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Survey about diffusion and adoption of glycaemic controller in European intensive care units

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Abstract: Stress-induced hyperglycaemia and glycaemic variability are both associated with worsened critically ill patient outcome. Glycaemic control (GC) aims to reduce and stabilize blood glucose (BG) levels, while minimizing hypoglycaemic risk. Several national surveys have been carried out about GC in intensive care unit (ICU). They mainly focused on characteristics of a GC protocol in terms of glycaemic target, on hyper/hypo-glycaemic thresholds and on the association between glycaemic levels and patient outcome. This survey aims to have a more overall European overview about GC, and more especially about the interest of medical staff for GC systems in European ICUs and the clinician specified key success factors related for these systems. This survey was conducted with 52 persons related to ICUs from 18 different European countries. Results show that some ICU clinicians (10/52, 19.2 %) are still reluctant to implement GC and attention should be paid to overcome their specific criticisms to aid the uptake of safe, effective GC systems. In particular, control-related issues of GC target and used centred on fear of hypoglycaemia. Clinicians thus preferred model-based systems (19/52, 36.5 %), especially if they could forecast the risk of hypoglycaemia. This survey results have highlighted the definition of key control issues by the end-user.

1. INTRODUCTION

Stress-induced hyperglycaemia and glycaemic variability are both associated with worsened critically ill patient outcome (Krinsley, 2003, Egi *et al.*, 2006, McCowen *et al.*, 2001). Glycaemic control (GC) aims to reduce and stabilize blood glucose (BG) levels, while minimizing hypoglycaemic risk. Some studies have shown beneficial impact of GC on patient outcome (Van den Berghe *et al.*, 2001, Krinsley, 2004, Chase *et al.*, 2008), while others failed to reproduce this positive impact (Preiser *et al.*, 2009, Finfer *et al.*, 2009).

Currently, GC in intensive care units (ICUs) is still a controversial clinical practice in Europe. However, an increasing number of GC systems have been developed over the last few years, indicating continuing interest in GC. We can cite the following GC systems: Glucommander (Davidson *et al.*, 2005, Davidson *et al.*, 2008), Clarian GlucoStabilizer (Juneja *et al.*, 2009), GRIP (Vogelzang *et al.*, 2005, Vogelzang *et al.*, 2008), eMPC (Amrein *et al.*, 2012, Pachler *et al.*, 2008), Glucosafe (Pielmeier *et al.*, 2010, Pielmeier *et al.*, 2012), SPRINT (Chase *et al.*, 2008, Chase *et al.*, 2010), and STAR (Evans *et al.*, 2012, Fisk *et al.*, 2012). All these protocols seek to provide structure to a difficult clinical task.

Several national surveys have been carried out about the GC in ICU. In a national survey in the Netherlands, Schultz *et al.* (2010) focused on characteristics of a GC protocol (BG target, insulin administration, control guidelines) and on opinions regarding GC, and more precisely about intensive insulin therapy (IIT). Mackenzie *et al.* (2005) also investigated GC in ICU in the United Kingdom. Their research also mainly focused on which BG targets to achieve during control. Other non-European surveys were also carried out to determine hyperglycaemia and hypoglycaemia thresholds (McMullin *et al.*, 2004) and to identify association between insulin inputs, glycaemic levels and patient outcome (Mitchell *et al.*, 2006).

Previous surveys were conducted nationally, but for widespread use it seems important to have a more overall European overview. Moreover, other aspects associated with GC should be considered. In particular, the interest of European medical staff for glycaemic controllers should be assessed, especially for the computerised controllers that are appearing now. Finally, key success factors associated with glycaemic controllers should be identified to help controller design meet clinician expectations and concerns.

This survey focuses on two features: (1) the interest of medical staff for glycaemic controllers in European ICUs; (2) the clinician specified key success factors related for these controllers. The overall objective is to gather information that would facilitate the diffusion and adoption of GC in ICU daily practice.

2. METHODS

2.1 Questioned population

The survey was addressed to ICU medical and nursing staff working in European hospitals.

2.2 Contact with questioned population

The questionnaire was sent by e-mail to 949 ICU clinicians on the European Society of Intensive Care Medicine (ESICM) faculty list, the authors of papers related to intensive care in Europe, the members of different European intensive care societies (Greece, Italy and Portugal), and ICU clinicians whose e-mail address was available on their hospital website. Limitations of this contact method include incorrect, wrong or expired e-mail addresses, and the inability to contact clinicians whose e-mail address is not publicly available. Hence, a very large survey cohort was created to overcome these limitations and the loss due to low return rates from busy individuals.

2.3 Survey format

Data were collected using a questionnaire as it is the most appropriate and relevant data collection method to meet the survey purpose. Questionnaires can be fast, answered at any time, and allow easy and consistent data-gathering across Europe.

2.4 Questionnaire design and diffusion

The questionnaire was written in English, the most internationally used language. This choice implies that only English-speaking people can answer the questionnaire, which may import a bias. However, the contact method and cohort ensures that many of those contacted will understand enough English to answer the survey. The questionnaire has been encoded in Google Drive (Google, Inc., Mountain View, California, United States) as it is easy-to-use, free and fast to design the questionnaire. Moreover, answers are automatically recorded in an Excel file to facilitate analysis. The online questionnaire link was sent by e-mail with an introduction cover letter.

The questionnaire was divided in five parts, based on the advice of Vermandele (2009).

- Part 1 (for all): survey purpose explanation.
- Part 2 (for all): general and simple questions to characterize responding ICU. This part helps to encourage people to fill the questionnaire (Vermandele, 2009) and drives people to the appropriate next part (3 or 4).
- Part 3 (for clinicians who don't usually use GC in their ICU): identify why they don't use GC.
- Part 4 (for clinicians who usually use GC in their ICU): identify and characterize GC method used by clinicians.
- Part 5 (for all): identify expectations and concerns about GC in ICU, identify the behaviour associated with glycaemic controllers and allow people to comment the survey or to give any further concern about the topic.

The questionnaire was designed to be easy-to-fill and quickly-answered. It uses open-questions associated with short answers or multiple choice questions. The questionnaire was tested by three colleagues working on GC to ensure basic errors were avoided, but their answers were not kept for analysis.

3. RESULTS

3.1 Response rate

Of 971 sent e-mails, 43 were associated with erroneous e-mail addresses that returned a notice. A total of 52 of the remaining 928 persons have filled the questionnaire. The return rate is thus 5.6 %.

3.2 Characterization of respondents

The population comprised 52 persons from 18 different European countries, 39 different cities (Fig.1). Characteristics of the responding ICUs and questioned population are summarized in Table 1.

Table 1: characteristics of responding ICUs and questionnaire respondents.

Type of hospitals, N (%)	
Tertiary or university hospitals	44 (84.6 %)
Non tertiary or university hospitals	8 (15.4 %)
Number of ICU beds, median [IQR] (*)	19.0 [8.0 – 31.0]
Respondent job in ICU, N (%)	
Clinicians	20 (38.5 %)
Consultants	11 (21.2 %)
ICU head	15 (28.8 %)
Nursing staff	2 (3.8 %)
Professors	4 (7.7 %)

(*): one missing response

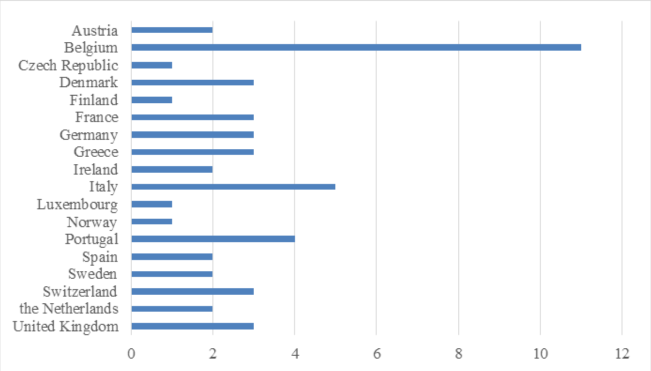

Fig.1: respondent per-country repartition.

Table 2: characteristics of current GC practice.

Type of controllers, N/Total (%)	
Flowchart-based	32/42 (76.2 %)
Formula-based	5/42 (11.9 %)
Model-based	2/42 (4.8 %)
Model-based and predictions	1/42 (2.4 %)
Other	2/42 (4.8 %)
Controller adjustment, N/Total (%)	
Insulin only	29/42 (69 %)
Insulin and nutrition	13/42 (31 %)
Insulin administration mode, N/Total (%)	
Boluses	2/42 (4.8 %)
Infusions	24/42 (57.1 %)
Mainly infusions with few boluses	14/42 (33.3 %)
Subcutaneously	0/42 (0 %)
All of previous modes	2/42 (4.8 %)
Other	0/42 (0 %)

3.3 Glycaemic control in ICU

About 80 % (N=42) of respondents have a formal use of GC in their ICU. GC is mainly flowchart-based (76.2 %), adjusts only insulin (69 %), and insulin is mainly administrated as infusions with few boluses (Table 2). Only 7 % (3/42) of glycaemic controllers are computerized but 66.7 % (26/39) of respondents would prefer a computerized glycaemic controller.

Absence of GC in ICU is mainly explained by fear of hypoglycaemia (6/10, 60 %). Lack of trust (1/10, 10 %) and no functional monitoring (1/10, 10 %) also hampers clinical implementation of GC.

3.4 ICU clinician expectations and opinions about glycaemic control

The main desired controller characteristics are ease of use, friendly interface, and ability to be customized to local clinical practice. Some respondents (29/52, whom 24/29 control glycaemia and 5/29 do not) mentioned the following other important characteristics: safety with limitation of hypoglycaemia (11/29, 37.9 %), flexibility (3/29, 10.3 %), connection to data management system (3/29, 10.3 %), and robustness (3/29, 10.3 %). In addition, performance, reliability, alarm system and low cost are other noted characteristics that could facilitate GC implementation in ICU, as each of these characteristics was cited twice.

Concerning the GC method, half of persons whose protocol only adjusts insulin would like to adjust both insulin and nutrition during GC (Table 3), which is surprising. Results show that all respondents who do not control glycaemia (10/52) would control glycaemia with a controller adjusting both insulin and nutrition. ICU staff also wants control protocol flexibility about insulin administration mode, with a preference for infusions with few boluses (results not shown).

Table 3: characteristics of current and wished protocol adjustment during glycaemic control.

	Current adjustment			
Wished adjustment	Insulin	Insulin & nutrition	None	Total
Insulin	14	2	0	16
Insulin & nutrition	15	11	10	36
Total	29	13	10	52

The type of controller is an important feature when considering GC. Survey results show that respondents would mainly use either a flowchart-based controller or a model-based controller with predictions. A third of persons using a flowchart-based controller would prefer to use or be willing to use a model-based method with predictions. Results also show that model-based controllers are interesting for GC only if they can predict future BG outcomes, thus capturing an element of risk.

Note that 69 % of respondents would like to see the results of virtual trials to assess a control clinical protocol before implementation in the ICU, indicating issues about confidence. This outcome is a strong support of an engineered design approach.

Finally, Figure 2 presents the criterion used for GC system selection. Pilot testing in ICU and publications about the controller are the main criteria.

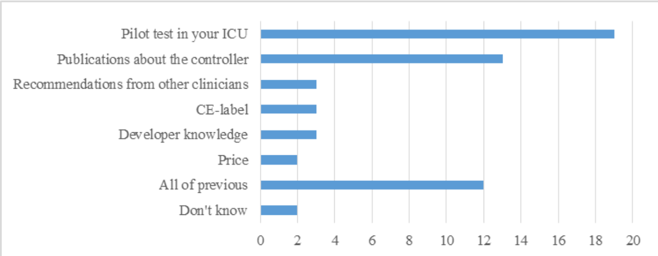

Fig.2: selection criterion for glycaemic control systems.

4. DISCUSSION

This survey was conducted to assess the interest of medical staff for GC in Europe, to identify key success factors associated with expected outcomes of GC, and to get more information on the purchase process of glycaemic controller in ICU to highlight interactions between how systems and goals are defined and the end-users.

Respondents of our survey were mainly ICU clinicians, consultants or managers, and they predominantly represented university and tertiary hospitals (85 %). We observed that 81 % (42/52) of responding ICUs use some form of GC. Schultz et al. (2010) observed that 98 % (86/88) of responding ICUs in the Netherlands implemented GC, while 41 % (12/29) of ICUs in Australia and New Zealand and only 25 % of English ICUs adopt intensive insulin therapy to tightly control patient glycaemia (Mackenzie et al., 2005, Mitchell et al., 2006).

Not surprisingly, fear of hypoglycaemia is the main impediment for GC implementation in ICUs as it is the main associated risk (Bagshaw et al., 2009, Egi et al., 2010, Krinsley and Keegan, 2010). This finding corroborates previous results (Mitchell et al., 2006). However, this study has also shown that lack of trust in the GC also hampers GC implementation. These two answers are related, but may also indicate specific versus general fears. Attention should thus be paid to reassure medical ICU staff about controller benefit, performance and safety.

The type of controller is an important feature when considering GC. This survey suggests that current controllers are mainly flowchart-based, as also shown by Schultz et al. (2010). However, respondents would use either flowchart-based or model-based controller with predictions. Moreover, a third of persons currently using a flowchart-based controller would switch to a computerized model-based controller with predictions. Interestingly, model-based controllers would not be implemented for GC if they cannot predict future BG outcomes, which may increase trust and allay fears. It should be noted that model-based controller are complex and are thus computerized (Eslami et al., 2010). Currently, only 7 % of glycaemic controllers in use by survey respondents are computerized. This finding corroborates results presented by Schultz et al. (2010). However, there is a real interest or need for computerization of GC as 67 % of respondents would prefer their paper-based glycaemic controller was computerized.

Considering the clinical implementation of GC in ICU, current protocols primarily adjust only insulin. However, there is a strong interest for controllers that are able to adjust insulin and nutrition, as well as accounting for different insulin administration modes (bolus, infusion). Future glycaemic controllers should thus be designed to allow flexible control in terms of insulin and nutrition inputs.

Controllers should be easy to use, have a friendly interface, and be able to be customized to local clinical practice. These results reflect the interaction of human factors, compliance and uptake (Chase et al., 2008a). Connection between a glycaemic controller and the data management system is also a real expectation of ICU staff. In addition, performance, reliability, alarm system and low cost are other expected characteristics that were noted.

Currently, glycaemic controllers can be customized in BG targets, control frequency, patient diabetic status (type I, type II or no diabetes), insulin administration mode with a maximum insulin and nutrition input. Present results show that patient weight, medication (steroids, catecholamine…), illness and glycaemic variability should also be taken into account by controllers to meet ICU staff expectations. Respondents also desire specific rules in the controller to deal with nutrition interruption or to manage hypoglycaemic risk and thus enhance safety.

Price does not seem to be a selection criterion for glycaemic controller. However, price was not a suggested answer and thus respondents may not have mentioned it because they did not think about it when answering the questionnaire. Interestingly, it should be noted that 69 % of respondents felt that virtual trials (Chase et al., 2010) could be a good way to assess a control clinical protocol before its clinical implementation in ICUs.

Limitations associated with this survey should be mentioned. First, respondents voluntarily participated in this survey and answers could be non-representative as ICUs that did not respond to the survey could potentially be less likely to be convinced of the benefits of GC. There may also be some errors associated with the questionnaire and its design. Closed questions can be associated with non-exhaustive response choice, with proposed answers influencing the final response, where the respondent may not have an opinion (Vermandele, 2009). These limitations could introduce bias into the responses. Moreover, some stated responses are not always a reflection of reality, but the de-identified format should reduce this phenomenon. Finally, it should be noticed that the survey was mainly filled by Belgian ICU staff members (11/52, 21.2 %).

It must also be noted that this research presents a qualitative analysis that aims to understand opinions and expectations. Qualitative analyses are always associated with a saturation phenomenon: after a given number of respondents, there is no supplemental information (Bachelet, 2012). We have observed this behaviour in this survey, suggesting that the response number obtained could be enough to capture all ICU staff opinions and expectations about GC.

5. CONCLUSIONS

The objectives of the current survey were to assess the interest of ICU medical staff in Europe and identify key success factors associated with GC systems. This survey (1) was the first survey about GC conducted across European ICUs, (2) highlighted main elements of preferred GC outlined by end-user to design GC systems, some of which are surprising, (3) showed the importance of the ability to manage risk associated with GC directly or by prediction, and (4) showed a clinical desire for engineered protocols (the interest for virtual trials).

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