GlucoWatch (TM) for the non-invasive monitoring of glucose levels

Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' conclusions
GlucoWatch® G2 Biographer is a watch-like device, worn on the wrist, which is capable of sampling interstitial glucose levels continuously for 12 hours by a process called reverse iontophoresis. The amount of glucose extracted across the skin correlates with blood glucose levels with a lag time of approximately 20 minutes. GlucoWatch® G2 Biographer may be useful as a tool in the management of insulin dependent diabetes and night time monitoring of glucose levels, potentially preventing episodes of hypoglycaemia.

There are no long-term trials that assess the safety and effectiveness of GlucoWatch® G2 Biographer and the effect of continuous glucose monitoring on diabetes related morbidity or mortality. In addition, the numbers of patients enrolled in the studies included in this assessment are small considering the prevalence of insulin dependent Type-1 and Type-2 diabetes in Western populations, such as the United States. Of the studies included in this assessment, four were conducted in a clinical setting and two studies were conducted both in the clinic and home setting. Four studies were conducted either in a home or camp environment exclusively.

It appears that GlucoWatch® G2 Biographer is effective at lowering HbA1c levels, a marker for diabetic control, significantly when compared to patients on standard care alone (8.4% vs 9.0%, p<0.05) (level II evidence). However, more long-term studies are required to ascertain if this effect is clinically significant. Level II evidence indicates that there was no effect on the quality of life of patients using GlucoWatch® G2 Biographer compared to those on standard care.

Level II evidence suggests that hypoglycaemic events were detected significantly more often in the GlucoWatch® G2 Biographer intervention group compared to the control group (p<0.005). In addition, those patients wearing the GlucoWatch® G2 Biographer intermittently were able to detect hypoglycaemia more easily even when not wearing the device, possibly due to increased awareness.

However, GlucoWatch® G2 Biographer failed to achieve an improvement in glycaemic control as it did not detect approximately 21 per cent of all hypoglycaemic events that actually occurred. In addition, glycaemic control did not improve as the percent of readings below 70 mg/dL (3.9 mmol/L), and therefore in the hypoglycaemic range, increased over the course of the three month intervention from 14.2% to 16.5%. The increase in the number of hypoglycaemic readings may be due to a more aggressive approach to glycaemic control management by patients over the course of the intervention period.

The majority of available studies were concerned with the diagnostic accuracy of GlucoWatch® G2 Biographer (diagnostic level 3b evidence). These studies reported the correlation of GlucoWatch® G2 Biographer readings with blood glucose readings obtained from the same patient using conventional finger-prick blood glucose testing. Glucose readings obtained by conventional blood glucose testing and GlucoWatch® G2 Biographer correlated well in the clinical setting (r= 0.88 to 0.90) and the mean difference between readings ranged from –0.92 (± 2.48) to 0.23 (± 1.55) mmol/L. One study conducted in the clinical setting reported the sensitivity for detecting hypoglycaemia was 23 per cent. Another study reported a positive predictive value of 26 per cent, indicating that for every 100 hypoglycaemic alerts, only 26 were true hypoglycaemic events. Readings obtained in the home setting did not correlate as well as those in the clinical setting (r= 0.74 – 0.85), however the mean difference between readings ranged from –0.33 (± 2.06) to 0.26 (± 2.4) mmol/L.

Of concern are the number of unsuccessful calibration attempts, the critical step in the use of GlucoWatch® G2 Biographer, and the number of missed data points. Studies reported between 33 to 51 per cent of calibration attempts were unsuccessful. The number of missed data points ranged from 10 to 45 per cent of the number of potential data
point readings possible. Common reasons for unsuccessful calibration and missed data points included excessive sweating, blood glucose reading being out of range and changes in the skin temperature, factors which are difficult to control.

The most serious safety concern is the one reported case of a child at a diabetic camp who experienced a non-arousable hypoglycaemic event, despite the hypoglycaemia alarm sounding (level III-2 evidence). Parents may reduce their vigilance and gain false reassurance from a device, which purports to have an alarm system.

A Monte Carlo simulation, conducted by an affiliate of Cygnus Incorporated, was used to model the cost effectiveness of GlucoWatch® G2 Biographer. The model predicted that the use of GlucoWatch® G2 Biographer, if sustained for life, would delay the onset of the first serious complication of diabetes by 4.1 years. Treating 18 patients with GlucoWatch® G2 Biographer would prevent one case of blindness and 1.4 cases of renal failure. However, the validity of the model used is questionable given that there are no long-term morbidity or mortality data reported in the study on which the model is based. The intervention costs US$91,059 per year of life, US$61,326 per quality adjust life year (QALY) and US$ 9,930 per year free of major complication. If GlucoWatch® G2 Biographer ceased to be effective after 17 years of age, the cost per QALY would increase to US$103,178 per QALY gained.

Of serious concern is that five of the eleven studies' primary authors were affiliated directly with Cygnus Incorporated, the company that manufactures GlucoWatch® G2 Biographer and of the remaining six studies, two studies involved more than one co-author affiliated with Cygnus Inc. This may raise issues of conflict of interest.

In summary, GlucoWatch® G2 Biographer cannot replace conventional finger-prick blood glucose testing completely but may be a useful adjunct in the overall management of diabetes. GlucoWatch® G2 Biographer may be effective in the assessment of hypoglycaemic patterns, which may impact on long-term therapeutic decisions by a clinical management team.

**Project page URL**

**INAHTA brief and checklist**

**Indexing Status**
Subject indexing assigned by CRD

**MeSH**
Blood Glucose /analysis; Blood Glucose Self-Monitoring /methods; Hypoglycemia /prevention & control

**Language Published**
English

**Country of organisation**
Australia

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**AccessionNumber**
32006000583

**Date bibliographic record published**
16/05/2006

**Date abstract record published**
16/05/2006