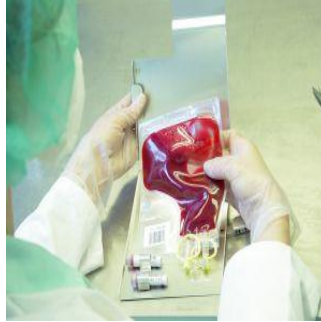

Study on Blood Glucose Monitoring Presented at Diabetes Meeting



An outcome study with Bayer's blood glucose monitoring system Contour™USB with AutoLog and trends features and Glucofacts™Deluxe as integrated data management software was recently started. The design of the study "Evaluation of the Impact of the Contour USB Blood Glucose Monitoring System with integrated Data Management on Glycemic Control in Insulin-treated Diabetic Patients" (CONGO) was presented by Professor Peter Schwarz, University of Dresden, Germany, at the World Diabetes Congress in Dubai.

Study design and objectives

This prospective, multicenter, randomized, controlled, open clinical outcome investigator initiated trial is conducted at 6 clinical sites with a total of 240 adult insulin treated type 2 diabetic patients.

The patients will be randomized in two groups (BGMS Contour USB vs. Contour™ (control)). The test group will use Bayer's Contour USB meter and will be taught to use all features of Contour USB (i.e., level 2), such as AutoLog, trends, target ranges, Contour USB integrated data management software including carbohydrates and insulin units and connecting meter to computer to view results. The control group will use Bayer's Contour meter and will be taught to use all features of the meter, and will be required to keep a paper log book. These patients will be managed using 'usual care' procedures which basically follow the German Diabetes Association Guidelines (DDG), and their blood glucose values will be communicated to their health care professionals via handwritten glucose log books.

The primary objective is to determine if the use of the Contour USB system is associated with improved glycemic control as determined by hemoglobin (HbA1c) values primary end point. Secondary Objectives are to determine the frequency of severe hypoglycemic events requiring emergency rescue visit, hospitalization, glucagon or in-vitro glucose, external attendance.

What makes SMBG effective?

In order for SMBG to be effective, there must be a means of recording patients' blood glucose data. Health care professionals must have access to accurate blood glucose data prior to, or at the time of, the patient's visit and the HCP and the patient must be able to understand and interpret the SMBG data in order to act appropriately.

As Professor Schwarz explained, "Traditionally, patients have kept handwritten blood glucose logs that they provide to their HCP to assist in their diabetes management. Although a useful and necessary component of diabetes management, logbooks can be incomplete, inaccurate and illegible, this may lead to faulty analyses when being presented to the HCP."

Moreover, correct interpretation of the SMBG data from these blood glucose logs can be a major challenge for both patients and health professionals. The information from blood glucose monitoring activity needs to be presented in a clear and understandable format which will allow realization of patterns and trends of normal, high and low BG values. Understanding of trends allows patients and HCP to make appropriate changes in medication, exercise and meal plan.

Tools to facilitate this effort include various data management systems, designed for both patients and HCP, that interface with blood glucose monitors, and present the data in an understandable form. Some data management systems allow for transfer of patient data and information directly to HCP. This can be accomplished by a number of means including directly via cable connection, via computer disk, remotely via modem, or e-mail, or via internet.

According to Professor Schwarz, "When used as an integral part of a comprehensive disease management program, these data management systems can assist persons with diabetes to make better decisions. They can assist health care professionals in making treatment recommendations and verifying compliance, and in understanding outcomes, and effectively managing patient populations."(2)

Patients who aim for tight control of their blood glucose levels may be at greater risk for hypoglycemia. Frequent self-monitoring of blood glucose (SMBG) is a valuable tool for these patients. In addition, emerging research suggests that tight control of postprandial BG values specifically, plays a key role in achieving overall optimum HbA1c levels. (3) The Contour USB AutoLog function allows the patient to mark results as before/after meal with one button press after a test. Given the special features and flexibility of the Contour USB system, it may be an ideal choice for highly motivated patients who are striving for tight control and HbA1c reduction.

First indication suggested by a non-interventional study

Initial indications that people with diabetes benefit from electronically evaluated data have come from a non-interventional study(4) in 2010. Included in this study(5) were more than 1,000 insulin-treated diabetes patients and more than 100 health care professionals assessed the

usability of Bayer's Contour USB blood glucose monitoring device in everyday life over a period of four to six weeks. A sub-analysis of documented laboratory parameters – postprandial and fasting blood glucose, and HbA1c – available for 237 patients showed that comparing the initial values at baseline to those of the final examination four to six weeks later, all three values had decreased. At the first visit, mean blood glucose was 133.8 mg/dl (fasting) and 181.2 mg/dl (postprandial). At the end of the evaluation, mean blood glucose levels were lower: 122.6 mg/dl (fasting) and 162.0 mg/dl (postprandial). Mean HbA1c was 7.8 percent at the start of the study and 7.4 percent at the end. These excellent findings initiated the CONGO trial.

Contour USB: Transforming blood glucose data into meaningful insights

Accurate, reliable blood glucose information and ongoing data tracking and sharing between patients and health care professionals are key to managing diabetes successfully. Bayer's Contour USB blood glucose monitoring system provides an effective approach to the self-monitoring of blood glucose values. The device combines established test strip sensor technology and convenient diabetes management software and thus facilitates life for people with diabetes and their health care providers. The blood glucose monitor plugs directly into a computer via USB port and is equipped with Glucofacts Deluxe diabetes management software, which allows easy retrieval of data as well as long-term electronic documentation and analysis of individual results.

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