Evaluation of the clinical accuracy of six portable blood glucose meters in dogs

Min-Keun Shin1,†, Hakhyun Kim1,†, Taesik Yun1, Ji-Houn Kang2,*, Byeong-Teck Kang1

1Veterinary Teaching Hospital, College of Veterinary Medicine, Chungbuk National University, Cheongju 28644, Korea
2Western Veterinary Medical Center, Seoul 04101, Korea

Abstract: Portable blood glucose meters (PBGMs) are widely used because of their practicality. However, the accuracy of PBGMs has frequently been questioned. The objectives of this study were to evaluate factors that might interfere with measurements made using PBGMs, and to assess the clinical utility of 6 PBGMs. The glucose concentrations measured using the PBGMs were compared with those obtained using a reference method. The agreement between the measured values was assessed using Spearman correlation analysis, Passing-Bablok regression analysis, Bland-Altman plots, and consensus error grid analysis. Mann-Whitney and Kruskal-Wallis tests were performed to identify the parameters affecting glucose measurement. The results indicated that all of the PBGMs tested perform adequately for use in veterinary practice. In most cases, measurements made using PBGM corresponded well with the blood glucose values obtained using the reference method. Error grid analysis revealed that most of the PBGM values fell within zones A and B. However, some measurements of blood glucose concentrations < 80 mg/dL fell into zone C. PCV, and triglyceride and total protein concentration, significantly affected the output of some of the PBGMs. Therefore, clinicians should be aware of the characteristics of the PBGM that they use.

Keywords: anemia, dogs, hematocrit, hypertriglyceridemia, hypoglycemia

Introduction

In veterinary practice, measurements of blood glucose concentrations are often used to make diagnoses and monitor patients [1-8]. In particular, glucose monitoring is essential for the management of diabetes, including the creation of a blood glucose curve. The reference method for the measurement of blood glucose concentration is the use of a chemistry analyzer and the hexokinase reaction [1,2,9,10]. However, this method involves animals visiting a hospital, undergoing venipuncture, and having a relatively large volume of blood collected on each occasion.

Portable blood glucose meters (PBGMs) are pocket-sized, relatively inexpensive devices that can be used to rapidly and easily measure blood glucose concentration. They can be used to screen animals for diabetes, monitor the status of critical patients, and plan short-term treatment strategies. Therefore, many studies have been conducted regarding the performance of PBGMs in human medicine and of PBGMs designed for humans being used in veterinary practice. The accuracy of PBGMs has frequently been questioned [11-13], and has been shown to vary according to the actual glucose concentration, as demonstrated by the identification of differences in the glucose values obtained using PBGMs and the reference method [1,3,5,6].

In human medicine, a number of factors, including packed cell volume (PCV), hemolysis, anemia, polycythemia, dehydration, serum triglyceride (TG), serum uric acid, blood pH, environmental temperature, and oxygen concentration, have been shown to interfere with blood glucose measurement and reduce the accuracy of PBGMs [5,6,14,15]. The American Society for Veterinary Clinical Pathology guidelines also list a number of factors affecting glucose measurement, including hematocrit, hyperlipidemia, bilirubin concentration, blood oxygen tension, blood pH, administered drugs, and other disease states [16]. These variables raise concern regarding the potential for measurement errors, which could affect clinical decision-making or result in erroneous adjustments to the insulin dose administered to diabetic dogs [10].
Therefore, the objectives of the present study were to compare the blood glucose concentrations obtained using PBGMs with those obtained using the reference method, to identify factors that interfere with the accurate measurement of glucose using PBGMs, and to evaluate the clinical utility of 6 PBGMs, including 2 manufactured in Korea.

**Materials and Methods**

**Dogs**

This study was performed between May and July 2015, and was approved by the Institutional Animal Care and Use Committee of the Laboratory Animal Research Center of Chungbuk National University (CBNUA-855-15-01). Sixty-seven dogs had been presented to the university veterinary medical center with various diseases, and blood samples were collected as part of routine diagnostic testing. All the owners provided informed consent for the blood sampling of their dogs prior to the dogs’ enrollment in the study.

**Glucose measurement devices**

Six PBGMs were evaluated: the AlphaTrak2 (Abbott Laboratories, Abbott Park, IL, USA), iPet (Ulticare, Excelsior, MN, USA), OneTouch Ultra (LifeScan Inc., Milpitas, CA, USA), Cerapet (Greencross Medis Corp., Cheonan, Korea), VetMate (i-SENS Inc., Seoul, Korea), and Optium Xceed (Abbott Diabetes Care Inc., Alameda, CA, USA) (Table 1). All 6 devices display “LO” or “HI” when the measured glucose concentration is less than or greater than, respectively, the limits of their measurement ranges. Any blood samples for which one or more of the meters provided a result of “LO” or “HI” were excluded from the study. For quality control, the manufacturer’s control solutions were tested each time a new test strip box was opened.

Glucose concentrations were also measured using a chemistry analyzer (Hitachi 7020, Hitachi High-Technologies Co., Tokyo, Japan) and the hexokinase reaction, which is the generally accepted reference method for the determination of glucose concentration. TG and total protein (TP) concentrations were measured using the same chemistry analyzer.

**Experimental protocol**

Blood samples were collected from a jugular vein using a 3 mL plastic syringe. A drop of blood was first expelled onto disposable gauze, then further blood drops were touched to the end of a test strip for each PBGM. Immediately afterwards, 2 mL of blood was expelled into a plain tube, which was centrifuged at 1,200 × g for 5 min, within 15 min. The harvested serum was decanted into 2 microcentrifuge tubes and stored at −70°C until assayed. One tube was used to measure the serum glucose concentration with each of the 6 PBGMs, and the other was used to measure TG, TP, and glucose concentrations using the chemistry analyzer. PCV was measured by filling micro-hematocrit tubes with fresh blood and centrifuging them in a micro-hematocrit centrifuge at 11,800 × g for 3 min, after which the PCV was read from a tube reader card.

**Intra- and inter-assay coefficients of variation**

Each PBGM was used to measure the glucose concentration of 10 blood samples 5 times within a 15 min period. These samples were then also measured using the reference method and divided into 5 glucose ranges: samples had a glucose concentration of < 100 mg/dL (n = 2), 100–199 mg/dL (n = 2), 200–299 mg/dL (n = 2), 300–400 mg/dL (n = 3), and > 400 mg/dL (n = 1). To evaluate inter-assay variation, glucose was measured in 8 blood samples using the same 2 meters for each type of PBGM. The coefficient of variation was calculated to indicate the meter-to-meter variation for each type of PBGM.

**Statistical analyses**

Data were analyzed using statistical software (SPSS Statistics Version 22, IBM Inc., Armonk, NY, USA; GraphPad Prism Version 6.01, GraphPad Software, La Jolla, CA, USA; Matlab Version 2018a, The Mathworks, Natick, MA, USA). The p < 0.05 was considered to represent statistical significance.

The relationships between glucose values obtained using PBGMs and the reference method were analyzed using Spearman’s correlation analysis. Passing-Bablok regression analysis was used to evaluate potential systematic and proportional bias associated with the use of each PBGM. Because the values obtained using the PBGMs and the reference method did not show direct proportionality, the PBGMs could possess systematic or proportional bias. Bland-Altman plots were then used to evaluate the accuracy of PBGMs.
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compared with the reference method [1-3,8].

The effects of PCV, TG, and TP on glucose values obtained using PBGMs were evaluated by comparing the absolute differences in the glucose concentrations obtained using the reference method and each PBGM. The Mann-Whitney test was used to evaluate the difference between samples with low PCV and normal PCV (37.3–61.7%), and between samples with normal TG (21–116 mg/dL) and high TG. Depending on their TP concentration, samples were divided into low TP, normal TP (5.4–7.1 g/dL), and high TP groups. The absolute differences in the glucose values obtained using the PBGMs and the reference method between the 3 groups were analyzed using the Kruskal-Wallis test.

The clinical accuracy of each PBGM was evaluated using consensus error grid analysis [1,3,6-8,17,18]. The grid was divided into 5 zones with a differing degree of accuracy. In zone A, there is no effect on clinical decision-making. In zone B, clinical decision-making may be somewhat affected, but with little or no effect on the clinical outcome. In zone C, clinical decision-making is affected, and this is likely to affect the clinical outcome. In zone D, clinical decision-making is affected, and may be associated with significant clinical risk. In zone E, clinical decision-making is affected, and may be associated with a dangerous outcome. The International Organization for Standardization (ISO) 15197:2013 recommends that 99% of measured values should be within zones A and B [19,20].

**Results**

A total of 219 samples with glucose concentrations ranging from 13 to 564 mg/dL, as determined using the reference hexokinase method, were included in this study. Seventy-four of the samples had a glucose concentration < 100 mg/dL, 59 samples 100–199 mg/dL, 36 samples 200–299 mg/dL, 31 samples 300–399 mg/dL, and 19 samples > 400 mg/dL.

Intra-assay coefficients of variation were calculated for the measurement of concentrations < 100 mg/dL, 100–199 mg/dL, 200–299 mg/dL, 300–399 mg/dL, and > 400 mg/dL. For the AlphaTrak2 these were 3.8%, 1.3%, 2.0%, 3.5%, and 2.1%, respectively; for the iPet, 2.7%, 1.9%, 3.8%, 1.7%, and 1.4%, respectively; for the OneTouch Ultra 5.7%, 1.3%, 2.4%, 2.0%, and 2.3%, respectively; for the Cerapet 4.5%, 3.0%, 1.7%, 1.7%, and 1.5%, respectively; for the VetMate 9.3%, 1.8%, 3.0%, 3.8%, and 2.9%, respectively; and for the Optium Xceed 4.8%, 1.9%, 3.8%, and 3.8%, respectively. The inter-assay coefficients of variation were 2.9%, 0.5%, 2.1%, 3.4%, 1.4%, and 3.2% for the AlphaTrak2, iPet, OneTouch Ultra, Cerapet, VetMate, and Optium Xceed, respectively.

The Spearman correlation coefficients for the comparison of each PBGM with the reference method were indicative of strong positive linear relationships (all \(p < 0.001\)). The correlation coefficients were 0.951, 0.955, 0.959, 0.948, 0.947, and 0.952 for the AlphaTrak2, iPet, OneTouch Ultra, Cerapet, VetMate, and Optium Xceed, respectively.

Passing-Bablok regression analyses of the relationships between the values generated using each PBGM and the reference method are shown in Fig. 1. Use of the AlphaTrak2 was associated with a slope of 1.18 (95% confidence interval [CI], 1.14 to 1.22), an intercept of −3.80 (95% CI, −9.79 to 2.16), and proportional bias. Use of the iPet was associ-

![Fig. 1. Passing-Bablok regression analyses reveal a linear relationship between blood glucose values obtained using the PBGMs and the reference method. PBGM, portable blood glucose meter; solid line, the regression line; dashed line, confidence interval for the regression line; dotted line, identity line; A, AlphaTrak2; B, iPet; C, OneTouch Ultra; D, Cerapet; E, VetMate; F, Optium Xceed.](image-url)
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Use of the OneTouch Ultra was associated with a slope of 1.02 (95% CI, 0.99 to 1.05), an intercept of 17.96 (95% CI, 12.57 to 23.08), and both proportional and systematic bias. Use of the OneTouch Ultra was associated with a slope of 1.02 (95% CI, 0.99 to 1.05), an intercept of

Fig. 2. Bland-Altman plots demonstrating the accuracy of the PBGMs. X axis and Y axis shows the serum glucose concentration measured by the reference method and the respective differences between glucose concentration in whole blood measured by PBGM and the serum glucose concentration measured by the reference method for 219 samples, respectively.

PBGM, portable blood glucose meter; dotted line, the mean difference in the glucose concentrations measured by the PBGM and the reference method; A, AlphaTrak2; B, iPet; C, OneTouch Ultra; D, Cerapet; E, VetMate; F, Optium Xceed.
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−16.99 (95% CI, −21.36 to −12.34), and systematic bias. Use of the Cerapet was associated with a slope of 0.76 (95% CI, 0.73 to 0.78), an intercept of 31.91 (95% CI, 28.47 to 36.23), and both proportional and systematic bias. Use of the VetMate was associated with a slope of 1.25 (95% CI, 1.20 to 1.29), an intercept of −11.88 (95% CI, −19.15 to −7.53), and

Fig. 3. Bland-Altman plots demonstrating the accuracy of the PBGMs for serum samples. X axis and Y axis shows the serum glucose concentration measured by the reference method and the respective differences between glucose concentration in serum measured by PBGM and the serum glucose concentration measured by the reference method for 154 samples, respectively. PBGM, portable blood glucose meter; dotted line, mean difference in the glucose concentrations measured by the PBGM and the reference method; A, AlphaTrak2; B, iPet; C, OneTouch Ultra; D, Cerapet; E, VetMate; F, Optium Xceed.
both proportional and systematic bias. Finally, use of the Optium Xceed was associated with a slope of 1.04 (95% CI, 1.00 to 1.07), an intercept of −9.79 (95% CI, −14.13 to −6.00), and systematic bias.

Bland-Altman plots revealed differences between values obtained using the reference method and the individual PBGMs (Fig. 2). There were no clear differences in the hypoglycemic and normoglycemic ranges, but the discrepancies increased gradually with the blood glucose concentration value obtained using the reference method increased. In the hyperglycemic range, most blood glucose values measured using the AlphaTrak2, iPet, and VetMate were overestimates and a few were slight underestimates. The Cerapet commonly underestimated blood glucose, but occasionally overestimated it. By contrast, the OneTouch Ultra and Optim Xceed did not demonstrate consistent over- or underestimation.

According to Bland-Altman plots of serum sample values (Fig. 3), most serum glucose concentrations measured using PBGMs were higher than those obtained using the reference method (AlphaTrak2, 100%; iPet, 99.4%; OneTouch Ultra; 90.9%; Cerapet, 90.9%; VetMate, 99.4%; and Optium Xceed, 96.1%). However, because 65 of the 219 serum samples measured gave a “HI” output using the PBGMs, these 65 samples were excluded from the Bland-Altman plots for serum samples (Fig. 3). Their glucose concentrations were 276–564 mg/dL, as determined using the reference method.

The absolute differences in the blood glucose values in the samples categorized according to their PCV, TG or TP concentrations, were compared to evaluate the effect of each parameter on glucose measurement using the PBGMs (Table 2). Significant differences were found between the low and normal PCV groups when using the iPet and OneTouch Ultra. The iPet showed a greater discrepancy in the low than in the normal PCV group, while the OneTouch Ultra showed a greater discrepancy in the normal PCV group. The AlphaTrak2, iPet, Cerapet, and VetMate demonstrated significant differences between the normal and high TG groups, and all of these 4 PBGMs demonstrated large differences in the high TG group. The OneTouch Ultra and Optim Xceed showed significant differences between the low, normal, and high TP groups, with a greater difference in the normal than in the low TP group.

Error grid analysis showed that all of the values obtained using the OneTouch Ultra and Optim Xceed were within zones A and zone B. In addition, 99% of the values obtained using the AlphaTrak2, Cerapet, and VetMate were within zones A and B. The AlphaTrak2, iPet, Cerapet, and VetMate yielded some values in zone C: 0.9%, 6.4%, 0.5%, and 0.5%, respectively (Table 3). However, these samples only had reference glucose concentrations of <100 mg/dL (measured between 13 and 80 mg/dL using the reference method). None of the samples were classified into zones D or E.

### Discussion

In the present study, the accuracy of 6 portable blood glucose meters was assessed by comparing the differences between the values obtained using each PBGM and the reference method. We confirmed that variation in PCV, TG and TP concentrations, can lead to inaccurate values being generated by some PBGMs. Finally, we evaluated the potential for these errors to lead to mistakes in medical decision-making using consensus error grid analysis.

All of the 6 PBGMs yielded values that significantly correlated with those obtained using the reference method. However, 5 PBGMs, excluding the AlphaTrak2, demonstrated systematic bias, and four, excluding the OneTouch Ultra and Optim Xceed, demonstrated proportional bias. These biases could lead to misinterpretations. In the hyperglycemic range, glucose concentrations measured using the AlphaTrak2, iPet, and VetMate were generally higher than those measured using consensus error grid analysis.

#### Table 2. Absolute differences in glucose values between dogs that had normal and abnormal values of PCV, TG, or TP

| Meter          | Low PCV (n = 55) | Normal PCV (n = 163) | p value | Normal TG (n = 130) | High TG (n = 87) | p value | Low TP (n = 54) | Normal TP (n = 141) | High TP (n = 24) | p value |
|---------------|-----------------|----------------------|---------|---------------------|-----------------|---------|----------------|---------------------|-----------------|---------|
| AlphaTrak2    | 27, 12–45       | 22, 8–51             | 0.2242  | 17, 7–34.25         | 33, 15–65       | <0.0001 | 29.5, 14.75–53.25 | 22, 8–48.5          | 18.5, 5.5–37.5   | 0.0506  |
| iPet          | 54, 39–73       | 44, 31–58            | 0.0230  | 41, 31–58           | 63, 39–107      | <0.0001 | 54.5, 36.75–80.75 | 45, 33–74          | 45.5, 29.75–62   | 0.4745  |
| OneTouch Ultra| 11, 6–19        | 20, 10–34            | 0.0002  | 18, 10–27           | 18, 7–35        | 0.8797  | 10, 6–21         | 19, 10–34           | 19.5, 13–27      | 0.0018  |
| Cerapet       | 14, 9–24        | 20, 10–43            | 0.0526  | 15.5, 8.5–26        | 25, 12–48       | <0.0001 | 16, 10.75–32.75  | 17, 8.5–41.5        | 19.9, 9.25–36    | 0.9732  |
| VetMate       | 30, 13–57       | 21, 9–57             | 0.3025  | 18, 7–37            | 48, 16–77       | <0.0001 | 27.5, 12.25–47.25 | 22, 9.5–61         | 20, 7–37.25      | 0.7401  |
| Optim Xceed   | 13, 6–24        | 15, 7–29             | 0.1222  | 13, 7–22            | 17, 6–37        | 0.0532  | 9, 4–16.5        | 16, 8–31           | 16, 5–24.75      | 0.0023  |

Data are summarized using the median, interquartile range, and (range).

PBGM, portable blood glucose meter; PCV, packed cell volume; TG, triglyceride; TP, total protein.

* Differences between groups were statistically significant (p < 0.05).
using the reference method, whereas the values obtained using the Cerapet were mostly lower than those obtained using the reference method. In some cases, this consistent over- or underestimation of blood glucose by a PBGM may help clinicians to predict the actual blood glucose concentration more accurately than if an error is relatively random and unpredictable.

Previous human studies showed that low PCV can lead to
overestimates of blood glucose using some PBGMs, while high PCV can lead to underestimation, and these trends are more marked in the presence of hyperglycemia [16,21-24]. In this study, data from one PBGM were consistent with these previous findings, but data from another PBGM showed the opposing trend, and data obtained using the others were not significantly affected by PCV. However, when comparing the data for whole blood samples (Fig. 2) and serum samples (Fig. 3), it was apparent that most of the glucose measurements were more substantially overestimated in serum than in blood samples using PBGMs. The lack of agreement with the findings of previous studies may be explained by few samples in the present study having very low PCV, as would be the case if the dogs had severe anemia. Nevertheless, we have shown that the output of the AlphaTrak2, Cerapet, Vet-Mate, and Optium Xceed is not affected by canine PCV when it is between 22.4% and 63.5%.

TG and TP concentrations have also been previously shown to affect the accuracy of PBGMs [14-16,25]. Lipid and protein, when present at very high concentrations, displace water from the blood, thereby reducing the volume of water present to react with a glucometer strip [14,15]. Therefore, high concentrations of either may interfere with some measurement methodologies and lead to an underestimation of blood glucose by some PBGMs. In this study, the data obtained using some PBGMs were consistent with those from previous studies, but not for every device. Thus, the effects of TP, TG, and PCV seem to depend on the characteristics and measurement methodology of each PBGM, rather than being universal. Therefore, clinicians should make themselves aware of the measurement methodology used by their PBGM of choice, the specific factors that can affect its output, and the disease processes that could significantly alter these factors, to more precisely predict the actual blood glucose concentration.

The error grid analysis indicated that all of the PBGMs are suitable for clinical use. Interestingly, even though the discrepancies between the glucose values obtained using the PBGMs and the reference method were much greater in the hyperglycemic range, none of the samples were placed in zone C. The samples that were in zone C, in which clinical decision-making is likely to be affected, all had concentrations < 100 mg/dL, and demonstrated small differences throughout the measured range of 13–80 mg/dL. This seemed to be due to the fact that, even if the differences were not large, hypoglycemic dogs could have been misdiagnosed as normal, leading to inappropriate clinical inaction. Therefore, particular attention should be paid when a PBGM displays a hypoglycemic value. PBGMs are commonly used to monitor blood glucose in diabetic dogs at home, fortunately meaning that most caregivers will be dealing with normo- and hyperglycemic values, rather than hypoglycemic values. However, if signs of hypoglycemia are observed, even if the measured glucose value is normal, careful observation is necessary, and the owner should consider taking their dog to the hospital. For effective diabetes management, proper selection of insulin type and dose, and accurate blood glucose measurement, is required. In this study, all of the PBGMs provided similar glucose values to the reference method. Nevertheless, there were some samples that yielded very different values, and these tended to be in the hyperglycemic range. However, inaccuracies in the measurement of hyperglycemic concentrations are unlikely to alter the clinical outcomes. Measured values lower than the actual blood glucose concentration could be mistaken for better diabetic control than is actually present, meaning that lower insulin doses are administered than are actually required, which may delay an improvement in clinical signs. Conversely, values above the actual blood glucose concentration may increase the likelihood of insulin overdose, causing a Somogyi response or hypoglycemia.

Aged dogs often have not only diabetes, but other concurrent diseases. It is difficult to accurately measure blood glucose concentration in dogs with multiple underlying diseases that affect PCV, TP, and/or TG alongside severe hyperglycemia. Thus, when planning the treatment of diabetic dogs, the measured glucose values should be carefully interpreted, considering the above factors. The differences in the values obtained using the PBGMs and the reference method were small when the actual blood glucose was < 100 mg/dL. However, even small errors in this range can cause hypoglycemia to be mistaken for normoglycemia. In addition to the use of PBGM, contaminants, such as hair from the user or patient, and inappropriate measuring technique can generate errors [14]. These errors can lead to more significant risk for a hypoglycemic patient. Therefore, the caregiver should be educated in the proper use of their PBGM and regarding the clinical signs of hypoglycemia. If the clinical signs and the glucose values obtained using PBGM are not consistent, the owner should be encouraged to consult their veterinarian and a more accurate glucose measurement should be obtained using the reference method.

There were several limitations to the present study. When using PBGMs in dogs, capillary blood obtained from the foot pad or ear pinna is usually used. However, because it was difficult to obtain enough capillary blood for glucose measurement using all 6 of the PBGMs and the reference method, we used only venous blood in this study. Second, we used error grid analysis to evaluate the clinical suitability of each PBGM, but this analysis is based on human diabetes treatment, and the target glucose range for humans and dogs tends to be different. We have determined that it is appropriate to apply this human-based analysis to dogs, but a specific canine error grid analysis may have yielded different results.

PBGMs are widely used because of their convenience for the monitoring of glucose concentrations in diabetic dogs. In the present study, some PBGMs consistently over- or underestimated glucose concentration, and some were affected by PCV, TP and TG concentrations. However, despite these
imperfections, all of the PBGMs were found to be appropriate for general clinical use. Nevertheless, when using a PBGM, it is important to understand the strengths and weaknesses of the device. Clinicians should interpret the measured glucose concentration on the basis of the characteristics of the particular device being used.

Acknowledgements

All authors agree to the conditions outlined in the copyright assignment form. This research was supported by the Basic Science Research Program, through the National Research Foundation of Korea, which was funded by the Ministry of Science, ICT, and Future Planning (NRF-2016R1A1A05005395). The authors would like to thank all the owners of the dogs included in this study.

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