Use of an Automated Device for Alternative Site Blood Glucose Monitoring

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OBJECTIVE — To evaluate the accuracy, comfort, and ease of use of a new automated device for blood glucose monitoring using the arm as an alternative sampling site.

RESEARCH DESIGN AND METHODS — These studies use an automated hand-held device that applies a small vacuum, lances the skin, transfers blood onto an electrochemical test strip, and measures glucose. Patients who had type 1 or type 2 diabetes and had received no prior training using this device were recruited from five diabetes clinics. Testing was performed by the patients using this device and by trained healthcare professionals. Blood glucose was measured by 354 patients: from the arm using the device, from the finger using a laboratory reference instrument, and from the finger using the device via the secondary test port. Each patient completed a questionnaire rating the level of pain and ease of use of the device.

RESULTS — Blood glucose results in samples obtained from the arm with the automated device agreed well with finger-stick plasma glucose results using a reference instrument (regression slope 0.98, intercept 0.01 mmol/l [0.1 mg/dl], $r = 0.96$). Error grid analysis showed that 100% of the measurements fell within zones A and B. In the survey, 60% of the patients reported that arm testing with the automated device was "painless;" another 31% of the patients stated that it was "much less painful," and 6% of patients considered using the device "less painful" than finger-stick testing. In a survey containing 15 questions for rating the ease of use with a scale of 1 to 6, the overall mean rating was 5.5.

CONCLUSIONS — The automated device is easy to use and provides accurate glucose results; 97% of the patients found it less painful than finger-stick testing.

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The principle barriers to effective self-monitoring of blood glucose (SMBG) are operator error and decreased compliance with recommended frequency of monitoring because of discomfort and inconvenience (1–3). Patients often have difficulty obtaining an appropriately sized drop of blood from a finger prick; even though some of the newest test strips do not require a large sample, this is still a major problem (4). Better vision and dexterity may be required for a patient to align the test strip with a smaller blood drop. Failure to apply enough blood for a test can lead to an erroneous result (5–7).

Alternative site sampling may reduce user pain. Currently available devices that use alternative sampling sites are as follows: the Microlet Vaculance (Bayer, West Haven, CT) is a lancing device that uses a manually applied vacuum; the FreeStyle (TheraSense, Alameda, CA) and FastTake (LifeScan, Milpitas, CA) glucose meters use a separate, manual lancing device; and the At Last Blood Glucose System (Amira Medical, Scotts Valley, CA) combines a lancing device with a meter but requires manual lancing and transfer of blood to the test strip. The automated device described herein combines lancing the skin, transferring sufficient blood to the test strip, and completing the measurement process for a glucose result. The system is designed to ensure proper sampling and minimize discomfort by use of an alternative sampling site. The objective of this study is to evaluate accuracy, comfort, and ease of use of this automated device.

RESEARCH DESIGN AND METHODS

— A total of 378 individuals (26% with type 1 diabetes, 64% with type 2 diabetes, and 10% without diabetes) were enrolled at five diabetes centers. Subjects were 18–84 years of age; 57% were female. The institutional review boards of participating centers approved the study, and all subjects gave their informed consent before participation.

The automated device

The Sof-Tact Diabetes Management System (named SoftSense in Europe) for alternative site (e.g., forearm or upper arm) SMBG is manufactured by Abbott Laboratories, MediSense Products (Bedford, MA) (Fig. 1*A*). After opening the cover, a lancet is inserted into its holder and a test strip is inserted into the alternative site test port (Port 1). An inserted test strip is stable for at least 8 h, providing a "pre-

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Abbreviations: SMBG, self-monitoring of blood glucose.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

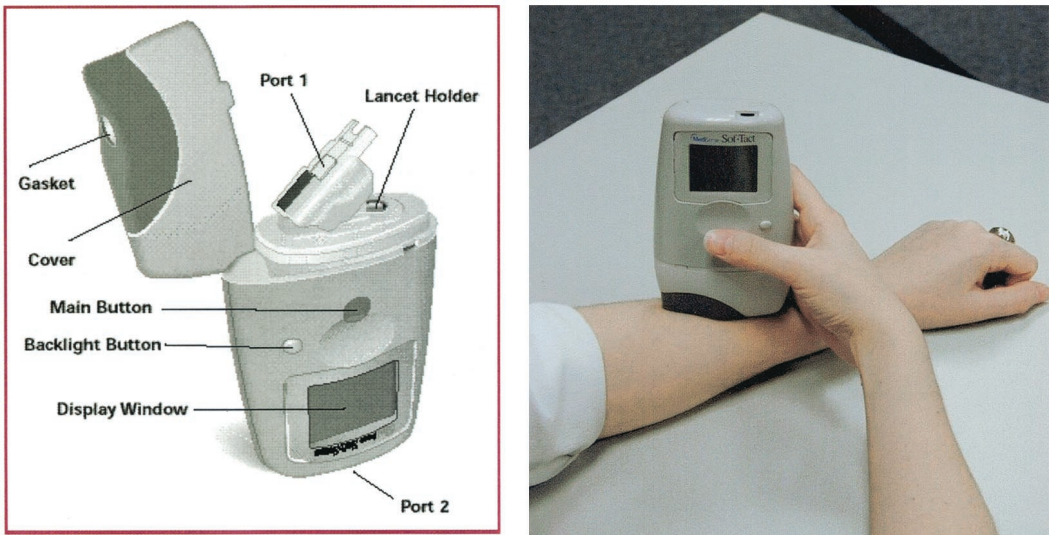

Figure 1—*A: The automated device for alternative site testing.* B: *Glucose testing on the arm with the device.*

load" capability. The user positions the loaded device on the arm and presses the main button (Fig. 1*B*). The device applies a slight vacuum to the skin, the lancet is released, and blood is drawn onto the strip. When sufficient blood reaches the trigger electrode, the test is started automatically. The device emits a beep in ~20 s, notifying the user that the test has started and the vacuum has been released. The glucose result, measured by amperometric biosensor technology, is calibrated to plasma equivalent values and shown in the display window after 20 s. The total time from placing the device on the arm to obtaining a test result is ~40 s. Backlighting of the display allows the test to be conducted in low-light conditions.

The glucose measurement range of the device is 1.7–25.0 mmol/l (30–450 mg/dl). Precision studies (data not presented; 20 tests on each of three samples at each of six glucose levels) on blood samples with glucose of 2.8–22.2 mmol/l (50–400 mg/dl) showed a coefficient of variation between 5.9 and 2.9%.

The device has a secondary test port (Port 2) for testing finger-stick blood samples and control solution and for downloading data to a personal computer. The device stores the last 450 test results with date and time.

Patient testing

Participants were instructed to read the user manual, calibrate the device, and perform testing on the arm. A healthcare professional then performed the same testing on the subject's arm. Testing using the arm was immediately followed by finger-stick blood testing by the patient and the healthcare professional with the de-

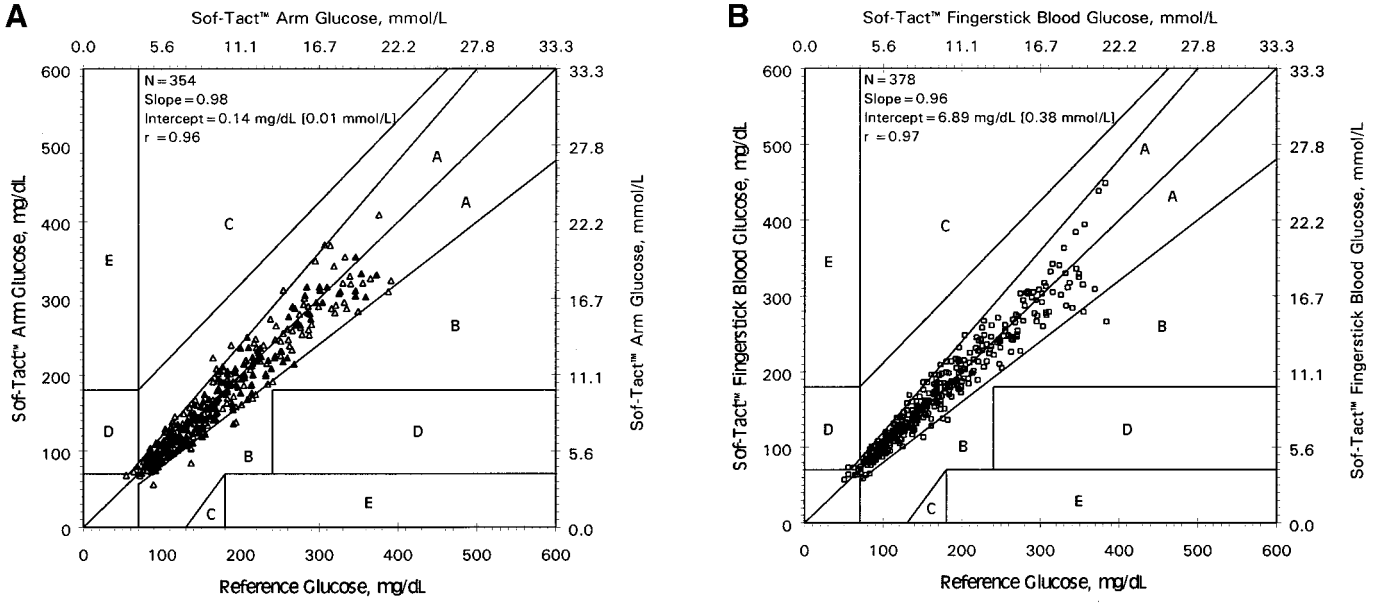

Figure 2—*Error grid analysis of* (A) *arm blood glucose results (△, forearm; ▲, upper arm) and* (B) *finger-stick blood glucose results obtained by patients using the Sof-Tact System compared with finger-stick plasma glucose values from the reference instrument.*

vice and with the YSI glucose analyzer (YSI, Yellow Springs, OH). Each subject then completed a questionnaire rating pain and ease of use.

RESULTS — Standards and guidelines (8,9) for evaluation of glucose meters typically specify that results between the test method and the comparative method should be compared on the same blood sample. However, in this study, we compared results of arm blood glucose testing performed by patients using the automated device with finger-stick plasma glucose results using the laboratory reference instrument. We found significant correlation between results obtained from the arm using the device and from the fingertip using the YSI analyzer (regression slope 0.98, intercept 0.01 mmol/l [0.1 mg/dl], $r = 0.96$, $n = 354$; arm testing data from 24 subjects were excluded because of protocol deviations.) Error grid analysis (10) showed that 100% of the measurements were within zones A (93.2%) and B (6.8%) (Fig. 2*A*). In arm testing, 87% of the subjects had a successful test in their first attempt with the device; another 10% of the subjects succeeded in their second attempt because not enough blood was collected in their first test and the device displayed an error message.

Results on the same finger-stick blood sample were compared between the device (Port 2 testing performed by the patients) and the YSI. We found satisfactory agreement (slope 0.96, intercept 0.4 mmol/l [6.9 mg/dl], $r = 0.97$, $n = 378$). Error grid analysis showed that all results except one were within zones A (96%) and B (3.7%) (Fig. 2*B*).

Patient accuracy with the automated device was comparable to the accuracy obtained by the trained health care professionals when they performed arm and finger-stick testing on the patients. Compared with the laboratory plasma reference, the arm results obtained by the trained professionals showed the following: regression slope 0.95, intercept 0.1 mmol/l [1.7 mg/dl], $r = 0.95$, $n = 352$; 90.1% in zone A and 9.9% in zone B by error grid analysis. The fingerstick results showed the following: regression slope 0.94, intercept 0.3 mmol/l [6.4 mg/dl], $r = 0.98$, $n = 378$; 97.4% in zone A and 2.4% in zone B by error grid analysis.

Regarding assessment of pain compared with the finger-stick method, the patients participating in the study rated the automated device as follows: 59.9% painless, 31.1% much less painful, 5.5% slightly less painful, 2.6% same amount of pain, 0.9% slightly more painful, and 0% much more painful. In a survey of 15 questions regarding ease of use, with a rating scale of 1 to 6 (with 1 representing very difficult and 6 representing very easy), the overall mean rating was 5.5, indicating that the patients found the automated device very easy to use.

CONCLUSIONS — Unlike previously published standards and guidelines (8,9) for evaluation of glucose meters, this study compared results of arm blood glucose testing performed by patients using the automated device with finger-stick plasma glucose results using the laboratory reference instrument. In this study, we found comparable accuracy between our patients and trained health care professionals in using the automated device, suggesting that there is no dependency on technique. After reading the user manual, the patients demonstrated a first-test success rate of 87%; an additional 10% succeeded on the second attempt. Therefore, the failure rate with the device was low in our previously untrained trial population. Incomplete coverage of the reaction area causes many glucose meters to give erroneous results with a small blood drop (5–7). The device tested herein automates the transfer of blood to the target area of the test strip, which has a trigger electrode to start the test only upon detection of sufficient quantity of blood. Compared with the fingertips, the arm has a lower density of sensory nerve endings (11). As confirmed by our five-center patient survey, pricking the arm to collect capillary blood caused much less discomfort than a finger stick. In this study, 60% of the patients found testing with the automated device painless, and a total of 97% found it less painful than finger-stick testing.

Despite its proven ease of use, the automated device also has some disadvantages due to incorporation of the vacuum and lancing mechanisms. It is larger and heavier than other glucose meters, such as the LifeScan OneTouch Profile. When the automated device is carried in its case, it is approximately the size of a typical carrying case for a glucose meter, test strip vial, and lancing device. This may create inconvenience for individuals who do not use a pocketbook or carrying pouch. During the first several seconds of a test, the vacuum pump produces a noise audible in a quiet environment and a slight sensation of vibration.

Although it is beyond the scope of this study, the option of an automated device for alternative site testing may be attractive to newly diagnosed patients who are just beginning to perform SMBG, to children (to avoid pain or squeezing blood from the finger), to individuals with limited vision or manual dexterity, and to people who would like to avoid sore or callused fingers. A preload capability and display backlighting may enable the user or family members to set up the device in advance for nighttime testing. This automated device may also be useful for improving patient adherence to frequent monitoring of blood glucose.

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