

## A Comparative study of how Bodyweight is a major determinant of Thyroxin sodium / Levothyroxine dosage in the treatment of Primary Hypothyroidism

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### Abstract

**Objective:** This study aims at exploring how body weight helps in determining the dosage level of Thyroxin sodium during the treatment of Primary Hypothyroidism. **Design of study:** A retrospective study. **Period of Study:** 1 year. **Materials and methods:** This study had explored the data that has been collected from patients regarding their medical reports viz-a-viz demographic details, TSH levels, FT4 levels, dosage levels etc. This study had also provided a detailed information of the TSH and FT4 levels throughout the treatment by mentioning the data collected up until the fourth dosage given to show the progress. **Result:** In this study, it was found that the patients of primary hypothyroidism selected for this study had examined before the dosage was given. All the patients had been given Levothyroxine dosage after an examination of their TSH, FT4 levels. However, these dosage levels did not entirely depend on the findings of these factors because people with lower levels of TSH or FT4, as compared to others, had also been given higher dosage. This is due to the fact that the body weights of the patients had been set as the yardstick for the amounts of dosage to be given to the patient. **Conclusion:** The study shows that body weight is a crucial factor that needs to be considered while adjusting the dosage level of Levothyroxine for primary hypothyroidism patients. It is also necessary because it would help in ensuring that no under-treatment or over-treatment has been done.

**Keywords:** Mucinous tumors, Surface epithelial, Ovary, Proliferative tumors.

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### Introduction

Hypothyroidism is a clinical condition that results from the low levels or deficiencies of the thyroid hormones-triiodothyronine (T3) and thyroxine (T4). It is one of the most prevalent endocrine disorder worldwide since it is encountered by primary care physicians time and time again. If goes untreated, hypothyroidism might contribute to other health issues viz-a-viz dyslipidemia, neuromuscular dysfunction, hypertension, infertility, and cognitive impairment [1]. The prevalence of hypothyroidism in the Western world counts upto about 4-5%. According to the findings of the National Health and Nutrition Examination Survey (NHANES), one in every 300 people suffers from hypothyroidism in the United States [2]. This prevalence heightens with age and is higher in females in comparison to males. Researches have compared the numbers of hypothyroidism prevalence in India with the US and the UK and the findings claim that in India, numbers go high up to about 11% as opposed to 4-6% in the US and 2% in the UK [3]. These stats in India had, however, lessened due to the introduction of the universal salt iodization program in the year 1983. Even though the treatment of hypothyroidism is considerably simple, in numerous cases people affected by this condition have only been suboptimally treated. Primary hypothyroidism is one of the types of hypothyroidism that is diagnosed with a serum thyroid-stimulating hormone or TSH concentration. In this type of hypothyroidism, when the TSH level of an individual is above the reference range and the FT4 level is lower than the range, he/she would have to be diagnosed. In case the TSH

is higher but the FT4 lies in the normal range, it would not be a case of primary hypothyroidism, rather it would be a case of subclinical hypothyroidism, which is also a type of hypothyroidism. The most common cause claimed as a trigger for primary hypothyroidism is autoimmune thyroiditis. Iodine deficiency had also been concluded as a possible cause for the same. However, when the treatment of primary hypothyroidism is concerned, a dosage of levothyroxine has been considered as the best choice. This dosage of levothyroxine or thyroxin sodium primarily depends on three essential factors: "the amount of residual thyroid function retained by the patient, the body weight or lean body mass of the patient, and the target thyrotropin or thyroid-stimulating hormone (TSH) level to be achieved during therapy" (Duntas and Jonklaas, 2019 and Elfenbeim et.al. (2019) mention that the quantity of the dosage required by a particular patient can be predicted by either the body weight or the body mass index of the patient [5,6]. The most accurate estimates are provided by the body weight, the lean body mass, the ideal body weight, and the BMI of the patient. Over the years, many researchers and medical practitioners had proposed varied formulae for easing the calculation methods of dose requirements, however, the formulae range is extensively based on the body weight and the BMI of the patient [7]. Given these understandings, this study aims at addressing the following research question: How is bodyweight a major determinant of Thyroxin sodium/Levothyroxine dosage in the treatment of Primary Hypothyroidism?

### Methodology

(a) Study design-This study is a retrospective observational study that reviews a collection of the clinical medical records of patient's data. These data spanning over the records of 100 patients had been collected from the Patna Medical College & Hospital.  
(b) Participants-The sample population of 100 people, chosen for this study were suffering from primary hypothyroidism and were undergoing the necessary treatments. With 87 females and 13 males

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included in the sample, this study had selected the participants by keeping in mind that they are able to conform to every requirement that the study demands. The medical records delineate the details of treatments received by the patients from a chart review between the period of September 2018 to October 2019.

(c) Data Collection-The medical records of the chosen patients had been used for collecting demographic details of the patients viz. age, sex, anthropometric measurements like height, weight, BMI etc, vital signs like pulse, BP etc, and a detailed information regarding the types and amounts of medical treatments received by the patients. In order to avoid any confusion between the patients, every patient was provided with an identification number or the serial numbers (1..2..3..) in the data table. After the collection of the data, it was crosschecked with the usage of variables like BMI, age etc in order to avoid errors. Moreover, it is worth mentioning that these patients had been visiting the doctor regularly which ensures that the data collected has been updated by the latest before the study. Furthermore, another important consideration made was that, since this study solely focussed on the factor of body weight being a necessary element in primary hypothyroidism, the data collected had been cross checked to avoid the selection of patients who are suffering from mild or subclinical hypothyroidism or even hyperthyroidism.

2. Ethics-In order to ensure that no ethical rules had been violated, this study had been conducted by conforming to the principles that had been established by the 18<sup>th</sup> World Medical Assembly. Pertaining to all the ICH guidelines and medical principles, written consent forms

had also been acquired from the participants involved in the study. Confidentiality of patients' data was maintained by the assigning of numbers for every patient rather than their name being used. There was perceived risk in case of the patients since confidentiality was strictly maintained. Irrespective of no benefits for them, this study would prove to be beneficial for future patients and also for medical practitioners, research projects etc.

3. Strengths & Limitations-The strength of this study arises from the usage of real world data and latest updated information used throughout. With diverse sample population from varying socio-economic diversity, this is one of the most crucial studies done on the subject that body weight plays a massive role in the amounts of Thyroxin sodium dosage to be given in cases of primary hypothyroidism. The limitations, however, lie in the fact that only a particular region of province database had been accessed for the study which insinuates that the findings of this study cannot be generalised. Since the data had not been directly collected, there exists a possibility of errors.

4. Findings-This article delineates frequency distribution analysis of the data that had been collected in order to answer the research question undertaken.

5. Characteristics of the sample-This study had included a total of 100 patients, out of whom 87 were females which 13 were males ranging from ages 16 to 80. Analysis by bodyweight was performed after the sample was divided into the cohort (weight in kgs). Figure 1 reveals the different body weights of the patients and distributes them into four different groups.

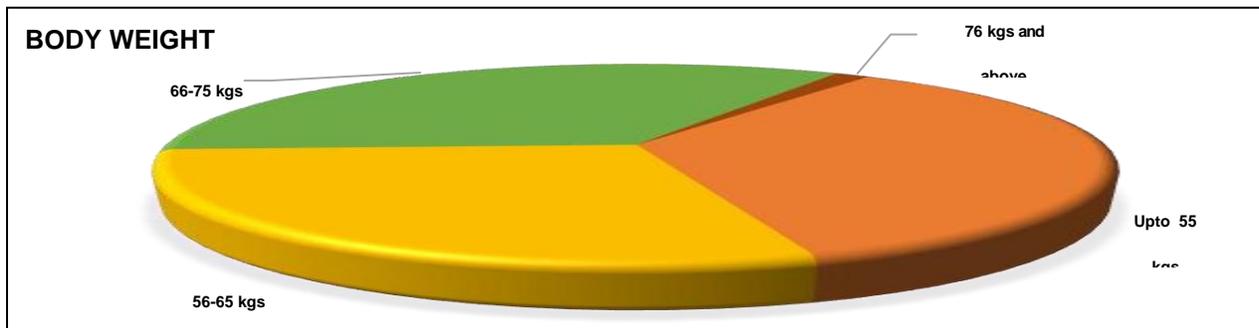


Fig 1: Body weight

Figure 1 tells us that the bodyweights of the sample was indeed diverse which would help us in analysing and exploring the research topic better. With a diversified bodyweight categories, this study would be able to explore more medical conditions to research on the impact of bodyweight in determining Thyroxin sodium dosage in the treatment of Primary Hypothyroidism.

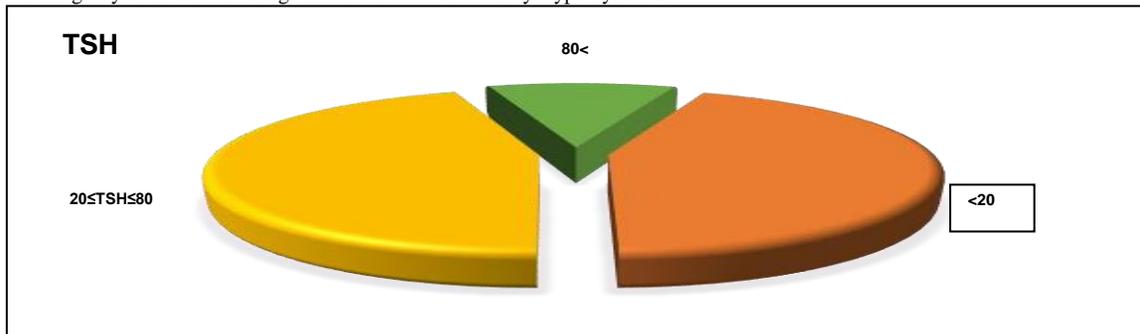
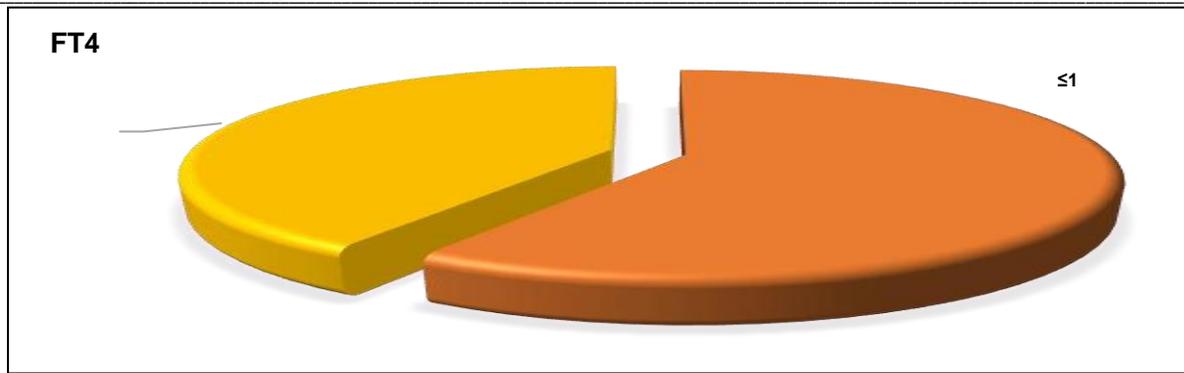
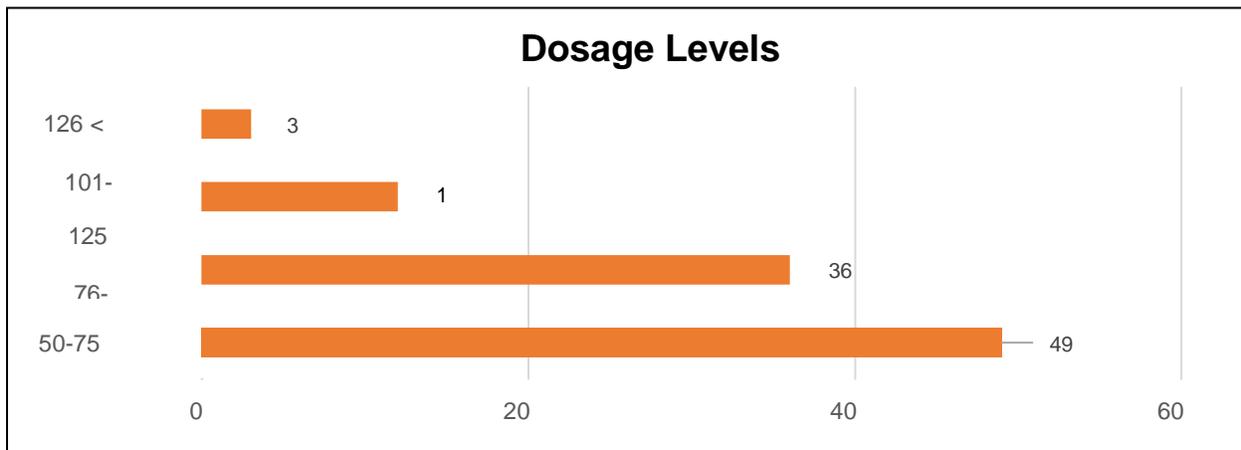


Fig 2: Distribution of TSH levels before treatment, first dosage level  
TSH levels



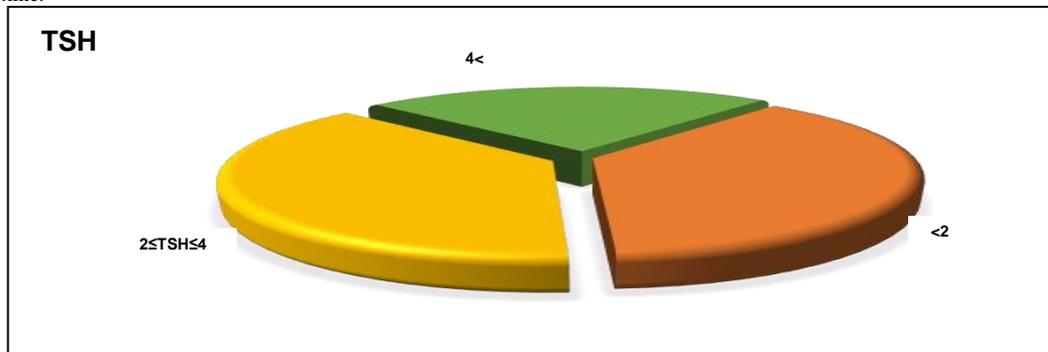
**Fig 3: Distribution of FT4 levels before treatment, first dosage level**  
FT4 levels

The above figures reveal patient’s medical data that had been collected before they were provided with any treatments in the clinic. Figure 2 reveals the differing levels in TSH component of the patients while Figure 3 reveals the differing levels in FT4 component. In figure 2, it is evident that 44% of the sample had TSH levels below 20 miu/ml, 45% had TSH levels in between 19 to 81miu/ml while the other 11% had TSH levels above 80 miu/ml. In figure 3, it can be seen that 59% of the total patients had FT4 level lesser than or equal to 1 ng/dl while the other 41% had FT4 levels higher than 1ng/dl.

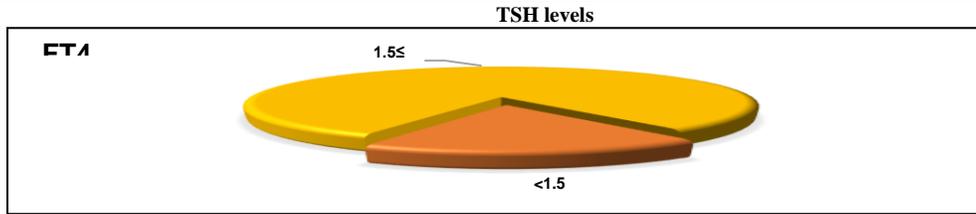


**Fig 4: Dosage levels**

The above figure reveals the level of the Thyroxine sodium dosage that had been given to the patients after the first health examination in the clinic. The figure reveals that 49 out of the total patients had been given 50-75 micrograms of Levothyroxine, 36 patients had been given about 76-100 micrograms, 12 patients had been given 101-125 micrograms and the other 3 patients had been given more than 126 micrograms of Levothyroxine.



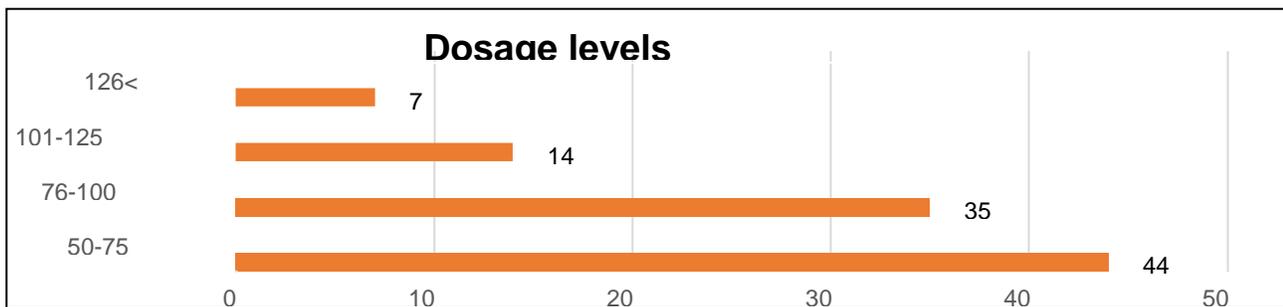
**Fig 5: Distribution of TSH levels after first dosage, second dosage level**



**Fig 5:Distribution of FT4 levels after first dosage, second dosagelevel**  
**FT4 levels**

The above figures reveal medical data of the patients after the first dosage was given. In figure 5, it is evident that 38% of the sample had TSH levels below 2 miu/ml, 38% had TSH levels in between 2 to 4 miu/ml while the other24%had TSH levels above 4miu/ml.In figure 6,it can be seen that 63% of the total patients had FT4 level lesser than 1.5 ng/dl while the other 37% had FT4 levels higher than or equal to 1.5ng

**Second dose level**



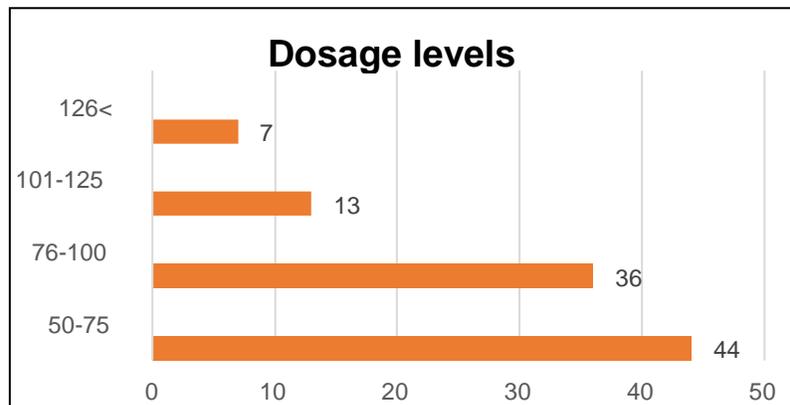
**Fig 8:Second dose level**

The above figure reveals that 44 out of the total patients had been given 50-75 micrograms of Levothyroxine, 35 patients had been given about 76-100 micrograms, 14 patients had been given 101-125 micrograms

In figure 8, it is evident that 31% of the sample had TSH levels below 2 miu/ml, 56% had TSH levels in between 2to 4miu/ml while the other13% had TSH levels above 4 miu/ml. In figure 9, it can be seen that 64% of the total patients had FT4 level lesser than 1.5 ng/dl while the other 36% had FT4 levels higher than or equal to 1.5 ng/dl.

**Third dosage level**

Other 7 patients had been given more than 126 micrograms of Levothyroxine.



**Fig 9:Third dose level**

The above figure reveals that 44 out of the total patients had been given 50-75 micrograms of Levothyroxine, 36 patients had been given about 76-100 micrograms, 13 patients had been given 101-125 micrograms and the other 7 patients had been given more than 126 micrograms of Levothyroxine.



Fig 10: Distribution of TSH levels after fourth dosage level

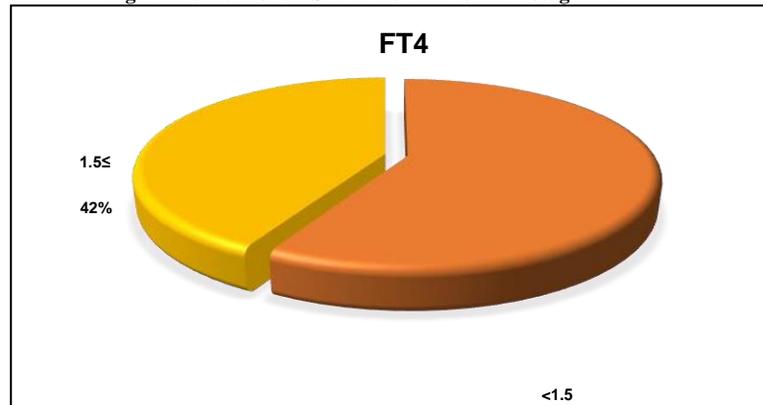


Fig 11: Distribution of FT4 levels after fourth dosage level

**Discussion**

Maximum researches done on primary hypothyroidism have claimed that dosage adjustment is a frequent requirement during the treatment process [8]. Dosage must be necessarily adjusted irrespective of the method that is being used for estimation of the Thyroxin sodium dose. It should be regulated according to the blood tests and also whenever any change in body weight is evident in the patient [9]. This adjustment, however, must be done in such a way that under treatment or overtreatment is avoided. According to previous studies, an approximate of 20% of hypothyroidism patients had been overtreated and a similar percentage of people had been undertreated. Many older patients had been at greater risk because they were being treated with large dosage of T4 or inappropriate TSH goal. In order to avoid such issues, factors like patient weight or lean body mass have been agreed upon as crucial for an estimation of LT4 dose. A study by Younis et.al. (2018) was performed to determine whether levothyroxine pharmacokinetics are affected by age, weight or sex. The findings had concluded that physicians need to consider patient’s weight accurately, rather than the age for the dosage so that

overtreatment and undertreatment are avoided. Similarly, Devdhar et.al. (2011) had claimed that both weight and gender of the patient matters in this process, but age is not essential [9]. While focussing on a safe and effective dosage level, a randomised trial had shown that a full dose based on the body weight i.e. (1.6 µg/kg/day) is effective [11]. It is far efficacious than using traditional approaches of starting with a small dosage and then gradually moving upwards. This dosage can equate to 125µg daily for an average man weighing 75 kgs and 100µg daily for an average sized woman weighing 60 kgs. In this study, it is evident that before the start of the treatment, the TSH levels of the patients were high. In figure 2 we can see that the groups of TSH levels are high as compared to the other TSH levels after the dosage. Groups with an upper limit of more than 80 mIU/ml had declined to as little as 4 mIU/ml. Furthermore, looking at the datasheet, it is noticed that patients with less weight had been given low dosage levels while patients with more weight had been given high dosage levels [12].

Let’s compare patient 3, 6 and 12 to study the weight and the dosage levels. The details of both patients are as follows:

**Table 1: Details of patients**

Patient	Weight	TSH		
(1)	FT4			
(1)	Dosage			
3	56	26.37	0.842	50
6	78	20.68	1.344	75
12	90	16.12	1.02	100

A comparison of the TSH and FT4 levels of the three patients tells us that patient 3 has the highest TSH level while patient 6 has highest FT4 level. Patient 12 has both TSH and FT4 level lower than the other patients. Irrespective of this, patient 12 has been given the highest level of dosage. This is due to the fact that the weight of the

patient is higher than the others which is why the patient has been given 100 micrograms of Levothyroxine dose. Thus, our study has reported that adjustments of Thyroxin sodium dosages need to be done based on the weight of the patients, although keeping in mind to check the TSH and FT4 levels at regular intervals.

**Conclusion**

In conclusion, a successful retrospective observational study had been conducted throughout in this study by focussing on the aim of analysing body weight as a major determinant for Thyroxin sodium dosage in primary hypothyroidism. For diagnosing and treating this disease, the levothyroxine dosage is the most convenient and essential treatment, and this must be given to patients by focusing on the body weight and the TSH, FT4 levels of the patients for avoiding overtreatment or undertreatment.

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