The 4 item Concise Aging adults Smell Test (4CAST) to screen for olfactory-related comorbidities

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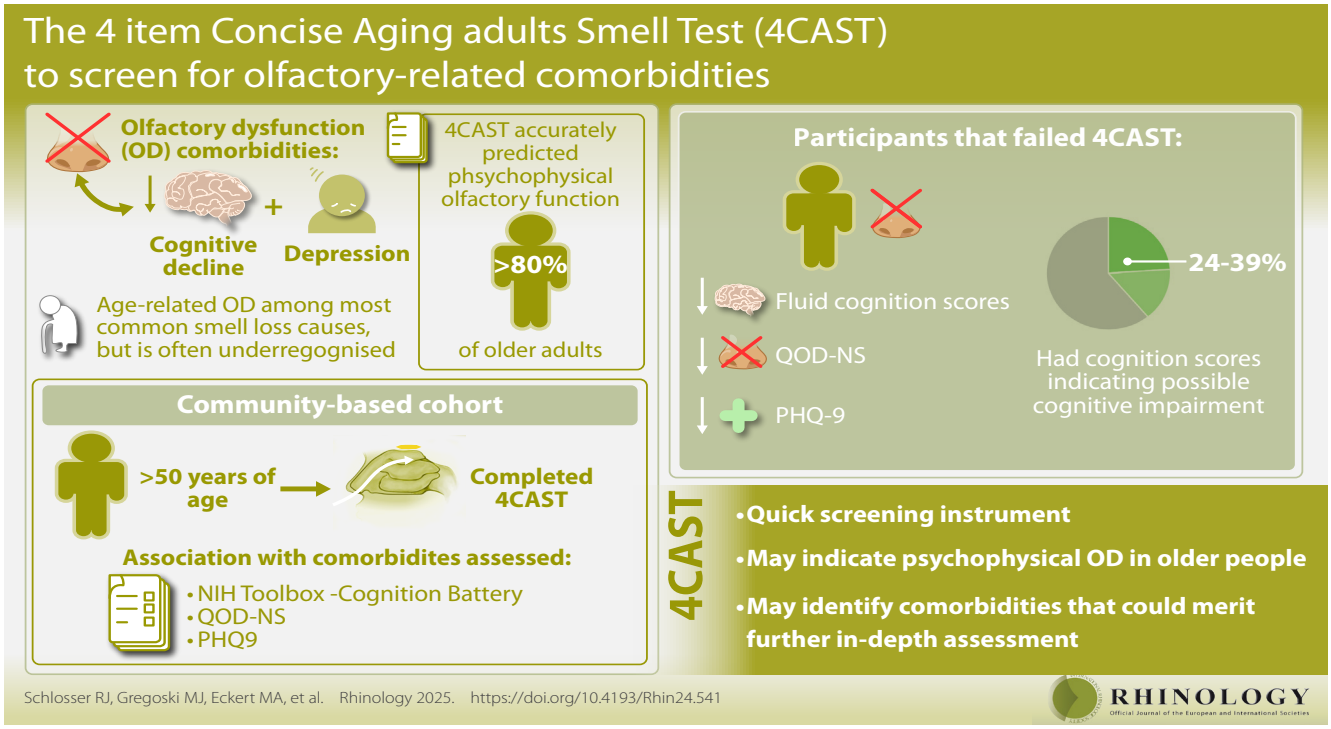

Abstract

Background: Olfactory dysfunction (OD) is associated with numerous comorbidities, including cognitive decline and depression. Age-related OD is one of the most common causes of smell loss, but it is often underrecognized. In previous research the 4 item Concise Aging adults Smell Test (4CAST) accurately predicted psychophysical olfactory function in over 80% of older adults. This study examined the relationship of 4CAST to olfactory-related comorbidities.

Methods: A community-based cohort of adults over 50 years of age completed the 4CAST. Its association with olfactory-related comorbidities was assessed using: 1) National Institutes of Health Toolbox -Cognition Battery; 2) Questionnaire for Olfactory Disorders-Negative Statements (QOD-NS); 3) Patient Health Questionnaire 9 (PHQ9); 4) DeJong Giervald (DJG) social isolation scale; and 5) Mini-Nutritional Assessment (MNA).

Results: Participants who failed the 4CAST had worse median scores for all measures of fluid cognition, QOD-NS, and PHQ9. Of participants who failed the 4CAST, 24-39% had cognition scores suggestive of possible cognitive impairment. Participant's 4CAST results did not differ in crystallized cognition (Picture Vocabulary Test), total DJG and MNA scores.

Conclusion: The 4CAST is a quick screening instrument that may indicate psychophysical OD in older adults and identify olfactory-related comorbidities (i.e. cognitive decline, depression) that may merit further in-depth assessments.

Key words: olfaction, aging, health screen

Introduction

Population-based studies using olfactory identification screening have estimated OD prevalence to be as high as 50% in older adults, with others estimating that all adults over 65 years of age have some form of OD [1,2]. This amounts to at least 50 million Europeans with decreased smell in 2020 and this number expected to grow with our aging population. Olfactory loss often goes undetected and up to 74% of older adults with OD are not aware they have a deficit [3]. Despite the lack of personal awareness, OD in aging is a stronger predictor of mortality than heart failure, lung disease, and cancer with a 5 year mortality rate of 40% in anosmics [4]. While not necessarily causal, reasons for the association between OD in aging and mortality are not clear. Thus, screening for OD and related co-morbidities has high public health relevance.

Despite the high prevalence of OD and its important impacts on daily life, screening for olfactory loss and associated comorbidities in aging adults on a population level is challenging. Given the lack of awareness, most aging adults with smell loss will not seek out medical care. Diagnosis requires formal psychophysical olfactory testing, such as the Sniffin' sticks or 40-item Smell Identification Test kits, that are usually only performed by otolaryngology providers. The limited availability of testing and associated time/cost burden limits formal psychophysical testing on a large-scale population level. In addition, screening for olfactory-associated comorbidities such as cognitive impairment, mental health conditions, isolation, and poor nutrition would require additional testing for each comorbidity, making this impractical. These comorbidities were examined due to their common prevalence in older adulthood, as the World Health Organization estimates their prevalence between 10 and 25% [5], and their known associations with OD. The 4-item Concise Aging adults Smell Test (4CAST) is a brief screening instrument that has been shown to identify psychophysical OD in over 80% of older adults [6]. Thus, the goal of this study was to determine whether screen failures on the 4CAST could also potentially indicate olfactory dysfunction-related comorbidities.

Materials and methods

Study sample

Community dwelling adults ≥50 years were recruited from the greater Charleston, South Carolina area using physical flyers, online advertisements, or word of mouth. Importantly, none of the participants were recruited based on their perceived ability to smell or olfaction-related complaints, nor were they recruited from a specialty smell loss clinic. Participants completed questions related to demographics, olfactory exposures and comorbidities. Participants were excluded if they had respiratory tract conditions such as allergies, viral infection or sinusitis in the last 2 weeks that could temporarily impact olfaction, and for a personal history of neurodegenerative disease. In addition, all participants completed the Telephone Interview for Cognitive Status (TICS) to screen for and exclude undiagnosed dementia. Scores <22 have shown sensitivity and specificity of 88% and 87% respectively for differentiating dementia from normal cognition [7].

Measures

Olfaction

Psychophysical olfaction was assessed using the Sniffin' sticks (Burghart Messtechnik, Holm, Germany) [8] which measures threshold, discrimination and identification (TDI). The 4CAST was developed and validated using a model based upon age, diabetes type II status, and two olfaction Visual Analog Scale (VAS) responses, each with their respective anchors: 1) Overall smell (0=excellent ability to smell and 10= poor ability) and 2) Safety due to sense of smell (0=no impact upon safety due to gas leak, smoke, etc and 10=biggest impact possible). VAS were completed on paper by placing a vertical line on a horizontal line 10 cm long. VAS values were then converted to a 0 to 100 scale for modeling purposes. The 4CAST model is calculated as follows: The summation variable=(age*0.043) + (VAS ratesmell*0.028) + (VAS safety*0.020) + (1.3 if yes to type II DM)-5.117. Odds=e raised to power of summation variable. Probability=Odds/(Odds+1). If probability > 0.50, ie 50%, then 4CAST result is fail, indicating likely dysosmia.

Olfactory dysfunction-related comorbidities

Cognition. Cognition was assessed in-person using the National Institutes of Health Toolbox Cognition Battery (NIHTB-CB version 2) [9] administered via iPads (10.2" 9th Gen Model No. A2602). The NIH Toolbox yields two Composite Scores: Fluid Cognition and Crystallized Cognition. Fluid Cognition (i.e. executive function, episodic memory, language, processing speed, working memory, attention) cognition is sensitive to changes in brain aging and in a variety of neurological, or systemic, disorders that alter brain structure and function. Fluid cognition includes 5 tests: flanker, dimensional change card sort, picture sequence memory, list sorting and pattern comparison. We evaluated all 5 parameters of fluid cognition to obtain a comprehensive assessment of this subdomain. Crystallized Cognition, in contrast, reflects accumulated knowledge and skill and is relatively consistent across the adult life span [10]. It was not anticipated to change due to aging or olfactory dysfunction. In this study, we only administered the NIH Toolbox Picture Vocabulary Test (PICVOC) as an indicator of Crystallized Cognition due to time constraints. Oral reading recognition is a component of the crystallized cognition portion of the NIHTB-CB, however, it was not assessed due to time constraints and anticipated lack of correlation to age-related olfactory dysfunction.

We evaluated three different parameterizations of both the Fluid

Table 1. Differences in cognition and health-related comorbidities stratified by 4CAST result.

Olfactory-related comorbidities	4CAST			
	Pass (n=159)	Fail (n=29)	Total (N=188)	p-value
Cognition				
Fluid Cognition, uncorrected standard score	98(16)	92(16)	96(16)	.001
Fluid Cognition, age-corrected standard score	105(23)	97(26)	104(23)	.021
Fluid Cognition, fully corrected T-score	53(15)	48(18)	53(15)	.011
PICVOC, uncorrected standard score	113(13)	112(13)	112(13)	.966
PICVOC, age-corrected standard score	106(18)	96(20)	104(22)	.822
PICVOC, fully corrected T-score	53(14)	43(15)	51(15)	.926
Health-related Comorbidities				
QOD-NS	2(3)	11(13)	3(3)	.001
PHQ9	1(4)	3(4)	1(4)	.044
DJG total	1(2.0)	1(2.5)	1(2)	.193
MNA total	13(2)	13(2)	13(2)	.698

All values in the table are Medians (IQR). Abbreviations: 4CAST=4 item Concise Aging adults Smell Test; PICVOC=Picture Vocabulary Test; QOD-NS=Questionnaire for Olfactory Disorders-Negative Statements; PHQ9=Patient Health Questionnaire 9; DJG= DeJong Giervald (DJG) social isolation scale; MNA=Mini-Nutritional Assessment; PICVOC=Picture Vocabulary; IQR=Interquartile range

Cognition Composite and the PICVOC, specifically nationally normed Age-Corrected and Uncorrected Standard Scores (Mean=100, SD=15) and Fully Corrected T-Scores (accounting for age, sex, race/ethnicity, educational attainment; Mean=50, SD=10), where higher scores indicate better cognitive abilities. One standard deviation or more below the mean for each of these parameters (i.e. Standard Score ≤ 85, T-score ≤ 40) corresponds to the ≤16th percentile, thus statistically indicating individuals who may have or be at risk for cognitive impairment.

Health-related outcomes

Patient reported outcome measures (PROMs) were used to examine the degree to which 4CAST could predict quality of life, mental health, isolation and nutrition screens, as defined by: 1) olfactory-specific quality of life (QOL), the Questionnaire for Olfactory Disorders-Negative Statements (QOD-NS); 2) depression-specific QOL, the Patient Health Questionnaire 9 (PHQ9); 3) social isolation, the DeJong Giervald (DJG) social isolation scale; and 4) nutrition, the Mini-Nutritional Assessment (MNA). All PROMs are validated for use in aging adults [11-15].

Statistical analysis

Statistical analyses were completed using SPSS version 28 (IBM corporation, Armonk, NY, USA). All continuous variable scores (i.e. cognitive score outcomes and PROMS) were examined with Kolmogorov-Smirnoff test for normality. Variables with significant deviations from normality ($p < .05$) were examined with independent sample Mann-Whitney U tests with 4CAST groups (i.e. pass vs fail) serving as the independent groups. Outcomes that did not significantly deviate from normality were examined using independent samples t-tests with 4CAST groups (i.e. pass vs fail) serving as the independent groups. In addition, normality distributed continuous outcomes were examined using Levene's Test for equality of variances. If significant variance differences were found between groups, results were reported based on adjusted degrees of freedom using the Welch-Satterthwaite method. For consistency, Medians and Interquartile ranges were calculated and presented for all continuous variables. Categorical variables based on cutoff scores for Cognitive measures and PROMS were assessed using χ^2 analyses or Fisher's exact tests as appropriate and frequencies and percentages across 4CAST groups are presented. Due to the non-parametric nature of the PROM analyses, effect sizes are not presented.

Results

Demographic and olfactory status

A total of N=190 participants were enrolled [6], they had a mean age of 65.2 (SD=8.7) years (range: 50-85), and 70% self-identified as having female sex at birth. Self-identified racial categories across the sample included White (n = 162; 85.3%), Black (n = 26; 13.7%) and other (n = 2; 1.0%). The mean total threshold, discrimination, identification score (TDI) across the cohort was 29.7 (SD=7.5), including mean Threshold score of 7.4 (SD=3.6), Discrimination of 10.9 (SD=2.9), and Identification of 11.4 (SD=2.9). Participants who passed the 4CAST screen had a mean TDI of 32.8 (4.6), while those who failed the 4CAST screen had mean TDI of 19.9 (6.2). Three or fewer participants failed to complete all testing. A total of 16 subjects were excluded for im-

Table 2. Prevalence of potential olfactory-related comorbidities stratified by 4CAST result.

Olfactory-related comorbidities	4CAST				Cutoffs
	Pass	Fail	Totals	P-Value	
Cognition					
Fluid cognition, uncorrected standard score	26/159 (17%)	11/29(39%)	37/188	.007	<85 suggests impairment
Fluid cognition, age-corrected standard score	12/159 (7.5%)	7/29 (24%)	19/188	.015	<85 suggests impairment
Fluid cognition, fully corrected T-score	18/158 (11%)	9/29 (31%)	27/187	.017	<40 possible impairment
Health-related comorbidities					
QOD-NS	1/160 (<1%)	12/29 (41%)	13/189	.001	>12.5 indicates OD
PHQ9	26/160	6/29	32/189	.59	>5 merits followup
DJG total	58/160	12/29	70/189	.60	No defined cutoff
MNA total	28/158	5/29	33/187	.95	<11 risk of malnutrition

4CAST=4 item Concise Aging adults Smell Test; QOD-NS=Questionnaire for Olfactory Disorders-Negative Statements; PHQ9=Patient Health Questionnaire 9; DJG= DeJong Giervald (DJG) social isolation scale; MNA=Mini-Nutritional Assessment; OD=Olfactory dysfunction.

munodeficiency (N=3), immunomodulatory medications (N=6), neurocognitive disorder (N=3), outside of age range (N=1), non-fluent English (N=1), memory loss (N=1) and unable to complete cognitive screen (N=1).

Cognition

Older adults who failed the 4CAST screen had significantly worse uncorrected, age-corrected, and fully corrected Fluid Cognition scores than those who passed (Table 1). For instance, participants who passed the 4CAST had a median Fluid Cognition T-score of 53, which was half a standard deviation higher than the median score of those who failed the 4CAST (T-score=48). When examining the prevalence of participants with Fluid Cognition scores that suggest the presence or risk of cognitive impairment (i.e. scores ≤ 16th percentile), between 24-39% of adults who fail the 4CAST had scores in this range (Table 2). This contrasts with 7.5-17% of participants who passed the 4CAST and had Fluid Cognition scores in this range, which is statistically more consistent with the normative estimate (i.e. ≤16th percentile). In contrast to Fluid Cognition scores, we found no differences in the PICVOC (Table 1).

Health-related comorbidities

Olfactory-specific quality of life and depression were also significantly different between participants who passed versus those who failed the 4CAST screen. As expected, participants who failed 4CAST screening had a lower QOD-NS score than those who passed (Medians: 11 vs 2; p=0.001, Independent-Samples Mann-Whitney U = 3624.500), with 41% of participants being above the QOD-NS cutoff of 12.5, which has been previously associated with psychophysical OD in chronic rhinosinusitis [16].

PHQ9 scores were also significantly higher for participants who failed 4CAST screening compared those who passed (Medians: 3 vs 1; p=0.044, Independent-Samples Mann-Whitney U = 2853.500). Other PROMs examining social isolation and malnutrition were not significantly different between the 4CAST fail and pass screening groups (Table 1). Thus, while isolation and malnutrition may be present in roughly 37% and 17% of the overall cohort (Table 2), these conditions do not appear be related to 4CAST results.

Discussion

Olfactory loss in the aging population may be considered like other "silent" diseases, such as hypertension or hypercholesterolemia. These d iseases typically go unrecognized by patients but can have significant impacts if not recognized. Screening is performed not simply to improve referral for further evaluation and treatment of these silent diseases, such as improving blood pressure or cholesterol, but rather to also prevent or treat associated conditions that impact quality of life and longevity. Similarly, while the 4CAST screening instrument was developed and validated specifically to detect psychophysical olfactory loss among aging adults, it appears to have additional sensitivity as a rapid screening tool that may indicate a variety of olfactory-related disorders that also impact quality of life.

The concept behind development of the 4CAST and its potential clinical utility is its ability to serve as a routine screening instrument for all individuals over 50 regardless of perceived smell ability or concern. It is not meant to replace screening for cognitive impairment, depression or other olfactory-related conditions. Rather, this study demonstrates that this simple 4 item

Table 3. Correlation between individual 4CAST items and health-related comorbidities.

Olfactory-related comorbidities	4CAST variables			
	Age	T2DM	VAS rate smell	VAS safety
Cognition				
Fluid Cognition, uncorrected standard score	-.495 p<.001	-.059 p=.423	-.288 p<.001	-.253 p<.001
Fluid Cognition, age-corrected standard score	-.151 p=.038	-.036 p=.423	-.221 p=.002	-.228 p=.002
Fluid Cognition, fully corrected T-score	-.225 p=.002	-.008 p=.423	-.274 p<.001	-.229 p=.002
PICVOC, uncorrected standard score	.091 p=.213	-.046 p=.531	.023 p=.750	.001 p=.986
PICVOC, age-corrected standard score	.016 p=.016	-.036 p=.620	.019 p=.798	.004 p=.952
PICVOC, fully corrected T-score	.074 p=.311	.088 p=.230	-.028 p=.708	.032 p=.661
Health-related Comorbidities				
QOD-NS	.162 p=.025	.022 p=.760	.598 p<.001	.625 p<.001
PHQ9	.091 p=.212	.046 p=.530	.124 p=.090	.186 p=.010
DJG total	.137 p=.059	.016 p=.830	.100 p=.171	.174 p=.017
MNA total	.013 p=.860	.014 p=.845	-.171 p=.019	-.114 p=.119

All values in the table are Pearson's Product-Moment Correlations across Age VAS ratesmell and VAS safety with significant values bolded. Values for T2DM are point-biserial correlations. Abbreviations: 4CAST=4 item Concise Aging adults Smell Test; PICVOC=Picture Vocabulary Test; QOD-NS=Questionnaire for Olfactory Disorders-Negative Statements; PHQ9=Patient Health Questionnaire 9; DJG= DeJong Giervald (DJG) social isolation scale; MNA=Mini-Nutritional Assessment; PICVOC=Picture Vocabulary.

screening tool, which identifies individuals most likely to have reduced smell, may also identify individuals who may benefit from further specialized evaluation of these related conditions if they are suspected. For example, when older individuals fail the 4CAST, clinicians can inform those individuals that: 1) more detailed olfactory testing is warranted and 2) that they may be at risk for olfactory-associated comorbidities. Individuals who pass the 4CAST will have no need for additional testing, especially psychophysical olfactory testing. It must be noted that as with all screening instruments, there are subjects who pass but may still have comorbidities. For example, of the subjects who passed the 4CAST, between 7.5 and 17% still had fluid cognition scores suggestive of impairment (Table 2). Thus, there may be patients who have cognitive impairment or other comorbidities that are not associated with olfactory loss or that are not detected by the 4CAST instrument. Physicians should always consider additional in depth testing if an individual patient experiences symptoms of these comorbidities regardless of 4CAST results.

The 4CAST is made up of 2 objective variables and 2 subjective variables. This likely improves its performance over studies which rely solely upon single variables, such as age or subjective olfactory questions. Systematic reviews in normal elderly adults have shown subjective awareness of olfactory impairment in 23% or less [17]. Incorporation of additional factors into the 4CAST, such as age and presence of T2DM, improves the performance of the 4CAST, as validation studies demonstrate detection of greater than 80% of older adults with OD, a dramatic improvement over the 23% noted using solely subjective questions. Similarly, while age is one of the 4 included variables, it is important to note that the 4CAST correlations for fluid cognition remained even after correcting for age and other demographic factors. Thus, while both olfactory function and cognition are known to decline with aging, aging alone does not appear to be the sole driving factor in our findings. Examination of the 4CAST model demonstrates that if age is the only factor examined, ie the subject does not have T2DM and no subjective olfactory loss, then subjects would need to be 119 years old to fail the 4CAST. In addition, other comorbidities such as vascular disease or hypertension have been associated with olfactory and cognitive function. However, in our validation studies of the 4CAST, these other comorbidities were not as predictive of psychophysical olfactory dysfunction as the four variables included in 4CAST. Other individual factors of the 4CAST, such as T2DM, have been shown to be associated with cognition measures, but only the discrimination component of TDI [18]. In our study, we did not find that T2DM as a single variable, was associated with any of our cognitive variables (Table 3). Regarding specific aspects of olfactory testing, our development and validation cohorts used the composite TDI score and SIT40. Given the ultimate desire to create a screening instrument and follow up psychophysical olfactory testing that could be completed remotely, we did not examine the specific correlation between individual items of the Sniffin' Sticks and individual items of the 4CAST instrument. This is certainly an area for future study. Finally, while prior studies have used brief psychophysical

tests for screening, these tests do require getting the test kits to patients and personnel to grade the results. This is especially challenging for Sniffin' Sticks which must be completed in person. The hope is that another advantage of the 4CAST is the potential to complete this instrument remotely.

There are several novel treatments being investigated specifically for olfactory loss, including smell training, nerve stimulation, stellate ganglion nerve blocks, and nutritional and pharmacologic agents. Some reports even suggest that treatments for OD, such as smell training, may not only improve olfaction, but also cognition and depression [19-21]. The impact of various therapies for age-related OD upon other comorbidities such as social isolation and nutrition are uncertain. Thus, there is a need for rapid, validated screening instruments to identify potential research participants with OD and the impact of treatments for OD upon other medical conditions, such as cognitive decline and depression.

Strengths of the current study include a large sample size, in-depth olfactory and cognition testing and a variety of olfactory-related PROMs. Weaknesses of our study include limited geographic region from which we recruited this convenience sample, and lack of detailed clinical assessments of depression, nutrition and cognition to verify the accuracy of these associations (that were based on screening tests for these conditions).

Conclusion

These preliminary findings justify subsequent investigations to enhance the generalizability and utility of the 4CAST, such as via studies with larger, more geographically and demographically diverse populations.

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Authorship contribution

Contributions: RJS, ZMS, MG, MAE and AB: acquisition, analysis, or interpretation of data; drafts and revisions during the writing process; final approval of the article before submission to Rhinology.

Conflict of interest

ZMS is a consultant for Optinose, medical director for Healthy Humming and has received grant support from Regeneron. RJS is a consultant for Optinose, Stryker, Cyrano and medical director for Healthy Humming. MG, MAE and AB have no disclosures. This work was done independent of any conflicts.

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