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Original

Late-Onset Hypogonadism in Male Hemodialysis Patients: Association with Statin Therapy and Cholesterol Levels

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Background: Late-onset hypogonadism (LOH), a condition characterized by age-related testosterone decline, is associated with impaired quality of life and adverse clinical outcomes. Although endocrine abnormalities are common in patients undergoing maintenance hemodialysis (MHD), the clinical characteristics and risk factors for LOH in this population remain unclear. This study investigated the prevalence of LOH and its associated clinical factors in male patients on MHD.

Methods: Sixty-nine male patients undergoing MHD were enrolled. LOH was defined as total testosterone ≤250 ng/dL combined with an Aging Male Symptoms Score (AMSS) of ≥27. Clinical features, laboratory parameters, and medication use were compared between patients with and without LOH. Factors associated with LOH were evaluated using multivariate analysis.

Results: Fifteen patients (21.7%) met the diagnostic criteria for LOH. Patients with LOH had significantly higher AMSS scores, particularly in the sexual domain. In the revised multivariate analysis excluding variables used in the definition of LOH, statin use remained independently associated with LOH (odds ratio: 8.12, p = 0.017), whereas total cholesterol showed a marginal inverse association (odds ratio: 0.97, p = 0.058).

Conclusions: LOH was observed in approximately 20% of male patients on MHD and was characterized mainly by sexual symptoms. Statin therapy may be associated with LOH; however, the findings should be interpreted cautiously due to potential confounding and limited sample size.

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Keywords: late-onset hypogonadism, maintenance hemodialysis, statins, total testosterone, cholesterol

Introduction

Late-onset hypogonadism (LOH), characterized by an age-related decline in testosterone levels, is associated with a broad spectrum of aging male symptoms (AMS), including sexual dysfunction, psychological disturbances, cognitive impairment, and physical frailty[1–6]. Beyond its symptom-associated burden, LOH has important clinical implications. Testosterone deficiency has been associated with reduced bone mineral density, impaired insulin sensitivity, an atherogenic lipid profile, and anemia, all of which predispose people to cardiovascular disease (CVD)[1–6]. Testosterone also plays a role in immune modulation through the regulation of anti-inflammatory and anti-infective cytokines; therefore, LOH has also been associated with increased susceptibility to infectious diseases[7–13]. Consequently, the condition is increasingly rec-

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ognized as a condition that adversely affects not only quality of life but also long-term clinical outcomes, including CVD, infection-related morbidity, and all-cause mortality[1–13].

Patients undergoing maintenance hemodialysis (MHD) frequently exhibit endocrine abnormalities, and previous studies have reported that approximately 40%–50% of male patients on MHD have reduced testosterone levels accompanied by clinical symptoms suggestive of LOH[12–16]. However, patients on MHD are also affected by multiple systemic uremia-associated complications, including chronic inflammation, uremic toxin accumulation, anemia, and mineral and bone disorders[12–17]. These factors can produce symptoms similar to AMS, making it difficult to determine whether the observed symptoms in patients on MHD are primarily attributable to testosterone deficiency or to the uremic milieu itself. Clarifying this distinction is clinically important, as the management strategies for LOH and uremia-related symptoms differ substantially.

Furthermore, the COVID-19 pandemic has significantly affected patients on MHD, who are known to be highly predisposed to infection and severe disease[7–11]. Although recent studies have suggested that low testosterone levels may influence susceptibility to or severity of COVID-19 in the general population, the relationship between LOH and COVID-19 infection in patients on MHD remains unclear.

Therefore, the present study aimed to investigate the prevalence of LOH and its association with clinical characteristics in male patients undergoing MHD. Specifically, we compared demographic features, comorbid conditions (including CVD), AMS severity, and history of COVID-19 infection between patients with and without LOH.

Materials and Methods

Study Design and Ethics

This single-center observational study was conducted to evaluate the association between LOH and clinical characteristics in patients on MHD. The study population included all adult male patients undergoing MHD at Nankai Medical Center between April 1, 2021, and May 7, 2023. The study was conducted following the principles outlined in the Declaration of Helsinki and Good Clinical Practice guidelines and was approved by the Ethics Committee of Nankai Medical Center (IRB approval number: NC-R3-005) as an epidemiological study conducted using validated questionnaires and patient blood samples. Written consent for enrollment and publication was obtained from patients for the extended use of validated questionnaires and patient blood samples obtained for usual clinical practice. Patients were informed about the details of the study using a documented explanation form and were given the right to withdraw consent after enrollment.

Participants and Eligibility Criteria

Eligible participants were male patients aged ≥40 years who had been receiving MHD thrice weekly for at least 3 months and were in stable clinical condition without hospitalization[18]. Patients with adrenal or testicular disease, a history of castration for prostate cancer, or significant psychiatric conditions were excluded[19–21].

Baseline clinical data, including age, dialysis vintage, and medical history (diabetes mellitus and CVD), were collected from medical records. We also recorded the use of medications known to affect testosterone levels, such as ACE inhibitors, ARBs, benzodiazepines, calcimimetics, cimetidine, statins (most commonly, atorvastatin and rosuvastatin), and steroids[22–25].

Assessment of LOH and Clinical Parameters

At baseline (April 1, 2021), the validated Japanese version of the Aging Male Symptom Score (AMSS)[1] was administered. This is a 17-item self-reported tool covering three domains: physical, psychological, and sexual. Symptom severity was categorized as normal (17–26), mild (27–36), moderate (37–49), or severe (≥50)[1–6,14]. Expert nurses, clinical engineers, or urologists provided guidance for patients who needed assistance.

Blood samples were collected once in the morning at the start of the first dialysis session of the week following an overnight fast[1–6,12–17,19–21]. Laboratory parameters included C-reactive protein levels, hemoglobin levels, complete blood counts, iron studies (ferritin, transferrin saturation), electrolyte panels, lipid profiles, total testosterone (TT), gonadotropins (FSH, LH), intact parathyroid hormone, and prolactin.

LOH Definition

Following established criteria[1], LOH was defined as a combination of TT ≤ 250 ng/dL and a total AMSS ≥ 27. Participants were divided into the LOH group (LOHg) and the non-LOH group (nLOHg).

Follow-Up and Outcome Definitions

CVD was defined as heart failure, ischemic heart disease, valvular disease, aortic disease, or stroke[26]. Following the

baseline assessment, patients were followed up until May 8, 2023. COVID-19 infection was confirmed by a positive PCR test result[7–11]. A history of CVD and COVID-19 vaccination status were obtained from medical records at the time of the AMSS survey.

Statistical Analysis

Continuous variables were presented as mean values with standard deviations (for normally distributed data) or medians with interquartile ranges (for skewedly distributed data) and compared using Student's t-test or the Mann–Whitney U test, respectively. Categorical variables were presented as frequencies with percentages, and for these variables, univariate and multivariate analyses were performed using multiple logistic regression to adjust for clinically relevant confounders and identify factors independently associated with LOH. To avoid circularity, variables used in the definition of LOH (total testosterone and AMSS-related scores) were excluded from regression analyses. Given the limited number of events, a parsimonious multivariable model was constructed using clinically relevant variables and those with $p < 0.10$ in univariate analysis. All analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, version 1.61), a graphical user interface for R[27]. The threshold for statistical significance was set at $p < 0.05$.

Results

Patient Characteristics and LOH Prevalence

The 69 study participants had a mean age of 69.3 ± 12.1 years and a mean dialysis vintage of 80.1 ± 72.1 months. The mean total AMSS and TT levels were 35.7 ± 11.8 and 381 ± 167 ng/dL, respectively. Among the 69 participants, 58 (84.1%) had an AMSS ≥ 27, and 15 (21.7%) had a TT ≤ 250 ng/dL. Overall, 15 patients (21.7%) met the established LOH diagnostic criteria. During the observation period, 14 patients (20.3%) were infected with COVID-19, of whom four were in the LOH group (LOHg).

Comparison between LOHg and NLOHg

There were no significant differences in age or dialysis vintage between the LOHg and nLOHg. Compared to the nLOHg, patients in the LOHg were significantly more likely to have diabetes mellitus, a history of CVD, and be receiving statin therapy. Additionally, the patients in the LOHg required significantly higher doses of darbepoetin alfa.

Regarding laboratory parameters, the patients in the LOHg exhibited significantly higher C-reactive protein levels and significantly lower levels of hemoglobin, total cholesterol (TC), and low-density lipoprotein cholesterol than those in the nLOHg (**Table 1**).

Aging Male Symptoms and Testosterone

The mean total AMSS was significantly higher in the LOHg than in the nLOHg (41.5 ± 11.8 vs. 34.1 ± 11.4, $p = 0.046$). The analysis of AMSS domains revealed that the sexual domain scores were significantly higher in the LOHg ($p < 0.01$), whereas no significant differences were observed in the physical or psychological domains. The incidence of COVID-19 infection did not differ significantly between the two groups.

Factors Associated with LOH and AMSS

In the revised multivariable logistic regression analysis excluding variables used in the definition of LOH, statin use remained significantly associated with LOH (odds ratio [OR]: 8.12; 95% confidence interval [CI]: 1.45–45.6; $p = 0.017$). Total cholesterol showed a marginal inverse association (OR: 0.97; 95% CI: 0.94–1.00; $p = 0.058$). Other variables, including diabetes mellitus, CVD history, and hemoglobin level, were not independently associated with LOH. Furthermore, the linear regression analysis showed that age was the only variable significantly correlated with the total AMSS (beta = 0.27, $p = 0.02$). Notably, TT levels were significantly and inversely correlated with the sexual domain score of the AMSS (beta = −1.01, $p = 0.015$), whereas no such correlation was found with C-reactive protein or intact parathyroid hormone levels (**Table 2**).

Discussion

This study investigated the prevalence and clinical features of LOH in male patients undergoing MHD. There were two main findings. First, approximately 20% of the study population met the diagnostic criteria for LOH, and these patients exhibited significantly higher AMSS, particularly in the sexual domain. Second, statin therapy was independently associated with the presence of LOH.

Clinical Relevance of AMS in Patients on MHD

Male patients receiving MHD frequently report symptoms that overlap with AMS, including fatigue, reduced physical function, and psychological distress[12–17]. In the present study, LOH and non-LOH patients both showed relatively high AMSS values, suggesting that the uremic environment itself contributes to nonspecific AMS mani-

Table 1 Characteristics of the patient in the two groups studied

Variable (unit: reference value)	Overall (n = 69)	LOH (n = 15)	Non-LOH (n = 54)	p-value
Age (years)	69.3 ± 12.1	70.6 ± 11.3	68.9 ± 12.3	0.64
MHD vintage (months)	80.1 ± 72.1	50.2 ± 45.2	87.6 ± 76.8	0.12
Diabetic patients	29	11	18	<0.01
Number of COVID-19 vaccination doses	2.90 ± 0.58	2.74 ± 0.85	2.94 ± 0.43	0.10
COVID-19 infected patients during follow-up	14	4	10	0.49
Number of household members	1.57 ± 1.50	1.07 ± 0.70	1.70 ± 1.63	0.15
Patients with CVD history	28	10	18	0.035
Darbepoetin Alfa (μg/month)	86.1 ± 92.5	131.9 ± 143.4	73.4 ± 69.1	0.029
Patients taking testosterone-reducing drugs				
Angiotensin-converting enzyme inhibitors and Angiotensin II receptor blockers	27	6	21	1
Benzodiazepine	8	2	6	1
Calcimimetrics	15	4	11	0.73
Cimetidine	1	0	1	1
Statins	18	9	9	<0.01
Steroids	3	1	2	0.53
Aging male symptom scores				
Mean total score (Q1–17)	35.7 ± 11.8	41.1 ± 11.3	34.2 ± 11.6	0.046
Mean physical domain score (Q1–5, 9, 10)	13.4 ± 4.6	15.0 ± 4.9	13.7 ± 4.5	0.34
Mean psychological domain score (Q6–8, 11, 13)	8.4 ± 3.9	8.9 ± 4.1	8.3 ± 3.9	0.61
Mean sexual domain score (Q12, 14–17)	13.8 ± 5.8	17.2 ± 5.5	12.3 ± 5.4	<0.01
Blood sampling data				
White blood cells (μL: 3,100–8,400)	5,681 ± 2,070	6,433 ± 2,080	5,472 ± 2,037	0.11
C-reactive protein (mg/L: 0.0–0.3)	0.45 ± 0.91	0.92 ± 1.59	0.32 ± 0.56	0.023
Hemoglobin (g/dL: 11.4–16.6)	10.6 ± 1.3	9.85 ± 0.81	10.77 ± 1.34	0.014
Ferritin (ng/mL: 20–500)	167.2 ± 134.8	188.8 ± 164.1	161.2 ± 126.6	0.49
Transferrin saturation (%: 20–30)	31.4 ± 14.9	28.8 ± 14.1	32.1 ± 15.1	0.45
Serum iron (μg/dL: 65–175)	69.7 ± 27.4	63.2 ± 28.8	71.5 ± 27.0	0.31
Phosphorus (mg/L: 2.5–4.5)	5.2 ± 1.4	4.95 ± 1.24	5.25 ± 1.39	0.45
Potassium (mEq/L: 3.5–5.0)	4.9 ± 0.7	4.67 ± 0.74	4.95 ± 0.70	0.19
Albumin (g/dL: 3.8–5.3)	3.49 ± 0.37	3.39 ± 0.43	3.51 ± 0.36	0.25
Triglyceride (mg/dL: 20–149)	139.1 ± 330.4	104.4 ± 92.2	101.6 ± 61.4	0.89
Total cholesterol (mg/dL: 140–199)	124.9 ± 31.8	102.2 ± 68.5	143.3 ± 31.0	0.037
High-density lipoprotein cholesterol (mg/dL: ≥40)	47.7 ± 15.7	44.1 ± 9.30	48.6 ± 17.0	0.33
Low-density lipoprotein cholesterol (mg/dL: 60–119)	73.8 ± 25.1	61.0 ± 17.7	77.3 ± 25.8	0.025
Total testosterone (ng/dL: ≥250)	381 ± 167	194 ± 43	433 ± 150	<0.01
Luteinizing hormone (mIU/mL: 0.57–12.07)	21.0 ± 20.6	24.2 ± 25.8	20.2 ± 19.1	0.51
Intact parathyroid hormone (pg/dL: 60–240)	259.5 ± 360.5	200.8 ± 157.9	275.8 ± 398.6	0.48
Prolactin (ng/mL: 3.5–19.4)	22.0 ± 12.3	24.8 ± 17.9	21.3 ± 10.6	0.36

Values are expressed as mean ± SD.
LOH: late-onset hypogonadism, MHD: maintenance hemodialysis, COVID-19: Coronavirus Disease 2019.

festations. However, the sexual domain score of the AMSS was significantly higher in the LOH group and was inversely correlated with total testosterone levels. These findings suggest that sexual dysfunction may represent a more specific clinical manifestation of testosterone deficiency in patients on MHD.

In contrast, the physical and psychological domains of the AMSS were not significantly associated with testosterone levels. This observation suggests that symptoms such as fatigue, reduced vitality, and mood disturbance may largely reflect uremia-related factors rather than androgen deficiency. Patients undergoing MHD are exposed to multiple systemic stressors, including chronic inflammation, anemia, accumulation of uremic toxins, and vascular dysfunction, all of which may contribute to these symptoms[12–17]. Therefore, although AMS questionnaires may be useful for symptom screening, clinicians should interpret nonsexual symptoms with caution in the hemodialysis population.

Patients with LOH also exhibited higher CRP levels and lower hemoglobin levels in the univariate analysis, which may reflect the potential influence of testosterone

Table 2 Univariate and multivariate analysis of factors associated with LOH

Explanatory variable	Odds ratio	95% confidence interval	p-value
Univariate analysis			
Age years	1.01	0.96–1.16	0.63
MHD vintage (months)	0.99	0.98–1.00	0.13
Diabetic patients	5.50	1.53–19.70	<0.01
COVID-19 infected patients during follow-up	1.60	0.42–6.68	0.49
Number of COVID-19 vaccination doses	0.64	0.25–1.65	0.36
Number of household members	0.69	0.41–1.16	0.16
CVD history	4.00	1.19–13.5	0.025
Darbepoetin Alfa (μg/month)	1.01	1.00–1.01	0.067
Patients taking testosterone-reducing drugs			
Angiotensin-converting enzyme inhibitors and Angiotensin II receptor blockers	1.05	0.33–3.37	0.94
Benzodiazepine	1.23	0.22–6.83	0.81
Calcimimetrics	1.42	0.38–5.33	0.60
Cimetidine	<0.01	0.00–Inf	0.99
Statins	7.50	2.13–26.4	<0.01
Steroids	1.86	0.16–22.0	0.62
White blood cells (μL: 3,100–8,400)	1.23	0.95–1.58	0.12
C-reactive protein (mg/L: 0.0–0.3)	1.94	0.87–4.35	0.11
Hemoglobin (g/dL: 11.4–16.6)	0.38	0.18–0.84	0.016
Ferritin (ng/mL: 20–500)	1.00	0.99–1.01	0.48
Transferrin saturation (%: 20–30)	0.98	0.94–1.03	0.44
Serum iron (μg/dL: 65–175)	0.99	0.97–1.11	0.30
Phosphorus (mg/L: 2.5–4.5)	0.83	0.51–1.34	0.44
Potassium (mEq/L: 3.5–5.0)	0.58	0.26–1.32	0.19
Albumin (g/dL: 3.8–5.3)	0.39	0.08–1.92	0.25
Triglyceride (mg/dL: 20–149)	1.00	0.99–1.01	0.89
Total cholesterol (mg/dL: 140–199)	0.98	0.96–0.99	0.044
High-density lipoprotein cholesterol (mg/dL: ≥40)	0.98	0.94–1.02	0.33
Low-density lipoprotein cholesterol (mg/dL: 60–119)	0.97	0.94–0.99	0.032
Lutenizing hormone (mIU/mL: 0.57–12.07)	1.01	0.98–1.04	0.51
Intact parathyroid hormone (pg/dL: 60–240)	1.00	0.99–1.00	0.49
Prolactin (ng/mL: 3.5–19.4)	1.02	0.98–1.07	0.35
Multivariate analysis			
Statins	8.12	1.45–45.6	0.017
Total cholesterol (mg/dL: 140–199)	0.97	0.94–1.00	0.058
Diabetes mellitus	3.21	0.78–13.2	0.10
CVD history	2.68	0.65–11.0	0.17
Hemoglobin	0.51	0.22–1.18	0.11

MHD: maintenance hemodialysis, COVID-19: Coronavirus Disease 2019.

deficiency on erythropoiesis[1–6] and inflammation[7–13].

Association between Statin Therapy and LOH

Another important finding of this study was the independent association between statin use and LOH. Statins inhibit 3-hydroxy-3-methylglutaryl coenzyme A reductase, the key enzyme in cholesterol biosynthesis[22–25]. Since cholesterol is a key precursor for steroid hormones, markedly inhibiting its production could potentially diminish androgen synthesis[22–25]. In our study, statin use was associated with a markedly increased risk of LOH (OR: 8.12). Total cholesterol showed a marginal inverse association, further supporting the biological link between cholesterol metabolism and testosterone production.

Statins are widely prescribed for cardiovascular risk reduction, particularly in high-risk populations like patients undergoing MHD[28–34]. However, our findings raise the possibility that excessive cholesterol lowering may contribute to androgen deficiency in some individuals. These findings are consistent with previous reports suggesting that statin therapy may reduce circulating testos-

terone levels or exacerbate symptoms of hypogonadism[22–25]. Although statin users often have a higher burden of CVD, multivariate analysis adjusting for potential confounders demonstrated that statin therapy remained independently associated with LOH.

Nevertheless, statins remain an essential component of CVD prevention, particularly in patients with established CVD[28–34]. Therefore, our findings should not discourage appropriate statin use but highlight the need for clinical awareness of potential endocrine consequences. Screening for LOH may be particularly relevant in statin-treated patients with MHD who present with sexual dysfunction. Given the widespread use of statins in patients undergoing MHD, our findings highlight the importance of considering LOH in statin-treated patients presenting with sexual symptoms.

COVID-19 and LOH

We also investigated the potential association between LOH and COVID-19 infection. Previous studies conducted in the general population have suggested that testosterone deficiency may be associated with worse outcomes in COVID-19[7–11]. However, in our cohort, no statistically significant relationship was observed between LOH and COVID-19 incidence. The analysis of COVID-19 infection was exploratory and had limited impact on the main findings. Therefore, it should be interpreted as supplementary information.

Study Limitations

Several limitations should be acknowledged. First, this was a single-center study with a relatively small sample size, which may limit the generalizability of the findings. Second, LOH diagnosis was based on single measurement of total testosterone levels and AMSS questionnaires; two measurements of total testosterone, additional endocrine parameters, such as free testosterone or sex hormone-binding globulin, were not measured, which may have limited diagnostic precision. Third, the cross-sectional design precludes conclusions regarding the causality between statin therapy, cholesterol levels, and LOH. Fourth, body composition parameters such as muscle mass and bone density were not evaluated and may provide further insights into the clinical impact of testosterone deficiency in patients with MHD. Finally, a major limitation is the potential confounding effect of uremic symptoms, as many AMSS items overlap with symptoms commonly observed in hemodialysis patients. Because a quantitative uremic symptom score was not available, misclassification of LOH cannot be excluded. We must also acknowledge the absence of BMI data. Obesity is a known risk factor for hypogonadism and may confound the association between statin use and LOH. Although statin use was associated with LOH, the wide confidence interval and potential residual confounding suggest that the findings should be interpreted cautiously. Further large-scale prospective studies are needed to confirm our findings.

Conclusions

LOH syndrome is prevalent among Japanese male maintenance hemodialysis patients and manifests predominantly through sexual symptoms. Statin administration and lower total cholesterol levels are independent risk factors for LOH in this population. Clinicians should consider the possibility of LOH in hemodialysis patients presenting with sexual dysfunction or those receiving intensive lipid-lowering therapy.

Author Contributions: TA planned and conducted the study, analyzed the data, and drafted the manuscript. HF planned and conducted the study and drafted the manuscript. YF and NS recruited patients and collected patient samples, collected the samples, and conducted the sample analysis. TS and TA supervised the study and drafted the manuscript. All authors read and approved the final version of the manuscript to be submitted for publication.

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Data Availability: The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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