AJMAS
https://journal.utripoli.edu.ly/index.php/Alqalam/index eISSN 2707-7179

Original article

Prevalence of Subclinical Hypothyroidism in Patients with Type II Diabetes Mellitus and Its Impact on Patient's Lipidemic Status?

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ARTICLE INFO

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Received*: 01-06-2023*
Accepted*: 20-06-2023*
Published*: 22-06-2023*

Keywords*. Subclinical Hypothyroidism, Diabetes Mellitus, Dyslipidemia. Castelli's Risk Index.*

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ABSTRACT

Background and aims*. Diabetes mellitus (DM) is a chronic endocrine diseases characterized by raised blood glucose level. Current data predict that the DM prevalence will reach up to 11% of the world`s population in 10 years from now. Subclinical hypothyroidism (SCH) is a condition where the circulating thyroid-stimulating hormone is elevated and free thyroxine and free tri-iodothyronine are within normal. This condition is associated with hypercholesterolemia. Dyslipidemia is a lipid imbalance that can result in complications affecting the cardiovascular system in particular. A common cause of dyslipidemia is diabetes. The correlation between subclinical hypothyroidism and type II DM is controversial. The aim of the study was to investigate the association between SCH and type II DM, and if there is an impact of SCH on diabetic dyslipidemia.* ***Methods.*** *A case-control study conducted from January 2018 to January 2023 in Kerbala, Iraq. It included 176 patients with type II DM and 180 subjects as controls. The study was carried on after the approval of the ethical committee at Kerbala College of medicine.* ***Results.*** *SCH was more prevalent (18.18%) in the diabetic versus (2.22%) in the control groups, ($p<0.0001$, OR = 9.78, 95% CI [3.38 to 28.29]). Females had higher prevalence of SCH (68.1% vs 45.46%) and (1.67% vs 0.56%) for diabetic and control groups, respectively. Dyslipidemia was more prevalent in the diabetic group (45.46%) versus (8.33%) in control groups, ($p<0.0001$, OR = 9.17, 95% CI [4.99 to 16.08]).* ***Conclusion.*** *The prevalence of SCH was higher in type II DM and in females. The dyslipidemia was more pronounced in diabetics with SCH. The degree of lipid control correlated with the TSH level, duration of diabetes and the degree of glycemic control.*

Cite this article. *Khazaal M. Prevalence of Subclinical Hypothyroidism in Patients with Type II Diabetes Mellitus and Its Impact On Patient's Lipidemic Status?. Alq J Med App Sci. 2023;6(2):331-338. https://doi.org/10.5281/zenodo.8070537*

INTRODUCTION

Diabetes mellitus (DM) is a chronic endocrine disease the hallmark of which is the raised blood glucose level. Diabetes is associated with many complications such as retinal detachment, nephropathies, neuropathies, vasculopathies, and multi-organ damage [1]. The prevalence of DM is increasing worldwide owing to the increased obesity and the population`s life expectancy [2]. Current data predict that DM prevalence will reach up to 11% of the world`s population in 10 years from now. Hence, DM has established itself as an epidemic disease that will inflict burdens on healthcare systems [3].

Subclinical hypothyroidism (SCH) is an interesting thyroid condition where patients have a circulating thyroid-stimulating hormone (TSH) concentration that is higher than the reference range yet their free thyroxine (FT4) and free tri-iodothyronine (FT3) are within normal values [4]. Despite the fact that SCH is generally asymptomatic, however, there is a growing evidence that it is associated with other adverse clinical outcomes [5]. For instance, SCH has been

correlated with hypercholesterolemia, high blood pressure, abnormal levels of homocysteine, metabolic syndrome, adverse cardiac events, and increased fatality rate [6, 7].
Dyslipidemia is a condition that results from lipid imbalance which may be due to smoking, unhealthy diet, or genetic abnormality [8]. Dyslipidemia can result in complications affecting the cardiovascular system in particular [9]. One of the common causes of dyslipidemia is diabetes which tend to cause increased both triglycerides (TGs) and low density lipoprotein (LDL) and decreased high density lipoprotein (HDL) [10]. This deranged diabetic lipid profile, commonly referred to as diabetic dyslipidemia, increases the atherogenic risk in type II diabetic patients [11]. There are several parameters to measure dyslipidemia which are basically delivered from reviewing the patient`s lipid profile. The Castelli risk Index-I (CRI-I) is one of these parameters and it is regarded as an excellent tool for predicting coronary artery plaque formation in relation to the total plasma cholesterol level [12].
Several epidemiological studies had documented an increased prevalence of SCH in type I DM patients and the guidelines recommend annual screening of thyroid function in such patients [13-15]. On the other hand, overt hypothyroidism is more prevalent in those with type II DM. However, the correlation between SCH and type II DM is controversial. This study was conducted to investigate the prevalence of SCH in type II DM, and to find out if there was any additional impact of SCH on diabetic dyslipidemia.

METHODS

Study design and data collection

The study was of a case-control type conducted from January 2018 to January 2023. It included 176 patients with type II DM and 180 diabetic-free subjects of age and sex matched controls. All participants confirmed their consent and the study was carried on after the approval of the ethical committee at Kerbala College of medicine. Participants were enrolled from private clinics by simple random selection. The sample size was calculated after assuming that SCH is 14% prevalent, which was the highest round figure obtained from reviewing some meta-analytic studies [16-18]. The margin of error was set at 5% and the confidence interval at 95%. The included criteria were any type II DM patient with an age of $\geqslant$ 35 years. While the study excluded patients with any current thyroid illness, thyroidal surgical intervention, history of thyroid disease, or thyroid radiation. The study also excluded patients taking drugs that may affect TSH level like iodide, amiodarone, metyrapone, and steroids. Any patients on current lipid lowering drugs or been using them for the past year were excluded as well. Other exclusion criteria were other types of DM such as secondary, gestational, or type I DM, pregnancy, unstable cardiac disease, renal impairment (serum creatinine >1.5 mg/dl), liver cirrhosis, and malignancies.
The designation of patients with type II DM was based on the World`s Health Organization (WHO) criteria for diagnosing diabetes [19]. The patients were designated as having a SCH when the TSH was higher than 5 mIU/L, and the free T3 and T4 were within 100-200 ng/dl and 5-12 µg/dl, respectively [20].
Castelli`s risk index I (CRI-I) was calculated as follows (CRI = total cholesterol/ HDL), where both measured in mg/dl. The reference value for the CRI-I is ≤ 5 [21]. Any patient with CRI-I > 5 was designated as dyslipidemic.
For each participant, the following data were recorded: age, gender, body mass index (BMI), concomitant diseases, glycosylated hemoglobin (HbA1c), duration of diabetes, TSH, free T3, Free T4, serum creatinine, fasting lipid profile (total cholesterol, LDL, HDL, triglycerides), and liver enzymes (ALT, AST, and, ALP). The participants were divided into two groups: A). Diabetic group: included all the 176 diabetic patients. Their mean age was (47.38 ± 4.06) years and it involved 98 (55.6%) males. B). Control group: comprised all participants with no diabetes. It included 180 patients with a mean age of (40.77 ± 3.7) years. It included 91 (50.5%) males.
The biochemical analysis was done using calorimetric method in which DMA 850 (provided by TA Instruments, Delaware, United States) was used. The estimation of HbA1c was done using DCA Vantage® Analyzer provided by Pharmaforte Singapore Pte. Ltd.

Statistical analysis

Data analysis was conducted using version 20 of SPSS (SPSS Inc., Chicago, IL, USA). The categorical variables were examined using chi-square test whereas continuous variables were analyzed using independent sample *t*-test. The impact of different dependent variables was calculated using multivariate regression analysis. Tests for association were calculated using Pearson correlation tests. The level of significance (*p* value) was set at 0.05.

RESULTS

The results of comparing study parameters between both groups are tabulated in table (1). The SCH was more prevalent in the diabetic group 18.18% (32 cases out of 176) versus 2.22% (4 cases out of 180) in the controls, as shown in figure (1). There was a statistically significant difference in the odds of having SCH between the diabetics and controls groups

(p<0.0001, OR = 9.78, 95% CI [3.38 to 28.29]). Females' registered higher prevalence of SCH compared to males were it was (68.1% vs 45.46%) in the diabetic group and (1.67% vs 0.56%) in the control groups.

Table 1. The baseline characteristics of all participants. All results are expressed as mean ± SD unless mentioned otherwise, a p value of > 0.05 was taken as significant.

Parameter	*Unit*	*Diabetics (n=176)*	*Controls (n=180)*	*P value*
Age	*Years*	41.38 ± 4.06	40.77 ± 3.7	0.138
Males	*(n and %)*	98 (55.4%)	91 (50.5)	0.363
Body mass index (BMI)	*(kg/m^2)*	34.87 ± 6.5	35.27 ± 7.3	0.503
Duration of DM	*(years)*	8.2 ± 0.23	-	NA
HbA1c *	*(%)*	8.01 ± 0.83	3.98 ± 0.21	<0.0001
TSH *	*(ng/dl)*	9.47 ± 1.71	2.02 ± 1.1	<0.001
FT3	*(pg/dL)*	202.69 ± 19.8	198.43 ± 24.1	0.068
FT4	*(ng/dL)*	1.73 ± 0.43	1.68 ± 0.57	0.349
Total cholesterol (TC)*	*(mg/dL)*	230.87 ± 33.4	190.88 ± 25.14	<0.0001
HDL*	*(mg/dL)*	46.04 ± 10.4	54.42 ± 10.07	<0.001
CRI-I*	--	5.33 ± 1.62	3.64 ± 0.88	<0.001
Number of SCH cases*	*(n and %)*	32 (18.18%)	4 (2.22%)	<0.0001
- ***Males****	*(n and %)*	7 (3.98%)	1 (0.56%)	<0.0001
- ***Females****	*(n and %)*	25 (68.1%)	3 (1.67%)	<0.0001
Number of dyslipidemics*	*(n and %)*	80 (45.46%)	15 (8.33%)	<0.0001
- ***Males****	*(n and %)*	56 (31.81%)	9 (5%)	<0.0001
- ***Females****	*(n and %)*	34 (19.31%)	6 (3.33%)	<0.0001
LDL*	*(mg/dL)*	136.3 ± 29.4	112.4 ± 33.2	<0.001
Triglycerides (TGs) *	*(mg/dL)*	133.59 ± 67.1	98.85 ± 50.3	<0.001
S. creatinine	*(mg/dL)*	0.9 ± 0.1	0.87 ± 0.09	0.008
ALT	*(U/L)*	32.6 ± 7.1	33.2 ± 5.12	0.37
AST	*(U/L)*	18.12 ± 3.1	17.89 ± 2.3	0.428
ALP	*(U/L)*	91.23 ± 12.6	88.47 ± 13.2	0.044
Hypertensives	*(n and %)*	48 (27.28%)	52 (28.89%)	0.587
Smokers	*(n)*	99 (56.25%)	103 (57.22%)	0.871

** Significant statistical difference.*

DM = diabetes mellitus, HbA1c = glycosylated hemoglobin, FT3 and FT4 = free thyronin and thyroxine, respectively, HDL=high density lipoprotein, CRI-I = Castelli`s risk index-I, LDL = low density lipoprotein, ALT = alanine transaminase, AST = aspartate transaminase, ALP = alkaline phosphatase, (n) = number, NA =not applicable.

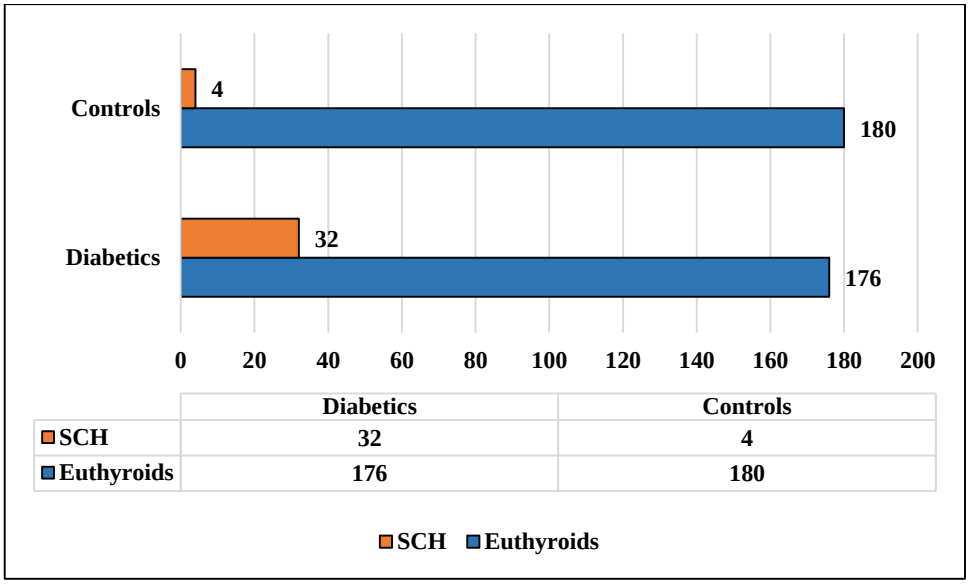

Figure 1. The prevalence of SCH in diabetic and control groups. The SCH was significantly higher among diabetic patients when compared to controls (p<0.0001). SCH= subclinical hypothyroidism.

As depicted in figure (2), the dyslipidemia was more prevalent in the diabetic group 45.46 % versus 8.33 % in the diabetic and control groups, respectively. There was significant statistical difference in the odds of having dyslipidemia between both groups (p<0.0001, OR = 9.17, 95% CI [4.99 to 16.08]). The dyslipidemia was more prevalent in males of both groups, (31.81% vs. 19.31%) for the diabetic group and (5% vs 3.33%) for the controls.

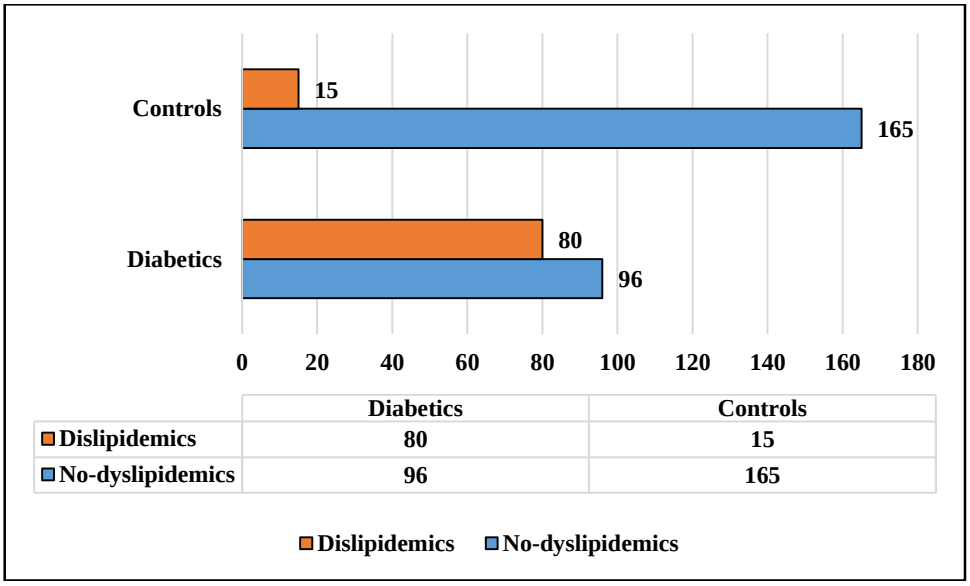

Figure 2. The prevalence of dyslipidemia in diabetic and control groups. The dyslipidemia was significantly higher among diabetic patients when compared to controls (p<0.0001).

The diabetic patients were furtherly subdivided, based upon their CRI-I, into non-dyslipidemic group with a CRI-I of ⩽ 5, and a dyslipidemic group with CRI-I of > 5. Table (2) shows the results of comparison of different study parameters between the aforementioned groups.

Table 2. The results of comparing various study parameters among the diabetic patients themselves based upon their dyslipidemic status.

Parameter	*Unit*	*Diabetics (n=176)*		*P value*
		Non-dyslipidemics i.e. CRI <5 (n=114)	*Dyslipidemics CRI ≥5 (n=62)*	
Age	*Years*	36.47 ± 7.55	40.17 ± 5.97	0.138
Males	*(n and %)*	61 (53.5%)	29 (46.77%)	NA
BMI	*(kg/m^2)*	38.6 ± 3.47	39.7 ± 4.77	0.134
Duration of DM *	*(years)*	6.7 ± 2.33	7.5 ± 3.13	<0.001
HbA1c *	*(%)*	5.13 ± 2.17	7.44 ± 2.89	<0.0001
TSH *	*(ng/dl)*	4.89 ± 2.56	9.13 ± 2.44	<0.0001
FT3	*(pg/dL)*	173.45 ± 42.18	179.88 ± 47.4	0.459
FT4	*(ng/dL)*	1.32 ± 0.63	1.51 ± 0.71	0.543
S. creatinine *	*(mg/dL)*	1.12 ± 0.21	1.81 ± 0.3	<0.001
ALT	*(U/L)*	32.58 ± 6.31	31.44 ± 7.04	0.273
AST	*(U/L)*	29.11 ± 5.21	27.84 ± 4.33	0.104
ALP **	*(U/L)*	77.74 ± 9.66	74.89 ± 7.34	0.044
Hypertensives	*(n and %)*	37 (32.48%)	24 (38.7%)	0.264
Smokers	*(n and %)*	28 (24.56%)	20 (32.26%)	0.082

** Significant statistical difference. ** Marginal statistical difference. All results are expressed as mean ± SD unless mentioned otherwise, a p value of > 0.05 was taken as significant. Note: the following parameters were omitted from the comparison: total cholesterol (TC), high density lipoprotein (HDL), low density lipoprotein (LDL), and triglycerides (TGs).*

The results revealed that non-dyslipidemic diabetics had relatively better glycemic control where their HbA1c level was significantly lower with a value of (5.13 ± 2.26 %) compared to (9.13 ± 2.44%) in the dyslipidemics (p<0.0001). At the same time, the TSH level was significantly higher in the diabetics with dyslipidemia, (p<0.0001). The TSH was 9.13 ±

2.44 ng/dl and 4.89 ± 2.56 ng/dl in the dyslipidemic and non-dyslipidemic diabetics, respectively. Likewise, the duration of diabetes was significantly longer in dyslipidemic patients in comparison to non-dyslipidemics (p<0.0001), (6.7 ± 2.33 years versus 7.5 ± 3.13 years, respectively).

Table 3. Multinomial regression analysis for factors predicting diabetic dyslipidemia in diabetic patients with SCH. The parameters were arranged in descending order based upon the odd ratios obtained after analysis.

Parameter	*Odd ratio*	*Confidence interval*	*P value*
TSH level	3.8	2.78-6.46	<0.0001
Degree of diabetic control (HbA1c)	2.9	2.01-5.66	<0.001
Diabetic duration	2.2	1.88-4.67	<0.001
S. creatinine	1.8	1.02-3.6	<0.008
ALP	0.94	0.78-1.69	<0.041

The results of multinomial regression analysis, as revealed in table (3), showed that the dyslipidemia could be predicted by the TSH level, degree of glycemic control, and the duration of the type II DM. The aforementioned factors added a significant increase in the statistical model predicting likelihood of developing dyslipidemia. The presence of SCH yielded an odd ratio of 3.8 (2.78-6.46) with significance (p<0.0001), followed by the level of glycemic control, as indicated by the HbA1c, where it ended up registering an odd ratio of 2.9 (2.01-5.66) with significance (p<0.001). Finally, the duration of diabetes added significant increase to the probability of having dyslipidemic status (p<0.001), with an odd ratio of 2.2 (1.88-4.67). The factors with the least impact on dyslipidemia were the serum creatinine and ALP levels.

DISCUSSION

The prevalence of SCH among patients with type II diabetes was estimated by this study to be around 18%. This figure was consistent with those reported by other studies. For instance, Zhang *et al.* reported a figure of 18.86% [22]. Another study made by Wang *et al.* reported a prevalence of 17.31% [23]. However, the results of the current study are not compatible with some other studies that reported different prevalence rates. For example, some studies reported a lower prevalence rates of 6.9% [24] and 6.16% [25] whereas others recorded higher rate of as high as 29.8% [26]. The contradiction in the reported values of SCH among type II diabetics by different studies might be attributable to the different methodologies, different sample sizes, different means of age, and the selection criteria of patients. It is documented that hypothyroidism and diabetes frequently coexist, it's possible that this link is not haphazard. The increased prevalence of SCH in this study might be explained by the fact that SCH establishes itself as a prerequisite for the development of frank hypothyroidism, if proper treatment is not initiated [27]. There has been some debate about the relationship between subclinical thyroid malfunction and insulin resistance. Patients with subclinical thyroid dysfunction had higher levels of insulin resistance as indicated by the higher HbA1C level and hyperinsulinemia [15]. The current study revealed that females had higher prevalence of SCH compared to males, (68.1% vs 45.46%) and (1.67% vs 0.56%) for diabetic and control groups, respectively. These findings are consistent with those reported by other studies [28, 29]. This is probably attributed to the fact that thyroid dysfunction has a gender predilection for females in general [30].

There was a substantial link between SCH and dyslipidemia. Dyslipidemia was more prevalent in SCH diabetics compared to euthyroid diabetics, and both, the CRI-I and total cholesterol were considerably greater in SCH diabetics. On the other hand, the HDL levels were substantially lower in diabetics with SCH. These conclusions are consistent with the findings of Hussein *et al.*, who discovered an increase in total cholesterol levels in SCH patients compared to the control group [31]. A further investigation, carried out by Ejaz *et al.*, found that both, total serum cholesterol and LDL levels in patients with SCH were considerably greater than control group [32]. The results are consistent with a meta-analytic study reported by Liu, *et al.*, the results of which reported an increased incidence of dyslipidemia in diabetics with SCH [33]. Another study finalized with correlating an increased levels of TC besides reduced HDL in patients with SCH and diabetes [32]. The abnormal lipid profile in diabetes may be attributed to increased body fat or poor control of diabetes, or even both [11]. In both conditions, there may be an increased free fatty acids level, resulting in an increased production of very-low-density lipoprotein (VLDL) by the liver. The elevated VLDL will enhance the production of TGs and LDL [34]. Another possible explanation is that in SCH, the ApoB levels may increase alongside the oxidizability of LDL, the size of lipid subparticles, and triglycerides level and this may in part explains the higher incidence of dyslipidemia [35]. However, researches has been inconclusive were some of them concluded that HDL and Lp(a) levels in SCH individuals are not affected [35, 36]. On the other hand, many researches have failed to demonstrate

the association between SCH and dyslipidemia, and this contradicts our findings [37, 38]. In fact, a study discovered that it was only the serum triglycerides levels to be greater in SCH patients' lipid profiles when compared to the control group. Subclinical hypothyroidism has a non-apparent influence on blood lipid levels.
From the statistical point of view, the study revealed several factors that can influence the incidence of dyslipidemia among type II diabetics when compared to euthyroid diabetics, these namely were: TSH level, degree of glycemic control, duration of the type II DM, serum LDL and ALP levels. The TSH level had the higher correlation with dyslipidemia, a result that is compatible with that reported by others [39, 40].

CONCLUSION

The prevalence of SCH was higher in patients with type II DM compared to the general population. The prevalence of SCH was also higher in females compared to males. The dyslipidemia was more pronounced in diabetics with SCH and can be regarded as a condition of atherogenicity since it increases cholesterol level. The degree of lipid control was correlating with the duration of diabetes and the degree of glycemic control.

Recommendations

The study suggests engaging patients with type II DM with screening programs for the early detection of dyslipidemia as the latter is the prime perpetuator for developing cardiovascular diseases. Also, the study suggests that diabetics with SCH should be scrutinized early and vigorously for dyslipidemia as they are at higher risk.

Conflict of interests

The author declares that there are no financial, personal, or professional conflicts of interest.

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AJMAS
https://journal.utripoli.edu.ly/index.php/Alqalam/index eISSN 2707-7179

مدى انتشار قصور الغدة الدرقية تحت الإكلينيكي لدى مرضى السكري من النوع الثاني وأثره على حالة المريض الدهنية؟

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المستخلص

الخلفية والأهداف. مرض السكري (DM) هو أحد أمراض الغدد الصماء المزمنة التي تتميز بارتفاع مستوى السكر في الدم. تتنبأ البيانات الحالية بأن انتشار DM سوف يصل إلى 11٪ من سكان العالم في غضون 10 سنوات من الآن. قصور الغدة الدرقية تحت الإكلينيكي (SCH) هو حالة يرتفع فيها هرمون الغدة الدرقية المنتشر ويكون هرمون الغدة الدرقية الحر وثلاثي يودوثيرونين الحر ضمن المعدل الطبيعي. ترتبط هذه الحالة بفرط كوليسترول الدم. عسر شحميات الدم هو خلل في الدهون يمكن أن يؤدي إلى مضاعفات تؤثر على نظام القلب والأوعية الدموية على وجه الخصوص. السبب الشائع لخلل شحميات الدم هو مرض السكري. العلاقة بين قصور الغدة الدرقية تحت الإكلينيكي والنوع الثاني DMمثير للجدل. كان الهدف من الدراسة هو التحقق من الارتباط بين SCH والنوع II DM ، وما إذا كان هناك تأثير لـ SCH على اضطراب شحميات الدم السكري. **طُرق الدراسة**. دراسة الحالات والشواهد التي أجريت في الفترة من كانون الثاني (يناير) 2018 إلى كانون الثاني (يناير) 2023 في كربلاء ، العراق. وشملت 176 مريضا من النوع الثاني DM و 180 شخصا كعناصر تحكم. تمت الدراسة بعد موافقة لجنة الأخلاقيات في كلية الطب بكربلاء. **النتائج**. كان SCH أكثر انتشارًا (18.18٪) في مرضى السكري مقابل (2.22٪) في مجموعات التحكم ، p <0.0001) ، OR = 9.78 ، 95٪ CI [3.38 إلى 28.29 .([كان لدى الإناث انتشار أعلى لمرض السكري (68.1٪ مقابل 45.46٪) و (1.67٪ مقابل 0.56٪) لمجموعتي السكري والسيطرة على التوالي. كان عسر شحميات الدم أكثر انتشارًا في مجموعة مرضى السكري (45.46٪) مقابل (8.33٪) في مجموعات التحكم ، p <0.0001) ، OR = 9.17 ، 95٪ CI [4.99 إلى 16.08 .الخاتمة. كان انتشار SCH أعلى في النوع الثاني DM وفي الإناث. كان عسر شحميات الدم أكثر وضوحا في مرضى السكر مع .SCH ترتبط درجة التحكم في الدهون بمستوى TSH ومدة مرض السكري ودرجة التحكم في نسبة السكر في الدم.

الكلمات الدالة. قصور الغدة الدرقية تحت الإكلينيكي ، داء السكري ، عسر شحميات الدم. مؤشر مخاطر كاستيلي.