Critical care, emergency medicine, blood gases, POCT

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THE SHARE OF CLINICAL BIOCHEMISTRY ON DIAGNOSTICS AND THERAPY OF CRITICALLY ILL PATIENTS.

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BACKGROUND-AIM

The treatment of critically ill patients is a very complex issue. It often demands a cooperation of multidisciplinary medical team. The main role of clinical biochemists is to submit a correct interpretation of laboratory findings in a full pathobiochemical context.

METHODS

The case report of the critically ill patient is described. His laboratory findings are shown in the tables. The value changeover had been checked on in regular intervals throughout 5 days. All findings, relations and developments are followed by commentaries.

RESULTS

The 25-years-old man with the 1st type diabetes mellitus was transferred to the ICU by ambulance in coma. The basic pathological finding was an extreme hyperglyceamia (107mmol/L), and severe disturbance of acid-base status (pH 6.739). The increase of effective osmolality caused by heperglyceamia results in decrease of natremia (127mmol/L). During 8 hours correction of hypergylceamia was followed by dramatic natremia increasing (162mmol/L). Simultaneously, a pre-renal failure with anuria and rhabdomyolysis were developed.

CONCLUSION

The case report presented shows a complexity and severity of the homeostasis disturbances. It has an educational significance; moreover, it demonstrates the share of clinical biochemistry on diagnostic and therapy of critically ill patients.

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POINT OF CARE TEST GLUCOSE METERS: THE BEAUTY OR THE BEAST?

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BACKGROUND-AIM

The Nova StatStrip®Glucose has proven to be an accurate blood glucose measuring system (BGMS) and was recently FDA approved as first BGMS for use in critical care patients. To ensure a good BGMS is fit for purpose, however, it is necessary to use such systems in a controlled clinical laboratory setting. In hospitalized patients blood glucose medication is immediately adapted based on these measurements, making accuracy more important than in the outpatient population.

METHODS

We perform a method validation study on each new batch of StatStrip® Glucose strips to ensure optimal performance, according to ISO 22870. The validation comprises an accuracy study in which the glucose values of the StatStrip® BGMS are compared with the hexokinase method on Roche Cobas 6000 c501, the routine method used in the core laboratory. Based on the CLSI EP9-A2 protocol, a minimum of 40 venous blood patient samples are analyzed, covering the entire BGMS measuring range. At least 2 different lot numbers are evaluated in parallel.

RESULTS

From September 2012 on, the accuracy of 11 different StatStrip® Glucose lot numbers was evaluated. A consistent negative bias against the hexokinase method was found, ranging from -3.5% to -12.3%. All lots were conform the ISO 15197:2003 acceptance criteria, but only 8 were compatible with the revised ISO 15197:2013 criteria. None met the recently postulated draft FDA BGMS criteria for hospital use. The laboratory retained only 5 lots for routine implementation, all with a mean negative bias less than 7%.
Because a possibly increasing negative bias over time was also noted, we initiated a root cause analysis in cooperation with the manufacturer (Nova, USA) and the distributor (A. Menarini, Italy).

CONCLUSION

For every BGMS used in hospital care, the central role of the laboratory in controlling the release of glucose strips, using stringent criteria is mandatory to allow appropriate clinical decision-making. One should be aware of the idealized conditions in which the lot validations are performed, thereby potentially overestimating the accuracy of the BGMS.

Critical care, emergency medicine, blood gases, POCT

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CARDIAC MARKERS IN "POINT OF CARE" DIAGNOSTICS: CHALLENGES AND PERSPECTIVES

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BACKGROUND-AIM

The most important word which is related to the benefit for patients of an early diagnosis of acute myocardial infarction (AMI) is "Time is muscle". Detection of cardiac markers is the basis of current diagnostic tests for AMI. The aim of the study was to analyze diagnostic efficiency of cardiac markers in point of care diagnostics.

METHODS

The studied subjects were the control group (50 non-AMI patients) and the experimental group (50 AMI patients). We examined the value of serum levels of myoglobin (Myo), cardiac troponin T (cTnT), creatine kinase (CK), creatine kinase MB (CK-MB) activity, CK relative index (RI), aspartate aminotransferase activity (ASAT), lactate dehydrogenase (LDH) and α -hydroxybutyrate dehydrogenase (α -HBDH) activity, together with electrocardiogram (ECG) abnormalities in patients with AMI. Patients with AMI from the Intensive Coronary Department were analyzed in the following time points: baseline (immediately after admission and 2, 4, 8, 12 and 24h after the onset of symptoms. Limits of decision for AMI (cut-off) values are for CK-MB 25 U/L, for CK 345,6U/L, for ASAT 37U/L, for RI 6%, for LDH 480U/L, for α-HBDH 220U/L for Myo 90 μg/L, for Troponin T 0, 1 ng/ml.

RESULTS

Myoglobin was the earliest marker and its negative predictive value (NPV) was significantly higher (89% 4 hours after the onset of symptoms) than for CK-MB. Troponin T wasn't an early marker for ruling out AMI and NPV changed over time, together with CK-MB activity. The NPV of CK-MB reached 95% 8 hours after the onset of symptoms. An early positive TnT test correlates with higher CK-MB activity and appears to identify patients at the highest clinical risk. The sensitivity of the rapid bedside assay of cTnT increased from 33% within 2 hours at the onset of chest pain to 86% after 8 hours, diagnostic specificity ranged from 86% to 100% during the same time interval.

CONCLUSION

The rapid assay for Troponin T and Myoglobin is useful point of care device for early triage of patients with acute coronary syndromes and useful confirmatory device for identifying patients with ST segment elevation in AMI. Because of that proper lifestyle from the earliest childhood is important key in primary prevention of atherosclerosis.

Critical care, emergency medicine, blood gases, POCT

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MEASURING PH IN PLEURAL AND ASCITES FLUIDS USING THE LAQUATWIN® COMPACT PH METER

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BACKGROUND-AIM

Pleural fluid pH measurement is important to determine whether chest tube drainage in parapneumonic effusion (PPE) is needed. The risk of PPE is greater if the pH is ≤ 7,2, and drainage of pleural fluid is indicated. Pleural fluid with pH > 7,2 has a favorable outcome and usually only antibiotic treatment is needed. The measurement of pH in ascites is used for early diagnosis of spontaneous bacterial peritonitis in alcoholic cirrhosis. There are several pre-analytical factors justifying the use of point-of-care devices to determine pH in body fluids: collection should be performed under anaerobic conditions. Transport and measurement of pH in a blood gas analyzer or pH meter should be done within 1 hour. This study discusses the analytical and diagnostic performance of the LAQUAtwin® compact pH meter (HORIBA scientific) in patients with pleural and ascites fluid.

METHODS

To assess the analytical performance of LAQUAtwin®, pH was measured in certified standard buffer solutions (Certipur®, Merck) having pH 4,0, 7,0 and 9,0. The diagnostic performance is evaluated by measuring pleural and ascites pH in clinical samples on the LAQUAtwin® and a blood gas analyzer (Rapid point 500®, SIEMENS healthcare diagnostics inc.) as a comparing reference.

RESULTS

Analytical performance was excellent. Our intra- and inter-assay standard deviation (SD), determined at three standard pH levels never exceeded the manufacturer's specification for intra-assay SD (< 0,1 pH). The absolute bias measured at the three pH levels was smaller than the manufacturer's specification for accuracy (< 0,1 pH). Body fluids were collected (36 pleural and 5 ascites). An overall clinical and diagnostic concordance of 76% (κ = 0,52 with 95%CI[0,30-0,75]) and 83% (κ = 0,57 with 95%CI[0,29-0,85]) respectively, was achieved. In 6 pleural fluids there was a diagnostic discordance using the two systems. LAQUAtwin® suggested a pH > 7,2 while RP 500® indicated a pH ≤ 7,2. In fact clinicians started thorax drainage for 4 of these patients because of PPE. Retesting a discordant sample with a solitary reference pH meter (CG820 SCHOTT®) revealed that the LAQUAtwin® measured the correct pH!

CONCLUSION

Analytical performance of LAQUAtwin® was excellent. More samples are needed for evaluating the clinical and diagnostic performance of LAQUAtwin®. Limited data are available concerning the validation of the RP 500® pleural fluid pH application. Our data show that at least in one sample the LAQUAtwin® result was correct and the RP 500® result was not.

Critical care, emergency medicine, blood gases, POCT

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EVALUATION OF THE RESULTS OF THE CROSS COMPARISON BETWEEN CLINICAL CHEMİSTRY AUTOANALYZER AND GLUCOMETER

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BACKGROUND-AIM

Blood glucose testing using glucometers is a fast method of monitoring blood glucose levels. Despite the increasing use of glucometers, there is no a standard procedure for assessing the effect of instrument quality on glucometers' technical and analytical performance.

METHODS

We evaluated 732 measurements from glucometers between clinics together with laboratory cross control procedures at the Trabzon Fatih State Hospital between January and November, 2014. The patients involved were hospitalized for treatment and were receiving blood sugar monitoring. During routine morning blood glucose measurement, a venous blood specimen was also collected and forwarded to the laboratory. Bedside glucose measurement was performed with Astracheck devices, and laboratory glucose measurement using a Vitros 5.1 Fusion chemical analyzer. The Vitros Fusion clinical chemistry analyzer CV value was 1.7% for glucose test. The baseline value in cross-comparison between glucometers and laboratory clinical chemical autoanalyzers was ±20%. Results which differed from ±20% were repeated.

RESULTS

Measurement results from glucometer and autoanalyzers were compared. All devices were assessed simultaneously with 2-level quality control material, and values were between expected limits. Five hundred twelve (57.1%) measurement results were within expected limits, while 220 (42.9%) were outside expected limits and were repeated. Ninety-seven (44.1%) repeat measurements were within expected limits, while 123 (55.9%) were still outside.

CONCLUSION

The reliability of clinical chemical autoanalyzer results in the laboratory can be tested with internal and external quality control. Daily quality control of bedside test devices is not usual in clinical practice. Weekly, two-weekly or monthly internal quality control and cross-comparison with the laboratory are performed instead. The baseline value in cross-comparison between glucometers and autoanalyzers is ±20%. The most significant parameter affecting this deviation is the preanalytical phase. In this study, unacceptable results were repeated in a manner compatible with specimen collection rules. More than half the repeat measurements still being inappropriate shows the importance in terms of test reliability of both the preanalytical and analytical phases, as with all devices.

Critical care, emergency medicine, blood gases, POCT

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WHITE BLOOD CELL COUNT: MICROSCOPY OR POINT-OF-CARE TEST?

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BACKGROUND-AIM

The white blood cell count (WBC) can be used as a valuable tool in the diagnostic workup of patients in primary care. Currently, our pediatrics use WBC results obtained by microscopy. HemoCue® WBC system (HemoCue AB) is a point-of-care test (POCT) that provides quantitative WBC results. We have evaluated both methods in terms of agreement (with each other and in relation to our laboratory analyzer ADVIA® 2120i (Siemens)), user-friendliness and cost.

METHODS

HemoCue® WBC System can be used on capillary or venous whole blood (EDTA) (measurement range 0.3-30.0x109/L).
ADVIA® 2120i can be used on venous whole blood (EDTA) (measurement range 0.02-400x109/L).
Microscopy (Bürker chamber and Türk's solution (Merck Millipore)) was performed by one experienced employee.
We collected:
- 14 whole blood (EDTA) specimens to compare the results obtained by ADVIA® 2120i and HemoCue®. Different studies already showed a good correlation between both methods.
- 37 whole blood (EDTA) specimens to compare the results obtained by ADVIA® 2120i and microscopy.
- 40 whole blood (EDTA) specimens to compare the results obtained by microscopy and HemoCue®.
The methods were compared using Passing-Bablok linear regression and Bland-Altman difference plots.

RESULTS

ADVIA® 2120i - HemoCue®: A slope of 0.93 (95% CI: 0.79 to 1.14) and an intercept of 0.12 (95% CI: -2.21 to 1.61) were found. Bland-Altman plot showed a mean systematic bias of 7.0%.
ADVIA® 2120i - microscopy: A slope of 1.06 (95% CI: 0.92 to 1.23) and an intercept of -0.94 (95% CI: -2.36 to 0.12) were found. Bland-Altman plot showed a mean systematic bias of -7.1%.
Microscopy - HemoCue®: A slope of 1.00 (95% CI: 0.89 to 1.14) and an intercept of -0.50 (95% CI: -1.51 to 0.34) were found. Bland-Altman plot showed a mean systematic bias of -6.8%.

CONCLUSION

Both microscopy and POCT HemoCue® are acceptable and can be used as a valuable tool in the diagnostic workup of paediatric patients. HemoCue® is user-friendly, easy to handle and results are available in 3 minutes but the method is much more expensive. Microscopy requires a more intensive training, but an experienced employee can complete the WBC count also in less than 3 minutes. Due to the higher cost of HemoCue®, manual microscopy still is a valuable alternative.

Critical care, emergency medicine, blood gases, POCT

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LYMPHOPENIA AS PREDICTOR OF BLOODSTREAM INFECTION IN PATIENTS WITH SUSPECTED SEPSIS IN AN EMERGENCY DEPARTMENT

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BACKGROUND-AIM

Bloodstream infection (BSI) is associated with a reduction in circulating lymphocytes. Lymphopenia has been proposed as an early marker of BSI in febrile adults in the emergency department (ED) setting. The aim of this study was to compare lymphocyte count (LC) with other conventional markers as predictor for bacteremia in patients presenting to the ED with systemic inflammatory reponse síndrome (SIRS) and suspected severe infection.

METHODS

Population study: Adult patients presenting to the ED of our hospital with two or more criteria for SRIS and clinically suspected infection were included. Cancer patients with febrile neutropenia were excluded.
Laboratory methods: In the initial assessment of patients in ED the following markers were measured: white cell count (WCC), neutrophil count (NC), LC, C-reactive protein (CRP) (inmunoturbidimetry, Dimension Vista, Siemens Heathcare) and procalcitonin (PCT) (ECLIA, Cobas e411, Roche Diagnostics). Besides, in all of them a sample was drawn for blood culture. To evaluate the utility of biomarkers, patients were classified into two groups: bacteremic SIRS and non bacteriemic SIRS. Bacteremia was defined according Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC) criteria.
For statistical analysis, SPSS software vs.20.0 was used. Area under the receiver operating characteristic curve (AUC ROC) was calculated to evaluate the diagnostic performance of the parameters tested.

RESULTS

A total of 123 patients (70 male (56.9%), median age: 67 (interquartile range (IQR): 31 years) were included. Blood culture was positive in 29 patients (23.6%). There were not significant differences in WBC, NC and CRP between both groups. PCT levels were higher and LC lower in bacteremic patients than non bacteremic patients (PCT: 2.02 ng/mL (IQR: 15.01) vs 0.48 ng/mL (IQR:1.26); p<0.001/LC: 610/mm3 (IQR: 440) vs 950/mm3 (IQR: 780); p=0,001). ROC area under the curve (ROC AUC) was similar for both parameters: PCT: 0.727 (Confidence interval (CI) 95%: 0.624-0.830; p<0.001) and LC: 0.708 (CI95%: 0.603-0.814; p=0.001).

CONCLUSION

In adult patients presenting to the ED with suspected sepsis, lymphopenia predicts bacteremia with similar performance than PCT and better than other conventional biomarkers of infection as CRP, WBC or NC. In our study diagnostic accuracy for LC was very similar than recent studies (Lowsby R et al. Lymphopenia as a predictor of bacteremia in the emergency department. Crit Care 2014)

Critical care, emergency medicine, blood gases, POCT

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EVALUATION OF UMBILICAL CORD BLOOD ARTERIAL REFERENCE INTERVALS FOR PH, PO2, PCO2, BICARBONATE AND BASE EXCESS FOLLOWING UNCOMPLICATED TERM VAGINAL DELIVERIES

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BACKGROUND-AIM

Umbilical cord blood gas analysis is now recommended in all high-risk deliveries and in our center it is performed routinely following all deliveries. The intrapartum acid-base status of the fetus is an important component in establishing the link between intrapartum events and neonatal condition. The analysis of cord blood gases from the umbilical artery is believed to be the best representation of the fetal acid-base status immediately before birth. The aim of this study was to obtain reference intervals for umbilical cord blood gases in arterial samples of term newborns with spontaneous vaginal delivery (SVD).

METHODS

We evaluated the cord blood from 326 infants born after uncomplicated labor and vaginal deliveries at 32 to 42 weeks´ gestation (weight median: 3330 g (interquartile range (IQR): 595) from July to October 2014. In all of them, pregnancy shown a normal evolution and an obstetric resolution without evidence of fetal damage.
Samples of umbilical arterial cord blood were collected before delivery of placenta into heparinized plastic syringes for each and analyzed for standard blood gas and pH, using ABL 90 FLEX blood gas analyzer (Radiometer Iberica) with Point-of-Care-Testing technology.
Statistical analysis was performed with SPSS 20.0 and MedCalc. Reference interval for each parameter was defined as the interval included between the 2,5th and 97,5th percentile, according CLSI recommendations (CLSI C28-A3).

RESULTS

Means or medians, standard desviations (SD) or interquartile range (IQR), according to distribution of the parameter, and reference intervals (RI), before excluding outliers, were:
• pH (n=313): median (IQR): 7.33 (0.09); RI: 7.18-7.43
• pO2 mm Hg (n=306): mean (SD): 29.9 (5.5); RI: 20.9-40.9 mm Hg
• pCO2 mm Hg (n=310): median (IQR): 40.9 (8.0); RI: 30.2-50.5 mm Hg
• Bicarbonate mmol/L (n=325): mean (SD): 21.8 (2.2); RI: 17.5-26.0 mmol/L
• Base excess mmol/L (n=322): mean (SD): -3.9 (2.6); RI: (-) 9.5-(+) 0.5

CONCLUSION

Analysis of blood gas and pH is a valuable tool in monitoring a newborn's condition. The reference intervals established are useful to evaluate this condition in our hospital. Interpretation of acid-base status of the fetal tissue requires intervals obtained with the methodology usually used to analyze these parameters.

Critical care, emergency medicine, blood gases, POCT

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COMPARISON BETWEEN A POC SYSTEM FOR CELL BLOOD COUNT AND C-REACTIVE PROTEIN AND ROUTINE ANALYZERS IN EMERGENCY DEPARTMENT SETTING

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BACKGROUND-AIM

Inflammatory symptoms are widely encountered among patients who show up to the emergency department of acute care hospitals. Cell Blood Count (CBC) and C-reactive protein (CRP) assays are mandatory to evaluate these patients. Laboratory testing requires different specimens, like whole blood for CBC and serum for CRP. The opportunity of using only one specimen for both tests and its application to a Point-Of-Care (POC) system appear very useful. However, analytical quality of POC testing should be good. Therefore, we compared the results of CBC and CRP, assayed on the same patient sample, using a new POC analyser and the current laboratory methods.

METHODS

The study included patients showing up at the hospital emergency department. When CBC and CRP assays were required, an additional whole blood specimen was collected in tube with ethylenediaminetetraacetic acid anticoagulant. As soon as possible, the sample was analysed for CBC and CRP simultaneously, with the haematology analyser Microsemi CRP system (Horiba Medical, Montpellier, France). This instrument incorporates a haematology analyser, based on impedance variation method, and a turbidimeter for CRP immunoassay, using 18 µL of whole blood as the single sample. The routine laboratory CBC uses the ADVIA 2120i analyser (Siemens Healthcare Diagnostics, Tarrytown, USA), a flow cytometry-based system with light scatter. The laboratory serum CRP immunoturbidimetric assay was operated on Modular Analytics SWA system (Roche Diagnostics, Mannheim, Germany). The study evaluated 99 patients for CBC and 62 for CRP. Comparison between POC and laboratory results was estimated by Passing and Bablock regression.

RESULTS

The regression equations of the quantitative POC CBC methods compared to the ADVIA 2120i were y=0.254 + 1.004x for leucocytes, y=-0.123 + 1.012x for erythrocytes, y=10.662 + 0.883x for platelets, y=0.148 + 0.968x for haemoglobin. The regression equation of the POC CRP method compared to the current CRP method was y=-0.048 + 1.057x.

CONCLUSION

The results obtained on the Microsemi CRP system are well correlated with routine methods, for the same patient samples. The micro-sampling method of this analyser may be valuable for POC testing in an emergency department setting.

Critical care, emergency medicine, blood gases, POCT

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USEFULNESS OF THE DETERMINATION OF PROCALCITONIN AS A PREDICTOR OF THE OUTCOME IN THE SEPTIC PROCESS

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BACKGROUND-AIM

Sepsis is one of the leading causes of mortality in critically ill patients. Procalcitonin (PCT) is a high diagnostic value marker of sepsis and is, therefore, the most widely used in managing septic patients, in the follow-up of antibiotic treatment and subsequent withdrawal, but its usefulness based on the prognostic value gives rise to controversy.
The aim of this study was to evaluate whether the measurement of PCT 24 and 48 hours after the admission, or the difference between both measurements, is able to prognosticate the patient's outcome.

METHODS

76 patients diagnosed with serious sepsis or septic shock were analyzed according to the Surviving Sepsis Campaign criteria, admitted in the Intensive Care Unit, whose PCT was measured 24 and 48 hours after the admission. The average age of the patients is 64.2 (18-85), 58.3% are men.
The measurement of PCT was performed using a chemiluminescent assay on Minividas®
The descriptive and comparative statistical analysis was performed using the statistical software packages Statistica ® Stat Soft Inc 7.1 and MedCalc ® 9.2.1.0.

RESULTS

After applying the U-Mann Whitney test, no significant differences are obtained ($p>0.01$) regarding the prognostic value of the measurement of procalcitonin after 24 and 48 hours, as well as in the existing increase between both measurements.

CONCLUSION

The quantification of PCT after 48 hours as much as after 24 hours has no prognostic value.

Critical care, emergency medicine, blood gases, POCT

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THE QUALITY CONTROL OF POINT OF CARE DEVICES WITH RESPECT TO THE MEASUREMENT OF BLOOD GLUCOSE IN GENERAL HOSPITAL CELJE

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BACKGROUND-AIM

For the past decade we are trying to overcome thinking that point of care (POCT) measurements are performed without the involvement of the Department of Laboratory Medicine in our hospital.

METHODS

The implementation of any POCT test requires a well organized quality assurance plan with a multi-department participation. In 2009 a POCT comittee was assembled. The evaluation of execution of all POCT glucometers were analysed and the internal and external quality control procedures were set. Currently there are 60 Accu-Check® Compact Plus glucometers (Roche Diagnostics) in our hospital. A standard operating procedure with the internal and external quality control (EQA) for glucose testing was implemented. EQA involves the analysis of pool serum samples with unknown value which are prepared at our department and are send to all users of the POCT glucometers twice a year. Results are recorded on the same day and returned to our departement responsible for evaluation of the data, liasing with POCT users regarding performance and determining appropriate action in the event of unsatisfactory perfomance.

RESULTS

We control precision performance among all glucometer. The last evaluation showed good performance and only one glucometer differed more than 10% of the average value.

CONCLUSION

Our EQA procedure and testing showed good compliance and precision of results and we remain persistant in training, education, surveillance and proficiency testing of all POCT operators.

Critical care, emergency medicine, blood gases, POCT

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UPCONVERTING NANOPARTICLES IN LATERAL FLOW ASSAYS

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BACKGROUND-AIM

Lateral flow assays (LFAs) contain simple technology and they are easy to use, which makes them suitable for untrained personnel and for field use. Usually the detection of a test result in LFA is based on a qualitative measurement of the reporter's signal. However to achieve assays of high sensitivity the signal should be measured quantitatively. Upconverting nanoparticles (UCNPs) are lanthanide-doped nanocrystals that have a unique capacity to convert long-wavelength radiation to short-wavelength radiation. This phenomenon enables both detection without autofluorescence and the use of UCNPs as high sensitivity reporters. In this study UCNPs were developed for LFA use.

METHODS

Two UCNP-batches with diameters of 21–34 nm and 45–88 nm were coated with silica using one- or two-step protocols creating water-dispersible reporters. The particle flow through the LF strip was examined and the flow properties were optimized for determination of the best reporter characteristics for LFA. The UCNP reporter with the best characteristics was used in a cardiac troponin I (cTnI) assay to assess its applicability to a true clinical assay. The assay was performed in cTnI-spiked buffer and the reporter signals were measured with a portable fluorometer.

RESULTS

The best flow properties were achieved when UCNPs with a diameter of 45–88 nm were coated with silica using the two-step protocol. This was seen as a clean LF strip profile with only little nonspecific binding in the junction of the sample pad and the analytical membrane. The good flow properties of the 45–88 nm UCNPs are based on size because large particles flow quickly through a porous membrane, whereas small molecules penetrate the pores taking a longer time to flow through. Also the two-step coating protocol improved the flow properties by creating more colloidal particles compared to the one-step protocol. The analytical sensitivity of the cTnI assay was 0.93 ng/L.

CONCLUSION

At this point UCNPs are already feasible reporters in LFAs, and with further optimization they have a real potential to be routinely used in high sensitivity assays.

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CLINICAL UTILITY OF ICTERUS INDEX IN A EMERGENCY LABORATORY

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BACKGROUND-AIM

Icterus is defined as an elevated level of different bilirubin species in serum and plasma. Total Bilirrubin (BILT) is not an emergency assay in our Hospital Laboratory; however in all samples processed we measure the Serum Index (Hemolysis Index (IndH), Lipemia Index (IndL) and Icterus Index (IndI)).
The information of IndI in our emergency laboratory should be considered as an indicative parameter to assist clinicians in the patient diagnosis.

METHODS

The purpose of this study was to compare BILT and IndI in our patients, evaluating the correlation of both parameters to asses if they provide enough information to prevent the introduction of BILT as an emergency assay to be requested. BILT and IndI were measured in parallel in 64000 serum samples from patients of our routine laboratory, during 2014 in the module c-702 of a cobas 8000 analyzer (Roche Diagnostics, Switzerland). BILT were determined by a quantitative colorimetric test.
The Serum Index (IndI) assay is based on calculations of absorbance measurements of diluted samples at different bichromatic wavelength pairs to provide a semi-quantitative representation of levels of icterus present in serum and plasma samples. With the use of scaling factors for international units, the displayed and printed out values for IndI correspond to an approximate concentration of bilirrubin in µmol/L, using a factor we recalculate IndI in conventional units (IdnI (conventional units)= IndI (international units) / 17.1). BILT and IndI results were obtained in mg/dlL with 2 decimals. We consider normal values of IndI between 0-2 and pathological values of IndI >2.
Statistical analysis was performed with SPSS v15.0 software.

RESULTS

IdnI within the normal range were found in 60493 samples. IndI (x) values obtained were compared with the BILT (y) values. The correlation between the two assays was as follows: y= 0.82 x - 0.17 and r = 0.98.

CONCLUSION

Using the linear regression, with the value of IndI for each patient we were able to report the approximate value of BILT with confidence intervals 99 % (IC99%), always considering that IndI is a semi-quantitative assay, but it never will be replaced the BILT as a clinical parameter confirmation assay

Critical care, emergency medicine, blood gases, POCT

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THE OBSERVANCE OF PREANALYTICAL RECOMMENDATIONS IN ACID-BASE AND BLOOD GAS ANALYSIS IN CLINICAL CHEMISTRY LABORATORY OF NORTH ESTONIA MEDICAL CENTRE

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BACKGROUND-AIM

The acid-base and blood gas analyses are widely used in intensive and emergency units and are the most important for patient care. The laboratory analysis issued measurements requiring that analysis must follow to the preanalytical recommendations. The preanalytical phase includes a set of processes that occur in different places and at different times. Errors arising during sample collection and specimen handling are the most common type of preanalytical errors. This work was carried out in clinical chemistry laboratory of North Estonia Medical Centre and was aimed to identify how properly the preanalytical recommendations are followed for the acid-base and blood gas (ABG) analyses.

METHODS

The work was carried out by direct and documental observation. 401 ABG samples from 15 departments were processed with ABL800 type of analyzer during 14 days. We worked out the special protocol for assessment the specimen labeling and laboratory request form completion (according to ISO 15189), sample quality (according ABL800 manual) and time before measurement (TB, consist of prepreanalytical and preanalytical times). Statistical analysis was performed by MS Office Excel 2007 and R-project (version 3.0.3).

RESULTS

We found 53 incompletely filled laboratory request forms. The most frequent error was the sampling time not indicated in the request form. There were the few problems with sample material quality, such as air contamination (2 samples) and clots (3 samples). TB of the most samples (95%) was 32 minutes. The statistically significantly ($p<0,05$) longer TB was obtained in one department on account of prolonged prepreanalytical time.

CONCLUSION

: Attention must be paid to the correct recording of laboratory request forms and observance of the recommendations for blood sampling and transportation to laboratory.

Critical care, emergency medicine, blood gases, POCT

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EVALUATION AND PERFORMANCE OF THE NOVA STATSENSOR® CREATININE POINT-OF-CARE MONITORING SYSTEM

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BACKGROUND-AIM

Creatinine point-of-care testing (POCT) and the availability thereof has become an essential part of evaluating the renal function in patients in the emergency departments and those undergoing radiological imaging with intravenous contrast media. Our aim was to compare POCT creatinine measurements (Nova StatSensor® Creatinine POCT Monitoring System) with laboratory based creatinine measurement (Siemens ADVIA® 1800) using kinetic Jaffe assay method.

METHODS

Imprecision (coefficient of variance, CV %) on the POCT device was evaluated using repeated analysis (n=10) of two levels of Nova StatSensor quality control (QC) material. The accuracy of creatinine results obtained with Nova StatSensor device was compared to the results obtained with the laboratory reference analyzer (Siemens ADVIA® 1800) using spiked (different creatinine concentrations) donor heparinised venous blood samples.

RESULTS

The comparison shows good alignment and demonstrates the same concordance, calculated using a typical creatinine cut off of 130 μmol/L. Within-run imprecision (CV %) was calculated as 5.3% for low QC material (range 44-124 μmol/L) and 0.8% for high QC material (range 398-663 μmol/L). The creatinine regression analysis equation obtained was y = 0.21x + 46.3 (r = 0.987). The negative predictive value (NPV) was found to be 100% while the positive predictive value (PPV) was 80%.

CONCLUSION

Based on these results, the simple to use Nova StatSensor® device can measure creatinine using a small volume of sample effectively and therefore has good practical potential for use as a point of care device in selected clinical settings. We are aiming to continue evaluating the StatSensor® device in different clinical settings, e.g. renal unit, emergency department and outpatient renal clinics to verify our laboratory evaluation findings.

Critical care, emergency medicine, blood gases, POCT

M360

A COMBINED IN VITRO/IN VIVO DIAGNOSTICS POINT-OF-CARE SYSTEM FOR HOME-CARE AND SELF-INSPECTION

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BACKGROUND-AIM

The purpose of this paper is to present a bedside Point-of-Care system, to be employed combined for in-vitro and in-vivo Diagnostics, based on any digital camera, smart-phone, scanner and/or any digital microscope.
A cardinal prerequisite to successfully fulfill this task is the individual and experimental determination of the Modulation Transfer Function (MTF) of all involved equipment involved.

METHODS

The system can capture and handle color absorption and/or reflectance data, as well as, full macroscopic and digital camera images and more specific:
• Colors on dry-chemistry strips.
• Colored forms (e.g. blots, dots etc.) on preloaded microfluidics-chips, in standard microscopy-slide-format and/or micro-arrays, after reaction with blood, plasma, serum and other body-fluids.
• "Blood-smears" on microscopy slides.
• Skin, female-breasts, wound etc. images acquired under white or red light.
The acquired colors, patterns and/or image data, are transmitted, along with a reference set of relevant absorption and reflectance standard-data, allowing for:
• First, the experimental determination of the individual Modulation Transfer Function of each employed acquisition/transmission device, based on the related spectra, acquired with an Ocean Optics UV -VIS -NIR modular spectrometer.
• The partial automatic evaluation of colors and patterns, by employing custom developed software-tools.

RESULTS

A synopsis of some MTF-determination measurements is presented including:
- Indicative acquired Reflection Spectra, acquired with an Ocean Optics UV-VIS-NIR modular spectrometer.
- RGB-values using various color-balance methods (for Smart-phones, digital cameras etc.).
- Original and scanner-transmitted color-palette etc.
These parameters enable the MTF-determination, in plain text, the influence of the individual characteristics of the employed equipment on the wavelengths transmitted.

CONCLUSION

The developed method allows for the color, patterns and images transmission errors correction and the elimination of their potential influence on the home-care and self-examination procedures.
Thus, this approach is allowing for the adoption of low-cost optical hardware, to be employed in appropriate bedside Point-of-care-testing solutions.

Critical care, emergency medicine, blood gases, POCT

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MONITORING OF WEANING FROM MECHANICAL VENTILATION IN CRITICAL ILL PATIENTS BY PATHFAST PRESEPSIN AT THE INTENSIVE CARE UNIT

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BACKGROUND-AIM

The role of biomarkers is not yet established in patients who require mechanical ventilation (MV) for non-surgical acute diseases. We intended to examine the prognostic value of presepsin during weaning from MV in critical ill patients at the intensive care unit.

METHODS

Plasma samples were obtained at 4 time points (1: shortly after intubation, 2: immediately before weaning, 3: shortly after extubation, 4: before discharge to peripheral ward) in 120 patients (mean age 67.9; 77.5% males) at the intensive care unit (ICU) with non-surgical acute diseases who underwent MV. Presepsin was determined using the PATHFAST Presepsin assay. Patients were followed throughout their hospital stay until patients reached the endpoint (death) or until discharge.

RESULTS

38 (31.7%) patients died during follow-up. The presepsin levels (medians) in survivors and non-survivors were 1098 and 1609 pg/ml, respectively (p=0.04). 16 (13.3%) patients developed sepsis. 9 patients with sepsis died, demonstrating a significant higher mortality rate of 56.3% compared to 31.7% of the total study group (p<0.00001). Presepsin differed highly significant between non-septic and septic patients (median values: 1098 (95% CI: 886-1263) and 3185 (95% CI: 1734-3904) pg/ml, respectively, p=0.0004). ROC analysis for discrimination between sepsis and non-sepsis revealed an AUC of 0.893 (sensitivity 85.7%, specificity 84.0%, cutoff 1965 pg/ml). The median values of presepsin at the time points 1 to 4 during the weaning process were increasing in patients with sepsis from 3185 (IQR: 1727-3905) to 5703 (IQR: 2764-6815) pg/ml, respectively. In patients without sepsis the presepsin concentrations remained below 1600 pg/ml.

CONCLUSION

Weaning success is lower in patients with sepsis. We showed that development of sepsis during weaning from MV was associated with a higher mortality risk. Therefore it is important to identify those patients early. The new sepsis biomarker presepsin distingished patients who developed sepsis and those who did not during weaning with high diagnostic accuracy. The PATHFAST Presepsin assay allows the determination within 16 min from whole blood. Therefore this assay might be useful to monitor weaning from MV at the point-of-care in the ICU.

Critical care, emergency medicine, blood gases, POCT

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RELIABILITY OF A POINT-OF-CARE TESTING FOR URINE ALBUMIN

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BACKGROUND-AIM

Urinary excretion of albumin is an important biomarker in kidney diseases, particularly in diabetes mellitus and hypertension. There are several immunoassays available for this determination, including turbidimetric, nephelometric and immunometric procedures. The emergence of new technologies has started a trend to perform certain laboratory tests at or near the site of patient care (point-of care testing – POCT). NycoCard® U-Albumin (Axis-Shield) is a solid phase, sandwich-format, immunometric assay being the results measured quantitatively by using the color densitometer NycoCard READER II. The aim of this study was to evaluate the performance of this point-of-care testing for urine albumin compared to a central laboratory analysis.

METHODS

In order to evaluate the performance of the NycoCard® U-Albumin test compared to the golden standard nephelometric assay for urine albumin (BNII – Siemens) we studied 98 midstream urine samples. After collection, all samples were centrifuged and conserved at 4°C, being analyzed up to 24 hours by both methods. The analytical procedures were conducted according to the manufacturers' protocols. Validation protocol included evaluation of precision (repeatability and reproducibility) and accuracy. Biological Variation Database was adopted as analytical quality requirements. Simple linear regression (least square method) and paired t-test were used to evaluate the correlation between both methods. The obtained data was analyzed with EP Evaluator® and Microsoft Excel software.

RESULTS

Inter and Intra-assay precisions ranged from 4 to 9%. Our results met the requirements for analytical quality regarding precision (CVs<desirable specifications for imprecision) as guidelines recommend an imprecision analytical goal of less than 15%. Results obtained by NycoCard® U-Albumin and those observed by the nephelometric assay were highly correlated ($y=1.0335x$, $r=0.99$). Paired t-test showed no significant difference between both methods ($p>0.05$).

CONCLUSION

As demonstrated above, our results exceeded the minimum demanded requirements for analytical quality. In summary, NycoCard® U-Albumin is a reliable, precise and convenient point-of-care testing for determination of urine albumin.

Critical care, emergency medicine, blood gases, POCT

M363

POCT GLUCOSE PILOT SURVEY IN SNEQAS

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BACKGROUND-AIM

Slovenian National External Quality Assessment Scheme (SNEQAS) consists of several interlaboratory comparison surveys which contribute to assurance of quality and reliable results of participants. SNEQAS programmes are designed to follow the needs of the laboratories. The need of a structured EQA programme for POCT- glucose was the initiative for implementing a pilot survey in 2014.

METHODS

Prepared aliquots of commercial sera are distributed to participants four times a year. The users are asked to analyse the samples and return results in defined time. The results are grouped according to the device producer into four groups. The basic statistics is calculated; the overall mean standard deviation and coefficient of variation. The results > +/-3sd are excluded. The same parameters are calculated for the producer group. The individual result is assessed within the group.
If the result exceeds the allowable limits the participant is instructed to check the device, expiry of reagent strips and analyze control.

RESULTS

All groups CV range from 6, 5% - 11, 0%; 1/14 65 laboratories participated with 170 results, mean +/- SD 6, 33 +/- 0,698, CV 11, 02%. As no limitations were imposed on number of results in second survey the number raised up to 292, mean 5,3 +/- 0,549, CV 10,4%, in 3/14 N 295, mean 7,5+/- 0,484, CV 6,5%, and in 4/14 N 335, mean 13,52 +/- 1,195, CV 8,84%. The participants are POCT users from hospital laboratories (16), labs from public healthcare centres (40) and from GP's with concession. (15)

CONCLUSION

Although The POCT quality policy has been implemented fairly recently, the IQC at times still being inconsistent the EQA results start to show improvement; intergroup variability decreases but above all EQAS proves to be an useful tool in raising quality awareness of POCT users.

Critical care, emergency medicine, blood gases, POCT

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PRESEPSIN CAN REPLACE PROCALCITONIN IN THE PREDICTION OF SEPSIS IN TRANSPLANT PATIENTS AFTER ANTITHYMOCYTE GLOBULIN ADMINISTRATION

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BACKGROUND-AIM

Presepsin (soluble CD14 subtype, PRS) has been studied as a predictor of sepsis in ICU patients. Antithymocyte globulin (ATG) increases procalcitonin (PCT) after transplantation without any relation to SIRS or sepsis. PCT therefore completely fails as a sepsis predictor in transplant patients after the administration of ATG. The aim of our study was to test predictive value of PRS in comparison to CRP and PCT in SIRS, sepsis and posttransplant (after ATG administration) period.

METHODS

We studied 4 groups of patients: Group 1: 12 patients with SIRS during ICU stay. Group 2: 28 patients with sepsis, severe sepsis or septic shock during ICU stay. Group 3: 28 patients (22 men, 6 women) after cardiac and serious abdominal surgery (median 229 minutes, interquartile range 180 – 284 minutes) without any signs of sepsis were evaluated prospectively up to 30 days after surgery. Blood samples were taken before surgery, +3 hours, +1 day, +3 and +7 days after surgery. Group 4: 50 patients after heart transplantation (HTx). ATG was administered during HTx, samples were taken before HTx, +1 day, +3 days (PRS), +7days (CRP, PCT). Groups 1 and 2 were used for biomarker comparison in SIRS and sepsis, groups 3 and 4 for time course of biomarkers.

RESULTS

All values are given as median (interquartile range). Group 1 (SIRS in ICU): CRP (mg/l) 148 (92 – 278), PCT (μg/l) 0,79 (0,35 – 1,46), PRS (ng/l) 1247 (795 – 1896). Group 2 (sepsis, severe sepsis and septic shock in ICU): CRP 138 (106 – 256), PCT 2,33 (0,73 – 31,1), PRS 2265 (1152 – 5286). Group 3 (model perioperative SIRS): CRP before 2,7 (1,3 – 6,3), +3H 5,3 (2,4 – 7,5), +1D 85,2 (67,2 – 103,2), +3D 139,2 (101,9 – 213,1), +7D 49,4 (40,1 – 113,4); PCT before 0,07 (0,05 – 0,11), +3H 0,26 (0,17 – 0,67), +1D 1,05 (0,33 – 1,70), +3D 0,40 (0,18 – 0,77), +7D 0,14 (0,08 – 0,21); PRS before 540 (393 – 658), +3H 792 (616 – 1215), +1D 897 (685 – 1292), +3D 670 (545 – 1057), +7D 590 (408 – 850). Group 4 (HTx): CRP (mg/l) +1D 112 (67 – 154), +7D 16,7 (11,2 – 31,0), PCT (ug/l) +1D 25,0 (11,4 – 52,8), +7D 0,50 (0,30 – 1,16), PRS (ng/l) +1D 1126 (781 – 1976), +3D 780 (528 – 1394).

CONCLUSION

Procalcitonin (PCT) and presepsin (PRS) were more increased in septic than SIRS patients, CRP was unable to distinguish between SIRS and sepsis. PCT was more influenced by perioperative SIRS than PRS. PCT but not PRS was influenced by the administration of antithymocyte globulin in HTx patients. Presepsin is thus candidate biomarker of sepsis in posttransplant patients.

Critical care, emergency medicine, blood gases, POCT

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EVALUATION OF POINT-OF-CARE MEASUREMENT OF INTERNATIONAL NORMALISED RATIO IN PATIENTS WITH ACUTE ISCHEMIC STROKE

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BACKGROUND-AIM

Intravenous thrombolysis with alteplase is the approved treatment for acute ischemic stroke. The use of oral anticoagulation (OAC) treatment in patients with an international normalized ratio (INR) higher than 1.7 is a contraindication for this therapy. The use of point-of-care (POC)-INR devices minimizes delay in treatment and is beneficial for patient outcome. POC-INR devices are known to have clinically acceptable accuracy compared to automated laboratory analyzers when used by patients on OAC therapy at home in a stable condition. In this study we compared the use of a POC coagulometer to the laboratory INR analysis in the setting of acute ischemic stroke.

METHODS

112 patients presenting with symptoms of acute ischemic stroke, who were using OAC (80%) or from whom information regarding OAC status was not available (20%) were included. INRs were measured both with an automated CA-1500 laboratory analyzer (Sysmex) and the Coaguchek XS Pro POC device (Roche) and data were compared.

RESULTS

Pearson correlation showed a high correlation between POC-INR and laboratory INR values ($r=0.948$; $P<0.01$). Bland-Altman analysis revealed a mean deviation of paired differences of 0,2 (SD 0.46), resulting in limits of agreement of -0.72 to +1.12. Bland-Altman sub-analysis of INR values <2 showed a mean deviation of paired differences: 0,0043 (SD 0.11), with limits of agreement (95% SD) -0.22 to + 0.22. Based on these findings a POC-INR decision limit of 1.5 was chosen, above which a laboratory INR was awaited before starting treatment. In 90% of the patients this procedure reduced time to treatment. 8% of the patients with a POC-INR between 1.5 and 1.7 had to wait for laboratory testing before thrombolysis (laboratory INR $\leq$1.7:). In 2% of the patients unjust thrombolysis was prevented by using this decision limit (POC-INR $\leq$1.7 and laboratory-INR >1.7) .

CONCLUSION

High correlation exists between POC-INR and laboratory INR values in patients presenting with acute ischemic stroke. However, a mean difference of 0.2 was found between POC-INR and laboratory INR. Introducing an POC-INR decision limit of 1.5, above which laboratory testing had to be awaited, reduced time to treatment for the majority of patients and prevented patients to receive unjust treatment.

Critical care, emergency medicine, blood gases, POCT

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GETTING CONNECTED – COBAS IT 1000® – CHALLENGES AND SOLUTIONS

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BACKGROUND-AIM

IT connectivity for POC in - vitro diagnostic medical testing devices can provide the opportunity to transmit POC results to a permanent electronic patient record. Naas General Hospital, Ireland, a 240 bedded facility, proposed a hospital wide, end to end connected glucometer service, using the Cobas IT 1000 management system and ward sited AccuChek 11 glucometers (Roche). The Cobas IT 1000 was interfaced to both PAS and LIS systems.

METHODS

A fully connected dedicated virtual test environment was established containing the PAS, Cobas IT 1000 and the LIS IT systems interfaced together. Unique virtual patients were created inclusive of three demographic identifiers, glucose analysis performed and result transmission to LIS checked for all ward areas, using the interface messaging viewer on Cobas IT 1000. Screenshots of all testing operations were captured to evidence the validation plan.

RESULTS

The correct transmission and receipt into Cobas IT 1000 of all demographics from PAS for inpatients was achieved following adjustment to the HL7 message section capture. Correct demographics were available on the AccuChek 11 at the point of testing and the correct glucose result was retransmitted to the LIS system inclusive of consultant and ward area. The uniquely identified POC glucose result was displayed in the LIS with both operator ID number and meter serial number attached. ED attendances required the creation of bespoke software in the Cobas IT 1000 and OPD attendances required bespoke OPD lists created by PAS for database management. The capture of mis - matched patient demographics at LIS entry was successfully demonstrated.

CONCLUSION

While interfacing of POC management systems to both PAS and LIS IT systems appears and may be marketed as a simple process, it is highly complex. In this study the creation of a virtual IT testing area facilitated the investigation and validation of diverse scenarios for all hospital ward areas without disruption to hospital or laboratory IT systems and an easily accessible space for retesting as various IT solutions were being developed by the IT providers. This study demonstrates the requirement for an in depth evaluation of Hospital IT systems, their communication capabilities and patient management processes at the initial evaluation of any POC management system, in addition to the analytical evaluation of the POC devices. In conclusion the creation of a virtual IT testing space is central to achieving POC quality assured connectivity.

Critical care, emergency medicine, blood gases, POCT

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A ROADMAP FOR IMPLEMENTING POINT OF CARE TESTING: A MODEL OF TEAMWORK.

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BACKGROUND-AIM

Point of Care Test (POCT) were performed in wards and critical care areas in AKUH without proper policies, absence of report generation, manual recording of patient results, lack of training and lack of evidence of quality control. Aim was to introduce a POCT program at AKUH to ensure patient testing is performed in compliance with regulatory standards to produce accurate test results.

METHODS

A proposal delineating the scope of services was developed by the Pathologists. A team comprising of representatives from Pathology, Biomedical Engineering, and Material and Management Division performed a detailed comparison of the available equipments for selection according to the preset criteria. A POCT Coordinator was identified. Quality Management Plan, policies/procedures and curriculum were written down. Equipment procurement was followed by validation, verification and instrument to instrument comparison. Connectivity of POCT equipment to server was established. Training was performed of TOTs from NES followed by training of the end users. On implementation training refresher for POCT users, review of instruments installation/inventory check was performed by POCT Coordinator. A 24/7 hotline was made to resolve POCT related query. A contingency plan was also put forward. The team was open to suggestion based on the feedback from end-users. The whole process was monitored by the POCT team for one week at site and to conclude implementation was signed off.

RESULTS

59 glucometers, 5 urine analysis devices and 5 arterial blood gas analyzer were installed at 22 sites. Fifty eight trainers were trained from NES. Trainers further conducted more than 100 sessions for >1000 nursing staff. Monitoring of multilevel daily quality control and compliance of POCT analyzers is now routinely performed by POCT Coordinator through online connectivity at the Central Lab. The comprehensive POCT management offers features such as operator and patient ID lockout, QC lockout, remote configuration and management of consumables, improving efficiency and giving us strict control of our testing program. Control of training/competence assessment, policies, procedures and quality is now under the oversight of Clinical Laboratory. The connectivity has given us the ability to monitor our whole program of >1000 operators and to produce audit trail.

CONCLUSION

Key to success of establishment of POCT infrastructure was a dedicated project lead and a multidisciplinary, multimodal approach.

Critical care, emergency medicine, blood gases, POCT

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GLUCOMETER PERFORMANCE EVALUATION: COMPARISON OF GLUCOMETERS WITH BIOCHEMISTRY AUTOANALYSER

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BACKGROUND-AIM

Glucometers are most commonly used bedside device. Frequency of using glucometers increase because of ease of use and accessibility. The performance of glucometers vary working with different methods. Glucometers constitute doubts in health care workers for reasons such the frequency of using internal quality control, limited use of external quality control. In our study we aimed to determine the performance of the three different devices for making comparison with the reference method (hexokinase) on autoanalyzer.

METHODS

In Sakarya University Training and Research Hospital between January 2014 and December 2014, the morning fasting venous blood samples were taken to the tubes with K2EDTA a total of 1359 individuals from 23 different services. Measurements were performed with determined Internal quality control results within the expected range by glucometers (ASTRACHECK Plus MM600, IME -DC Idia and Abbott Freestyle Optium H). Venous blood glucose measurements were performed on Abbot c16000 (USA) autoanalyzer after 4000g centrifugation for 5 minutes. Glucose levels detected below 75mg / dL were evaluated by ±15 criteria and above by ± 20% criteria.

RESULTS

Glucose measurements of glucometer's means (Astracheck Plus MM600, IME-DC Idia and Abbott Freestyle Optium H) were 148.5±59.8, 135.5±52.1 and 152.9±50.6 mg/dl; autoanalyzer's(Abbot C16000) mean 140.2±57.6, 131.9±50.7 and 148.1±48.7 mg/dl were found respectively. Strong positive correlation were found($r=0.970$; $p<0.001$) that the glucometers compared with autoanalyzer. Deviation percent of POCTs were %3.4 (%74.3 negative, %25.7 positive)for Astracheck Plus MM600, %2.2 (%50 negative, %50 positive) for IME-DC Idia, %2.7 (%100 positive) for Abbott Freestyle Optium H and all of 3.2% were determined. The difference between the glucometers in terms of the frequency deviation were not statistically significant ($p>0.05$).

CONCLUSION

In our study deviation were identified between 2.2 % and 3.4 % according to the glucometers, in terms of deviation percentages were found no significant difference between glucometers. To perform internal quality control, comparison with the reference method in certain periods and continuing education of health professionals contribute in order to improve the performance of glucometers to minimize preanalytical errors.

Critical care, emergency medicine, blood gases, POCT

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BINDING CAPACITIES OF STREPTAVIDIN COATED MICROPARTICLES USED AS SOLID SUPPORT IN POC ASSAYS

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BACKGROUND-AIM

Many diagnostic assays are heterogeneous which means that analyte binder must be attached to a solid support, for example microtiter well, to enable washing steps. Microparticles have many desirable properties as a solid support especially in point of care (POC) assays. With microparticles the area of solid support is easily increased without increasing the volume of the assay. Microparticles also enhance the assay kinetics as they float in the liquid making the distance between binder and analyte minimal. Streptavidin-biotin link is often used in immunology assays to enhance for example antibody binding to the solid support. Different kinds of plastics can be coated with streptavidin (SA) with various methods. Biotinylated antibody or other binders can be easily bound to the SA very efficiently. In this study different SA coatings of polystyrene microparticles are tested and compared to commercial microtiter well coating.

METHODS

Polystyrene microparticles were coated with SA using glutaraldehyde (GA) cross-linked SA and unmodified SA. Polystyrene particles irradiated with 60Co were coated using 1-Ethyl-3-[3-dimethylaminopropyl]carbodiimide hydrochloride (EDC) and N-hydroxysulfo-succinimide (sulfo-NHS) linking. Binding capacities of commercial SA coated high capacity microtiter well and SA-microparticles were defined by saturating with europium chelate labeled biotin (bio-Eu) and comparing the signal to a standard curve of the bio-Eu.

RESULTS

The capacity of the commercial SA wells is reported to be more than 15 pmol/well. The result obtained with our method for the wells was 32.5 pmol/well which equals 0.217 pmol/mm2. Capacity of the unmodified SA coated microparticles was 0.019 pmol/mm2 and of the GA cross-linked SA coated microparticles 0.653 pmol/mm2. EDC-sulfo-NHS coating of irradiated particles did not result in any advantage compared to other coatings.

CONCLUSION

These results show that the GA crosslinking of SA before microparticle coating improves the biotin binding capacity three fold compared to the commercial SA coated microtiter well. Commercial wells are also coated using some method of crosslinking which explains the better binding capacity of the wells compared to microparticles coated with unmodified SA.

Critical care, emergency medicine, blood gases, POCT

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EXPERIENCES WITH POCT IN MILITARY UNIVERSITY HOSPITAL IN PRAGUE

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BACKGROUND-AIM

Measurements or tests in vitro performed outside the laboratory are called point-of-care testing (POCT). It is a measurement performed at the patient site and its results may lead to treatment adjustment. POCT denotes every testing performed outside the laboratory by medical professionals without primary laboratory education or by the patients themselves (self-monitoring).
Aim of this report: two-year experiences of the central laboratory with implementation and use of POCT devices.

METHODS

In the Military University Hospital in Prague, there are two POCT systems working under the responsibility of the laboratory of clinical biochemistry: blood gases and electrolytes analyses and glucose monitoring. Blood gases and electrolytes tests are performed using Radiometer blood gas analyzers ABL800, there are 4 of them at intensive care units. The hospital system of blood glucose monitoring includes 24 Nova StatStrip Connectivity glucose meters. They are placed in selected clinical departments. The laboratory has been actively involved in the POCT project, from the design and choice of POCT devices, their installation, user training and continuous education, responsibility for internal quality control and participation in the external quality assessment programme, to authorisation and release of measurement results from the laboratory to the hospital information system. In the laboratory, there is a team of 4 qualified workers responsible for the above described procedures.

RESULTS

Advantages associated with the introduction of POCT in the hospital are obvious– quick analysis of small blood volume, measurement results available almost immediately, which facilitates immediate response of the attending physician, reduction of errors caused by incorrect sample transport to the laboratory. Nevertheless the fact that POCT is performed by clinical staff (nurses), who is not educated for laboratory work, may lead to some preanalytical errors, e.g. patient identification errors, inadequate sample mixing, interferences.

CONCLUSION

We find the cooperation of the laboratory with clinical staff and its correct use of POCT supervision essential to minimize preanalytical errors and provide reliable results that contribute to the improvement of health care.

Critical care, emergency medicine, blood gases, POCT

M371

QUANTITATIVE MEASUREMENT OF PROTHROMBIN TIME/INTERNATIONAL NORMALIZED RATIO (PT/INR) TEST ON THE XPRECIA STRIDE™ COAGULATION ANALYZER* FOR WARFARIN MONITORING: A VALIDATION STUDY

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BACKGROUND-AIM

The Xprecia Stride™ Coagulation Analyzer from Siemens Healthcare Diagnostics (SHD) is a novel, handheld POC device that generates rapid PT/INR results from fingerstick samples for oral anticoagulant therapy monitoring (OAT). This external validation study, conducted under the International Conference on Harmonization/Good Clinical Practice (ICH/GCP) guidelines, assessed the clinical substantial equivalence of the Xprecia Stride analyzer PT/INR test against an established laboratory hemostasis method (BCS® XP System).

METHODS

One hundred study subjects, comprising patients receiving warfarin therapy and individuals not on warfarin therapy, were enrolled at four clinical sites over a seven-week period. At each site, subjects provided two separate whole blood capillary samples via a finger puncture for immediate PT/INR testing by qualified POC operators on the Xprecia Stride Coagulation Analyzer. Each subject also provided a whole blood sample collected in a citrated tube which was centrifuged to generate platelet-poor plasma and then frozen. Frozen samples were shipped to a laboratory for PT/INR testing on the reference Siemens BCS XP System using Dade® Innovin® reagent. Intermediate precision data were generated by qualified operators at each of the four sites using the Xprecia Stride analyzer and two levels of Liquid Quality Control (LQC) over 20 days. Differences between results from pairs of capillary samples were used to assess repeatability. The expected range for non-therapeutic individuals was calculated from 120 patients.

RESULTS

Weighted Deming regression analysis yielded a slope of 0.95 and an intercept of 0.12, with R^2=0.91 across the range of 0.8 to 7.0 INR. Repeatability using whole blood demonstrated %CVs were <5.9 across the reportable range. LQC demonstrated intermediate precision %CVs were <7.0 for both levels. The Expected Range for the PT/INR on the Xprecia Stride analyzer was 0.9 to 1.1 INR for subjects not on OAT.

CONCLUSION

The Xprecia stride analyzer PT/INR test results were substantially equivalent to the BCS XP system.
*Not available for sale in the U.S. Product availability varies by country.

Critical care, emergency medicine, blood gases, POCT

M372

POINT OF CARE TEST GLUCOSE METERS: THE BEAUTY OR THE BEAST?

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BACKGROUND-AIM

The Nova StatStrip® Glucose has proven to be an accurate blood glucose measuring system (BGMS) and was recently FDA approved as first BGMS for use in critical care patients. To ensure a good BGMS is fit for purpose, however, it is necessary to use such systems in a controlled clinical laboratory setting. In hospitalized patients blood glucose medication is immediately adapted based on these measurements, making accuracy more important than in the outpatient population.

METHODS

We perform a method validation study on each new batch of StatStrip® Glucose strips to ensure optimal performance, according to ISO 22870. The validation comprises an accuracy study in which the glucose values of the StatStrip® BGMS are compared with the hexokinase method on Roche Cobas 6000 c501, the routine method used in the core laboratory. Based on the CLSI EP9-A2 protocol, a minimum of 40 venous blood patient samples are analyzed, covering the entire BGMS measuring range. At least 2 different lot numbers are evaluated in parallel.

RESULTS

From September 2012 on, the accuracy of 11 different StatStrip® Glucose lot numbers was evaluated. A consistent negative bias against the hexokinase method was found, ranging from -3.5% to -12.3%. All lots were conform the ISO 15197:2003 acceptance criteria, but only 8 were compatible with the revised ISO 15197:2013 criteria. None met the recently postulated draft FDA BGMS criteria for hospital use. The laboratory retained only 5 lots for routine implementation, all with a mean negative bias less than 7%.

CONCLUSION

For every BGMS used in hospital care, the central role of the laboratory in controlling the release of glucose strips, using stringent criteria is mandatory to allow appropriate clinical decision-making. One should be aware of the idealized conditions in which the lot validations are performed, thereby potentially overestimating the accuracy of the BGMS.

Critical care, emergency medicine, blood gases, POCT

M373

PROGNOSTIC SIGNIFICANCE OF PRESEPSIN IN PATIENTS WITH SEPSIS

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BACKGROUND-AIM

Sepsis is the leading cause of death in critically ill patients. Presepsin is a novel marker of systemic inflammatory response, which is a humoral factor of phagocytosis. The aim of this study was to determine the prognostic value of presepsin in assessing the severity of infection and septic complications in patients undergoing cardiac surgery.

METHODS

The study group included 96 patients of ICU, 57 (44-64) years old, with signs of SIRS, PCT level more than 0.5 ng/ml and endotoxemia after open-heart surgery with cardiopulmonary bypass. The source of infection in 60% cases was ventilator-associated pneumonia confirmed by clinical assessment and X-ray imaging. Positive blood cultures were obtained in 22% of the patients in the study group. Positive bronchoalveolar lavage fluid was obtained in 56% (K. pneumoniae, A. baumannii, P. aeruginosa). All patients were measured for plasma levels of procalcitonin (PCT), the activity of endotoxin (EAA), C-reactive protein (CRP) and presepsin (PSP). All data are expressed as median and interquartile range. Receiver operating curve analysis including the area under the ROC (AUC) was used to compare prognostic methods as predictors of sepsis and 28-days mortality. The level of significance was set at $p < 0.05$.

RESULTS

PSP concentration was 1756 (999; 3686) pg/ml, PCT – 5.7 (2.5; 18.4) ng/ml, CRP – 10.0 (5.1; 16.3) mg/dl. EAA level (0.58 (0.44; 0.69)) was more than reference limits in all examined patients. In 58 patients of study group sepsis was diagnosed, in 38 multiple organ failure was determined. Septic patients have the higher level of PSP (2598 (1414; 5298) pg/ml vs 907 (719; 1498) pg/ml, p=0,01), PCT (8.6 (2.9; 25.9) ng/ml vs 4.5 (1.2; 8.9)ng/ml, p=0.04) and EAA (0.62 (0.51; 0.71) vs 0.44 (0.40; 0.56)) than the patients with multiple organ failure. There was no significant difference of CRP levels between patients groups (10.6 (5.8; 17.9)mg/dl vs (9.1 (4.3; 13.1)mg/dl, p=0.26). AUC for the diagnosis of sepsis were: PSP 0.83 (95%CI: 0.74-0.92, p=0.01), PCT 0.66 (95%CI: 0.53-0.79, p=0.03), EAA 0.77(95%CI: 0.66-0.89, p=0.01). The high levels of PSP were associate with high level risk of mortality (AUC 0.66 (95%CI: 0.54-0.78, p=0.01), cutoff 1642pg/ml; Se=68%, Sp=67%).

CONCLUSION

These results conclude that the levels of PSP included in the algorithm of laboratory diagnosis of infection and septic complications help to identify groups of sepsis risk and predict lower survival of cardiac patients with endotoxemia in the early postoperative period.

Critical care, emergency medicine, blood gases, POCT

M374

POINT-OF-CARE HBA1C TESTING IN A CLINICAL SETTING: PERFORMANCE ANALYSIS

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BACKGROUND-AIM

Haemoglobin A1c (HbA1c) test reflects glycaemic control over past three months, predicts diabetic complications and can now be used for diabetes diagnosis and screening. Although POCT HbA1c assays may be NGSP-certified the ADA doesn't recommend them for diagnostic purposes. PTS Diagnostics (Indianapolis, USA) has recently introduced POCT and at-home HbA1c monitoring system (A1cNow), NGSP and IFCC-certified, CLIA-waived. This immune-assay provides results in 5 minutes and requires a blood sample volume of 5 µl. We investigated A1cNow test performance in diabetic patients.

METHODS

HbA1c levels of 81 Italian diabetic subjects were measured with A1cNow devices, using capillary blood samples, and the Tosoh G8 Analyzer in the hospital laboratory, using EDTA venous blood samples. Precision was evaluated by the coefficient of variation (CV%) of ten replicates, in two consecutive days, using low (5.4%) and high (10.0%) NOD HbA1c control solutions from Nova-One Diagnostics (Woodland Hills, USA).

RESULTS

Diabetic patients Tosoh results were 7.6±1.2% (range 5.3-11.0%) vs A1cNow 7.4±1.3% (5.1-10.5%). The A1cNow results correlated highly with laboratory results ($r= 0.95$, $p<0.001$), but mean difference between A1cNow results minus Tosoh results was -0.26±0.42% (from -1.60 to 1.10); the 95% confidence intervals (CIs) of mean difference were -0.17 and 0.35 ($p<0.001$). The relative error (bias/reference x 100) was 3.3±5.4% and showed a non-normal distribution: skewness 0.70 and kurtosis 3.79 ($p<0.001$). The within- and between-run CVs were well <5% for both levels of control solutions.

CONCLUSION

The A1cNow results showed a good agreement with Tosoh results but demonstrated a negative bias from those values and a non-gaussian relative error. Thus, although the majority of A1cNow measurements were accurate in comparison with results of the reference method, a small percentage (3%) of mismatched results could lead to inappropriate medical decision. With this warning, application of A1cNow POCT could support screening in general population. These preliminary results of an on going study prompted us to investigate which factors contribute to reported error rates: the research is in progress.

Critical care, emergency medicine, blood gases, POCT

M375

ANALYTICAL PERFORMANCE OF THE PHILIPS CTNI HANDHELD POINT-OF-CARE TEST

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BACKGROUND-AIM

Point-of-care (POC) diagnostics is very demanding in a number of areas: analytical performance, ease-of-use, and reliability. The Philips Minicare system utilizes an optomagnetic immunoassay technology based on nanoparticles that are magnetically actuated and optically detected in a stationary sample fluid. The actuation of nanoparticles by magnetic fields provides a high degree of control over each step of the assay, resulting in a low imprecision. The optical detection potentially yields sensitive and multiplexed assays in a cost-effective disposable cartridge.
Applications are foreseen in the emergency department. The first test under development is a cardiac Troponin I (cTnI) assay with a turn-around time of less than 10 minutes. The sample-taking procedure is an important usability aspect. A convenient way to perform near-patient testing is to utilize capillary samples. In this study we investigate whether capillary samples could be used as an alternative sample type for cTnI testing.

METHODS

We collected and analyzed capillary and Li-heparin venous whole blood samples from 78 patients at the Cardiac Care Unit of two different hospitals covering a cTnI concentration range of up to 15,000 ng/l. 44/78 patients presented cTnI levels in the lower range (<500 ng/l) that is of particular clinical interest. Samples were tested in duplicate at the patient bedsite on a prototype of the Minicare cTnI assay and the averages of these duplicate measurement values were compared between the two sample types.

RESULTS

The correlation between the capillary and venous whole blood sample was very good. Over all patients (n=78), with cTnI values covering the full range of measurement, a correlation coefficient of R=0.998 and a slope of 1.05 (95%CI:1.03-1.07) were found. In the lower range of cTnI concentrations below 500 ng/l similar strong correlation was observed with a correlation coefficient of R=0.991 and a slope of 1.03 (95%CI:0.99-1.06).

CONCLUSION

The results obtained for the various sample types are very comparable and offer the potential to interchangeably use both capillary and venous samples. This supports near-patient testing in the workflow of patients suspected of Acute Coronary Syndrome arriving at the Emergency Department, enabling faster diagnosis or treatment.

Critical care, emergency medicine, blood gases, POCT

M376

DIAGNOSTIC PERFORMANCES OF CLINICAL LABORATORY TESTS USING TRITON X-100 TO REDUCE THE BIOHAZARD ASSOCIATED WITH ROUTINE TESTING OF EBOLA VIRUS-INFECTED PATIENTS

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BACKGROUND-AIM

Ebola virus, an enveloped virus, is the leading cause of the largest and most complex Ebola Virus Disease (EVD) outbreak currently accelerating in West Africa. The infection is spread by direct contact with the blood or body fluids of an infected person. Specimens from infected patients may represent a biohazard to laboratory workers. Laboratory tests of virus-containing specimens should be conducted at biosafety level 4, but based on the severity of clinical symptoms, basic laboratories located far from referral centres might be required to execute urgent tests for patients suspected of EVD. In this context they must be prepared to safely perform at least the emergency diagnostic panel at level 2.
The aim of this work was to compare the analytical performances of laboratory tests when Triton X-100, a chemical agent able to inactivate enveloped viruses, was added to specimens.

METHODS

Results of clinical chemistry, coagulation and haematology parameters on samples before and after the addition of 0.1% (final concentration) of Triton X-100 and 1 hour of incubation at room temperature were compared.

RESULTS

Triton X-100 at 0.1% did not significantly affect the results for the majority of the analytes tested. Measured concentrations ranged from 87% (Total Bilirubin) to 126% (Platelets count) with an average of 100.51% of the untreated values. Overall, results showed very good agreement by all statistical analyses.

CONCLUSION

Triton X-100 at 0.1% can be used as an inactivating agent to safely perform laboratory tests on samples from patients with EVD without affecting clinical decisions.

Critical care, emergency medicine, blood gases, POCT

M377

EVALUATION OF ANALYTICAL PERFORMANCES OF POINT OF CARE CAPILLARY BLOOD HEMOGLOBIN A1C AND LIPID TESTING AND THE UTILIZATION AT PRIMARY CARE UNITS

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BACKGROUND-AIM

Point of care testing (POCT) device, Cobas b101, is a new technology for determination of HbA1c and lipid profile by using small volume of capillary blood samples and can be performed at primary care units (PCUs). This study aims to evaluate analytical performances of Cobas b101 and to determine the associations of HbA1c and lipid obtained from Cobas b101 and reference analyzer.

METHODS

Within run and between day run precisions were determined by using manufacturer control material of Cobas b101. Capillary blood and venous blood samples were obtained from 207 subjects including healthy adults and diabetic mellitus patients. Capillary Hb_{A1c} and lipids were measured at 5 primary care unites when venous blood samples were sent to Clnical Chemistry Laboratory to determined those parameters.

RESULTS

The results showed that HbA1c, total cholesterol (TC), triglyceride (TG), high density lipoprotein (HDL), and low density lipoprotein (LDL) determinations were precised and imprecisions were within acceptable limits. HbA1c, TC, TG, HDL, and LDL obtained from Cobas b101 revealed excellent correlations ($P < 0.05$, $r = 0.96$-0.98) with those obtained from the central laboratory reference analyzer. However, means of triglyceride obtained from POCT device were significantly higher ($P < 0.05$) than those from the reference analyzer for 21 mg/dL.

CONCLUSION

In conclusions, HbA1c and lipid profile measured by Cobas b101 were valid and could be used for monitoring in patients with DM and dyslipidemia.

Critical care, emergency medicine, blood gases, POCT

M378

UNUSUAL BIOMARKERS IN SERUM AND URINE OF SEPTIC PATIENTS

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BACKGROUND-AIM

In spite of the modern antibiotic era sepsis still remains the most challenging disorder at intensive care units (ICU). Early diagnosis is essential for a favorable outcome. Therefore, our work was focused on two nonconventional laboratory parameters: serum gelsolin (se-GSN), as an actin binding protein, and orosomucoid in urine. Our aim was to investigate whether these molecules have additional information in sepsis care, and may serve as potential, fast markers of this systemic inflammation.

METHODS

Serum and urine samples were obtained from healthy individuals (n=30) and from septic patients (n=21: 8 survivor, 13 non-survivor). We carried out a follow up study (67 samples) in ICU with ethical permission. Serum gelsolin (se-GSN) and urinary orosomucoid (u-ORM) were assessed by western blot with quantitative enhanced chemiluminescence (ECL) detection. We used in our measurements internal standards with defined concentrations. The obtained u-ORM data were referred to urinary total protein and creatinine (u-ORM/CREAT) as well. Parallel conventional laboratory tests were performed in patients' sera (procalcitonin, hs-CRP, ORM, cytokines) by routine automated methods. For statistical analyses we used SPSS software version 22.

RESULTS

All the septic patients showed significantly lower se-GSN concentrations compared to those of the control patients ($p<0.001$). Sera of surviving patients had increasing gelsolin concentrations, whereas in sera of non-survivors the opposite tendency was seen. The median se-GSN value in survivors (19.96 mg/L) was higher than in non-survivors (10.43 mg/L). Furthermore, in all cases the u-ORM values from the onset of sepsis was found to be extremely high compared to those of the control group. We found an almost 50-fold increase in the u-ORM/CREAT ratio in sepsis vs controls (5.11 vs 0.11 mg/mmol).

CONCLUSION

Our data show that serum gelsolin gives reliable information on the septic state and moreover, u-ORM provides an early sign to support the diagnosis of sepsis. We suggest, that se-GSN and u-ORM seem to be promising markers in this severe acute inflammatory process. Currently we are developing automated and validated methods for the measurements of se-GSN and u-ORM with a clinically acceptable turnaround time.

Critical care, emergency medicine, blood gases, POCT

M379

COMPARISON OF THE NEW QUIKREAD® GO WRCRP+HB POINT-OF-CARE TEST TO FOUR CLINICAL LABORATORY METHODS

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BACKGROUND-AIM

A new, easy-to-use POC test, QuikRead go wrCRP+Hb, has been introduced on the QuikRead go® platform. The test gives two results, the C-reactive protein (CRP) and the haemoglobin (Hb) value, from one whole blood sample in a single analysis. CRP can be measured also on serum/plasma samples. In this study we evaluated the performance of the new QuikRead go wrCRP+Hb test against four dfferent clinical chemistry analysers. The CRP results were evaluated against Roche Modular PPPE CRP, Beckman Coulter CRP, Siemens Advia 1800 CRP and Abbot Architect CRP tests using plasma samples. The Hb results were evaluated against the ICHS (cyanomethemoglobin) standard 1995 method using whole blood samples.

METHODS

In the QuikRead go wrCRP test, the CRP measurement is an immunoturbidimetric assay based on agglutination reaction and the Hb assay is based on photometric measurement of oxyhemoglobin. The sample is added into a cuvette which is closed with a reagent cap. The cuvette is placed into the QuikRead go instrument which automatically measures CRP and in whole blood samples, also Hb, in two minutes. The sample volume is 10 µl. The CRP measurement range is 0.5–300 mg/l in whole blood and 0.5–180 mg/l in serum or plasma. The system automatically detects the sample type (whole blood or serum/plasma) and the CRP value is corrected based on the hematocrit level of the sample. The Hb measurement range is 50–245 g/l.

RESULTS

The CRP results of plasma samples (n=100) were as follows: the linear correlation of CRP results to the Roche Modular PPPE CRP test was y=1.06x-0.6, r=0.99, to Beckman Coulter CRP test y=1.01x-1.0, r=0.99, to Siemens Advia 1800 CRP test y=0.98x-1.3, r=0.99 and to Abbot Architech CRP test y=0.99x-1.8, r=0.99.
The linear correlation of the Hb result to the ISCH 1995 method was y=1.06x-8.1, r=0.98 (n=60). The precision of the CRP and Hb results were determined according to CLSI guideline EP5-A2. The total precision (CV%) during 20 days was 3.4–7.0% for the CRP results and 1.7–4.9% for the Hb results.

CONCLUSION

The performance of the new QuikRead go wrCRP+Hb POC-test correlates well with all the tested clinical laboratory methods. The QuikRead go wrCRP+Hb test is a fast, reliable and precise method for simultaneous analysis of CRP and Hb.

Critical care, emergency medicine, blood gases, POCT

M380

PERFORMANCE OF COBASB101 AND QUO-TEST POC DEVICES FOR HBA1C AND LIPID PROFILE MEASUREMENT IN PEDIATRIC POPULATION.

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BACKGROUND-AIM

Glycated hemoglobin (HbA1c), total cholesterol (TC), HDL-cholesterol (HDLC), LDL-cholesterol (LDLC) and triglycerides (TG) can be considered as a part of preventive health care. All these parameters are currently available on POC setting. Although CobasB101 passed the generally accepted performance criteria for HbA1c no information on efficiency of this POC instrument using pediatric samples with different matrix has been published.

METHODS

HbA1c was measured in diabetic children using CobasB101 (Roche), Quo-Test (EKF Diagnostics), and Vitros (Ortho-Clinical Diagnostics) instruments. TC, HDLC, LDLC, and TG were measured in children with kidney disease on CobasB101 (LDLC calculated) and Vitros (direct LDLC). Coefficient of correlation and average deviation in relative % (bias) of the POC methods in comparison to Vitros were calculated. Parametric and non-parametric statistical analysis were used for data comparison.

RESULTS

No significant differences between the results of HbA1c by three methods tested and lipids parameters by two methods tested were noted. Coefficient of correlation and average deviation in relative % were r=0.977 and 3.54% (the mean HbA1c 7.38%) for Cobas-Vitros and r=0.984 and 2.18% (the mean HbA1c 7.29%) for Quo-Test-Vitros. However, for children with HbA1c level less than 6.5% the bias was 6.35% for Cobas (the mean value 6.04%) and 5.34% for Quo-test (the mean value 5.98%). Cobas TC and TG methods were well correlated with Vitros method (r=0.986 and r=0.989 respectively) with average deviation in relative % equal 4.31% (the mean value 5.32 mmol/l) for TC and -0.89% (the mean value 1.39 mmol/l) for TG. The correlation between Cobas and Vitros methods for HDLC was much worse (r=0.833) with the bias -1.18% (the mean value 1.42 mmol/l). Although the correlation between Cobas and Vitros for LDLC estimations revealed good correlation (r=0.977) the average deviation in relative % was as high as 10.6% (the mean value 3.24mmol/l).

CONCLUSION

Measurement of HbA1c concentration on CobasB101 and Quo-Test devices can be used for monitoring but not for diagnosing the pediatric diabetic patients. Performance of CobasB101 in TC and TG measurement is good but LDLC measurement is still a concern, especially in children with kidney disease whose sera have a difficult matrix.

Critical care, emergency medicine, blood gases, POCT

M381

BACHELOR OF SCIENCE IN BIOMEDICAL SCIENCES 3RD-YEAR IN-SERVICE STUDENT

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BACKGROUND-AIM

High quality malaria diagnosis is the pillar to proper treatment and reduction in mortality and morbidity in a malaria endemic area like the community surrounding Lubwe Mission Hospital. Although microscopy is the golden standard method of malaria diagnosis, but due to erratic power supply in the area, RDTs are often preferred to microscopy. The other factor is that RDT results are quick to obtain and significantly reduces the waiting time for the patients at the Point of Care sites at Lubwe Mission Hospital. However, the results obtained are not of quality assured standards as compared to the golden microscopy method. Finding the factors contributing to the causes of high false positive and negative results will help improve and provide quality assured accurate reliable laboratory results.

METHODS

Malaria RDT tests results data were routinely captured in registers in all the 5 PoC sites. Comparison with microscopy data and repeated RDTs based on Hospital numbers for 11 months period (including OPD, Wards, Doctors room, MCH and CTC) were entered in a database and analyzed to identify which PoC sites are commonly affected. And what could be the main causes and what false results prevailed (false positive or negative).

RESULTS

From May 2012 to March 2013, Lubwe Mission Hospital recorded a total of 93,116 with 4,595 false (positive and negative) results tested with a mean of 417 false (positive and negative) RDT results per month. False negative results recorded a higher percentage (4.0%) than false positive results (0.9%). Although false (both positive and negative) results were recorded from all the 5 PoC sites, OPD and wards accounted for 80.7% of all false malaria RDT results.

CONCLUSION

There is a high rate of false malaria RDT tests results in PoC sites at Lubwe Mission Hospital. Therefore the interventions required will be to sensitize and train personnel especially at OPD and nurses in the wards because from the reasons these staff give, shows either they ready results before manufacturer recommended time leading to getting false negative results or they use other fluids as Diluent assay; hence getting false positive results; also to establish a quality assurance system in all the sites performing RDTs. Emphasis will be made to see to it that quality control of all RDT kits are done before distribution to PoC sites. It is anticipated that there will be improvement of quality assured and accurate reliable malaria diagnosis in PoC sites using RDTs.

Critical care, emergency medicine, blood gases, POCT

M382

COMBINED ASSESSMENT OF PRESEPSIN (SCD14-ST) AND MORTALITY IN EMERGENCY DEPARTMENT SEPSIS (MEDS) SCORE IMPROVES OUTCOME PREDICTION OF SEPSIS

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BACKGROUND-AIM

Sepsis represents a common complication of patients in the emergency department (ED) and intensive care unit (ICU). The incidence is increasing going along with increasing admittance of outpatients suspicious for sepsis at the ED. Assessment of disease severity at the time of initial presentation could be helpful in the patient management as the mortality of severe sepsis or septic shock is 30 to 60% whereas the mortality of sepsis without organ failure remains below 10%. The aim of our study was to evaluate presepsin (PSEP) for assessment of disease severity and outcome prediction in comparison with the MEDS score.

METHODS

121 septic patients were included. Primary endpoint was death within 30 days. The combined endpoint “major adverse events” (MAE) consisted of at least either the primary or at least one of the secondary endpoints intensive care, mechanical ventilation or dialysis. MEDS score, PSEP, and procalcitonin (PCT) were determined at the time of initial presentation to the ED. PSEP was measured by use of the PATHFAST system which allows POC testing.

RESULTS

21 patients died and 34 patients exhibited MAEs during 30 day follow up. The number of decedents and patients with MAEs were 2 (3.2%) / 5 (8.1%), 8 (21.6%) / 15 (40.5%) and 11 (50,0%) / 14 (63.6%) in patients with sepsis (n=62), severe sepsis (n=37) and septic shock (=22), respectively. Median values of MEDS score and PSEP in sepsis (n=62) were 8 and 738 ng/L compared to 11 and 1407 ng/L ($p<0.0001$) in severe sepsis or septic shock (n=59). 30-day mortality was 17.4 %, ranging from 0 % in the 1st to 43.3 % in the 4th quartile of presepsin concentration. ROC analysis revealed AUC values for MEDS score and PSEP of 0.851 and 0.810, respectively, compared to 0.549 of PCT. The logistic regression of combined MEDS score and PSEP regress revealed a AUC value of 0.909. Similar results were found regarding MAEs.

CONCLUSION

MEDS score and PSEP demonstrated strong relationship with disease severity and outcome in patients with sepsis in the ED. The combined assessment of MEDS score and PSEP provided a significant higher predictive value than both markers alone. The PATHFAST system allows early determination of PSEP from whole blood in the ED in addition to MEDS score and may improve the management of sepsis.

Critical care, emergency medicine, blood gases, POCT

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ROUTINE CHEMISTRY, HEMATOLOGY & BLOOD GAS VALUES ON FOUR SUCCESSFULLY TREATED EBOLA PATIENTS.

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BACKGROUND-AIM

BACKGROUND: Several Ebola patients have recently been successfully treated at our hospital and had laboratory testing to help guide their treatment. Results over the course of treatment offer insight into the disease course and highlight the inter-individual responses to infection

METHODS

METHODS: Patients with confirmed Ebola Zaire were admitted to the specialized isolation unit at Emory University Hospital (Atlanta, GA) from August to October 2014. Laboratory analyses were performed in a dedicated laboratory (BSL-2) . All testing was performed on point of care (POC) instruments. Testing instruments were: a chemistry analyzer (Abaxis Piccolo Xpress ABAXIS, Inc, Union City, CA), a blood-gas analyzer (GEM Premier 4000 (Werfen, Barcelona, Spain), an automated urinalysis analyzer (CLINITEK Status Siemens Corp., Munich, Germany), and a hematology analyzer (pocH 100i Sysmex Corp., Kobe, Japan). Additionally, we used the BinaxNOW malaria assay (Alere, Orlando, FL) and the Biofire PCR instrument (Biofire Diagnostics, Salt Lake City, UT).

RESULTS

RESULTS: Results for these patients were typical of inpatients experiencing trauma with significant organ damage. All patients showed signs liver damage with elevated aspartate aminotransferase (AST) and alanine aminotransferase (ALT). Some showed abnormal electrolytes, reduced protein levels, and elevated lactates. Potassium values, as expected, were elevated in samples with hemolysis while sodium values were elevated in samples with lipemia. Patients displayed reduced red blood cell and platelet counts initially and these normalized with treatment. Three of the four patients had elevated white counts at discharge. Liver enzymes remained elevated at discharge.

CONCLUSION

CONCLUSIONS: Our dedicated POCT laboratory was able to provide necessary testing to successfully treat these patients. Laboratory values in these patients were similar and may reflect the course of the disease. Values appear to be dependent on days post infection when the patient entered the unit, and the patient's general health before being infected. It is clear that at discharge, though no longer infectious (negative PCR), these patients still exhibit liver function problems as well as other lingering abnormalities.

Critical care, emergency medicine, blood gases, POCT

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ANALYTICAL VALIDATION OF POINT-OF-CARE EMERGENCY TESTS ON THE PATHFAST SYSTEM IN COMPARISON WITH AUTOMATED LABORATORY ANALYZERS

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BACKGROUND-AIM

The PATHFAST system consists of an automated analyzer that uses single cartridges containing ready to use reagents for quantitative measurement in human whole blood (WB), serum and heparinized, citrated plasma or EDTA plasma. The turn-around-time (TAT) lies within 16 min. We evaluated the analytical performance of the PATHFAST system for the determination of the 6 emergency parameters cardiac troponin I (cTnI), high sensitivity C-reactive protein (hsCRP), myoglobin (Myo), CK-MB, NT-proBNP, and D-Dimer in comparison with the Roche E 170 and Roche cobas Integra 800.

METHODS

Intra- and inter-assay imprecision were evaluated using BioRadLiquicheK Cardiac Markers Control, patient plasma and patient WB samples. Linearity, analytical and functional sensitivity, limit of blank (LoB) were determined by using predefined samples and zero calibrators. The method comparison with Roche E 170 and Roche cobas Integra 800 was performed using patient samples with marker concentrations comprising the whole measurement range.

RESULTS

Coefficients of variation (CVs) of intra- and inter-assay imprecision ranged between 3.3% and 8.0%. All assays showed recovery between 91% and 105% and complete linearity across the total measurement range. The LoB was determined by measurement of 10 replicates of the zero calibrator and of the lowest non-zero calibrator in parallel. Sample matrix evaluation was performed using WB and plasma samples. All assays showed high comparability between WB, serum, heparinized, citrated plasma or EDTA plasma. The method comparison with Roche E 170 and cobas Integra 800 revealed high concordance rates.

CONCLUSION

The evaluation of determination of cTnI, hsCRP, myoglobin, CK-MB, NT-proBNP, and D-Dimer concentration on the PATFAST system revealed high concordance with the Roche E 170 and cobas Intregra 800 analyzer. Point-of-care testing on the PATHFAST analyzer allows measurement of whole blood samples within 16 min after blood drawing in the point-of-care setting providing comparable results with the central laboratory.