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Comparison of Two Veterinary Blood Glucose Meters and One Human-Based Glucose Meter for Use in Dogs

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Abstract:

BACKGROUND: Recently, tendency to use veterinary specific Portable blood glucose meter (PBGMs) has increased. However, assessment of their analytical and clinical accuracy is a matter of concern.

OBJECTIVES: To assess accuracy of two veterinary (AlphaTRAK2 and CERA-PET) and one human-based (Bionime) PBGMs for canine blood samples.

METHODS: In this cross-sectional study, a total of 160 client-owned dogs with various signalment and disease were included. Venous blood samples were obtained from a peripheral vein of each dog and blood glucose was measured with the three PBGMs. Immediately afterward, serum was harvested and sent to laboratory until analysis with reference methods.

RESULTS: Blood glucose measured with the reference method was 21 to 650 mg/dl. There was a significant correlation between results of the reference method and PBGMs. Both of the veterinary specific PBGMs showed significant proportional and constant bias, nevertheless, no proportional and constant bias were recorded for human-based one. Mean deviation from reference methods was -7.4, 9.8, and -3.9 for AlphaTRAK2, CERA-PET, and Bionime respectively. Although most of the PBGMs readings lay in the calculated 95% limits of agreement, none of the devices completely satisfied the International Organization for Standardization (ISO 15197:2013) criteria. Error grid analysis revealed all measurements for AlphaTRAK2 in zone A and B, while CERA-PET demonstrates one measurement in zone D. Bionime showed two measurements in zone C and D.

CONCLUSIONS: Only the result of AlphaTRAK2 could be interpreted without any hazardous outcome on medical decision making.

Keywords:

Blood Glucose, Diabetes mellitus, Dog, PBGMs, Veterinary

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Introduction

As a Primary source of energy in companion animals, Glucose plays an important role in the regulation of body function. Thus, tight glycemic assessment is a crucial and initial step in evaluating, monitoring, treating and management of many pathologic conditions cause hypoglycemia and hyperglycemia in dogs, particularly diabetes mellitus (Johnson et al., 2008; Cohn et al., 2000). Glucose can be measured via different methods and samples. In veterinary medicine, chemistry analyzer which utilizes enzymatic reactions such as hexokinase and glucose oxidase are considered as the gold standard. The procedure is time consuming and serum or plasma sample is required (Kang., 2016; Sacks., 2015; Lane 2105., Nelson., 2012). Portable Blood Glucose Meters (PBGMs) provide rapid, inexpensive, field accessible and repeated measurements of blood glucose concentration by means of merely a small amount of whole blood sample. PBGMs are now being widely used in most of the veterinary settings such as hospitals and clinics. In addition, they allow home monitoring for better glycemic control of diabetic status by the pet owner to determine glucose nadir following insulin administration, insulin efficacy and time of peak insulin effect (Allison., 2010; Casella., 2005). Several PBGMs from various manufacturers are now available on the market. However, accuracy of human-based PBGMs designed for the capillary blood samples varies considerably when used in dogs and other animals (Quandt., 2018; Fracassi et al., 2017; Summa, 2014). Recently, tendency to employ PBGMs specifically designed for use in dogs and cats has increased, devices are more accurate and precise than human-based ones (Clemmons, 2016; Kang., 2016; Higbie, 2014; Cohen., 2009). Based on the literature, to date, AlphaTRAK2 is the one of the most accurate veterinary specific PBGMs all around the world and CERA-PET is now readily available in Asia (Kang., 2016; Cohen., 2009). To our knowledge, human-based PBGM, Bionime GM110 (Bionime) has not been previously assessed for clinical use in dogs.

The aim of the study presented here was to evaluate the clinical and analytical accuracy of three commercially available PBGMs against reference chemistry analyzer, over a wide range of glucose concentration in diabetic and non-diabetic dogs. In addition, since access to veterinary specific PBGMs might not be easy in some regions or settings, we want to compare the result obtained with one of the available human-based PBGMs with veterinary specific meters to see whether we can employ this human-based device instead with no or minimal difference in the therapeutic decision or not.

Material and Methods

Experimental protocol and blood sampling: This is a cross-sectional study and took place in the Tehran Small Animal Research Referral and Teaching Hospital. After signing the designed consent form by the owners, dogs were manually restrained and 2 ml of whole fresh blood was drawn from the cephalic veins, with a 23-gauge needle and a syringe. One drop of the withdrawn blood was assessed by each PBGM and the rest was transferred to plain collecting tubes. The order of which devices were used was determined randomly by statistical programs. Immediately afterward, with-

in 15 min samples were centrifuged, serum was harvested and kept in -20 °C refrigerators until analysis. The whole procedure was approved by the local ethics and welfare committee of our veterinary medicine faculty.

Dogs: Total of 160 client-owned dogs with various signalments and diseases were included in this study. The study was conducted from Sept 2015 until April 2017. Inclusion criteria was blood sampling for routine check-up and treatment follow-up.

Description of chemistry analyzer and PBGMs: The automated chemistry analyzer (Selectra Pro M, ELITech group) measures plasma glucose level via an enzymatic hexokinase oxidase (YSI) reaction. This device can determine glucose range from 40 to 650 mg/dl within 10 min. Selectra Pro M was considered as the reference method in this study and the result of each PBGM was compared against it. The automated analyzer was calibrated daily by using the commercial quality control and all tests were performed by trained laboratory technicians.

Three PBGMs were used in current study. Two of them were veterinary specific glucometers and one is validated for the human diabetic patients.

The AlphaTrak2® (Abbott Laboratories, Abbott Park, IL, USA) veterinary PBGM measures blood glucose by means of electrochemical technology and glucose dehydrogenase enzymatic reaction. This device requires minimum blood volume of 0.3 µl and the result is shown in approximately 8 seconds. The linear range of 20 to 750 mg/dl was reported by the manufacturer.

The CERA-PET® (Ceragem Medisys, Seoul, Korea) veterinary PBGM employed electrochemical technology and glucose dehydrogenase enzymatic reaction for blood glucose measurement and needs 0.6 µl of a blood sample. Results appeared in 5 seconds and the testing range is 10 to 900 mg/dl.

The Bionime GM110® (Bionime, Taiwan) measures blood glucose via glucose oxidase-based amperometric electrochemistry. Testing time is reported to be 8 s and the recommended sample size is between 1.4 to 2.5 µl. The measurable range is 10 to 600 mg/dl.

For all PBGMs, if glucose concentration is higher or lower than the detectable ranges, HI or LO was displayed on the device monitors respectively, and the corresponding results were excluded from the study. Each PBGM was calibrated according to manufacturer's guideline and provided control solution at the onset of the study, every week, and whenever new test strip box was needed. Also, all sampling processes and devices were performed in similar environmental condition with a single trained investigator to minimize associated errors.

Data analysis: Data were analyzed with a commercially available medical statistics program (Medcalc version 17.9). Values are expressed as the mean ± standard deviation (SD). Glucose values reported LO or HI by a PBGM were excluded from statistical analysis, as these values could not be compared with the reference method values.

To assess the precision of PBGMs, one blood sample in each glycemic range (hyperglycemic, normoglycemic and hypoglycemic) is measured 10 times with 15 s intervals and coefficient of variance (CV) calculated for all PBGMs. Correlation coefficients (r) between each PBGM and reference analyzer were calculated, and values were interpreted as follows: 0.85 to 1.00,

Table 1. Descriptive statistics (mean±SD, minimum and maximum value) of glucose level form dogs by reference methods and PBGMs.

	Mean±SD	Minimum	Maximum
YSI mg/dl	168.06±3.81	21	624
AlphaTRAK2 mg/dl	175.47±1.3	20	681
CERA-PET mg/dl	158.3±22.71	18	513
Bionime mg/dl	172.1±1.89	26	650

Table 2. CV of PBGMs used in this study.

CV%	Hyperglycemic	Normoglycemic	Hypoglycemic
AlphaTRAK2	4.1%	3.8%	4.1%
CERA-PET	6.2%	5.1%	5.7%
Bionime	4.6%	4.7%	4.4%

Table 3. Error grid analysis of blood glucose value as measured with PBGMs.

Devices	Zone A	Zone B	Zone C	Zone D	Zone E
AlphaTRAK2	94.27	5.73	0	0	0
CERA-PET	88.54	10.83	0	0.64%	0
Bionime	92.36	6.37	0.64	0.64	0

very high; 0.60 to 0.84, high; 0.40 to 0.59, moderate; 0.20 to 0.39, low; and 0 to 0.19, little, if any, correlation respectively. Passing-Bablok regression analysis was used to determine constant and proportional bias between the reference method and PBGMs. If 95% CI for the intercept included value 0, it is implying that there was no constant bias. If 95% CI for the slope included value 1, then it is implies that there was no proportional bias (Bablok and Passing., 1985).

In order to analyze the agreement between two methods, Bland-Altman plots were constructed and the result of each PBGM was compared with reference method (Bland and Altman., 2010).

In addition, to assess the clinical accuracy of PBGMs, error grid analysis (EGA) was evaluated.

The EGA divided the plot of chemistry-analyzer values (x-axis) versus the PBGM values (y-axis) into 5 different zones associated with the following risk levels: values in zone A, indicate clinically accurate measurement, values in zone B, altered clinical action without any harmful effect on medical action. Values in zone C would lead to misinterpretation and affect clinical outcome and finally, values in zones D and E, altered clinical action and treatment plan associated with jeopardous consequences (Kang., 2016; Clarke et al., 1987).

Referencing the International Organization for Standardization (ISO 15197: 2013) requirement, if blood glucose level is <100 mg/dl, 95% of the measurement must be within ±15 mg/dl of the reference value, and when blood glucose level ≥100 mg/dl, then 95% of the measurement should be within ±15%. If a PBGM passes this standard, it could be considered accurate (Brito-casillas., 2014).

Results

Totally, 157 blood samples from 157 dogs were included in this study. Three samples were excluded from the statistical analysis due to hemolysis, technical problems from

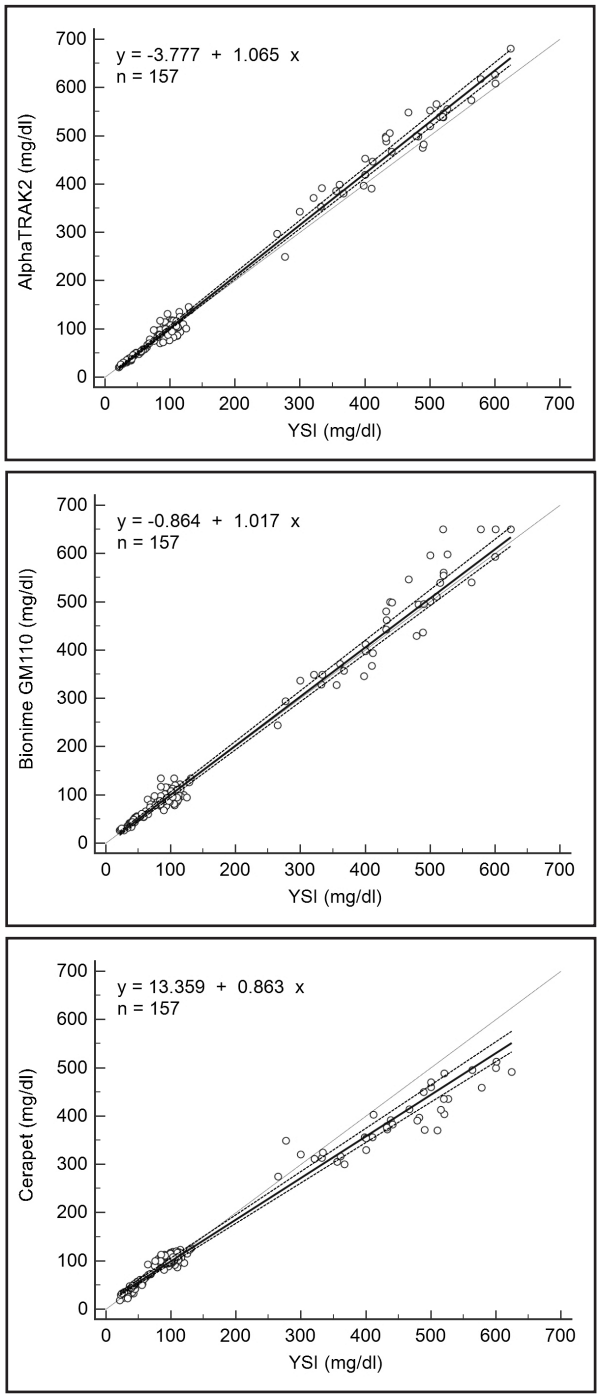

Figure 1. Passing-Bablok linear regression analysis of each PBGM versus the reference method.

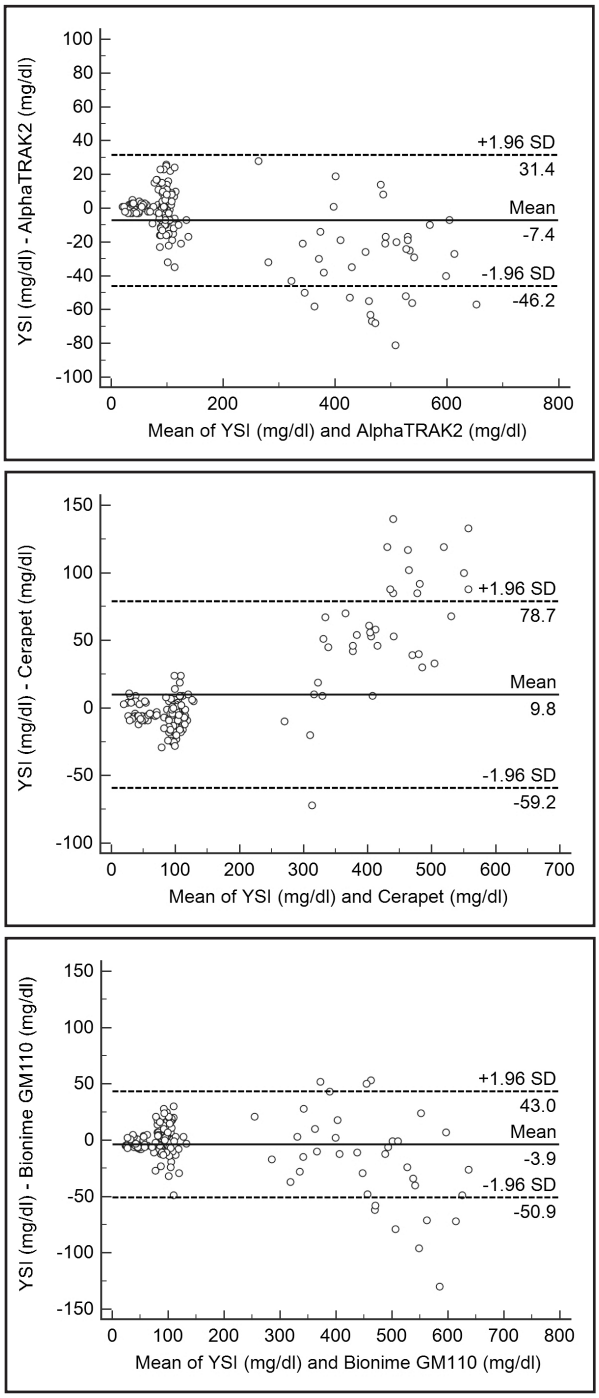

Figure 2. Bland-Altman difference plots of blood glucose concentrations measured with the PBGM and reference methods.

a reading from one PBGM, and HI reading from Bionime, respectively. Blood glucose ranged from 21 to 624 mg/dl when measured with the reference method. Among the study population, 87 dogs were female (68 spayed) and 70 males (45 spayed). Thirty-four dogs were diabetics and 2 had Insulinoma. The mean age of dogs was 5.55 years old. Descriptive statistics were summarized in (Table 1).

There was a very high and positive correlation between blood glucose measured with PBGMs and reference method. The correlation coefficient (r) was 0.995, 0.990,

and 0.991 for AlphaTRAK2, CERA-PET, and Bionime, respectively.

Also, CV for each device in different glycemia was calculated and presented in Table 2.

Among 3 PBGMs used, AlphaTRAK2 and Bionime showed acceptable CV less than 5% in all glycemic ranges. While, value for CERA-PET was more than 5% with different control samples.

Passing-Bablok linear regression analysis of each PBGM versus the reference method is presented in Fig. 1. Veterinary specific PBGMs showed significant constant and proportional bias: AlphaTRAK2 versus reference methods yielded an intercept of -3.78 (95% CI, -6 to -1.72) and a slope of 1.07 (95% CI, 1.05 to 1.09); and CERA-PET presented an intercept of 13.36 (95% CI, 10.77 to 16.35) and a slope of 0.86 (95% CI, 0.84 to 0.9). Human-based PBGM Bionime had an intercept of -0.86 (95% CI, -4.07 to 2.25) and a slope of 1.02 (95% CI, 0.99 to 1.05). Thus, neither constant nor proportional bias exists for this device. On the basis of these findings, CERA-PET exhibit the highest constant bias and none of the meters was identical to the reference method. The Bland-Altman difference plots (Fig. 2) revealed different deviation between PBGSs versus reference method. Mean deviations from reference method were -7.4, 9.8, and -3.9 for AlphaTRAK2, CERA-PET, and Bionime respectively. Almost all the measurements lay in the calculated 95% limits of agreement. (93.36% for AlphaTRAK2 and Bionime, and 93% for CERA-PET).

According to the (ISO 15197:2013), none of the PBGMs used in this study were considered accurate. However, 87.3% of measurements for AlphaTRAK2 were plotted in the desirable acceptance limit. While 81.6% and 66.9% of measurements for Bionime and CERA-PET were within the acceptable limit, respectively.

Error grid analysis (Table 3) revealed all measurements were in zone A and B for AlphaTRAK2. For Bionime, 98.73% (155 samples) were plotted in zone A and B, while 1.28% (2 samples) were plotted in zone C and D. CERA-PET revealed 0.64% (1 sample) measurement in zone D and 98.92 (156 samples) were plotted in zone A and B.

Discussion

PBGMs are pocket-sized devices broadly employed in the most veterinary settings. They offer great advantages over the reference chemistry analyzers due to the small sample required and prompt results. New PBGMs are frequently produced and are available on the market. They readily aid monitoring of blood glucose levels, especially in emergency situations. However, their results can differ among themselves and with the reference analyzers especially when human-based ones have been used (Corradini, 2016; Tauk,2015; Zini, 2009; Hirsch, 2008; Johnson, 2008; Cohn, 2000).

In the present study, among 3 PBGMs utilized, 2 were veterinary specific and the other was for human use.

Veterinary specific PBGMs, AlphaTRAK2, and CERA-PET have been examined previously in different regions (Kang, 2016; Paul, 2011; Cohen, 2009; Wess and Reusch, 2000a, c). Yet the human-based device Bionime is evaluated for the first time in this study for calculating blood glucose level in dogs. We chose this device on the basis of a pilot study performed by the first author.

We found very high and positive cor-

relation between PBGMs and the reference method and correlation coefficient (r) was more than 0.99 for all of the devices. Yet these types of statistics could be misleading, because (r) only shows the strength of association between two methods not the strength of agreement. Moreover, as the extent of the measured value increases, correlation coefficient would increase accordingly. This finding was in agreement with the result of previous study (Wess and Reusch, 2000c).

In order to evaluate the reproducibility of results, precision assessment of all PBGMs was performed and showed CV below 5% for AlphaTRAK2 and Bionime in all glycemic ranges. CERA-PET demonstrated CV more than 5% in all glycemic scopes which were not correlated with a previous study (Kang et al., 2016). AlphaTRAK2 showed the lowest CV in normoglycemic samples (3.8%), while CERA-PET presented the highest CV in hyperglycemic samples (6.2%). On the basis of these findings, AlphaTRAK2 is the most precise meter. Also, Bionime showed acceptable CV in comparison with CERA-PET.

Considering the Passing-Bablok linear regression analysis, the two-veterinary specific PBGMs showed significant proportional and constant bias. This finding was in agreement with the previous study using these devices in dogs (Kang et al., 2016). On the other hand, human-based PBGM had no proportional and constant bias in the present study. To our knowledge, this is the first time Bionime has been utilized for blood glucose determination in dogs and further investigation is warranted for evaluation of the accuracy of this device for the canine blood sample.

In the direction of evaluating agreement between the result of each PBGM versus the reference method, corresponding Bland-Altman difference plot would allow more straightforward interpretation of the results. In this study, roughly most of the measured samples with PBGMs lay in the deliberated 95% limits of agreement with the referenc method. Following ISO recommendations, a PBGM is considered accurate if 95% of the measurements are within ±15 mg/dl of the Reference plasma glucose values when the glucose concentration is <100 mg/dl and within ±15% when it is ≥100 mg/dl. Nevertheless, given the acceptability limits for ISO 15197:2013, none of the PBGMs which we used in this study satisfied the mentioned acceptance criteria. To date none of the PBGMs could meet these criteria completely. In order to find the most suitable device, we should utilize devices which have lower discrepancy for ISO recommendation criteria.

The possible explanation for disagreement in veterinary specific PBGMs could be due to obvious proportional and constant bias. Although statistical evidence of proportional and constant bias was not evident for human-based one, disagreement could be explained partially by the differences in dogs and human blood cells morphology referencing the fact that this device is not calibrated for veterinary use. Although constant and proportional bias alone is not the only essential factor in the accuracy of PBGMs. Furthermore, clinical accuracy is the most prominent subject in the evaluation of PBGMs.

Several studies assessed the human-based PBGMs previously and results were variable among them. Some of these devices reported accurate enough for measuring glucose in dogs (Cohn, 2009; Cohen, 2000; Wess and Reusch, 2000b). Similar to previ-

ous studies, the human-based PBGM used in this study showed lower results in comparison with reference methods.

AlphaTRAK2 and Bionime tend to underestimate the results, especially as the blood glucose level increases. On the contrary, CERA-PET likely overestimates the results in the hyperglycemic state. These findings were in contrast with former studies (Kang et al., 2016; Paul, 2011).

While analytical accuracy accounts for how closely the results of PBGMs being evaluated compares with reference methods, clinical accuracy illustrates the outcome of decision making and treatment based on blood glucose measurement by PBGMs. By virtue of EGA, besides analytical accuracy, we can assign clinical error associated with PBGMs (Klonoff et al., 2012). With respect to the result of EGA in this study, only values of AlphaTRAK2 lies in zone A and B. Thus, the adequate clinical accuracy with no to minimal effect in the therapeutic decision is associated with this device. CERA-PET showed one reading in zone D due to overestimation of blood glucose. Also, Bionime exhibits a couple of measurements in zone C and D caused by overestimation. On the basis of these findings, among the PBGMs which we used in the present study, only AlphaTRAK2 showed adequate clinical accuracy and similar to a previous study, CERA-PET could not be totally suitable for use in dogs (Kang et al., 2016).

Although some of the measurements regarding Bionime and CERA-PET are plotted in zone C and D, we should bear in mind that most of the results of the Bionime lie in zone A (92.36%), while only 88.85% of CERA-PET results were in zone A. If we compare these devices, we can assume that Bionime showed more respectable clinical accuracy in comparison with a veterinary-specific CERA-PET meter.

All the PBGMs used in the study are presented here, designed and labeled for capillary blood samples. Nonetheless, we used venous blood samples. Based on the literature, there is a discrepancy between venous and capillary blood glucose concentration depending on the prandial state (Paul et al. 2011). Since we used venous blood samples for all PBGMs and the reference analyzer, this division should be similar for all methods. Furthermore, most of the previous studies utilized venous sample due to ease of sampling and to prevent frequent puncturing of the corresponding sampling sites (Kang, 2016; Cohn, 2009; Johnson, 2008; Cohn, 2000). Also, it is not feasible to obtain an adequate blood sample from capillary sampling sites for evaluating all three PBGMs and gathering plasma or serum required for the chemistry analyzer at the same time.

There were some limitations in our study. First, we did notassess the effect of HCT on blood glucose level. Polycythemia and anemia could falsely decrease and increase the results of PBGMs respectively (Stockham et al., 2002). We did not have HCT values for all single cases thus, further investigation with mentioned devices and evaluating HCT for each sample is warranted in the future studies.

Second, we used venous blood rather than the capillary blood samples. There are some reports in veterinary and human medicine which indicate that no significant difference exists among different sampling sites for blood glucose determination (Kang, 2016; Nelson, 2012; Park, 2010). Further work through the capillary samples with devices we employed in this study and especially

human-based one could be helpful.

In conclusion, the result of this study demonstrates that only AlphaTRAK2 is clinically acceptable for use in dogs. However, expense and accessibility of PBGMs is another important factor that should be kept in mind when we decide to pick a suitable PBGM for practice. According to the result of our study, there is no significant difference between Bionime and veterinary specific PBGM CERA-PET and we can employ Bionime under some conditions.

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Conflicts of interest

The author declared no conflict of interest.

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مقایسه نتایج حاصل از دو دستگاه گلوکومتر دامپزشکی و یک دستگاه گلوکومتر انسانی برای اندازه گیری گلوکز خون سگ ها

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چکیده

زمینه مطالعه: اخیرا تمایل به استفاده از گلوکومتر های مخصوص دامپزشکی افزایش یافته است. با این وجود ارزیابی دقت آماری و کارآیی بالینی آن‌ها همواره مورد بحث بوده است.

هدف: ارزیابی دقت دو دستگاه گلوکومتر قابل حمل دامپزشکی و یک دستگاه انسانی با روش استاندارد آزمایشگاهی به منظور ارزیابی میزان گلوکز خون در سگ ها بود.

روش کار: در این مطالعه مقطعی تعداد ۱۶۰ قلاده سگ صاحب دار ارجاعی به بیمارستان دانشکده دامپزشکی با شرایط بالینی متفاوت مورد بررسی قرار گرفتند. نمونه خون وریدی، از یکی از ورید های سطحی هر حیوان اخذ و میزان گلوکز آن به وسیله ی هر سه دستگاه اندازه گیری شد. سپس باقی خون اخذ شده به لوله آزمایش ساده منتقل و جهت جداسازی سرم و تعیین مقدارگلوکز به روش استاندارد آزمایشگاهی به آزمایشگاه منتقل شد.

نتایج: محدوده گلوکز اندازه گیری شده به روش استاندارد آزمایشگاهی بین ۴۰ تا ۶۵۰ میلی گرم بر دسی لیتر بود. همبستگی بسیار زیادی بین نتایج روش مرجع و گلوکومتر ها بود. هر دو گلوکومتر دامپزشکی خطای پایدار و مقایسه ای مشخصی را نشان دادند، در حالی که هیچ خطای مقایسه‌ای و پایداری برای دستگاه انسانی ثبت نشد. میانگین انحراف از روش آزمایشگاهی برای دستگاه AlphaTRAK۲، CERA-PET و Bionime به ترتیب ۷/۴- ، ۹/۸ و ۳/۹- بود. اگرچه اکثر خوانش دستگاه ها در محدوده محاسبه شده ۹۵درصد قابل قبول محدودیت توافق قرار داشت، هیچ یک از دستگاه ها نتوانستند به طور کامل شاخص های سازمان جهانی استاندارد را بدست بیاورند. ارزیابی روش آماری ارور گرید، تمام نتایج اندازه گیری شده برای دستگاه AlphaTRAK۲ را در ناحیه A و B نشان داد، در حالی که دستگاه CERA-PET یک اندازه گیری را در ناحیه D نشان داد. دستگاه Bionime دو اندازه گیری را در ناحیه C و D نشان داد.

نتیجه گیری نهایی: بنابراین، تنها نتایج حاصل از دستگاه AlphaTRAK۲ میتواند بدون ایجاد پیامد های خطرناک برای اقدامات بالینی تفسیر و مورد استفاده واقع شود.

واژه‌های کلیدی:
گلوکز خون، دیابت ملیتوس، سگ، دستگاه پرتابل اندازه گیری گلوکز خون، دامپزشکی

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