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Evaluation of Clinical Accuracy of Portable Glucometers in Sheep at the Beginning of the Breeding Season

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ABSTRACT Measurements of blood glucose concentrations are frequently used to diagnose and monitor diseases in sheep. Portable blood glucometers are widely used in human medicine because of their practicality. However, there are not enough studies on the accuracy of these devices in sheep. In this study, it was aimed to determine the changes in the measurement values of two different portable blood glucometers and biochemistry autoanalyzer devices. The study was carried out on a total of 47 Kangal sheep, 17-18 months old, healthy and sick. According to the clinical examination, 35 healthy sheep (Group 1) and 12 patients whose hematocrit and total protein values were higher than the reference values were included in the study (Group 2). Glucose concentrations measured with portable glucometers were compared with the result obtained using the biochemistry autoanalyzer device. The agreement between the measured values was evaluated by Pearson correlation analysis and Bland-Altman plots. In addition, Tukey's test was performed to evaluate glucose measurement between groups. In the study found that there were -3.63% and 6.83% differences in the blood glucose measurement readings between the Optium Xceed (OX), On Call Pluss (CP), and biochemistry autoanalyzer devices in Group 1. These figures were found to be 6.08% and 9.66% in Group 2. The variety of measurement differences between the biochemistry autoanalyzer and glucometers should therefore be known in the clinical evaluation of blood glucose levels.

Keywords: *Glucometer, Glucose, Hematocrit, Sheep.*

ÖZ

Üreme Sezonu Başlangıcında Koyunlarda Portatif Şeker Ölçüm Cihazlarının Klinik Doğruluğunun Değerlendirilmesi

Koyunlarda hastalıkların tanısını koymak ve takibini izlemek için sıklıkla kan glikoz konsantrasyonlarının ölçümlerinden yararlanılmaktadır. Taşınabilir kan glukometreler beşerî hekimlikte pratiklikleri nedeniyle yaygın olarak kullanılmaktadır. Ancak, bu cihazların koyunlarda doğruluğu üzerine yeterli sayıda çalışma yoktur. Bu çalışmada iki farklı taşınabilir kan glukometre ile biyokimya otoanalizör cihazı ölçüm değerlerinin değişimlerinin belirlenmesi amaçlandı. Çalışma 17-18 aylık sağlıklı ve hasta olmak üzere toplam 47 kangal ırkı koyun üzerinde gerçekleştirildi. Yapılan klinik muayene göre 35 sağlıklı koyun (kontrol grubu) ile hematokrit ve total protein değerlerinin referans değerleri dışında yüksek olan 12 hasta koyun çalışmaya dâhil edildi (hasta grubu). Taşınabilir glukometreler ile ölçülen glikoz konsantrasyonları, biyokimya otoanalizör cihazı kullanılarak elde edilen sonuçlarla karşılaştırıldı. Ölçülen değerler arasındaki uyum Pearson korelasyon analizi ve Bland-Altman grafikleri ile değerlendirildi. Ayrıca gruplar arasındaki glikoz ölçümünü değerlendirmek için Tukey testi yapıldı. Çalışmada Grup 1'de Optium Xceed (OX), On Call Pluss (CP) ve biyokimya otoanalizör cihazları arasındaki kan glukoz ölçüm değerlerinin değişimleri sırasıyla, -3.63% ve 6.83% olarak belirlendi. Grup 2 'de ise bu değerler 6.08%, 9.66% olarak saptanmıştır. Sonuç olarak; Klinik olarak kan glikoz seviyelerinin değerlendirilmesinde, biyokimya otoanalizör ile glukometrelerin arasındaki ölçüm farklarının değişimleri bilinmelidir.

Anahtar Kelimeler: *Glikoz, Glukometre, Hematokrit, Koyun.*

INTRODUCTION

Portable glucometers have started to be widely used in the field of medicine due to their practicality. However, the reliability of these devices is a matter of debate and clinical studies are required for their safety. In veterinary practice, blood glucose concentration measurements are frequently used to diagnose and monitor certain diseases (Cohen et al. 2009; Tauk et al. 2015; Renaud et al. 2022). Glucose

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monitoring is necessary to determine some diseases such as pregnancy toxemia, which is frequently encountered in sheep, and to establish a blood glucose curve. Especially in the diagnosis of pregnancy, early diagnosis and taking necessary precautions are important to prevent loss of mother and offspring (Kabakci et al. 2003; Brozos et al. 2011; Aly and Elshahawy 2016).

In practice, a biochemistry autoanalyzer is needed for the measurement of blood glucose concentration in the field of medicine. However, continuous application of this method is impractical in field conditions due to the difficulty of animal transport or the need for equipped laboratories for the examination of blood samples. Portable glucometers are devices used to quickly and easily measure blood glucose concentration. In herd health, blood glucose levels are evaluated to monitor lactating sheep, monitor the condition of critically ill patients, and plan short-term treatment strategies (Wiedmeyer et al. 2005; Mair et al. 2016; Ekici et al. 2021).

The aim of this study is to compare the results of blood glucose concentrations obtained by using 2 portable glucometers with the biochemistry autoanalyzer device. In addition, it is to reveal the changes in these devices of animals whose total protein and hematocrit levels are outside the reference values.

MATERIAL AND METHODS

The study protocol was approved by the Sivas Cumhuriyet University Ethics Committee (Approval No: 2022/534).

This study was carried out a total of 200 head, 17-18 months old healthy and patient Kangal sheep before the breeding season. According to the clinical examination, 35 healthy sheep (Group 1) and 12 patient sheep were included in the study. It was determined that hematocrit (PCV) and total protein (TP) values of all sheep in the patient group were outside the reference values.

Group 1 Healthy group, hematocrit (27-45%), total protein (6.0-7.9 g/dL)

Group 2 Patient group, hematocrit (>45%), total protein (>8 g/dL)

After systematic clinical examination of all animals used in the study, hematocrit measurements were measured with microhematocrit tubes (3 min centrifugation at 11,800 x g in a micro-hematocrit centrifuge). Blood samples were taken from Vena Jugularis of the sheep included in the study using a 2.5 mL plastic syringe. The measurements of fresh blood samples were made in portable glucometer devices AbottOptium Xceed, (USA) and On Call Pluss (German). The blood sample without anticoagulant was taken into sterile plastic tubes and centrifuged at 3000 rpm for 10 minutes. Glucose, total protein and triglyceride measurements were made from the obtained serum samples using a biochemistry autoanalyzer in fresh blood (Mindray BS-200, PRC).

Statistical Analysis

Shapiro Wilk-Smirnov was used to assess the study's numerical data's distribution. The glucose concentrations evaluated within the parameters of the study were found to have a normal distribution. The difference between groups was determined using One-way ANOVA and Tukey post hoc test. The agreement between glucose levels obtained by various devices was assessed using Bland-Altman plots and Pearson correlation analysis. The computations were performed using the statistical package program SPSS (ver. 15). The statistical significance level for the calculation was taken as $p<0.05$.

RESULTS

This study was conducted among 47 sheep, 17-18 months old, 42-46 kg in weight, and body condition score (BCS) in the range of 3-3.5, with glucose concentrations between 40-93 mg/dL.

The sheep included in the study were divided into 2 different groups according to their total protein and hematocrit values. Animals in Group 1 whose total protein and hematocrit values were within the reference range were included (PVC 27-47%, total protein 6.0-7.9 g/dL). Sheep included in Group 2 were accepted as those outside the reference values (Frye et al. 2022).

Table 1 show the mean glucose values measured with OX, CP and Biochemistry autoanalyzer in sheep, minimum-maximum values, and the importance of the differences between the groups. In the study, it was determined that there were statistically insignificant differences between the measurements of the OX portable device and the biochemistry autoanalyzer device in Group 1 and Group 2 (Table 1).

Table 2 shows the correlation values of glucose values measured with OX, CP, and Biochemistry autoanalyzer. It was determined that there was a 0.714 correlation between glucose values measured in OX and biochemistry autoanalyzer.

Bland-Altman method was applied to evaluate the relationship between the results of glucose concentrations measured in OX, CP and biochemistry autoanalyzer device. The evaluation results for each sample of the two measurement methods are shown in Figure 1-4. In this study, the difference between the accuracy of the OX and the CP blood glucose meter and the biochemistry autoanalyzer device was determined as -3.63% (Figure 1) and 6.83% in group 1 animals, (Figure 2) respectively. Among group 2 animals, 6.08% (figure) and 9.66% (figure 4) were detected. In figure 4, it was determined that the greatest difference was between the values measured on the CP and the biochemistry autoanalyzer between Group 2 animals. It was determined that the least difference was between OX and biochemistry autoanalyzer devices in the Group 1.

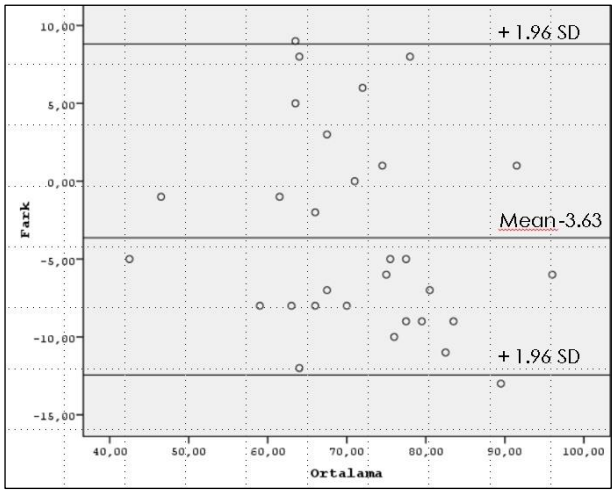

Figure 1. Bland-Altman Plot for Comparison of Optium Xceed and Biochemistry Autoanalyzer Measurement Techniques for Group.

Table 1. Glucose Means, Minimum-Maximum Values and Significance of Differences Between Groups in Healthy Sheep (Group I).

Glucose (mg/dL)	Optium Xceed $\bar{x} \pm S\bar{x}$	On Call Pluss $\bar{x} \pm S\bar{x}$	Biochemistry autoanalyzer $\bar{x} \pm S\bar{x}$	P
Group I	73.30±12.89[a] (45-99)	62.83±13.82[b] (34-99)	68.60±11.51[ab] (40-93)	0.007
Group II	74.58±9.59[a] (55-85)	58.83±13.39[b] (45-95)	64.92±10.04[a] (44-78)	0.006

- : p>0.05 * p<0.05 ** : p<0.01 *** : p<0.001, a, b: Differences between group means containing different letters of the same column are significant (p<0.05).

Table 2. Correlation of Glucose Levels Between Optium Xceed, On Call Pluss and Biochemistry Autoanalyzer Devices.

	Optium Xceed	On Call Pluss	Biochemistry Autoanalyzer
Optium Xceed	-	.695**	.871**
On Call Pluss	.695**	-	.660**

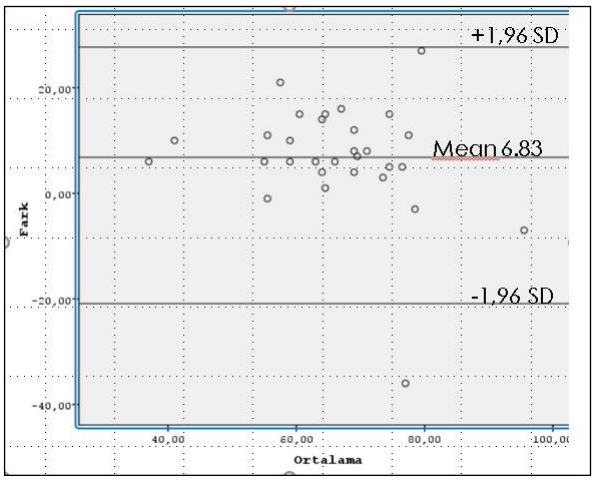

Figure 2. Bland-Altman Plot for Comparison of On Call Pluss and Biochemistry Autoanalyzer Measurement Techniques for Group 1.

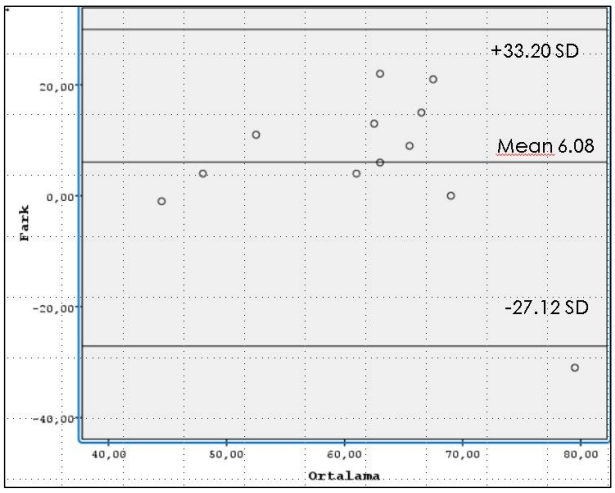

Figure 3. Bland-Altman Plot for Comparison of Optium Xceed and Biochemistry Autoanalyzer Measurement Techniques for Group 2.

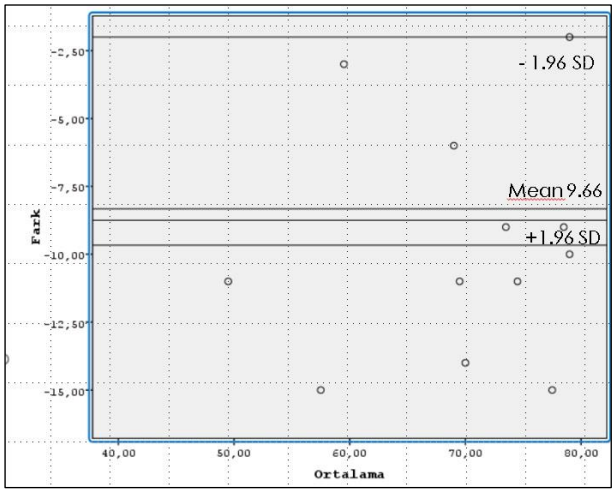

Figure 4. Bland-Altman Plot for Comparison of On Call Pluss and Biochemistry Autoanalyzer Measurement Techniques for Group 2.

DISCUSSION AND CONCLUSION

Glucometers are widely used in human medicine because they provide fast results (Karon et al. 2008). Diagnostic parameters that are suitable for animal species, reliable and can give fast results are extremely important in the field of veterinary medicine. Evaluation of glucose levels in sheep health plays an important role in clinical intervention and patient follow-up. Therefore, it is important that glucometer readings are accurate and precise. Failure to do so can lead to critical medical errors (Kabakci et al. 2003; Cohen et al. 2009; Tauk et al. 2015; Renaud et al. 2022).

Numerous factors have been tested in different studies that could potentially affect the accuracy of measurements obtained with portable blood glucose devices, including sample volume, PCV, source of blood (venous, arterial or capillary blood), hemolysis of blood samples, blood temperature, environmental factors (Devreese and Leroux 1993; Arens et al. 1998; Ginsberg 2009) Considering these data, in this study, animals were divided into 2 groups as those within reference limits and those with high PCV and TP values. Blood samples with hemolysis in all groups were not included in the study and all samples were provided under the same environmental conditions.

In some studies, it has been shown that high PCV may cause erroneous blood glucose readings, and there may be more pronounced errors in the presence of hyperglycemia (Tang et al. 2000; Lane et al. 2015). Its effects on glucose and hematocrit measurements have been expressed in different studies (Karon et al.2008; Paul et al.2011; Lane et al. 2015). It has been reported that when lipid and protein levels are at high limits, it can cause changes in the liquid

part of the blood, thus causing measurement errors in the test strip of the glucometer (Ginsberg 2009).

In this study, the accuracy of 2 portable blood glucose meters was evaluated by comparing the differences between the values obtained using the spectrophotometric method in the biochemistry autoanalyzer device. In addition, in sheep with high PCV and TP concentrations, the comparison of portable blood glucose devices with a biochemistry autoanalyzer was shown in the study. In the study, although there were insignificant differences between the glucose levels measured with 2 glucometers and the biochemistry autoanalyzer device in both groups, significant changes were determined between the glucometers at the rate of p=0.007. In addition, the highest level of correlation (0.871) was found between the biochemistry autoanalyzer and the OX glaucometer.

The compatibility of the measurements of different devices with other reported devices is evaluated by method comparison methods. In this context, taking into account the distribution of the data of different devices, Pearson's correlation analysis for dependent groups and Bland-Altman method are statistical methods that are frequently used to determine the consistency between measurement techniques (Van Stralen et al. 2008; Giavarina 2015; Aykal et al. 2016).

A popular statistical method for contrasting the medical approach is the Bland-Altman Method. The first step in these comparisons is to create a scatterplot showing the discrepancies between the measured values' means. Measurement errors are included in the means versus differences plot for the data points. It enables the investigation of any potential connections between If the differences are normally distributed, it is predicted that 95% of them would fall between "-1.96sd and +1.96sd" and that they will be randomly dispersed around zero. The Bland-Altman analysis objectively reveals the evaluation of different methods or tests and leaves the evaluation of the acceptability level of the differences to the interpretation of the physician (Bland and Altman 1999; Eren et al. 2013). In this study, the difference between the accuracy of the OX and the CP blood glucose meter and the biochemistry autoanalyzer device was determined as -3.63% and 6.83% in group 1 animals, respectively (Figure 1-2). Among group 2 animals, 6.08% and 9.66% were detected (Figure 3-4). When the Bland-Altman analysis and correlation results are evaluated, it shows parallelism with the analytical performance of the devices used in glucose concentration measurement with different methods used in the study. Correlation coefficients (r) values in the range of 0.70-0.89 are expressed as high correlation (Johnson et al. 2009; Domori et al. 2014). In the study, the r value of 0.871 between the OX and the biochemistry analyzer device shows that there is a high correlation between the two devices.

The results of this study show that; The difference between the accuracy of the OX and CP blood glucose meter and the biochemistry autoanalyzer device for glucose levels in sheep before the breeding season is within acceptable limits. However, we still think that it would be beneficial for clinicians to evaluate the differences between these groups in terms of both the follow-up and treatment of patients.

CONFLICTS OF INTEREST

The authors report no conflicts of interest.

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The study protocol was approved by the Sivas Cumhuriyet University Ethics Committee (Approval No: 2022/534).

AUTHOR CONTRIBUTIONS

Idea / Concept: OB
Supervision / Consultancy: OB
Data Collection and / or Processing: OB, AT
Analysis and / or Interpretation: OB
Writing the Article: OB
Critical Review: AT

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