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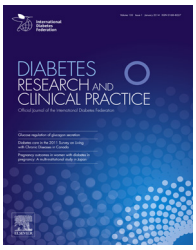

Comparing patient generated blood glucose diary records with meter memory in type 2 diabetes

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ABSTRACT

Aim: To assess agreement between meter and diary self monitoring of blood glucose (SMBG) records, over a year, in a sample of patients with type 2 diabetes.
Methods: Meter and diary records were available, for 95 individuals, who took part in the Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes study.

Pearson's correlation coefficient was used to explore the relationships between the types of error. Maximum likelihood estimation was used to explore changes over time through a structural equation modelling approach. Paired samples *t*-tests were used to determine if the presence of errors led to a significant difference between the mean diary and meter SMBG concentrations or coefficients of variation. Multiple regression was used to explore possible predictors of the error indices.
Results: Mean over-reporting, under-reporting, concordance and overall reliability were 8.4%, 10.0%, 83.5% and 71.3%, respectively. The first week of monitoring had significantly more under-reporting, over-reporting and less concordance and overall reliability than subsequent weeks. The majority of concordance errors were not clinically significant. Those that were, tended to occur during the first three months of monitoring. Participants' at one trial site were significantly more likely to have recording errors than those at the largest site.
Conclusions: Error levels were similar to those described previously in type 1 diabetes and there was a suggestion of an initial learning curve for record keeping. For some individuals diary records would not be considered acceptable if held to the same standards as blood glucose meters.

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Abbreviations: SMBG, self monitoring blood glucose; ESMON, efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes study; ANOVA, analysis of variance; NIMDM, Northern Ireland Multiple Deprivation Measure.

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1. Introduction

Most modern blood glucose meters can record the value, date and time of each blood glucose measurement [1]. Despite this clinicians still rely heavily on patient diaries when it comes to making therapeutic decisions based on self monitoring of blood glucose (SMBG) data [2]. This may be because meter memory reviews take more time, are more costly and can be complicated and inconvenient for health care providers to perform [1,3]. However, diaries consist of self-reported glucose values and may contain intentional or unintentional recording 'errors'.

A recent systematic review, exploring diary and meter SMBG record agreement, identified three types of recording error in patient diaries. These were incorrectly recording a value that has been measured (lack of concordance), failing to record a value that has been measured (under-reporting) and adding a value to the diary that has not been measured (over-reporting) [4]. Allowing for a minimal amount of disagreement between the meter and diary SMBG records just over 50% of adult diaries could be considered as 'accurate/reliable' [4,5].

However, little information was available specifically relating to those with type 2 diabetes, perhaps because monitoring was not common practice in this population when the majority of articles were published [4,5]. This is an important gap in the literature considering that, in developed countries, the majority (85–95%) of those with diabetes have type 2 diabetes [6,7]. Meter and diary agreement were also assessed over limited time frames [3,8,9] ignoring the potential for changes in recording behaviour with time.

The aim of this study was to explore the level of agreement between diary and meter SMBG records, over a year, in a sample with type 2 diabetes.

2. Subjects

Blood glucose meter and diary SMBG records were available for 95 individuals, 55 men and 40 women ranging from 35 to 80 years of age (mean 57.6), who had taken part in the Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON) study [10]. This was a multicentre, year long, randomised controlled trial which aimed to assess the effect of SMBG on glycaemic control and psychological indices in patients with newly diagnosed type 2 diabetes. All patients were treated with lifestyle intervention and oral hypoglycaemic agents as necessary, according to a defined treatment algorithm. Ethical approval for the ESMON study was obtained from the University of Ulster ethics committee. Those in the monitoring group were asked to monitor their blood glucose eight times a week. At each three month review appointment, as part of the trial protocol, their meter SMBG record was printed and their diaries were collected.

3. Methods

It was suspected that monitoring behaviour and the amount of agreement may vary in relation to clinic appointments. As a result, for each three month review period the first week after clinic, the middle week between clinics and the week directly before clinic were explored. Over these 12 weeks percentage under/over-reporting, concordance and overall reliability, which has been proposed as a combined measure of agreement [11], were determined. These were calculated as follows:

% Over-reporting = (number of values added to diary/number of diary values) × 100.

% Under-reporting = (number of values not recorded in diary/number of meter values) × 100.

% Concordance = (number of meter values recorded accurately/number of meter values recorded at all) × 100.

% Overall Reliability = (number of meter values recorded accurately/(number of meter values + number of values added to diary)) × 100. In other words this is the number of times the meter was used and readings correctly entered into the diary, as a percentage of the total number of times over-reporting, under-reporting, concordant or non-concordant reporting occurred.

The clinical significance of concordance errors was determined using the Clarke error-grid analysis. This is an established tool for assessing blood glucose meter accuracy when compared with laboratory measurement [12]. It determines the clinical significance of the difference between two blood glucose estimations by taking into account the size of the difference and the absolute blood glucose concentration [13]. This is important as two measurements which differ by the same amount from their true values (e.g. 50%) can have radically different clinical implications depending on the patient's true blood glucose level [14].

The mean SMBG value and the coefficient of variation were also determined for the diary and meter at each time point.

The exploration of any change over time in the error indices was complicated by missing data, one of the most pervasive problems in data analysis [15]. In order to have complete data patients must remember to bring both meter and diary to every clinic appointment and measure and record blood glucose values at least once each week. The most popular method of dealing with missing data is listwise deletion. This means that all cases which have a missing value for any of the variables in the data are excluded from all computations. In comparison in pairwise deletion only cases with missing values on variables tagged for a particular computation are excluded from the analysis [16]. Both these approaches result in a decrease in sample size with a resulting decrease in statistical power. For example in this sample listwise deletion would have significantly reduced the sample size for all the error indices, from $n = 24$ for concordance to $n = 38$ for overall reliability.

An alternative theory based approach to missing data is full information Maximum Likelihood estimation [16]. Full information Maximum Likelihood estimation uses all the available data while reducing the bias and decrease in statistical power that are associated with listwise or pairwise deletion [16,17]. It was used in a structural equation modelling framework, a statistical methodology that takes a hypothesis-testing approach to the analysis of relationships between variables [18]. Structural equation modelling allows for greater flexibility than traditional multivariate methods when testing statistical