An Evaluation of Blood Glucose Measurement Using TRUEresult Blood Glucose Monitoring System

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Background: *Point of care testing using glucose meters that measure capillary blood are the most popular and widely used method for the routine monitoring of blood glucose level. TRUEresult is one of such commonly used blood glucose measuring tools with high accuracy and precision profile according to the manufacturer's data.*
Objective: *To evaluate the performance of TRUEresult in real life practice by examining the agreement between capillary and venous glucose result using TRUEresult and a laboratory plasma glucose.*
Material and Method: *The present study is a cross sectional analytical study. All the data were collected from the patients whose blood samples were drawn for the measurement of plasma glucose at the outpatient department of Srinagarind Hospital, Khon Kaen University, Thailand. TRUEresult blood glucose monitoring system was used to perform blood glucose measurement in whole blood samples from capillary and veins. This was compared with plasma glucose result from the automated analyzer in the central laboratory, which was considered as reference method at Srinagarind Hospital.*
Results: *The ISO 15197:2013 criteria was used to determine technical accuracy of the TRUEresult tool. Blood glucose levels in whole blood sample from capillary and veins, as measured using the TRUEresult, were 88.24% and 92.16% of the acceptable bias limits. This is below the minimal acceptable criteria. When Parkes error grid analysis was used to define the significance in clinical decision, all the errors of blood glucose levels measured using the TRUEresult were within zone A and zone B, meaning that the errors have no or little influence on clinical decision.*
Conclusion: *The blood glucose levels in whole blood from capillary and veins measured using TRUEresult blood glucose monitoring was within acceptable accuracy limit. The observed error had no or little influence on clinical decision.*

Keywords: *Evaluation, Blood glucose measurement, TRUEresult*

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Blood glucose measurement is the key process in diabetic care, not only for the screening of undiagnosed cases, but also for monitoring after therapy, which leads to proper adjustment for long-term treatment. At the present, blood glucose measurement using glucose meters as a point of care testing has been accepted worldwide for self-home monitoring as well as for glucose monitoring in hospitalized patients. Glucose meters are the important tool and effective method in managing the treatment plan, blood glucose control, and preventing long-term diabetic complications[1-3].

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Nowadays, many brands of modern handheld blood glucose meters are available. The devices for self-monitoring of blood glucose (SMBG) must be accurate and reliable for treatment adjustments, which must be certified by the accuracy testing based on the manufacturer standard of the International Organization for Standardization (ISO) guideline 15197[4]. The TRUEresult® (TRUEresult, Nipro Diagnostics Inc., Florida, USA) is one of the blood glucose measuring tools with high accuracy of 98.5% according to the manufacturer's data[5]. This information is based on a study in a controlled operator and patient related factors, such as for very high or low glucose concentrations, and extremes of hematocrit and temperature. However, in real life practice, glucose meters are utilized by a diverse population of patients, representing all ages and acuteness of medical conditions. Therefore, the present study was

designed to assess the performance of TRUEresult in clinical practice by comparing glucose results using TRUEresult in both capillary blood taken from the fingertip and venous blood with that in venous plasma glucose determined using standard laboratory method according to the ISO 15197 guideline.

Material and Method

The present study was a cross sectional analytical study and performed according to the Declaration of Helsinki. The study was approved by the Khon Kaen University Ethics Committee, and all the subjects participated in the present study gave a written informed consent prior to study procedure.

Study population

All the data were collected from the patients who were 20 to 79 years of age and underwent venous blood samples drawn for plasma glucose measurement at the outpatient clinic of Srinagarind Hospital. Patients with contraindication to use the tool (i.e., patient currently on peritoneal dialysis or hemodynamically unstable patients as specified in the user's manual) were excluded from the study. Moreover, patients whose plasma glucose readings using the automated analyzer was less than 20 mg/dL or more than 600 mg/dL were excluded from the study (since these values were beyond the reading limits of TRUEresult).

Sample size is calculated using the following formula:

$$n = \frac{(Z_{\alpha/2})^2 P(1-P)}{d^2}$$

Assuming the prevalence of the reading error of the glucose meter <10% compared with the reference method (p = 0.53)[6] and the acceptable value that allow deviation from the real value in the population (d = 0.085) with the standard normal deviation at the confidence of 95% (Z = 1.96), the calculated sample size in the study was 133.

Study instruments

A TRUEresult blood glucose monitoring system, which consists of a TRUEresult blood glucose meter and TRUEresult blood glucose test strips, is the product of Nipro Diagnostics Inc. (Florida, US). The principle of measurement is as follows. When whole blood sample is dropped on to the test strip, glucose in the sample reacts to form a compound, of which concentration is measured, converted, and reported as the glucose level. This tool can measure the glucose level range of 20 to 600 mg/dL. In this study, as the reference method, plasma glucose levels in venous blood samples were measured using a Cobas C501 automated analyzer (Roche Inc.).

Data collection

Data collection was performed by two co-authors who are nurses and have been trained of the study design, TRUEresult user's instruction, and the details of case record form. We first collected blood samples from the patients' vein and a drop of whole venous blood from each sample was used to measure the glucose level immediately using a TRUEresult. The rest of the venous blood samples were sent for plasma glucose measurement in the central laboratory unit of our hospital. Then, the patient's fingertip was pricked with a lancet to obtain capillary whole blood samples. First droplet of blood from the fingertip was wiped out and the second droplet was used for the test. This process was done within five minutes after the venous blood collection. The measurement was performed according to the technical protocol of the manufacturer to minimize errors. 1) the performance of TRUEresult was checked after every 30 patients measurements using control solution to see the consistency of the measurements, 2) the expiring date of each test strip was checked when the new bottle of strip was used, 3) the blood sampling must be within one minute after the insertion of test strip into the glucose meter, 4) blood droplet must be topped up enough on the test strip, 5) every day after the data collection, the authors compared the recorded glucose level in the glucose meter to the glucose levels in the case records, and 6) all equipment were stored in tidy place with appropriate temperature. In addition, the venous blood samples with three different plasma glucose levels were selected to assess an intra-assay precision by duplicated measurements for 30 times in each sample.

Statistical analysis

The statistical analyses were performed using Stata SE, version 10.0 (Stata, College Station, TX). Percentage, range, mean, median, and standard deviation were used to analyze the descriptive data. The correlation between capillary whole blood sample, venous whole blood sample, and plasma glucose was analyzed by the Pearson's correlation coefficients. Percentage error was calculated from the following formula, and then analyzed further for the significance in the clinical decision using the Parkes error grid analysis[7] and the Bland-Altman plot. For

Table 1. The accuracy parameters of ISO 15097:2003[4] and 2013[8]

Accuracy parameters	ISO 15197:2003	ISO 15197:2013
Target blood glucose level from which to base mg/dL bias or % bias	75 mg/dL	100 mg/dL
Acceptable bias from reference value for lower target glucose levels	±15 mg/dL	±15 mg/dL
Acceptable bias from reference value for higher target glucose levels	±20%	±15%
Acceptable % of all results within bias limits	95%	95%
Parkes error grid	Not required	99% of results within Zones A and B

the intra-assay precision analysis, mean, standard deviation, and coefficient of variation were used.

$$\frac{\text{(Glucose level from TRUEresult - Glucose level from reference method) x 100}}{\text{Glucose level from reference method}}$$

Parkes error grid analysis is the tool to demonstrate accuracy of glucose meter based on significance on clinical decision in graph form. The y-axis represented the measured glucose levels by the test tool and x-axis represented the measured plasma glucose by the reference method. The graph was divided in to five zones (Zone A: difference between glucose level is in the acceptable range and no effect on clinical action, Zone B: difference between glucose level is in the acceptable range but may alter clinical action, Zone C: difference between glucose level can cause alteration in clinical action, although the correct glucose level was in the acceptable range (overcorrection), Zone D: difference between glucose level is in the acceptable range, but in fact, the correct glucose level was too low or too high (failure to correct), and Zone E: difference between glucose level cause alteration in clinical action which was in the opposite way of the correct glucose level and harmful to the patient (anticorrection)).

For the reference, the parameters for the glucose meter accuracy provided by the ISO 15197 guideline 2003[4] and 2013[8] were shown in Table 1.

Results

Of 153 patients recruited, 72 were men and 81 were women. Among them, 89 patients (58.2%) were diagnosed as diabetes and 64 patients (40.8%) had plasma glucose level between 100 and 139 md/dL (Table 2).

The average glucose levels in the capillary and venous whole blood samples measured by the TRUEresult were 107.62 and 111.05 mg/dL, respectively, whereas that in the venous plasma measured by the reference method was 120.54 mg/dL (Table 3). The average glucose levels obtained from the TRUEresult were, regardless of the source of samples, significantly (p-value <0.001) lower than that in the venous plasma determined by the reference method (Table 3).

The correlation between glucose levels in the capillary and venous whole blood obtained from TRUEresult and that in the venous plasma measured by the reference method was 98.5% and 97.2%, respectively. The correlation of glucose levels between capillary and venous whole blood determined using the TRUEresult was 97.2%. Using the TRUEresult, the glucose levels in the capillary whole blood was significantly (p-value <0.001) lower than that in the venous whole blood (Table 3).

When the results of the glucose levels in the capillary and venous whole blood samples obtained from the TRUEresult were compared with those of venous plasma glucose using an automated analyzer (reference method), the percentage error was 10.7% and 7.7%, respectively (Table 3).

Table 2. Patient characteristics

Patient characteristics	Total n = 153 (%)
Gender	
Male	72 (47.1)
Female	81 (52.9)
Age (years)	
Mean (± SD)	58 (±10.7)
20-29	3 (2.0)
30-39	4 (2.6)
40-49	18 (11.8)
50-59	62 (40.5)
60-69	41 (26.8)
70-79	25 (16.3)
Comorbidities	
Diabetes	89 (58.2)
No diabetes	64 (41.8)
Plasma glucose (mg/dL)	
Median (min-max)	113 (64-238)
<60	0 (0)
60-99	55 (36.0)
100-139	64 (41.8)
140-179	23 (15.0)
180-219	9 (5.9)
≥220	2 (1.3)

According to the ISO 15197:2013 (Table 1), more than 95% of glucose meter readings must be within the acceptable bias limit. The acceptable limit is the absolute error of <15 mg/dL for the samples with <100 mg/dL of plasma glucose and the absolute error less than 15% for the samples with ≥100 mg/dL of plasma glucose. In present study, 88.2% and 92.2% of the results of glucose levels in the capillary and venous whole blood obtained from TRUEresult were within the acceptable bias limit (Table 4). However, using the ISO 15197 guideline that was published in 2003 with less stringent criteria (glucose meter must also reach more than 95% of readings within acceptable bias limit, but different acceptable limit was used, which was absolute error less than 15 mg/dL in less than 75 mg/dL of plasma glucose and absolute error less than 20% in 75 mg/dL or over of plasma glucose), the results of TRUEresult capillary and venous whole blood readings reached 97.4% within the acceptable limit similarly (Table 5).

The results of the Parkes Error Grid plot are shown in Fig. 1. Sufficient clinical accuracy (i.e., values in zone A or B) of the glucose readings obtained by TRUEresult for the capillary and venous whole blood samples was 100% (96% in zone A and 4% in zone B) and 100% (99% in zone A and 1% in zone B), respectively. Thus, this method for both samples fulfilled the minimum requirements defined by the ISO 15197:2013 guideline.

Using the Bland-Altman analysis, TRUEresult capillary whole blood samples have the mean relative error of -12.9 mg/dL and have 95% limit of agreement ranged from -26.61 to 0.76 mg/dL. Similarly, TRUEresult venous whole blood samples have with mean relative error of -9.5 mg/dL and have 95% limit of agreement ranged from -26.92 to 7.93 mg/dL. The samples with the values outside of the 95% limit of agreement were all due to underestimated readings for the plasma glucose of >150 mg/dL (Fig. 2).

Table 3. Mean glucose level and mean percentage error using TRUEresult capillary and venous whole blood compared with Plasma glucose from automated analyzer (reference method)

Method	Mean glucose level (± standard deviation) n = 153	Mean percentage error (± standard deviation) n = 153
TRUEresult capillary sample	107.62±32.1	10.72±4.25
TRUEresult venous sample	111.05±32.22	7.66±6.06
Plasma glucose from automated analyzer	120.54±35.52	

Table 4. The number and percentage of blood samples using TRUEresult capillary and venous whole blood compared with reference using ISO 15197:2013 guideline

	Plasma glucose <100 mg/dL			Plasma glucose ≥100 mg/dL			ISO 15197:2013 n = 153 (%)
	±5 mg/dL n = 55 (%)	±10 mg/dL n = 55 (%)	±15 mg/dL n = 55 (%)	±5% n = 98 (%)	±10% n = 98 (%)	±15% n = 98 (%)	
TRUEresult capillary whole blood sample	5 (9.09)	32 (58.18)	51 (92.73)	10 (10.20)	44 (44.90)	84 (85.71)	135 (88.24)
TRUEresult venous whole blood sample	26 (47.27)	44 (80.00)	51 (92.73)	28 (28.57)	59 (60.20)	90 (91.84)	141 (92.16)

Table 5. The number and percentage of blood samples using TRUEresult capillary and venous whole blood compared with reference using ISO 15197:2003 guideline

	Plasma glucose <75 mg/dL			Plasma glucose ≥75 mg/dL			ISO 15197:2003 n = 153 (%)
	±5 mg/dL n = 4 (%)	±10 mg/dL n = 4 (%)	±15 mg/dL n = 4 (%)	±5% n = 149 (%)	±10% n = 149 (%)	±20% n = 149 (%)	
TRUEresult capillary whole blood sample	1 (25.00)	4 (100)	4 (100)	13 (8.72)	69 (46.30)	145 (97.32)	149 (97.38)
TRUEresult venous whole blood sample	2 (50.00)	3 (75.00)	4 (100)	47 (31.54)	93 (62.42)	145 (97.32)	149 (97.38)

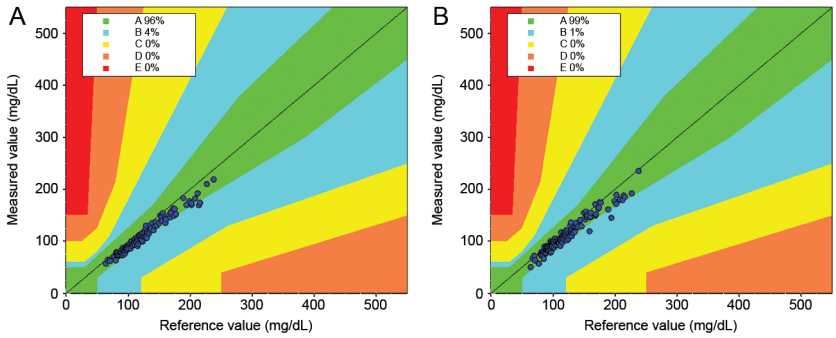

Fig. 1 Parkes error grid analysis of TRUEresult capillary and venous samples. A) Shows clinical accuracy of the glucose readings (i.e., values in zone A or B) was 100% (96% in zone A and 4% in zone B) and 100% (99% in zone A and 1% in zone B). B) Shows clinical accuracy of the glucose readings (i.e., values in zone A or B) was 100% (99% in zone A and 1% in zone B) which passed the minimum requirements defined by the ISO 15197:2013 guideline.

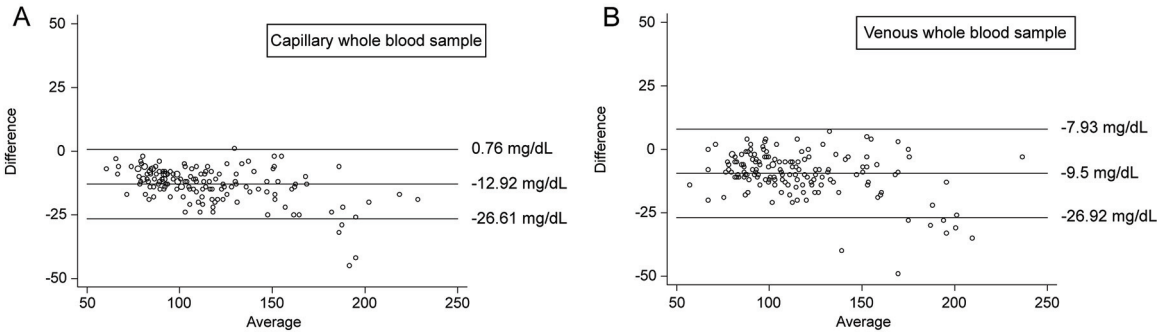

Fig. 2 Bland-Altman analysis demonstrated that TRUEresult capillary whole blood sample with mean relative error of -12.9 mg/dL had 95% limit of agreement ranged from -26.61 to 0.76 mg/dL (A). While TRUEresult venous whole blood sample with mean relative error of -9.5 mg/dL had 95% limit of agreement ranged from -26.92 to 7.93 mg/dL (B). The values outside the 95% limit of agreement were all underestimated readings with plasma glucose of more than 150 mg/dL.

In three different blood samples with plasma glucose levels of <75 mg/dL, 75-180 mg/dL, and >180 mg/dL, mean glucose reading and standard deviation in duplicated samples measured for 30 times using TRUEresult device were 51.3±1.86, 83.73±2.77, and 182.8±11.23, with the coefficient of variation percentage (%CV) of 3.63%, 3.30%, and 6.14%, respectively.

Discussion

In the present study, the results obtained using TRUEresult glucose monitoring system were correlated well in a linear pattern with the plasma glucose references and thus it can be used as representatives of plasma glucose to guide clinical decision making. However, since the mean readings form TRUEresult were significantly lower (10.7 and 7.9% for the capillary and venous samples, respectively) than plasma glucose level determined with the reference method, this discrepancy should always be in consideration. Our results confirmed the previous reports in that glucose meter readings were 2.6% to 10.6% lower than plasma glucose level[9-13]. For the difference between capillary and venous samples, we found that the capillary readings were 3.1% lower than the venous readings with statistical significance. Similarly, Boyd et al[14] reported that the capillary readings were 5.94 mg/dL lower than venous readings in the emergency room study. However, this difference has little influence on clinical decision and may not affect clinical practice nowadays. Practically, we can use venous samples for glucose interpretation in most patients who have necessities of venepuncture for other purposes.

To assess the performance of SMBG devices, the ISO 15197:2003 is a widely accepted standard

system[4], which defined as closeness of agreement between a measurement result and the accepted reference value determined by the manufacturer's measurement procedure. We found that using the TRUEresult, 97.4% of readings for the capillary and venous whole blood samples were within the limit. However, considering the recently published revision ISO 15197:2013 with more stringent criteria[8], 88.2% and 92.2% of the systems' measurement results for the capillary and venous samples were within the required limits, which were lower than that given in the manufacturer's study (98.5 and 100% of readings are within the acceptable limits)[5,15]. In the ISO 15197:2003, the criteria for the parameter were divided into two categories, the groups of plasma glucose below and above 75 mg/dL. In the present study, only four patients have plasma glucose level of <75 mg/dL. Therefore, it is difficult to apply this criterion to our results. Moreover, the conflict of results could be explained due to several factors which will influence glucose readings i.e., patient's hematocrit, serum maltose and serum uric acid, different test strip lots, storage conditions of test strips. In the present study, we decided not to include those factors into our inclusion or exclusion criteria to mimic real life situation as much as possible, since these factors are not routinely monitored while using the glucose meter in daily practice.

To interpret the performance of the results of SMBG systems, several factors potentially affect the accuracy of the results should be taken into account. In addition, it should be recognized that not only the result bias that should be as small as possible but also the high precision is important. Despite inability to meet the requirement of ISO 15197:2013, the results of the Parkes error grid analysis showed acceptable performance of the TRUEresult in clinical decision, because 100% of glucose readings using TRUEresult were within the zone A or B, which exceeded the minimal criteria of ISO 15197:2013. These results implied that the TRUEresult met sufficient clinical accuracy limit and their errors had no or little effect on clinical decision-makings.

The results plotted in the Bland-Altman plot showed that the deviation of both capillary and venous readings outside of the 95% limit of agreement were of the samples having plasma glucose of >150 mg/dL and their results from TRUEresut were underestimated compared with the results from venous plasma glucose. These findings implicated that the gap between the TRUEresult reads and the venous plasma glucose level will be bigger at the higher plasma glucose level. Similar problem of reading with various glucose meters has been reported previously[9,16]. This problem seems to be not due to the glucose meter brand, but rather due to the difference between glucose meter and reference methods of the source of blood samples and the processing of glucose readings. In the present study, the numbers of samples with extremely "high" or "low" range of plasma glucose were not enough to conclude the reasons for the bigger gaps between glucose meter readings and the plasma glucose levels at high or low glucose samples.

In terms of intra-assay precision testing, the coefficient of variation of 3 different plasma glucose samples were 3.6%, 3.3%, and 6.1%, which are considered within the acceptable limit and are comparable with the previous studies which reported the coefficient of variation ranged from 6% to 15%[17,18].

There were number of limitations to interpret the present findings. Some factors that influenced the glucose readings regarding the manufacturer were not controlled, including patient's hematocrit, serum maltose, and serum uric acid, different test strip lots, and storage conditions of test strips. Thus, care should be taken when extrapolating these results to other populations. The clinical accuracy of TRUEresult in the present study may have limitations to generalization because of the lack of the patients with plasma glucose of <20 or >600 mg/dL.

Conclusion

Errors in measuring blood glucose levels in whole blood from fingertips and veins using TRUEresult blood glucose monitoring system were within the acceptable accuracy limit in real life practice. The intra-assay precision was also within the acceptable limit. According to the results of Parkes error grid analysis, the presence of error seems to have no or little influence on clinical decision-makings. The error was increased in the samples with extremely higher blood glucose levels.

What is already known on this topic?

Self-monitoring of blood glucose is the key process in diabetic care.

Several glucose meters have proven to be efficacious and accurate in performing self-monitoring of blood glucose.

TRUEresult is one of such commonly used blood glucose measuring tools with high accuracy and precision profile according to the manufacturer's data.

What this study adds?

TRUEresult clinical performance in real life practice is verified according to the results of Parkes error grid analysis. The presence of error seems to have no or little influence on clinical decision-making.

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Potential conflicts of interest

None.

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การศึกษาผลของการตรวจระดับน้ำตาลในเลือดด้วยเครื่องตรวจวัดระดับน้ำตาลทรูรีซอลท์ในเวชปฏิบัติ

สุรณัฐ เจริญศรี, สัมฤทธิ์ คะมะปะเต, แก้วใจ เทพสุธรรมรัตน์, ฉัตรเลิศ พงษ์ไชยกุล

ภูมิหลัง: การตรวจระดับน้ำตาลในเลือดด้วยเครื่องตรวจวัดระดับน้ำตาลปลายนิ้วเป็นวิธีการตรวจวัดระดับน้ำตาลในเลือดอย่างง่ายที่นิยมใช้กันอย่างแพร่หลาย โดยเครื่องตรวจวัดระดับน้ำตาลทรูรีซอลท์ (TRUEresult) เป็นหนึ่งในเครื่องตรวจวัดระดับน้ำตาลที่ได้รับการศึกษาจากผู้ผลิตว่ามีความแม่นยำสูง

วัตถุประสงค์: เพื่อศึกษาผลการตรวจระดับน้ำตาลของผู้ป่วยในเวชปฏิบัติจริง โดยใช้เครื่องตรวจวัดระดับน้ำตาลทรูรีซอลท์ในการตรวจเลือดครบส่วนทั้งจากหลอดเลือดฝอยและจากหลอดเลือดดำ เปรียบเทียบกับระดับน้ำตาลในพลาสมาโดยการตรวจจากห้องปฏิบัติการ

วัสดุและวิธีการ: เป็นการศึกษาแบบตัดขวางเชิงวิเคราะห์ เก็บข้อมูลจากผู้ป่วยซึ่งมารับการเจาะเลือดทางหลอดเลือดดำ เพื่อส่งตรวจระดับน้ำตาลในพลาสมา ที่แผนกห้องตรวจผู้ป่วยนอก โรงพยาบาลศรีนครินทร์ โดยใช้เครื่องตรวจวัดระดับน้ำตาลทรูรีซอลท์ตรวจค่าระดับน้ำตาลในเลือดด้วยตัวอย่างเลือดครบส่วนจากหลอดเลือดฝอยและหลอดเลือดดำ เปรียบเทียบกับระดับน้ำตาลในพลาสมาด้วยเครื่องตรวจวิเคราะห์อัตโนมัติ ซึ่งถือเป็นวิธีมาตรฐานของโรงพยาบาลศรีนครินทร์

ผลการศึกษา: เมื่อใช้เกณฑ์ของ ISO 15197:2013 ค่าระดับน้ำตาลที่ตรวจด้วยเครื่องตรวจวัดระดับน้ำตาลทรูรีซอลท์ในการตรวจเลือดครบส่วนจากหลอดเลือดฝอยและจากหลอดเลือดดำอยู่ในช่วงผิดพลาดที่ยอมรับได้ร้อยละ 88.24 และร้อยละ 92.16 ตามลำดับ ซึ่งถือว่าต่ำกว่าเกณฑ์น้อยที่สุด แต่เมื่อวิเคราะห์ความสำคัญในการตัดสินใจทางคลินิกโดยการใช้ Parkes error grid analysis พบว่าความผิดพลาดจากการตรวจด้วยเครื่องตรวจวัดระดับน้ำตาลทรูรีซอลท์ในการตรวจเลือดครบส่วนทั้งจากปลายนิ้วและจากหลอดเลือดดำนั้น ร้อยละ 100 อยู่ใน zone A หรือ zone B ทั้งสองวิธี ซึ่งถือว่าไม่มีผลหรือมีผลน้อยต่อการตัดสินใจทางคลินิก

สรุป: การใช้เครื่องตรวจวัดระดับน้ำตาลทรูรีซอลท์ในเวชปฏิบัติโดยการตรวจเลือดครบส่วนทั้งจากหลอดเลือดฝอยและจากหลอดเลือดดำในผู้ป่วยเมื่อเปรียบเทียบกับระดับน้ำตาลในพลาสมาโดยการตรวจจากห้องปฏิบัติการนั้นมีความแม่นยำอยู่ในเกณฑ์ที่ยอมรับได้ ความผิดพลาดที่พบไม่มีผลหรือมีผลน้อยต่อการตัดสินใจทางคลินิก