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Evaluation of Thyroid Stimulating Hormone and Free Thyroxine among Diabetes Mellitus Patients at Shendi Locality, Sudan

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: Diabetes Mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Thyroid disease is found commonly in most forms of diabetes and is associated with advanced age, particularly in type 2 diabetes and underlying autoimmune disease in type 1 diabetes.

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Objective: This study aims to evaluate TSH and Free T4 among Diabetes Mellitus Patients in the Shendi locality, from August to December 2021.
Methodology: The present study was a case-control study. Conducted in the Shendi locality, from August to November 2021. Convenience sampling technique was used to include a total of 50 participants in this study of which 30 Sudanese patients with diabetes mellitus were enrolled as cases group and 20 healthy Sudanese were enrolled as control group. Blood samples were collected from each subject and estimated for the level of thyroid stimulating hormone (TSH) and free T4 (FT4) using the 360 Automated Immunoassay Analyzer (TOSOH). And the results were analyzed using the computer program SPSS (Social Science Statistical Package).
Results: The result of this study showed that the mean concentration of TSH and Free T4 level in the diabetic subjects was (Mean ± SD): (1.6 ± 0.99) (13.5 ± 2.3) and control (2.0 ± 0.81) (12.5 ± 2.0) respectively with *P. value* =0.148, 0.124 which is insignificant. Also showed the mean concentration of TSH and FT4 according to gender is (1.6, 14.7) respectively for males (1.7, 12.7), and a female with *P. value* (0.718 for TSH which is insignificant) and (0.016 of Free T4 which is significant). Diabetes has an insignificant association with TSH and Free T4 levels, with P values (0.417, 0.277). Furthermore, there is a significant relationship between the presence of hypertension and the levels of TSH and FreeT4 with P. value (0.043, 0.018).
Conclusion: There is no statistical difference between TSH and FT4 levels between cases and controls. There was a ssocition between FT4 levels and gender, with FT4 being higher in females than in males. FT4 is significantly elevated in patients with a family history of diabetes. No significant difference in FT4 levels by age.

Keywords: Diabetes mellitus; thyroid stimulating hormone; free thyroxine; thyroid hormones.

1. INTRODUCTION

The term diabetes is derived from the Greek word [Dia; pass through and betes; to go]. Diabetes mellitus (DM) is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion or increased cellular resistance to insulin [1]. Diabetes mellitus is broadly classified into two main types; Type I diabetes mellitus: which is also known as immune-mediated diabetes, insulin-dependent diabetes, or juvenile-mediated diabetes. It accounts for 5-10% of diabetes mellitus and results due to autoimmune destruction of pancreatic B-cells. Type II diabetes mellitus: It is also known as non-insulin-dependent diabetes or adult-onset diabetes. It accounts for 90-95% of diabetes mellitus and occurs because of insulin resistance and progressive insulin deficiency [2]. The estimated prevalence of DM in Africa in 2017 was 3.3%, and Sudan was among the countries that had a prevalence of DM of more than 12%. The prevalence and incidence of DM in Sudan, as in many other low-income countries, are increasing to epidemic proportions, leading to the emergence of a public health problem of major socioeconomic impact [3]. Diabetes Mellitus in Sudan is associated with poor glycemic control, a high prevalence of complications, a low quality of life, and particularly with morbidity. Patients with a median duration of diabetes of 9 years showed a high prevalence of micro and macro vascular complications [4]. The thyroid, the largest endocrine organ located in the neck region, consists of two right and left lateral lobes associated with a narrow band of the thyroid tissue called Isthmus, it weighs about 25-30gr and is usually larger in men than women [5]. And stores many inactive hormones within extracellular follicles [6,7]. These hormones play a vital role in the regulation of glucose metabolism, and hepatic lipid cholesterol and mediate important physiological processes like growth and development [8]. On the other hand, thyroid diseases had also become common among the general population affecting 750 million people worldwide according to the data provided by the World health organization [9].

Thyroid hormones are produced by a butterfly-shaped thyroid gland located in the lower anterior neck [10]. Thyroxine (T4) is the primary hormone secreted by the thyroid gland which is relatively inactive and is converted to the highly active form triiodothyronine (T3) by the enzyme thyroxine 5-deiodinase [11]. Thyroid-stimulating hormone (TSH; thyrotropin) and TSH receptor (TSHR) are key proteins in the control of thyroid function. TSH synthesis in the anterior pituitary is stimulated by thyrotropin-releasing hormone (TRH) and inhibited by thyroid hormone in a classical endocrine negative-feedback loop [12]. The thyroid hormones are insulin antagonists and influence the action of insulin indirectly which could be responsible for the occurrences of low

thyroid hormone levels in diabetic Mellitus patients [13]. Insulin, an anabolic hormone has been found to enhance the levels of FT4 and suppresses the levels of FT3 by inhibiting the hepatic conversion of T4 to T3. Therefore, this may be the reason for low FT3 in type 2 diabetes mellitus patients. Diabetes mellitus influences thyroid functions mainly at two sites; first, at the level of hypothalamic control of thyroid-stimulating hormone release, and second, at the conversion of T4 to T3 in the peripheral tissue [14].

Different prevalence rates of thyroid hormone disorders in type 2 diabetes have been reported by various studies. Diabetes patients have a higher prevalence of thyroid disorders than the general population, with hypothyroidism being the most common disorder. Iodine deficiency is the main cause of hypothyroidism in regions where goiter is common. The prevalence rates of thyroid dysfunction in diabetes are still debatable because there are regional variations in the prevalence rates of hypo- or hyperthyroidism. Undiagnosed thyroid dysfunction may change how diabetic patients regulate their metabolism and increase their already high cardiovascular risk. Diabetes patients with thyroid disorders may experience better glycemic control, reduced cardiovascular risk, and overall improved health if they are identified and treated [13,14].

Only few data are available about subject understudy. In light of this, we set out to conduct a study to check for thyroid dysfunction in diabetic patients.

2. MATERIALS AND METHODS

2.1 Study Setting and Population

The present study was a case-control study. Conducted in the Shendi locality, from August to November 2021, the study included Sudanese diabetes mellitus patients as a case group and healthy individuals as a control group. Anon probability sampling technique was used to include a total of 50 study participant of which 30 Sudanese patients with diabetes mellitus were enrolled as case group and 20 healthy Sudanese were enrolled as control group.

2.2 Inclusion and Exclusion Criteria

The American Diabetes Association's criteria were used to determine a person's diabetes status. To gather participants for the study, consecutive sampling was used. The study included all newly diagnosed type 2 DM patients who visited a hospital during that time period and who met the inclusion criteria. Controls are apparently healthy and matched the cases in the sociodemographic feature. Exclusion criteria for the study included those with chronic inflammatory illnesses and infections, liver, kidney, heart, ascites, abdominal hernias, tumors, complications of diabetes, a history of thyroid disorders, and women who were pregnant.

2.3 Sample Collection and Processing for the TSH and FT4 level

Venous blood was collected using a sterile, single-use plastic syringe, the venipuncture site was washed with 70% ethanol, and the blood was placed in a heparin container and mixed gently. Each sample was centrifuged at 4000 (rpm) for 5 minutes to separate the plasma and stored at -20°C until analysis. TSH and Free T4 were estimated using specific kits according to the manufacturer instructions through Automated Immune assay Analyzer 360 (TOSOH). The precision and accuracy of the method used in this study were checked and analyzed by commercially prepared control sera.

2.4 Data Collection and Statistical Analysis

Questionnaire was used to collect data from cases including demographic data and clinical data including presence of hypertension, history of diabetes and diabetes control status. Data were analyzed by using the SPSS computer program. The means and standard deviations of serum levels of TSH, and free T4 were detected, and t-test was used for comparison (*P. value* of < 0.05 is significant).

3. RESULTS

The results of this study revealed that the mean concentration of TSH and Free T4 level ng/dl in diabetic subjects was (Mean SD): (1.6 0.99) (13.5 2.3) and control (2.0 0.81) (12.5 2.0), respectively, with P. value =0.148, 0.124. (Table 1-2). The mean concentration of TSH and FT4 ng/dl according to gender level was also (1.6, 14.7) for males (1.7, 12.7) and females (1.6, 14.7) with a P. value (of 0.718 TSH, which is insignificant) and (0.016 of Free T4, which is significant) (Table 3). Among cases group there was insignificant difference between age groups

in the level of TSH (P-value 0.456) while cases with 41-50 years have significant higher mean of FT4 14.8 ng/dl compared to the other groups with P-value of 0.035 (Table 4). TSH and Free T4 levels have an insignificant association with P. value (0.417, 0.277), respectively (Table 5). Furthermore, the presence of hypertension was associated with a significant increase in TSH and FreeT4 levels with a P value of (0.043, 0.018). (Table 6). In addition, there is a significant association of history of diabetes with Free T4 level with P. value (0.018), but not with TSH level with P. value (0.773). (Table 7). It was also discovered that the mean concentration of TSH and Free T4 with diabetes treatment intake was insignificant (Table 8).

Table 1. The mean of TSH levels and St.d between case and control

Variables	No	Mean ng\dl	St.d	P. value
Case	30	1.6	0.99	0.148
Control	20	2.0	0.81	

Table 2. The Mean of FT4 levels and St.d between case and control

Variables	No	Mean ng\dl	St.d	P.value
Case	30	13.5	2.3	0.124
Control	20	12.5	2.0	

Table 3. The concentration of TSH and FT4 according to gender among case group

Gender	Frequency	Percent %	Mean of TSH ng\dl	Mean of FT4 ng\dl
Male	12	40%	1.6	14.7
Female	18	60%	1.7	12.7
P. value			0.718	0.016

Table 4. The concentration of TSH and FT4 according to age among case group

Age	No	Mean of TSH ng\dl	Mean of FT4 ng\dl
30-40	2	2.5	13.8
41-50	12	1.6	14.8
51-60	16	1.6	12.6
P. value		0.456	0.035

Table 5. The concentration of TSH and FT4 according to type of diabetic mellitus among case group

Type of diabetic mellitus	Mean of TSH ng\dl	Mean of FT4 ng\dl
Type1	1.9	12.8
Type2	1.5	13.8
P. value	0.417	0.277

Table 6. The concentration of TSH and FT4 according to presence of hypertension among case group

Hypertension	Mean of TSH ng\dl	Mean of FT4 ng\dl
Yes	2.1	12.7
No	1.4	13.9
P. value	0.043	0.018

Table 7. The concentration of TSH and FT4 according to history of diabetes among case group

History of D.M	Mean of TSH ng\dl	Mean of FT4 ng\dl
Yes	1.7	14.0
No	1.5	11.6
P. value	0.773	0.018

Table 8. The concentration of TSH and FT4 according to uses of medication of D.M among case group

Treatment of D.M	Mean of TSH ng\dl	Mean of FT4 ng\dl
Regular	1.8	13.5
Irregular	1.2	13.6
P. value	0.213	0.902

4. DISCUSSION

Diabetes mellitus and thyroid abnormalities are the two most prevalent endocrine diseases [15,16]. The results of this study showed that there was no significant difference in TSH and FT4 levels between diabetic and non-diabetic subjects (*P. value* = 0.148 and 0.124, respectively). This result is in agreement with the result obtained by Islam and her colleague in South East Asia (2008), who denoted that there is no significant statistical difference in TSH and FT4 levels among diabetic and non-diabetic participants [17]. This result was opposed to a study carried out by Panneerselvam and his collage in 2015, they showed that serum levels of FT4 were significantly lower in diabetic subjects as compared to the non-diabetic subjects while serum level of TSH was found to be significantly higher in type 2 diabetes mellitus patients as compared to normal individuals [13]. The variation in the results may be related to the difference in the geographical area or environmental difference between countries. Also, there is a correlation between FT4 level and gender, the level of FT4 increased in males (Mean =14.7) than in females (Mean=12.7) with a statistically significant difference between them (*P. value* =0.016) this result consensus with Kaur I and his team's 2017, said that hypothyroidism is frequently observed and most commonly seen in female patients [5]. Although there are statistically insignificant differences between the level of TSH and the gender (*P.value*= 0.718) and this was infringing with a study carried out by Uppal Vand and his classmates Said Hypothyroidism was more common in females (15%) than in males (4%) [18]. these differences belong to Thyroid hormone levels may be altered by various medications that diabetic subjects used to take and determine the change in body composition. Moreover, there was a statistically significant difference in FT4 according to age (*P. value*=0.035) and this is agreed by SU Ogbonna 2010 and his colleague were show that T2DM increases were prevalent with age. Also, there are no differences in age in TSH between diabetic patients with (*P. value*=0.456) this disagree with the study carried out by Khalid S Aljabri who said there was a statistically non-significant difference between thyroid dysfunctions in males compared to females (P<0.0001) [19]. This might be due to the sociodemographic and lifestyle differences in the represented populations. Also this study show, there is no variation among type one diabetic and type two in the level of TSH, and FT4 with insignificant value (*P. value*= 0.456)(*P. value* = 0.277) respectively this result differs from the study conducted by Mirella Hage, and his team It has been shown that thyroid dysfunctions are more prevalent in people with diabetes and particularly type 1 diabetes this belong to social status or the genetic factor of the population who shared in the study [20]. The findings of the study indicated that there is a significant statistical variation of diabetic people who have hypertension disease with (P. value =0.043) of TSH and (P. value =0.014) of FT4, which is similar to the findings of Pradeep Talwalkar and colleagues in India 2019, who reported a high prevalence of hypothyroidism in patients with T2DM (24.8%), hypertension (33.5%), and T2DM + hypertension (28.9%) [21]. on another hand, there is a significant difference between the history of diabetes in FT4 with (*P. value*= 0.018) and no difference in TSH level. There was no different statistical study in patients who intake diabetes treatment in the level of TSH and FT4 with insignificant value (P. value= 0.213), (0.902), and this is not accepted with a study conducted in Iraq in 2019 by Khalid Ibrahim Al-Lehibi and his college were accessed to metformin has a significant TSH lowering effect in hypothyroid patients. This variation in outcome is most likely due to variations in physical activity or nutrition status [22].

5. CONCLUSION

There is no statistical difference between TSH and FT4 levels between cases and controls. There was a correlation between FT4 levels and gender, with FT4 being higher in females than in males. FT4 is significantly elevated in patients with a family history of diabetes. No significant difference in her FT4 levels by age.

CONSENT AND ETHICAL APPROVAL

The written informed consent form was obtained from each participant before recruitment into the study. Ethical approval for the study was obtained from the Board of the Faculty of Graduates Studies at Shendi University. All protocols in this study were done according to the Declaration of Helsinki (1964).

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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