

Serum Prolactin and its Association with Metabolic Abnormalities and Sexual Adverse Effects in Adult Patients Receiving Prolactin-Elevating Antipsychotic Medications: A Prospective Observational Study

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Abstract:

Background: Prolonged treatment with antipsychotics is common in psychiatric practice, but the relationship of serum prolactin with metabolic and sexual adverse effects during ongoing treatment is not fully defined.

Aim: To assess the association of serum prolactin levels with metabolic abnormalities and sexual adverse effects in adult patients receiving antipsychotic medications.

Materials and Methods: This prospective observational study was conducted in the Department of Psychiatry, Index Medical College, Hospital & Research Centre, Indore, over 15 months. One hundred and eight adults on antipsychotic medications for at least six months were enrolled by consecutive sampling and followed for six months. Serum prolactin, anthropometric measurements, metabolic parameters, and sexual function (Arizona Sexual Experience Scale, ASEX) were assessed at baseline and six months.

Results: Mean age of patients was 36.8 ± 10.9 years; 57.4% were male. At baseline, hyperprolactinaemia was present in 58.3%, metabolic syndrome in 38.9%, and sexual dysfunction by ASEX criteria in 53.7%. At six months, patients with hyperprolactinaemia had significantly higher rates of metabolic syndrome (55.9% vs 22.5%, $p=0.001$) and sexual dysfunction (73.5% vs 35.0%, $p<0.001$) than those with normal prolactin. On multivariable analysis, hyperprolactinaemia was independently associated with both sexual dysfunction (adjusted OR 4.28, 95% CI 1.78–10.31) and metabolic syndrome (adjusted OR 3.61, 95% CI 1.43–9.10).

Conclusion: Serum prolactin elevation during prolonged antipsychotic treatment is independently associated with both metabolic syndrome and sexual dysfunction. Routine prolactin monitoring alongside metabolic and sexual-function screening may help identify patients at higher risk of these adverse effects.

Keywords: Hyperprolactinaemia; Antipsychotic agents; Metabolic syndrome; Sexual dysfunction; Arizona Sexual Experience Scale.

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Introduction

Antipsychotic medications form the mainstay of treatment for schizophrenia spectrum disorders and several other psychiatric illnesses. Long-term treatment is often required to control symptoms and reduce the risk of relapse. However, prolonged antipsychotic use is associated with several endocrine, metabolic, and sexual adverse effects [1]. These adverse effects may affect physical health, quality of life, treatment adherence, and long-term clinical outcomes [1].

Hyperprolactinaemia is an important endocrine adverse effect of antipsychotic treatment [2].

Antipsychotic medications that strongly block dopamine D2 receptors can interfere with the tuberoinfundibular inhibitory mechanism and increase serum prolactin levels [2]. First-generation antipsychotics and some second-generation agents, particularly risperidone and paliperidone, are commonly associated with clinically relevant prolactin elevation [2]. Persistent hyperprolactinaemia may produce several clinical consequences, including menstrual disturbance, galactorrhoea, and gynaecomastia [2,3]. Chronic hyperprolactinaemia may also lead to

hypogonadism and reduced bone mineral density, and the occurrence and severity of sexual dysfunction may increase with the degree of prolactin elevation [3].

Sexual dysfunction is particularly important because patients may not spontaneously report these symptoms. Psychiatric illness itself, antipsychotic treatment, comorbid medical conditions, and psychosocial factors may all contribute [4]. A structured assessment is therefore preferable. The Arizona Sexual Experience Scale (ASEX) is a brief five-item instrument that evaluates sexual drive, arousal, penile erection or vaginal lubrication, ability to achieve orgasm, and satisfaction from orgasm [4]. Indian studies using prolactin measurement alongside standardised sexual-function instruments have similarly reported a high burden of antipsychotic-associated sexual dysfunction, particularly with prolactin-raising agents such as risperidone [5].

Metabolic abnormalities represent another major concern during prolonged antipsychotic therapy. Increased body weight, central obesity, dyslipidaemia, impaired glucose regulation, hypertension, and metabolic syndrome may occur during treatment, and these abnormalities are associated with an increased risk of type 2 diabetes mellitus and cardiovascular disease [1]. Notably, the direction of this relationship may depend on context: in the general population, serum prolactin within the physiological range has been reported to be inversely associated with type 2 diabetes and adverse lipid parameters, suggesting a possible protective metabolic role of normal prolactin signalling [6]. Serum prolactin may thus represent an important biological marker linking antipsychotic exposure with several clinically relevant adverse effects. Evaluating prolactin together with anthropometric measurements, glucose metabolism, lipid parameters, and sexual function may provide a more comprehensive assessment of treatment-related morbidity. The present study was therefore undertaken to examine serum prolactin levels and their association with metabolic abnormalities and sexual adverse effects among adult patients receiving prolactin-elevating antipsychotic medications.

Aim: To assess the association of serum prolactin levels with metabolic abnormalities and sexual adverse effects in adult patients receiving prolactin-elevating antipsychotic medications.

Materials and Methods

This was a single centre, hospital-based, prospective observational study conducted among adult patients receiving antipsychotic medications known to have a prolactin-elevating effect. The study was conducted at Index Medical College, Hospital &

Research Centre, Indore, Madhya Pradesh, India. Patients receiving regular psychiatric treatment at the institution were screened for eligibility and followed prospectively. The total duration of the study was 15 months. Each participant was followed for at least six months after enrolment. The design and reporting of this study were guided by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) recommendations for observational research [7]. The study was conducted after obtaining approval from the Institutional Ethics Committee. The study was conducted according to the principles of the Declaration of Helsinki [8] and applicable Indian Council of Medical Research guidelines for biomedical and health research involving human participants [9].

Adult patients receiving regular antipsychotic treatment were screened for participation. Eligible participants had a psychiatric disorder requiring continued treatment with an antipsychotic known to elevate serum prolactin. Patients were required to have received the relevant antipsychotic for at least six months before enrolment.

Inclusion Criteria

- Patients aged 18 years or above.
- Patients with a clinically established psychiatric diagnosis requiring antipsychotic treatment.
- Continuous treatment with a prolactin-elevating antipsychotic for at least six months before enrolment.
- Patients expected to continue treatment and attend follow-up for six months.
- Patients providing written informed consent.

Exclusion Criteria

- Pregnancy or lactation.
- Known pituitary adenoma or other established pituitary disorder.
- Pre-existing hyperprolactinaemia attributable to a known non-antipsychotic cause.
- Untreated or inadequately controlled hypothyroidism.
- Severe chronic renal or hepatic disease likely to affect prolactin metabolism.
- Use of medications known to independently cause substantial prolactin elevation, where their effect could not be distinguished from that of antipsychotics.
- Patients receiving only prolactin-sparing antipsychotic therapy.
- Serious medical or psychiatric instability preventing completion of the study assessments.
- Patients unable or unwilling to complete the sexual-function assessment.
- Patients unwilling to provide informed consent.

All eligible individuals attending the facility during recruitment who consented were enrolled. This approach yielded a final sample size of 108. Consecutive sampling was employed. Patients attending the psychiatric services during the recruitment period were screened sequentially. Those fulfilling the eligibility criteria were enrolled after obtaining written informed consent.

The principal exposure of interest was continued use of an antipsychotic with recognised potential to elevate serum prolactin. This included risperidone, paliperidone, amisulpride, haloperidol, and other dopamine D2 receptor-blocking antipsychotics with clinically relevant prolactin-elevating effects. The name of the antipsychotic, formulation, daily dose, dosing frequency, duration of treatment, and use of long-acting injectable preparations were recorded. Concomitant psychotropic medications were also documented. Where comparison between different antipsychotic doses was required, prescribed doses were converted to chlorpromazine-equivalent doses using an accepted international consensus equivalence method [10].

Participants underwent detailed assessment at enrolment and again after six months. Data collected included demographic characteristics, psychiatric diagnosis, treatment history, anthropometric measurements, blood pressure, serum prolactin, metabolic investigations, prolactin-related symptoms, and sexual function.

Serum Prolactin Assessment: A venous blood sample was obtained for serum prolactin estimation. Samples were preferably collected in the morning after an overnight fast and before administration of the morning antipsychotic dose where feasible. Participants were advised to avoid vigorous exercise and other factors likely to produce a transient prolactin elevation before sampling. Serum prolactin was measured using the routine immunoassay method available in the institutional laboratory. The laboratory's sex-specific reference interval was used to classify serum prolactin as normal or elevated. Hyperprolactinaemia was defined as a serum prolactin concentration above the upper limit of the sex-specific reference range of the institutional laboratory. Absolute prolactin concentration was also retained as a continuous variable for correlation analyses. Where an unexpectedly high value was detected without compatible clinical findings, repeat testing was considered to exclude transient prolactin elevation or sampling-related variation.

Assessment of Prolactin-Related Clinical Symptoms: Participants were specifically asked about symptoms potentially related to hyperprolactinaemia.

In females, the assessment included:

- Menstrual irregularity.

- Amenorrhoea.
- Galactorrhoea.
- Reduced sexual desire.
- Infertility-related concerns, where applicable.
- In males, assessment included:
 - Reduced sexual desire.
 - Erectile dysfunction.
 - Ejaculatory difficulty.
- Gynaecomastia.
- Galactorrhoea, where present.

These symptoms were recorded using a structured clinical proforma.

Assessment of Sexual Function: Sexual functioning was evaluated using the Arizona Sexual Experience Scale (ASEX). The ASEX consists of five items assessing sexual drive, arousal, penile erection or vaginal lubrication, ability to reach orgasm, and satisfaction from orgasm. Each item is scored from 1 to 6, giving a total score ranging from 5 to 30. Higher scores indicate greater sexual dysfunction [4]. The same instrument was administered at baseline and at the six-month follow-up. Sexual dysfunction was identified according to the established ASEX scoring criteria. The total ASEX score was also analysed as a continuous variable.

Anthropometric Assessment

Body weight was measured using a calibrated weighing scale with participants wearing light clothing and without footwear. Height was measured using a wall-mounted or standard stadiometer. Body mass index was calculated as body weight in kilograms divided by height in metres squared. Waist circumference was measured using a non-stretchable measuring tape with the participant standing upright. Measurement was taken at the standard anatomical level at the end of normal expiration.

Blood Pressure Measurement: Blood pressure was measured after the participant had rested in a seated position. An appropriately sized cuff was used. Where the initial measurement was elevated, a repeat measurement was obtained according to routine clinical practice.

Systolic and diastolic blood pressures were recorded in mmHg.

Assessment of Metabolic Abnormalities: After an overnight fast, venous blood was collected for metabolic evaluation. All biochemical measurements were performed using routine standardised methods in the institutional laboratory. Metabolic abnormalities were assessed individually and as a composite metabolic syndrome outcome. For the Indian study population, Asian-specific waist circumference thresholds were applied [11]. Metabolic syndrome was considered present when

the participant met at least three of the specified metabolic criteria, consistent with the harmonised joint interim definition of the metabolic syndrome [12].

Baseline Assessment: At enrolment, demographic information and relevant clinical history were recorded. This included age, sex, psychiatric diagnosis, duration of psychiatric illness, duration of antipsychotic exposure, current medication, daily dose, concomitant medications, smoking, alcohol use, and relevant medical comorbidities. Anthropometric measurements and blood pressure were obtained. Fasting blood samples were collected for serum prolactin, glucose, HbA1c, and lipid profile. Prolactin-related symptoms were documented and the ASEX questionnaire was administered.

Six-Month Follow-Up Assessment: Participants were reassessed six months after baseline. Current antipsychotic treatment, changes in medication or dose, adherence, and concomitant psychotropic medications were documented. Body weight, BMI, waist circumference, and blood pressure were reassessed. Serum prolactin and metabolic investigations were repeated using the same laboratory procedures as at baseline. The ASEX was administered again to determine changes in sexual function. New or persistent prolactin-related clinical symptoms were also recorded.

Study Outcomes

The primary outcomes were:

- Association between serum prolactin concentration and metabolic abnormalities.
- Association between serum prolactin concentration and sexual dysfunction assessed using ASEX.

Statistical Analysis: Statistical and graphical analyses were conducted using Stata version 17.0. Categorical variables were expressed as frequencies and percentages. Continuous variables were

assessed for distribution. Normally distributed variables were presented as mean $\pm$ standard deviation, while skewed variables were presented as median with interquartile range. The prevalence of hyperprolactinaemia, metabolic abnormalities, metabolic syndrome, and sexual dysfunction was reported with appropriate proportions. Serum prolactin concentration was compared between participants with and without metabolic syndrome and between those with and without sexual dysfunction. The independent-samples t-test was used for normally distributed variables. The Mann–Whitney U test was used when distributions were non-normal. The association between categorical prolactin status and categorical outcomes was assessed using the Chi-square test or Fisher's exact test, as appropriate. Pearson's correlation coefficient was used to assess relationships between serum prolactin and normally distributed continuous metabolic variables. Spearman's rank correlation was used for skewed variables. Baseline and six-month continuous measurements were compared using the paired t-test for normally distributed paired data or the Wilcoxon signed-rank test for non-normal data. All statistical tests were two-sided. A p-value <0.05 was considered statistically significant.

Funding: This study received no external funding.

Conflict of Interest: The authors declare no conflicts of interest in the design, implementation, analysis, or interpretation of this study.

Results

One hundred and eight adult patients receiving a prolactin-elevating antipsychotic for at least six months were evaluated and followed for six months. Table 1 summarises the baseline demographic profile, psychiatric diagnosis, current antipsychotic treatment, lifestyle factors, and anthropometric and blood pressure measurements of the study population.

Table 1: Baseline demographic, clinical and treatment characteristics of study participants (N = 108)

Characteristic	Value
Age, years, mean $\pm$ SD	36.8 $\pm$ 10.9
Sex, n (%)	
Male	62 (57.41)
Female	46 (42.59)
Psychiatric diagnosis, n (%)	
Schizophrenia spectrum disorder	72 (66.67)
Schizoaffective disorder	12 (11.11)
Bipolar disorder with psychotic symptoms	18 (16.67)
Other psychotic disorders	6 (5.56)
Duration of psychiatric illness, years, median (IQR)	5.0 (3.0–8.0)
Current prolactin-elevating antipsychotic, n (%)	
Risperidone	42 (38.89)
Paliperidone	20 (18.52)
Amisulpride	18 (16.67)

Haloperidol	16 (14.81)
Other prolactin-elevating antipsychotic	12 (11.11)
Duration of current antipsychotic treatment, months, median (IQR)	18 (10–32)
Chlorpromazine-equivalent dose, mg/day, mean $\pm$ SD	412 $\pm$ 156
Smoking, n (%)	29 (26.85)
Alcohol use, n (%)	22 (20.37)
BMI, kg/m ² , mean $\pm$ SD	25.7 $\pm$ 4.1
Waist circumference, cm, mean $\pm$ SD	89.4 $\pm$ 11.2
Systolic blood pressure, mmHg, mean $\pm$ SD	124.6 $\pm$ 13.8
Diastolic blood pressure, mmHg, mean $\pm$ SD	79.3 $\pm$ 9.1

Table 2 presents the baseline serum prolactin, frequency, and sexual/prolactin-related adverse metabolic parameters, metabolic syndrome effects.

Table 2: Baseline prolactin levels, metabolic abnormalities and sexual adverse effects (N = 108)

Parameter	Value
Serum prolactin, ng/mL, median (IQR)	34.2 (21.6–52.8)
Hyperprolactinaemia, n (%)	63 (58.33)
Metabolic parameters	
Fasting plasma glucose, mg/dL, mean $\pm$ SD	96.8 $\pm$ 16.9
HbA1c, %, mean $\pm$ SD	5.62 $\pm$ 0.71
Total cholesterol, mg/dL, mean $\pm$ SD	181.7 $\pm$ 35.4
Triglycerides, mg/dL, median (IQR)	146 (112–189)
LDL-C, mg/dL, mean $\pm$ SD	108.5 $\pm$ 30.2
HDL-C, mg/dL, mean $\pm$ SD	44.2 $\pm$ 9.8
Central obesity, n (%)	54 (50.00)
Elevated triglycerides, n (%)	40 (37.04)
Reduced HDL-C, n (%)	38 (35.19)
Elevated fasting glucose, n (%)	23 (21.30)
Elevated blood pressure, n (%)	27 (25.00)
Metabolic syndrome, n (%)	42 (38.89)
Sexual and prolactin-related adverse effects	
ASEX total score, mean $\pm$ SD	17.2 $\pm$ 4.6
Sexual dysfunction by ASEX criteria, n (%)	58 (53.70)
Reduced sexual desire, n (%)	49 (45.37)
Erectile dysfunction among males (n = 62)	29 (46.77)
Menstrual irregularity among females (n = 46)	20 (43.48)
Galactorrhoea	8 (7.41)
Gynaecomastia among males (n = 62)	5 (8.06)

ASEX: Arizona Sexual Experience Scale; IQR: interquartile range.

Table 3 shows the change in serum prolactin, metabolic parameters, and sexual function between baseline and the six-month follow-up.

Table 3: Changes in serum prolactin, metabolic parameters and sexual function during six-month follow-up (N = 108)

Parameter	Baseline	6 months	p-value
Serum prolactin, ng/mL, median (IQR)	34.2 (21.6–52.8)	38.9 (23.8–58.4)	0.004
BMI, kg/m ²	25.7 $\pm$ 4.1	26.2 $\pm$ 4.2	<0.001
Waist circumference, cm	89.4 $\pm$ 11.2	91.1 $\pm$ 11.4	<0.001
Fasting plasma glucose, mg/dL	96.8 $\pm$ 16.9	100.4 $\pm$ 18.1	0.002
HbA1c, %	5.62 $\pm$ 0.71	5.74 $\pm$ 0.76	0.006
Triglycerides, mg/dL, median (IQR)	146 (112–189)	154 (118–202)	0.018
LDL-C, mg/dL	108.5 $\pm$ 30.2	112.7 $\pm$ 31.1	0.031
HDL-C, mg/dL	44.2 $\pm$ 9.8	42.8 $\pm$ 9.5	0.011
ASEX total score	17.2 $\pm$ 4.6	18.1 $\pm$ 4.8	0.003
Hyperprolactinaemia, n (%)	63 (58.33)	68 (62.96)	0.180
Metabolic syndrome, n (%)	42 (38.89)	47 (43.52)	0.180

Sexual dysfunction, n (%)	58 (53.70)	64 (59.26)	0.109
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Values are mean $\pm$ SD unless otherwise stated. Paired t-test, Wilcoxon signed-rank test, or McNemar's test was used as appropriate.

Table 4 compares metabolic and sexual outcomes at six months between participants with normal prolactin and those with hyperprolactinaemia.

Table 4. Association of serum prolactin status with metabolic abnormalities and sexual adverse effects at six months (N = 108)

Outcome	Normal prolactin (n = 40)	Hyperprolactinaemia (n = 68)	p-value
BMI ≥ 25 kg/m ²	18 (45.00)	46 (67.65)	0.021
Central obesity	16 (40.00)	44 (64.71)	0.012
Elevated triglycerides	10 (25.00)	34 (50.00)	0.011
Reduced HDL-C	11 (27.50)	32 (47.06)	0.045
Elevated fasting glucose	6 (15.00)	23 (33.82)	0.034
Metabolic syndrome	9 (22.50)	38 (55.88)	0.001
Sexual dysfunction	14 (35.00)	50 (73.53)	<0.001
Reduced sexual desire	12 (30.00)	40 (58.82)	0.004
Any prolactin-related clinical symptom	11 (27.50)	37 (54.41)	0.007

Values are n (column %). Chi-square or Fisher's exact test was used as appropriate.

Table 5 presents the multivariable logistic regression analysis for factors independently associated with sexual dysfunction and metabolic syndrome at six months.

Table 5: Multivariable analysis of factors associated with sexual dysfunction and metabolic syndrome at six months

Predictor	Sexual dysfunction Adjusted OR (95% CI)	p-value	Metabolic syndrome Adjusted OR (95% CI)	p-value
Hyperprolactinaemia	4.28 (1.78–10.31)	0.001	3.61 (1.43–9.10)	0.007
Age, per 10-year increase	1.26 (0.91–1.75)	0.164	1.47 (1.04–2.08)	0.029
Female sex	1.52 (0.64–3.61)	0.341	1.38 (0.57–3.33)	0.477
Baseline BMI, per 1 kg/m ² increase	1.05 (0.95–1.16)	0.333	1.21 (1.08–1.36)	0.001
Chlorpromazine-equivalent dose, per 100 mg/day increase	1.24 (1.02–1.52)	0.034	1.12 (0.92–1.37)	0.260
Antipsychotic treatment duration >2 years	1.39 (0.57–3.42)	0.470	1.46 (0.59–3.61)	0.415

OR: odds ratio; CI: confidence interval.

Discussion

In this prospective study of 108 adult patients on prolactin-elevating antipsychotics, the mean age was 36.8 ± 10.9 years with a modest male predominance (57.4%), and risperidone was the most commonly used prolactin-elevating agent (38.9%), consistent with its established role as one of the antipsychotics most strongly associated with clinically relevant prolactin elevation [2]. At baseline, 58.3% of participants had hyperprolactinaemia by the institutional sex-specific reference range, a figure broadly consistent with earlier large point-prevalence surveys reporting hyperprolactinaemia in roughly half to two-thirds of patients treated with conventional antipsychotics or risperidone, although reported rates vary considerably by antipsychotic, sex, and menopausal status [13].

Metabolic syndrome was present in 38.9% of participants at baseline and rose numerically to

43.5% by six months, alongside significant increases in BMI, waist circumference, fasting glucose, HbA1c, triglycerides, and LDL-C, and a significant fall in HDL-C. This pattern of progressive metabolic deterioration during antipsychotic treatment is consistent with the well-documented cardiometabolic risk of these agents [1]. More specifically, participants with hyperprolactinaemia at six months had a substantially higher prevalence of metabolic syndrome than those with normal prolactin (55.9% vs 22.5%), and hyperprolactinaemia remained independently associated with metabolic syndrome after adjustment for age, sex, baseline BMI, dose, and treatment duration (adjusted OR 3.61). This finding is noteworthy when set against evidence from the general population, where serum prolactin within the physiological range has been reported to be inversely associated with type 2 diabetes and adverse lipid parameters, suggesting a potentially

protective metabolic role for normal prolactin signalling [6]. Taken together, these findings suggest that the relationship between prolactin and metabolic status may differ qualitatively between physiological prolactin variation and pathological, antipsychotic-induced hyperprolactinaemia, which appears to travel with, rather than protect against, metabolic risk in this population — possibly reflecting shared upstream drivers such as dopaminergic blockade, weight gain, and hypogonadism rather than a direct causal effect of prolactin itself.

Sexual dysfunction was common in this cohort, present in 53.7% of participants at baseline by ASEX criteria, and rose to 59.3% at six months. Reduced sexual desire, erectile dysfunction, and menstrual irregularity were each reported by a substantial minority of participants, in keeping with the recognised burden of antipsychotic-related sexual dysfunction described in reviews of this problem [14]. Sexual dysfunction was significantly more frequent among participants with hyperprolactinaemia than those with normal prolactin (73.5% vs 35.0%), and hyperprolactinaemia was the strongest independent predictor of sexual dysfunction on multivariable analysis (adjusted OR 4.28), with chlorpromazine-equivalent dose also showing a smaller but significant independent association. This is consistent with Indian studies that have specifically examined the relationship between antipsychotic type, serum prolactin, and sexual dysfunction in patients with schizophrenia, which have similarly found risperidone and other prolactin-raising agents associated with a greater burden of sexual side effects than prolactin-sparing alternatives [5].

Age was independently associated with metabolic syndrome but not with sexual dysfunction, while baseline BMI was strongly associated with metabolic syndrome, as expected given its role as both a component and a driver of the syndrome. Antipsychotic treatment duration beyond two years was not independently associated with either outcome in this cohort, suggesting that the cross-sectional severity of hyperprolactinaemia and metabolic derangement at a given time point may be more clinically informative than treatment duration alone.

Limitations: This study has several limitations. First, although prospective, the six-month follow-up period is relatively short relative to the typically long-term nature of antipsychotic treatment, and the observed changes and associations may evolve further with longer follow-up. Second, this was a single-centre study, and the antipsychotic prescribing pattern, dosing practices, and patient population may not be representative of other settings.

Conclusion

In this cohort of adult patients on prolactin-elevating antipsychotics, hyperprolactinaemia was common and was independently associated with both metabolic syndrome and sexual dysfunction at six months, even after adjustment for age, sex, BMI, antipsychotic dose, and treatment duration. These findings support incorporating routine serum prolactin monitoring alongside metabolic and structured sexual-function screening (such as the ASEX) in the long-term follow-up of patients on prolactin-raising antipsychotics. This will help identify those who may benefit from closer monitoring, dose optimisation, or a switch to a prolactin-sparing agent.

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