**Technology:** Heart rate monitor for psychiatric diagnosis

**Manufacturer:** The circadian rhythm monitor (The HeartLink system) was developed by HeartLink Diagnostics in Perth, Australia. Canadian licence rights to the monitor are held by HeartLink Canada (1999) Inc., in Vancouver.

**Purpose:** Measurement of circadian heart rate and body movement to diagnose mental illness.

**Current Regulatory Status:** Regulatory approval for marketing this product is yet to be obtained. The HeartLink Canada web site states that the technology is not yet in use and that the HeartLink companies have been formed to conduct further validating clinical research.¹

**Description:** The circadian rhythm monitor is worn around the waist, attached with a cotton strap. Two leads from the monitor plug into two stick-on electrode patches that are fixed to the sternum and the third rib on the left side. The monitor, which is worn by the patient for 24 hours, records minute-averaged heart rates and physical activity. These data are downloaded to a computer.²

The arrangements proposed by the manufacturer are based on the coordination of activities through a diagnostic centre. Physicians would refer patients to a centre to have the monitor attached. Upon completion of 24 hours of continuous monitoring, data would be downloaded and transmitted to the HeartLink database, after which, a diagnostic report would be sent to the referring doctor.³ The report would be made available in 48 to 72 hours.¹

The HeartLink Canada web site suggests that objective diagnosis indicators may be particularly helpful in those patients who cannot describe – or admit to – mental disorder symptoms. It suggests that serial monitoring can provide objective feedback about the effectiveness of medication and other treatments.¹

**Cost:** The cost of the monitor device, fitting and report generation is unavailable. A 2003 profile of HeartLink estimates that the service in Australia will be delivered for $100 per diagnostic report.³

**Evidence:** This diagnostic method was developed by Stampfer et al. In a study to investigate the relationship between psychiatric status and the circadian pattern of heart rate, serial 24-hour recordings of minute-average heart rate were obtained from 30 normal volunteers and 200 patients representing a range of Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM-III-R) diagnoses.⁴ Records of heart rate profiles were grouped into pattern types and compared with the psychiatric diagnoses for the study participants.
Conditions such as generalized anxiety and depression were reported to be strongly associated with a distinctive circadian pattern. Other conditions, such as somatoform disorder (symptoms that cannot be traced to a specific physical cause) showed more variation. Serial recordings showed that a change in clinical status led to a change in the circadian pattern. It was suggested that such data can provide objective indices of clinical status.

In a study to establish the basic reliability of the circadian heart rate monitor, data were obtained from 50 persons, on two occasions, separated by an average of 6.6 weeks. A blinded rating of the data was used to classify subjects as “definitely psychiatric,” “probably psychiatric,” “borderline,” “broadly normal” or “signature normal.” The proportion of patients correctly assigned to their exact categories was 78%. If a one-category difference was permitted, the proportion correctly assigned was 92%.

Two studies have evaluated this approach in the diagnosis of depression. Iverson et al. examined 48 primary care outpatients and 25 controls. Patients with depression were sorted into two equal groups based on a median split of their Beck Depression Inventory-II scores. Those with more severe depression had lower activity levels than the other patient groups. The overall proportion of patients who were correctly classified by the heart rate monitor was 74.0%. Fifty per cent of the more severely depressed group; and 86% of the other depressed patients and the controls were correctly classified. Gaetz et al. determined whether a neural network could create a clinically meaningful distinction of “depression” versus “no depression” based on cardiac time-series data. In a series of 84 subjects, agreement between different types of classifications from the neural network and the clinical diagnosis ranged from 54.0% to 70.2%.

A study of persons with panic disorders that did not involve the use of the HeartLink monitor considered the correlation of therapeutic response with heart rate variability and sleep measures. A double-blind RCT (n=27) of clonazepam versus placebo weighed standard sleep measures and heart rate variability from conventional 24-hour heart rate monitoring (i.e., Holter monitor) at baseline and at the end of the study. None of the heart rate measures correlated with response, but compared with placebo, clonazepam led to a decrease in all the time and frequency domain measures of heart rate variability. The authors concluded that central mechanisms are related to the therapeutic response of patients with panic disorder presenting with palpitations, but it does not directly correlate with heart rate variability.

The diagnosis of mental illness is typically based on the clinical observation of signs and symptoms; and subjective reports from patients. Psychometric scales are often used to evaluate the severity of the condition or to monitor the response to treatment.
Emerging Technology List

CIRCADIAN HEART RATE MONITORING FOR PSYCHIATRIC DIAGNOSIS

Commentary:
The HeartLink system is a non-invasive diagnostic technology that is intended to provide measures of some psychiatric disorders. It could complement standard approaches to the diagnosis of mental illness and provide objective data.

The available evidence in support of this technology is limited. An association between heart rate variability and psychiatric conditions has been shown, but no peer-reviewed reports were located that described the use of the system in clinical practice. Further work is needed to establish the sensitivity and specificity of this approach; and its effectiveness and utility in routine psychiatric investigations.

References:


This summary was prepared by David Hailey; CCOHTA.

This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

These summaries have not been externally peer reviewed.

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