DEPARTMENT OF MEDICAL PHYSIOLOGY
SCHOOL OF MEDICINE
COLLEGE OF HEALTH SCIENCES
ADDIS ABABA UNIVERSITY

PREVALENCE OF HYPOGONADISM AND ASSOCIATED FACTORS AMONG MALE LEPROSY PATIENTS AT ALERT COMPREHENSIVE SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA, 2023.

BY

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Department of Medical Physiology
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Prevalence of Hypogonadism and Associated Factors among Male Leprosy Patients at Alert Comprehensive Specialized Hospital, Addis Ababa, Ethiopia, 2023.

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Acronyms and abbreviations

ADAM:	Androgen deficiency in aging male
ASA:	American society of andrology
AUA:	American urology association
BB:	Mid borderline
BL:	Borderline lepromatous
BT:	Borderline tubercloid
CDC:	Centers for disease control and prevention
EAA:	European association of andrology
ED:	Erectile dysfunction
EMoH:	Ethiopian Ministry of Health
FSH:	Follicle stimulating hormone
FT:	Free testosterone
GnRH:	Gonadotropin-releasing hormone
HD:	Hansen's disease
ISSAM:	International Society for the Study of Aging Male
LH:	Luteinizing hormone
LL:	Polar lepromatous
MB:	Multibacillary leprosy
MDT:	Multidrug therapy
NIHDDK:	National institutes of diabetes and digestive and kidney diseases
PB:	Paucibacillary
REM:	Rapid eye movement sleep
SPSS:	Statistical package for social science
TT:	Total testosterone
WHO:	World health organization

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Abstract

***Background**: Hypogonadism is a clinical and biochemical disorder characterized by symptoms and findings resulting from androgen deficiency caused by insufficient testosterone production due to different medical disorders or old age. It has a significant negative impact on one's quality of life by negatively influencing a variety of systems and has become more prevalent in recent years. It is a common disorder in male population that affects a higher percentage of men with chronic illness like leprosy.*

***Objective**: To assess hypogonadism and associated factors among leprosy patients at Alert Comprehensive Specialized Hospital, Addis Ababa, Ethiopia, 2023.*

***Methods**: An institution based cross-sectional study design was conducted from June 01, 2022, to June 29, 2023. Source population were all male leprosy patients attending follow-up at Alert Comprehensive Specialized Hospital. 146 participants were selected by a convenient sampling method from male leprosy patients over age of 18 to 65 years attending follow-up at leprosy outpatient clinic. Data was gathered both from patient charts and through patient interviews. Androgen deficiency symptoms were assessed by androgen deficiency in ageing male questionnaire, and 5ml of blood samples were taken from study participants to measure serum total testosterone, LH, and FSH. The data was analyzed by Stata version 14.0 and descriptive statistics were presented as percentage means and standard deviations. Spearman's correlation was employed to asses statistical correlation between total testosterone and independent continuous variables. A multivariable binary logistic regression model was used to identify the independent factors associated with hypogonadism and P-value <0.05 was used to declare statistical significance.*

***Results**: The prevalence of hypogonadism was 39 (26.7%) (95% CI: 19.7%–34.7%). Out of this, 34 (87.2%) had primary hypogonadism, whereas 5 (12.8%) had secondary hypogonadism. Total testosterone was inversely correlated with Body mass index (r = -0.37, p = 0.002), Luteinizing hormone (r = -0.43, p 0.001), and Follicular stimulating hormone (r = -0.42, p< 0.001). However, Total testosterone was not significantly correlated with age (r = -0.019, p = 0.81).* BMI *[AOR= 1.32, 95%CI (1.16-1.51)]* and grade-II disability *[AOR= 4.80, 95%CI (1.38-16.57)]* were identified as independent risk factors for hypogonadism.

***Conclusion**: Nearly one fourth of male leprosy patients had hypogonadism. Overweight and grade-II disability were independent risk factors for hypogonadism. All concerned bodies should work together on identifying risk factors, early diagnosis and treatment of hypogonadism in male leprosy patients.*

***Keywords**: Hypogonadism Leprosy Testosterone LH FSH*

1. Introduction

1.1 Background

Hypogonadism is a clinical and biochemical disorder characterized by symptoms and findings resulting from androgen deficiency caused by insufficient testosterone production due to different medical disorders or old age (Haydar Guler and Mustafa Aydin, 2019). Testosterone is a crucial sex hormone for men. It has a variety of biological effects, such as promoting secondary men's sexual features' development and preservation during puberty, facilitating synthesis of hemoglobin and formation red blood cells, develop and sustain sexual function, suppressing adipose tissue formation, stimulating anabolic muscular development, and increasing resting energy expenditure, has an impact on mood. Androgens are necessary for men's sexual function to be maintained and developed. The Hypothalamic-pituitary-gonadal (HPG) axis is involved in the regulation of testosterone production in eugonadal men. Gonadotropin-releasing hormone (GnRH) is produced by the hypothalamus and acts on the anterior pituitary to produce follicle-stimulating hormone (FSH) and luteinizing hormone (LH). FSH drives spermatogenesis and Sertoli cell activity, while LH stimulates the Leydig cells produce testosterone (Dandona and Rosenberg, 2010). Serum testosterone levels in men fluctuate throughout the day, with the greatest levels in the morning and the lowest levels in the late afternoon. The variance in testosterone levels in young men is roughly 35%. Early morning total testosterone levels in healthy adult males typically vary from 300 ng/dL to 1000 ng/dL (Carnegie, 2004).

Centers for Disease Control and Prevention (CDC) defines leprosy (Hansen's Disease, HD) as a chronic, treatable infectious disease caused by the slow-growing *Mycobacterium leprae* that primarily affects the eyes, skin, upper respiratory tract mucosal surfaces and peripheral nerves. It can affect people of any age, from infants to the elderly (CDC, 2017). Leprosy is a major medical concern, and its complications include bacterial infiltration, neurological damage, and immune leprosy reactions (Walker, 2007). *M. leprae* is often detected in Schwann cells of the peripheral nervous system by binding to α2-laminin and adhesins in the basal lamina, and α-dystroglycan and ErbB2 receptors on the cell membrane. This attachment causes cells to differentiate to immature cells, which allows the bacteria to multiply (Rambukkana, 2010).

Every year, approximately 720,000 new cases of leprosy are diagnosed globally, with over two million people living with leprosy-related disability. India, Brazil, Myanmar, Madagascar, Nepal, and Mozambique are the six biggest endemic nations, accounting for 88 percent of all new cases (Singh *et al*., 2015). According to EMoH, in 2018–2019, the national program received 3426 leprosy cases, 96.2% of which were newly diagnosed; 68% cases were multibacillary, 15% were in children under the age of 15, and 14% had grade 2 impairment during diagnosis (EMoH, 2021). Since the testis can serve as a reservoir for *M.leprae*, testes involvement in leprosy patients is common. Testicular shrinkage, bacterial infiltration causes orchitis, which is frequently bilateral and causes disturbance in endocrine function of testis and result in hypogonadism (Mohta *et al*., 2020).

Despite the fact that several researches have reported the incidence and risk factors for hypogonadism among various chronic illnesses in Ethiopia. However, no research has been done to assess magnitude of hypogonadism and risk factors among leprosy patients in Ethiopian. So, the aim of this the aim of this study is to evaluate hypogonadism and risk factors among leprosy patients.

1.2 Statement of problem

Official data from 139 countries in six WHO regions show that 127,558 new leprosy cases were found worldwide in 2020. 8,629 of this were children below the age of Fifteen. For children, the new case reported rate was 4.4 per million (WHO, 2022). Since 2005, there has been an annual increase in obvious deformity, with a prevalence of disability of 34.8% among new cases in 2015. (Li *et al*., 2021). To date, an average of 250,000 new leprosy cases have been reported every year all over the world (Alemu Belachew and Naafs, 2019). The prevalence of this disease varies greatly by countries, with developing countries bearing the burden of both new cases and patients on treatment (Makhakhe, 2021). Physical changes (deformities or disabilities) caused by leprosy disease and the religious and social connotations attached to them have generated stigmatizing attitudes and unfavorable beliefs about individuals affected by leprosy disease in many parts of the world (White and Franco-Paredes, 2015). leprosy patients seek medical care too late and with complications due to the disease's long incubation period and social stigma. Skin lesions, sensory and motor nerve damage, blindness, nasal stiffness and septal perforation, renal disease, and testicular shrinkage that results in hypogonadism are all leprosy-related complications (Lockwood, 2007). Because testes can operate as a reservoir for the lepra bacilli and immune induced testicular cell death, hypogonadism is common among leprosy patients (Khan *et al*., 2021). In addition to chronic non-communicable diseases, infectious and inflammatory disorders like mumps, AIDS, and lepromatous leprosy are common causes of testicular damage in many tropical countries (Belchetz *et al*., 2010).

Male hypogonadism is a clinical disorder characterized by a grouping of symptoms, as well as gonadal malfunction of either interstitial cells or Sertoli cells, resulting in reduced sperm production, which frequently occurs combined. Morning total testosterone in a man should be from 300 to 1,000 ng/dl, and hypogonadism is defined when total testosterone less than 300 ng/dL by the Endocrine Society (Cohen *et al*., 2019).

Hypogonadism has a significant negative influence on one's quality of life by negatively influencing a variety of systems. Reduced libido, erectile dysfunction, diminished penile sensation, difficulties reaching orgasms, escalated irritability, diminished vigor, strength, and vitality, depression, and impaired concentration are all symptoms of hypogonadism (Haydar Guler and Mustafa Aydin, 2019). Hypogonadism has become more prevalent in recent years. It is a common disorder in male population that affects a higher percentage of aged men, obese men, and men with chronic illness. Hypogonadism affects approximately 35% of men over 45 years old, as well as 30-50% of men with obesity or chronic illness (endocrine society, 2022).

In middle-aged and older males in Europe and United States, hypogonadism was discovered in 2.1% and 38.7% of cases, and twelve new cases are estimated to occur per 1,000 person-years. Patients with concurrent illnesses such as type 2 diabetes, leprosy, and obesity had higher prevalence. The burden of hypogonadism in the general population could be very high. With age and the presence of certain illness conditions, the burden appears to increase (Zarotsky *et al*., 2014). Hypogonadism is seen in 10–80 percent of leprosy patients (Rée GH, 1981). According to a study conducted in India, 72.1% of patients showed testicular atrophy, 39.5% had low blood testosterone, 20.9% had high serum FSH levels, and 11 25.6% had high LH levels. The levels of testosterone and FSH, as well as LH, had a strong negative correlation. A substantial positive association was also found between testicular volume and testosterone levels (Mohta *et al*., 2020).

Study conducted in Brazil found that 37.5% leprosy patients had primary hypogonadism and it's more common among lepromatous leprosy and above 60 years old leprosy patients (Luis *et al.,* 2010). A study among 55 leprosy patients in Turkey discovered that 51% had total testosterone levels below the normal range, Patients with lepromatous leprosy had smaller testicular volumes, and the period of leprae illness and testicular volumes was inversely correlated (Haydar Guler and Mustafa Aydin, 2019). Prevalence of hypogonadism among leprotic patients in Egypt was 27.5% and 52.5% of patients showed depressive disorders (Moussa *et al*., 2017).

Because of the high magnitude of symptomatic hypogonadism, there is a significant public health impacts in regards to sexual function and possible infertility. Hypogonadism, which is the most common among leprosy patients, is not only linked to reproductive function, but also to depression, anemia, osteoporosis, fractures, frailty, metabolic syndrome and increased risk of cardiovascular

mortality (Corona *et al*., 2011). Male sexual drive and performance are significantly reduced when plasma testosterone levels fall below the normal range (Michael, 1985).

An International Society of Aging Male, European Academy of Andrology and Endocrine Society, recommended measurement of testosterone in men with chronic illnesses and infectious diseases like AIDS and leprosy (Wang *et al*., 2009; Corona *et al*., 2020). Phosphodiesterase inhibitors, such as sildenafil citrate, do not normally help these people with low testosterone. As a result, failing to detect testosterone in these patients wastes a lot of money and extends the time it takes to identify an alternate treatment for the patients unnecessarily (Kapoor *et al.*, 2007).

Despite the fact that hypogonadism has a detrimental health impact on leprosy patients, open discussion of sexually related concerns is frowned in Ethiopia. As a result, most patients are hesitant to discuss sexual issues with their doctor. In spite of the limited resources, health care providers are not conducting necessary standard questioning or clinical assessments to diagnose hypogonadism. As a result, hypogonadism is under-recognized and under-treated.

Although some studies have reported the magnitude and predictors of hypogonadism among some medical disorders in Ethiopia. However, there is no study conducted to assess hypogonadism and associated factors among leprosy patients in Ethiopia. Therefore, the aim of this research is to evaluate hypogonadism and risk factors among leprosy patients.

1.3 Rationale and significance of the study

Few researches have been conducted and published focusing on the incidence of hypogonadism and risk factors among leprosy patients in Sub-Saharan Africa. (John *et al.*, 2007), but as to our knowledge in Ethiopia there is none Hypogonadism among leprosy patients is neglected public health issue with limited information on its prevalence and contributing factors. Previous research in Ethiopia has focused on different leprosy complications. There was a research gap about the magnitude and contributing factors of hypogonadism in leprosy patients, which is crucial for providing the best possible follow-up care and treatment.

There was a need for study to identify effective solutions and hopefully to notify clinicians on effective monitoring of hypogonadism among leprosy patients and to halt it in its earliest stages. This study going to alert clinicians, policy makers and health planners to give attention to this problem to designing best and appropriate hypogonadism screening and effective intervention. This study identified the potential risk factors associated with hypogonadism. Recognizing those risk may aid in the early detection, prevention, and early management of hypogonadism, which in turn enhances patients' quality of life. Additionally, the results of this research will serve as the basis for further study on related areas.

2. Literature review

2.1 Leprosy

Leprosy is a leading contributor of non-traumatic peripheral nerve damage worldwide. It is a chronic illness that predominantly affects the skin and peripheral nerves, resulting in neuropathy as well as other long-term effects like disability and deformities. This disease is stigmatized, particularly when defects are apparent. WHO recommends at least one of the following cardinal signs must be present to diagnose leprosy: thickened or enlarged peripheral nerve; evident absence of sensibility in a reddish or hypopigmented patch of skin; A slit-skin smear will reveal positive acid-fast bacilli (WHO, 2018).

Those who are infected with Mycobacterium leprae experience a wide spectrum of clinical and pathological symptoms. This diversity has been attributed to individual differences in the capacity to produce an immune cell response to M. leprae.

According to the **Ridley-Jopling classification,** an infected individual with an elevated cell-mediated immunity harbors a low number of bacilli and manifests a one, clearly defined lesion having central hypoesthesia and hypopigmentation. These lesions' biopsies reveal rare acid-fast bacilli as well as established epithelioid granulomas; this classified as polar tuberculoid (TT). Individuals with minimal or no cellular immunity to Mycobacterium leprae have a substantial number of bacilli, and a biopsy of massive infiltrates or nodular skin lesions shows pictures of macrophages that are foamy in the dermis, which contain huge number of bacilli and micro-colonies and are highly contaminated. This form is polar lepromatous (LL). However, most of the patients are "borderline" between the between the 2 extreme categories. Mid borderline (BB), borderline lepromatous (BL), and borderline tuberculoid (BT) disease are subdivided into the "borderline" group, each having a distinctive bacilli load and an inflammatory infiltration structure. (Scollard, 2018).

In 2017 WHO modified the case classifications for Paucibacillary and Multibacillary leprosy as “Paucibacillary (PB) case: a case of leprosy with 1 to 5 skin lesions, without demonstrated presence of bacilli in a skin smear;” and “Multibacillary (MB) case: a case of leprosy with more than five skin lesions; or with nerve involvement (pure neuritis, or any number of skin lesions and neuritis); or with the demonstrated presence of bacilli in a slit-skin smear, irrespective of the number of skin

lesions". The WHO simplified clinical categorization system classifies types BB, BT, and LL as "multibacillary," while types TT and BT are categorized as "paucibacillary" (PB)." (WHO, 2018).

There are two types of hypersensitivity reactions: type 1 leprosy reaction and type 2 leprosy reaction. Type 1 leprosy reactions are thought to be caused by a shift in cell mediated immunity and only occur in borderline cases (BT, BB, and BL). It causes inflammation of the skin lesions and/or nerves. Type 2 leprosy reaction occurs only in BL and LL patients and is thought to be caused by antigen-antibody accumulation in tissues. The most common symptom is erythema nodosum leprosum (ENL), however it can also cause fever and some organ infection (Bhat and Prakash, 2012)

2.2 Hypogonadism

According to the Endocrine Society, the term " male hypogonadism" refers to a clinical condition in which the hypothalamic-pituitary-gonadal (HPG) axis is disturbed at one or more sites that impair the production of normal quantities of testosterone and spermatozoa by the testes. Hypogonadism is a general word to describe any condition characterized by low total or free testosterone levels in the blood (Belchetz *et al*., 2010).

The brain produces gonadotropin-releasing hormone (GnRH), which causes the anterior pituitary to produce luteinizing hormone (LH) and follicle-stimulating hormone (FSH). While LH activates the Leydig cells, leading them to produce testosterone, FSH drives spermatogenesis and Sertoli cell function (Marques *et al*., 2022).

Primary hypogonadism is due to defects of the hypothalamic-pituitary-testicular axis at the testes level, which leads to low serum testosterone levels, impaired spermatogenesis, and increased gonadotropin hormone, whereas secondary testicular failure is due to abnormality of the hypothalamus or pituitary, which leads to low serum testosterone levels, impaired spermatogenesis, and reduce or reduced to normal gonadotropin levels. Hypogonadism can also be caused by a combination of abnormalities affecting both the testis and the pituitary gland (Kumar *et al*., 2010).

In the bloodstream, testosterone can be found in a number of different forms. In the blood, 40%–48% of testosterone is bound to albumin and 50–60% of testosterone is bounded to sex hormone binding globulin and approximately 2% of testosterone circulate as free in circulation. Because SHBG binds tightly to testosterone, the free and albumin-bound testosterone is primarily available for biological activity. As a result, bioavailable testosterone refers to both free testosterone (FT) and albumin-bound testosterones (BT). Hypogonadism is diagnosed when there are specific symptoms and signs present, as well as a drop in testosterone levels in the blood (Lunenfeld *et al*., 2013).

2.3 Pathogenesis of hypogonadism in leprosy

Leprosy first affects the peripheral nerves and skin, then followed by the lymph nodes, eyes, testicles and bones. The bacilli reach the testicles through skin tissue invasion, blood or the lymphatic system, and the testes can serve as a reservoir for Mycobacterium leprae. A lower testicular temperature than internal body temperature may promote M. leprae growth in testicle. Testicular atrophy is caused by a change in the immune response driven by inflammatory cytokines, as well as local alterations caused by vascular thickening and fibrosis and also caused by bacillary infection. These cause low testosterone production among leprosy patients (Gunawan *et al.*, 2020).

Testicular infection by M. leprae can result in three stages of histopathological alterations that can induce hypogonadism. First, the thickening and constriction of vessels occurs during the vascular phase or active leprous orchitis, in which lymphocytes and bacilli infiltrate vessels of various diameters. Second, collagen deposition during the interstitial phase causes interstitial fibrosis and Leydig cell clumping. Third, fibrosis develops during the obliterative phase, leading to the hyalinization and obliteration of seminiferous tubules and Leydig cells. Reduced blood flow during this phase damages Sertoli and Leydig cells and impairs testosterone secretion (Richard et al., 2022).

Both interstitial cells and seminiferous tubules are affected by leprosy, resulting in decrease in testosterone production. Testicular atrophy, characterized by a reduced testosterone production,

which results in a change in sexual function. Testicular atrophy can be caused by a variety of circumstances, including severity of testicular involvement, timely treatment, length of time of the leprosy disease, and erythema nodosum leprosum (Kamel *et al*., 2014).

2.4 Hypogonadism and leprosy patients

According to study conducted among male leprosy patients in Bandung, Indonesia, 93.75% of individuals had decreased testicular volume, and serum testosterone was low in 40.62%. Increased levels of serum Follicular Stimulating Hormone and Luteinizing Hormone were observed in 21.88%and28.13% of individuals, respectively, and 18.75% of male leprosy patients had low testosterone but elevated LH, while 9.38% of men had normal testosterone but increased LH. There were many clinical manifestations in some of these patients. Libido was reduced in 21.87%, gynecomastia in 6.25%, and two of the cases had secondary infertility. None of the individuals had primary infertility and erectile dysfunction (Gunawan *et al*., 2020).

In a study of 76 male leprosy patients in Uttar Pradesh, India, it revealed that 9.9% showed clinical hypogonadism symptoms such as gynecomastia, diminished sexual hair, and infertility. Serum testosterone levels were measured in 31 of the patients, and 25.8% of them had low levels (Mean 4.65±3.37 ng/ml). Hypogonadism was strongly correlated with age, leprosy duration, and economic status (Aggrawal *et al*., 2005).

In a study among 43 male leprosy patients conducted in dermatology, venereology, and leprology outpatient department, India, low testosterone levels were found in 39.5% patients, high serum FSH levels in 20.9% of patients, high LH levels in 25.6% patients, and a normal hormonal profile in 48.8% patients. Four patients had normal testosterone with high FSH, three had normal testosterone and elevated LH level. Total testosterone levels were found to have a significant negative correlation with both FSH and LH. total testosterone levels and testicular volume and were found to have a strong positive relationship ($r = 0.57$, $P = 0.001$) (Mohta *et al.*, 2020).

Serum FT was found to be reduced below normal in 37.5% of patients, whereas 18.8% and 6.3% of male leprosy patients had elevated serum levels of LH and FSH, respectively in a study conducted in Brazil, among 21 individuals with chronic lepromatous illness. In people over 60, LH and FSH mean basal levels were significantly greater, while testosterone levels were significantly lower. The lepromatous dimorphic had significantly higher basal serum Follicular stimulating hormone (8.24 ± 2.56 mlU/ml) and Luteinizing Hormone (6.96 ± 4.45 mlU/ml) and. In tuberculoid leprosy, plasma gonadotropins were within normal limits. The mean plasma FSH level in lepromatous leprosy was 6.88 ± 3.02 mlU/ml, while LH levels were 3.53 ± 1.02 mlU/ml. Dimorphic leprosy had a basal plasma FT level of 10.51 ± 5.48 pg/ml, lepromatous leprosy had a basal plasma FT level of 11.53 ± 4.31 pg/ml, and tuberculoid leprosy had a basal plasma FT level of 16.103 ± 6.51 pg/ml (Andrade *et al.*, 2010)

A comparative study conducted among 51 leprosy patients and 55 control group in Turkey revealed that, Leprosy patients had significantly decreased levels of total testosterone, free testosterone, and bioactive testosterone, but LH, FSH ($p<00001$), and SHBG ($p< 0039$) were substantially greater in leprosy group, In the leprosy group, 51% had total testosterone levels below the normal range, compared to 10% in the control group. Leprosy patients' testicular volumes were reduced than those of control group. In terms of sexual desire ($p = 0076$), no substantial difference among groups, but Patients with leprosy showed reduced levels of erection, sexual satisfaction, orgasm, and overall satisfaction. ($p< 0001$) (Haydar Guler and Mustafa Aydin, 2019).

According to a study done at the in Nilphamari, Bangladesh, and the Dhaka program of the Leprosy Mission International-Bangladesh, 16.2% of patients had low testosterone whereas 36.9% had normal testosterone levels but elevated levels of FSH and/or LH. In multibacillary leprosy affected individuals, a positive bacillary index, grade-II disability, and reduced testicular volume viewed as contributing factors for hypogonadism (Farhana *et al*., 2019)

A study conducted among 30 male leprosy patients in South Africa revealed that, the mean serum Luteinizing hormone and Follicular stimulating hormone levels in the lepromatous group were substantially higher than in the tubercloid ($p< 0001$) group. The length of leprosy and basal LH have a strong positive connection ($r = 0.4452$, $P<0.05$). There was no link between leprosy duration

and basal FSH and LH. The lepromatous group's mean basal plasma testosterone level was significantly reduced compared to tubercloid group (John *et al.*, 1977).

In a study comparing 40 male leprosy patients with 40 healthy men in Egypt, it was discovered that 25% of the patients had gynecomastia, 2% of them having a history of ENL. 22.5% of who had a history of ENL had tiny, hard testes. Patients' mean levels of the hormones FSH and LH were significantly higher than those of controls' mean. Testosterone levels were significantly lower among leprosy patients than control group. The time length of the disease and the hormonal levels of FSH and LH were strongly positively correlated. Both the length of the disease and the physiological level of testosterone and the number of sperm produced were negatively correlated, with a significant difference between groups. ($P < 0.01$) (Kamel *et al*., 2014).

2.5 Conceptual framework

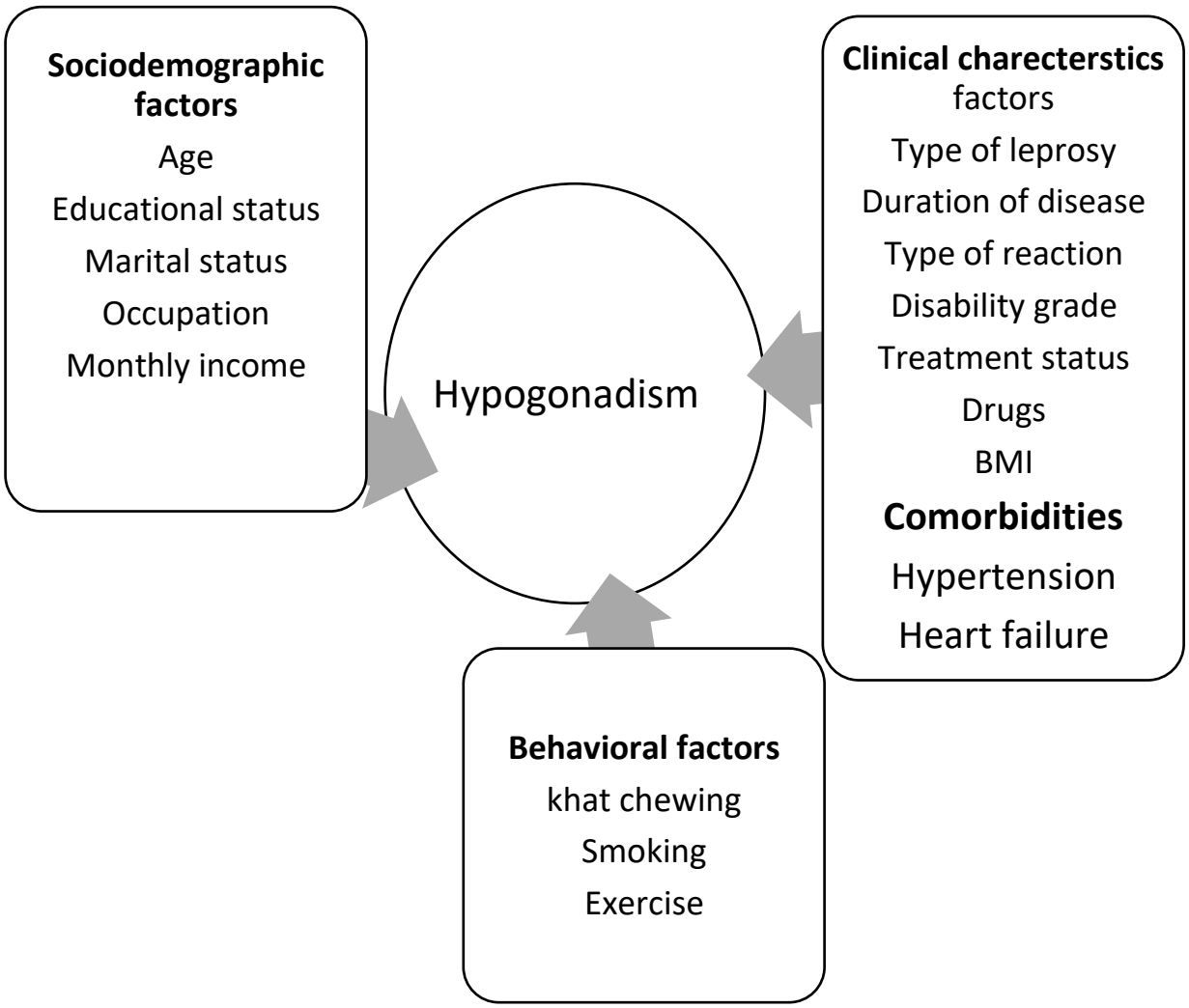


Figure 1. Conceptual framework of Hypogonadism.

3. Objectives

3.1 General objective

To assess hypogonadism and risk factors among male leprosy patients at Alert Comprehensive Specialized Hospital, Addis Ababa, Ethiopia, 2023

3.2 Specific objectives

- ✓ To determine prevalence of hypogonadism among male leprosy patients
- ✓ To identify associated factors with hypogonadism among male leprosy patients
- ✓ To assess correlation of testosterone and FSH & LH among male leprosy patients

4. Materials and methods

4.1 Study area

The research was conducted at Alert Comprehensive Specialized Hospital. It was a WHO-accredited international leprosy training center and Ethiopia's largest tertiary level referral center for leprosy patients that sits 2,303 meters above sea level. It provides a variety of outpatient and inpatient services. Outpatient clinics give outpatient service for: leprosy follow-up clinics and general medical clinics for leprosy patients. Alert Comprehensive Specialized Hospital is located southwest of Addis Ababa on the way to Jimma.

4.2 Study period

Conducted from June 01, 2022 to June 29, 2023.

4.3 Study design

Cross-sectional study design was used.

4.4 Source population

Source population was all male leprosy patients attending at Alert Comprehensive Specialized Hospital.

4.5 Study population

Study population was male leprosy patients who come to Alert Comprehensive Specialized Hospital, leprosy outpatient clinic during period of data collection

4.6 Inclusion and exclusion criteria

4.6.1 Inclusion criteria

Male leprosy patients age of 18- 65 years who have been diagnosed with leprosy were included.

4.6.2 Exclusion criteria

- ✓ Patients receiving testosterone replacement therapy.
- ✓ Patients who had a history of pelvic chemotherapy, radiation, and mechanical testicular damage.

- ✓ Patients who had a history of diagnosed chronic illnesses such DM, liver cirrhosis, cancer, Alcoholic abuse or AIDS were not included. Patients who are unable to speak, mentally unstable and severely ill during data collection were not included in the study.

4.7 Sample size determination and sampling technique

4.7.1 Sample size determination

A single population proportion formula was used to calculate the sample size by using 16% of prevalence of hypogonadism among leprosy patients in Bangladesh (Farhana *et al*., 2019), 95% confidence interval (CI), margin of error of 5% and 10% non-response was added to calculated sample size.

$$n = \frac{(Z\,\alpha/2)^2 * p(1-p)}{d^2}$$

Where

n= determined sample size

Z= cut off value of the normal distribution at 95% CI = 1.96

P= proportion of hypogonadism among leprosy patients= 0.16

d= marginal error= 0.05

$$n = \frac{(Z\,\alpha/2)^2 * p(1-p)}{d^2} = \frac{(1.96)^2 * 0.16(1-0.16)}{(0.05)^2}$$

$$n = 206$$

Non response rate 10% will be added then

n= 206+20= 226

The source population was less than 10,000(N= 420, which was taken from the last 2months follow up). Then sample size was corrected by using correction formula.

Corrected sample size = $\frac{n}{1+n/N} = = \frac{226}{1+226/420}$ = 146

4.8 Sampling techniques

146 study participants were selected using a convenience sampling technique.

4.9 Study variable

4.9.1 Dependent variable

- Hypogonadism among male leprosy patients

4.9.2 Independent variable

Sociodemographic factor

- Age
- Occupation
- Educational status
- Marital status
- Income/month

Behavioral factors

- Smoking
- Physical exercise
- Khat chewing

Clinical characteristics factors

- Type of leprosy
- Treatment (MDT) status
- Leprosy reaction
- Duration of disease
- Disability grade
- Drugs
- BMI

- Other comorbidities
  Hypertension
  CHF

4.10 Operational definition

ADAM Positive: - "study participants who responded "yes" to questions 1 and 7 or to any other three questions on ADAM questionnaire" (Morley, 2000).

ADAM Negative: - if study participants did not answer "yes" to both questions 1 and 7 or did not answer "yes" at least to any other 3 questions on ADAM questionnaire (Morley, 2000)

Low TT: Total testosterone ≤12.1nmol/L

Normal TT: - Total testosterone greater than 12.1nmol/L (Lunenfeld *et al*., 2013)

Hypogonadism: Male leprosy patients with ADAM positive and TT≤12.1nmol/L (Dandona and Rosenberg, 2010).

Primary hypogonadism: "hypogonadism with elevated serum FSH (>14 mIU/ml), LH (>7.8 mIU/ml) or both".

Secondary hypogonadism – "Hypogonadism with either low or normal FSH (≤14 mIU/ml), LH (≤7.8 mIU/ml) or both" (Lunenfeld *et al*., 2013).

Disability Grading in leprosy

Grade 0: - no visible disability (no anesthesia) and no visible deformity on eye hands and feet.

Grade I: - Loss of protective sense in feet and hands but no visible deformity and damage

Grade II: - Presence of visible damage and deformity to eye, hands and feet (WHO, 2010)

BMI classification

Underweight – participants with BMI < 18.5kg/m2

Normal- participants with BMI of 18.5 – 24.9kg/m2

Overweight- participants with BMI 25 - 29.9 kg⁄m2.

Obese: participants with BMI ≥ 30 kg⁄m2 (CDC, 2017)

Regular exercises

Low (less than three days a week & each lasting less than 20 minutes) of fast walking or jogging

Medium- three to five days in a week for 20 to 30 minutes of fast walking or jogging

High- five to seven days in a week for greater than 20-30 minutes of fast walking or jogging (CDC, 2017).

4.11 Data collection tools

Data was gathered from both patients charts and the self-report of patients. Data collection was carried out by interviewers administering questionnaires after briefing the aim of the research and getting informed consent. Questionnaires written in English, then translated into Amharic, and then retranslated to English by another person

the Androgen Deficiency in Aging Male (ADAM) questionnaire was used to asses androgen insufficiency symptoms. The ADAM questioner is the most widely used androgen deficiency screening tool. It has ten questions that evaluate the severity and kind of low androgen symptoms. With low testosterone levels, it exhibits low variable specificity but high sensitivity. 5ml of whole blood samples were taken from the participants by experienced nurses early in the morning, before 11 AM and left for thirty minutes to clot and then Centrifugated at 1500 rpm to separate the serum. Separated Serum was allocated for the chemistry test. Prior to analysis, the serum samples were kept at – 20^0C in refrigerator at alert hospital. The refrigerated serum samples have been taken to St. Paul's Hospital's laboratory at the end of sample collection for analysis. Using the fully automated Cobas 6000 and Cobas e411 analyzers, hormones (LH, TT and FSH) were tested with Electrochemiluminescence method. Abnormal test results were linked to an internist for further treatment.

4.12 Data quality assurance

Data quality assurance was employed throughout the whole research process, including the design of the questionnaire, collecting data, data entry, as well as data analysis. Questionnaire was objective based, non-leading, and sequenced to preserve the logical flow of ideas (from easy to difficult and broad to specific). At end of every data collection day, every questionnaire was evaluated for consistency and completeness. Besides this, the data was cleaned before the commencement of analysis.

By following the standard operating procedures, quality of blood sample was protected throughout collection and analysis. The samples were kept in a refrigerator at the proper temperature (-20^{o}C)

until analysis. The collected samples were transported to St. Paul's Clinical Chemistry Laboratory by using ice box. Quality controls were undertaken to evaluate the performance of automated chemistry analyzer.

Post analytical: After ensuring that all test results were appropriate, the results had been printed and then test results were carefully entered into EpiData version 3.1 for statistical analysis.

4.13 Data processing and analysis

Stata version 14.0 was used to analyze the data after it was exported from EpiData version 3.1. Means and standard deviations were used to present the descriptive statistics, in contrast percentage and frequencies were used to display categorical variables. After normality test was done by Kolmogorov-Smirnov and Shapiro-Wilk test, Statistical correlation between TT and continuous independent variables was checked by Spearman correlation. logistic regression analysis was employed to evaluate statistical relation. To determine the existence of crude association, the bivariate logistic regression analysis was applied. Variables that were clinically significant and had a P-value of less than 0.25 in the bivariate logistic regression analysis were chosen to be included in the multivariable logistic regression. The independent variables contributed to hypogonadism were assessed using a multivariable logistic regression analysis. both adjusted odd ratios and crude odd ratios with 95% CI were depicted as summary measures and Statistical significance were considered at a P-value < 0.05.

4.14 Ethical consideration

ethical approval and clearance were obtained from Ethical Review Committee of Medical Physiology Department, School of Medicine, College of Health Sciences, Addis Ababa University and AHRI/Alert Ethics Review Committee. The support letter from Addis Ababa University was submitted to Alert Comprehensive specialized Hospital to obtain their cooperation. Written All study participants were told about the study's aim and provided with any extra information they needed before each responder gave their written informed consent. Personal data collected from participants were kept confidential. Their name was not written on the questionnaire. The collected data was coded and become unrecognizable once it was entered into a computer. Consent and information sheet hard copy forms were placed in a locked cabinet. A blood sample was labeled with code and was discarded after the laboratory test was done.

4.15 Dissemination of results

This study will be disseminated to the School of Graduate Studies of Addis Ababa University, Alert Comprehensive Specialized Hospital, AHRI. In addition, it will be presented at workshops and seminars, the findings will also be published peer reviewed international journals.

4. Results

4.1 Socio- demographic characteristics of study subjects

Total of 146 of male leprosy patients were included in this study. Participants age ranged from 20 to 65 years with mean age 41 ±13.09SD and 40 (27.4%) of study participants' age ranged between 50-65 years. As summarized in the Table 1, the majority of these participants 112 (76.7%) were married and only 1 was widowed. Majority of respondents, 111 (76.0%) had some formal education, and 35 (23.9%) had no formal education. Of those with formal education, 72(23.9%) subjects had primary education, and 39 (26.7%) had secondary and post-secondary education.

Most of the study subjects 41 (28.1%) were government employees and 18 (12.3%) were others (beggar, no work). As well as 98(67.1%) had income between 1500- 5000 ETB per month and 35 (24.0%) had income less than 1500 ETB per month.

Table 1.Socio-demographic Characteristics of Respondents among Male Leprosy Patients. (n=146)

Variables	Frequency	Percentage
Age Categories		
20- 34	54	37.0
35 – 49	52	35.6
50-65	40	27.4
Marital status		
Married	112	76.7
Single	29	19.9
Widowed and Divorced	5	3.4
Level of education		
No formal education	35	23.9
Primary	72	49.3
Secondary and College	33	22.6
University and above	6	4.2
Occupation		
Farmer	38	26.1
Daily laborer	19	13.0
Merchant	26	17.8
Government employee	41	28.1
Others (beggar, no work, NGO employee)	22	15.1
Income per month		
<1500	35	24.0

1500-4999	98	67.1
5000-10000	11	7.5
>10000	2	1.4

4.2 Behavioral characteristics of respondents

As indicated in the table below, out of total study participants, 16 (10.9%) had a history of khat chewing. Out of those who had a history of khat chewing, 11 (7.5%) had chewed khat for greater than 5 years. Most study participants had never smoked cigarettes, while 5 (3.4%) had a history of cigarette smoking (Table 2).

Table 2. Behavioral Characteristics of Study Participants among Male Leprosy Patients. (n=146)

Variables		Frequency	Percentage
Khat chewing history			
Yes		16	11.0%
No		130	89.0%
For how long they chewed			
<5 years		5	3.4%
≥ 5 years		11	7.5
Cigarette Smoking history			
Yes		5	3.4%
No		141	96.6%
For how long they smoked cigarette			
<5 years		2	1.4%
≥5 years		3	2.1%
Regular exercise			
No		25	17.1%
Yes	Low	36	24.7%
	Medium	72	49.3%

High	13	8.9%

4.3 Clinical characteristics of respondents

Out of 146 respondents, 69 (47.3%) were diagnosed less than five years, 49 (33.6%) within the last five to ten years, and 28 (19.1%) more than ten years ago. The majority of respondents, 142 (97.3%), had multibacillary (MB) leprosy, whereas 4 (2.7%) had paucibacillary (PB) leprosy. 46 (31.5%) of respondents were on treatment (MDT), and 100 (68.5%) were released from treatment (completed MDT). The majority of study participants, 61 (41.8%), had grade-I disability (figure 2).

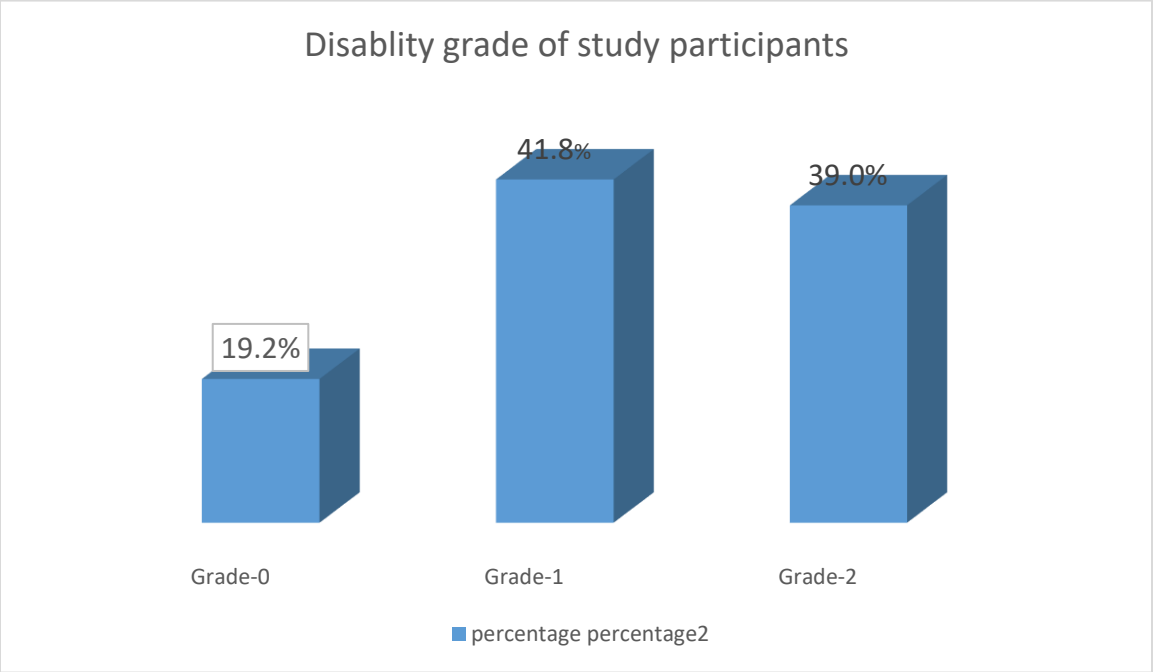


Figure 2. Disability Grade of Study Participants among Male Leprosy Patients. (n=146).

Majority of study participants, 41(28.1%) had a history of reaction. Out of those with a history of reaction, 28 (68.3%) had a type-I reaction, whereas 13 (31.7%) had history of an erythema nodosum leprosum (ENL). Almost all participants who had history of reaction 40(97.6%) were treated with prednisolone for the reaction. 32 (21.9%) took other drugs (not include MDT and prednisolone).

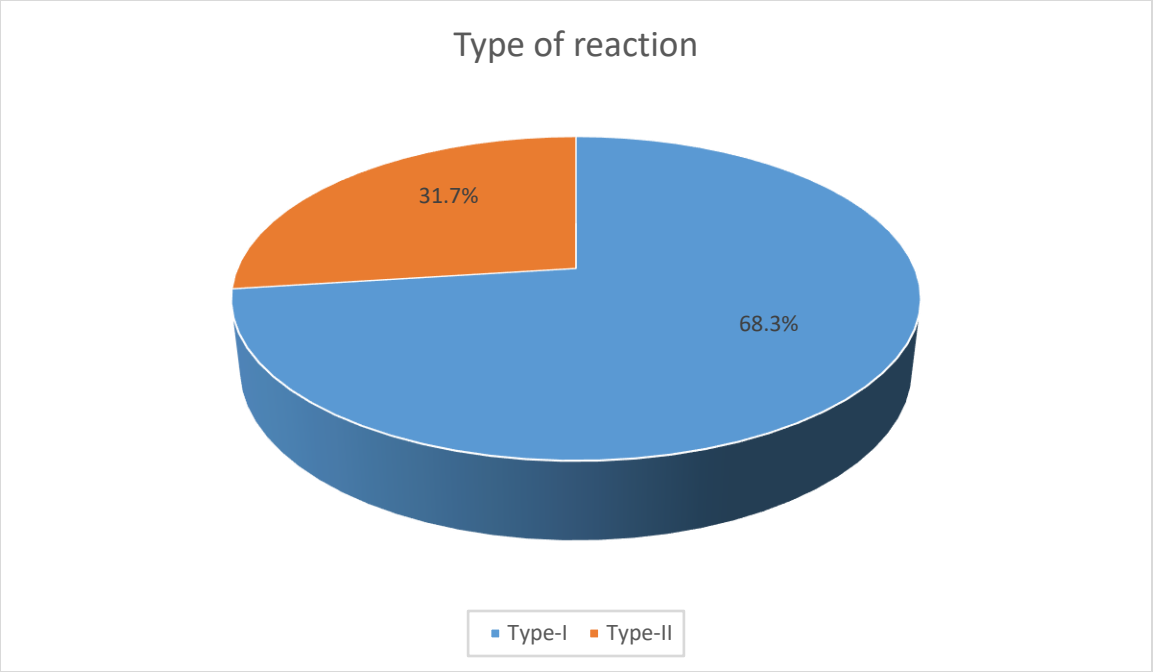


Figure 3.Distribution of Type of Reaction among Study participants who had History of Leprosy Reaction. (n=41)

Majority of respondents 137 (93.8%) had no diagnosed with chronic non-communicable disease, whereas 9 (6.2%) had a diagnosed with chronic non communicable disease. Out of those 9, 7 (4.8%) had diagnosed hypertension and they were all taking antihypertensive drugs.

The BMI ranged from 16.5 kg/m2 to 31.6kg/m2, with a mean of 22.0 kg/m2 and a standard deviation of 3.3 kg/m2. The majority of the participants, 114(78.1%), were in normal BMI range (18.5-24.9 kg/m2), while 7 (4.8%) were underweight (BMI less than 18.5), 22 (15.1%) were overweight (BMI, 25 - 29.9 kg/m2), and only 3 (2.0%) were obese (BMI ≥30 kg/m2).

4.4 Prevalence of androgen deficiency symptoms

the prevalence of androgen insufficiency symptoms among the study subjects were summarized in Table 3. The most reported symptom was lack of energy 101 (69.2%) followed by decrease in strength/endurance 98 (67.1%). Two relatively specific symptoms, erectile dysfunction was reported by 65 (44.5%) out of 146 patients participated in this study and loss of libido was reported by 80 (54.8%) of the study participants (Table 3).

Table 3. The Frequency of Androgen Deficiency Symptoms among Male Leprosy Patient Study Participants (n=146)

s.no	Symptoms	Responses	
		Yes (%)	No (%)
01	Decreased libido	80 (54.8%)	66 (45.2%)
02	Lack of energy	101(69.2%)	45(30.8%)
03	Decrease in strength/endurance	98(67.1%)	48(32.9%)
04	Lost height	6(4.1%)	140(95.9%)
05	Decreased enjoyment of life	67(45.9%)	79(54.1%)
06	Often sad or grumpy	57(39.0%)	89(61.0%)
07	Erectile dysfunction	65(44.5%)	81(55.5%)
08	Recent deterioration in sporting ability	30(20.5%)	116(79.5%)
09	Falling asleep quickly after dinner	27(18.5%)	119(81.5%)
10	Deterioration in work performance	12 (8.2%)	134 (91.8%)

4.5 Hormone data of study participants

Table 4. Hormone data of study participants among male leprosy patients. (n=146)

Hormones	Mean±SD	Minimum value	Maximum value
TT (nmol/L)	22.6±11.6	4.4	45.1
LH (mIU/ml)	7.76±5.05	1.62	33.6
FSH (mIU/ml)	12.7±5.65	4.98	36.2

4.6 Prevalence of hypogonadism among study participants

Symptoms of hypogonadism among study participants were evaluated using the ADAM questionnaire. Based on the classification criteria for responses to the ADAM questionnaire described in the methodology section, 115 (78.8%) of study participants were ADAM positive, and the remaining 31 (21.2%) were ADAM negative.

Out of the total 146 study participants, only 39 (26.7%) had a low total testosterone level (TT≤12.1nmol/L) and were positive for ADAM. Only 3 (2.05%) of the ADAM negative individuals had low TT levels (Table 5). Therefore, only 26.7% (95%CI: 19.7%–34.7%) of study participants fulfilled the criteria for hypogonadism, as it is currently defined as the existence of both androgen deficiency symptoms and a low serum testosterone level. Out of the participants who had hypogonadism, 34 (87.2%) had primary hypogonadism, whereas 5 (12.8%) had secondary hypogonadism.

Table 5. Frequency of Testosterone Level Group in ADAM Negative and ADAM Positive Study Participants. (n=146)

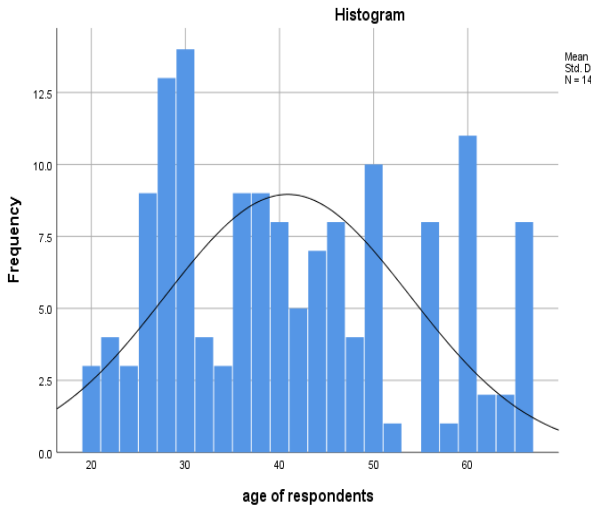
ADAM Questionnaires' response	Testosterone level	
	Low (TT≤12.1nmol)	Normal (TT>12.1nmol/L)
ADAM Positive(n=115)	39(26.7%)	76(52.05%)
ADAM Negative(n=31)	3(2.05%)	28(19.2%)

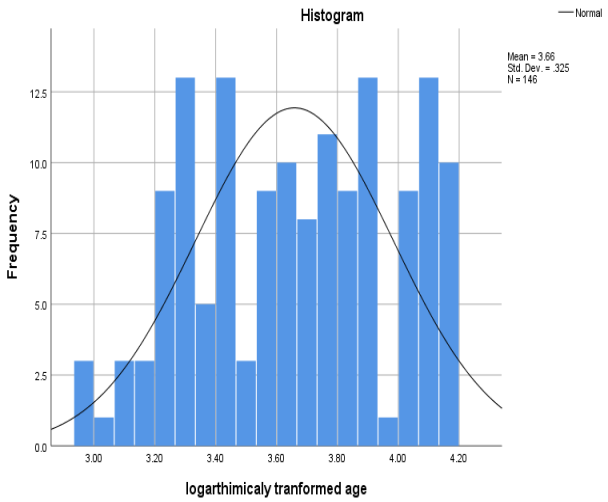
4.7 Distribution of some clinical and laboratory data

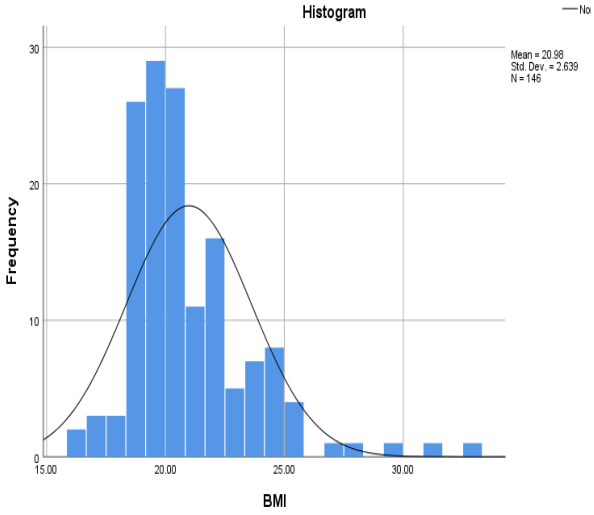
All continuous variables used in this investigation, including BMI, Age, TT, FSH, and LH were checked for normality distributions. All of these variables failed to have a normal distribution even after being logarithmically transformed (Table 6, figure 4).

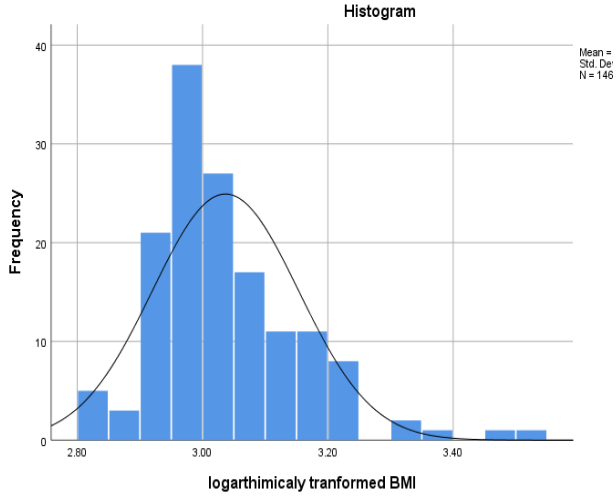
Table 6. Normality Test, Skewedness and Kurtosis of Continuous Variables of Study Participants. (n=146)

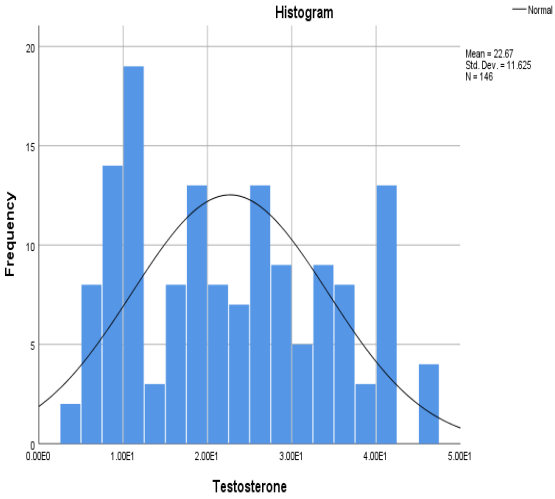
Parameters	Normality tests			
	Kolmogorov -Smirnov (K-S)	Shapiro-Wilk test	Skewness	Kurtosis
	p-value	p-value		
Age of respondents	<0.001	<0.001	0.340	-1.012
Log10(age)	0.001	<0.001	-0.100	-1.043
BMI	<0.001	0.002	1.691	4.510
Log10(BMI)	<0.001	<0.001	1.147	2.252
TT	0.001	0.001	0.241	-1.130
Log10 TT	0.001	0.002	-0.503	-0.785
LH	<0.001	<0.001	2.516	8.652
Log10 LH	<0.001	0.014	0.356	0.643
FSH	<0.001	<0.001	1.505	2.766
Log10 FSH	0.045	0.034	0.432	-0.102

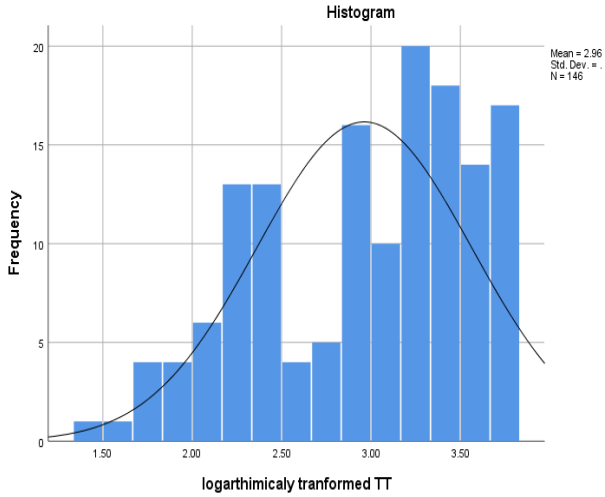

Histogram
Mean
Std. D
N = 14
Frequency
age of respondents


Histogram
Normal
Mean = 3.66
Std. Dev. = .325
N = 146
Frequency
logarthimicaly tranformed age


Histogram
Mean = 20.98
Std. Dev. = 2.639
N = 146
Frequency
BMI


Histogram
Mean =
Std. Dev.
N = 146
Frequency
logarthimicaly tranformed BMI


Histogram
Normal
Mean = 22.67
Std. Dev. = 11.625
N = 146
Frequency
Testosterone


Histogram
Mean = 2.96
Std. Dev. = .
N = 146
Frequency
logarthimicaly tranformed TT

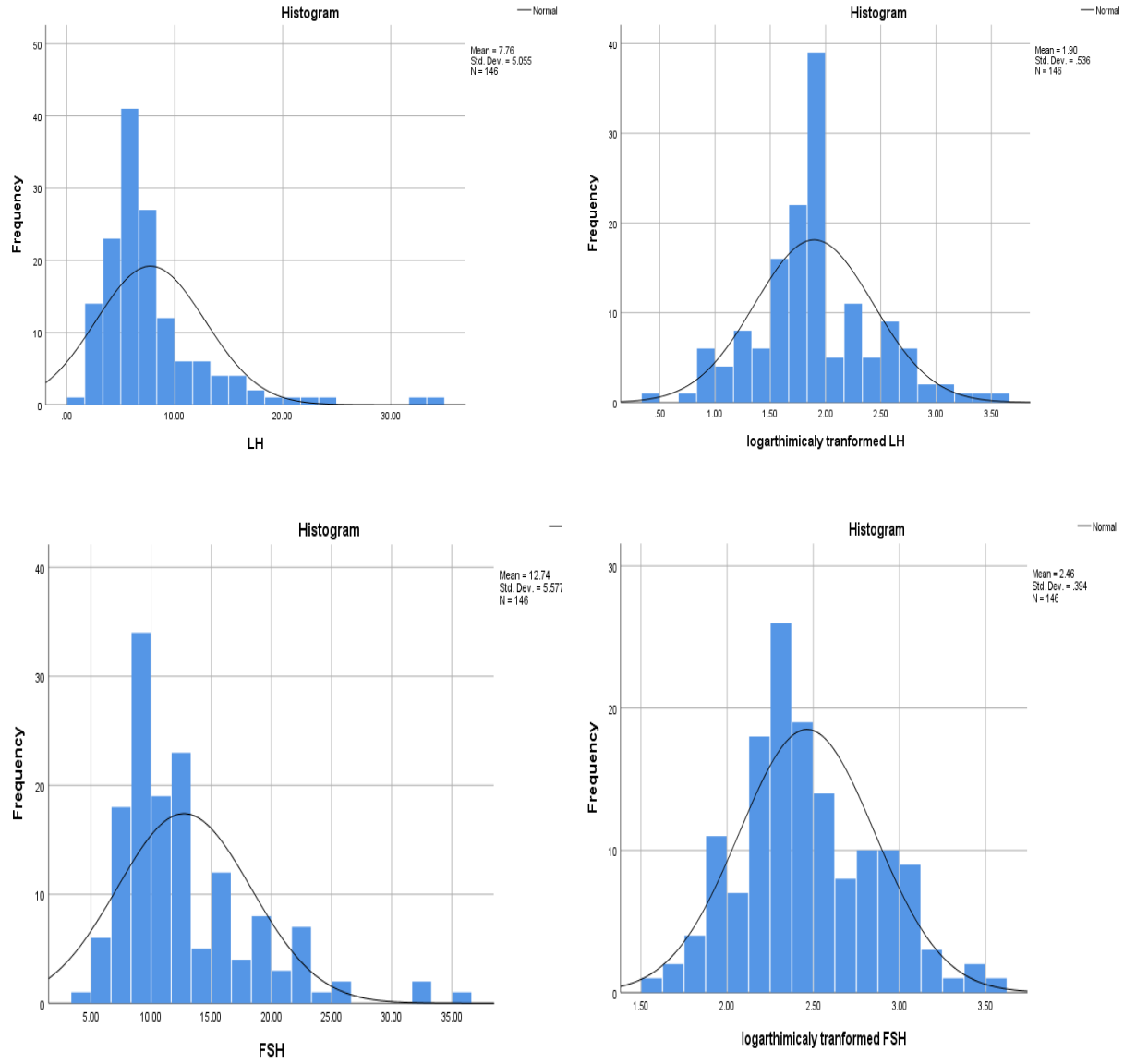
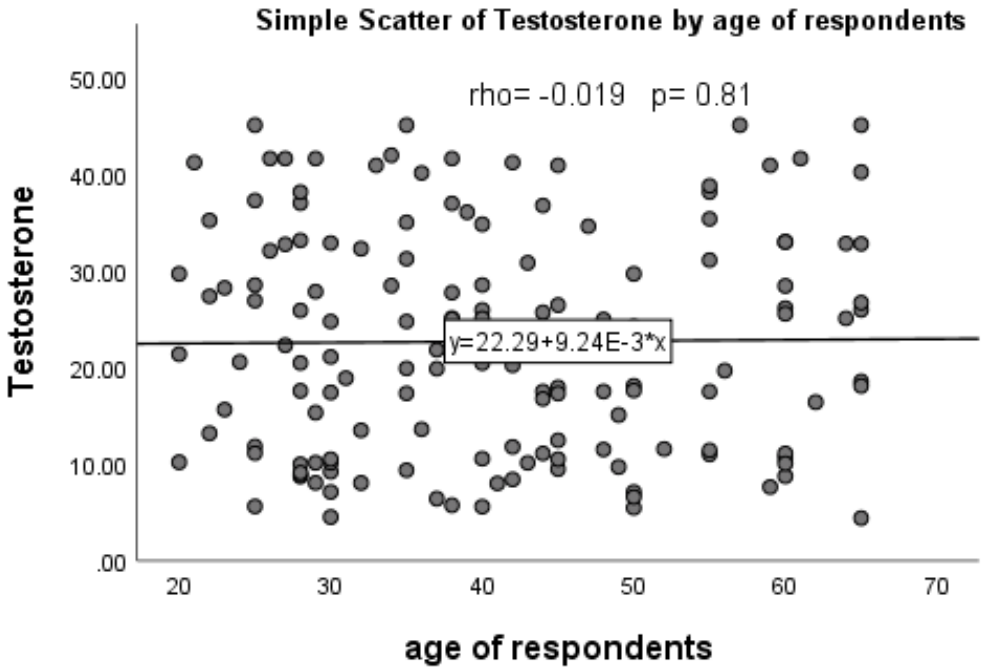
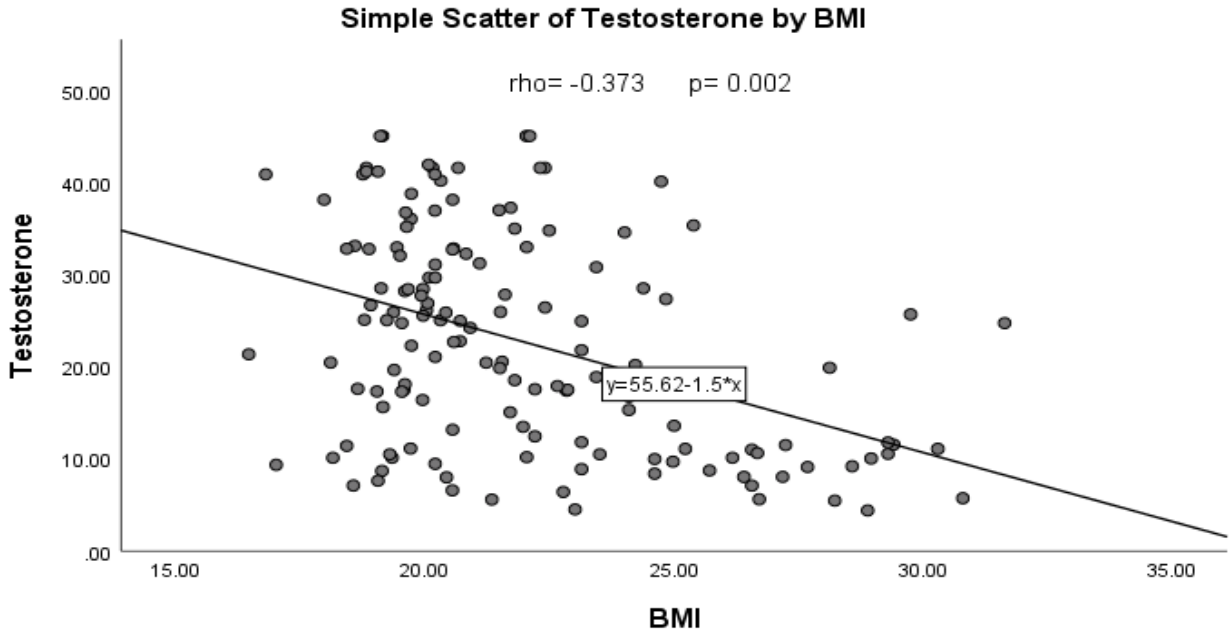


Figure 4. Shows Histograms of Age, BMI, LH, FSH TT and their Logarithmically Transformed Value of Study Participants

4.8 Correlation of independent variables with total testosterone

Spearman's correlation analysis was employed to assess correlation of TT and continuous independent variables including age, BMI, LH and FSH. As depicted below TT was inversely correlated with BMI (r= -0.37, p=0.002), LH (r= -0.43, p<0.001) and FSH (r= -0.42, p< 0.001). However, TT was not significantly correlated with age (r= -0.019, p=0.81) (figure 5).





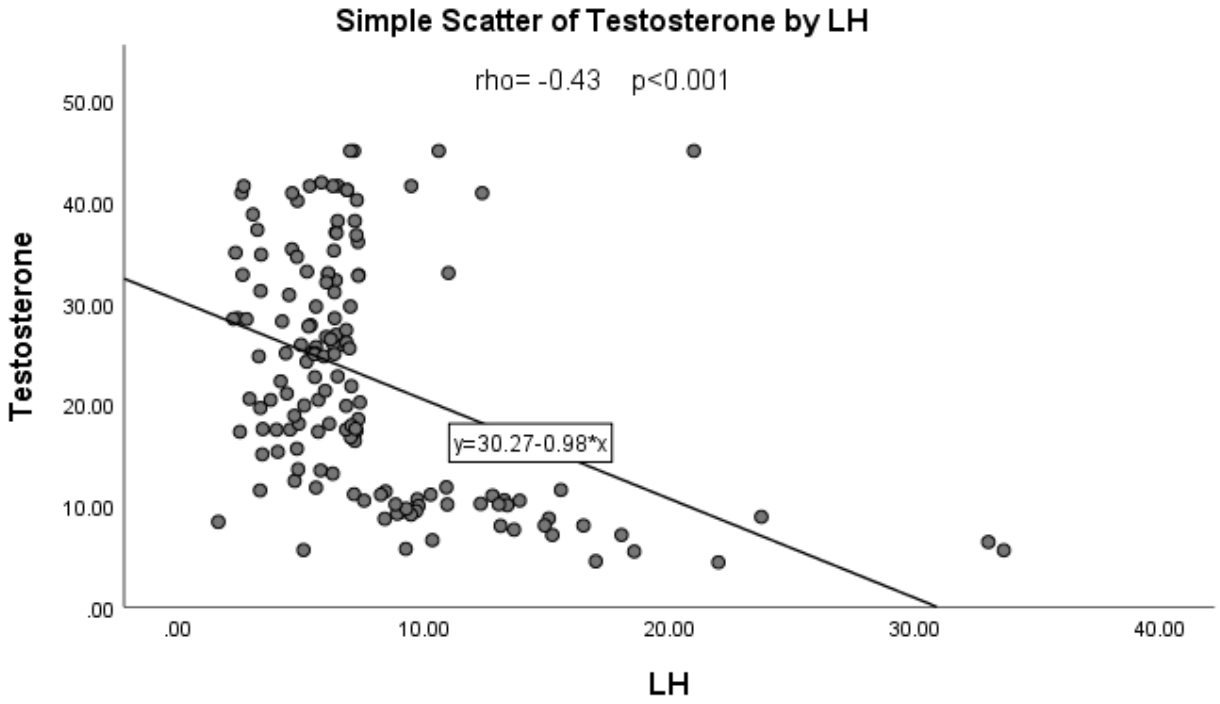


Figure 5. The Relationship between TT and Age, TT and BMI, TT and LH, TT and FSH.

4.9 Associated factors of hypogonadism among male leprosy patients

Bivariate logistic regression was applied to identify crude association of independent variables characteristics including age, time of diagnosis, MDT status, disability grade, history of leprosy reaction, history of other drugs taken, history of chronic non communicable disease, history of khat chewing, history of cigarette smoking and regular exercise with hypogonadism. According to Bivariate logistic regression, disability grade, history of leprosy reaction, history of taking other drugs (not including leprosy drugs) and BMI were significantly associated with hypogonadism at P<0.25. Those variables that showed significant association with hypogonadism in bivariate analysis were again analyzed on multivariate logistic regression analysis. In multivariate logistic regression, disability grade and BMI were factors significantly associated with hypogonadism at p<0.05 (Table 8).

Participants who had grade-II disability were 4.80 times more likely to have hypogonadism as compared to those participants who had grade-0 disability [AOR= 4.80, 95%CI (1.38-16.57)]. A 1kg/m2 increase in BMI of participants was 1.32 times more likely to have hypogonadism [AOR= 1.32, 95%CI (1.16-1.51).

Table 7. Multivariate Logistic Regression Analysis for Selected Factors Associated with Hypogonadism in Bivariate Logistic Regression among Leprosy Male Patients (n=146).

Variables	Categories	Hypogonadism		COR (95%CI)	AOR (95%CI)	p-value
		Yes (%)	No (%)			
Disability grade	Grade-0	5(17.9)	23(82.1)	1	1	
	Grade-I	9(14.8)	52(85.2)	0.80(0.24-2.64)	1.12(0.29-4.16)	0.87
	Grade-II	25(43.6)	32(72.4)	3.59(1.2-10.79)	4.8(1.39-16.57)	0.013*
History of leprosy reaction	No	23(21.7)	82(77.4)	1	1	
	Yes	16(39.0)	25(41.0)	2.28(1.05-4.98)	1.85(0.75-4.57)	0.182
History of other drugs taken	No	28(25.4)	86(74.6)	1	1	
	Yes	11(34.4)	21(65.6)	1.61(0.69-3.75	1.49(0.56-3.94)	0.42
BMI (mean±SD)		24±4.1	21±2.5	1.33(1.17-1.50)	1.32(1.15-1.51)	0.001*

1= indicate for reference group * =indicate significance at <0.05

Discussion

Using the serum total testosterone cutoff number and latest criteria for hypogonadism from the International Society of the Aging Men, this study revealed that prevalence of hypogonadism among male leprosy patients was 26.7% (n=146, 95%CI: 19.7%–34.7%), which is higher than study done in Bangladesh 16.2% (Farhana *et al*., 2019). A number of factors could be reason for the higher prevalence and difference with the aforementioned study. The first contributor might be the small sample size in study conducted in Bangladesh compared to our study. Another reason could be differences in selected study participants, in the study conducted in Bangladesh, time of onset of symptoms most of participants was less than five years when compared to our study: because, the higher prevalence of hypogonadism in male leprosy patients has been confirmed to be significantly contributed by chronic leprosy cases (Aggrawal *et al*, 2005).

In contrast, the prevalence of hypogonadism in this study was lower than studies conducted in Brazil 37.5% (Andrade *et al*., 2010), India 39.5% (Mohta *et al.*, 2020), Indonesia 40.6% (Gunawan *et al*., 2019), and Turkey 51% (Haydar Guler and Mustafa Aydin, 2019). This discrepancy might be due to many factors-: All of these studies didn't use the current definition of hypogonadism stated by ISSAM, which includes sex hormone level and symptoms of hypogonadism together, and in some studies, the cut-off point for low testosterone was not stated. One factor contributing to the difference in prevalence between this study and previous studies could be the age of the study participants. In a study conducted in Brazil, 47% of study participants age ranged from 60 to 75 years (mean: 48.43±18.65 SD), and in a study conducted in Turkey, (mean age: 58±10.5 years, which is higher compared to this study (mean age: 40±13.05SD). Advanced age was a contributing factor in the decrease of the testosterone level (Stanworth RD, 2008).

Another reason for the higher prevalence in previous studies could be the cut-off point for low total testosterone. In a study conducted in India 39.5% (Mohta *et al.*, 2020), the cut-off point for low testosterone was 6ng/ml, which is higher than the cut-off point used in this study. The reason for the higher prevalence of hypogonadism in the study conducted in Turkey could be the duration of disease of participants included in the study. Only male leprosy patients diagnosed 5 years prior to the time of the study were included, and the avarage duration of disease was 36±11.68 years

because, chronic leprosy cases were important contributors to the higher prevalence of hypogonadism in leprosy patients (Aggrawal *et al*., 2005).

The prevalence of hypogonadism obtained in this study was nearly in line with the prevalence of hypogonadism obtained from studies conducted in India, 25.8% (Aggrawal *et al*., 2005), and Bangladesh, 30.0% (Mashfiqul *et al*., 2017).

In this study, it is found that BMI, LH and FSH were negatively correlated with total testosterone. This finding was partly in apparent agreement with studies in India (Farhana *et al*., 2019, Mohta *et al.*, 2020), Bangladesh (Farhana *et al*., 2019), Indonesia (Gunawan *et al*., 2019). Significant negative correlation between TT and LH, and TT and FSH could be due to M. *lepraea* testicular infiltration and change in the immune response driven by inflammatory cytokines, as well as local alterations caused by vascular thickening and fibrosis of testicular tissue. This has an impact on the Leydig cells as well as the seminiferous tubules (Kamel *et al*., 2014). An increase in LH and a decrease in testosterone have a definite causal connection, since testosterone controls the release of LH through negative feedback, so Between testosterone and LH, there was a significant negative connection. FSH and testosterone also correlated negatively, despite the fact that testosterone does not control FSH secretion, this could indicate that Sertoli cell destruction and Leydig cell damage happen simultaneously.

This study found that, grade-II disability and BMI remained significantly associated risk factors of hypogonadism. Excess adipose tissue in overweight and obesity causes an increase in aromatase enzyme activity, which converts testosterone to estradiol (E2). Estrogens reduce the amount of testosterone produced overall by inhibiting the release of GnRH from the hypothalamus, as well as LH and FSH from the pituitary, through a negative feedback mechanism (Liu, Y., and Ding, Z., 2017).

The secretion of leptin and pro-inflammatory cytokines is also increased with increased visceral fat. Pro-inflammatory cytokines cause Leydig cell destruction, directly impair LH function, and decrease GnRH release from the hypothalamus, which decreases testosterone levels. Leptin has receptors in the hypothalamus and Leydig cells that suppress the secretion of GnRH from the

hypothalamus and testosterone secretion in Leydig cells (Mushannen *et al*., 2019). These could be clear evidence for the reason why this study identified an increase in BMI as a risk factor for hypogonadism.

Even though it did not reach a level of statistical significance, history of reaction (p = 0.095) was also observed to be in higher frequency among those with hypogonadism in this study. A possible explanation for this could be that participants on MDT for leprosy were included in this study. Because of reaction can happen both before and after RFT but more commonly after RFT (Kou-Huang *et al*., 2022), importance of reaction as risk factor of hypogonadism may be reduced by their inclusion. An increased disability grade was associated with a higher bacillary load and leprosy reaction (de Paula *et al*., 2019). When there is a higher bacillary load, bacillary testicular infection increases since M. *lepraea* prefers low temperatures in testicles and causes testicular tissue damage. Leprosy reaction was also associated with grade-II disability that could contribute to testicular damage through deposition of the immune complex in testicles or direct attack of the testes by pro-inflammatory cytokines (Richard *et al.*, 2022). This could be possible evidence for the reason why this study identified a grade-II disability as a risk factor for hypogonadism. Thus, clinical conditions like grade-II disability and overweight may help in the early detection of hypogonadism in male leprosy patients.

Conclusion

Nearly one fourth of male leprosy patients had hypogonadism and primary hypogonadism occurred in approximately four fifth of who had hypogonadism, whereas, hypogonadotropic hypogonadism occurred in one fifth of them.

BMI, LH and FSH were negatively correlated with total testosterone.

This study demonstrated that grade-II disability and overweight were independent associated factors for hypogonadism.

Recommendation

Based on this study's finding, we recommend that:

- ✓ Hypogonadism occurs nearly in one fourth of male leprosy patients. So, it needs special attention from clinicians, health policy makers and health planners.
- ✓ The measurement of serum testosterone levels in male leprosy patients with grade-II disability, and overweight might help in the early detection of hypogonadism.
- ✓ This study may need to be repeated with more specific tests, such as measurements of free testosterone SHBG and inhibib-B, due to the high frequency of hypogonadism symptoms but low incidence of low testosterone.
- ✓ Further, it is also important to do interventional and long-term studies to assess how effectively testosterone replacement therapy works for hypogonadal male leprosy patients.

Strength and limitation of the study

Strengths of the study

This study did not merely rely on testosterone level to assess hypogonadism as most of studies in the world did. It comprised both testosterone level and androgen insufficiency symptoms.

Selection bias was reduced because subsequent patients who fulfilled the criteria were chosen..

The study is first of its type in Ethiopia.

Limitations of the study

Because of financial constraints, further laboratory tests such as lipid profiles, liver function tests, blood sugar levels, and others were not performed.

the gold standard test, FT and SHBG, which compute free testosterone or bioavailable testosterone, cannot be measured because these tests are expensive and not available in our practice.

Since cross-sectional study design was used, this make difficult to infer causal connections between dependent variable and independent variables

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Annexes

Annex-1 Participant information sheet- English version

Greeting

You are invited to participate in a study to be conducted by MSc student Nafyad Tolossa at Addis Ababa University, College of Health Sciences and Department of Medical Physiology. Before you decide, it is important that you understand why the research is being done, what it would involve, and other information. Please read the following statements and ask any unclear points before you agree to participate.

Introduction: The study's topic is "Assessment of hypogonadism and its associated risk factors among men leprosy patients alert hospital," and it aimed to assess the sex hormone status of leprosy patients, which is significant to recommend policymakers and health planners to appropriately design effective and accessible services in monitoring sexual related compliance of leprosy patients.

Objectives; objective of this study is to assess prevalence of hypogonadism and associated factors in leprosy patients.

The reason why you are selected: this study intended to involve 146 male leprosy patients. You are invited as one of them.

Procedures to be carried out: If you agree to participate, you will be asked some general questions about yourself and specific questions on the risk factors and associated factors. The questionnaire has four parts and interview will last approximately 15_20 minutes. 5ml(tea spoonful) of blood sample will be collected under a complete aseptic technique, which will help us to determine, which will be used to determine serum TT, LH, FSH. Your will also let us measure weight and height.

Your responsibility in this study: As a participant in this study, you will be expected to give a 5ml (tea spoonful) blood sample, which will be used to determine serum TT, LH, and FSH. You will also be expected to let us measure your weight and height. You are also expected to respond to questions included in the questioner, which will be used as relevant data for this particular research.

Confidentiality: Personal information you are going to give during the data collection will be confidential. Your name will not be written in the questionnaire and I will ask you in a separate room for your privacy. Once the collected data is entered into a computer, it will be coded and become unidentifiable. Information on the computer will be password protected. Hard copy

(paper) documents such as consent and information sheet forms will be kept in a secured locked cabinet. A blood sample will be labeled with code and will be discarded after the laboratory test is done. The data will be analyzed and presented as general, and no personally identifiable information will be shared in any publication or presentation.

Expected benefit from study: The result of study will be used to recommend policy makers and health planners to appropriately design effective and accessible services in monitoring of sexual related compliant of leprosy patient and providing appropriate service sexual problem for patients

Compensation for participation: you will not get direct payment. But, you will get laboratory test result of total testosterone, luteinizing hormone and follicle stimulating hormone which are costly for free. If the test result is not in the normal range, I will link you with an internist for further treatment.

Risks and discomforts: There are no procedures in this study that could harm you. During drawing of blood sample you will feel temporary discomfort or bleeding from the needle stick.

Right to participate or not: Participation in the study is completely voluntary, and there are no penalties or loss of benefits to which you are entitled if you choose not to participate. You have the full right to accept or refuse participation in this study at any time.

Study Result Dissemination: The general findings of this study will be disseminated to Addis Ababa University, ALERT hospital and will be published in international journals

Research funding: this research is partially funded by Addis Ababa University.

Conflict of interest: no conflict of interest

Who has reviewed the study: This study has been reviewed and approved by AHRI/Alert ethical review committee to protect participants' right and interests. Any person with concerns or complaints about the conduct of this study should contact them with:

Email: ahri.alerterc@ahri.gov.et

Phone: +251118342742

Person to contact: If you have any question about the study, you can contact the principal investigator

Nafyad Tolossa, Phone No: 0993378168, Emal: nafytol430@gmail.com.

Addis Ababa University, School of Medicine, Medical Physiology department

Annex-2 Written consent form (English version)

According to the above information given to me regarding the introduction, objective of the study, the reason why I selected, procedures to be carried out, my responsibility in this study, confidentiality, expected benefit from study, compensation for participation, risks and discomforts, right to participate or not, study result dissemination**,** I agree to give 5ml blood sample and to be interviewed for all the questions that the interviewer asks me and I approve with my signature. If the participant is unable to sign please ask her/him to put inked thumb prints on the consent form.

Name of participant _____ Signature of participant _____

Date_____

Signature of the witness_____ date: _____

Name of investigator: _____ signature of investigator_____

Date _____

May I have your permission to proceed to the interview?

1. Yes..... (If yes, start the interview)

2. No..... (Thank you, stop here)

Annex-3 English Version Questionnaire

Part one: Socio-demographic characteristics

Number	Question	Response
101	Age	_____year
102	Marital status	1. Married 2. Single 3. Widowed 4. Divorced
103	Educational level	1. Illiterate 2. Primary and junior 3. Secondary and College 4. University and above
104	Occupation	1. Farmer 2. Daily Laborer 3. Merchant 4. Government employee 5. NGO employee 6. Other(s)
105	Income	1. <1500 2. 1500- 5000 3. 5000- 10000 4. > 10000

Part two: leprosy and other health related characteristics

201	When was the diagnoses made?	1. < 5 year 2. 5-10 year 3. >10
202	Type of leprosy(from chart)	1. Paucibacilliary 2. Multibacilliary
203	Disability grade(from chart)	
204	Type of reaction (from chart)	
205	Do you take any drugs other than for leprosy?(from chart)	1. _____ 2. _____

		3. _____
206	Do you have chronic non communicable diseases (from chart)?	1. Yes 2. No
207	If yes to Q208 select from the following list	1. Hypertension 2. Congestive Heart Failure /IHD

Part three: Behavioral characteristics

Number	Question	Response
301	Do you chew khat?	1. Yes 2. No
302	If yes to Q 301, for how long did you chew khat?	
303	Do you smoke a cigarette?	1. Yes 2. No
304	If yes to Q305, how many cigarettes do you smoke daily (in pcs)?	_____
305	Do you exercise regularly?	1. Yes 2. No
306	If yes to Q307, how often	1. Low (< 3 days per week & each lasting < 20 minutes) 2. Medium (3-5 days per week, each lasting 20 -30 minutes) 3. High (5-7 days per week, each lasting > 20-30 minutes)

Part four: English version of Androgen Deficiency in the Aging Male (ADAM) questionnaire about symptoms of low testosterone Patients Card number_____

		yes	No
401	Do you have a decrease in libido (sex drive)?		
402	Do you have a lack of energy?		
403	Do you have a decrease in strength and/or endurance?		
404	Have you lost height?		
405	Have you noticed a decreased "enjoyment of life"		
406	Are you sad and/or grumpy?		

407	Are your erections less strong?		
408	Have you noticed a recent deterioration in your ability to play sports?		
409	Are you falling asleep after dinner?		
410	Has there been a recent deterioration in your work Performance		

ቃለመጠይቅ

አባሪ-1 የተሳታፊ መረጃ ቅጽ (የአማረኛ ቅጂ)

ሰላም

በአዲስ አበባ ዩኒቨርሲቲ በህክምናና በጤና ሳይንስ ኮሌጅ በህክምና ፊዚዮሎጂ ትምህርት ክፍል የሁለተኛ ዲግሪ ተማሪ ናፍያድ ቶሎሳ በሚያደርገው ጥናት ላይ እንድትሳተፉ ተጋብዘዋል። ከመወሰንዎ በፊት ጥናቱ ለምን እንደሚደረግ፣ ምን እንደሚያካትት እና ሌሎች መረጃዎችን መረዳትዎ አስፈላጊ ነው። ለመሳተፍ ከመስማማትዎ በፊት እባክዎ የሚከተሉትን መግለጫዎች ያንብቡ እና ግልጽ ያልሆኑ ነጥቦችን ይጠይቁ።

መግቢያ፡ የጥናቱ ርዕስ "የቴስቶስቴሮን ሆርሞን ማነስ ጋር የሚያያዙ የወሲብ ጤና ችግሮች እና ተያያዥ ምክንያቶችን በአለርት ሆስፒታል በወንድ የሥጋ ደዌ ህመምተኞች ላይ መገምገም" የሚለው ሲሆን የሥጋ ደዌ በሽተኞችን የጾታ ሆርሞን ሁኔታ ለመገምገም ያለመ ሲሆን ፖሊሲ አውጪዎች እና የጤና እቅድ አውጪዎች የሥጋ ደዌ ሕመምተኞችን ከጾታዊ ግንኙነት ጋር በተያያዙ ጉዳዮች ላይ ክትትል ለማድረግ ውጤታማ እና ተደራሽ አገልግሎቶችን በአግባቡ እንዲነድፉ ለመምከር ጥቅም ላይ ይውላል።

የጥናቱ ዓላማ፡- የዚህ ጥናት ዋና ዓላማ የቴስቶስቴሮን ሆርሞን ማነስ ጋር የሚያያዙ የወሲብ ጤና ችግሮች፤ እና ተያያዥ ጉዳዮችን በስጋ ደዌ ህሙማን ላይ ማጥናት ነው::

የተመረጥክበት ምክንያት፡ ይህ ጥናት 146 ወንድ የሥጋ ደዌ በሽተኞችን ለማሳተፍ ታስቦ ነው። ከነሱ እንደ አንዱ ተጋብዘዋል።

የሚከናወኑ ሂደቶች፡ ለመሳተፍ ከተስማሙ ስለራስዎ አንዳንድ አጠቃላይ ጥያቄዎች እና በአደጋ ምክንያቶች እና ተያያዥ ምክንያቶች ላይ ልዩ ጥያቄዎች ይጠየቃሉ። መጠይቁ አራት ክፍሎች ያሉት ሲሆን ቃለ መጠይቁ በግምት 15_20 ደቂቃዎች ይቆያል። 5 ሚ.ሊ (አንድ የሻይ ማንኪያ የሚሆን) የደም ናሙና በተሟላ ንፁህ ዘዴ ይሰበሰባል ፤ ይህም የደም ናሙና በደምዎ ውስጥ የሚገኘውን ቴስቶስትሮን ፤ፎሊክል ኢስቲሙሌቲግ ሆርሞን ፤ ሉተናይዚንግ ሆርሞን ለመለካተ ጥቅም ላይ ይውላል. በመጨረሻም ክብደትህን እና ቁመትህን እንለካለን።

.በዚህ ጥናት ውስጥ ያለዎት ኃላፊነት፡- በዚህ ጥናት ውስጥ እንደ ተሳታፊ፣ 5 ሚ.ሊ(አንድ የሻይ ማንኪያ የሚሆን) የደም ናሙና እንዲሰጡ ይጠበቅብዎታል፣ ይህም ይህም የደም ናሙና በደምዎ ውስጥ የሚገኘውን ቴስቶስትሮን ፤ፎሊክል ኢስቲሙሌቲግ ሆርሞን ፤ ሉተናይዚንግ ሆርሞን ለመወሰን ይጠቅማል። እንዲሁም ክብደትዎን እና ቁመትዎን እንድንለካው ይጠበቅብዎታል. በመጠየቁ ውስጥ ለተካተቱት ጥያቄዎችም ምላሽ እንዲሰጡ ይጠበቅብዎታል፣ ይህም ለዚህ የተለየ ምርምር እንደ አስፈላጊ መረጃ ጥቅም ላይ ይውላል።

ሚስጥራዊነት፡ በመረጃ አሰባሰብ ወቅት የምትሰጡት የግል መረጃ ሚስጥራዊ ይሆናል። ስምህ በመጠይቁ ውስጥ አይጻፍም እና ለግላዊነትህ በተለየ ክፍል ውስጥ እጠይቅሃለሁ። አንዴ የተሰበሰበው መረጃ ኮምፒዩተር ውስጥ ከገባ በኋላ በኮድ ይቀመጥና የማይታወቅ ይሆናል። በኮምፒዩተር ላይ ያለ መረጃ በይለፍ ቃል ይጠበቃል። የሃርድ ኮፒ (ወረቀት) ሰነዶች እንደ ስምምነት እና የመረጃ ወረቀት ቅጾች ደህንነቱ በተጠበቀ የተቆለፈ ካቢኔ ውስጥ ይቀመጣሉ። የደም ናሙና በኮድ ምልክት ይደረግበታል እና የላብራቶሪ ምርመራ ከተደረገ በኋላ ይጣላል. መረጃው ተንትኖ እንደ አጠቃላይ ይቀርባል፣ እና ምንም አይነት የግል መለያ መረጃ በማንኛውም ህትመት ወይም አቀራረብ ላይ አይጋራም።

ከጥናት የሚጠበቀው ጥቅም፡ የጥናቱ ውጤት ፖሊሲ አውጪዎች እና የጤና እቅድ አውጪዎች የሥጋ ደዌ ሕመምተኞችን ከጾታዊ ግንኙነት ጋር በተያያዙ ጉዳዮች ላይ ክትትል ለማድረግ እና ለታካሚዎች ተገቢውን አገልግሎት ለማቅረብ ውጤታማ እና ተደራሽ አገልግሎቶችን በአግባቡ እንዲነድፉ ለመምከር ጥቅም ላይ ይውላል።

ለተሳትፎ ማካካሻ፡ ቀጥታ ክፍያ አያገኙም። ነገር ግን፣ በነጻ ውድ የሆኑ በደምዎ ውስጥ የሚገኘውን የጠቅላላ ቴስቶስትሮን ፤ፎሊኪል ኢስቲሙሌቲግ ሆርሞን ፤ ሉተናይዚንግ ሆርሞን የላብራቶሪ ምርመራ ውጤት ያገኛሉ። የምርመራ ውጤቱ በተለመደው ክልል ውስጥ ካልሆነ ለበለጠ ህክምና ከኢንተርኒስት ጋር አገናኝዎታለሁ።

አደጋዎች እና ምቾት፡ በዚህ ጥናት ውስጥ እርስዎን ሊጎዱ የሚችሉ ምንም አይነት ሂደቶች የሉም። የደም ናሙና በሚወሰድበት ጊዜ ጊዜያዊ ህመም ይሰማዎታል.

የመሳተፍ ወይም ያለመሳተፍ መብት፡ በጥናቱ ውስጥ መሳተፍ ሙሉ በሙሉ በፈቃደኝነት ላይ የተመሰረተ ነው፣ እና ላለመሳተፍ ከመረጡ ምንም አይነት ቅጣቶች ወይም ጥቅማ ጥቅሞች ማጣት የሉም። በዚህ ጥናት ውስጥ መሳተፍን በማንኛውም ጊዜ የመቀበል ወይም የመከልከል ሙሉ መብት አልዎት።

የጥናት ውጤት ስርጭት፡- የዚህ ጥናት አጠቃላይ ግኝቶች ለአዲስ አበባ ዩኒቨርሲቲ፣ ለአለርት ሆስፒታል ይሰራጫሉ እና በአለም አቀፍ ጆርናሎች ይታተማሉ።

የምርምር ገንዘብ፡ ይህ ጥናት በከፊል የሚሸፈነው በአዲስ አበባ ዩኒቨርሲቲ ነው።

የጥቅም ግጭት፡ የጥቅም ግጭት የለም።

ጥናቱን የገመገመው ማነው፡ ይህ ጥናት የተሳታፊዎችን መብት እና ጥቅም ለመጠበቅ በአለርት ሆስፒታል ስነምግባር ገምጋሚ ኮሚቴ ታይቶ ጸድቋል። በዚህ ጥናት ሂደት ላይ ስጋት ወይም ቅሬታ ያለው ማንኛውም ሰው ሊያነጋግራቸው ይገባል፡-

ኢሜል፡ ahri.alerterc@ahri.gov.et

ስልክ፡

የምታነጋግረው ሰው፡- ስለ ጥናቱ ምንም አይነት ጥያቄ ካሎት ዋናውን መርማሪ ማነጋገር ይችላሉ።

ናፍያድ ቶሎሳ፣ ስልክ ቁጥር፡ 0993378168፣ ኢማል፡ nafytol430@gmail.com

አዲስ አበባ ዩኒቨርሲቲ, የሕክምና ትምህርት ቤት, የሕክምና ፊዚዮሎጂ ት/ክፍል

አባሪ-2 የጽሁፍ ፍቃድ ቅጽ (የአማረኛ ቅጂ)

ከላይ በቃለ መጠይቅ አድራጊው ስለጥናቱ አጠቃላይ ሀሳብ ፣ የጥናቱ ዓላማ፣ የመረጥኩበት ምክንያት፣ መካሄድ ስላለባቸው ሂደቶች፣ በዚህ ጥናት ውስጥ ያለኝን ኃላፊነት፣ ሚስጥራዊነት፣ የጥናት ጊዜ የሚጠበቀው ጥቅም፣ ለተሳትፎ ካሳ፣ ለአደጋና ለችግር የሚዳርጉ ሁኔታዎችን ፣ የመሳተፍ ወይም ያለመሳተፍ መብት እና የጥናት ውጤት ስርጭት በሚመለከት በተሰጠኝ መረጃ መሠረት 5 ሚ.ሊ የደም ናሙና ለመስጠት እና ቃለ-መጠይቅ አድራጊው ለሚጠይቀኝ ጥያቄዎች ሁሉ ቃለ መጠይቅ ለማድረግ ተስማምቻለሁ እናም በፊርማ አጽድቄአለሁ። ተሳታፊው መፈረም ካልቻለ እባኮትን በስምምነት ፎርሙ ላይ ባለ ቀለም ያሸበረቁ አውራ ጣት ህትመቶችን እንዲያደርግ ይጠይቁት።

የተሳታፊው ስም _____ የተሳታፊ ፊርማ _____ ቀን_____

የምሥክሩ ስም እና ፊርማ _____ ቀን፡ _____

የመርማሪው ስም፡- _____ የመርማሪው ፊርማ_____ ቀን _____

ወደ ቃለ መጠይቁ ለመቀጠል ፍቃድዎን ማግኘት እችላለሁን?

1. አዎ..... (አዎ ከሆነ ቃለ መጠይቁን ይጀምሩ)

2. አይ..... (አመሰግናለሁ እዚህ አቁም)

አባሪ-3 የአማርኛ ቃለመጠይቅ

ክፍልአንድ፡ የሶሺዮ-ስነ-ሕዝብባህሪያት

ቁጥር	ጥያቄ	ምላሽ
101	ዕድሜ	----------ዐመት
102	የጋብቻ ሁኔታ	1. ያገባ 2. ያላገባ 3. በሞት የተለየ 4. የተፋታ
103	የትምህርት ትደረጃ	1. ያልተማረ 2. የመጀመሪያ ደረጃ 3. ሁለተኛ ደረጃ እና ኮሌጅ 4. ዩኒቨርሲቲ እና ከዚያ በላይ
104	ስራ	1. ገበሬ 2. የቀን ሰራተኛ 3. ነጋዴ 4. የመንግስት ሰራተኛ 5. NGO ሰራተኛ 6. 6. ሌሎች
105	የወር ገቢ	1. <1500 2. 500- 5000 3. 5000- 10000 4. > 10000

ክፍል ሁለት፡የስጋ ደዌ እና ሌሎች ከጤናጋር የተያያዙ ባህሪያት

201	የሥጋደዌ በሽታ እንዳለብህ መቼ ታወቀ?	1. < 5 ዐመት 2. > 5 ዐመት
202	የሥጋደዌ ዓይነት (ከሠንጠረዥ)	1. Paucibacilliary 2. Multibacilliary
203	የአካል ጉዳት ደረጃ (ከሠንጠረዥ)	
204	የሪዓክሽን ዓይነት (ከሠንጠረዥ)	
205	ከ የሥጋደዌ በሽታ መዳነህት ወጭ ለላ ወስደዉ ያዉቃሉ(ከሠንጠረዥ)	1. 2.
206	ሥር የሰደደ ተላላፊ ያልሆነ በሽታ አለብዎት?	1. አዎ 2. አይ
207	ለ ጥያቄ 208 መልስዎ አዎ ከሆነ ከሚከተለው ዝርዝር ውስጥ ይምረጡ	1. የደም ግፊት 2. የልብ ድካም

ክፍል ሶስት፡ ባህሪያዊ ድርጊቶች

ቁጥር	ጥያቄ	ምላሽ
301	ጫት ይቅማሉ?	1. አዎ 2. አይ
302	ለ ጥያቄ 301 መልስዎ አዎ ከሆነ ለምን ያህል ጊዜ ጫት ቃሙ?	----------
303	ሲጋራ ታጨሳለህ?	1. አዎ 2. አይ
304	ለ ጥያቄ 305 መልስዎ አዎ ከሆነ በየቀኑ ስንት ሲጋራ ያጨሳሉ (በቁጥር)?	----------
305	አዘውትረህ የአካል ብቃት እንቅስቃሴ ታደርጋለህ?	1. አዎ 2. አይ
306	ለ ጥያቄ 307 መልስዎ አዎ ከሆነ በየስንት ግዜው?	1. ዝቅተኛ (በሳምንት ከ3 ቀናት በታች ወይም እያንዳንዳቸው ከ20 ደቂቃዎች በታች የሚቆዩ) 2. መካከለኛ (በሳምንት 3-5 ቀናት እያንዳንዳቸው ከ20-30 ደቂቃዎች የሚቆዩ) 3. ከፍተኛ (በሳምንት 5-7 ቀናት እያንዳንዳቸው ከ20-30 ደቂቃዎች በላይ የሚቆዩ)

ክፍሌ አራት፡ ADAM መጠይቆች

ተ.ቁ	ጥያቄዎች	አዎ	አይደለም
401	ያለወትሮዉ የወሲብ ፍላጎትዎ ቀንሷል?		
402	ያለወትሮዉ የአቅም ማነስ ችግር ገጥሞዎታል?		
403	ጥንካሬዎት ወይም ጽናትዎ ላይ መቀነስ አስተዉለዋል ?		
404	ቁመትዎ ከበፊቱ ቀንሷል?		
405	ያለወትሮው በሕይወትዎ ደስኛ ያለመሆን ሁኔታ አስተዉለዋል?		
406	የሀዘን እና የቁጣ ስሜት በተደጋጋሚ ይሰማዎታል?		
407	ብልትዎ ሲነሳ ጥንካሬ ያንሰዋል?		
408	የሰውነት እንቅስቃሴ የማድረግ ችሎታዎ የማሽቆልቆል ሁኔታ መኖሩን አስተዉለዋል?		
409	ከእራት በኋላ ወዲያው እንቅልፍ እንቅልፍ ይሎታል?		
410	ያለወትሮው በስራ አፈጻጸምዎ ላይ የማሽቆልቆል ሁኔታ አስተውለዋል?		

Checklist to record BMI

No	Variables	Value	Remark
1	Body weight		

2	Height		
3	BMI		

Checklist to record laboratory findings

No	Laboratory findings	Value	Remark
1	TT		
2	LH		
3	FSH		