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Accuracy and utility of a 10-test disk blood glucose meter☆

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Abstract

We evaluated the clinical accuracy, precision, and ease-of-use of a whole blood referenced glucose meter system that uses a 10-test disk (Ascensia® Confirm™ Blood Glucose Monitoring System, Bayer Healthcare LLC). The meter system was tested by 100 subjects and eight health care professionals at two separate diabetes centers. Meter blood glucose test results, obtained by the subjects and health care professionals, were accurate and correlated well when compared with laboratory results. The means of the subject and healthcare professional blood glucose results were within 4.8% of the laboratory mean glucose result. When compared with laboratory results, the correlation coefficient was 0.96 for subject meter results and 0.97 for health care professional meter results. Error grid analyses demonstrated that all subject and health care professional blood glucose measurements fell within zones A and B ('no effect on clinical action' and 'altered clinical action with little or no effect on clinical outcome,' respectively). Ninety-three percent (93%) of subjects rated the meter system favorably on an 'ease-of-use' questionnaire. A majority of subjects correctly performed blood glucose self-monitoring tasks simply by reviewing the user guide. In summary, this unique meter that uses a 10-test disk was shown to be both accurate and precise, and subjects with diabetes were able to use the system properly with minimal instructions.

Keywords: Blood glucose self-monitoring; Diabetes mellitus; Reagent strips; Patient satisfaction; Blood glucose

1. Introduction

Self-monitoring of blood glucose (SMBG) has become an established standard of good diabetes care. Patients, newly diagnosed with diabetes and those just beginning SMBG, are often faced with a large amount of new information about their disease, and require training in specific care techniques, including SMBG, medication use, and dietary changes. Structured and comprehensive diabetes education processes are used for dosing and injecting insulin, instruction on SMBG, meal and exercise planning, carbohydrate counting, and other aspects of diabetes care. However, many patients learn how to use a new blood glucose meter

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simply by reviewing the instructions for use. Although the American Diabetes Association recommends initial and regular review of SMBG technique by health care providers [1], the lack of periodic meter use technique evaluations has been noted as the most significant problem causing inaccurate meter results [2].

To the best of our knowledge, most studies that evaluate the use of blood glucose meters do not specifically assess the ability of patients to use the meter after simply reviewing the written instructions for use. Since many patients do not receive formal training on meter use, an easily understood and comprehensive user guide is vital to assure that the meter is used properly. The International Organization for Standardization (ISO) recently published a standard specifying performance criteria for blood glucose monitoring systems [3]. This standard specifies that an evaluation should be performed to demonstrate that patients are able to operate the meter using the manufacturer's instructions for use.

A new blood glucose monitoring system (Ascensia® Confirm™ Blood Glucose Monitoring System, Bayer Healthcare LLC, Elkhart, IN) has recently been introduced that uses a 10-test disk (Ascensia® Glucodisc® strips). The user is not required to handle individual test strips and each strip is retained in a foiled and desiccated disk until immediately before use. The current study was designed to evaluate the clinical performance and ease-of-use of this unique meter system when used by either subjects with diabetes or by health care professionals. The ease with which subjects could independently learn to use the meter from the user guide was also assessed.

2. Materials and methods

The study was conducted at two separate diabetes centers, and enrolled a total of 100 subjects with type 1 or type 2 diabetes who were currently performing SMBG. A total of eight health care professionals from both centers also participated in the study. Fifty (50) subjects were enrolled at each center and were selected to represent a variety of educational backgrounds. All subjects made one visit to the clinic to learn to use the new meter, to perform capillary blood glucose and control solution tests, and to complete a questionnaire on the ease of use of the device. Education on meter use was completed by review of the device instructional material. Subjects received assistance from the study staff only if they were not able to complete specific SMBG tasks independently within 5 min. The study staff member documented the details of any assistance that was provided for a specific task. Study staff categorized the assistance provided as 'no assistance', 'minor assistance', or 'needed instructions'. Twenty-five (25) subjects from each center also took the glucose meter home to test in parallel with their personal meter for 7–10 days before completing the ease-of-use questionnaire. Institutional Review Boards at each institution approved the study and informed consent was obtained from all subjects.

2.1. Blood glucose monitoring system

The meter system uses an electrochemical glucose oxidase method for glucose determinations on capillary blood samples. The blood glucose results are referenced to whole blood glucose values. The test strips are packaged in 10-test disks that are loaded into the meter. Each test strip is individually sealed in the foil disk with a desiccant. The test strip uses approximately 2.5–3.5 μl of blood to fill the test chamber. The glucose test range for the meter system is 0.6–33.3 mol/l and the system has been cleared for alternative site testing (palm, forearm, abdomen, and thigh) by the US Food and Drug Administration.

2.2. Blood glucose monitoring system accuracy

All subjects performed a blood glucose test with the study meter for comparison with laboratory glucose method results. Immediately after this test, the health care professionals performed a second blood glucose test using the same meter and blood from the subject's finger. Additional capillary blood was immediately collected into a micro-tube with lithium heparin anticoagulant and a gel barrier for duplicate laboratory comparative glucose assays. Capillary blood was also collected into micro-hematocrit tubes for centrifugation and hematocrit measurement (site 1) or into a device for electrical conductivity hematocrit measurement (site 2). The laboratory comparative plasma glucose assay was performed immediately, or the specimen was refrigerated and the assay was performed later the same day.