

Point-of-Care Coagulation Testing for Trauma Patients in a Military Setting: A Prospective Study

Jean Cotte, MD; Erwan D'Aanda, MD; Vincent Chauvin, MD;
Eric Kaiser, PhD; Eric Meaudre, PhD

ABSTRACT

Background and Objective: Almost 50% of military trauma patients who need transfusions develop a coagulopathy. Immediately treating this coagulopathy improves the patient's prognosis. Field military hospitals often lack laboratory devices needed to diagnose a clinically significant coagulopathy and have limited blood product resources such as plasma. Point-of-care (POC) devices for the measurement of prothrombin time (PT) are available and have been tested in a variety of situations, including hemorrhagic surgery. The authors compared a POC device, the Coaguchek XS Pro (F. Hoffmann-La Roche Ltd., Basel, Switzerland), with laboratory measures for determining the PT in military trauma patients in a field hospital. **Methods:** This single-center prospective study was designed to compare POC coagulation monitoring with traditional laboratory testing. It was conducted at the French military hospital located at Kabul International Airport. All patients with trauma injuries resulting from war operations were included. A blood sample was drawn immediately on admission. PT was determined both in the laboratory and with use of the Coaguchek XS pro. **Results:** Forty patients with war trauma were enrolled during a 3-month period. The authors recorded 69 measurements. The two methods were correlated with a correlation coefficient of 0.78 ($p < .001$). The Bland-Altman plot showed a mean difference of 5.8% (95% confidence interval -14.9% to 26.6%). Using a PT cutoff of 60%, POC had a sensitivity of 77.1% and a specificity of 94.1%. Results from POC PT measurement were available within a mean of 25.8 minutes before laboratory measures. **Conclusions:** The Coaguchek XS Pro device can be used successfully in an austere environment without compromising its performance.

KEYWORDS: *point-of-care, coagulation, prothrombin time, military trauma*

Introduction

Severe trauma is a common occurrence in military operations, and trauma patients are at risk of developing

a multifactorial coagulopathy.¹ Almost 50% of military trauma patients who need transfusions develop a coagulopathy.² Mortality is increased 6-fold in combat casualties with a coagulopathy.² On the other hand, immediately treating this coagulopathy improves the patient's prognosis.³ Field military hospitals often lack laboratory devices needed to diagnose a clinically significant coagulopathy and have limited blood product resources such as plasma. Traditional laboratory measures are so slow to acquire that the results are outdated when they are available. Point-of-care (POC) devices for the measurement of prothrombin time (PT) are available and have been tested in a variety of situations, including hemorrhagic surgery.^{4,5} These new devices might be the answer to the drawbacks of laboratory testing in military operations, but they have never been tested in this setting. In this study, the authors compared a POC device, the Coaguchek XS Pro (F. Hoffmann-La Roche Ltd., http://www.roche.com/about_roche/roche_worldwide.htm?mz_id=2300#/country:CH/), with laboratory measures for determining the PT in military trauma patients in a field hospital.

Patients and Methods

This single-center prospective study was designed to compare POC coagulation monitoring with traditional laboratory testing. It was conducted at the French military hospital located at Kabul International Airport from October 2011 to January 2012. Oral consent was obtained from all patients. This study was approved by the ethics committee of Sainte Anne Military Teaching Hospital (Toulon, France).

All trauma patients admitted to the KAIA hospital were included. Exclusion criteria were preexisting nontraumatic coagulopathy and any technical issue that made it impossible to obtain and treat blood samples with use of the two evaluated methods.

Every patient was admitted to the emergency department. A venous or an arterial blood sample was drawn

immediately on admission for routine laboratory testing. A sample of 5 ml was collected in a vacuum tube containing sodium citrate and immediately sent to the laboratory. The blood was processed according to the routine procedures of the laboratory. The PT was determined using a Start 4[®] analyzer (Diagnostica Stago, <http://www.stago.com/>). The PT reagent was neoplastin CI (Diagnostica Stago), and the analyzer was calibrated daily.

The same blood sample was used for POC PT measurement using a Coaguchek XS Pro device. Measurements were made by one of the two hospital anesthesiologists. These values were not used for clinical decisions. Some patients who had significant clinical evolution underwent several paired measures according to the same protocol.

Time differences between availability of laboratory and POC measurements, demographic data, characteristics of the trauma, full coagulation testing, and the outcome of the patient were recorded.

POC and laboratory results were compared with use of a Spearman's rank correlation test. A Bland-Altman plot was showed the agreement of the two methods. A receiver operating characteristic curve was drawn with several cutoffs of POC PT to obtain the best cutoff for PT of greater than 50%. Statistical analyses were conducted using Medcalc[®] 11.4 statistical software (<http://www.medcalc.org/>).

Results

A total of 40 patients with war trauma were enrolled over a 3-month period. No patients were excluded. The authors recorded 69 measurements for the 40 patients (Figure 1). The median age of the patients was 22.5 years (range, 6–70 years), 95% were men, and 85% were of Afghan nationality. Sixteen patients were civilians, and the remainder were Soldiers or policemen. A majority of lesions were caused by war operations (66.6%), and the

remaining were caused by road accidents (20%) and various other causes (13.4%). Most of the trauma injuries were open (69.2%), 46.2% were caused by bullets, and 10.3% were caused by improvised explosive devices or mines. The mean International Severity Score (ISS) was 13.7 (range, 1–41). Vasopressor support was required for 10% of patients, and the mean infusion volume during initial resuscitation was 466 ml (range 0–1500 ml). Eight patients (20%) had packed red blood cell (PRBC) transfusions with a median volume of 2 units. Thirteen (32.5%) required French lyophilized plasma and two (5%) required whole blood transfusions. Thirty-three patients had surgery (82.5%) and 17 (42.5%) remained on mechanical ventilation for a median of 1 day (range 1–2 days). The physician in charge evaluated 10.2% of patients as being in critical condition at initial presentation. No patient died during his or her hospital stay.

Laboratory PT showed a median of 59.7% (range 32%–95.6%), and POC PT showed a median of 64% (range 30%–101%). A clear correlation between the two methods resulted with a correlation coefficient of 0.78 ($p < .001$) for the PT in percentage and 0.79 ($p < .001$) for the PT in seconds (Figure 2). The Bland-Altman plot showed a mean difference of 5.8% (95% confidence interval –14.9% to 26.6%) (Figure 3). Using a PT cutoff of 60%, POC had a sensitivity of 77.1% and a specificity of 94.1% (Figure 4). Results from POC PT were available within a mean of 25.8 minutes (range 13–78 minutes) before laboratory measures.

Discussion

This study showed a good correlation between laboratory and POC PT measurements. The Coaguchek XS Pro was initially developed for home measurement of international normalized ratio for patients on oral anti-coagulants and has shown good correlation with laboratory measures in this context.⁴ Similar results have been found in other studies in a perioperative,⁵ emergency department,^{6,7} or pediatric intensive care unit⁸ setting.

Figure 1 Study flow diagram.

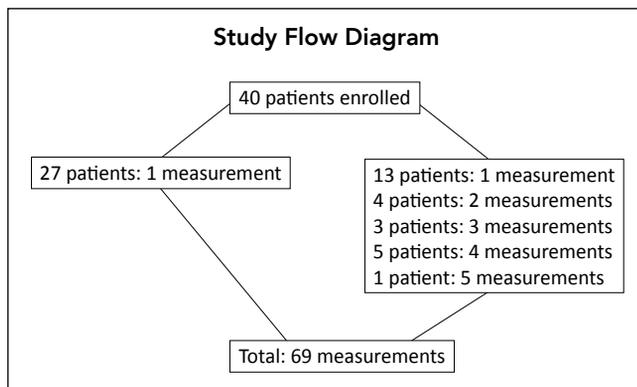


Figure 2 Associate of point-of-care prothrombin time (PT) with laboratory PT measurements.

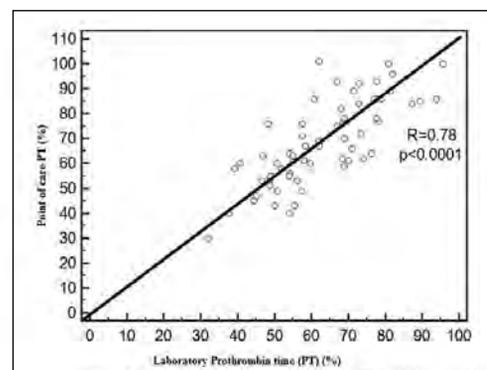


Figure 3 Bland-Altman plot showing the agreement between point-of-care and laboratory prothrombin time. The mean difference is represented as the solid line, and the dashed lines represent the 95% confidence interval of the difference.

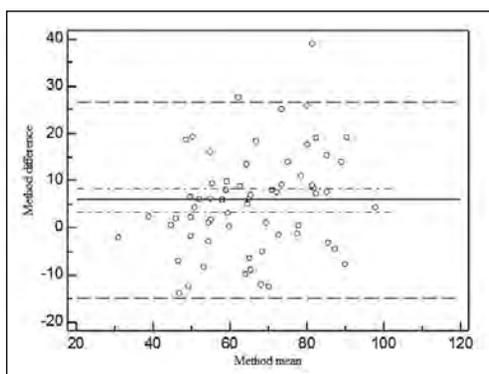
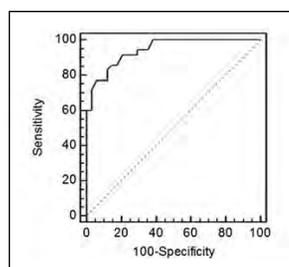


Figure 4 Receiver operating characteristic curve of point-of-care prothrombin time (PT) >60% for diagnosis of PT >50%.



This study showed that the Coaguchek XS Pro device can be used successfully in an austere environment without compromising its performance. Military field hospitals face two challenges for managing coagulopathy: they often cannot properly monitor coagulation status because traditional devices are heavy and cumbersome and require laboratory technicians. They also frequently have a limited supply of blood products, and using them without biological documentation would rapidly lead to a shortage. The Coaguchek XS Pro device is small and portable and does not require specially trained technicians. It can be used in settings where traditional laboratory measures cannot be used, leading to better recognition of coagulopathy in military trauma patients and better use of blood products.

A second advantage of POC is that it saves time. Time is critical in trauma management, and prompt treatment of a coagulopathic state could improve the prognosis of severe trauma patients.³ The Coaguchek XS Pro device permits the diagnosis of a clinically significant coagulopathy within a few minutes of the patient's arrival. This shortens the delay before beginning specific treatments.

Nonetheless, this study had limits. Although the Coaguchek XS Pro has several potential advantages in a military setting, this was only a descriptive study. A

prospective study using a tailor-made transfusion protocol with POC PT could show whether this device effectively permits better and faster treatment of trauma-induced coagulopathy in military patients.

The Coaguchek XS Pro device also has some limitations; it only measures PT, whereas coagulopathic states observed in severe trauma can also lead to deficiencies in platelets or fibrinogen. This is problematic since an alteration in PT would require plasma substitution, whereas platelets and fibrinogen require specific compensation.

Recently, the guidelines regarding traumatic bleeding emphasized that traditional hemostasis tests might not be ideal for the precise evaluation of a coagulopathic state. They suggested the use of global hemostasis tests, like a thromboelastogram.⁹ These devices are quite portable but are not as user-friendly as the Coaguchek XS Pro. A comparison of these devices should be made in an austere environment.

While the mean difference between POC and laboratory PT is small, some measures show greater discrepancy. The Coaguchek XS Pro device should not be used to determine an exact PT in trauma patients but rather to rule in or out a clinically significant coagulopathy. Similar observations have been made in perioperative studies. Larger studies will be necessary to determine the best cutoff value.

Conclusions

This study is, to the authors' knowledge, the first to evaluate the use of POC PT testing in a military trauma setting. The results indicate that this device can be used in this setting with acceptable accuracy. Further studies are needed to test implementing it in a global management strategy of coagulopathy in military trauma patients.

Presentation

Paper previously presented at the Société Française d'Anesthésie et Réanimation annual meeting, Paris, France, 19–22 September 2012.

Disclosures

The authors have nothing to disclose.

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Dr. Cotte is staff physician in the Intensive Care Unit at the Sainte Anne Military Teaching Hospital in Toulon, France. E-mail: jean.cotte@gmail.com.

Dr. D'Aranda is staff physician in the Intensive Care Unit at the Sainte Anne Military Teaching Hospital in Toulon, France.

Dr. Chauvin is staff physician in the Intensive Care Unit at the Sainte Anne Military Teaching Hospital in Toulon, France.

Pr. Kaiser is head of the Anesthesia and Intensive Care Department at the Sainte Anne Military Teaching Hospital in Toulon, France.

Pr. Meaudre is head of the Intensive Care Unit at the Sainte Anne Military Teaching Hospital in Toulon, France.