ORIGINAL ARTICLE

Self-Monitoring of Blood Glucose—An Overview

Satish K. Garg¹ and Irl B. Hirsch²

Introduction

PREVALENCE OF DIABETES is increasing globally. As estimated by the International Diabetes Federation, there will be more than a billion people with diabetes by the year 2030 (1). Recent data from the United States show that more patients are reaching the target glycosylated hemoglobin (HbA1c) values without hypoglycemia. This has resulted in a significantly lower rate of microvascular complications associated with diabetes. Because of new insulin analogs (basal and prandial insulins), new oral and noninsulin injectables, self-monitoring of blood glucose (SMBG), and new technologies such as continuous glucose monitor (CGM) and continuous subcutaneous insulin infusion (CSII), diabetes management has become easier.

SMBG is an effective therapy for the management of diabetes (type 1 diabetes mellitus [T1DM] and type 2 diabetes mellitus [T2DM]). In T2DM, the use of SMBG clearly results in early therapeutic changes even in non-insulin-requiring subjects with T2DM. Current and new generations of glucose meters are meeting the International Organization for Standardization (ISO) benchmark of less than 20% variability (2). However, all of the manufacturers soon will have to meet the ISO benchmark of less than 15% variability. A multicenter analysis including 24,500 patients from 191 centers in Germany and Australia showed that frequent SMBG is associated with better metabolic control in patients with T1DM and T2DM (3).

In this chapter, we reviewed articles on SMBG that were published from July 1, 2012, to June 30, 2013. We found 315 articles/abstracts, of which we are commenting on 13 SMBG abstracts. We strongly believe that these 13 abstracts represent the current scenario, usefulness, and recommendations for SMBG in both T1DM and T2DM.

Possible impacts of new accuracy standards of self-monitoring of blood glucose

Garg SK¹, Reed K¹, Grey J¹, Westerman A¹

¹Barbara Davis Center for Diabetes, University of Colorado, Denver

US Endocrinol 2013; 9: 28–31

Self-monitoring of blood glucose (SMBG) was an integral part of the reduction of complication rates in type 1 diabetes during the landmark Diabetes Control and Complications Trial (DCCT). However, the accuracy and standardized reporting of SMBG devices remains a key concern, with the 2003 version of the ISO 15197 standard allowing for 5% of readings to fall outside of the acceptable ranges. A recently revised 2013 version of the ISO 15197 standard includes stricter accuracy benchmarks, with a 36-month transition period recommended before compliance becomes mandatory. These new accuracy standards will have implications not only for manufacturers of currently available and future devices but also for the end users, who may face rising costs and necessary measures to improve patient error rates associated with SMBG in routine clinical practice.

Comment

Although SMBG is an integral part of diabetes management, the older SMBG devices were not accurate. However, with strict guidelines and implementation of ISO requirements, newer SMBG devices are fairly accurate and improving. This article reviews the accuracy and standards for glucose meters. However, new ISO standards might pose additional cost burden with which the companies must comply.

Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D Exchange clinic registry participants

Miller KM¹, Beck RW¹, Bergenstal RM², Goland RS³, Haller MJ⁴, McGill JB⁵, Rodriguez H⁶, Simmons JH⁷, Hirsch IB⁸ for the T1D Exchange Clinic Network

¹Jaeb Center for Health Research, Tampa, FL; ²International Diabetes Center/Park Nicollet, Minneapolis, MN; ³Naomi Berrie Diabetes Center, Columbia University, New York City, NY; ⁴University of Florida, Gainesville, FL; ⁵Washington University, St. Louis, MO; ⁶University of South Florida, Tampa, FL;

¹Barbara Davis Center for Childhood Diabetes, University of Colorado, Denver Health Sciences Center, Aurora, CO.

²University of Washington Medical Center, Seattle, WA.

⁷Vanderbilt University Medical Center, Nashville, TN; and

⁸University of Washington Medical Center, Seattle, WA

Diabetes Care 2013; 36: 2009–14

Objective

Despite substantial evidence of the benefit of frequent self-monitoring of blood glucose (SMBG) in type 1 diabetes, certain insurers limit the number of test strips that they will provide. The large database of the T1D Exchange clinic registry provided an opportunity to evaluate the relationship between the number of SMBG measurements per day and HbA1c levels across a wide age range of children and adults.

Research Design and Methods

The analysis included 20,555 participants in the T1D Exchange clinic registry with type 1 diabetes ≥ 1 year and not using a continuous glucose monitor (11,641 aged less than 18 years and 8,914 aged 18 years or older). General linear models were used to assess the association between the number of SMBG measurements and HbA1c levels after adjusting for potential confounding variables.

Results

A higher number of SMBG measurements per day were associated with non-Hispanic whites, insurance coverage, higher household income, and use of an insulin pump for insulin delivery ($p < 0.001$ for each factor). After adjusting for these factors, a higher number of SMBG measurements per day were strongly associated with a lower HbA1c level (adjusted $p < 0.001$), with the association being present in all age groups and in both insulin pump and injection users.

Conclusions

There is a strong association between higher SMBG frequency and lower HbA1c levels. It is important for insurers to consider that reducing restrictions on the number of test strips provided per month may lead to improved glycemic control for some patients with type 1 diabetes.

Clinical review: consensus recommendations on measurement of blood glucose and reporting glycemic control in critically ill adults

Finfer S¹, Wernerman J², Preiser JC³, Cass T⁴, Desai T⁵, Hovorka R⁶, Joseph JJ⁷, Kosiborod M⁸, Krinsley J⁹, Mackenzie I¹⁰, Mesotten D¹¹, Schultz MJ¹², Scott MG¹³, Slingerland R¹⁴, Van den Berghe G¹¹, Van Herpe T^{11,15}

¹The George Institute for Global Health and Royal North Shore Hospital, University of Sydney, St. Leonards, Sydney, Australia;

²Department of Anesthesiology & Intensive Care Medicine, Karolinska University Hospital, Solna, Sweden;

³Department of Intensive Care, Erasme University Hospital, Brussels, Belgium;

⁴Institute of Biomedical Engineering, Imperial College, South Kensington Campus, London, United Kingdom;

⁵GIGA—Cardiovascular Sciences, University of Liege, Institute of Physics, Liege, Belgium;

⁶Institute of Metabolic Science, University of Cambridge Metabolic Research Laboratories, Level 4, Institute of Metabolic Science, Addenbrooke's Hospital, Cambridge, United Kingdom;

⁷Department of Anesthesiology, Jefferson Artificial Pancreas Center & Anesthesiology Program for Translational Research, Jefferson Medical College of Thomas Jefferson University, Philadelphia, PA;

⁸Saint-Luke's Mid America Heart Institute, University of Missouri—Kansas City, Kansas City, MO;

⁹Division of Critical Care, Stamford Hospital and Columbia University College of Physicians and Surgeons, Stamford, CT;

¹⁰Department of Anaesthesia and Intensive Care Medicine, Queen Elizabeth Hospital Birmingham, Queen Elizabeth Medical Centre, Birmingham, United Kingdom;

¹¹Department of Intensive Care Medicine, University Hospitals Leuven, Leuven, Belgium;

¹²Department of Intensive Care Medicine, Academic Medical Center at the University of Amsterdam, Amsterdam, The Netherlands;

¹³Division of Laboratory and Genomic Medicine, Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, MO;

¹⁴Isala Klinieken, Department of Clinical Chemistry, JW Zwolle, The Netherlands; and

¹⁵Department of Electrical Engineering (ESAT-SCD), Katholieke Universiteit Leuven, Leuven, Belgium

Crit Care 2013; 17: 229

The management reporting and assessment of glycemic control lacks standardization. The use of different methods to measure the blood glucose concentration and to report the performance of insulin treatment yields major disparities and complicates the interpretation and comparison of clinical trials. We convened a meeting of 16 experts plus invited observers from the industry to discuss and, where possible, reach consensus on the most appropriate methods to measure and monitor blood glucose in critically ill patients and on how glycemic control should be assessed and reported. Where consensus could not be reached, recommendations on further research and data needed to reach consensus in the future were presented. Recognizing their clear conflict of interest, industry observers played no role in developing the consensus or recommendations from the meeting. Consensus recommendations were agreed upon for the measurement and reporting of glycemic control in clinical trials and for the measurement of blood glucose in clinical practice. Recommendations covered the following areas: How should we measure and report glucose control when intermittent blood glucose measurements are used? What are the appropriate

Comment

This multicenter study, funded originally by the Helmsley Trust Foundation through Jaeb Center, involving more than 67 leading diabetes centers in the United States enrolled more than 20 thousand patients with T1DM. The data have been presented at national and international scientific meetings. This real-life, large database clearly shows the role of SMBG in improving glucose control in subjects with T1DM. There was a difference of more than 1.5% in HbA1c between subjects who tested none and those who tested more than eight times per day. However, this is a self-reported database (reported by patients or parents or clinical staff). The data were not verified by any other organizations, including Jaeb Center. At least for T1DM, it clearly documents the importance of SMBG in improving glucose control.

performance standards for intermittent blood glucose monitors in the ICU? Continuous or automated intermittent glucose monitoring—methods and technology: can we use the same measures for assessment of glucose control with continuous and intermittent monitoring? What is acceptable performance for continuous glucose monitoring systems? If implemented, these recommendations have the potential to minimize the discrepancies in the conduct and reporting of clinical trials and to improve glucose control in clinical practice. Furthermore, to be fit for use, glucose meters and continuous monitoring systems must match their performance to fit the needs of patients and clinicians in the intensive care setting.

Comment

This is an excellent review on the consensus of SMBG and CGM in diabetes management. It further includes recommendations for inpatient diabetes management. This report is an attempt to standardize recommendations of frequency of SMBG in subjects with diabetes.

Intensive structured self-monitoring of blood glucose and glycemic control in noninsulin-treated type 2 diabetes: the PRISMA randomized trial

Bosi E^{1,2}, Scavini M^{1,2}, Ceriello A³, Cucinotta D⁴, Tiengo A⁵, Marino R⁶, Bonizzoni E⁷, Giorgino F⁸ on behalf of the PRISMA Study Group

¹Diabetes Research Institute, San Raffaele Hospital and Scientific Institute, Milan, Italy; ²San Raffaele Vita-Salute University, Milan, Italy; ³Institut d'Investigacions Biomèdiques August Pi Sunyer and Centro de Investigacion Biomedica en Red de Diabetes y Enfermedades Metabólicas Asociadas, Barcelona, Spain; ⁴Department of Internal Medicine, Policlinico Universitario Gaetano Martino, Messina, Italy; ⁵Division of Metabolic Diseases, Department of Clinical and Experimental Medicine, University of Padova, Padova, Italy; ⁶Medical Affairs, Roche Diagnostics, Monza, Italy; ⁷Section of Medical Statistics and Biometry G.A. Maccacaro, Department of Occupational Health Clinica del Lavoro L. Devoto, School of Medicine, University of Milan, Milan, Italy; and ⁸Section of Internal Medicine, Endocrinology, Andrology, and Metabolic Diseases, Department of Emergency and Organ Transplantation, University of Bari School of Medicine, Bari, Italy
Diabetes Care 2013 Jun 4: [Epub ahead of print]; DOI: 10.2337/dc13-0092

Objective

We aimed to evaluate the added value of intensive self-monitoring of blood glucose (SMBG), structured in timing and frequency, in non-insulin-treated patients with type 2 diabetes.

Research Design and Methods

The 12-month randomized clinical trial enrolled 1,024 patients with non-insulin-treated type 2 diabetes (median baseline HbA1c, 7.3% [interquartile range, 6.9–7.8%]) at 39 diabetes clinics in Italy. After standardized education, 501 patients were randomized to intensive structured monitoring (ISM) with four-point glycemic profiles (fasting, preprandial, 2-hour postprandial, and postabsorptive measurements) performed 3 days/week; 523 patients were randomized to

active control (AC) with four-point glycemic profiles performed at baseline and at 6 and 12 months. Two primary end points were tested in hierarchical order: HbA1c change at 12 months and percentage of patients on target for being at risk for low and high blood glucose index.

Results

Intent-to-treat analysis showed greater HbA1c reductions over 12 months in ISM (−0.39%) than in AC patients (−0.27%), with a between-group difference of −0.12% (95% confidence interval, −0.210 to −0.024; $p=0.013$). In the per-protocol analysis, the between-group difference was −0.21% (−0.331 to −0.089; $p=0.0007$). More ISM than AC patients achieved clinically meaningful reductions in HbA1c (>0.3 , >0.4 , or $>0.5\%$) at study end ($p<0.025$). The proportion of patients reaching/maintaining the risk target at month 12 were similar in ISM (74.6%) and AC (70.1%) patients ($p=0.131$). At visits 2, 3, and 4, diabetes medications were changed more often in ISM than in AC patients ($p<0.001$).

Conclusions

The use of structured SMBG improves glycemic control and provides guidance in prescribing diabetes medications in patients with relatively well-controlled non-insulin-treated type 2 diabetes.

Comment

The PRISMA study is a randomized controlled trial of structured SMBG in non-insulin-treated subjects with T2DM—a controversial topic. The results clearly show that the appropriate use of SMBG results in guidance for prescribing diabetes therapies. As expected, it also resulted in improvement in glucose control. The study highlights the need for reviewing the SMBG data by the providers and the patients so that necessary modifications in therapy can be made.

Frequency of blood glucose testing in well-educated patients with diabetes mellitus type 1: how often is enough?

Minder AE¹, Albrecht D¹, Schäfer J^{2,3}, Zulewski H¹

¹Division of Endocrinology Diabetes and Metabolism, ²Basel Institute for Clinical Epidemiology and Biostatistics, and ³Clinical Trial Unit, University Hospital Basel, Basel, Switzerland

Diabetes Res Clin Pract 2013 May 29: [Epub ahead of print]; DOI: 10.1016/j.diabres.2012.12.024

Aims

Self-monitored blood glucose (SMBG) and knowledge of insulin requirements are pivotal for good metabolic control in patients with diabetes mellitus type 1. However, the SMBG frequency needed for optimal glycemic control especially in well-educated patients is unclear.

Methods

In patients with type 1 diabetes treated with flexible intensified insulin therapy, we evaluated HbA1c values and the

directly preceding computerized SMBG frequencies over a 12-month period. To estimate the association between HbA1c and SMBG frequency, we fitted a piece-wise linear spline model with a change in slope at four SMBGs per day, which is the recommended minimal SMBG frequency at our institution.

Results

A total of 150 patients were available for analysis, with a median baseline HbA1c of 7.1% (interquartile range 6.6–7.8). In the multivariable analysis (adjusted for sex and psychological problems), each additional SMBG measurement was associated with an estimated difference in HbA1c of -0.19% (95% confidence interval $-0.42, 0.05$) for ≤ 4 SMBGs per day and of -0.02% (95% confidence interval $-0.10, 0.06$) for >4 SMBGs per day.

Conclusions

Good diabetes control can be achieved in routine diabetes care with flexible intensified insulin therapy based on continuing patients' education and with a minimum of four SMBGs per day.

Value and utility of self-monitoring of blood glucose in non-insulin-treated patients with type 2 diabetes mellitus

Blevins T

Texas Diabetes and Endocrinology, Austin, TX

Postgrad Med 2013; 125: 191–204

Self-monitoring of blood glucose (SMBG) levels provides important information regarding glycemic control for patients with diabetes and is recommended by European and American diabetes organizations as an essential adjunct to periodic glycated hemoglobin (HbA1c) level monitoring. The benefits of SMBG in improving glycemic control in patients with type 1 diabetes and those with type 2 diabetes mellitus (T2DM) who are being treated with insulin are well recognized. In contrast, the potential role of SMBG in patients with T2DM not treated with insulin remains controversial, which may lead to underutilization of SMBG in this population. Structured SMBG, introduced as part of a treatment intervention, has been associated with modest but significant improvements in HbA1c levels in patients with T2DM who are not taking insulin as part of their management plan. Patient-obtained readings provide valuable real-time feedback on glucose responses to meals and exercise and provide the patient with guidance on the day-to-day management of their diabetes. Studies have shown that when patients perform self-monitoring as part of their treatment interventions, support through appropriate educational initiatives is critical to ensure that patients understand the rationale for SMBG. Patients should be trained in correct testing techniques and data recording for SMBG, as well as target blood glucose and goal HbA1c levels so that they will know when their SMBG readings are out of range.

Technology has a potential role in facilitating SMBG-based interventions by improving patient-physician communication and optimizing glycemic control through the use of remote data uploading, data analysis tools, and, perhaps, even text messaging. This review outlines the benefits of SMBG in the management of patients with T2DM not treated with in-

sulin, and highlights strategies for improving the effectiveness of SMBG-based treatment interventions in this population.

Comment

The above two studies further highlight the importance of SMBG in T1DM and T2DM. In the first study, at least four SMBG measurements a day resulted in better glucose control in T1DM, and the results are similar to those in T1DM Exchange clinic data presented in the second abstract of this chapter.

2-year follow-up to STeP trial shows sustainability of structured self-monitoring of blood glucose utilization: results from the STeP practice logistics and usability survey (STeP PLUS)

Friedman K¹, Noyes J¹, Parkin CG²

¹Roche Diagnostics, Indianapolis, IN; and ²CGParkin Communications, Inc., Boulder City, NV

Diabetes Technol Ther 2013; 15: 344–47

We report findings from a follow-up survey of clinicians from the STeP study that assessed their attitudes toward and current use of the Accu-Chek® 360° View tool (Roche Diagnostics, Indianapolis, IN) approximately 2 years after the study was completed. The Accu-Chek 360° View tool enables patients to record/plot a seven-point self-monitoring of blood glucose (SMBG) profile (fasting, preprandial/2-hour postprandial at each of the three meals and at bedtime) on 3 consecutive days, document meal sizes and energy levels, and comment on their SMBG experiences. Our findings showed that the majority of these physicians continue to use the tool with their patients, citing enhanced patient understanding and engagement, better discussions with patients regarding the impact of lifestyle behaviors, improved clinical outcomes, and better practice efficiencies as significant benefits of the tool.

Comment

Last year, the STeP study showed better glycemic control (in a randomized controlled trial) with structured SMBG in T2DM. The randomization in this clinical trial was cluster randomization in which clinics were randomized, not the individual patients. The 2-year follow-up reported in this abstract shows the majority of the providers continue to use the tools with their patients and improve clinical outcomes.

Early management of type 2 diabetes based on an SMBG strategy: the way to diabetes regression—the St. Carlos study: a 3-year, prospective, randomized, clinic-based, interventional study with parallel groups

García de la Torre N¹, Durán A¹, Del Valle L¹, Fuentes M², Barca I³, Martín P¹, Montañez C¹, Perez-Ferre N¹, Abad R¹, Sanz F¹, Galindo M¹, Rubio MA¹, Calle-Pascual AL¹

¹Endocrinology and Nutrition Department, Hospital Clinico San Carlos-IdISSC, Professor Martin Lagos s/n, Madrid, Spain; ²Preventive Medicine Department, Hospital Clínico San Carlos-

IdISSC, Madrid, Spain; and ³Rehabilitation Service, Hospital Clínico San Carlos-IdISSC, Madrid, Spain

Acta Diabetol 2013 Mar 27: [Epub ahead of print]; DOI: 10.1007/s00592-013-0467-9

Aims

The aims are to define the regression rate in newly diagnosed type 2 diabetes after lifestyle intervention and pharmacological therapy based on a self-monitoring of blood glucose (SMBG) strategy in routine practice as compared to standard HbA1c-based treatment and to assess whether a supervised exercise program has additional effects.

Methods

The St. Carlos study is a 3-year, prospective, randomized, clinic-based, interventional study with three parallel groups. One hundred ninety-five patients were randomized to the SMBG intervention group [I group ($n=130$): Ia, SMBG ($n=65$); Ib, SMBG+supervised exercise ($n=65$)] and to the HbA1c control group (C group) ($n=65$). The primary outcome was to estimate the regression rate of type 2 diabetes (HbA1c <6% on metformin treatment).

Results

After 3 years of follow-up, diabetes regression was achieved by 56 patients, 6 (9.2%) from the C group, 21 (32.3%) from the Ia group, and 29 (44.6%) from the Ib group. The risk ratio (95% confidence interval) for diabetes regression in the intervention group (Ia+Ib) was 4.5 (2.1–9), $p<0.001$, and remained after stratification by sex, age, and body mass index. This difference was associated with healthier changes in lifestyle and greater weight loss. The risk ratio for a weight loss >4 kg was 3.6 (1.8–7), $p<0.001$.

Conclusion

This study shows that the use of SMBG in an educational program effectively increases the regression rate in newly diagnosed type 2 diabetic patients after 3 years of follow-up. These data suggest that SMBG-based programs should be extended to primary care settings where diabetic patients are usually attended.

Comment

This study clearly shows that, in non-insulin-treated subjects with T2DM who are newly diagnosed, SMBG use results in increased regression rate for T2DM with 3-year follow-up. The HbA1c only gives us a snapshot of overall glucose control for the previous 3 months. However, frequent SMBG use results in behavioral change (by the patient) and allows the providers to implement necessary therapeutic changes early in the course of the disease.

ROSSO-in-praxi-international: long-term effects of self-monitoring of blood glucose on glucometabolic control in patients with type 2 diabetes mellitus not treated with insulin

Kempf K¹, Tankova T², Martin S¹

¹Düsseldorf Catholic Hospital Group, West-German Centre of Diabetes and Health, Düsseldorf, Germany; and ²Clinical Center of Endocrinology, Medical University, Sofia, Bulgaria

Diabetes Technol Ther 2013; 15: 89–96

Background

Effects of lifestyle change on blood glucose levels can be observed by self-monitoring of blood glucose (SMBG) in type 2 diabetes mellitus (T2DM) patients. We analyzed whether the SMBG-structured lifestyle intervention program ROSSO-in-praxi-international can improve glucometabolic control in the short- and the long-term.

Subjects and Methods

One hundred twenty-four SMBG-naïve ambulatory non-insulin-treated T2DM patients were randomly assigned to an SMBG group ($n=63$) and a control group ($n=61$). Both groups received a 12-week structured lifestyle guidance manual. The SMBG group additionally got a blood glucose meter with 150 test strips and was instructed to measure blood glucose regularly as well as during life events. Glucometabolic parameters were assessed at baseline, after 12 weeks, and after 1.5 years.

Results

During the 12 weeks of intervention, the SMBG group significantly improved glycated hemoglobin (HbA1c) levels (from $7.4\pm1.6\%$ to $6.9\pm1.1\%$ [$p<0.001$]) and weight (-0.9 ± 1.9 kg [$p<0.05$]), whereas HbA1c reduction (from $7.5\pm1.0\%$ to $7.3\pm1.0\%$) and weight loss (-0.6 ± 2.4 kg) were not significant in the control group. Of the 124 patients, 122 completed the 1.5-year follow-up. In the control group, HbA1c increased again, reaching baseline values ($7.5\pm0.7\%$). In the SMBG group, HbA1c remained stable ($6.9\pm0.9\%$ [$p=0.0003$ for trend]), and weight (-1.6 ± 3.0 kg vs. baseline [$p=0.0003$ for trend]) improved further. Eighty-seven percent of participants in the SMBG group continued to perform SMBG. Those who measured their blood glucose more than three times per week ($n=24$) demonstrated an overall reduction in HbA1c of 1.0% ($p=0.006$ vs. three times or fewer per week) after 1.5 years.

Conclusions

Integration of SMBG into basic therapy of T2DM for monitoring the effect of lifestyle changes improves glucometabolic control and has long-term effects.

Comment

The ROSSO study done in Germany highlights the effectiveness of SMBG in T2DM patients on lifestyle modifications. This was a randomized trial where half of the patients received a glucose meter along with 150 test strips and they were instructed to check blood glucose regularly as well as event-driven monitoring, whereas the control group did not receive the SMBG. The authors conclude that integration of SMBG into basic T2DM management, which includes lifestyle changes, improves glucometabolic control.

Glucose control in diabetes: the impact of racial differences on monitoring and outcomes

Campbell JA¹, Walker RJ^{1,2}, Smalls BL¹, Egede LE¹⁻³

¹Center for Health Disparities Research, Medical University of South Carolina, Charleston, SC; ²Center for Disease Prevention and Health Interventions for Diverse Populations, Charleston VA REAP, Ralph H. Johnson VA Medical Center, Charleston, SC; and ³Division of General Internal Medicine and Geriatrics, Department of Medicine, Medical University of South Carolina, Charleston, SC

Endocrine 2012; **42**: 471–82

Type 2 diabetes is the seventh leading cause of death in the United States and is projected to increase in prevalence globally. Minorities are disproportionately affected by diabetes and data suggest that clinical outcomes consistently fall below American Diabetes Association recommendations. The purpose of this systematic review was to examine ethnic differences in self-monitoring and outcomes in adults with type 2 diabetes. Medline was searched for articles published between January 1990 and January 2012 by means of a reproducible strategy. Inclusion criteria incorporated the following: (a) published in English; (b) targeted African Americans, Hispanic, or Asian adults, ages 18+ years with type 2 diabetes; (c) cross-sectional, cohort, or intervention study; and (d) measured change in glycemic control, blood pressure, lipids, or quality of life by race. Twenty-two articles met the inclusion criteria and were reviewed. Overall, significant racial differences and barriers were found in published studies in diabetes management as it pertains to self-monitoring and outcomes. African Americans tend to consistently exhibit worse outcomes and control when compared to other minority populations and non-Hispanic whites. In conclusion, significant racial differences and barriers exist in diabetes management as it pertains to self-monitoring and outcomes when compared to non-Hispanic whites. Explanatory and intervention studies are needed to determine the mechanisms and mediators of these differences and strategies to reduce these disparities. In addition, more research is needed to investigate the impact of racial differences in self-monitoring and outcomes on quality of life.

Comment

Even in the 21st century we are still talking about racial differences in glucose monitoring, especially in African Americans, whose frequency of SMBG is significantly lower. Proper action is mandated to remove these barriers for effective SMBG use in the minority population.

Self-monitoring of blood glucose (SMBG) improves glycemic control in oral hypoglycemic agent (OHA)-treated type 2 diabetes

Harashima S¹, Fukushima T¹, Sasaki M¹, Nishi Y¹, Fujimoto S¹, Ogura M¹, Yamane S¹, Tanaka D¹, Harada N¹, Hamasaki A¹, Nagashima K¹, Nakahigashi Y¹, Seino Y², Inagaki N¹

¹Department of Diabetes and Clinical Nutrition, Graduate School of Medicine, Kyoto University, Kyoto, Japan; and ²Department of Diabetes and Clinical Nutrition, Kansai Electric Power Hospital, Osaka, Japan

Diabetes Metab Res Rev 2013; **29**: 77–84

Background

We conducted a clinical research study to determine the effect of self-monitoring of blood glucose (SMBG) on glycemic control and the value of a putatively less painful blood sampling technique on SMBG in oral hypoglycemic agent-treated type 2 diabetes patients; SMBG has not been broadly applied in non-insulin-treated patients in Japan.

Methods

One hundred thirty-seven subjects were recruited for the 24-week, prospective comparison study and randomized into three groups: 46, no SMBG group; 46, fingertip group; and 45, palm group. The primary endpoint was change in HbA(1c). The secondary endpoints were SMBG compliance, dropout rate, treatment changes, and patient's and physician's satisfaction.

Results

Six subjects in the fingertip group (13.2%) and one subject in the palm group (2.2%) were dropped because of pain. A(1C) level of all subjects at 24-week was decreased more in the fingertip (−0.23%) and palm (−0.16%) groups than that in the no SMBG group (+0.31%) ($p < 0.05$). SMBG compliance was higher in the fingertip group (2.17 times/day) than that in the palm group (1.65 times/day) ($p < 0.05$). A(1C) level of treatment-unchanged subjects was decreased more in the fingertip (−0.25%) and palm (−0.21%) groups than that in the no SMBG group (+0.30%) ($p < 0.05$). SMBG compliance was higher in the fingertip group (2.24 times/day) than that in the palm group (1.65 times/day) ($p < 0.05$). Patient's questionnaire showed that 84.1% of the fingertip group and 90.2% of the palm group were satisfied with SMBG. Physician's satisfaction was higher in the palm group (94.0%) than that in the fingertip group (80.0%) ($p < 0.05$).

Conclusion

SMBG is beneficial for glycemic control, and palm blood sampling is a useful procedure for oral hypoglycemic agent-treated type 2 diabetes.

Comment

Although this is a relatively small study, it again suggests that there are alternative sites one could measure blood glucose. Although it is unlikely that accuracy would be different with palm glucose readings, more studies should be considered as this might make glucose testing more practical for some patients.

Is there a suitable point-of-care glucose meter for tight glycemic control? Evaluation of one home-use and four hospital-use meters in an intensive care unit

Gijzen K¹, Moolenaar DL², Weusten JJ³, Pluim HJ², Demir AY¹

¹Department of Clinical Chemistry and Hematology and ²Intensive Care Unit, Meander Medical Center, Amersfoort, The

Netherlands; and ³DSM Resolve, Process Analysis & Statistics, Geleen, The Netherlands

Clin Chem Lab Med 2012; 50: 1985–92

Background

Implementation of tight glycemic control (TGC) and avoidance of hypoglycemia in intensive care unit (ICU) patients require frequent analysis of blood glucose. This can be achieved by accurate point-of-care (POC) hospital-use glucose meters. In this study, one home-use and four different hospital-use POC glucose meters were evaluated in critically ill ICU patients.

Methods

All patients ($n=80$) requiring TGC were included in this study. For each patient, three to six glucose measurements ($n=390$) were performed. Blood glucose was determined by four hospital-use POC glucose meters, Roche Accu-Chek Inform II System, HemoCue Glu201DM, Nova StatStrip, and Abbott Precision Xceed Pro, and one home-use POC glucose meter, Menarini GlucoCard Memory PC. The criteria described in ISO 15197, Dutch TNO quality guideline, and in NACB/ADA-2011 were applied in the comparisons.

Results

According to ISO 15197, the percentages of the measured values that fulfilled the criterion were 99.5% by Roche, 95.1% by HemoCue, 91.0% by Nova, 96.6% by Abbott, and 63.3% by Menarini. According to the TNO quality guideline, these percentages were 96.1%, 91.0%, 81.8%, 94.2%, and 47.7%, respectively. Application of the NACB/ADA guideline resulted in percentages of 95.6%, 89.2%, 77.9%, 93.4%, and 45.4%, respectively.

Conclusions

When ISO 15197 was applied, Roche, HemoCue, and Abbott fulfilled the criterion in this patient population, whereas Nova and Menarini did not. However, when TNO quality guideline and NACB/ADA 2011 guideline were applied, only Roche fulfilled the criteria.

Performance variability of seven commonly used self-monitoring of blood glucose systems: clinical considerations for patients and providers

Brazg RL¹, Klaff LJ¹, Parkin CG²

¹Rainier Clinical Research Center, Renton, WA; and ²CGParkin Communications Inc., Boulder City, NV

J Diabetes Sci Technol 2013; 7: 144–52

Background

Blood glucose data are frequently used in clinical decision making; thus, it is critical that self-monitoring of blood glucose (SMBG) systems consistently provide accurate results. Concerns about SMBG accuracy have prompted the development of newly proposed International Organization for Standardization (ISO) standards: $\geq 95\%$ of individual glucose results shall fall within ± 15 mg/dL of the results of the

manufacturer's reference procedure at glucose concentrations < 100 mg/dL and within $\pm 15\%$ for values ≥ 100 mg/dL. We evaluated seven marketed systems against the current and proposed ISO criteria (criterion A).

Method

Capillary blood samples were collected from 100 subjects and tested on seven systems: Accu-Chek Aviva Plus, Advocate Redi-Code, Element, Embrace, Prodigy Voice, TRUE-balance, and WaveSense Presto. Results were compared with manufacturer's documented reference system, YSI, or per-chloric acid hexokinase; three different strip lots from each system were tested on each subject, in duplicate.

Results

Compared against current ISO criteria ($\geq 95\%$ within ± 15 mg/dL for values < 75 mg/dL and $\pm 20\%$ for values ≥ 75 mg/dL) the Accu-Chek Aviva Plus, Element, and WaveSense Presto systems met accuracy criteria. However, only the Accu-Chek Aviva Plus met the proposed ISO criteria (criterion A) in all three lots. The other six systems failed to meet the criteria in at least two of the three lots, showing lot-to-lot variability, high/low bias, and variations because of hematocrit.

Conclusions

Inaccurate SMBG readings can potentially adversely impact clinical decision making and outcomes. Clinicians can reduce controllable variables by prescribing accurate SMBG systems. Adherence to the proposed ISO criteria should enhance patient safety by improving the accuracy of SMBG systems.

Comment

These two studies point out that strip quality is not equal between brands of meters. In the first study, which assessed four inpatient meters used for intravenous insulin infusions in the ICU (and one outpatient meter), only accuracy was generally poor depending on which criteria of accuracy was used. With the most rigorous quality guidelines, only one meter met the standard. Is it any wonder we have so much hypoglycemia in the ICU? In the second study, results for mostly "off-shore" meters showed unacceptable results for accuracy, despite the fact that these meters will become widely used in the United States as a result of the government's "competitive bidding" law. The impact on potential catastrophic outcomes is of obvious concern.

Conclusions

As we are now well into our third decade of SMBG, some of our questions have been noted for many years, while others are new. In the case of the former, the use of SMBG by non-insulin-requiring patients continues to be controversial, partly because it is next to impossible to design a study that replicates all practice patterns and philosophies of care. It is curious how bias works. If a study is designed by a payer who has a financial incentive to minimize any impact of SMBG, the

results of the study are usually negative. The opposite of course is the rule when the sponsor has a potential for financial gain. Certainly, in a practice situation where one has no more than 3–5 minutes to review the diabetes, it is not surprising that SMBG is discouraged and patients do not find it helpful since they rarely are able to review the data with their provider. When time is available to review the information with the provider, SMBG can be extremely important.

One topic that is not controversial, and emphasized by the Miller study, is the importance of SMBG in type 1 diabetes (T1DM). Hopefully, payers and governments will not be questioning this technology for this population until CGM or some other better strategies for glucose determination are available.

Although cost has always been an issue, there is a related issue that, although not new, has become more obvious. While blood glucose meter accuracy is in itself not a controversial topic, it appears that, at least at the end of 2013, in the United States poor accuracy is acceptable if costs can be reduced. While this situation is much more complex and is certainly not isolated to the United States, one can only hope

that all payers will appreciate the importance of accuracy so that inappropriate treatment decisions are not made. When we review SMBG in 2014, hopefully this problem will be improved.

Author Disclosure Statement

No competing financial interests exist.

References

1. Wild S, Roglic G, Green A, et al. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care* 2004; **27**: 1047–53.
2. Garg SK, Reed K, Grey J, Westerman A. Possible impacts of new accuracy standards of self-monitoring of blood glucose. *US Endocrinology* 2013; **9**: 28–31.
3. Schütt M, Kern W, Krause U, et al. DPV Initiative: Is the frequency of self-monitoring of blood glucose related to long-term metabolic control? Multicenter analysis including 24,500 patients from 191 centers in Germany and Austria. *Exp Clin Endocrinol Diabetes* 2006; **114**: 384–88.