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DIFFERENCES IN ACTIVATED PARTIAL THROMBOPLASTIN TIME (aPTT) & PROTHROMBIN TIME (PT) METHODS POINT-OF-CARE TESTING (POCT) AND ELECTROMECHANIC SEMI AUTOMATIC

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ABSTRACT
Currently, there are several methods of coagulation testing, one of which is the Point-of-care testing (POCT) method which has emerged as a tool that plays an important role in modern healthcare, enabling fast, convenient diagnosis as well as more economical costs and can be done directly at the patient's treatment site. Some laboratories have also used the semi-automatic elecromechanic coagulation analyser as a coagulation testing tool. Objective to see the difference of aPTT and PT values in POCT method and semi automatic electromechanic method, so that it is useful in the selection of coagulometer. This study is an observational study with a cross sectional design conducted at H. Adam Malik Hospital Medan. Using 100 samples obtained through non-probability sampling with the consecutive sampling technique, each sample was examined for aPTT, PT, and INR using the POCT method and the electromechanical semi-automatic method. The results of each examination were analysed using the Mann Whitney statistical test. The results of the comparative test between INR of the POCT method and electromechanic semi-automatic found a significant difference between the two examination methods (p = <0.001). While in the aPTT an PT parameter, the POCT method with semi-automatic electromechanic did not find a significant difference between the two examination methods (p = 0.434 and p= 0.371). The average value of the difference between the two tools was 4.12 seconds in aPTT parameters and 0.50 in INR. There is no significant difference in the results of the aPTT and PT parameter between the two methods but there is a difference in the results of the INR parameter.

Keywords: aPTT; electromechanic semi automatic; POCT; PT

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INTRODUCTION

Hemostasis is the mechanism that leads to cessation of bleeding from a blood vessel. It is a process that involves multiple interlinked steps. This cascade culminates into the formation of a “plug” that closes up the damaged site of the blood vessel controlling the bleeding. It begins with trauma to the lining of the blood vessel. Hemostasis facilitates a series of enzymatic activations that lead to the formation of a clot with platelets and fibrin polymer. This clot seals the injured area, controls and prevents further bleeding while the tissue regeneration process takes place. Once the injury starts to heal, the plug slowly remodels, and it dissolves with the restoration of normal tissue at the site of the damage. (LaPelusa A et al., 2023).

Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT) are hemostasis tests that are useful for assessing coagulation function and the effects of drug use. These tests are employed to monitor the safety and effectiveness of anticoagulants and are sensitive to deficiencies of various coagulation factors. The PT test evaluates the role of clotting factors in the extrinsic and common

pathways, specifically factors I (Fibrinogen), II (Prothrombin), V, VII, and X. On the other hand, the aPTT test assesses the role of clotting factors in the intrinsic and common pathways. In summary, PT is sensitive to deficiencies of factors II, V, VII, and X, whereas aPTT is sensitive to deficiencies of prekallikrein, High Molecular Weight Kininogen (HMWK), and factors XII, XI, IX, and VIII (Jean BN et al., 2020; O'Donnel et al., 2019).

Currently, several coagulation testing methods are available, one of which is Point-of-Care Testing (POCT). This method has emerged as an important tool in modern healthcare, enabling rapid and convenient diagnosis at a more economical cost, and can be performed in various medical settings near the patient's point of care. In POCT, the test strip contains thromboplastin, a substance that plays a role in the blood clotting process. Thromboplastin helps activate coagulation factors and initiates the formation of a fibrin clot. Some POCT models use electrochemical methods to detect changes during the blood clotting process, where electrochemical sensors record changes in current or voltage that occur during clot formation. The results of POCT aPTT are presented in seconds, while POCT PT results are expressed in INR or seconds, with INR values standardized according to international reference standards (Ferreira CS et al., 2018)

Another study that compared the POCT method (CoaguChek® Pro II) with other clinical laboratory analyzers demonstrated a high correlation for PT-INR measurement, approaching a value of 1.0 (0.945 and 0.947). This indicates that PT-INR measurements obtained from both devices have a high and comparable level of correlation (Pulcer M et al., 2020). A similar study also showed consistent findings when comparing three POCT methods in patients undergoing warfarin therapy. Although some variations were observed, good agreement was noted within the INR range of 2.0–2.9, where more than 40% of measurements fell within this range and inter-method differences were less than 9%. Moreover, methods that used recombinant human thromboplastin (CoaguChek XS and Siemens BCS) demonstrated significant agreement, particularly for INR values below 3.0. This level of agreement reflects the extent to which two measurement methods yield similar or consistent results (Wendy S et al., 2017).

However, another study reported different findings, namely in the measurement of Activated Partial Thromboplastin Time (aPTT) and Prothrombin Time (PT) in patients with Diabetes Mellitus using the COATX Biosystem Coagulation device with a photocolorimetric method. The results of that study showed significant differences in aPTT values between the electromechanical and photo-optical methods (Ardina et al., 2020). Considering the importance of the differences in values between these two tests, this study aims to examine the differences in Activated Partial Thromboplastin Time (aPTT) and Prothrombin Time (PT) values using the point-of-care testing (POCT) method compared to the electromechanical semi-automatic method.

METHOD

This study is an observational analytic research with a cross-sectional design, in which data were obtained from patients' laboratory test results to assess the differences in Activated Partial Thromboplastin Time (aPTT) and Prothrombin Time (PT) values using the point-of-care testing (POCT) method and the electromechanical semi-automatic method. This study was conducted at Adam Malik Hospital for sample collection and at Setia Budi Hospital in Medan for sample processing, using non-probability consecutive sampling with a total of 100 participants, with approval from the Research Ethics Committee of Universitas Sumatera Utara (USU). The research and data collection were carried out from July 2024 to August 2024, followed by processing and analysis of the collected data. The population in this study consisted of inpatients and outpatients at Adam Malik General Hospital in Medan. Research samples were collected if they met the inclusion and exclusion criteria.

Data analysis was performed using statistical software. The data were first analyzed descriptively to determine the frequency distribution of the research subjects' characteristics. This was followed by inferential analysis, beginning with a normality test using the Kolmogorov-Smirnov test. If the data were normally distributed, an independent t-test was applied. If the data were not normally distributed, the Mann-Whitney test was used. Results were considered statistically significant at $p < 0.05$. Sampling was conducted using a non-probability sampling method, specifically consecutive sampling. In this technique, samples were collected consecutively according to the inclusion and exclusion criteria until the minimum required sample size was achieved. The total sample size was 100 subjects, with the inclusion criteria consisting of: whole blood samples with citrate anticoagulant for POCT testing, sufficient blood volume (blood/anticoagulant ratio of 9:1), and patients who agreed to participate in the study and signed informed consent. This study was conducted after obtaining ethical approval from the Health Research Ethics Committee of the Faculty of Medicine, Universitas Sumatera Utara, Medan, with approval number 49/KEPK/USU/2024.

RESULT

Table 1.
Demographic Characteristics

Variable	Results
Age, Median (Minimum - Maximum), in years	45(5 – 74)
Sex, f (%)	
Male	58 (58,0)
Female	42 (42,0)

The study subjects had a median age of 45 years (range: 5–74 years), with 58% male and 42% female. Median values for aPTT, PT, and INR showed slight differences between the POCT and electromechanical semi-automatic methods (Table 2). Since the Kolmogorov-Smirnov test indicated non-normal data distribution ($p < 0.05$), the Mann-Whitney test was used for comparison.

Table 2.
Results of aPTT and PT/INR Examination Using POCT and Electromechanical Semi-Automatic Methods

Variabel	POCT	*Electromechanic semi automatic*	P Value*
	Median (Min-Max)	Median (Min-Max)	
aPTT	32.65 (25,90 – 55,70)	33.85 (24,50 – 79,90)	0.434
INR	1,37 (1,00 - 9,01)	1,04 (,00 – 3,33)	<0.001
PT	15,4 (11,5 – 90,0)	16,2 (11,6 – 70,0)	0.371

*Mann-Whitney Test

In the comparative test using the Mann-Whitney test, the aPTT and PT parameters measured by the POCT method and the electromechanical semi-automatic method showed no significant differences between the two methods, with p-values of 0.434 and 0.371, respectively. In contrast, for the INR parameter, a significant difference was found between the POCT method and the electromechanical semi-automatic method ($p < 0.001$). The comparative agreement test of aPTT results between the two methods was performed using Bland-Altman Plot analysis [Figure1] and linear regression.

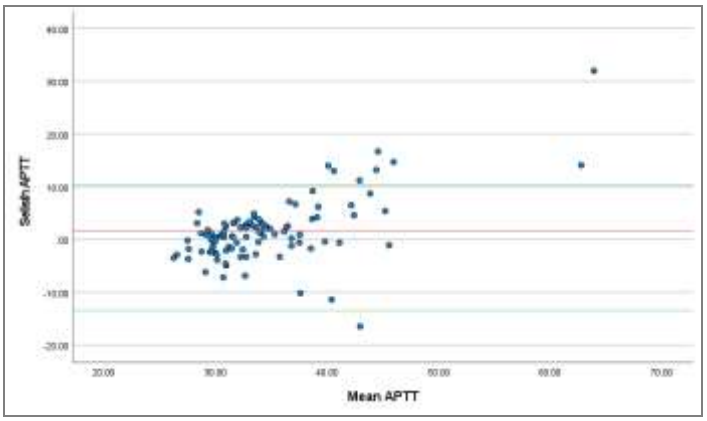

Figure 1. Bland-Altman Plot of Agreement for aPTT Results Using the POCT Method and the Electromechanical Semi-Automatic Method

A mean difference of 1.571 with a standard deviation (SD) of 6.073 was found between the two measurements. The upper limit of agreement (Upper LoA) for platelet testing between the two methods was 10.332, while the lower limit of agreement (Lower LoA) was –13.474. Since the majority of the data points fell within the limits of agreement, it can be concluded that the two methods demonstrated good agreement, indicating that POCT can still be used as a method for aPTT testing. The beta coefficient from the linear regression analysis was 0.704 ($p < 0.05$).

The comparative agreement test of PT results between the two methods was performed using Bland-Altman Plot analysis [Figure 2] and linear regression.

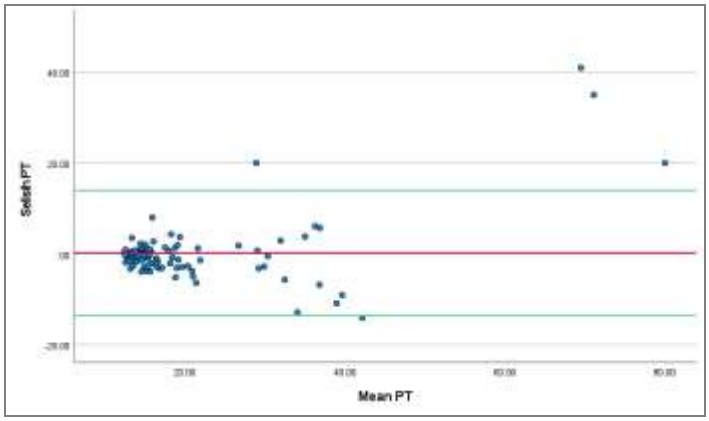

Figure 2. Bland-Altman Plot of Agreement for PT Results Using the POCT Method and the Electromechanical Semi-Automatic Method

The Bland-Altman analysis of prothrombin time (PT) measurements using the Point-of-Care Testing (POCT) method and the Electromechanical Semi-Automatic method showed a mean difference of 0.197 with a standard deviation (SD) of 7.032. The upper limit of agreement (Upper LoA) between the two methods was 13.979, while the lower limit of agreement (Lower LoA) was –13.586. Since the majority of the data points were within the limits of agreement, it can be concluded that the two methods demonstrated good agreement, indicating that POCT can still be used as a method for PT testing. The beta coefficient from the linear regression analysis was 0.878 ($p < 0.05$). Although a significant linear relationship was observed, it was not strong enough to indicate a systematic pattern. The comparative agreement test of INR results between the two methods was performed using Bland-Altman Plot analysis [Figure 3] and linear regression.

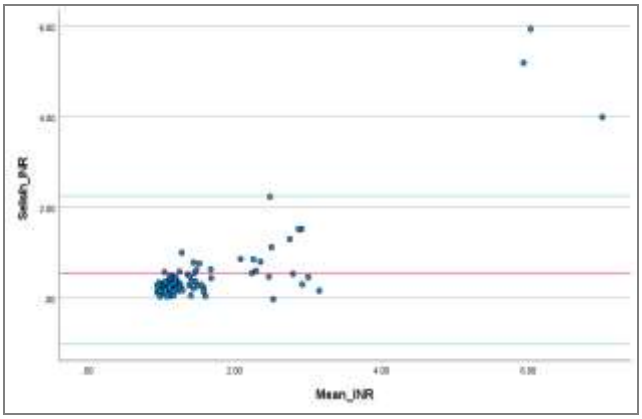

Figure 3. Bland-Altman Plot of Agreement for INR Results Using the POCT Method and the Electromechanical Semi-Automatic Method

A mean difference of 0.536 with a standard deviation (SD) of 0.877 was found between the two INR measurements. The upper limit of agreement (Upper LoA) between the two methods was 2.255, while the lower limit of agreement (Lower LoA) was –1.183. The majority of data points in this study fell within the limits of agreement, indicating good agreement between the two methods and supporting the use of POCT as a method for INR testing. The beta coefficient from the linear regression analysis was 0.878 ($p < 0.05$). Based on this analysis, most of the data points were distributed around the zero line, suggesting that, in general, both methods provided similar results without systematic differences. However, a pattern was observed in which the data points became more widely spread as the values of aPTT, PT, and INR increased. This indicates the presence of proportional bias, meaning the difference between the two methods becomes greater at higher measurement values. In other words, one method tends to yield higher results than the other at elevated aPTT, PT, and INR levels. Therefore, careful interpretation is required, particularly for extreme values. For aPTT, 29 samples showed differences in interpretation between the two methods, while 32 samples showed differences in the INR parameter, and 22 samples in the PT parameter. The mean differences between the two instruments were 4.12 seconds for aPTT, 3.2 seconds for PT, and 0.50 for INR. These results are presented in Table 3.

Table 3.
Comparison of aPTT, PT, and INR Results Between the POCT Method and the Electromechanical Semi-Automatic Method

POCT	*Elctromechanic semi automatic*	Total
aPTT normal (22 – 38 seconds)	normal (25,6 – 35,2 seconds)	60
prolonged (> 38 seconds)	prolonged (> 35,2 seconds)	11
normal (22 – 38 seconds)	prolonged (> 35,2 seconds)	26
prolonged (> 38 seconds)	normal (25,6 – 35,2 seconds)	3
PT normal (10 – 14)	Normal (11.7 – 15.3)	27
prolonged (>14)	prolonged (> 15.3)	51
Normal (10 – 14)	Prolonged (> 15.3)	5
prolonged (>14)	Normal (11.7 – 15.3)	17
INR normal (0.7 – 1.3)	normal (0.8 – 1.2)	38
prolonged (> 1.3)	prolonged (> 1.2)	30
normal (0.7 – 1.3)	prolonged (> 1.2)	0
prolonged (> 1.3)	normal (0.8 – 1.2)	32

DISCUSSION

Standard coagulation monitoring is used to evaluate hemostasis and bleeding status in hospitalized patients, including those undergoing surgical procedures and during cardiac surgery with cardiopulmonary bypass (CPB). Many factors can influence the coagulation status of hospitalized patients, particularly in the perioperative setting, including the type of procedure, history of surgery at

the same anatomical site, the degree of tissue injury, and the baseline condition of the hemostatic system (Levy JH et al., 2014). With the advancement of technology, point-of-care testing (POCT) has become an attractive alternative for coagulation testing, as it allows rapid analysis directly at the patient's bedside. Point-of-care coagulation testing (POCCT) has been widely used to monitor anticoagulant therapy, particularly warfarin, and its use is now expanding in perioperative settings, emergency departments, and intensive care units. The advantages of POCT lie in its speed and ease of use, thereby accelerating clinical management. POCT devices can provide results within minutes, particularly for PT, INR, and aPTT parameters, which are crucial for assessing the early phases of the coagulation pathway through to fibrin formation (Balendran et al., 2017; Srivastava et al., 2013).

The point-of-care (POC) PT test was initially developed for the rapid monitoring of outpatient warfarin therapy. This test has been validated for use in non-cardiac surgery, reducing the turnaround time between blood sampling and test results by up to 60 minutes, and is beneficial as a rapid guide for transfusion practice (Meester MI et al., 2016). CoaguChek Pro DM (Roche, Basel, Switzerland) is one of several systems that use recombinant human thromboplastin as a reagent to activate the coagulation pathway in PT, aPTT, and INR testing. This POCT has been proven to provide results comparable to those of standard laboratory testing (Srivastava et al., 2013). CoaguChek® (Roche, Basel, Switzerland) is also a POCT device for PT and INR, specifically designed for monitoring patients receiving vitamin K antagonists (ebner M et al., 2015).

The device used for the POCT method in this study was the Wondfo Optical Coagulation Analyzer, which operates on a semi-automatic optical blood principle. It can test each parameter using a special capillary kit preloaded with reagents, and the results are displayed on the touchscreen within less than 5 minutes. The sample used was whole blood with citrate anticoagulant, with a volume of 20 μL, which was then applied to the cartridge. This study involved 100 subjects with a median age of 45 years, a minimum age of 5 years, and a maximum age of 74 years. There were more males (58%) than females (42%). The demographic characteristics of the study samples provide important context for understanding the variability of aPTT and PT test results using different methods.

The findings of this study showed that most patients were concentrated in the middle-aged group (44–60 years), accounting for 59% of the total sample. This age variation provides insight that allows for a comprehensive analysis of the effect of age on hemostasis test results. Increasing age may influence various hemostatic changes, including elevated levels of several coagulation proteins such as fibrinogen and factors V, VII, VIII, IX, XI, and XII (Tzoran I et al., 2018). In this study, a comparative evaluation was conducted on aPTT and PT testing in patients using the Point-of-Care Testing (POCT) method and the electromechanic semi-automatic method. The median value of the aPTT parameter obtained with the POCT method was 32.65 seconds, while with the electromechanic semi-automatic method it was 33.85 seconds. For the PT parameter, the median value with the POCT method was 15.4 seconds, and with the electromechanic semi-automatic method it was 16.2 seconds. The results of the Mann-Whitney comparative test showed that for the aPTT and PT parameters, there was no significant difference between the POCT method and the electromechanic semi-automatic method, with p-values of 0.434 and 0.371, respectively. This finding is consistent with the study by Niederdöckl et al., which reported that both POCT PT and POCT aPTT demonstrated good agreement with laboratory-based PT and aPTT measurements (Niederdöckl J et al., 2016).

However, for the INR parameter, a significant difference was found between the two examination methods ($p < 0.001$). This finding is consistent with the study by Lawrie et al., which compared POCT INR CoaguChek XS Plus with laboratory PT/INR and found differences of less than or equal to 0.5 INR units in 64% of patients when tested using recombinant human thromboplastin, and in only 50% of patients when tested using rabbit-derived thromboplastin. Overall, 25% to 30% of POCT INR and laboratory PT/INR measurements showed differences large enough to affect clinical decisions,

particularly regarding warfarin dose adjustment. Although INR was designed to minimize inter-laboratory variability, these discrepancies remain clinically significant due to variations in instruments and reagent composition (Nam M et al., 2020).

INR is a value obtained through the calculation of the prothrombin time ratio (patient PT compared to normal PT), which is influenced by the International Sensitivity Index (ISI) of each reagent used. The reagents applied in POCT devices and semi-automatic analyzers have different ISI values; therefore, even if the PT values appear similar, the resulting INR can differ significantly. Moreover, since INR is calculated using a logarithmic formula, even small differences in PT values can lead to relatively large changes in INR results—especially when combined with variations in reagent sensitivity. Consequently, although PT and aPTT results may appear consistent across methods, INR calculations are more sensitive to instrument-to-instrument variation, both in terms of reagents and detection methods, thereby producing statistically significant differences (Harris L et al., 2016; Hernaningsih Y et al., 2017).

The results of the Bland-Altman analysis in this study showed that the majority of the data fell within the limits of agreement, indicating no systematic difference between the two examination methods and demonstrating a good level of agreement. This finding is consistent with the study by Bai B, which reported that all data obtained during the research showed that patient results measured using a photo-optical detection system were reliable and statistically equivalent to those obtained with a mechanical detection system. The results of coagulation testing can be influenced by various factors, including sample condition, testing time, instrument characteristics, and the type of reagent used. One of the main factors is the difference in working principles between methods. POCT generally applies the principle of optical detection, which identifies changes in viscosity or clot formation by observing variations in density or light scattering when the blood sample is mixed with the reagent. In contrast, the electromechanical semi-automatic method operates based on mechanical detection, in which a steel ball within a cuvette containing plasma and reagent oscillates under the influence of an electromagnetic force, and the cessation of oscillation marks the occurrence of coagulation. This difference in principle leads to varying sensitivities of the two methods to interferences such as hemolysis, lipemia, and icterus (Harris L et al., 2016; Hernaningsih Y et al., 2017; Zou Z et al., 2023; Song H et al., 2021).

According to the guidelines of the National Committee for Clinical Laboratory Standards (NCCLS), coagulation tests should be performed within 2 hours if the sample is stored at room temperature, within 4 hours if stored at 2–4 °C, and can be preserved for up to two weeks if frozen at –20 °C. However, several other studies have shown that PT and APTT testing may remain stable for longer periods than those recommended by NCCLS. Meanwhile, the Clinical and Laboratory Standards Institute (CLSI) recommends that PT testing be analyzed within 24 hours, and APTT within 4 hours if stored at room temperature (25 °C) (Goyal VK 2015). Previous studies have also shown results similar to the present study, namely that the POCT method produces values that are nearly equivalent to those of laboratory methods. Balendran reported that PT results from the laboratory (Micro-Coagulometer, Lemgo, Germany) and POCT (CoaguChek XS Pro, Roche, Sweden) were comparable when the prothrombin level was >60% of the baseline value. However, in cases of severe coagulopathy, PT results obtained by POCT were less accurate and showed a significant increase. The data from this study support the use of POC PT testing, such as CoaguChek XS Pro, to confirm prothrombin thresholds for coagulopathy, as well as a rapid, simple, and convenient method to guide therapy in bleeding trauma patients.

However, in the study by Lardinois et al., simultaneous measurements of APTT were performed using POCT (CoaguCheck®, Roche Diagnostics), laboratory APTT (C.K. Prest), and anti-Xa activity (STA® Liquid anti-Xa, Stago) six times per day. The results showed that the average turnaround time

for laboratory APTT was 92 minutes (IQR 69.3–121.2), which was significantly longer compared to POCT APTT ($p < 0.0001$). A strong correlation was observed between POCT-APTT and laboratory APTT ($rs = 0.77$; $p < 0.0001$), as well as between POCT-APTT and anti-Xa activity ($rs = 0.46$; $p < 0.0001$). However, the level of agreement between methods was relatively low, with kappa (κ) values of 0.27 between POCT and laboratory APTT, and 0.30 between POCT and anti-Xa (Lardinois B et al., 2022). Considering all these findings, POCT is a highly useful tool for rapid coagulation testing, particularly in emergency departments and operating rooms. However, its limitations in accuracy and sensitivity to interference make it less suitable as a standalone diagnostic method. Conventional laboratory methods remain necessary for confirmation, especially in clinical situations that require high precision. A combined approach using both POCT and laboratory testing can provide a more effective and efficient strategy for monitoring patient coagulation.

CONCLUSION

This study demonstrates that the Point-of-Care Testing (POCT) method provides PT and aPTT results comparable to the semi-automatic electromechanic method, with a good level of agreement based on Bland-Altman analysis. However, a significant difference was observed in INR values, attributed to variations in reagent ISI and the logarithmic calculation principle of INR, which makes it more sensitive to differences in methods and instruments. The difference in working principles between methods—optical detection in POCT and mechanical detection in the semi-automatic method—leads to varying sensitivities to interference factors (hemolysis, lipemia, icterus). Nevertheless, PT and aPTT results remain relatively consistent across methods.

POCT has been proven useful for rapid coagulation testing, especially in emergency and operating rooms, as it provides results quickly and practically. However, limitations in accuracy, sensitivity to interference, and variability in INR results make it less suitable as a stand-alone diagnostic method, hence confirmation with conventional laboratory methods remains necessary. A combination of both approaches may serve as the most effective and efficient strategy for patient coagulation monitoring.

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