Characteristics, Management, and Outcomes of Elderly Patients With Diabetes in a COVID-19 Unit: Lessons Learned.

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Abstract

Background

Diabetes may affect in-hospital mortality of patients with Coronavirus disease 2019 (COVID-19). We have retrospectively evaluated clinical characteristics, diabetes management, and outcomes in a sample of COVID-19 patients with diabetes admitted to our hospital.

Methods

All patients admitted to the Infectious Diseases Unit from March 28th, 2020, to June 16th, 2020, were enrolled. Clinical information and biochemical parameters were collected at the time of admission. Patients were ranked according to diabetes and death.

Results

Sixty-one patients with COVID-19 were analyzed. Most of them were from a long-term health care facility. Mean age was 77±16 years, and 19 had type 2 diabetes (T2D). Eighteen patients died, including 8 with T2D and 10 without T2D (p=0.15). Patients with diabetes were significantly older, had a higher prevalence of cardiovascular diseases, and a significantly lower lymphocyte count. No significant relationship was found between diabetes and in-hospital mortality [OR 2.3; CI 0.73-7.38, p=0.15]. Patients with diabetes were treated with insulin algorithm titration algorithm, with no severe hypoglycemic events, ketoacidosis and hyperosmolar hyperglycemies occurring during hospitalization. Mean fasting pre-meal capillary blood glucose was 157±45 mg/dL, and the coefficient of variation of glycaemia was 29%.

Conclusions

Our study, albeit limited by the small number of subjects, did not describe any significant association between T2D diabetes and mortality. Clinical characteristics of patients, and acceptable glucose control prior and during hospitalization may have influenced the result, thus suggesting that the insulin algorithm titration algorithm applied should be validated.

Background

The prevalence of diabetes in CoronaVirus Disease-2019 (COVID-19) hospitalized patients is similar to the overall prevalence of diabetes in the general population. Chinese researchers reported a prevalence of diabetes in COVID-19 patients ranging from 5.3 to 19.5%, compared to a prevalence of 11% in the general population [1]. The US reports are quite similar, with prevalence of diabetes in COVID-19 patients of 11%, and the overall prevalence in the population of 13% [2]. In Italy, the prevalence of diabetes was demonstrated to be slightly lower in infected patients (9%), but again similar to the prevalence of the general population (11%) [3]. Although diabetes cannot be considered a risk factor of COVID-19 infection, it may be responsible for worse outcomes such as death and mechanical ventilation [4]. Unfavorable prognosis due to diabetes was also been described during MERS and SARS CoV-1 epidemic [5-7].
However, relationship between diabetes, death, and admission into the Intensive Care Unit (ICU) seemed to be mediated by other comorbidities, which were more prevalent in patients with diabetes, such as cardiovascular and cerebrovascular diseases, chronic kidney disease, and hypertension [8]. The relationship between glycated hemoglobin (HbA1c) at the time of hospital admission and outcome seems to be controversial. Indeed, one study demonstrated a greater risk of death among those with poor glycemic control [9], while the French nationwide CORONADO study did not find any significant associations between HbA1c, death and mechanical ventilation within seven days after hospitalization [10]. By contrast, unlike HbA1c, hyperglycemia at the time of the admission, in patients with and without prior diabetes, was a strong predictor of worse outcomes [11-12].

Appropriate management of diabetes during hospitalization is crucial to provide better outcomes, and to reduce length of hospitalization. Insulin therapy should be preferred to other non-insulin treatments, as suggested by the American Diabetes Association [13]. Experts recommend a feasible and structured insulin regimen, and a target glucose range of 140-180 mg/dL. Recently, it is growing the interest in glycemic variability, which seems to be an independent risk factor for morbidity and mortality in hospitalized patients [14].

In the present research, we have retrospectively evaluated clinical characteristics, diabetes management, and outcomes in a sample of COVID-19 patients with type 2 diabetes (T2D) admitted to our hospital in order to assess whether an insulin algorithm titration algorithm was able to maintain glycaemia into a desirable range and explore possible effects on patient death.

**Materials And Methods**

The research is a retrospective study including all patients admitted to the Infectious Diseases Unit at the “Mater Domini”, Teaching Hospital, University Magna Graecia, Catanzaro, Italy from March 28th to June 16th, 2020. Almost all were elderly patients from long-term health care facility (LTHCF). Clinical and biochemical parameters [fasting plasma glucose, lipids, Interleukin-6 (IL6), C-Reactive Protein (CRP), fibrinogen, ferritin, alanine amino transaminase (ALT), aspartate amino transaminase (AST), γ-glutamyltransferase (γGT), lactate dehydrogenase (LDH), creatinine, lymphocytes count, platelet count (PLT), D-dimer, sodium, total cholesterol, HDL-cholesterol, triglycerides], were collected at the time of the admission into the hospital, while the presence of prior T2D, hypertension, cardiovascular disease (CVD), chronic obstructive pulmonary disease (COPD), cerebrovascular disease, psychiatric and neurological disorder, and ongoing treatments were collected from clinical records provided by the LTHCF.

At the time of the admission, non-insulin hypoglycemic treatment was discontinued, while ongoing basal-bolus insulin therapy was confirmed. In insulin naïve patients, a starting safe basal-bolus treatment (long-acting insulin 10 U, and rapid-acting insulin 10 U) was suggested. Insulin dose was adjusted daily according to the fasting pre-meal capillary blood glucose (Table 1). Long-acting insulin dose was adjusted every 1-2 days according to fasting plasma glucose (Table 2). In case of persistent high blood glucose level despite insulin titration, intravenous insulin injection was suggested.
Statistical analyses were performed by IBM-SPSS Statistics v.23. Patients were divided into two groups according to the presence or absence of diabetes. Subjects with diabetes were further divided into deceased and not-deceased patients. Variables not normally distributed were: plasma glucose, lipids, IL6, CRP, fibrinogen, ferritin, ALT, AST, γGT, LDH creatinine, lymphocytes count, D-dimer, sodium, total cholesterol, HDL-cholesterol, and triglycerides. Data are expressed as mean ± standard deviation (SD), and percentage. Differences between groups were evaluated by t-test and Mann Whitney U test for unpaired data and chi-square test. Univariate regression analysis was performed to evaluate the relationship between diabetes and in-hospital mortality. Fasting pre-meal capillary blood glucose values of each patient measured during hospitalization at each insulin injection were grouped and mean±SD was calculated. Glycemic variability was calculated as the coefficient of variation (CV) using the following formula: (Standard deviation/mean blood glucose)*100.

A p-value of less than 0.05 was considered to be statistically significant.

Results

A total of 61 patients were enrolled in the study. Nineteen patients out of 61 (31%) had T2D. No patients had diabetic ketoacidosis or hyperosmolar hyperglycemia state at the admission or during hospitalization or severe hypoglycaemia. As far as COVID-19 treatment is concerned, a total of 46/61 patients received combination therapy with hydroxychloroquine plus azithromycin according to the study protocol by Gautret et al. [15], followed by ECG monitoring. No patients had cardiac complications. On the basis of clinical judgment, in 30/61 patients corticosteroid therapy was administered. All patients received anticoagulant therapy with low molecular weight heparin. Three patients received as add-on therapy subcutaneous tocilizumab. None of the patients was admitted into the ICU during the hospitalization.

Clinical characteristics and biochemical parameters of all patients and of patients divided according to the presence or absence of T2D are displayed in Table 3. Creatinine and fasting blood glucose were the only variables significantly different between the two groups.

Eighteen patients (29.5%) died, including 8 (44%) with T2D and 10 (56%) without T2D (p=0.15). The mean time from admission to in-hospital mortality was 14±11 days in patients without diabetes and 9±6 days in T2D patients (p=0.46). Patients with T2D were further divided according to in-hospital mortality, and characteristics are described in Table 4. Patients who died were significantly older, had a higher prevalence of prior cardiovascular diseases, and a significantly lower lymphocytes count. No significant relationship was found between diabetes and in-hospital mortality (OR: 2.3; 95% CI 0.73-7.38, p=0.15).

The insulin dose was titrated at each meal according to the titration algorithm and fasting pre-meal blood glucose in nine patients. Mean daily capillary pre-meal blood glucose values of 20 days of hospitalization have been displayed in Figure 1. Blood glucose data of the remaining nine patients has not been displayed for the following reasons: three patients died in the first 2 days of hospitalization, five patients did not receive insulin due to acceptable blood glucose values, one patient was managed during
hospitalization with intravenous insulin due to persistent high blood glucose values despite appropriate titration.

None of the nine patients who were managed by the titration algorithm died. The mean and standard deviation of pre-meal capillary blood glucose from the hospitalization until discharge, in insulin-treated patients, was 157±45 mg/dL, and the CV 29%.

**Discussion**

The present study suggests that, at least in elderly patients with COVID-19, adequate controlled diabetes at the time of admission and during hospitalization might reduce the risk of in-hospital mortality associated with T2D. This interpretation may explain why T2D *per se* was not demonstrated to be an independent predictor of death in our previous analysis in the same patients [16], in apparent contrast with other studies [17]. Zhu et al. [18] have recently described, in a retrospective longitudinal study, that well-controlled blood glucose (blood glucose values within 70 to 180 mg/dl) was associated with markedly lower mortality compared to individuals with poorly controlled blood glucose (blood glucose values exceeding 180 mg/dl).

Glucose control during hospitalization appeared to be appropriate both for the mean pre-meal blood glucose value and for CV, which were acceptable for hospitalized patients in our study. The CV in patients with diabetes was lower than 30%, which is the threshold value suggested by the international consensus on new glucometric parameters [19]. Furthermore, none of the patients managed with the titration algorithm had severe hypoglycaemia during hospitalization. The absence of hypoglycaemic events might have also influenced the result of the study. Indeed, as known from the literature, hypoglycaemia associates with increased mortality in hospitalized patients [20]. Therefore, the titration algorithm used during hospitalization seemed to be effective to obtain glucose control in our study. Unfortunately, in the studies conducted so far, the possible impact of glycemic control during hospitalization was not appropriately assessed as a time-dependent variable. Although, due to a small number of patients, we were not able to perform a survival analysis with glycaemia as a time-dependent variable, our study suggests that maintaining glycemic control may dilute the impact of T2D *per se* in the analyses conducted so far. Among variables which may impact on glucose levels, further analysis should also consider the effect of concomitant drugs. More than 2/3 patients in our group received hydroxychloroquine and approximately half of them received corticosteroids. Hydroxychloroquine may lower blood glucose and corticosteroids may raise it, so further studies in COVID-19 patients should consider their effects. Also, in clinical practice, the possible effects of these drugs on glucose control should be considered, with pre-prandial glycaemia measured even in non-diabetic patients taking these drugs. The benefit of a strict monitoring, should be balanced, however, against the risk of infections for the healthcare workers. For this reason, we prioritized to diabetic patients or those symptomatic for hypo or hyperglycaemia, while the other patients were not monitored.
An alternative interpretation for the lack of an association between T2D and mortality could be that possible pre-existing complications of T2D are more important. In apparent support to this interpretation, in our previous analysis [16], CV diseases (and not T2D) emerged as an independent predictor of death over T2D *per se*. More in general, cardiovascular disease is a predictor of mortality in infected patients regardless of diabetes and even in non COVID-19 patients [21]. Along the same line, Apicella et al [22] showed that, in COVID-19 patients, poorer prognosis of people with diabetes is likely to be the consequence of a syndromic nature of diabetes, in which hyperglycaemia, hypertension, obesity, and cardiovascular diseases all contribute to increase the risk of death. Therefore, albeit TD2 *per se* may not emerge as a risk factor, attention should be given to these patients who may be more fragile for comorbidities, especially the cardiovascular one.

We found that patients with diabetes who died were older and had lower lymphocyte count than patients with diabetes who survived. The recent meta-analysis by Huang et al [23] has demonstrated the strong relationship between diabetes and poor COVID-19 outcomes but not with ICU admission. The authors have also demonstrated that the relationship between diabetes and worst infection outcomes is complex and affected by the prevalence of other comorbidities as hypertension. In our sample the prevalence of hypertension was comparable between patients with and without diabetes as well as between deceased and survivors with diabetes.

Our study is affected by several limitations. First, the small number of patients may have precluded to get a definitive answer as to whether or not T2D *per se* is a variable independently correlated or predictive of death in COVID-19 patients. Second, unfortunately, we did not have a recent glycated haemoglobin value and could not measure it during hospitalization. Without HbA1c it is impossible to separate undiagnosed T2D (for example, HbA1c 11% and casual plasma glucose 250 mg/dl) and new onset diabetes after COVID-19 infection (for example, HbA1c 5.6% and casual plasma glucose 260 mg/dl). Notwithstanding these limitations, our study has strengths. First, as far as age is concerned, population was quite homogeneous. Second, almost all (50 patients) came from LTHCF where a COVID-19 outbreak occurred, so they were infected almost at the same time, making the analysis of intra hospital mortality more accurate and not biased by different length of infection prior to enrollment. Lastly, our operational study, evaluated for the first time, titration algorithm which appeared to be beneficial in allowing a good glucose control. At the same time, our protocol was designed with the aim of reducing the number of contacts between healthcare workers and infecting patients, thus allowing to contain the intra hospital risk of infection.

**Conclusion**

In conclusion, mortality rate in elderly patients with COVID-19 may not be affected by diabetes to a significant extent, provided that glycemic control is acceptable both at admission and during hospitalization, avoiding severe hypoglycemic events, and concomitant with optimized management of complications. Our protocol for management of diabetes could also help control the intra-hospital risk of SARS-CoV-2 infection. More studies are needed to validate these results.
Abbreviations

γGT: γ-glutamyl-transferase
ALT:Alanine amino transaminase
AST:Aspartate amino transaminase
COPD:Chronic obstructive pulmonary disease
COVID-19:Coronavirus disease 2019
CRP:C-Reactive Protein
CV:Coefficient of variation
CVD:Cardiovascular disease
HBA1C:Glycated hemoglobin
ICU:Intensive Care Unit
IL-6:Interleukin-6
LDH:Lactate dehydrogenase
LTHCF:long-term health care facility
OR:Odds Ratio
PLT:Platelet count
T2D:Type 2 diabetes

Declarations

Ethical Approval and Consent to participate: This retrospective study was notified to the Ethics Committee of the Calabria Region on May 13th, 2020 and conducted in accordance with the declaration of Helsinki. The study was carried out using retrospectively collected and anonymized data. In Italy, such studies do not require ethical approval by an Ethics Committee as determined by the Italian Drug Agency note 20 March 2008 (GU Serie Generale n°76 31/3/2008). The need for written informed consent was waived for patients owing to the retrospective nature of the study.

Consent for publication: not applicable
**Availability of supporting data:** The datasets generated and/or analysed during the current study are not publicly available due to privacy and presence of personal data but are available from the corresponding author on reasonable request.

**Competing interests:** The authors declare that they have no competing interests.

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Tables

Table 1: Titration algorithm to adjust rapid-acting insulin dose according to pre-meal fasting glycemia.
### Table 2: Titration algorithm to adjust long-acting insulin dose according to fasting blood glucose.

| Fasting pre-meal blood glucose mg/dl | Insulin (unit, U)                      |
|--------------------------------------|----------------------------------------|
| 60-69                                | Start meal and inject half U after meal within 20 min |
| 70-79                                | -3 U                                   |
| 80-99                                | -2 U                                   |
| 100-139                              | -1 U                                   |
| 140-160                              | No change                              |
| 160-180                              | +1 U                                   |
| 181-200                              | +2 U                                   |
| 201-250                              | +3 U                                   |
| 251-300                              | +4 U                                   |
| 301-350                              | +6 U delay meal (1/2 h)                |
| >350                                 | +8 U delay meal (1/2 h)                |

### Table 3. Clinical and biochemical characteristics of COVID-19 patients grouped and divided according to the presence or absence of diabetes.

| Fasting blood glucose mg/dl | Insulin (unit, U) |
|-----------------------------|-------------------|
| >140                        | +2 U              |
| 139-110                     | No change         |
| <110                        | -2 U              |
|                               | Total (No 61) | With diabetes (No 19) | Without diabetes (No 42) |
|-------------------------------|--------------|-----------------------|--------------------------|
| Age, years                    | 77 (16)      | 81 (16)               | 75 (15)                  |
| Male, %                       | 48           | 47                    | 48                       |
| FPG, mg/dL                    | 119 (53)     | 157 (77)              | 102 (19)*                |
| AST, U/L                      | 56 (1555)    | 94 (272)              | 37 (21)                  |
| ALT, U/L                      | 54 (208)     | 111 (371)             | 36 (22)                  |
| GT, U/L                       | 45 (55)      | 53 (82)               | 41 (38)                  |
| Creatinine, mg/dl             | 1.05 (0.5)   | 1.17 (0.5)            | 0.99 (0.5)*              |
| Fibrinogen, mg/dL             | 434 (112)    | 426 (129)             | 438 (105)                |
| Ferritin, ng/mL               | 656 (801)    | 750 (1149)            | 614 (598)                |
| CRP, mg/L                     | 56 (75)      | 60 (69)               | 54 (78)                  |
| LDH, mU/mL                    | 610 (270)    | 632 (225)             | 600 (290)                |
| Il-6, pg/mL                   | 58 (102)     | 68 (84)               | 53 (110)                 |
| PLT, x10^3/uL                 | 210 (87)     | 183 (75)              | 222 (90)                 |
| Lymphocytes count, x10^3/uL   | 1.28 (0.7)   | 1.08 (0.5)            | 1.36 (0.7)               |
| D-dimer, mg/l                 | 2.2 (4.2)    | 2.7 (4.6)             | 2 (4)                    |
| Sodium, mmol/L                | 140 (18)     | 143 (7)               | 138 (21)                 |
| Total Cholesterol, mg/dl      | 153 (36)     | 145 (37)              | 156 (36)                 |
| HDL-cholesterol, mg/dl        | 34 (9)       | 32 (7)                | 35 (10)                  |
| Triglyceride, mg/dL           | 134 (58)     | 147 (65)              | 129 (54)                 |
| CVD (%)                       | 32           | 31                    | 32                       |
| Neurological disorder, %      | 43           | 42                    | 44                       |
| Hypertension, %               | 68           | 78                    | 63                       |
| Psychiatric disorder, %       | 25           | 37                    | 20                       |
| COPD, %                       | 15           | 21                    | 12                       |

Data are expressed as mean (SD) and percentage. *p<0.05
**Table 4:** Clinical and biochemical characteristics of deceased and surviving COVID-19 patients with diabetes

|                                | Deceased (No 8) | Survivors (No 11) |
|--------------------------------|-----------------|-------------------|
| Age, years                     | 90 (8)*         | 74 (18)           |
| Glycaemia, mg/dL               | 159 (86)        | 155 (74)          |
| AST, U/L                       | 185 (418)       | 28 (11)           |
| ALT, U/L                       | 257 (592)       | 18 (10)           |
| GGT, U/L                       | 70 (119)        | 41 (41)           |
| Creatinine, mg/dl              | 1.32 (0.6)      | 1.06 (0.3)        |
| Fibrinogen, mg/dL              | 388 (160)       | 454 (100)         |
| Ferritin, ng/mL                | 1045 (1875)     | 562 (194)         |
| CRP, mg/L                      | 94 (91)         | 35 (35)           |
| LDH, mU/mL                     | 690 (235)       | 596 (233)         |
| IL-6, pg/mL                    | 107 (119)       | 39 (25)           |
| PLT, x10^3/uL                  | 147 (30)        | 209 (87)          |
| Lymphocytes count, x10^3/uL    | 0.72 (0.3)*     | 1.3 (0.5)         |
| D-dimer, mg/l                  | 4.8 (6.7)       | 1.1 (0.7)         |
| Sodium, mmol/L                 | 147 (6)         | 141 (6)           |
| Total Cholesterol, mg/dl       | 141 (56)        | 148 (24)          |
| HDL-cholesterol, mg/dl         | 31 (8)          | 33 (7)            |
| Triglycerides, mg/dl           | 157 (101)       | 143 (42)          |
| CVD, %                         | 62*             | 9                 |
| Neurological disorder, %       | 50              | 36                |
| Hypertension, %                | 75              | 82                |
| Psychiatric disorder, %        | 50              | 27                |
| COPD, %                        | 25              | 18                |

Data are expressed as mean (SD) and percentage. *p<0.01