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Simplified Evaluation and Documentation of Data from Glucose-Controlled Insulin Infusion Systems Part II: Artefact Handling

Computerunterstützte Datenauswertung und Dokumentation beim Einsatz glucosekontrollierter Insulin-Infusionssysteme Teil II: Artefaktbehandlung

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Key-words: Glucose-controlled insulin infusion, artificial beta cell, data processing, artefact handling

A computerized method for handling artefacts occurring during recording and evaluation of data with glucose-controlled insulin infusion systems (GCIIS) is demonstrated:

1) Recording phase:
   - »Interrupt«-Mode: Maintenance of the original linear data-time relation is achieved by using an additional time channel. Analogous structuring of time- and parameter data files permits correct correlation.
   - »Communication I/0 error«: An error-handling subroutine prevents the interruption of the program caused by lead characters which occur when restarting the GCIIS thereby disturbing GCIIS-microcomputer communication.
   - Risk of data loss caused by power failure is minimized by an appropriate interaction between intermediate store and floppy disk.
2) Evaluation phase:
   - Implausible data: Obstruction of double lumen catheter as well as loss of glucose sensor sensitivity result in inappropriate data with consecutive incorrect computation of glycemic indices such as MAGE and M-value.
   - Zero-values: In the »HOLD«-mode, all blood glucose values are set to zero by the GCIIS causing forbidden arithmetic operations. These artefact periods are marked in the prepared time-file, deleted and interpolated subsequently.

In conclusion, our method permits automatic artefact handling during the recording phase and complete correct data processing during the evaluation phase.

Schlüsselwörter: Glucosegesteuerte Insulin-Infusion, künstliche Beta-Zelle, Meßdatenverarbeitung, Artefaktbehandlung

Eine computerunterstützte Methode zur Behandlung von Artefakten bei der Aufzeichnung und Auswertung von Daten glucosegesteuerter Insulin-Infusions-Systeme (GCIIS) wird vorgestellt:

1. Aufzeichnungsphase:
   - »INTERRUPT«-Mode: Ein zusätzlicher Zeitkanal ermöglicht die Aufrechterhaltung der originalen Zeit-Daten-Relation. Die analoge Struktur der Zeit- und Parameterdateien erlaubt es, den jeweiligen Meßwerten den Zeitpunkt der Messung zuzuordnen.
   - »Communication I/0 error«: Ein übergeordnetes Fehlerprogramm verhindert den Programmabbruch durch steuerzeichenbedingte Störung der Datenübertragung vom GCIIS zum Mikrocomputer.
   - Das Risiko des Datenverlustes durch Stromausfall wird durch geeignete Wechselbeziehungen zwischen Floppy-Disk und Zwischenspeicher reduziert.
2. Auswertungsphase:
   - Nicht plausible Daten: Verstopfung des Doppellumenkatheters sowie Defekt der Glucoseoxidasemembran führen zu Falschbestimmungen der Blutglucose und damit zu falsch berechneten descriptiven Parametern wie MAGE und M-Value.
   - Null-Werte: Im »HOLD«-Mode werden alle Blutglucosewerte vom GCIIS gleich Null gesetzt. Bei der Berechnung der glycämischen Parameter treten nicht definierte arithmetische Ausdrücke auf. Diese Artefaktperioden werden in der Zeitdatei gekennzeichnet, ausgeschlossen, und nachträglich werden die fehlenden Werte interpoliert.

Die Methode erlaubt die automatische Behebung von Störungen während der Datenaufzeichnung und vollständige, korrekte Auswertung von GCIIS-Daten.

Introduction

Recently we have published a method which permits complete processing of data from glucose-controlled insulin infusion systems (GCIIS) [1]. Our device has proved to be particularly useful in the improvement of conventional subcutaneous insulin therapy in diabetes mellitus, as well as in the treatment of acute myocardial infarction with feedback controlled glucose-insulin-potassium therapy [2]. However, data handling is often disturbed by several undesired events:

- Interruption of the GCIIS control period because of technical or clinical problems or break of electric current results in stop of data flow from the GCIIS to the microcomputer.
- Obstruction of the doublelumen catheter or defect of the glucose sensor produce implausible data, which have to be excluded subsequently (fig. 1).

Therefore, we developed a BASIC computer-program for the detection, evaluation and exclusion of artefacts from the GCIIS.

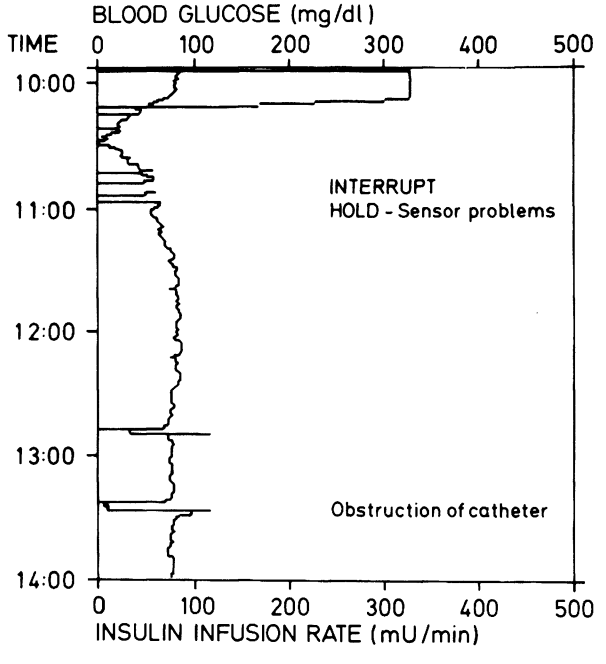

Fig. 1. Original plot of blood glucose (BG) and insulin infusion rate (IR) obtained from the GCIIS during an insulin hypoglycaemia test demonstrating common problems of data recording:
1. At 10.50 »INTERRUPT«-Mode is started and results in stop of data flow for 6 minutes.
2. After restarting GCIIS at 10.56 communication I/0 error occurs, which would lead to program break.
3. »HOLD«-Mode from 10.58 to 11.00 sets blood glucose levels to zero.
4. Obstruction of doublelumen catheter produces implausible value at 13.25.

Methods:

I. Artefact handling during the recording phase

1. »INTERRUPT«-Mode:

Technical and clinical problems sometimes make it necessary to stop feedback controlled insulin/dextrose infusion by »INTERRUPT«-Mode.

During this mode blood glucose is no longer measured by the GCIIS and neither insulin/dextrose infusion nor transmission of data to the microcomputer takes place. As a result, GCIIS data do no longer appear in their time related position in the computer-plot. Therefore a major goal of data processing must be to restore the original linear data-time relation. This implies simultaneous transmission and recording of parameters (fig. 2) [blood glucose (BG), insulin infusion rate (IR), dextrose infusion rate (DR)] and time by two seperated analogous files. Parameters from the intermediate store are transmitted to the floppy disk in 30-minute intervals. Identical structure of time file and parameter file allows analogous treatment. Thus, correct correlation between parameters and time is possible. In case of »INTERRUPT«-Mode or break of current the missing interval is replaced by line feed in the plot.

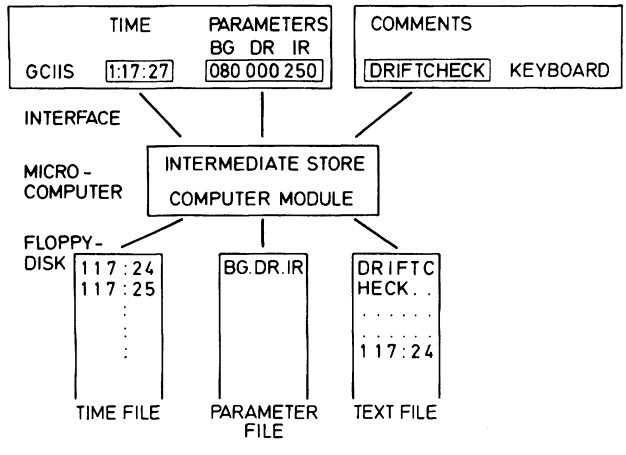

Fig. 2.
1. Input parameter data contain of 9 bits (3×3 bits), which are reduced by storage procedure to 6 bits (3×2 bits) using special characters.
2. During storage procedure one redundant bit (first colon) is omitted to achieve analogous structure of time and parameter file. The remaining colon later on is used for marking artefacts.
3. Any comment entered via keyboard is stored in its time related position with a maximum of 24 bits.

A further problem concerning »INTERRUPT«-Mode is »Communication I/0 error« which occurs after restarting the GCIIS. In these cases specific constants (body weight, basal insulin infusion rate, etc.) are printed by the GCIIS and transferred by the interface to the microcomputer. This data sequence contains lead-characters disturbing GCIIS-microcomputer communication, which results in break of the program. This problem is dealt with by means of an error handling subroutine:

If such lead characters occur, input and output channels are closed. A loop proves if utilizable data are received. Not until information without disturbing lead

characters is transmitted, all channels are reopened and recording continues. This kind of interruption effects only a one-minute pause.

2. Break of electric circuit

Two technical problems result from breakdown of electric circuit:

- Although it lasts only a few seconds until the emergency current is started, parameters from the intermediate store are cleared.
- Files are not regularly finished by »CLOSE«-demand.

Such incomplete files cannot be recalled from floppy-disk. Break of current may occur at any program-step regardless whether channels are still open or already closed. Thus, it is necessary to coordinate input and output channels by time sharing to keep the storage procedure-implying open channels – in comparison to the storage interval as short as possible.

A long storage interval increases the risk of data-loss from the intermediate store; a short one that of complete data-loss from floppy disk as a result of circuit-breakdown occuring during the storage procedure.

Further, mechanical overload of disks is more likely to occur with a short storage-interval. As a compromise we choose a 30-minute storage interval, so that a maximum of 30 triplets (G, DR, IR) is lost and the risk of interruption during the vulnerable storage phase is about 1:1000.

II. Artefact handling during the evaluation phase

There are several reasons for recording false values:

- Obstruction of the doublelumen catheter results in an inappropriate decrease of blood glucose levels.
- Defect of the glucose sensor produces implausible data.
- During »HOLD«-Mode all blood glucose values are set to zero.

Therefore an additional channel is applied: Comments concerning these different artefacts may be entered via keybord, stored on floppy disk (fig. 2) and finally printed in their time related position (fig. 1).

However, all these artefacts cannot definitely be dealt with, until the original GCIIS control period is finished, because the identification of implausible or systematic errors requires experience in GCIIS-handling. Exclusion of these artefacts is especially important for the calculation of descriptive parameters such as MAGE [3], M-value [4], MBG etc. and calculation of infinitezimal parameters as slopes and areas under the curve (AUC). Zero values of blood glucose (»HOLD«-Mode) cause forbidden arithmetic operations as division by zero. Sudden decrease of blood glucose (defect of the glucose sensor) falsifies the determination of MAGE, slopes and AUC. Subsequent deletion of these artefacts is managed by a subroutine reduplicating the original time-file and marking those time-points where artefacts are identified (fig. 3). In the printer-plot the missing values of an artefact interval are interpolated linearly. The excluded period is marked on the time scale (fig. 4). Thus, stepwiese exclusion of artefacts with subsequent time scale marking is achieved and maintenance of the original documentation is guaranteed.

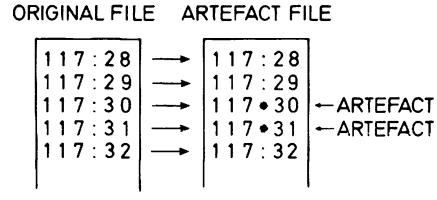

Fig. 3. For exclusion of artefacts the original time file is reduplicated. The position of the remaining colon (fig. 2) is used to mark the time-point where artefacts are identified.

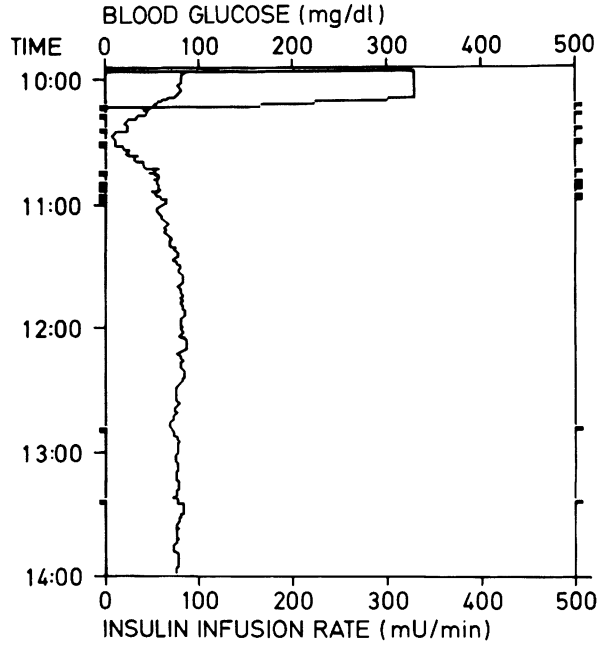

Fig. 4. Original data plot from fig. 1 after exclusion of artefacts during the evaluation phase. Missing data during »INTERRUPT«-Mode are interpolated. Inappropriate low (obstruction of double catheter) or zero blood glucose values (»HOLD«-Mode) have been marked on the time scale (black bars) and linearly interpolated, too.

Results:

Fig. (1) and fig. (4) show as an example the stepwise handling of artefacts during a GCIIS guided insulin hypoglycaemia test.

During the recording phase (fig. 1) an error handling subroutine prevents break of programm, which would have taken place after restarting the GCIIS at 10.56 as

a result of »Communication I/0 error«. Data transmission continues after having only paused for a one minute interval. Automatic interpolation of the missing recording periods during »INTERRUPT«-Mode and »Communication I/0 error« maintains linear timescale.

During the evaluation phase (fig. 4) implausible BG data, i.e. zero during »HOLD«-Mode, inappropriately low during obstruction of the doublelumen catheter, are deleted and interpolated subsequently.

In conclusion our method sucessfully deals with the various problems which may occur during the recording of GCIIS data. It permits complete and correct data processing during the recording and the evaluation phase.

Only by this, further computing, e.g. calculation of descriptive glycaemic parameters, slopes and areas under the curve, is possible.

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