The Prevalence of Thyroid disfunction in patients with type 2 diabetes mellitus

Project Proposal Submitted to Midnapore City College
for the Partial Fulfillment of the Degree of
Master of Science (MMLT)

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2023

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Ref. No.: MCC/DIR-CER(PG)/07/23-8270

Date: 13.07.2023

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Declaration

I do hereby declare that the present Master thesis entitled "**The Prevalence of Thyroid disfunction in patients with type 2 diabetes mellitus**" embodies the original research work carried out by me in the Department of Biological Sciences, Midnapore City College, Paschim Medinipur, West Bengal, India under the supervision of Mr. Surya Kanta Dey, Assistant Professor, Department of Paramedical & Allied Health Sciences, Midnapore City College. Whenever I have used materials (data, theoretical analysis, and text) from other sources, I have given due credit to them by citing them in the text of the thesis and giving their details in the references. I have followed the guidelines provided by the Institute in writing the thesis. I further declare that the results of this work have not been previously submitted for any other degree or Diploma or fellowship.

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Dedicated to my Parents and Teachers

Acknowledgement

I would first like to acknowledge Dr. Pradip Ghosh, Hon'ble Founder Director, Midnapore City College, Paschim Medinipur for providing me the opportunity to study and complete my thesis work in this college. I am gratefully indebted to him for his very valuable comments on this thesis.

I would like to thank my thesis advisor Mr. Surya Kanta Dey of the Paramedical and Allied Health Science Department. The door to Mr. Surya Kanta Dey office was always open whenever I ran into a trouble spot or had a question about my research or writing. He consistently allowed this paper to be my own work, but steered me in the right the direction whenever he thought I needed it.

I would also like to thank the other faculties Dr. Kuntal Ghosh, Mrs. Monalisha Karmakar, Dr. Santanu Kar Mahapatra, Mrs. Shilpa Sharkhel and Mr. Sourya Sekhar Mitra and non-teaching staffs Mr. Pintu Manik, Mr. Pathik Laha and Mr. Nimay Chandra Maji for their support to carry out this research project. Without their passionate participation and input, the validation survey could not have been successfully conducted.

Finally, I must express my very profound gratitude to my parents for providing me with unfailing support and continuous encouragement throughout my years of study and through the process of researching and writing this thesis. This accomplishment would not have been possible without them. Thank you.

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Abstract

There is increasing evidence that sex and gender differences influence the epidemiology, pathophysiology, treatment, and outcomes of many diseases, including type 2 diabetes (T2DM). The sexual dimorphism of androgens in the pathophysiology of T2DM suggests that there are inequalities in both the preventive strategies and treatment between women and men. on the other hand, Thyroid disorders have increased recently and are considered the commonest endocrine diseases. a number of studies have estimated the prevalence of thyroid dysfunction among diabetes patients to be varying from 2.2 to 17 %, However, fewer studies have estimated a much higher prevalence of thyroid dysfunction in diabetes. The study aimed to evaluate The Prevalence of Thyroid disfunction in Patients with type 2 diabetes Mellitus. Total thirty subject including male and female were selected for the study and their serum free T3, T4, TSH hormones, glycated hemoglobin (HbA1c) and serum creatine were analyzed. Results showed that the level of FT3 and FT4 were significantly decreased compared to control (non-diabetic). However, the TSH level in type 2 diabetic patients was significantly ($p<0.001$) increased to 4.53 mIU/L compared to control. HbA1c and creatinine levels of type 2 diabetic patients were found significantly increased compared to control. The Pearson correlation was established to analyze the correlation between T3, T4, and TSH with HbA1c and creatinine. Results suggested a positive correlation between T3 and T4 with creatinine but a negative correlation was observed between T3 and T4 with HbA1c. On the other hand, a positive correlation between serum TSH with glycated hemoglobin (HbA1c) and serum creatinine was observed. The finding suggested that in type 2 diabetes, serum thyroxine level was decreased and serum TSH level was increased. This may produce hypothyroidism which were correlated with increased level of serum creatinine leading to chronic kidney disease (CKD). Failure to recognize the presence of abnormal thyroid function may be a primary cause of poor management of diabetes mellitus. Therefore, there is a need for the routine assay of thyroid hormones in type 2 diabetics in order to improve the quality of life and reduce morbidity.

Keywords: Type 2 diabetes mellitus (T2DM), Thyroid disfunction, hypothyroidism

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Chapter 1: Introduction

Introduction

Diabetes mellitus (DM) is a chronic disease with rapidly increasing prevalence worldwide. Hyperglycemia in DM injures many organs, such as the circulatory organ, kidneys, and nerves. Gastrointestinal (GI) motility is also affected by hyperglycemia in DM. The most common GI disorder in DM is gastroparesis, which is a chronic condition characterized by delayed gastric emptying (GE) without mechanical obstruction. (Camilleri et al., 2011; Kishi et al., 2019)

Role of Thyroid in Diabetes mellitus

Thyroid diseases and diabetes mellitus are the two most common endocrine disorders encountered in clinical practice. Diabetes and thyroid disorders have been shown to mutually influence each other and associations between both conditions have long been reported. On one hand, thyroid hormones contribute to the regulation of carbohydrate metabolism and pancreatic function, and on the other hand, diabetes affects thyroid function tests to variable extents. (Feely and Isles, 1979; Gray et al., 1979; Hage et al., 2011).

Diabetes mellitus (DM) is a very common disease with a global prevalence rate of 8.5% in adult subjects, most of which are type 2 DM (T2D) (Shi et al., 2018; Song et al., 2017; Zhao et al., 2018) Hyperthyroidism (thyroid hormone excess) may affect the secretion, action, and clearance of insulin and many aspects of carbohydrate metabolism and thus lead to hyperglycemia. (Dimitriadis et al., 1985; Maratou et al., 2010). On the contrary, hypothyroidism (thyroid hormone deficiency) may also interfere with the action and metabolism of insulin and induce insulin resistance. Both hyperthyroidism and hypothyroidism are also common clinical disorders with similar prevalence rates of around 0.5% to 2% (Vanderpump, 2011). The thyroid hormone can modulate carbohydrate metabolism; thus, in theory, thyroid dysfunctions may influence the development of DM. However, there is a lack of studies on the influence of thyroid dysfunctions on T2D occurrence, and existing studies are inconsistent (Ashrafuzzamam et al., 2012; Chaker et al., 2016). It is therefore necessary to further investigate the development of T2D after the presentation of both hyperthyroidism and hypothyroidism. (Chen et al., 2019).

Role of Sex hormone in Diabetes mellitus

There is increasing evidence that sex and gender differences influence the epidemiology, pathophysiology, treatment, and outcomes of many diseases, including type 2 diabetes (T2DM)

(Regitz-Zagrosek et al., 2016). The term sex is used to primarily indicate biological differences and the term gender predominantly describes the psychosocial differences between sexes. Sex differences between women and men include differences in sex hormones and their effects on organ systems. Gender differences arise from sociocultural processes and include different forms of nutrition, lifestyles or stress, or attitudes toward treatments and prevention of diseases. Sex and gender differences are equally important in terms of development, awareness, presentation, diagnosis, and therapy, as well as the prevention of T2DM, influencing each other, above all through the impact on obesity. There is a general agreement that obesity is the major risk factor for T2DM in both sexes, as supported by the data on the prevalence patterns of T2DM across regions which resemble those of obesity (Kautzky-Willer et al., 2016; Gambineri and Pelusi, 2019).

Testosterone deficiency is common in men with type 2 diabetes which may contribute to impaired performance, mood, and libido (Kapoor et al., 2007). Although a direct relationship between testosterone deficiency and cardiovascular risk remains controversial (Liu et al., 2003), there is evidence that testosterone levels are inversely associated with insulin resistance. The pancreatic beta-cell is a target of estrogens, (Kapoor et al., 2005) which plays an important role in blood glucose homeostasis. 17b-estradiol (E2) levels above or below the physiological range may promote IR and type 2 diabetes.

All these indicated the association between sex steroids and glucose metabolism. Therefore, understanding the mechanisms of sex hormonal action is critical for improving strategies in the prevention and treatment of diabetes.

Chapter 2: Review of Literature

Review of literature

A cross-sectional study was conducted in the Diabetes Center at King Fahad Armed Forces Hospital, Jeddah, Saudi Arabia from January 2018 to December 2018. Thyroid-stimulating hormone (TSH), free thyroxin (FT4), and HBa1c were measured. A total of 2069 subjects with T2DM were included in this study. The average age of the study population was 51.3±16.4 years. 1511 (73%) were euthyroid, primary hypothyroid was present in 229 (11.1%) and subclinical hypothyroidism was present in 3 (3%) patients. Hyperthyroidism was present in 33 (1.6%), and subclinical hyperthyroidism was present in 125 (6%) patients. there was a statistically non-significant difference between thyroid dysfunctions in males compared to females. In addition, there was a statistically non-significant difference between thyroid dysfunctions in males compared to females. The results also showed a statistically significant difference between HbA1c below and above 7% in correlation to thyroid dysfunctions (Aljabri, 2019).

Type 2 diabetes mellitus (T2DM) affect the quality of life very much and causes various complications. Diabetic autonomic neuropathy (DAN) is one of the common complications in diabetes. The study is undertaken with the objective to compare the alteration in taste threshold for four primary sensations in Type 2 DM with autonomic neuropathy. 60 patients of T2DM with autonomic neuropathy and 60 healthy controls were taken for the study. The study found a significant correlation between taste dysfunction, HbA1C level, and blood sugar fasting level in T2DM patients. The taste dysfunction was mainly for sweets. Sour and bitter did not show any difference in the case of groups compared to controls (Kushwaha et al., 2022).

the relationship between thyroid hormone levels and T2DM risk remains highly contested and human studies have demonstrated conflicting findings. Several reports have suggested a positive effect of high TSH and low free thyroxine levels on hyperglycemia and insulin resistance. The study aimed to evaluate the associations and dose-response relationships between thyroid function/hormone levels and the risk of T2DM and cardiovascular disease (CVD) risk among T2DM patients. The meta-analysis of this study determined that abnormal thyroid hormone level is associated with an increased risk of T2DM, showing a J-shaped relationship with TSH and inverted-J-shaped relationships with FT3 and FT4 (Rong et al., 2021).

Type 2 diabetes mellitus (T2DM) is a long-term metabolic disorder. It is characterized by hyperglycemia, insulin resistance (IR), and relative impairment in insulin secretion. IR plays a major role in the pathogenesis of T2DM. Many previous studies have investigated the relationship between estrogen, androgen, and obesity, but few focused on the relationship between sex hormones, abnormal lipid metabolism, and IR. The goal of this study was to identify the association of IR with sex hormones, abnormal lipid metabolism in type 2 diabetes, and impaired glucose tolerance (IGT) patients. luteinizing, progesterone, estradiol, prolactin, and follicle-stimulating hormone levels decreased significantly in T2DM and IGT patients compared with those in normal control people. The association between IR and lipid metabolism disorders in T2DM and IGT patients was also observed (Wang et al., 2017).

Thyroid hormones are insulin antagonists, both insulin and thyroid hormones are involved in cellular metabolism. Excess or deficit of any one can result in functional derangement of the other (Muka et al., 2017). Sub–clinical hypothyroidism is an independent risk factor for development of diabetic nephropathy. Serum TSH and tissue insulin sensitivity have important effects on serum lipid parameters in type 2 diabetic patients. At low insulin sensitivity, relatively minor changes in TSH levels are associated with marked changes in lipid risk factors and thus cardiovascular risk. Unrecognized thyroid dysfunction may impair metabolic controls in patients with diabetes and in addition may amplify existing cardiovascular risk. Recognition and treatment of thyroid dysfunction in diabetic patients will benefit glycaemic control, attenuate cardiovascular risk, and improve general wellbeing (Wang et al., 2017).

The aim of the present study was to evaluate the association of the thyroid hormones levels (T3 and T4), TSH, with serum creatinine, and glycated haemoglobin (HbA1c) in type 2 diabetics.

Chapter 3: Aim and Objectives

Aim and Objectives

The aim of the present study was to evaluate the association of the thyroid hormones levels (T3 and T4), TSH, with serum creatinine, and glycated haemoglobin (HbA1c) in type 2 diabetics. The objectives of the study are

1. To investigate the role of thyroid disfunction in type 2 Diabetes Mellitus patients.
2. To evaluate The Prevalence of Thyroid Disorders in Patients with Diabetes Mellitus.
3. To find out the correlation between T3, T4 and TSH with HbA1c and serum creatinine in type 2 Diabetes Mellitus patients.

Chapter 4: Materials and Methods

Materials and Methods

Selection of Subject:

Subjects were selected from Paschim Midnapore, West Bengal. Diabetes Mellitus patients were diagnosed based on the standard criteria. Patients with type 2 diabetes with a duration of more than 5 years were considered.

30 subjects were selected including male and female. Control was considered non-diabetic and contained 15 subjects. The subjects were selected based on inclusion and exclusion criteria.

Inclusion criteria:

1. Case of Type II DM
2. Consenting patients of age >50 years
1. Any sex with diabetes duration of more than 5 years

Exclusion criteria:

2. Type 1 diabetes mellitus patients
3. Smokers and alcoholics
4. Pregnant and lactating women,
5. Patients with upper respiratory dysfunction and herpes infection
6. Recent covid 19 patients
7. Patients with any reproductive or hormonal disorder

Duration of the study:

The duration of this study was 3 months.

Parameters studied:

Blood samples were taken from all patients to check HbA1c derivatives, fasting insulin, fasting blood sugar, and post-prandial blood sugar.

High-performance liquid chromatography will be used to determine the HbAc.

TSH and serum-free thyroxine (FT3 and FT4) were measured by the ELISA method. The assays have intra- assay precision of 4.3%. TSH levels between 0.22-4.2 mIU/L and Free T4 12.0-22.0 pmol/L were regarded as normal (American Diabetes Association, 2019).

Statistical analysis:

The statistical significance and multigroup comparisons of the data were analyzed by using one and one-way analysis of variance (ANOVA), followed by a Tukey post hoc test using Origins 8 (OriginLab, Northampton,USA). Data are presented as means ± standard deviation (SD). Statistical significance was considered at $p < 0.05$.

Chapter 5: Results

Results

Serum FT3 and FT4 levels were found to be decreased in type 2 diabetic patients. Serum T3 and T4 values of type 2 diabetic patients were found to be 83.48 ± 23.02 ng/dL and 2.89 ± 0.82 µg/dL which were significantly ($p<0.001$) decreased from the control. However, the TSH level in type 2 diabetic patients was significantly ($p<0.001$) increased to 4.53 ± 0.21 mIU/L compared to control (Table 1).

In type 2 diabetic patients, HbA1c and creatinine levels were found to be 5.45 ± 1.29 and 2.63 ± 1.82 respectively which were significantly increased compared to control (Table 1).

Table 1. Serum T3, T4, TSH, creatinine, and HbA1c of type 2 diabetic patients. Results are expressed as Mean ± SD; p= <0.05 significant.

Parameters	Control (n=15)	Type 2 diabetics (n=30)	p value
FT3 (ng/dL)	136.08 ± 15.19	83.48 ± 23.02	≤ 0.001
FT4 (µg/dL)	5 ± 1.14	2.89 ± 0.82	≤ 0.001
TSH (mIU/L)	2.01 ± 0.82	4.53 ± 0.21	≤ 0.001
HbA1c	4.1 ± 1.51	5.45 ± 1.29	≤ 0.01
Creatinine (mg/dL)	0.88 ± 0.1	2.63 ± 1.82	≤ 0.001

The Pearson correlation was established to analyze the correlation between T3, T4, and TSH with HbA1c and creatinine. Results suggested a positive correlation between T3 and T4 with creatinine but a negative correlation was observed between T3 and T4 with HbA1c. On the other hand, a positive correlation between serum TSH with glycated hemoglobin (HbA1c) and serum creatinine was observed (Table 2; Fig 1).

Table 2. Correlation between FT3, FT4, TSH with glycated haemoglobin (HbA1c) and serum creatinine in type 2 diabetics patients; p= <0.05 significant

Parameters correlated	r value	F value	p value
T_3 with • HbA1c • Serum Creatinine	 -0.30119 0.37594	 2.79337 4.6086	 ≤ 0.105 ≤ 0.04
T_4 with • HbA1c • Serum Creatinine	 -0.08756 0.22173	 0.21632 1.44776	 ≤ 0.645 ≤ 0.238
TSH with • HbA1c • Serum Creatinine	 0.34343 0.15495	 3.74391 0.68877	 ≤ 0.413 ≤ 0.063

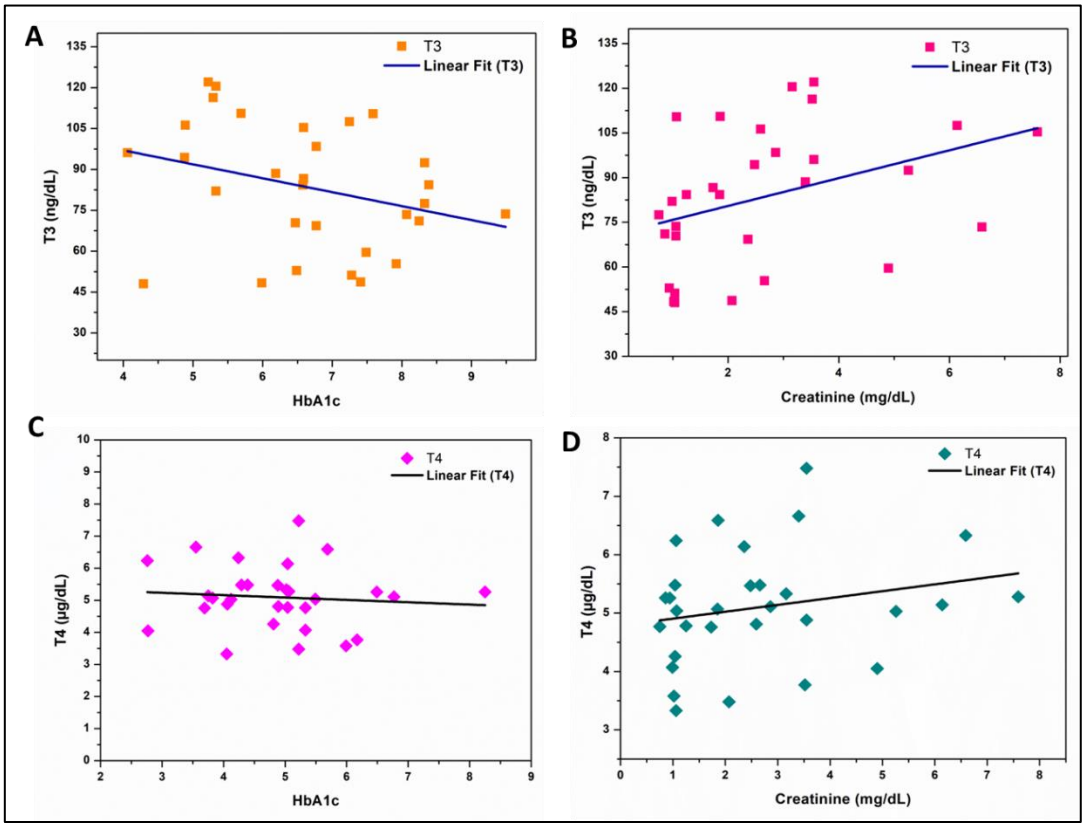

Figure 1. (A-B) correlation between T3 with HbA1c and serum creatinine; (C-D) correlation between T4 with HbA1c and serum creatinine

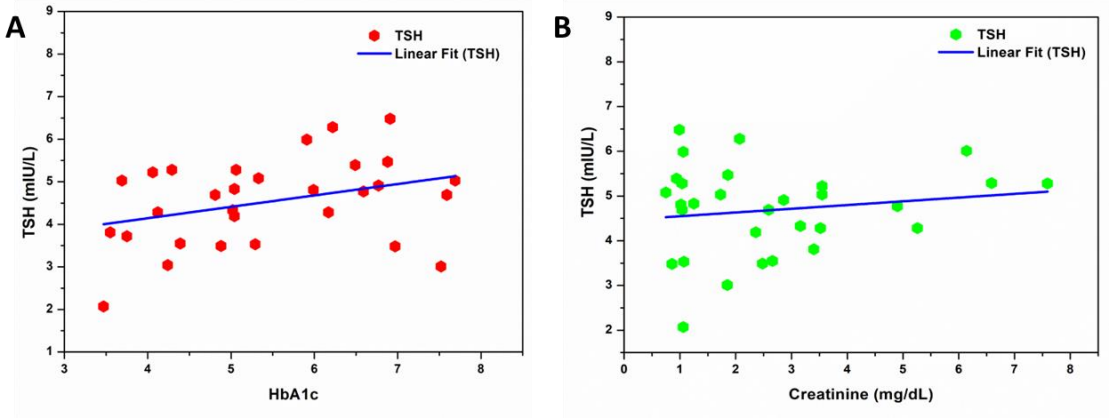

Figure 2. (A-B) correlation between TSH with HbA1c and serum creatinine.

Chapter 6: Discussion

Discussion

The present study was undertaken to evaluate the relationship of serum T3, T4, and TSH, serum creatinine, and glycated hemoglobin with type 2 diabetes. The study showed that the serum T3 and serum T4 levels were decreased, and serum TSH levels were increased significantly in type 2 diabetic patients compared to controls. A study by Singh G et al., showed that patients with type 2 diabetes had abnormal thyroid hormone levels. The level of T3, T4, FT3, and FT4 were significantly lower while the levels of TSH were significantly higher in type 2 diabetics as compared to non-diabetics. Significantly higher levels of serum creatinine and glycated hemoglobin were observed in diabetics as compared to non-diabetics subjects (Singh et al., 2011) which agrees with the findings of our study. A study by Swamy RM et al., showed that the serum T4 level was low and TSH was high in type 2 diabetics when compared with controls and this difference was statistically significant. T3 was also low in type 2 diabetics when compared with controls but this difference was not statistically significant (Swamy et al., 2012) which correlates with our findings. A study by Chubb SA et al., had shown that the prevalence of subclinical hypothyroidism among type 2 diabetics is 8.6% (Chubb et al., 2005).

Hypothyroidism was defined as a clinical syndrome of hypothyroidism associated with elevated TSH >4.2 mIU/l and decreased serum levels of FT4. Decreased levels of thyroid hormones cause increased TSH release from the anterior pituitary gland by feedback mechanism (Bharat et al., 2013). Most of the T2DM patients were obese and might have increased levels of leptin. This increased level of leptin develops leptin resistance centrally which causes decreased formation of thyroid hormones and increase TSH secretion (Radaideh et al., 2004). Moreover, the binding affinity of TT4 is increased in T2DM which causes a decreased formation of FT4 in blood (Bharat et al., 2013). T2DM is also associated with obesity, stress, and infection that caused changes in the hypothalamo-pituitary thyroid axis leading to a decreased level of FT4 and increased TSH level in T2DM (Radaideh et al., 2004).

The presence of both raised and low levels of thyroid hormones in diabetics may be due to modified thyrotropin-releasing hormone (TRH) synthesis and release. The hyperglycemia seen in type- 2 diabetics is known to have a negative effect on thyroid function precisely blunting the pituitary TSH response to stimulation by hypothalamic TRH. This may be due to possible alteration of post-translational glycosylation of TRH hence affecting its biological activity. T2DM is associated with increased insulin levels and C-peptide levels. Insulin is an anabolic hormone known to enhance TSH turnover, which is protein in nature. Recently, C-peptide has been shown to enhance Na^+/K^+ ATPase activity, an action that may also increase protein

synthesis. Such an action would induce increased turnover of TSH, a protein hormone (Suresh et al., 2014).

Serum creatinine and glycated hemoglobin (HbA1c) were increased in type 2 diabetics compared with controls. A positive correlation was observed between Serum TSH with serum creatinine and HbA1c whereas, the correlation between Serum T3, Serum T4 with HbA1c was negative. Chronic Kidney Disease (CKD) influences the hypothalamo – pituitary - thyroid axis. Secretion of hypophyseal TSH is disturbed and the TSH response to the hypothalamic Thyrotropin Releasing Hormone (TRH) is reduced. CKD affects the thyroid function by lowering levels of circulating thyroid hormones, interfering with hormones binding to protein carriers, disrupting metabolism, and elimination of thyroid hormones (Jusufovic et al., 2011).

Chapter 7: Conclusion

Conclusion

The present study evaluated the relationship between type 2 diabetes and thyroid function. The finding suggested that in type 2 diabetes, serum thyroxine level was decreased and serum TSH level was increased. This increased level of TSH was positively correlated with HbA1c and serum creatinine leading to an increase in the risk of chronic kidney disease. Failure to recognize the presence of abnormal thyroid function may be a primary cause of poor management of diabetes mellitus. Therefore, there is a need for the routine assay of thyroid hormones in type 2 diabetics to improve the quality of life and reduce morbidity.

Chapter 8: Future scope

Future scope

This investigation found that the thyroid hormone (serum T3 and T4) was significantly decreased in the patients with type 2 diabetes whereas, the THS level was increased. This may produce hypothyroidism in type 2 diabetic patients. This study suggests the following scope for further research

1. Failure to recognize the presence of abnormal thyroid function may be a primary cause of poor management of diabetes mellitus. Therefore, there is a need for the routine assay of thyroid hormones in type 2 diabetics in order to improve the quality of life and reduce morbidity.
2. Based on the high risk of hypothyroidism among type 2 diabetic patients, routine screening for hypothyroidism is highly recommended.

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