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Complaint of insomnia as a predictor of aging symptoms in males at a men's health clinic

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Introduction: Issues of men's health have been greatly researched by scholars in recent decades. At men's health clinics, many patients complain of both insomnia and aging males' symptoms (AMS). These symptoms might be influenced by biological, psychological or even social factors. The aim of this study was to investigate different aspects of the relationship between insomnia and aging symptoms. **Methods:** This cross-sectional study included 231 males from a men's health clinic. Participants completed a set of general data and screening assessments, including the AMS rating scale, insomnia severity index (ISI), Beck depression inventory-II (BDI-II) and Beck anxiety inventory Chinese version (BAI), to investigate the severity of aging symptoms, insomnia, depression and anxiety. **Results:** The ISI correlated significantly with the AMS scale, both with (partial correlation coefficient = 0.470) and without ($r = 0.580$) controlled variances of depression and anxiety. Using linear regression, aging symptoms were statistically predicted by the severity of the ISI, and a substantial proportion of the variance was explained (adjusted $R^2 = 0.410$). When all variables were included, this proportion rose to 55.3% (adjusted $R^2 = 0.553$). **Conclusion:** We suggest that insomnia is a good predictor of aging symptoms across all age groups of men.

Keywords: Aging males' symptoms, insomnia, men's health, androgen deficiency, anxiety, depression

Introduction

A men's health clinic was established at Chang Gung Memorial Hospital comprised of the departments of andrology, psychiatry and traditional Chinese medicine, to provide medical service for partial androgen deficiency in aging males (PADAM), sexual dysfunction, lower urinary tract symptoms, infertility, mental problems among others. More studies have appeared

in the field of male health-related quality of life (HRQoL), but they focus mostly on aging men or discuss these issues from the viewpoints of urologists or endocrinologists. Because insomnia is common and has detrimental effects on the quality of life, it has inspired the author to explore the relationship of sleep disturbances and aging males' symptoms (AMS).

Patients with PADAM, which has quite a complex etiology [1], present various clinical symptoms and endocrinological dysregulation [2]. Many social factors might influence severity of aging symptoms directly [1]. To assess aging symptoms (independent from disease-related symptoms) between groups of males under different conditions [3], a valuable and easily applicable screening tool should be selected. In the present study, the AMS rating scale was chosen as the screening questionnaire for several reasons. First, the validity and reliability of the AMS scale had been established in Taiwan [4]. Also, the internal structures of the AMS scale in healthy and androgen deficiency males across other countries have been sufficiently similar to conclude that the scale measures the same phenomenon in varying contexts [5]. Second, the AMS scale was developed in response to insufficiently standardized scales [6,7], such as the androgen deficiency in aging males (ADAM) questionnaire. Third, it can measure the severity of aging symptoms over time from different dimensions as well as their impact on health-related quality of life, even at young ages [8].

This study aimed to examine whether insomnia could be a reliable predictor for aging symptoms.

Methods

Participants and collection of general data

From July 2008 through March 2009, 231 consecutive male outpatients who visited the Men's Health Clinic at

Chang-Gung Memorial Hospital completed comprehensive bio-psycho-social surveys for their initial visits. All participants gave written informed consent for participation, and approval was obtained from the Human Subject Research Ethics Committee/Institutional Review Board (IRB). The collection of basic and demographic data included age, education, employment status, and marital status, physical condition, chief complaints, current pharmacotherapy, body weight/height, waistline, body mass index (BMI), consumption of alcohol and cigarette smoking. A World Health Organization (WHO) Expert Consultation concluded that Asians with a high risk of type 2 diabetes and cardiovascular disease [9] have BMIs lower than the existing WHO cut-off point for being overweight. Therefore, we adjusted the BMI cut-off points in this study to: underweight: BMI <18.5; normal: $18.5 \leq \text{BMI} < 24$, overweight: $24 \leq \text{BMI} < 27$, obese: BMI ≥ 27 , based on data from Bureau of Health Promotion, Department of Health, Taiwan [10].

Administered screening scales

All participants were asked to complete the following standard self-administered questionnaires.

ADAM questionnaire

This 10-question checklist is a useful but non-specific screen that is assumed to be related to ADAM [11]. A positive result on the scale is defined as answering “yes” to item 1 or 7 or any three other questions.

The AMS rating scale

This 17-question self-administered scale [3] by men over the age of 40 can also help assess the severity of aging symptoms. An improvement over the ADAM questionnaire, the AMS scale does not include dichotomous responses, and it contains three domains of psychological factors (five items), somatovegetative symptoms (seven items) and sexual complaints (five items). The intensity of each item is rated from 0 to 5 points. A higher total score indicates more severe presentation. The AMS questionnaire was translated into a Chinese version and validated in 2007 [4].

Insomnia severity index (ISI)

This is a valid and brief self-report questionnaire. It is a reliable instrument to quantify perceived insomnia over the last 2 weeks. It also is a clinically useful device as an outcome measure in insomnia treatment. The ISI is composed of seven items [12] that evaluate the difficulty of sleep-onset, the difficulty of sleep maintenance, problems related to early morning awakening, satisfaction with the current sleep pattern, interference with daily functioning, noticeability of impairment attributed to sleep problems and level of distress caused by sleep problems. Each item is rated from 0 (not at all) to 4 (extremely), except for satisfaction with the current sleep pattern, which is scored from 0 (satisfied) to 4 (extremely dissatisfied). The total score ranges from 0 to 28 to indicate the severity of insomnia.

Chinese version of the Beck depression inventory-II (BDI-II)

The BDI-II was published in 1996 [13], and like the BDI, it is a 21-item self-report questionnaire for measuring the severity of depression. It is comprised of measurements of symptoms relating to depression and physical symptoms. The BDI-II has a maximum score of 63, with each question scored on a scale of 0–3. In the Chinese version [14], the cut-offs differ from those in the original (American), with 0–13 indicating minimal depression, 14–19 indicating mild depression, 20–28 indicating moderate depression and 29–63 severe depression. For the Taiwanese, the assessment of whether a person presents with depression uses a best cut-off point equal to or greater than 17.

Chinese version of the Beck anxiety inventory (BAI)

The 21-question self-report inventory has discriminative validity and can differentiate anxiety from depression [15]. The BAI has a maximum score of 63, with each question scored on a scale of 0–3. The cut-offs are the same as those in the American version. However, the best cut-off point in Taiwanese is higher than or equal to 14 [16], which indicates a person with prominent symptoms that may possibly have clinical significance.

Laboratory assays

Blood testing, including a profile of sex hormone levels, was selectively performed depending on the overall assessment based on clinical presentation and the severity of the questionnaire assessments.

Statistical analysis

The data were analyzed and exported to the Statistical Package for the Social Sciences (SPSS, version 17.0) for Windows 7. The evaluation of primary statistics, Pearson's correlations and partial correlations was performed to compare the AMS, ISI, BDI-II and BAI scores. To test the differences among variables, we used the Student's *t*-test and one-way ANOVA to compare the means of two or more groups. Statistical significance was assessed by the Pearson's χ^2 test for categorical variables. Linear regression was performed to assess the trends and impact of factors such as sleep disturbances, anxiety, depression, BMI and age on the severity of the AMS scale. A *p* value ≤ 0.05 was considered to be statistically significant. The Bonferroni test was used to correct for multiple comparisons.

Results

The mean age of subjects was 46.1 years (SD = 11.0). Table I demonstrates the demographic characteristics of all 231 participants without any missing data.

Analysis of factors that influence AMS

Parameters were collected from participants with respect to general data and questionnaires, which might influence severity of AMS (Table II). To verify whether these factors truly had significant effects on the AMS total scores, independent

Table I. Description of initial participant sample (N=231): percentage of characteristics in subjects.

	n = 231	%
Age [†]		
<40	62	26.84
40–49	81	35.06
50–59	63	27.27
≥60	25	10.82
Education		
Junior high school and below	51	22.08
Senior high school and above	180	77.92
Marital status		
Single (unmarried, divorced, widowed)	184	79.65
Married/cohabited	47	20.35
Employment		
Unemployed	52	22.51
Employed	179	77.49
Waistline [#]		
<90	158	68.40
≥90	73	31.60
Physical condition		
Healthy	106	45.89
With chronic disease	125	54.11
Alcohol consumption		
No	139	60.17
Yes	92	39.83
Cigarette smoking		
No	150	64.94
Yes	81	35.06
BMI		
Underweight	5	2.16
Normal	95	41.13
Overweight	83	35.93
Obese	48	20.78
BDI-II score		
≤16	151	
>16	80	34.6
BAI score		
<14	130	56.28
≥14	101	43.72

[†]Age, yr. Mean \pm SD = 46.1 \pm 11.0; [#]Waistline, cm; BMI, Kg/m²: body mass index; underweight: BMI <18.5, normal: 18.5 \leq BMI <24, overweight: 24 \leq BMI <27 and obese: BMI \geq 27; BDI-II: Chinese version of the Beck depression inventory-2nd edition; BAI: Chinese version of the Beck Anxiety Inventory.

sample tests were performed on two-group samples for education, marital status, employment status, waistline, physical condition, alcohol consumption, cigarette smoking, BDI-II score, BAI score and ISI score. ANOVA was performed on three-group or four-group samples for age and BMI. There were significant differences for employment ($p < 0.001$), physical condition ($p = 0.004$), BDI-II score ($p < 0.001$), BAI score ($p < 0.001$) and ISI score ($p < 0.001$).

In determining how these parameters might influence three different dimensions of the AMS scale, we found that the parameters for employment, BDI-II score, BAI score and ISI score had significant effects in all subscales. Cigarette smoking and physical condition each played role in the somatovegetative subscale, and age and physical condition were important factors in the sexual subscale (Table II).

Correlations between the ISI and AMS scores

Insomnia severity correlated well with the AMS scale, with a Pearson's r value of 0.580 ($p < 0.001$) (Table III). People with some degree of psychiatric illness had poor sleep quality, as insomnia is one criterion of depression. We then controlled the variances of BDI-II and BAI, which exhibited a partial correlation coefficient of 0.470 ($p < 0.001$).

Moreover, the fourth item (i.e., sleep problems, including difficulty in falling asleep, difficulty in sleeping through the night, waking up early and feeling tired, poor sleep and sleeplessness) [3] was removed from the somatovegetative dimension of the AMS (AMS-som). Correlations among the ISI, the rest of the AMS-som and the rest of the AMS scale remained significant, with Pearson's r values of 0.496 ($p < 0.001$) and 0.533 ($p < 0.001$), respectively. As we controlled the variances of BDI-II and BAI, correlations among the ISI, the rest of the AMS-som and the rest of the AMS scale, which exhibited a partial correlation coefficient of 0.379 ($p < 0.001$) and 0.406 ($p < 0.001$), respectively.

Predictability of AMS

Even there was no significance in ANOVA statistic, factor of age that we thought may influence AMS was included in the regression model. Table IV lists the determinants of three dimensions of the AMS and the AMS scale. Aging symptoms were statistically predicted in increasing order by the ISI, and a substantial proportion (41.0%) of the variance was explained (adjusted $R^2 = 0.410$, $p < 0.001$). Age added little to the overall statistical prediction. Inputting all variables into the regression, including BDI-II and BAI, this proportion of the variance explained rose to 55.3% (adjusted $R^2 = 0.553$, $p < 0.001$).

After eliminating the fourth item (i.e., sleep problems) [3] from the AMS scale, we analyzed the sample again. Aging symptoms were still statistically predicted in increasing order by the ISI, with adjusted $R^2 = 0.343$ ($p < 0.001$). Inputting all variables into the regression, including BDI-II and BAI, a substantial proportion (49.4%) of the variance was explained (adjusted $R^2 = 0.494$, $p < 0.001$).

The AMS questionnaire is a measurement used in aging men. Thus, we used the same strategy outlined above to focus our analysis on 169 men aged equal to or greater than 40 of the 231 participants. Pearson's r was 0.553 ($p < 0.001$) with respect to the correlation between the ISI and AMS scores. When the variances of the BDI-II and BAI were controlled, the partial correlation coefficient was 0.478 ($p < 0.001$). Aging symptoms were still statistically predicted in increasing order by the ISI, with adjusted $R^2 = 0.340$ ($p < 0.001$). Inputting all variables into the regression, including BDI-II and BAI, a substantial proportion (49.7%) of variance was explained (adjusted $R^2 = 0.497$, $p < 0.001$).

Discussion

Analyzing the factors influencing AMS, only the scores of the sexual subscale of the AMS increased significantly with age. This result was similar to findings from a previous Japanese study of men visiting a multi-phasic health screening clinic

Table II. AMS total and subscales scores.

	AMS-PSY score			AMS-SOM score			AMS-SEX score			AMS-TOTAL score		
	Mean	SD	p-value	Mean	SD	p-value	Mean	SD	p-value	Mean	SD	p-value
Age [†]			0.478			0.949			<0.001***			0.725
<40	11.45	5.36		16.82	5.64		10.16	3.68		38.44	12.48	
40–49	11.16	5.14		17.00	5.75		11.64	4.03		39.80	13.26	
50–59	10.44	4.25		16.46	5.27		12.52	3.85		39.43	11.20	
≥60	9.96	4.22		16.88	4.48		14.84	3.17		41.68	10.07	
Employment			0.006**			0.015*			<0.001***			<0.001***
No	12.75	5.51		18.40	5.71		14.02	3.74		45.17	12.15	
Yes	10.38	4.56		16.32	5.28		11.20	3.88		37.90	11.69	
Waistline [#]			0.161			0.060			0.096			0.050*
<90	10.61	4.69		16.34	5.26		11.53	3.88		38.47	11.47	
≥90	11.58	5.24		17.78	5.72		12.48	4.27		41.84	13.32	
Physical condition			0.138			<0.001***			0.032*			0.004**
Healthy	10.40	4.39		15.46	4.67		11.22	4.12		37.08	11.31	
With chronic disease	11.35	5.23		17.92	5.80		12.35	3.88		41.62	12.49	
BMI			0.193			0.121			0.058			0.055
Underweight	13.40	3.85		20.80	4.97		15.80	5.81		50.00	9.30	
Normal	10.85	5.07		16.26	5.57		11.76	4.15		38.87	12.58	
Overweight	10.27	4.15		16.52	4.80		11.31	3.45		38.10	10.38	
Obese	11.90	5.59		17.90	6.05		12.46	4.30		42.25	13.70	
BDI-II score			<0.001***			<0.001***			<0.001***			<0.001***
≤16	8.66	3.12		14.82	4.05		10.90	3.58		34.38	8.40	
>16	15.16	4.77		20.51	5.79		13.59	4.23		49.26	12.23	
BAI score			<0.001***			<0.001***			<0.001***			<0.001***
<14	8.28	2.96		14.41	4.10		10.50	3.49		33.19	8.12	
≥14	14.30	4.78		19.86	5.42		13.54	4.02		47.70	11.62	
ISI score			<0.001***			<0.001***			0.002**			<0.001***
<15	9.19	3.60		14.80	4.00		11.10	3.70		35.10	8.90	
≥15	13.80	5.40		20.10	5.80		12.90	4.30		46.80	13.40	

[†]Age, yr. Mean \pm SD = 46.1 \pm 11.0; [#]Waistline, cm; BMI: body mass index, with underweight: BMI <18.5, normal: 18.5 \leq BMI < 24, overweight: 24 \leq BMI < 27 and obese: BMI \geq 27; BDI-II: Chinese version of the Beck depression inventory-2nd edition; BAI: Chinese version of the Beck Anxiety Inventory; ISI: insomnia severity index; AMS: Chinese version of the Aging Males' Symptoms Rating Scale; AMS-PSY: psychological subscale of the AMS questionnaire; AMS-SOM: somatovegetative subscale of the AMS questionnaire; AMS-SEX: sexual subscale of the AMS questionnaire.

Table III. Comparison of ISI total scores and AMS total/subscales scores.

	AMS-PSY	AMS-SOM	AMS-SEX	AMS-TOTAL	AMS (16 items)
ISI total scores	0.538*	0.604*	0.283*	0.580*	0.533*
ISI total scores [#]	0.413*	0.512*	0.163*	0.470*	0.406*

AMS: Chinese version of the Aging Males' Symptoms Rating Scale; AMS-PSY: psychological subscale of the AMS questionnaire; AMS-SOM: somatovegetative subscale of the AMS questionnaire; AMS-SEX: sexual subscale of the AMS questionnaire; AMS (16 items): AMS without item 4 (sleep problems).

[#]Partial correlation was performed, controlling for the variances of BDI-II and BAI.

*Correlation was significant at the 0.01 level (2-tailed).

[17], which revealed that the severity of the total score and the sexual subscale of the AMS increased significantly with age. This means that sexual function was observed to decline with age. A major portion of our participants were between 40 and 59 years old with chaotic etiologies; the interaction between the biological and psychosocial changes [18] that took place during the mid-life transition caused somatovegetative and psychological but not sexual symptoms domains, but these changes were not significantly influenced by age.

Correlations between the three subscale domains and the total AMS scale were high (0.741–0.926), as compared to those among the subscales (0.397–0.745). One review article collected data on aging males from many countries, which

revealed high correlations between each AMS subscale and the total scale (0.8–0.9) as compared to lower correlations among the subscales (0.5–0.7) [5]. Although the age groups of the study populations were different, both studies suggested that the subscales were not fully independent.

The correlation coefficients between the total AMS scale, the psychological domain, the somatic domain, the sexual domain and the BDI-II scale were 0.776 ($p < 0.001$), 0.773 ($p < 0.001$), 0.686 ($p < 0.001$) and 0.444 ($p < 0.001$), respectively. This can be compared with a Japanese study, in which 43 patients aged 40–70 years old who visited the male-climacteric outpatient clinic exhibited correlation coefficients between the total score, the psychological score, the somatic score,

Table IV. Effect of ISI, BDI-II, BAI and other clinical characteristics on the severity of aging male' symptoms.

Dependent variable	Predictors without BDI-II and BAI (with ISI)				Predictors with BDI-II and BAI (with ISI)			
	Adjusted R ²	β	95%	CI	Adjusted R ²	β	95%	CI
AMS-PSY	0.353	0.519***	0.273	0.414	0.554	0.334***	0.158	0.284
AMS-SOM	0.398	0.573***	0.347	0.498	0.499	0.455***	0.259	0.411
AMS-SEX	0.232	0.286***	0.092	0.219	0.286	0.192**	0.038	0.171
AMS-TOTAL	0.410	0.559***	0.752	1.089	0.553	0.399***	0.498	0.818
AMS (16 items)	0.343	0.512***	0.628	0.957	0.494	0.346***	0.379	0.691
AMS-TOTAL [#]	0.340	0.537***	0.668	1.076	0.497	0.401***	0.464	0.839
AMS (16 items) [#]	0.289	0.486***	0.542	0.939	0.458	0.345***	0.343	0.709

BDI-II: Chinese version of the Beck depression inventory-2nd edition; BAI: Chinese version of the Beck Anxiety Inventory; ISI: Insomnia Severity Index; AMS: Chinese version of the aging males' symptoms rating scale; AMS-PSY: psychological subscale of the AMS questionnaire; AMS-SOM: somatovegetative subscale of the AMS questionnaire; AMS-SEX: sexual subscale of the AMS questionnaire; AMS (16 items): AMS without item 4 elimination (sleep problems).

[#]We selected participants aged ≥ 40 years ($N=169$).

**Statistical significance, p value < 0.01 .

***Statistical significance, p value < 0.001 .

the sexual score and the BDI score of 0.788 ($p < 0.001$), 0.793 ($p < 0.001$), 0.652 ($p < 0.001$) and 0.453 ($p < 0.01$), respectively [19]. Increasing numbers of research studies [20,21] have investigated sleep disturbances and anxiety related distress or subclinical anxiety symptoms in males with adrenal deficiency, but few have focused on interactions between aging symptoms, sleep disturbances and anxiety. Indeed, among existing studies, there has been a lack of comparisons of AMS, insomnia and anxiety.

If a male patient complains of both prominent AMS and insomnia, there may be several relationships between these two clinical presentations: simultaneous co-morbidity, as a result of the interaction between the biological, psychological and social changes caused by insomnia or a deterioration in sleep disturbances due to AMS. However, the present results reveal that the severity of AMS can actually be worsened by insomnia. The high correlations between the AMS score and the ISI score support this contention. Longitudinal or experimental studies should be performed in the future to better explore this casual relationship.

As shown in the above correlations, the variables studies have been interrelated, thus requiring multivariate analysis. Two concepts were employed to explore the impact of sleep disturbances on AMS. One aimed to clarify whether increasing AMS scores were directly or indirectly interacting with insomnia. The latter would mean that patients with sleep disturbances were aggravated by depression or anxiety. Another, in order to evaluate the independent contribution of insomnia to the severity of AMS questionnaire score, we performed the same statistical techniques as above to analyze the sample while eliminating the fourth item (sleep problems) [3] from AMS scale. Table IV lists all the predictabilities (adjusted $R^2 = 0.343$ – 0.554) by varying control conditions to account for AMS. The ISI could positively explain AMS both with and without considering factors related to depression and anxiety, suggesting more complicated influences of insomnia and the other 16 items of AMS scale. Additionally, the results of correlation and predictability tests revealed similar trends in both the total sample analyses and in analyses including only men aged ≥ 40 .

From literature reviews, some chronic illnesses and physical conditions can depress testosterone levels. Physical

problems such as diabetes, insulin resistance, and obesity [22–24], pituitary diseases such as Prader–Willi syndrome, Klinefelter's syndrome, and Kallmann's syndrome [25], men who are HIV-positive [26], who are hepatitis C-positive and receive interferon therapy [27], and those who have taken long-acting opioid preparations such as methadone [28] have shown reduced androgen levels. Therefore, screening for pathological factors should be included in primary care practice for young-aged to middle-aged males other than only considering aging as a cause of primary hypothalamic-pituitary gonadal axis failure.

The results appear to suggest that AMS are predictive of the severity assessed by the ISI scale, regardless of age. Men with higher ISI scores indicated more severe AMS with a poorer HRQoL. As this was a hospital-based population, the results of the present study should not be extrapolated to community dwelling populations. This was the first study to analyze if insomnia can be a predictor of AMS, and therefore no other evidence from the same contexts to be compared with.

Limitations and further studies

There were some primary limitations in our study. The sample size was small, and the hospital-based population, together with the clinical approach, meant that subjects had already suffered from a degree of discomfort that caused them to seek medical advice before participating in the study [29]. Additionally, it was a cross-sectional study. The results cannot provide insight as to whether the severity of insomnia was a cause or consequence of AMS. Exclusion criteria were not set, and the evaluation of social factors during this study was simplified, such as income, work-related stress or serious co-morbidity.

The relationship between gonadal hormonal data and AMS is still a popular and controversial topic of debate. According to the guidelines of the International Society for the Study of the Aging Male (ISSAM) [30], also the reference of the revised guidelines [31], the diagnosis of late-onset hypogonadism in males should be determined by both clinical pictures and biochemistry. Males with classic hypogonadism can have unequivocally low free testosterone levels and typical

symptoms. However, newer studies have revealed a wide variance in the relationship between symptoms and hormone levels [32]. For example, some people with low testosterone levels have ambiguous clinical presentations that could be misinterpreted as other conditions or illnesses [33]. Although the gold standard for the diagnosis of hypogonadism is the measurement of serum free or bioavailable testosterone, such data are not available on every male suspected of having decreased testicular function [34]. The phenomenon of so-called “relative hypogonadism” has been proposed, according to each person has particular normal hormonal levels and testosterone levels that can vary within one day [35]. A syndrome of androgen deficiency with physical and/or psychological complaints reflects different but complementary aspects [34] of a problem that appears as a multisystem disease [36].

Not all participants underwent complete blood testing in our study. Besides economic and technical constraints, some people were hesitant about blood-drawing. Indeed, neither the ADAM, the AMS nor the Massachusetts male aging study (MMAS) questionnaires had relatively good specificity for the diagnosis of hypogonadism (scale vs. age comparison). Thus, building a reasonable approach to identify aging symptoms through a non-invasive, useful tool is important for further consideration [37].

Conclusions

This study demonstrates that insomnia complaints can be a good predictor for aging symptoms in male patients visiting men's health clinics, and those psychiatrists can play an important role in managing sleep disturbances. The ISI predicted the AMS scores in increasing order. If insomniac aging males visit clinics, we should evaluate the possibility of andropause and consider a referral to urological departments for further investigation. If younger insomniac patients have prominent AMS, both physical and psychological problems should be considered.

In addition, the present study was initially illuminated by a representative survey in France [8], which indicated that the AMS scale could be considered as a valid and simple HRQoL tool across various ages of males in general population. It inspires that Taiwanese AMS questionnaire might be used to explore both aging symptoms and the HRQoL beyond andropause state. One is trying to extend investigation to community dwelling subjects. Another is to research how sleep disturbance and interactions between insomnia and other aging symptoms may influence males' quality of life in the future.

Declaration of interest: The authors declare no conflicts of interest.

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