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TITLE PAGE

Title

Validity and reliability of the Patient Centered Assessment Method and association between alcohol consumption/alcohol use disorders and patient complexity in a primary care setting: a cross-sectional study

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ABSTRACT

Objectives The primary objective was to clarify the relationship between alcohol consumption/alcohol use disorders and patient complexity. The secondary objective was to examine the validity and reliability of the Patient Centered Assessment Method (PCAM) in a primary care setting.

Design Cross-sectional study.

Setting A clinic located on a remote island in Okinawa, Japan, providing general outpatient practices and round-the-clock emergency services.

Participants Patients living on the island and aged ≥20 years.

Main outcome measures Alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT) and patient complexity as scored by PCAM.

Results Exploratory factor analysis of PCAM scores newly revealed a two-factor structure—biomedical and psychosocial complexity—which differed from that of a previously reported study in a secondary care setting. Cronbach's alpha, an index of internal consistency, was 0.81. Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT score was a statistically significant predictor of PCAM score ($p=0.027$). Additionally, multiple regression analysis of biomedical and psychosocial complexity after the same adjustments showed that AUDIT score was also a statistically significant predictor of biomedical complexity ($p<0.001$) but was not a predictor of psychosocial complexity ($p=0.156$).

Conclusions PCAM is a valid and reliable tool in regard to assessment of patient complexity in a primary care setting. Patient complexity, which is assessed by PCAM, consists of two factors—biomedical and psychosocial complexity. Alcohol consumption

and alcohol use disorders are associated with patient complexity, specifically biomedical complexity, but not with psychosocial complexity. Physicians should not overlook hidden alcohol-related problems even in patients without psychosocial complexity.

Keywords

patient complexity, alcohol consumption, alcohol use disorders, the Patient Centered Assessment Method, the Alcohol Use Disorders Identification Test

Strengths and limitations of this study

- This is the first study to identify a relationship between alcohol consumption/alcohol use disorders as measured by AUDIT and patient complexity as scored by PCAM.
- This study examined the validity and reliability of PCAM in a primary care setting.
- The study's generalizability is limited, because it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous.
- It was a cross-sectional study and therefore a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred.
- Although consecutive sampling was used, some otherwise eligible participants were not enrolled, which may have resulted in selection bias.

INTRODUCTION

Alcohol use is one of the leading risk factors for global deaths and disease burden, accounting for 2.8 million deaths (2.2% and 6.8% of age-standardized deaths in women and men, respectively) and leads to 1.6% and 6.0% of disability-adjusted life-years (DALYs) in women and men, respectively.[1]

The use of alcohol has been identified as a causal factor for more than 200 diseases and injuries.[2] It causes not only physical conditions, including gastrointestinal diseases such as liver cirrhosis and pancreatitis and a wide variety of cancers, but also neuropsychiatric conditions, including alcohol use disorders, epilepsy, depression, and anxiety disorders.[3] Excessive alcohol intake impairs cognitive function.[4] The use of alcohol is also associated with both intentional injuries such as suicide and violence, and unintentional injuries.[3, 5, 6]

In addition to these harmful effects on the physical and mental health, alcohol drinking is related to adverse social consequences. Transgression of boundaries between normal and abnormal drinking, namely the harmful use of alcohol or alcohol dependence, gives rise to social problems such as family disruption, loss of earnings, and unemployment.[7] Moreover, those who have alcohol problems are likely to be subjected to social disapproval or be stigmatized by members of their community.[7, 8] Stigmatization reportedly leads to reduced accessibility to medical service and worse quality of medical care.[7, 9-12] Additionally, expenditure on alcohol consumption causes economic problems, especially when the individual concerned has a low income.[3, 13]

It is now increasingly accepted that these psychological and social factors contribute to deterioration in health; however, they have received little attention in the past. It has been newly proposed that the biopsychosocial model be substituted for the biomedical model, the latter having been preponderant in the mid-20th century but now

being recognized as limited by its understanding of patients exclusively from a biological point of view. As its name implies, the biopsychosocial model is a holistic model that incorporates biological, psychological, and social characteristics of patients' illnesses.[14] These characteristics are all included in what is termed "patient complexity."[15]

Some tools, such as INTERMED[16, 17] and the Minnesota Complexity Assessment Method (MCAM)[15], have been developed for assessing this patient complexity. Another of these tools, the Patient Centered Assessment Method (PCAM)[18] was designed mainly for use in primary care settings. PCAM assesses patient complexity from four perspectives: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[19] The first domain "Health and Well-being" is certainly subject to being influenced by alcohol consumption, because it contains a question regarding lifestyle behaviors related to drinking. Furthermore, as described above, alcohol consumption causes a wide variety of biological, psychological, and social problems. Therefore, it is expected to have pervasive influences not only on the first domain, but also the other domains: "Social Environment," "Health Literacy and Communication," and "Service Coordination."

Thus, it remains unclear how alcohol consumption influences patient complexity holistically and quantitatively. The primary objective of this study was to clarify the relationship between alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT)[20] and patient complexity as scored by PCAM, the rationale being that better understanding of this relationship could guide physicians on optimal provision of medical care to patients with alcohol-related problems or biopsychosocial complexity. The secondary objective was to examine the validity and reliability of PCAM in a primary care setting.

METHODS

Design

This was a cross-sectional study and reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[21]

Setting

This study was conducted on Tarama Island, a remote island in Okinawa, Japan. The island is located about 67 km from Miyako Island[22] (125 minutes by ferry[23] or 25 minutes by air[24]), which is the fourth largest island of Okinawa[25] and is located about 300 km from the main island of Okinawa[26] (55 minutes by air[24]). The island's population is 1194, 555 women and 639 men, the population density being 54.3/km^2.[27, 28] The percentage of the population aged 65 years and older is 26.4%, which is almost the same as the national average (26.6%).[29] Other than a dental clinic, the island has only one medical institution without beds, Tarama Clinic, Okinawa Miyako Hospital. This clinic has four staff members (a physician, a nurse, a nurse assistant, and a clerk) and provides general outpatient practices and round-the-clock emergency services.

Japan has a "free access system," which means that patients are allowed to visit any clinics or hospitals. However, most residents of the island are expected to choose Tarama Clinic because there are considerable geographical restrictions to attending other medical institutions. This particular condition enabled this study to be population-based, that is, it included almost all patients living in the region.

Participants

Patients who lived on the island and visited Tarama Clinic from April 1st, 2018 to June 30th, 2018 were included in this study. Patients who were aged less than 20 years, who refused to participate, or who lacked decision-making capacity were excluded, as

were patients, whose participation was judged by the principal investigator to have unfavorable influences on the patient–physician relationships. When the principal investigator was out of the office and so unable to seek informed consent, or when obtaining informed consent would have interfered with routine medical practice because there were too many patients in the waiting-room, otherwise eligible patients were not enrolled.

Outcome Measures

Data described below were collected from April 1st, 2018 to March 31st, 2019.

PCAM

PCAM is a tool for assessing patient complexity in terms of 12 items across four domains: "Health and Well-being" (four items), "Social Environment" (four items), "Health Literacy and Communication" (two items), and "Service Coordination" (two items). Each item is scored from one to four; thus, the lowest possible score is 12 and the highest possible score 48. Patient complexity becomes greater as the score increases. The validity and reliability of PCAM have been verified in a secondary care setting,[30] but remain unclear in a primary care setting. PCAM scores were determined in accordance with the user guide[31] by the principal investigator during patients' office visits.

AUDIT

AUDIT is a tool for screening for hazardous drinking, harmful drinking, and alcohol dependence in terms of 10 items across three domains: "Hazardous Alcohol Use" (three items), "Dependence Symptoms" (three items), and "Harmful Alcohol Use" (four items). Each item is scored from zero to four; or zero, two, or four. The lowest possible

score is zero and the highest possible score 40. Likelihood and severity of hazardous drinking, harmful drinking, and alcohol dependence become greater as the score increases. AUDIT scores were determined by filling in a self-administered questionnaire. A nurse supported patients to answer the questions, if needed or desired.

Other Explanatory Variables

Age, sex, and medical history were obtained from medical records and annual medical expenses during the previous year were calculated from medical fee receipts. Education ("<High school" or "≥High school"), occupation ("In work" or "Out of work"), physical activity ("Exercising" or "Not exercising"), smoking ("Current smoker," "Ex-smoker," or "Never smoker"), and number of family members living with the patient were obtained from a self-administered questionnaire. A nurse also assisted patients, if needed or desired. "In work" included full-time or part-time workers, and housewives or househusbands; "Out of work" included those without an occupation. "Exercising" was defined as engaging in physical activity for more than 30 minutes, twice a week, and for one year or more.

Statistical Analysis

Confirmatory factor analysis with maximum likelihood estimation was first performed. In accordance with previous study findings about the validity of PCAM, a two-factor structure, patient-oriented and medicine-oriented complexity, model was hypothesized.[30] Patient-oriented complexity included "Health and Well-being" items #2, #3, and #4; "Social Environment" items #2 and #3; and "Health Literacy and Communication" items #1 and #2. Medicine-oriented complexity included "Health and Well-being" item #1; "Social Environment" items #1 and #4; and "Service Coordination" items #1 and #2.

Where statistical testing found the model fit to be poor, exploratory factor analysis with iterated principal factor method and promax rotation was used to examine the construct validity of PCAM. The cutoff values of eigenvalue 1.0 and factor loading 0.4 were adopted to determine how many factors and which items should be included.

Additionally, Cronbach's alpha was calculated as an index of internal consistency to examine the reliability of PCAM.

Spearman's rank-correlation coefficient was employed to evaluate the association between PCAM and AUDIT scores. Furthermore, multiple regression analysis was also employed to adjust for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient.

All of these statistical analyses were performed using STATA/MP Ver.15.1 and p-values less than 0.05 were considered to denote statistical significance.

Patient and public involvement

This study was conducted without patient involvement.

RESULTS

During the three months study period, 521 patients visited Tarama Clinic, of whom 355 were included. The characteristics of study participants are shown in table 1. Of the 166 patients who were excluded, 13 did not live on the island, 57 were aged less than 20 years, 28 refused to participate, 25 lacked decision-making capacity, the participation of nine was judged to have unfavorable influences on the patient–physician relationships, and informed consent was not obtained from two because the principal investigator was out of the office and from another 32 because there were too many patients in the waiting-room.

Table 1. Characteristics of study participants

Age, mean (SD), years	66.4 (13.6)
By age group, No. (%)	
<35 years	6 (1.7)
35 to <45 years	19 (5.4)
45 to <55 years	42 (11.8)
55 to <65 years	86 (24.2)
65 to <75 years	85 (23.9)
≥75 years	117 (33.0)
Sex, No. (%)	
Women	163 (45.9)
Men	192 (54.1)
Education, No. (%)	
<High school	187 (52.7)
≥High school	168 (47.3)
Occupation, No. (%)	
In work	307 (86.5)
Out of work	48 (13.5)
Physical activity, No. (%)	
Exercising	53 (14.9)
Not exercising	302 (85.1)
Smoking, No. (%)	
Current smoker	50 (14.1)

Ex-smoker	118 (33.2)
Never smoker	187 (52.7)
Annual medical expenses, No. (%)	
<100,000 yen	194 (54.6)
100,000 to <200,000 yen	108 (30.4)
200,000 to <300,000 yen	31 (8.7)
≥300,000 yen	22 (6.2)
Number of family members living with the patient, No. (%)	
0	66 (18.6)
1	165 (46.5)
2	73 (20.6)
3	29 (8.2)
4	8 (2.3)
≥5	14 (3.9)

SD, standard deviation.

PCAM and AUDIT scores were distributed as shown in figure 1. The mean ± SD of PCAM and AUDIT scores were 21.4 ± 5.7 and 7.0 ± 7.5, respectively. Spearman's rank-correlation coefficient between PCAM and AUDIT scores was 0.08.

The fit indices of confirmatory factor analysis were chi-squared (χ^2) 580.9, standardized root mean square residual (SRMR) 0.14, comparative fit index (CFI) 0.63, and root mean square error of approximation (RMSEA) 0.17. Because the data did not

fit sufficiently, exploratory factor analysis was performed to evaluate the factor structure.

Exploratory factor analysis of PCAM scores newly revealed a two-factor structure, which differed from that of a previously reported study in a secondary care setting (table 2). First, a factor comprising four items was extracted: "Health and Well-being" items #1 and #3 and "Health Literacy and Communication" items #1 and #2. This extracted factor was labeled "biomedical complexity" because it concerns biomedical issues such as physical health needs, lifestyle behaviors, and understanding of and engagement in mainly physical health needs. Second, another factor comprising six items was extracted: "Health and Well-being" item #2; "Social Environment" items #1, #2, and #3; and "Service Coordination" items #1 and #2. This extracted factor was labeled "psychosocial complexity" because it concerns psychosocial issues such as mental well-being, home environment, daily activities, social networks, and service coordination. Additionally, "Health and Well-being" item #4 and "Social Environment" item #4 were found to be unique factors and not included these two common factors.

Table 2. Exploratory factor analysis of the Patient Centered Assessment Method (PCAM) scores

PCAM	First factor	Second factor
Health and Well-being		
1	0.6595	−0.0192
2	0.0922	0.5704
3	0.8727	−0.1606
4	0.1404	0.3652

Social Environment			
	1	−0.1158	0.5003
	2	−0.0574	0.5581
	3	−0.2734	0.6898
	4	0.0967	0.3288
Health Literacy and Communication			
	1	0.8295	0.0555
	2	0.4826	0.3404
Service Coordination			
	1	0.2248	0.5368
	2	0.2086	0.4827

Underlining indicates included items.

Cronbach's alpha, an index of internal consistency, was 0.81.

Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT score was a statistically significant predictor of PCAM score (p=0.027) (table 3). Among explanatory variables, the variance inflation factors ranged from 1.03 to 2.08.

Table 3. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) scores

	Coefficient	95% CI	P-value
AUDIT score	0.113	0.013 to 0.212	0.027
Age	−0.007	−0.062 to 0.049	0.813
Male	0.383	−1.013 to 1.778	0.590
<High school	1.296	0.039 to 2.553	0.043
Out of work	3.843	2.187 to 5.500	<0.001
Not exercising	1.882	0.398 to 3.366	0.013
Current smoker	3.436	1.819 to 5.054	<0.001
Annual medical expenses ($\times 10^4$ yen)	0.162	0.109 to 0.214	<0.001
Number of family members living with the patient	−0.508	−0.915 to −0.101	0.015

CI, confidence interval; the Alcohol Use Disorders Identification Test, AUDIT.

Multiple regression analysis of biomedical and psychosocial complexity after the same adjustments showed that AUDIT score was also a statistically significant predictor of biomedical complexity ($p<0.001$) but was not a predictor of psychosocial complexity ($p=0.156$) (table 4).

Table 4. Multiple regression analysis of biomedical and psychosocial complexity

Biomedical complexity

	Coefficient	95% CI	P-value

AUDIT score	0.137	0.086 to 0.187	<0.001
Age	0.001	−0.027 to 0.029	0.925
Male	0.380	−0.327 to 1.087	0.291
<High school	0.685	0.048 to 1.321	0.035
Out of work	0.878	0.040 to 1.717	0.040
Not exercising	0.783	0.032 to 1.534	0.041
Current smoker	2.199	1.380 to 3.018	<0.001
Annual medical expenses ($\times 10^4$ yen)	0.079	0.052 to 0.105	<0.001
Number of family members living with the patient	−0.056	−0.262 to 0.150	0.592

Psychosocial complexity

	Coefficient	95% CI	P-value
AUDIT score	−0.043	−0.102 to 0.016	0.156
Age	−0.005	−0.037 to 0.028	0.777
Male	0.243	−0.581 to 1.068	0.562
<High school	0.554	−0.189 to 1.297	0.144
Out of work	2.715	1.736 to 3.694	<0.001
Not exercising	1.022	0.145 to 1.900	0.022
Current smoker	0.852	−0.104 to 1.809	0.080
Annual medical expenses ($\times 10^4$ yen)	0.073	0.042 to 0.104	<0.001
Number of family members living with the patient	−0.388	−0.629 to −0.147	0.002

CI, confidence interval; the Alcohol Use Disorders Identification Test, AUDIT.

DISCUSSION

PCAM was a valid and reliable tool for assessing patient complexity in a primary care setting. Additionally, alcohol consumption and alcohol use disorders were associated with patient complexity, specifically biomedical complexity, but not with psychosocial complexity.

First, PCAM was a valid and reliable tool for assessing patient complexity in a primary care setting. The distribution of PCAM scores was found to be skewed to the right, that is, inclined to be low, whereas a previous study had shown a widespread distribution and higher mean ± SD of PCAM scores at 25.0 ± 7.3.[30] This discrepancy is likely attributable to differences in clinical settings. The previous study was conducted in a secondary care setting and the participants were inpatients of a hospital, in which patients were presumed to be biomedically and psychosocially more complex than those in a primary care setting. Similarly, that confirmatory factor analysis, statistical testing of a two-factor structure (patient-oriented and medicine-oriented complexity), revealed a poor fit is presumably due to the differences in clinical settings, together with disparities in residential areas, given that interlinking mechanisms cascade from social–structural conditions down to biomedical and psychological problems.[32]

In contrast, exploratory factor analysis identified another new two-factor structure, comprising biomedical and psychosocial complexity. This provides strong support for the construct validity of PCAM in light of the fact that PCAM was developed for assessing patient complexity from a biopsychosocial perspective in a primary care setting.[18]

Cronbach's alpha exceeded the threshold level of α=0.7 to 0.8,[33] which indicates the reliability of PCAM. This finding is consistent with that of previous research.[30]

Of the 12 items of PCAM, "Health and Well-being" item #4 and "Social Environment" item #4 were included in neither biomedical nor psychosocial complexity, whereas the remaining 10 items belonged to the two identified factors. The factor loadings of the two excluded items for psychosocial complexity were, however, 0.3652 and 0.3288; the fact that they were both more than 0.3 indicates that they had a tendency to belong to psychosocial complexity. This is an unsurprising and consistent finding, given that "Health and Well-being" item #4 concerns mental well-being and "Social Environment" item #4 concerns financial resources.[19]

Second, alcohol consumption and alcohol use disorders were associated with patient complexity, specifically biomedical complexity, but not with psychosocial complexity. Although Spearman's rank-correlation coefficient between PCAM and AUDIT scores was relatively low, that is, PCAM scores correlated poorly with AUDIT, AUDIT scores were found to be associated with PCAM scores. Additionally, all of the variance inflation factors were less than 4.0 and high multicollinearity was not detected. Much previous research has examined and clarified the relationship between alcohol consumption and different individual physical and psychological conditions and social circumstance.[3-13] However, this is the first study to provide a holistic perspective on the detrimental impact of alcohol consumption and alcohol use disorders on patient complexity.

With regard to factors extracted by exploratory factor analysis, AUDIT scores were demonstrated to be associated with biomedical complexity, which is consistent with past findings of alcohol causing physical harm.[3, 5, 6] Conversely, a relationship between alcohol consumption/alcohol use disorders and psychosocial complexity was not established in this study. Considering the fact that drinking alcohol plays roles in

creating and maintaining social identity and relationships,[34-38] these roles presumably offset the well-known negative effect of alcohol on psychosocial complexity.[3, 7-13] These opposite and conflicting influences of alcohol make it much more difficult for physicians to motivate patients to reduce alcohol intake or practice abstinence.

Thus, physicians should scrutinize whole patient complexity carefully when they encounter a patient with alcohol-related problems. Certainly, physicians are, in general, well trained to obtain a history of alcohol intake when managing a patient who has either biomedical or psychosocial problems. However, they also need to consider possible hidden alcoholic problems even in patients who do not have psychosocial complexity.

This study had several limitations. First, it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous. Both alcohol intake and patient complexity of participants could have been affected by these factors in a biased direction; thus, the association between them may have been under- or over-estimated. This limits generalizability of the present findings. Second, this was a cross-sectional study; thus, a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred. Finally, some otherwise eligible participants were not enrolled, although consecutive sampling was used. This failure in sampling could have led to selection bias. The main reason for judging a patient's participation as likely to unfavorably impact the patient–physician relationship was that they had confirmed or suspected mental or personality disorders. These disorders are inclined to cause biopsychosocial problems (i.e., high patient complexity). Thus, their exclusion could have resulted in underestimation of patient complexity. Most patients from whom informed consent was not obtained because the principal investigator was absent or there were too many patients waiting for a consultation made only a single visit to the clinic (for

mild acute diseases, such as upper respiratory inflammation or gastroenteritis) during the registration period. Exclusion of these low complexity, or otherwise-healthy, patients would obviously have resulted in overestimation of patient complexity.

FUTURE RESEARCH

The development of a Japanese version of PCAM and the examination of its validity and reliability in a primary care setting are planned to promote dissemination of the concept of patient complexity in Japan.

CONCLUSION

PCAM is a valid and reliable tool in regard to assessment of patient complexity in a primary care setting. Patient complexity, which is assessed by PCAM, consists of two factors—biomedical and psychosocial complexity. Alcohol consumption and alcohol use disorders are associated with patient complexity, specifically biomedical complexity, but not with psychosocial complexity. Physicians should not overlook hidden alcohol-related problems even in patients without psychosocial complexity.

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Contributors

YS designed the study; collected, analyzed, and interpreted the data; and prepared and reviewed the manuscript. MM contributed to design of the study, analysis and

interpretation of the data, and review of the manuscript. HY contributed to design of the study and review of the manuscript.

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Disclaimer

The sponsor of this study had no role in the study design; the study conduct: collection, analysis, or interpretation of the data; the manuscript preparation; or the decision to submit the manuscript for publication.

Competing interests

YS and HY are former trainees of the Jikei Clinical Research Program for Primary-care. MM is a program director for the Jikei Clinical Research Program of Primary-care.

Ethics approval

This study was approved by the Ethics Committee of Okinawa Miyako Hospital (approved on February 8th, 2018).

Data sharing statement

No additional data are available.

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prefectures, all gun of prefectures, shi*, ku*, machi*, mura* and municipalities in 2000. https://www.e-stat.go.jp/en/stat-search/file-download?statInfId=000031473213&fileKind=1 (accessed 9 Aug 2019) [In Japanese].

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Figure 1. Distribution of PCAM and AUDIT scores

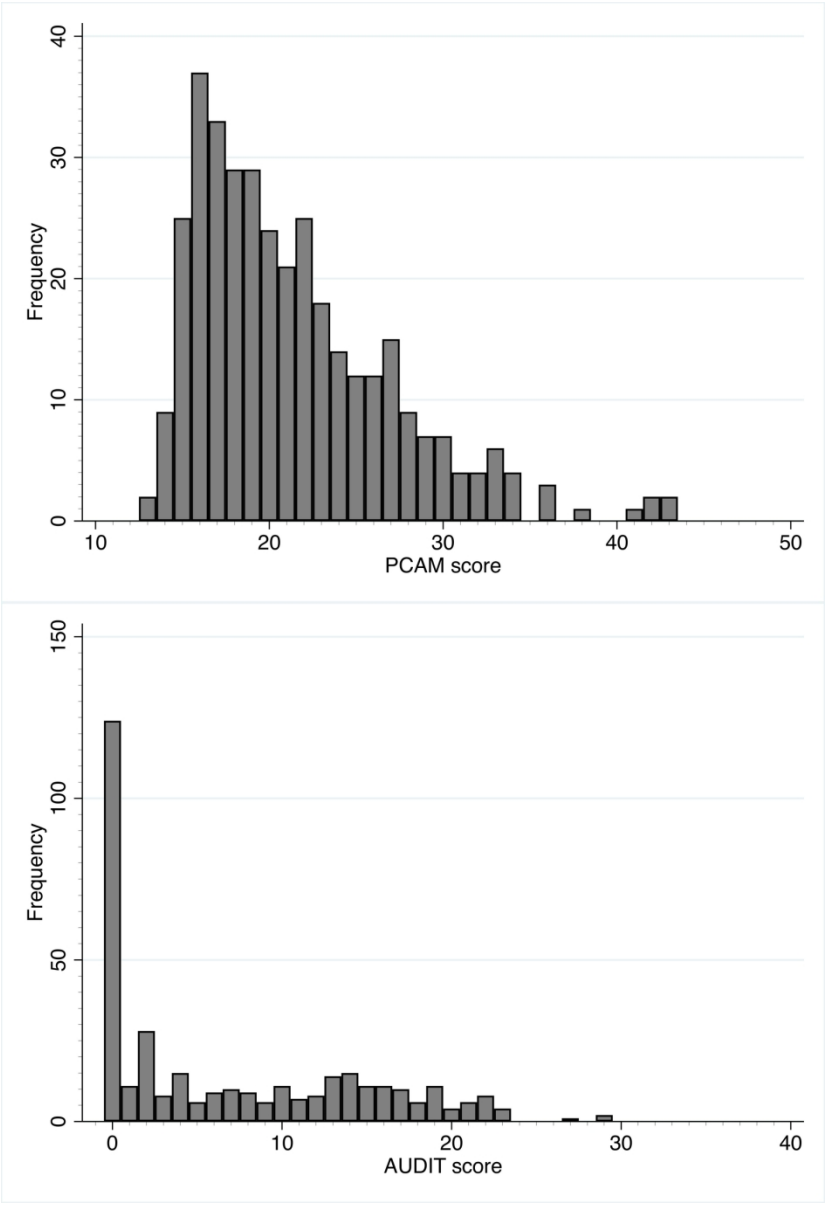

Figure 1. Distribution of PCAM and AUDIT scores

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1, 3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	5, 6
Objectives	#3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	#4	Present key elements of study design early in the paper	7
Setting	#5	Describe the setting, locations, and relevant dates, including periods of	7

		recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7, 8
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	8, 9
Bias	#9	Describe any efforts to address potential sources of bias	n/a
Study size	#10	Explain how the study size was arrived at	n/a
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	8, 9, 11
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	9, 10
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
Statistical methods	#12c	Explain how missing data were addressed	n/a
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	n/a
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	10
Participants	#13b	Give reasons for non-participation at each stage	10
Participants	#13c	Consider use of a flow diagram	n/a

Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	10, 11, 12
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	12
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	14, 15, 16
Main results	#16b	Report category boundaries when continuous variables were categorized	n/a
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	#18	Summarise key results with reference to study objectives	17
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	19
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	19
Generalisability	#21	Discuss the generalisability (external validity) of the study results	19
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20, 21

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Validity and reliability of the Patient Centered Assessment Method and association between alcohol consumption/alcohol use disorders and patient complexity in a primary care setting: a cross-sectional study

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TITLE PAGE

Title

Validity and reliability of the Patient Centered Assessment Method and association between alcohol consumption/alcohol use disorders and patient complexity in a primary care setting: a cross-sectional study

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ABSTRACT

Objectives The primary objective was to clarify the relationship between alcohol consumption/alcohol use disorders and patient complexity. The secondary objective was to examine the validity and reliability of the Patient Centered Assessment Method (PCAM) in a primary care setting.

Design Cross-sectional study.

Setting A clinic located on a remote island in Okinawa, Japan, providing general outpatient practices and round-the-clock emergency services.

Participants Patients who lived on the island, visited Tarama Clinic from April 1st, 2018 to June 30th, 2018, were aged ≥20 years, and had decision-making capacity were judged to be eligible for this study.

Main outcome measures Alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT) and patient complexity as scored by PCAM.

Results During the three-month study period, 355 patients (163 women and 192 men) with mean (standard deviation) age of 66.4 (13.6) years were included. Exploratory factor analysis of PCAM scores newly revealed a two-factor structure—biomedical and psychosocial complexity—which differed from that of a previously reported study in a secondary care setting. McDonald's omega was 0.84. Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT scores classified as "Dependence likely" were associated with PCAM scores (p-value=0.040).

Conclusions PCAM is a valid and reliable tool in regard to assessment of patient complexity in a primary care setting. Alcohol consumption and alcohol use disorders classified as "Dependence likely" are associated with patient complexity.

Keywords

patient complexity, alcohol consumption, alcohol use disorders, the Patient Centered Assessment Method, the Alcohol Use Disorders Identification Test

Strengths and limitations of this study

- This is the first study to identify a relationship between alcohol consumption/alcohol use disorders as measured by AUDIT and patient complexity as scored by PCAM.
- This study examined the validity and reliability of PCAM in a primary care setting.
- The study's generalizability is limited, because it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous.
- It was a cross-sectional study and therefore a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred.
- Although consecutive sampling was used, some otherwise eligible patients were not enrolled, which may have resulted in selection bias.

INTRODUCTION

Alcohol use is one of the leading risk factors for global deaths and disease burden, accounting for 2.8 million deaths (2.2% and 6.8% of age-standardized deaths in women and men, respectively) and leads to 1.6% and 6.0% of disability-adjusted life-years (DALYs) in women and men, respectively.[1]

The use of alcohol has been identified as a causal factor for more than 200 diseases and injuries.[2] It causes not only physical conditions, including gastrointestinal diseases such as liver cirrhosis and pancreatitis and a wide variety of cancers, but also neuropsychiatric conditions, including alcohol use disorders, epilepsy, depression, and anxiety disorders.[3] Excessive alcohol intake impairs cognitive function.[4] The use of alcohol is also associated with both intentional injuries such as suicide and violence, and unintentional injuries.[3, 5, 6]

In addition to these harmful effects on the physical and mental health, alcohol drinking is related to adverse social consequences. Transgression of boundaries between normal and abnormal drinking, namely the harmful use of alcohol or alcohol dependence, gives rise to social problems such as family disruption, loss of earnings, and unemployment.[7] Moreover, those who have alcohol problems are likely to be subjected to social disapproval or be stigmatized by members of their community.[7, 8] Stigmatization reportedly leads to reduced accessibility to medical service and worse quality of medical care.[7, 9-12] Additionally, expenditure on alcohol consumption causes economic problems, especially when the individual concerned has a low income.[3, 13]

It is now increasingly accepted that these psychological and social factors contribute to deterioration in health; however, they have received little attention in the past. It has been newly proposed that the biopsychosocial model be substituted for the biomedical model, the latter having been preponderant in the mid-20th century but now

being recognized as limited by its understanding of patients exclusively from a biological point of view.[14] As its name implies, the biopsychosocial model is a holistic model that incorporates biological, psychological, and social characteristics of patients' illnesses.[14] These characteristics are all included in what is termed patient complexity, which is defined as "the person-specific factors that interfere with the delivery of usual care and decision-making for whatever conditions the patient has".[15] Although medical professionals often become frustrated in the face of such factors due to the lack of clear ideas of how the patient is complex and what to do about it, the concept of patient complexity provides them with a common vocabulary and method to identify and act in systematic and comfortable way.[15]

Some tools, such as INTERMED[16, 17] and the Minnesota Complexity Assessment Method (MCAM)[15], have been developed for assessing this patient complexity. Another of these tools, the Patient Centered Assessment Method (PCAM)[18] was designed mainly for use in primary care settings. PCAM assesses patient complexity from four perspectives: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[19] The first domain "Health and Well-being" is certainly subject to being influenced by alcohol consumption, because it contains a question regarding lifestyle behaviors related to drinking.[19] Furthermore, as described above, alcohol consumption causes a wide variety of biological, psychological, and social problems. Therefore, it is expected to have pervasive influences not only on the first domain, but also the other domains: "Social Environment," "Health Literacy and Communication," and "Service Coordination."

Thus, it remains unclear how alcohol consumption influences patient complexity holistically and quantitatively. The primary objective of this study was to clarify the relationship between alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT)[20] and patient complexity as scored

by PCAM, the rationale being that better understanding of this relationship could guide physicians on optimal provision of medical care to patients with alcohol-related problems or biopsychosocial complexity. The secondary objective was to examine the validity and reliability of PCAM in a primary care setting.

METHODS

Design

This was a cross-sectional study and reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[21]

Setting

This study was conducted on Tarama Island, a remote island in Okinawa, Japan. The island is located about 67 km from Miyako Island[22] (125 minutes by ferry[23] or 25 minutes by air[24]), which is the fourth largest island of Okinawa[25] and is located about 300 km from the main island of Okinawa[26] (55 minutes by air[24]). The island's population is 1194, 555 women and 639 men, the population density being 54.3/km^2.[27, 28] The percentage of the population aged 65 years and older is 26.4%, which is almost the same as the national average (26.6%).[29] Other than a dental clinic, the island has only one medical institution without beds, Tarama Clinic, Okinawa Miyako Hospital. This clinic has four staff members (a physician, a nurse, a nurse assistant, and a clerk) and provides general outpatient practices and round-the-clock emergency services.

Japan has a "free access system," which means that patients are allowed to visit any clinics or hospitals. However, most residents of the island are expected to choose Tarama Clinic because there are considerable geographical restrictions to attending

other medical institutions. This particular condition enabled this study to be population-based, that is, it included almost all patients living in the region.

Participants

Patients who lived on the island and visited Tarama Clinic from April 1st, 2018 to June 30th, 2018 were consecutively included in this study. Patients who were aged less than 20 years or who lacked decision-making capacity were excluded. Those who met these conditions were judged to be eligible for this study. Otherwise eligible patients who refused to participate were excluded, as were patients, whose participation was judged by the principal investigator to have unfavorable influences on the patient–physician relationships. When the principal investigator was out of the office and so unable to seek informed consent, or when obtaining informed consent would have interfered with routine medical practice because there were too many patients in the waiting-room, otherwise eligible patients were not enrolled.

After the principal investigator had fully informed the patients of the content of this study, those who agreed to participate provided written consent.

Outcome measures

Data described below were collected from April 1st, 2018 to March 31st, 2019.

PCAM

PCAM is a tool for assessing patient complexity across four domains: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[19] Each domain has two or four areas of inquiry: "Health and Well-being" inquires about items #1 "Physical health needs," #2 "Physical health impacting on mental well-being," #3 "Lifestyle impacting on physical or mental well-being," and #4

"Other mental well-being concerns"; "Social Environment" about items #1 "Home environment," #2 "Daily activities," #3 "Social networks," and #4 "Financial resources"; "Health Literacy and Communication" about items #1 "Health literacy" and #2 "Engagement in discussion"; and "Service Coordination" about items #1 "Other services" and #2 "Service coordination."[30] Each of the twelve items has four defined levels of complexity, which are labeled as "Routine care," "Active monitoring," "Plan action," and "Act now" in order of increasing complexity.[19] Each item is also scored from one to four; thus, the lowest possible score of PCAM is 12 and the highest possible score 48.[19] Patient complexity becomes greater as the score increases. The validity and reliability of PCAM have been verified in a secondary care setting,[31] but remain unclear in a primary care setting. PCAM scores were determined during patients' office visits by a single physician, the principal investigator, in accordance with the user guide,[30] which eliminated any inter-rater variability.

AUDIT

AUDIT is a tool for screening for hazardous drinking, harmful drinking, and alcohol dependence in terms of 10 items across three domains: "Hazardous Alcohol Use" (three items), "Dependence Symptoms" (three items), and "Harmful Alcohol Use" (four items).[20] Each item is scored from zero to four; or zero, two, or four. The lowest possible score of AUDIT is zero and the highest possible score 40.[20] Likelihood and severity of hazardous drinking, harmful drinking, and alcohol dependence become greater as the score increases. AUDIT scores were determined by filling in a self-administered questionnaire. A nurse supported patients to answer the questions, if needed or desired. As for multiple regression analyses, AUDIT scores were divided into the following categories based on four levels of risk in accordance with the guidelines:

"Low risk" being designated for AUDIT scores from 0 to 7; "Medium risk" 8 to 15; "High risk" 16 to 19; and "Dependence likely" 20 to 40.[20]

Other explanatory variables

Age and sex were obtained from medical records and annual medical expenses during the previous year were calculated from medical fee receipts. Education ("<High school" or "≥High school"), occupation ("In work" or "Out of work"), physical activity ("Exercising" or "Not exercising"), smoking ("Current smoker," "Ex-smoker," or "Never smoker"), and number of family members living with the patient were obtained from a self-administered questionnaire. A nurse also assisted patients, if needed or desired. "In work" included full-time or part-time workers, and housewives or househusbands; "Out of work" included those without an occupation. "Exercising" was defined as engaging in physical activity for more than 30 minutes, twice a week, and for one year or more.

Sample size

To the best of our knowledge, there have been no published studies on the association between alcohol consumption/alcohol use disorders and patient complexity, which made it difficult to determine the meaningful effect size to calculate the required sample size. The sample size was therefore estimated by factor analysis. A wide range of sample sizes are recommended in factor analysis, these usually being described as either the sample size or the ratio of a sample size to number of variables. A sample size of 300 is considered good.[32] In contrast, a larger ratio of sample size to the number of variables such as 20:1 is reportedly better.[33] This resulted in calculation of a sample size of 240 for 12 PCAM items. Of these two possibilities, 300 was adopted as an adequate required sample size.

Statistical Analysis

Confirmatory factor analysis with weighted least square mean and variance adjusted (WLSMV) estimation was first performed. In accordance with previous study findings about the validity of PCAM, a two-factor structure, patient-oriented and medicine-oriented complexity, model was hypothesized.[31] Patient-oriented complexity included "Health and Well-being" items #2, #3, and #4; “Social Environment” items #2 and #3; and “Health Literacy and Communication” items #1 and #2. Medicine-oriented complexity included "Health and Well-being" item #1; “Social Environment” items #1 and #4; and “Service Coordination” items #1 and #2.

Where statistical testing found the model fit to be poor, exploratory factor analysis with WLSMV estimation and promax rotation was used to examine the construct validity of PCAM. A scree plot and cut off value for factor loading of 0.4 were adopted to determine how many factors and which items should be included.

Confirmatory factor analysis with WLSMV estimation was performed again, hypothesizing the model revealed by exploratory factor analysis, to verify the model fit. Factors were assumed to be correlated (oblique) or uncorrelated (orthogonal) with each other. The results were also compared with those of confirmatory factor analysis that hypothesized a one-factor structure model and a four-factor structure, consistent with the four domains of PCAM, model. Two of the four factors in the four-factor structure model each had two items. A factor with fewer than three items is reportedly weak and unstable.[33] Therefore, this analysis was performed for reference only.

Additionally, McDonald’s omega was calculated as an index of internal consistency to examine the reliability of PCAM.

Spearman’s rank-correlation coefficient was employed to evaluate the association between PCAM and AUDIT scores. Furthermore, multiple regression analysis was also

employed to adjust for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient.

Confirmatory and exploratory factor analyses were performed using Mplus version 8.4;[34] McDonald's omega was calculated using R version 3.6.0;[35] and Spearman's rank-correlation coefficient was calculated and multiple regression analyses were performed using Stata/MP version 15.1.[36] P-values less than 0.05 were considered to denote statistical significance.

Patient and public involvement

This study was conducted without patient or public involvement.

RESULTS

During the three-month study period, 521 patients who visited Tarama Clinic were consecutively included. Of these patients, 95 did not meet the eligibility criteria: 13 did not live on the island, 57 were aged less than 20 years, and 25 lacked decision-making capacity. This left 426 eligible patients, 71 of whom were excluded: 28 refused to participate, the participation of nine was judged to have unfavorable influences on the patient–physician relationships, and informed consent was not obtained from two because the principal investigator was out of the office and from another 32 because there were too many patients in the waiting-room. The main reason for judging a patient's participation as likely to unfavorably impact the patient–physician relationship was that they had confirmed or suspected mental or personality disorders, the concern being that information about the study and invitation to participate might be experienced as a psychological burden and lead to interruption of their regular visits. Thus, 355 patients, 83.3% of eligible patients, were finally included (figure 1). The

characteristics of the 355 study participants are shown in table 1. There were no missing values among outcome measures and other explanatory variables for the study participants.

Table 1. Characteristics of the 355 study participants

Age, mean (SD), years	66.4 (13.6)
By age group, No. (%)	
<35 years	6 (1.7)
35 to <45 years	19 (5.4)
45 to <55 years	42 (11.8)
55 to <65 years	86 (24.2)
65 to <75 years	85 (23.9)
≥75 years	117 (33.0)
Sex, No. (%)	
Women	163 (45.9)
Men	192 (54.1)
Education, No. (%)	
<High school	187 (52.7)
≥High school	168 (47.3)
Occupation, No. (%)	
In work	307 (86.5)
Out of work	48 (13.5)
Physical activity, No. (%)	
Exercising	53 (14.9)
Not exercising	302 (85.1)
Smoking, No. (%)	
Current smoker	50 (14.1)
Ex-smoker	118 (33.2)
Never smoker	187 (52.7)
Annual medical expenses, No. (%)	
<100,000 yen	194 (54.6)
100,000 to <200,000 yen	108 (30.4)
200,000 to <300,000 yen	31 (8.7)
≥300,000 yen	22 (6.2)
Number of family members living with the patient, No. (%)	
0	66 (18.6)
1	165 (46.5)
2	73 (20.6)
3	29 (8.2)
4	8 (2.3)
≥5	14 (3.9)

SD, standard deviation.

PCAM and AUDIT scores were distributed as shown in figure 2. The mean (SD, standard deviation) of PCAM and AUDIT scores were 21.4 (5.7) and 7.0 (7.5), respectively.

The fit indices of confirmatory factor analysis were chi-squared (χ^2) 662.3, root mean square error of approximation (RMSEA) 0.18, comparative fit index (CFI) 0.83, and standardized root mean square residual (SRMR) 0.14 (table 2). Because the data did not fit sufficiently, exploratory factor analysis was performed to evaluate the factor structure.

Table 2. Fit indices of confirmatory factor analysis

	χ^2	RMSEA	CFI	SRMR
Two-factor structure model revealed by a previous study[31]	662.3	0.18	0.83	0.14
Two-factor structure model revealed by this study (oblique)	333.3	0.12	0.92	0.10
Two-factor structure model revealed by this study (orthogonal)	742.7	0.19	0.81	0.18
One-factor structure model	701.0	0.18	0.82	0.14
Four-factor structure model	397.7	0.14	0.90	0.11

A four-factor structure is consistent with the four domains of the Patient Centered Assessment Method (PCAM).

χ^2, chi-squared; RMSEA, root mean square error of approximation; CFI, comparative fit index; SRMR, standardized root mean square residual.

Exploratory factor analysis of PCAM scores newly revealed a two-factor structure, which differed from that of a previously reported study in a secondary care setting (table 3). First, a factor comprising four items was extracted: "Health and Well-being" items #1 and #3 and “Health Literacy and Communication” items #1 and #2. This extracted factor was labeled "biomedical complexity" because it concerns biomedical issues such as physical health needs, lifestyle behaviors, and understanding of and engagement in mainly physical health needs. Second, another factor comprising eight items was extracted: "Health and Well-being" items #2 and #4; "Social Environment" items #1, #2, #3, and #4; and "Service Coordination" items #1 and #2. This extracted factor was labeled "psychosocial complexity" because it concerns psychosocial issues such as mental well-being, home environment, daily activities, social networks, financial resources and service coordination.

Table 3. Exploratory factor analysis of the Patient Centered Assessment Method (PCAM) scores

PCAM	First factor	Second factor
Health and Well-being		
1	0.701	−0.035
2	0.081	0.578
3	0.895	−0.136
4	0.190	0.442
Social Environment		
1	−0.122	0.630
2	−0.059	0.683
3	−0.266	0.715
4	0.256	0.452
Health Literacy and Communication		
1	0.894	0.117
2	0.621	0.358
Service Coordination		

1	0.109	0.806
2	0.137	0.835

Underlining indicates included items.

The fit indices of confirmatory factor analysis, which hypothesized two-factor structure models revealed by this study (oblique and orthogonal), a one-factor structure model, and a four-factor structure model, are shown in table 2. Of these four models, the two-factor structure model revealed by this study (oblique) showed the best fit.

McDonald's omega was 0.84.

Spearman's rank-correlation coefficient between PCAM and AUDIT scores was 0.08.

Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT scores classified as "Dependence likely" compared with those classified as "Low risk" were associated with PCAM scores (p-value=0.040), whereas those classified as "Medium risk" and "High risk" were not (p-values=0.215 and 0.187) (table 4). Moreover, the standardized regression coefficient of AUDIT scores classified as "Dependence likely" was 0.111, the 95% confidence interval (CI) of which overlapped with those of other variables (table 4). Among explanatory variables, the variance inflation factors ranged from 1.04 to 2.12.

Table 4. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) scores

	Regression	95% CI	P-value	Standardized	95% CI

		coefficient			regression coefficient	
AUDIT score						
	Low risk	Reference				
	Medium risk	1.050	−0.613 to 2.713	0.215	0.077	−0.045 to 0.199
	High risk	1.361	−0.666 to 3.387	0.187	0.074	−0.036 to 0.183
	Dependence likely	2.480	0.117 to 4.843	0.040	0.111	0.005 to 0.217
Age		−0.009	−0.065 to 0.047	0.746	−0.022	−0.155 to 0.111
Sex						
	Female	Reference				
	Male	0.615	−0.722 to 1.952	0.366	0.054	−0.063 to 0.170
Education						
	≥High school	Reference				
	<High school	1.320	0.056 to 2.584	0.041	0.115	0.005 to 0.226
Occupation						
	In work	Reference				
	Out of work	3.814	2.146 to 5.483	<0.001	0.228	0.128 to 0.328
Physical activity						
	Exercising	Reference				
	Not exercising	1.838	0.341 to 3.335	0.016	0.115	0.021 to 0.208
Smoking						
	Never smoker and ex-smoker	Reference				
	Current smoker	3.465	1.828 to 5.101	<0.001	0.211	0.111 to 0.310
Annual medical expenses ($\times 10^4$ yen)		0.160	0.107 to 0.212	<0.001	0.297	0.199 to 0.396
Number of family members living with the patient		−0.492	−0.902 to −0.082	0.019	−0.114	−0.209 to −0.019

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

Multiple regression analysis of biomedical and psychosocial complexity after the same adjustments showed that AUDIT scores classified as “Medium risk”, “High risk”, and “Dependence likely” compared with those classified as “Low risk” were also associated with biomedical complexity (all p-values<0.001), but not with psychosocial complexity (p-values=0.406, 0.405, and 0.986, respectively) (table 5).

Table 5. Multiple regression analysis of biomedical and psychosocial complexity

Biomedical complexity

		Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI
AUDIT score						
	Low risk	Reference				
	Medium risk	1.525	0.680 to 2.371	<0.001	0.215	0.096 to 0.334
	High risk	1.940	0.910 to 2.971	<0.001	0.201	0.094 to 0.308
	Dependence likely	2.494	1.292 to 3.696	<0.001	0.214	0.111 to 0.317
Age		−0.001	−0.029 to 0.028	0.958	−0.003	−0.133 to 0.126
Sex						
	Female	Reference				
	Male	0.617	−0.063 to 1.296	0.075	0.103	−0.011 to 0.217
Education						
	≥High school	Reference				
	<High school	0.696	0.053 to 1.338	0.034	0.117	0.009 to 0.224
Occupation						
	In work	Reference				

Out of work	0.864	0.015 to 1.712	0.046	0.099	0.002 to 0.196
Physical activity					
Exercising	Reference				
Not exercising	0.778	0.016 to 1.539	0.045	0.093	0.002 to 0.184
Smoking					
Never smoker and ex-smoker	Reference				
Current smoker	2.157	1.324 to 2.989	<0.001	0.252	0.155 to 0.349
Annual medical expenses (×10⁴ yen)	0.078	0.051 to 0.105	<0.001	0.279	0.182 to 0.375
Number of family members living with the patient	−0.047	−0.255 to 0.161	0.659	−0.021	−0.113 to 0.072

Psychosocial complexity

	Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI
AUDIT score					
Low risk	Reference				
Medium risk	−0.475	−1.599 to 0.648	0.406	−0.053	−0.178 to 0.072
High risk	−0.580	−1.949 to 0.789	0.405	−0.048	−0.160 to 0.065
Dependence likely	−0.014	−1.611 to 1.582	0.986	−0.001	−0.109 to 0.107
Age	−0.008	−0.046 to 0.029	0.659	−0.031	−0.167 to 0.106
Sex					
Female	Reference				
Male	−0.002	−0.905 to 0.901	0.997	−0.000	−0.120 to 0.119
Education					
≥High school	Reference				
<High school	0.624	−0.230 to 1.478	0.152	0.083	−0.030 to 0.196
Occupation					
In work	Reference				
Out of work	2.951	1.823 to 4.078	<0.001	0.268	0.165 to 0.370
Physical activity					
Exercising	Reference				
Not exercising	1.060	0.049 to 2.072	0.040	0.100	0.005 to 0.196
Smoking					
Never smoker and ex-smoker	Reference				
Current smoker	1.308	0.202 to 2.414	0.021	0.121	0.019 to 0.223
Annual medical expenses (×10⁴ yen)	0.082	0.046 to 0.117	<0.001	0.231	0.130 to 0.332
Number of family members living with the patient	−0.445	−0.722 to −0.168	0.002	−0.157	−0.254 to −0.059

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

DISCUSSION

PCAM was a valid and reliable tool for assessing patient complexity in a primary care setting. Additionally, alcohol consumption and alcohol use disorders classified as "Dependence likely" were associated with patient complexity.

First, PCAM was a valid and reliable tool for assessing patient complexity in a primary care setting. The distribution of PCAM scores was found to be skewed to the right, that is, inclined to be low, whereas a previous study had shown a widespread distribution and higher mean (SD) of PCAM scores at 25.0 (7.3).[31] This discrepancy is likely attributable to differences in clinical settings. The previous study was conducted in a secondary care setting and the participants were inpatients of a hospital, in which patients were presumed to be biomedically and psychosocially more complex than those

in a primary care setting. Similarly, that confirmatory factor analysis, statistical testing of a two-factor structure (patient-oriented and medicine-oriented complexity), revealed a poor fit is presumably due to the differences in clinical settings, together with disparities in residential areas, given that interlinking mechanisms cascade from social–structural conditions down to biomedical and psychological problems.[37]

Conversely, exploratory factor analysis identified another new two-factor structure, comprising biomedical and psychosocial complexity, which showed a better fit than the other hypothesized models. This provides strong support for the construct validity of PCAM in light of the fact that PCAM was developed for assessing patient complexity from a biopsychosocial perspective in a primary care setting.[18]

McDonald's omega exceeded the threshold level of 0.7 to 0.8, which indicates the reliability of PCAM. This finding is consistent with that of previous research.[31]

Second, alcohol consumption and alcohol use disorders classified as "Dependence likely" were associated with patient complexity. Although Spearman's rank-correlation coefficient between PCAM and AUDIT scores was relatively low, that is, PCAM scores correlated poorly with AUDIT, AUDIT scores classified as "Dependence likely" were found to be associated with PCAM scores. Additionally, we did not detect any significant differences in the strength of relationships with AUDIT scores between the variables because the 95% CIs of standardized regression coefficients overlapped. Much previous research has examined and clarified the relationship between alcohol consumption and different individual physical and psychological conditions and social circumstance.[3-13] However, this is the first study to provide a holistic perspective on the detrimental impact of alcohol consumption and alcohol use disorders on patient complexity.

With regard to factors extracted by exploratory factor analysis, AUDIT scores were demonstrated to be associated with biomedical complexity, which is consistent with past findings of alcohol causing physical harm.[3, 5, 6] Conversely, a relationship

between alcohol consumption/alcohol use disorders and psychosocial complexity was not established in this study. Considering the fact that drinking alcohol plays roles in creating and maintaining social identity and relationships,[38-42] these roles presumably offset the well-known negative effect of alcohol on psychosocial complexity.[3, 4, 7-13]

This study had several limitations. First, it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous. Both alcohol intake and patient complexity of participants could have been affected by these factors in a biased direction; thus, the association between them may have been under- or over-estimated. This limits generalizability of the present findings. Second, this was a cross-sectional study; thus, a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred. Third, PCAM scores were determined by a single physician, who was the only physician on the island. This eliminated any inter-rater variability; however, the inter-rater reliability was not evaluated. Finally, although consecutive sampling was used, some otherwise eligible patients were not enrolled: 83.3% of eligible patients were included. This failure in sampling could have led to selection bias. Especially, the main reason for judging a patient's participation as likely to unfavorably impact the patient–physician relationship was that they had confirmed or suspected mental or personality disorders. These disorders are inclined to cause biopsychosocial problems (i.e., high patient complexity). Thus, their exclusion could have resulted in underestimation of patient complexity. Most patients from whom informed consent was not obtained because the principal investigator was absent or there were too many patients waiting for a consultation made only a single visit to the clinic (for mild acute diseases, such as upper respiratory inflammation or gastroenteritis) during the registration period.

Exclusion of these low complexity, or otherwise-healthy, patients would obviously have resulted in overestimation of patient complexity.

FUTURE RESEARCH

The development of a Japanese version of PCAM and the examination of its validity and reliability in a primary care setting are planned to promote dissemination of the concept of patient complexity in Japan.

CONCLUSION

PCAM is a valid and reliable tool in regard to assessment of patient complexity in a primary care setting. Alcohol consumption and alcohol use disorders classified as "Dependence likely" are associated with patient complexity.

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Contributors

YS designed the study; collected, analyzed, and interpreted the data; and prepared and reviewed the manuscript. MM contributed to design of the study, analysis and interpretation of the data, and review of the manuscript. HY contributed to design of the study and review of the manuscript.

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Disclaimer

The sponsor of this study had no role in the study design; the study conduct: collection, analysis, or interpretation of the data; the manuscript preparation; or the decision to submit the manuscript for publication.

Competing interests

YS and HY are former trainees of the Jikei Clinical Research Program for Primary-care. MM is a program director for the Jikei Clinical Research Program of Primary-care.

Ethics approval

This study was approved by the Ethics Committee of Okinawa Miyako Hospital (approved on February 8th, 2018) and the Ethics Committee of The Jikei University School of Medicine (the acceptance number: 30-412 (9433)).

Data sharing statement

No additional data are available.

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Figure 1. A flow chart detailing the process of inclusion and exclusion of study participants

Figure 2. Distribution of PCAM and AUDIT scores

PCAM, the Patient Centered Assessment Method; AUDIT, the Alcohol Use Disorders Identification Test.

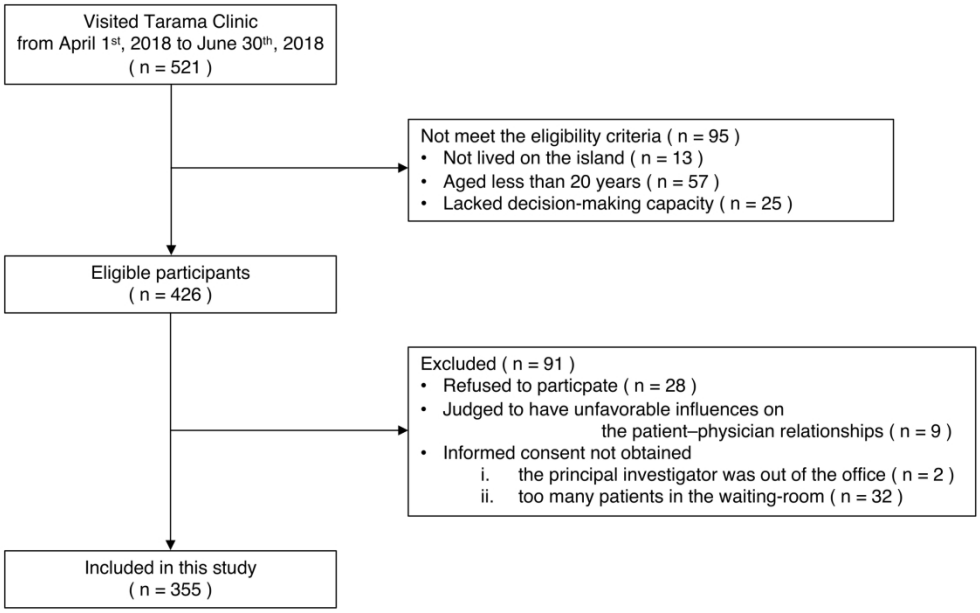

Figure 1. A flow chart detailing the process of inclusion and exclusion of study participants

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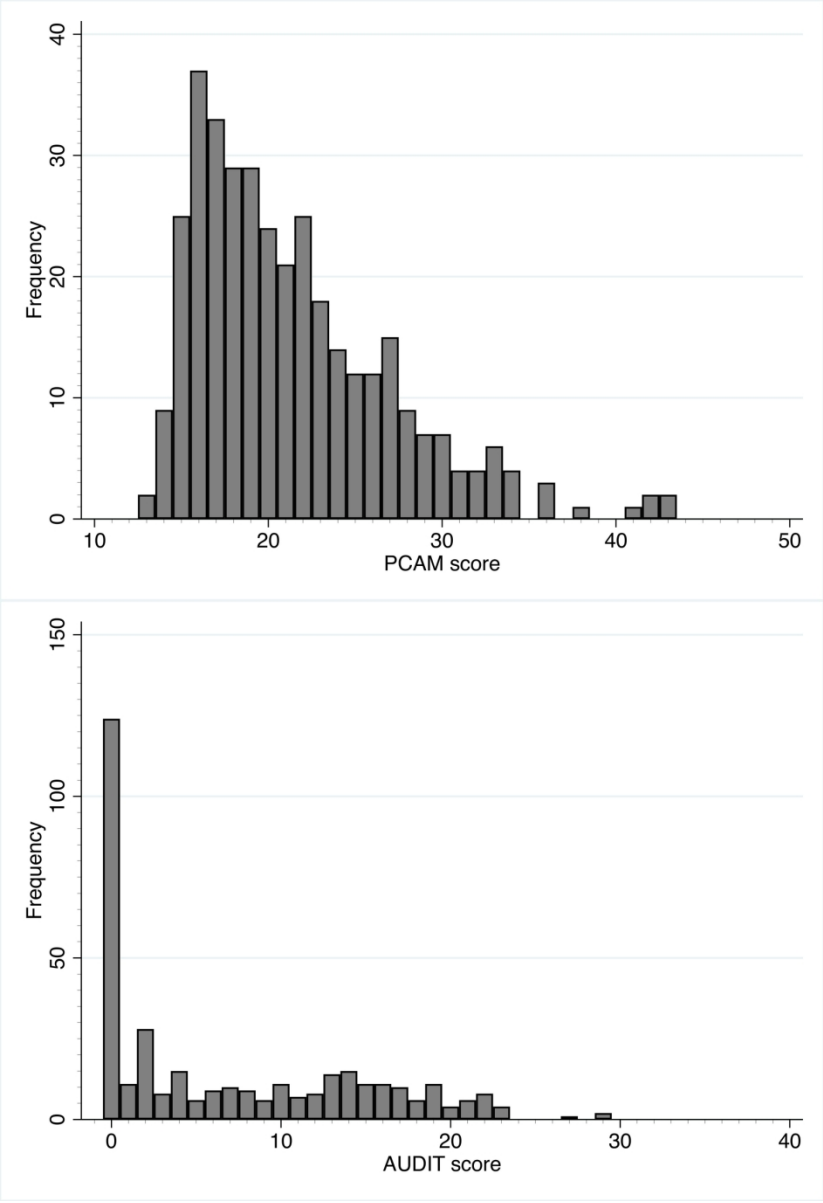

Figure 2. Distribution of PCAM and AUDIT scores
PCAM, the Patient Centered Assessment Method; AUDIT, the Alcohol Use Disorders Identification Test.

139x203mm (300 x 300 DPI)

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1, 3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	5, 6
Objectives	#3	State specific objectives, including any prespecified hypotheses	6, 7
Methods			
Study design	#4	Present key elements of study design early in the paper	7
Setting	#5	Describe the setting, locations, and relevant dates,	7, 8

		including periods of recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	8
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9, 10
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	8, 9, 10
Bias	#9	Describe any efforts to address potential sources of bias	7 (population-based), 8 (consecutive inclusion), 9 (elimination of inter-rater variability)
Study size	#10	Explain how the study size was arrived at	10
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	8, 9, 10, 11, 12
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	11, 12
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
Statistical methods	#12c	Explain how missing data were addressed	13 (no missing values)
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	Sensitivity analyses were not performed
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg	12, 28 (Figure1)

		numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	
Participants	#13b	Give reasons for non-participation at each stage	12, 28 (Figure1)
Participants	#13c	Consider use of a flow diagram	28 (Figure1)
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	12, 13, 14
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	13 (no missing values)
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	14
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	16, 17, 18
Main results	#16b	Report category boundaries when continuous variables were categorized	9, 10
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Other analyses were not performed
Discussion			
Key results	#18	Summarise key results with reference to study objectives	18
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	20, 21
Interpretation	#20	Give a cautious overall interpretation considering	20, 21

		objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	
Generalisability	#21	Discuss the generalisability (external validity) of the study results	20
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21, 22

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Association between alcohol consumption/alcohol use disorders and patient complexity: a cross-sectional study

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Association between alcohol consumption/alcohol use disorders and patient complexity: a cross-sectional study

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ABSTRACT

Objectives The objective was to clarify the relationship between alcohol consumption/alcohol use disorders and patient complexity.

Design Cross-sectional study.

Setting A clinic located on a remote island in Okinawa, Japan, providing general outpatient practices and round-the-clock emergency services.

Participants Patients who lived on the island, visited Tarama Clinic from April 1st, 2018 to June 30th, 2018, were aged ≥20 years, and had decision-making capacity were judged to be eligible for this study.

Main outcome measures Alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT) and patient complexity as scored by the Patient Centered Assessment Method (PCAM).

Results During the three-month study period, 355 patients (163 women and 192 men) with mean (standard deviation) age of 66.4 (13.6) years were included. Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT scores classified as "Dependence likely" were associated with PCAM scores (p-value=0.040).

Conclusions Alcohol consumption and alcohol use disorders classified as "Dependence likely" are associated with patient complexity.

Keywords

patient complexity, alcohol consumption, alcohol use disorders, the Patient Centered Assessment Method, the Alcohol Use Disorders Identification Test

Strengths and limitations of this study

- This is the first study to identify a relationship between alcohol

consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test and patient complexity as scored by the Patient Centered Assessment Method.

- The particular condition, where most residents of the island were expected to choose Tarama Clinic because of the considerable geographical restrictions preventing them attending other medical institutions, enabled this study to be population-based.
- The study's generalizability is limited, because it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous.
- It was a cross-sectional study and therefore a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred.
- Although consecutive sampling was used, some otherwise eligible patients were not enrolled, which may have resulted in selection bias.

INTRODUCTION

Alcohol use is one of the leading risk factors for global deaths and disease burden, accounting for 2.8 million deaths (2.2% and 6.8% of age-standardized deaths in women and men, respectively) and leads to 1.6% and 6.0% of disability-adjusted life-years (DALYs) in women and men, respectively.[1]

The use of alcohol has been identified as a causal factor for more than 200 diseases and injuries.[2] It causes not only physical conditions, including gastrointestinal diseases such as liver cirrhosis and pancreatitis and a wide variety of cancers, but also neuropsychiatric conditions, including alcohol use disorders, epilepsy, depression, and anxiety disorders.[3] Excessive alcohol intake impairs cognitive function.[4] The use of alcohol is also associated with both intentional injuries such as suicide and violence, and unintentional injuries.[3, 5, 6]

In addition to these harmful effects on the physical and mental health, alcohol drinking is related to adverse social consequences. Transgression of boundaries between normal and abnormal drinking, namely the harmful use of alcohol or alcohol dependence, gives rise to social problems such as family disruption, loss of earnings, and unemployment.[7] Moreover, those who have alcohol problems are likely to be subjected to social disapproval or be stigmatized by members of their community.[7, 8] Stigmatization reportedly leads to reduced accessibility to medical service and worse quality of medical care.[7, 9-12] Additionally, expenditure on alcohol consumption causes economic problems, especially when the individual concerned has a low income.[3, 13]

It is now increasingly accepted that these psychological and social factors contribute to deterioration in health; however, they have received little attention in the past. It has been newly proposed that the biopsychosocial model be substituted for the biomedical model, the latter having been preponderant in the mid-20th century but now

being recognized as limited by its understanding of patients exclusively from a biological point of view.[14] As its name implies, the biopsychosocial model is a holistic model that incorporates biological, psychological, and social characteristics of patients' illnesses.[14] These characteristics are all included in what is termed patient complexity, which is defined as "the person-specific factors that interfere with the delivery of usual care and decision-making for whatever conditions the patient has".[15] Although medical professionals often become frustrated in the face of such factors due to the lack of clear ideas of how the patient is complex and what to do about it, the concept of patient complexity provides them with a common vocabulary and method to identify and act in systematic and comfortable way.[15]

Some tools, such as INTERMED[16, 17] and the Minnesota Complexity Assessment Method (MCAM)[15], have been developed for assessing this patient complexity. Another of these tools, the Patient Centered Assessment Method (PCAM)[18] was designed mainly for use in primary care settings. PCAM assesses patient complexity from four perspectives: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[19] The first domain "Health and Well-being" is certainly subject to being influenced by alcohol consumption, because it contains a question regarding lifestyle behaviors related to drinking.[19] Furthermore, as described above, alcohol consumption causes a wide variety of biological, psychological, and social problems. Therefore, it is expected to have pervasive influences not only on the first domain, but also the other domains: "Social Environment," "Health Literacy and Communication," and "Service Coordination."

Thus, it remains unclear how alcohol consumption influences patient complexity holistically and quantitatively. The objective of this study was to clarify the relationship between alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT)[20] and patient complexity as scored by PCAM,

the rationale being that better understanding of this relationship could guide physicians on optimal provision of medical care to patients with alcohol-related problems or biopsychosocial complexity.

METHODS

Design

This was a cross-sectional study and reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[21]

Setting

This study was conducted on Tarama Island, a remote island in Okinawa, Japan. The island is located about 67 km from Miyako Island[22] (125 minutes by ferry[23] or 25 minutes by air[24]), which is the fourth largest island of Okinawa[25] and is located about 300 km from the main island of Okinawa[26] (55 minutes by air[24]). The island's population is 1194 (555 women and 639 men), of whom 916 (76.7%) are aged 20 years or older.[27, 28] The percentage of the population aged 65 years and older is 26.4%, which is almost the same as the national average (26.6%).[28] The population density being 54.3/km^2.[29] Other than a dental clinic, the island has only one medical institution without beds, Tarama Clinic, Okinawa Miyako Hospital. This clinic has four staff members (a physician, a nurse, a nurse assistant, and a clerk) and provides general outpatient practices and round-the-clock emergency services.

Japan has a "free access system," which means that patients are allowed to visit any clinics or hospitals. However, most residents of the island were expected to choose Tarama Clinic because there are considerable geographical restrictions preventing them

attending other medical institutions. This particular condition enabled this study to be population-based, that is, it included almost all patients living in the region.

Participants

Patients who lived on the island and visited Tarama Clinic from April 1st, 2018 to June 30th, 2018 were consecutively included in this study. Patients who were aged less than 20 years or who lacked decision-making capacity were excluded. Those who met these conditions were judged to be eligible for this study. Otherwise eligible patients who refused to participate were excluded, as were patients, whose participation was judged by the principal investigator to have unfavorable influences on the patient–physician relationships. When the principal investigator was out of the office and so unable to seek informed consent, or when obtaining informed consent would have interfered with routine medical practice because there were too many patients in the waiting-room, otherwise eligible patients were not enrolled.

After the principal investigator had fully informed the patients of the content of this study, those who agreed to participate provided written consent.

Outcome measures

Data described below were collected from April 1st, 2018 to March 31st, 2019.

PCAM

PCAM is a tool for assessing patient complexity across four domains: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[19] Each domain has two or four areas of inquiry: "Health and Well-being" inquires about items #1 "Physical health needs," #2 "Physical health impacting on mental well-being," #3 "Lifestyle impacting on physical or mental well-being," and #4

"Other mental well-being concerns"; "Social Environment" about items #1 "Home environment," #2 "Daily activities," #3 "Social networks," and #4 "Financial resources"; "Health Literacy and Communication" about items #1 "Health literacy" and #2 "Engagement in discussion"; and "Service Coordination" about items #1 "Other services" and #2 "Service coordination."[30] Each of the twelve items has four defined levels of complexity, which are labeled as "Routine care," "Active monitoring," "Plan action," and "Act now" in order of increasing complexity.[19] Each item is also scored from one to four; thus, the lowest possible score of PCAM is 12 and the highest possible score 48.[19] Patient complexity becomes greater as the score increases. PCAM scores were determined during patients' office visits by a single physician, the principal investigator, in accordance with the user guide,[30] which eliminated any inter-rater variability. PCAM scores and PCAM four-domain scores were used for the multiple regression analyses.

AUDIT

AUDIT is a tool for screening for hazardous drinking, harmful drinking, and alcohol dependence in terms of 10 items across three domains: "Hazardous Alcohol Use" (three items), "Dependence Symptoms" (three items), and "Harmful Alcohol Use" (four items).[20] Each item is scored from zero to four; or zero, two, or four. The lowest possible score of AUDIT is zero and the highest possible score 40.[20] Likelihood and severity of hazardous drinking, harmful drinking, and alcohol dependence become greater as the score increases. AUDIT scores were determined by filling in a self-administered questionnaire. A nurse supported patients to answer the questions, if needed or desired. For the descriptive statistical analyses, AUDIT scores were divided into the following categories to compare with a nationwide survey in Japan: patients scoring 12 or more points; 15 or more points (potential alcoholism); and 20 or more

points (suspected alcoholism).[31] As for multiple regression analyses, AUDIT scores were divided into the following categories based on four levels of risk in accordance with the guidelines: "Low risk" being designated for AUDIT scores from 0 to 7; "Medium risk" 8 to 15; "High risk" 16 to 19; and "Dependence likely" 20 to 40.[20]

Other explanatory variables

Age and sex were obtained from medical records and annual medical expenses during the previous year were calculated from medical fee receipts. Education ("<High school" or "≥High school"), occupation ("In work" or "Out of work"), physical activity ("Exercising" or "Not exercising"), smoking ("Current smoker," "Ex-smoker," or "Never smoker"), and number of family members living with the patient were obtained from a self-administered questionnaire. A nurse also assisted patients, if needed or desired. "In work" included full-time or part-time workers, and housewives or househusbands; "Out of work" included those without an occupation. "Exercising" was defined as engaging in physical activity for more than 30 minutes, twice a week, and for one year or more.

Sample size

To the best of our knowledge, there have been no published studies on the association between alcohol consumption/alcohol use disorders and patient complexity, which made it difficult to determine the meaningful effect size to calculate the required sample size. As a next step in this study, we planned to examine the validity and reliability of PCAM in a primary care setting, so the sample size was estimated using factor analysis. A wide range of sample sizes are recommended in factor analysis, these usually being described as either the sample size or the ratio of a sample size to number of variables. A sample size of 300 is considered good.[32] In contrast, a larger ratio of sample size to the number of variables such as 20:1 is reportedly better.[33] This

resulted in calculation of a sample size of 240 for 12 PCAM items. Of these two possibilities, 300 was adopted as an adequate required sample size.

Statistical Analysis

Descriptive statistical analyses were used to demonstrate the distribution of PCAM and AUDIT scores and to compare AUDIT scores with a nationwide survey in Japan. Multiple regression analyses were used to evaluate the association between PCAM and AUDIT scores after adjustment for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient.

Statistical analyses were performed using Stata/MP version 15.1.[34] P-values less than 0.05 were considered to denote statistical significance.

Patient and public involvement

This study was conducted without patient or public involvement.

RESULTS

During the three-month study period, 521 patients who visited Tarama Clinic were consecutively included. Of these patients, 95 did not meet the eligibility criteria: 13 did not live on the island, 57 were aged less than 20 years, and 25 lacked decision-making capacity. This left 426 eligible patients, 71 of whom were excluded: 28 refused to participate, the participation of nine was judged to have unfavorable influences on the patient–physician relationships, and informed consent was not obtained from two because the principal investigator was out of the office and from another 32 because there were too many patients in the waiting-room. The main reason for judging a

patient's participation as likely to unfavorably impact the patient–physician relationship was that they had confirmed or suspected mental or personality disorders, the concern being that information about the study and invitation to participate might be experienced as a psychological burden and lead to interruption of their regular visits. Thus, 355 patients, 83.3% of eligible patients, were finally included (figure 1). The characteristics of the 355 study participants are shown in table 1. There were no missing values among outcome measures and other explanatory variables for the study participants.

Table 1. Characteristics of the 355 study participants

Age, mean (SD), years	66.4 (13.6)
By age group, No. (%)	
<35 years	6 (1.7)
35 to <45 years	19 (5.4)
45 to <55 years	42 (11.8)
55 to <65 years	86 (24.2)
65 to <75 years	85 (23.9)
≥75 years	117 (33.0)
Sex, No. (%)	
Women	163 (45.9)
Men	192 (54.1)
Education, No. (%)	
<High school	187 (52.7)
≥High school	168 (47.3)
Occupation, No. (%)	
In work	307 (86.5)
Out of work	48 (13.5)
Physical activity, No. (%)	
Exercising	53 (14.9)
Not exercising	302 (85.1)
Smoking, No. (%)	
Current smoker	50 (14.1)
Ex-smoker	118 (33.2)
Never smoker	187 (52.7)
Annual medical expenses, No. (%)	
<100,000 yen	194 (54.6)
100,000 to <200,000 yen	108 (30.4)
200,000 to <300,000 yen	31 (8.7)

≥300,000 yen	22 (6.2)
Number of family members living with the patient, No. (%)	
0	66 (18.6)
1	165 (46.5)
2	73 (20.6)
3	29 (8.2)
4	8 (2.3)
≥5	14 (3.9)

SD, standard deviation.

PCAM and AUDIT scores were distributed as shown in figure 2. The mean (SD, standard deviation) of PCAM and AUDIT scores were 21.4 (5.7) and 7.0 (7.5), respectively. In total, 3.7% of women, 54.7% of men, and 31.3% overall scored 12 or more points, 2.5%, 36.5%, and 20.8% scored 15 or more points, and 0.6%, 12.5%, and 7.0% scored 20 or more points.

Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT scores classified as "Dependence likely" (compared with those classified as "Low risk") were associated with PCAM scores (p-value=0.040), whereas those classified as "Medium risk" and "High risk" were not (p-values=0.215 and 0.187) (table 2). Moreover, the standardized regression coefficient of AUDIT scores classified as "Dependence likely" was 0.111, the 95% confidence interval (CI) of which overlapped with those of other variables (table 2). Among explanatory variables, the variance inflation factors ranged from 1.04 to 2.12.

Table 2. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) scores

		Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI
AUDIT score						
	Low risk	Reference				
	Medium risk	1.050	−0.613 to 2.713	0.215	0.077	−0.045 to 0.199
	High risk	1.361	−0.666 to 3.387	0.187	0.074	−0.036 to 0.183
	Dependence likely	2.480	0.117 to 4.843	0.040	0.111	0.005 to 0.217
Age		−0.009	−0.065 to 0.047	0.746	−0.022	−0.155 to 0.111
Sex						
	Female	Reference				
	Male	0.615	−0.722 to 1.952	0.366	0.054	−0.063 to 0.170
Education						
	≥High school	Reference				
	<High school	1.320	0.056 to 2.584	0.041	0.115	0.005 to 0.226
Occupation						
	In work	Reference				
	Out of work	3.814	2.146 to 5.483	<0.001	0.228	0.128 to 0.328
Physical activity						
	Exercising	Reference				
	Not exercising	1.838	0.341 to 3.335	0.016	0.115	0.021 to 0.208
Smoking						
	Never smoker and ex-smoker	Reference				
	Current smoker	3.465	1.828 to 5.101	<0.001	0.211	0.111 to 0.310
Annual medical expenses (×10⁴ yen)		0.160	0.107 to 0.212	<0.001	0.297	0.199 to 0.396
Number of family members living with the patient		−0.492	−0.902 to −0.082	0.019	−0.114	−0.209 to −0.019

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

Multiple regression analysis of PCAM four-domain scores after the same adjustments showed that AUDIT scores classified as “High risk” and “Dependence likely” (compared with those classified as “Low risk”) were also associated with “Health and Well-being” (p-values 0.008 and 0.001). “Medium risk,” “High risk,” and “Dependence likely” were all associated with “Health Literacy and Communication” (p-values 0.008, 0.030, and 0.012). However, AUDIT scores were not associated with “Social Environment” and “Service Coordination” (table 3).

Table 3. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) four-domain scores

Health and Well-being

	Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI

AUDIT score					
Low risk	Reference				
Medium risk	0.634	−0.053 to 1.321	0.070	0.116	−0.010 to 0.242
High risk	1.136	0.299 to 1.973	0.008	0.153	0.040 to 0.266
Dependence likely	1.713	0.737 to 2.689	0.001	0.191	0.082 to 0.300
Age	−0.020	−0.043 to 0.003	0.094	−0.117	−0.254 to 0.020
Sex					
Female	Reference				
Male	0.180	−0.372 to 0.733	0.521	0.039	−0.081 to 0.159
Education					
≥High school	Reference				
<High school	0.261	−0.262 to 0.783	0.327	0.057	−0.057 to 0.170
Occupation					
In work	Reference				
Out of work	0.702	0.013 to 1.391	0.046	0.105	0.002 to 0.280
Physical activity					
Exercising	Reference				
Not exercising	0.613	−0.005 to 1.232	0.052	0.095	−0.001 to 0.192
Smoking					
Never smoker and ex-smoker	Reference				
Current smoker	1.463	0.787 to 2.140	<0.001	0.222	0.119 to 0.325
Annual medical expenses (×10⁴ yen)	0.047	0.026 to 0.069	<0.001	0.221	0.119 to 0.323
Number of family members living with the patient	−0.227	−0.396 to −0.058	0.009	−0.131	−0.229 to −0.033

Social Environment

	Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI
AUDIT score					
Low risk	Reference				
Medium risk	−0.204	−0.766 to 0.358	0.476	−0.045	−0.171 to 0.080
High risk	−0.328	−1.013 to 0.357	0.347	−0.054	−0.166 to 0.059
Dependence likely	−0.375	−1.174 to 0.424	0.356	−0.051	−0.159 to 0.058
Age	−0.008	−0.027 to 0.011	0.393	−0.059	−0.196 to 0.077
Sex					
Female	Reference				
Male	−0.453	−0.905 to −0.001	0.049	−0.120	−0.239 to −0.000
Education					
≥High school	Reference				
<High school	0.640	0.213 to 1.067	0.003	0.170	0.056 to 0.283
Occupation					
In work	Reference				
Out of work	1.650	1.086 to 2.214	<0.001	0.300	0.197 to 0.402
Physical activity					
Exercising	Reference				
Not exercising	0.239	−0.267 to 0.745	0.354	0.045	−0.051 to 0.141
Smoking					
Never smoker and ex-smoker	Reference				
Current smoker	0.367	−0.186 to 0.920	0.193	0.068	−0.034 to 0.170
Annual medical expenses (×10⁴ yen)	0.021	0.003 to 0.039	0.021	0.120	0.019 to 0.221
Number of family members living with the patient	−0.170	−0.308 to −0.031	0.016	−0.119	−0.217 to −0.022

Health Literacy and Communication

	Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI
AUDIT score					
Low risk	Reference				
Medium risk	0.708	0.185 to 1.231	0.008	0.164	0.043 to 0.285
High risk	0.707	0.070 to 1.344	0.030	0.121	0.012 to 0.229
Dependence likely	0.952	0.209 to 1.695	0.012	0.134	0.030 to 0.239
Age	0.016	−0.001 to 0.034	0.068	0.123	−0.009 to 0.255
Sex					
Female	Reference				
Male	0.415	−0.006 to 0.835	0.053	0.114	−0.002 to 0.230
Education					
≥High school	Reference				
<High school	0.530	0.133 to 0.928	0.009	0.146	0.037 to 0.256
Occupation					
In work	Reference				
Out of work	0.799	0.274 to 1.324	0.003	0.151	0.052 to 0.250
Physical activity					
Exercising	Reference				
Not exercising	0.431	−0.040 to 0.902	0.073	0.085	−0.008 to 0.177
Smoking					
Never smoker and ex-smoker	Reference				
Current smoker	1.188	0.673 to 1.703	<0.001	0.228	0.129 to 0.327
Annual medical expenses (×10⁴ yen)	0.047	0.030 to 0.063	<0.001	0.276	0.178 to 0.374
Number of family members living with the patient	−0.003	−0.131 to 0.126	0.968	−0.002	−0.096 to 0.092

Service Coordination

	Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI
AUDIT score					
Low risk	Reference				

Medium risk	−0.088	−0.603 to 0.426	0.736	−0.022	−0.152 to 0.108
High risk	−0.155	−0.782 to 0.473	0.628	−0.029	−0.146 to 0.088
Dependence likely	0.190	−0.541 to 0.921	0.610	0.029	−0.083 to 0.142
Age	0.002	−0.015 to 0.020	0.791	0.019	−0.123 to 0.161
Sex					
Female	Reference				
Male	0.473	0.059 to 0.887	0.025	0.142	0.018 to 0.266
Education					
≥High school	Reference				
<High school	−0.111	−0.502 to 0.280	0.577	−0.033	−0.151 to 0.084
Occupation					
In work	Reference				
Out of work	0.663	0.147 to 1.180	0.012	0.137	0.030 to 0.243
Physical activity					
Exercising	Reference				
Not exercising	0.555	0.092 to 1.018	0.019	0.119	0.020 to 0.219
Smoking					
Never smoker and ex-smoker	Reference				
Current smoker	0.446	−0.061 to 0.953	0.084	0.093	−0.013 to 0.200
Annual medical expenses (×10⁴ yen)	0.044	0.028 to 0.060	<0.001	0.283	0.177 to 0.388
Number of family members living with the patient	−0.092	−0.219 to 0.034	0.152	−0.074	−0.175 to 0.027

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

DISCUSSION

More than 30% of people in the study had problematic alcohol consumption. Additionally, alcohol consumption and alcohol use disorders classified as “Dependence likely” were associated with patient complexity.

First, more than 30% of people in the study had problematic alcohol consumption. Assuming that those not included in this study (561 people, or the total population aged 20 years or older of 916 people minus 355 study participants) were non-problematic drinkers, this still means that the proportion of problematic drinkers on the island is more than 12%. A national survey reported that 1.3%, 10.6%, and 5.5% of Japanese women, men, and overall had AUDIT scores of 12 or more points; 0.6%, 5.3%, and 2.7% had 15 or more points and 0.2%, 2.0%, and 1.0% had 20 or more points.[31] Our findings strongly suggest that the percentages of individuals on the island with potential and suspected alcoholism is much higher than the national average. This might be because there is a regionally-specific drinking custom called “Otōri” in the island, where a group of people pass around a glass of alcohol.[35] This custom is broadly accepted, but may cause alcohol-related problems.[36, 37]

Second, alcohol consumption and alcohol use disorders classified as "Dependence likely" were associated with patient complexity. AUDIT scores classified as "Dependence likely" were found to be associated with PCAM scores. Additionally, we did not detect any significant differences in the strength of relationships with AUDIT scores between the variables because the 95% CIs of standardized regression coefficients overlapped. Other variables not included in this study could also lead to the relatively small impact of AUDIT scores on PCAM scores. Much previous research has examined and clarified the relationship between alcohol consumption and different individual physical and psychological conditions and social circumstance.[3-13] However, this is the first study to provide a holistic perspective on the detrimental impact of alcohol consumption and alcohol use disorders on patient complexity.

AUDIT scores classified as "High risk" and "Dependence likely" were associated with "Health and Well-being" on the PCAM four-domain scores. This is consistent with previous findings that alcohol causes physical harm.[3, 5, 6] However, a relationship between alcohol consumption/alcohol use disorders and "Social Environment" was not established in this study. Considering the fact that drinking alcohol plays roles in creating and maintaining social identity and relationships,[38-42] these roles presumably offset the well-known negative effect of alcohol on "Social Environment."[3, 4, 7-13] Limited health literacy, such as underestimation of drinking alcohol and lack of knowledge of resources to help with problematic drinking, are also associated with harmful drinking[43]. This is consistent with the result that "Medium risk," "High risk," and "Dependence likely" were all associated with "Health Literacy and Communication." This study did not find a relationship between alcohol consumption/alcohol use disorders and "Service Coordination." This is probably because there is only one medical institution on the island. The limited number of services enable good interconnection and coordination. This coordination may mitigate the harmful impact of alcohol such as

reduced accessibility to medical services and worse quality of medical care, which are related to "Service Coordination." These findings could therefore be linked to the relatively small impact of AUDIT scores on PCAM scores.

Despite the small sample size, the high prevalence of problematic alcohol consumption on the island enabled the study to clarify the relationship between alcohol consumption/alcohol use disorders and patient complexity. Internationally, estimates of prevalence of alcohol dependence, as a percentage of total adult population aged 15 years or more, are reported to be high in Eastern European countries such as Belarus (11.0%) and Hungary (9.4%), and in Russia (9.3%).[3] These figures are comparable with those in our study. We found that problematic drinking was associated with patient complexity, and it is not hard to imagine that a high proportion of problematic drinking may lead to an increase in patients with high complexity in other societies and regions. However, the effect of alcohol drinking on patient complexity will vary across societies and regions. This remote island has the unique custom of "Otōri", and it is thought likely that the specific circumstances of each society and region mediate between problematic alcohol drinking and patient complexity.

This study had several limitations. First, it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous. Both alcohol intake and patient complexity of participants could have been affected by these factors in a biased direction; thus, the association between them may have been under- or over-estimated. This limits generalizability of the present findings. Second, this was a cross-sectional study; thus, a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred. Third, although consecutive sampling was used, some otherwise eligible patients were not enrolled: 83.3% of eligible patients were included. This failure in sampling could have led to selection bias. Especially, the main reason for judging a

patient's participation as likely to unfavorably impact the patient–physician relationship was that they had confirmed or suspected mental or personality disorders. These disorders are inclined to cause biopsychosocial problems (i.e., high patient complexity). Thus, their exclusion could have resulted in underestimation of patient complexity. Most patients from whom informed consent was not obtained because the principal investigator was absent or there were too many patients waiting for a consultation made only a single visit to the clinic (for mild acute diseases, such as upper respiratory inflammation or gastroenteritis) during the registration period. Exclusion of these low complexity, or otherwise-healthy, patients would obviously have resulted in overestimation of patient complexity.

FUTURE RESEARCH

The development of a Japanese version of PCAM and the examination of its validity and reliability in a primary care setting are planned to promote dissemination of the concept of patient complexity in Japan.

CONCLUSION

Alcohol consumption and alcohol use disorders classified as "Dependence likely" are associated with patient complexity.

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Contributors

YS designed the study; collected, analyzed, and interpreted the data; and prepared and reviewed the manuscript. MM contributed to design of the study, analysis and interpretation of the data, and review of the manuscript. HY contributed to design of the study and review of the manuscript.

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Disclaimer

The sponsor of this study had no role in the study design; the study conduct: collection, analysis, or interpretation of the data; the manuscript preparation; or the decision to submit the manuscript for publication.

Competing interests

YS and HY are former trainees of the Jikei Clinical Research Program for Primary-care. MM is a program director of the Jikei Clinical Research Program for Primary-care.

Ethics approval

This study was approved by the Ethics Committee of Okinawa Miyako Hospital (approved on February 8th, 2018) and the Ethics Committee of The Jikei University School of Medicine (the acceptance number: 30-412 (9433)).

Data sharing statement

No additional data are available.

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Figure 1. A flow chart detailing the process of inclusion and exclusion of study participants

Figure 2. Distribution of PCAM and AUDIT scores

PCAM, the Patient Centered Assessment Method; AUDIT, the Alcohol Use Disorders Identification Test.

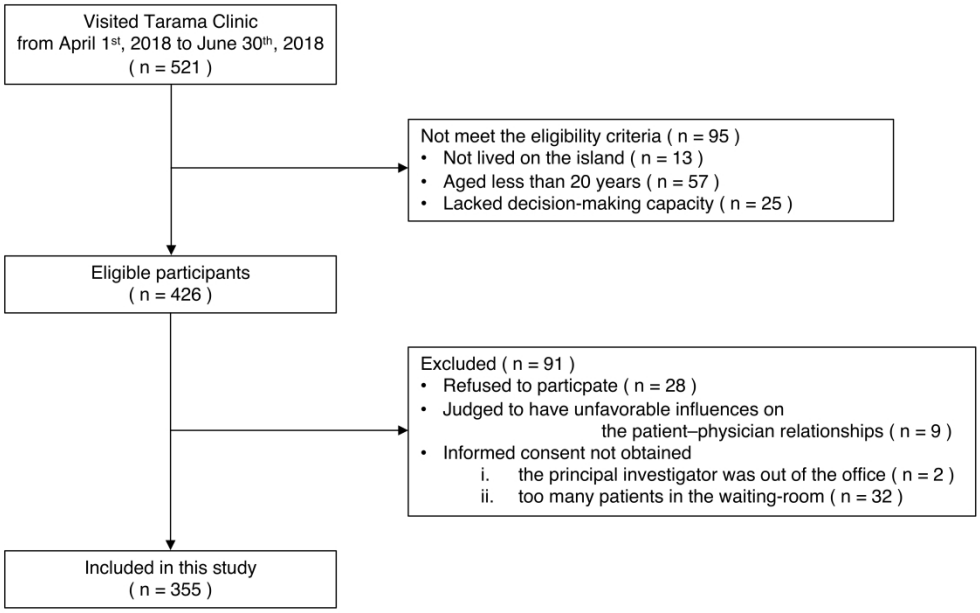

Figure 1. A flow chart detailing the process of inclusion and exclusion of study participants

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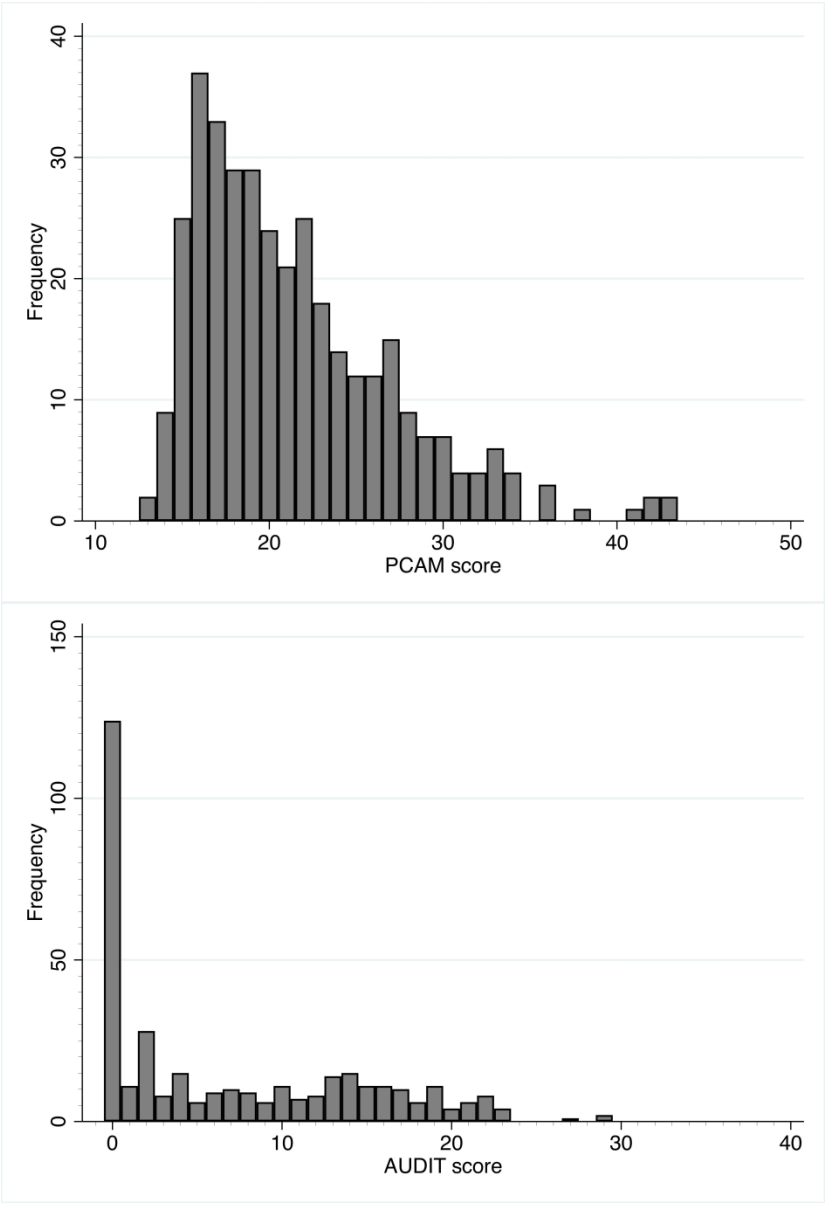

Figure 2. Distribution of PCAM and AUDIT scores
PCAM, the Patient Centered Assessment Method; AUDIT, the Alcohol Use Disorders Identification Test.

139x203mm (600 x 600 DPI)

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

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Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1, 2
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4, 5, 6
Objectives	#3	State specific objectives, including any prespecified hypotheses	5, 6
Methods			
Study design	#4	Present key elements of study design early in the paper	6
Setting	#5	Describe the setting, locations, and relevant dates,	6, 7

		including periods of recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7, 8, 9
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	7, 8, 9
Bias	#9	Describe any efforts to address potential sources of bias	6, 7 (population-based), 7 (consecutive inclusion), 8 (elimination of inter-rater variability)
Study size	#10	Explain how the study size was arrived at	9, 10
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	7, 8, 9, 10
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	10
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
Statistical methods	#12c	Explain how missing data were addressed	11 (no missing values)
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	Sensitivity analyses were not performed
Results			

Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	10, 11, 25 (Figure1)
Participants	#13b	Give reasons for non-participation at each stage	10, 11, 25 (Figure1)
Participants	#13c	Consider use of a flow diagram	25 (Figure1)
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	11, 12
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	11 (no missing values)
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	12
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12, 13, 14, 15
Main results	#16b	Report category boundaries when continuous variables were categorized	7, 8, 9
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Other analyses were not performed
Discussion			
Key results	#18	Summarise key results with reference to study objectives	15
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	17, 18

Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	17, 18
Generalisability	#21	Discuss the generalisability (external validity) of the study results	17
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

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Association between alcohol consumption/alcohol use disorders and patient complexity: a cross-sectional study

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TITLE PAGE

Title

Association between alcohol consumption/alcohol use disorders and patient complexity: a cross-sectional study

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ABSTRACT

Objectives The objective was to clarify the relationship between alcohol consumption/alcohol use disorders and patient complexity.

Design Cross-sectional study.

Setting A clinic located on a remote island in Okinawa, Japan, providing general outpatient practices and round-the-clock emergency services.

Participants Patients who lived on the island, visited Tarama Clinic from April 1st, 2018 to June 30th, 2018, were aged ≥20 years, and had decision-making capacity were judged to be eligible for this study.

Main outcome measures Alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT) and patient complexity as scored by the Patient Centered Assessment Method (PCAM).

Results During the three-month study period, 355 patients (163 women and 192 men) with mean (standard deviation) age of 66.4 (13.6) years were included. Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT scores classified as "Dependence likely" were associated with PCAM scores (p-value=0.040).

Conclusions Alcohol consumption and alcohol use disorders classified as "Dependence likely" are associated with patient complexity.

Keywords

patient complexity, alcohol consumption, alcohol use disorders, the Patient Centered Assessment Method, the Alcohol Use Disorders Identification Test

Strengths and limitations of this study

- This is the first study to identify a relationship between alcohol

consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test and patient complexity as scored by the Patient Centered Assessment Method.

- The particular condition, where most residents of the island were expected to choose Tarama Clinic because of the considerable geographical restrictions preventing them attending other medical institutions, enabled this study to be population-based.
- The study's generalizability is limited, because it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous.
- It was a cross-sectional study and therefore a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred.
- Although consecutive sampling was used, some otherwise eligible patients were not enrolled, which may have resulted in selection bias.

INTRODUCTION

Alcohol use is one of the leading risk factors for global deaths and disease burden, accounting for 2.8 million deaths (2.2% and 6.8% of age-standardized deaths in women and men, respectively) and leads to 1.6% and 6.0% of disability-adjusted life-years (DALYs) in women and men, respectively.[1]

The use of alcohol has been identified as a causal factor for more than 200 diseases and injuries.[2] It causes not only physical conditions, including gastrointestinal diseases such as liver cirrhosis and pancreatitis and a wide variety of cancers, but also neuropsychiatric conditions, including alcohol use disorders, epilepsy, depression, and anxiety disorders.[3] Excessive alcohol intake impairs cognitive function.[4] The use of alcohol is also associated with both intentional injuries such as suicide and violence, and unintentional injuries.[3, 5, 6]

In addition to these harmful effects on the physical and mental health, alcohol drinking is related to adverse social consequences. Transgression of boundaries between normal and abnormal drinking, namely the harmful use of alcohol or alcohol dependence, gives rise to social problems such as family disruption, loss of earnings, and unemployment.[7] Moreover, those who have alcohol problems are likely to be subjected to social disapproval or be stigmatized by members of their community.[7, 8] Stigmatization reportedly leads to reduced accessibility to medical service and worse quality of medical care.[7, 9-12] Additionally, expenditure on alcohol consumption causes economic problems, especially when the individual concerned has a low income.[3, 13]

It is now increasingly accepted that these psychological and social factors contribute to deterioration in health; however, they have received little attention in the past. It has been newly proposed that the biopsychosocial model be substituted for the biomedical model, the latter having been preponderant in the mid-20th century but now

being recognized as limited by its understanding of patients exclusively from a biological point of view.[14] As its name implies, the biopsychosocial model is a holistic model that incorporates biological, psychological, and social characteristics of patients' illnesses.[14] These characteristics are all included in what is termed patient complexity, which is defined as "the person-specific factors that interfere with the delivery of usual care and decision-making for whatever conditions the patient has".[15] Although medical professionals often become frustrated in the face of such factors due to the lack of clear ideas of how the patient is complex and what to do about it, the concept of patient complexity provides them with a common vocabulary and method to identify and act in systematic and comfortable way.[15]

Some tools, such as INTERMED[16, 17] and the Minnesota Complexity Assessment Method (MCAM)[15], have been developed for assessing this patient complexity. Another of these tools, the Patient Centered Assessment Method (PCAM)[18] was designed mainly for use in primary care settings. PCAM assesses patient complexity from four perspectives: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[19] The first domain "Health and Well-being" is certainly subject to being influenced by alcohol consumption, because it contains a question regarding lifestyle behaviors related to drinking.[19] Furthermore, as described above, alcohol consumption causes a wide variety of biological, psychological, and social problems. Therefore, it is expected to have pervasive influences not only on the first domain, but also the other domains: "Social Environment," "Health Literacy and Communication," and "Service Coordination."

Thus, it remains unclear how alcohol consumption influences patient complexity holistically and quantitatively. The objective of this study was to clarify the relationship between alcohol consumption/alcohol use disorders as measured by the Alcohol Use Disorders Identification Test (AUDIT)[20] and patient complexity as scored by PCAM,

the rationale being that better understanding of this relationship could guide physicians on optimal provision of medical care to patients with alcohol-related problems or biopsychosocial complexity.

METHODS

Design

This was a cross-sectional study and reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[21]

Setting

This study was conducted on Tarama Island, a remote island in Okinawa, Japan. The island is located about 67 km from Miyako Island[22] (125 minutes by ferry[23] or 25 minutes by air[24]), which is the fourth largest island of Okinawa[25] and is located about 300 km from the main island of Okinawa[26] (55 minutes by air[24]). The island's population is 1,194 (555 women and 639 men), of whom 916 (76.7%) are aged 20 years or older.[27, 28] The percentage of the population aged 65 years and older is 26.4%, which is almost the same as the national average (26.6%).[28] The population density being 54.3/km^2.[29] Other than a dental clinic, the island has only one medical institution without beds, Tarama Clinic, Okinawa Miyako Hospital. This clinic has four staff members (a physician, a nurse, a nurse assistant, and a clerk) and provides general outpatient practices and round-the-clock emergency services.

Japan has a "free access system," which means that patients are allowed to visit any clinics or hospitals. However, most residents of the island were expected to choose Tarama Clinic because there are considerable geographical restrictions preventing them

attending other medical institutions. This particular condition enabled this study to be population-based, that is, it included almost all patients living in the region.

Participants

Patients who lived on the island and visited Tarama Clinic from April 1st, 2018 to June 30th, 2018 were consecutively included in this study. Patients who were aged less than 20 years or who lacked decision-making capacity were excluded. Those who met these conditions were judged to be eligible for this study. Otherwise eligible patients who refused to participate were excluded, as were patients, whose participation was judged by the principal investigator to have unfavorable influences on the patient–physician relationships. When the principal investigator was out of the office and so unable to seek informed consent, or when obtaining informed consent would have interfered with routine medical practice because there were too many patients in the waiting-room, otherwise eligible patients were not enrolled.

After the principal investigator had fully informed the patients of the content of this study, those who agreed to participate provided written consent.

Outcome measures

Data described below were collected from April 1st, 2018 to March 31st, 2019.

PCAM

PCAM is a tool for assessing patient complexity across four domains: "Health and Well-being," "Social Environment," "Health Literacy and Communication," and "Service Coordination."[19] Each domain has two or four areas of inquiry: "Health and Well-being" inquires about items #1 "Physical health needs," #2 "Physical health impacting on mental well-being," #3 "Lifestyle impacting on physical or mental well-being," and #4

"Other mental well-being concerns"; "Social Environment" about items #1 "Home environment," #2 "Daily activities," #3 "Social networks," and #4 "Financial resources"; "Health Literacy and Communication" about items #1 "Health literacy" and #2 "Engagement in discussion"; and "Service Coordination" about items #1 "Other services" and #2 "Service coordination."[30] Each of the twelve items has four defined levels of complexity, which are labeled as "Routine care," "Active monitoring," "Plan action," and "Act now" in order of increasing complexity.[19] Each item is also scored from one to four; thus, the lowest possible score of PCAM is 12 and the highest possible score 48.[19] Patient complexity becomes greater as the score increases. PCAM scores were determined during patients' office visits by a single physician, the principal investigator, in accordance with the user guide,[30] which eliminated any inter-rater variability. PCAM scores and PCAM four-domain scores were used for the multiple regression analyses.

AUDIT

AUDIT is a tool for screening for hazardous drinking, harmful drinking, and alcohol dependence in terms of 10 items across three domains: "Hazardous Alcohol Use" (three items), "Dependence Symptoms" (three items), and "Harmful Alcohol Use" (four items).[20] Each item is scored from zero to four; or zero, two, or four. The lowest possible score of AUDIT is zero and the highest possible score 40.[20] Likelihood and severity of hazardous drinking, harmful drinking, and alcohol dependence become greater as the score increases. AUDIT scores were determined by filling in a self-administered questionnaire. A nurse supported patients to answer the questions, if needed or desired. For the descriptive statistical analyses, AUDIT scores were divided into the following categories to compare with a nationwide survey in Japan: patients scoring 12 or more points; 15 or more points (potential alcoholism); and 20 or more

points (suspected alcoholism).[31] As for multiple regression analyses, AUDIT scores were divided into the following categories based on four levels of risk in accordance with the guidelines: "Low risk" being designated for AUDIT scores from 0 to 7; "Medium risk" 8 to 15; "High risk" 16 to 19; and "Dependence likely" 20 to 40.[20]

Other explanatory variables

Age and sex were obtained from medical records and annual medical expenses during the previous year were calculated from medical fee receipts. Education ("<High school" or "≥High school"), occupation ("In work" or "Out of work"), physical activity ("Exercising" or "Not exercising"), smoking ("Current smoker," "Ex-smoker," or "Never smoker"), and number of family members living with the patient were obtained from a self-administered questionnaire. A nurse also assisted patients, if needed or desired. "In work" included full-time or part-time workers, and housewives or househusbands; "Out of work" included those without an occupation. "Exercising" was defined as engaging in physical activity for more than 30 minutes, twice a week, and for one year or more.

Sample size

To the best of our knowledge, there have been no published studies on the association between alcohol consumption/alcohol use disorders and patient complexity, which made it difficult to determine the meaningful effect size to calculate the required sample size. As a next step in this study, we planned to examine the validity and reliability of PCAM in a primary care setting, so the sample size was estimated using factor analysis. A wide range of sample sizes are recommended in factor analysis, these usually being described as either the sample size or the ratio of a sample size to number of variables. A sample size of 300 is considered good.[32] In contrast, a larger ratio of sample size to the number of variables such as 20:1 is reportedly better.[33] This

resulted in calculation of a sample size of 240 for 12 PCAM items. Of these two possibilities, 300 was adopted as an adequate required sample size.

Statistical Analysis

Descriptive statistical analyses were used to demonstrate the distribution of PCAM and AUDIT scores and to compare AUDIT scores with a nationwide survey in Japan. Multiple regression analyses were used to evaluate the association between PCAM and AUDIT scores after adjustment for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient.

Statistical analyses were performed using Stata/MP version 15.1.[34] P-values less than 0.05 were considered to denote statistical significance.

Patient and public involvement

This study was conducted without patient or public involvement.

RESULTS

During the three-month study period, 521 patients who visited Tarama Clinic were consecutively included. Of these patients, 95 did not meet the eligibility criteria: 13 did not live on the island, 57 were aged less than 20 years, and 25 lacked decision-making capacity. This left 426 eligible patients, 71 of whom were excluded: 28 refused to participate, the participation of nine was judged to have unfavorable influences on the patient–physician relationships, and informed consent was not obtained from two because the principal investigator was out of the office and from another 32 because there were too many patients in the waiting-room. The main reason for judging a

patient's participation as likely to unfavorably impact the patient–physician relationship was that they had confirmed or suspected mental or personality disorders, the concern being that information about the study and invitation to participate might be experienced as a psychological burden and lead to interruption of their regular visits. Thus, 355 patients, 83.3% of eligible patients, were finally included (figure 1). The characteristics of the 355 study participants are shown in table 1. There were no missing values among outcome measures and other explanatory variables for the study participants.

Table 1. Characteristics of the 355 study participants

Age, mean (SD), years	66.4 (13.6)
By age group, No. (%)	
<35 years	6 (1.7)
35 to <45 years	19 (5.4)
45 to <55 years	42 (11.8)
55 to <65 years	86 (24.2)
65 to <75 years	85 (23.9)
≥75 years	117 (33.0)
Sex, No. (%)	
Women	163 (45.9)
Men	192 (54.1)
Education, No. (%)	
<High school	187 (52.7)
≥High school	168 (47.3)
Occupation, No. (%)	
In work	307 (86.5)
Out of work	48 (13.5)
Physical activity, No. (%)	
Exercising	53 (14.9)
Not exercising	302 (85.1)
Smoking, No. (%)	
Current smoker	50 (14.1)
Ex-smoker	118 (33.2)
Never smoker	187 (52.7)
Annual medical expenses, No. (%)	
<100,000 yen	194 (54.6)
100,000 to <200,000 yen	108 (30.4)
200,000 to <300,000 yen	31 (8.7)

≥300,000 yen	22 (6.2)
Number of family members living with the patient, No. (%)	
0	66 (18.6)
1	165 (46.5)
2	73 (20.6)
3	29 (8.2)
4	8 (2.3)
≥5	14 (3.9)

SD, standard deviation.

PCAM and AUDIT scores were distributed as shown in figure 2. The mean (SD, standard deviation) of PCAM and AUDIT scores were 21.4 (5.7) and 7.0 (7.5), respectively. In total, 3.7% of women, 54.7% of men, and 31.3% overall scored 12 or more points, 2.5%, 36.5%, and 20.8% scored 15 or more points, and 0.6%, 12.5%, and 7.0% scored 20 or more points.

Multiple regression analysis of PCAM scores showed that, after adjusting for age, sex, education, occupation, physical activity, smoking, annual medical expenses, and number of family members living with the patient, AUDIT scores classified as "Dependence likely" (compared with those classified as "Low risk") were associated with PCAM scores (p-value=0.040), whereas those classified as "Medium risk" and "High risk" were not (p-values=0.215 and 0.187) (table 2). Moreover, the standardized regression coefficient of AUDIT scores classified as "Dependence likely" was 0.111, the 95% confidence interval (CI) of which overlapped with those of other variables (table 2). Among explanatory variables, the variance inflation factors ranged from 1.04 to 2.12.

Table 2. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) scores

		Regression coefficient	95% CI	P-value	Standardized regression coefficient	95% CI
AUDIT score						
	Low risk	Reference				
	Medium risk	1.050	−0.613 to 2.713	0.215	0.077	−0.045 to 0.199
	High risk	1.361	−0.666 to 3.387	0.187	0.074	−0.036 to 0.183
	Dependence likely	2.480	0.117 to 4.843	0.040	0.111	0.005 to 0.217
Age		−0.009	−0.065 to 0.047	0.746	−0.022	−0.155 to 0.111
Sex						
	Female	Reference				
	Male	0.615	−0.722 to 1.952	0.366	0.054	−0.063 to 0.170
Education						
	≥High school	Reference				
	<High school	1.320	0.056 to 2.584	0.041	0.115	0.005 to 0.226
Occupation						
	In work	Reference				
	Out of work	3.814	2.146 to 5.483	<0.001	0.228	0.128 to 0.328
Physical activity						
	Exercising	Reference				
	Not exercising	1.838	0.341 to 3.335	0.016	0.115	0.021 to 0.208
Smoking						
	Never smoker and ex-smoker	Reference				
	Current smoker	3.465	1.828 to 5.101	<0.001	0.211	0.111 to 0.310
Annual medical expenses (×10⁴ yen)		0.160	0.107 to 0.212	<0.001	0.297	0.199 to 0.396
Number of family members living with the patient		−0.492	−0.902 to −0.082	0.019	−0.114	−0.209 to −0.019

Omnibus test: p-value <0.001 and Adjusted R^2 0.236

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

Multiple regression analysis of PCAM four-domain scores after the same adjustments showed that AUDIT scores classified as “High risk” and “Dependence likely” (compared with those classified as “Low risk”) were associated with “Health and Well-being” (p-values=0.008 and 0.001) (table 3). However, AUDIT scores were not associated with “Social Environment” (table 4). “Medium risk,” “High risk,” and “Dependence likely” were all associated with “Health Literacy and Communication” (p-values=0.008, 0.030, and 0.012) (table 5). Meanwhile, AUDIT scores were not associated with “Service Coordination” (table 6).

Table 3. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) four-domain scores (Health and Well-being)

	Regression	95% CI	P-value	Standardized

		coefficient			regression coefficient
AUDIT score					
	Low risk	Reference			
	Medium risk	0.634	−0.053 to 1.321	0.070	0.116
	High risk	1.136	0.299 to 1.973	0.008	0.153
	Dependence likely	1.713	0.737 to 2.689	0.001	0.191
Age		−0.020	−0.043 to 0.003	0.094	−0.117
Sex					
	Female	Reference			
	Male	0.180	−0.372 to 0.733	0.521	0.039
Education					
	≥High school	Reference			
	<High school	0.261	−0.262 to 0.783	0.327	0.057
Occupation					
	In work	Reference			
	Out of work	0.702	0.013 to 1.391	0.046	0.105
Physical activity					
	Exercising	Reference			
	Not exercising	0.613	−0.005 to 1.232	0.052	0.095
Smoking					
	Never smoker and ex-smoker	Reference			
	Current smoker	1.463	0.787 to 2.140	<0.001	0.222
Annual medical expenses (×10⁴ yen)		0.047	0.026 to 0.069	<0.001	0.221
Number of family members living with the patient		−0.227	−0.396 to −0.058	0.009	−0.131

Omnibus test: p-value <0.001 and Adjusted R^2 0.188

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

Table 4. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) four-domain scores (Social Environment)

		Regression coefficient	95% CI	P-value	Standardized regression coefficient
AUDIT score					
	Low risk	Reference			
	Medium risk	−0.204	−0.766 to 0.358	0.476	−0.045
	High risk	−0.328	−1.013 to 0.357	0.347	−0.054
	Dependence likely	−0.375	−1.174 to 0.424	0.356	−0.051
Age		−0.008	−0.027 to 0.011	0.393	−0.059
Sex					
	Female	Reference			
	Male	−0.453	−0.905 to −0.001	0.049	−0.120
Education					
	≥High school	Reference			
	<High school	0.640	0.213 to 1.067	0.003	0.170
Occupation					
	In work	Reference			
	Out of work	1.650	1.086 to 2.214	<0.001	0.300
Physical activity					
	Exercising	Reference			
	Not exercising	0.239	−0.267 to 0.745	0.354	0.045
Smoking					
	Never smoker and ex-smoker	Reference			
	Current smoker	0.367	−0.186 to 0.920	0.193	0.068
Annual medical expenses (×10⁴ yen)		0.021	0.003 to 0.039	0.021	0.120
Number of family members living with the patient		−0.170	−0.308 to −0.031	0.016	−0.119

Omnibus test: p-value <0.001 and Adjusted R^2 0.195

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

Table 5. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) four-domain scores (Health Literacy and Communication)

	Regression coefficient	95% CI	P-value	Standardized regression coefficient
AUDIT score				
Low risk	Reference			
Medium risk	0.708	0.185 to 1.231	0.008	0.164
High risk	0.707	0.070 to 1.344	0.030	0.121
Dependence likely	0.952	0.209 to 1.695	0.012	0.134
Age	0.016	−0.001 to 0.034	0.068	0.123
Sex				
Female	Reference			
Male	0.415	−0.006 to 0.835	0.053	0.114
Education				
≥High school	Reference			
<High school	0.530	0.133 to 0.928	0.009	0.146
Occupation				
In work	Reference			
Out of work	0.799	0.274 to 1.324	0.003	0.151
Physical activity				
Exercising	Reference			
Not exercising	0.431	−0.040 to 0.902	0.073	0.085
Smoking				
Never smoker and ex-smoker	Reference			
Current smoker	1.188	0.673 to 1.703	<0.001	0.228
Annual medical expenses (×10^4 yen)	0.047	0.030 to 0.063	<0.001	0.276
Number of family members living with the patient	−0.003	−0.131 to 0.126	0.968	−0.002

Omnibus test: p-value <0.001 and Adjusted R^2 0.247

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

Table 6. Multiple regression analysis of the Patient Centered Assessment Method (PCAM) four-domain scores (Service Coordination)

	Regression coefficient	95% CI	P-value	Standardized regression coefficient
AUDIT score				
Low risk	Reference			
Medium risk	−0.088	−0.603 to 0.426	0.736	−0.022
High risk	−0.155	−0.782 to 0.473	0.628	−0.029
Dependence likely	0.190	−0.541 to 0.921	0.610	0.029
Age	0.002	−0.015 to 0.020	0.791	0.019
Sex				
Female	Reference			
Male	0.473	0.059 to 0.887	0.025	0.142
Education				
≥High school	Reference			
<High school	−0.111	−0.502 to 0.280	0.577	−0.033
Occupation				
In work	Reference			
Out of work	0.663	0.147 to 1.180	0.012	0.137
Physical activity				
Exercising	Reference			
Not exercising	0.555	0.092 to 1.018	0.019	0.119
Smoking				
Never smoker and ex-smoker	Reference			
Current smoker	0.446	−0.061 to 0.953	0.084	0.093
Annual medical expenses (×10^4 yen)	0.044	0.028 to 0.060	<0.001	0.283
Number of family members living with the patient	−0.092	−0.219 to 0.034	0.152	−0.074

Omnibus test: p-value <0.001 and Adjusted R^2 0.132

CI, confidence interval; AUDIT, the Alcohol Use Disorders Identification Test.

DISCUSSION

More than 30% of people in the study had problematic alcohol consumption. Additionally, alcohol consumption and alcohol use disorders classified as "Dependence likely" were associated with patient complexity.

First, more than 30% of people in the study had problematic alcohol consumption. Assuming that those not included in this study (561 people, or the total population aged 20 years or older of 916 people minus 355 study participants) were non-problematic drinkers, this still means that the proportion of problematic drinkers on the island is more than 12%. A national survey reported that 1.3%, 10.6%, and 5.5% of Japanese women, men, and overall had AUDIT scores of 12 or more points; 0.6%, 5.3%, and 2.7% had 15 or more points; and 0.2%, 2.0%, and 1.0% had 20 or more points.[31] Our findings strongly suggest that the percentages of individuals on the island with potential and suspected alcoholism is much higher than the national average. This might be because there is a regionally specific drinking custom called "Otōri" on the island, where a group of people pass around a glass of alcohol.[35] This custom is broadly accepted and may cause alcohol-related problems.[36, 37]

Second, alcohol consumption and alcohol use disorders classified as "Dependence likely" were associated with patient complexity. AUDIT scores classified as "Dependence likely" were found to have an average of 2.48 points higher PCAM scores, which is corresponding to approximately 6.9% of the range of PCAM scores (36 points: the highest score 48 minus the lowest score 12), compared with those classified as "Low risk." Additionally, we did not detect any significant differences in the strength of

relationships with AUDIT scores between the variables because the 95% CIs of standardized regression coefficients overlapped. Other variables not included in this study could also lead to the relatively small impact of AUDIT scores on PCAM scores. Much previous research has examined and clarified the relationship between alcohol consumption and different individual physical and psychological conditions and social circumstance.[3-13] However, this is the first study to provide a holistic perspective on the detrimental impact of alcohol consumption and alcohol use disorders on patient complexity.

AUDIT scores classified as "High risk" and "Dependence likely" were associated with "Health and Well-being" on the PCAM four-domain scores. This is consistent with previous findings that alcohol causes physical harm.[3, 5, 6] However, a relationship between alcohol consumption/alcohol use disorders and "Social Environment" was not established in this study. Considering the fact that drinking alcohol plays roles in creating and maintaining social identity and relationships,[38-42] these roles presumably offset the well-known negative effect of alcohol on "Social Environment."[3, 4, 7-13] Limited health literacy, such as underestimation of drinking alcohol and lack of knowledge of resources to help with problematic drinking, are also associated with harmful drinking[43]. This is consistent with the result that "Medium risk," "High risk," and "Dependence likely" were all associated with "Health Literacy and Communication." This study did not find a relationship between alcohol consumption/alcohol use disorders and "Service Coordination." This is probably because there is only one medical institution on the island. The limited number of services enable good interconnection and coordination. This coordination may mitigate the harmful impact of alcohol such as reduced accessibility to medical services and worse quality of medical care, which are related to "Service Coordination." These findings could therefore be linked to the relatively small impact of AUDIT scores on PCAM scores.

Despite the small sample size, the high prevalence of problematic alcohol consumption on the island enabled the study to clarify the relationship between alcohol consumption/alcohol use disorders and patient complexity. Internationally, estimates of prevalence of alcohol dependence, as a percentage of total adult population aged 15 years or more, are reported to be high in Eastern European countries such as Belarus (11.0%) and Hungary (9.4%), and in Russia (9.3%).[3] These figures are comparable with those in our study. We found that problematic drinking was associated with patient complexity, and it is not hard to imagine that a high proportion of problematic drinking may lead to an increase in patients with high complexity in other societies and regions. However, the effect of alcohol drinking on patient complexity will vary across societies and regions. This remote island has the unique custom of "Otōri", and it is thought likely that the specific circumstances of each society and region mediate between problematic alcohol drinking and patient complexity.

This study had several limitations. First, it was conducted on a remote island in Okinawa, Japan, the community of which is ethnically, religiously, culturally, and politically homogeneous. Both alcohol intake and patient complexity of participants could have been affected by these factors in a biased direction; thus, the association between them may have been under- or over-estimated. This limits generalizability of the present findings. Second, this was a cross-sectional study; thus, a causal relationship between alcohol consumption/alcohol use disorders and patient complexity cannot be inferred. Third, although consecutive sampling was used, some otherwise eligible patients were not enrolled: 83.3% of eligible patients were included. This failure in sampling could have led to selection bias. Especially, the main reason for judging a patient's participation as likely to unfavorably impact the patient–physician relationship was that they had confirmed or suspected mental or personality disorders. These disorders are inclined to cause biopsychosocial problems (i.e., high patient

complexity). Thus, their exclusion could have resulted in underestimation of patient complexity. Most patients from whom informed consent was not obtained because the principal investigator was absent or there were too many patients waiting for a consultation made only a single visit to the clinic (for mild acute diseases, such as upper respiratory inflammation or gastroenteritis) during the registration period. Exclusion of these low complexity, or otherwise-healthy, patients would obviously have resulted in overestimation of patient complexity. Finally, patient complexity has a multidimensional structure and PCAM is only one method. Patient complexity might involve other factors that PCAM does not include and can also be measured by other methods such as patient self-reporting. Thus, patient complexity as scored by PCAM might have been under- or over-estimated.

FUTURE RESEARCH

The development of a Japanese version of PCAM and the examination of its validity and reliability in a primary care setting are planned to promote dissemination of the concept of patient complexity in Japan.

CONCLUSION

Alcohol consumption and alcohol use disorders classified as “Dependence likely” are associated with patient complexity.

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Contributors

YS designed the study; collected, analyzed, and interpreted the data; and prepared and reviewed the manuscript. MM contributed to design of the study, analysis and interpretation of the data, and review of the manuscript. HY contributed to design of the study and review of the manuscript.

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Disclaimer

The sponsor of this study had no role in the study design; the study conduct: collection, analysis, or interpretation of the data; the manuscript preparation; or the decision to submit the manuscript for publication.

Competing interests

YS and HY are former trainees of the Jikei Clinical Research Program for Primary-care. MM is a program director of the Jikei Clinical Research Program for Primary-care.

Ethics approval

This study was approved by the Ethics Committee of Okinawa Miyako Hospital (approved on February 8th, 2018) and the Ethics Committee of The Jikei University School of Medicine (the acceptance number: 30-412 (9433)).

Data sharing statement

No additional data are available.

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Figure 1. A flow chart detailing the process of inclusion and exclusion of study participants

Figure 2. Distribution of PCAM and AUDIT scores

PCAM, the Patient Centered Assessment Method; AUDIT, the Alcohol Use Disorders Identification Test.

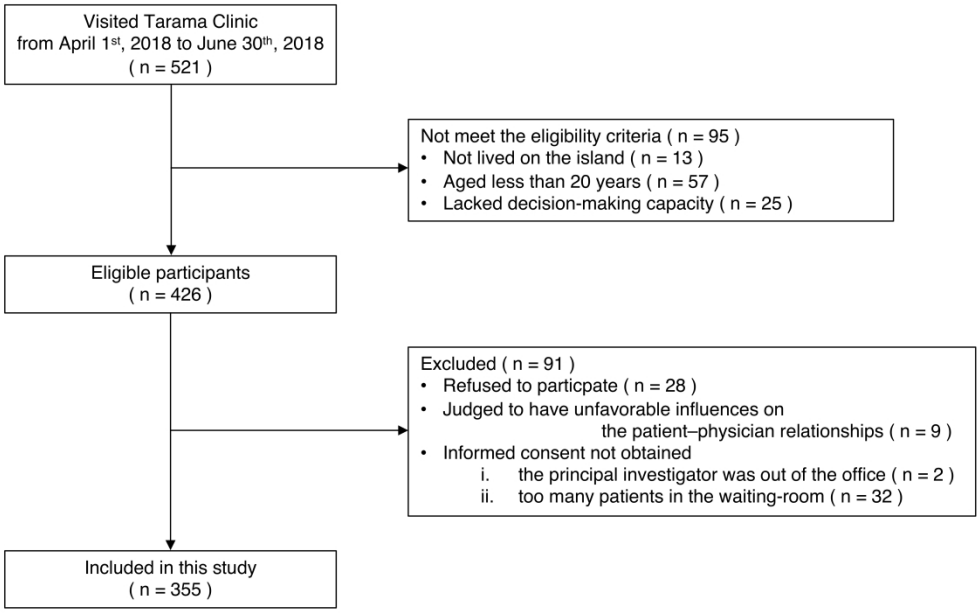

Figure 1. A flow chart detailing the process of inclusion and exclusion of study participants

209x135mm (600 x 600 DPI)

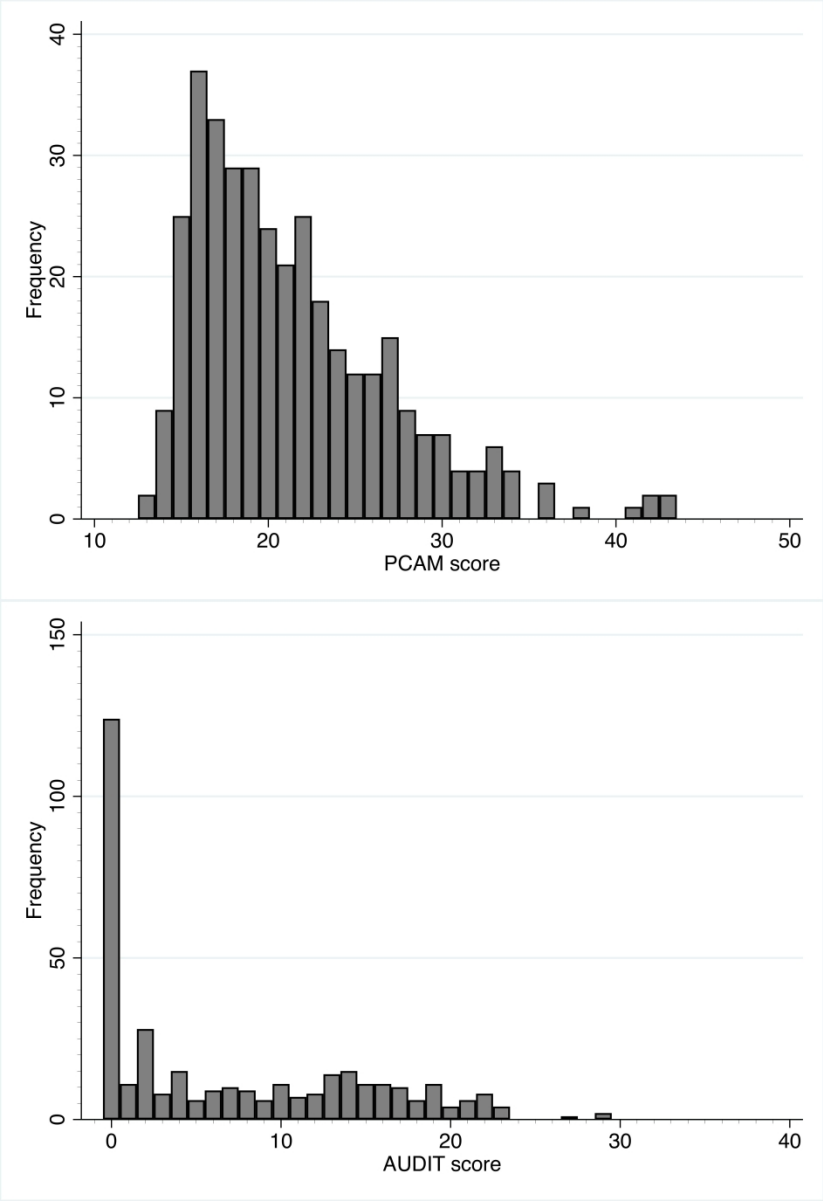

Figure 2. Distribution of PCAM and AUDIT scores
PCAM, the Patient Centered Assessment Method; AUDIT, the Alcohol Use Disorders Identification Test.

139x203mm (600 x 600 DPI)

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In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1, 2
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	4, 5, 6
Objectives	#3	State specific objectives, including any prespecified hypotheses	5, 6
Methods			
Study design	#4	Present key elements of study design early in the paper	6
Setting	#5	Describe the setting, locations, and relevant dates,	6, 7

		including periods of recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7, 8, 9
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	7, 8, 9
Bias	#9	Describe any efforts to address potential sources of bias	6, 7 (population-based), 7 (consecutive inclusion), 8 (elimination of inter-rater variability)
Study size	#10	Explain how the study size was arrived at	9, 10
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	7, 8, 9, 10
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	10
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
Statistical methods	#12c	Explain how missing data were addressed	11 (no missing values)
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
Statistical methods	#12e	Describe any sensitivity analyses	Sensitivity analyses were not performed
Results			

Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	10, 11, 26 (Figure1)
Participants	#13b	Give reasons for non-participation at each stage	10, 11, 26 (Figure1)
Participants	#13c	Consider use of a flow diagram	26 (Figure1)
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	11, 12
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	11 (no missing values)
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	12
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12, 13, 14, 15, 16
Main results	#16b	Report category boundaries when continuous variables were categorized	7, 8, 9
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	Other analyses were not performed
Discussion			
Key results	#18	Summarise key results with reference to study objectives	16
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	18, 19

Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	18, 19
Generalisability	#21	Discuss the generalisability (external validity) of the study results	18
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20