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RESEARCH ARTICLE

Depression in Type II Diabetes Mellitus Outpatients: The Effect of Gender, Glycosylated Hemoglobin and Type of Treatment

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Abstract:

Introduction:

Diabetes is a chronic illness that can occur in different periods of the person's life.

Methods:

The purpose of this study is to investigate the correlation of depression levels with HbA1c glycosylated hemoglobin values and gender, to determine the rate of depression in patients with type II diabetes in relation to the presence of co-morbidities and how depression is associated with the type of treatment (diet, insulin).The study involved 150 diabetic outpatients. A questionnaire consisting of two sections was used to collect the research data: (a) the Zung depression rating scale (ZDRS); and (b) the Questionnaire designed by researchers, which deals with demographic and somatometric data. In the evaluation of the association of depression with the value of glycosylated hemoglobin, the results did not show a statistically significant correlation between the two above-mentioned variables ($r = 0.098$, $p = 0.258 > 0.05$).

Results:

Those on a diet had lower levels of depression (62.57) than those who did not follow a diet (77.50, $p = 0.029 < 0.05$). Those with diabetic neuropathy experienced higher levels of depression (104.25) compared to those who did not suffer (66.81, $p = 0.010 < 0.05$).

Conclusion:

The presence of complications as well as the treatment seem to influence the depression variable.

Keywords: Diabetes mellitus, Depression, Mental health, Outpatients, Gender, Somatometricdata, Hemoglobin.

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1. INTRODUCTION

T2DM is a chronic metabolic disease characterized by the complexity of its effects at the individual, family and social level. The non-essential cure of the disease and its chronicity require investigation of the quality of life and mental health of these patients to understand the factors that affect them and their optimal modification. The study of T2DM-related quality of life is of great importance, firstly, for the patient himself, secondly, for the medical community in order to investigate the effects of various therapeutic interventions and, thirdly, for the state regarding the effectiveness and their cost. Therefore, the need to create and use appropriate tools to measure the quality of life and mental health of these patients is deemed imperative [1].

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Results of studies on the quality of life and mental health of patients with T2DM and their families showed that there is a correlation between the specific variables with HbA1c, gender, education, marital status and social support and that the EQ-5D questionnaire is a valid tool for assessing quality of life as it can identify the impact and consequences of diabetic complications on various dimensions of the health-related quality of life of sufferers [1 - 4].

Research has shown that the behavior of the diabetic person regarding his disease depends on a series of demographic, anthropometric and socio-economic factors, such as age, gender, marital status, co-existing diseases, obesity, education, unemployment and the duration of the disease [5, 6].

It has been observed that, due to personal experiences, older people cope better with the demands of the disease, its complications and treatment side effects. Also, it has been

found that there are differences between the two sexes in dealing with the disease and in the perception of their health status. Thus, while women appear more pessimistic and negative and find it difficult to accept the existence of chronic illness, men, on the contrary, adapt better to the new reality, see the future more optimistically, face their health condition more easily and manage to cope with the demand's disease. An additional stabilizing factor is married life, which seems to play a positive role in the perception of the state of health and mental health. Dealing with the demands of the disease in the context of family support is made much easier and the affected person is relieved of negative mental states, such as depression. Also, the coexistence of complications or other diseases has a negative effect on the diabetic's quality of life since they increase the possibility of symptoms and/or disabilities [5, 6].

Factors influencing satisfaction with T2DM treatment are shown in another research. According to the findings, treatment dissatisfaction is associated with appetite disturbances, hypoglycemia, weight gain, gender, complications and type of treatment. Also, it was found that diabetic patients who have difficulty following medical instructions and receive antidiabetic treatment with insulin, require more attention in order to improve satisfaction with their treatment [7]. Armentano's study showed that insulin-treated diabetics using the simple syringe were less satisfied than those using the pre-filled pen devices [8]. According to the study by Escudero - Carretero *et al*. [9], diabetic patients seem more satisfied with their treatment when they are attended by doctors who understand them, empathize with their situation, encourage them, share their views and needs while at the same time demonstrating scientific competence, professionalism, responsibility and humanity. Finally, another research has shown that the satisfaction of diabetic patients is more influenced by the physician's interpersonal skills and not so much by the quality of care provided [10, 11].

Papadopoulos *et al*. [12] conducted research on a Greek island regarding the determination of the factors that influence the quality of life of diabetics and to determine the necessary actions for their improvement. The result of the study showed that the health-related quality of life of diabetic patients is influenced by a number of demographic and socioeconomic factors, such as the individual's age, gender, educational level and marital status. In addition, it was found that clinical factors, such as the duration and complications of diabetes, contribute to shaping the level of quality of life of patients [12].

In a study conducted in the routine diabetes clinic of the University Hospital of Ioannina regarding the assessment of the quality of life and satisfaction with treatment in patients suffering from T2DM, it appeared that the health-related quality of life was lower compared to the general population, while the satisfaction with treatment was good. According to the results of the specific study, determining factors in shaping the quality of life and mental health were female sex, obesity, the existence of complications, poor blood sugar regulation, recent hospitalization and accompanying diseases. In addition, younger patients, those receiving combination antidiabetic therapy with tablets and insulin, and diabetics with HbA1c>7 appeared to be less satisfied with treatment [13].

Antonopoulou [14], conducted a study in a Greek secondary general hospital, which concluded that the health-related quality of life of diabetic patients is affected both by depression and insomnia as well as by a number of socio-demographic factors, such as age and gender.

Arvanitaki [15], in her postgraduate study in a rural population, showed that obesity is not related to quality of life or patient satisfaction, while, on the contrary, it is related to the cost of pharmaceutical treatment for co-morbidities.

After researching a Greek province population, Kontodimopoulos *et al*. [16] identified age, female gender, complications, co-existing diseases, obesity, insulin therapy and duration of the disease as aggravating factors of diabetes-related quality of life. Treatment satisfaction was found to be influenced by glycated hemoglobin value and insulin therapy.

In his diplomatic research at a private Athens diabetes clinic, Papamatthaiu [17] came to a conclusion that, in some circumstances, demographic information, sleep issues, depression, and satisfaction with treatment can affect the quality of life of diabetic patients.

In Cyprus, the magnitude of the problem was highlighted by Loizos [18] in his epidemiological study on the "Assessment of the frequency of T2DM, Hypertension and Dyslipidemia in the General Population of Free Cyprus". According to the specific research, the percentage of diabetic people in the free areas of Cyprus is 10.3%, while the percentage of undiagnosed and unregulated people with T2DM is estimated at 37%. In addition, 73% of T2D sufferers do not receive any treatment to control the disease.

Filippou [19] in her dissertation research carried out in a hospital in Cyprus involving 150 people with diabetes, concluded that the health-related quality of life of patients with T2DM and their satisfaction with treatment is both influenced by a series of social and demographic factors, such as gender, age, level of education, marital status, as well as clinical parameters, such as the value of HbA1c, insulin use, obesity, duration of the disease and the existence of complications.

Based on all of the above, the negative effect of depression on the quality of life of patients suffering from T2DM is evident. The innovation of the research is based on the fact that no similar studies have been carried out in Greece regarding the evaluation of depression in the patients in question in relation to the values of the glycated hemoglobin HbA1c, the presence of complications as well as the type of treatment.

The purpose of the present study is to investigate the levels of depression in patients with Type II Diabetes Mellitus. Moreover, the following were studied:

1. The effect of glycated hemoglobin HbA1c values on depression levels.

2. The determination of the rate of depression in patients with diabetes mellitus type II in relation to the presence of co-morbidities. Specifically, it was examined if there were differences in depression among those who suffered from diabetic neuropathy compared to those who did not.

3. How depression in type II diabetic patients is related to

the type of treatment (*e.g.* insulin, diet).

4. Finally, it was examined if there were differences between males and females regarding the level of depression.

2. METHODS

A quantitative cross-sectional study was performed. A questionnaire consisting of two parts was used to collect the research data: (a) The Zung Depression Rating Scale (ZDRS), which contains a total of 20 questions that assess emotional, psychological and physical symptoms [20] and (b) a Questionnaire designed by the researchers, which concerns demographic and somatometric data, the duration of the disease, the years of follow-up in a diabetes clinic, the level of glycemic control, the accompanying diseases, the presence of complications and the followed therapeutic regimen for the regulation of diabetes.

The research involved 150 diabetic patients who were followed up at an outpatient clinic with simple random sampling from the population, with which the reduction of bias and statistical error is achieved. Patients were selected based on the inclusion criteria for the study, which are as follows:

- The patient's consent.
- Age over eighteen years.
- Diagnosed with Type 2 Diabetes Mellitus.
- Ability to communicate in the Greek language.
- His (patient's) general state of health allows him to take part in the study.

All research participants were informed in writing and verbally and signed a consent form. The collection of the sample was preceded by approval of the research protocol, following the relevant request of the researcher.

There was contact with the patients themselves or their companions in order to set an appointment and complete the said questionnaire. The present research study responded to the fundamental ethical principles which govern the conduct of social research. Particularly:

1. Full confidentiality of patient information was maintained, and security of related material was maintained.

2. Patient anonymity was secured.

3. The results obtained were used exclusively and only for the purposes of the specific research and exclusively and only by the specific research team.

4. Patient stress or emotion was kept to a minimum.

The reliability of the findings was ensured by the accurate and complete description of the methods, the sample, the material and the general conditions of conducting the research.

After the data was collected, it was decoded and analyzed using SPSS v.23. Cronbach's an index was used to assess the internal consistency of the questionnaire. A tolerable type I error was set as p=0.05. For the presentation of the results related to the responses of the patients to the questionnaires, who participated in the research, a frequency analysis was carried out. Quantitative variables are presented as mean (± standard deviation), while qualitative variables are presented as frequency (%). Also, a sample normality test was performed using the Kolmogorov Smirnov test. Non-parametric tests (Spearman correlation analysis, Mann-Whitney test, Kruskal Wallis test) were performed in order to investigate possible associations between depression and glycated hemoglobin, complications and type of treatment. Mann-Whitney test was also conducted so as to see if there are differences between males and females in depression. Moreover, to investigate the relation of depression to glycaozone hemoglobin value, regression analysis was performed.

3. RESULTS

First, we should emphasize that in the context of assessing the reliability of the psychometric tool used for depression, it showed very good reliability, namely 0.74 (Cronbach's an index).

In this research, a total of 150 patients answered the questionnaires. 51.3% of patients were male, and 48.7% were female. The majority of patients had basic education (75 patients, 50%) and were married (136 patients, 90.7%). The mean value of age was 67.05±10.81 years of life, height 164.54±10.51 cm and weight 87.34±19.63 kg. Regarding the diagnosis of the disease, 98 patients (65.3%) learned that they had the disease by chance, 7 patients (4.7%) during hospitalization, and 45 patients (30%) in another way. In detail, all the clinical and demographic characteristics of the study patients are presented in Table **1**.

Only 27 patients reported smoking (18%), while 122 (81,3%) reported not smoking. One patient (0,7%) has never smoked, and 46 patients (30,7%) stated that they were former smokers.

In the context of Table **2**, the type of treatment followed by the patients is examined. More specifically, 80 patients followed a diet, 136 patients received tablets, 41 patients received insulin, and only 2 patients combined all of the above.

Table 1. Clinical and demographic characteristics of study patients.

N	**150**	
Gender		
(Male) n (%)	77	(51,3)
(Female) n (%)	73	(48,7)
Education		
Basic education	75	(50,0)
Secondary education	67	(44,7)

(Table 1) contd.....

N	150	
Technological education	6	(4,0)
Higher education	2	(1,3)
Marital Status		
Single	10	(6,7)
Married	136	(90,7)
Other	2	(1,3)
Age	67,05	±10,809
Height	164,54	±10,510
Weight	87,34	±19,631
Waist circumference	125,14	±20,252
Number of children	2,14	±0,949
Disease duration (in years)	10,71	±7,684
Diagnosis of the Disease		
Accidentally	98	65,3
During hospitalization	7	4,7
Other	45	30,0
Duration of medical follow-up (in years)	7,72	±5,906
Glycozonehemoglobinvalue	7,118	±1,3466
Smoking years	29,67	±11,130
Number of cigarettes per day	20,69	±9,081
Smoking cessation (in years)	14,16	±11,567
Overall depression score (Zung test)	34,4453	±9,35487

Table 2. Type of treatment.

Diet		
Yes n (%)	80	53,3
Non (%)	70	46,7
Tablets		
Yes n (%)	136	90,7
Non (%)	14	9,3
Insulin		
Yesn (%)	41	27,3
Non (%)	109	72,7
Combine all		
Yes n (%)	2	1,3
Non (%)	148	98,7

Table 3. Complications.

Diabeticretinopathy		
Yes n (%)	3	2,0
Non (%)	147	98,0
Diabetic foot		
Yes n (%)	0	0,0
Non (%)	150	100,0
Erectiledys function		
Yes n (%)	2	1,3
Non (%)	148	98,7
Diabeticnephropathy		
Yes n (%)	1	,7
Non (%)	149	99,3
Amputation		

(Table 3) contd.....

Diabeticretinopathy		
Yes n (%)	1	,7
Non (%)	149	99,3
Diabeticneuropathy		
Yes n (%)	9	6,0
Non (%)	141	94,0
Othercomplication		
Yes n (%)	1	,7
Non (%)	149	99,3

Table 4. Diseases other than diabetes mellitus.

Hypertension		
Yes n (%)	111	74,0
Non (%)	39	26,0
Coronaryheart disease		
Yes n (%)	37	24,7
Non (%)	113	75,3
Acutemyocardialinfarction		
Yes n (%)	10	6,7
Non (%)	140	93,3
Dyslipidemia		
Yes n (%)	102	68,0
Non (%)	48	32,0
Cerebrovascular accident		
Yes n (%)	8	5,3
Non (%)	142	94,7
Other		
Yes n (%)	57	38,0
Non (%)	93	62,0

Table 5. Depression levels (Zung test).

20-44 Normal range	116	77,3
45-59 Mild depression	19	12,7
60-69 Moderate depression	2	1,3

Table 6. Association of depression and glycated hemoglobin.

-			**Depression - Zung (Overallrating)**	**Glycozonehe Moglobin value**
Spearman'srho	Depression - zung (overall rating)	Correlationlevel	1,000	,098
		p-value	.	,258
		N	137	135
	Glycozonehemoglobinvalue	Correlationlevel	,098	1,000
		p-value	,258	.
		N	135	146

Table **3** shows the results regarding patients' complications due to their disease. Specifically, only 3 patients reported having diabetic retinopathy, 2 patients erectile dysfunction, 1 patient diabetic nephropathy, 1 patient amputation, 9 patients diabetic neuropathy, and 1 patient another complication.

Table **4** shows the results regarding whether patients have conditions other than diabetes mellitus. The majority of them (111 patients - 74% and 102 patients - 68% respectively) suffered from hypertension and dyslipidemia, respectively. Below, the results are presented in detail.

Table 7. Differences between depression levels in terms of glycated hemoglobin.

-	Depression - Zung	N	Mean	p-value
Glycozonehemoglobinvalue	20-44 Normal values	114	68,81	0,787
	45-59 Mild depression	19	64,71	
	60-69 Moderate depression	2	53,00	
	Total	135	-	

Table 8. Differences between dieters and those who do not follow in terms of depression levels.

-	Type of Treatment - Diet	N	Mean	p-value
Depression – zung	Yes	78	62,57	0,029
	No	59	77,50	
	Total	137	-	

Table 9. Differences between patients taking insulin and those not in terms of depression levels.

-	Type of Treatment - Insulin	N	Mean	p-value
Depression – zung	Yes	37	79,91	0,05
	No	100	64,97	
	Total	137	-	

Table 10. Differences between patients with diabetic neuropathy and those withoutdepression levels.

-	Diabeticneuropathy	N	Mean	p-value
Depression – zung	Yes	8	104,25	0,010
	No	129	66,81	
	Total	137	-	

Table **5** shows the levels of depression. In particular, 116 patients showed a normal range, 19 patients showed mild depression and only 2 patients had moderate depression.

In the context of evaluating the correlation of depression with the value of glycated hemoglobin (Table **6**), the results did not show a statistically significant correlation between the two aforementioned variables (r=0.098, p=0.258>0.05).

The association of depression with glycated hemoglobin value was also examined in the context of depression levels (Table **7**). In particular, the results showed no statistically significant differences in glycated hemoglobin between patients with normal depression values, mild depression and moderate level of depression (p=0.787>0.05).

Further, regression analysis was performed to investigate if the level of glycated hemoglobin was a prognostic factor of depression. The results indicated that it was not (p=0,665).

Regarding patients' adherence to dietary instructions during the treatment process, dieters had lower levels of depression (62.57) compared to non-diet patients (77.50, p=0.029<0.05, Table **8**).

Regarding patients taking insulin as part of the treatment process, those taking it showed higher levels of depression (79.91) compared to patients not taking it (64.97, p=0.05, Table **9**).

Regarding the comorbidity (complications) of the patients in the sample, those who suffered from diabetic neuropathy presented higher levels of depression (104.25) compared to those patients who did not (66.81, p=0.010<0.05, Table **10**).

Regarding the effect of gender, there were no statistically significant differences between males and females (p=0,737>0,05) in depression levels.

4. DISCUSSION

The main findings of the present study indicate that in the evaluation of the association of depression with the value of glycosylated hemoglobin, no statistically significant correlation between the two variables mentioned above is observed. Those on a diet have lower levels of depression than those who do not follow a diet. Those with diabetic neuropathy experience higher levels of depression compared to those who do not suffer.

From the results of this study, we see that the majority of patients with T2DM do not show symptoms of depression. In addition, very few patients experience mild and moderate depression. In contrast to the findings of the present study, in a randomized controlled trial (RCT) by Katon *et al*. [21] in 164 diabetic patients in a collaborative care intervention *versus* 165 diabetic patients receiving usual care revealed that depressive symptoms assessed with the Hopkins Symptom Checklist 90 (SCL-90) persisted in 59.9% of the intervention group in

compared with 68.3% of the usual care group over the next 12-month period.

Fischer *et al*. [22] also conducted a longitudinal study on 508 patients with type 2 diabetes who were assessed three times over 18 months (baseline, 9 months and 18 months). Major depression—assessed by the CIDI—was present in 14.9% of patients at baseline and 19.8% at any point in the study.

Of the total 422 diabetic patients approached for another study, 397 provided complete responses (94% response rate). Of these, 37% had depression: 23% mild, 9% moderate, and 5% severe [23].

The relationship between diabetes mellitus and mental disorders is interdependent. The disease can trigger mental disorders while, in turn, depression can negatively affect the progression of the disease, through neuroendocrine and behavioral mechanisms [24]. In conclusion, depression is extremely persistent and/or recurrent in diabetes mellitus, even after successful initial treatment. Therefore, patients with a history of depressive episodes should be considered at high risk of relapse, especially under the influence of psychosocial pressures.

Also, the research findings showed that there is no correlation between the level of depression and glycated hemoglobin. In a recent meta-analysis, Lustman *et al*. [25] observed that depression was associated with hyperglycemia in T2DM patients, but unfortunately, the causal relationship remains unclear. In the same study [25], high glycated hemoglobin values in diabetic patients were found to be associated with reduced response to antidepressants and poor course of depression over the remaining 5 years. Hyperglycemia is responsible for the development of microangiopathy and macroangiopathy in diabetic patients with poor glucose regulation and may be a factor in the development of depression. In another study [26], the sample comprised 2886 participants aged 50 years who participated in three clinical assessments over an 8-year period (21% with prediabetes and 7% with diabetes at baseline). It was found that there was an association between depressive symptoms and HbA1c levels:

Additionally, we see that T2DM patients who follow a diet experience lower depression compared to those who do not. This finding is consistent with other research findings, showing a close relationship between dietary nutrition and mental health [27, 28]. A good physical condition and diet seem to contribute to a better well-being and quality of life of these patients [27, 28].

Regarding the effect of taking insulin on depression levels, it appears that patients taking insulin are more depressed. This finding is in contrast to other research findings, which demonstrate a positive correlation between insulin resistance and the occurrence of depressive symptoms [29]. It may be interpreted that this type of treatment is restrictive for these patients but on the other hand, it provides favorable health with less symptoms and better functioning [29].

Furthermore, it seems that comorbidity is a burden for T2DM patients as depression levels are rising. This particular finding is in line with other studies' findings, which demonstrated the strong correlation between these two variables..

In addition, the domain of quality of life has been recognized as of major importance in patients with chronic diseases, including diabetes mellitus.In addition to its intrinsic importance, the quality of life has also been linked to a number of unfavourable outcomes, making it a crucial outcome to take into account when assessing the objectives and efficacy of any treatment plan for the management of this disease.

Depression has been associated with significant impairment of quality of life in patients with diabetes mellitus. However, since the majority of studies that have been conducted are cross-sectional, a firm conclusion about causality cannot easily be drawn. Still, the relationship seems to be a two-way street.

Schram *et al*. [30] conducted a systematic review of the literature that included 20 studies. They conclude that quality of life (physical and mental) is significantly affected in diabetic patients with co-occurring depression, demonstrating mild to moderate impairment in studies that used general quality of life questionnaires and a moderate to severe impairment of quality of life in studies that used specific questionnaires for the disease. Although potential confounders, such as demographics or factors related to the disease and comorbidity, were assessed in only half of the studies, controlling for confounders did not significantly affect the association between depression and impaired quality of life.

Ali *et al*. [31] also conducted a systematic literature review, including 14 studies, and concluded that depression had a significant negative impact on the quality of life of patients with diabetes mellitus, even in studies controlling for potential confounding effects such as duration of diabetes, diabetic complications or medical comorbidity. This negative association was independent of the type of quality-of-life assessment tools (general or disease-specific). Specifically, despite the negative association of depression with overall quality of life, depression was not consistently associated with any specific quality of life domain across all studies reviewed.

Depression is a matter of great concern to patients with diabetes mellitus. It is not only prevalent but also highly persistent and recurrent, leading to a significant negative impact on both clinical outcomes and quality of life. In addition, impaired quality of life worsens clinical outcomes and increases mortality in diabetes mellitus [32]. Nevertheless, depression remains rather underdiagnosed and under-characterized.

Moreover, it does not seem that the variable of gender may affect depression in the present study. This finding is in line with the findings of other studies [33].

Overall, the findings of this study can be seen as useful at a theoretical and practical level. At a theoretical level, a model for mental health in diabetes mellitus can be proposed, indicating the effect of depression in this group of patients. On a practical level, the findings are useful to health professionals, physicians, psychologists, nurses, as well as health service administrators tasked with providing medical treatment to

diabetes sufferers. For example, it could be proposed to develop individualized psychotherapeutic interventions aimed at the psychological support of these patients, who report symptoms of depression and anxiety. Also, psychoeducational type interventions and health promotion programs could be developed, which focus on awareness and education on specific components of mental health, such as depressive elements, but also on strengthening patients' beliefs about their ability to have a decisive role in matters concerning their health. In addition, taking into account the findings of this study, as well as other related studies, it is proposed to create a research agenda focusing on psychological intervention and support for people suffering from diabetes, aiming to improve their quality of life.

CONCLUSION

Finally, regarding the limitations of the present research, it is noted that the patients of the study were a clinical sample, which was available (convenience sample). Therefore, it is not possible to generalize to the entire population of diabetic patients. The results obtained from the present study can be further investigated in samples from other nursing contexts, private or even in regional units, allowing the possibility of controlling the variables under study, and comparing the results so that more general conclusions can be drawn.

The limitations of the study include the lack of investigation of the effect of other clinical factors or even sociodemographic factors, such as age, educational level, marital status, *etc.*, or other clinical parameters regarding the patient's perceptions of quality life and his mental health.

Finally, other studies can be conducted in the future to analyze the relationship between depression and diabetes, as the main aim of this study was to investigate the effect of specific independent factors on the level of depression in this group of patients.

LIST OF ABBREVIATIONS

ZDRS	=	Zung depression rating scale
RCT	=	Randomized controlled trial
SCL-90	=	Symptom checklist 90

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This research study was approved by the institutional ethic committee of the participating hospital.

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All procedures performed in studies involving human participants were in accordance with the ethical standards of institutional and/or research committees and with the 1975 Declaration of Helsinki, as revised in 2013.

CONSENT FOR PUBLICATION

All research participants were informed in writing and verbally and signed a consent form.

AVAILABILITY OF DATA AND MATERIAL

All the data and supporting information are provided within the article.

STANDARDS OF REPORTING

STROBE guidelines were followed in this study.

CONFLICT OF INTEREST

The author declared no conflict of interest, financial or otherwise.

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