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Targeted Glycemic Goals and Monitoring the time in Range Glycemia in Diabetic Long-Term Residents of a Geriatric Hospital a Pilot Study

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ABSTRACT

Background: *There are significant research gaps concerning the management of diabetic patients in long-term geriatric care, those afflicted by chronic diseases, disability and frailty. Under the principle of mitigating hyperglycemia and preventing hypoglycemia we compared two modalities of glycemia treatment for insulin dependent diabetic residents in geriatric hospital care.*

Population and Methods: *Eligible for this study were 30 out of 58 diabetic patients, residing in two departments of comprehensive geriatric care and two departments of prolonged mechanical ventilation. Point of care capillary glycemia was assessed 4 times daily. Two consecutive 14-day periods were designated to assess the quality of glycemia control. In the first period, the physicians' intuitively chosen glycemia goals were applied; in the second period, numerical upper and lower glycemia targets were set and applied in treatment. Two independent observers reviewed the data in retrospect. For both study periods, point of care glycemia was qualified with reference to glycemic upper and lower targets as specified for the second study period.*

Results: *The patients' ages ranged 64 - 82 years. Both genders were equally represented. The length of residency in our institution ranged between 4 months and 5 years. All patients were diagnosed with frailty of moderate or severe degree. Besides diabetes mellitus, most patients had two or more chronic diseases. All patients were moderately to severely frail. The patients' mean HbA1c on study entry was 7.2%. The studies' main outcome measures were "glycemia high", that means exceeding the decided target, and hypoglycemia. In study phase 1 the percent of "glycemia high" tests was near 30% in two departments, and near 10% in other two departments. The percentage "glycemia high" was unchanged during study phase 2 or decreased insignificantly. There was one hypoglycemic event during the study.*

Conclusion: *A matter of potential practical importance, we probed whether treatment according to strict upper and lower glycemia targets may produce better results than usual by physician intuitively chosen glycemia goals. Under the shared principle of tailoring glycemia to frailty severity, the two models of treatment produced similar results. Future studies comparing the two models of management might overcome some limitations of the present investigation: small patient population, short study period, and retrospective analysis of data.*

Keywords
Diabetes mellitus, Glycemia, Time in range, Frailty.

Introduction

Older people are a diverse population with a wide range of morbidity, cognitive status, and life expectancy [1-3]. Likewise, clinical heterogeneity characterizes older diabetic people, their status ranging from robust to severely frail. Older diabetic persons may require different treatment than adults of the general population [1-6]. Personalized treatment goals should be implemented in people with extreme frailty, terminal illnesses, or limited life expectancy, such are long-term residents in geriatric hospitals. Indeed, frailty as well as ischemic heart disease, cerebrovascular disease, and chronic renal failure are associated with increased risk of hypoglycemia. Recent guidelines uniformly recommend tailoring the glycemic targets to frailty levels, giving priority to quality of life, minimizing symptomatic hyperglycemia, drug side effects including hypoglycemia, and reducing treatment burden [1-6]. Adjusting glycemic targets for frail persons to HbA1c 7.5–8.5% reduces the risk of overtreating hyperglycemia [3]. Yet, limitations are recognized in monitoring diabetes treatment based on HbA1c, because HbA1c low sensitivity to hypoglycemic events, long half-life of HbA1c around 3 months, that does not allow to follow short-term glycemia changes. In preference to HbA1c, the percentage of time the patient's glycemia is in the range adequate for the individual can be assessed by monitoring the "time in range glycemia" (TIR) [2,6,7]. Management based on targeted glycemia goals and monitoring TIR glycemia aims to prevent hypoglycemia, mitigate hyperglycemia and glycemic variability [1-5]. Technologies such as continuous glucose monitoring systems and AI-based tools can improve the control of glycemia, but complexity of their integration in routine and high costs are barriers to their large-scale assimilation in geriatric hospitals [8-10]. While expert guidance is provided for treatment of diabetic nursing home residents [11-13], there are significant research gaps regarding management of diabetic residents of long-term geriatric hospitals. The severity of the patients' clinical condition in long-term geriatric hospitals stands for the difference in their needs compared to residents of nursing homes [14-17]. The present study focused on a population of diabetic elders hospitalized in long-term comprehensive care and in departments of prolonged mechanical ventilation. Under the shared principles of mitigating hyperglycemia, preventing hypoglycemia and reducing treatment burden we compared two modalities of management: a) 'usual glycemia care' based on guideline recommended glycemia goals and targeting at HbA1c 7.5–8.5%, and b) 'glycemia to target - TIR monitored' care that defines upper and lower glycemia targets, to be maintained and monitored by the time in range glycemia. We assessed whether applying individualized, numerically outlined, glycemia goals and watching TIR glycemia can improve glycemia control.

Population and Methods

Our study was designed as an observational cohort survey, approved by the Institutional Review Board (BDL-0013-25), comparing two models of diabetes care. Our institution, Bayt Balev Nesher, is a university-affiliated 240 bed geriatric hospital, comprising wards for comprehensive geriatric care, prolonged mechanical ventilation and rehabilitation. Entered were patients with insulin treated type 2 diabetes mellitus, in two departments of comprehensive geriatric care and two departments of prolonged mechanical ventilation. The necessary length of hospital stays for patients to be included in the present study eliminated the option of including subjects under rehabilitation. Excluded were subjects having their glycemia controlled alone on oral medications, patients with hospital stay shorter than 6 weeks, patients after pancreatectomy, or on the brink of death. Excluded from data analysis were subjects who developed during the designed study period any acute disease needing referral to hospital.

The patients' electronic files were reviewed for demographic data, comorbidities, frailty score, cognitive functioning, and polypharmacy defined as daily use of five or more drugs. Major comorbidities were checked as follows: dementia rated according to the clinical dementia rating scale. Patients' cognitive status was qualified according to the Clinical Dementia Rating Scale (CDR) status, scoring 0 for normal, 0.5 for mild cognitive impairment, 1 for mild dementia, 2 for moderate and 3 for severe dementia [18]. Frailty was estimated according to the Rockwood Clinical Frailty Scale [19] ranging from robust health (score 1), mild frailty (score 5), moderate frailty (score 6) to degrees of severe frailty (scores 7-9). Chronic heart failure was rated according to the New York Heart Association Classification [20]. COPD [21], mechanical ventilation, ischemic heart disease, CKD serum creatinine >1.5 mg/dL, liver cirrhosis was also surveyed among 'major comorbidities'.

Point of care capillary glycemia was assessed four times daily. Two periods of treatment 14 days each were outlined to assess the quality of glycemia control. The first period allocated for analysis a section of the habitual diabetes care that is based on the prevalent guidelines aimed at mitigation of hyperglycemia, HbA1c goal of 7.5% - 8.5% in frail persons, prevention of hypoglycemia, and reducing treatment burden [22]. The second study period shared with the former the principles of care but differed by applying explicit upper and lower glycemia targets [1] and by proactively monitoring the time in range glycemia (TIR). To start the study, the physicians in charge were informed about a change of policy for management of patients with type 2 diabetes mellitus, to be started on the following day. Glycemia targets were tailored to patients as follows: non-frail subjects were assigned to glycemia target 140-180 mg/dL (target A); patients > 65 years old with mild-moderate cognitive and or functional decline were assigned to glycemia target 155 – 200 mg/dL (target B); in persons > 65 years old with cognitive and physical dependence the glycemia target was 180-250 mg/dL (target C). Antidiabetic medications and doses remained at the discretion of the permanent staff, aiming at maximizing TIR glycemia while avoiding hypoglycemia. At this point, study period 2 began. After completion of the study period, the patients' electronic records were reviewed by two independent observers to compare efficiency of glycemia control under the two

models of treatment. The results of point of care glycemia were rated as follows: hypoglycemia (glycemia ≤70 mg/dL), borderline low (glycemia 71 - 80 mg/dL), optimal (glycemia >80 mg/dL< target), matching target, high (glycemia > target) along the 14-day study periods. Glycemia data was compared between the two study periods. Comparison of proportions by the Chi-squared test was used for analysis.

Results

In two departments of comprehensive geriatric care and two departments of prolonged mechanical ventilation there were 58 candidates to be included in the study. Thirty patients were found eligible and all completed the study. Eighteen patients were excluded, among them 11 receiving only oral antidiabetic medications, 3 patients being terminally ill, and 3 patients who did not terminate the study because of intercurrent illnesses. The characteristics of the study patients of the four departments are shown in Table 1, along with HbA1c values at commencing the study, and signing up of patients to glycemia targets A, B or C.

All patients were of European or Middle Eastern descent. Their ages ranged between 64 and 82 years. Both genders were equally represented. Duration of residency in our institution ranged between 4 months and 5 years. All patients were diagnosed with dementia, most of moderate or severe degree. Besides diabetes mellitus and cognitive disorder, the patients had one or several among the following chronic diseases: heart failure cases 2-4 by New York Heart Association Functional Classification, ischemic heart disease, chronic obstructive pulmonary disease, chronic kidney disease stages 3 or 4, and liver cirrhosis. All patients were moderately to severely frail. The HbA1c during the first study period of habitual diabetes care met the recommended 7.5–8.5% with few exceptions. During the second study period, 8 patients were assigned to glycemia target A, 11 patients to glycemia target B, and 11 patients to glycemia target C, under monitoring the TIR.

In Table 2 the point of care glycemia levels is represented with reference to glycemia targets A, B and C, separately for each department. The percent of 'glycemia high' tests was about 30% in two departments, and close to 10% in other two departments. The percentage of 'glycemia high' tests in phase 2 of the study was unchanged or decreased insignificantly. During study phase 2 one hypoglycemic event was recorded; none was diagnosed during study phase 1. Glycemia in the range 71-80 mg/dL was noticed twice in study period 2 and once in period 1.

Discussion

Typically, diabetic elders residing in geriatric hospitals are frail, suffer from chronic diseases and cognitive decline. Guidelines uniformly recommend tailoring glycemic targets to frailty levels, minimizing hyperglycemia and hypoglycemia, reducing treatment burden, giving priority to quality of life. Choice is given to medications carrying no or minimal risk of causing hypoglycemia. When insulin treatment becomes necessary the effects of treatment are closely monitored.

The goals of glycemia treatment are set individually, based traditionally on the physicians' intuition [3-5,22], or recently, founded on numerically defined upper and lower glycemia targets [1]. We searched the literature for studies comparing diabetes

Table 1: Patient characteristics and glycemia targets. Ger: department of comprehensive geriatric care; Vent: department for prolonged mechanical ventilation; CDR: clinical dementia rating scale; Chronic dis: chronic diseases defined as heart failure NYHA 2-4, COPD, ischemic heart disease, chronic kidney disease stages 3 or 4, and liver cirrhosis; Frailty: according to the Clinical Frailty Scale; Glycemia targets A,B and C as specified in the text.

Dept	Patients (no)	Age years Avg (SD)	Male %	CDR Avg (SD)	Chronic dis (no) Avg (SD)	Frailty Avg (SD)	HbA1c Avg (SD)	Target A (no)	Target B (no)	Target C (no)
Ger A	9	68.6 (7.6)	56	0.9 (1)	2 (0.7)	4.9 (1)	7.6 (1)	4	4	1
Ger B	8	73.4 (10.3)	50	1.6 (1)	2.4 (0.7)	5.5 (1.2)	6.7 (0.6)	3	3	2
Vent A	8	70.1 (8.1)	50	2.1 (0.8)	1.9 (1)	7.9. (1.1)	6.7 (0.7)	1	4	3
Vent B	5	78.4 (7.2)	20	3	2.8 (1.2)	8.75 (0.4)	7.9 (1)	0	0	5

Table 2: Glycemia according to categories: hypoglycemia ≤70 mg/dL, borderline low glycemia 70 - 80 mg/dL, optimal glycemia >80< target, matching target, high glycemia > target. Data is expressed in percent of all measurements during monitoring.

Department	Study phase	Glycemia ≤70 mg/dL events	Glycemia borderline %	Glycemia TIR %	Glycemia optimal %	Glycemia high %
Geriatric A	1	0	1 (02%)	44	20	36
	2	0	2 (0.4%)	42	28	30
Geriatric B	1	0	0	30	54	16
	2	0	0	26	59	15
Mech Ventilation A	1	0	0	37	53	10
	2	0	2 (0.4%)	36	59	5
Mech Ventilation B	1	0	0	45	27	28
	P2	1 (0.4%)	0	53	22	25

treatment according to defined upper and lower glycemia targets in comparison to physicians' intuitively chosen glycemia goals. In not finding a convincing answer to the question we devised the present pilot study. The study was planned for two short periods, in anticipating the risk of intercurrent events that would disqualify cases from analysis: the longer the observation period the greater the risk. Fourteen-day periods were presumed to be long enough to achieve a meaningful effect after the change of the treatment protocol. Thirty patients were eligible to study out of 58 diabetics among 160 residents of the four wards.

It is important to consider the following data while interpreting the study's results. First, the HbA1c at the beginning of the study which reflects the last 3 months' glycemia control was in line with the recommended HbA1c <8.5% targets in patients who are medically complex and frail, as recommended by many clinical practice guidelines [22,23]. Second, hypoglycemia occurred only in one instance out of daily 4-time glycemia measurements in 30 patients, for 28 study days period. This result is in line with the safety goal of avoiding hypoglycemia. Third, “glycemia high” (the time above TIR) was in the range of 10% - 36% in study period 1, very different among departments. Fourth, there was no clinically important improvement of glycemia control after initiating the protocol “glycemia to target - TIR glycemia monitoring”: it was 3%-30% during study period 2. This is due to many reasons among which could be poor diet compliance with dietician recommendations, some physicians’ inertia to change treatment and possibly the short time periods of the study.

There are limitations of the study, primarily the retrospective design, small numbers of patients, and short observation period. Continuous glucose monitoring was not available to patients of this study. These limitations could be possibly overcome in future studies.

Conclusions

sGuidelines recommend **r**elaxed glycemic targets for treating diabetic patients who are medically complex and frail. Such are elderly people hospitalized in institutions for long-term geriatric care, as were subjects of our study. We probed whether treatment according to strict upper and lower glycemia targets may produce better results than usual by physician intuitively chosen glycemia goals. Under the same principle of tailoring glycemia to frailty levels, the two models of treatment produced similar results.

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