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Denmark

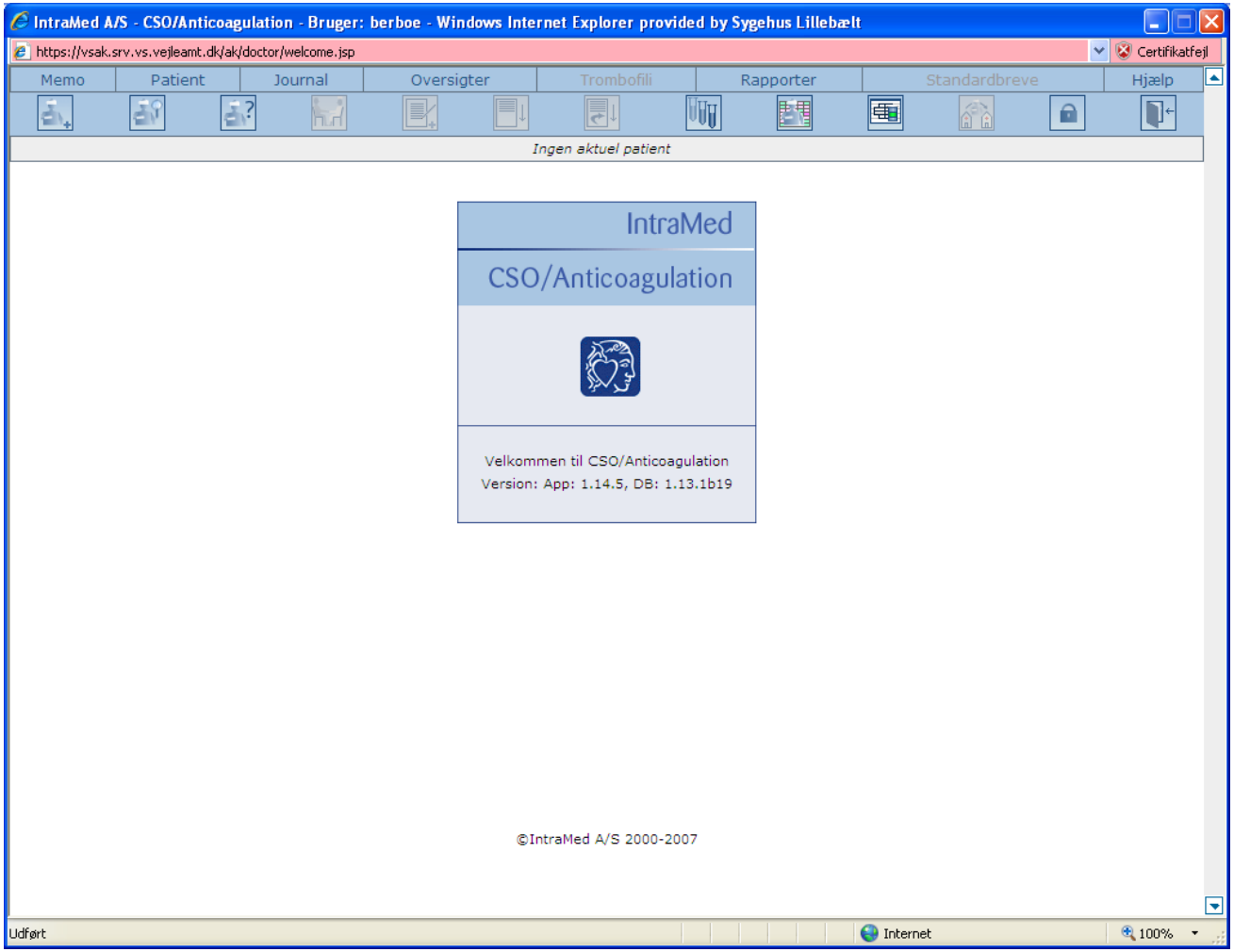
Lillebaelt Hospital

Region of Southern Denmark

E-sundhedsobservatoriets konference 2010

Hjemmemonitorering af patienter i antikoagulations-behandling

EPJ presentation picture



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Untreated laboratory results

Ubehandlede laboratorieresultater

Der er ingen ubehandlede blå laboratorieresultater.

Status	Laboratorie-navn	CPR-nummer	Navn	Resultat	Kommentar	Sidste behandler	Dato	Registrer kontrol
	Vejle Sygehus, AK-Ambulatorium		(BA) Bodil Koch	2,8		evrabr	28.04.2010 19:31	
	Vejle Sygehus, AK-Ambulatorium		Kirstine Thygesen	2,4	Type: NPU01685	padiso	28.04.2010 14:00	
	Vejle Sygehus, AK-Ambulatorium		(BA) Lilli Kirstine Lützen	1,8		evrabr	29.04.2010 08:26	
	Vejle Sygehus, AK-Ambulatorium		Tove Knudsen	3,5	Type: NPU01685	ibr	28.04.2010 14:00	
	Vejle Sygehus, AK-Ambulatorium		(AA) Tonni Nicolai Ersteiner	3,0		halela	29.04.2010 08:51	
	Vejle Sygehus, AK-Ambulatorium		(AA) Lisbeth Kjellstrøm Christensen	2,1		evrabr	29.04.2010 08:38	
	Vejle Sygehus, AK-Ambulatorium		(AA) John Linck	2,7		evrabr	29.04.2010 08:24	
	Vejle Sygehus, AK-Ambulatorium		(AA)Poul Ejersbo	2,4		evrabr	29.04.2010 08:13	
	Vejle Sygehus, AK-Ambulatorium		(CA) Lis Bente Munk Bech	3,0		evrabr	29.04.2010 08:05	
	Vejle Sygehus, AK-Ambulatorium		#Mette Jensen	3,8		ibr	29.04.2010 08:27	

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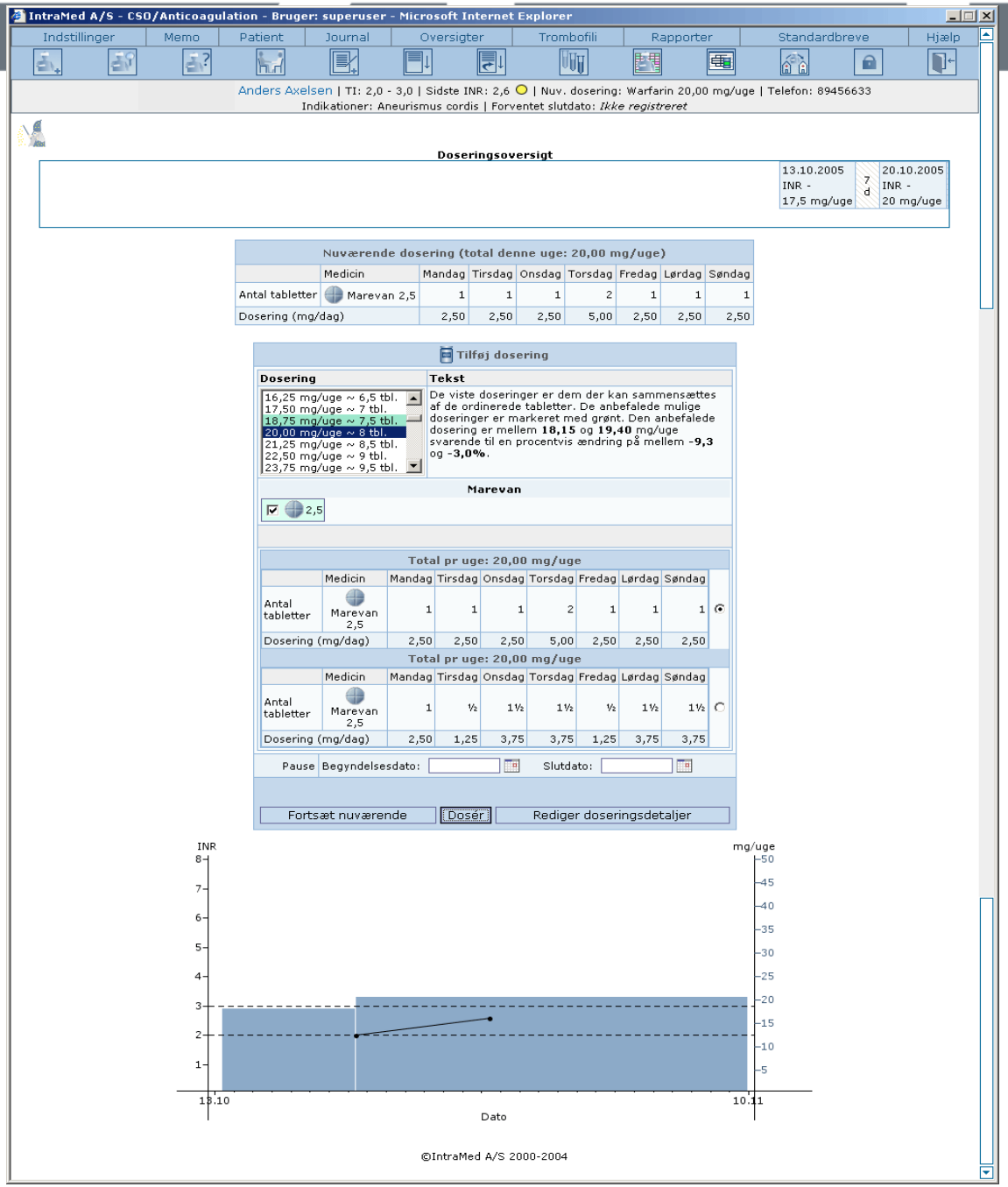
Expert support for correct dosage



Letter to the patient

Test Let
kabbeltoft 25,
7100 Vejle

Vejle 10.11.2009

Doseringsbrev vedrørende Deres blodfortyndingsbehandling

Navn: Test Let
CPR nummer:

Ved blodprøvekontrol den 10.11.2009 var Deres INR 2,2

Fra De modtager dette brev, skal De tage Deres tabletter således:

Medicin		ma	ti	on	to	fr	lø	sø
Antal tabletter	Marevan 2.5	1	1	0	1	1	½	1

Doseringen svarer til 13,75 mg/uge

De skal have blodprøven kontrolleret næste gang den 08.12.2009

Med venlig hilsen
Vejle Sygehus, AK- Ambulatorium

Vejle Sygehus, AK- Ambulatorium, Kabbeltoft 25, 7100 Vejle
Tlf.: 79406509, Fax nr.: 79406877, E-mail: Klinisk.Kemisk.afdeling@vgs.regionsyddanmark.dk, Træffetid: INR kontrol kl. 7.30 - 12.00, Telefontid 11.00-12.00

Agreement between the CSO/AK computer system and the doctor's prescription

	N	%
100% dose agreement	215	74.4
+/- 3% in mg deviation	30	10.4
+/- 3-5 % in mg deviation	30	10.4
+/- 5-8% in mg deviation	9	3.1
> +/- 5-8% in mg deviation, but safe	5	1.7
>+/- 8% and unsafe	0	0
Total	**289**	**100**

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Comparison between manually or paper based AC and computer CSO/AC guided AC: Ability to obtain correct target area at the next visit

	Paper based 382		Computer based *) 326	
	N	**%**	**N**	**%**
Correct hit interval	268	70.1	223	68.4
Deviation < +/- 0.5 INR	93	24.5	74	22.6
Deviation < +/- 1.0 INR	18	4.7	24	7.4
Deviation > 1.0 INR	3	0.8	5	1.5
*) CSO/AC was followed, - in daily practise only used as a guideline				

Deaths among 741 patients on AC during 1 year

Indication	No of patients	Deaths	Age	Causes of death		
				Not related to AC (terminal cancer etc.)	Thromboembolism	Hemorrhagia
Atrial fibrillation	329	22	80.6	15	4	3
Deep venouos thrombosis	68	5	70.2	5	0	0
Artificial heart valves	62	0	-	0	0	0
Pulmonary embolus	43	2	60.0	2	0	0
Cerebral ischemia	30	0	-	0	0	0
Cardiac disease	19	1	79.0	1	0	0
Thrombophilia genes, anti-phosfolipid syndrome and other causes	190	10	69.8	7	1	2
Total	**741**	**40**	**♂73.3 ♀77.0**	**30**	**5**	**5**

Major non-fatal hemorrhage, treated in hospital during AC

Diagnosis	Indication for AC	INR at admission	Caused by AC	Amplified by AC	Unrelated
Colon polyposis	Unspecified	2.6	0	0	1
Colon polyposis	Artif.heart valves	1.5	0	0	1
Colon polyposis	Artif.heart valves	7.6	0	1	0
Gastrointestinal	Isch.heart dis.	1.6	0	0	1
Gastric ulcer	Artif. Heart valves	3.6	0	1	0
Haemorrhoids	Artif.heart valves	7.2	0	1	0
Haemorrhoids	Atrial fib.	3.6	0	1	0
Rectal bleeding	DVT + pulm. Emb.	2.5	0	1	0
Haemoptysis	Pulm. Embol.	4.5	0	1	0
Haemoptysis	Atrial fib.	1.9	0	1	0
Haemoptysis	Atrial fib.	1.9	0	1	0
Hematuria	Atrial fib.	4.7	0	1	0
Hematuria	Atrial fib.	5.6	1	0	0
Cerebral hem.	Artif.heart valves	1.7	0	0	1
Subdural traum.	Unspecified	2.3	0	1	0
Oesophag. ulcer	Vascul.prosthesis	2.5	0	1	0
Epistaxis	Unspecified	1.1	0	0	1
Vaginal	Atrial fib.	15.0	1	0	0

Non-fatal thromboembolism, treated in hospital during AC

Diagnosis	Indication	INR at admission	Caused by insuff. AC	unrelated
Thrombosis ext. Inf. + DVT	atrial fib.	1.6	1	0
Cerebral infarct	Artif. Heart valves	4.0	0	1
Cerebral ischemia	Artif. Heart valves	2.2	0	1

CoaguChek®XS

fra Roche Diagnostics

XS …

for eXtra

- **Small**
- **Simple**
- **FaSt**
- **PreciSe**
- **Safe**

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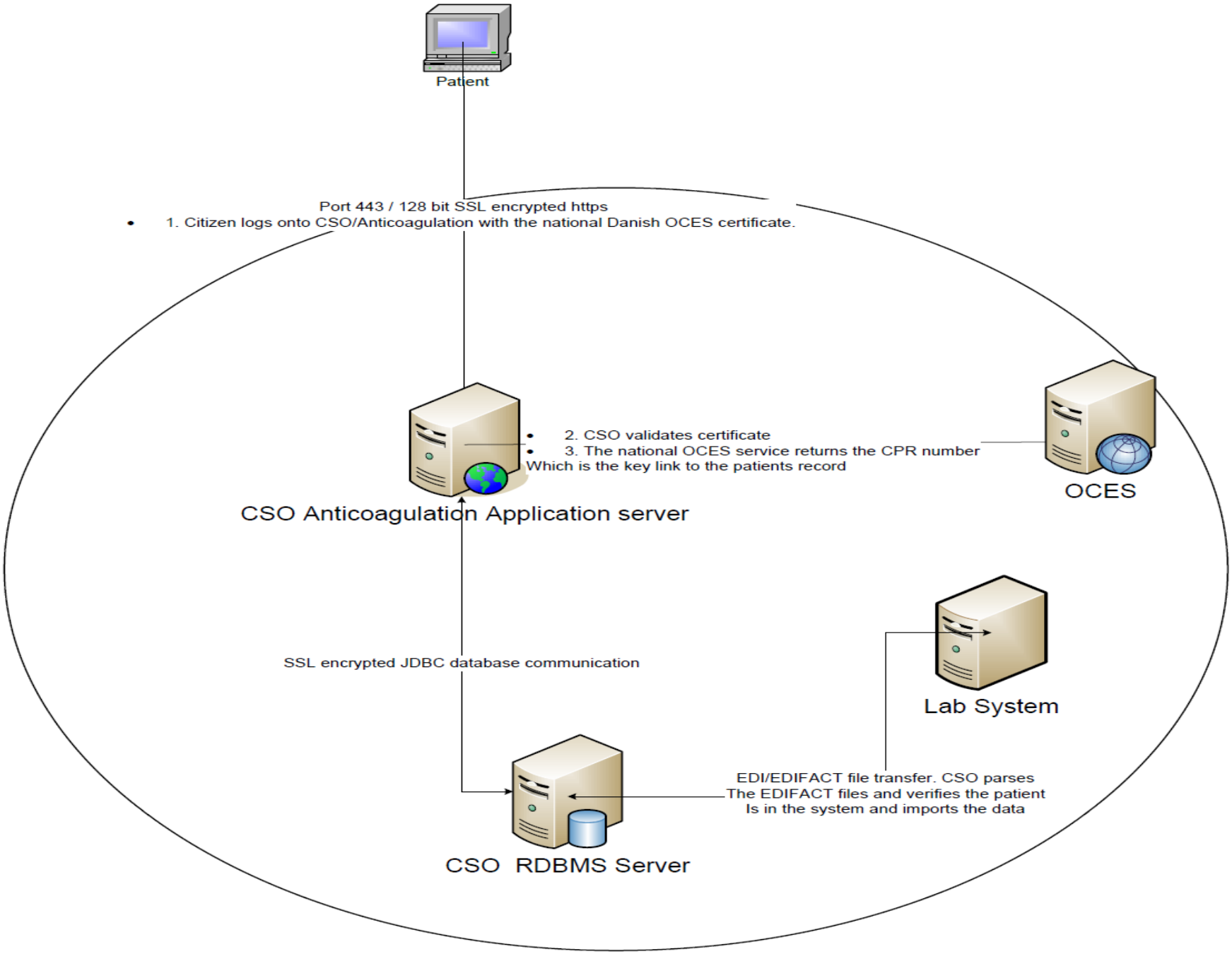
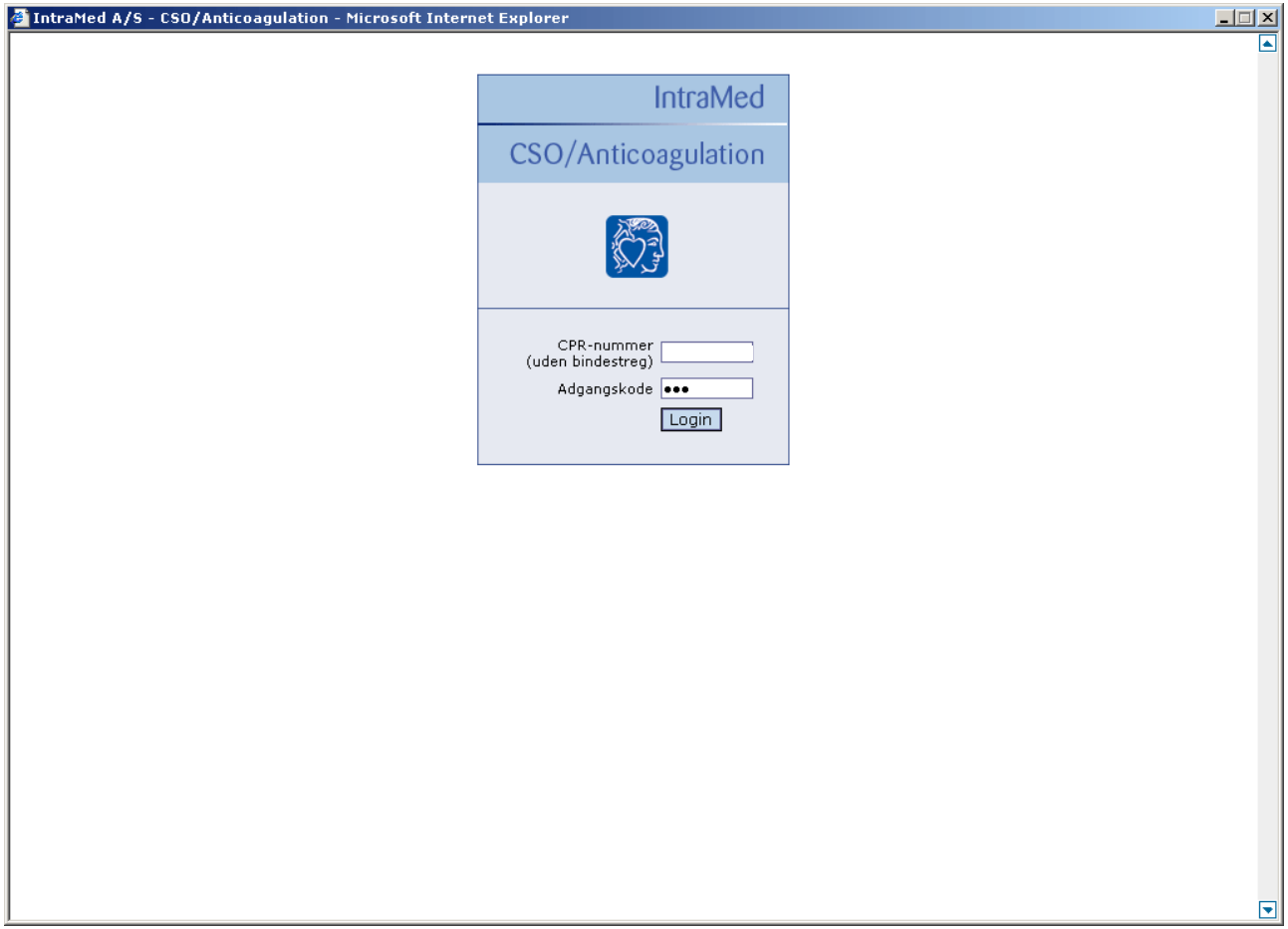

Patient
Port 443 / 128 bit SSL encrypted https
1. Citizen logs onto CSO/Anticoagulation with the national Danish OCES certificate.
2. CSO validates certificate
3. The national OCES service returns the CPR number
Which is the key link to the patients record
OCES
CSO Anticoagulation Application server
SSL encrypted JDBC database communication
Lab System
EDI/EDIFACT file transfer. CSO parses
The EDIFACT files and verifies the patient
Is in the system and imports the data
CSO RDBMS Server

Storyboard – Patient Self Testing



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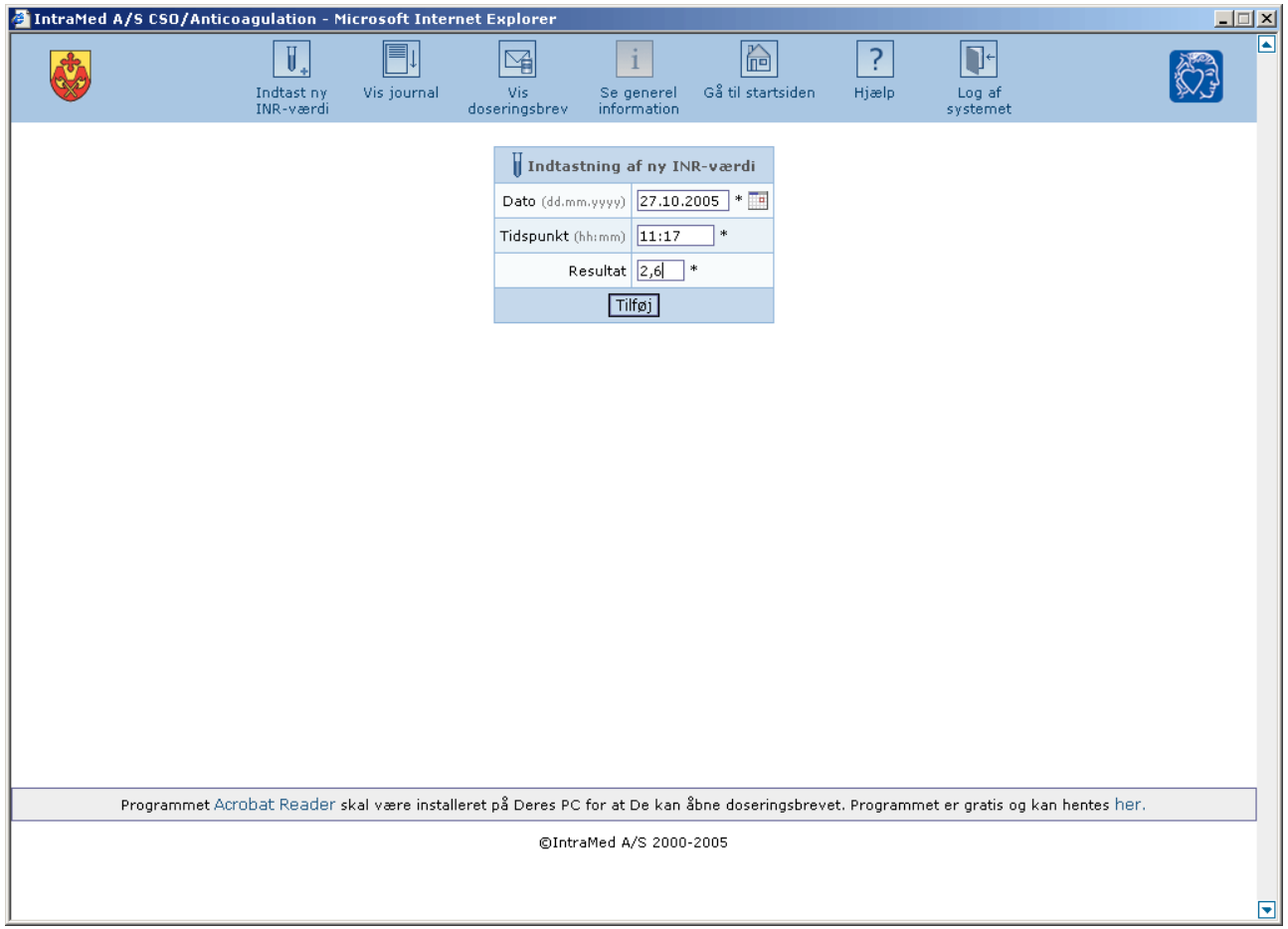
Input of new INR-value



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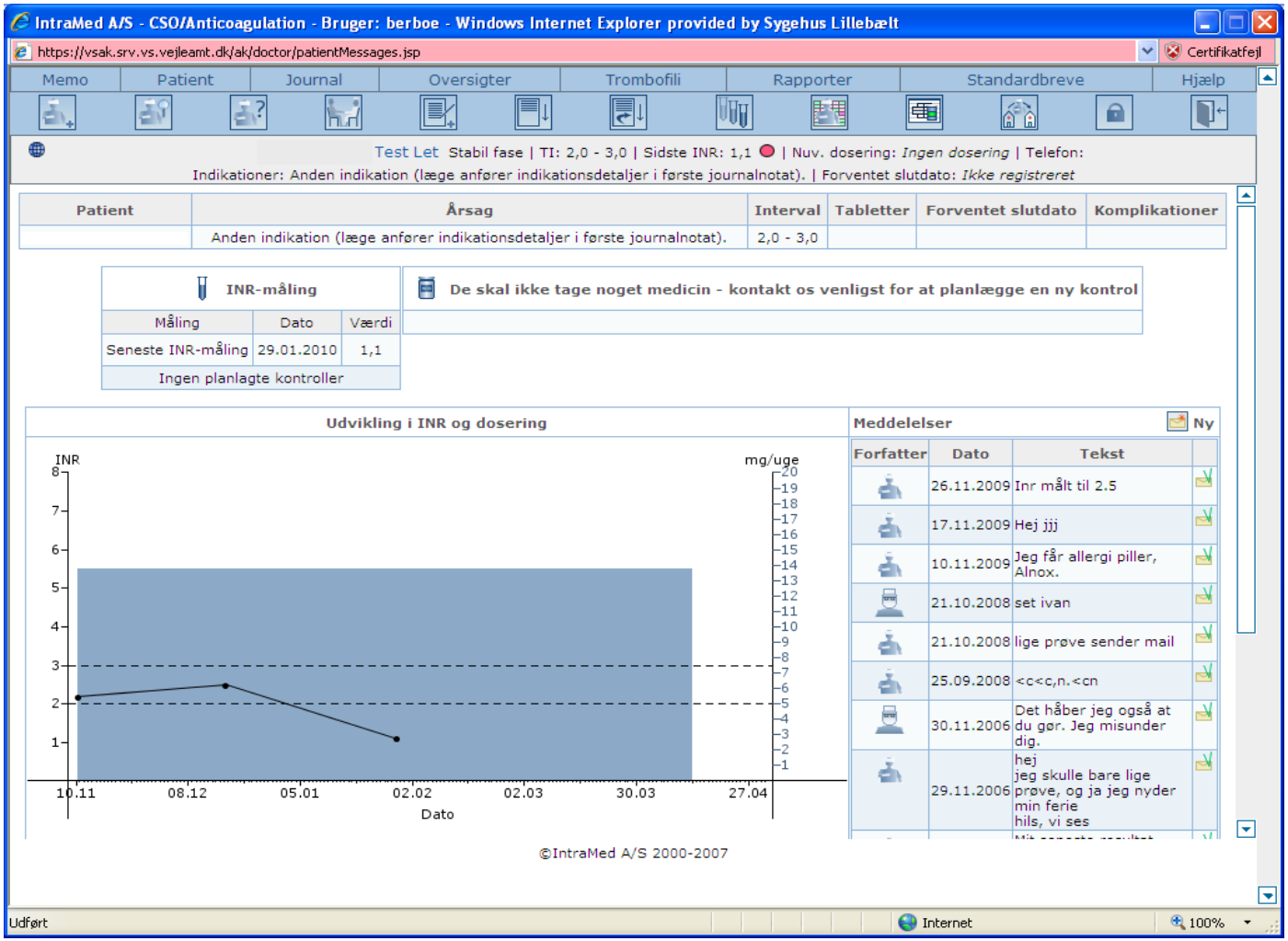
E-mail correspondence with the patient via the CSO-system



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	AC clinic	Study pop.
Number	669	123
Mean Age (range)(p=?)	66.9(19-93)	63.5(21-86)
Male (%)(p=0.018)	424(63.3)	92(74.8)
Female (%)	245(36.6)	31(25.2)
Race		
Caucasian	668	123
Other	1	0
Indication (numbers (%))(p=0.51)		
Cardiac aneurysms	4(0.6)	2(1.6)
Antiphospholipid syndrome	6(0.9)	4(3.25)
Atrial fibrillation	357(53.4)	71(57.7)
Cardiomyopathy	19(2.8)	7(5.7)
DVT/PE (deep vein thrombosis/pulmonary embolism)	109(16.3)	25(20.3)
Factor II and V mutation	2(0.3)	
Ischaemic heart disease	13(1.9)	2(1.6)
Prosthetic heart valves	83(12.4)	23(18.7)
Mistral stenosis	1(0.1)	
Cerebral infarct/cerebral ischaemia	65(9.7)	18(14.6)
Other	45(6.7)	9(7.3)

Study population

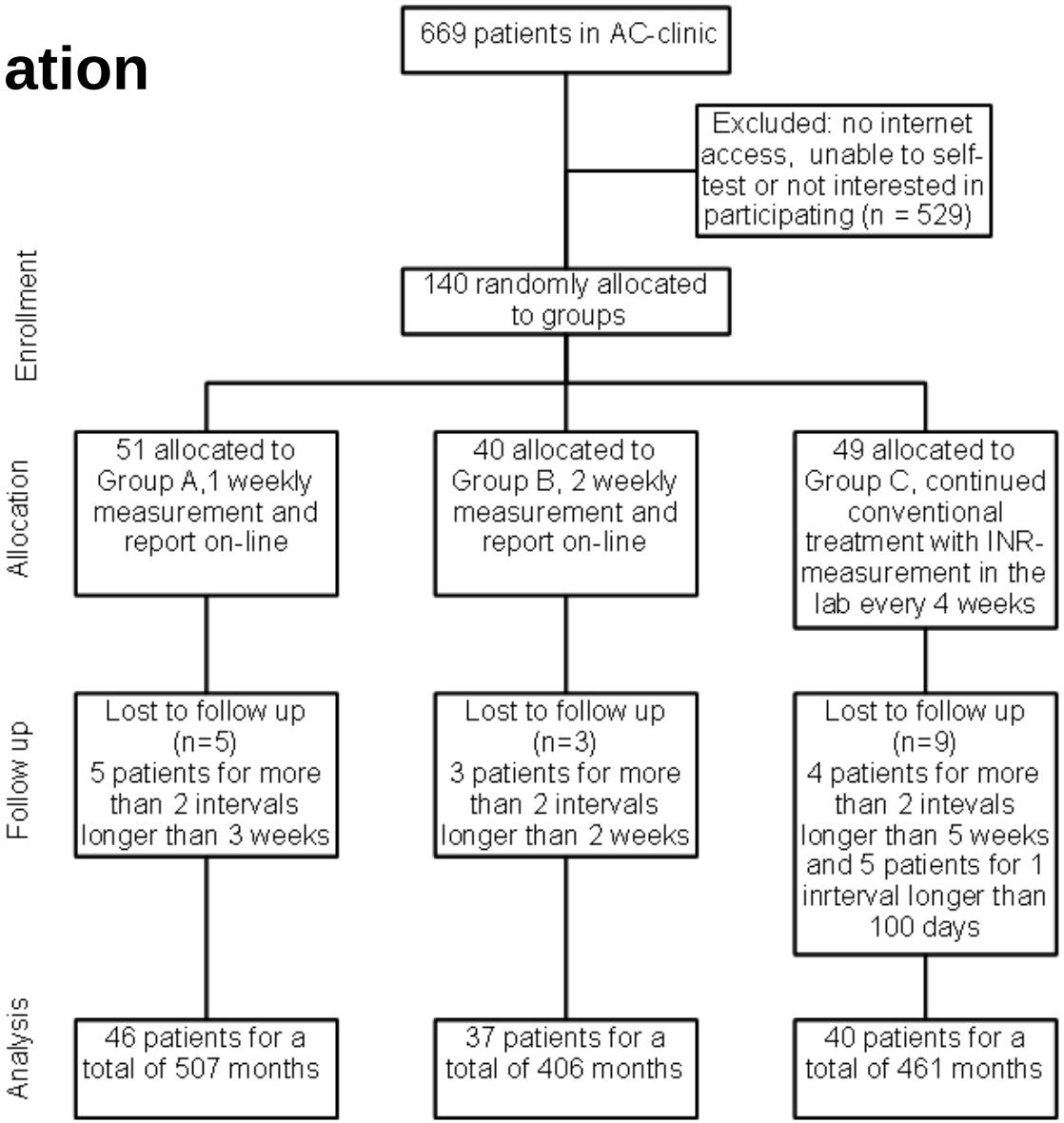
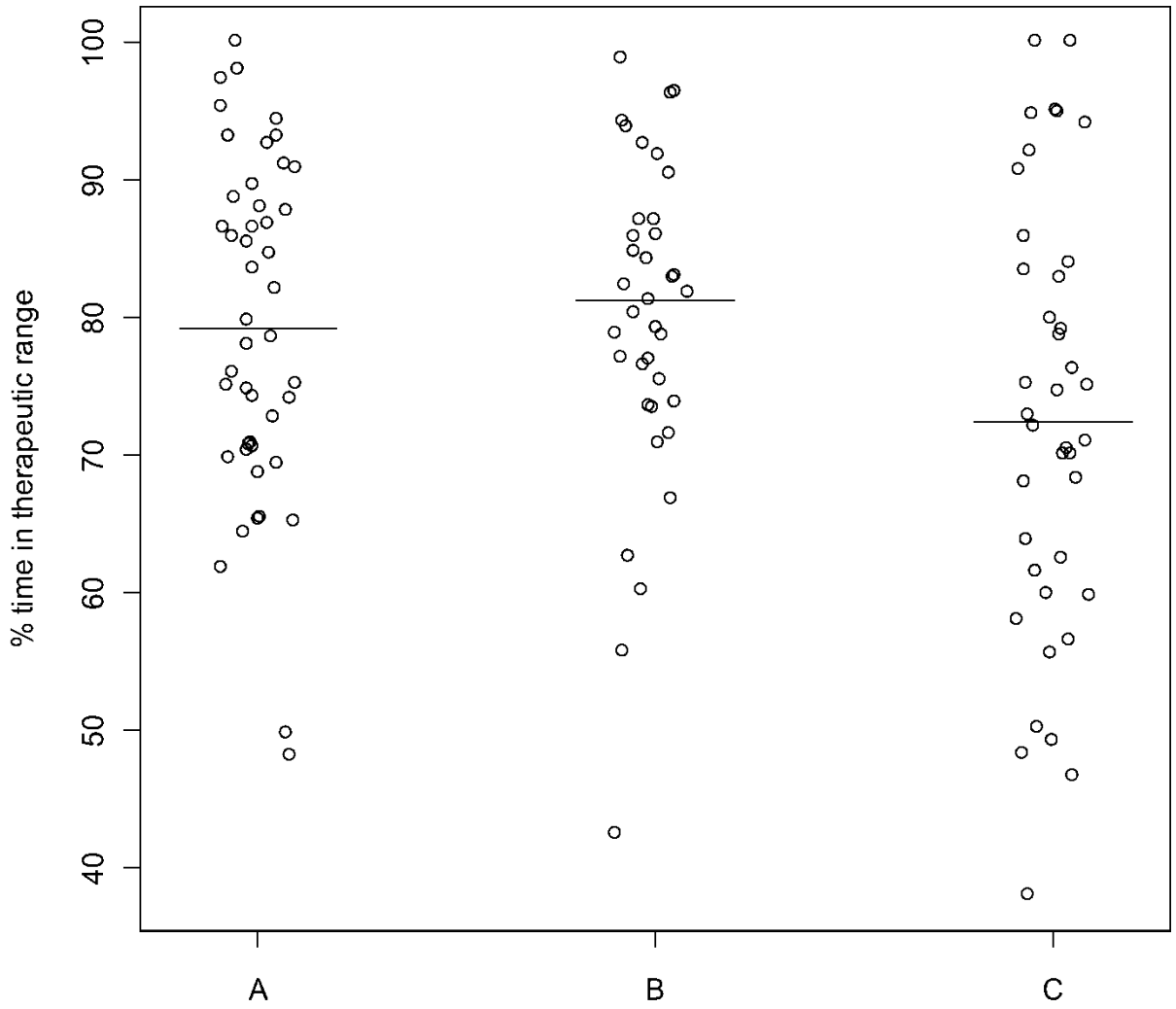


Table 1 Patient demographics

	AC clinic	Group A	Group B	Group C
Number	669	46	37	40
Mean Age (range)	66.9(19-93)	61.6(21-83)	63.3(34-86)	66.0(49-82)
Gender				
Male (%)	424(63.3)	32(69.6)	25(67.6)	35(87.5)
Female (%)	245(36.6)	14(30.4)	12(32.4)	5(12.5)
Race				
Caucasian	668	46	37	40
Other	1			
Indication (numbers (%))				
Cardiac aneurysms	4(0.6)	1(2.2)	1(2.7)	
Antiphospholipid syndrome	6(0.9)	2(4.4)	2(5.4)	
Atrial fibrillation	357(53.4)	25(54,4)	19(51.4)	27(67.5)
Cardiomyopathy	19(2.8)	3(6.5)	2(5.4)	2(5.0)
DVT/PE	109(16.3)	9(19.6)	7(18.9)	9(22.5)
Factor II and V mutation	2(0.3)			
Ischaemic heart disease	13(1.9)	1(2.17)		1(2.5)
Prosthetic heart valves	83(12.4)	7(15.2)	7(18.9)	9(22.5)
Mistral stenosis	1(0.1)			
Cerebral infarct/cerebral ischaemia	65(9.7)	6(13.0)	6(16.2)	6(15.0)
Other	45(6.7)	3(6.5)	4(10.8)	2(5.0)
Target INR range (numbers (%))				
1.8-2.5	3(0.4)			
1.8-2.7	1(0.1)			1(2.5)
1.8-2.8	1(0.1)	1(2.2)		
2.0-2.5	28(4.2)		1(2.7)	1(2.5)
2.0-3.0	590(88.2)	39(84.8)	31(83.78)	36(90.0)
2.5-3.0	4(0.6)			
2.5-3.5	36(5.4)	5(10.9)	4(10.8)	1(2.5)
3.0-4.0	6(0.9)	1(2.2)	1(2.7)	1(2.5)

Abbreviations: DVT, deep venous thrombosis; PE, pulmonary embolism; INR, international normalized ratio



<fig 2>

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Table Wilcoxon signed rank test of differences in individual mean doses and standard deviation(SD) before and in the trial

-	Mean weekly dose mg/week (range)		p-value	Mean SD of weekly dose mg/week		p-value
	Before trial	In trial		Before trial	In trial	
A	39.1(5.5-144.2)	38.9(5.8-131.1)	0.8813	2.15	1.95	0.8660
B	35.6(10.8-60.2)	36.8(16.8-66.6)	0.1815	2.29	1.79	0.3992
C	37.4(5.7-88.4)	38.3(6.1-90.1)	0.06728	1.68	1.93	0.5112

Table Chi-squared test on INR measurements in and outside TR, for the three groups before trial and in the trial

-	INR measurements in and outside TR(%)		p-value
	Before trial	In trial	
A	323/133 (70.8/29.2)	1635/452 (78.3/21.7)	0.0005576
B	295/158 (65.1/34.8)	2407/572 (80.8/19.2)	$3.035\ 10^{-14}$
C	307/127 (70.7/29.3)	616/300 (67.2/32.8)	0.198

Table 2 Frequency of testing and extreme INR values

	All before trial	A in trial	B in trial	C in trial
Mean frequency of testing ± SD in days	21.3 ± 11.2	7.4 ± 2.7	4.1 ± 1.8	15.3 ± 8.8
No of extreme INR (<1.5, >5.0) (%)	23(1.7)	16(1.2)	21(0.7)	31(3.4)
No of < 1.5 (%)	23(1.7)	13(0.6)	16(0.5)	25(2.7)
No of > 5.0 (%)	0(0.0)	3(0.1)	5(0.2)	6(0.7)

	No of patients	Months	Avg. months per patient	Days in TR(%)(95% confidence interval)	p-value
A	46	507.2	11.03	12288(79.7) (79.0-80.3)	$<2.2\ 1^{16}$ (A vs. C)
B	37	406.0	10.97	9904(80.2) (79.4-80.9)	$<2.2\ 10^{-16}$ (B vs. C)
C	40	461.0	11.52	10195(72.7) (71.9-73.4)	-

	No of patients	Months	Avg. months per patient	p-value	No of INR measurements in TR(%) (95% confi-dence interval)	p-value	p-value
A	46	507.2	11.03	0.2516 (A vs. B)	1635(78.3) (76.5-80.1)	$1.046\ 10^{-10}$ (A vs. C)	0.0321 (A vs. B)
B	37	406.0	10.97	-	2407(80.8) (79.3-82.1)	$<2.2\ 10^{-16}$ (B vs. C)	-
C	40	461.0	11.52	-	616(67.2) (64.1-70.2)	-	-

The TTR of 80% is to our knowledge the highest published value in RCT until now. A recent paper had a TTR with conventional versus PST of 59% and 74%, but with wide confidence intervals caused by a relatively low number of 66 observation years for 132 patients, and with measurement every 4.6 days. The Dabigatran study had only 60% in TTR, using conventional management.

The absolute value of TTR is important as it is a marker for the risk of bleeding and thrombosis. A 10% difference in TTR thus corresponds to an increased risk of 1.29 for mortality, 1.10 for stroke, and 1.12 for other thrombotic events.

When comparing PSM (testing and self dosing) against PST as in this paper, it seems that quality of management is better with PST, 79.7% of time in TR against 70.2-74% for PSM.

Conclusion

Home measurement of INR weekly and the reporting and dosing of results on-line increase time in therapeutic range from 73% to 80% as compared to conventional computer assisted monitoring in an AC-clinic.

1. august 2010

Telemedicinens indvirkning på et patientforløb

Et effektstudie i følgekonsekvenserne ved implementering af Telemedicin

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Martin Schmidt Lauridsen &
Christian Benjamin Bokmand

Vejleders navn
Lars Haahr

ITKO Speciale afhandling
Århus Handelshøjskolen
1 August 2010
Åben hylde

Region of Southern Denmark