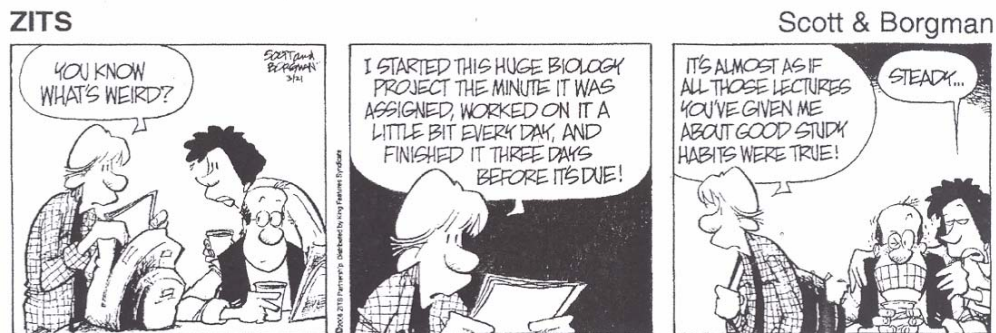


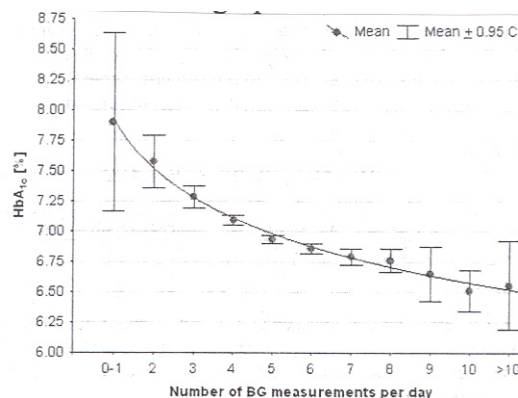
Windy City Whispers 67th Scientific Sessions American Diabetes Association June 2007

Self Blood Glucose Monitoring

Since we have been talking about monitoring, I thought I would next go into the reports on self-blood glucose monitoring. There were not as many since there were no significant new meters out. The emphasis seems to be mostly on the continuous glucose monitoring so there was much less said about standard blood glucose monitoring.



The first study is an “I told you so” sort of report. It is from France and Germany and showed that multiple daily blood glucose tests is strongly associated with optimal glucose control in pump patients. They found that they could achieve a Hgb A1c of less than 7.5% in 70.6% of their patients. The actual targeted Hgb A1c level of less than 7% was only achieved when daily blood glucose measurements were done five or more times per day. They found that glucose control was highly correlated with the number of daily glucose measurements. I have included the graph which shows a steady decline in Hgb A1c with more tests per day.



This is one of those times where I get to say I told you so. There really is an advantage in doing frequent blood glucose testing. Now all I have to do is figure out how to convince my adolescents that this is in fact true. Another study from Germany looked at what time is appropriate for most useful post-prandial glucose measurements. They looked at both blood glucose measurements and interstitial tissue fluid measurements. They gave patients a fast and a slow absorbed meal with the same amount of carbohydrates, 50 grams. They found that the time to maximum tissue glucose peak was 43 minutes with the fast meal and 58 minutes with the slow meal. The time to maximum blood glucose level was 36 minutes with the fast meal and 44 minutes with the slow meal. Thus they concluded that the mean post-prandial glucose peaks occur less than one hour after the start of the meal. They did see the expected time delay of about ten minutes of the tissue glucose and blood glucose readings. I won't try to go into fast and slow absorbing carbohydrates right now. I may well get to that later in the discussion, but we need someone self-proclaimed smarter than me (i.e. the dieticians) to explain this to you better. It is rapidly becoming a new (or revisited?) concept in dietary management. This study shows, however, that maybe we should be doing our post-prandial blood sugars one hour after eating rather than two hours if we want to know our maximal rise with the food. Another study from Milpitas, California was interesting in that they looked at the counterfeit test strips for our glucose meters. It turns out that counterfeit medical products are becoming more prevalent on the market. This study looked at counterfeit test strips designed for the One-Touch ultra meter that have been released to the United States and in the international marketplace. They found that 29% of the counterfeit ultra strips produced error messages or no result. They also found that 20% of the tests were in the unacceptable range for accuracy. These values generally over-estimated the glucose concentration, which can certainly pose a health hazard if we over compensate for false hyperglycemia. They concluded that it is therefore important for health care professionals, regulators, manufacturers, distributors, retailers and patients to be on the alert for counterfeit products as an important step toward their elimination. They did not say how to recognize these counterfeit strips, however. I guess this is just one more hazard in our medical lives. It behooves us to look at the containers and strips that we buy to be certain that they are the real thing. If there is any question about irregularities, please take them back to the pharmacy so they can check. There was a study from Minneapolis looking at the performance of the new Ascensia Contour blood glucose monitoring system. I thought I would include it because I have not been a fan of the meter. They found that over 99% of the subjects correctly performed the blood glucose testing using the instructions with the meter. Ninety-six percent of the patients stated that the Contour met their needs and 95% indicated that the system was easy to use. Clinically accuracy was demonstrated by 97% of those subjects with their results falling in Zone A of the error grid. Thus I have to grant Ascensia good accuracy and acceptance. Another study looked at the concern about mis-coding with the One-Touch Ultra meter. As you know, the strips come with a code and it is important that the meter be calibrated to the code. They found that when the code was dialed in correctly, 98.6% of the readings were in the desired Zone A of the grid. When the codes were not applied appropriately, only 79% of the results were in the A grid. On the other hand, 21.2% were in the B Zone and thus they concluded that if the code on the meter does not match the code on the test strip vial, there is a low risk of adverse health outcomes in the Ultra Meter system. Be that as it may, we would very much ask that you code your meters properly. The more accuracy we can get the better.

There were a few reports on non-invasive meters. As you know, the ultimate goal is to have a meter that could rest on the skin and requires no penetration of the skin. We have not been able to achieve the technology to this point and people are still working to see if they can develop a totally non-invasive approach. A study from Santa Barbara study looked at a device from Sensys Medical. The skin had to be prepped (including shaving) and a disposable guide was adhered to the forearm in a manner which did not distort the skin and yet assured the same location for each measurement. When a trained technician was able to use the device (which is about the size of two quarters and uses infrared technology), 79.6% were in the Clarke A grid. Ninety-nine point seven percent were in the A/B grid which is very good. When it was just the patient doing the testing, however, only 37.5% were in the A grid and 83% were in the A/B grids. Thus, they concluded that it is effective technology for accurately measuring glucose non-invasively when performed by trained technicians. They pointed out, however, that their study revealed significant degradation in the result when the consumer used the sensor. This sensor is not ready for commercial use, obviously. *It is bulky at the moment and very temperamental apparently. It does give hope, however, that we may someday actually have a non-invasive system that works. Our patients who hate to prick themselves will be delighted when that day comes.* A study from Zurich, Switzerland looked at the use of impedance spectroscopy as a non-invasive approach to blood testing. This was a very preliminary study and just showed that the changes that they found in levels were due to either changes in blood perfusion or sweat. They concluded (without providing any data) that by using a multi-sensor approach, they could compensate for the perturbing effects and impedance spectroscopy may be a potential non-invasive form in the future. Another study from Hershey, Pennsylvania looked at optical coherence tomography as a non-invasive, sensitive and accurate way of providing continuous monitoring. They studied 33 patients with diabetes and found that 18% of the matched points with lab glucose results were in the Clarke Grid A with 19% in Grid B. They found that 80% were within +/- 20% for a blood glucose greater than 75 mg/dL. They could not conclude about blood glucose levels less than 75 mg/dL since only 6 values occurred. They concluded that this study demonstrated that the OCT sensor has a high degree of accuracy in the prediction of blood glucose levels in patients with diabetes and was comparable to the commercially available DexCom and Guardian devices. They also found that the device maintained calibration for over four days with no adverse effects. *Here again is another form of non-invasive testing that may prove to be useful years from now.* A group from Galway, Ireland used non-linear di-electric spectroscopy which is a technique that relies on transducing reflected harmonics, which are generated in a glucose concentration dependent fashion, due to the conformational change of membrane bound glucose receptor proteins when they are stimulated by a low-frequency, low-voltage electrical field. They tested five patients and found that all of the data pairs with the lab glucose fell within the Grid A (79.6% and Grid B 20.4%) zones. I did not get to see the device but they claim they use four carbon-loaded polyester electrodes applied to the shaven abdomen of the patient. *Yet another non-invasive approach. Obviously all of these will have to be refined and made more user friendly before they could even be considered.* Finally there was a study from Israel using the OrSense device which is based on red/near infra-red occlusion spectroscopy. They studied patients for eight sessions lasting 24 hours each. The study was done in an Outpatient Clinic representing a home-like setting. They found that 96.9% of all points fell in the A-B zones (74.2% in A and 22.7% in B), indicating good accuracy. They concluded that this study shows a significant improvement in the device performance as a profiler and indicates great promise for its use as a non-invasive continuous glucose monitoring system. They said that it was currently under evaluation in broader clinical settings. *I have to believe that all of this research is*

encouraging to our patients. They are looking at several different approaches to non-invasive continuous monitoring and it would seem logical that at least one of these will become a practical approach. Thus there is hope that we will have techniques in the not too distant future that will allow for accurate and safe measurement of glucose levels without having to draw blood or prick the skin for interstitial fluid measurements. The dream of managing diabetes without doing blood tests or pricks seems more possible now than it did a few years ago.

At the commercial exhibits, there was very little new about self blood glucose monitoring. The Ascensia Contour has the advantage of no coding or calibration. It has dropped down to a five second test so it is now competitive with the other meters. BD announced that they would no longer make meters which was well received by most of us since their meters seem to break down frequently and were thought to be fairly inaccurate. LifeScan will be teaming up with Medtronic so that they will make a meter that communicates with the Mini-Med pumps. That meter should be out sometime next spring. Other than those minor announcements, very little is new in the field of blood glucose monitoring.