

# Patient Self-Testing & Patient Self-Management of Warfarin Therapy

Jack Ansell, M.D.

Lenox Hill Hospital, NY

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Disclosures

Consultant: Roche Diagnostics, ITC, HemoSense

# The Dilemma of Anticoagulation Management

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- Warfarin has a **narrow therapeutic window** of effectiveness and safety.
- Many **factors influence a patient's stability** in that window.
- **Frequent monitoring** is required to maintain patients in the therapeutic window.
- Monitoring is **labor intensive** and complex.
- **Physicians avoid warfarin use** because of its complexity.

# Models of Anticoagulation Management

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- **Routine Medical Care (Usual Care)**  
AC managed by physician or office staff w/o any systematic program for education, follow-up, communication, and dose management. May use POC device or laboratory INR
- **Anticoagulation Clinic (ACC)**  
AC managed by dedicated personnel (MD, RN or pharmacist) with systematic policies in place to manage and dose patients. May use POC device or laboratory INR
- **Patient Self-Testing (PST)**  
Patient uses POC monitor to measure INR at home. Dose managed by UC or ACC
- **Patient Self-Management (PSM)**  
Patient uses POC monitor to measure INR at home and manages own AC dose

Who is able to perform PST or PSM?

# Considerations for Patient Selection

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## Willing to:

- Learn and perform testing procedure
- Keep accurate written records
- Communicate results in timely fashion

## Able to:

- Participate in a training program to acquire skills/competencies to perform self-testing
- Generate an INR
- Understand implications of test result
- Maintain records

## Reliable to:

- Perform procedure with acceptable technique to obtain accurate results

# The THINRS Trial: *Design*

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- **Purpose:**  
Compare HQACM with PST to HQACM alone on major health outcomes
- **Patient population:**  
Atrial fibrillation or mechanical heart valve
- **Participating Centers**  
28 VA Med Ctrs with ACC of > 100 patients
- **Two parts:**  
Part 1: Training and home testing for 2-4 weeks  
Part 2: Competency assessment and, if capable, randomization to HQACM every 4 weeks or PST every week

# The THINRS Trial: *Design*

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A key attribute of this trial is that “everyone” was trained for PST and those who were deemed capable, then randomized to either PST or ACC management

# The THINRS Trial: *Intervention & Outcomes*

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## Interventions:

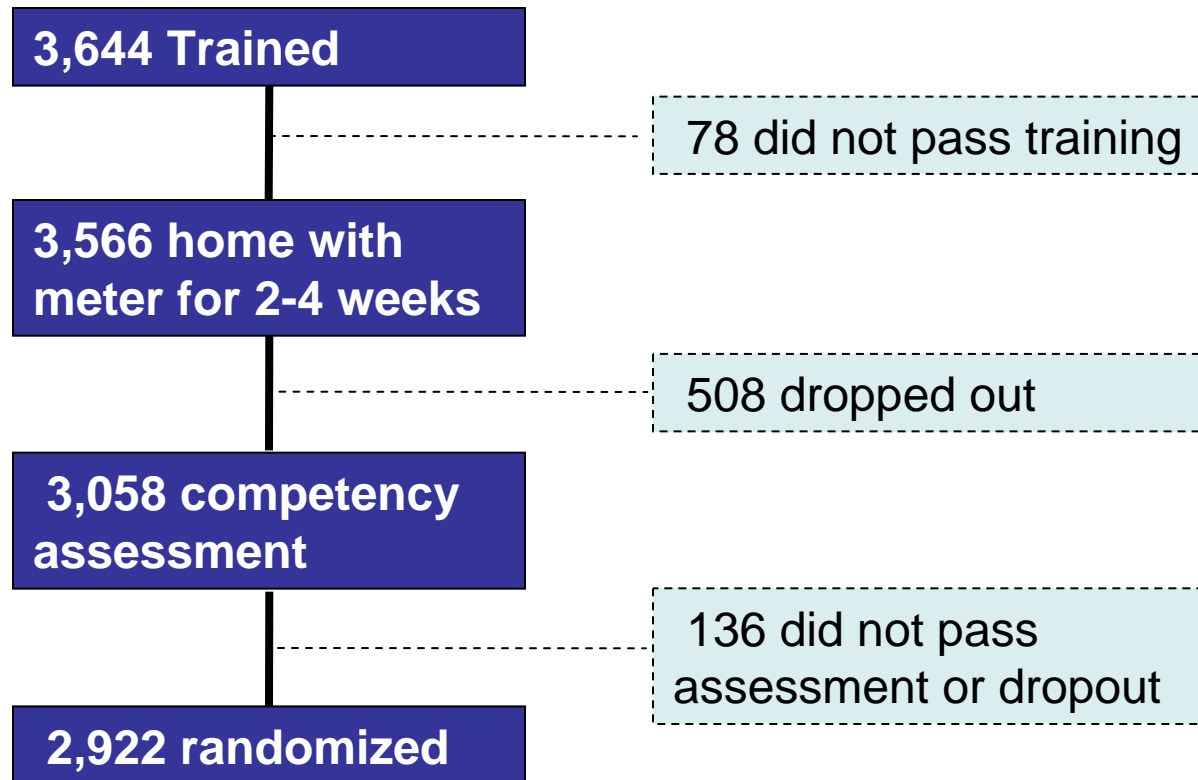
- HQACM (monthly INR)
  - Designated, trained staff person
  - Local standard management algorithm
- PST (Weekly INR)
  - Interactive value response reporting system with web-based local monitoring

## Outcomes:

- Primary
  - time to first major event (stroke, major bleed, death)
- Secondary
  - time in range, satisfaction, quality of life

# The THINRS Trial: *Participants*

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**2,922 / 3,644 = 80% Passed Competency**

## Summary from THINRS: *Outcomes*

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- 80% of screened subjects demonstrated PST competency and were randomized
  - approx. 4 out of 5 pass
- Patients were less likely to pass PST, if
  - Older, h/o CVA, poor cognition, low literacy, poor manual dexterity

# Summary from THINRS: *Outcomes*

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- Training results showed that PST failures had
  - higher # of practice attempts (used higher # of cuvettes)
  - Less able to perform fingerstick
  - Less able to use device (blood in cuvette, timing)
  - Less able to use 1-800 number
- Competency results showed that PST failures were due to
  - Poor cuvette integrity
  - Less able to perform fingerstick
  - Higher cuvette wastage (> 150% usage)
  - Required more than 1 assessment visit

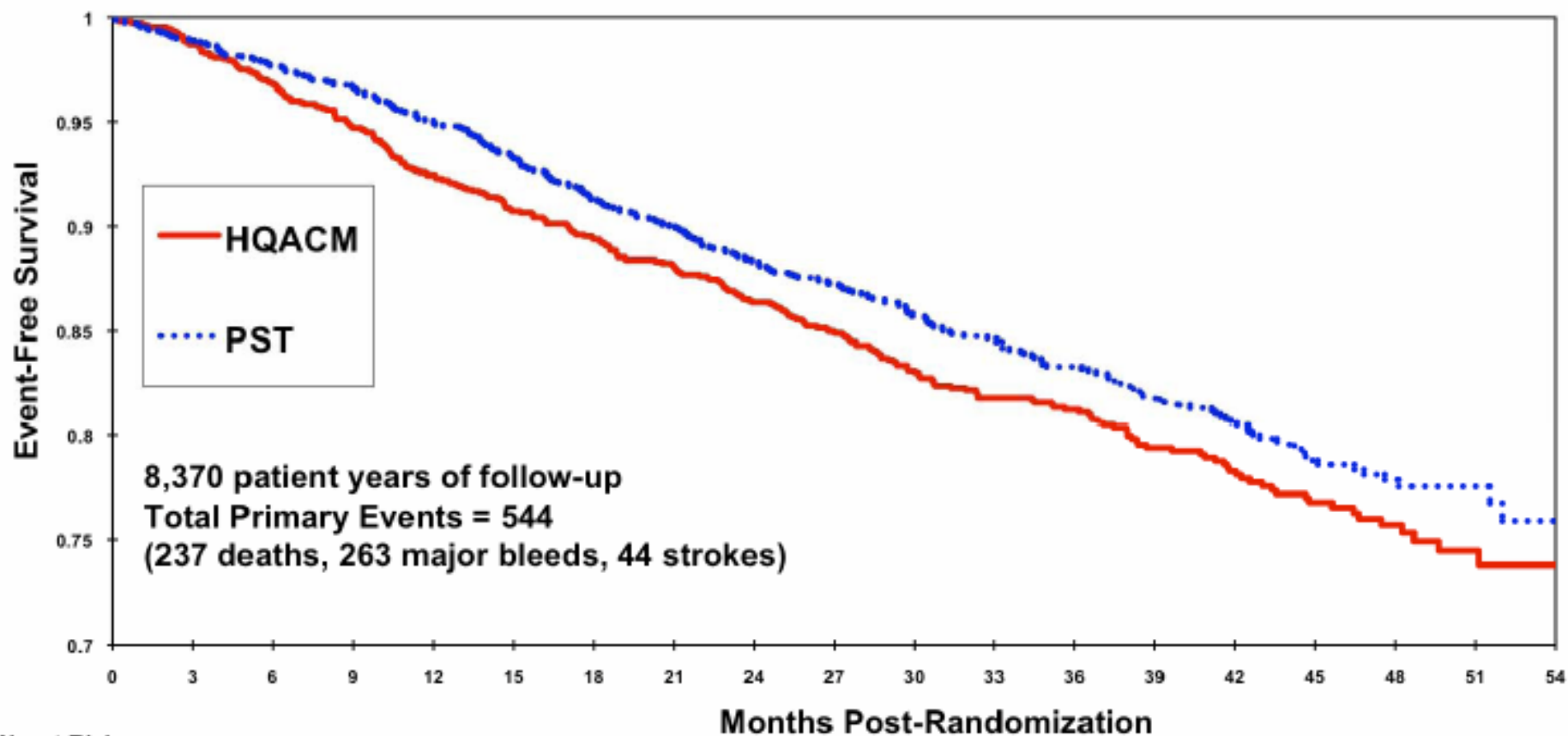
Assessing Outcomes from PST or PSM?

# Summary from THINRS: *Outcomes*

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<b>Event Type</b>	<b>4,235 pt yrs HQACM</b>	<b>Rate per pt-yr</b>	<b>4,495 pt yrs PST</b>	<b>Rate per pt-yr</b>	<b>Total</b>	<b>Rate per pt-yr</b>
<b>Stroke</b>	32	0.76%	31	0.69%	63	0.72%
<b>Major Bleed</b>	189	4.46%	173	3.85%	362	4.15%
<b>Death</b>	157	3.71%	152	3.38%	309	3.54%
<b>Total</b>	378	8.93%	356	7.92%	734	8.41%

# Primary Outcome: Time to first event

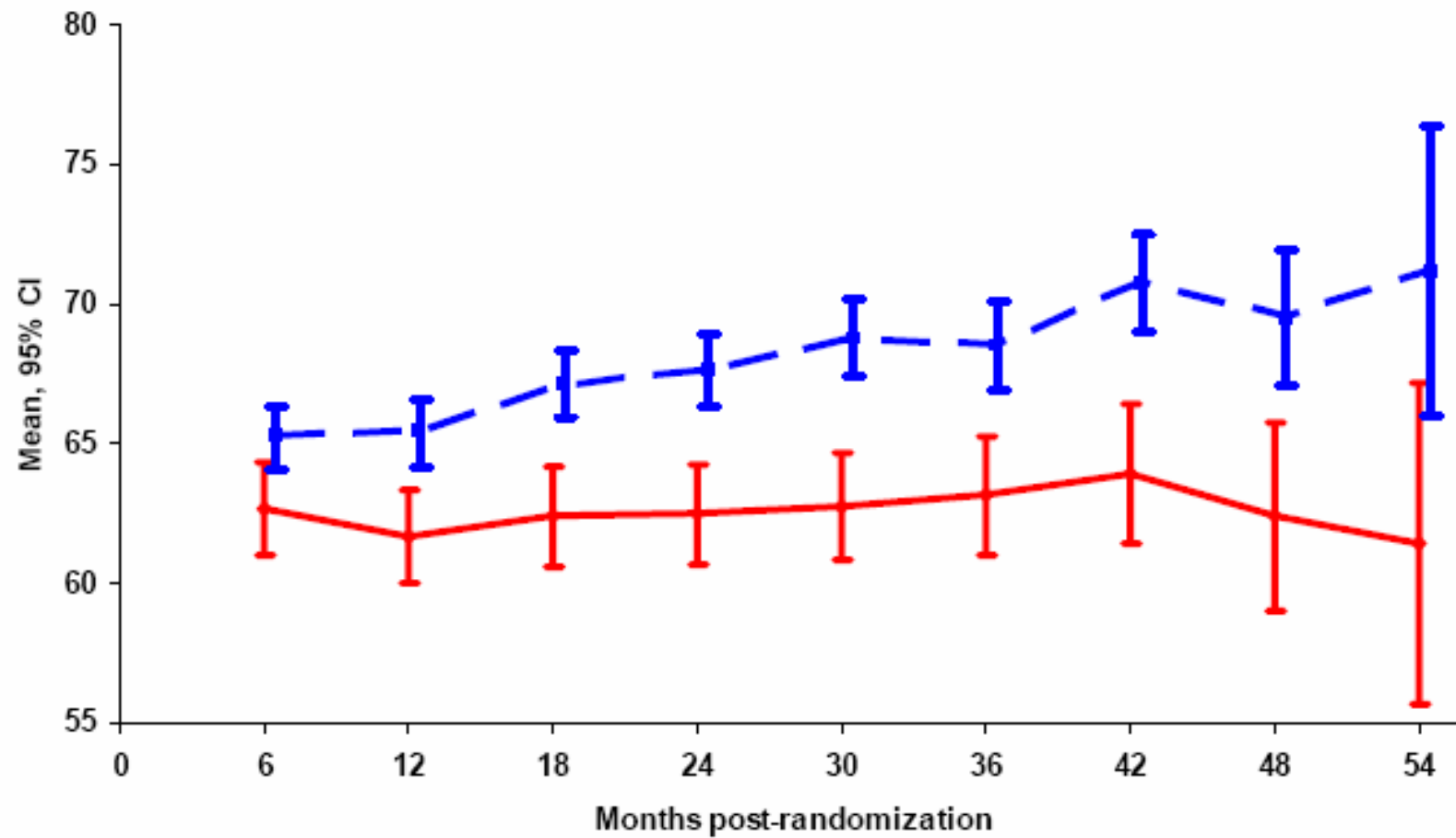


No. at Risk

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54
HQACM	1457	1414	1357	1307	1253	1221	1181	1147	1089	1012	932	809	685	534	461	359	228	119	46
PST	1465	1437	1407	1378	1341	1312	1273	1247	1181	1109	1016	909	774	637	536	403	276	139	48

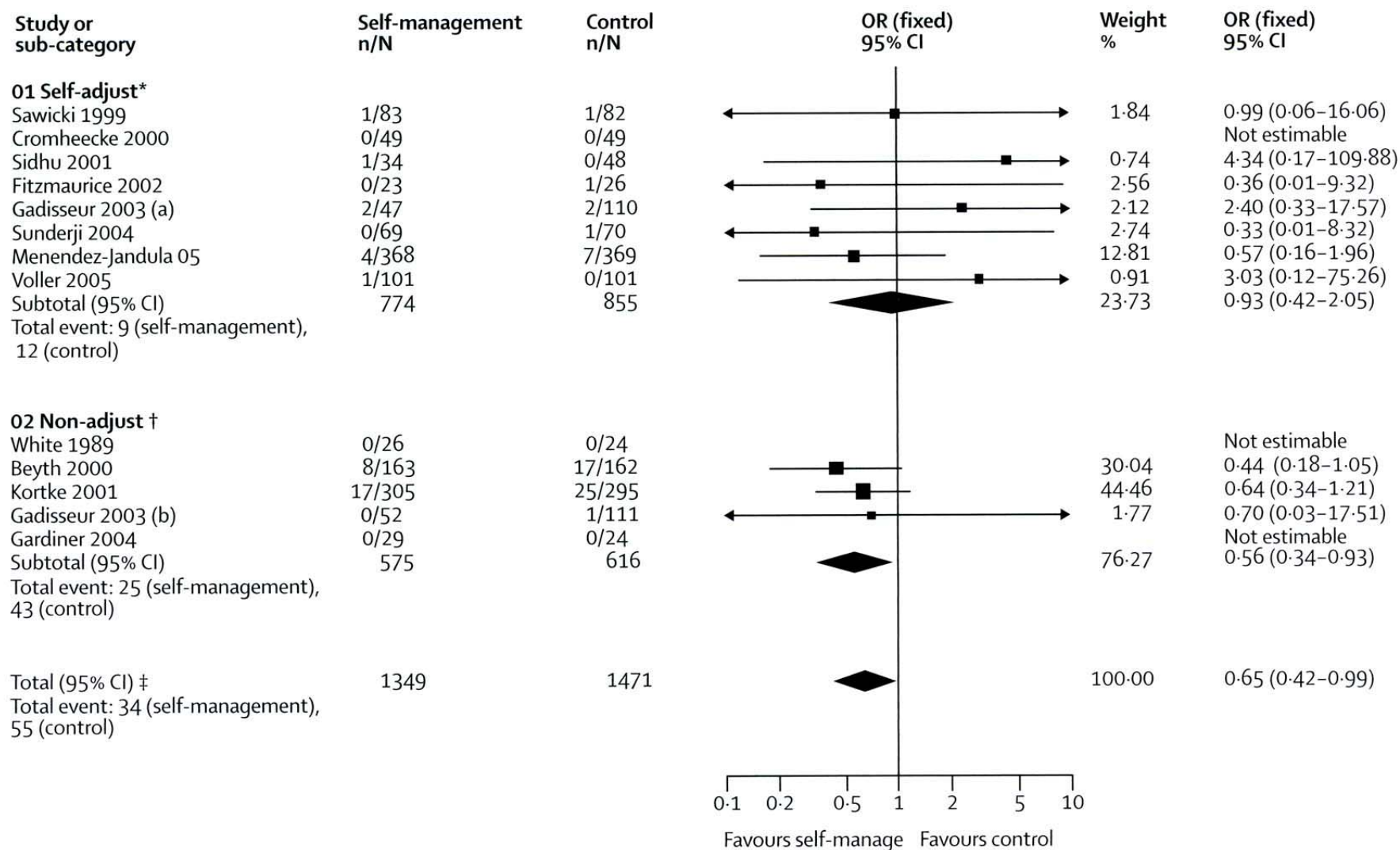
## Time in target range

—●— HQACM    —■— PST

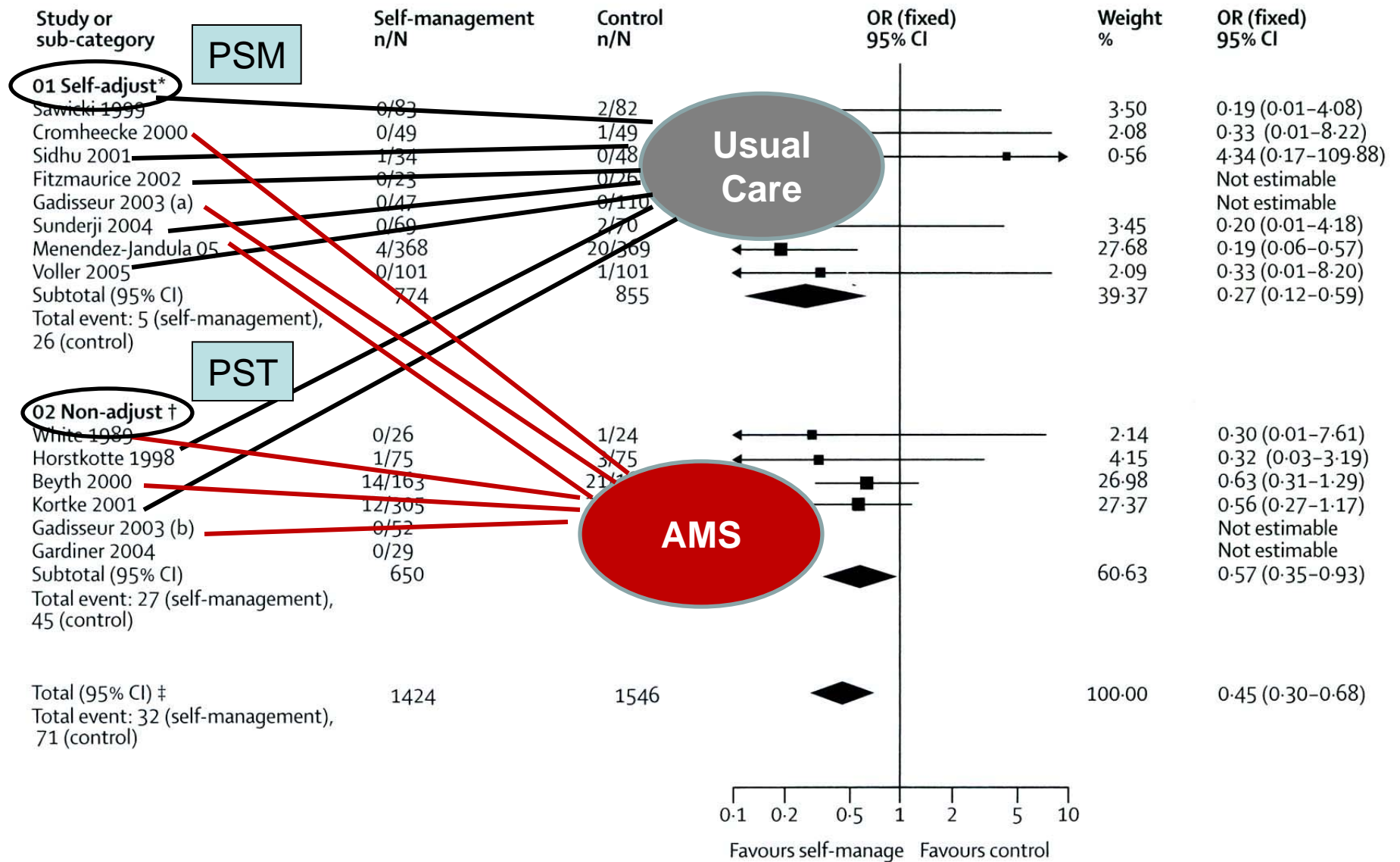




# Major Hemorrhage with PST and PSM



# Thromboembolism with PST or PSM



Author Year	Intervention	# Patients	TTR (% or time in range)	Major Hemorrhage	Thromboembolism
<b>PST vs UC</b>					
Beyth 2000	PST/ams* vs UC	163 vs 162	56 vs 32 p<0.001	12 % vs 5.6% p=0.049	8.6 % vs 13% p = 0.2
<b>PST vs AMS</b>					
White 1989	PST/ams* vs AMS	23 vs 24	93 vs 75 p=0.003	0	0
Kaatz 2001	PST/ams* vs AMS		63 vs 65 p=NS		
Gadisseur 2003	PST/ams* vs AMS	52 vs 60	63.9 vs 61.3 p=0.14	0 vs 1 event	0
THINRS 2009	PST /ams vs AMS		~68% vs 63% p = NS		
<b>PSM vs UC</b>					
Horstkotte 1998	PSM vs UC	75 vs 75	92.4 vs 58.8		
Sawicki 1999	PSM vs UC	83 vs 82	57 vs 33.8 p=0.006	1 event vs 1 event	1 event vs 2 events
Fitzmaurice 2002	PSM vs UC	23 vs 26	74 vs 77 p=NS	0 vs 1 event	0
Kortke 2001	PSM vs UC	305 vs 295	78.3 vs 60.5 p= $\leq$ 0.001	1.7 % vs 2.6% p=NS	1.2% vs 2.1% p=NS
Sidhu 2001	PSM vs UC	34 vs 48	76.5 vs 63.8 p<0.0001	1 event vs 0	1 event vs 0
Sunderji 2004	PSM vs UC	69 vs 70	71.8 vs 63.2		
Voller 2005	PSM vs UC	101 vs 101	67.8 vs 58.5 p=0.0061	2 events vs 0	0 vs 1 event
<b>PSM vs AMS</b>					
Watzke 2000	PSM vs AMS	49 vs 53	84.5 vs 73.8	1 event vs 0	1 event vs 0
Gadisseur 2003	PSM vs AMS	47 vs 52	66.3 vs 63.9 p=0.14	1 event vs 1 event	0
Khan 2004	PSM vs AMS	40 vs 39	71.1 vs 70.4		
Menendez-Jandula 2005	PSM vs AMS	368 vs 369	58.6 vs 55.6 p=NS	4 events vs 7 events	4 events vs 20 events

# Some persisting questions . . .

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- What accounts for “potential” benefits of PST/PSM
  - ? Frequency of testing
  - ? Timeliness of testing
  - ? Knowledge and training
  - ? Empowerment and compliance
  - ? Consistency of instrumentation
- A problem that is slowly resolving . . .
  - Lack of robust RCTs of PST or PSM compared with Usual Care or with Anticoagulation Clinic care