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Original Research Article

Fast, Accurate and Cost-Effective Detection and Diagnostics of Diabetes Mellitus Thanks to Using New, Patented Diagnostic Procedure and Clinical Expert Decision Support System Bio Analyst

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Abstract

The main aim of this study is to present a new, effective approach to diagnose Diabetes Mellitus in a timely, accurate and cost-effective manner, thanks to using technology and new, patented diagnosing procedure. This study shows results of diagnosing Diabetes Mellitus in two different Clinical Expert Decision Support Systems and presents a new way to diagnose diabetes through commonly used urine test strips. It also shows, how this new approach may be reflected into diagnosing algorithms that can be used in diagnostics systems.

Keywords: Diabetes Mellitus, Diagnostics, Expert Systems, CEDSS, eHealth, Telemedicine.

INTRODUCTION

It is possible to argue that effective knowledge sharing in the sphere of preventive medicine, health care, diagnostics, treatment, as well as post-therapeutic care, plays an extremely important role not only for individual patients, but also for the world's population as such. According to T. Pang *et al*., [1] capturing, creating and disseminating the new health-care- and medicine – related knowledge on a global level and its consequent implementation and utilization to improve diagnostics, treatment and post-treatment care should be a world-wide effort that would consequently lead to improved disease prevention, faster and better diagnostics, effective treatment or even elimination of certain diseases, which would, as a result, lead to improved quality of welfare of humankind. The above mentioned global vision, however, might become real only via effective and efficient utilization of knowledge management methods, that encompass application of best practices and know how – together with information, knowledge management and expert systems – also on local and even institutional level, while having an active support of the government and national and multinational corporations and organizations [2]. An example of a system that could be used as a tool to help meet such vision and detect and diagnose Diabetes Mellitus (DM) in a fast, accurate and, at the same time, cost-effective manner is a Clinical Expert Decision Support System (CEDSS) BioAnalyst, used together with a recently patented approach to detect sugar in urine based on using common Diabetes test strips.

EXPERIMENTAL SECTION

The main goal of the research was to define an effective approach to diagnose Diabetes Mellitus, as a serious metabolic disease, in a timely, accurate and cost-effective manner.

The following tasks may be considered objectives of the research:

- Gain new knowledge about possibilities of using technology to diagnose diabetes.
- Identify benefits of using CEDSS based on experimental testing of diagnosing Diabetes in BioAnalyst and Statgraphics.
- Gain new knowledge about possibilities, opportunities, purpose and advantages of using new practices and procedures, as well as technology and systems in the field of diagnosing diseases based on interpretation of laboratory tests.

The order of the above-stated partial goals does not reflect their importance or sequence of their realization.

The research was based on using methods of analysis and synthesis, deduction, description, method of comparison, observation, as well as experimental testing and validation. Methodology was based on using

both, qualitative, as well as quantitative research methods.

System BioAnalyst

In 1990s, after several years of thorough research, experts from former Czechoslovakia (today Slovakia and Czech Republic) developed a Clinical Expert Decision Support System to efficiently monitor the health condition of vast population; a program that enables not only to diagnose diseases, but also to reveal pre-disease changes and monitor effectiveness of a particular treatment. The original thrust of its design was to complement physicians' skills in diagnosing processes by suggesting possible disease and showing the percentage of diagnosing accuracy [3]. Over the years, the system has been revised, modified and adjusted to meet the demands of the rapidly changing trends in the field of ICT. Current version of the system – BioAnalyst 4.0 provides user-friendly and intuitive environment is available online and can be used in the cloud.

BioAnalyst is a system for multi-factorial processing of biochemical and other paraclinical data. It may be used to support primary disclosure of osteoporosis and diseases of liver, kidneys, disturbed metabolism, cardio-vascular and tumor diseases. BioAnalyst works as an open, expert, self-learning system, and therefore may be used for statistical processing of any kind of data, eventually, i.e. can be applied wherever the process of decision-making needs to be supported. However, the main aim of system usage is to support decision-making in stating diagnosis in internal medicine, oncology, cardiology, or to interpret clinical laboratory data in order to reveal diseases or pre-/post-disease changes.

Because the standardization of biochemical and paraclinical methods and methodologies on a global basis is very difficult and could cause errors in data interpretation and stating diagnosis at different places, the possibility to modify and prepare essential a priori data at different places became unavoidable. That is why BioAnalyst also incorporates tools that enable users to define their own "primary methodology files" based on data of local probands. Simply said, these tools offer the possibility to create new, customized and more efficient or more simple methods to ensure inexpensive but, at the same time, reliable differential diagnostics at different places [4].

BioAnalyst Encompasses the Following Objects:

- Client Manager – allows end users to create, preview and edit client's electronic health records.
- Diagnostics [of] Diseases – runs diagnostics based on choosing a desired diagnostic group and, at the same time, based on real patient's biochemical parameters.
- Diagnosis Manager – enables end users to create, edit, and view statistics of data that represents individual diagnoses.
- Diagnosis Group Manager – enables creation and management of diagnostic groups, supports collection and merging of diagnoses with identical parameters into common groups – clusters, and allows for visualization of diagnostics. The exploratory summarizing statistics feature also provides a quick reference to many frequently used statistics, such as the mean, standard deviation, skewness, and kurtosis. In addition, the summary statistics provides the user with the correlation matrix and the variance/covariance matrix.
- Monte Carlo Modeling – performs data classification based on a set of artificially generated data and consequently statistically processes the results of classification. This feature also provides end users with information about validity of values/parameters based on using a small amount of real data. Besides, Monte Carlo module visualizes results and presents the output in form of histograms.

The above described objects were used during the research, main role of which was to find an effective way to diagnose Diabetes Mellitus.

RESULTS AND DISCUSSION

Comparing diagnostics of Diabetes Mellitus in CEDSS BioAnalyst and Statgraphics

In order to find out possible impact on [increased] efficiency/accuracy of diagnostics, CEDSS BioAnalyst and Statgraphics were used to diagnose DM based on using laboratory blood test results. To be more specific, this particular experiment was based on using 2 modules in BioAnalyst – Diagnostics [of] Diseases, i.e. Real Data and Monte Carlo, and Cluster Analysis procedure in Statgraphics, while using real blood test results of patients diagnosed with DM and blood test results of healthy probands. All the real values – blood test results were analyzed by Real Data module in BioAnalyst and Statgraphics. Besides, while using these real blood test results, BioAnalysts's Monte Carlo module generated 100 values for each category of probands.

During the diagnosing experiment, we recorded the amount of correctly diagnosed results (either real data or artificially generated values in Monte Carlo module), the number of unclassified results, and the amount of false negatives or false positives, i.e. incorrectly diagnosed results. As for false negatives and positives, these incorrectly diagnosed results may be, and during the research also were, considered much worse than unclassified results, because in case of unclassified results both systems showed diagnostics error and asked to repeat the diagnostics procedure. The research was conducted in Slovakia, in January 2017.

Diagnostics of DM was conducted based on using and monitoring four parameters – glycemia values gained from oral glucose tolerance tests (oGTT) in 0., 1., a 2. hour and a glycohemoglobin (GHb). These tests were done on three groups of probands – 1. healthy individuals, 2. probands with impaired glucose tolerance (IGT), and 3. patients with recently diagnosed DM.

Table-1: Comparison of Diagnosing DM in BioAnalyst and Statgraphics

			BioAnalyst/Real Data		BioAnalyst/Monte Carlo		Statgraphics	
	# of probands/ real data values	# of Monte Carlo values	Accurate Diagnosis	Unclassified	Accurate Diagnosis	Unclassified	Accurate Diagnosis	Unclassified
Healthy	35	100	100	0	100	0	92	8
IGT	40	100	83	11	83	11	70	18
DM	30	100	76	19	66	29	68	25

The table above (Table-1) summarizes the number of probands and real data, as well as artificially generated (Monte Carlo) values, plus the percentage of correct diagnostics and unclassified results in two different Modules of BioAnalyst – Diagnostics [of] Diseases (Real Data) and Monte Carlo, and Statgraphics. As can be seen in the table above, both modules of BioAnalyst accurately diagnosed 100% of healthy probands, eventually normal values. As for Statgraphics, this system correctly diagnosed 92% of healthy individuals and the rest was unclassified, i.e. it was necessary to run the tests again. Both BioAnalyst modules were able to accurately diagnose 83% of probands with IGT and 11% of tests remained unclassified. The rest – 6% was classified as false negatives, i.e. individuals having IGT were organized under the healthy category. Statgraphics correctly diagnosed IGT in 70% of tests, 18% were unclassified and as much as 12% were false negatives. As for the diagnostics of DM, BioAnalyst - Real Data approach correctly diagnosed 76% of real values, asked to repeat the diagnostics in 19% of tests and diagnosed 5% of patients false negatives, i.e. 5% of patients diagnosed with DB were considered healthy or IGT. BioAnalyst - Monte Carlo approach correctly diagnosed 66% of generated values, asked to repeat the diagnostics in 29% of tests and, again, diagnosed 5% of patients with false negatives. Finally, Statgraphics accurately diagnosed 68% of real values, asked to repeat the diagnostics in 25% of tests and, as much as 10% of patients diagnosed false negatives.

Based upon the above-mentioned results, it's possible to claim that accuracy of diagnostics related to blood test results of healthy probands in BioAnalyst reached 100%. On the other hand, Statgraphics in this case was not able to classify and consequently appealed to do the diagnostics again in 8% of tests. As for IGT diagnostics, both modules of BioAnalyst reached accuracy of 83%. On the other hand, Statgraphics, used in this case, may be considered the leader in false negatives. However, in case of diagnosing DM, the accuracy of diagnostics in both, BioAnalyst and Statgraphics was lower. In this particular category, BioAnalyst - real Data approach diagnosed patients with DM most accurately, at the same time, however, BioAnalyst – Monte Carlo was the leader in the „unclassified" category. On the other hand, Statgraphics diagnosed the most false negatives, therefore, it's possible to say that in case of diagnosing IGT and DM was BioAnalyst – Real Data the best tool.

As can be seen in the results and analysis above, success rate of accurate diagnostics in both systems did not drop below 65%, which is percentage that can be, from the clinical diagnostics aspect, considered significant. However, although the diagnosing results of both systems may be considered important, based on the analysis of diagnostic accuracy of BioAnalyst and Statgraphics, BioAnalyst may be considered better not only because of the better results in accurate diagnostics, but also lower rate of false positivity or negativity. All in all, importance and benefits related to using CEDSS during decision-making processes concerning diagnostics of DM may be considered undeniable. Using CEDSS in such case may not only help physicians to accurately diagnose patients, but also save time and costs that relate to diagnostics of DM, eventually the amount of specialized examinations or laboratory tests. At the same time, it is needed to pinpoint the fact, that DM diagnostics approach based on using usage of CEDSS together with self-diagnostics of patients based on a specific procedure could be even more effective. An example of such a combination is in part described in the upcoming section.

New DM Diagnostics Approach Based on Using Common Diabetes Test Strips

DM belongs to a group of metabolic diseases and one of its typical characteristic attributes is changing level of glucose in blood caused by impact of insulin or defects in insulin secretion [5]. Diabetes 2 may be considered the most common. Symptoms of this disease may be hidden or hard to recognize, so Diabetes 2 may persist asymptomatically and may not be revealed and diagnosed for several years.

Normal level of glucose in blood is between 3.6 – 5.8 mmol/l, if it is higher, then it's recommended

to have oGTT tests. Besides the above mentioned blood tests (see the previous section), it is also possible to test it in urine through glucose oxidase tests. It is an examination based on using diagnostics strips that change color if the level of glucose exceeds 8.9 mmol/l, while in case of healthy individuals, the color does not and cannot change. These diagnostics strips are commonly used by individuals at home, during preventive check-ups at physicians, eventually during DB therapy or stabilization control at diabetologic ambulances. This particular diagnostic approach is considered underestimated, however, under certain circumstances – precisely followed criteria (based on Slovak patent UV # 7756 approved on March 24, 2017) could this approach, together with using CEDSS, be used in vast population as a very cost-effective way to discover and accurately diagnose DM.

To confirm the above-mentioned statement, there were conducted 188 comparative experiments, comparing concentration of glucose in blood together with semi quantitative urine examination using diagnostic strips of a particular brand. The study was conducted in alignment with UV # 7756, i.e. 90 minutes after the main dough or pasta dish, testing the capillary blood to monitor glucose concentration and, at the same time, examining urine semi-quantitatively. Main criteria were the level of glucose in blood not exceeding 8.9 mmol/l, together with possible occurrence of glucose in urine. The tests took part in Trencin, Slovakia in January – March, 2017. Results of this comparative experiment are summarized in the following chart (Figure-1).

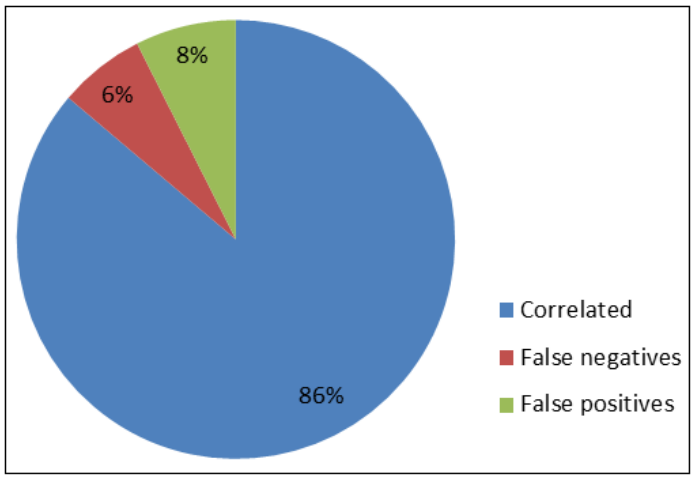

Fig-1: Results of DM Diagnosing Experiment

As can be seen in the chart above, as much as 86% of tests correlated. To be more specific, 162 out of 188 comparative experiments showed the same final verdict. 12 tests, i.e. 6% could be considered false negatives, which means, that the level of glucose in blood 90 minutes after the given main dish was higher than 8.9 mmol/l, while the urine test results were negative. On the other hand, 14 experiments, which makes 8%, can be considered false positives, because based on following the exact criteria, the level of glucose in blood was less than 8.9 mmol/l, while the urine test results were positive.

The results of the experiment prove significant accuracy of DM Diagnostics via simple DM urine test stripes and new diagnostic procedure, which was reflected in DIABSCREEN procedure – a brand new diagnosing module created in BioAnalyst, that is based on the following decision-making algorithm (Figure-2).

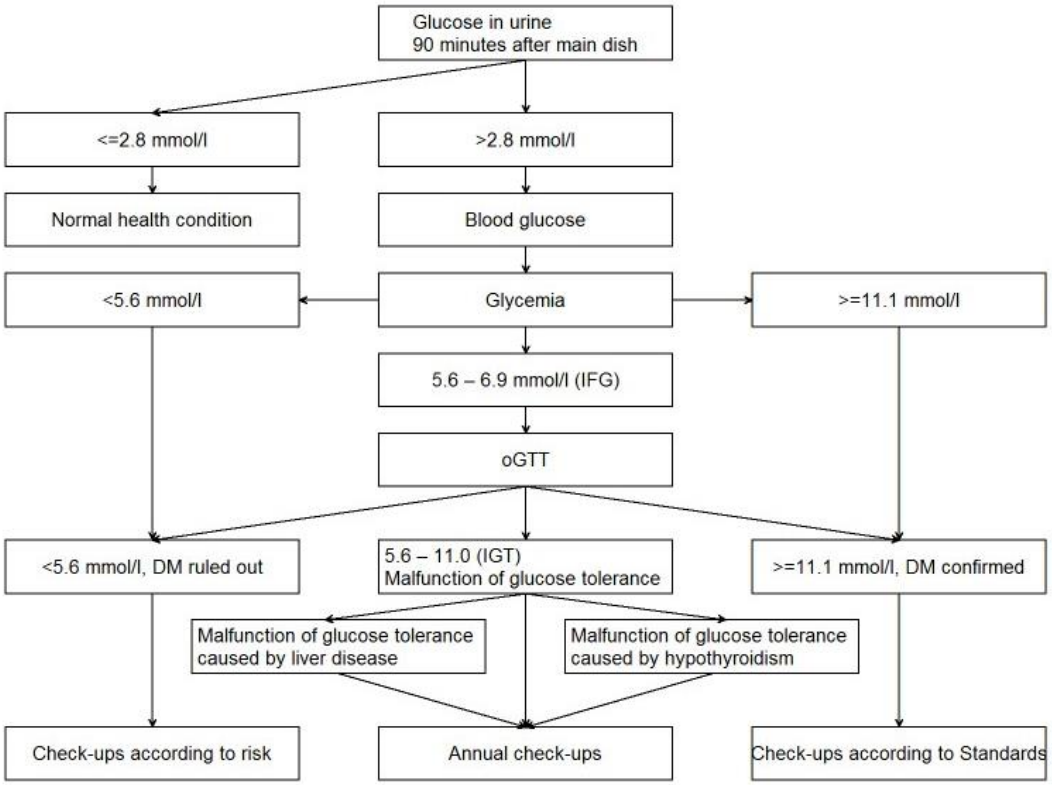

Fig-2: DIABSCREEN Algorithm

DIABSCREEN module is currently being tested on an international level and the results of this experiment should be available in the near future [5].

CONCLUSION

The results of this study suggest that technology may be utilized to accurately diagnose DM, eventually be used as a helpful tool to support decision-making needs of physicians or even specialists, while diagnosing pre/post-disease changes or monitoring the treatment methods related to DM. To be more specific, the results of the first partial study show that accuracy of DM diagnostics through CEDSS exceeded 60% in all cases, which creates new opportunities even for local physicians to effectively screen, monitor and consequently even diagnose DB in vast population in a fast, easy, time-saving and cost-effective manner. The other partial study shows, that there exist alternative ways to diagnose DM, which can be immediately reflected in CEDSS algorithms and consequently to even more increase efficiency of DM screening and diagnostics. Utilization of such approach might lead to significant time saving in DM diagnostics, faster detection of DM or even some pre-disease changes, faster deployment of adequate treatment, effective screening of health in vast population, increased efficiency of health-care personnel, and consequently cost-effective performance of health-care institutions. What's even more important, it's possible to claim that such methods have the potential to become a reasonable, unavoidable and irreplaceable place in the field of clinical diagnostics and thanks to using them it will be possible to provide adequate healthcare at the right time, on the right place and in the most effective manner and so increase the well-being not only of individuals, but also entire peoples, even in the less developed countries.

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