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A Non-Interventional Data Collection to Determine Correlation of Obesity and Thyroid Levels in Female Patients Diagnosed with Endometriosis

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I. Introduction

1.1.Obesity:

Obesitya non-communicable disease, is becoming increasingly significant on a global scale and is rapidly emerging as a major health concern in developed nations. It is a chronic condition marked by excessive body fat accumulation. Recognized as one of the most preventable diseases in developed countries, obesity's prevalence is rising not only in industrialized nations but also in countries undergoing changes in diet and lifestyle due to the adoption of Western cultural habits.[1]

1.2. Classification of obesity:

Obesity can be classified into two main types: central (android) and peripheral (gynecoid) obesity. In central obesity, fat is predominantly distributed in the upper trunk (chest and abdomen) and is more common in males. This type is strongly associated with metabolic disorders such as disordered lipid and glucose metabolism and diseases like diabetes mellitus, gout, atherosclerosis, osteoarthritis, cardiovascular disease (especially hypertension), and certain cancers.[15]] Conversely, peripheral obesity primarily involves fat distribution around the hips and thighs and is more common in females. Before menopause, fat tends to accumulate in the abdominal and femoral regions, but post-menopause, these differences diminish due to hormonal changes.[2]

II. Thyroid disease:

The thyroid gland plays a crucial role in maintaining hormone balance, even when faced with various disruptions. It can often compensate for these challenges by increasing levels of thyroid-stimulating hormone (TSH) . n adults, we can gauge the effectiveness of this compensation through markers of thyroid hormone action. However, assessing this during fetal development, infancy, and childhood is much more complex. One of the most critical pathways influenced by thyroid hormones is brain development, which is particularly sensitive to any disruptions in thyroid hormone signaling.Timing and local activation of the active form of thyroid hormone, tri-iodothyronine (T3)are essential for proper brain and sensory development. Disruptions during this sensitive period can be subtle and hard to measure, making early detection of thyroid-related issues even more vital. Recent efforts have focused on identifying the earliest signs of thyroid dysfunction caused by environmental factors. The TSH assay has become the most effective screening tool for both hyperthyroidism and hypothyroidism, and it is particularly useful in outpatient settings for detecting even mildthyroidhormoneimbalances. For conditions like Graves' disease, treatment options include radioactive iodine currently the preferred methodanti-thyroid medications, and, though less common today, thyroidectomy In cases of clinical hypothyroidism, levothyroxine replacement therapy is the standard approach, tailored to each individual's needs.[3]

III. Endometriosis:

Endometriosis is a chronic systemic inflammatory condition where endometrial-like tissue grows outside the uterus, causing symptoms such as pelvic pain, dysmenorrhea, dyspareunia, and infertility. Affecting 5–10% of women of reproductive age globally, it is the leading cause of pelvic pain and involves complex hormonal, neurological, and immune factors. Commonly, the tissue is found in the peritoneum, ovaries, fallopian tubes, and other pelvic or extra pelvic locations.

The condition is driven by sustained pelvic inflammation due to proinflammatory cytokines and immune cell changes. It significantly impacts quality of life, presenting medical, social, and economic challenges. Endometriosis is linked to psychiatric conditions such as depression, anxiety, and eating disorders, as well as cardiovascular risks like atherosclerosis, hypertension, and myocardial infarction, underscoring its broad and multifaceted health implications.[4]

3.1Types of Endometrioses:
Endometriosis can be classified into four main types based on its location and severity:[5]

3.1.1. Superficial Peritoneal Endometriosis
This is the least severe form, where endometrial-like tissue attaches to the peritoneum, a thin membrane lining the abdomen and pelvis and covering most organs in these cavities. It may appear as white lesions, red or black-blue foci, bright vesicles, or dilated blood vessels. Peritoneal endometriosis is found in 15–50% of women diagnosed with the condition, and laparoscopic surgery is the most effective diagnostic method.

3.1.2. Endometriomas (Ovarian Endometriosis)
Also known as "chocolate cysts," these dark, fluid-filled cysts primarily affect the ovaries. Ovarian endometriosis is one of the most common forms, occurring in 2–10% of women of reproductive age and in up to 50% of women undergoing treatment for infertility.

3.1.3. Deeply Infiltrating Endometriosis (DIE)
This severe form involves endometrial tissue invading deep into the extraperitoneal space, affecting pelvic organs like the bladder, ureters, intestines, sacro-uterine ligaments, or the vagina. In rare cases, extensive scar tissue can bind organs together, leading to a condition called "frozen pelvis," which affects 1–5% of individuals with endometriosis. The exact pathomechanism of DIE remains unclear.[69]

3.1.4. Abdominal Wall Endometriosis:
In some instances, endometrial-like tissue grows on the abdominal wall, often attaching to surgical scars, such as those from a C-section.

IV. Aim:
The Aim of the study is to determine the correlation of obesity and thyroid levels in female patients diagnosed with Endometriosis.

V. Objective:
The Objective of the study is to examine the association between obesity and thyroid function in women diagnosed with endometriosis. Comparison between obesity and thyroid levels in female patients with normal BMI.Comparision between obesity and thyroid levels in female population with Overweight. Comparison between obesity and thyroid levels in female patients with Obese.Comparision between obesity and thyroid levels in female patients with Severe Obese.[6]

VI. Methodology:[7]
Type of Research: Academic Research
Study Sites: Single site
Study Period: Planned Enrolment Duration: Approximately 3 months.
Planned Total Duration of the Study: 6 months.
Study Visits: Single visit study
Study Population: Female population
Study Design:A Non interventional cross-sectional pilot study.
Number of Subjects:120 subjects.
Study End Points: The end point of the study is to determine the correlation of obesity and thyroid levels in female patients diagnosed with Endometriosis by assessingBMI in Female PopulationT3,T4,TSH levelsDiagnosis of Endometriosis

6.1.Main Inclusion Criteria
•Female Patients of age 18 to 60 years old.
•Patients who are willing to sign the written informed consent
•Clinically diagnosed with Endometriosis
•Patients who are willing to follow the study procedures
•Patients who are with abnormal BMI

6.2.Main Exclusion Criteria
•Pregnant women
•Underlying or diagnosed with serious diseases or deemed unsuitable for this clinical study by the study's clinician
•Being treated with a high dose of steroids or immunosuppressant therapy or systemic antibiotics
•Presenting a progressive neoplastic lesion treated with radiotherapy or chemotherapy
•Subjects included in clinical study at present or during the past 30 days.

6.3.Statistical methods and planned analysis:
Participants who have signed an Informed Consent Form indicating that they understand the purpose of and the procedures required for the study and are of age 18 to 60 years and above will be included in the statistical analysis. Participants who have complied with the study procedures followed the study instructions and completed the clinical study will be included in the statistical analysis.
Ethical Considerations: Informed consent must be obtained from all participants. The study must be conducted in compliance with ethical guidelines and approved by an Institutional Review Board (IRB).Confidentiality and privacy of participant data must be maintained at all times.

6.4.Data Analysis Plan:
A. Descriptive Statistics: Demographic and baseline characteristics: Use descriptive statistics (mean, standard deviation, and range) for continuous variables (age, BMI, thyroid hormone levels).[8]
The data describes a group of 120 patients with an average age of 40 years (SD ±10.29), mostly in the

young to middle-aged range. The mean height is 1.60 meters (SD ±0.11), while the average weight is 74.91 kilograms (SD ±13.86). The mean BMI of 35.76 kg/m² (SD ±9.51) indicates that the group falls within the obese category (Class II), with BMI values spanning from overweight to severe obesity. These findings suggest a population at elevated risk of weight-related health issues, emphasizing the importance of targeted interventions data showed in (table-1).

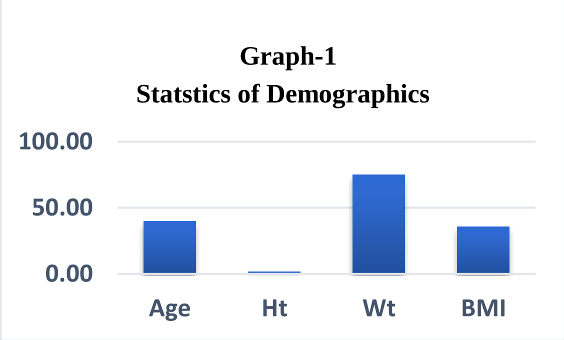
Use frequencies and percentages for categorical variables (e.g., severity of endometriosis, presence of comorbidities).
Summary statistics for thyroid hormone levels:
TSH, T3, T4 levels will be summarized with mean, standard deviation, and range for the overall cohort.

B. Exploratory Analysis:
Distribution of variables: Check for normality of continuous variables (e.g., thyroid hormone levels, BMI) using histograms and Shapiro-Wilk test.[9]
If data is non-normal, apply log transformation or use non-parametric tests. Comparing thyroid hormone levels by obesity categories: DivideBMI into categories: Normal weight (BMI< 25), Overweight (25 ≤ BMI< 30), and Obese (BMI ≥ 30). Compare thyroid levels across these categories using one-way ANOVA (for normally distributed data) or Kruskal-Wallis test (for non-normally distributed data).[10]
C. Correlation Analysis: Pearson/Spearman correlation:
To assess the relationship between BMI and thyroid hormone levels (TSH, T3, T4):If the data is normally distributed, use Pearson's correlation.[1]
If the data is not normally distributed, use Spearman's rank correlation.
Stratification by Endometriosis Severity:
If data on endometriosis severity is available, stratify the analysis by endometriosis stage (e.g., mild, moderate, severe) to explore if the relationship between obesity and thyroid levels differs by severity.
D. Multivariate Analysis: Linear Regression Analysis:
Use multiple linear regression to model the relationship between thyroid levels (dependent variables: TSH, T3, T4) and obesity (independent variable: BMI).
Adjust for confounders such as age, physical activity, comorbidities, and endometriosis severity.

VII. Results:

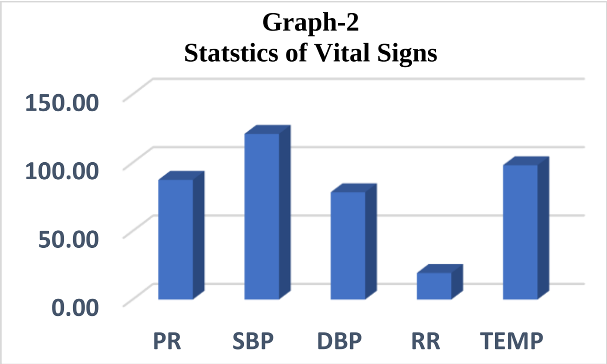
7.1.Table-1 showing the descriptive statistics of demographic and anthropometric parameters of patients

Parameter	Total No of Patients (n=120) Mean ± SD
Age (Yrs)	40.00±10.29
Height (Mts)	1.60 ± 0.11
Weight (Kgs)	74.91 ± 13.86
BMI (kg/m$^{2)}$	35.76 ± 9.51



7.2.Table:2 showing statistical of vital signs parameters:

Parameter	Total No of Patients (n=120) Mean ± SD
Pulse Rate	87.51 ± 8.17
SBP	121.16 ± 7.43
DBP	78.40 ± 7.24
Respiratory Rate	19.42 ± 2.23
Body Temperature	98.20 ± 0.66



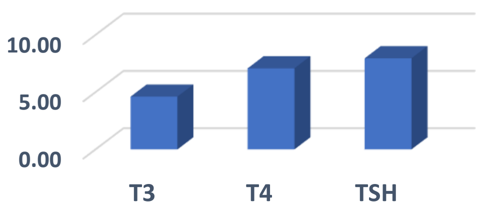
The vital sign measurements for 120 patients indicate overall stability and normal physiological profiles. The average pulse rate was 87.51 ± 8.17 beats per minute, falling within the normal range of 60–100 bpm. The mean systolic blood pressure

(121.16 ± 7.43 mmHg) and diastolic blood pressure (78.40 ± 7.24 mmHg) were both within normal limits, reflecting healthy blood pressure levels. The respiratory rate averaged 19.42 ± 2.23 breaths per minute, consistent with the normal adult range of 12–20 breaths per minute. Additionally, the mean body temperature of 98.20 ± 0.66°F was within the expected normal range as shown intable-2.

7.3.Table:3showing the statistics of T3, T4, TSH

Parameter	Total No of Patients (n=120) Mean ± SD
T3	4.61 ± 3.64
T4	7.08 ± 6.44
TSH	7.96 ± 9.75
BMI	35.76 ± 9.51

Graph:3
Statstics of Thyroid Profile among 120 Patients

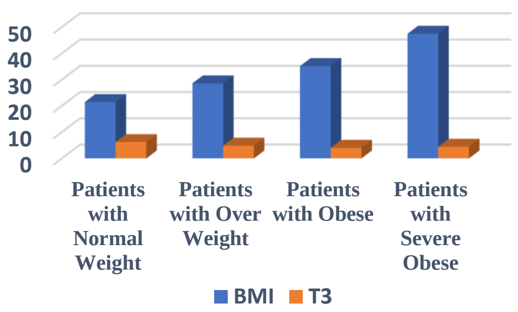


The thyroid hormone summary statistics for the patient group diagnosed with endometriosis show abnormal levels. The mean **T3** level was 4.61 ± 3.64 ng/ml, which is higher than normal, indicating potential thyroid dysfunction. The mean **T4** level was 7.08 ± 6.44 ng/dl, also abnormal, suggesting possible issues with thyroid hormone production or regulation. Additionally, the mean **TSH** level was 7.96 ± 9.75 µIU/ml, which is elevated, pointing to potential hypothyroidism or a disrupted feedback mechanism in this group of patients which is shown in table-3.

7.4.Table-4 Showing a statistical analysis of correlation between BMI and T3 levels:

Parameter	Patients with Normal BMI n=18 (15%)	Patients with Over Weight n=19 (15.9%)	Patients with Obese n=47 (39.1%)	Patients with Severe Obese n=36 (30%)
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
BMI	21.47 ± 2.58	28.58 ± 1.28	35.16 ± 2.72	47.48 ± 4.35
T3	6.23 ± 5.50	4.84 ± 5.12	4.03 ± 2.59	4.43 ± 2.50

Graph:4
Statstics of BMI Correlated with T3 Levels

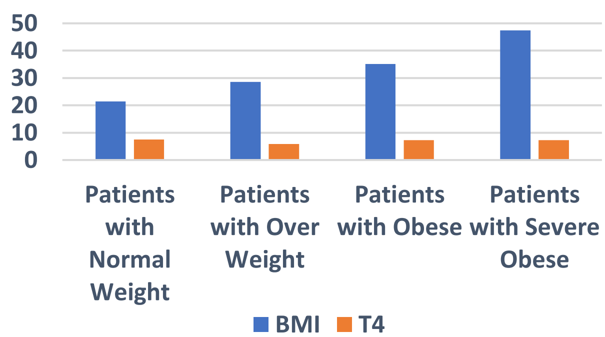


The data examines the relationship between BMI categories and T4 levels among 120 patients the data does not show a consistent trend in T4 levels across BMI categories. While T4 levels are lower in the overweight group compared to normal BMI patients, they rise slightly in the obese and severely obese groups. This variation suggests that the relationship between BMI and T4 levels may be complex, potentially influenced by other factors such as metabolic changes or thyroid function data showed in table-5.

7.5.Table-5 showing the statistical of BMI correlated with T4 levels:

Parameter	Patients with Normal BMI n=18 (15%)	Patients with Over Weight n=19 (15.9%)	Patients with Obese n=47(39.1%)	Patients with Severe Obese n=36 (30%)
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
BMI	21.47 ±	28.58 ±	35.16 ± 2.72	47.48 ±
T4	7.51 ±	5.83 ±	7.32 ± 6.97	7.23 ±

Graph-5
Statstics of BMI
Correlated with T4 Levels



thyroid function is essential for metabolic regulation, these irregularities could indicate underlying metabolic disturbances. The high TSH levels often suggest hypothyroidism, while the abnormal T3 and T4 levels may point to a subclinical thyroid issue, potentially exacerbated by obesity.

A key finding was the decreasing T3 levels as BMI increased, which may indicate a connection between obesity and thyroid dysfunction. This observation aligns with existing research that links obesity with impaired thyroid function, potentially due to factors such as insulin resistance, imbalances in adipokines, or chronic inflammation. These thyroid changes may further complicate metabolic health in obese individuals, as thyroid hormones are essential for maintaining metabolic rate and energy balance.

However, the study also revealed that thyroid dysfunction was not solely dependent on BMI. This suggests that other factors—such as genetic predispositions, the presence of conditions like endometriosis, or environmental influences—could contribute to thyroid abnormalities. The inconsistent patterns in T4 and TSH levels across different BMI groups reinforce the idea that thyroid dysfunction in obesity is not simply a direct result of body weight, but rather a complex interaction of multiple factors.

The one-way ANOVA conducted in the study showed significant BMI variation across groups, but did not find significant differences in thyroid hormone levels, further suggesting that thyroid abnormalities are not solely driven by BMI. This highlights the multifactorialnature of thyroid dysfunction in obesity, where changes in weight might influence thyroid hormones, but are not the only factor at play.

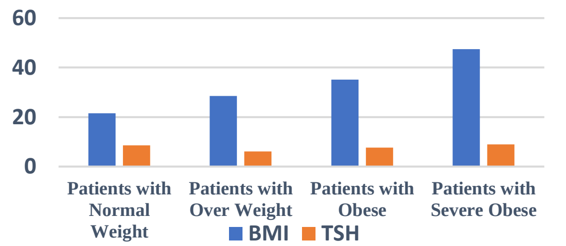
The findings underscore the importance of a comprehensive approach to managing obesity and associated endocrine issues. Healthcare providers must consider the interconnectedness of obesity, thyroid health, and other underlying conditions when planning treatment. Approaches that address both weight management and thyroid health may improve outcomes, especially for patients with conditions like endometriosis, which could further complicate hormonal and metabolic balance.

This study findings underscore the complex relationship between obesity and thyroid function. While BMI appears to play a role in thyroid dysfunction, it is clear that other factors also contribute to thyroid health. These findings emphasize the need for a personalized, holistic approach to care that takes both endocrine and metabolic health into account. Future research should investigate the mechanisms behind these observations and explore how interventions like weight loss or thyroid hormone therapy might help improve thyroid function and overall health in obese individuals.

7.6.Table:6 showing the statistics of BMI correlated with TSH levels

Parameter	Patients with Normal BMI n=18 (15%)	Patients with Over Weight n=19 (15.9%)	Patients with Obese n=47 (39.1%)	Patients with Severe Obese n=36 (30%)
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
BMI	21.47 ± 2.58	28.58 ± 1.28	35.16 ± [illegible]	47.48 ± 4.35
TSH	8.62 ± 12.11	6.15 ± 3.09	7.66 ± 8.95	8.97 ± 11.78

Graph-6
Statstics of BMI Correlated with TSH Levels



The data presents the relationship between BMI categories and TSH levels among 120 patients the TSH levels fluctuate across BMI categories without a clear pattern. The highest levels are observed in the normal BMI and severe obesity groups, while the lowest are in the overweight group. These variations suggest that factors beyond BMI, such as individual differences in thyroid function or metabolic conditions, may influence TSH levels as shown in above table-6.

7.7.Table:7 One-way Anova analysis BMI and Thyroid function parameters:

Parameter	One-Way ANOVA		
	f Ratio	p Value	Significance
BMI	324.67917	< .00001	Significant at p <0 .05
T3	1.66371	0.178685	Not-Significant at p <0
T4	0.28557	0.835739	Not-Significant at p <0
TSH	0.38304	0.76541	Not-Significant at p <0

The results of the one-way ANOVA analysis shows that the BMI shows a statistically significant variation across groups, indicating its strong association with the parameters under study. In contrast, thyroid hormone levels (T3, T4, and TSH) do not exhibit significant differences, suggesting that their variation is not influenced by the group categories in this analysis as shown in table-7.

VIII. Discussion:

This study analysed a group of 120 patients to investigate the relationship between BMI, vital signs, and thyroid hormone levels, providing important insights into the complex interaction between obesity and endocrine health. With an average age of 40 years and a mean BMI of 35.76 kg/m², the group was classified as obese (Class II), placing them at an increased risk for obesity-related health complications such as cardiovascular disease, type 2 diabetes, and metabolic disorders. Despite this elevated BMI, most participants had normal vital signs, suggesting immediate physiological stability.

However, the study found elevated levels of thyroid-stimulating hormone (TSH) and abnormal thyroid hormone profiles—particularly elevated T3 and altered T4 levels—which suggest the presence of thyroid dysfunction. Since physiological stability. Thyroid function tests revealed abnormalities, with elevated T3, abnormal T4, and significantly high TSH levels, particularly among patients with endometriosis.

Interestingly, no significant correlation was found between obesity and thyroid insufficiency. While T3 and TSH levels were abnormal across all BMI categories (normal weight, overweight, obese, and severely obese), T4 levels remained within normal ranges. This suggests that thyroid dysfunction in endometriosis patients may not be directly linked to obesity but rather influenced by other factors. Additionally, the observed trend of decreasing T3 levels with increasing BMI highlights a potential relationship between elevated BMI and thyroid hormone regulation, though inconsistencies in T4 and TSH patterns indicate the need for further investigation.

In conclusion, while thyroid dysfunction is evident in endometriosis patients, obesity does not appear to play a direct role in its development within this study population. These findings underscore the need for comprehensive interventions addressing both weight management and endocrine health. Further research involving larger, more diverse populations is warranted to confirm these results and explore the complex mechanisms underlying obesity, thyroid function, and related conditions.

IX. Conclusion:

This study provides valuable insights into the health profiles of 120 patients, emphasizing the interplay between obesity, thyroid function, and endometriosis. The majority of patients were obese, with a mean BMI of 35.76 ± 9.51 kg/m², classifying the group as obese (Class II) and indicating a high risk for weight-related complications. Despite this, vital signs such as pulse rate, blood pressure, respiratory rate, and body temperature were within normal ranges, reflecting overall

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