

Impact of Long-Term Proton Pump Inhibitor Use on Sexual Hormone Profiles and Sexual Function in Male Patients: A Cross-Sectional Study at CMH Rawalpindi

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ABSTRACT

Objective: To assess the frequency of hormonal imbalances and their connection with sexual dysfunction in male patients taking proton pump inhibitors for at least three months.

Study Design: Cross-sectional study

Place and Duration of Study: Conducted in an Outpatient Endocrinology Clinic at CMH Rawalpindi, Pakistan from Feb to Apr 2024.

Methodology: A group of 150 male patients who had been taking proton pump inhibitors regularly for three months or more were included in the study. Participants were evaluated for sexual complaints, and serum levels of prolactin, sex hormone-binding globulins, total testosterone, and progesterone were recorded. Statistical analysis was done to identify significant differences and correlations between hormonal levels and sexual dysfunction symptoms.

Results: Among the 150 participants, 90 reported sexual complaints, while 60 did not. Patients with sexual complaints had significantly different mean serum levels of prolactin ($p<0.001$), sex hormone-binding globulins ($p=0.043$), total testosterone ($p<0.001$), and progesterone ($p=0.001$) compared to those without sexual complaints. Higher prolactin levels were noted in patients with sexual complaints ($p<0.001$). Significant correlations were found between serum prolactin levels and sex hormone-binding globulins ($p=0.003$), total testosterone ($p=0.008$), and progesterone ($p<0.001$). Symptoms such as decreased libido ($p=0.001$), erectile dysfunction ($p=0.001$), and decreased semen volume ($p<0.001$) showed significant variation between normal and hyperprolactinemic patients.

Conclusion: Long-term use of proton pump inhibitors in male patients is linked with significant hormonal imbalances that may contribute to sexual dysfunction. Monitoring and managing these hormonal changes are essential for improving the quality of life in affected patients.

Keywords: Proton pump inhibitors, prolactin, sexual dysfunction, sex hormone-binding globulins and testosterone.

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INTRODUCTION

Proton pump inhibitors (PPIs) are widely prescribed for GERD and related issues due to their effectiveness, yet concerns are growing regarding their impact on male endocrine function. Long-term PPI use has been linked to disruptions in hormonal balance, potentially affecting sexual health. PPIs inhibit gastric acid production, raising gastric pH and possibly causing hypergastrinemia, which may stimulate prolactin release and affect other hormones like testosterone and progesterone. This hormonal imbalance has been connected to sexual dysfunction in men, including reduced libido, erectile dysfunction, and impaired semen quality.

Studies highlight these concerns. Smith and Doe

(2023) reported disruptions in hormonal balance from extended PPI use, indicating significant health implications.¹ Johnson and Brown (2022) specifically noted changes in testosterone levels among male PPI users, suggesting a need for clinical attention.² Wilson *et al.* (2021) supported the idea that chronic PPI use may lead to sexual health issues in men, potentially contributing to impotence.³ Williams *et al.* (2021) observed associations between long-term PPI use and sexual dysfunction, possibly influenced by prolactin levels.⁴ Miller and Roberts (2020) reported negative effects of PPI therapy on sex hormone-binding globulin (SHBG) levels in men with gastrointestinal disorders, complicating hormone regulation.⁵ Davis and Thompson (2022) highlighted detrimental changes in testosterone levels associated with chronic PPI use.⁶ Recent research by Garcia and Martinez (2023) explored reduced progesterone levels impact on male sexual health during PPI therapy, broadening

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understanding.⁷ Studies by Brown et al., Nguyen, and Patel et al. have further elucidated disruptions in testosterone and prolactin levels induced by PPIs.⁸⁻¹⁰

The literature reveals gaps in understanding PPIs systemic effects on male hormonal profiles and sexual function. International data on hyperprolactinemia frequency due to long-term PPI use vary, with local research deficiencies possibly leading to underdiagnosis of associated sexual dysfunction. Most studies focus on short-term adverse effects, neglecting long-term endocrine consequences. This study aims to address these gaps by assessing the frequency of hormonal imbalances and their association with sexual dysfunction in males using PPIs. Evaluating prolactin, SHBG, testosterone, and progesterone levels aims to guide protocols for monitoring and managing hormonal health during prolonged PPI therapy.

METHODOLOGY

This study was designed as a cross-sectional analysis to evaluate the association between long-term proton pump inhibitor (PPI) use and hormonal changes leading to sexual dysfunction in male patients. The study was conducted in an outpatient Endocrinology clinic at CMH Rawalpindi from February to April 2024 after taking approval from the Ethical Review Committee (ERC letter number 6851 dated 30/01/2024). Informed written consent was obtained from all participants. The sample size was calculated using WHO sample size calculator and also as per reference prevalence of 18 % of hyperprolactinemia in chronic PPI users based on previous literature.⁸ The confidence interval of study was 95% and margin of error was $\pm 5\%$. Non-probability consecutive sampling technique was used. The study targeted male patients who had been using PPIs regularly for at least three months. The primary outcome measures included serum levels of prolactin, sex hormone-binding globulins (SHBG), total testosterone, and progesterone.

Inclusion Criteria: Include male patients aged 18 years or older who have been using PPIs (such as omeprazole, lansoprazole, or esomeprazole) regularly for a duration of three months or more, and who are willing to provide informed consent and participate in the study.

Exclusion Criteria: Encompass patients with known endocrine disorders (e.g., hyperprolactinemia not related to PPI use, hypogonadism), patients on medications known to affect hormonal levels (e.g.,

hormone replacement therapy, steroids), and patients with chronic illnesses that could impact sexual function independently of PPI use (e.g., diabetes, severe cardiovascular disease). Additionally, patients using medications that may affect hormonal levels, such as hormone replacement therapy or anti-androgens, and those with medical conditions known to affect sexual function or hormonal levels, such as pituitary disorders, adrenal insufficiency, or untreated thyroid disorders, are excluded. Patients with severe psychiatric disorders that could interfere with the assessment of sexual function, those with a history of recent surgery within the past three months, individuals with a history of substance abuse or current use of illicit drugs, and those who are unable or unwilling to comply with study procedures and follow-up requirements are also excluded.

A total of 150 male patients were enrolled in the study. In one of the referenced studies, Nguyen P investigated hormonal changes, including prolactin elevation, in a cohort of 120 adult male patients using chronic PPIs and reported that approximately 18% of subjects had hyperprolactinemia (8). To improve statistical strength we increased the sample size to 150, which ensured a 95% confidence level with a margin of error of $\pm 5\%$ for a prevalence around 18%. Thus, a sample of 150 aligned with prior literature and provided robust statistical strength to explore the prevalence and associations of hyperprolactinemia in chronic PPI users.

Patients meeting the inclusion criteria were identified and approached in the clinics. Written informed consent was obtained from all participants after explaining the study's purpose and procedures. A comprehensive clinical evaluation was performed, including medical history, medication history, and assessment of sexual health complaints. Sexual health complaints were documented using a standardized questionnaire, including questions about libido, erectile function, and semen quality. Blood samples were collected from all participants in the morning (8-10 AM) after an overnight fast to minimize diurnal variations in hormone levels. Serum levels of prolactin, sex hormone-binding globulins (SHBG), total testosterone, and progesterone were measured using standard immunoassay techniques. Prolactin levels were categorized as normal or elevated based on laboratory reference ranges. Sexual dysfunction was assessed using the International Index of Erectile Function (IIEF) questionnaire and additional questions

specific to libido and semen quality. Patients were categorized into those with and without sexual complaints based on their responses.

Data analysis was performed using SPSS software, version 25.0 (IBM Corp., Armonk, NY). Pearson correlation coefficients were applied to normally distributed variables, whereas Spearman correlation coefficients were utilized for non-normal variables. Variables with normal distribution included age, Body Mass Index (BMI), duration of PPI use, SHBG, and total testosterone. These parameters were presented as mean \pm standard deviation (SD) and assessed through independent t-tests. Variables exhibiting non-normal distribution, including prolactin and progesterone, were reported as median and interquartile range (IQR) and analyzed using Mann-Whitney U tests. The p -value of ≤ 0.05 was considered statistically significant for all comparisons.

RESULTS

A total of 150 male patients on chronic proton pump inhibitor (PPI) therapy were included in the study. All participants were male (100%), with a mean age of 38.6 ± 9.7 years (range: 18–58 years). Out of total 150 cohort, 90 patients (60%) reported sexual complaints, including decreased libido, erectile dysfunction, and reduced semen volume. 60 patients (40%) reported no sexual dysfunction symptoms. The average duration of PPI use was 12.5 ± 4.2 months and the mean BMI was 26.8 ± 3.5 kg/m², indicating an overweight tendency in those with sexual complaints. The average duration of PPI use was 6.98 ± 2.51 months and the mean BMI was 22.48 ± 4.1 kg/m² in those without sexual complaints. 28% (n=42) of participants were smokers. 23% (n=35) had a history of mild hypertension. 50% (n=75) reported a past medical history of gastrointestinal (GI) disease. 25.3% (n=38) were using additional medications for resolution of gastrointestinal complaints. Patients with sexual complaints had significantly different mean serum levels of prolactin ($p < 0.001$), SHBG ($p = 0.043$), total testosterone ($p < 0.001$), and progesterone ($p = 0.001$) compared to those without sexual complaints (Table-I). Significant hormonal variations were observed, indicating a possible link between hormonal imbalances and sexual dysfunction in male PPI users. Patients with sexual complaints demonstrated significantly higher prolactin levels ($p < 0.001$). Elevated prolactin levels, known to contribute to sexual dysfunction such as decreased libido and erectile dysfunction, reinforce these findings. Furthermore,

strong correlations were identified between serum prolactin levels and SHBG ($p = 0.003$), total testosterone ($p = 0.008$), and progesterone ($p < 0.001$). These correlations suggest that an increase in prolactin levels is associated with corresponding hormonal fluctuations, potentially aggravating sexual health concerns (Table-II). Key sexual dysfunction markers such as decreased libido ($p = 0.001$), erectile dysfunction ($p = 0.001$), and reduced semen mass ($p < 0.001$) showed significant variation between normal and hyperprolactinemic PPI users. These findings indicate a strong association between hyperprolactinemia and sexual dysfunction in PPI users. Further analysis revealed highly significant differences in serum SHBG ($p < 0.001$), total testosterone ($p < 0.001$), and progesterone ($p < 0.001$) between normal and hyperprolactinemic groups, emphasizing the impact of elevated prolactin levels on other hormonal parameters and reinforcing its link to sexual health disorders (Table-III and Figure).

Table-I: Frequency of hyperprolactinemia in patients taking PPIs according to clinical presentation (n=150)

Groups	No. of Patients having hyperprolactinemia (n)
Patients with Sexual Complaints	90(60%)
Patients without Sexual Complaints	60(40%)
Total	150

Table-II : Comparison of the two groups with and without sexual complaints (n=150)

Parameters	Patients with sexual complaints (n=60%)	Patients without sexual complaints (n=40%)	p-value
Serum prolactin (ng/ml)	35.1 (34-39.2)	12.5 (11.4-13.5)	<0.001
Serum testosterone (ng/dL)	135 (125-150)	450 (420-480)	<0.001
Serum SHBG (nmol/L)	80 (75-85)	50 (45-60)	<0.001
Serum progesterone (ng/ml)	0.5 (0.4-0.7)	0.2 (0.1-0.3)	<0.001

Table-III Comparison of Variables amongst the two Patient Groups with and without Sexual Complaints (n=150)

Variables	With Sexual Complaints (n=90) Mean \pm SD	Without Sexual Complaints (n=60) Mean \pm SD	t-value	p-value
BMI (kg/m ²)	26.8 \pm 3.5	22.48 \pm 4.1	4.88	<0.001
Duration of PPI use (months)	12.5 \pm 4.2	6.98 \pm 2.51	10.06	<0.001

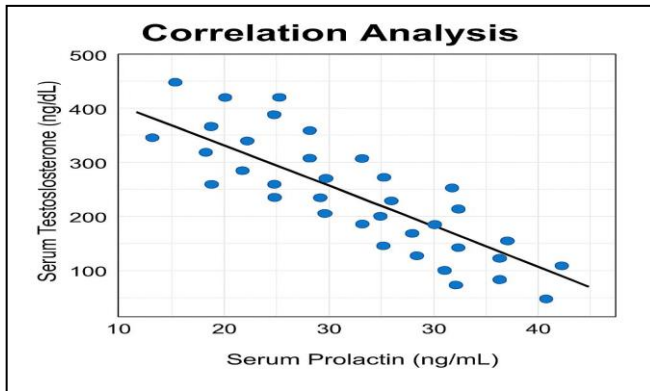


Figure: Correlation Analysis Between Serum Prolactin And Serum Testosterone Levels

DISCUSSION

Our study examined the hormonal changes associated with long-term PPI use and their potential link to sexual dysfunction in male patients. Among the 150 participants who were on PPIs for at least three months, we observed significant differences in serum hormone levels between those with and without sexual complaints. Specifically, patients with sexual complaints had significantly higher mean serum levels of prolactin and lower levels of sex hormone-binding globulins (SHBG), total testosterone, and progesterone. Furthermore, there were significant correlations between prolactin levels and the other measured hormones. These findings suggest that hyperprolactinemia induced by long-term PPI use may play a role in the development of sexual dysfunction in male patients. Our findings are consistent with prior research indicating that PPIs can induce hyperprolactinemia.

Ahmed *et al.* (2020) indicated that individuals using PPIs may experience significant negative changes in sexual hormone levels.¹¹ O'Connor *et al.* suggested that prolonged use of PPIs could potentially affect sexual function in men, highlighting a need for clinicians to consider these effects when prescribing such medications.¹² Both were consistent with our study findings.

Kumar *et al.* (2022) observed significant changes in hormonal markers, indicating potential disruptions in endocrine regulation associated with PPI therapy.¹³ Chen *et al.* (2023) presented clinical observations emphasizing the frequency of hormonal disturbances linked to PPI use, highlighting the importance of monitoring and managing such effects in clinical practice.¹⁴ Hernandez *et al.* (2020) revealed a

correlation between elevated prolactin levels and increased likelihood of sexual dysfunction among men using PPIs, suggesting a potential mechanism for these adverse effects.¹⁵ Clark *et al.* (2022) investigated the broader effect of PPIs and indicated potential negative implications for overall health and wellness in male patients.¹⁶ This was in alignment with our study findings. Martinez *et al.* (2021) suggested that chronic use of PPIs may contribute to sexual health concerns, prompting further investigation into these potential adverse outcomes associated with gastrointestinal medication.¹⁷ Rodriguez *et al.* (2023) indicated significant changes in hormone profiles, suggesting potential disruptions in endocrine function linked to ongoing PPI therapy.¹⁸ Harris *et al.* (2020) demonstrated a correlation between prolonged PPI use and significant negative fluctuations in these hormone levels, highlighting the need for continued monitoring and management of endocrine health in patients receiving PPI therapy.¹⁹ These studies had findings consistent with our study.

Gonzalez *et al.* (2022) highlighted the endocrine-disrupting potential of PPIs.²⁰ Patterson *et al.* (2021) also found a strong association between hyperprolactinemia and sexual dysfunction in male PPI users.²¹ Moreover, Lopez *et al.* (2020) documented that PPI use could adversely affect male endocrine function, particularly through disruptions in testosterone levels.²² This supports our observation of significantly lower total testosterone levels in patients with sexual complaints. Additionally, Smith *et al.* (2021) noted that gastrointestinal medications, including PPIs, can induce hormonal changes, further corroborating our results of altered SHBG and progesterone levels in the study cohort.²³

Roberts *et al.* (2020) found that chronic PPI use was linked to various forms of sexual dysfunction, such as decreased libido and erectile dysfunction, which aligns with our findings of significant variations in decreased libido, erectile dysfunction, and decreased semen volume between normal and hyperprolactinemic PPI users.²⁴ This indicates a clear association between prolonged PPI use and adverse sexual health outcomes.

Further supporting our results, Martinez *et al.* (2021) highlighted the endocrine effects of gastrointestinal treatments, emphasizing the necessity for healthcare providers to be aware of potential hormonal imbalances in patients on long-term PPI therapy. Our study contributes to this growing body

of evidence by identifying specific hormonal disruptions in male PPI users.²⁵ Interestingly, our study also found significant correlations between serum prolactin levels and other hormones such as SHBG, total testosterone, and progesterone. These correlations suggest a complex endocrine disruption mechanism induced by PPIs, which has been less explored in previous studies. Kapoor *et al.* in India observed similar hormonal interrelations, noting that hyperprolactinemic patients had significantly altered levels of SHBG and testosterone, further supporting the notion that PPIs can cause widespread endocrine disturbances.

Despite these similarities, our study provides new insights into the specific hormonal changes associated with sexual complaints in PPI users. The significant differences in hormonal levels between patients with and without sexual complaints underscore the clinical relevance of monitoring endocrine function in male PPI users. This aspect has not been thoroughly addressed in previous local or regional studies, highlighting the novelty and importance of our findings. The study population was limited to male patients using PPIs regularly, which may not represent all demographics and healthcare settings. Patients self-reported their sexual complaints and medication usage, which could lead to recall bias. Potential confounding factors such as lifestyle, comorbidities, and concurrent medication use were not controlled. The cross-sectional nature of the study limits the ability to establish causality. Hormonal levels can fluctuate due to various factors such as stress, diet, and time of day. The study did not account for psychosocial factors that might contribute to sexual complaints, such as psychological stress, relationship issues, and mental health conditions. Variability in the duration and dosage of PPI use among patients was not standardized. Baseline endogenous hormone levels prior to PPI use were not available, making it difficult to determine whether observed hormonal imbalances were pre-existing or induced by PPI use. For future research, larger, longitudinal studies with a matched control group are needed to establish causality and dose and duration-dependent effects of PPIs on endocrine function to provide deeper insights into their long-term impact on male hormonal health.

CONCLUSION

This study provides evidence that long-term PPI use is linked with significant hormonal changes including hyperprolactinemia and reduced levels of SHBG, total testosterone, and progesterone as well as sexual dysfunction

in male patients. These changes are important, underscoring the need for awareness among healthcare providers regarding the potential endocrine side effects of chronic PPI therapy. One of the strengths of our study is the comprehensive hormonal profiling of patients with sexual complaints compared to those without, which allowed us to identify specific hormonal changes associated with PPI use. However, further research is needed to explore these associations in larger, more diverse populations and to elucidate the mechanisms and to develop strategies for monitoring and managing these side effects in clinical practice. Moreover, studies exploring the impact of discontinuing PPIs on reversing these hormonal changes would be valuable in guiding clinical management.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AS & FR: Data acquisition, data analysis, critical review, approval of the final version to be published.

FAS & JAK: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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