Point of Care testing, critical care, emergency medicine.

W174

NOVA BIOMEDICAL STAT STRIP XPRESS2 LACTATE METER VERIFICATION IN TARTU AMBULANCE FOUNDATION

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BACKGROUND-AIM

Sepsis is a sequela of severe infection characterized by a systematic inflammatory response. Mortality rates from sepsis are high. Early antibiotic therapy can improve clinical outcomes and should be given within one hour of suspected sepsis. Prehospital assessment can potentially impact and improve outcomes and time to initiation of treatments. Ambulance Foundations (AF) are focused on rapid diagnostic and treatment of patients with acute and urgent illnesses and injuries, including patients with sepsis. The objective of this study was to verify the professional StatStrip Xpress2 lactate meter (Nova Biomedical, USA) with Tartu AF. We assessed the performance of this lactate meter by using a spreadsheet program for estimating the bias between two methods using patient samples. The verification of precision was performed by using control samples (Nova Biomedical, USA).

METHODS

The Rapidpoint 500e (Siemens, USA) was used as a comparative method for the study. According to EP09 (CLSI), 40 whole blood heparinized samples used in comparison. Precision of the lactate meter was determined by measuring of two levels of quality control samples in 5 replicates over 5 days (EP15, CLSI).

RESULTS

The linear regression analysis of the method comparison study demonstrated a slope and intercept of 1,28 and -0,93, respectively. The results correlated well (R2= 0,987) and demonstrated that StatStrip Xpress2 and Rapidpoint 500e had no significant bias (p-0,536). The range of lactate was from 0,72 to 17,46 mmol/L, mean lactate concentration was 3,64 mmol/L and the mean bias was -0,10 mmol/L (-8,9%). The intralaboratory imprecision of lactate across two levels (0,6/6,4 mmol/L) was 21,6/10,6 %. The control results corresponded to a confidence level of 95% was 0,67 ±0,28 mmol/L and 6,12 ± 1,29 mmol/L.

CONCLUSIONS

The StatStrip Xpress2 Lactate meter demonstrated a close correlation to the laboratory method. Precision of the meter exceeded the manufacturer's claims, but was below biological intraindividual variation (CVi-27,3%). We conclude that the Nova StatStrip Xpress2 Lactate meter is suitable for use in the Tartu Ambulance Foundation. Prehospital lactate measurement improve outcomes by early identification of sepsis and initiation of treatment within one hour.

Point of Care testing, critical care, emergency medicine.

W175

USING BULL'S ALGORITHM FOR POCT ANALYSERS IN HAEMATOLOGY PATIENTS

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BACKGROUND-AIM

Bull's algorithm (XbarB protocol) is a methods used for calculating moving average as internal quality control in laboratory. It uses batches of 20 continuous patient results. Truncation, and action and target limits must be set up. Any shift or trend of data out of the set target limit by more than the set action limit should be reviewed.
POCT analysers are used by non-laboratory personnel at out-of-laboratory sites. More quality control procedures are needed to detect system faults since supervision is not always possible by the overseer.

METHODS

Although some haemotology analysers have automatic moving average calculation within their software, the one we use (pocH-100i (Sysmex, Germany)) does not, as such we used XbarB protocol to calculate it ourselves. The parameters used to calculate moving average are erythrocyte constants, which, if there is no significant change in patient population, varies up to 0.5% on a day-to-day basis. We set truncation limits for MCHC between 250 and 370 g/L based on previous experience for sample acceptance; if lower or higher, the sample is rejected due to preanalytical errors (such as sample dilution or blood clots). The action limit was set to 3% to detect a system error of over 3%, and stable moving average as the target limit.

RESULTS

During January 2020 in Clinical Hospital Center Rijeka all patient results were collected from the Haematology Day Clinic and processed Bull's algorithm to detect analyser system fault. There were 349 samples with 3 excluded due to truncation limits. One instance of moving average was detected exceeding the set action limit of 3%, on the day there was a change of reagents lot.

CONCLUSIONS

To use Bull's algorithm, a population of patients is needed where similar results are expected for parameters which do not statistically differ day-to-day. This analyser and site were convenient due to the homogeneous patient population. XbarB protocol is useful for detecting system faults as shown by detecting a shift the day the reagents lot was changed, which is one of the expected reasons for a shift.

Point of Care testing, critical care, emergency medicine.

W176

PROENKEPHALIN (PENKID) AS A BIOMARKER FOR ACUTE KIDNEY INJURY AND ITS ANALYTICAL PERFORMANCEON A POINT OF CARE PLATFORM

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BACKGROUND-AIM

Acute kidney injury (AKI) is defined as a rapid decline in renal filtration function. AKI is frequent in critically ill patients, and biomarkers can facilitate its early diagnosis and its prevention. Proenkephalin (penKid) is a stable opioid peptide cleaved from the same precursor of endogenous opioids as enkephalins. penKid has been identified as a functional biomarker for kidney function and its plasma concentration are inversely correlated to the glomerular filtration rate (GFR). The aim of our study was to evaluate the reliability of a new point-of-care testing (POCT) system for measuring penkid with a short turnaround time of analysis (TAT).

METHODS

Inter-assay imprecision of the IB10 sphingotest® penKid® assay was assessed by repetitive measurement of human EDTA plasma pools. Method comparison was performed with the reference to Immunoluminometric assay (ILMA) by measuring 50 plasma samples. Correlation and agreement between methods were tested using Bland-Altman plot and Passing Bablok linear regression. Usability of the POCT instrument was assessed by the multidisciplinary staff handling the POCT device through a dedicated questionnaire.

RESULTS

The inter-assay CVs of the IB10 sphingotest® penKid® test were 19.7% for a concentration of 113 pmol/L and 9.3% for a concentration of 307 pmol/L. The IB10 sphingotest® penKid® was significantly correlated to the ILMA (r=0.97). The Passing-Bablok linear regression showed a slope of 0.905 and an intercept of 7.49. The Bland-Altman plot showed a mean bias of 4.93% pmol/L between the two methods. The POCT usability questionnaire was overall satisfying. The TAT analysis with the IB10 sphingotest® penKid® was below 20 minutes.

CONCLUSIONS

Our results showed a good analytical performance of the IB10 sphingotest® penKid® combined with a short TAT. In addition, an excellent correlation with the reference method was observed and the usability of the instrument was evaluated as satisfactory by high majority of the users.

Point of Care testing, critical care, emergency medicine.

W177

EVALUATION OF NEW POINT OF CARE TESTS PANEL FOR THE ASSESSMENT OF LIVER FUNCTION

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BACKGROUND-AIM

The use of point-of-care testing (POCT) is increasing because of its capacity of offering accurate and rapid diagnosis. Clinical laboratories and specialists in laboratory medicine play an important role for the implementation and validation of POCT instruments. The aim of our study was to determine the analytical performances of a recently developed POCT device for the measurement of tests related to liver function.

METHODS

We evaluated the performances of liver panel (Albumin, Alkaline phosphatase, AST, ALT, GGT, Direct Bilirubin, Total bilirubin, Indirect Bilirubin, Glucose, Total Protein and Globulin) performed on the LINX EVO® POCT device (Menarini Diagnostics). The imprecision was determined with the Bio-Rad Liquichek Unassayed Chemistry Control. Method comparison was performed with Cobas® 8000 analyzer. Samples from twenty healthy volunteers were used to verify the reference intervals. Furthermore, practicability assessed by the staff handling the POCT device through a dedicated questionnaire.

RESULTS

The imprecision observed for all the liver panel tests was matching the criteria provided by Westgard table. The only exception was the globulin with an observed imprecision of 6.3% and a criterion of 5.7%. Method comparison showed an excellent agreement with the routine laboratory method for all tests with however weaker agreement for total and direct bilirubin. The verification of reference intervals showed that more than 90% of the healthy volunteers values were included into the reference interval claimed by the manufacturer with the exception of glucose and globulin where adjustments will be needed. The POCT practicability questionnaire was overall satisfying for users and the rapidity of measurement was confirmed.

CONCLUSIONS

Our study showed overall very good analytical performances for the liver panel performed on the LINX EVO® POCT instrument. The user friendliness and rapidity of the system was also confirmed. To overcome the limited bias with routine laboratory assays, the validation of local reference intervals and decision limits remain mandatory.

Point of Care testing, critical care, emergency medicine.

W178

ASSESSMENT OF NOVEL PANEL OF POINT OF CARE TESTS TO EVALUATE RENAL FUNCTION

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BACKGROUND-AIM

The use of point-of-care testing (POCT) is increasing because of its capacity of offering accurate and rapid diagnosis. Beside all the potential advantages that POCT devices offer, it is important to validate the reliability and quality of the systems. The aim of this study was therefore to evaluate the analytical performances of a recently developed POCT device for the measurement of tests related to renal function.

METHODS

We evaluated the performances of renal panel (albumin, creatin kinase, creatinine, calcium, glucose, chlorine, phosphorus, potassium, sodium and GFR) of the LINX EVO® (Menarini Diagnostics) POCT instrument. The imprecision was determined with quality control materials. Method comparison was performed with Cobas® 8000 analyzer. Samples from twenty healthy volunteers were used to verify the reference intervals. Practicability of system was also review by the staff handling the POCT device through a dedicated questionnaire.

RESULTS

The imprecision was estimated for each parameter and compared to the references provided by Westgard table. Albumin, creatin kinase, glucose and phosphorus were falling into the criteria whereas creatinin, calcium, chloride, potassium and sodium were slightly above. Method comparison showed a good agreement with the routine laboratory method with however weaker agreement for creatinin, calcium, chloride and potassium. The verification of reference intervals showed that more than 90% of the healthy volunteers value were included into the reference interval claimed by the manufacturer with the exception of glucose, calcium, phosphorus and GFR where adjustments will be needed. The POCT practicability questionnaire was overall satisfying for users and the rapidity of measurement was confirmed.

CONCLUSIONS

Our study showed overall good analytical performances for the renal panel performed on the Linx Evo POCT instrument. The user friendliness and rapidity of the system was also confirmed. To overcome the limited bias with routine laboratory assays, the validation of local reference intervals and decision limits remain mandatory.

Point of Care testing, critical care, emergency medicine.

W179

LONG-TERM PERFORMANCE OF POINT-OF-CARE HEMOGLOBIN A1C ASSAYS

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BACKGROUND-AIM

With evolving laboratory technology and, in particular, miniaturization of processes and reduction in required sample size, point-of-care (POC) measurement has become a key modality to provide rapid information needed for clinical decisions. POC testing of HbA1c is used as a time-efficient tool to improve treatment and management planning for diabetes in the pediatric clinical service. We assessed the reliability of POC HbA1c assay techniques in a real world clinic setting over a 4-year period, comparing the results to 2 central laboratory techniques.

METHODS

We compared the DCA Vantage® from Siemens™ immunoassay-based POC techniques to the G8® from Tosoh™ and Variant II® from Bio-Rad™ ion-exchange high-performance liquid chromatography (HPLC) central laboratory methods in a study lasting 4 years. In total, 80 patients in pediatric service participated in this study diagnosed with type 1 diabetes and undergoing treatment. A venous blood sample was taken for routine HbA1c analysis by the diagnostic laboratory method, a blood sample was taken from the fingertip For the POCT HbA1c at the same time. The HbA1c results of three methods were compared and analyzed with a Bland-Altman agreement plot.

RESULTS

The DCA Vantage® also has good concordance HbA1c ranged from 5 −14#% with the central laboratory G8® (Bland–Altman plots Coef R2: 0.997) and Variant II® (Bland–Altman plots Coef R2: 0.995). Despite high correlations among the 3 techniques, there were variable differences obtained over time. The Bio-Rad and Tosoh values varied from 0.1 to 0.2% higher than the DCA values but the difference is clinically insignificant.

CONCLUSIONS

POCT HbA1c measurements using the DCA Vantage system, compared to the standard laboratory method, are highly sensitive and accurate, as well as being less time-consuming and costly, with a more convenient blood collection. Therefore, this POCT system is a suitable tool for diabetes screening and management in the service pediatric. However, the linearity limit for the DCA Vantage® is 14% above this value, the HbA1c must be carried out in the laboratory.

Point of Care testing, critical care, emergency medicine.

W180

ACCURACY OF POINT-OF-CARE OF MEASURING NEONATAL BILIRUBIN CONCENTRATION

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BACKGROUND-AIM

The Point-of-Care (POCT) ABL 90 Flex plus® blood gas analyzer has the advantage of measuring total bilirubin (tBil) with a capillary sample and a very small volume of blood in neonatology. Since the marketing of this machine, no organization has offered an external quality control (EQC) to estimate the accuracy of the tBil. The objective of our study is to evaluate the accuracy of total bilirubin measured by the POCT ABL 90 Flex plus® from Radiometer™ using EQC from Probioqual for Cobas 6000®.

METHODS

45 EQC for tBil between 2018 and 2021 intended for the diazo method in cobas 6000 c 501® from Roche™ were analyzed by co-oximetry in POCT ABL 90 Flex plus® from Radiometer™ in the neonatology department. The samples were measured on the same day on two automates. The results were processed via the guidelines method validation according to ISO 22870 and were compared and analyzed with a Bland-Altman agreement plot.

RESULTS

The tBil concentrations covered a range of 16 to 322 µmol/L, a good correlation between the two techniques with a correlation coefficient of 0.993 and the regression equation y: 1.0163X- 1.2738.
For all tBil concentration levels the observed deviation was in acceptable limits for the French Society of Clinical Biology. A small bias is observed for low values compared to the cobas peer group but it's statistically and clinically insignificant.

CONCLUSIONS

In the absence of a tBil EQC on ABL90 Flex plus® from Radiometer™, this alternative measurement can be adapted by the laboratory to assure the monitoring of the performance of this sensitive and important setting for the diagnosis of jaundice in newborns.

Point of Care testing, critical care, emergency medicine.

W181

IMPACT OF THE COVID-19 CRISIS ON THE POINT-OF-CARE BLOOD GASES MANAGEMENT (GEM PREMIER SERIES, WERFEN) IN AN ISO 22870 ACCREDITED LABORATORY IN PARIS (FRANCE)

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BACKGROUND-AIM

Our laboratory is accredited for point-of-care (POC) blood gases activities according to the ISO 22870 standard. When, in March 2020, the Covid-19 crisis hit France, risk assessment was done to adapt POC management to the setting up of 3 new dedicated Covid-19 intensive care units.

METHODS

We used our change management procedure based on risk assessment management (CLSI EP-23) and prioritization of risks (criticality scale) to reveal new risks to take into account:
Material: - Insufficient number of blood gases devices. - Shortage of reagents requiring anticipating the potential peak of analysis (units full of ventilated patients).
Manpower: - Newly trained-empowered people recruited for the Covid-19 crisis requiring to derogate from the usual training procedure to increase the rate of operational users. - Staffing shortage in the clinical units or in the laboratory due to illness.
Methods: - Reduced initial analyzer performance check for quick commissioning. - Necessity of indicators to monitor the impact of derogations to usual procedures and to verify the adequacy with the clinicians needs.
Environment: - Potential impact of SARS-CoV-2 on analyzers management (device contamination, waste, protection of users).

RESULTS

Material: One GEM Premier 4000 was put back into service and 2 additional GEM Premier 5000 (Werfen) were ordered and put into service the day of reception 9 days later. Reagent orders were tripled to avoid shortage due to potential future manufacturer's deficiency. Eventually, POC blood gases activity increased +300% at the peak of the crisis in April without any particular problem.
Manpower: 35 new users were trained-empowered with a quick-training procedure. A punctual lack of trained user never happened and daily monitoring of rejected analysis (new indicator) showed even better results than expected.
Methods: Indicators allowed to verify that specific requirements of ISO 22870 were still achieved.
Environment: No special procedure was required for the analyzer itself aside the general procedure for COVID-19 clinical unit management.

CONCLUSIONS

Our change management procedure allowed our ISO 22870 accredited laboratory to add these new locations/POC analyzers to our scope of accreditation during the peak of the COVID-19 crisis.

Point of Care testing, critical care, emergency medicine.

W182

ASSESSMENT OF THE ANALYTICAL PERFORMANCES OF STATSTRIP GLU/KET FOR GLUCOSE MEASUREMENT IN CEREBROSPINAL FLUID

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BACKGROUND-AIM

Measurement of cerebrospinal fluid (CSF) glucose (GLU) provides essential information to the clinician: hypoglycorrhachia is a symptom of various abnormal clinical conditions and is also a useful piece of evidence in the differential diagnosis of bacterial (low GLU) and viral (normal GLU) meningitis. GLU biochemistry assays require sample centrifugation which may delay time-to-result. In this study, we evaluated the measurement of GLU in CSF using a blood GLU monitoring systems (BGMS). Our goal is to propose this method to clinicians to obtain a rapid GLU result in CSF with a minimal sample volume requirement of 0.6µl at the bedside.

METHODS

We submitted a routine StatStrip GLU/KET meter (Nova Biomedical, Waltham, USA) to an intra-assay (10 runs with 2 lots of strips) and inter-assay (twice daily for 20 days in duplicate with 2 lots of strips) precision using clinical samples of CSF with low and high GLU level. Method comparison was performed using consecutive clinical CSF samples and comparing results obtained on the biochemistry routine platform (cobas 8000, Roche Diagnostics, Mannheim, DE) versus StatStrip GLU/KET (duplicate with 2 lots of strips).

RESULTS

The coefficients of variation observed for the intra-assay were 6.2% on average for both the low (18 mg/dL) and high (58 mg/dL) value samples. The CVs for inter-assay (median (95% CI)) were 9.6% (9.3-13.0) and 8.0% (6.4-8.6) for the low (18 mg/dL) and high (75 mg/dL) levels respectively. The analysis of the precision on 60 clinical samples (median age; 95% CI: 26.7; 0.2-48.4) showed a slope of 0.81 and a coefficient of determination (R^2) of 0.94, with an underestimation of the high values (>100 mg/dL). For values ≤100 mg/dL, the slope was 0.94 (R^2= 0.92). No difference was found between the 2 strip lots (P>0.05; Wilcoxon test).

CONCLUSIONS

StatStrip is suitable for measuring GLU in CSF. The use of this widely deployed instrument in our hospital departments for this new application will provide critical, clinically actionable information in a timely manner. This will be especially useful to pediatricians, neonatologists and in emergency departments, and offers the additional advantages of other point-of-care tests, including small sample volume, ease of use and rapid results (6 seconds).

Point of Care testing, critical care, emergency medicine.

W183

POINT-OF-CARE ASSESSMENT OF BIOCHEMISTRY PANELS: COMPARISON OF TWO MULTI-PURPOSE DEVICES

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BACKGROUND-AIM

POCT instruments make it possible to measure more and more biological parameters at the patient's bedside and facilitate rapid diagnosis. However, the number of parameters per device is often limited. As a consequence, multiplying the number of POCT analyses often means increasing the number of instruments. Apart from blood gas analyzers, which are generally large, there are few instruments able to carry out several determinations at the same time. In this study, we evaluated Piccolo Xpress and LINX EVO, 2 compact analyzers capable of measuring ten biochemical parameters at once.

METHODS

Routine serum samples previously assessed on a cobas® 8000 platform (Roche Diagnostics, Mannheim, DE) were tested with the ER III and Biochemistry Plus panels respectively on LINX EVO (A.Menarini Diagnostics, Firenze, IT) and Piccolo Xpress (Abaxis, Inc., Union City, CA, USA). The slope, intercept and coefficient of determination R^2 were calculated for each available parameter. Values outside the lower and upper measurement range of both LINX EVO and Piccolo Xpress were removed from the statistical analyses.

RESULTS

49 clinical samples were analyzed in parallel with ER III and Biochemestry Plus panels. All the coefficients of determinations after comparison to the cobas® were >0.90, with the exception of sodium on LINX EVO (0.87) and of calcium (0.83) and albumin (0.88) on Piccolo Xpress. All regression equations were excellent, with slopes between 0.85 and 1.13, except for albumin (0.78) and amylase (1.29) on Piccolo Xpress.

CONCLUSIONS

To our knowledge, LINX EVO and Piccolo Xpress are the only POCT devices which are able to assess several biochemistry analyses at the same time in approximately 15 minutes. Their degrees of agreement are very good compared to our routine biochemistry system. Both panels are suitable for use in emergency medicine, however ER III provides results for total bilirubin and lipase, two important parameters for the management of abdominal pain. Using such integrated solution in emergency rooms will help the physician in a faster management and throughput of patients.

Point of Care testing, critical care, emergency medicine.

W184

TURNING A LABORATORY HAEMATOLOGY INSTRUMENT INTO A POINT OF CARE TESTING (POCT)

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BACKGROUND-AIM

Although there are a multitude of POCT instruments for the determination of chemistry parameters, there are few for haematology. Also we did not have the opportunity to test the pocH-100i (Sysmex, Kobe, Japan) for reasons of unavailability in Belgium. We installed a Beckman DxH-520 (Beckman-Coulter, Brea, CA, USA) laboratory analyser in an emergency room (ER) so that it could be used as a point-of-care instrument in order to objectify the time saved by testing the patient directly in the ER.

METHODS

For one week, all patients requiring a blood sample for a haematology formula were drawn with an additional EDTA tube for in situ analysis. The clinician was asked to record the time of the blood test to assess the difference in turn-around time (TAT) between the instrument used as a POCT and the central laboratory analysis.

RESULTS

Forty consecutive patients were included: median age 59.4 years (95% CI: 53.2-65.6); sex ratio M/F=1/2.1. For 2 patients, DxH-520 did not provide a leukocyte formula due to probable handling errors by emergency users. The median TAT (95% CI) for the DxH-520 and in situ analysis were 10 min (6-14) and 32 min (16.9-37.1) respectively (P<0.0001, Mann-Whitney U-test).

CONCLUSIONS

The DxH-520, although not a POCT, was used as such and helped speed up the rendering of haematology results significantly. However, even if its use is simple for a laboratory professional, the interface is neither simple nor intuitive for nurses and physicians. In addition it has external reagents and waste, and required a lot of maintenance. However, it has advantages such as speed and small size and could be adapted for use like a POCT: prevention of errors in use, POCT-1A connectivity, simplified display and unique reagent/waste cassette like POCT blood gas analysers. We therefore encourage the manufacturer to develop a solution in the way of POCT. The availability of such an instrument in an oncology day hospital could bring a real added-value because the initiation of chemotherapy depends on the rapid achievement of the complete blood count.

Point of Care testing, critical care, emergency medicine.

W185

EVALUATION OF TWO POINT-OF-CARE INSTRUMENTS FOR LIPID AND GLUCOSE DETERMINATION

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BACKGROUND-AIM

POCT instruments are primarily oriented for the determination of vital or urgent parameters. However, decentralized measurement tools are also used in consultation rooms, including for monitoring chronic diseases such as diabetes or cardiovascular diseases. Some authors have also studied the impact of an immediate outcome on the patient's compliance with the regimen and medication. In this study, we evaluated the degree of agreement of the lipid panels of LINX DUO and LINX EVO, two POCT instruments that can be used for both emergency and chronic disease follow-up testing by comparing them to our routine biochemistry technique.

METHODS

57 samples of serum from the routine tested on cobas 8000 (Roche Diagnostic, Mannheim, DE) with a wide variation in cholesterol, triglyceride and HDL-cholesterol values were selected for POCT analysis. The Lipid Panel Plus was used on LINX DUO and the Lipid Panel on LINX EVO (A.Menarini Diagnostics, Firenze, IT) for the measurement of triglycerides, total cholesterol, HDL and glucose. LDL and VLDL are calculated parameters. Values outside the measurement limits were removed from the statistical analysis. The glucose results were compared to the performance criteria defined in international standards ISO 15197, POCT 12-A3 and FDA Draft Guidance Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.

RESULTS

57 samples were tested with LINX EVO and 54 with LINX DUO. The coefficients of determination (R^2) were ≥0.89 for all the lipids, with a slope between 0.88 and 1.11 and between 0.84 and 1.18 for LINX DUO and LINX EVO respectively. For glucose, R^2 were ≥0.96 with a slope of 0.97 for LINX DUO and of 1.00 for LINX EVO. The concordance of LINX EVO with ISO 15197, POCT 12-A3 and FDA criteria were 100%, ≥96% and ≥95.9% respectively. The concordance of LINX DUO with ISO 15197, POCT 12-A3 and FDA criteria were ≥92%, ≥88% and ≥93.6% respectively.

CONCLUSIONS

LINX DUO and LINX EVO are two decentralized biology instruments that are suitable for lipid dosing in a preventive medicine or nutritionist's office. In addition, LINX EVO shows outstanding performance in glucose determination. The turnaround time of the LINX EVO is 15 minutes for one sample versus 8 minutes for 1 or 2 samples at a time on LINX DUO.

Point of Care testing, critical care, emergency medicine.

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INFLUENCE OF A POCT MULTI-PARAMETER BIOCHEMISTRY ANALYZER ON THE MANAGEMENT OF PATIENTS WITH ABDOMINAL PAIN IN EMERGENCY DEPARTMENT

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BACKGROUND-AIM

Abdominal pain (AP) accounts for 5 to 10% of the admissions to emergency departments (ED). Management of APs usually requires clinical biology tests and imaging. Except in major emergencies, clinicians wait for the labs results to refer the patient to a CT-scanner (contrast-enhanced or not), or to an ultrasound. We evaluated the time saved in the management of ED-patients with AP by analyzing blood samples in parallel on a POCT device performing several biochemistry tests in 15 minutes.

METHODS

An additional Lithium-heparin tube was drawn for the POCT tests. POCT analyses were performed with the ER III panel on LINX EVO (A.Menarini Diagnostics, Firenze, IT). The usual blood sample was sent at the same time to the central laboratory. The response time for biochemistry analyses was recorded according to the LINX EVO timer. The response time of the laboratory was recorded regarding the log of the lab information system. The time frames were calculated based on the time of blood collection.

RESULTS

62 patients were included (median age [95% CI]: 46.6 [41.5-51.6]). The median response times to the patient record were 21 [16.6-25.4] minutes for LINX EVO and 90 [50.2-129.8] minutes for the routine blood analyses. The median time gain in the availability of results on LINX EVO was 58 [17.5-98.5] minutes ($p<0.001$). The imaging examinations performed were CT with (N=30) and without contrast enhancement (N=12), ultrasound (N=10), plain abdomen film (N=2), none (N=10). 25 patients were hospitalized, 2 were temporary hospitalized and 35 were discharged. Final diagnosis were common AP (N=6), biliary pain (N=8), gastric ulcer (N=5), gastroenteritis (N=6), gynecological pain (N=3), obstruction (N=5), pancreatitis (N=2), peritonitis/perforation/appendicitis (N=7), urolithiasis (N=3), urinary tract infection (N=4), other (N=13).

CONCLUSIONS

LINX EVO allowed a median gain of 58 minutes in patient management: need and choice of an imaging examination, possibility of contrast agent injection, diagnosis of inflammatory syndrome. The ER III panel was previously evaluated in our laboratory and showed performance equivalent to routine instruments. To our knowledge, it is the only POCT device able to dose lipase which is essential for the management of APs.

Point of Care testing, critical care, emergency medicine.

W187

HIGH-SENSITIVITY TROPONIN ON ATELLICA VTLI PATIENT-SIDE IMMUNOASSAY ANALYZER (SIEMENS): EVALUATION, RISK ASSESSMENT AND PRACTICABILITY

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BACKGROUND-AIM

To evaluate the Atellica VTLI analyzer (Siemens), a new handheld device for high-sensitivity (HS) troponin I testing at point-of-care (POC), producing results in 8 minutes from a small sample volume (30-100 µL) of whole blood, capillary or venous samples. The system consists of a small instrument (<1 kg) with disposable cartridges and is based on the precisely controlled motion of magnetic beads coated with antibodies. Evaluation was performed in the laboratory and in the Emergency Department (ED) with POC users.

METHODS

Evaluation was performed according to the French Society of Clinical Biology (SFBC): within-run precision and between-day precision at 3 levels, comparison of methods with 110 routine patient samples, reportable range. Comparison analyzer was our biochemistry routine Atellica IM (Siemens) with a HS troponin I assay (dual capture sandwich immunoassay). Risk assessment was done using Ishikawa diagram and FMECA method. Practicability was evaluated using a survey (17 questions) in the laboratory by 15 users and 15 POC users in the ED.

RESULTS

Within-run and between-day imprecision gave conform CV values. Linearity was within the expected range given by Siemens (from limit of quantification up to 1250 ng/L). Method comparisons showed a close agreement (r = 0.96) but results with the Atellica VTLI assay were 3 times lower than those of the Atellica IM assay (y = 0.33x + 6.7 ng/L). Risk assessment showed Atellica VTLI very well designed for a POC or a stat laboratory usage. Users, both in the laboratory and the ED, gave positive reviews and believe there is a strong benefit for patients to have this device in POC.

CONCLUSIONS

Atellica VTLI analytical performances for POC HS troponin are validated with the reliability of traditional systems. This device fulfils all the requirements for a POC or a stat laboratory usage. However, hospitals equipped with Atellica IM in their routine labs will have to take into account for patient's follow-up that methods and results are different although belonging to the same "Atellica" brand from Siemens. A strong educational program for clinicians will be essential.

Point of Care testing, critical care, emergency medicine.

W188

EVALUATION OF THE EMERGENCY PANEL ER III ON THE LINX EVO ANALYZER

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BACKGROUND-AIM

The LINX EVO analyzer (A.Menarini Diagnostics, Firenze, IT) is a new POCT instrument that enables the dosage of several biochemistry parameters in 15 minutes in whole blood or serum. The manufacturer offers 11 different reagent discs which allow dosing combinations of 4 to 13 parameters. Some additional parameters are calculated. We aimed to evaluate the ER III panel, which is to be the most suitable one for rapid dosages in emergency rooms. The parameters tested are: C reactive protein, glucose, aspartate and alanine transaminases, gamma-glutamyltransferase, bilirubin, amylase, lipase, blood urea nitrogen, creatinine, sodium and potassium.

METHODS

Intra-assay precision was calculated by testing 20 times 2 levels of Liquid Unassayed Multiqual® controls (Bio-Rad, Hercules, CA). Inter-assay precision was calculated by testing the same controls for 20 consecutive working days. Matrix correlation was evaluated on 10 clinical samples collected both on serum and lithium-heparin tubes. The degree of agreement was assessed by comparing the results from the ER III to 73 clinical samples analyzed on a cobas® 8000 (Roche, Mannheim, DE). The clinical samples were chosen to obtain a range of low to high values within the measurement range of LINX EVO.

RESULTS

Coefficients of variation of ER III ranged from 0% to 5.5% for intra-assay precision and from 0% to 5.8% for inter-assay, excepted for low bilirubin values (10.7%). The slopes ranged from 0.86 to 1.14. All coefficients of determination (R^2) were >0.90, excepted for sodium (0.86). The matrix correlation showed R^2 >0.93 and slopes between 0.962 and 1.044 for all parameters but bilirubin, sodium and potassium.

CONCLUSIONS

The ER III panel allows to measure 12 biochemistry parameters simultaneously (plus one calculated) in 15 minutes. Even if some parameters (ions, glucose, and bilirubin) can be measured on a blood gas analyzer, often available in the emergency rooms, the panel provides other valuable results for rapid management of patients in the emergency room. The results are very reliable compared to our large platform of routine biochemistry. The artificially poor R^2 values of the matrix comparison for Na, K and bilirubin are due to the small number of samples combined to the limited dispersion of the values.

Point of Care testing, critical care, emergency medicine.

W189

QUANTITATIVE MEASUREMENT OF C-REACTIVE PROTEIN (CRP) BY POCT WITH LINX DUO ANALYZER AND COMPARISON TO TWO OTHER INSTRUMENTS

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BACKGROUND-AIM

Respiratory tract infections (RTIs) are the most frequent infections in primary care (about 23% of general practice). We distinguish the upper (pharyngitis, tonsillitis, laryngitis, rhinosinusitis, otitis media) and lower (pneumonia, bronchitis, tracheitis, exacerbation of COPD) RTIs. Most RTIs are of viral origin, but a small number are due to bacteria and can thus respond to antibiotics (AB). However, overprescription of AB is common in primary care with risk of antimicrobial resistance. CRP testing can be an interesting tool to confirm the bacterial cause of RTIs in general practice. Studies on POCT CRP seem to conclude that CRP is better at ruling in than in ruling out bacterial cause of RTIs. In this study, we tested LINX DUO, a POCT analyzer recently available on the market and compared it to 2 other devices of the same type marketed longer.

METHODS

A panel of samples was selected from fresh samples tested on cobas 8000 (Roche Diagnostics, Mannheim, DE), used as a comparison method. Samples were selected to achieve a dispersion of results between low and very high values. Samples were tested fresh and under the same conditions with LINX DUO (A.Menarini Diagnostics, Firenze, IT), Cube-S (Eurolyser Diagnostica, Salzburg, AT) and Afinion 2 (Abbott Diagnostics, Lake Forest, IL, USA) according to manufacturers' instructions. Values obtained outside the measurement range of the devices have been removed from the statistical analysis (Afinion 5-160 mg/dL; Cube-S 1-180 mg/dL; LINX DUO 5-200 mg/dL).

RESULTS

The number of samples tested with Afinion 2, Cube-S and LINX DUO were 89, 92 and 86 respectively. The respective equations of the regression curves were $y=1.06x-0.92$ ($r^2=0.99$); $y=0.94x+1.63$ ($r^2=0.95$); $y=1.22x-0.13$ ($r^2=0.92$). With a cutoff of 10 mg/dL for the suspicion of the bacterial etiology of pneumonia, the respective sensitivity/specificity [95% CI]; Cohen's kappa (κ) score were 97.4% [91%-99%]/84.6% [58%-96%]; $\kappa=0.82$; 94.7% [87%-98%]/94.1% [73%-99%]; $\kappa=0.83$; 97.3% [91%-99%]/90.9% [62%-98%]; $\kappa=0.85$.

CONCLUSIONS

LINX DUO is a reliable alternative to the other POCT methods for the quantitative measurement of CRP. Its performance is comparable to that of the other 2 instruments tested.

Point of Care testing, critical care, emergency medicine.

W190

EVALUATION OF THE DOSAGE OF C-REACTIVE PROTEIN WITH LINX DUO

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BACKGROUND-AIM

LINX DUO (A.Menarini Diagnostics, Firenze, IT) is a point-of-care testing instrument that is able to assess the dosage of C-reactive protein (CRP), lipids, and glycated hemoglobin. In this study, we aimed to evaluate the precision and the accuracy of the CRP reagent kit.

METHODS

Intra-assay precision was performed using two clinical samples on EDTA, with low (11.3 mg/dL) and high (47.8 mg/dL) CRP values preliminary tested on a cobas 8000 chemistry module c 702 (Roche Diagnostic, Mannheim, DE). Those two samples were tested for 20 consecutive runs. Inter-assay precision was performed using Randox Acusera Liquid CRP Control levels 2 and 3 (Randox Laboratories LTD, Crumlin, UK) for 20 days. The degree of agreement was assessed by testing 80 serum samples from the routine tested with the cobas c 702 module. All the samples were included into the range of measurement of the LINX DUO (5-200 mg/dL).

RESULTS

Intra-assay precision was 18.3% for low values and 8.9% for high values. Inter-assay precision was 8.5% for low values and 8.3% for high values. The regression curve obtained after comparison to the cobas c 702 module was y = 1.20x - 0.38 with a coefficient of determination of 0.96. The mean bias was -14.2%. The total errors for low and high values were 20.9% and 2.5% respectively (95% confidence interval). The sigma scores for low and high values were 4.3 and 8.7 respectively.

CONCLUSIONS

The CRP kit on LINX DUO is a precise and accurate tool for the measurement of CRP at the bedside. It allows a quantitative dosage of CRP between 5 and 200 mg/dL in about 6 minutes. The total errors observed for both low and high values are much lower than the allowable total error.

Point of Care testing, critical care, emergency medicine.

W191

COMPARATIVE STUDY OF THE DETERMINATION OF BIOCHEMICAL TESTS IN THE COBAS 8000 AND POCT I-STAT ANALYZERS

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BACKGROUND-AIM

In recent years, the implementation of Point-of-Care Testing (POCT) equipment has increased considerably, especially blood gas analyzers. However, new trends suggest that these same analyzers can perform more comprehensive tests, including basic biochemistry (glucose urea, creatinine, sodium and potassium), becoming tools of high diagnostic value in few minutes.
The aim of this study has been to evaluate the correlation and transferability of the results between the COBAS® 8000 analizer (Roche Diagnostics) and the POCT i-STAT® equipment (Abbott) for measured parameters relative to the basic biochemistry profile.

METHODS

60 samples from our hospital's Emercency Room were included to determine a basic biochemistry profile. The analysis of the samples was carried out in both equipment following a correlative order to minimize preanalytical error: first in the COBAS® 8000 analyzer and followed on the POCT i-STAT®.
Statistical analysis for method comparison was performed using Passing-Bablok regression and the analysis of the mean differences using the Bland-Altman method with the program Statistical MedCalc v18.2.1.

RESULTS

For glucose with a 95% IC of slope 0,8182 to 1,2683, Pearson correlation coefficient (r) was 0,803 (p=0,0002); urea with a 95% IC of slope 0,5000 to 1,0000, r was 0,937 (p<0,0001); creatinine with a 95% IC of slope 0,6897 to 1,3043, r was 0,915 (p<0,0001); sodium with a 95% IC of slope 1,0000 a 2,5000, r was 0,665 (p=0,0049) and potassium with a 95% IC of slope 0,4000 a 1,2000, r was 0,867 (p<0,0001).

CONCLUSIONS

Results obtained on the POCT i-STAT® analyzer are traceable and comparable to those of the COBAS® 8000 analyzer as there are neither systematic or proportional differences in any of the outcomes, so it is possible to ensure the transferability of the results between both equipment.
The correlation coefficient shows a strong positive association between both analyzers. Since the POCT i-STAT® analyzer is smaller, it is better for handling and transportation. In addition, the speed to give a result implies a reduction in the time for taking decisions and therapeutic intervention.

Point of Care testing, critical care, emergency medicine.

W192

POINT OF CARE TESTING (POCT) IN DIABETES MANAGEMENT: RURAL AND REMOTE PRIMARY CARE SETTINGS

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BACKGROUND-AIM

In recent years there has been an exponential development of POCT tests, the existing evidence shows that one of the key advantages is the availability of these devices at the "bedside", a fact that supports their use in rural and large healthcare areas with population dispersion. Using POCT technology response times are shortened, which speeds up clinical decision-making and optimizes the therapeutic approach.
The most recent recommendations of the POCT International Clinical Practice Guidelines, which mention the figure of the POCT Coordinator as key in the management and approach to the implementation of any biomarker, in a hospital or out-of-hospital area, in order to create close collaborations between the Laboratory and Physicians, providing added value to the POCT laboratory networks.
The aim of this study was to evaluate the impact of the results between POCT stations, located in rural and remote departments, and Central Laboratory according to healthcare needs in diabetes management.

METHODS

This is a retrospective observational study, performed using information stored in the Laboratory Information System (LIS) with regard to critical result notifications reported between 01.01.2021 and 01.08.2021. The devices used were professional glucometers Accu-chek Inform II by Roche. Laboratory technicians remotely verify and monitor all POCT systems with the programme Cobas IT. Two levels of quality control for glucose are performed once a day and if it is not made the department staff cannot perform any glucose test before quality control performance. Central Laboratory supervises the quality control performance and gives a technical assistance when it is required. A list of critical values for all POCT devices was prepared by the Central Laboratory in consultation with the attending Physicians. All POCT results are released via the LIS to the patient sheet and become part of their clinical history.

RESULTS

It available 28 glucometers in 4 departments of Primary Care and there are 20 glucometers all over the Hospital connected by Wi-Fi. A total of 14129 samples and 4257 quality controls were processed, all of them accepted from Central Laboratory according to Westgard rules. Furthermore, 20 patients showed results of glucose lower than 40 mg/dl and 9 patients presented results of glucose upper than 600 mg/dl. Physicians activated protocol of critical values of glucose in 37 patients. Additionally, during the period of this study, a total of 15 patients were diagnosed of Diabetes type 2 from Primary Care with POCT technology. Only 2 devices were disconnected due to technical assistance, but the new devices were available 24 hours later by technical service.

CONCLUSIONS

In conclusion, the scope of this organizational model of POCT laboratory network is the improvement of quality of patient care. This technology assists laboratory and non-laboratory staff who are working with POCT improving the management and safety patient of Diabetes. The integration between decentralized diagnostics and Central Laboratory aims at guaranteeing that analytical quality is maintained, in order to ensure results reliability and precision, and patient safety.

Point of Care testing, critical care, emergency medicine.

W193

LOW PARTIAL PRESSURE OF OXYGEN CAUSES SIGNIFICANT UNDERESTIMATION OF GLUCOSE CONCENTRATION MEASURED BY GEM 5000 BLOOD GAS ANALYZER IN WHOLE BLOOD

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BACKGROUND-AIM

Glucose determination by GEM blood gas analyzer manufactured by Instrumentation Laboratory (IL) is based on enzymatic reaction of glucose with oxygen in the presence of glucose oxidase and the electrochemical oxidation of the resulting hydrogen peroxide at the platinum electrode. It was noted that measurement of glucose on GEM 4000, was subject to significant negative bias in the presence of low partial pressure of oxygen (pO2) in whole blood sample. The aim of this study was to verify if new GEM 5000 analyzer is underestimating concentration of glucose in whole blood in the presence of low pO2.

METHODS

Whole blood samples from healthy volunteers have been collected in BD Li Heparin vacutainers and artificially depleted of oxygen after sitting at room temperature for 72 hours. Subsequently, samples have been spiked with glucose solution and serial measurement of blood gas panel was performed on GEM 5000 blood gas analyzer, with oxygen content gradually increasing. Glucose concentration in the sample was confirmed using Siemens Vista chemistry analyzer. The difference between serial glucose measurements obtained on the blood gas analyzer and confirmatory testing on Siemens Vista was plotted against the pO2 content of the whole blood sample.

RESULTS

Concentration of glucose measured by GEM 5000 was up to 29% lower than that on Siemens Vista analyzer at pO2 of 25 mmHg. The rate of glucose underestimation by GEM 5000 was decreasing as pO2 was increasing. The difference between two methods becomes clinically insignificant at pO2 greater than 30-35 mmHg, depending on the lot of GEM cartridges.

CONCLUSIONS

Whole blood glucose measurement by GEM 5000 blood gas analyzer is subject to significant negative interference in the presence of pO2 below 35 mmHg.

Point of Care testing, critical care, emergency medicine.

W194

METHOD COMPARISON OF SIEMENS HEALTHINEERS' BLOOD GAS SYSTEMS FOR COMMON ANALYTES: EPOC BLOOD ANALYSIS SYSTEM VERSUS RAPIDPOINT 500E BLOOD GAS SYSTEM

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BACKGROUND-AIM

The objective of the study was to demonstrate harmonization between the Siemens Healthineers epoc® Blood Analysis System for patient-side testing and the RAPIDPoint® 500e Blood Gas System designed for the Point-of-Care. All common analytes were evaluated to demonstrate correlation between the two systems and to minimize the opportunity for misinterpretation of test results that could adversely impact patient outcomes.

METHODS

A method comparison study was performed on the Siemens epoc Blood Analysis System (y) versus the RAPIDPoint 500e Blood Gas System (x) following the study design and analysis in the CLSI EP09c guideline. The analytes assessed included blood gas (pH, pCO_2, pO_2), electrolytes (sodium, potassium, chloride, ionized calcium) and metabolites (glucose, lactate). A minimum of 100 heparinized whole blood samples per analyte were assayed on two of each system. Correlation statistics including slope, intercept, coefficient of determination (r^2), and biases at the medical decision levels were generated.

RESULTS

Correlation statistics and regression graphs will be presented for each analyte.

CONCLUSIONS

The method comparison demonstrated harmonization between the epoc Blood Analysis System and the RAPIDPoint 500e Blood Gas System at the clinically relevant medical decision levels.

Point of Care testing, critical care, emergency medicine.

W195

EVALUATION CAPILLARY VERSUS VENOUS BLOOD FOR HBA1C ON THE LAB 001 POCT INSTRUMENT

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BACKGROUND-AIM

The aim of this study was to evaluate capillary blood versus venous blood for HbA1c on a new capillary electrophoresis point-of-care (POC) analyser (ARKRAY's The Lab 001). The results were also compared with the IFCC Certified Secondary Reference Measurement Procedure (SRMP) Tosoh G8.

METHODS

From 62 donors with HbA1c values over the clinical range, capillary and venous blood was drawn. Capillary and venous blood were analysed on 2 The Lab 001 instruments and in duplicate on the Tosoh G8.

RESULTS

Deming regression analysis between capillary and venous blood showed a slope of 1.018 (1.004 to 1.032) and an intercept of -0.6689 (-1.428 to 0.09026). Bias at 30, 48 and 75 mmol/mol was 29.9 mmol/mol (28.48 to 30.25), 48.2 mmol/mol (47.92 to 48.44) and 75.7 mmol/mol (75.23 to 76.10). Deming regression analysis between the Tosoh G8 and The Lab 001 capillary blood showed a slope of 0.9479 (0.9279 to 0.9679), an intercept of 1.248 (0.2255 to 2.271) and a bias of 29.7 (29.20 to 30.17), 46.8 (46.44 to 47.05) and 72.3 (71.73 to 72.9). Deming regression analysis between the Tosoh G8 and The Lab 001 venous blood showed a slope of 0.9647 (0.9388 to 0.9906), an intercept of 0.6017 (-0.7034 to 1.907) and a bias of 29.5 (28.96 to 30.13), 46.9 (46.58 to 47.24) and 73.0 (72.20 to 73.71).

CONCLUSIONS

Statistically there was a difference between capillary blood and venous blood analysed on The Lab 001 as the slope of 1.000 and bias at 75 mmol/mol were not within the 95% confidence intervals. However, these differences were so small that clinically seen there was no difference. Compared to the Tosoh G8 these differences were larger and statistically significant, showing a negative bias particularly for very high HbA1c values (> 70 mmol/mol). The fast measurement time, small sample volume and ease of use whilst giving clinically accurate results, makes The Lab 001 analyser a very suitable platform to be placed in a diabetes facility or other appropriate point of care locations.

Point of Care testing, critical care, emergency medicine.

W196

HEMOLYSIS DETECTION WITH THE H-10 HEMCHECK DEVICE IN WHOLE BLOOD AND PLASMA STAT SAMPLES

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BACKGROUND-AIM

Hemolysis in blood samples causes analytical errors and can induce mistaken clinical decisions. It is only detectable visually or photometrically by autoanalyzers after sample centrifugation. However, hemolysis is undetectable in whole blood (WB) in the increasingly utilized point-of-care (POC) devices.
A recently developed POC device (H-10, Hemcheck) allows for photometric detection of hemolysis (as free hemoglobin -fHb) in WB samples in syringes and tubes prior to their centrifugation. The fHb concentration is translated into a binary hemolytic index (HI).

METHODS

We aimed first, test the concordance between the HI result reported by the H-10 device in WB and an autoanalyzer (Alinity c) in plasma lithium-heparinized tubes collected from our ordinary clinical wards and second, use the H-10 for knowing the frequency and potential consequences of hemolysis in syringes obtained for blood gas analysis in our Intensive Care Unit (ICU).
Concordance between the H-10 and the Alinity was tested at the clinical lab by two technicians in 860 blood samples in lithium heparin tubes; the frequency of undetected hemolysis in syringes was analyzed in 929 samples processed in POC systems (ABL90 Flex) by the ICU personnel. We considered a fHb ≥1.0 g/L as a significant interference, and hence the cut-off configured in and used by the H-10 device.

RESULTS

In plasma, a fHb ≥1.0 g/L was detected in 3.37% of samples by the Alinity and in 3.02% by the H-10, with 4 false negatives and 1 false positive in the latter. Thus, H-10 showed 86.2% sensitivity, 99.9% specificity and 96.2% positive and 99.5% negative predictive values compared with the Alinity. As an average, HI result was obtained 44 minutes before by H-10 than by Alinity. In syringes, hemolysis was detected in 10.9% of venous and in 8.1% of arterial samples. Mean K+ was significantly higher (4.32 vs 4.06 mmol/L; $p<0.001$) and elevated pCO_2 values (≥48 mmHg) were more frequently observed in hemolyzed (47%) than in non-hemolyzed (36%) samples.

CONCLUSIONS

We conclude that the H-10 device had a similar performance as the autoanalyzer to detect hemolysis and detects a high prevalence of hemolysis in syringes. The rapid and easy detection of hemolysis by the H-10 system previous to sample centrifugation or analysis will avoid false results and erroneous clinical decisions and save wasting of sample and reagents.

Point of Care testing, critical care, emergency medicine.

W197

ANALYTICAL VALIDATION OF PROCISE DX POC ANALYSER FOR THERAPEUTIC DRUG MONITORING OF INFLIXIMAB

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BACKGROUND-AIM

Within the past 20 years the use of biologic drug infliximab (IFX) in inflammatory bowel disease (IBD) treatment has been an important step forward in improving disease course and keeping the inflammation at remission for a prolonged period of time. Therapeutic drug monitoring (TDM) of IFX using the point-of-care (POC) methods showed to be able to produce results fast enough to allow IFX dose adjustments prior to drug infusion. This study aimed to compare two POC tests, Procise IFX (Procise Dx) and Quantum Blue infliximab assay (Bühlmann Laboratories AG) used in University Hospital Osijek.

METHODS

Serum samples from 22 IBD patients on IFX maintenance therapy were collected immediately before drug infusion. Capillary blood was also collected from 6 IBD patients by finger prick using whole blood pipettes (Procise Dx). Analytical imprecision was assessed using the human serum sample obtained from a patient on IFX therapy with IFX concentration 5,4 mg/L. For method comparison a Passing Bablok regression was used and for qualitative comparison weighted kappa statistics was obtained after stratification of results by therapeutic range (<3 mg/l, ≥3 to 7 mg/L, and ≥7 mg/L).

RESULTS

Within- and between-laboratory precision of Procise IFX assay was 3,9% and 1,4%, respectively. Passing Bablok regression analysis of IFX concentration in serum sample has showed proportional deviation between POC methods (y=0.416 (-0.654 to 1.279) + 0.753 (0.648 to 0.923)x). Good comparison has been observed for capillary blood measured using Procise IFX test and serum samples measured using Quantum Blue Infliximab assay (y=-2.732 (-4.315 to 1,867) + 1.263 (0.278 to 1.566)x), although IFX concentration was lower in capillary blood. Classification of results according to therapeutic interval showed good agreement for serum samples as well as for serum and whole capillary blood measurements (κ=0.79 (0.59-0.999) and κ=0.80 (0.45-1.00), respectively).

CONCLUSIONS

Procise IFX assay showed good analytical performances. Because of proportional differences, two POC tests can't be used interchangeably for longitudinal TDM of infliximab in IBD patients. The use of whole capillary blood for TDM of IFX should be evaluated in a larger number of subjects.

Point of Care testing, critical care, emergency medicine.

W198

INTERFERENCE TESTING ON THREE POINT-OF-CARE BLOOD GAS ANALYZERS

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BACKGROUND-AIM

The purpose of this study was to evaluate several substances that potentially could influence co-oximetry and electrolyte results on point-of-care blood gas analyzers. Interference by hemolysis, lipemia, benzalkonium chloride (BzCl) and methylene blue (MB) was investigated.

METHODS

Three point-of-care blood gas analyzers were evaluated in this study: (1) GEM® Premier™ 5000 (GP5000, Werfen, Barcelona, Spain), (2) RAPIDPoint® 500e (RP500e, Siemens Healthineers, Erlangen, Germany), and (3) ABL90 Flex Plus (Radiometer Medical ApS, Brønshøj, Denmark). Heparin anticoagulated whole-blood samples from healthy volunteers were collected by venous puncture, after which they were spiked with the interfering substance of interest. Interference of hemolysis was studied by spiking a freeze-thawed whole-blood sample in fresh whole-blood samples to reach different degrees of hemolysis. Lipid interference was investigated by spiking SmofLipid® (Fresenius Kabi, Bad Homburg, Germany) in different concentrations (0.5, 1.0 and 2.0%) in whole blood. BzCl interference was tested in three different concentrations (5, 10 and 20 mg/L) in whole blood. MB was spiked in four different concentrations (5, 10, 40 and 80 mg/L) in whole blood. Samples were offered in triplicate to each blood gas analyzer for every concentration of the interfering substance in all spiking experiments, together with a blank whole-blood sample.

RESULTS

All analyzers experienced equal positive interference of hemolysis on potassium determination (up to +54%). BzCl positively interfered with the sodium measurement on ABL90 (up to +11%) and RP500e (no result), but not on the GP5000. Small interferences due to lipemia were observed on co-oximetry results on all analyzers, while only hematocrite on GP5000 was positively influenced by lipemia (up to +17%). MB influenced co-oximetry results equally on all three analyzers and sodium results on ABL90 (up to +13%) and RP500e (up to +9%).

CONCLUSIONS

All blood gas analyzers are influenced to a greater or lesser extent by the tested interfering substances. Each laboratory should know for their own blood gas analyzer which interfering substances are important and to which extent, and should inform their clinicians about this.

Point of Care testing, critical care, emergency medicine.

W199

DETECTION OF SEVERE IN VIVO HEMOLYSIS DURING EXTRACORPOREAL MEMBRANE OXYGENATION SUPPORT IN COVID-19 PATIENTS. RELATION OF PLASMA FREE HEMOGLOBIN WITH ENDOGENOUS CARBON MONOXIDE PRODUCTION.

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BACKGROUND-AIM

In the COVID-19 pandemic, the Extracorporeal Membrane Oxygenation (ECMO) treatment has proved its usefulness in patients with acute lung injury. In vivo hemolysis (ivH) is one of its complications, characterised by peaks of plasma free hemoglobin (fHb). Moreover, an increase in carboxyhemoglobin (COHb) has been observed in several cases due to Hb metabolism by heme-oxygenase that releases carbon monoxide. The aim of this study is to evaluate the incidence of ivH events and their relation to COHb in COVID-19 patients with ECMO treatment.

METHODS

From March 2020 to June 2021, 32 COVID-19 patients received ECMO in our Intensive Care Unit, with an average duration of 4 weeks. Daily analytical monitoring was carried out including arterial blood gas test with cooximetry (ABL90 FLEX, Radiometer) and biochemical parameters (Atellica Solution, Siemens Healthineers), incorporating the estimation of fHb using quantitative hemolysis index (HI) (spectrophotometric measurement). Significant ivH was considered with fHb>100 mg/dL, whereas severe ivH required fHb>500 mg/dL.
Daily maximum value of HI and COHb was selected to analyse the results, obtaining a total of 825 pairs of results. These were grouped by weeks and the weekly mean was calculated for both to evaluate their correlation.

RESULTS

One fourth of the patients presented at least one peak of significant ivH, out of which 62,5% died. Severe ivH was detected in 4 patients (12,5%), associating a 50% mortality rate. Half of the hemolytic events required ECMO membrane or circuit exchange.
The COHb mean value from all the results was significantly higher when compared to the upper reference limit of the normal range in non-smokers (3,1% vs 1,5%, p<0,01). COHb>4% was detected in all the cases of severe ivH. The highest peak of fHb was 1237mg/dL with a COHb of 7,1%.
A positive correlation was observed between the weekly means of HI and COHb (Pearson coefficient r=0,47; p<0,01).

CONCLUSIONS

During ECMO treatment, episodes of ivH are very frequent, in which the increase of fHb is positively correlated with COHb. Moreover, maintained high COHb levels in these patients imply higher toxicity and oxygen transport impairment. Thus, detection of ivH events using HI and Point-of-Care COHb can aid in better monitoring and management of ECMO-related hemolysis.

Point of Care testing, critical care, emergency medicine.

W200

THE TRAINING STRATEGY IN POCT GOVERNANCE

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BACKGROUND-AIM

The diffusion of SARS-CoV-2 pointed out several problems in the Italian health system, highlighting the need to improve new fields, like for example: the implementation of the POCT's governance in the public and private Hospital departments.
Nowadays, the development of rapid tests is constantly increasing, but on the other hand there is an uncontrolled commercialization of unsafe products. So, the diffusion of these tests, without an appropriate management, could be economical expensive but also really dangerous in the Hospital departments.

METHODS

It's really necessary to develop an informatic network in order to improve the governance of the POCT. In fact, in this study we decided to create several levels of trainings, in order to answer to the different problems in our Hospital and University Health System which includes a wide area from the mountains to the sea.

RESULTS

In details we developed:
1. POCT lab technician Specialist Training: this pool of lab techician will manage in the future the administration and management of the POCT'S instruments, they will be concerned with the execution of the Internal/External QCs;
2. Lab technician Training: in this training the previous Specialists will introduce to the lab technicians the innovation of the POCT'S government and instrument, just to let them know the advantages and application of POCT in the critical areas;
3. Users training: this training it's addressed to the other health professional (e.g nurses) in Hospital to let them know how to use the POCT instruments, but also the right way to execute the different types of sample in the medical fields (e.g. pathology, microbiology).
4. Creation of a University First level Master: in this Master the aim is to improve knowledges and skills of the POCT applied to clinical pathology, microbiology/virology through a new cross-curricular formative course addressed to health professional, such as pharmacist, clinical engineer and obviously lab technicians.

CONCLUSIONS

To conclude, this study highlighted the need to introduce a new training approach, by using the new technological platforms (e.g videoconferences, apps), especially after the diffusion of SARS-CoV-2, in order to reduce the face-to-face contacts.

Point of Care testing, critical care, emergency medicine.

W201

POINT-OF-CARE TESTING IN THE EMERGENCY DEPARTMENT: IMPROVING PATIENTS' OUTCOMES

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BACKGROUND-AIM

Overcrowding in the Emergency Department (ED) is a global health problem. It's necessary to find new strategies to reduce length of stay (LOS) in this area and thus optimize workflows and use of resources. Point of Care Testing (POCT) can be a very useful tool to achieve these objectives, since, as has been observed in different studies, laboratory turnaround time (LTAT) has a substantial influence on the total LOS in ED. In this study, we aim to demonstrate that the use of POCT devices reduces total ED LOS in patients with intermediate priority and frequent reasons for consultation.

METHODS

We conducted a prospective cluster-randomized study to assess the impact of POCT in patients' outcomes. The study was carried out in February 2020 in the Virgen Macarena University Hospital (Seville, Spain). 208 Emergency Severity Index 3 (ESI3) patients (age older than 16) with the most common pathologies seen at this priority level in the ED of our hospital (respiratory, genitourinary and abdominal) and with the need for analytical tests included in a simple analytical profile (haemogram, creatinine, urea, sodium, potassium, urianalysis, blood gas and/or International Normalized Ratio) were studied in two different groups, interventional arm (laboratory analyses performed on POCT analyzers implemented in ED; 101 patients) or control arm (central laboratory; 107 patients). Statistically, distributions were examined using the Shapiro-Wilk test and as data had non-normal distributions, the Mann-Whitney test was applied to assess whether there were statistically significant differences ($p < 0.05$) in the ED LOS and LTAT between both groups.

RESULTS

Results are expressed in median and interquartile range:
Interventional arm
LOS: 155.00 minutes [114.00-223.00]
LTAT: 22.65 minutes [16.82-30.27]
Control arm
LOS: 239.00 minutes [198.00-300.00]
LTAT: 94.18 minutes [72.27-121.33]
pLOS: 0.001
pLTAT: 0.001

CONCLUSIONS

We found a significant reduction in LTAT of 71.53 minutes and in LOS of 84.00 minutes. So, although further studies are necessary, we think that implementation of POCT devices in the ED for ESI3 patients' care can be a very useful tool to reduce LOS and, consequently, optimize resources, while improving workflows and management of all patients in this area.

Point of Care testing, critical care, emergency medicine.

W202

COMPARATIVE STUDY OF HAEMOGLOBIN MEASUREMENT BETWEEN TWO POINT-OF-CARE TESTING DEVICES

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BACKGROUND-AIM

The use of Point-of-Care Testing (POCT) devices has become one of the most interesting tools in the Emergency Department (ED). To ensure the analytical quality of the results of a POCT device that is intended to be implemented and its interchangeability with the reference analyzer, a method comparison study must be carried out between both as part of the evaluation.
In this study, we aim to verify the interchangeability of two analysers for the measurement of haemoglobin, which is a basic parameter handled in ED.

METHODS

A study was carried out to compare haemoglobin measurement methods in the Virgen Macarena University Hospital (Seville, Spain) between ABL90 FLEX PLUS (Radiometer; BrØnshØj, Denmark) and pocH-100i (Sysmex; Norderstedt, Germany) analysers, the latter being the reference analyser in the POCT setting of ED of our hospital.
Haemoglobin was determined in parallel in a total of 110 whole blood samples from 55 patients attended in ED of our hospital. Samples were collected in a venous blood gas syringe if processed in ABL90 FLEX PLUS or in a haemogram tube if processed in pocH-100i.
The analysis was carried out with the statistical packages MedCalc and SPSS Statistics 25, comparing the results by Passing-Bablok regression and determining Spearman rank and intraclass correlation coefficients.

RESULTS

The results and their 95% confidence interval (95%CI) obtained were:
Spearman rank correlation coefficient: 0.953 (0.921-0.973)
Passing-Bablok
Slope: 1.0800 (0.9368-1.1286)
Intercept: -0.5521 [(-0.6414)-0.6452]
Intraclass correlation coefficient (R): 0.932 [(-0.061)-0.984]
Spearman rank correlation coefficient was ~1 ($p<0.01$) and there were no significant deviations from linearity (pCusum <0.05).
Passing-Bablok regression showed no systematic differences of constant type between the two analysers (95%CI of the intercept contains the value 0) or of proportional type (95%CI of the slope contains the value 1).
R was ~1, but with low precision (95%CI).

CONCLUSIONS

A strong and positive correlation is observed according to Spearman rank correlation coefficient. Passing-Bablok regression indicates that methods are comparable for haemoglobin measurement and according to the intraclass correlation coefficient, the agreement is very good (R> 0.90), but there is very low precision.

Point of Care testing, critical care, emergency medicine.

W203

USEFULNESS OF CARBOXYHEMOGLOBINEMIA VALUE IN THE DEVELOPMENT OF COVID-19 PNEUMONIA

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BACKGROUND-AIM

Carboxyhemoglobin (COHb) is generated as a result of CO binding to the haemoglobin molecule, decreasing its oxygen-carrying capacity. Its value is increased in cases of intoxication, sepsis, haemolysis and severe inflammatory conditions. In the context of the current COVID-19 pandemic, the COHb value can be obtained relatively easily and inexpensively from patient blood gases. Our study aims to find out whether its elevation is proportional to the severity of the illness, assessing this according to the type of admission required. In addition we are going to evaluate if there is a correlation between the peak reached and the duration of the admission.

METHODS

An analysis was made of the COHb results obtained in our centre using the Radiometer ABL800 FLEX analyser in 140 patients with SARS-Cov2 infection. The duration and type of admission were recorded from the clinical history: Non-admitted (NA), ICU and ward. In patients with multiple determinations, the highest result during the course of infection was selected. A Levene's test was performed (p=0.000), so the analysis was continued with the Kruskal-Wallis test. We used the spearman's Rho to test the relationship between the COHb and days of admission.

RESULTS

COHb values follow a normal distribution, finding significance with the Kruskal-Wallis test for non-admitted (x#=0.89 ± 0.35), ward-admitted (x#=1.47± 0.63) and ICU-admitted (x#= 1.92 ± 0.96). Pairwise comparison showed a p=0.007 for NA-plant, p= 0.000 for NA-ICU and p= 0.023 for plant-ICU.
Spearman's test showed a correlation between days of admission and COHb values (p= 0.000). With a ρ of 0.493.

CONCLUSIONS

COHb is a test available in most blood gas analysers and its determination by spectrophotometry does not usually imply an additional cost when performing the patient's blood gas analysis. Our group has found significant differences in the values of this parameter depending on the severity of the infection. There is also a correlation with the duration of hospitalisation, although this does not show a good ρ. Based on these results, the COHb value provides an added value to the determination of blood gases in COVID-19 patients that can help the clinician in assessing the severity of the condition. Further studies on the importance of COHb are needed to understand the role it plays in the development of infection.

Point of Care testing, critical care, emergency medicine.

W204

A COMPARISON STUDY BETWEEN ROCHE ACCU-CHEK AND ROCHE COBAS 8000.

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BACKGROUND-AIM

The provision of health care has been profoundly changing in recent years, including through the Point Of Care Testing (POCT), to respond effectively to a patient-centred concept of care. Various esteemed organisations, both national and international, have defined guidelines for the correct management of POCT, but continuous monitoring of POCT data remains essential to ensure the quality and reliability of the data obtained. This work aimed to verify the comparability of glucose values between those obtained in the analysis laboratory with Roche Cobas 8000 and those obtained with the POCT device Roche Glucometer Accu-Chek® Inform II system.

METHODS

A total of 685 laboratory glucose samples obtained with Cobas 8000 modular analyzer and 708 glucose samples obtained with Accu-Chek Glucometer between January to March 2019, 2020 and 2021 were collected. The agreement between glucose concentration (mmol/L) acquired on the same day and close of the same hour, with Roche Cobas 8000 and with Accu-Chek has been evaluated with the Bland-Altman analysis and Passing-Bablok regression analysis. In addition, data were analysed based on their distribution into concentration ranges.

RESULTS

The Bland-Altman analysis highlights that the Bias% was not significant in all the three years taken into account (2019: 0.813%, 95%CI: -0.504 to 2.130; 2020: 0.561%, 95%CI: -1.899 to 3.022; 2021: 0.569%, 95%CI: -0.611 to 1.749). However, a constant and proportional error was found through the years with the Passing-Bablok regression analysis, with respectively the following regression equations: 2019 (y=0.309 + 0.951 x), 2020 (y=0.622 + 0.899 x) and 2021 (y=0.426 + 0.941 x). Analyzing the glucose results on the basis of concentration ranges, a consensus between results is found, for example, for glucose concentration included between 6.99 mmol/L and 11.1 mmol/L: 46.56% in 2019, 37.7% in 2020 and 39.15% in 2021 of the laboratory results; 45.1% in 2019, 38.5% in 2020, and 39.5% in 2021, for POCT results.

CONCLUSIONS

The methods analyzed appear to be comparable, with no significant differences in Bias% through the years. However, the Passing-Bablok regression analysis reveals a constant and proportional error between laboratory results and POCT results. These results underline the importance of continuous and dedicated monitoring of POCT devices, in all analytical phases, to managing errors and the reliability of POCT results.

Point of Care testing, critical care, emergency medicine.

W205

MULTICENTRE EVALUATION OF A NEW STRIP-BASED BLOOD GLUCOSE SYSTEM (COBAS® PULSE, ROCHE DIAGNOSTICS) FOR NEAR-PATIENT TESTING IN CRITICAL AND NON-CRITICAL CARE SETTINGS

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BACKGROUND-AIM

cobas® pulse is a new near-patient blood glucose testing system for use in professional healthcare environments. This multicentre study aimed to evaluate the performance of this system using arterial (A), venous (V), capillary (Cap) and neonatal heel stick (HS) whole blood samples.

METHODS

The performance of the cobas® pulse system was compared with that of a plasma-based hexokinase reference method on the Roche cobas® 6000 system (GLUC3) and to that of Nova StatStrip® (Nova Biomedical). Accuracy was assessed by CLSI POCT12-A3 criteria: ≥95% of results within ±12 mg/dL (±0.67 mmol/L) of the reference method at <100 mg/dL (5.55 mmol/L) and ±12.5% of the reference method at ≥100 mg/dL (12/12.5 criteria); and ≤2% of results exceeding ±15 mg/dL (±0.83 mmol/L) at <75 mg/dL (4.2 mmol/L) and ±20.0% of the reference method at ≥75 mg/dL (15/20 criteria).

RESULTS

Overall, 1142 samples (n=316 A, n=706 V, n=120 HS) were collected from 975 adult, paediatric and neonatal patients in critical and non-critical care settings at 12 US sites. Cap measurements (n=702) were performed on samples from 117 non-critically ill adult subjects at one US site in a separate study. For the cobas® pulse system, 98.7%, 97.9% and 95.0% of A, V and HS results, respectively, met CLSI 12/12.5 criteria at the 100 mg/dL breakpoint and 0.6%, 1.1% and 0% exceeded the CLSI 15/20 cut-off at the 75 mg/dL breakpoint (vs the reference method), fulfilling the criteria. By contrast, for StatStrip®, 87.7%, 92.5% and 92.5% of A, V and HS results, respectively, met CLSI 12/12.5 cut-off at the 100 mg/dL breakpoint, which is below the required 95% threshold, and 0.9%, 0.9% and 1.7% exceeded the CLSI 15/20 cut-off at the 75 mg/dL breakpoint, fulfilling the second criteria. For Cap results, the cobas® pulse system met CLSI criteria at both breakpoints (99.4% were within 12/12.5 criteria at 100 mg/dL; 0.3% exceeded 15/20 criteria at 75 mg/dL), whereas StatStrip® met CLSI 15/20 criteria (0.9% exceeded limits), but not 12/12.5 criteria (94.0% were within limits).

CONCLUSIONS

The cobas® pulse system met CLSI POCT12-A3 accuracy criteria for all A, V, Cap and HS samples, and the performance exceeded that of StatStrip®.

Point of Care testing, critical care, emergency medicine.

W206

REPEATING THE CRITICAL VALUES OF COVID-19 PATIENTS ON POCT ANALYZERS EXPEDITES PHYSICIAN REPORTING

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BACKGROUND-AIM

The monitoring of COVID-19 patients has become a global challenge in many clinical laboratories, and there is an increasing incidence of critical values in laboratory results as compared to other patients in intensive care units. Critical values represent those laboratory results that indicate a life-threatening condition of the patient, and it is common practice in many laboratories to repeat critical results before reporting the value to the physician. Such results should be reported within 30 minutes of confirmation, and waiting for a re-measurement may delay reporting.

METHODS

Since it was noticed that COVID-19 patients had the highest percentage of critical values for potassium (K), sodium (Na), chloride (Cl) glucose (Glc), and lactate (Lac), the aim of this summary was to compare results obtained primarily on a biochemical (Beckman Coulter DxC 700 AU) and repeatedly on a less time-consuming POCT (Siemens RapidLab 1265) analyzer. For this purpose, 40 serum samples were used for the determination of K, Na, Cl and Glc and 10 plasma samples for the determination of Lac. Statistical comparison of the results was performed using Passing-Bablock (for electrolytes and Glc) and Deming regression analysis (for Lac).

RESULTS

Analysis of the results revealed neither proportional, nor constant error for K [y = -0.15 (-0.29-0.02) + 1.03 (0.99-1.07) x], Na [y = -4.08 (-15.47-5.19) + 1.03 (0.96-1.11) x], Cl [y = 5.00 (-2.96-5.00) + 1.00 (1.00-1.08) x], and Glc [y = -0.10 (-0.24-0.04) + 1.00 (0.98-1.02) x] determination on a biochemical analyzer as compared to the POCT instrument. Also, no proportional error [y = 0.17 (0.07-0.27) + 1.06 (0.99-1.13) x] was found in the determination of Lac on a biochemical (CV = 1.79%) vs. POCT (CV = 4.37%) analyzer. Although a constant error was observed, it had no clinical significance (mean BIAS = -17.4%; calculated RCV = +/-75.9%)

CONCLUSIONS

In conclusion, repeating the critical values of K, Na, Cl, Glc, and Lac on the POCT rather than on the biochemical analyzer is justified because the analytical process for determination on the POCT analyzer takes much less time and the critical results are reported to the physician much earlier.

Point of Care testing, critical care, emergency medicine.

W207

AN INVESTIGATION TO ASSESS HOOK EFFECTS IN PREGNANCY TESTING KITS AND DEVICES

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BACKGROUND-AIM

Introduction
Pregnancy testing kits or devices are used routinely in the UK both by health care professionals in clinical settings and by patients for home use. Research showed that the stated hook cut off varied greatly between kits / devices.
Aims
To assess if there are any hook effects seen for Pregnancy Testing kits and devices (readers) registered on the Weqas Urine Pregnancy Testing EQA Programme (Proficiency testing).
To assess if the observed hook effects match the manufacturers' claims.
To assess performance of Pregnancy Testing kits and devices at very high hCG concentrations.

METHODS

Urine was collected from healthy, non-pregnant female volunteers, filtered to 0.2µm and Gentamycin added to maintain sterility. Intact hCG was added to the urine to a concentration of 700,000 IU/L. The pool was sent out to 180 participants, selected to ensure similar numbers of results returned for each kit / device registered.
Pools were also distributed at concentrations of 50 IU/L and 1000 IU/L, plus a negative sample.

RESULTS

Overall % positive rates for each pool were 1.3% for the negative pool, 78.6% for the pool at 50 IU/L, 98.7% for the pool at 1000 IU/L and 90.4% for the pool at 700,000 IU/L. Three kits had significantly lower % positive rates for the 700,000 IU/L pool than the pool at 1000 IU/L.
Of the 157 results returned for the pool at 700,000 IU/L:
11 sites submitted a Negative result, across 6 kits / devices (7% of results).
4 sites submitted a weak positive result across 3 kits (2.5% of results).
142 sites submitted a positive result (90% of results).
Only 1 reader submitted a negative result for the pool at 700,000 IU/L.

CONCLUSIONS

This study identified that hook effects were present in the kits / devices evaluated. Of the two kits and one device that showed significantly lower % positive rates for the pool at 700,000 IU/L, one kit insert did state a hook cut off of <500,000 IU/L. Data was not readily available from the other two manufacturers.
The results demonstrate that it is imperative that users are aware of the limitations of the kits in use and that they can easily identify hook cut off limits.

Point of Care testing, critical care, emergency medicine.

W208

EVALUATION OF THE RELIABILITY OF THE HEMATOLOGICAL DATA OF AN INSTRUMENT IN POCT

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BACKGROUND-AIM

The widespread use of Point of Care Testing has allowed us to obtain many clinical / therapeutic needs in an emergency regime, to provide accurate and rapidly available results. Decentralized diagnostics uses PoCT technology, currently represents one of the most suitable organizational solutions to support those situations in which it is necessary to have a rapid laboratory diagnostic result, but validated and correlated and correlated with the data provided by the Central Laboratory (Hub) , in compliance with the required quality standards. This need is evident above all in the Emergency / Urgency departments, such as the First Aid, intensive therapy and / or oncological departments where clinical evaluations on patients must be rapid and decisive, according to a precise classification of the patient and an adequate therapeutic course.

METHODS

In our study we preliminarily assessed the reliability of the main haematological parameters and of the leukocyte formula of the PoCT ICON5 (A.DeMori) by analyzing 52 patients (26 F 26 M) chosen from the samples of the haematological routine of the S Chiara (TN) laboratory - Clinical Multizonal Pathology Unit, aged 1-86 years, who come from different parts and with different pathologies. To evaluate the feasibility of the project, we synchronously evaluated the new generation ICON 5 automatic hematology analyzer, capable of determining the haematological parameters with differentiation of the leukocyte formula in 5 populations and the instrument used in routine XN10 (Dasit-Sysmex) user in our chain routine. The statistical analysis was carried out using the Bland Altman and Passing Babblok regression tests (Analyze.it).

RESULTS

From the still preliminary tests carried out to date, it is possible to deduce a good search between the two instruments, with a significant percentage Bias only for the parameter Hb. By way of example, we report four graphs of the statistical processing of some parameters of the blood count and of the leukocyte formula.

CONCLUSIONS

We therefore hope that this tool can be of support for the emergencies above. A quick and reliable tool to support the need for a quick and precise clinical classification, probably to be completed also with the evaluation by the laboratory

Point of Care testing, critical care, emergency medicine.

W209

ASSESSING THE ACTUAL ACCURACY OF BLOOD STATSTRIP (NOVA) GLUCOSE METERS.

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BACKGROUND-AIM

The StatStrip Glucometer (Nova Biomedical,USA) are cleared by US FDA and Health Canada for use with all patients, including critically ill. They have proven to be an accurate blood glucometer, but every laboratory needs to ensure that the glucometer used in the hospital is and stays fit for purpose. In hospitalized patients, decision are often based on measurements with these glucometers, and predefined and strict accuracy criteria are used. To follow the performance of our glucometers we continuously extract data of our laboratory information system (LIS) to evaluate the actual accuracy of our Statstrip glucose meters compared to our gold-standard, the Cobas (Roche) core lab analysers.

METHODS

Data from 1608 fasting patients having concurrent capillary and venous blood glucose measurements are compared. The capillary samples are analyzed immediately with the Statstrip glucometer (Nova biomedical, USA) by trained nurses. The venous samples are taken by the same nurses. The venous samples follow the routine pre-analytical process to be afterwards analyzed on the core-lab Cobas (Roche) analyzers. The bias between Statstrip and Cobas is calculated. Biaises were interpreted using the predefined accuracy Clinical and Laboratory Standards Institute (CLSI) POCT12-A3 criteria ((1) 95% of samples should be within ±12.5 mg/dL for reference glucose values under 100.0 mg/dL and within ±12.5% for reference glucose values over 100.0 mg/dL and 2) 98% of samples should be within ± 15.0 mg/dL for reference glucose values under 75.0 mg/dL or wihtin ± 20% for the reference glucose for values over 75.0 mg/dL)).

RESULTS

The mean bias calculated (-1.7 mg/dL for values under 100 mg/dL and -3.1% for values over 100mg/dL) met the CLSI POCT12-A3 criteria but more than 5% of the samples did not meet the criteria ([-14.1 mg/dL- 10.7 mg/dL] 95% Confidence interval for values under 100 mg/dL and [-24.9% - 18.7%] 95% confidence interval for values over 100mg/dL).

CONCLUSIONS

The Statstrip glucometer does not meet the POCT12-A3 criteria in our routine setting. As the mean bias lies well within the predefined accuracy criteria but too many deviations are seen, causes, going from the preanalytical to the postanalytical phase, needed to be identified to explain these sporadic inaccurate test results.

Point of Care testing, critical care, emergency medicine.

W210

USEFULNESS OF MULTIPLEX PCR IN THE RAPID DIAGNOSIS OF MENINGITIS/ENCEPHALITIS IN THE EMERGENCY LABORATORY

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BACKGROUND-AIM

Early recognition of causative pathogens is critical for the appropriate management of and improved outcomes. The BioFire® FilmArray® Meningitis/Encephalitis Panel (BioFire® ME Panel, BioFire Diagnostics) is a multiplex PCR assay that allows the rapid detection of 14 pathogens, including bacteria (n = 6), viruses (n = 7), and fungi (n = 1), from cerebrospinal fluid (CSF).
The objective was to evaluate the usefulness of a multiplex PCR for diagnosis of meningoencephalitis in an emergency laboratory and correlate this technique with usual parameters of cellularity, proteins and glucose ratio in CSF.

METHODS

In this retrospective study, we used the BioFire® ME Panel in 96 subjects who presented to the emergency department with symptoms of M/E in our hospital from July 20, 2018, to October 20, 2021. The results were compared to conventional culture, and various laboratory findings including the cell count and biochemistry.

RESULTS

From 96 processed CSF samples, 16 (16,67%) were positive including: four (25%) Varicella zoster virus, five (31,25%) Enterovirus, three (18,75%) Streptococcus agalactiae, one (6,25%) Human herpes virus 6, one (6,25%) Listeria monocytogenes, one (6,25%) Streptococcus pneumoniae, and one (6,25%) Cryptococcus neoformans/gatii.
The median age of patients was 41 (IQR: 69,25) years, 58 (60,42%) were males. Bacterial meningitis cases were confirmed with culture except those of S. agalactiae which received antibiotics before analysis.
In positive samples from adult patients, leukocytes median was 510 (IQR: 3580), protein was 268 (IQR: 422) and CSF / blood glucose ratio was 0.36 (IQR: 0,39). Considering pediatric patients, leukocytes median was 89 (IQR: 141,5), protein was 40,5 (IQR: 18,5) and CSF / blood glucose ratio was 0,61 (IQR: 0,29).
The mean response time from sample extraction was 120 minutes.
In four of 16 cases the antibiotic treatment was suspended (2 of viral etiology) or adjusted (2 of bacterial etiology).

CONCLUSIONS

The BioFire® ME Panel offers a rapid, syndrome-based approach for the detection of select meningitis and encephalitis pathogens helping to establish adequate rapid treatment and avoiding the use of antibiotics in cases of viral etiology. Its low complexity in handling the sample makes it affordable for implantation in any emergency laboratory.

Point of Care testing, critical care, emergency medicine.

W211

CARE IMPROVEMENT THROUGH THE REMODELING OF THE POINT OF CARE TESTING (POCT) NETWORK OF GASOMETERS

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BACKGROUND-AIM

In our hospital, the POCT gasometers (Radiometer, Madrid, Spain) do not have a connection to the laboratory information system (LIS), so all this information was not only lost in absolute terms, but also in relative terms, it was not possible access patient information retroactively if necessary. Therefore, it became a priority to improve the management of POCT gasometers data as well as to review the available instruments. Our objective is to improve the connection of POCT gasometers with the LIS so that the information about gasometry is linked to the patient's medical history and is available at any time.

METHODS

We review the configuration of the POCT gasometer network, which consists of 7 devices. Through a simple remote management program we check the operation status and obtain simple statistics. Given that the software does not allow the transmission of patient data, we request a new middelware capable of transmitting these data in real time, for which we need: authorization from the Management and the IT service to access the patient's medical history, installation of the new middleware by Radiometer, planning of the project schedule as well as the circuit of each gasometry and testing with fictitious patients to verify the data circuit.

RESULTS

We managed to install and configure the new middelware to create a network of POCT devices in different locations in the hospital that have been linked to a clinical service. This aspect is important when defining the minimum set of data that configure the demographics of the requests in the LIS. Gasometries are identified with the patient's clinical history number, the gasometer connects with the digital history program and returns the patient's demographics. Finally, a request is registered in the LIS in which the results are downloaded.

CONCLUSIONS

After all the measures adopted, we managed to improve the POCT gasometer network as well as the quality of care and patient safety. The loss of patient information has been minimized, as well as the possibility of an error in data processing. In addition, the results of the gasometries are saved in the patient's clinical history, so they are available at any time for consultation. Finally, digitizing data makes it possible to dispense with or reduce the use of paper.

Point of Care testing, critical care, emergency medicine.

W212

DIAGNOSTIC ACCURACY OF ICTERIC INDEX TO UNMASK EMERGENCY DEPARTMENT PATIENTS WITH HYPERBILIRUBINEMIA VALUES

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BACKGROUND-AIM

The icteric index is used to avoid total bilirubin measurement. The utility to unmask patients with high total bilirubin values, has not yet been evaluated. The objective was twofold. To perform a diagnostic accuracy study for the icteric index to detect patients with high total bilirubin values, and to show an intervention to detect high total bilirubin values in emergency department patients without total bilirubin request.

METHODS

From June 1st to December 31st, 2021, we retrospectively reviewed all the requested total bilirubin values and their corresponding icteric index results and performed a diagnostic accuracy study to determine the optimal cut-off value of icteric index to discriminate high total bilirubin values, considered as the gold standard, and positive when values were above 3 mg/dL, value agreed with emergency department clinicians.
An intervention was designed and established from November 1st, 2021, to January 31st 2022. The Laboratory Information System would automatically register the total bilirubin when icteric index over the calculated cutoff, when total bilirubin was not requested and either, in the previous 48 hours. The medical record of every identified patient was reviewed.

RESULTS

The first study included total bilirubin and icteric index results of 1427 patients. The diagnostic accuracy study suggested 3.2 as the optimal icteric index threshold to identify total bilirubin values above 3 mg/dL.
Seventy patients had an icteric index value >3.2, and consequently total bilirubin was measured. The medical record review showed pathology compatible with hyperbilirubinemia in 44. In 26 was a new finding, corresponding 12 to patients with a median age of 77,6 years and chronic multiple pathologies. In the remaining 14, with a median age of 63,2 years, there was not previous liver history, although 4 (5.71%) had a previous hypertransaminemia. Only in two (2.86%) there was a clinician response to the high total bilirubin results by writing a note in the clinical record, and were classified as Idiopathic hyperbilirubinemia.

CONCLUSIONS

The study supports the use of icteric index to identify patients with unrequested total bilirubin high values. More studies are necessary to recognize its utility in clinical practice.