer
- Antitrombotisk behandling
  - Hjerteklap
  - Hjerteklap + AFLI
- Evidensen bag anbefalingerne
- Fremtiden

Dumme spørgsmål eksisterer ikke…..

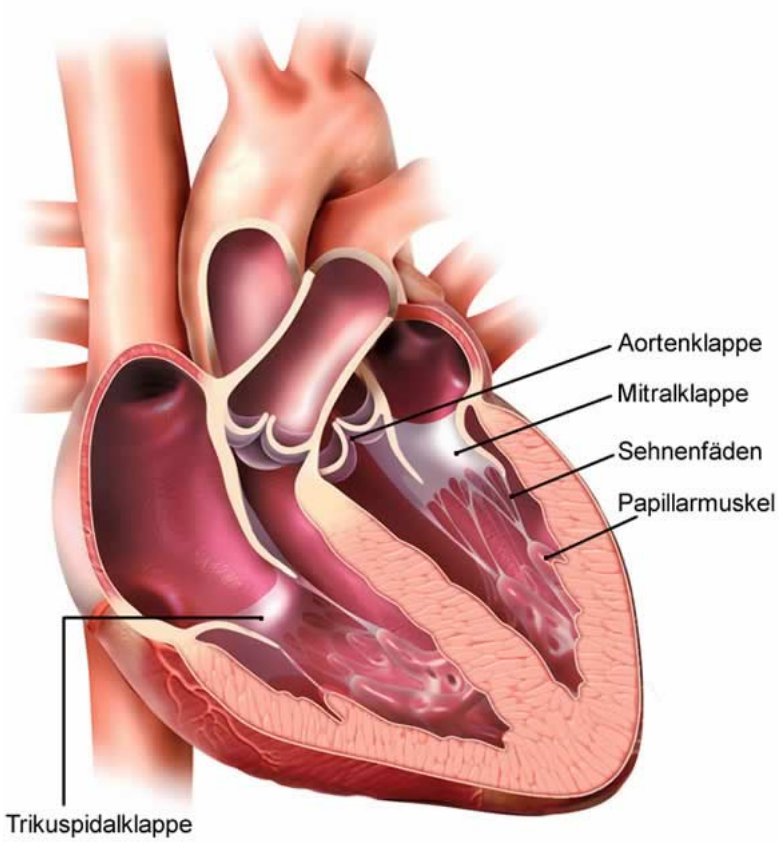
Hvad vil vi gerne undgå……



Cannegieter SC et al. N Engl J Med 1995;333:11-17

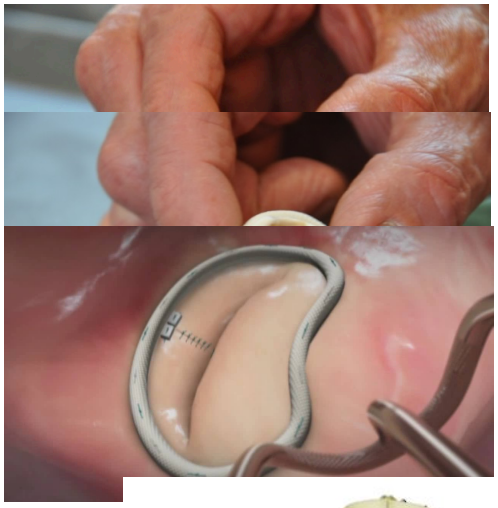
Hjerteklapper

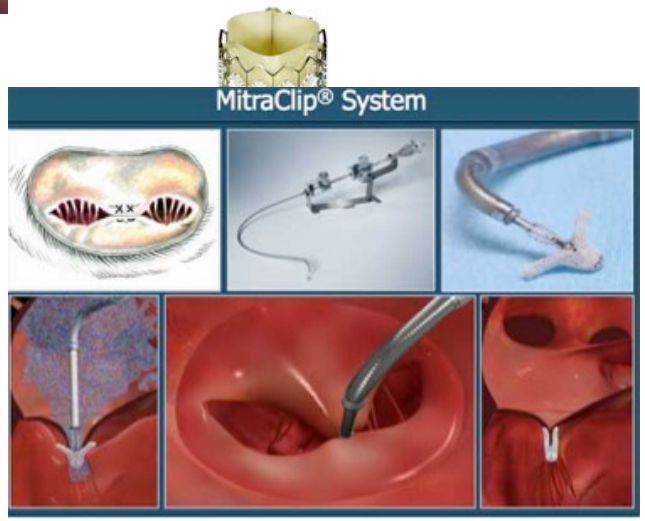
- Aortaklap
- Mitralklap
- ~~Trikuspidalklap~~
- ~~Pulmonalklap~~



Typer af operationer (A+M klapper)

- Mekanisk hjerteklap
- Biologisk hjerteklap
- Plastik af mitralklappen
- Kateter appliceret procedure
  - Stent klap
  - Mitraclip
- +/- AFLI





Antitrombotisk medicin som kan anvendes

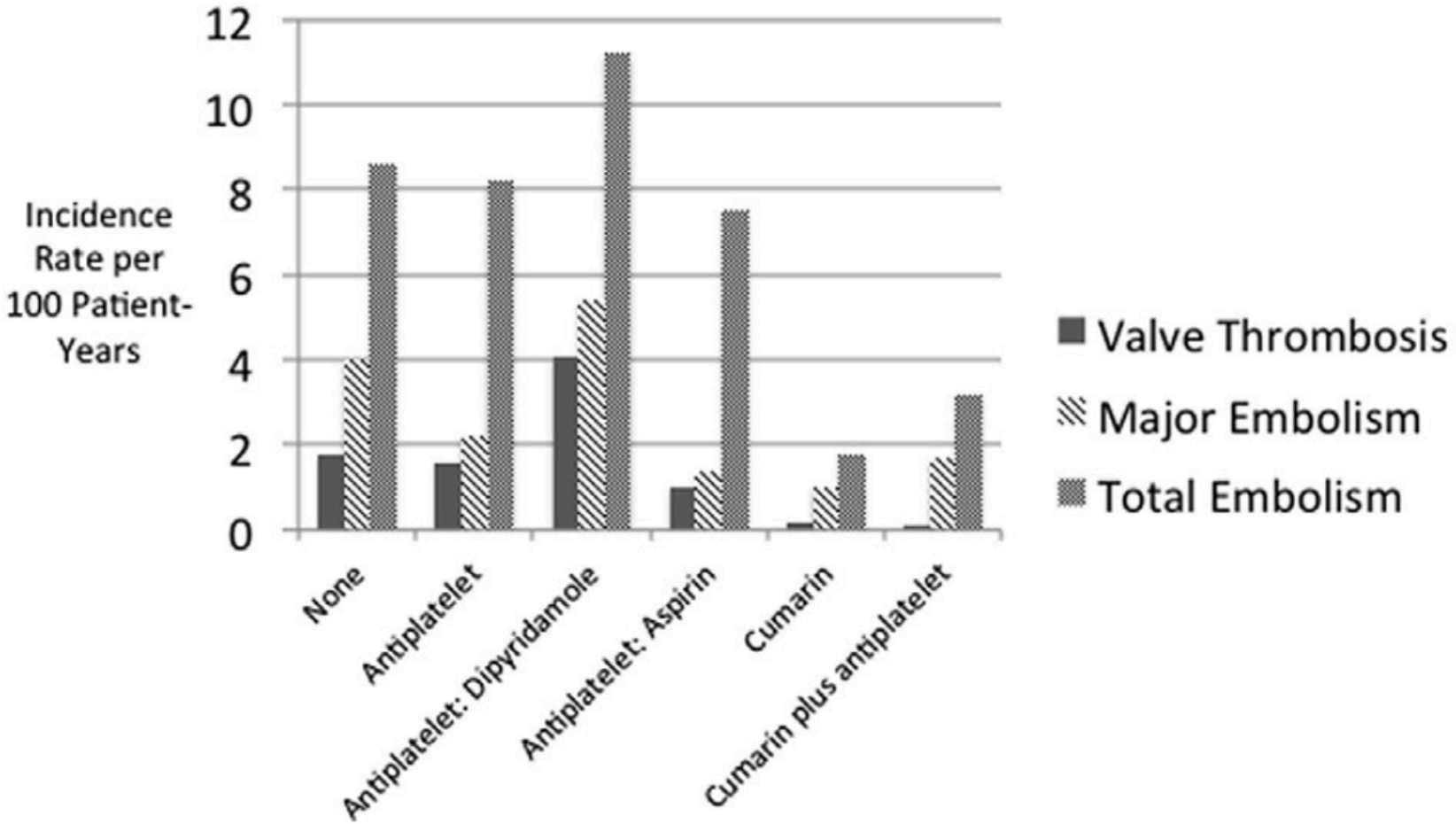
- Antikoagulerende medicin:
  - Kumariner (warfarin (Marevan®), phenprocoumon (Marcoumar®): Vitamin K-Antagonist (VKA)
  - Non Vitamin K antagonister (NOAK):
    - Dabigatran etexilate (Pradaxa®)
    - Apixaban (Eliquis®)
    - Rivaroxaban (Xarelto®)
    - Edoxaban (Lixiana®)
  - Fondaparinuxnatrium (Arixtra®)
  - Lavmolekylært heparin (LMWH)
  - Heparin
- Trombocytfunktionshæmmere:
  - ASA/magnyl
  - Dipyridamol (Persantin®)
  - Clopidogrel (Plavix®)
  - Ticagrelor (Brilique®)
  - Prasugrel (Efient®)
  - Vorapaxar (Zontivity®)

Guidelines / instrukser i Danmark

- NBV på www.cardio.dk
  - Kap. 6 + 14
- Trombokardiologirapporten (www.cardio.dk eller www.dsth.dk)

Antitrombotisk behandling

Mekaniske hjerteklapper: Risikoen for tromboemboliske komplikationer



Roudaut R et al. Heart 2007:93:137-142

Mekaniske klapper

- Aortaklapper
  - Marevan med INR 2.0 – 3.0
  - ASA 75 mg * 1 dgl.?
- Mitralklapper
  - Marevan med INR 2.5 – 3.5
  - ASA 75 mg * 1 dgl.?
- MEN: ASA 75 mg * 1 dgl. til alle patienter med AFLI
- Patienter skal styre deres AK – behandling selv[1]

[1]*Heneghan C et al. Lancet 2012;379:322-334*

INR niveau

- Puskas J et al; PROACT investigators.

  Reduced anticoagulation after mechanical aortic valve replacement: Interim results from the Prospective Randomized On-X Valve Anticoagulation Clinical Trial randomized Food and Drug Administration investigational device exemption trial.

  J Thorac Cardiovasc Surg 2014;147:1202-1211

Sponsoreret af Medical Carbon Research Institute, LLC, USA

PROACT investigators

Abstract

OBJECTIVE:

Under Food and Drug Administration investigational device exemption, the Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT) has been testing the safety of less aggressive anticoagulation than recommended by the American College of Cardiology/American Heart Association guidelines after implantation of an approved bileaflet mechanical valve.

METHODS:

In this first limb of the PROACT, patients with elevated risk factors for thromboembolism were randomized at 33 US centers to receive lower dose warfarin (test international normalized ratio [INR], 1.5-2.0) or continue standard warfarin (control INR, 2.0-3.0), 3 months after mechanical aortic valve replacement. The INR was adjusted by home monitoring; all patients received 81 mg aspirin daily. Adverse events were independently adjudicated.

RESULTS:

A total of 375 aortic valve replacement patients were randomized into control (n = 190) and test (n = 185) groups from September 2006 to December 2009. The mean age ± standard deviation was 55.2 ± 12.5 years; 79% were men; and 93% were in sinus rhythm preoperatively. Calcific degeneration was present in 67%; active endocarditis was excluded. Concomitant procedures included coronary artery bypass grafting (27%), aortic aneurysm repair (14%), and other (25%). The follow-up duration averaged 3.82 years (755.7 patient-years [pt-yrs] for control; 675.2 pt-yrs for test). The mean INR was 2.50 ± 0.63 for the control and 1.89 ± 0.49 for the test groups (P < .0001). The test group experienced significantly lower major (1.48% vs 3.26%/pt-yr; P = .047) and minor (1.32% vs 3.41%/pt-yr; P = .021) bleeding rates. The incidence of stroke, transient ischemic attack, total neurologic events, and all-cause mortality were similar between the 2 groups.

CONCLUSIONS:

INR can be safely maintained between 1.5 and 2.0 after aortic valve replacement with this approved bileaflet mechanical prosthesis. With low-dose aspirin, this resulted in a significantly lower risk of bleeding, without a significant increase in thromboembolism.

?

INR

$$INR = \left(\frac{PT_{patient}}{MNPT} \right)^{ISI}$$

INR-niveau fra 2.0 – 3.0: 0.7 INR*
INR-niveau fra 2.5 – 3.5: 1.0 INR*

* Kan skyldes rent tilfældige årsager ved konsekutive målinger (95 % CI)[1]

Ofte > 15 % forskel ml. INR målt på laboratorium og coagulometer[2]

I studiet sammenlignes INR-niveau 1.5 – 2.0 vs. 2-0 – 3.0

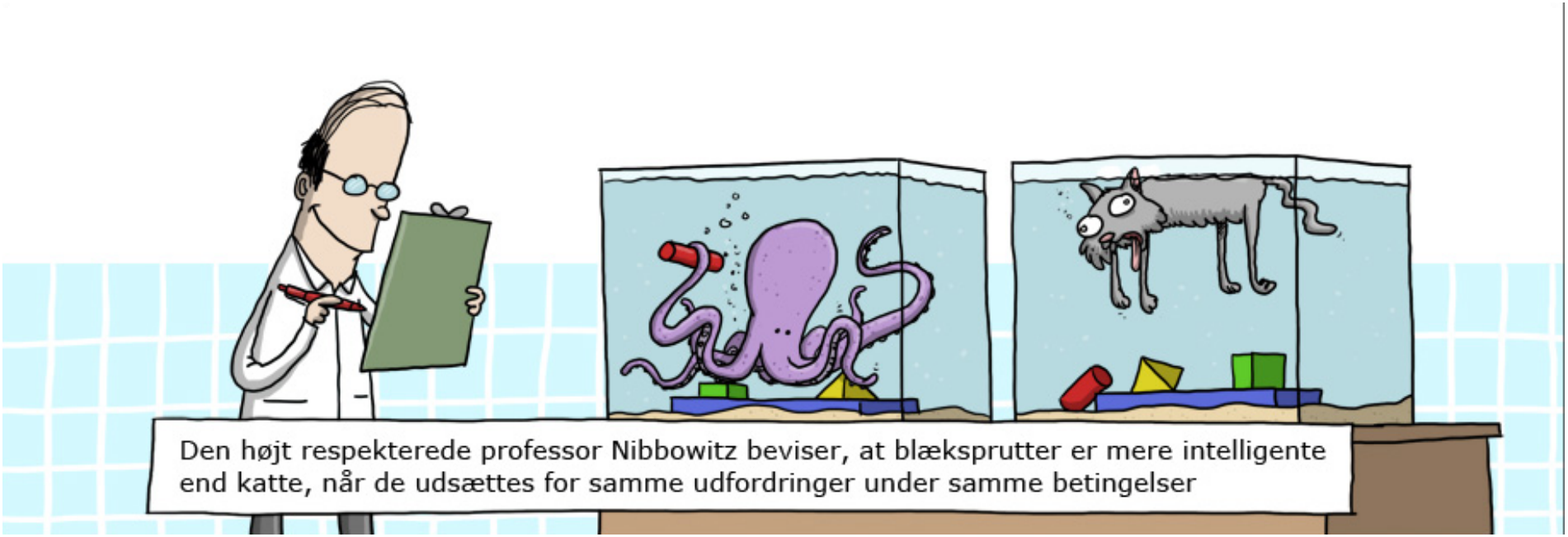
Dvs. at man nærmest har sammenlignet to ens INR-niveauer
pga. variabiliteten på INR-målinger

[1]Lassen JF et al. Clin Chem 1995;41:1171-1176
[2]Christensen TD et al. Thromb Haemost 2009;101: 563–569

Hvad mere….

- Non-inferiority trial med en margin 1.5% point på TE, trombose og blødning
- Lille antal patienter (N = 375)
- Blødning: 1,5 % versus 3,5 % (alfa 5% og power 80 %): Vil kræve ca. 1.100 patinter i hver gruppe at teste det, altså 2.200 i alt.
- Et eller to flere events i testgruppen flytter p-værdien over den magiske 5 % signifikansgrænse, så der skal ikke så meget til for at pille lidt ved den forholdsvis skråsikre konklusion
- En interim analyse
  - Når den endelige opfølgning foretages, skal man så justere signifikansgrænsen, da de allerede har set på data tidligere
- Kvaliteten og styring af AK-behandlingen?

Mekaniske hjerteklapper og INR-niveau



<u>Så:</u>

INR niveau er fortsat 2.0 − 3.0 for A-klapper og 2.5 − 3.5 for M-klapper

Mekaniske hjerteklapper og NOAK

- McKellar SH et al. J Thorac Cardiovasc Surg 2011;141:1410-6
  - 30 grise randomiseret til:
    - Ingen behandling
    - Enoxaparin 2 mg/kg s.c. * 2 dgl.
    - Dabigatran 20 mg/kg p.o. * 2 dgl.

  Conclusion:

  - *Dabigatran is as effective as enoxaparin for short-term thrombo-prophylaxis of mechanical valves. It prevents valve thrombus and platelet deposition at 30 days without increased adverse events. These promising results serve as a foundation for prospective clinical trials with dabigatran etexilate as an alternative to warfarin in patients with bileaflet mechanical aortic valves.*

Mekaniske hjerteklapper og NOAK

FDA Warns Against Use of Dabigatran in Patients With Mechanical Heart Valves[1]

RE-ALIGN trial

The study was terminated early because the dabigatran arm had significantly more thromboembolic events (valve thrombosis, stroke, and myocardial infarction) and major bleeding (predominantly postoperative pericardial effusions requiring intervention for hemodynamic compromise) than did the warfarin arm.

[1]20. December 2012

RE-ALIGN (1)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dabigatran versus Warfarin in Patients with Mechanical Heart Valves

John W. Eikelboom, M.D., Stuart J. Connolly, M.D., Martina Brueckmann, M.D., Christopher B. Granger, M.D., Arie P. Kappetein, M.D., Ph.D., Michael J. Mack, M.D., Jon Blatchford, C.Stat., Kevin Devenny, B.Sc., Jeffrey Friedman, M.D., Kelly Guiver, M.Sc., Ruth Harper, Ph.D., Yasser Khder, M.D., Maximilian T. Lobmeyer, Ph.D., Hugo Maas, Ph.D., Jens-Uwe Voigt, M.D., Maarten L. Simoons, M.D., and Frans Van de Werf, M.D., Ph.D., for the RE-ALIGN Investigators*

N ENGL J MED 369;13 NEJM.ORG SEPTEMBER 26, 2013

RE-ALIGN (2)

ABSTRACT

BACKGROUND

Dabigatran is an oral direct thrombin inhibitor that has been shown to be an effective alternative to warfarin in patients with atrial fibrillation. We evaluated the use of dabigatran in patients with mechanical heart valves.

METHODS

In this phase 2 dose-validation study, we studied two populations of patients: those who had undergone aortic- or mitral-valve replacement within the past 7 days and those who had undergone such replacement at least 3 months earlier. Patients were randomly assigned in a 2:1 ratio to receive either dabigatran or warfarin. The selection of the initial dabigatran dose (150, 220, or 300 mg twice daily) was based on kidney function. Doses were adjusted to obtain a trough plasma level of at least 50 ng per milliliter. The warfarin dose was adjusted to obtain an international normalized ratio of 2 to 3 or 2.5 to 3.5 on the basis of thromboembolic risk. The primary end point was the trough plasma level of dabigatran.

RESULTS

The trial was terminated prematurely after the enrollment of 252 patients because of an excess of thromboembolic and bleeding events among patients in the dabigatran group. In the as-treated analysis, dose adjustment or discontinuation of dabigatran was required in 52 of 162 patients (32%). Ischemic or unspecified stroke occurred in 9 patients (5%) in the dabigatran group and in no patients in the warfarin group; major bleeding occurred in 7 patients (4%) and 2 patients (2%), respectively. All patients with major bleeding had pericardial bleeding.

CONCLUSIONS

The use of dabigatran in patients with mechanical heart valves was associated with increased rates of thromboembolic and bleeding complications, as compared with warfarin, thus showing no benefit and an excess risk. (Funded by Boehringer Ingelheim; ClinicalTrials.gov numbers, NCT01452347 and NCT01505881.)

NOAK og mekaniske hjerteklapper er nok ikke lige det næste….

N ENGL J MED 369;13 NEJM.ORG SEPTEMBER 26, 2013

Mekaniske hjerteklapper og NOAK

- Dabigatran (Pradaxa®): RE-ALIGN studiet (se tidl.)
- Rivaroxaban (Xarelto®): CATHAR studiet (suspenderet/ afbrudt)
- Ingen planlagte studier på nuværende tidspunkt (www.clinicaltrials.gov)

- Marevan® (warfarin) vil formentlig være 1. valg i mange år fremover…
- Selvstyret AK – behandling reducerer incidensen af større tromboembolier signifikant[1]

[1]*Heneghan C et al. Lancet 2012;379:322-334*

Biologiske hjerteklapper

- Næsten ingen randomiserede, kontrollerede studier
- Øget risiko for tromboembolier de første 3 mdr. efter operationen[1]
- Hypotesen: Antitrombotisk behandling er nødvendig indtil en endothialisering af syringen er sket
- Risikoen for tromboemboliske komplikationer er størst ved M-klappen
- To alternativer pt.:
  - 3 mdr. Marevan med INR 2.0 – 3.0
  - 3 mdr. ASA 75 – 150 mg * 1 dgl.

[1]*Cohn LH et al. N Engl J Med 1981;304:258-262*

Evidensen bag

Comparison of clinical trials evaluating different antithrombotic regimens after surgical bioprosthetic valve replacement

Study	Design	Valve position: n	Mean f/u (mo)	Antithrombotic Therapy	Thromboembolic results	Bleeding results
Merie [24] 2012	Retro cohort	A: 4,075	78.8 pers-mo	W, ASA, W + ASA, no Rx	IRR 2.93 [1.54-5.55] for no W vs W	IRR 2.32 [1.28-4.22] for no W vs W
Brennan [25] 2012	Retro cohort	A: 25,656	3	W, ASA, W + ASA, no Rx, other	RR 1.52 [0.35 to 0.76] for W + ASA vs ASA	RR 2.80 [2.18-3.60] for W + ASA vs ASA
Colli [26] 2007	Pro, rando	A: 75	3	3-mo W then ASA vs ASA alone	No difference in ischemic events	No difference in bleeding events
Brueck [8] 2007	Retro cohort	A: 288	12	ASA vs no ASA	No difference in TE events	No difference in bleeding events
Aramendi [27] 2005	Pro, rando, multicenter	A:181 (94%), M:10 (5%), B: 2 (1%)	6	3-mo VKA vs anti-plt	No difference in TE events	Significantly more bleeding w/ VKA
Sundt [28] 2005	Retro cohort	A:1151 (641 [56%] w/ CABG)	3	W vs no W; any anti-plt	HR 1.51 [0.66 to 3.46] for W vs no W	HR 1.49 [0.43 to 5.11] for W vs no W
Gherli [29] 2004	Pro, single-center, obs	A: 249	> 6	3-mo ASA or W then ASA	No difference in cerebral ischemic events or survival	No difference in major bleeding events
Moinuddeen [30] 1998	Retro cohort	A: 185	53	W, ASA, or no Rx	No difference in ischemic events	No difference in bleeding events
Goldsmith [31] 1998	Retro cohort	A: 145 (37 [26%] w/ CABG)	25	ASA	Rate of TE 0.7%/year	Rate of hemorrhage 0.4%/year
Heras [5] 1995	Retro cohort	A:424 (52%), M:326 (40%), B: 66 (8%)	103.2	W, ASA, DP, or no Rx	AC reduced risk of TE but anti-plt did not	AC increased risk of bleeding
Blair [32] 1994	Retro cohort	A: 378 (51%) M: 370 (49%)	84	W, ASA, no Rx	AVR: no diff. MVR: bleed w/ W=TE w/ ASA or no Rx	Hemorrhage w/ W > w/ ASA or no Rx
Nuñez [33] 1984	Retro cohort	M: 435 (57%) B: 333 (43%)	32	ASA (500mg QOD or 1000 mg QD)	TE rate 3% w/ high dose, 0.4% w/ low dose)	Not reported

Results are presented with [95% Confidence interval].

A = aortic; AC = anticoagulation; anti-plt = anti-platelet (triflusal); ASA = aspirin; B = both aortic and mitral; CABG = coronary artery bypass graft; DP = dipyridamole; HR = hazard ratio; IRR = incidence rate ratio; M = mitral; obs = observational; pers-mo = person-months; Pro = prospective; QD = daily; QOD = every other day; Rand = randomized; Retro = retrospective; RR = relative risk; TE = thromboembolism; VKA = vitamin K antagonist (acenocoumarol); W = warfarin.

Carnicelli AP et al. Am J Cardiol 2016;118:1419-1426

Et nyt dansk studie

Rafiq S et al. Thromb Res 2016 [Epub ahead of print]

- Randomiseret, kontrolleret studie
- N = 328 (inkluderet i perioden 2005 – 2012)
- Biologiske aortaklapper (BAVR) +/- CABG randomiseret til:
  - VKA
  - ASA 150 mg * 1 dgl.

Konklusion:

Our results suggest that aspirin might be equally effective as warfarin in preventing thromboembolic events after BAVR, but with less major bleedings. Although this is numerically the largest trial testing this hypothesis in a prospective randomized trial, further adequately powered studies are warranted.

Biologiske hjerteklapper

- Aortaklapper (inkl. aorta-homograft, rørprotese):
  - ASA 75 mg. i 3 mdr.
- Mitralklapper:
  - Marevan med INR 2.0 – 3.0, alternativt ASA 75 mg. i 3 mdr.
- Stentless biologisk klap (Freestyle): Ingen behandling
- Stor variabilitet i klinisk praksis og lav evidens på området[1]
- + AFLI: ? (se næste slide)

[1]*Colli A et al. Eur J Cardiothorac Surg 2008;33:531-536*

Biologiske hjerteklapper og AFLI

- NOAK:
  - Ikke i de første 3 mdr. efter operationen
- Marevan:
  - Anvendes de første 3 mdr. efter operationen

Heidbuchel H et al. Europace 2015:17:1467-1507

Plastik / reparation af M-klappen

- Dårlig evidens
- Regimer:
  - Marevan med INR 2.0 – 3.0, alternativt ASA 75 mg. i 3 mdr.
- + AFLI:
  - NOAK:
    - Ikke i de første 3 – 6 mdr. efter operationen
  - Marevan:
    - Anvendes de første 0 – 6 mdr. efter operationen

Stentklapper (TAVI procedure)

- ASA 75 mg * 1 dgl. livslangt + clopidogrel 75 mg * 1 dgl. i 3 – 12 mdr.[1]
- + AFLI:
  - Ca. 35% af patienterne vil have/får AFLI[2]
  - Triple terapi bør undgås/minimeres i tid
  - AK -behandling med warfarin nedsætter måske risikoen for tromboser sammenlignet med trombocytfunktions-hæmmer[3]
  - Studier pågår (se næste slide)

[1]Holmes DR et al. JAMA 2015:313:1019-1028
[2]Rodes-Cabar J et al. JACC 2013:62:2349-2359
[3]Hansson NC et al. JACC 2016:68:2059-2069

Studier på vej (TAVI)

Studies underway evaluating antithrombotic therapy after TAVR

Author/ Sponsor	ClinicalTrials.gov ID	Title (abbreviated)	Design	Intervention	Primary Outcome	Estimated completion
St. Antonius Hospital [45]	NCT02247128	Anti-plt Rx in TAVI (POPular-TAVI)	OL, rando, Phase 4	ASA + clop, ASA, AC + clop, AC	Bleeding @ at 1 year	August 2016
Romo [46]	NCT02224066	Platelet Reactivity After TAVI: (REAC-TAVI)	OL, rando, Phase 4	Ticag, ASA + clopi	Suppression of platelet activity	November 2016
Zidar [47]	NCT02486367	Inflammation/ Thrombosis after TAVI	OL, rando, Phase 0	Clop vs Ticag	Platelet responsiveness	February 2017
Bayer [48]	NCT02556203	Rivaroxaban vs Anti-plt after TAVI	OL, rando, Phase 3	Rivaroxaban + ASA; Clop + ASA	Death or TE event; life-threatening bleeding	January 2018
Hospital do Coracao [49]	NCT02303795	Rivaroxaban for VHD and AF (RIVER)	OL, rando, Phase 2	Rivaroxaban vs W	Combined TE events, bleeding, death	August 2018
Makkar [50]	NCT02318342	TAVI or Surgical Bio-Valve Thrombosis & AC (RESOLVE)	OL, Phase 1 and 2	3-mo W in patients w/ valve thrombus on CT or echo	% of patients w/ resolution of thrombus w/ AC	December 2019

AC = oral anticoagulation; AF = atrial fibrillation; Anti-plt = antiplatelet; ASA = aspirin; clop = clopidogrel; OL = open label; Rando = randomized; Ticag = ticagrelor; VHD = valvular heart disease; W = warfarin.

Carnicelli AP et al. Am J Cardiol 2016;118:1419-1426

Mitraclip

- Ingen væsentlige studier på området – meget dårlig evidens[1,2]
- Mange patienter har AFLI før operationen
- Anbefalinger:
  - ASA 75 mg * 1 dgl. livslangt
  - Clopidogrel 75 mg * 1 dgl. i 1 – 3 mdr.
- + AFLI: ?????

[1]*Polzin A et al. Vascul Pharmacol 2016;77:54-59*
[2]*Hamm K et al J Heart Valve Dis. 2013;22:713-715*

Amerikanske anbefalinger

ACCP and AHA/ACC guidelines for antithrombotic therapy in patients with mechanical or bioprosthetic heart valves

		Mechanical MVR	Mechanical AVR	Bioprosthetic MVR	Bioprosthetic AVR	TAVI	TMVI
ACCP Guidelines [16]	Anticoagulation	Indefinite VKA, INR 2.5-3.5 (2C)	Indefinite VKA, INR 2.0-3.0 (1B)	3-months VKA, INR 2.0-3.0 (2C)	No VKA if no other indication (2C)	No VKA if no other indication (2C)	NR
	Antiplatelet	Indefinite ASA 50-100mg/day* (1B)	Indefinite ASA 50-100mg/day* (1B)	3-months ASA 50-100mg/day (2C)	3-months ASA 50-100mg/day (2C)	3-months ASA 50-100mg/day + clopidogrel 75mg/day (2C)	NR
AHA/ACC Guidelines [17]	Anticoagulation	Indefinite VKA, INR 2.5-3.5 (I,B)	Indefinite VKA, INR 2.0-3.0 if no risk factors; INR 2.5-3.5 if risk factors† (I,B)	3-months VKA, INR 2.0-3.0 (IIa,C)	3-months VKA, INR 2.0-3.0 (IIb,B)	NR	NR
	Antiplatelet	Indefinite ASA 75-100mg/day (I,A)	Indefinite ASA 75-100mg/day (I,A)	Indefinite ASA 75-100mg/day (IIa,B)	Indefinite ASA 75-100mg/day (IIa,B)	Indefinite ASA 75-100mg/day + 6-months clopidogrel 75mg/day (IIb,C)	NR

ACCP and AHA/ACC guidelines with grade of strength of recommendation (ACCP) and class of recommendation, level of evidence (AHA/ACC).

ASA = aspirin; AVR = aortic valve replacement; MVR = mechanical valve replacement; NR = no recommendation; TAVI = transcatheter aortic valve implantation. TMVI = transcatheter mitral valve implantation.

* For those with low risk of bleeding.

† Risk factors = atrial fibrillation, prior thromboembolism, left ventricular dysfunction, hypercoagulable state.

Carnicelli AP et al. Am J Cardiol 2016;118:1419-1426

AFLI og hjerteklap sygdom

KONKLUSION

Patienter med mekanisk hjerteklapprotese eller moderat-svær mitralstenose og AFLI bør behandles med VKA.

Patienter med AFLI og andre native hjerteklapsygdomme end mitralstenose samt patienter med AFLI og klapplastik eller biologisk klapprotese indsat > 3 måneder tidligere kan behandles med VKA eller NOAK efter individuel vurdering af bivirkningsprofilen i samråd med patienten. Evidensen for NOAK til disse patienter er alene baseret på subgruppeanalyser. Der er imidlertid ikke noget, der indikerer, at trombemekanismen og responset på NOAK hos disse patienter adskiller sig substantielt fra effekten hos andre patienter med AFLI. Der kan formentlig også ekstrapoleres til patienter med operationskrævende klapsygdom, som ikke indgik i studierne, men antages at have samme gevinst af NOAK.

Vi anbefaler VKA frem for NOAK til patienter, der har fået foretaget TAVI og har AFLI, indtil resultaterne af de igangværende studier foreligger.

Betegnelsen valvulær AFLI anbefales erstattet med benævnelsen af de specifikke hjerteklapsygdomme.

Acetylsalicylsyre anbefales ikke til forebyggelse af tromboemboli ved AFLI.

oagulantia anbefales ikke til pati-
nter med mekanisk hjerteklap eller
oderat-svær mitralstenose.

cetylsalicylsyre anbefales ikke til
rebyggelse af tromboemboli ved
trieflimren.

Bovin A et al. Ugeskr Læger 2017;179:V02170156

Europace (2017) 0, 1–21
doi:10.1093/europace/eux240

Antithrombotic therapy in atrial fibrillation associated with valvular heart disease: a joint consensus document from the European Heart Rhythm Association (EHRA) and European Society of Cardiology Working Group on Thrombosis, endorsed by the ESC Working Group on Valvular Heart Disease, Cardiac Arrhythmia Society of Southern Africa (CASSA), Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), South African Heart (SA Heart) Association and Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLEACE)

Gregory Y. H. Lip[1]*, Jean Philippe Collet[2], Raffaele de Caterina[3], Laurent Fauchier[4], Deirdre A. Lane[5], Torben B. Larsen[6], Francisco Marin[7], Joao Morais[8], Calambur Narasimhan[9], Brian Olshansky[10], Luc Pierard[11], Tatjana Potpara[12], Nizal Sarrafzadegan[13], Karen Sliwa[14], Gonzalo Varela[15], Gemma Vilahur[16], Thomas Weiss[17], Giuseppe Boriani[18] and Bianca Rocca[19]

Atrial fibrillation (AF) is a major worldwide public health problem, and AF in association with valvular heart disease (VHD) is also common. However, management strategies for this group of patients have been less informed by randomized trials, which have largely focused on 'non-valvular AF' patients.

Thrombo-embolic risk also varies according to valve lesion and may also be associated with CHA_2DS_2VASc score risk factor components, rather than only the valve disease being causal.

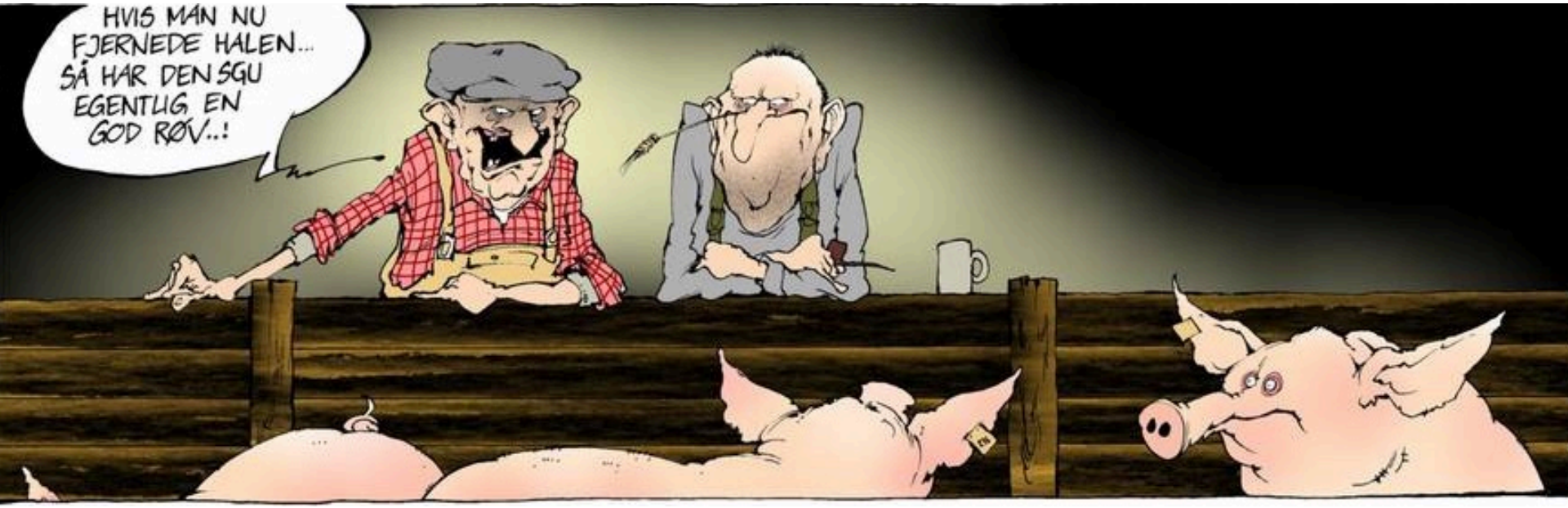
Given marked heterogeneity in the definition of valvular and non-valvular AF and variable management strategies, including non-vitamin K antagonist oral anticoagulants (NOACs) in patients with VHD other than prosthetic heart valves or haemodynamically significant mitral valve disease, there is a need to provide expert recommendations for professionals participating in the care of patients presenting with AF and associated VHD.

To address this topic, a Task Force was convened by the European Heart Rhythm Association (EHRA) and European Society of Cardiology (ESC) Working Group on Thrombosis, with representation from the ESC Working Group on Valvular Heart Disease, Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), South African Heart (SA Heart) Association and Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLEACE) with the remit to comprehensively review the published evidence, and to publish a joint consensus document on the management of patients with AF and associated VHD, with up-to-date consensus recommendations for clinical practice for different forms of VHD.

This consensus document proposes that the term 'valvular AF' is outdated and given that any definition ultimately relates to the *evaluated practical use* of oral anticoagulation (OAC) *type*, we propose a *functional* Evaluated Heartvalves, Rheumatic or Artificial (EHRA) categorization *in relation to the type of OAC use* in patients with AF, as follows: (i) EHRA Type 1 VHD, which refers to AF patients with 'VHD needing therapy with a Vitamin K antagonist (VKA); and (ii) EHRA Type 2 VHD, which refers to AF patients with 'VHD needing therapy with a VKA or a Non-VKA oral anticoagulant (NOAC)', also taking into consideration CHA_2DS_2VASc score risk factor components.

This consensus document also summarizes current developments in the field, and provides general recommendations for the management of these patients based on the principles of evidence-based medicine.

Spørgsmål.....



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