EVALUATION 0F A BEDSIDE MONITOR OF INTERNATIONAL NORMALISED RATIO (INR) IN HEMODIALYSIS PATIENTS ON ACENOCOUMAROL

Dimitrios Hadjiyannakos[1], Vassilis Filiopoulos[1], Georgios Loukas[1], Sotirios Pagonis[2], Christos Andriopoulos[3], Athina Drakou[3], Dimosthenis Vlassopoulos[1]

[1]Nephrology and [2]Blood Transfusion Departments «Sismanogleio-Amalia Fleming» Hospital, Athens, Greece; [3]NEFROIATRIKI Renal Unit, Athens, Greece

Background

End-stage renal disease (ESRD) patients exhibit an increased risk of bleeding compared with non-chronic kidney disease patients due to several factors including heparin use during dialysis. In ESRD patients receiving vitamin K antagonists (acenocoumarol is the most widely used oral anticoagulant in Greece) the intensity of anticoagulation must be monitored frequently with prothrombin time, expressed as, INR. The use of a portable International Normalized Ratio monitor is considered a safe and effective alternative to laboratory INR testing for oral anticoagulation monitoring. There is paucity of data on a similar use of this device in the management of hemodialysis patients on chronic P.OS anticoagulation treatment.

Aim

We conducted a prospective study to determine the safety and reproducibility of portable device INR values compared to standard laboratory in hemodialysis patients receiving acenocoumarol therapy.

Methods

• From a pool of 87 chronic hemodialysis patients, 18 patients receiving acenocoumarol, at least 1 month before enrollment, were included in the study. Patient characteristics are summarized in Table 1.
• During a 6 month period, each patient provided at least 4 blood samples. Blood samples were drawn from the vascular access (fistula, graft or permanent venous catheter: 10, 5 and 3 patients, respectively), immediately before hemodialysis session and heparin initiation. In patients with a central venous catheter blood sampling was performed after withdrawal of 5 cc of blood from each limb. In each sample prothrombin time/INR was tested by laboratory method and by the portable device in the Dialysis Unit.
• For laboratory plasma prothrombin time/INR measurement blood samples were collected in 3.8% citrated tubes and thromboplastin reagent was used with an International Sensitivity Index (ISN) of 1.0. Portable device measurement was performed by applying a drop of blood directly to the single-use test strip of a CoaguCheck XS (Roche diagnostics).
• During the study, acenocumarol dose adjustments were based on the plasma INR results.
• Mean INR values were compared using paired t-test, with statistical significance at P<0.05. Bland-Altman plots were used to illustrate the degree of agreement or divergence between the two methods.

Table 1. Patient characteristics

Age (median, range) years	71 (57-87)
Sex (Men,/Women)	11/7
Hemodialysis duration (median, range) months	63 (6-372)
Primary nephropathy	
Glomerulonephritis	2
Nephrosclerosis	1
Diabetic nephropathy	3
Chronic pyelonephritis	1
Polycystic kidneys	1
Unknown	10
Vascular access	
Fistula	10
Graft	5
Central venous catheter	3
Acenocoumarol indication	
Atrial fibrilation	13
Mechanical heart valve	5
INR goal range	
2.0 – 2.5	13
3.0 – 3.5	5

Results

• The 18 study patients provided 79 blood samples and there were 158 INR measurements. Excellent correlation was obtained between portable device and laboratory INRs values (r=0.95, p<0.0001, Figure 1).

• According to Bland-Altman analysis the mean difference between portable device and laboratory INRs measurements was 0.03 with 95% limits of agreement between -0.43 και 0.49 (Figure 2).

• Measured INR values differed by 0,5 in one and ≥ 1 units in two samples (one in the case of sampling via a permanent catheter). In no instance there were conflicting INR results indicating different dose alterations in the opposite direction from the paired INR.

• In only 7 occasions a change in acenocoumarol dose was suggested either by the portable device or the laboratory but not by both.

• There were no major hemorrhagic or thromboembolic complications during the study period. A patient that presented with epistaxis was treated with a posterior nasal packing.

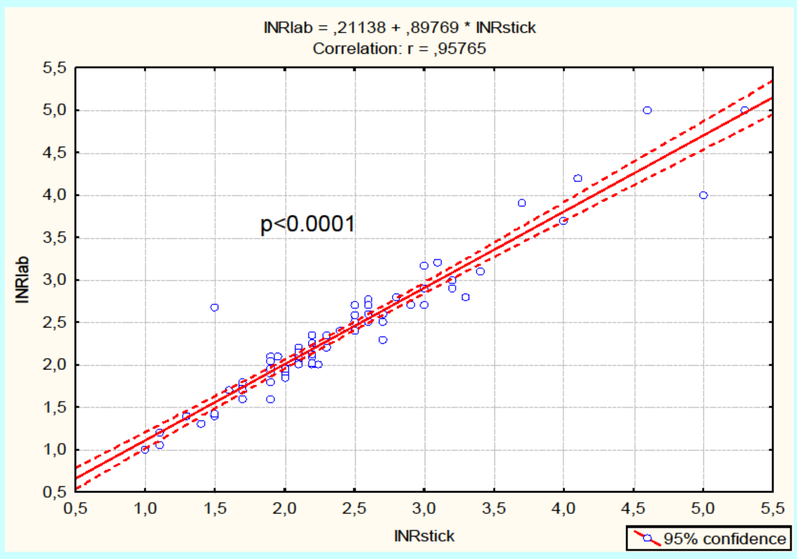

Figure 1.
Correlation of laboratory (INRlab) and portal device (INRstick) INR values.

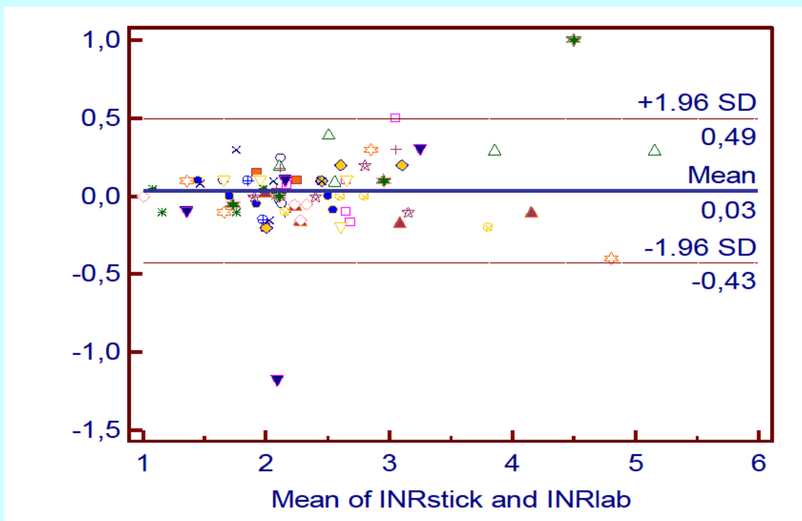

Figure 2.
Bland-Altman plot of the difference of laboratory (INRlab) and portable device INR (INRstick) values vs the mean of the two measurements. Horizontal lines represent the mean difference = 0.03 and 95% limits of agreement –0.43 to 0.49.

Conclusions

• INR controlled by a bedside prothrombin time monitor in hemodialysis patients on P.Os anticoagulation, using a blood drop from the vascular access, resulted in an excellent agreement with an in-hospital laboratory INR measurement and with very few discrepant results.
• This immediately available INR results obtained by an easily applied method has the advantage for on time therapeutic decisions in this patient population continually exposed to hemorrhagic adverse events.

References

1. Hoel RW, Albright RC, Beyer LK et al. Correlation of point-of-care INR to laboratory INR in hemodialysis patients taking warfarin. Clin J Am Soc Nephrol 4: 99-104, 2009
2. Sunderji R, Gin K, Shalansky K et al. Clinical impact of point-of-care vs laboratory measurement of anticoagulation. Am J Clin Pathol 123: 184-188., 2005

51ERA-EDTA
522--MP
H) Clinical Nephrology, CKD. H1) Lab methods, progression & risk factors for CKD 1-5, nutrition in CKD, renal diseases (except GNs and cystic diseases).
Dimitrios Hadjiyannakos
DOI: 10.3252/pso.eu.51era.2014
Poster presented at: 51 ERA-EDTA CONGRESS AMSTERDAM THE NETHERLANDS MAY 31 JUNE 3 2014