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Effect of diabetes mellitus control on diabetes burden in elderly Egyptians patients

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Research Article

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Abstract

Older adults with diabetes have a higher risk for hypoglycemia due to altered adaptive physiologic responses to low glucose levels. Patients also have comorbidities, such as cognitive and functional loss, that interfere with prompt identification and/or appropriate treatment of hypoglycemia.

The aim of this study was to evaluate the effect of diabetic state control on diabetes burden in elderly.

Methods: Our study was a case control pilot study conducted on 100 old patients (> 65 years) with type 2 Diabetes Mellitus. All patients recruited from Mansoura Specialized Medical Hospital in the period from April 2019 to February 2020. Medical consents were taken from all patients.

Patients were divided into 2 groups: those with HBA1c (glycosylated hemoglobin A1c) > 8.5% were the cases group whereas control subjects were those having HBA1c ≤ 8.5%.

Calculation of Burden state is based on Elderly diabetes Burden scale (EDBS); Which is 23-item consisting of 6 subscales including symptom burden, social burden, burden of dietary restrictions, burden of worry about diabetes, burden of treatment dissatisfaction, and burden of treatment. Total score of the scale ranges between 19 and 92.

Results: our Study showed no statistically significant difference between two groups regarding serum creatinine, and albumin/creatinine ratio, polyuria, paresthesia, visual disturbance, oedema, chest pain and dyspnea, treatment dissatisfaction, while there was statistically significant difference between two groups regarding fasting Glucose, symptom burden, social burden, dietary restrictions, worry about diabetes, burden by tablets or insulin and total score EDBS being higher in cases than control subjects.

Conclusion: EDBS may be a simple and rapid questionnaire to assess effect of diabetes control on quality of life in elderly patients.

Aim Of The Work

Of all the diseases, type 2 diabetes mellitus (T2DM) is the single most disease affecting a large number of elderly populations along with Hypertension. Diabetes and its complications take a major toll on the quality of life of the elderly and the healthcare costs of the society **(1).**

A previous study showed that DM in Elderly has impact on quality of life “Diabetes burden” **(2)**. However, to the best of our knowledge, Association between diabetic state control and diabetes burden was not determined in previous studies.

The aim of this study is to evaluate the effect of diabetic state control on diabetes burden in elderly.

Subjects & Methods

Study design**:** A case control pilot study was conducted on 100 old patients (> 65 years) 56 males and 44 females with type 2 Diabetes Mellitus.

All patients were recruited from Mansoura Specialized Medical Hospital in the period from April 2019 to February 2020. Medical consents were taken from all patients. Patients were divided into 2 groups:

- 50 Diabetic subjects with HBA1c > 8.5% (cases)
- 50 Diabetic subjects with HBA1c < 8.5% (control)

The HBA1c cutoff point for control was chosen according to Taylor, et al. 2016 (3).

Exclusion criteria: visual problems beyond diabetic retinopathy, decompensated organ failure: chronic renal failure, congestive heart failure or liver cell failure

- Malignancies or those with acute febrile illness

All participants in the study will be subjected to history taking & general examination with special stress on:

- Age / gender, blood pressure, history of polyuria, paresthesia, visual disturbance

Examination of extremities, test for peripheral sensory diabetic neuropathy Monofilament test (Superficial sensation test): (**4**).

- Cardiovascular symptoms: chest pain & dyspnea

- Laboratory investigation:

- HbA1c
- Fasting blood glucose by Glucose Oxidase method
- Serum creatinine by Cobas 400 (Made in Germany)
- Urine Albumin & Alb./Creatinine ratio

Thesis was accepted by Mansoura Faculty of Medicine Institutional Research Board for Ethics.

1. HbA1c test: (5).

Measurement: It was measured by ion exchange resin chromatography kits supplied by Stan Bio.

2. Measurement of urinary albumin to creatinine ratio (ACR) (In spot morning urine): Albumin in urine sample causes agglutination of latex particles coated with anti-human albumin.

3. ELDERLY DIABETES BURDEN SCALE

EDBS is a 23-item Likert-type scale (0-4). It consists of 6 subscales including symptom burden (scores from 0 to 16), social burden (from 5 to 20), burden of dietary restrictions (from 4to 16), burden of worry about diabetes (from 4 to 16), burden of treatment dissatisfaction (from 3 to 12), and burden of oral antidiabetic drugs &/or insulin (from 3 to 12). Total score of the scale ranges between 19 and 92. While a higher score indicates higher burden, a lower score indicates lower burden **(6).**

Statistical analysis and data interpretation:

Data were fed to the computer and analyzed using IBM SPSS Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Qualitative data were described using number and percent. Quantitative data were described using median (minimum and maximum) for non-parametric data and mean, standard deviation for parametric data after testing normality using Kolmogrov-Smirnov test. Significance of the obtained results was judged at the (0.05) level.

Data analysis

Qualitative data:

- Chi-Square test for comparison of 2 or more groups

Quantitative data between groups:

Parametric tests:

- Student t-test was used to compare 2 independent groups

Non-Parametric tests:

- Mann-Whitney U test was used to compare 2 independent groups
- *Correlation:*
- *Spearman's correlation:*
- The Spearman's rank-order correlation is used to determine the strength and direction of a linear relationship between two non-normally distributed continuous variables and / or ordinal variables.
- Diagnostic accuracy
- Receiver Operating Characteristic (ROC) curve analysis:
- The diagnostic performance of a test, or the accuracy of a test to discriminate diseased cases from non-diseased cases is evaluated using Receiver Operating Characteristic (ROC) curve analysis. Sensitivity and Specificity were detected from the curve and PPV, NPV and accuracy were calculated through cross tabulation.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

- P> 0.05 = non-significant (NS)
- P < 0.05 = significant (S)
- P < 0.001 = highly significant (HS).

Results

Table (1): Comparison between Control group (no. =50) and Cases group (no. =50) regarding Demographic characteristics

	Control group N=50	Cases groups N=50	test of significance
Age/years Mean ±SD	71.38±5.38	71.52±6.48	t=0.118 p=0.907
Age groups	n (%)	n (%)	
65-70	22(44.0)	22(44.0)	χ^2=0.902 p=0.637
70-80	23(46.0)	20(40.0)	
>80	5(10.0)	8(16.0)	
Gender	n (%)	n (%)	
Male	31(62.0)	25(50.0)	χ^2=1.46 p=0.227
Female	19(38.0)	25(50.0)	

P-value >0.05: Non significant; P-value <0.05: Significant; P-value< 0.01: highly significant

***: Chi-square test, •: Independent t-test**

Table (2): Comparison between Control group (no. =50) and Cases group (no. =50) regarding Clinical and laboratory findings

	Control group N=50	Cases groups N=50	test of significance
Systolic blood pressure (mm Hg) Mean ±SD	133.70±7.81	136.50±7.64	t=1.81 p=0.073
Diastolic blood pressure (mm Hg) Mean ±SD	86.70±4.69	86.70±3.13	t=0.0 p=1.0
Serum creatinine (mg/dl) Mean ±SD	1.04±0.25	1.03±0.26	t=0.282 p=0.778
Fasting Glucose (mg/dl) Median (range)	188(966-378)	286(124-635)	z=4.83 p=<0.001*
U albumin (mg) Median (range)	7.9(2.4-29)	6.65(1.3-28)	z=0.762 p=0.446
Albumin/creatinine (mg/gm) Median (range)	24(7.5-88)	25.15(6.6-52.0)	z=0.831 p=0.406

Table (3): Comparison between Control group (no. =50) and Cases group (no. =50) regarding Presenting symptoms

	Control group N=50	Cases groups N=50	test of significance
Polyuria	24(48.0)	26(52.0)	χ^2=0.160 p=0.689
paresthesia	26(52.0)	23(46.0)	χ^2=0.360 p=0.548
Visual disturbance	31(62.0)	34(68.0)	χ^2=0.396 p=0.529
Oedema	15(30.0)	12(24.0)	χ^2=0.457 p=0.499
Chest pain	8(16.0)	4(8.0)	χ^2=1.52 p=0.218
Dyspnea	13(26.0)	15(30.0)	χ^2=0.198 p=0.656

Table (4): Comparison between Control group (no. =50) and Cases group (no. =50) regarding EDBS score distribution

	Control group N=50	Cases groups N=50	test of significance
Symptom burden	2.0(0.0-4.0)	4.0(2.0-9.0)	z=6.95 p<0.0001*
Social burden	5.0(5.0-8.0)	14.0(8.0-20.0)	z=9.05 p<0.001*
Dietary restrictions burden	4.0(4.0-8.0)	10.0(4.0-14.0)	z=8.22 p<0.001*
Worry about diabetes	4.0(4.0-8.0)	10.0(5.0-13.0)	z=8.13 p<0.001*
Treatment dissatisfaction burden	4.0(2.0-8.0)	4.0(3.0-8.0)	z=0.296 p=0.767
Burden by tablets or insulin	3.0(2.0-7.0)	6.0(3.0-11.0)	z=7.72 p<0.001*
Total score EDBS	25.0(21.0-30.0)	47.0(37.0-66.0)	z=8.63 p<0.001*

Table (5): Validity of EDBS in predicting burden of Diabetes Mellitus treatment

	AUC (95% CI)	P-value	Cut off point	Sensitivity	Specificity	PPV	NPV	Accuracy
Total EDBS score	1.0(1.0-1.0)	<0.001*	38.0	98.0%	100.0%	100.0%	98.0%	99.0%

AUC: Area Under Curve, PPV: Positive predictive value, NPV: Negative predictive value

Findings:

There was no statistically significant difference found between cases & control groups regarding age and gender. (table1).

There was no statistically significant difference found between two groups regarding systolic blood pressure (mmHg), diastolic blood pressure (mmHg), serum creatinine, urine albumin and albumin/creatinine ratio, and there was statistically significant difference between two groups regarding fasting glucose being higher in cases group than in control group. (table2).

There was no statistically significant difference between two groups regarding polyuria, paresthesia, visual disturbance, oedema, chest pain and dyspnea. (table3).

- There was no statistically significant difference between two groups regarding treatment dissatisfaction, while cases had higher significant values regarding symptom burden, social burden, dietary restrictions, worry about diabetes, burden by tablets &/or insulin and total score EDBS. (Table4).
- Receiver operating characteristic curve (ROC) shows that the best cut off point of total EDBS score to detect burden of Diabetes Mellitus treatment was found 38.0 with sensitivity of 98.0%, specificity of 100.0%, PPV of 100.0%, NPV of 98.00% and total accuracy of 99.0%. (Table 5).

Discussion

With improvement in diabetes management and better glycemic control in the general population, there is an increase in the prevalence of hypoglycemia, which is the complication of the treatment of diabetes. Older adults with diabetes have a higher risk for hypoglycemia due to altered adaptive physiologic responses to low glucose levels. These patients also have comorbidities, such as cognitive and functional loss, that interfere with prompt identification and/or appropriate treatment of hypoglycemia. (**7**)

- In many older patients, the risks of over-treating diabetes outweigh the benefits. The American Geriatrics Society recommends a goal a1c of 7.5-8% in older patients with moderate comorbidities and life expectancy less than 10 years (**8**); the American Diabetes Association recommends a more relaxed goal of 8-8.5% for older patients with complex medical issues (**9**). These recommendations are supported by evidence that low HbA1c targets. did not reduce risk of macrovascular complications in VADT (Veterans Affairs Diabetes Trial) , ADVANCE (Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation) and ACCORD trial (Action to Control Cardiovascular Risk in Diabetes) (**10**, **11**, **12**). In fact, strict glycemic control increased cardiovascular events in patients who experienced hypoglycemic episodes. Secondary analysis of ADVANCE data found that participants with severe hypoglycemic episodes had significantly higher adjusted risk of major cardiovascular events and death from major cardiovascular events (**13**). This is explained by the pathophysiology of hypoglycemia in patients with underlying cardiovascular disease, in whom low blood glucose and the resultant catecholamine surge can induce cardiac arrhythmias, contribute to sudden cardiac death, and cause ischemic cerebral damage (**14, 15**).
- Risk factors for hypoglycemia include advanced age, renal impairment, memory problems and sulfonylurea use. In ADVANCE participants, advanced age was an independent risk factor for severe

hypoglycemic episodes (**11**). Similarly, ACCORD subjects who screened positive for memory problems were at high risk for hypoglycemia (**12**). Additionally, severe hypoglycemic episodes are associated with increased risk of dementia (**16**).

Despite these risks, glycemic control should not be completely abandoned in older patients. Better glucose control in the elderly has been associated with improvement in cognitive functioning and lower mortality following myocardial infarction (**17**).

On the other hand, a large observational study reported that an HbA1c level > 8% was associated with increased risk of all-cause, cardiovascular, and cancer mortality in older adults with diabetes **(18).** Actually, the best glycemic target to achieve for elderly diabetic patients is still a matter of debate. However, there is agreement on tailoring glycemic goals in function of patient's life expectancy, diabetes duration, functional status, existing comorbidities, and pursuing moderate (HbA1c between 7 and 8%) rather than tight control in old diabetic patients **(19).**

The aim of this study was to evaluate the effect of diabetic state control on diabetes burden in elderly. To achieve this aim, a Case control pilot study was conducted on 50 Diabetic subjects with HBA1c>8.5% (cases) and 50 Diabetic subjects with HBA1c <8.5% (control).

Our study revealed no statistically significant difference between cases and control groups regarding polyuria, paresthesia, visual disturbance, oedema, chest pain and dyspnea (Table3). We also found no statistically significant difference between two groups regarding dissatisfaction by treatment, but highly statistically significant difference regarding symptom burden, social burden, dietary restrictions, worry about diabetes, Burden by tablets or insulin and total score EDBS (elderly diabetes burden scale) being higher in cases than control subjects (Table4).

The EDBS was designed to assess the burden, worry, and treatment dissatisfaction comprehensively in elderly patients with diabetes mellitus. Our study showed that the best cut off point of total EDBS score to detect burden of Diabetes Mellitus treatment was found 38.0 with sensitivity of 98.0%, specificity of 100.0%, PPV of 100.0%, NPV of 98.00% and total accuracy of 99.0% (Table5).

Previous studies have found that a significant number of elderly patients with diabetes have a high disease burden **(20, 21).** However, the EDBS score of the current study was lower than that of several other studies **(2,20,21)** which is likely because of differences in the study design and sample size. On the other hand, highest scores were observed for the subscale's symptom burden and burden by tablets or insulin. These findings could be explained by the fact that the majority of participants also had other chronic diseases, and thus used multiple drugs. In **Araki et al, 2003** study **(22)**, found significant association between the EDBS and diabetic complications which was not inconsistent with other studies by **(23, 24, 25)**. In particular, diabetic proliferative retinopathy, symptomatic neuropathy and CVD (cardio-vascular disease) resulted in increased EDBS scores as well as low well-being. Also, **Araki et al, 2003 (22)** revealed that the total EDBS and all the subscales correlated significantly with either HbA1c or frequency of hypoglycemia.

Dalal J, et al. 2020 (26) had said that dissatisfaction with care was significantly related to the self-care behaviors of general diet, worse blood glucose levels, and lower scores on the mental health component of quality of life, which was inconsistent with this study where there was no statistically significant correlation between HbA1c and treatment dissatisfaction in cases group (Table7). But there was statistically significant correlation between HbA1c and symptom burden, dietary restriction, burden by treatment and social burden in cases group (Table7), and this was in agreement with **(Walker RJ, et al. 2015 (27)** who studied social determinants of health in adults with type 2 diabetes – contribution of mutable and immutable Factors.

Message

The EDBS may be a simple, reliable and a valid measure of diabetic-specific QOL (quality of life) in elderly people with diabetes mellitus. Its use may be helpful to assess diabetes treatment in elderly patients.

Declarations

The authors have declared that there was no conflict of interest.

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