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A Pilot Study of GlucoPro[™] Application for Glycemic Control Feasibility in Intensive Care Units

Abstract - Tight glycemic control has been proven difficult due to frequent monitoring and high nursing effort. Given the adverse effect of poor glycemic control, including organ failure, sepsis and mortality, it is necessary to adopt tight glycemic control in Intensive Care Units (ICU). Incorporating the latest technology may improve the precision of glycemic control and, at the same time, reduce the nursing effort. In this study, a decision support system for glycemic control, GlucoProTM, has been developed. GlucoProTM provides recommendations for insulin dose and timing based on the glucose control protocol of the particular ICU. The aim is to evaluate the usability of GlucoPro[™] for controlling glycemic levels in the clinical setting. The pilot study indicates that most nurses agree to use an automated system to replace the sliding scale method for glycemic management. Most nurses expressed positive feedback on using GlucoProTM, although some interventions were introduced during the pilot study. These interventions were due to nurse intuition and changing shift activity. The evaluation of the GlucoProTM application indicated that most nurses wanted to use GlucoProTM regularly, and they also responded that the mobile application is easy to use. However, the nurses agree that more extensive training is needed. Critical criteria such as effective, low risk, comprehensive, and providing an alert system in an emergency are among the requirement of a decision support system for controlling the glycemic level. Improvement of the GlucoPro[™] system will ensure the benefits of applying it to clinical settings.

Keywords – Critical care, glycemic control, hyperglycemia, insulin therapy, patient care management

1 INTRODUCTION

Hyperglycemia is common in critically ill patients, where patients experience high blood glucose levels of more than 11 mmol/L [1]. According to National Diabetes Registry Report 2023, Malaysia has 870,771 active diabetes patients, 99.48% being Type 2 Diabetes Mellitus (T2DM), 27.12% of the patients were treated with insulin [2], and 21.8% received insulin therapy from government hospitals [3]. Insulin therapy is essential to maintain the glucose within the blood 8-10 mmol/L normoglycemia range, [4,5].Moreover, poor management of hyperglycemia may lead to severe sepsis and acute kidney injury. with the mortality rate within 24 hours of ICU admission in Malaysia being 42.3% and 40.5%, respectively, in 2016 [6].

In Malaysia, most hospitals adopt a sliding-scale protocol for managing hyperglycemia [7]. The sliding scale protocol is easy to adopt since the dosing value is usually straightforward and depends on the current blood glucose value [7], even though some require clinical experience due to the protocol's complexity and dosing variation. However, managing hyperglycemia in ICU is very challenging, and the monitoring process involves nursing efforts to monitor blood glucose levels, identify proper insulin dosage, record clinical data, medication. Additionally, provide inappropriate dosing results in resistance and adverse effect on the patients, such as the macrovascular complications of and

microvascular, renal failure, multiple organ failure, sepsis, and even a cause of death [1, 8-9].

Successful implementation of glycemic control dramatically depends on the nursing effort and administration, including nurses' knowledge, attitude, and behaviours [10]. Several studies indicate that a heavy nursing workload adversely affects patient safety and care [11-15]. The heavy nursing workload may be due to the high nurse-patient ratio, reduction of nursing staff due to increasing health care costs, and high demand for health care needs. Notably, the heavy workload of hospital nurses is a significant problem for the health care system worldwide. It is muchly associated with the increasing population, resulting in increased demand for nursing staff [16]. However, the ideal nursing ratio to patient is 1:1.

A heavy nursing workload may result in other issues, such as poor communication between nurses and physicians [17]. Nurses may experience stress and burnout [18-19] due to heavy workload, which reduces their physical and cognitive resources and consequently unable to perform efficiently and effectively. Heavy nursing workload has also been associated with the execution of errors and mistakes in performing a task [20]. Therefore, the possibility of making mistakes and misjudgments may occur during the shift, especially in emergencies.

Additionally, patients in the ICU need more care and monitoring, especially in the quality of care and patient safety [18,21]. An interval of 1-4 hours of measurement is typically adopted in most ICUs. However, more frequent measurement leads to more clinical effort and higher nursing workload, such as taking blood glucose measurements, recording the value on the patient's chart, identifying appropriate insulin dosage, recording new insulin rate, and providing and adjusting the insulin infusion rate [22]. Thus, hourly monitoring in tight glycemic control and adjusting intravenous insulin doses requires additional work by the nurses in the ICU [12, 23-25].

The use of technology and systems to assist clinical staff has been reported in several studies. The objective is to provide a more comprehensive and systematic approach for treating patients, especially in data recording, which facilitates data-driven decisions. Examples of glucose management systems that are commercially available are Glucommander™, EndoTool®, GlucoStabilizer®, and GlucoTab® [26-29]. These computerized decision support systems enable automated insulin dosage calculation for

managing glycemic levels. They also have the ability to minimize hypoglycemia events while achieving and maintaining patients at their target blood glucose level.

In this study, a mobile application, GlucoProTM was developed to support glycemic control in clinical settings by helping determine the appropriate insulin dosage for patients. The insulin dosage is guided by clinical protocols specific to the healthcare facility. This study aims to evaluate the usability of GlucoProTM for controlling glycemic levels in the clinical setting. Additionally, the adaptability of the GlucoProTM is assessed through a structured questionnaire administered to nursing staff.

2 METHODOLOGY

2.1 Nurse's Perception of Tight Glycemic Control

A simple questionnaire has been developed to identify the nurses' understanding and perception of glycemic control protocol. The questionnaire consists of two parts: participants' backgrounds, such as years of working experience, and questions about knowledge and understanding of glycemic control protocol. The second part of the questionnaire consists of nine short answer questions. The questionnaire was given to 30 nurses working in the ICU.

2.2 Development of GlucoPro™

GlucoProTM is a mobile application of a glycemic control protocol used in clinical settings to help identify appropriate insulin for patients. The insulin value is determined based on the clinical protocol used in the clinical unit. GlucoProTM provides a selection of glycemic control protocols based on the centre's clinical practice. The primary outcome parameters of the application are the suggested insulin value to be delivered to the patients and the suitable treatment interval.

In GlucoProTM, nurses were required to enter the value of specified parameters, for example, current blood glucose level, initial insulin dosage and clinical parameters related to the patient identification. The insulin dose is calculated based on the input entered by the nurses in conjunction with the glycemic control protocol selected. GlucoProTM provides a selection of measurement intervals of 1, 2, and 4 hours depending on the chosen control protocol.

If the suggested amount of insulin is not desirable, intervention is allowed but needs to be notified in the application. The treatment's analysis and graphical representation are incorporated to

allow the nurses and clinicians to observe patient conditions easily. An alert system and reminder are included to ensure proper management of insulin therapy.

Figure 1 shows the conceptual method of GlucoProTM. Initially, the measured blood glucose value is entered into the system. Then, the control algorithm will decide the amount of insulin the patient needs. Next, the nurses provide the insulin following the GlucoProTM recommendation. This process will be repeated until the patient is released from the insulin therapy regime.

Figure 2 shows examples of the GlucoPro[™] interface in the mobile application, illustrating the key features of the app. It provides a recommendation of the insulin dose based on the scale option. Upon selection, the treatment time interval is also displayed and captured as a reminder. One of the key features includes the analytics and the records of the blood glucose and insulin values of the patients during the stay.

2.3 Pilot Trial of GlucoPro™

A pilot trial was conducted at the HUSM from June 2019 until Dec 2019. The GlucoPro[™] application has been installed on a tablet and provided in one of the ICUs of HUSM. Nurses involved in the study were given a briefing on how to use the GlucoPro[™] application. Nurses were also trained before the commencement of the study. Ethical approval to conduct the study was obtained from the Internal Review Board of the Human Research Ethics Committee, Universiti Sains Malaysia (USM/JEPeM/18100517). The research was performed in accordance with the Declaration of Helsinki by the World Medical Association (WMA). Informed consent was obtained from all subjects and/or legal guardians. Additionally, informed consent from all subjects and/or their legal guardians for the publication of identifying information/images was also obtained.

During the pilot trial, the nurses were required to enter patient information and clinical data according to the GlucoProTM requirement. The GlucoProTM will suggest the insulin dosage needed by the patient after entering the patient's blood glucose level. The nurses were required to follow the suggestion and deliver the insulin dosage as recommended. An alert system will indicate if the patient's blood glucose is too high or too low, and nurses must inform the doctor. In a case where intervention is needed, the nurses will have to select an option for intervention in the GlucoProTM menu.

Figure 3 shows the flowchart of the GlucoProTM application activity. The clinician will identify suitable patients. Once the patient satisfies the GlucoProTM inclusion criteria, patient information will be entered into the GlucoProTM application. The system will process the data and calculate the insulin value based on the selected control protocol. After providing the treatment, the user must update the treatment information in the GlucoProTM application. This process will be repeated until the end of the insulin treatment. This pilot trial aims to evaluate the usability of GlucoProTM and nurse acceptance towards a decision support system for blood glucose control.

2.4 Feedback on the Use of the GlucoPro[™] Application

A short questionnaire was conducted among the nurses involved in the pilot trial to evaluate the usability of the GlucoPro[™] application. During the pilot trial, 15 nurses were requested to complete insulin therapy using GlucoPro™. The pilot trial was conducted for three consecutive days. After that, the nurses were required to evaluate the use of the GlucoProTM application by answering questions in a survey form provided. This survey used a Likert scale question, with 1 representing strongly disagree and 5 representing strongly agree. The data were analyzed using descriptive statistics, including mean, standard deviation (SD), and percentage. No inferential statistical IBM SPSS Statistics tests were conducted. version 26 was used to analyze the data.

3 RESULTS

3.1 Perception of Nurses on Tight Glycemic Control

Thirty nurses participated in this study and were classified into four age groups. Table 1 shows the demographic of the participants. Most of the respondents are between 31-40 years old. The number of years working in the ICU was classified into three categories. 70% of respondents had working experience below ten years.

Table 2 summarizes the questions and results obtained from the respondents. There were two open questions on the questionnaire. If the respondent answered 'Yes' for question 5, the following question was 'What do you understand about tight glycemic control (TGC)?'. Another open question was asked following the answer to question 6. If the respondent selected 'No' for question 6, the following question was 'What do you need to help you to control the patient's blood glucose?'.

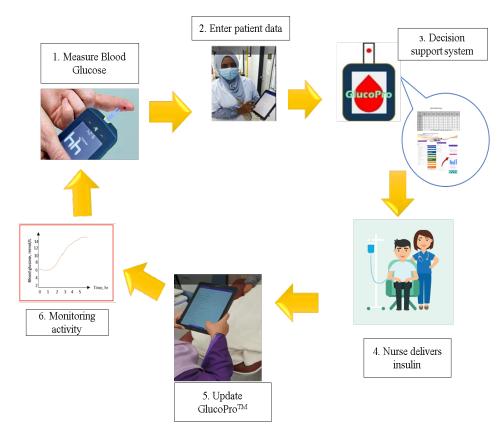


Figure 1. Conceptual method of $GlucoPro^{TM}$

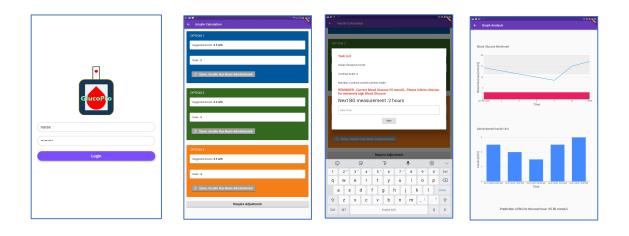


Figure 2. Sample interface screenshots from the GlucoPro™ mobile application

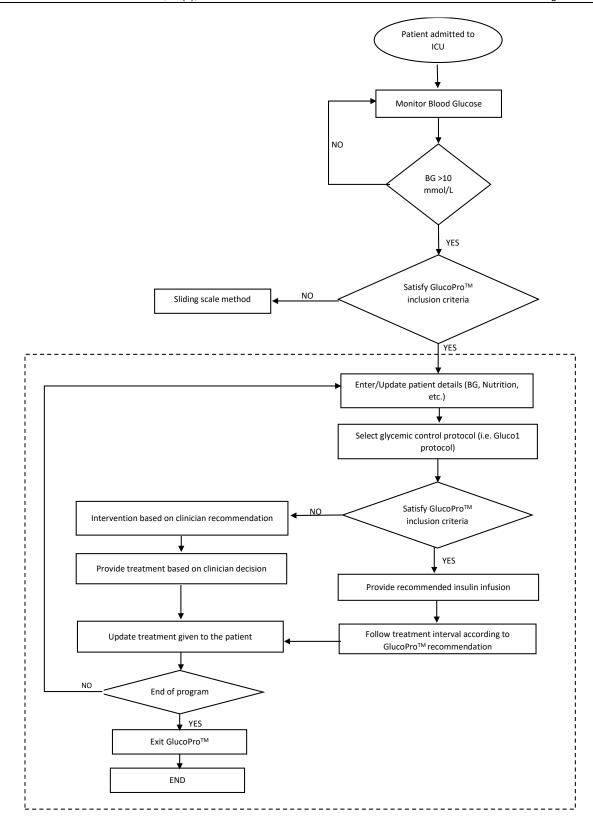


Figure 3. Flowchart of the GlucoPro™ application activity

Questions 1, 3, 5, and 6 required the participants to choose between Yes or No. Meanwhile, question 4 provided five different selective answers based on the Likert scale. Question 1 shows that all participants have experience using the sliding scale method for controlling patients' blood glucose, and 100% responded that it is easy to use. 97% of participants followed the recommended insulin value from the sliding scale, and 83% agreed that the sliding scale method could control a patient's blood glucose in current practice. 33% knew about TGC, and 93% responded that they needed an automated support system to determine insulin value for controlling a patient's blood glucose.

3.2 Evaluation of the GlucoPro[™] Application

Table 3 shows the question and answers from 15 nurses who participated in the pilot trial. Data is presented in percentage, mean and standard deviation (SD). The evaluation of the use of the GlucoProTM application showed that 46.6% of the nurses wanted to use GlucoProTM regularly, whereas 53.4% were neutral. 60% responded that GlucoProTM is not complicated, and 66.7% agreed that GlucoProTM is easy to use. 40% and 33.4% were neutral on whether GlucoProTM is complicated, and easy to use, respectively.

However, 46.7% of the respondents agree that they require help from others when using the GlucoProTM, 20% neutral, and 33.3% disagree. 60% of the respondents found that the functions in this mobile application are well integrated, while 6.7% disagree. Similarly, 6.7% of the respondents found that a lot of the content in the GlucoproTM app is inconsistent. Regarding usability, 60% of the nurses believed most people would quickly learn to use this application. However, almost half of the respondents (46.7%) responded that they have to learn too many things before they can use this mobile app. Nevertheless, none of the respondents found that the GlucoproTM app tedious and were not confident when using it.

4 DISCUSSION

Tight glycemic control has been proven difficult to adapt due to several limitations and minimal nursing resources available in the clinical centre. Despite that, it has shown positive effects, primarily on patient healthcare. Thus, implementing tight glycemic control is a must to ensure better patient outcomes and improve clinical service. A study conducted in Malaysia ICU, reported that the compliance achieved up to 98.8% for the administered insulin following a

STAR (stochastic targeted) glycemic control protocol [30, 31].

In this study, the GlucoPro[™] application has been tested via a pilot trial on the patients admitted to the ICU of the HUSM. Several interventions occurred during the pilot trial for many different reasons. The reason is the patient's unstable condition while receiving treatment, nurse intuition based on their experience, and timing errors due to nurses changing shifts. Interestingly, most interventions gave a higher insulin dosage than the insulin suggested by the GlucoProTM. Further investigation with the clinician and nurses concluded that the operator wanted to be safe and treat the glycemic level slowly. Fear of providing a high dosage has been the most common answer from the nurses, eventhough the dosage is not extraordinarily high.

Besides that, mismatched insulin dosage was commonly observed due to the timing of the updated insulin dosage. This especially happens when a new blood glucose value is obtained. Ideally, insulin dosage will be updated with a new blood glucose value. The insulin dosage is then adjusted based on the updated value. However, the time interval between these activities typically exists, leading to the mismatch between the GlucoProTM application and clinical management.

Based on the evaluation of the GlucoPro[™] trial, this study concludes that most nurses agree with the idea of using an automated system to replace the sliding scale method for glycemic management. Most nurses expressed positive feedback, although some neutrally wanted to use it regularly. A high probability of neutral respondents may feel convenient and easy to use after multiple usages, based on the Likert scale mean value of 3.80.

However, looking at the performance of the pilot trial, it seems that many interventions were introduced, causing less trust in the application in deciding the proper insulin dosage to be administered. It is either the system's incompetence in making the right decision as expected or lacking trust in using new devices or technology in the field. If the system is considered incapable, perhaps the control protocol embedded into the GlucoProTM application must be improved.

New technology introduced for clinical settings must have several features, such as simple, user-friendly, and safe to be implemented. A decision support system for controlling glycemic levels must be effective, low-risk, comprehensive, and provide an alert system in an emergency.

Table 1. Background of nurses who participated in the questionnaire

Demographic Variable		N	Percentage (%)
Age (years)	20-30	12	40.0
	31-40	14	46.7
	41-50	3	10.0
	51-60	1	3.3
Gender	Male	7	23.3
	Female	23	76.7
	0-10	21	70.0
Experience in ICU (years)	11-20	8	26.7
	>21	1	3.3

Table 2. Summary of questions and results from the questionnaire

Question			Answer			
1. Have you ever used the Cliding	Yes			No		
 Have you ever used the Sliding Scale for controlling the patient's blood glucose? 		30		-		
If Yes, what is your opinion on the current Sliding Scale?	Easy to apply Confusing		Hard to apply			
	30		-	-		
Do you always follow to the recommended insulin values from the Sliding Scale table?	Yes		No			
	29		1			
In your opinion, does Sliding Scale able to control patient's blood glucose in current practice?	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	
	3	22	5	-	-	
Did you know about tight glycemic control (TGC)?	Yes			No		
	10			20		
6. Do you need an automated support system in determining insulin values to control the patient's blood glucose?		Yes		N	0	
		28		2		

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Table 3. Feedback received from the nurses who participated in the pilot test

			Answer				
	Question	Mean (SD) -	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1.	I think I want to use this mobile app regularly	3.80 (0.94)	0	0	53.4	13.3	33.3
2.	I think this mobile app is complicated	2.13 (0.83)	26.7	33.3	40.0	0	0
3.	I think this mobile app is easy to use	4.00 (0.83)	0	0	33.4	33.3	33.3
4.	I need help from someone to use this mobile app	3.07 (1.22)	13.3	20.0	20.0	40.0	6.7
5.	I find the functions in this mobile application to be well integrated (related)	3.73 (0.88)	0	6.7	33.3	40.0	20.0
6.	I think there is a lot of content in this mobile app that is inconsistent with each other	2.27 (1.10)	26.7	33.3	33.3	0	6.7
7.	I imagine that most people will quickly learn to use this mobile app	3.80 (0.78)	0	0	40.0	40.0	20.0
8.	I find this mobile app tedious to use	2.00 (0.84)	33.3	33.3	33.4	0	0
9.	I feel confident using this mobile app	3.73 (0.79)	0	0	46.7	33.3	20.0
10.	I have to learn too many things before I can use this mobile app	2.80 (1.47)	26.7	20.0	13.3	26.7	13.3

More extensive study is needed to understand the acceptance of automated glycemic control protocol in the field. Perhaps a robust protocol is needed to be embedded into an application to serve the purpose. GlucoPro™ provides the platform for automated glycemic control, but a more intelligent protocol must be proposed to ensure its effectiveness in delivering tight glycemic control. Moreover, more input from nurses and clinicians is needed to understand the reason and cause of interventions.

Despite the valuable findings presented in this study, several limitations should be acknowledged. One major limitation was the relatively small sample size included in the pilot trial, which may affect the generalizability of the results. Additionally, the study was conducted over a short duration, which limited the ability to observe long-term outcomes and trends. As the study involved the integration of a new

technological application at the bedside within an active clinical environment, the number of sessions was intentionally limited to minimize disruption to routine clinical services and patient care. This constraint may have influenced the extent of user engagement and the comprehensiveness of data collection.

5 CONCLUSIONS

TGC has been proven to reduce mortality and increase patient outcomes based on other established studies. However, implementing tight glycemic control is challenging, particularly when additional effort is needed in clinical settings. This study demonstrates the GlucoProTM application for managing glycemic levels in the ICU. A pilot trial of the GlucoProTM shows several differences between actual and GlucoProTM suggestions due to some interventions. Interestingly, the mismatch may be due to nurse intuition based on their

experience and timing errors due to changing shifts. From the evaluation, the nurses can accept the GlucoPro[™] application for managing glycemic levels: however, a more intelligent system is potentially needed to ensure the nurse's workload is not repeated and can be reduced. Notably, the protocol adapted in the GlucoProTM must be robust to ensure less intervention is required. The intelligent automated control protocol is expected to reduce the nurse workload and provide a more standardized method and minor non-comply issues for tight glycemic control to be practised clinically. Implementing a computerized decision system requires understanding, support resources, and cooperation of the whole team member in a particular unit. Adequate training and acceptance of new technology are crucial to ensure the sustainability of the decision support system.

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