

Procjena uređaja za samoodređivanje glukoze Accu Chek Compact Plus

Accu Chek Compact Plus blood glucometer evaluation

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Sažetak

Cilj: Cilj našeg istraživanja bio je odrediti netočnost i nepreciznost Accu Chek Compact Plus glukometra usporedbom s referentnim laboratorijskim sustavom.

Metoda: Kao referentna metoda za određivanje koncentracije glukoze korišten je originalni reagens tvrtke Olympus na analizatoru Olympus AU 2700. Razlika između koncentracija izmjerenih na analizatoru Olympus i glukometru Accu Chek određivana je parnim t-testom. Netočnost glukometra je određivana: izračunom odstupanja (%), regresijskom analizom Passing-Bablock, analizama Bland-Altman i Clarke error grid. Nepreciznost glukometra je određivana mjerenjem 10 uzastopnih mjerenja na tri razine koncentracija glukoze.

Rezultati: Srednje odstupanje glukometra Accu Chek iznosilo je -6,6%; analiza Passing-Bablock je pokazala kako nije bilo značajnog odstupanja od linearosti; analiza Bland-Altman pokazala je da se više od 95% rezultata nalazilo unutar ± 1.96 SD. Svi rezultati analize Clarke Error Grid su bili 100% unutar zone A.

Zaključak: Glukometar Accu Chek Compact Plus je u usporedbi s našim laboratorijskim referentnim sustavom pokazao zadovoljavajuću nepreciznost i netočnost i može se koristiti za dnevnu samokontrolu koncentracije glukoze.

Ključne riječi: netočnost; nepreciznost; analitička evaluacija; uređaj za samokontrolu koncentracije glukoze; analiza Bland-Altman; analiza Clarke Error Grid

Abstract

Aim: We aimed to evaluate Accu Chek Compact Plus blood glucometer by comparing its accuracy and precision with laboratory reference system.

Methods: Original Olympus Glucose reagent on Olympus AU 2700 analyzer served as a reference method. The difference between Olympus and Accu Chek glucose concentrations was tested by paired t-test. Glucometer accuracy was evaluated using: bias (%), Passing-Bablock regression, Bland-Altman and Clarke Error Grid analysis. Intra-assay glucometer precision was examined by 10 consecutive measurements at three glucose levels.

Results: The average bias of Accu Chek was -6.6%; Passing-Bablock analysis revealed that there was no significant deviation from linearity; as of Bland-Altman analysis more than 95% of our values lied between mean ± 1.96 SD. The results of the Clarke Error Grid analysis were 100% in zone A of the error grid.

Conclusions: Accu Chek Compact Plus blood glucometer has a good accuracy and precision compared with our laboratory referent-system and may be used for daily blood glucose self monitoring.

Key words: accuracy; precision; analytical evaluation; self monitoring blood glucose device; Bland-Altman; Clarke Error Grid analysis

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Uvod

Uređaji za samokontrolu koncentracije glukoze osiguravaju brzu informaciju o koncentraciji glukoze u krvi i nisu namijenjeni za postavljanje dijagnoze (1). Ti uređaji su vr-

Introduction

Blood glucose monitoring devices provide us with instant feedback about approximate concentrations of blood glucose and are not supposed to be used for setting the

lo jednostavni za upotrebu, mali i vrlo praktični za široku primjenu. No, pokazalo se da uređaji za samokontrolu koncentracije glukoze u krvi imaju upitnu točnost i značajnu nepreciznost. (2).

Primarni cilj ovog istraživanja bio je evaluirati glukometar Accu Chek Compact Plus tvrtke Roche, tako da se usporedi njegova netočnost i nepreciznost s našim laboratorijskim referentnim sustavom. Kriteriji prihvaćanja su bili: nepreciznost < 5%, netočnost < 10%.

Materijali i metode

Ispitanici

Uzorci krvi su sakupljeni od ambulantnih bolesnika koji su dolazili na redovitu kontrolu glukoze u krvi, tijekom rujna 2007. godine. Svi su bolesnici pristali sudjelovati u ovom istraživanju.

Uzorci

Krv je vadio vrlo iskusan laboratorijski tehničar. Kapilarna krv je skupljena nakon jednog uboda lancetom u jagodicu prsta i odmah je izmjerena koncentracija glukoze na glukometru. Potom je od svakog bolesnika skupljeno 500 μ L pune krvi u epruvete BD Microtainer® uz dodatak NaF/Na₂-EDTA (Becton Dickinson, Franklin Lakes, USA), uzorak je centrifugiran na 3500 \times g 10 minuta i koncentracija glukoze u plazmi je određena na referentnom analizatoru Olympus AU 2700 (Olympus, Tokyo, Japan).

Analizator Olympus AU 2700

Koncentracija glukoze određivala se s originalnim reagensom na analizatoru Olympus AU 2700 (Olympus, Hamburg, Germany), enzimatskom metodom s heksokinazom. Metoda se kalibrirala dnevno, a unutarnja analitička kontrola kvalitete provodila se na dvije razine komercijalnim kontrolnim uzorcima Olympus Control Level 1 i 2 (Olympus, Hamburg, Germany; O₁ = 5,4 mmol/L i O₂ = 13,2 mmol/L) svakih osam sati i/ili nakon 100 provedenih mjerenja. Kalibratori su sljedivi prema referentnom materijalu National Institute of Standards and Technology Standard reference Material (NIST SRM 965).

Prema navodima proizvođača, metoda je linearna u rasponu koncentracija 0,6–45,0 mmol/L; donja granica detekcije je 0,04 mmol/L; nepreciznost u seriji izražena koeficijentom varijacije (engl. *coefficient of variation*, CV) je 0,9% za O₁ i 1,0% za O₂, dok je netočnost metode -0,2% za O₁ i 0,4% za O₂ (3).

Preosivi uređaj za samokontrolu glukoze u krvi Accu Chek Compact Plus

Preosivi uređaj za samokontrolu glukoze u krvi Accu Chek Compact Plus (Roche Diagnostics GmbH, Mannheim, Germany) koristi enzimatsku metodu s glukozaoxidazom, uz detekciju refleksnom fotometrijom.

diagnosis (1). Those devices are very easy to handle, small in size and very practical for general use. However, it has been reported that self monitoring blood glucose (SMBG) devices have questionable accuracy and low precision (2). The primary objective of this study was to evaluate Accu Chek Compact Plus blood glucometer by comparing its accuracy and precision to a laboratory reference system. Our preset acceptance criteria were: for precision: CV < 5%; for accuracy: bias < 10%.

Materials and methods

Subjects

Blood samples were obtained from a consecutive series of outpatients enrolled during September 2007, scheduled for their routine glucose measurement. Data on gender and age were collected for all patients. All patients consented to participate in this study.

Samples

Blood collection was done by a well trained laboratory phlebotomist. Whole capillary blood was collected by pricking the patient fingertip once and glucose measurement was done immediately on glucometer, from the first drop of blood. 500 μ L of whole blood was then collected from each patient in a BD Microtainer® tube with NaF/Na₂-EDTA additive (Becton Dickinson, Franklin Lakes, USA), centrifuged at 3500 \times g for 10 minutes and blood glucose was assayed in plasma on Olympus AU 2700 referent laboratory instrument (Olympus, Tokyo, Japan).

Olympus AU 2700 chemistry analyzer

Glucose was assayed with original Olympus reagents (Olympus, Hamburg, Germany) employing reference method with hexokinase on Olympus AU 2700 analyzer (Olympus, Tokyo, Japan). The method is calibrated daily and Olympus control sera Olympus Control Level 1 i 2 (Olympus, Hamburg, Germany) are run on two levels (O₁ = 5.4 mmol/L and O₂ = 13.2 mmol/L) every eight hours or/and after 100 glucose tests. The glucose calibrators are traceable to the National Institute of Standards and Technology Standard Reference Material (NIST SRM 965). According to the manufacturer, the method is linear within the concentration from 0.6 to 45.0 mmol/L; the limit of detection is 0.04 mmol/L; intra-assay coefficient of variation (CV) for Olympus control specimens are 0.9% and 1.0% for O₁ and O₂ respectively and accuracy (bias) of the method is -0.2% and -0.4% for O₁ and O₂ respectively (3).

Accu Chek Compact Plus portable blood glucometer

Accu Chek Compact Plus portable instrument (Roche Diagnostics GmbH, Mannheim, Germany) employs method with glucose-oxidase measured by reflex photometry. As declared by the manufacturer, the method is linear

Prema navodima proizvođača metoda je linearna u rasponu koncentracija 0,6–33,3 mmol/L, donja granica detekcije je 0,6 mmol/L, a srednja nepreciznost u seriji izražena koeficijentom varijacije je < 2% (4).

Statistička analiza

Normalnost raspodjela je ispitana Kolmogorov-Smirnovljevim testom. Značajnost razlike između koncentracija glukoze mjerene na analizatoru Olympus AU 2700 i uređaju Accu Chek ispitana je parnim t-testom. Netočnost glukometra je evaluirana korištenjem četiriju metoda: (a) usporedbom koncentracija dobivenih dvjema metodama, izražena kao odstupanje (engl. *bias*) (%); (b) regresija Passing-Bablok; (c) analiza Bland-Altman; (d) analiza Clarke Error Grid (5).

Nepreciznost u seriji ispitana je na 10 uzastopnih određivanja koncentracije glukoze u jednom uzorku kapilarne krvi bolesnika i dva originalna komercijalno dostupna kontrolna uzorka za uređaj Accu Chek (Roche, Mannheim, Germany). Deklarirane ciljne koncentracije kontrolnih uzoraka glukometra Accu Chek su 3,3–5,0 mmol/L za K₁ i 8,8–11,9 mmol/L za K₂.

Statistička analiza je rađena MedCalc® statističkim programom (MedCalc 9.3.3.0, Frank Schoonjans, Mariakerke, Belgium). Vrijednost $P < 0,05$ se smatrala statistički značajnom. Analiza Clarke Error Grid je načinjena u programu Microsoft Excel (Microsoft Corporation, Santa Rosa, USA). Formule za izračun i izradu grafa nam je velikodušno proslijedio prof. Michael P. Kane, Pharm. D., (Department of Pharmacy Practice, Albany College of Pharmacy).

Rezultati

U istraživanje je bilo uključeno 48 bolesnika, čija je srednja dob izražena medijanom iznosila 64 godine (interkvartilni raspon 58–66). U skupini bolesnika je bilo 28 žena (58 %).

Netočnost

Odstupanje je određeno računanjem srednje razlike (%) između rezultata mjerenih glukometrom Accu Chek i referentnom metodom u našem laboratoriju. Mjerenja se nisu značajno razlikovala (odstupanje –6,6%, $P = 0,146$) između glukometra Accu Chek ($10,8 \pm 3,5$ mmol/L) i referentne metode ($11,6 \pm 3,8$ mmol/L).

Regresija Passing-Bablok

Regresija Passing-Bablok korištena je za usporedbu uređaja za samokontrolu glukoze u krvi s referentnom metodom Olympus AU 2700. Regresijska jednadžba glasi: $y = 0,1478 + 0,9130x$ i nema značajnog odstupanja od linearosti.

Analiza Bland-Altman

Graf Bland-Altman prikazuje odnos razlike dvaju mjerenja u ovisnosti o srednjoj vrijednosti ta dva mjerenja (Slika 1).

within the range 0.6–33.3 mmol/L, detection limit is 0.6 mmol/L and the mean intra-assay CV is < 2% (4).

Statistical analysis

Each distribution was examined for normality by Kolmogorov-Smirnov test. The difference between Olympus and Accu Chek glucose concentrations was tested by paired t-test. Glucometer accuracy was evaluated using four methods and respective commonly used criteria: (a) By comparing SMBG system values with the reference value and expressed as bias (%); (b) Passing-Bablok regression; (c) Bland-Altman analysis; (d) Error Grid Clarke analysis (5).

Intra-assay precision of the glucometer was examined by 10 successive measurements from one random capillary whole blood patient sample and two commercially available Accu Chek control samples (Roche, Mannheim, Germany). Control values as declared by the manufacturer for Accu Chek were 3.3–5.0 and 8.8–11.9 mmol/L for K1 and K2 control samples respectively.

Statistical analysis was performed with MedCalc® statistical software (MedCalc 9.3.3.0, Frank Schoonjans, Mariakerke, Belgium). P value < 0.05 was considered statistically significant. Error Grid Clarke analysis was done using Microsoft Excel (Microsoft Corporation, Santa Rosa, USA). Excel sheet with formulas and predesigned graph were generously obtained from prof. Michael P. Kane, Pharm.D., (Department of Pharmacy Practice, Albany College of Pharmacy).

Results

The study included 48 patients, with a median age 64 years (interquartile range 58–66) out of which 28 were females (58%).

Bias

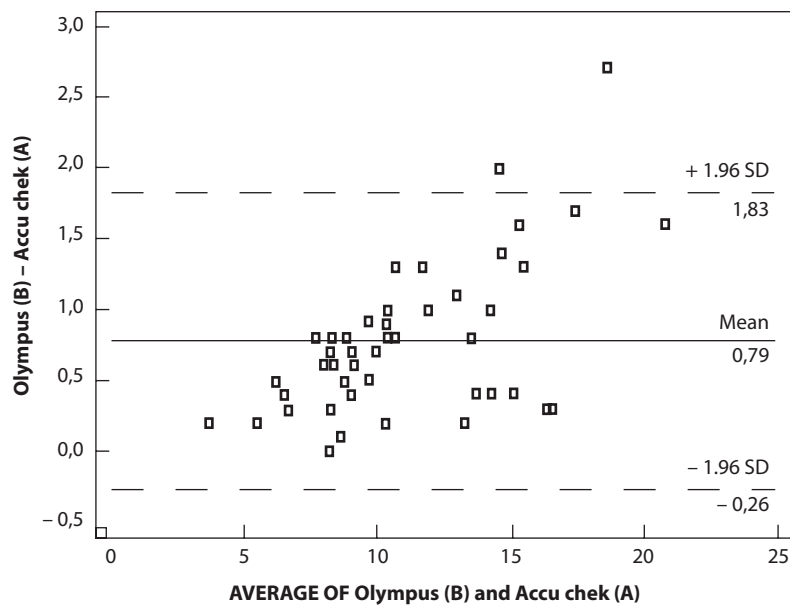
Bias was assessed by calculating the mean difference (%) between the Accu Check device results and results measured with reference method. Measurements did not differ significantly (bias –6.6%, $P = 0.146$) between Accu Chek and reference method (mean and standard deviation were 10.8 ± 3.5 and 11.6 ± 3.8 mmol/L respectively).

Passing-Bablok regression

Passing-Bablok regression was used to compare the SMBG system with the Olympus AU2700 reference method. The regression equation was: $y = 0.1478 + 0.9130x$ and there was no significant deviation from linearity.

Bland-Altman analysis

The graph displays a scatter diagram of the differences plotted against the averages of two measurements (Figure 1). Horizontal lines were drawn at the mean difference,



SLIKA 1. Regresija Bland Altman

FIGURE 1. Bland-Altman regression

Vodoravne linije na grafu označavaju srednju vrijednost razlike i $\pm 1,96$ SD razlike (6). U našem istraživanju srednja razlika između dvaju mjerenja koncentracije glukoze je bila $0,8 \pm 0,5$ mmol/L.

Analiza Clarke Error Grid

U analizi Clarke Error Grid, na apscisu su nanese koncentracije glukoze u krvi mjerene referentnom metodom, a na ordinatu koncentracija izmjerena ispitivanom metodom na glukometru. Graf je podijeljen u pet područja koje definiraju zone rezultata s različitim interpretacijom. Vrijednosti unutar zona A i B, predstavljaju područja ispravnih rezultata. Vrijednosti koje se nalaze unutar zone A ne razlikuju se za više od 20% od koncentracije izmjerene referentnom metodom. Vrijednosti unutar zone B veće su za više od 20% od vrijednosti izmjerene referentnom metodom. Iako zaključci koje možemo izvući iz rezultata unutar zone B, nisu posve prihvatljivi, oni neće dovesti do ozbiljnih posljedica za bolesnika. Vrijednosti unutar područja C, značajno se razlikuju od stvarnih vrijednosti. Rezultati koji se nalaze unutar zone D upozoravaju na klinički značajnu razliku, tj. grubu pogrešku. U tom će slučaju za bolesnika u hiperglikemičnom stanju, koncentracija glukoze izmjerena glukometrom biti unutar referentnog raspona. Zona E predstavlja područje pogrešne kliničke odluke, budući da su u tom slučaju koncentracije glukoze suprotne onima mjerenim referentnom metodom. Naime, za bolesnika u hipoglikemiji, izmjerena koncentracija glukoze na glukometru biti će iznad granica referentnog raspona (hiperglikemija). Odluke temeljene na podacima

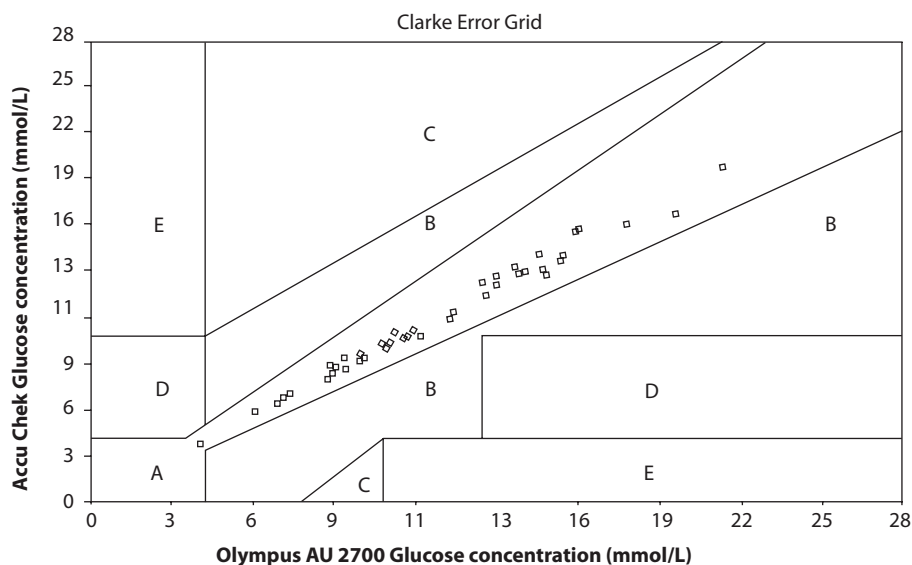
and the mean difference ± 1.96 times the standard deviation of the differences (6). The mean difference of the two glucose measurements was 0.8 ± 0.5 mmol/L.

Error Grid Clarke analysis

In Error Grid Clarke analysis, x-axis is defined as reference method measured blood glucose and the y axis as the value obtained by the glucometer. The error grid is divided into five zones of clinical accuracy; including the appropriateness of the laboratory result. Values in zone A and B are considered to be clinically accurate. Values in zone A do not vary by more than 20% from the laboratory reference value. The difference in zone B is greater than 20% from the reference. While decisions based on zone B results, would not be entirely appropriate, they would not lead to serious consequences for the patient. Values in zone C would result in an overcorrection of blood glucose values, resulting in hyperglycaemia or hypoglycaemia. Zone D represents a dangerous failure to detect and treat errors; the reference values are in hyperglycaemic range, while the blood glucometer displays values that are in normal range. Zone E is defined as "erroneous treatment zone" – glucose values are opposite to the reference values and the treatment decisions would be unsuitable and dangerous (5). The results of the error grid analysis were 100% in zone A of the error grid (Figure 2).

Precision

Intra-assay precision was determined using ten consecutive measurements of one patient sample and K1 and



SLIKA 2. Analiza Clarke Error Grid

FIGURE 2. Clarke Error Grid analysis

iz zone E su netočne i opasne (5). Svi rezultati analize Clarke error grid su bili 100% unutar zone A (Slika 2).

Nepreciznost

Nepreciznost u seriji ispitana je na 10 uzastopnih određivanja koncentracije glukoze u jednom uzorku kapilarne krvi bolesnika i dva originalna komercijalno dostupna kontrolna uzorka za uređaj Accu Chek (Roche, Mannheim, Germany). Izmjerena nepreciznost za uzorak bolesnika u kojemu je koncentracija glukoze bila $6,2 \pm 0,1$ mmol/L, iznosila je 1,83%. Za kontrolni uzorak K_1 u kojem je izmjerena koncentracija glukoze $4,5 \pm 0,1$ mmol/L, nepreciznost u seriji iznosila je 2,72%, dok je za kontrolni uzorak K_2 koncentracije $11,0 \pm 0,2$ mmol/L nepreciznost u seriji bila 1,43%. Izmjerene nepreciznosti bile su unutar naših zadanih kriterija prihvaćanja.

Rasprava

Međunarodne agencije su preporučile više različitih kriterija za analitičku evaluaciju mjerenja koncentracije glukoze glukometrom. Ti se kriteriji međusobno značajno razlikuju. Tako, primjerice, Nacionalni odbor za standarde u kliničkom laboratoriju (engl. *National Committee on Clinical Laboratory Standards*, NCCLS) dopušta razliku u rezultatima dobivenih referentnom metodom i na glukometru do čak 20%. Za razliku od NCCLS, Američka udruga za šećernu bolest (engl. *American Diabetes Association*, ADA) dopušta odstupanje rezultata od referentne metode od samo 5%. Kriterij za netočnost < 10% odstupanja od referentne la-

K_2 Accu Chek control samples. Mean, standard deviation and CV were as follows: 6.2 ± 0.1 mmol/L, 1.83%; 4.5 ± 0.1 mmol/L, 2.72%; 11.0 ± 0.2 mmol/L, 1.43% respectively. Precision was within our preset acceptance criteria and therefore regarded as acceptable.

Discussion

Several criteria have been recognized by regulatory agencies as standards for the testing accuracy of glucose monitors. These criteria differ significantly, ranging from high tolerance of up to 20% from the laboratory reference value (National Committee on Clinical Laboratory Standards, NCCLS) to a deviation of only 5% from the reference value (American Diabetes Association, ADA). The most frequently used accuracy criteria is < 10% deviation from the laboratory reference value (International Organization for Standardization, ISO). The average bias of the SMBG system in our study was -6.6%. Our results met the quality specifications of the ISO standards but failed to reach the ADA criterion. 91.7% of our measurements were within the $\pm 10\%$ of the reference values, as proposed by ISO. Several authors have addressed the issue of accuracy of SMGB systems (7,8,9). The accuracy of SMGB systems reported in those articles, showed 78.3%, 73% and 55% of measurements within $\pm 10\%$ of the reference values. The "good" SMBG systems were defined if > 60% of the measurements are within the $\pm 10\%$ of the reference values (7).

boratorijske vrijednosti, koji je najčešće u primjeni, izdala je Međunarodna organizacija za standarde (engl. *International Organization of Standardization*, ISO). U našem istraživanju srednje odstupanje glukometra iznosilo je $-6,6\%$. Ti su rezultati prihvatljivi prema kriteriju organizacije ISO, ali ne zadovoljavaju kriterije udruge ADA. 91,7% naših rezultata nalazi se u rasponu od $\pm 10\%$ od vrijednosti dobivenih referentnom metodom, kao što to propisuje ISO. Prema literaturnim navodima netočnost uređaja za samokontrolu glukoze u krvi značajno se razlikuje: za točnost glukometra dobivene su vrijednosti 78.3% (7), 73% (8) i 55% (9) mjerenja koja se nalaze unutar 10% odstupanja od vrijednosti izmjerenih referentnom metodom. Glukometar zadovoljavajuće kvalitete je onaj kojemu je više od 60% mjerenja unutar 10% odstupanja od vrijednosti izmjerenih referentnom metodom (7). Korelacija između uređaja za samokontrolu glukoze i referentne metode se često interpretira kao mjerilo netočnosti. Razni su autori dobivali koeficijente korelacije u rasponu od 0,904 do 0,998 (10,11). Naš koeficijent korelacije je bio relativno nizak ($R = 0,913$, $P < 0,05$), najvjerojatnije zbog razlika između koncentracija glukoze u punoj krvi i plazmi. Regresijska analiza Passing-Bablock i procjena greške izražene odstupanjem nisu najbolji statistički pokazatelji analitičke pogreške. Čak i kada korelacija ne pokaže značajnije odstupanje od linearnosti i kad je apsolutna greška unutar dozvoljenih granica, između dva mjerenja još uvijek može postojati odstupanje uz postojanje konstantne razlike u koncentracijama. Zbog toga se uz regresijsku analizu Passing-Bablock preporučuje koristiti i osjetljivije statističke analize, kao što su analiza Bland-Altman i analiza Clarke Error Grid (6,12). Na grafu Bland-Altman uspoređuje se razlika između mjerenja sa srednjom vrijednosti oba mjerenja. S obzirom da se više od 95% naših rezultata nalazi unutar $\pm 1,96$ SD, nema statistički značajne razlike između metoda te se koncentracija glukoze može mjeriti i na glukometru kao zamjenskom analizatoru (6). Analiza naših podataka metodom Bland-Altman pokazala je da su razlike između glukometra i referentne metode veće u području viših koncentracija glukoze što su također opazili Cohen i suradnici u svom istraživanju (13). Opažene razlike mogu biti posljedica korištenja različitih vrsta uzoraka, a ne samo različitih analitičkih metoda mjerenja. Netočnost smo procijenili i analizom Clarke Error Grid. Kao što je ranije spomenuto, tom metodom računaju se razlike između koncentracija glukoze mjerene referentnom metodom i glukometrom te ispravnost kliničke odluke koja se donosi na temelju koncentracije glukoze izmjerene glukometrom. U novije vrijeme, analiza Clarke Error Grid je prihvaćena kao zlatni standard za određivanje netočnosti glukometara. Svi naši rezultati bili su 100% unutar zone A te se, kao takvi, smatraju valjanima. Odstupanje naših rezultata za sve je koncentracijske razine bilo niže od preporučenih kriterija. Nadalje, izmjerena

The correlation between SMBG and glucose concentration of reference method is often interpreted as a measure of accuracy. Some investigators have reported coefficient of correlation ranging from 0.904 to 0.998 (10,11). Though pointing to the significant association of two methods, our correlation coefficient ($R = 0.913$, $P < 0.05$) was relatively low, most probably due to the matrix differences of biological samples (whole blood vs. serum). Passing-Bablock regression analysis and bias (absolute error) may not be good enough for this assessment. Despite the fact that correlation showed no significant deviation from linearity and the absolute error is within the permitted limits, two measurements can still differ for the constant bias. Therefore it is highly recommended to supplement the initial analysis with some other, more sensitive statistical tests, such as Bland-Altman plot and Error-grid analysis (6,12). Bland-Altman graph displays a scatter diagram of the differences plotted against the averages of two measurements. Since more than 95% of our values are between mean ± 1.96 SD, the differences between these two methods are not statistically important and they may be used interchangeably (6). As shown in the Bland-Altman analysis of our results observed differences between the glucometer and the reference method were larger at higher glucose concentrations. Cohen et al. had same observation (13). The difference may be not only due to the different measurement systems, but also due to the different specimens used. Last, we assessed accuracy by error grid analysis. As already mentioned previously, the error grid takes into account both the differences between the reference and the SMBG-system values and the relevance of the treatment decision resulting from the SMBG value. The Clarke Error Grid analysis is nowadays accepted as a gold standard statistical method for determining the accuracy of blood glucose meters. Our results of the error grid analysis were 100% in zone A of the error grid and were considered clinically accurate. The overall variability of our results was low, much lower than the preset acceptance criteria for all three glucose levels measured. Furthermore, precision at two out of three levels have even met the stringent Westgard criteria (less than 2.2%) (14). According to the literature reports, it is well known that SMBG systems rarely fulfil Westgard's criteria. According to some authors the overall imprecision for SMBG systems ranges from 6–15 % (9,13). Based on our results we conclude that Accu Chek Compact Plus blood glucometer has a good accuracy and precision compared with our laboratory referent-system and may be used for daily blood glucose self monitoring.

nepreciznost na dvije razine zadovoljava i stroge kriterije prema Westgardu (< 2,2%) (14). Do sada u literaturi nije zabilježeno da glukometri zadovoljavaju kriterije prema Westgardu. Prema nekim autorima, izmjerena nepreciznost glukometara iznosi čak 6-15% (9, 13).

Temeljem naših opažanja Glukometar Accu Chek Compact Plus je u usporedbi s našim laboratorijskim referentnim sustavom pokazao zadovoljavajuću nepreciznost i netočnost i može se koristiti za dnevnu samokontrolu koncentracije glukoze.

Zahvala

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