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ORIGINAL RESEARCH

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Study on the construction of risk prediction model and efficacy validation of cognitive decline in elderly patients with type 2 diabetes

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Abstract

This study aims to construct a predictive model for assessing the risk of cognitive decline among elderly patients diagnosed with type 2 diabetes and validate its effectiveness. A total of 480 elderly patients with type 2 diabetes who signed a family doctor and underwent chronic disease management were selected and divided into a cognitive decline group (n = 62) and a non-cognitive decline group (n = 418) based on cognitive decline. Various clinical variables, lifestyle choices, medication regimens, complications, and medical histories were subjected to statistical analysis for both groups. Univariate and multivariate logistic regression analyses were performed to identify risk factors, based on which a risk prediction model was constructed. Hosmer and Lemeshow were used to investigate the goodness of fit of the risk prediction model, and Statistical Product and Service Solutions (SPSS) was used to draw Receiver Operating Characteristic (ROC) curves to assess the predictive value of the risk prediction model. Age, infrequent exercise, inadequate sleep, and the presence of depression emerged as significant risk factors for cognitive decline. The goodness-of-fit test using the Hosmer and Lemeshow statistic yielded $\chi^2 = 0.041$ and $p = 0.855$, confirming the model's appropriateness. ROC curve analysis demonstrated an Area Under the Curve (AUC) of 0.912 (95% CI: 0.874 to 0.950), underscoring the model's predictive capability. Age, infrequent exercise, inadequate sleep and depression could be risk factors for cognitive decline in elderly individuals with type 2 diabetes, and the proposed risk prediction model displays robust predictive accuracy for identifying those at risk of cognitive decline.

Keywords

Elderly type 2 diabetes; Cognitive decline; Risk prediction; Model construction; Efficacy validation

1. Introduction

Due to the escalating challenges posed by the aging population, the prevalence of type 2 diabetes among elderly individuals has shown a noticeable upward trend [1]. Among the elderly population aged over 60 years in China, the prevalence of type 2 diabetes is approximately 20%, ranking highest globally [2]. Consequently, diabetes has emerged as a significant healthcare concern seriously affecting the elderly population in China [2]. Recent studies have uncovered a range of complications that diabetic patients may develop as the disease progresses, with cognitive decline being a novel complication identified in clinical practice in recent years. Cognitive decline in diabetic patients not only elevates the risk of dementia, disability, falls and even mortality but also extends hospital stays and substantially diminishes the overall quality of life, imperiling the health and well-being of affected individuals [2]. Furthermore, it has been observed that the incidence of cognitive decline is notably higher in male elderly patients with type 2 diabetes compared to their female counterparts. Thus, our present study is directed toward male elderly patients. While there has been some research on the cognitive decline among type 2 diabetes patients, the knowledge gap on the male demographic remains substantial. By focusing on male participants, this study aims to bridge this research gap and improve our understanding of cognitive decline in male individuals with type 2 diabetes, which could facilitate the formulation of targeted intervention measures to enhance healthcare provision for this specific group. Presently, clinical research on cognitive decline in elderly type 2 diabetes patients predominantly centers on treatment modalities. Studies investigating influencing factors tend to be limited to single-factor analyses, with a lack of in-depth exploration of risk factors. Furthermore, related risk prediction models remain limited, leading to a lack of clinical guidance regarding effective preventive strategies for cognitive decline in elderly type 2 diabetes patients [3]. Therefore, the primary

objective of this study is to construct a risk prediction model for cognitive decline and substantiate its effectiveness on elderly patients diagnosed with type 2 diabetes.

2. Materials and methods

2.1 Clinical data

A total of 480 elderly patients diagnosed with type 2 diabetes who had enrolled in a family doctor program and received chronic disease management were recruited from our hospital between October 2020 and October 2021. The study inclusion criteria were as follows: (1) Fulfillment of clinical diagnostic criteria for type 2 diabetes; (2) Disease duration exceeding 6 months; (3) Age of participants being over 60 years; (4) Patients having provided informed consent. The exclusion criteria encompassed: (1) A definitive diagnosis of dementia or psychiatric disorders; (2) Coexistence of severe complications; (3) Pre-existing visual or language impairments predating the diabetes diagnosis; (4) Concomitant neurological disorders excluding dementia.

2.2 Study design

All study participants underwent cognitive assessment based on internationally recognized criteria for cognitive decline diagnosis. The criteria used for diagnosing cognitive decline in our study were as follows: (1) Patient or family-reported perception of cognitive decline; (2) Utilization of the Clinical Dementia Rating (CDR) scale [4] to determine cognitive status, with scores classified as follows: 0 (normal), 0.5 (suspicious), 1.0 (mild), 2.0 (moderate) and 3.0 (severe); (3) Application of the Frailty Phenotype (FP) scale to assess frailty status, with scores ranging from 1 to 5, where 0 indicated non-frailty, 1–2 indicated pre-frailty, and 3–5 indicated frailty; and (4) Employing the Montreal Cognitive Assessment (MoCA) to evaluate cognitive function, with scores in the range of 14 to 25 considered indicative of cognitive decline. The MoCA total score is 30, and a score of $\geq$26 signifies normal cognitive function.

The criteria for diagnosing cognitive decline: (1) Patient or family-reported perception of cognitive decline; (2) Absence of a clinical dementia diagnosis, with a CDR score of 0.5; (3) An FP scale score falling within the range of 1 to 5; and (4) MoCA score between 14 and 25.

Based on the diagnostic outcomes, the patients were categorized into two groups: the cognitive decline group and the non-cognitive decline group. We collected and organized clinical data, encompassing information related to clinical profiles, lifestyle habits, medication regimens, complications and medical histories.

The diagnosis of depression was determined following the criteria outlined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) [5]. Sleep deprivation was assessed using the Pittsburgh Sleep Quality Index (PSQI) [6], which assigns total scores ranging from 0 to 21, with higher scores indicating poorer sleep quality. Sleep deprivation was defined as a total PSQI score falling within the range of 16 to 21 points.

2.3 Sample size calculation

The sample size for the modeling group was determined using a preliminary estimation formula for logistic regression analysis. It was estimated that there would be approximately 5 to 6 significant independent variables in the model, and for each independent variable, at least 15 patients were required. Additionally, accounting for a literature-based incidence rate of approximately 20.8% and allowing for a 10% potential sample loss, the minimum sample size needed for the modeling group was calculated as follows: Minimum Sample Size = (5 to 6) $\times$ 15 $\times$ (1 + 10%)/20.8% $\approx$ 397 cases ~ (6) $\times$ 15 $\times$ (1 + 10%)/20.8% $\approx$ 476 cases. To ensure that the study's requirements were met, a sample size of 480 participants was selected, which exceeded the calculated minimum requirement of 476 cases.

2.4 Statistical methods

2.4.1 Univariate analysis

Statistical analysis was conducted using SPSS version 27.0 (International Business Machines Corporation, Armonk, NY, USA). Descriptive statistics were performed to characterize measurement data that adhered to a normal distribution, expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$). For measurement data that did not conform to a normal distribution, the median and the upper and lower quartiles (M (Q1, Q3)) were utilized. The appropriate statistical test, either the *t*-test (for normally distributed data) or the rank sum test (for non-normally distributed data), was applied accordingly. Enumeration data are presented in terms of the number of cases and corresponding percentages (n (%)). Comparisons between groups for enumeration data were made using the chi-square (χ^2) test. A significance level of $p < 0.05$ was considered to indicate statistically significant differences.

2.4.2 Multivariate logistic regression analysis

The analysis was conducted using SPSS version 27.0, employing binary logistic regression for multivariate analysis to estimate the effect of multiple risk factors while controlling for confounders. Initially, the χ^2 test was used to conduct univariate analyses to identify statistically significant factors, which were then analyzed using multivariate analysis based on a stepwise entry method with inclusion criteria set at $\alpha \leq 0.05$ and exclusion at $\alpha \geq 0.10$ to facilitate the construction of a regression model, where a *p*-value < 0.05 indicated statistical significance. Subsequently, odds ratios (OR) and 95% confidence intervals (CI) were calculated for the identified risk factors, effectively eliminating the influence of confounding variables.

2.4.3 Predictive model development

The regression equation was formulated based on risk factors that exhibited statistical significance ($p < 0.05$) and their corresponding regression coefficients derived from the multivariate logistic regression analysis of the samples. The equation is represented as Logit (P) = ln [P/(1 − P)] = $\beta + \sum$ BiXi, where the predictive probability model is defined as P = Exp $\sum$ BiXi/(1 + Exp $\sum$ BiXi). Here, as the *p* value approaches 1, the probability increases, and conversely, as the *p* value

approaches 0, the probability decreases.

2.4.4 Fit and evaluation of prediction model

The assessment of the prediction model's fit involved the application of the Hosmer-Lemeshow test. At the core of this test lies the null hypothesis, which posits that the regression equation aligns well with the original data, suggesting that the established equation is robust and the computed results are dependable. If the obtained p-value is less than 0.05, it indicates a poor model fit, while a p-value greater than 0.05 signifies a good model fit.

2.4.5 Plot ROC curve

Logistic regression models were applied to the raw data to generate a smoothed receiver operating characteristic curve (ROC). The predictive accuracy of this model was assessed by computing the area under the curve (AUC). A larger AUC corresponds to a more convex curve, signifying a higher predictive value. Predictive performance was categorized as low when the AUC fell between 0.5 and 0.7, moderate when it ranged from 0.7 to 0.9, and high when it exceeded 0.9.

3. Results

3.1 Incidence of cognitive decline in elderly patients with type 2 diabetes

Our data analysis showed that in the cohort of 480 elderly patients with type 2 diabetes, 62 were diagnosed with cognitive decline, resulting in an incidence rate of 12.92%.

3.2 Univariate analysis of cognitive decline in elderly patients with type 2 diabetes

Univariate analysis revealed several significant differences between the two groups (Table 1). Patients in the cognitive decline group were found to be older, had a higher prevalence of infrequent exercise, experienced sleep loss at a greater rate and had a higher incidence of depression compared to the non-cognitive decline group ($p < 0.05$).

3.3 Logistic multivariate regression analysis of cognitive decline in elderly patients with type 2 diabetes

Herein, we considered the development of cognitive decline in elderly patients with type 2 diabetes as the dependent variable. The variables that exhibited significant differences in the univariate analysis, namely age, infrequent exercise, lack of sleep and depression (Table 2), were included as independent variables in the binary logistic regression analysis model, and the results confirmed that these variables, including age, infrequent exercise, lack of sleep and depression, all displayed statistically significant differences ($p < 0.05$), with OR >1. Therefore, age, infrequent exercise, lack of sleep and depression were identified as risk factors (Table 3).

3.4 Risk prediction models for the incidence of cognitive decline in elderly patients with type 2 diabetes

According to the four risk factors and their coefficients in Table 3, a binary logistic multivariate regression analysis model was constructed using the following formula:

$$\begin{aligned} Logit(P) &= ln[P/(1-P)] \\ &= -5.678 + 3.855X_1 + 2.893X_2 + 3.327X_3 + 2.120X_4 \end{aligned}$$

Model for the development of cognitive decline in elderly patients with type 2 diabetes was predicted:

$$P = 1/[1+exp(5.678-3.855X_1-2.893X_2-3.327X_3-2.120X_4)]$$

3.5 Goodness of fit tests for risk prediction model for the incidence of cognitive decline in elderly patients with type 2 diabetes

The goodness of fit of the probability model was assessed using the Hosmer and Lemeshow test, which yielded a χ^2 value of 0.041 with a corresponding p-value of 0.855. These results indicate that the probability model exhibited a good fit to the data. Detailed findings are presented in Table 4.

3.6 Predictive value analysis on risk prediction models for the development of cognitive decline in elderly patients with type 2 diabetes

ROC curve analysis demonstrated that the prediction model possessed significant predictive value, with a p-value < 0.05 and an AUC of 0.912 (95% CI, 0.874 to 0.950). A visual representation of these results is shown in Fig. 1.

4. Discussion

Our results revealed that among the 480 elderly patients diagnosed with type 2 diabetes, 62 individuals, accounting for 12.92%, exhibited cognitive decline. This finding aligns with reports both domestically and internationally, underscoring the concerning prevalence of cognitive decline among elderly individuals with type 2 diabetes. Notably, we observed a higher incidence of cognitive decline in male patients compared to their female counterparts. These findings emphasize the importance of increased clinical vigilance and the implementation of effective interventions and strategies for early identification and prevention of cognitive decline in elderly patients with type 2 diabetes [4].

Clinical studies have confirmed [5, 6] the significant threat posed by cognitive decline to the health of the elderly population, especially in later stages of life, and its association with increased risks of adverse health outcomes among elderly individuals with diabetes [5, 6]. Elderly diabetic patients, who often have prolonged diabetes durations and advanced age, experience systemic functional weakening and organ damage, thus elevating their vulnerability to cognitive decline

TABLE 1. Univariate analysis of cognitive decline in elderly patients with type 2 diabetes.

Variables	Cognitive decline group (n = 62)	Cognitive decline group (n = 418)	Statistical value	*p* value
Age (yr)	78.36 ± 5.64	68.55 ± 4.55	10.660	<0.001
Disease duration (yr)	6.26 ± 0.60	6.24 ± 0.61	0.241	0.809
Family history (n, %)				
Yes	16, 25.81	111, 26.56	0.016	0.901
No	46, 74.19	307, 73.44		
Smoking history (n, %)				
Yes	25, 40.32	171, 40.91	0.008	0.930
No	37, 59.68	247, 59.09		
Alcohol history (n, %)				
Yes	23, 37.10	158, 37.80	0.011	0.915
No	39, 62.90	260, 62.20		
Exercise infrequently (n, %)				
Yes	37, 59.68	132, 31.58	18.687	<0.001
No	25, 40.32	286, 68.42		
Lack of sleep (n, %)				
Yes	28, 45.16	89, 21.29	16.688	<0.001
No	34, 54.84	329, 78.71		
Depression (n, %)				
Yes	25, 40.32	50, 11.96	32.941	<0.001
No	37, 59.68	368, 88.04		
Malnutrition (n, %)				
Yes	19, 30.65	50, 11.96	15.312	<0.001
No	43, 69.35	368, 88.04		
Living alone or not (n, %)				
Yes	11, 17.74	75, 17.94	0.002	0.969
No	51, 82.26	343, 82.06		
History of falls within 1 year (n, %)				
Yes	5, 8.06	36, 8.61	0.021	0.886
No	57, 91.94	382, 91.39		
Injected insulin (n, %)				
Yes	32, 51.61	213, 50.96	0.009	0.923
No	30, 48.39	205, 49.04		
Hypertension (n, %)				
Yes	16, 25.81	111, 26.56	0.016	0.901
No	46, 74.19	307, 73.44		
Cardiovascular disorders (n, %)				
Yes	18, 29.03	121, 28.95	0.000	0.989
No	44, 70.97	297, 71.05		

TABLE 2. Logistic multivariate regression analysis of variable assignment in elderly patients with dry eye after cataract surgery.

Variables	B	Value assignment
Whether elderly patients with type 2 diabetes develop cognitive decline	Y	Binary Variables: Yes: Assign Value 1; No: Assign Value 0
Age	X_1	Continuous variable
Exercise infrequently	X_2	Binary variables: Yes: assigned value 1; None: assigned value 0
Lack of sleep	X_3	Binary variables: Yes: assigned value 1; None: assigned value 0
Depression	X_4	Binary variables: Yes: assigned value 1; None: assigned value 0

TABLE 3. Binary logistic multiple factor regression analysis of cognitive deficiency in elderly patients with type 2 diabetes mellitus.

Variables	β	Standard error	wald	p	OR value	95% Confidence Interval for OR value	
						Lower Limit	Upper Limit
Age	3.855	0.472	66.796	<0.001	47.252	18.744	119.114
Exercise infrequently	2.893	0.460	39.622	<0.001	18.050	7.332	44.433
Lack of sleep	3.327	0.427	60.651	<0.001	27.846	12.055	64.321
Depression	2.120	0.443	22.886	<0.001	8.329	3.495	19.849
Constant	−5.678	0.463	150.679	<0.001	0.003		

OR: odds ratios.

TABLE 4. Hosmer-Lemeshow test for probability models.

χ^2	p
0.041	0.855

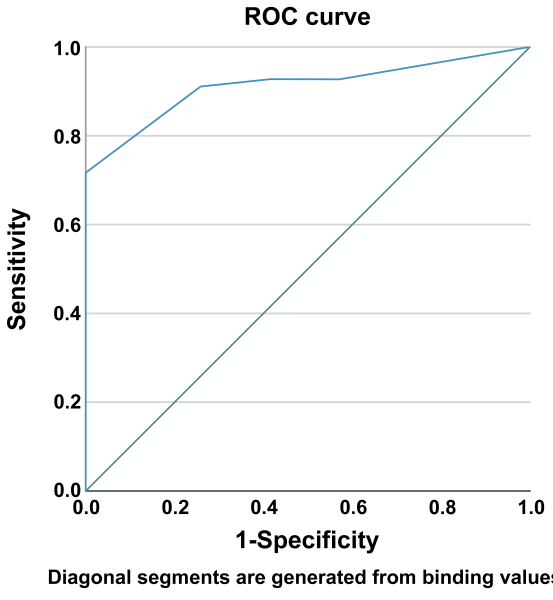

FIGURE 1. ROC curves for risk prediction models for the development of cognitive decline in elderly patients with type 2 diabetes. ROC: receiver operating characteristic curve.

[7]. This heightened susceptibility, in turn, amplifies the risk of dementia, disability, and even mortality. Consequently, the effective prevention of cognitive decline has emerged as a focal point in clinical practice. Previous clinical studies have predominantly relied on univariate analyses to examine influencing factors, with a predominant focus on pathology, treatment modalities, and the clinical prognosis of patients [8]. However, a notable gap exists in research concerning predictive models for assessing the risk of cognitive decline in elderly patients diagnosed with type 2 diabetes.

Moreover, we analyzed the differences in clinical data, lifestyle patterns, medication regimens, complications and medical histories among these elderly individuals to determine variations between patients exhibiting cognitive decline and those without such decline. Through a combination of univariate and multivariate logistic regression analyses, a risk prediction model was established, and our findings revealed that age, infrequent exercise, insufficient sleep and depression were significant risk factors for cognitive decline in this elderly patient population.

According to international consensus [9], cognitive decline is defined as the combination of physical frailty and cognitive impairment, excluding Alzheimer's disease and other dementias. Research indicates a strong correlation between advancing age and cognitive decline in individuals with type 2 diabetes. As people age, a decline in various bodily functions occurs, including reduced activity in brain tissue and cells and muscle atrophy, which subsequently increases the risk of cognitive decline. Studies [10, 11] have shown that sleep duration affects the neuroendocrine system, particularly through its influence on the hypothalamic-pituitary-adrenal axis, altering cortisol responsiveness, and decreasing insulin-like growth

factor and growth hormone levels, thereby contributing to the progression of cognitive decline. Clinical evidence [12, 13] also reveals a significant link between depression and cognitive decline, noting shared aspects in their pathogenesis, with pathological aging of the brain and cerebrovascular diseases identified as common contributing factors. These conditions have a reciprocal relationship, exacerbating each other [14], with depression in diabetic patients leading to an increased risk of cognitive impairment. Conversely, regular physical activity is recognized as a protective factor against cognitive decline. Studies [15, 16] have demonstrated that sustained exercise can significantly enhance physical and muscle strength, thereby improving cognitive functions in the elderly with cognitive decline. Further analysis [17, 18] reveals that irregular physical activity can accelerate protein degradation, suppress muscle protein synthesis, and disrupt bone metabolism balance, resulting in bone loss. Therefore, older individuals with type 2 diabetes are at a heightened risk of cognitive decline due to these factors.

Moreover, a binary logistic multivariate regression analysis model was developed based on the risk factors identified in the preceding studies. The adequacy of the prediction model's fit was assessed using the Hosmer-Lemeshow test, while its predictive capacity was evaluated through ROC curve analysis. The outcomes revealed that the model exhibited a strong fit and significant predictive value.

In response to the findings above, targeted interventions against these risk factors can effectively mitigate and potentially prevent cognitive decline. Firstly, while age remains immutable, the risk of age-related cognitive decline can be diminished by adopting a healthy lifestyle, which encompasses maintaining a well-balanced diet, engaging in cognitive training exercises, nurturing social interactions, and actively participating in physical activity and exercise routines. Secondly, increasing physical activity and exercise yields considerable benefits for cognitive function. Thus, elderly patients with type 2 diabetes should engage in at least 150 minutes of moderate-intensity aerobic exercise per week, such as walking, swimming or cycling. Additionally, incorporating strength training into their regimen can further improve muscle and bone health, ultimately contributing to improved cognitive function. Thirdly, prioritizing quality sleep is essential for the proper functioning of cognitive faculties. Elderly patients with type 2 diabetes should establish a consistent sleep schedule and cultivate healthy sleep habits. Strategies encompass avoiding excessive caffeine and stimulant substances, creating a comfortable sleep environment, and reducing the overuse of electronic devices to enhance sleep quality. Lastly, considering the association between depression and cognitive decline, it is recommended that individuals collaborate with healthcare professionals to access mental health support and treatment options, such as psychological counseling, cognitive-behavioral therapy or medication. Furthermore, in addition to addressing these aforementioned factors, adopting other healthy lifestyles can further promote the preservation and enhancement of cognitive function. These could include maintaining social interactions, engaging in cognitive training activities (*e.g.*, puzzle games or acquiring new skills and languages), safeguarding psychological and emotional well-being, managing blood glucose levels and blood pressure, maintaining a healthy weight, and more. It is important to recognize that enhancing cognitive function is a multifaceted challenge requiring a holistic assessment of multiple factors and collaborative efforts with healthcare professionals to develop personalized health plans tailored to individual needs.

5. Conclusions

In conclusion, this study highlights the significance of age, infrequent exercise, lack of sleep and depression as risk factors in the development of cognitive decline among elderly individuals with type 2 diabetes. The risk prediction model, derived from these factors, demonstrates substantial clinical predictive value. However, it is important to acknowledge the limitations of this study, primarily due to the size and source of the study cohort. Moreover, potential biases may have arisen from the data collection process, particularly when relying on patient self-reporting, which could introduce memory distortion or subjective bias, thereby compromising the accuracy of results. Furthermore, the cross-sectional design employed in this study precludes the observation of temporal variations and hinders the determination of causality, potentially leading to incidence-prevalence bias.

Future research could consider broadening the scope of study subjects and incorporating additional factors into prediction model investigations to enhance the robustness and applicability of such models in clinical practice. Additionally, longitudinal studies could provide valuable insights by tracking changes over time within the same group of individuals, thereby facilitating a deeper understanding of causality and addressing incidence-prevalence bias.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

LZZ, YM and WML—designed the study and carried them out; LZZ—supervised the data collection, analyzed the data, interpreted the data, prepared the manuscript for publication and reviewed the draft of the manuscript. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Beijing Chao-Yang Hospital, Capital Medical University (Approval no. 2023-149). Written informed consent was obtained from a legally authorized representative for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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