Performance of a novel fully automated method for the detection of dephospho-uncarboxylated Matrix Gla Protein (dp-ucMGP)

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Background
Matrix Gla-protein (MGP) is one of the strongest inhibitor of vascular calcification, produced by many cells, including vascular smooth muscle cells and chondrocytes. Circulating dp-ucMGP reflects the amount of uncarboxylated MGP produced in the arterial vessel wall and is a direct marker for the vascular vitamin K status. Different studies, using cumbersome ELISA methods, have shown conflicting results regarding the association of dp-ucMGP and abdominal aortic calcification score. We assess the performance of the fully automated IDS-iSYS InaKtif MGP assay (IDS, UK) and compare the results vs. an ELISA method in a cohort of haemodialysis patients.

Materials and Methods
- Precision profile: determined with 4 plasma pool levels twice a day for 10 days.
- Linearity: verified with 2 sets of high/low plasma.
- Method comparison: plasma samples from 175 patients
  - Without Vitamin K supplementation,
  - Under thrice-weekly hemodialysis for at least 3 months,
  - Mean age 68.7±14.4 years,
  - Median dialysis vintage: 21 months (3 – 396)
  - 78 (65.0%) had history of cardiovascular diseases.

Results
- Precision
  Within-run %CV were 2.9 - 8.9%. Total %CV were 4.1 - 13.4%.

- Linearity
  Obtained = 0.95 x Expected + 209, R²=0.99 in 18 dilutions.

Method Comparison
- iSYS = 1.26 x (ELISA) + 420 pM; 95% CI slope: 1.16 – 1.36.
- Pearson correlation r = 0.89 (P<0.0001); 95% CI: 0.86 - 0.92.

Conclusion
- The IDS-iSYS InaKtif MGP is the first fully automated dp-ucMGP kit which will be soon available commercially for the measuring of the dephosphor-uncarboxylated MGP levels.
- Different observations in the studies that used the ELISA method might be explained by its poor linearity in the higher range.
- The dp-ucMGP blood test could be included as part of routine monitoring biomarkers for hemodialysis patients after further proven its clinical validity.

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