

VITALS

Major Finding: Patients with type 1 diabetes are 10 times more likely to have an enterovirus infection, compared with patients without diabetes.

Data Source: A meta-analysis of 34 case-controlled studies using molecular diagnosis of enterovirus.

Disclosures: The investigators reported that they have no relevant financial relationships.

established type and eventual type 1 diabetes) was the outcome. This systematic review of 33 prevalence studies, involving 1,931 patients and 2,517 nondiabetic individuals.

They identified 34 studies – 9 involv-

ing patients with prediabetes (198 cases and 733 controls) and 25 studies of diabetes patients (1,733 cases and 1,784 controls).

Thirty studies used RT-PCR or in situ hybridization to detect enterovirus

RNA; immunostaining for the enterovirus capsid protein vp1 on autopsy pancreas specimens was used on four studies. Most studies investigated children and adolescents up to age 16 years, though some included adults up to age 53 years.

The summary odds ratio of identifying enterovirus in patients with prediabetes compared with patients without diabetes was 3.7 (P less than .001). All but one of the 25 studies of patients with type 1 diabetes had odds ratios greater than one for patients with diabetes testing positive for enterovirus, with a sum-

mary odds ratio of 9.8 (P less than .001).

They used sensitivity analyses to test the robustness of the results by country and study quality.

In all, 19 studies were conducted in Europe. “There was some evidence for geographical differences; in non-European studies the odds ratio was 13.5, compared with 8.6 in European studies, though there was considerable overlap in the confidence intervals,” they wrote.

In addition, “the odds of having an enterovirus infection in people with established diabetes (OR, 11) suggest that persistent enterovirus infection is also common among patients with type 1 diabetes.” ■

Indications for Use

The CGMS *iPro* Digital Recorder is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices. The information collected by the digital recorder may be downloaded and displayed on a computer and reviewed by healthcare professionals.

This information may allow identification of patterns of glucose-level excursions above or below the desired range, facilitating therapy adjustments which may minimize these excursions.

The CGMS *iPro* Digital Recorder:

- Is intended for prescription use only.
- Will not allow readings to be made available directly to patients in real time.
- Provides readings that will be available for review by physicians after the recording interval (72 hours).
- Is currently intended for occasional rather than everyday use.
- Is to be used only as a supplement to, and not a replacement for, standard invasive measurement.
- Is not intended to change patient management based on the numbers generated, but to guide future management of the patient based on response to trends noticed. That is, these trends or patterns may be used to suggest when to take fingerstick glucose measurements to better manage the patient.

The glucose sensor, tester, charger, and CGMS *iProWand* are intended for use with the CGMS *iPro* Digital Recorder. The Sen-serter® device is indicated only for insertion of the Medtronic MiniMed glucose sensor.

Important Safety Information

Contraindication

Do not use magnetic mattress pads while wearing the CGMS *iPro* Digital Recorder.

Warning

Product contains small parts and may pose a choking hazard for young children.

Important Safety Information, continued

Sensor

The glucose sensor should be removed if redness, bleeding, pain, tenderness, irritation, or inflammation develops at insertion site, or if you experience unexplained fever. An optional occlusive dressing should be removed if irritation or reaction to the tape develops.

The glucose sensor may create special needs regarding your patients' medical conditions or medications. Healthcare professionals should discuss this with their patients before they use the glucose sensor.

Wait 5 minutes after glucose sensor insertion before setting up the CGMS *iPro* Digital Recorder with Solutions CGMS *iPro*.

- Make sure that the site is not bleeding before connection.
- If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, attach the digital recorder to the glucose sensor.
- If bleeding persists after 3 minutes, remove the glucose sensor and discard. Insert a new glucose sensor in a different location.

Contact the 24 Hour HelpLine if you experience any adverse reactions associated with the digital recorder or glucose sensor.

Precautions

If performing multiple CGMS *iPro* Digital Recorder studies on the same patient, establish a rotation schedule for choosing new glucose sensor sites. Avoid sites that are constrained by clothing, have scar tissue, or are subject to rigorous movement during exercise.

For additional information, please consult the *iPro* CGM user guides.

iPro™ is a trademark of Medtronic MiniMed, Inc.
Sen-serter® is a registered trademark of Medtronic MiniMed, Inc.

References

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2. Solutions® Software for CGMS® *iPro*™ Continuous Glucose Recorder User Guide.
3. Chico A, Vidal-Rios P, Subira M, Novials A. *Diabetes Care*. 2003;26:1153-1157.

Insulin Regulator Gene Tied to Type 2 Diabetes

FROM JAMA

Patients with type 2 diabetes were more likely to have genetic variations for a key protein regulating cells' insulin receptors, according to a multinational case-control study.

The variants' presence could serve as an early predictive marker of insulin resistance and type 2 diabetes, particularly in patients with a family history of the disease, the study's authors noted.

The investigators examined variations in the high-mobility group A1 protein, or HMGA1, a key regulator of insulin receptor gene expression. The protein's most frequent functional variant was found in 7.2% of the study's 3,278 Italian patients with type 2 diabetes, compared with 0.4% and 3.3% of two Italian control groups (2,544 and 784 patients) without diabetes, significant differences resulting in adjusted odds ratios of 15.8 and 2.0, respectively.

In addition, the variant was found in 7.7% of 970 U.S. case patients, compared with 4.7% of 958 U.S. control patients (adjusted odds ratio, 1.6), a significant difference, and in 7.6% of 354 French case patients vs. 0% of 50 French controls, also a significant difference, reported Dr. Eusebio Chieffari of the University of Catanzaro (Italy) and colleagues (*JAMA* 2011;305:903-12).

Three other functional variants also were observed in the Italian population, although those variants were not studied in the U.S. and French populations because of the relatively small sample sizes.

Overall, when all four variants were analyzed, nearly 10% of Italian patients with type 2 diabetes were found to have HMGA1 defects, compared with less than 1% of controls.

The four variants of the HMGA1 gene were also shown to be associated with decreased insulin receptor gene and insulin receptor protein expression.

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—Sharon Worcester