A NON-INTERVENTIONAL DATA COLLECTION TO DETERMINE THE RATE OF CONSUMPTION OF VITAMIN D3 COMPARED IN THYROID POPULATION AND NORMAL POPULATION

Abstract: Thyroid is an endocrine gland. It is located in neck and consists of two connected lobes. Due to low Vitamin D3 levels it leads to Thyroid deficiencies. The present article describes aboutthe comparitive study between Thyroid population and Normal population based on Vitamin D3 consumption. The main aim is to determine the percentage of patients consuming Vitamin D3 drug in normal population and thyroid population. In this 20 patients are collected and is divides into 2 groups i.e., Group A n=10 and Group B n=10. The data is collected through Informed Consent forms, Consent Study Forms, Patient Life Questionnaires. From this test the results obtained are the Quality of Life in Thyroid population was 98% and in Normal population was 4.5%. It was observed that Thyroid patients are consuming Vitamin D3 as Supportive medicine are with good quality of life when compared with that of Normal patients (Healthy Volunteers), are not consuming any Vitamin D3 Suppliment.

KeyWords: Thyroid gland, Vitamin D3, Quality, Population, Consumption, Hypothyroidism, Hyperthyroidism. Thyroid Hormone:

INTRODUCTION

The thyroid, or thyroid gland, is an endocrine gland in vertebrates. In humans it is in the neckand consists of two connected lobes. The lower two thirds of the lobes are connected by a thin band of tissue called the thyroid isthmus.[1] The thyroid gland secretes three hormones: The two thyroid hormones – triiodothyronine (T3) and thyroxine (T4) and a peptide hormone, calcitonin. [1] The thyroid hormones influence the metabolic rate and protein synthesis, and in children, growthand development. Calcitonin plays a role in calcium homeostasis. Secretion of the two thyroid hormones is regulated by thyroid-stimulating hormone (TSH), which is secreted from the anterior pituitary gland. TSH is regulated by thyrotropin-releasing hormone (TRH), which is produced by the hypothalamus. Euthyroid is the term used to describe a state of normal thyroid function in the body. Thyroid disorders include hyperthyroidism, hypothyroidism, thyroid inflammation (thyroiditis), thyroid enlargement (goitre), thyroid nodules, and thyroid cancer. [1]

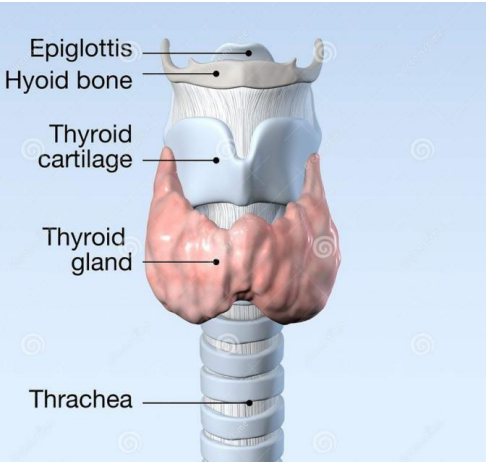

Figure-1: Thyroid Gland

Hyperthyroidism:

Hyperthyroidism is the condition that occurs due to excessive production of thyroid hormones hormone of any cause and therefore includes hyperthyroidism. It is noted that thyrotoxicosis is related to hyper-kinetic movement disorders including chorea and myoclonus. Some, however, use the terms interchangeably. Signs and symptoms vary between people and may include irritability, muscle weakness, sleeping problems, a fast heartbeat, heat intolerance, diarrhea, enlargement of the thyroid, hand tremor, and weight loss.[2] Graves' disease is the cause of about 50% to 80% of the cases of hyperthyroidism in the United States. Other causes include multinodular goiter, toxic adenoma, inflammation of the thyroid, eating too much iodine, and too much synthetic thyroid hormone. Typically blood tests show a low thyroid stimulating hormone (TSH) and raised T3 or T4. Radioiodine uptake by the thyroid, thyroid

scan, and TSI antibodies may help determine the cause.

Hypothyroidism:

Hypothyroidism (also called underactive thyroid, low thyroid or hypothyreosis) is adisorder of the endocrine system in which the thyroid gland does not produce enough thyroid hormone.[3] It can cause a number of symptoms, such as poor ability to tolerate cold, a feeling of tiredness, constipation, slow heart rate, depression, and weight gain. Occasionally there may be swelling of the front part of the neck due to goiter.

Worldwide, too little iodine in the diet is the most common cause of hypothyroidism. Thediagnosis of hypothyroidism, when suspected, can be confirmed with blood tests measuring thyroid-stimulating hormone (TSH) and thyroxine levels. Thyroid medication is safe in pregnancy.

Vitamin D3:

Vitamin D is a group of fat-soluble secosteroids and in humans, the most important compounds in this group are vitamin D3 (also known as cholecalciferol) and vitamin D2 (ergocalciferol).[4]

The major natural source of the vitamin is synthesis of cholecalciferol in the lower layers of epidermis of the skin through a chemical reaction that is dependent on sun exposure (specifically UVB radiation). Cholecalciferol and ergocalciferol can be ingested from the diet and supplements. Only a few foods, such as the flesh of fatty fish, naturally contain significant amounts of vitamin D. Mushrooms exposed to ultraviolet light contribute useful amounts of vitamin D.

Cholecalciferol is converted in the liver to calcifediol (25-hydroxycholecalciferol); ergocalciferol is converted to 25-Hydroxyergocalciferol.These two vitamin D metabolites (called25-hydroxyvitamin D or 25(OH)D) are measured in serum to determine a person's vitamin D status.

Calcifediol is further hydroxylated by the kidneys and some of the immune system cellsto form calcitriol (also known as 1,25-dihydroxycholecalciferol), the biologically active form of vitamin D. Calcitriol circulates as a hormone in the blood, having a major role regulating the concentration of calcium and phosphate, and promoting the healthy growth and remodeling of bone. Calcitriol also has other effects, including some on cell growth, neuromuscular and immune functions, and reduction of inflammation.[4] PROTOCOL SYNOPSIS[5]

Protocol Title	A non-interventional data collection to determine the rate of consumption of Vit-D3 compared in Thyroid population and normal population.
Protocol ID Version & Date Data Collection Centers	NRI/02/2022 Version No 1.0, Dated: 01/03/2022 01
Study Period	1 month
Total No of population selected for data collection	20 Patients Non-interventional data.
No of Study Visits No of groups	01 02
Study Type	Non-interventional data Collection
Study Objective	The objective of the study is to determine rate of consumption of Vit-D_3 in Thyroid population vs normal population.
Primary End points	1) No of patients diagnosed with Thyroid and consumption of Vit-D_3 drug.
Secondary End points	2) No of patients of Non-diagnosed with Thyroid and consumption of Vit-D_3 drug.
Study population	Male and females of age 18 yrs and above who are diagnosed with Thyroid and Normal population.
Inclusion criteria Exclusion criteria	✓ Patients of age 18 yrs and above. ✓ Male and female genders ✓ Patients who are diagnosed with diagnosed with Thyroid and Normal population. ✓ Patients who suffering from severe chronic diseases ✓ Patients who underwent for surgery related to Thyroid problems. ✓ Patients who are having abnormality in hormonal levels.
Data Capturing	✓ Paper CRF ✓ Patient quality of life questionnaires

Table-1: protocol synopsis

Background of the study: Vit-D3 is the vitamin which plays a major role in human body and our study is designed to determine the consumption of Vit-D3 compared in Thyroid effected patients Vs Normal population[6].

Rationale of study: The study rationale is to determine the percentage of patients consuming Vit-D3 drug in normal population and Thyroid effected patients.

Study Objective: The study objective is to prove the usage of Vit-D3 in the study population.

Study Design:[7]

Visit -1: The study designed to collect the patients in the single visit and the following data willbe captured.

- The acceptance of the patient to give their data in the form of informed consent form.
- Patient demographics will be collected.
- Patient past medical history will be collected.
- The patient medication data will be collected in two groups.

Group 1: Data:

- The patient's data will be categorized in to two group.
- In group 1 the patients suffering from hyperthyroidism or hypothyroidism.
- The patient's medication history should be recorded.

Group 2: Data:

- In group 2 the patient should be normal population and not be previous hyperthyroidism orhypothyroidism effected.
- The patient's medication history should be recorded.

Institutional ethics committee review:

Before the start of the study, the study protocol, ICF, and any other essential documents will be submitted to the Institutional Ethics Committee with a cover letter or form listing the documents submitted, their dates and versions of issue for which approval is sought.

As per institutional requirements, the study protocol and any other appropriate documentswill be submitted to scientific committees for approval. The study team will forward to the sponsor, or designee, a copy of the Institutional Ethics Committee approval of this protocol, ICF.

The study team will also keep documentation of study approval by internal scientific committees as per institutional requirements.

Confidentiality:

- Subject names will remain confidential and will not be included in the database collected.
- Only enrolment number, subject initials, and birth date will be recorded on the CRF.
- If the patient name appears on any other document collected (e.g., hospital discharge summary), the name must be obliterated before the document is transmitted in to CRF.
- Subjects will be informed that all personal information made available for inspection will be handled in the strictest confidence and in accordance with all state, local, and federal data protection/privacy laws.

Case report forms:[8]

- The study case report form (CRF) is the primary source of data collection the study.
- All the data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A".All entries should be printed legibly in black or Blue ink.
- If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initiated and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it

Informed Consent Form: Informed consent form the basic requirement of the study to prove the acceptance the patient or participant to give their voluntary acceptance to participate in the study.

Sample size & Statistical Analysis Plan:

The total sample size calculated for the study in two groups was 20Group 1: n = 10

Group 2: n = 10

Total n No. of patient's data planned to collect in the study 20. The above study will be analyzed in standard excel sheet with calculating n number patients comparing in both groups and percentage of patients consuming Vit-D3 in Thyroid Population vs normal population.

Publication policies:

All information collected in the study will be published on the name of student and behalfof the Guide and Co-guide.

No other parties have rights to include their name without taking permission of concerncandidates and guides and co-guides.

Clinical study report:

The Clinical Study Report will be prepared after the completion of study.

STUDY REPORT

Protocol Title:[9]

We have collected the total 20 patient's data with all required approvals prior starting thedata collection and we have used basic informed consent form of version no 1.0 dated: 01/03/2022 as a proof of acceptance from the patient to collect the required medical data from them in case report form of version no 1.0, dated: 01/03/2022.

We have divided the 20 patients in to two groups and in group A we have collected the data of Thyroid effected patients with normal BMI and in the group B we have collected the dataof Normal healthy voluntaries data and the total past medical and medication histories of both groups based on the data collected and post analysis we observed the following results.

VIT D3 Consumption compared in group A and group B			
Subject ID	**Group A**	**Subject ID**	**Group B**
1	YES	11	No
2	YES	12	No
3	YES	13	No
4	YES	14	No
5	YES	15	No
6	YES	16	No
7	YES	17	No
8	YES	18	No
9	YES	19	No
10	YES	20	No

Table-2: Vitamin D3 consumption compared in Group A and Group B

Quality of life questionnaires compared in both groups A and group B			
Subject ID	**Group A**	**Subject ID**	**Group B**
1	12	11	6
2	6	12	5
3	11	13	3
4	9	14	3
5	9	15	4
6	10	16	5
7	11	17	5
8	12	18	5
9	8	19	4
10	10	20	5

Table-3: Quality of life questionnaires compared in group A and group B

QUALITY OF LIFE DIFFERENCE BETWEEN TWO GROUPS GRAPHICALREPRESENTATION

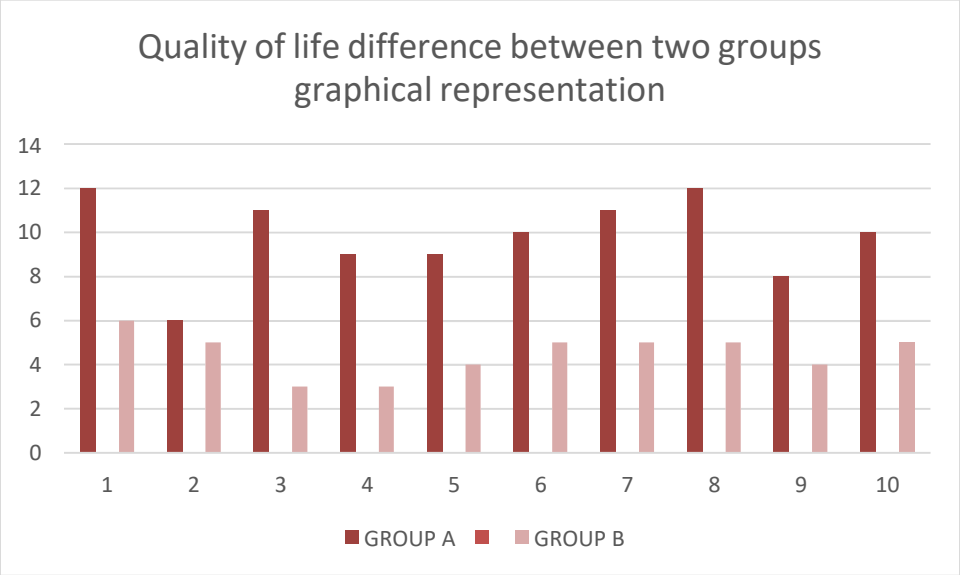

Figure-2: Quality of life compared in Thyroid Population and Normal Population

FINAL DATA REPORT

Patient ID	Vit D3 Consumption	Quality of life	Patient ID	Vit D3 Consumption	Quality of life
1	Yes	12	11	No	6
2	Yes	6	12	No	5
3	Yes	11	13	No	3
4	Yes	9	14	No	3
5	Yes	9	15	No	4
6	Yes	10	16	No	5
7	Yes	11	17	No	5
8	Yes	12	18	No	5
9	Yes	8	19	No	4
10	Yes	10	20	No	5
Mean	**100%**	**9.8%**	**Mean**	**0%**	**4.5%**

Table-4: Quality of life based on Vitamin D3 Consumption

GROUP -A		GROUP -B	
N no of population	10	N no of population	10
Vitamin D3 Consumption	100%	Vitamin D3 Consumption	0%
Quality of life	9.8%	Quality of life	4.5 %

Table-5: Comparision of quality of life between group A and B Population

Conclusion:

The final conclusion of the data collection was the population of Thyroid patients are consuming Vitamin D3 as a supportive medicine are with good quality of life when compared with that of Normal patients (Healthy Volunteers), not consuming any Vitamin D3 Suppliment.

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