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Review Article

Insulin Therapy Decision Support System: A Study of its Evolutionary Path

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Abstract

Scientists are trying to create clinical decision support systems (CDSSs) to keep blood glucose level of diabetics in the permitted range, which is performed through precisely estimated dosage of insulin. This study aims at examining the evolution of CDSSs. In this review, scientific databases using a combination of sensitive keywords were searched out in articles published in accredited journals. The purpose was to find software associated with insulin therapy, with any technology used in them. The findings indicated that insulin therapy can be performed through new technologies related to CDSSs with two different approaches, open and closed, each consisting of two different functions. Furthermore, the effectiveness of CDSSs in glycemic control and development of related technologies were remarkable. It is anticipated that in the near future, CDSSs based on closed approach will be created, can act as an expert system in the form of a very small pump attached to the patient's body. Pump performance is not only affected by the improvements of CDSS, but also related to the daily growth of Nanoelectronics.

Keywords

Decision support systems; Insulin therapy; Insulin dosage; Insulin pump; Glucose controlling

Introduction

Today, the world is confronted with "Diabetes mellitus" which is a chronic progressive disease as a serious challenge [1,2]. According to the reports of the World Health Organization, a considerable number of people are annually afflicted with this disease [2,3]. America, India and China have also the greatest number of patients suffering from diabetes mellitus. It is anticipated that by the year 2035, the impressive prevalence of the disease will be globally significant [4,5]. The first WHO Global report on diabetes demonstrates that the number of adults living with diabetes has almost quadrupled from 108 million in 1980 to 422 million in 2014 [6]. It appears that due to the burden that is imposed on different societies, a serious effort needs to be made to control and prevent this disease [7,8]. Diabetes Mellitus has various types, the most important of which are Type I and Type II. The main cause of Type I diabetes is the loss of pancreatic beta cells, which is responsible for producing insulin in the body. In order to control this type of diabetes, frequent insulin injection is required daily. On

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the other hand, Insulin resistance (IR) is generally regarded as an underlying condition in type II diabetes in which cells fail to respond to the normal actions of insulin, sometimes insulin deficiency also exists in the patient's body. If blood glucose in Type II diabetes is not controlled with oral medication, insulin injection is necessary [9]. In the process of insulin therapy after advanced beta cell failure, which is the best way of getting optimal blood glucose, attempt is made to simulate the normal function of insulin production by the pancreas with frequent subcutaneous insulin injections [10,11]. This process may be done in three steps which includes [12,13]:

- i. Measuring blood glucose levels by monitoring devices.
- ii. Estimating the amount of insulin that required.
- iii. Insulin injection through equipment such as syringes, pens, pumps, etc.

The major problem for diabetics is estimating the amount of insulin in a way that blood glucose level is placed within the physiological proper scope in the body [3,9,14]. Insulin drug consumption can be very risky. If the amount of drug consumption is prescribed slightly higher or lower than the amount needed by the body, the patient's life or health can be threatened by very serious and destructive effects [15,16]. If insulin consumption exceeds, it will cause hypoglycemia, which can lead to unconsciousness and ultimately, the death of patient [17-19]. On the other hand, if insulin consumption is insufficient, it will cause hyperglycemia which leads to destruction and loss of many organs like eyes, kidneys, nerves, heart and blood vessels [2,20,21]. In the process of insulin therapy, because of the impact of too many internal and external factors, the need for insulin constantly changes and thus blood glucose control is done with great difficulty. These factors include stress level, type of diet, exercise, quality of sleep, changes in body weight, physical state, the secretion of endogenous hormones and other discovered and undiscovered factors and the complexities of the body's metabolism [14,22-24]. In order to resolve this problem, specialists in medical informatics are trying to prepare Clinical Decision Support Systems (CDSS) to support health care providers and patients by providing consultation, adjusting drug dosage and monitoring health status [25-27]. CDSSs include applications which offer the best possible decision to the providers or patient after receiving the required data, and avoid errors [28,29]. The results reported from the modern insulin therapy using innovative technologies and CDSSs represent the fact that the possibility of adjusting the amount of insulin in a short period of time has been provided and patients' blood glucose is set in a stable and acceptable condition [15,28]. This study is aimed at examining the evolution of CDSSs for insulin therapy by utilizing different models.

Materials and Methods

In this review, scientific databases (Including PubMed, Scopus, Elsevier, IEEE, Springer, Web of Science, Proquest and ACM) were searched from January 2015, with no time limitation. The purpose was to find software and technologies associated with insulin therapy, with published articles in accredited journals. Major extracted essays were related to years 2000 to 2015.

Initially, a total number of 89 articles were collected. After excluding the repeated titles and those which did not overlap with the

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research domain, 61 articles which met the criteria of admission to the research with useful information were selected. All the abstracts of selected essays were studied by the researchers. During the initial reviews, the articles were classified based on the type of system functioning. Then, the selected articles in each class were carefully studied. It is noteworthy that in case there was a need to get acquainted with the medical engineering or medical-related materials, the scope of studies were extended. Ultimately, the obtained results were reported in the present article.

Background

The development of CDSSs of insulin therapy and the associated equipment owes Rodbard's predictions in1988. He proposed the capability and the role of computers in the management of diabetes in four distinct groups as follows [22,30]:

- i. Database systems in clinics and hospitals.
- ii. Small personal computers for the use of physicians and patients in order to store analyze and transfer data.
- iii. Portable devices for patients to get consultation on the estimate of the amount of insulin.
- iv. Blood Glucose Monitoring Devices with memory, along with statistical and graphical software.

Access to these technologies was made possible just over a decade. Moreover, developments in science have made it possible to integrate such equipment for the users' convenience [22]. Rodbard's second and third predictions were the most challenging ones that have either been accomplished or are being realized through CDSS based on modern medical equipment. In general, controlling insulin is introduced with two different approaches known as "open" and "closed" which will be discussed below:

Open loop control approach

Controlling blood glucose in the open control approach is carried out through three component parts (CDSSs, provider and patient).In this approach, insulin injections are done by providers or patients based on the implementation of three mentioned steps in the process of insulin therapy. It is notable that the second step of this process (i.e., estimating the amount of insulin) is done using CDSSs [31,33]. CDSSs, which are designed to simplify the process of this therapeutic approach, provide the users with suggested amount of insulin according to collected data. Providers or patients are authorized in applying the suggestions received from these systems. This therapeutic approach could be divided into two distinct types as follows:

At healthcare institute

In this type of open approach, while the patient is in the health care institute, CDSSs are used to estimate the amount of insulin for injection by providers. It is also possible that the adjustments of CDSSs at healthcare institute is personalized by the providers for the use of patients at home and its performance will be controlled in the next referrals [15,34]. Many scientists believe that the use of these systems, which makes it possible to get various data for providing a more accurate decision, is more successful in the control of patients' blood glucose [33]. For example, DIAS software system (The Diabetes Advisory System), which was devised in 1997 to adjust the amount of insulin, is a CDSS based on the learning model. Using this system for

patients is accompanied by significant reducing of hyperglycemia and predicting the likelihood of hypoglycemia [22,34,35].

Distant control: In this kind of open approach, information and communication technology is used for data exchange between health care institute on the one hand and the patient on the other hand. The patients' blood glucose and physiologic data are distantly sent to a health care institute. The providers inform the patient about the amount of insulin for injection with the help of CDSS. Then, the patients themselves administer the injection. DIABtel software is an applied sample of distant control of CDSSs that helps the diabetics by providing consultation and telemedicine services [34]. Other examples of this approach are: SESAM-DIA-BETA, AIDA, DIACRONO,T-IDDM, MELLITUS MANAGER, DIABETEX

Closed loop control approach

Closed loop control implies the portable insulin pumps which are known as artificial pancreas and automatically injects insulin based on glucose level measurement [3,31,32].

These pumps include hardware and software and form three different components as follows [36]:

- A device for measuring blood glucose.
- A device for injecting insulin.
- A CDSS installed on a microcomputer using the algorithms for estimating the amount of insulin.

This approach is introduced in two ways: Distant control (threecomponential), the pump and the patient (two- componential).

It is worth noting that the evolution of CDSSs for insulin therapy starts from the open loop control approach and ends in closed loop control approach.

Distant control (three-componential)

These systems, which consist of three components of insulin pump, patient and health care provider, receive the required data (such as the patient's blood glucose and insulin injection dose) from the insulin pump and report the results to the specialist based on information technology to obtain a decision. The new type of these systems makes it possible for the providers to execute the therapeutic instructions on the insulin pump distantly in order to change the pump's settings and control its function [28,37,38].

The pump and the patient (two -componential)

These CDSSs, which consist of two components of insulin pump and patient, are installed on a microcomputer on the insulin pump, and use different algorithms to estimate the amount of insulin. The automatic control of drug injection by the insulin pump fixed on the patient's body is done by these CDSSs [3,36,39,40].What is clear is that the two-componential decision support systems with the expert system approach are suitable alternatives for the three-componential decision support systems.

Results

Utilizing the computer software and CDSSs for insulin therapy has been welcomed by diabetics [41]. In this regard, and by employing different approaches, researchers are trying to provide the possibility of developing this way of therapy by designing CDSSs that have high degree of efficiency [22,34,42]. For example, Deutsh was able to Citation: Moghaddasi H, Ayani S, Valizadeh M, Rahimi F (2017) Insulin Therapy Decision Support System: A Study of its Evolutionary Path. J Health Inform Manag 1:1.

develop an insulin therapy software system to balance the amount of insulin, adjust the timing of insulin injections and choose the optimized kind of insulin [43]. Schneider designed a system that in addition to containing the features mentioned above makes it possible for the patients to forecast their future status of blood glucose [44]. However, the model that could suggest the required amount of blood glucose and insulin based on food consumption (carbohydrates) was introduced by Tudor [45]. Lehmann's focus has been on the lack of data and uncertainties of metabolic status of the body affecting the process of insulin therapy and also on tackling such problems [46]. Some scholars like Zainuddin have tried to reduce the probable occurrence of errors by adding usable variables such as weight, sex and age to the decision maker model [2]. Integrated models such as the proposed model of Montani, which has been prepared on the basis of patients' data, are also used in the creation of such CDSSs [47]. Other scientists like Smale believe that the workflows must be carefully introduced to the system in order to make it possible to get accurate results [48]. Some researchers, like Pappada, have been able to make self-trained models by applying the knowledge of Artificial Intelligence [14]. Having linked the two systems of Computer Physician Order Entry(CPOE) and CDSSs for insulin therapy, Boord and his colleagues realized that proposing new instructions can speed up the nurses' performance, improve the patient's condition, and reduce errors [49,50]. Similarly, having had the idea that it takes a long time for the nurse to analyze the patient's blood glucose data, Vogelzang tried to develop a CDSS in the intensive care unit [50,51]. Barendes, likewise, made the operation control of insulin pumps under the supervision of nurses and reduced the errors of nurses and insulin pumps by offering suggestions associated with the amount of insulin by designing a CDSS [37]. In two separate comprehensive reviews conducted by Hoekstra (2009) and Campion (2010) on CDSSs associated with hospitalized critically ill patients ,the quality of many of such systems have been pointed out [28,52]. The findings indicate that researchers have used a variety of methods and models for producing CDSSs for insulin therapy. However, the expert systems using different techniques listed below are more commonly used in controlling the blood glucose [22,53]:

- i. Mathematical methods
- ii. Neural networks methods
- iii. Algorithm approach methods
- iv. Fuzzy Logic methods
- v. Rule based methods

Each of these methods has subset models which are selected and used where required. For example, mathematical methods are mainly used to simulate metabolic conditions of the human body with regard to insulin and glucose production cycle which can be used in building closed loop systems [3,33,54].

A study into this method reflects the fact that various mathematical models have been used to control blood glucose, among which Minimal Model can be referred to as the most important one. It is worth mentioning that a few parameters have been used for building this model [34]. It is notable that the definite cause of the failure of some decision making methods are briefly summarized in three main reasons as follows [53]:

There is no possibility of generalizing constructive models of the system to the diabetics which means it covers only a certain group of patients. Lack of accurate recognition of influential parameters and their interactions leads to creation of complex models which can increase the risk of error.

Most models are developed considering the internal effective factors of the body while external factors such as the amount and type of food consumption, exercise routine, etc. are not considered.

Despite the existing difficulties and obstacles, scholars' effort to solve this problem continues. The findings of this research can highlight valuable benefits of applying CDSSs of insulin therapy such as the followings [55]:

- 1. Saving time for treating and improving the control of the disease.
- 2. Reducing the likelihood of risks and the side effects of the medication.
- 3. Shortening hospitalization.
- 4. Reducing the expenses caused by the illness.
- 5. Improving the patients' confidence and quality of life.

In addition, one of the valuable uses of these systems was the control of diabetic children's blood glucose condition which makes it possible for them to experience a normal life by minimizing the number of hypoglycemia during the day [56].

Discussion

The results obtained from the studies in this review indicate that there are two approaches to controlling the insulin through decision support system, open and closed, each of which consisting of two types. The open approach is more common due to the technological problems and the high cost of the closed approach [11]. Currently, the advantage of the open approach is that patients are under medical surveillance. Meanwhile, the supervision of providers or patients on suggestions received from CDSSs or the application of past experiences on those suggestions reduce the incidence of risks and serious damage. One of the problems of these systems is the possibility of the data being hacked in the distant control type of open loop approach [38]. In the closed approach, the distant control decision support systems (threecomponential) are mostly used to process strict insulin therapy on the hospitalized diabetics in intensive care units such as heart, surgical, and trauma units to control mortality rate and enhance the quality of treatment [28,37,57,58]. However, in any situation where the CDSSs are not used, nurses will have a big responsibility to control patients' blood glucose [57]. Existing problems in the current insulin pumps (including being time-consuming and exhausting to set manually [50] or the lack of an exact sensor that can accurately measure the blood glucose, [3] make nurses to continuously test patients' blood glucose and control the function of insulin pumps [57]. The error caused by this process is irrecoverable and leads to patients' mortality [28,58]. The distant control type of closed loop approach is designed and implemented to report the status of insulin pump and patients' blood glucose to the providers in the unit or even outside the hospital. The pump's settings can be changed based on the final instructions received from the providers. In addition, this type of CDSS can forecast the future status of the patient who is using the pump and give some suggestions to providers with regard to continuity of the patients' treatment [28,51]. Certainly, such services can be provided to outpatients who use insulin pumps. For various reasons including the followings, these systems are still of no interest to most patients for regular use.

- The possibility that the data can be hacked distantly which may cause irrevocable risk to patients' lives [38].
- Constant contact between providers and the system which may cause some mistakes due to human-made error.

In the pump and patient type of decision support systems (twocomponential), providers play no role in controlling insulin pump, a point which is the main interest of researchers and patients [32]. One basic problem in this domain is that extra-low-weighted accurate point of care system and fully-developed algorithms of blood glucose do not exist, a point which makes the general use of these services limited. Currently, due to the various reasons including deficiency of data (such as hormone status, the amount of food consumption) or the absence of an appropriate algorithm to estimate the exact amount of insulin, it is not possible to use such systems certainly as an excellent alternative to normal pancreas [3,36,39,40].

Sim et al. (2017) conducted a study entitled "developing diabetesspecific clinical decision support system (Diabetes Dashboard) interface for displaying glycemic, lipid and renal function". The results showed that the software has positive effect on the management of diabetics care. The study has emphasized the necessity of estimating the cost-effectiveness of a clinical decision support system for diabetes care [59].

Conclusion

The results of this study indicate that the most successfully-used models have been applied based on artificial neural networks that simulate the factors affecting the blood glucose using non-linear perspective. It is noteworthy that this approach has been known to be quite suitable to adjust the dose of medicine specially insulin and is quite appealing in the field of medical informatics [54]. The main reason for the popularity of this approach depends on the training models which suggest the optimal dose of insulin for the patient after receiving the input data [60,61]. Therapeutic results using CDSSs for insulin therapy indicate the control of blood glucose and quality improvement in inpatient and outpatient treatment [27,28,41,50,55]. Moreover, there has not been any report on the existence of harmful side effects arising from the use of such systems [41]. Considering the fact that 50% of the studies clearly demonstrate these systems' success in treatment [15], acquiring and using these systems can be recommended to all patients, particularly the providers, children and their families [56]. It is anticipated that in the near future, pump and patient decision support systems (two-componential), which have a high potential for improving the process of therapeutic control, can be an alternative to the traditional treatment of these patients.

These systems will be designed based on Nano electronic equipment, and will be the foundation of producing very small and light pumps by the help of reliable and intelligent decision making method. In addition, by controlling the disease safely and automatically, these systems can completely eliminate deficiency in patients (in all biological functions including resting or moving).

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