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ECRES and CREID: two new tools to estimate the amount of carbohydrates needed to prevent hypoglycemia during exercise in type 1 diabetic patients

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Management of glucose control in patients with type 1 (insulin dependent) diabetes is an ongoing day-to-day task, and experience is needed to achieve an appropriate balance between diet and insulin therapy. This experience is not easy to obtain from real life and may be associated with high risk of hypoglycaemia and/or hyperglycaemia. Taking advantage from information technology, several different algorithms have been proposed relating insulin and carbohydrates to assist patients in the adjustment of their insulin therapy and/or carbohydrate intake (1-13). Despite the large number of different models and approaches, to date these systems have not yet entered the daily life of patients, presumably because the real relationships between carbohydrate intakes and insulin doses are more complex than the used models assume (14, 15), and are influenced by several unpredictable and/or unknown variables. Exercise is one of the main factors affecting glycaemic balance in type 1 diabetic patients for which the commonly known carbohydrate/insulin relationships do not apply. Moreover, since in several instances exercise is unforeseen, a change in the insulin dose cannot always be easily implemented, causing increased importance of additional glucose ingestion to prevent hypoglycemia.

The new tools described here are: (1) a specifically developed algorithm, named “ECRES” (Exercise Carbohydrate Requirement Estimating Software), which estimates the amount of carbohydrates a type 1 diabetic patients has to consume before/during exercise to prevent hypoglycemia, provided that habitual therapy (i.e. types, doses and time scheduling of insulin together with the amounts and time scheduling of dietary carbohydrates), training habits and actual exercise characteristics (i.e. intensity, duration and scheduled start time) are known; (2) a novel designed electronic device, named “CREID” (Carbohydrate Requirement Estimating Instrument for Diabetics), which runs the above software and, in addition, performs a count down of the carbohydrates eaten to prevent hypoglycaemia during the effort, producing an advertising signal when the risk of an excessive lowering of glycaemia becomes high. The proposed tools are based on the following scientific evidences. First, the amount of glucose oxidized during exercise can be easily estimated from HR also in type 1 diabetic patients (16). In turn, patients can prevent the excessive lowering of glycaemia by eating an appropriate amount of carbohydrates, which is linearly related to insulin concentration (17). We are claiming the patent for both the software and the electronic device.

The ECRES software processes two conceptually different sets of data. The first part of the software, based on the patient's usual therapy and amounts of carbohydrates consumed, aims at defining, for each time of the day, the percentage carbohydrates he/she has to consume before/during the effort to avoid the occurrence of hypoglycaemia. Subsequently, on each exercise occasion, the second variable data set (i.e. intensity, duration, starting daytime of the effort and actual metabolic conditions) is processed, yielding as final result the amount of carbohydrates to be consumed by the patient before/during the effort to prevent the onset of hypoglycaemia. To take advantage of the CREID device, an appropriate heart monitor belt has to be worn during the exercise; at the start of the effort, the device has to be activated to perform the count down of the eaten carbohydrates according to actual exercise intensity.

A validation test was carried out on twenty type 1 diabetic patients (12M, 8F) aged 18-70 years, who performed, in different days, three 1-hour runs on a treadmill at an intensity eliciting 65% of the maximal estimated heart rate (i.e. 220 – age). Each run was scheduled so as to start at different time distances from the insulin injection (1.5, 4 and 5.5 hours after insulin). During the trials, patients wore a simple heart rate monitor to verify heart rate during the run, while glycaemia was tested before the start of exercise and subsequently at regular intervals by means of commonly used reactive strips. About half an hour before the start, 50% of the amount of carbohydrates estimated by means of the ECRES software (mainly in the form of sugar, sugar-drops) was given to the diabetic patient. The remaining fraction was administered to the patient during the first 30 min of exercise, except in the case of clinically unacceptable high glycaemic levels (i.e. > 240 $mg \cdot dl^{-1}$). On the contrary, if glycaemia was falling below 90 mg· dl^{-1}, the patient received other small amounts of sugar (5 g each time). Overall, sixty runs were performed by the patients. Average heart rate amounted to 113 ± 7 beats· min^{-1}; glucose level at the start of exercise amounted on average to 170 ± 62 mg· dl^{-1} and decreased to 135 ± 50 mg· dl^{-1} at the very end of the trials.

The amount of carbohydrates predicted by the ECRES software was insufficient to prevent hypoglycaemia during the exercises in 7 cases out of 60 (13%), which required the administration of further amounts of sugar. On the contrary, the estimate was excessive in other 7 cases (13%), and if completely administered it would have lead to theoretically unacceptable high glycaemic levels (>240 mg· dl^{-1}). In the remaining cases (46 cases out of 60 corresponding to 75%), the estimate fulfilled the actual requirement, the average difference amounting to –0.8 ± 6.1 g. These results demonstrate that the ECRES software provides a useful tool for type 1 insulin-dependent diabetic patients to help them in determining the amount of carbohydrates they have to eat before/during exercise to avoid the onset of hypoglycaemia.

Many different implementations of the ECRES software can be hypothesized. It can be developed in a physicians-oriented version, printing a tabular output usable by the patients to calculate their own carbohydrate requirement. For a direct patient’s use, a desktop PC and/or a handheld device implementation can be hypothesized, which, if programmed as to perform also the calculations needed on the exercise occasions, will make the use of the system even easier. The implementation of a web version, with appropriate access to physicians and/or patients may be a further solution. The CREID device can be produced as an independent specific instrument, similar to a common wrist heart monitor. However, the appropriate electronic circuits can be integrated in several different training equipments, patient’s personal data being recorded on individual removable cards.

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