Improved Diabetic Prognosis Following Telecommunication and Graphical Processing of Diabetic Data

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Abstract

The thesis that an integrated telecommunications/ reporting system would affect diabetic prognosis was tested. Over fifteen months a double crossover study compared traditional diaries versus graphical display of telecommunicated blood glucose data. Significant drops in glycohemoglobin were observed in both groups during the telecommunications period, while no significant drops were observed in the groups while diaries were employed.

Introduction

An important aspect of home monitoring which has not received close attention is the information transfer of the home monitoring results to the health care provider. This project examined traditional versus computer enhanced tools for information transfer in diabetes mellitus. Patients were requested to connect a glucometer device to an intelligent modem weekly. Graphical and mathematical tools were developed to extract and emphasize the information content of the home monitoring data arriving at the central site. Data smoothing, trend analysis and calculation of quality control statistics were incorporated into a graphical time series oriented report to the health care provider.

The integrated home monitoring system was tested on 20 diabetes mellitus patients in a double cross-over design over a fifteen month period.

Methods

Patient selection

The patients with the highest blood glyco-hemoglobins on record during the preceding 18 months at the White River Junction Veterans Administration Hospital and who were on insulin therapy were queried by mail if they wished to participate in the study. Informed consent was obtained if they wished to enroll. Thirty patients were originally enrolled, and ten dropped out of the study due to medical complications unrelated to the study or because they declined to continue, leaving 20 available for data analysis.

Glyco-hemoglobin determination: Blood glyco-hemoglobin determinations were obtained on entry into the study and every three months thereafter if possible. A Borate affinity method was used, which measures all glycated products and excludes the labile fraction. Glyco-hemoglobin determinations were performed within one week of specimen collection, generally with 48 hours.

Communications Hardware/Software: A prototype intelligent modem designed by Ames Laboratories (Elkhart, IN) was used in conjunction with a Ames "Glucometer-M" to capture and transmit the information. The Glucometer-M was used to measure, date and record glucose values obtained from finger-stick glucoses. Values were obtained twice daily, except on two days when four values were obtained, generally before meals or bedtime. In addition, the patients were instructed to use glucose solutions on a weekly basis to provide quality control. Data was transmitted weekly to the lab of one of the authors (EKS) which received the data on an IBM clone computer which was available 24 hours a day, The program provided error checking of the transmitted data. The data would be re-transmitted if the line was busy.

Report Construction: The data was transferred to an Apple Macintosh for data analysis and report construction, which was done using Apple's Hypercard with XCMD extensions. The report consisted of four graphs, a set of numeric summary statistics and a prose portion of 4 to 6 sentences. Two of the graphs employed a Parzen window with an exponential kernal to smoothly approximate the 20th and 80th percentiles of the glucose data versus time. This resulted in an "envelope" which contained multiple hidden points and was intended to demonstrate trends in a clearer way than points alone. These were constructed for the glucose values sampled before breakfast and before dinner. Histograms were used to show the range, the 10th and 90th percentiles and the medians of glucose values determined during four periods of the day: before breakfast, before lunch, before dinner and before bedtime. The fourth graph was a dot plot of all values in the preceding six days.

The statistical section informed the care giver of the average glucose value, the percent of glucose values above 200 mg/dl, the percent below 60 mg/dl, the total number of values submitted and the previously determined glyco-hemoglobin value.

The prose section used algorithms previously developed [1] to determine whether significant hyper or hypoglycemia had occurred. It also reported whether there were enough values for analysis and the general precision of the quality control materials being performed.

Study Design: Twenty patients were stratified by sex and glyco-hemoglobin value and randomly assigned to one of two groups. During the first six months one group used the communications device to report glucose data, while the other used traditional diaries. At six months the groups switched and for the next nine months used the opposite method in a double cross-over fashion.

Statistical Analysis: Patient data was linearly transformed by subtracting the regressed value of the midpoint in the study interval for each patient. The resultant data was regressed versus time. An F test was used to determine significance.

Results

There were 9048 (4756 in group 1) blood glucose measurements collected during an 18 month period. Either two or three glyco-hemoglobin were determined during each segment of the trial for each patient, generally occurring at the beginning, midpoint and end of each study period. There were 111 glyco-hemoglobin values analyzed. For patients in group 1 (n=11) initially sending results via by intelligent modem there was a significant decline ($p<.008$) in glyco-hemoglobin values during the first six months, while group 2 (n=9) initially employing diaries did not record a significant decline ($p>.18$) during the same time interval. During the following nine month period group 2 switched from diary to electronic communication of results and recorded a significant decline in glyco-hemoglobin results ($p<.001$), while group 1 switched from graphed results to diaries and recorded no significant changes ($p>.4$).

Discussion

Chronic disease hospital days outnumber acute disease by 3 to 2 [2]. This ratio can only be expected to increase as the population age mode becomes higher. An increasingly employed method to efficiently address this trend is to use health monitoring and care in the home.

Chronic care patients are employing more advanced therapeutic and physiologic monitoring procedures in the home. Intravenous drugs for chronic illness [3-5], Factor VIII for hemophilia [6], and home blood glucose [7-9] monitoring for diabetes mellitus are common examples of techniques formerly found only in hospitals which represent a cost-effective approach to chronic disease.

There has been little investigation into provision for ongoing accurate communication between patient and the primary health care provider. Patient /physician communication is known to influence compliance with physician instructions [10-11]. A study in diabetic patients indicated that patients using diaries made non-random errors in reporting self monitoring results to physicians [12].

A reasonable question is the cost effectiveness of the home monitoring procedures. One of the few examples in the literature of a home based monitor /telecommunication system showed $1370/patient/year savings in 1983 dollars [13]. In another study cost reductions were demonstrated when patients on intravenous drugs were sent, along with the intravenous therapy, home earlier from inpatient admissions [3].

A second problem associated with home care is the large amount of data generated. Crucial information can be missed if imbedded in a large mass of data [14-15]. For home monitoring to be effective, efficient information storage, abstraction and result presentation are necessities .

In this study diabetic results were communicated to physicians using the clinical laboratories as a middle link. This avoids the difficulties clinicians often encounter when having to support instrument training, support, quality control and automated data processing of results. Clinical laboratories have years of experience in these areas and can be effectively integrated into the process. The results indicate the total sum of the processes involved were more effective than the traditional diary in reducing glyco-hemoglobin levels. A spurious placebo or Hawthorne effect of glucometer use was controlled through a double-crossover design. The study design did not elucidate the relative contributions of components of the study. Having data phoned in on a weekly basis may itself affect patient diet and exercise therapy compliance as a side effect. Alternatively, the majority of the effect observed may be more effective abstraction of the data by the clinician who uses the graphs to modify insulin therapy. There are ongoing studies to delineate the relative contributions of these two components. At this point, it appears there is a benefit in terms of decreased blood glyco-hemoglobin in the use of telecommunications followed by graphical display of data.

A significant advantage of the techniques proposed is that the cost of implementing them, while low initially, will decrease even further in time as microprocessors decrease in price. While only diabetes mellitus is addressed in this study, the results would be expected to extend to other chronic diseases. The ability to follow pulmonary function in chronic pulmonary disease and blood pressure in hypertensive disease, technologically feasible, could impact a sizable fraction of the chronic care population. Diabetes mellitus is the

source of 2.8 million (or 5 percent) of all yearly office visits to internists [2]. The results of this study should be of interest not only to the individual practitioner but also to policy makers.

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