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Cardiovascular diseases - Cardiac markers

Cod: T001

NOVEL 10-MINUTE ASSAY FOR RAPID AND SENSITIVE DETECTION OF CARDIAC TROPONIN I

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Background. Acute coronary syndrome (ACS) is the major cause of cardiovascular disability and death worldwide. In its diagnosis, the cardiac troponins (cTn) I and T have gained a central role. Thus, fast and highly sensitive assays for cTn detection are needed in order to ensure the efficient treatment of patients suspected with ACS. Here, our aim was to develop a rapid and sensitive assay for cTnI detection by combining the highly fluorescent europium(III) doped nanoparticles with condensed immunocomplex formation.

Methods. The novel assay used three capture antibodies and one tracer antibody conjugated to 97 nm Eu(III)-nanoparticles. The capture antibodies were immobilized on wells with streptavidin-coated spots (Ø 4 mm). The analyte and tracer were added to the wells in 10 µl and 40 µl, respectively, and incubated for 10 min at +36°C with shaking at 900 rpm. For kinetics studies, the wells were additionally incubated up to 180 min. Fluorescence was measured directly from the washed well surface in a time-resolved mode with Victor X4 Multilabel Counter.

Results. Analytical sensitivity (3SD of blank, n=20) of the novel assay was 1.9 ng/L and the assay gave linear response up to 50,000 ng/L (y=75.0x, R^2=0.992). Equilibrium was reached in 60 min and 120 min with low and medium level samples (≤100 and ≤1,000 ng/L cTnI, respectively) and in 180 min with high level samples (≥5,000 ng/L cTnI). After 10-minute incubation, the low level samples reached >90% of the steady-state. The mean analytical recovery of 5,000 ng/L cTnI was 90% in heparin plasma (n=10). Regression analysis with Abbott Laboratories Architect hs-cTnI assay yielded a slope (95% confidence intervals) of 0.27 (0.21─0.33) and a y-intercept of 5.81 (-1.83─13.45) ng/L (n=30). Correlation between the assays was good (Spearman´s r=0.962, p<0.001).

Conclusions. Utilization of Eu(III)-nanoparticles with condensed binding surface enabled the development of a fast and highly sensitive assay for cTnI detection. Although the validation process is currently ongoing, the present results show a great promise about the performance characteristics of the novel assay.

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Cardiovascular diseases - Cardiac markers

Cod: T002

CELL-FREE DNA AND NUCLEOSOMES ARE INCREASED IN SERA OF PATIENTS WITH OBSTRUCTIVE SLEEP APNEA

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INTRODUCTION
The obstructive sleep apnea syndrome (OSA) is a multifactorial medical condition where the upper airway dimensions are reduced, thus resulting in intermittent hypoxia and an increased cardiovascular risk. It has been suggested as an independent risk factor for cardiovascular events and other cell death-related diseases. However, the pathophysiological mechanisms underlying such relationships are not clear to date.
During cell death, intracellular components are leaked into the bloodstream, so the measurement of nucleosomes and cell-free double-stranded DNA (dsDNA) in serum could help in the understanding of the molecular mechanisms and the high cardiovascular risk seen in patients with OSA.

METHODS
Up to 114 individuals were recruited and underwent a sleep study (polysomnography) in our hospital. OSA was considered when the apnea-hypopnea index (AHI) was ≥10 h-1, and subjects were classified as either controls (N=52) or OSA (N=62). Anthropometric data were registered and blood analyses were performed, including glucose, HDL cholesterol (Architect platform, Abbott), serum dsDNA (Quant-iT Picogreen® dsDNA kit, Invitrogen) and serum nucleosome concentrations (Cell Death Detection ELISA Plus kit, Roche Diagnostics). Student's t-test and linear regression models were used for data comparison. Statistical significance was set at 0.05.

RESULTS
Nucleosome and dsDNA levels were higher in patients with OSA than in controls (nucleosomes: 1.47±0.88AU vs. 1.00±0.33AU; $p<0.001$, dsDNA: 315.6±78.0ng/mL vs. 282.6±55.4ng/mL; $p=0.007$). Both of them also correlated positively with AHI (nucleosomes: $r=+0.562$, $p<0.001$; dsDNA: $r=+0.267$, $p=0.004$)
In a multivariate analysis (adjusting for age, gender, body mass index, glucose, cHDL and systolic blood pressure), both cell death biomarker levels remained statistically different between OSA and the control group ($p=0.049$ and $p<0.001$, respectively).

CONCLUSIONS
Nucleosomes and dsDNA are increased in patients with OSA. Our results highlight that cell death-related mechanisms might be exacerbated in OSA, and could play an important role in the high cardiovascular risk observed in those patients.

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Cardiovascular diseases - Cardiac markers

Cod: T003

GALECTIN-3 IS RELATED TO CARDIAC AND VASCULAR FUNCTION IN HOSPITALIZED PATIENTS WITH ACUTE HEART FAILURE AND PRESERVED EJECTION FRACTION

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Background. Acute heart failure (AHF) syndromes, one of the most common causes of hospitalizations, are related to increased morbidity and mortality. Galectin-3 is released by macrophages in response to inflammation and has been considered to be a marker of myocardial fibrosis but also an independent predictor of cardiovascular and total mortality in heart failure patients. The aim of the study was to investigate the role of Galectin-3 in hospitalized patients with AHF and its association with clinical and biochemical parameters.
Methods. We enrolled 76 consecutive patients admitted in a tertiary cardiology department with a diagnosis of AHF (mean age 71 years, 82% males). All participants were evaluated after clinical stabilization 1-2 days prior to discharge. A complete echocardiogram, vascular function (arterial stiffness) and functional status (6 minute walking test – 6MWT) were assessed in all participants. All patients were followed for 6 months and the occurrence of cardiovascular events (fatal, non-fatal or HF rehospitalization) was investigated.
Results. Galectin-3 levels were positively associated with age ($r=0.272$, $p=0.018$), female gender ($r=0.225$, $p=0.052$), NTproBNP levels ($r=0.224$, $p=0.053$), and inversely with creatinine clearance levels (CrCL) ($r=-0.244$, $p=0.035$) in the total population. In patients with preserved left ventricular ejection fraction (LVEF)>40% (n=30), increased Galectin-3 was associated with female gender, reduced CrCL, increased aortic pulse wave velocity, E/E' ratio and systolic pulmonary artery pressures ($p<0.05$ for all). In patients with LVEF >45% (n=13), there was a strong association of Galectin-3 with LVEF ($r=-0.575$, $p=0.040$) and NTproBNP ($r=0.768$, $p=0.002$), while the presence of LVEF >45% was associated with higher Galectin-3 levels ($r=0.262$, $p=0.025$). No relation was observed between Galectin-3 levels and 6MWT or future events. No significant association between Galectin-3 and other parameters was seen in patients with reduced LVEF.
Conclusions. In patients hospitalized with an AHF syndrome, Galectin-3 was shown to differentially relate to clinical and biochemical parameters according to the HF phenotype. In patients with preserved LVEF, Galectin-3 was associated with natriuretic peptides levels, arterial stiffness and echocardiographic indices of heart congestion. No relation of Galectin-3 with cardiovascular events was observed at 6 month follow-up.

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Cardiovascular diseases - Cardiac markers

Cod: T004

SERUM COPEPTIN (CTPROAVP) AND COPEPTIN/TNI RATIO - A NEW TOOLS TO DIFFERENTIATE TAKOTSUBO CARDIOMYOPATHY FROM ACUTE MYOCARDIAL INFARCTION

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Background: Takotsubo cardiomyopathy (TTC) and ST-segment elevation myocardial infarction (STEMI) have many common clinical features. Today, no established biomarkers are available for the early diagnosis of TTC and differentiation from AMI. Our attention was focused on the two known biomarkers: copeptin and cardiac troponin I (cTnI). We hypothesized that these markers could by used distinction of TTC and STEMI.
Methods: We investigate consecutive 10 female patients (pts) with TTC and compared with consecutive 10 pts with STEMI hospitalized in 1st Department of Cardiology Medical Univeristy od Warsaw. Cardiac troponin I (Siemens Healthcare Diagnostics Ltd.) and copeptin (Phoenix Pharmaceuticals, Inc.) were blindly assayed from venous blood samples obtained at admission. Continuous variables are presented as median with interquartile range (IQR). Categorical variables are shown as number and percentages and analyzed using Fisher's exact test. Receiver operating characteristic (ROC) curve analysis was performed for copeptin and copeptin/cTnI or cTnI/copeptin ratios at baseline as diagnostic parameters using deLong test. The area under the curve (AUC) and optimized cut-off values as the value providing the optimal test accuracy from the ROC curve were also calculated.
Results: The copeptin levels (0,68 ng/mL) were significantly lower in patients with TTC in respect to patients with STEMI (1,55 ng/mL), p = 0,0032. Serum copeptin levels effectively discriminate patients with STEMI (AUC = 0,8596, 95% CI: 0,65-1,00) at the time of admission. The best differentiation of STEMI patients exhibited copeptin concentration 1,31 ng/mL with a sensitivity 0,90% and specificity 0,80%. AUC for copeptin in TTC patients was only 0,1403 (95% CI: 0,00 – 0,35). In our study we have shown that the best parameter differentiating the TTC of STEMI is the ratio of cTnI/Copeptin ≥0,241 with a specificity 0,80% and sensitivity 1,00%. In contrast, copeptin/cTnI ratio ≥ 5,784 identified subjects with a specificity 1,00% and sensitivity 0,80%.
Conclusions: Copeptin seems to be a good biomarker with cTnI to quickly distinguish between patients with TTC from those of STEMI. The ratio of copeptin/cTnI may be additionally useful tool for non-invasive differentiation TTC and STEMI at admission.

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Cardiovascular diseases - Cardiac markers

Cod: T005

HIGH SENSITIVITY TROPONIN HAS NO UPPER LIMIT OF NORMAL

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BACKGROUND
This is an extension of the study reported two years ago which showed that cardiovascular-disease-free survival of hospital patients in whom troponin was measured was stratified by the peak troponin measured during the episode of hospital care. That study the examined outcomes following Abbott TnI assay; this one examines outcomes following troponin measurement with the Abbott hsTnI assay which was released for clinical use in April 2014.

METHODS
Records of all patients in an acute general hospital serving a population of about 460,000 who had troponin-I (Abbott Architect high-sensitivity assay) measured over a 2.5 year period from 15 April 2014 to 27 September 2016 were extracted in October 2016 to determine the patients' outcomes. During this period, the laboratory recommended a reference range <25ng/L and reported results below 2ng/L as "<2".

The patients' troponin assays were organised into "episodes of care", defined as one or more troponin assays with no intervening interval greater than 24 hours. During the study period the hospital laboratory performed 82,712 troponin assays comprising 51,545 episodes of care in 32,737 patients. These episodes had a single troponin assay in 27,670 cases, two assays in 18,822 cases, and 3 or more assays in 5053 cases.

The patients' survival curves were stratified by peak troponin within an episode, where "cardiovascular disease (CVD) free survival" was defined as absence of a record of death, or of subsequent readmission to hospital with a diagnosis of CVD. The survival curves showed clear stratification by peak troponin in outcomes for all time periods.

CONCLUSONS
We have confirmed with the high-sensitivity assay our finding with the previous assay that CVD-free survival is predicted by troponin in a continuous fashion, with lower troponin indicating better outcome. There is no "upper limit of normal" for troponin in acute hospital patients.

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Cardiovascular diseases - Cardiac markers

Cod: T006

LP-PLA2 AND MPO IN PATIENTS WITH SUSPECTED MYOCARDIAL INFARCTION

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Background
Cardiovascular disease is the most common cause of death in developed countries. There is still need for biomarkers used in prediction and diagnosis of acute myocardial infarction (AMI). We aimed to evaluate 2 biomarkers in this topic – Lipoprotein-associated phospholipase 2 (Lp-PLA2) and myeloperoxidase (MPO).
Methods:
44 patients with chest pain admitted to the Department of cardiology with suspected myocardial infarction were enrolled in this study. In all patients blood samples were collected immediately on admission (sample A), then 6 h (sample B) later and finally 12 hours after admission (sample C). In all samples cardiac troponin I (cTnI), MPO and Lp-PLA2 concentrations were measured. MPO and cTnI levels were measured using ARCHITECT immunochemical assay kit. Lp-PLA2 levels were measured by ELISA kit using microtiter plate reader. According to the clinical diagnosis patients were divided into two subgroups – patients with myocardial infarction (MI) and patients without myocardial infarction (nonMI). For statistical analysis R software (version 3.1.3) was used. Wilcoxon non-parametric test (paired version) was used for comparisons between both groups. Kruskal-Wallis test was used for comparison of changes in concentrations in samples A, B and C in both subgroups. P-value <0.05 was used as statistically significant.
Results:
In comparison with nonMI patients, MI patients showed statistically significant difference in TnI ($p<0.001$) and MPO ($p<0.001$) concentrations, however Lp-PLA2 levels did not show statistically significant difference ($p=0.92$) in any of the sampling time points.
Time changes (samples B and C in comparison with sample A) showed statistically significant increase in TnI levels ($p=0.003$) and statistically significant decrease in MPO levels ($p=0.003$ resp.) in MI patients, however Lp-PLA2 levels did not show statistically significant differences in this group ($p=0.44$). In nonMI patients any of measured parameters did not show statistically significant changes in all mentioned parameters.
Conclusions:
MPO shows significant changes during acute myocardial infarction. However, its role in AMI diagnosis should be elucidated. Lp-PLA2 doesn´t seem to give any additional information in AMI diagnostics.

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Cardiovascular diseases - Cardiac markers

Cod: T007

SUBPOPULATION OF LYMPHOID CELLS ANALYSIS FOR RISK PROGNOSIS IN INFECTIVE ENDOCARDITIS.

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BACKGROUND-AIM.Infective endocarditis (IE) - a life-threatening disease with rapid development of heart failure and high risk of fatal complications. Infection process, immunological reactions and systemic inflammatory process in addition with cardiac tissue damage are considered as main mechanisms of disease. The purpose of the study was to investigate role subpopulation of lymphoid cells analysis for prediction of prognosis in IE.
MATERIALS AND METHODS. The subpopulation of lymphoid cells were analyzed on admission in blood samples of 48 IE patients (pts): 19 pts –High initial patient risks (HIPR) group (which had: previous prosthetic heart valves, rheumatoid arthritis or previous IE) and 29 pts-Low initial patient risks (LIPR) group (without previous prosthetic heart valves, rheumatoid arthritis and IE (16 women and 32 men, age 22 to 88 years) by Navios flow cytometer (Beckman Coulter, Inc). Also the CRP concentration was measured by ELISA (Vektor-Best,Russia). During follow up, 10 pts died (adverse outcomes-AO) within the first 2 weeks of treatment: 6 pts –LIPR group, 4 pts – HIPR group.
RESULTS. Where were no any significant difference ($p>0,05$) between CD3+ T-cell (% and #), leukocyte-T-cell index, activated T-cells HLA-DR+ (% and #), T-helper CD3/4(% and #), T killer CD3/8(% and #),CD16+NK-cells,CD56 (% and #),CD16 T-NK-cells,CD56 (% and #), phagocytic activity of granulocytes and monocytes levels in LIPR and HIPR groups with AO and without it.
The total leukocytes number(#) and %B-cellsCD19+ correlated with outcomes IE and were significantly higher in AO pts ($16,7\pm10,2)*10^9$/L and $16,4\pm7,1$% respectively) than without AO pts. ($11,5\pm6,5)*10^9$/L and $11,7\pm7,8$% in both groups, respectively ($p \leq 0,05$). Total number of white blood cells correlated with CRP levels on admission ($r=0,69$ $p<0,05$). It was found that the %lymphocytes in LIPR is almost 2 times higher than the HIPR group ($22,2 \pm 11,2$% and $11,3 \pm 5,5$, respectively) ($p<0,05$). The %lymphocytes levels in LIPR AO pts group was significantly lower than in HIPR group (10,5% and 22,2 %respectively) ($p\leq0,01$).
CONCLUSIONS. In infective endocarditis patients admitted to hospital, only the total level of white blood cells, the % B-lymphocytes, as well as the %lymphocytes can be useful laboratory predictors of adverse outcome of the disease.

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Cod: T008

ELEVATION OF ISOPROSTANES IN WOMEN WITH HEART FAILURE: ITS RELATION TO THE SEVERITY

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Background: In congestive heart failure (CHF) prooxidant mechanisms predominate over the antioxidant mechanisms; it can decrease myocardial function directly. Recent findings show that this disease is associated with increased oxidative stress (OS).
F2-Isoprostanes (F2-IsoPs) are products of lipid peroxidation; they are considered as one of the most sensitive and reliable standard biomarkers of OS in vivo because they are not influenced by the intake of dietary lipids and are chemically stable and easy molecules detect.
The aim of this study was to determine whether there is difference in the serum level of F2-IsoPs between women with CHF and healthy women.
Methods: In this case control study, which was performed at the Laboratory Medicine of University-Hospital of Murcia (Spain), 70 patients 18-40 years were enrolled in two groups: CHF women and healthy women. Amino-terminal probrain natriuretic peptide (NT-proBNP), F2-IsoPs, Triglycerides (Try), Total cholesterol (CHO), HDL-cholesterol, LDL-cholesterol, Glucose and C-reactive protein serum levels were measured.
All statistical analyses were performed using SPSS® version 22.0. The level of significance was set at $p<0.05$ for statistical tests.
Results: CHF group consisted of 35 women (32.5 ± 5.3 years) and 35 control group (30.7 ± 5.9 years). Serum concentrations of F2-IsoPs were significantly higher in CHF group, 93 pg/mL (59-134), than control group, 58 pg/ml (38-83), $p<0.01$. Using the median of F2-IsoPs in CHF group as cutoff, they were classified as CHF patients with high F2-IsoPs (≥108 pg/mL) and those with low F2-IsoPs (<108 pg/ml). Biochemical variables between these two groups were compared.
Medians of NT-proBNP and CHO were significantly higher in those CHF women with high levels of F2-IsoPs, 1443 pg/mL (177-8662) and 126 mg/dl (107-154) respectively, than in those CHF women with low levels of F2-IsoPs, 239 pg/mL (158-469) and 155 (120-188) mg/dL respectively, $p<0.01$. No significant differences between both groups in other variables were found.
In the correlation analysis Spearman, F2-IsoPs level was positively correlated with TRY ($\rho= 0.381$, $p<0.05$).
Conclusion: The findings made in this study suggest that CHF women have high levels of F2-IsoPs, which could be related to the severity of the heart failure. Improving our understanding of the regulation of OS, should lead to new therapeutic strategies in the treatment of CHF. It is possible that consumption of dietary antioxidants have beneficial effects.

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Cardiovascular diseases - Cardiac markers

Cod: T009

HUMAN BASED READY TO USE MULTI-ANALYTE LINEARITY VERIFICATION MATERIAL COVERING FIVE LEVELS OF CARDIAC MARKERS FOR ACCURATE ASSESSMENT OF THE TEST SYSTEMS' REPORTABLE RANGE

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Introduction. Calibration is the first step to ensuring reliable patient results. Linearity testing assesses the system's calibration to verify its validity and if a method is linear across the full reportable range of the instrument. Calibration verification involves assaying materials of known concentrations in the same manner as patient samples to substantiate the instrument or test system's calibration across the reportable range for patient test results. Stable, ready to use multi-analyte calibrators, covering at least five levels and meeting the requirements of individual analysers should be used to challenge the complete reportable range, therefore ensuring accurate patient testing. A human based multi-analyte verification material covering five levels of seven cardiac markers is reported.

Methodology. Human based multi-analyte linearity verification material covering the cardiac markers: CK-MB Mass, D-dimer, myoglobin, NT-proBNP, troponin I, troponin T and hs troponin T at up to five levels for each analyte, was manufactured. Values were assigned on the Roche Cobas C system and Beckman Access System.

Open vial stability was determined as the percentage recovery of each level stored 36 days at $+2^0$C to $+4^0$C related to a vial of the same material opened at day 0. Shelf life stability was determined by accelerated testing at $+25^0$C, $+37^0$C and $+45^0$C using the Arrhenius model for prediction.

Results. Assigned concentrations spanned the analytical range of each system, the ranges covered were for Roche Cobas systems: 0.598 - >300ng/mL (CK-MB mass), 162-7833ng/mL (D-dimer), 36.6->3000ng/mL (myoglobin), 16.7-32046pg/mL (NT-proBNP), 0.045-23.1ng/mL (Troponin T), 21.4-9356pg/mL (hs Troponin T). For Beckman sytems: 0.7-265ng/mL (CK-MB mass), 9.72-3641ng/mL (myoglobin), 0.06-80.3ng/mL (Troponin I). The open vial stability assessment showed recovery values ranging from 86 to 117% (CK-MB mass, myoglobin, troponin I, troponin T and hs Troponin T) at all levels, and from 73 to 105% for D-dimer. Shelf life stability predicted: at least 2 years stored at $+2^0$C-$+8^0$C.

Conclusion. The reported multi-analyte verification material for cardiac markers is suitable for use to challenge the complete reportable range of the specified analysers to ensure accurate sample assessment.

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Cardiovascular diseases - Cardiac markers

Cod: T010

TRIMETHYLAMINE N-OXIDE (TMAO): A RISK FACTOR FOR ISCHEMIC HEART INCIDENT IN CHRONIC KIDNEY DISEASE PATIENTS

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Background:
Trimethylamine N-oxide (TMAO) is produced by gut microbiota from dietary L-carnitine and choline and is associated with cardiovascular (CV) events. Chronic kidney disease (CKD) patients commonly suffer CV disease, but traditional risk factor not always predicts CV events. The aim of the present study is to investigate the relation between TMAO and cardiovascular events in CKD patients.

Methods:
Thirty six CKD patients were treated with hemodialysis (16 patients) and dialysis peritoneal (20 patients) systems. Predyalisis samples were collected and kept at -80ºC until TMAO was measured. Measurement of TMAO was carried out by a LC-MS system with a method developed in our lab. Quantification of TMAO was performed by using an internal standard (D9-TMAO). Cardiovascular events were considered when the CKD patient presented an ischemic heart incident. The Chi-square and Mann-Witney tests were used to evaluate the relationship between TMAO levels and CV events.

Results:
TMAO levels in CKD hemodialysis (median: 430μM) and dialiysis peritoneal (median: 320 μM) were not statistically significant (p= 0.297).
TMAO levels in CKD patients which suffer ischemic heart incidents (median: 621 μM) were higher than patient without CV event reported (289 μM), and were statistically significant (p=0.019).
Three patients with CV events showed TMAO levels above percentile 90 (median: 850μM, p= 0.005).

Conclusions:
Our results suggests high levels of TMAO may be a risk factor for ischemic heart incident in CKD patients. However, further studies are needed to resolve if can be used in clinical routine.

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Cardiovascular diseases - Cardiac markers

Cod: T011

DOES GLYCOSYLATION INFLUENCE THE DIAGNOSTIC ACCURACY OF N-TERMINAL PRO-B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HEART FAILURE?

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Background: N-terminal fragment of pro-B-type natriuretic peptide (NT-proBNP) is a useful biomarker for heart failure (HF) diagnosis. NT-proBNP is O-glycosylated within the central part and present in the circulation as a pool of molecules with different glycosylation levels. Currently an automated NT-proBNP immunoassay manufactured by Roche is widely used for NT-proBNP measurements. This immunoassay is based on antibodies, one of which is specific to partially glycosylated region of NT-proBNP (epitope 42-46 aar), and known to detect only a subfraction of endogenous NT-proBNP. It still remains unclear if epitope specificity of antibodies recognizing either partially glycosylated or not glycosylated regions of NT-proBNP impacts the diagnostic value of NT-proBNP assays. The aim of this study was to compare the diagnostic accuracy of Roche NT-proBNP assay and HyTest in-house NT-proBNP method, based on monoclonal antibodies (mAbs), targeting glycosylation-free regions of NT-proBNP.
Methods: EDTA-plasma samples were obtained from 51 patients, diagnosed with HF, and 53 healthy individuals (age-matched). NT-proBNP levels were measured with Roche Cobas e 411 analyzer and in-house sandwich immunoassay, based on capture mAb 15C4 (epitope 63-71 aar) and detection mAb 13G12 (epitope 13-20 aar) labeled with stable europium chelate. Recombinant non-glycosylated NT-proBNP (HyTest, produced in E. coli) was used as a calibrator. Diagnostic accuracy of two assays was compared using ROC curve analysis.
Results: NT-proBNP levels measured by Roche assay for HF patients were 25-11066 ng/L and for non-HF subjects 0-1071 ng/L. For in-house NT-proBNP assay biomarker levels were 419-20166 ng/L for HF patients and 238-3097 ng/L for non-HF individuals. ROC-AUC for Roche assay was 0.965 (sensitivity 0.86 and specificity 0.98). For in-house assay ROC-AUC was 0.950 (sensitivity 0.84 and specificity 0.98).
Conclusions: Our study shows that NT-proBNP assays specific to glycosides-free regions of NT-proBNP have the same clinical value for HF diagnosis as Roche NT-proBNP assay, specific only to a subfraction of endogenous NT-proBNP. It requires further investigation to define whether assays not sensitive to NT-proBNP glycosylation might be advantageous in certain groups of HF patients.

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Cardiovascular diseases - Cardiac markers

Cod: T012

CARBOXY-TERMINAL FRAGMENT OF INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-4 (CT-IGFBP-4). A NEW PROGNOSTIC BIOMARKER IN SURVIVORS OF A ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI)?

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BACKGROUND
ST-elevation myocardial infarction (STEMI) is still a life-threatening presentation of coronary artery disease. Patients who survive are at high risk of future events so accurate risk stratification could improve further prognosis.
Pregnancy associated plasma protein-A (PAPP-A) is a matrix-metalloproteinase found in vulnerable atherosclerotic plaques that cleaves IGFBP-4 into N- and C-terminal fragments. PAPP-A has been proposed as a prognostic biomarker of major adverse cardiac events (MACE) but its measurement is affected by several factors that limit its usefulness as a biomarker. Circulating IGFBP-4 fragments reflect PAPP-A activity avoiding its limitations.
AIM
To investigate if CT-IGFBP-4 values measured at admission in STEMI patients could add value to the prognostic role of the currently used variables.
METHODS
We included 196 patients who survived after hospitalization for STEMI. Risk of MACE was calculated at admission with GRACE Risk Score 2.0 (Global Registry of Acute Coronary Events). CT-IGFBP-4 concentrations were measured with a research-use-only ELISA in EDTA-plasma obtained at admission and stored at -80 ºC. Non-fatal myocardial infarction (MI), need of percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG) or death were registered as MACE up to 6-months after hospital discharge.
RESULTS
Mean age was 65 years and 26% were female. After 6-months follow-up, 26 MACE (8 MI, 12 PCI, 1 CABG, 5 deaths) were registered. Age, gender, cardiovascular risk factors or renal diseases, smoke habit, Killip class, body mass index or high sensitivity troponin T and NT-proBNP concentrations did not differed between patients with and without MACE.
The ability of CT-IGFBP-4 to predict MACE was investigated by area under ROC curves (AUC) analysis. CT-IGFBP-4 was a predictor of MACE [AUC 0.630 (95% CI 0.498-0.762; p=0.043)]. Kaplan–Meier survival curves were analyzed with a log rank test with chi-square of 7.40 (p=0.007). CT-IGFBP-4 ≥62 µg/L was associated with an increased risk of future MACE [Hazard ratio (HR)= 2.95 (95% CI, 1.3-6.7), p=0.01]. After adjusting the model for the GRACE 2.0, CT-IGFBP-4 concentrations were still associated with increased risk of MACE [HR= 2.80 (95% CI. 1.2-6.7); p=0.02].
CONCLUSIONS
CT-IGFBP-4 concentrations (≥62 µg/L) in STEMI patients who survived hospitalization were associated with 2.95 times higher risk of developing a MACE at 6 months follow-up.

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Cardiovascular diseases - Cardiac markers

Cod: T013

SERUM LEVELS OF GALECTIN-3 AND HIGH SENSITIVITY TROPONIN I AT 30 DAYS AND 1 YEAR FOLLOW-UP IN ACUTE HEART FAILURE PATIENTS: COMPARISON WITH NT-PROBNP

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Heart failure is an increasing health concern, as in patients over 65 discharges from hospitals is today the most common diagnosis. The diagnosis of heart failure is based on the clinical criteria collected in the Framinghan study. Prognostic biomarkers are needed to improve the management of heart failure patients, the B-type natriuretic peptides being the most valuable. However, increases in natriuretic peptides can be seen in other processes such as renal dysfunction, obesity or advanced age. Furthermore natriuretic peptides increase only following a myocardial overload, but are not able to reflect other mechanisms that also lead to HF. There are new cardiac markers that may have value in the prognosis of patients with acute heart failure (AHF). Galectin-3 is a protein expressed by activated macrophages that promotes fibroblast proliferation and cardiac remodeling.

We have evaluated Troponin I and Galectin-3 and compare them with NT-proBNP for the prognosis of AHF. 146 patients attended in the ED with AHF were included in this prospective observational study, with measurements of mentioned biomarkers, functional, clinical and echocardiographic variables. All-cause mortality at 30 days, and at 1 year were studied. A one-step immunoassay sandwich procedure VIDAS Galectin-3 of Biomerieux was used to measure Galectin-3. The Troponin I was measured with the Troponin I Centaur of Siemens. NT-ProBNP was measured with the Elecsys® NT-proBNP of Roche.

Galectin-3 levels correlated with several parameters associated with worse prognostics in HF as NT-proBNP levels, age and glomerular filtration rate while they did not correlated with Troponin I and the ejection fraction of the right ventricle. At enrollment time high Galectin-3 values, but not Troponin I, were related with all cause mortality at 30 days follow up but none of them at one year follow up. The area under the ROC curve of Galectin-3 for mortality at 30 days was 0.712, compared to 0.572 for NT-proBNP. It is of note that no deaths at 30 days were observed among patients in the first quartile of Galectin-3. At one year follow-up we only found differences for NT-proBNP with an AUC of 0.674.

These results suggest that Galectin-3 can help to prognose early mortality in patients with an episode of AHF.

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Cardiovascular diseases - Cardiac markers

Cod: T014

PROGNOSTIC VALUE OF INTACT FIBROBLAST GROWTH FACTOR 23 IN PATIENTS WITH HEART FAILURE.

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Background: Biomarkers contribute to the prognostic of heart failure (HF) patients and to a more tailored based treatment approach. Levels of C-terminal fragments of Fibroblast Growth Factor 23 (FGF-23), a potent phosphaturic hormone regulating bone and mineral metabolism, are strong and independent factors of cardiovascular outcomes in HF patients. We aimed to determine with a novel automated assay the circulating levels of intact FGF-23 (iFGF-23) in HF patients with reduced ejection fraction (HFrEF) as well as the relation with cardiac biomarkers and cardiovascular death.

Methods: Intact FGF-23 levels were measured in 133 chronic HF patients (females n=31; males n=102; NYHA II-IV; mean age: 67 years; etiology: ischemic n=92, dilated cardiomyopathy n=41; mean EF: 23 %). The primary outcome was CV death. Levels of iFGF-23 were measured at baseline with a recently released fully automated and sensitive immunoassay. The 95th percentile of the reference interval of this assay is 81 pg/mL. Levels of B-type natriuretic peptide (BNP), N-terminal proBNP (NT-proBNP), soluble ST2 (sST2), Galectin-3 (Gal-3), 25-hydroxyvitamin D (25(OH)D), 1,25-dihydroxyvitamin D (1,25(OH)2D) and PTH(1-84), were also determined.

Results: The median plasma level of iFGF-23 was 73 pg/mL and 56 HF patients (42%) had values higher than the 95th of the reference interval. HF patients NYHA III-IV have significantly higher iFGF23 (81 pg/mL) than NYHA II (57 pg/mL). Concentrations of iFGF23 were not significantly different between dilated and ischemic cardiomyopathies (67 vs. 77 pg/mL). Intact FGF23 correlated with left ventricular ejection fraction ($r = -0.18$; $P = .04$), estimated glomerular filtration rate (eGFR; $r = -0.43$; $P < .001$), Gal-3 ($r = -0.39$; $P < .001$), (1,25(OH)2D) ($r = -0.46$; $P < .001$) and PTH(1-84) ($r = 0.41$; $P < .001$), but not with age, BNP, NT-proBNP, sST2 or 25(OH)D. After 8 years of follow-up, 84 patients died. Concentration of iFGF23 was significantly higher in HF patients who died in comparison to survivors (87 vs 57 pg/mL). In patients with eGFR >60 mL/min, levels of iFGF23 remain associated to cardiovascular death.

Conclusions: Levels of intact FGF-23 measured with a new sensitive automated immunoassay are increased in HFrEF patients and are related to cardiovascular mortality.

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Cardiovascular diseases - Cardiac markers

Cod: T015

DEVELOPMENT OF A HIGHLY SPECIFIC MONOCLONAL ANTIBODY PAIR FOR THE DETECTION OF D-DIMER

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Background. D-dimer is a cross-linked poly-peptide degradation product, which is produced following degradation of fibrin by plasmin. It contains cleaved fragments of the alpha, beta and gamma chains of fibrinogen. D-dimer testing is applied in the clinical diagnosis of deep venous thrombosis (DVT), pulmonary embolism (PE) or disseminated intravascular coagulation (DIC). Furthermore, it is currently being evaluated for diagnosis of aortic dissection and it has also demonstrated utility for the diagnosis of stroke, in which elevated D-dimer levels correlate with the degree of damage and neurological outcome.The aim of this study was to develop a highly specific monoclonal antibody pair (capture antibody and detector antibody), which can be employed for the development of a robust, quantitative immunoassay for D-Dimer.
Methods. Sheep were immunized with an enzymatically cleaved fibrinogen product that was used to mimic D-dimer epitopes. Lymphocytes were collected and fused with heteromyeloma cells. Supernatants from the resulting hybridomas were screened for the presence of specific antibody using ELISA based assays. Positive hybridomas were cloned to produce stable monoclonal hybridomas. The antibodies were purified and evaluated by direct binding ELISA to determine their specificity for D-dimer and fibrinogen. Sandwich pairs were evaluated employing ELISA based strategies and the optimal combination was identified.
Results. Initial evaluation of the ELISA based assay, employing the selected monoclonal antibody pair, showed specificity for D-dimer (percentage cross-reactivity with fibrinogen was 0.4%). The measuring range of the assay was 0-1000ng/mL and it exhibited a sensitivity <10ng/mL.
Conclusion. Data indicate optimal analytical performance of the monoclonal antibody pair for the specific detection of D-dimer and its suitability for application to the development of robust, quantitative immunoassays. The determination of D-dimer will contribute to the study of its role in cardiovascular and cerebrovascular disease states.

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Cardiovascular diseases - Cardiac markers

Cod: T016

EFFECT OF DIFFERENT SEX CUT-OFFS ON BECKMAN COULTER TNI+3 POSITIVITY RATES

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Background: The use of high sensitivity troponin (Tn) assays to the clinical laboratory has highlighted potential sex differences in the 99th percentile for the healthy population. Whether laboratories should use sex-stratified reference intervals for Tn is controversial. This study examined whether indeed there is a sex difference in the 99th percentile cuttoffs for TnI in an Asian population and its potential effect on positivity rates.

Methods: As part of routine method validation studies, 498 anonymised left-over serum samples from wellness screening were analysed for TnI using the Beckman Coulter TnI+3 assay (Beckman Coulter DxI-800). Race, age and sex were used together with TnI to establish 99th percentiles for males, females and the combined sample set. These cut-offs were applied to 1 month of TnI results to assess the effect on positivity rates.

Results: 248 male and 250 female samples were tested. The 99th percentiles were male: 48 ng/L, female: 19 ng/L; combined: 40 ng/L. In 1 month, 3436 male and 2556 female sample were analysed in the laboratory. For males, using 48 ng/L as the cutoff, 1134 were positive which rose to 1318 using a cutoff of 40 ng/L. For females, using 19 ng/L, 1287 were positive dropping to 899 with a cutoff of 40 ng/L.

Discussion: There is a clear difference in TnI+3 99th percentiles for men and women in a Singaporean population, with the male cutoff of 48 ng/L over twice that of the females (19 ng/L). Using a common cutoff of 40 ng/L will increase the positivity rate for men by 16% but decrease that for women by 30%. More work is needed to establish whether this difference translates to differences in management and outcome.

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Cardiovascular diseases - Cardiac markers

Cod: T017

ST2 AS A NOVEL PROGNOSTIC MARKER IN ESRD PATIENTS ON HEMODIAFILTRATION: INCREASED VALUES ARE ASSOCIATED WITH MORTALITY

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Background: ST2 (growth STimulation expressed gene 2) is a member of the interleukin-1 receptor family that is expressed as a transmembrane (ST2L) and soluble isoform (sST2). Plasma sST2 is expressed by fibroblasts in the heart and elevated in response to heart failure (HF) disease or injury, and it is a direct participant in the fibrosis or cardiac remodeling process. sST2 is a novel prognostic biomarker of HF risk assessment with growing importance in the prediction of cardiovascular events. Patients with end-stage renal disease (ESRD) are prone to several life-threatening events and to severe heart failure. The role of sST2 as prediction factor for mortality in ESRD patients is not known. The aim of our study was to investigate the prognostic value of sST2 in ESRD patients on hemodiafiltration (HDF).

Methods: Baseline serum sST2 was measured in 117 ESRD patients on HDF (median age 66 (25-87) years); 41% women; median dialysis vintage 50 (20.5-89.5) months). Blood was sampled by venepuncture before HDF. sST2 concentrations were measured using a manual ELISA method. Primary endpoint was the composite of all-cause death. Patients were divided to a low sST2 group (sST2≤35 ng/mL, n=83) or a high sST2 group (sST2>35 ng/mL, n=34) according to their sST2 at the start of the study. Kaplan-Meier survival curves and Cox regression model were used in statistical analysis. Patients were observed from the date of the sST2 measurement until their death or maximally up to 829 days (mean 721 days).

Results: The median (interquartile range) sST2 concentration of all patients was 28(19-38) ng/mL. During a follow-up 30(25.6%) patients died. Results of Kaplan-Meier survival analysis showed that survival rate of the high sST2 group was significantly lower than that of the low sST2 group (Log Rank test: $P<0.0001$) (Fig.1). In a Cox regression model, which included age, gender, dialysis vintage, hemoglobin, sensitive CRP and sST2 only age ($P<0.002$) and sST2 ($P<0.0001$) turned out to be independent predictors of death.

Conclusions: Increased serum levels of sST2 were associated with mortality in ESRD patients on HDF.

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Cardiovascular diseases - Cardiac markers

Cod: T018

MINICARE I-20 ALLOWS RAPID AND RELIABLE NEAR PATIENT cTnI TESTING USING LI-HEPARIN WHOLE BLOOD, LI-HEPARIN PLASMA OR CAPILLARY WHOLE BLOOD SAMPLES IN PATIENTS WITH SUSPECTED AMI.

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Background: Philips developed a novel Minicare I-20 near patient IVD POC device. Results are available in less than 10 minutes. This approach supports optimizing work flow by shortening turn-around time (TAT) in critical diseases like acute myocardial infarction (AMI). We present sample type comparison, 99th percentile URL and clinical sensitivity and specificity data of the new Philips Minicare cTnI test for the diagnosis of AMI.

Methods: Sample type comparison between capillary, Li-heparin whole blood and Li-heparin plasma was performed using 122 samples with cTnI (range 18-7000 ng/L). Analysis followed Passing Bablock linear regression and Bland Altman method.

750 healthy volunteers (373 males and 377 females) were evaluated to establish the 99th percentile URL in all three sample types, using non parametric method (proc univariate with interpolation option) and Pearsons chi-square analysis.

A European prospective non-randomized multi-center study, was performed in 7 hospitals from 4 European countries, with 465 patients presenting at the ED with suspicion of AMI. Li-heparin whole blood and Li-heparin plasma samples were evaluated at the ED at presentation, at t=3h and t=6h. The patients were independently adjudicated for AMI. Two-sided exact 95% confidence intervals were calculated using the Clopper-Pearson method.

Results: Sample type comparison (n=122) showed correlation coefficients (r) between 0.99 – 1.00 and slopes between 1.03 – 1.08 for all three samples types. The 99th percentile URL was 43 ng/L (90% CI: 35-61 ng/L) and not significantly different for sample types nor genders. Specificity and PPV were 93% and 65% at admission, 91% and 68% at t=3h and 87% and 71% at t=6h. Sensitivity and NPV were 69% and 94% at admission, 92% and 98% at t=3h, and 91% and 96% at t=6h. The AUCs at 0h, 3h and 6h in whole blood were 88%, 96% and 95%. The optimal diagnostic cut off at 3h was at the 99th percentile URL (43ng/L).

Conclusion:
The Minicare I-20 is a next generation point of care device with cTnI testing as first application. Minicare cTnI is a rapid and reliable assay for the diagnosis of AMI using either Li-heparin whole blood, Li-heparin plasma or capillary whole blood samples and has the potential to reduce TAT for patients suspected of AMI.

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Cardiovascular diseases - Cardiac markers

Cod: T019

LAZAROID (U-74389G) PREVENTS LUNG ISCHEMIA-REPERFUSION INJURY CAUSED BY THORACOABDOMINAL AORTIC OCCLUSION

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Introduction: Lung ischemia-reperfusion injury after thoracoabdominal aortic occlusion represents a major complication, which increases morbidity and mortality. In the present study we hypothesized that lazaroid U-74389G intravenous administration protects from lung ischemia-reperfusion injury through lipid peroxidation inhibition.
Materials and methods: A total of 24 pigs were randomized in three groups. Group I (n=8) underwent sham operation, group II (n=8) underwent thoracoabdominal aortic occlusion for 45 min and received placebo and group III (n=8) received 3 doses of lazaroid (3mg/kg) 60 and 30 min before thoracoabdominal aortic occlusion and at 30 min of thoracoabdominal aortic occlusion (duration 45 min). Aortic occlusion was performed with aortic balloon-catheters under fluoroscopic guidance. All animals were sacrificed at the 7th postoperative day and lung specimens were received for molecular analysis. Total mRNA was isolated with NucleoSpin® RNA/Protein kit (Macherey-Nagel, Germany) and cDNA was prepared with RT^2 First Strand kit (Qiagen, Germany). mRNA levels of leukotrienes LB4, LC4 and nitric oxide synthase isoforms including eNOS, nNOS and iNOS were quantified and compared to beta2-microglobulin reference gene with real-time RT-qPCR using RT^2 SYBR Green ROX Fast MasterMix kit and RT^2 qPCR Primer Assays at Rotor Gene Q MDX PCR platform (Qiagen, Germany). The $2^{-\Delta\Delta Ct}$ method was used for the relative quantitation of gene expression and SPSS V.21 IBM Statistics package for statistical analysis.
Results: Nitric oxide can either induce (iNOS) or inhibit (eNOS and iNOS) lipid peroxidation based on its specific isoform origin. Group III showed significantly reduced levels of both LB4 (-63.7%) and LC4 (-35.9%) when compared with group II ($P<0.05$). Isoform nNOS was not detected in lung specimens of all three groups. iNOS was significantly reduced (-60.2%) in Group III when compared with group II ($P<0.05$). Finally, eNOS was slightly increased (+2.1%) in group III when compared with group II ($P=0.467$).
Conclusion: Lazaroid U-74389G may represent an effective pharmacologic intervention in reducing lung ischemia-reperfusion injury following thoracoabdominal aortic occlusion.

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Cardiovascular diseases - Cardiac markers

Cod: T020

IMPROVING THE SENSITIVITY IN CARDIAC TROPONIN I IMMUNOASSAY BY REDUCING THE NON-SPECIFIC BINDING OF UPCONVERTING NANOPARTICLE REPORTERS

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Background: Upconverting nanoparticles (UCNPs) are promising reporters for high sensitivity immunoassays because of their unique ability to convert low energy infrared radiation to high energy emission at visible wavelengths. Due to this anti-Stokes emission measurements can be done free of autofluorescence, which could enable sensitive assays. UCNPs, however, have not been widely utilized as reporters in cardiac troponin I (cTnI) immunoassay because of high non-specific binding of the nanoparticles and therefore limited sensitivity of the assays. The aim of this study was to improve the sensitivity of cTnI-immunoassay by lowering the nonspecific binding of the UCNPs.

Methods: $NaYF_4$:Yb^{3+},Er^{3+} UCNPs with a diameter of 30 nm were functionalized with polyacrylic acid (PAA, Mw 2000) and conjugated with cTnI specific monoclonal antibody. Biotinylated capture-Mab and capture-Fab-fragment, specific for different epitopes of cTnI, were immobilized on streptavidin coated microtiter wells. Human cardiac troponin I-T-C complex was detected in a heterogeneous sandwich type assay with the Mab-conjugated UCNPs. In order to decrease the non-specific binding of the UCNPs, free PAA (Mw 2000) was added to the assay buffer for the reporter incubation step to a final concentration of 0.016%. Upconversion emission was measured from dry wells with a modified plate reader equipped with a 980 nm laser diode.

Results: The addition of the PAA to the assay buffer for the reporter incubation step lowered the assay background obtained from the zero calibrator over threefold when compared to the assay performed without the addition of PAA. The analytical sensitivity was also improved due to the addition of PAA. The sensitivity of the cTnI-immunoassay was 2.3 ng/L and 0.85 ng/L without and with the added PAA in the assay buffer, respectively.

Conclusions: The addition of PAA to the buffer lowered the nonspecific binding and therefore improved the analytical sensitivity. The non-specific binding was reduced most likely because the UCNPs were coated with the same molecule that was added to the assay buffer for the reporter incubation. The free PAA in the assay buffer binds to the surface of the wells where the PAA coated UCNPs might bind non-specifically. The decrease in non-specific binding of the UCNPs enables the development of high sensitivity immunoassays.

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Cardiovascular diseases - Cardiac markers

Cod: T021

EVALUATION OF HIGH-SENSITIVITY TROPONIN T AND I IN CLINICALLY STABLE DIALYSIS PATIENTS

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BACKGROUND
It is well known that clinically stable patients with end-stage renal disease (ESRD) have raised troponin levels compared to the general population. The aim of this study was to evaluate and compare high-sensitivity troponin T (hs-TnT) and I (hs-TnI) in our local clinically stable dialysis patients. In addition, we will also evaluate prognostic values of hs-TnT and hs-TnI, whether they are predictive of all-cause mortality at 9 months.

METHODS
Both hs-TnT and hs-TnI were measured in 300 stable dialysis patients at Middlemore Hospital (Auckland, New Zealand), in the blood samples collected for routine monthly blood tests in August 2016. The Roche hs-TnT assay was performed on Roche Cobas e411 and the Abbott Architect hs-TnI assay was performed on Abbott Architect C16/i2000. The 99th percentile upper reference limits were used as the cut off values; hs-TnT = 14ng/L and hs-TnI = 26ng/L. Mortality data will be collected in May 2017, to assess their predictive values for all-cause mortality at 9 months.

RESULTS
Out of 300 stable dialysis patients, 162 (54%) were male. 298/300 (99%) patients had hs-TnT greater than the cut off, with median concentration of 79ng/L (interquartile range: 49 – 131ng/L). Hs-TnT ranged from 10 to 616ng/L. For hs-TnI, 158/300 (53%) patients had hs-TnI greater than the cut off, with median concentration of 28ng/L (interquartile range: 15 – 53ng/L). Hs-TnI ranged from <2 to 1088ng/L. 140/300 (47%) patients had discrepant hs-troponin results; raised hs-TnT but normal hs-TnI. In this group, the median hs-TnT level was 56ng/L and ranged from 15 to 540ng/L.
The results on their predictive values for all-cause mortality at 9 months are to follow.

CONCLUSIONS
In clinically stable dialysis patients, a large proportion of the patients had elevated hs-troponins in their routine bloods, and in some cases hs-troponins were grossly elevated. Significantly more patients had elevated hs-TnT than hs-TnI, which led to many patients having discrepant results; raised hs-TnT but normal hs-TnI. It is important for clinicians to be aware of this phenomenon, especially when interpreting hs-troponin levels in an acute clinical settings. Establishing baseline hs-troponins in patients on dialysis could be very useful.

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Cardiovascular diseases - Cardiac markers

Cod: T022

PERFORMANCE OF MAGLUMI hs-cTnI(CLIA METHOD)

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Background:
High-sensitivity Troponin (hs-cTnI) assays, in the guidelines of ACC and ESC, should have a coefficient of variation (CV) less than 10% at the 99th percentile value in the population of interest. To be classified as high-sensitivity assays, concentrations below the 99th percentile should be detectable above the assay's limit of detection for >50% of healthy individuals in the population of interest. In this study, we verify the 99th percentile, sensitivity and system comparison of Maglumi hs-cTnI (CLIA) in Chinese population on fully-auto chemiluminescence immunoassay analyzer (Maglumi 4000).
Methods and Materials
99th percentile of Healthy population: By using our laboratory information system, weidentified and collected 212 clinical healthy sample bases on EP28-A3c. We currently perform the hs-cTnI were determined with chemiluminescentautomated method on Maglumi 4000 analyzer (Snibe,China) and STAT hs-cTnI were tested by Architect i4000SR(Abbott, USA). Statistical analyses were performed by SPSS 19.0 (SPSS Inc.USA)
Results
99th percentile of Healthy population: The performance of 99th percentile is 7.987pg/mL, CV<10% was achieved. 3.2 Perfomance of sensitivity: (1)LOB# LOB=1.368 pg/mL. (2)LOD: LOD=3.040 pg/mL. (3) LOQ: When y=7.987 pg/mL, x=9.4%,CV of 99th percentile was 9.4%; when x=10%, y=7.597 pg/mL, LOQ is 7.597 pg/mL. 3.3 System Comparison: 169 serum samples from hospitalized patients were collected and tested on both systems, y=0.12547 x +0.8917, r2=0.929.
Conclusions:
In this study, we verified the 99th percentile, detection Capability of Maglumi hs-cTnI base on Chinese population, and conducted System Comparison with Abbott Architect STAT hs-cTnI. The 99th percentile of Maglumi hs-cTnI is 7.987 pg/mL, with CV 9.4% (<10%)[2], meanwhile 167 cases out of 212 serums samples from healthy person give results higher than LOD (3.040 pg/mL), accounting for 78.7% of healthy person, according to Apple F S cTn assay scorecard standard, Maglumi hs-cTnI can be defined as "guideline acceptable" on acceptance designation and Level 3 (second generation, hs) regarding assay designation.
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Cardiovascular diseases - Cardiac markers

Cod: T023

DECREASED RISK OF BLEEDING IN CARDIOVASCULAR SURGERY BY PREDETERMINATION OF FUNCTIONAL PLATELETS.

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BACKGROUND: Platelet function is critically important in the acute-care settings of cardiovascular surgery, which are commonly associated with the adverse vascular events of hemorrhage and thrombosis, respectively. The use of thrombolytics, anticoagulación or antiplatelets agents may be suboptimal in clinical environments because of interpatient variability with regard to platelet count, platelet response, receptor concentration on the platelet, and other factors. Hence there is a clinical need to monitor such therapies on an individual basis.
OBJECTIVES: Development and implementation of a protocol agreed between the Laboratory and Anesthesia Service, for the determination of functional platelets in patients with pretreatment with antiplatelet agents which will be undergoing cardiavascular surgery.
METHODS: Even with a normal platelet count, the platelets may be dysfunctional. If platelets are not aggregating normally, the outcome may be either hemorrhage or unwanted clotting. PlateletworksR (Helena Laboratories Beaumont) is an in vitro diagnostic and has demonstrated utility in monitoring platelet response to all current antiplatelet agents. This two-step method involves using a cell counter to measure the total platelet count in a whole blood sample and then to re-determine the platelet count on a second sample that has been exposed to a known platelet agonist such as collagen, arachidonic acid, or ADP (adenosine diphosphate). The agonist will stimulate those platelets that are functional to aggregate into clumps, and they will not be counted as platelets in the second sample. The use of an impedance counter then measures only the nonfunctional or inhibited platelets. The difference in the platelet count between samples 1 and 2 provides a direct measurement of platelet aggregation.
RESULTS: 10 patients who were undergoing cardiovascular surgery determining functional platelets was performed. In 9 cases, the results allowed further intervention while one of them was suspended because of the risk of bleeding.
CONCLUSION: In our experience, Plateletworks may be useful in predicting postoperative blood loss and to guide timing of surgery and bleeding treatment in patients. As advantages is easy, inexpensive and quick to perform.

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Cardiovascular diseases - Cardiac markers

Cod: T024

APPLICABILITY OF THE NEW RANDOM ACCESS CONTINUOUS LOADING ANALYSER RX MODENA TO THE MEASUREMENT OF LIPID PROFILE TESTS

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Background. The lipid profile, which includes a panel of tests, is used as part of a cardiovascular risk assessment and to monitor response to lipid modifying treatments. Cholesterol, HDL, LDL and triglycerides are among the analytes measured in this panel. The availability of fully automated clinical chemistry analysers capable of facilitating quick and precise analysis is beneficial in the process of patient monitoring and diagnosis. This study evaluates four assays (cholesterol, HDL, LDL and triglycerides) applied to a newly developed fully automated, random access, floor standing clinical chemistry analyser, the RX modena. The instrument can complete 1200 tests/hour, which combined with its continuous loading capability, means instrument down time is reduced and cost effectiveness is increased. The application of this new instrument to the measurement of clinical chemistry parameters contributes to a reliable analytical assessment of samples thus benefiting the process of patient care.
Methods. On-board and calibration stabilities were tested by storing the reagents uncapped on the analyser for 28 days. Assay precision was assessed by testing serum samples at defined levels, 2 replicates twice a day for 20 days. Correlation studies were conducted using another commercially available clinical chemistry analyser ($n \geq 100$ serum samples).
Results. The reagents presented an on-board stability and calibration frequency of 28 days. The assays presented Limit of Blanks of < 0.1mmol/L. The linearity values of the assays were as follows: 17 mmol/L (cholesterol), 3.8 mmol/L (HDL) 24 mmol/L (LDL) and 11.5 mmol/L (triglycerides). The within-run and total precision for three different concentration levels typically had CV's (%) $\leq$4% for the four assays. In the correlation studies serum patient samples were tested and compared against an existing method. All slopes fell within 0.90 – 1.10 and all correlation coefficients were > 0.95.
Conclusion. The results from this evaluation of cholesterol, HDL, LDL and triglycerides assays on the new RX modena analyser indicate optimal analytical performance and overall the system represents a rapid, user friendly, cost-effective analytical tool with reduced down time for the clinical chemistry laboratory.

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Cardiovascular diseases - Cardiac markers

Cod: T025

USE OF VITAMIN D AS A MOLECULAR MARKER FOR CARDIOVASCULAR DISEASES

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A growing body of research indicates that Vit D deficiency and CVD contributes to a broad spectrum of conditions such as high hypertension, hyperlipidemia and metabolic syndrome leading to mortality. CVD risk is partly genetically determined, but is strongly influenced by lifestyle factors. They acts mostly through traditional or emerging risk on the pathology of atherosclerosis and plays a significant role in the relationship between Vit D and CVD through different mechanisms such as anti-inflammatory, anti-arrhythmic and by influencing serum lipids.

The study of this relationship and use of Vit D as molecular marker was new for the Dehradun district of Uttarakhand state, India. The study consisted of 200 adults CVD patients and controls measuring their serum lipid panels and Vit D concentrations with other CVD risk factors.

The average serum Vit D in CVD patients was 20.22±5.09 ng/ml and 26.12±5.22 ng/ml in controls showing that 65% of CVD patients were Vit D deficient while only 30% of controls were Vit D deficient. Serum lipids levels were positive which correlated with CVD as high total cholesterol, triglycerides and LDL-C while low HDL-C levels. Other risk factors like hypertension, lifestyle, smoking, dietary factors and nutritional status were significantly correlated with CVD with P value 0.001 as compared with controls.

There is no uncertainty that the relationship between Vit D deficiency and CVD is multifactorial, but one prospective clarification could be the attachment of altered serum lipid concentrations with Vit D status. Clarification of this relationship had supported in the appropriate target population(s) and study designs for intervention studies aimed to explain the relationship between lipid profile and Vit D status by using Vit D as a molecular marker for CVD patients.

Study had allowed to recognizing CVD cases with VD deficiency early and help to decrease the CVD motility using Vit D as a molecular marker.

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Cardiovascular diseases - Cardiac markers

Cod: T026

ASSESMENT "ASYMMETRIC DIMETHYL ARGININE", CK-MB AND hsTnI IN A PATIENT WITH CORONARY VASOSPASM: A CASE REPORT.

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CASE REPORT
Assesment "asymmetric dimethyl arginine", CK-MB and hsTnI in a patient with coronary vasospasm: a case report.

BACKGROUND
Our aim in this case report is to examine the relationship between cardiac markers with asymmetric dimethyl arginine.
METHODS
History
41 years old male patient, non-obese, 1.5 packs a day smoker patients, dizziness, palpitations and high the systemic blood pressure (170/130 mmHg) complaint was admitted to the emergency services. After the first examination, 25 mg of captopril (sublingual, ACE II inhibitor) was used. Subsequently, under observation 120/80 mmHg were sent down to the patient home. The patient next morning (after 12 hours) he was admitted to the cardiology clinic, results; CK and CK-MB of normal output, while High-sensitive Troponin I (hsTnI) was significantly higher (365.1 pg/mL). The patient was performed radial coronary angiography in spite of echo and ECG normal. Because he did not pass his complaint of chest pain.
The ADMA parameter examined with a plasma sample, blood was taken from patient with a biochemistry tube before radial coronary angiography. The plasma was placed with lithium Heparin (LH tube, PST II, 4.5 mL, green top). The plasma sample were then put in the centrifuge for 15 min at 1000 rpm and kept in 80C0. The working day (SAU Biochemistry Lab.) with BioTek's Elx800 Elisa device CUSABIO Human Asymmetrical dimethylarginine ELISA Kit (E09298h) was used. 450 nm optical density value (OD) and ADMA percent concentration in plasma (pg/mL) were measured.

RESULTS
Coronary vasospasm after; 12, 36 and 72 hours test parameters results were determined as follows by sequence. hsTnI (pg/L): 365.1, 225.2 and after 36 hours 57.3. CK-MB (IU/L): 11.7, 9.8 and after 36 hours 9.5. The radial angiography performed, was diagnosed with minimal coroner artery disease. The patient's plasma ADMA; optical density value (OD): 0.128 and plasma concentration: 4.471 ng/mL were detected.
CONCLUSIONS
Minimal coroner artery syndrome in patients with ADMA could be found between hsTnI and CK-MB. On the other hand; hsTnI the coroner artery disease marker as a safe forefront. In our case the ADMA and cardiac biomarker correlation not shown, but this data must be evaluated by experimental studies.

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Cardiovascular diseases - Cardiac markers

Cod: T027

RED BLOOD CELL DISTRIBUTION WIDTH (RDW) AND 5-YEAR CEREBROVASCULAR AND CARDIOVASCULAR MORTALITY AFTER ISCHEMIC STROKE IN 16-55 YEARS OLD PATIENTS

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Background:
Red blood cell distribution width (RDW) is a measure of erythrocyte anisocytosis that recently has been associated with myocardial infarction, stroke and all-cause mortality.

Aim:
Assessing the association between RDW and cerebrovascular/cardiovascular mortality after ischemic stroke in patients aged less than 55 years.

Population and Methods:
Patients aged 16-55 years, presenting with an ischemic stroke at the University Hospital Centre “Mother Theresa”, Tirana, during 2010-2011 were enrolled. Hematologic, infectious, inflammatory and autoimmune diseases, malignancy and hemodialysis were considered exclusion criteria. At baseline, the RDW cut-off value of 14% was used to define the two groups. After a 5-year long follow-up period, cerebrovascular mortality and cardiovascular mortality, including stroke and myocardial infarction, were assessed either physically or telephonically.

Results:
158 patients (84.2% males), mean age 48.4 years (SD 7.22) were included in the final analysis. Mean RDW was 14.27% (SD 1.1%) and 94 patients presented a RDW value over 14%. Hypertension, diabetes, dyslipidemia and smoking were present in 57.0%, 26.6%, 24.9% and 36.7% of the patients respectively, but their prevalence was not significantly different in the two groups, except for diabetes that was more prevalent in the higher RDW group (32.0% vs 17.2%, p=0.027). During follow-up, 10 cerebrovascular and 8 cardiac deaths were registered, of which 9 and 6 respectively occurred in the higher RDW group. Cerebrovascular and cardiovascular mortality proportions in this group were 6.1-fold (p=0.042) and 3.4-fold (p=0.029) higher.

Conclusions:
In ischemic young patients, RDW over 14% at baseline is associated with higher 5-year cerebrovascular and cardiovascular mortality.

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Cardiovascular diseases - Cardiac markers

Cod: T028

DIFFERENT CUT OFF OF hsTnI CHANGE THE RULE OUT OF PATIENTS IN EMERGENCY UNIT?

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BACKGROUND: Chest pain is a common cause of hospital admission worldwide and is a major burden on health-care resources. Cardiac troponin has substantially improved the accuracy of diagnosis and prognostic assessment of patients with suspected acute coronary syndrome (ACS). The aim of this work is investigated if the use of more sensitive assays for cardiac troponin, in the emergency department, cause an incremental percentage of patients with low-positive values and consequently if the cut off adopted could influenced the rule out of the patients.
METHODS: We have conducted a retrospective analysis based on 1,759 women and 1,954 men (six months) arriving in Emergency Department (ED). We have use high-sensitivity troponin I (ARCHITECT STAT high-sensitive troponin I assay; Abbott Laboratories®) to measure cardiac troponin I concentrations on plasma, this assay has a limit of detection of 1·2 ng/L, and an upper reference limit (99th centile) of 34 ng/L in men and 15 ng/L in women. It has a coefficient of variation of 23% at the limit of detection (1·2 ng/L) and less than 10% at 6 ng/L.
RESULTS: we have classified the patients based on the admission in emergency unit using triage colors classification. We adopted the manufacturer's cut off of positivity (34 ng/l for men and 15 ng/l for women) and we correlated with the latest proposed by Shah et al of 12 ng/l. Women are 1795 for color classification: 30 withe, 996 green, 671 yellow and 98 red; men are 1954: 29 white, 969 green, 834 yellow and 122 red. For women the rule out is equal for both cut off: 12 ng/L and 34 ng/l. A careful observation should be paid for men: if we adopt 12 ng/L (and not 35 ng/L) we registered an increased discharged of: 40% (218 men) in green code, 35% (97 men) in yellow and 58% in red (5 men). None of the patients ware readmitted for ischemia in emergency unit subsequent 15 days.
CONCLUSION: we have registered only one difference between the proposed cut off for men we had a lower percentage of admission if we didn't adopted the Abbott's cut off. So in the light of this observational study we conclude that while for women the difference of the two cohorts is minimal, for the men the use of the safer upper limit of detection allow three diagnosis of every single patient.

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Cardiovascular diseases - Cardiac markers

Cod: T029

SERUM CYSTATIN C: IS IT A STRONG BIOMARKER FOR PREDICTING OUTCOMES AFTER CARDIAC SURGERY?

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Introduction
Acute kidney injury (AKI) is a common and serious complication in hospitalized intensive care units patients with incidence of 11% to 67%, and mortality of 13% to 36%. S-cystatin C has been suggested as a more sensitive marker for determining impaired renal function. We aimed in this study to investigate the predictive value of preoperative s-cystatin C, in identifying those at higher risk of postoperative mortality, in a tunisian cohort of patients undergoing cardiac surgery
Materials and methods
Patients undergoing cardiac surgery with cardiopulmonary bypass (CPB) were enrolled prospectively in this study.To evaluate AKI after cardiac surgery, we used the Risk, Injury, Failure, Loss, and End-stage Kidney (RIFLE) classification, proposed by the Acute Dialysis Quality Initiative (ADQI). S-cystatin C value was measured with particle-enhanced turbidimetric immunoassay (PETIA) using a Cobas® e 411 analyzer
Results
42 patients were enrolled in this study, 2 patients died, leaving 40 [17 women, 23 men]. Mean age was 56,1±14,9 years [18 - 77]. The 30-day mortality was 2.5%. Overall survival was 87.5 % at 1 year. S-cystatin C levels decreased significantly between H0 and H4, then increased gradually. Positive associations were observed between s-cystatin C value and EuroSCORE ($r = 0.372$, $p=0.02$) and with RIFLE classification ($p=0.02$ at H24, $p=0.01$ at H48). After multivariate analysis, independent variables tested in different models of binary logistic regression, were cardiovascular events accuracy (CV) and rehospitalization , dependent variables were age, s-cystatin C, s-creat and troponin baseline levels . S-cystatin C was independly associated with CV accuracy and rehospitalization risk after cardiac surgery.
Conclusion
Our results demonstrated that baseline s-cystatin C could be a strong predictor for mortality and serious outcomes after cardiac surgery.

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Cardiovascular diseases - Cardiac markers

Cod: T030

PREVALENCE OF METABOLIC SYNDROME IN HYPERTENSIVE SUBJECTS ATTENDING THE FEDERAL MEDICAL CENTRE ABEOKUTA OGUN STATE, NIGERIA

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Background: Metabolic syndrome (MS) is a major health problem worldwide. It is characterized by a cluster of conditions that predispose an individual to developing coronary heart disease, stroke and diabetes mellitus. Most data on the prevalence of MS in the clinical and community setting have emanated from developed countries of the world. Several metabolic diseases, stroke, diabetes mellitus and cancer are on the increase in Nigeria. Data emanating from Africa and Nigeria are sparse. This study was designed to evaluate the prevalence of MS in hypertensive subjects attending the Federal Medical Centre, Abeokuta, Ogun State, Nigeria Ethical clearance was obtained from the ethical review committee of the Federal Medical Centre, Idi-Aba, Abeokuta. Informed and written consent were obtained from the subjects before recruitment.
Subjects and Methods: A total of one hundred and eighty six (186) subjects, ninety (90) men and ninety six (96) women were enrolled for the study. However one hundred and fifty four subjects (73 men and 81 women) completed the study. The International Diabetes Federation (2005) criteria was used to identify MS. Baseline clinical and demographic characteristics were obtained from the subjects by the administration of questionnaire. Anthropometric indices (body weight, height, waist and hip circumferences, BMI) and blood pressure (BP) were obtained by standard methods. Fasting plasma glucose (FPG), total cholesterol (TC), triglycerides (TG) and high density lipoprotein cholesterol (HDLC) were determined by enzymatic methods while low density lipoprotein cholesterol (LDLC) was calculated. Data analyzed were considered statistically significant at $P<0.05$.
Results: The prevalence of metabolic syndrome among the studied hypertensives was 67.5%. Approximately thirty-one percent (31.2%) of the hypertensives had abnormal FPG, 58.4 % had low HDLC, 11.7 % had high plasma triglycerides while 80.5% had high WC.
Conclusion: The prevalence of MS appears to be very high in this Nigerian Hypertensive population. Hypertensive patients in this community should be screened for MS at the time of initial evaluation to better enhance treatment against future cardiovascular events.

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Cardiovascular diseases - Cardiac markers

Cod: T031

EFFECT OF CORONARY ARTERY DISEASE RISK SNPS ON PRO-/ANTI-INFLAMMATORY CYTOKINE IMBALANCE IN PREMATURE CORONARY ARTERY DISEASE

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Background: Inclusion of genetic information and its effect on biochemical markers can prove to be a robust measure to improve early risk prediction of Premature Coronary Artery Disease (PCAD). Aim was to estimate the genotypic distribution and risk allele frequencies of 13 Single Nucleotide Polymorphisms (SNPs) in loci identified by the CARDIoGRAMplusC4D consortium namely MIA3 rs17465637;9p21 rs10757274; CXCL12 rs1746048; APOA5 rs662799; APOB rs1042031; LPA rs3798220; LPA 10455872; MRAS rs9818870; LPL rs328; SORT1 rs646776; PCSK9 rs11591147; APOE rs429358; APOE rs7412 in Pakistani PCAD patients and controls and to determine the differential serum cytokine levels (IL-18,IL-10,IL-6, TNF-alpha, IL-18:IL-10 & TNF-alpha:IL-10 ratios) with respect to the genotypic distribution of these selected SNPs.
Material and Methods: The case-control study was carried out in National University of Sciences and Technology, Islamabad in collaboration with the Cardiovascular Genetics Institute, University College London, UK. Subjects (n=340) with > 70% stenosis in at least a single major coronary artery on angiography were taken as PCAD cases along with 310 angiographically verified controls. Enzyme Linked Immunosorbent Assay was performed for measuring the concentrations of serum IL18, TNFA, IL6 and IL10. Genotyping was done using TAQMAN assay.
Results: APOE SNP rs429358 had the greatest influence among the selected Coronary Artery Disease (CAD) risk SNPs by significantly altering the serum levels of TNF-alpha, IL-10 and TNF-alpha:IL-10 ratio followed by APOE rs7412 and CXCL12 rs1746048 which significantly altered the serum levels of IL-18; TNF-alpha and IL-18; IL-18:IL-10 ratio respectively. The cytokine imbalance denoted by IL-18:IL-10 was significantly higher in the risk allele carriers MIA3 rs17465637 and CXCL12 rs1746048 while TNF-alpha:IL-10 ratio was significantly raised in the risk allele carriers of APOE rs429358; MRAS rs9818870 and LPL rs328. The addition of the gene risk score to the Framingham risk score significantly improved the discrimination for PCAD.
Conclusion: The association of the selected SNPs with differential serum cytokine levels especially the cytokine imbalance points towards their potential causal role in the immune inflammatory pathogenic pathway of PCAD.

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Cardiovascular diseases - Cardiac markers

Cod: T032

PERFORMANCE EVALUATION OF THE ADVIA CENTAUR HIGH SENSITIVITY TROPONIN I ASSAY

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Background: In 2015, the European Society of Cardiology published guidelines that propose algorithms for faster rule-in or rule-out of AMI patients. High-sensitivity troponin I assays will more accurately and precisely measure changes in cTnI concentrations affording acceptable rule-in and rule-out claims within 1–3 hours. The analytical performance of the Siemens High-sensitivity Troponin I assay on the ADVIA Centaur® family of automated random-access immunoassay analyzers is presented.

Method: The ADVIA Centaur® High-sensitivity Troponin I assay is a dual-capture sandwich immunoassay using magnetic latex particles and a proprietary acridinium ester. The detection reagent is a recombinant sheep Fab antibody covalently linked to a TSPAE-BSA conjugate. TSPAE (tri-sulfo propyl acridinium ester) is a proprietary acridinium ester developed by Siemens. Addition of solid phase and detection reagents to the sample forms an immune complex. Chemiluminescence is initiated and measured. Relative light units are proportional to the cTnI concentration.

Results: The assay range is from the limit of detection (LoD) to 25,000 pg/mL. The LoD is determined with three reagent lots on four ADVIA Centaur Systems collecting n = 720 replicate measurements for each of 10 serum and LiHep samples. The LoD ranged from 0.6 to 1.7 pg/mL. The limit of blank (LoB) was determined by rank order described by CLSI guideline EP17-A2 and ranged from 0.10 to 1.10 pg/mL, with a typical value of 0.5 pg/mL. LoQ, defined as the cTnI concentration at 20% within-lab CV, ranged from 1.3 to 2.4 pg/mL. The 99th percentile estimate of an apparently healthy population with equal number of males and females, n = 2026, is 48 pg/mL. The 99th percentile for females ranged from 37 to 41 pg/mL, and for males 57 to 64 pg/mL. Recoveries were identical with matched lithium heparin plasma and serum samples. The within-lab CV at the 99th percentile is less than 3%.

Conclusion: The ADVIA Centaur High-sensitivity performance represents an 10-fold sensitivity increase over current contemporary sensitive cTnI methods affording a new analytical window at low cardiac troponin I levels, supporting the evaluation of clinical delta changes.

* Under development. Not available for sale. The performance characteristics of this device have not been established. Product availability will vary from country to country and will be subject to varying regulatory requirements.

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Cardiovascular diseases - Cardiac markers

Cod: T033

CHANGES IN HIGH SENSITIVITY CARDIAC TROPONIN T AFTER CARDIAC SURGERY

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BACKGROUND
Early diagnosis of peri-operative myocardial infarction during cardiac surgery remains to be peculiar. Post-operative cardiac troponin concentrations have been shown to be a predictor of mortality and morbidity after cardiac and non-cardiac surgery. The aim of our study was to describe high-sensitive cardiac troponin T (hscTnT) release dynamics after various cardiac surgeries and propose the most promising parameter for an early detection of "unexpected" time-course of cardiac troponin.
METHODS
We conducted a retrospective analysis of all planned cardiac surgery procedures during 11 consecutive months (February to December 2015): aortal valve replacement (AVR, n = 55), coronary artery bypass grafting (CABG, n = 115) or mitral and tricuspidal valve replacement ev. MAZE surgery (OTHERS group, n = 74). HscTnT (Roche Diagnostics) was measured at 4 timepoints: 30 minutes after finishing the surgery (A), 4 (B) and 8 (C) hours later and next morning (D). Non-parametric descriptive statistics and graphical analysis was used to characterize "expected" and "unexpected" time-course of hsTnT after cardiac surgery. Kruskal-Wallis test was used for testing differences among groups.
RESULTS
Graphical analysis revealed following hsTnT dynamics pattern: an increase between A to B, a plateau or decrease between B and C and a decrease between C and D. The most consistent results for outliers detection offered a relative change in hsTnT values between B and C samples – median [the 90th percentile] for whole group, AVR, CABG and OTHERS groups were as follows: -13 [+23] %, -14 [+24] %, -21 [+5] % and -2 [+32] % respectively. Groups were significantly different from each other ($p < 0.0001$)
CONCLUSIONS
Relative change in hsTnT levels between 4 and 8 hours after cardiac surgery can be useful in detection of "unexpected" results. Generally, a relative increase of hsTnT > 30 % requires detailed search of possible peri-operative myocardial infarction. However, prospective clinical validation against reliable markers for peri-operative myocardial infarction is needed.

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Cardiovascular diseases - Cardiac markers

Cod: T034

INTRODUCTION OF HIGH SENSITIVITY TROPONIN T ASSAY IN AN ACUTE HOSPITAL SETTING (IV)

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Background:Published data on the clinical consequences of the introduction of high sensitivity cardiac troponin (hsTnT) assays in acute hospital setting are scarce. This is a retrospective study on the patient cohort investigated for chest pain in an acute hospital setting following the introduction of hsTnT assay. Aims were to investigate the occurrence of cardiac related events and all cause mortality.
Methods: Admission and hsTnT within 3-6h were available in patients with a final diagnosis of:NSTEMI (n=18), angina (n=10), heart failure (HF, n=4), other cardiac causes (n=14) (eg ventricular ectopy), atrial fibrillation AF (n=9), musculoskeletal pain MSKP (n=7), other causes (n=32) (eg chest infection) and patients discharged from the emergency department ED (n=26). Cardiac event readmission was due to eg angiography (with recorded abnormities), chest pain, death, (HF), acute myocardial infarction,(AMI). Cardiac event free survival over a 12 month period was determined by retrospective analysis of patient notes and mortality data was from the UK National Database on mortality.
Results: Based on cut-off levels derived from receiver operated curves, in this population, an increase in hsTnT of 10 ng/L to a value greater than 20 ng/L was estimated to have a sensitivity of 92.9% , specificity 93.3%, positive predictive value 65% and negative predictive value 98.8%. Of the 18 patients with NSTEMI 4 were lost to follow up, 3 died of unknown causes and one was readmitted for cardiac related causes (AMI). Of the angina patients 7/10 were readmitted for chest pain and angina. All four coronary angiograms carried out showed abnormalities. Of the 7 patients classified as MSKP, one patient was readmitted with AF. Of the 26 patients discharged from ED one died and a second readmitted with AF.
We constructed Kaplan Meier curves to display cardiac event or mortality by NSTEMI/non-NSTEMI groups. Cardiac event free survival and mortality curves were not statistically different by the log rank (Mantel-Cox) test. 365 day survival and cardiac event free survival was approximately 80% for both cohorts.
Conclusions: Similar survival curves were observed for NSTEMI and non-NSTEMI patients following the introduction of hsTnT assay. Patients with angina were at higher risk of cardiac events.

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Cardiovascular diseases - Cardiac markers

Cod: T035

INTERDEPENDENCE BETWEEN SERUM FAS/FASL LEVEL AND INFLAMMATORY MARKERS IN PATIENTS WITH ISCHEMIC HEART DISEASE

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Background. Ischemic heart disease is mostly a consequence of atherosclerosis. The Fas/Fas ligand (FasL)/caspase death pathway and chronic inflammation are documented in atherosclerotic lesions. The goal of this study is to compare the values of soluble forms of Fas and FasL in patients with different presentations of coronary disease and to correlate Fas/FasL levels with biomarkers of inflammation such as high sensitive C-reactive protein (hsCRP), erythrocyte sedimentation rate (SE) and total number of leucocytes (LE).
Patiens and Methods. We studied 30 patients with chronic stable angina pectoris (SAP), 27 with unstable angina pectoris (USAP), and 39 had acute ST-elevation myocardial infarction (STEMI) and 27 age-matched healthy volunteers (Control group). Serum Fas/APO1 and FasL concentrations were determined using commercially available immunoassays (ELISA). Inflammatory markers were determined by standard biochemical and hematological methods.
Results. Fas/APO-1 levels in STEMI patients (6.981±2.689 ng/ml) were significantly higher than Fas levels in controls (5.092±1.252 ng/ml, $p<0.01$), but not significantly higher than Fas values in SAP (5.952± 2.069 ng/ml) and USAP patients (5.627±2.270 ng/ml). Levels of FasL did not show any significant difference between the studied groups. In SAP patients Fas/APO1 showed a significant positive correlation with hsCRP ($p<0.05$). Fas and FasL levels between the patients with hsCRP lower than 3.0 mg/L and those with hsCRP higher than 3.0 mg/L of SAP group showed a significant differences ($p<0.001$, $p<0.05$, respectively).
Conclusions. These results showed that apoptotic process is dysregulated in patients with ischemic heart disease. Fas and FasL showed interdependence with inflammatory markers.

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Cardiovascular diseases - Cardiac markers

Cod: T036

ASSESSMENT OF ANALYTICAL PERFORMANCE OF GLUCOSE METER IN PEDIATRIC AGE GROUP IN REFERRAL HOSPITAL

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Background
Glucometers are the excellent tools for self-monitoring of blood glucose (SMBG). They are important especially in the circumstances where continuous monitoring is mandatory and at decision making levels. Tight glycemic control protocols are important for preventing the ill effects of fluctuating glucose levels. This increases the use of glucometers in various healthcare settings. As technology advances, glucometers are getting better in terms of quality of results. But still some lacunae are there. We therefore decided to study quality of glucose meter results in terms of clinical outcomes.
Methods
Present study was conducted in the tertiary care referral hospital. 125 patients were recruited from pediatric wards. Bland-Altman plot, Parke error grid and Surveillance error grid analysis were used for comparing results of glucose meter with that of standard laboratory method.
Results
It is found that there is significant difference between the results by two methods. Though minimal but glucose meter results deviate from the results of standard lab method. This will affect the overall patient care especially in emergency conditions. Sometimes the risk may be so high that patient may be mislabeled as hypoglycemic when actually is hyperglycemic and vise-versa.
Conclusion
This study is the first of its kind as no similar studies have been reported in the pediatric population. For effective use of glucose meter it should give as accurate as possible estimate of actual glucose levels. Results should not only be accurate but also precise without which critical errors may be possible. We recommend that for any glucose meter there should be regular maintenance as well as calibration is to be done. So that agreement with reference laboratory method is maintained and effective medical decisions are made.

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Cardiovascular diseases - Cardiac markers

Cod: T037

ANALYTICAL PERFORMANCE OF THE NEW LUMIPULSE® G MYOGLOBIN IMMUNOASSAY FOR THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN

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Background: Myoglobin is a small heme protein located in the cytoplasm of both cardiac and skeletal muscle cells and is rapidly released into the circulation following skeletal or cardiac muscle injury.
Myoglobin plasma concentrations are elevated 2-4 hours after myocardial infarction (MI), peak at 6-12 hours, and return to normal within 24-36 hours. It is the earliest appearing biochemical marker that is routinely available for assessment of acute coronary syndrome (ACS), which includes MI and unstable angina.
We have developed a fully automated chemiluminescence immunoassay for LUMIPULSE G systems for the quantitative measurement of myoglobin.
In this study the analytical characteristics of the new Lumipulse G Myoglobin assay were evaluated.

Methods: Parameters studied included limit of detection (LoD), limit of quantitation (LoQ) with a 10% coefficient of variation (CV), linearity, interferences and antibody specificity, imprecision, 95% reference interval and measurement comparison. All studies were performed according to CLSI guidelines. The reference interval and measurement comparison was evaluated by the participating hospital using heparinized plasma obtained as left-over material from routine clinical practice.

Results: The minimum detectable myoglobin concentration (LoD) was 0.077 ng/mL. The myoglobin concentration corresponding to a total CV of 10% was 0.209 ng/mL (LoQ). Linearity was demonstrated over the range 1.6 to 1954.3 ng/mL. Common interferences did not affect measurement results. The assay's total imprecision was ≤ 4% (%CV). The observed 95% reference intervals for a healthy population were overall 15.3-96.1 ng/mL and, 16.4-97.4 ng/mL and 14.1-96.4 ng/mL in males and females respectively. For the measurement comparison between the Lumipulse G Myoglobin and the ARCHITECT STAT Myoglobin, the estimated correlation coefficient was 0.997. The intercept of the fitted Passing-Bablok regression line was -3.863, the estimated regression slope was 1.052.

Conclusion: The Lumipulse G Myoglobin assay showed overall good performance and excellent levels of imprecision across the dynamic range. The assay is well-suited for routine myoglobin measurements in human samples.

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Cardiovascular diseases - Cardiac markers

Cod: T038

ANALYTICAL PERFORMANCE OF THE NEW LUMIPULSE® G TROPONIN I IMMUNOASSAY FOR THE QUANTITATIVE AND HIGH SENSITIVE MEASUREMENT OF CARDIAC TROPONIN-I (cTnI)

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Background: Cardiac Troponin I is currently the preferred biomarker for the detection of myocardial necrosis compared to other available biomarkers.
We have developed a fully automated chemiluminescence immunoassay for LUMIPULSE G systems for the quantitative and high sensitive measurement of cardiac troponin I.
In this study the analytical characteristics of the new Lumipulse G Troponin I assay were evaluated.

Methods: Parameters studied included limit of detection (LoD), limit of quantitation (LoQ) with a 10% coefficient of variation (CV), linearity, interferences and antibody specificity, imprecision and 99th percentile upper reference limits (URL). All studies were performed according to CLSI guidelines. Different hospitals participated in the study for reference limits. A total of 1018 matched serum and heparinized plasma samples, 590 male and 428 female subjects, were collected from healthy individuals with normal levels of BNP or NT-proBNP, glucose, urea and creatinine.

Results: The minimum detectable cTnI concentration (LoD) was 2.1 pg/mL. The cTnI concentration corresponding to a total CV of 10% was 7.3 pg/mL (LoQ). Linearity was demonstrated over the range 1.0 to 43098.1 pg/mL. Common interferences did not affect measurement results. The assay's total imprecision was ≤ 7.2% (%CV). The observed 99th percentile cTnI URL in serum for a healthy population were overall 26.9 pg/mL and, 29.4 pg/mL and 21.4 pg/mL in male and female respectively. The percentage of measurable cTnI values below the 99th percentile and above the LoD was 68.1%. The imprecision estimated at the 99th percentile was ≤ 4.3%CV (calculated from the precision profile).
The values and levels of precision at the 99th percentile together with the percent measurable cTnI values in heparinized plasma, were comparable to the values estimated in the matched serum set.

Conclusion: The Lumipulse G Troponin I assay showed to be sensitive, specific and precise. The performance of the assay meets current requirements for a high sensitive assay to be used as an aid in the diagnostics and risk management of acute coronary syndrome patients.

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Cardiovascular diseases - Cardiac markers

Cod: T039

CHARACTERISTICS OF THE NEW BECKMAN COULTER ACCESS hsTnI ASSAY

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BACKGROUND: In order to meet new IFCC guidance new Troponin I assays should exhibit increased sensitivity (LoB, LoD and LoQ), precise measurement of cTnI concentrations in the range seen in healthy individuals and the capability to accurately detect changes in cTnI concentration within this range.
RESULTS: Beckman Coulter's new high sensitivity Access hsTnI assay exhibits superior sensitivity in comparison to other currently marketed devices with an estimated LoB of < 0.0005 ng/mL (0.5 pg/mL), LoD < 0.002 ng/mL (2 pg/mL) and 10% CV LoQ < 0.020 ng/mL (20 pg/mL). The estimated 99th percentile URL of a random healthy population is 0.032 ng/mL (32 pg/mL) determined with < 3% intra-assay and 8% Total imprecision. In addition, this new Access hsTnI assay is capable of accurately measuring 0.010 ng/mL (10 pg/mL) changes in cTnI concentrations. This Access hsTnI assay accurately measures cTnI in comparison to a currently validated device (correlation between Access AccuTnI+3 and hsTnI within 5%) and exhibits < 5% bias between sample types (serum, plasma). The assay does not exhibit cross reactivity to cardiac TnT, cardiac TnC, skeletal TnI or skeletal TnT and is robust against common interferences (400 mg/dL hemoglobin, 40 mg/dL bilirubin, 3000 mg/dL triglyceride 60 mg/mL albumin, 1000 mg/dL fibrinogen, 28.8 U/mL heparin).
CONCLUSIONS: Beckman Coulter's new high sensitivity Access hsTnI assay is highly sensitive and sufficiently accurate to precisely measure cTnI in > 90% of the normal population and meets new IFCC guidance to accurately detect changes in cTnI concentration within healthy subjects. This new assay is currently is in development, pending achievement of CE compliance and is not available for in vitro diagnostic use.

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Cardiovascular diseases - Cardiac markers

Cod: T040

PLASMA VEGF AND PLGF – AS INDICATORS OF RISK HEART TRANSPLANT REJECTION

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Background. Cardiovascular complications such as acute cellular rejection (ACR) and antibody mediated rejection (AMR) reduce the survival rate in recipients after heart transplantation (HTx). The development of non-invasive immunochemical assays that can accurately detect heart transplant rejection would be an alternative to invasive endomyocardial biopsy. Multimarkers analysis allows to increase the sensitivity and specificity of diagnosis.
Aim: to determine the clinical significance of vascular endothelial growth factors VEGF-A, VEGF-D, PlGF-1 to assess the risk of cardiovascular complications in heart recipients by multiplex assay.
Materials and methods. 103 pts, aged 16 to 73 years, 85 males and 18 females. Before HTx 65 recipients (47 men and 18 women) had dilated cardiomyopathy, 38 – coronary heart disease. The pts were monitored on ACR and AMR by endomyocardial biopsy. The concentration of VEGF-A, VEGF-D, PlGF-1 was measured using xMAP technology with sets of reagents Simplex ProcartaPlex™ before and after HTx.
Results. Before HTx there were no correlations between the levels of VEGF-A, VEGF-D and PlGF-1 with age, gender and diagnosis. After HTx the level of VEGF-A significantly decreased, p=0.001. Posttransplantation level of VEGF-A was higher in recipients with ACR than in those without it (p=0.001). ACR frequency was significantly higher in patients with high VEGF-A level (≥316.5 pg/ml, RR = 5.8 ± 0.5, AUC = 0.779). PlGF-1 level also was higher in recipients with ACR (p = 0.039). ACR frequency was significantly higher in patients with high PlGF-1 level (≥5.33 pg/ml, RR = 1.8 ± 0.5, AUC = 0.65). There were no correlations between VEGF-D level with ACR and all three biomarkers with AMR. ACR frequency was significantly higher in patients with both high VEGF-A and PlGF-1 levels (RR = 6.4).
Conclusion. Plasma levels of VEGF-A and PlGF-1 but not VEGF-D after HTx correlated with development of ACR. Both high levels of VEGF-A and PlGF-1 may be regarded as indicators of increased risk of ACR.

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Cardiovascular diseases - Cardiac markers

Cod: T041

THE INFLUENCE OF ATORVASTATIN ON THE LEVELS OF 25-HYDROXYVITAMIN D

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Background: Low levels of 25-hydroxyvitamin D (25(OH)D) are associated with a higher risk of cardiovascular morbidity and mortality. The vitamin D deficiency is a highly prevalent condition, present in approximately 30% to 50% of the general population. The aim of this study was to investigate the possible effect of atorvastatin on the vitamin D metabolism.
Methods: The study group consisted of 34 patients (aged 56±10.4yrs) after the first acute myocardial infarction (AMI) who had not been treated with lipid lowering medications. Atorvastatin (40mg/day) was given to all subjects as secondary prevention. Lipid parameters, 25(OH)D, renal and liver function tests were obtained at the baseline and after 4 weeks of atorvastatin treatment. Serum lipids and other biochemical tests were determined by automated analyzer Cobas c501 (Roche Diagnostics, Germany). Serum 25(OH)D was measured by chemiluminescence method (DiaSorin Liaison, Italy).
Results: In more than 83% of patients vitamin D deficiency (25(OH)D<20 ng/mL) was stated at baseline. After 4 weeks of atorvastatin therapy, the concentration of 25(OH)D in all population increased by 8.63% (14.04±6.51ng/ml vs. 15.3±7.40ng/ml; p=0.04). Regardless of that situation, we were be able to distinguish 2 groups of patients with the increased concentration of 25(OH)D (n=21) (group A) and the decreased concentration of 25(OH)D (n=13) (group B). The atorvastatin therapy in group A revealed an increase in the concentration of 25(OH)D (14.7±7.6ng/ml vs. 17.9±7.8ng/ml; p<0.0001), while the reverse effect was achieved in group B, the concentration of 25(OH)D decrease from 13.0±4.3ng/ml to 11.0±4.13ng/ml; p=0.003. In both groups independently to the effect on 25(OH)D levels, atorvastatin normalizes (statistically significance) the concentrations of serum lipids: TCh, TG, LDL-Ch and HDL-Ch.
Conclusions: Atorvastatin exhibited a different effect on the serum level of 25(OH)D. The short term atorvastatin therapy resulted in lipid lowering in patients after AMI, independently of its effect on the concentration of 25(OH)D. The mechanism by which 25(OH)D levels increase and/or decrease during the atorvastatin treatment is not clarified. Further studies are needed to clarify the relationships between statins and vitamin D physiology.

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Cardiovascular diseases - Cardiac markers

Cod: T042

SURVEY OF CURRENT LABORATORY AND CLINICAL PRACTICES FOR CARDIAC TROPONIN TESTING IN AUSTRALIA AND NEW ZEALAND (PART 1)

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Introduction:
Recent international surveys have reported on the lack of harmonisation of cardiac troponin (cTn) measurement in the routine laboratory and at the point-of-care (POC). The Australasian Association of Clinical Biochemists (AACB) conducted a recent survey in April/May of 2016 to assess the current laboratory and clinical practices for cTn testing.
Methods:
Participants were asked about pre-analytical, analytical and post-analytical issues relating to cTn measurement in automated laboratories and at the POC. They were asked to tick all answers that applied to their location or to provide text, e.g. cTn decision cut-off value.
Results:
The 177 respondents represented largely Australia (75.4%), New Zealand (13.5%), and South East Asia (7.9%). Of the 11.9% of quantitative POC assays being used, the predominant assay was Abbott i-STAT cTnI. Automated laboratory cTn assays included the highly sensitive assays Abbott Architect STAT hs-cTnI (16.8%) and Roche Elecsys / cobas hs-TnT (32.3%), with other sensitive assays comprising 38.4%. The cTn decision cut-off was defined as the concentration above the 99th percentile by 34.4%, 10% CV by 7.2%, 20% CV by 2.4%, WHO cut-off by 4.8%, a cut-off from the reagent supplier by 19.6%, a cut-off derived and validated locally by 12.4%, and 15.8% did not know. Male and female cut-offs were used by 31 laboratories and age-specific cut-offs by 7 laboratories. Troponin decision cut-offs for hs-TnT ranged from 3-30 ng/L (57.9% used 14 ng/L), and for hs-TnI, from 23-50 ng/L (63.6% used a male cut-off of 26 ng/L and 95.5% a female cut-off of 16 ng/L). Troponin units were mainly µg/L (29.9%) and ng/L (57.1%).
Conclusions:
While decision cut-offs for hs-TnI and hs-TnT assays are fairly well harmonised between the 49% of laboratories using them, cut-offs used for sensitive and POC assays are less well harmonised. Units require improved harmonisation to ng/L in whole numbers.

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Cardiovascular diseases - Cardiac markers

Cod: T043

SURVEY OF CURRENT LABORATORY AND CLINICAL PRACTICES FOR CARDIAC TROPONIN TESTING IN AUSTRALIA AND NEW ZEALAND (PART 2)

J. Tate [6], R. Tirimacco [4], P. Simpson [4], A. Horvath [2], L. Cullen [3], F. San Gil [2], C. Martin [6], G. Koerbin [5], P. Tideman [4], P. Graham [1]

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Introduction:
Recent international surveys have reported on the lack of harmonisation of cardiac troponin (cTn) measurement in the routine laboratory and at the point-of-care (POC), including other tests ordered with cTn, sample haemolysis, optimal blood sampling and turnaround times (TAT). The Australasian Association of Clinical Biochemists (AACB) conducted a recent survey in April/May of 2016 to assess the current laboratory and clinical practices for cTn testing.
Methods:
Participants were asked about pre-analytical, analytical and post-analytical issues relating to cTn measurement in automated laboratories and at the POC. They were asked to tick all answers that applied to their location.
Results:
Other cardiac biomarkers routinely ordered with cTn included total CK (30.1%), CK-MB (13.7%), myoglobin (3.6%), and natriuretic peptides (17.7%) compared with no other biomarkers ordered (27.7%). A timed myocardial infarction protocol was used by 55.3% (94 sites), but not by 29.4% (50 sites), and 15.3% (26 sites) did not know. Of 221 responses, the recommended blood draw times for cTn within the timed protocols were 0 h (presentation; 31.2%), 1 h (2.7%), 2 h (9.0%), 3 h (9.0%), 4 h (8.1%), 6 h (21.7%), 9 h (0.5%), 12 h (3.6%), 24 h (1.8%), unknown (5.0%), and other (7.2%). The procedures for handling haemolysed samples were to reject samples and asked for a recollection (11.6%), reject results above a specified haemolytic index and ask for a recollection (38.8%), report cTn without a comment (15.0%), or provide a comment about the potential for interference (17.0%). 82.8% of participants had a TAT goal for cTn of < 60 min (56.5%) that was based on specimen receipt in the laboratory to time of reporting cTn.
Conclusions:
The survey has provided important data about laboratory and clinical practices in cTn testing particularly in Australasia. A concerted effort is required to harmonise practices where appropriate.

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Cardiovascular diseases - Cardiac markers

Cod: T044

PON1, ADIPONECTIN AND CARDIOVASCULAR RISK IN TYPE 2DIABETES

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Background: Considering the increased risk of cardiovascular complications in patients with type 2 diabetes, we realize this study to verify whether paraxonase 1 activity (PON1) and adiponectin could be a risk factor for cardiovascular disease (CVD) in type 2diabetic patients.
Methods: This study included 390 patients with diabetes type 2 mean age 59.71 ± 11.32 years (133 men (34, 10%) and 257 women (65.9%)) compared to 90 controls non diabetic mean age 52.75 ± 13.38 years witnesses (19 men (21, 11%) and 71 women (78.89%)). All patients and controls were followed for three years to assess cardiovascular risk.
Results: We found that the lowest values of PON1 and adiponectin are observed in type 2 diabetic group especially with CVD.
After adjustment for confounding factors according to PON1, we obtained an odds ratio (OR) of 1.575; p = 0.172 and IC 95% from 0.820 to 3.023 for CVD and an OR of 0.812; p = 0.606 and IC 95% from 0.368 to 1.791 for new cardiovascular events.
After adjustment for confounding factors according to adiponectin, we obtained an OR of 5.888; p = 0.013 and IC95% from 1.452 to 23.872 for CVD.
Conclusion: The implication of diabetes and CVD in the decrease of PON1 activity seems highly probable but PON1 activity seems not to be in itself a marker of CVD. Adiponectin appears to be a good marker of CVD.

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Cardiovascular diseases - Cardiac markers

Cod: T045

VITAMIN D, LDL OXIDIZED, CRP, CRP ULTRASENSITIVE AND CARDIOVASCULAR RISK IN TYPE 2DIABETES

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Background: Considering the increased risk of cardiovascular complications in patients with type 2 diabetes, we realize this study to verify whether vitamin D, LDL oxidized, CRP and CRP ultrasensitive could be a risk factor for cardiovascular disease (CVD) in type 2diabetic patients.
Methods: This is a cross-sectional study that examined 390 patients with diabetes type 2 (mean age of 59.71 ± 11.32 years), diabetes age is 7 years [1-50] and 90 controls non diabetic (mean age 52.75 ± 13, 38 years). All patients and controls were followed for three years to assess cardiovascular risk.

Results: We found that the highest values of CRP, CRP ultrasensitive, vitamin D, and LDL oxidized are observed in Type 2 diabetic group with a significant difference. In type 2 diabetic patients, we noted a significant increase in CRP and CRP ultrasensitive in patients with cardiovascular disease.
After adjustment for confounding factors according to CRP, we obtained an odds ratio (OR) of 1.909; p = 0.029 and IC 95% from 1.067 to 3.418 for CVD and an OR of 1.386; p = 0.002 and IC 95% from 1.125 to 1.709 for new cardiovascular events.
After adjustment for confounding factors according to CRP ultrasensitive, we obtained an OR of 2.135; p = 0.006 and IC95% from 1.246 to 3.660 for CVD and an OR of 1.507; p = 0.302 and IC 95% from 0.691 to 3.284 for new cardiovascular events.
Conclusion: We found no association between levels of vitamin D and LDL oxidized with CVD. CRP appears to be a good marker of CVD installed and in the next two years while CRP ultrasensitive is associated with installed CVD.

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Cardiovascular diseases - Cardiac markers

Cod: T046

EVALUATION OF A NOVEL DIRECT IMMUNOFLUOROMETRIC ASSAY FOR FREE PAPP-A

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BACKGROUND-AIM

Circulating pregnancy-associated plasma protein A (PAPP-A) and especially its noncomplexed free form (fPAPP-A) has been documented to predict adverse cardiac events. However, assay that could measure fPAPP-A directly has been unavailable. Total PAPP-A (free and complexed PAPP-A together) and two-assay fPAPP-A (difference of the results of total PAPP-A and complexed PAPP-A assays) measurements suffer from the baseline levels of complexed PAPP-A that vary between individuals and are not sensitive and reliable enough in measuring low level samples. Here, a novel direct sandwich-type immunofluorometric immunoassay for fPAPP-A is presented.

METHODS

A capture antibody recognizing only the free form of PAPP-A was biotinylated and bound to streptavidin coated microtiter well. As the tracer antibody we used a PAPP-A antibody that recognizes PAPP-A in free and complexed form. The tracer antibody was labelled with an intrinsically fluorescent Eu^{3+} chelate and the fluorescence measurement was done in time-resolved manner. The developed assay was evaluated according to CLSI guidelines using recombinant fPAPP-A as the measurand and serum and heparin plasma samples from healthy individuals, acute coronary syndrome patients and vascular surgery patients as endogenous materials.

RESULTS

LoB, LoD and LoQ were determined to be 0.25 mIU/L, 0.40 mIU/L and 1.21 mIU/L (20% CV), respectively. The assay detected recombinant fPAPP-A similarly in buffer, serum and heparinized plasma (mean recoveries 93%, 113% and 100%, respectively). Cross-reactivity towards complexed form of PAPP-A was <3%. With serum samples of healthy individuals (60 women, 59 men, 31-84 years) the median fPAPP-A was 1.05 mIU/L (25th-75th %ile 0.77-1.45 mIU/L). Method comparison with fPAPP-A two-assay approach using acute coronary syndrome patients (n=301, fPAPP-A 0.42-50.51 mIU/L) showed good correlation (Pearson's r=0.818) but novel direct fPAPP-A assay measured on average 13% lower concentrations.

CONCLUSIONS

We have developed a direct fPAPP-A assay that is both sensitive and reliable in measuring fPAPP-A from blood samples. Taking into account the low concentrations of free PAPP-A in control individuals, our new assay is expected to enable improved risk prediction over the previous two-assay approach.

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Cardiovascular diseases - Cardiac markers

Cod: T047

HEPARIN-INDUCED FREE PAPP-A RELEASE IN SUSPECTED CORONARY ARTERY DISEASE PATIENTS

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BACKGROUND-AIM

Elevated circulating pregnancy-associated plasma protein A (PAPP-A) has been detected in patients with coronary artery disease (CAD). PAPP-A has been found in eroded and ruptured arterial plaques but not in stable ones. PAPP-A and especially its noncomplexed free form (fPAPP-A) has been suggested to reflect the vulnerability of the atherosclerotic plaques and increased risk of myocardial infarction. Heparin administration has been found to increase rapidly and significantly circulating PAPP-A in haemodialysis, myocardial infarction and intensive care patients and in healthy individuals. We set out to study the extent of heparin-induced fPAPP-A release in patients with suspected CAD.

METHODS

Patients with suspected CAD (n=34) scheduled for CT-angiography were included in the study. The patients were given a small intravenous dose (0.2 mg/kg) of low molecular weight heparin (LMWH). Blood samples were drawn from a vein cannula before LMWH administration and 3, 5 and 10 minutes after (a pilot study to confirm post-LMWH sampling time, n=8) or only before and 5 minutes after LMWH. FPAPP-A concentrations were measured with a novel in-house immunoassay for fPAPP-A utilizing antibodies that detect only the free form of PAPP-A.

RESULTS

For the post-LMWH sampling time 5 min was chosen for the whole cohort as the patients of the pilot study showed highest PAPP-A levels at 5 min (median 14.81 mIU/L) as compared to the other sampling times (3 min 7.53 mIU/L; 10 min 14.40 mIU/L). Median fPAPP-A concentration among the patients of the whole cohort was 0.55 mIU/L before LMWH administration and 15.06 mIU/L 5 min after LMWH administration. The fPAPP-A responses varied significantly between individuals (min increase 0.13 mIU/L, max increase 23.77 mIU/L).

CONCLUSIONS

After LMWH administration, a clear increase in circulating fPAPP-A was seen in all patients with suspected CAD, although the extent of the response varied significantly between individuals. Therefore, it will be interesting to compare the immunoassay results to the extent and severity of changes discovered in coronary arteries in the CT angiography.

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Cardiovascular diseases - Cardiac markers

Cod: T048

PERFORMANCE EVALUATION OF THE ATELLICA™ IM HIGH-SENSITIVITY TROPONIN I ASSAY

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Background: The Siemens Atellica IM High-sensitivity Troponin I (TNIH) assay[1] is an in vitro diagnostic immunoassay for the quantitative determination of cardiac troponin I in serum or plasma. The primary objective of this study is to demonstrate the analytical performance of TNIH assay on the Atellica Immunoassay System[2].
Method: The Atellica IM TNIH assay uses the same reagents and calibrators as the ADVIA Centaur XP/XPT TNIH assay. The TNIH assay is a dual-capture sandwich immunoassay. The detection reagent is a recombinant sheep Fab antibody covalently linked to Tri-Sulfo Propyl Acridinium Ester-BSA conjugate. The sample is incubated with the magnetic solid phase capture and detection reagents which are subsequently washed and treated with acid and base reagents to initiate chemiluminescence. The relative light units are proportional to the cTnI concentration. The Atellica IM TNIH assay precision, Limit of Blank (LOB), Limit of Detection and (LoD) are evaluated according to CLSI protocol EP05-A3. LoQ is defined as the cTnI dose at 20% Within-Lab CV.
Results: Within-run precision at the 99th percentile, 45 pg/mL, is less than 2.8% determined with 3 reagent lots on 2 systems in a 20-day ANOVA study. Between 9 pg/mL and 20 pg/mL the repeatability ranged from 4.0% to 5.4% and within-lab precision ranged between 5.2% and 7.0%. Above 20 pg/mL, the repeatability ranged from 0.9% to 3.2% CV, and within-lab precision ranged from 1.9% to 5.2% CV. The LoB is 0.55 pg/mL. The LoD ranged from 1.1 pg/mL to 1.3 pg/mL. LoQ ranged from 1.9 pg/mL to 2.9 pg/mL. The between lot reagent bias measured on the Atellica IM Analyzer is less than 4% as measured by method comparison with n=160 AMI patient samples.
Conclusion: The Atellica IM TNIH assay has demonstrated accuracy and precision for use in detecting low cardiac troponin I levels.
[1.] Assay under development, not available for sale.
[2.] Not CE Marked. Not available for sale. Any features listed are part of the design goals. Future availability cannot be guaranteed.

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Cardiovascular diseases - Cardiac markers

Cod: T048 bis

MAGNESIUM DURING HOSPITALISATION AFTER ACUTE INFARCT OF MIOCARD

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BACKGROUND: Determination of the only physiologically active form of magnesium (Mg), ionized magnesium (iMg), is insufficiently clinically performed. Potentially established importance of iMg would contribute to the implementation of Mg in prophylaxis, diagnosis and therapy of acute infarct of myocardium (AIM).
METHODS: Venous blood was anaerobically collected from 91 patients at admission, during the following four days and on the tenth day. Determination of serum iMg levels were performed by the AVL 988/4 ion selective analyzer and creatine kinase (CK) activities were determined spectrophotometrically.
RESULTS: Mean values of iMg levels continuously increased during hospitalisation. All the days except for the tenth day after the onset of symptoms iMg levels were significantly lower (Mann Whitney test) than the reference group. The stated limits presented mean value of reference range ± one standard deviation (0.744 ± 0.0555 mmol/L). According to dynamics of changes of iMg levels during hospitalisation patients could be differentiated into four groups: normal (36%, N), all the days iMg levels were within the limits; subnormal (24%, S), all the days iMg levels were below lower limit; effective normalisation (19%, E), the first day iMg levels were below lower limit, afterwards they were within the limits; prolonged normalisation (21%), the first four days iMg levels were below lower limit, afterwards within the limits. The most prominent decrease in initial iMg levels was noted in the group S (0.629 mmol/L) and the least one in the group E (0.680 mmol/L). Limit values mostly corresponded with decision limit values. The presence of deceased patients and patients whose maximum CK values (peak) are greater than 1800 U/L is the largest in the group S, but does not exist in group N which is characterized by the smallest CK peak (735 U/L) and the lowest representation of AIM with ST segment elevation.
CONCLUSIONS: The results sugest that decrease of iMg levels was not registered in some AIM, probably of smaller volume. Intensity of acute stress in AIM affected the degree of reduction of iMg levels. The reduction of iMg levels was greater, a risk for their delayed normalisation is higher. The iMg normalisation was more delayed, the concern for the successful outcome is greater. If iMg levels were not normalized for three days from the onset of symptoms there is a need for caution.