TITLE: Prevalence of Hyperglycemia and its Correlates in Diabetic Non-Critically Ill Patients in a Lebanese Tertiary Care Hospital.

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Abstract:

Objectives: To examine the prevalence of hyperglycemia and assess the correlates of hyperglycemia in diabetic non-critically ill patients admitted to the medical ward of a tertiary care teaching hospital in Lebanon. The secondary endpoints were to evaluate the management of diabetes micro and macrovascular complications.

Methods: A retrospective chart review was conducted from January 2014 until September 2015. Diabetic patients admitted to Internal Medicine floors were identified using a medication report generated from the in-house developed pharmacy informatics system. All patients who were prescribed oral antidiabetic agents (OAM) or insulin were identified. Patients were eligible for study inclusion if they were adult patients admitted to medical ward with type 1 or type 2 diabetes treated with OAM or insulin. Using a combination of the hospital's computer system and the paper medical records, patients' socio-demographic data, length of stay, types of insurance as well as information on diabetes therapy before and during hospitalization were collected. A descriptive analysis was first carried out, using frequency and percentage for nominal and dichotomous variables, and mean and standard deviation for continuous variables. For bivariate analysis, the chi square test was used to compare nominal variables between groups, while the Student –T- test was used to compare means between two groups and the ANOVA between more than two groups. Finally, a multivariable analysis was carried out using a

stepwise descending logistic regression, to study the correlates of hyperglycemia occurrence. In all cases, a p-value <0.05 was considered statistically significant.

Results: A total of 235 medical charts were reviewed. Seventy percent of participants suffered from hyperglycemia during their hospital stay. The identified significant positive correlates for hyperglycemia, were the inpatient use of insulin sliding (SSI) scale alone (OR=16.438 ± 6.765-39.941, p=0.001) and the frequency of glucose monitoring. Measuring glucose every 8 hours (OR= 3.583 ± 1.506-8.524, p=0.004) and/or every 12 hours (OR=7.647 ± 0.704-79.231, p=0.0095) was associated with hyperglycemia. Adherence to diabetes inpatient management guidelines occurred in 69% of our study patients and 37.44% of the participants were on sliding scale insulin alone.

Regarding secondary outcomes, blood pressure readings were controlled in most patients (91.7%), statins were appropriately used based on the patients' 10-year primary risk of atherosclerotic cardiovascular disease scores in 75% of the times. However, improvements are needed in CAD primary prevention since almost 50% of patients were not on recommended aspirin therapy

Conclusion: Considerable mismanagement of hospitalized diabetic non-critically ill patients exists, indicating a compelling need for the development and implementation of evidence-based, protocol-driven insulin order forms A. comprehensive education plan on insulin use and the multifactorial risk-reduction approaches is also recommended to positively impact diabetes care.

Keywords: diabetes; hyperglycemia; non-critically ill; insulin.

1. Introduction

Diabetes Mellitus is a chronic metabolic disease that affects 387 million people around the world [1]. In the Middle East and North Africa (MENA) region, 37 million people suffer from diabetes mellitus with an expected increase to 285 million by the year 2035 [1]. In Lebanon, The prevalence of diabetes mellitus in Lebanon is around 12.2% [1]. In 2015, 464,200 patients are living with diabetes and 5,724 patients died due to its complications [1].

Hyperglycemia is defined as a fasting blood glucose level above 130 mg/dl or postprandial glucose level above 180 mg/dl and hypoglycemia is referred to when a measured blood glucose level is equal to less than 70 mg/dl [2]. Episodes of hyperglycemia and/or hypoglycemia in hospitalized diabetic patients are associated with poor clinical outcomes and an increase in morbidity and mortality [2]. Indeed it was shown that hyperglycemia can lead to delayed wound healing, decreased immune response, and increased inflammatory markers, oxidative stress, risk of infection, and hospital length of stay (LOS), while hypoglycemia has been associated with lethargy, cerebral damage, coma and even death if not adequately monitored, controlled, and treated [3,4].

Therefore the prevention of both hyperglycemia and hypoglycemia in diabetic hospitalized patients is critical to decrease length of hospital stay (LOS) and to reduce complications and readmissions [2].

The American Association of Clinical Endocrinologists (AACE), the American Diabetes Association (ADA), and The Endocrine Society (TES) published standards for in-hospital blood glucose level monitoring as part of a treatment plan for diabetic patients which specify recommendations on the measurement of A1C levels on admission, the frequency of blood

glucose level monitoring, and the target blood glucose levels [5]. HbA1c levels should be performed on all hospitalized diabetic patients if it was not performed in the previous 3 months [2]. Insulin therapy should be started on all patients having a persistent hyperglycemia above 180 mg/dl with target glucose levels between 140 mg/dl and 180 mg/dl for most patients. For some critically ill patients at low risk of hypoglycemia, a tighter glycemic target between 110 mg/dl and 140 mg/dl may be appropriate [2].

In order to achieve the target blood glucose levels, scheduled basal insulin with a long acting agent and correctional/bolus insulin with a short acting agent is the preferred method to treat hospitalized non-critically ill patients with diabetes taking into account their nutritional intakes [2]. Sliding scale insulin (SSI) is currently the most commonly used correctional method to control blood glucose levels in hospitalized diabetic patients [6]. Its use as the sole approach to achieve target glucose levels is no longer recommended because it does not mimic the physiologic principles of glucose regulation and can result in frequent fluctuations in blood glucose levels [7]. To prevent hypoglycemia and/or hyperglycemia during hospital stay, the guidelines recommend each hospital develop and implement management protocols with appropriate documentation in hospitalized patients' medical records [2].

Results from a pubmed search from 1998 to 2016 revealed no studies conducted in Lebanon or the MENA region that evaluated hyperglycemia management in hospitalized non-critically ill patients.

Therefore, the objective of this study is to evaluate the glycemic control of diabetic non-critically ill and assess the hyperglycemia treatment regimen in patients admitted to the medical ward of a tertiary care medical center in Lebanon.

2. Methods

Study Setting

Lebanese American University Rizk Hospital (LAUMCRH), a tertiary care, academic medical center with 125 beds, is the teaching hospital for the Lebanese American University, located in Beirut, Lebanon. To date, the hospital does not have a standardized institutional protocol for hyperglycemia assessment and management on the Internal Medicine wards. Patients are managed according to the discretion of the medical team and are eligible to be followed by endocrinologists if their admitting physician consults endocrinology. Nurses are in charge of administering insulin and performing bedside glucose monitoring and clinical pharmacists intervene on glycemic control when they are available on rounds as members of the interdisciplinary team.

Study Design

We conducted a retrospective, observational study of diabetic patients admitted to Internal Medicine (IM) floors at a teaching tertiary care hospital in Beirut, between the dates of January 2014 until September 2015 (21 month period). Study patients were identified using a medication report generated from the in-house developed pharmacy informatics system. All patients who were prescribed oral antidiabetic agents (OAM) or insulin were identified. Patients were eligible for study inclusion if they were adult patients admitted to medical ward with type 1 or type 2 diabetes treated with any OAM (metformin, sulfonylurea, thiazolidinedione, DDP4 Inhibitors), or insulin. Patients were excluded from the study if they were less than 18 years of age, pregnant women/gestational diabetes, patients admitted for diabetic ketoacidosis or hyperosmolar

hyperglycemic state or actively receiving medications significantly altering glycemic levels. Critically ill patients requiring admission to the intensive care unit were also excluded.

Using a combination of the hospital's computer system and the paper medical records, the following patient data were collected: sociodemographic information, including smoking and insurance type, allergy information, weight and height, BMI, past medical history, home antidiabetic medications, admission diagnosis using the International Classification Disease 9th revision codes, length of stay (LOS) on the medical ward, blood glucose levels during hospital stay, frequency of fingertip blood glucose testing, the use of insulin (SSI or Basal) or other OAD while hospitalized, HbA1c, serum creatinine, GFR, albumin, blood pressure, lipid panel and use of select medications such as aspirin, statin or ACE inhibitors. Previous acute diabetes complications, defined as diabetic ketoacidosis (DKA), hyperosmolar hyperglycemic state (HHS), diabetic foot ulcer or peripheral neuropathy were also collected.

The Institutional Review Board of the Lebanese American University approved this study.

Endpoints

The primary endpoints were to assess patients' glycemic control while detecting the prevalence of hyperglycemia (defined as BG $\geq$ 180 mg/dL), and hypoglycemia (defined as BG $\leq$ 70 mg/dL). The secondary endpoints were to evaluate the management of diabetes micro and macrovascular complications.

Statistical Analysis

Data were entered and analyzed using SPSS, version 22.0. A descriptive analysis was first carried out, using frequency and percentage for nominal and dichotomous variables, and mean

and standard deviation for continuous variables. For bivariate analysis, the chi square test was used to compare nominal variables between groups, while the Student T test was used to compare means between two groups and the ANOVA between more than two groups. Finally, a multivariable analysis was carried out using a stepwise descending logistic regression, to study the correlates of hyperglycemia occurrence. In all cases, a p-value <0.05 was considered statistically significant.

3. Results

3.1. Sample description:

A total of 235 medical charts were reviewed. Among study participants, 99.6% had diabetes mellitus type 2, 55.7% were males, and had ages ranging between 35 and 96 years with a median of 70 years. The mean glycosylated hemoglobin (HbA1C) was 6.52 (SD=3.06).The majority of our sample population was non-smokers (68.5%), with no major allergies (76.6%) and no previous acute diabetes complications (90.6%). In addition to diabetes, patients had at least one of the following comorbidities: hypertension (81.7%), dyslipidemia (42.6%), obesity (17.9%), cancer (16.6%), congestive heart failure (9.4%), chronic kidney disease (CKD) (7.7%) and asthma (3.4%).

The most commonly occurring reasons for admission were coronary artery disease, dyspnea, pneumonia and heart failure. Most of the patients had private medical insurance (55.7%) and 13.6% reported being insured. The median reported length of stay (LOS) on the medical ward was 3.5 days. The reported home antidiabetic regimens consisted of single oral antidiabetic (OAD) agent (47.2%), dual OAD agents (28.1%) and triple OAD agents (9.4%). Among patients treated with OAD (n=199), metformin was most the commonly used agent (n=159, 79.9%),

either alone (13.2%) or combined with sulfonylureas (n= 59, 40.9%), DDP4-Inhibitors (n=39, 24.5%) or thiazolidinediones (n=2, 1.3%). Home regimen included basal insulin as monotherapy (11.9%), or insulin combined to 1 OAD (13.2%), 2 OADs (5.5%) or 3 OADs (1.3%).

3.2. Blood Glucose Levels and Rates of hyperglycemia:

In this study, the mean of Fasting Blood Glucose (FBG) in mg/dL across hospital stay is shown in figure 1. At admission, mean FBG was 153.56 (±53.574), 158.79 (±53.947) at day 1, 159.63 (±59.634) at day 2, 152.51 (±53.471) at day 3, 160.49 (± 103.364) at day 4, (153.90 ± 60.935) at day 5 and 162.23 (± 64.522) 24 hours before discharge.

Figure 1 also shows the fluctuation of the mean Random Blood Glucose (RBG) in mg/dL across patients' stay. The mean RBG was 176.02 (± 62.66) upon admission; 190.31 (±62.51) at day 1, 186.77 (±61.75) at day 2, 192.3 (±65.66) at day 3, 194.64 (±64.44) at day 4, 197.48 (±71.300) at day 5 and 197.24 (±84.066), 24 hours before discharge. The calculated prevalence of hyperglycemia was 70.2% and that of hypoglycemia was 8.5%.

3.3. Inpatient hyperglycemia management

SSI use

The use of SSI occurred in 60.4% of study participants. SSI was used alone (without OAD or basal insulin) in 88 (37.44%) patients. SSI was combined to home OAD agents in 58 (24.6%) patients and to home basal insulin in 161 (69%) of patients. Some of the hospitalized patients (n= 77, 32.8%) did not receive any insulin during their stay and had their home OAD regimens continued. Additionally, 13 (17.3 %) patients on home basal insulin had their regimen unchanged.

Glucose monitoring

The frequency of glucose monitoring using fingerstick devices was 39.1% for every 6 hours (q6 h), 29.8% for every 8 hours (q 8h), 2.6 % for every 12 hours. In 26.6% of the charts, glucose monitoring was not documented. The rate of ordering laboratory test for hemoglobin A1c was 19.15%.For almost half of the patients, an endocrinologist was consulted (53.2%). Patients receiving insulin prior to admission or started on SSI were the significant predictors for endocrinology consult.

3.4. Correlates of hyperglycemia:

Table 1 presents the results of the multivariate analysis conducted to study the correlations between hyperglycemia and patients' socio-demographic data, length of stay, types of insurance (private vs public), diabetes management before and during hospitalization. None of the patients' sociodemographic characteristics or LOS appeared to significantly affect hyperglycemia occurrence. The identified significant positive correlates for hyperglycemia, were the inpatient use of insulin sliding (SSI) scale alone (OR=16.438 ± 6.765-39.941, p=0.001) and the frequency of glucose monitoring. Measuring glucose every 8 hours (OR= 3.583 ± 1.506-8.524, p=0.004) and/or every 12 hours (OR=7.647 ± 0.704-79.231, p=0.0095) was associated with hyperglycemia. A negative correlate was the sole use of OAD during hospital stay (OR=-1.355 ± 6.765-39.941, p=0.001).

3.5. Management of diabetes chronic complications:

When looking at diabetes chronic complications management as secondary outcomes, study findings revealed that the majority of hypertensive patients had controlled blood pressures of at

least 140/90 mm Hg (91.7%, p=0.799). Choice of antihypertensive medication varied and 50% adequately received ACEI/ARB agents. CAD primary prevention was ensured by the use of aspirin as recommended by the ADA guidelines in 54.9% of patients. Statins were also adequately used in 65% of the patients and while on statins, LDL goals of at least 100 mg/dl were achieved in 75% of the times. Concerning microvascular complications, 50% of neuropathy patients received appropriate treatment (pregabalin and or gabapentin) and 38.9% of CKD patients were on ACEI/ARB therapies.

4. Discussion

The study findings revealed constantly elevated FBG and RBG levels starting from patients' admission to the medical ward and throughout the hospital stay. Additionally patients appeared to be discharged without proper regulation of their glycemic levels. The unmet, recommended glycemic targets of less than 140 mg/dl and less than 180 mg/dl for FBG and RBG levels respectively, are also reflected in the high prevalence of hyperglycemia. More than two third of admitted patients (70.2%) developed hyperglycemia during their stay. When looking at the correlates of hyperglycemia occurrence, a clear mismanagement appears in the inpatient treatment regimens used as well as the frequency of glucose monitoring. While the preferred treatment consists of discontinuing all OAD and using basal plus correction insulin or bolus regimen, adherence to guidelines only occurred in 69% of our study patients. Additionally, the recommendations strictly discourage the sole use of SSI, however, 37.44% of the participants were on SSI alone [2]. Moreover, 32.8% of patients did not receive any type of insulin and

remained on their home oral agents. This could be related to the facts that OAD are easier to use and require less expertise compared to insulin, which is dosed according to patients' weight, calorie consumption and glucose levels [2]. Also, despite the endorsement of the use of basal bolus insulin regimen by diabetes guidelines, there is still little evidence on the effectiveness of its use on mortality, morbidity and hospital length of stay [8-14].

Interestingly, patients who continued on OAD had less incidence of hyperglycemia as shown in Table 1. This was also seen in a similar study where patients developed less hyperglycemia while on OAD in addition to as needed SSI [14].

Other important problematic findings pertain to glucose monitoring frequency and poor documentation practices. Despite the ADA guidelines' recommendations on the optimal frequency of glucose monitoring (every 6 hours), glucose monitoring was sub-optimal in almost half of the patients; performed every 8 h (29.8%) and every 12 h (2.6%) [2]. Glucose monitoring was accompanied by a lack of documentation of the nutritional intake of the patient, the timing of glucose monitoring and its relationship to meals. Unfortunately, complete absence of glucose monitoring documentation was found in 26.6% of the cases.

The correlates of hyperglycemia in our study echo the results of many studies which also found a strong association between hyperglycemia and the use of SSI alone and the low frequency of glucose monitoring [9,10,12, 14].

Regarding HbA_{1C} monitoring, this test was ordered only in 19.15% of the patients. The reported number is low if compared to previously completed studies where the reported HbA_{1C} levels were almost 60% [15]. This could be explained by financial reasons since a prior approval from insurance companies is required before ordering this test.

Moreover, it was noticed that there was a high number of endocrinology consults where more than 50% of patients were followed by an endocrinologist. This could be related to the teaching setting of the hospital where medical residents might have not been comfortable in managing diabetes patients and dosing insulin. For instance, Cheekati et al conducted a study looking at medical residents' perception of hyperglycemia in hospitalized patients. The results showed that around 50% of residents were "somewhat comfortable" or "not at all comfortable" in treating hyper and hypoglycemia in a hospital setting [16].

Hypoglycemia seemed less of a problem, it occurred rarely in our study population (8%). It was managed according to a specific order given by the treating physician.

Insulin is the preferred method for achieving glycemic control in hospitalized diabetic non-critically ill patients [2]. But since it is among the high risk medications, prone to medication errors, the American Society of Health-system Pharmacists developed ten goals to ensure safe insulin use in hospitalized patients [17]. Among those goals are those related to development of protocols for specific uses of insulin, eliminating the routine administration of correctional sliding scale insulin doses as primary strategy to treat hyperglycemia, eliminating the use of "free text" insulin orders in medical records and replacing them with evidence-based, protocol-driven insulin orders with adequate monitoring the rates of hyper/hypoglycemia [17].

As a follow-up, a multidisciplinary team made up of pharmacists, nurses and endocrinologists developed a hyperglycemia/hypoglycemia inpatient management protocol. The protocol will be implemented in the hospital following a series of educational sessions to all healthcare providers on its use.

Also, knowing that diabetes is a complex chronic disease requiring management beyond glycemic control; multifactorial risk-reduction approaches are essential to prevent acute and

long-term complications. Thus, in our study we were able to assess some of the strategies proven to improve diabetes outcomes. Indeed, blood pressure readings were controlled in most patients (91.7%), statins were appropriately used based on the patients' 10-year primary risk of atherosclerotic cardiovascular disease scores in 75% of the times. However, improvements are needed in CAD primary prevention since almost 50% of patients were not on recommended aspirin therapy. Practitioners are encouraged to further adhere to recommendations on the use of ACE/ARBs for albuminuria treatment as well as appropriate management of neuropathic pain [2].

In light of these findings, we propose the establishment of a diabetes discharge counseling service. The service will be run by an interdisciplinary team of health care providers who will be in charge of: ensuring glycemic targets are met throughout patients' hospital stay and upon discharge, reinforcing preventative measures against diabetes complications, reviewing medications' appropriateness and performing counseling as well as patient education on diabetes self-management.

Study Limitations

The present study does have potential limitations. Similarly to all retrospective studies, there might have been bias. Collected data may not be extrapolated to other institutions. Additionally, under-or inaccurate reporting might have occurred due to paper charting and the lack of appropriate documentation practices. Despite the mentioned limitations, the major strength of our study resides in the fact that it was the first one to report on inpatient hyperglycemia management practices in Lebanon.

5. Conclusion

Our findings revealed prevalence in hyperglycemia among hospitalized patients when SSI was used alone in addition to a low frequency of glucose monitoring. The authors recommend the development and implementation of evidence-based, protocol-driven insulin order forms, a

comprehensive education plan on the appropriate use of insulin and the establishment of a diabetes management team that can positively impact diabetes care and prevent acute and long-term complications.

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TABLE 1: Results of the Multivariate Analysis: correlates of hyperglycemia

Correlates	Occurrence of Hyperglycemia Adjusted OR (CI)	P-value
Sociodemographic characteristics		
Male	**0.964 (0.43-2.158)**	**0.928**
Age	**1.001 (0.966-1.037)**	**0.958**
Private Insurance	**0.886 (0.397-1.976)**	**0.767**
Diabetes Management before admission (Home treatment regimen)		
OADs	**0.301 (0.117-0.775)**	**0.013**
Basal Insulin	**2.089 (0.35-12.46)**	**0.419**
Inpatient Diabetes Management		
Endocrinology consult	**1.346 (0.532-3.407)**	**0.531**
Use of SSI alone	**16.438 (6.765-39.941)**	**0.01**
Use of OAD alone	**-1.355 (6.765-39.941)**	**0.001**
finger stick q 8hr	**3.58 (1.506-8.524)**	**0.04**
Fingerstick q 12 hr	**7.47 (0.704-79.231)**	**0.0095**

Figure 1: Fluctuations of Fasting and Random Blood Glucose during Hospital Stay