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Off-line control of the postprandial glycemia in type 1 diabetes patients by a fuzzy logic decision support

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ABSTRACT

The target of this paper is to describe the use of fuzzy techniques in the development of a decision support system that allows the optimization of postprandial glycemia in type 1 diabetes patients taking into account the kind of meal taken by patients, the preprandial glycemia and the insulin resistance (the response of the body to insulin dose injection therapy). The decision support system can, in many cases, provide patients with the correct number of rapid insulin units that must be assumed to assure an optimal glycemic profile, keeping the blood glucose level close to the homeostatic condition, several hours after the meal.

1. Introduction

Diabetes mellitus is actually one of the most diffuse metabolic diseases and represents a growing serious problem around the world. Who is affected by diabetes mellitus has usually got a high blood glucose level as a consequence of either the body not producing enough insulin, or the body cells not properly responding to the insulin produced by pancreas (insulin-resistance). Insulin is a hormone produced in pancreas which enables body cells to absorb glucose, turning it into energy. If body cells do not absorb glucose, this last one accumulates in the blood (hyperglycemia), leading to various potential medical complications (World Health Organization, 2006). There are many types of diabetes (Expert Committee, 2003), but the most common of which are called type 1 diabetes and type 2 diabetes. The cause of the first form of diabetes (type 1 diabetes) is a pancreatic beta-cells failure to produce insulin, obliging patients to inject it subcutaneously, with external insulin doses, necessary for their survival. The second form of diabetes (type-2 diabetes) is due to a condition in which an absolute or relative insulin deficiency is combined with cell failure to use insulin properly. Insulin therapy simulates the activity of pancreas and different kinds of insulin may be used, with different time of action (rapid, ultra-rapid, slow or basal etc.). The patients affected by type 1 diabetes are exposed to frequent post-prandial hyperglycemia defined as an high blood glucose concentration after meal and/or post-prandial hypoglycemia defined as a low blood glucose concentration. Diabetes has therefore to be kept under control necessarily, because these abnormal low or high blood glucose levels may lead respectively to cardiovascular problems or to fainting and also diabetic coma. Unfortunately, there are not, until now, useful tools that provide the correct dose of insulin that patients assume just before the meal (rapid insulin), taking into account the kind of meal and to the clinical state of the patient.

The changes of the insulin therapy made by diabetologists are subsequent to glycemic decompensations (Ahern et al., 1993; Jenkins & Jenkins, 1987; Smith, 1994). It is well known from literature that insulin pump manufacturers have recently engineered a *bolus calculator*. The bolus calculator takes into account the current patient blood glucose level, the target blood glucose, the amount of carbohydrate consumed, and other factors such as the insulin sensitivity, the insulin-to-carbohydrate ratio and the duration of the insulin action helping patients to obtain a good control over the blood glucose level by calculating bolus insulin doses based on data input inserted by the pump wearer. Each pump company calculates insulin doses in a slightly different way but the results are actually not satisfactory in clinical practice (Zisser et al., 2008). Several systems have been already proposed. They differ for the variables used as inputs and outputs, the calculation algorithm and the validation method. Ambrosiadou, Gogou, Maglaveras, and Pappas (1996) proposed a decision support for insulin regime prescription based on neural-network approach as well as Mougiakakou and Nikita (2000) and Gogou, Maglaveras, Ambrosiadou, Goulis, and Pappas (2001). These last investigate the application of a neural network approach for the development of a prototype system for knowledge classification in insulin regimen specification and dose adjustment. Lehmann (2004) examined the hurdles that may rise implementing computerized decision-support tools in diabetes care; Campos Delgado, Hernandez-Ordonez, Femat, and Gordillo-Moscoso (2006) proposed, on the contrary, a system that works like a two loops off line control system: one control loop regulates the rapid insulin to be injected at meals time while the second loop works on a daily basis regulating the slow insulin. Their controller uses as input only

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the preprandial glycemia. The validation of the system has been carried out by simulation using a compartmental model. A bolus calculator that takes into account the energy of carbohydrates, the metabolic efficiency and the dependence on the person of the energy transformed in blood glucose was proposed by Mathews and Pelzer (2009). Shapira, Yodfat, HaCohen, Feigin, and Rubin (2010) took into account the carbohydrate content of the meal as well, but to overcome the uncertainty of its determination they proposed a decision support tool based on the optimization of insulin doses for carbohydrate ranges. Pankowska and Blazik (2010) proposed a bolus calculator taking into account proteins and lipids, in addition to carbohydrates for two out of phase insulin injections that are justified by the different absorption time. Tadic, Popovic, and Djukic (2010) presented a new fuzzy model for evaluation and choice of optimal therapeutic procedure on individual level for patients with type 2 diabetes. More recently Simon et al. (2011) developed a web-based decision support system for evaluation of blood glucose levels and adjustment of the insulin dose (insulin self-titration).

The author developed a decision support system conceived to provide patients with the number of rapid insulin units that may assure optimal glycemic behavior after a meal. The decision support system must be fed with data concerning the meal, the physical and clinical personal conditions, including pre-prandial glycemia. The operation principle is the same of an offline mixed feedback-feedforward controller. It is based on the measurement of the output controlled variable (blood glucose level) and the measurement of the main disturbances (kind and amount of the food taken). Fuzzy and neurofuzzy techniques were chosen for the implementation of the offline decision support system. The choice of fuzzy system (Kahramanli & Allahverdi, 2008; Osuagwu & Okafor, 2010; Ganji & Abadeh, 2011) is justified by the need of both handling food data that are usually not accurate, and inherently fuzzy, and taking into account the features of a very complex biological system as the glucose metabolism in the human body may be, for which until now a reliable and effective mathematical model is not available, despite many research attempts already tried (Bergman, Ider, Bowden, & Cobelli, 1979; Sorensen, 1985). Three main phases characterize the development of the decision support. In the first phase, data concerning the physical and clinical conditions of a group of type 1 diabetes patients involved, the kind and amount of food eaten during their meals together with glycemia levels before and after them, were recorded for a period of time. In the second phase the development of the hierarchical

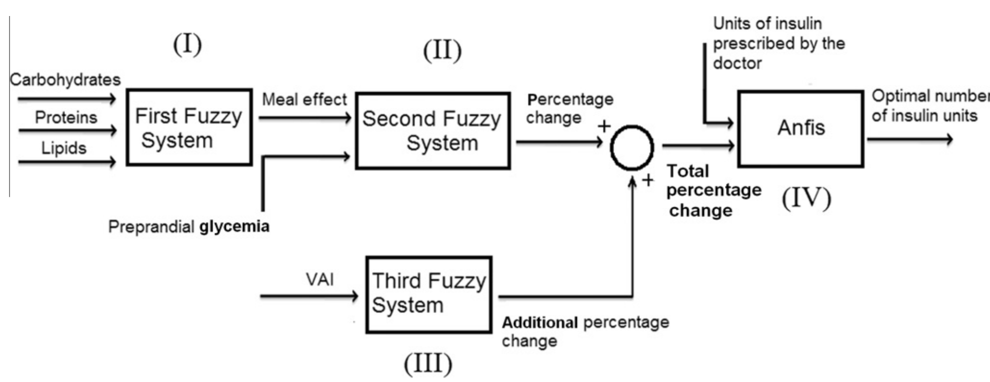

Fig. 1. Block diagram of the fuzzy system.

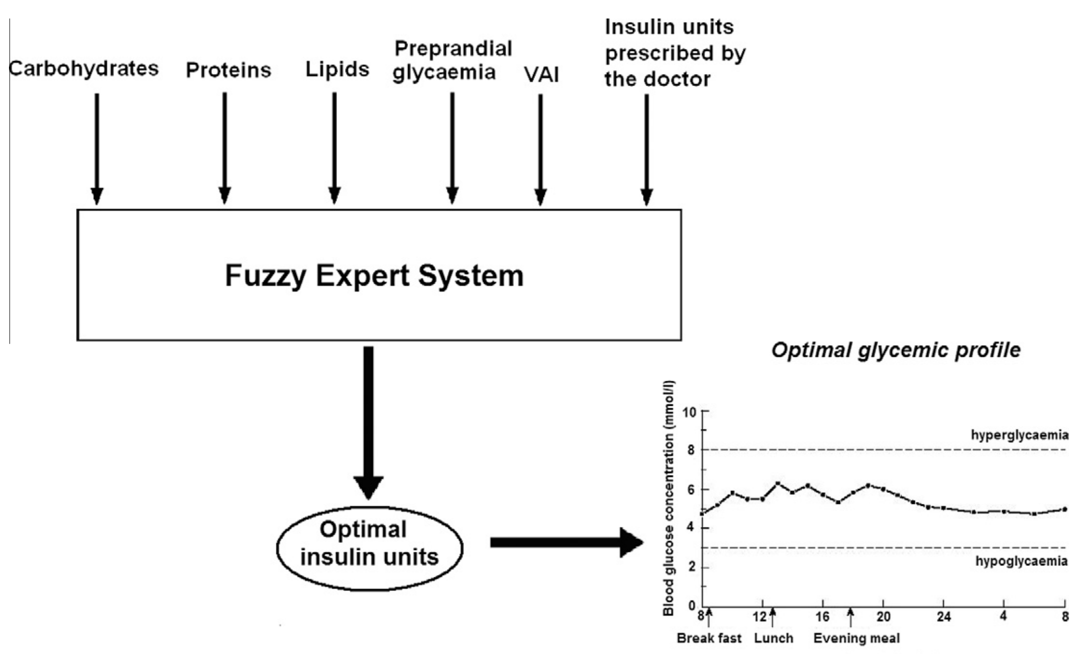

Fig. 2. Input–output of the fuzzy expert system. The output of the fuzzy expert system assures an optimal glycemic profile.