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Oral health and orofacial pain in older people with dementia in UK care settings

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APPENDIX 1 | Sample size calculation.

The following simple formula was used:
$n = (Z^2P(1-P))/d^2$

where n = sample size,
Z = Z statistic for a level of confidence
P = expected prevalence or proportion (in proportion of one)
d = precision

For the level of confidence of 95%, Z value is 1.96.
With an assumed prevalence of 12%, P is 0.12.
With a precision of +/-5 percentage points (0.05), d should be set at 0.05.

$n = (1.96^2 \times 0.12 \times (1-0.12))/0.05^2 = 162$

4

Orofacial pain during rest and chewing in people with dementia admitted to acute hospital wards

Validity testing of the Orofacial Pain Scale for Non-Verbal Individuals

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Abstract

Aims
To assess the validity of the resting and chewing components of the recently developed observational diagnostic tool, the Orofacial Pain Scale for Non-Verbal Individuals (OPS-NVI).

Methods
This cross-sectional observational study was carried out in two UK hospitals. A total of 56 participants with dementia who were admitted to the acute hospital were observed for 3 minutes during rest and during chewing, and the OPS-NVI was used to identify orofacial pain. Afterwards, the participants were asked about the presence of orofacial pain using self-report pain scales. The sensitivity, specificity, and area under the receiver operating curve (AUROC) of the OPS-NVI were calculated for each activity. Spearman coefficient was calculated to assess the correlation between the number of positively scored behavior items of the OPS-NVI and the presence of orofacial pain according to self-report.

Results
According to the OPS-NVI, orofacial pain was present in 5.4% of participants during rest and in 9.1% participants during chewing. According to self-report. the prevalence of orofacial pain was 5.4% during rest and 10.7% during chewing. The specificity of the OPS-NVI was 98.1% to 100%, the sensitivity was 66.7% to 83.3%, and the AUROC was 0.824 to 0.917. The predictive validity showed a strong correlation (0.633 to 0.930, *P*<.001) between the number of positive behavior items and the self-reported presence of orofacial pain.

Conclusion
The resting and chewing components of the OPS-NVI showed promising concurrent and predictive validity. Nevertheless, further validation is required and highly recommended.

Keywords
Dementia; Facial Pain; Hospital; Observation; OPS-NVI; Toothache; Validation

Introduction

A 2015 report from the United Nations on global ageing shows a substantial recent increase in the number of older people [1]. In 2050, the population of older people will double in size, resulting in a projected estimate of 100 million people having dementia [1, 2].

Almost half of people with dementia experience pain daily, which can be difficult to detect and is therefore likely to be undertreated [3-5]. Undetected pain may lead to distress and cause aggression, depression, agitation, or vocalisations [6, 7]. Undertreated pain may also increase the risk of delirium and decreases quality of life [8, 9].

Orofacial pain, originating from the teeth, the joints and muscles of the masticatory system, or other non-odontogenic tissues [10, 11] is common in older people. Previous studies comparing the prevalence of orofacial pain in people with and without dementia showed a prevalence of 7.4 to 21.7% in people with dementia and a prevalence of 6.7 to 18.5% in people without dementia [12-14].

Adequate diagnosis is essential as a first step in provision of effective treatment. The gold standard for the diagnosis of pain is self-report [15, 16]. For a successful self-report pain assessment, it is important that the person is able to verbally communicate [8]. However, in people with severe dementia, progressive decline of verbal communication may result in inability to answer simple yes-or-no questions [8]. Therefore, self-report pain scales are not suitable in this population, and direct observation is needed [3, 8].

There is a lack of research and instruments dealing with the assessment of dental and orofacial pain in people with dementia who are no longer able to communicate verbally [11]. Therefore, the Orofacial-Pain Scale for Non-Verbal Individuals (OPS-NVI) has recently been developed to diagnose orofacial pain in people who are unable to communicate verbally [3]. The OPS-NVI is focused on behavior items to explore possible nonverbal communication to express orofacial pain. The OPS-NVI consists of four components: resting; chewing; drinking; and oral hygiene care [3].

The aim of this study was to assess the concurrent and predictive validity of the resting and chewing components of the OPS-NVI.

Materials and methods

Design and participants

All participants in this cross-sectional cohort study were observed during a single assessment in two different hospitals, both in London, UK (one in central London, one in suburban London). Participants were included if they were □ 70 years of age; had a diagnosis of dementia in their clinical notes; their command of the English language was sufficient to complete the study rating; and they were able to self-report the presence or absence of pain. Nursing staff identified potential participants and asked if they could be approached by a researcher. Patients who indicated either verbally or nonverbally that they did not wish to participate were excluded. Patients with delirium, those who were moribund or comatose, or those with clinical concerns that ward nursing staff felt should preclude them being approached were excluded as well.

Ethics

The procedure for obtaining informed consent complied with capacity legislation governing England and Wales (Mental Capacity Act 2005, Sections 30-34). Written informed consent was obtained from the participants with the capacity to consent. If the participant did not have capacity to consent, a personal or professional consultee was asked to follow a structured procedure to give agreement for the person's participation in the study and to sign their consent. The London Queen Square Research Ethical Committee and the UK Health Research Authority reviewed and approved this study (17/LO/0430).

Instruments

Demographic information was collected, including age, gender, ethnicity, marital status, number of years in general education, and highest completed level of education. The OPS-NVI consists of four components: resting; chewing; drinking; and oral hygiene care [3]. For this study, the components resting and chewing were used. During the cross-sectional assessment, the participant was observed for 3 minutes during rest and for 3 minutes during eating a routine meal or snack. A score sheet of the OPS-NVI was completed during or immediately after the observation for each component. Behavior items in the categories facial activities, body movements, vocalizations, and specific were scored as yes, no, or not applicable. These items are shown in *Table 1*. For each activity, the estimated pain intensity was rated with a number from 0 to 10, with 0 indicating no pain and 10 indicating pain as bad as it could possibly be. The intensity of the perceived pain was rated by the researcher [17].

TABLE 1 | Behavior items on the Orofacial Pain Scale for Non-Verbal Individuals.

Category	Behavior	Description
Facial activities	Frowning	Lowering and drawing brows together
	Narrowing or closing eyes	Narrowed eyes with tension around the eyes; not just blinking
	Raising upper lip	Upper lip raised, nose may be wrinkled
	Opened mouth	The lips are parted, jaw is dropped
	Tightened lips	Lips are pressed together and appear more narrow
Body movements	Resisting care	Resisting care, being uncooperative
	Guarding	Protecting affected area, holding body part, avoiding touch, moving away
	Rubbing	Tugging or massaging affected area
	Restlessness	Fidgeting, wringing hands, rocking back and forth
Vocalizations	Using offensive words	Cursing, swearing, or using foul language
	Using pain-related words	Using pain words, like 'ouch', 'ow', or 'that hurts
	Screaming/shouting	Using a loud voice to express sounds/words
	Groaning	Making a deep, inarticulate sound
Specific	Restricting jaw movement	Making smaller jaw movements than possible
	Refusing prosthetics	Removing prosthetics again and again
	Drooling	Flowing of saliva outside the mouth

After observation with the OPS-NVI, the participants were asked if they experienced pain in the orofacial area during each activity. To determine the intensity of orofacial pain according to self-report, brief self-report pain scales (i.e., numeric rating scale [NRS], verbal descriptor scale [VDS], and the Faces Pain Scale-Revised [FPS-R]), were used in case pain was present during the activity [18-22]. To determine whether the participant was able to self-report pain, their understanding of the scales was assessed with test questions. The participants were asked: 'Which number reflects more pain; a 3 or a 7?'; 'Which word means more pain; moderate or severe?'; and 'Which face shows more pain? This one (point to face 2) or this one (point to face

8)?'. If the participants did not answer all test questions correctly, they were excluded from the study.

Data analysis

SPSS Version 24 Software (IBM) was used for data analyses.

Concurrent validity

Concurrent validity refers to the extent to which the results of a certain test correspond with a previously developed gold standard. To assess concurrent validity of the OPS-NVI, the estimated pain intensity rated by the researcher was compared to the outcomes of the three self-report pain scales using Spearman coefficient, with a significance level of $P < .05$. This was analyzed for the resting and chewing components separately, for both hospitals together. A correlation (r) of 0.5 indicates a large effect, of 0.3 a medium effect, and of 0.1 a small effect, according to Cohen's guidelines[23]. The sensitivity, specificity, and area under the receiver operating curve (AUROC) were calculated for each activity by comparing the presence of orofacial pain according to the OPS-NVI to the presence of pain according to self-report. Orofacial pain, according to the OPS-NVI, was marked as present when the estimated pain intensity was rated 1 by the researcher and as absent when the estimated pain intensity was rated 0 by the researcher. An AUROC of 0.9 to 1.0 indicates the accuracy of a diagnostic test as outstanding, 0.8 to 0.9 excellent, 0.7 to 0.8 acceptable, and 0.5 or lower suggests no discrimination [24].

Predictive validity and agreement

To determine if the single behavior items and the total number of positively scored behavior items on the OPS-NVI were related to the presence of orofacial pain according to self-report, the Spearman coefficient was used, with a significance level of $P < .05$.

To determine whether the presence of orofacial pain according to the OPS-NVI agreed with the presence of orofacial pain according to self-report, the prevalence-adjusted and bias-adjusted kappa (PABAK) was used [25].

These were analyzed for the activities resting and chewing separately, for both hospitals together. To identify the size of the correlations, Cohen's guidelines were used as well [23]. A PABAK value below 0.4 represents poor agreement, values between 0.4 and 0.75 indicate fair to good agreement, and values of 0.75 and higher represent excellent agreement [26].

Results

In total, 145 patients were approached by nursing staff. Patients who indicated they did not wish to participate, or whose consultees indicated that the patient would not wish to participate, were excluded. If the personal consultee who gave verbal agreement over the phone did not return the signed consultee form, the patient did not participate in the study. In 15 cases, patients were discharged from the hospital before they could be screened. Informed consent was obtained from 101 patients; however, 45 patients were not able to correctly self-report the presence or absence of pain (i.e., they were not able to answer all test questions correctly). Therefore, they were excluded from this study, and 56 participants were included. The mean ± standard deviation (SD) age was 84.2 ± 6.54 years old, and 58.9% were female. Further demographics are shown in *Table 2*. There were no significant differences between the two hospitals concerning demographics. All 56 participants were observed during rest. One participant received enteral nutrition, which precluded him from being observed during chewing. Therefore, the remaining 55 participants were observed during chewing.

Concurrent validity

The prevalence of orofacial pain according to the OPS-NVI was 5.4% (3 out of 56 participants) during rest. The prevalence of pain according to self-report was also 5.4% (3 out of 56 participants) during rest. During chewing, the prevalence of orofacial pain according to the OPS-NVI, was 9.1% (5 out of 55 participants), and was 10.7% (6 out of 55 participants) according to self-report. The cross tables with the number of true positives, true negatives, false positives, and false negatives are given in *Table 3* for each activity separately. During rest, the specificity was 98.1%, the sensitivity was 66.7%, and the AUROC was 0.824, indicating an excellent accuracy. During chewing, the specificity was 100%, the sensitivity was 83.3%, and the AUROC was 0.917, indicating an outstanding accuracy. Since there were only two true positives during rest and only five true positives during chewing, the Spearman correlation between the estimated pain intensity rated by the researcher and by the self-report pain scales could not be assessed. *Table 4* shows the estimated pain intensity rated by the researcher and the outcomes of the three self-report pain scales in the participants in whom orofacial pain was present for each activity.

Predictive validity and agreement

The correlations between the behavior items on the OPS-NVI and the presence of orofacial pain according to self-report are shown in *Table 5*. The correlation between the number of positively scored behavior items on the OPS-NVI and the presence

TABLE 2 | Descriptive analysis of demographic characteristics of all participants and from each hospital separately.

		Total (n = 56)	Hospital 1 (n = 14)	Hospital 2 (n = 42)
Gender [n (%)]	Female	33 (58.9)	5 (35.7)	28 (66.7)
	Male	23 (41.1)	9 (64.3)	14 (33.3)
Age M, SD (range)		84.2, 6.5 (70-97)	82.0, 7.0 (70-92)	84.9, 6.3 (73-97)
Ethnicity [n (%)]	White	40 (71.4)	12 (85.7)	28 (66.7)
	Mixed/Multiple ethnic groups	0 (0)	0 (0)	0 (0)
	Asian/Asian British	6 (10.7)	1 (7.1)	5 (11.9)
	Black/African/Caribbean/ Black British	6 (10.7)	1 (7.1)	5 (11.9)
	Other ethnic group	4 (7.1)	0 (0)	4 (9.5)
Marital Status [n (%)]	Married	19 (33.9)	4 (28.6)	15 (35.7)
	Divorced	6 (10.7)	3 (21.4)	3 (7.1)
	Widowed	19 (33.9)	2 (14.3)	17 (40.5)
	Single	12 (21.4)	5 (35.7)	7 (16.7)
Years in general education M, SD (range)		10.7, 3.1 (6-18)	10.8, 2.8 (7-18)	10.6, 3.2 (6-18)
Highest completed level of education [n (%)]	Higher degree	0 (0)	0 (0)	0 (0)
	Degree	2 (3.6)	1 (7.1)	1 (2.4)
	A level (or equivalent)	2 (3.6)	0 (0)	2 (4.8)
	HNC/HND (or equivalent)	0 (0)	0 (0)	0 (0)
	NVQ (or equivalent)	0 (0)	0 (0)	0 (0)
	GCSE (or equivalent)	5 (8.9)	2 (14.3)	3 (7.1)
	No qualification	47 (83.9)	11 (78.6)	36 (85.7)

NOTE | Hospital 1 = central London, Hospital 2 = suburban London, M = Mean, SD = Standard deviation, HNC/HND = Higher National Certificate/Higher National Diploma, NVQ = National Vocational Qualification, GCSE = General Certificate of Secondary Education.

TABLE 3 | Cross table of the presence of orofacial pain, according to OPS-NVI and according to self-report during rest and chewing.

		Resting				Chewing			
		Self-report				Self-report			
		Yes	No	Total		Yes	No	Total
OPS-NVI	Yes	TP 2	FP 1	3	OPS-NVI	TP 5	FP 0	5
	No	FN 1	TN 52	53		FN 1	TN 49	50
	Total	3	53			6	49	

NOTE | OPS-NVI = Orofacial-Pain Scale for Non-Verbal Individuals, TP = true positive, TN = true negative, FP = false positive, FN = false negative.

TABLE 4 | Estimated pain intensity according to OPS-NVI and outcomes of the self-report pain scales in all participants who self-reported the presence of orofacial pain.

	Resting				Chewing			
	Observation	Self-report			Observation	Self-report		
Participant	OPS-NVI	NRS	VDS	FPS-R	OPS-NVI	NRS	VDS	FPS-R
1	2	6	Severe	4	3	6	Severe	4
2	0	5	Moderate	4	0	6	Moderate	6
3	3	4	Moderate	6	4	6	Severe	8
4	2	0	None	0	3	2	Mild	4
5	0	0	None	0	2	5	Moderate	6
6	0	0	None	0	4	3	Mild	2

NOTE | OPS-NVI = Orofacial-Pain Scale for Non-Verbal Individuals, NRS = numeric rating scale, VDS = verbal descriptor scale, FPS-R = Faces Pain Scale-Revised.

TABLE 5 | Correlations between behavior items of OPS-NVI and presence of orofacial pain according to self-report.

Behavior	Resting		Eating	
	r	P value	r	P value
Frowning	0.648	<.001	0.813	<.001
Narrowing or closing eyes	0.567	<.001	0.389	.003
Raising upper lip	-0.032	.814	–	–
Opened mouth	0.296	.027	–	–
Tightened lips	–	–	–	–
Resisting care	–	–	–	–
Guarding	–	–	–	–
Rubbing	0.382	.004	0.389	.003
Restlessness	0.382	.004	0.555	<.001
Using offensive words	–	–	–	–
Using pain-related words	–	–	–	–
Screaming/shouting	–	–	–	–
Groaning	–	–	–	–
Restricting jaw movement	–	–	0.686	<.001
Refusing prosthetics	–	–	–	–
Drooling	–	–	0.555	<.001

NOTE | OPS-NVI = Orofacial-Pain Scale for Non-Verbal Individuals.

of orofacial pain according to self-report during rest was 0.633 (P<.001, n = 56), indicating a large effect. The correlation during chewing was 0.930 (P<.001, n = 55), also indicating a large effect. The PABAK during rest was 92.9% (95% confidence interval [CI] 75.4% to 99.1%), indicating excellent agreement. The PABAK during chewing was 96.4% (95% CI 80.6% to 99.9%), also indicating excellent agreement.

Discussion

The aim of this study was to assess the validity of the resting and chewing components of the OPS-NVI. The specificity of the OPS-NVI was 98.1% to 100.0%, the sensitivity was 66.7% to 83.3%, and the AUROC was 0.824 to 0.917. The predictive validity showed a strong correlation (0.633 to 0.930, P<.001) between the number of yes-scored behavior items and the presence of orofacial pain according to self-report. Furthermore, there was excellent agreement between the presence of orofacial pain according to the OPS-NVI and according to self-report.

The Spearman correlation between the OPS-NVI and self-report pain scales could not be assessed because of the low prevalence of orofacial pain, and possibly also due to the limited number of people who were able to self-report pain due to the severity of their dementia. The specificity, sensitivity, and AUROC were favourably high; however, it must be considered that only six participants verbally communicated that they were in pain during chewing. It is recommended to further validate the OPS-NVI in a verbal population in which the prevalence of pain is higher and more severe pain is present. Predictive validity showed a strong correlation (0.633 to 0.930, P<.001) between the number of positively scored behavior items and the presence of orofacial pain according to self-report. During rest, frowning and narrowing or closing eyes showed a significant strong correlation with the presence of self-reported pain, and opened mouth, rubbing, and restlessness showed a significant medium correlation. During eating, frowning, restlessness, restricting jaw movement, and drooling showed a significant strong correlation, and narrowing or closing eyes and rubbing showed a significant medium correlation with the presence of self-reported pain. This indicates that participants who self-reported the presence of orofacial pain where likely to have more of these observed pain-indicative behaviors.

Strengths and Limitations

The OPS-NVI was recently developed to identify orofacial pain in nonverbal individuals and needs further validation. This study is the first to validate the OPS-NVI in an acute hospital setting.

When verbal communication becomes difficult or even impossible, observational tools are needed to identify orofacial pain [3]. However, it is important to acknowledge that the observed behaviour could also be caused by other causes of distress – for example, pain at other sites of the body or other medical reasons for which the participants were admitted to the hospital [27]. There were only 56 participants in this study who could verbally communicate if they were in pain, and of this group, only 6 reported pain. Further psychometric evaluation of the OPS-NVI is recommended using a larger sample size and/or a population with a higher prevalence of orofacial pain.

For this study, only the resting and chewing components of the OPS-NVI were used. All participants were admitted to the acute hospital, so the authors could not

intervene in their routine daily care on the ward; therefore, they could not be asked to drink or perform oral care just for research purposes. However, participants were able to be observed during rest and chewing, since eating food and resting were scheduled parts of their daily routine.

All data were collected by one researcher (LR). Therefore, the inter-observer reliability of the OPS-NVI could not be tested. A previous study shows fair to good to excellent inter-observer and intra-observer reliability for the chewing component [28]. Another recently published study about the psychometric evaluation of the OPS-NVI indicated that the component oral hygiene care could not be assessed reliably between observers [17]. Furthermore, the components drinking and chewing should be further validated in a population that can communicate verbally and self-report the presence of orofacial pain.

A recently published study indicated that some oral health factors (e.g. brush frequency, indication of chewing quality, consistency of the food, presence of extra-oral abnormalities, person who performed mouth care, and oral hygiene) are significant predictors for the presence of orofacial pain observed with the OPS-NVI [29]. However, another study examined oral health status in relation to the self-report of orofacial pain and indicated that, although oral health problems such as ulcers and caries were frequently present, no pain was reported [17]. Consequently, the presence of oral health problems cannot be used as a reference standard for the presence of orofacial pain, and oral health examinations remain necessary for oral health-related quality of life.

Clinical implications

In the current study, the OPS-NVI was used to identify orofacial pain in people with dementia in acute hospital wards. Adequate diagnosis of orofacial pain is important for providing effective treatment. Since there is no assessment tool besides the OPS-NVI to identify orofacial pain in people who are no longer able to communicate verbally, further validation of this observational tool is highly recommended [30]. Until further validation of the OPS-NVI has been performed, it is suggested to use the approach of Herr et al. in clinical situations to identify orofacial pain in people who are no longer able to communicate verbally [30, 31]. This approach includes anticipating the presence of possible pain-causing conditions, identifying pain indicators, and establishing a baseline behaviour [30, 31]. To clarify whether changes in behavior are caused by pain, an empirical trial of simple analgesics could be used [30, 31].

Conclusion

The resting and chewing components of the OPS-NVI showed promising concurrent and predictive validity. Nevertheless, further validation is required and highly recommended. The components drinking and oral hygiene care of the OPS-NVI also require further validation. It is recommended to further validate the OPS-NVI in a population with a greater prevalence and intensity of orofacial pain; for example, in a specialized clinic for dental care for older people.

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