



Qualità dell'anticoagulazione con i POC: cosa dicono gli studi

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*Il sottoscritto Francesco Dentali
ai sensi dell' art. 3.3 sul Conflitto di Interessi, pag. 17 del Reg. Applicativo
dell' Accordo Stato-Regione del 5 novembre 2009,
Dichiara che negli ultimi due anni ha avuto rapporti diretti di finanziamento
con i seguenti soggetti portatori di interessi commerciali in campo sanitario:*

- Bayer
- Sanofi
- BMS/Pfizer,
- Boehringer
- Alfa Wassermann
- Daiichi
- IL

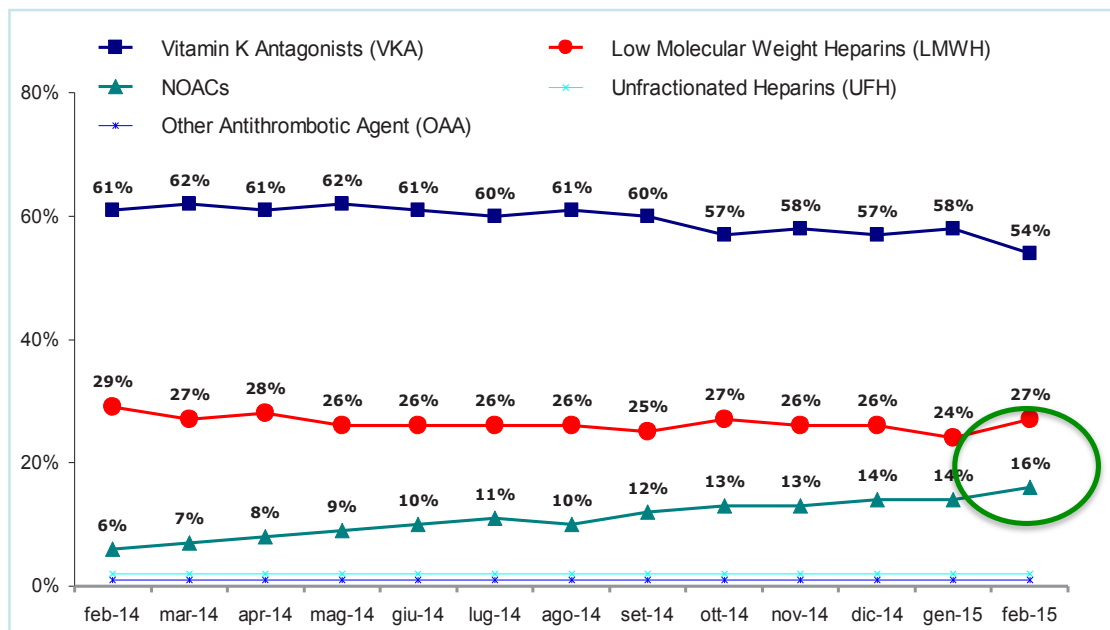
Conflitto d'interesse intellettuale



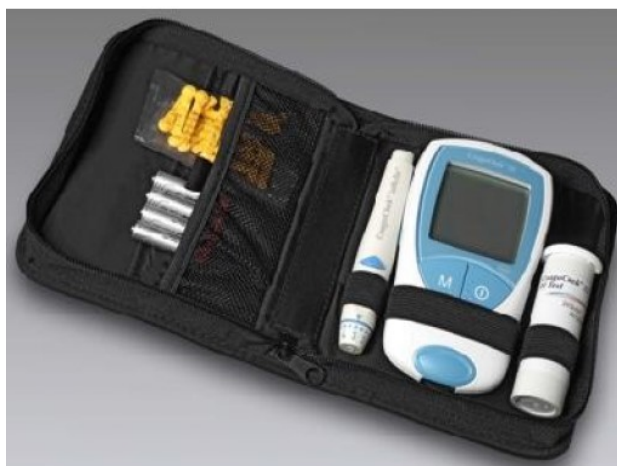
Il sottoscritto Francesco Dentali

dichiara che prima e durante la preparazione della relazione (a differenza del Professor Palareti) *non credeva nell'utilità e nella sicurezza dei POC nei pazienti in terapia con gli AVK (in particolare in caso di "Self Management")*

MONTHLY Days of Therapy Trend IMS, Feb 2015



Point of Care Testing



Il paziente...



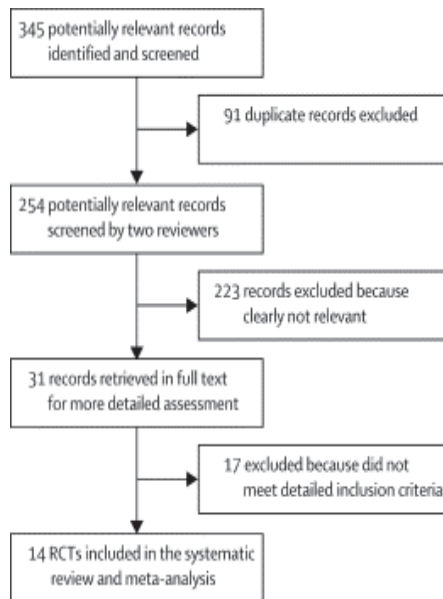
Mondo Reale 2026?



POC: Obiettivi x il paziente e il medico

- Numero non inferiore di eventi tromboembolici
- Numero non inferiore di eventi emorragici
- Numero non inferiore di morti

Meta-Analisi

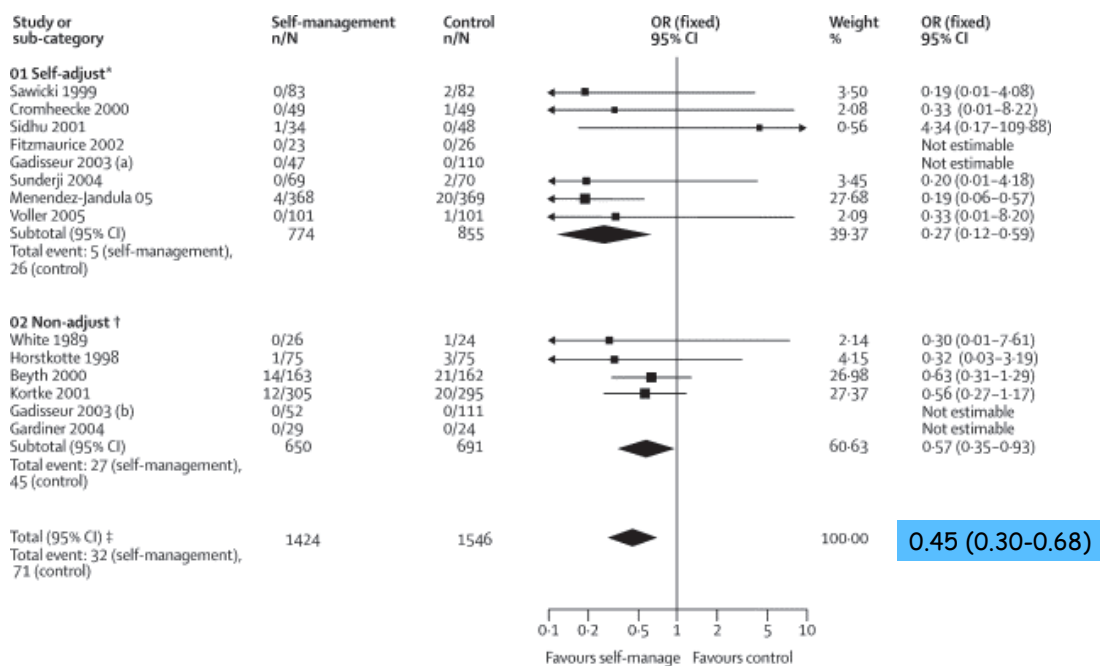


Inclusion criteria	Duration of study (months)	Mean age (years)	Numbers analysed		Control-group intervention	Education and intervention for self-monitoring group	
			Control (n=1385)	Intervention (n=1464)			
White 1989, USA ^a	Inpatients receiving intravenous heparin with a planned duration of warfarin therapy of at least 8 weeks*	2	50	24	26	Specialist anticoagulation clinic care. Managed by nurse specialists	Patients managed directly by general internists
Horstotte 1998, Germany ^b	Outpatients with isolated aortic or mitral valve replacement with the St Jude Medical prosthesis†	N/A	N/A	75	75	Managed by home physician	Standardised training, measured INR twice a week, and contacted coagulation clinic by phone
Sawicki 1999, Germany ^b	Any indication for anticoagulation and on life long treatment	6	55	82	83	Twice-monthly adjustment by family doctor	Three educational sessions. Self adjusted
Beyth 2000, USA ¹	Inpatients aged >65 years receiving 10 000 units or more of intravenous heparin*	6	75	162	163	Managed by primary care physician as per usual practice	1-h education session, patients phoned results to coach who made recommendations
Cromheecke 2000, Netherlands ²	Long term anticoagulation, at least 6 months treatment†	3	42	49	49	Testing at intervals of 1-2 weeks and managed by a specialised anticoagulation service	Two educational sessions, self adjusted
Kortke 2001, Germany ^b	Permanent oral anticoagulation after mechanical heart valve surgery†	24	62.5	295	305	Managed by primary care physician as per usual practice	Trained in self-monitoring 6-11 days after operation
Sidhu 2001, UK ³	Permanent oral anticoagulation after mechanical heart valve surgery performed by one surgeon†	24	61	48	34	Managed by family doctor as per usual practice	Two educational sessions, doctor availability to receive calls, patients self-adjusted as per protocol
Fitzmaurice 2002, UK ³	Long-term anticoagulation at least 6 months treatment, with satisfactory INR control (INR within 0.5 of target value 60% of the time)†	6	63	26	23	Managed by primary care physician as per usual practice	Two educational workshops, daytime access to medical care. Self adjusted warfarin according to a dosing algorithm
Gadisseur 2003, Netherlands ⁴	Long term oral anticoagulation at least 3 months treatment†	6	57	221	99	Routine care by anticoagulation clinic physicians	Three educational sessions. Self adjustment confirmed by telephone
Gardiner 2004, UK ³	At least 8 months of oral anticoagulation treatment with a previous record of good compliance†	6	58	24	29	Testing every 4 weeks or more often if indicated by anticoagulation clinic staff	Two educational sessions 1 week apart
Khan 2004, UK ³	At least 12 months treatment with warfarin patients with AF. Age >65 years†	6	Median 73	39	40	Managed by anticoagulation clinic review according to INR	2-h education session, study co-ordinator liaised by phone and gave advice on dosage for next 7 days
Sunderji 2004, Canada ⁵	Receiving warfarin for at least 1 month and required anticoagulation for at least 1 year†	8	60	70	69	Managed by primary care physician as per usual practice	Two educational sessions, self adjusted using a nomogram
Menendez-Jandula 2005, Spain ⁶	Any indication of anticoagulation and at least 3 months therapy†	11.8	66	369	368	Testing at least every 4 weeks and managed by a haematologist at an anticoagulation clinic	Two educational sessions, taught by nurse. Card system to aid self adjustment
Voller 2005, Germany ³	Long-term oral anticoagulation in patients with non-valvular AF†	5	64	101	101	Managed by family doctor as per usual practice	Standard training course of three sessions

AF=atrial fibrillation. *Coumatrack monitor. †Coumatrack system. ‡Pro time microcoagulation system.

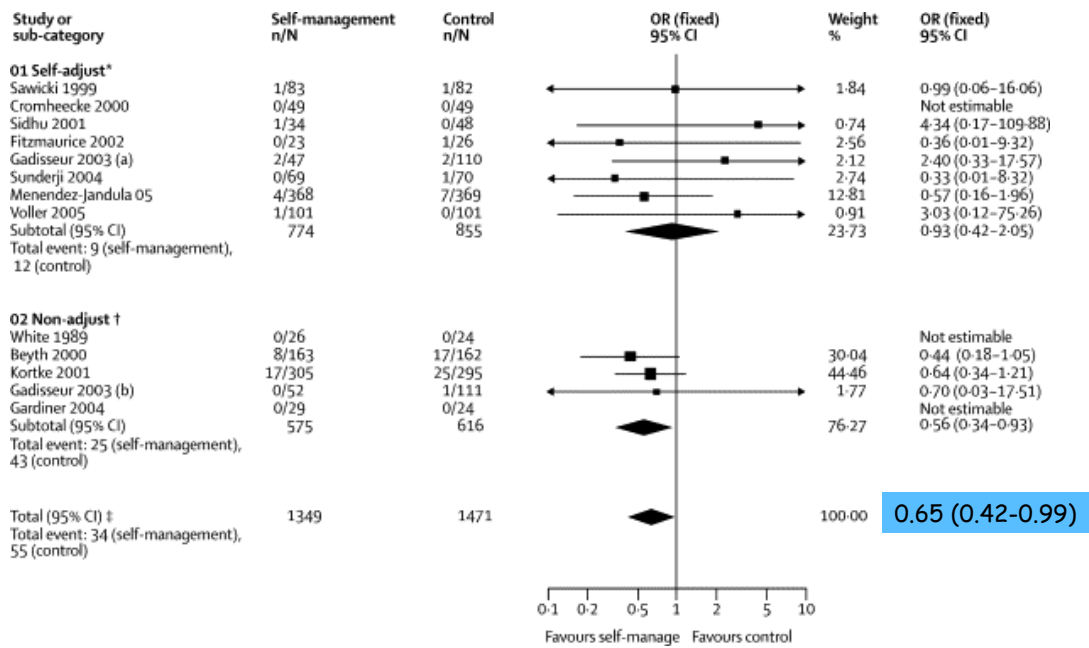
Heneghan et al Lancet 2006

Eventi Tromboembolici



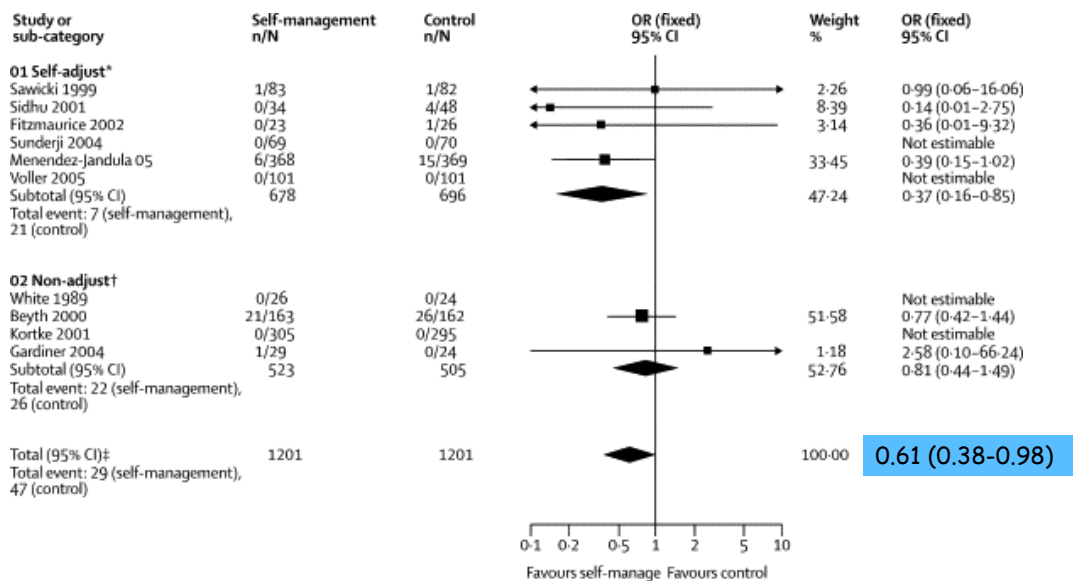
Heneghan et al Lancet 2006

Eventi Emorragici



Heneghan et al Lancet 2006

Mortalità



Heneghan et al Lancet 2006



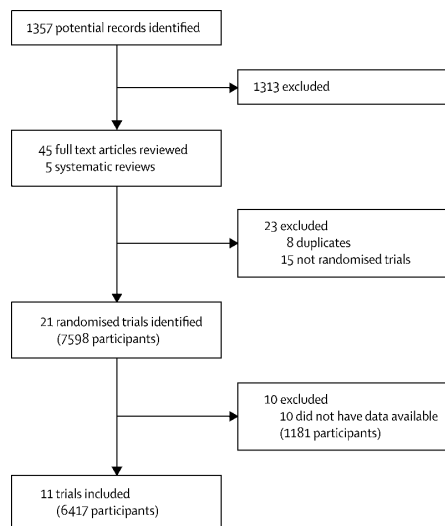
CARE MANAGEMENT STRATEGIES

Self-monitoring and self-dosing of oral anticoagulation improves survival ☆

James D Douketis, Debbie Singh



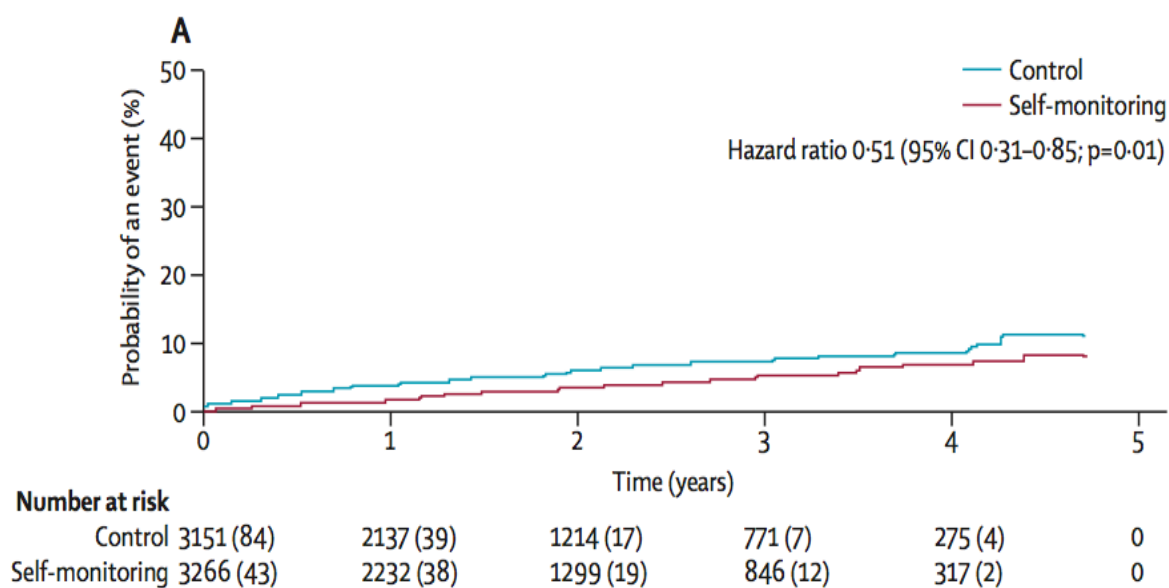
Individual Patient Meta-Analysis



	Country	Dates of recruitment	Year of publication of primary results	Study duration (months)	Age range, years (mean)	Total number of patients	Female	Atrial fibrillation	Mechanical valve	Other	Self management	Type of control group care
Beyth et al ^{1*}	USA	1992-95	2000	6	65-94 (74.7)	325 (5%)	184 (57%)	54 (17%)	36 (11%)	235 (72%)	No	Primary Care
Cromheecke et al ^{2†}	Holland	1998	2000	3	22-71 (42.3)	49 (1%)	21 (43%)	11 (22%)	23 (47%)	15 (31%)	Yes	Anticoagulation clinic
Koertke et al ^{3†}	Germany	1994-97	2001	24	17-77 (59.7)	930 (14%)	293 (32%)	-	930 (100%)	-	Yes	Primary care
Sundeji et al ^{4‡}	Canada	1998-2002	2004	20	20-85 (60.0)	139 (2%)	41 (29%)	47 (34%)	82 (59%)	10 (7%)	Yes	Primary care
Mendiola Jándula et al ^{5†}	Spain	2001-02	2005	12	19-90 (63.5)	737 (11%)	347 (47%)	296 (40%)	285 (39%)	154 (21%)	Yes	Anticoagulation clinic
Voller et al ^{6†}	Germany	1999-2001	2005	19†	36-85 (64.4)	202 (3%)	53 (26%)	202 (100%)	-	-	Yes	Primary care
Fitzmaurice et al ^{7†}	UK	2001-02	2005	12	18-87 (65.1)	617 (10%)	217 (35%)	343 (56%)	97 (16%)	177 (29%)	Yes	Both
Christensen et al ^{8†}	Denmark	2002-03	2006	6	21-78 (50.7)	100 (2%)	33 (33%)	24 (24%)	35 (35%)	41 (41%)	Yes	Both
Siebenhofer et al ^{9†}	Austria	2002-05	2007	36	60-89 (68.8)	195 (3%)	81 (42%)	89 (46%)	32 (16%)	74 (38%)	Yes	Both
Matchar et al ^{10‡}	USA	2003-06	2010	36	23-90 (67.0)	2922 (46%)	51 (2%)	2236 (77%)	684 (23%)	2 (<1%)	No	Anticoagulation clinic
Kaatz et al ^{11†}	USA	1998-99	2001	12	30-87 (64.1)	201 (3%)	84 (42%)	86 (43%)	39 (19%)	76 (38%)	No	Anticoagulation clinic
Totals	-	1992-2006	2000-10	-	17-94 (65.0)	6417	1405 (22%)	3388 (53%)	2243 (35.0%)	784 (12%)	-	-

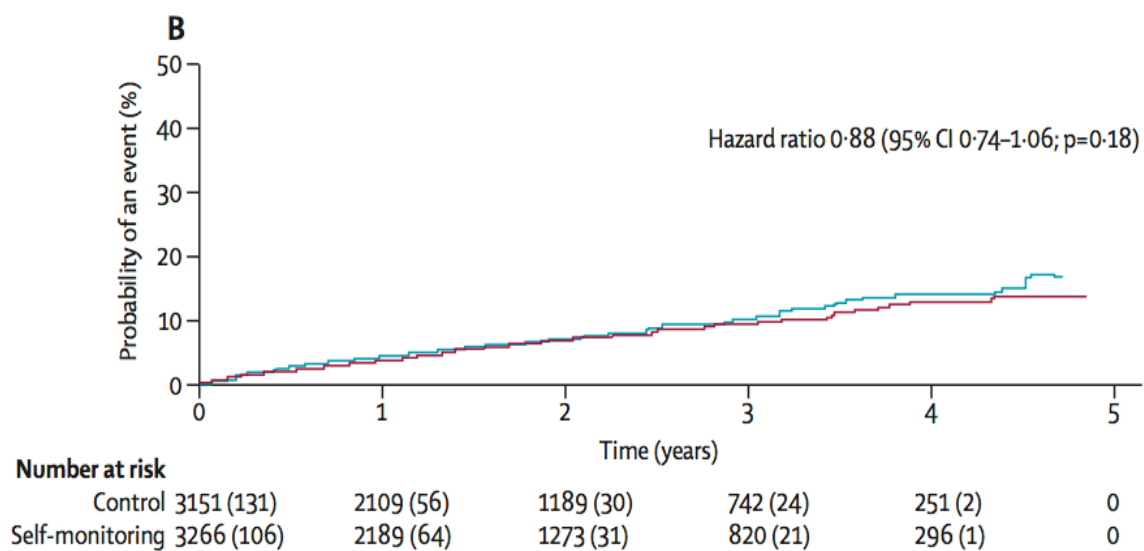
Heneghan et al Lancet 2012

Eventi Tromboembolici



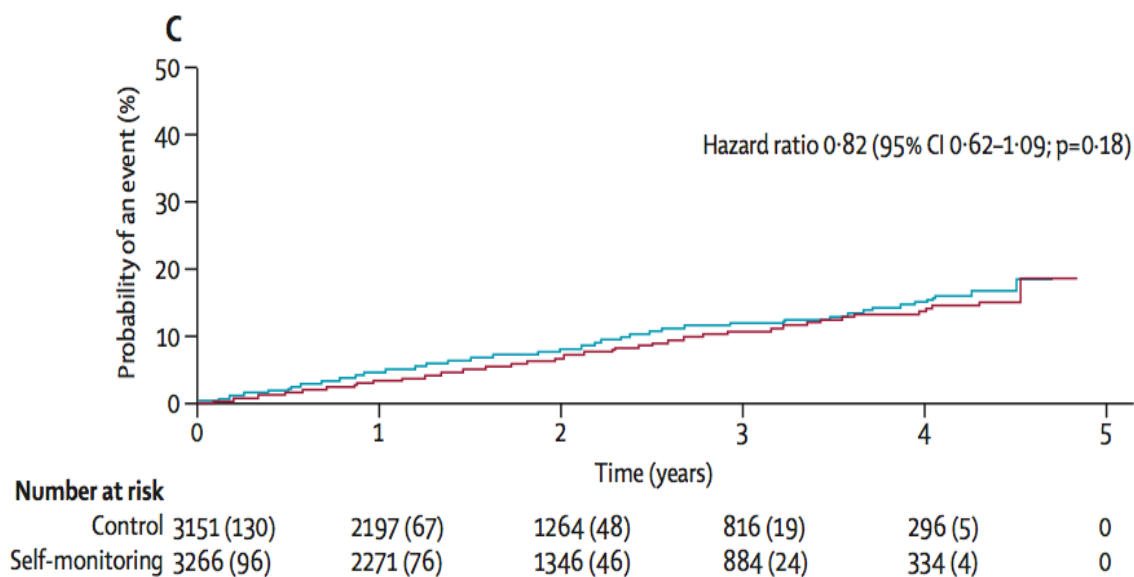
Heneghan et al Lancet 2012

Eventi Emorragici



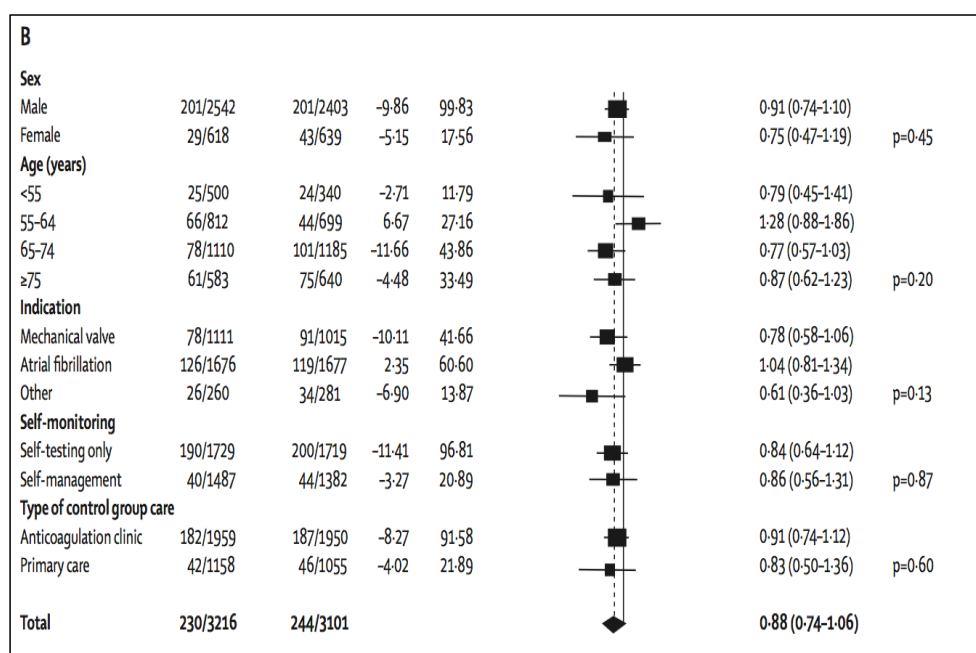
Heneghan et al Lancet 2012

Mortalità



Heneghan et al Lancet 2012

Sottogruppi



Heneghan et al Lancet 2012

TTR e INR Test

AF

	Time in therapeutic range			Number of tests		
	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value
7 days	12.25% (8.99 to 15.51)	0	<0.001	0.25 (0.10 to 0.39)	77%	0.001
30 days	6.13% (-0.09 to 12.35)	72%	0.05	2.28 (1.59 to 2.97)	94%	<0.001
6 months	5.13% (-1.13 to 11.40)	79%	0.11	12.71 (9.33 to 16.10)	96%	<0.001
1 year	2.71% (-6.10 to 11.51)	94%	0.55	24.22 (18.40 to 30.04)	93%	<0.001

Data % or % (95% CI).

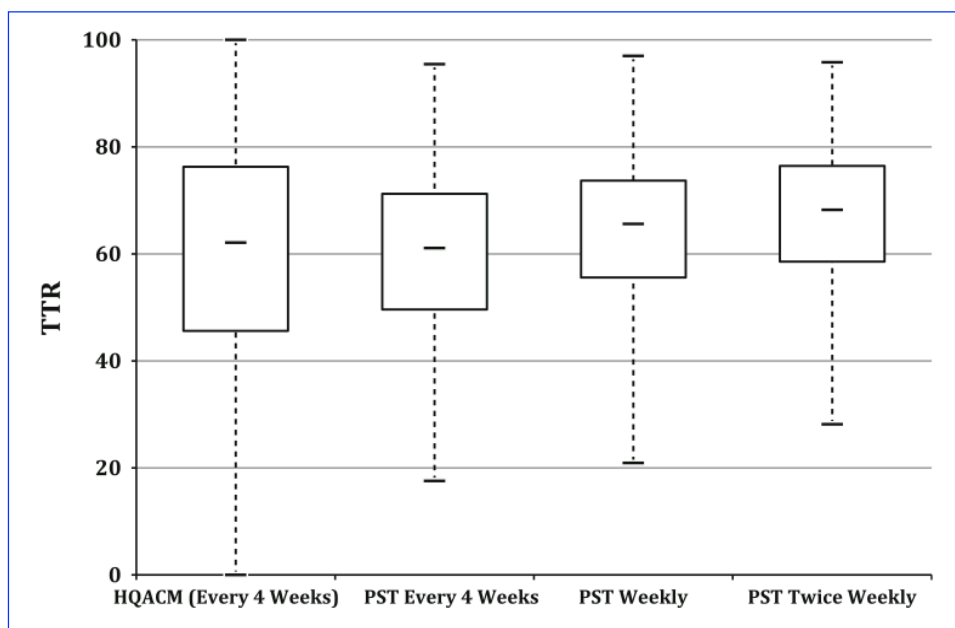
MHV

	Time in therapeutic range			Number of tests		
	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value
7 days	10.38% (8.56 to 12.20)	0%	<0.001	0.01 (-0.25 to 0.28)	92%	0.91
30 days	3.16% (-4.07 to 10.39)	77%	0.39	1.78 (0.97 to 2.60)	97%	<0.001
6 months	4.40% (-0.86 to 9.67)	79%	0.10	12.03 (7.46 to 16.60)	99%	<0.001
1 year	5.13% (0.97 to 9.28)	57%	0.02	21.74 (13.11 to 30.37)	98%	<0.001

Data % or % (95% CI).

Heneghan et al Lancet 2012

TTR e INR Test



Matchar et al JTT 2015

POC: Obiettivi x il SSN

- Risparmiare!
- Possibilmente subito, non nel lungo periodo!

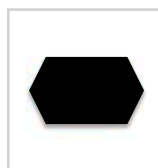



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ASSISTENZA CLIENTI
E ORDINI TELEFONICI

Numero Verde
800 09 66 22

SALDI
di inizio anno
CLICCA QUI
fino al 31 gennaio

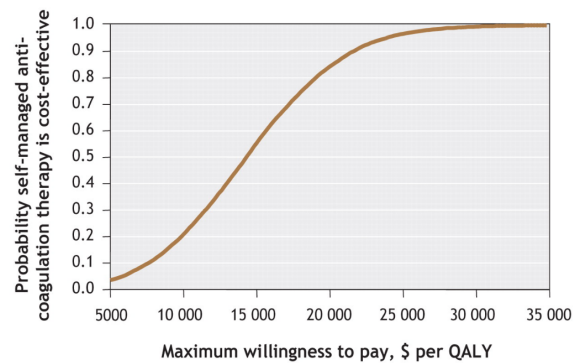
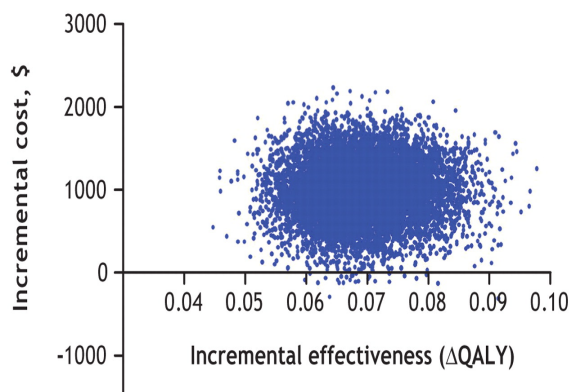
Risultato PT/INR in 1 minuto con una sola goccia di sangue.

Disponibilità: disponibile

Prezzo di listino: ~~€ 787,00~~
Prezzo Amico: € 699,00



Impatto Economico



The cost-effectiveness of self-management was \$14 129 per QALY gained.

Regier et al CMAJ 2006

POC x Tutti ?

bjh guideline

An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation

D. A. Fitzmaurice,¹ C. Gardiner,² S. Kitchen,³ I. Mackie,² E. T. Murray¹ and S. J. Machin² on behalf of The British Society of Haematology Taskforce for Haemostasis and Thrombosis

¹Department of Primary Care and General Practice, The Medical School, The University of Birmingham, Birmingham, ²Haemostasis Research Unit, Haematology, UCL, London, and ³UK NEQAS for Blood coagulation, Rutledge Mews, Sheffield, UK

bjh guideline

An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation

9. Guidelines for patient self-testing or -management of oral anticoagulation

Given the relative lack of evidence, the following recommendations are necessarily consensual (evidence level C).

1. Only patients with long-term indications for warfarin therapy should be considered for self-testing or -management. In exceptional circumstances, patients with short-term indications (e.g. first deep vein thrombosis) may be considered for self-testing, however, it should be noted that it can take 2–3 months before a patient becomes fully accustomed to this method of therapy management.

Fitzmaurice et al BJH 2005

An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation

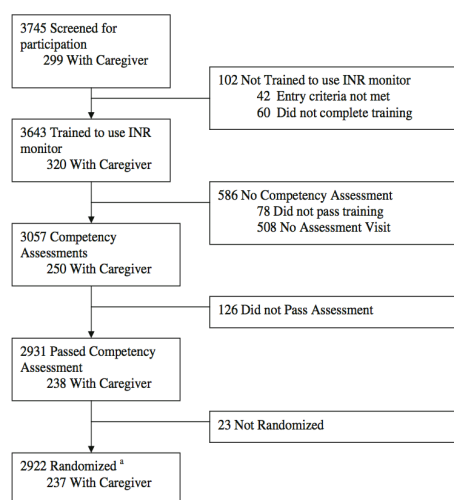
2. Only conformite european-marked devices that have undergone acceptable evaluations by an expert, independent body (e.g. the MHRA in the UK) subject to external peer-review, are to be used for self-testing. Discussions should be held with the local haematologist (where appropriate) and with the Trust POC committee before initiating patient self-testing. Local guidelines and procurement rules should also be checked.
3. Patients (or patient carers) must give informed consent to undertake patient self-management. This will include agreement to attend clinic regularly and to record results accurately.
4. Competence to perform an INR must be assessed by a trained healthcare professional prior to allowing home testing.
5. Competence to correctly interpret an INR result must be assessed by a healthcare professional prior to allowing self-management. This must be based on an individualised patient algorithm (Table IV).
6. Previous stability of INR is not a prerequisite to home testing as unstable patients may benefit from increased autonomy and the possibility of increased frequency of testing.
7. Patients considered for self-testing or -management must have a documented INR target in line with accepted guidelines and clinical practice.
8. Contraindications for patient self-testing or -management will include previous non-compliance, in terms of either attendance at clinic or taking of medication.
9. Patients undertaking self-testing or -management must retain contact with a named clinician. This will, in most

cases, be a consultant haematologist who will be clinically responsible. In all cases the patient's GP and the clinician who initiated the warfarin therapy must be informed.

10. Patients undertaking self-management must be reviewed at least every 6 months by the responsible clinician.
11. Electronic QC where available should be used each time the monitor is used.
12. The IQC material should be analysed when introducing a new batch/lot number of test strips or when commencing use of newly delivered test strips (even when they are the same lot number as used previously).
13. The IQC material should be re-tested if an unexpectedly high or low result occurs.
14. The IQC should be tested every 1 and 3 monthly, or with each test if the interval between testing exceeds 12 weeks.
15. Patients who are self-testing should participate in at least one form of EQA, i.e. one of a, b or c below. If a patient has persistent problems the monitor should be assessed in a centre that participates satisfactorily in a formal EQA programme and patient self-testing should be suspended if persistent problems are unresolved. This is the case whichever option is employed.

..... Fitzmaurice et al BJH 2005

POC x Tutti (ii) ?



Characteristic	Did not pass assessment (n = 126)	Passed assessment (n = 2931)	Total ^a (n = 3057)	P-value
Tester				
Patient alone	112 (89%)	2693 (92%)	2805 (92%)	0.0013
Patient with help from caregiver	12 (10%)	238 (8%)	250 (8%)	
Missing	2 (2%)	0 (0%)	2 (<1%)	
Integrity of cuvettes (good)	116 (92%)	2835 (97%)	2951 (97%)	0.0002
Qualifying test by tester using patient's device and cuvettes				
Able to perform finger stick (yes)	71 (56%)	2925 (100%)	2996 (98%)	<0.0001
Able to obtain INR independently				
Yes, little or no difficulty	31 (25%)	2837 (97%)	2868 (94%)	<0.0001
Yes, lots of difficulty	36 (29%)	93 (3%)	129 (4%)	
Unable to perform test	52 (41%)	1 (< 1%)	53 (2%)	
Missing	7 (6%)	0 (0%)	7 (<1%)	
Cuvette wastage^b (yes)	15 (12%)	28 (1%)	43 (1%)	<0.0001
Number of weeks of testing				
2 weeks	106 (84%)	2698 (92%)	2804 (92%)	0.0016
4 weeks	20 (16%)	233 (8%)	253 (8%)	
Competent to proceed to Part 2 (yes)	0 (0%)	2931 (100%)	2931 (96%)	<0.0001
Adverse event since last contact	0 (0%)	0 (0%)	0 (0%)	-

Dolor et al JTT 2015

Conclusioni

- Ottima efficacia e sicurezza dei POC nei pazienti in AVK
- Effetto mediato dal miglioramento del TTR?
- Necessaria selezione del paziente
- Carico dei costi



In Italia?