



## ORIGINAL ARTICLE

## Older people with swallowing dysfunction and poor oral health are at greater risk of early death

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**Abstract****Objectives:** We investigated the associations between swallowing dysfunction, poor oral health and mortality among older people in intermediate care in Sweden.**Methods:** This prospective cohort study investigated 391 older people in 36 intermediate care units (clusters). Swallowing function was assessed with the timed water swallow test (TWST), and oral health with the revised oral assessment guide (ROAG) at baseline. Data were collected on age, sex, education level, multimorbidity, cognitive impairment, care dependency and body mass index (BMI). Time to mortality was recorded during the following year. The mixed effects Cox regression model with cluster as a random factor was used to estimate hazards ratios (HR) with 95% confidence intervals (CI).**Results:** The median age of the participants was 84 years (interquartile range [IQR]: 11), and 53.3% were females. Mortality within one year was 25.1%. In the adjusted model, swallowing dysfunction and poor oral health were both independently associated with mortality (adjusted HR [aHR]: 1.67, 95% CI 1.02-2.75;  $P = .041$  and aHR: 1.98, 95% CI 1.07-3.65;  $P = .029$ , respectively). Participants with combined swallowing dysfunction and poor oral health showed the highest mortality (35.0%) and 2.6 (95% CI 1.15-5.89;  $P = .022$ ) times higher mortality risk than those with normal swallowing function and good oral health (13.0%).**Conclusions:** Swallowing dysfunction and poor oral health were identified as independent risk factors for mortality in older people in intermediate care. Although further studies are required to verify these findings, they suggest that systematic assessment of swallowing function and oral health status should be performed for care considerations.**KEYWORDS**

mortality, nursing homes, oral care, oral hygiene, swallowing disorders

**1 | INTRODUCTION**The health status of older people is complex, and seldom can a single aspect serve as the sole predictor of outcomes like mortality.<sup>1,2</sup>Many older people have multimorbidity, which leads to greater care dependency and increased mortality risk.<sup>3</sup> Swallowing dysfunction (ie dysphagia) and poor oral health are reported to be highly prevalent among older individuals. These conditions are considered a

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geriatric syndrome, although they are rarely assessed in care settings.<sup>4-6</sup> Compromised oral health and untreated swallowing dysfunction are major concerns; both conditions increase the risk of pulmonary infection, which in turn, increases mortality risk.<sup>7,8</sup>

Swallowing dysfunction increases with age and frailty and is often unrecognized and poorly treated in care settings.<sup>4</sup> It is frequently associated with neurological diseases, sarcopenia, functional status, poly medication and multimorbidity.<sup>4,9-14</sup> Impaired swallowing safety with aspiration of food and liquids into the airways is a predictor for aspiration pneumonia,<sup>15,16</sup> and an impaired swallowing efficacy with ineffective preparation and passage of the bolus through pharynx may cause malnutrition and dehydration.<sup>10,13</sup> Cabre et al<sup>12</sup> found that older people with impaired swallowing were at higher risk of mortality than those with normal swallowing function.

Due to improvements in oral health care and treatment, a large proportion of older people have retained their natural teeth, but they also have extensive restorations.<sup>17,18</sup> As a result, oral diseases, such as caries and periodontal disease, have increased among older people.<sup>19,20</sup> Oral diseases are sometimes a consequence of age-related diseases, conditions that can lead to deterioration of oral health and changes in oral bacterial flora.<sup>21</sup> There are also complex relationships between oral infections and the initiation or progression of myocardial infarction, stroke, diabetes, Alzheimer's disease and rheumatoid arthritis.<sup>22</sup>

Older people have been found to be at greater risk of aspiration pneumonia if they have poor oral health.<sup>11</sup> A possible explanation may be that poor oral health changes the composition and amount of bacteria in the saliva with increased risk of infection when aspiration occurs.

Since knowledge is limited on whether swallowing dysfunction and poor oral health are associated with higher mortality in older individuals, we aimed to investigate the associations between poor oral health, swallowing dysfunction and mortality (with follow-up over one year) in older individuals in intermediate care.

## 2 | METHODS

### 2.1 | Study design

This prospective cohort study was part of a multidisciplinary, multicenter project, called Swallowing function, Oral health, and Food Intake in old Age (SOFIA).<sup>23</sup> The study was approved by the Uppsala Regional Ethics Review Board, Sweden (Dnr 2013/100/3).

### 2.2 | Participants and settings

This study was performed in 36 intermediate care units in five regions of Sweden, both rural and urban. Intermediate care provides nursing care for periods of days to months for people who are, for example, recovering after a hospital discharge, waiting for care-home placement, or undergoing rehabilitation, respite care or end-of-life care.<sup>24</sup> We included 391 residents who fulfilled the following inclusion criteria:  $\geq 65$  years old, stayed for at least 3 days, could understand Swedish and could participate in clinical assessments. Each

participant provided written informed consent. Older individuals in end-of-life care or with moderate or severe cognitive impairment were excluded. In total, 931 residents were available in the intermediate care units, 477 did not fulfil the inclusion criteria and 63 (13.2%) declined to participate.

We collected socio-demographic and medical data from care documentation and self-reports. These data included age, sex, height, weight, number of chronic diseases, multimorbidity and education level. Multimorbidity was defined as three or more diagnoses that involved a minimum of three different organs/organ systems.<sup>25</sup> Care dependency (ie functional status) was assessed with the modified Katz Index of Activities of Daily Living (Katz-ADL). In this assessment, individuals receive a 'yes' or 'no' score, based on whether they exhibited control in bathing, dressing, toilet-related tasks, transferring, continence and feeding.<sup>26,27</sup> Assessments were performed by the responsible nurse at each intermediate care unit. Individual height and weight were used to calculate the body mass index (BMI); BMI was defined as low  $< 20$  (age  $\leq 69$  years) or  $< 22$  (age  $\geq 70$  years),<sup>28</sup> as normal 20/22-29 (age  $> 65$  years) and as high (eg overweight and obesity)  $\geq 30$ .<sup>29</sup> Mild cognitive impairment was based on medical records and judged subjectively by the responsible nurse at each intermediate care facility.

### 2.3 | Assessment of oral health and swallowing dysfunction

Eight registered dental hygienists (RDHs) and one speech-language pathologist (SLP) were trained and their processes calibrated in how to examine and perform assessments in oral health and swallowing function prior to study commencement. All assessments were conducted in intermediate care facilities. RDHs carried out oral assessments with a mouth mirror and flashlight.<sup>23</sup> Both the RDHs and the SLP assessed swallowing function. An earlier study has shown that staff in dentistry and speech pathology, when compared, have high agreement in clinical assessments of swallowing dysfunction in older people.<sup>30</sup>

### 2.4 | Oral health

Oral health was assessed with the Revised Oral Assessment Guide (ROAG).<sup>31</sup> Eight categories were included: voice, lips, mucous membranes, tongue, gums, teeth/dentures, saliva and swallowing sensation (eg pain or dryness when swallowing saliva). Each category was described and rated from healthy (score 1) to severe (score 3). The total score ranged from 8 (healthy) to 24 (severe oral health problems).

### 2.5 | Swallowing function

We assessed swallowing function (ie swallowing efficacy) by measuring swallowing capacity with a timed water swallow test (TWST).<sup>32</sup> Initially, the participant was given three teaspoons of water; when swallowing was successful with no sign of aspiration, the participant

**TABLE 1** Baseline characteristics of the total cohort (n = 391), stratified by survived and deceased

Variables	Total cohort (n = 391)	Survived (n = 293)	Deceased (n = 98)	P-value
Age	84.0 [11]	82.0 [10]	86.0 [11]	.002
Sex				
Male	182 (46.5)	139 (47.4)	43 (43.9)	.621
Female	209 (53.5)	154 (52.6)	55 (56.1)	
BMI <sup>a</sup>	23.9 [6.4]	-	-	
Low	131 (36.7)	85 (31.8)	46 (51.1)	.001
Normal	171 (47.9)	132 (49.5)	39 (43.3)	
High	55 (15.4)	50 (18.7)	5 (0.06)	
Multimorbidity <sup>b</sup>				
No	185 (47.3)	141 (48.1)	44 (44.9)	.662
Yes	206 (52.7)	152 (51.9)	54 (55.1)	
Katz-ADL				
A-D	193 (49.4)	157 (54.7)	36 (36.7)	.003
E-G	192 (49.1)	130 (45.3)	62 (63.3)	
Cognition				
Normal cognition	344 (88.0)	255 (87.0)	89 (90.8)	.413
Mild cognitive impairment	47 (12.0)	38 (13.0)	9 (9.2)	
Education				
Compulsory school	251 (64.2)	194 (66.7)	57 (60.0)	.496
Upper secondary school	99 (25.3)	71 (24.4)	28 (29.5)	
Higher education	36 (9.2)	26 (8.9)	10 (10.5)	
ROAG				
Good oral health (score 8)	100 (25.6)	85 (29.0)	15 (15.3)	.007
Poor oral health (score >8)	291 (74.4)	208 (71.0)	83 (84.7)	
TWST				
Normal swallowing ( $\geq 10$ mL/s)	172 (44.7)	142 (49.1)	30 (30.6)	.002
Dysfunctional swallowing (<10 mL/s)	213 (55.3)	147 (50.9)	66 (67.3)	

Note: Data are presented as n (%) or the median [IQR]. Statistical analysis was performed with the chi-squared test for categorical variables and the Mann-Whitney *U* test for continuous variables. Abbreviations: ADL, activity of daily living; BMI, body-mass index; ROAG, revised oral assessment guide; TWST, timed water swallowing test.

<sup>a</sup>Low BMIs were <20 (age  $\leq 69$ ) or <22 (age  $\geq 70$ ), normal BMI was 20/22-29 and high BMI including overweight and obesity  $\geq 30$ .

<sup>b</sup>Defined as three or more diagnoses in three different organs/organ systems.

was given 150 mL of water in a glass. Participants were instructed to drink the water as fast as possible, but stop if they experienced any difficulties. Residual volume was measured when the TWST was interrupted or incomplete. The swallowing capacity was calculated as the amount of swallowed water per second (mL/s). In accordance with previous studies, swallowing dysfunction was defined as a swallowing capacity <10 mL/s.<sup>32,33</sup>

## 2.6 | Outcome measures

All participants were followed prospectively for one year from inclusion in the SOFIA project to assess survival time. The cause of death was not registered.

## 2.7 | Statistical analysis

We evaluated associations between baseline characteristics and survival. Categorical and continuous variable were compared between those who died and those who survived using the chi-squared and Mann-Whitney *U* tests, respectively. The standard cut-offs for poor oral health and swallowing dysfunction were used: oral health score was dichotomized as good (score 8) and poor (score 9-24) oral health,<sup>31,34</sup> and swallowing function as normal ( $\geq 10$  mL/s) or dysfunctional (<10 mL/s) swallowing.<sup>32</sup> To graphically illustrate the impact of oral health and swallowing function (separately and combined) on survival, we used Kaplan-Meier plots. We performed mixed effects Cox regression models with

cluster (ie care units) as a random factor and estimated hazard ratios (HR) with 95% confidence intervals (CI) to evaluate oral health and swallowing function as mortality risk factors. We estimated the corresponding adjusted hazard ratios (aHRs) and 95% CIs with a multivariable model adjusted for age, sex, multimorbidity, BMI and cognition. Age was modelled using restricted cubic splines with knots at the 10th, 50th and 90th percentiles, allowing a non-linear relationship between age and mortality hazard. The mixed effects Cox regression models were fitted using the R-function *coxme* from the *coxme* package (version 2.2-10). The assumption of proportional hazard was assessed using visual inspections of graphs and statistical tests based on weighted Schoenfeld residuals. Two-sided *P*-values < .05 indicated statistical significance. All statistical analyses were performed with R (version 3.5.1).

### 3 | RESULTS

#### 3.1 | Participants

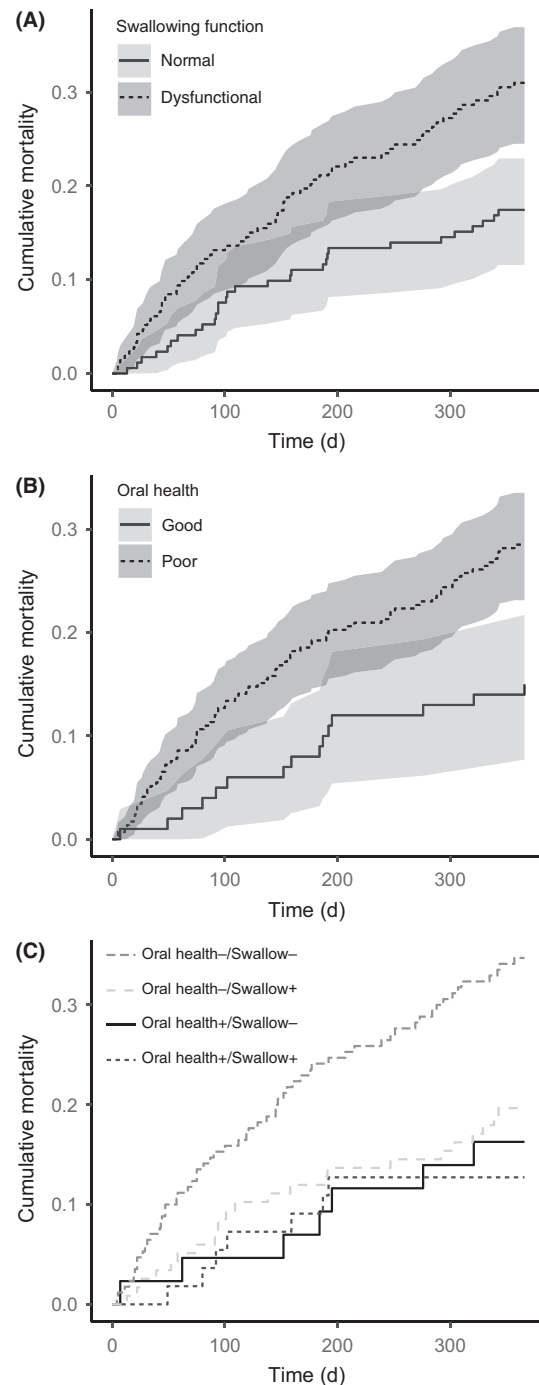
We enrolled 391 participants (53.5% female) with a median age of 84 [IQR: 11] years (Table 1). During the 1-year follow-up, 98 participants (25.1%) died and median time to death was 125 days (min 4-max 357). These participants were significantly older than the survivors (median ages: 86 vs 82 years, *P* = .002), more likely to be care-dependent (63.3% vs 45.3%, *P* = .003), were more likely to have low BMIs (51.1% vs 31.8%, *P* = .001), had more inefficient swallowing (median swallowing capacity 6.36 mL/s vs 9.81 mL/s, *P* < .001) and poorer oral health (median ROAG scores: 11 vs 10, *P* < .001).

#### 3.2 | Kaplan-Meier plots

The Kaplan-Meier plots showed that participants with swallowing dysfunction had a higher mortality (31.0%) than participants with normal swallowing function (17.0%, Figure 1A). Similarly, individuals with poor oral health had a significantly higher mortality (28.5%) than those with good oral health (15.0%, Figure 1B). Older people with combined swallowing dysfunction and poor oral health had the highest mortality (35.0%) and those with normal swallowing function and good oral health the lowest (13.0%, Figure 1C).

#### 3.3 | Risk factors for mortality

The univariable mixed effects Cox models (Table 2) showed HRs for mortality of 2.09 (95% CI: 1.20-3.61, *P* = .009) for participants with poor oral health and 2.02 (95% CI: 1.29-3.17, *P* = .002) for those with swallowing dysfunction. The multivariable mixed effects Cox models showed only slight reductions in the aHRs for mortality among participants with poor oral health and swallowing dysfunction (aHR = 1.98, 95% CI: 1.07-3.65, *P* = .029; aHR = 1.67, 95% CI: 1.02-2.75, *P* = .041, respectively). An additional independent predictor for mortality was low BMI (aHR = 1.65, 95% CI: 1.04-2.61, *P* = .034) in comparison with normal BMI. However, age, sex,



**FIGURE 1** Kaplan-Meier cumulative mortality plots of factors associated with mortality among older individuals in intermediate care. (A) Participants with swallowing dysfunction showed higher mortality compared with normal function. (B) Participants with poor oral health had significantly higher mortality than those with good oral health. In (C) mortality in groups with various combinations of normal swallowing (Swallow+), swallowing dysfunction (Swallow-), good oral health (Oral health+) and poor oral health (Oral health-) are shown. Swallowing dysfunction combined with poor oral health showed the highest mortality

multimorbidity and cognition were not associated with mortality over the 1-year follow-up period. Adding a multiplicative interaction for the association between swallowing dysfunction and poor oral

**TABLE 2** Predictors of 1-year mortality among older individuals in short-term care according to five different mixed effects Cox regression models

Variables	HR (95% Confidence Interval)									
	Model 1 <sup>a</sup>	P-value	Model 2 <sup>b</sup>	P-value	Model 3 <sup>c</sup>	P-value	Model 4 <sup>d</sup>	P-value	Model 5 <sup>e</sup>	P-value
Swallowing (<10 mL/s)	2.02 (1.29-3.17)	.002	1.80 (1.10-2.94)	.019	-	-	1.67 (1.02-2.75)	.041	0.99 (0.32-3.05)	.980
Oral health (poor)	2.09 (1.20-3.65)	.010	-	-	2.02 (1.12-3.66)	.019	1.98 (1.07-3.65)	.029	1.39 (0.58-3.34)	.460
Age	NA	NA	NA	.045	NA	.083	NA	.059	NA	.059
Sex (woman)	1.19 (0.78-1.75)	.450	0.89 (0.57-1.39)	.610	1.00 (0.64-1.55)	.990	0.93 (0.59-1.45)	.740	0.91 (0.58-1.43)	.690
BMI										
Low	1.72 (1.11-2.65)	.014	1.78 (1.13-2.82)	.013	1.63 (1.03-2.58)	.036	1.65 (1.04-2.61)	.034	1.62 (1.02-2.57)	.042
High	0.37 (0.14-0.93)	.036	0.38 (0.15-0.97)	.043	0.36 (0.14-0.93)	.034	0.36 (0.14-0.92)	.033	0.35 (0.13-0.90)	.029
Multimorbidity (yes)	1.15 (0.77-1.73)	.490	1.53 (0.98-2.38)	.058	1.51 (0.97-2.35)	.066	1.51 (0.97-2.36)	.066	1.48 (0.95-2.30)	.086
Cognition (mild impairment)	0.62 (0.30-1.27)	.190	0.66 (0.31-1.40)	.280	0.61 (0.29-1.31)	.210	0.68 (0.32-1.44)	.310	0.66 (0.31-1.41)	.290
Swallowing-by-oral health interaction	1.63 (0.51-5.23)	.410	-	-	-	-	-	-	0.98 (0.93-1.05)	.600

Note: For the Cox mixed effects regression model with cluster as random effect, the reference categories were: normal swallowing, good oral health, male sex, normal BMI, no multimorbidity and no cognitive impairment. Age was modelled using restricted cubic splines with knots at the 10th, 50th and 90th percentiles of the population's age distribution (77, 84, 88.5 years, respectively), allowing non-linear relationship between age and mortality. HR for age cannot be obtained from the Cox mixed effects model, only P-values.

Abbreviations: BMI, body mass index; HR, hazard ratio; NA, not applicable.

<sup>a</sup>The model includes only the variable indicated.

<sup>b</sup>The model includes swallowing function and all covariates.

<sup>c</sup>The model includes oral health and all covariates.

<sup>d</sup>The model includes swallowing function, oral health and all covariates based on 354 participants without missing data.

<sup>e</sup>The model includes an interaction between oral health and swallowing dysfunction with covariates as in the model 4.

**TABLE 3** Analysis of swallowing dysfunction, poor oral health and risk for mortality

Poor oral health	Swallowing dysfunction	No. of deaths	No. of survival	Hazard ratio (95% CI) <sup>a</sup>	P-value
Yes	Yes	59	111	2.60 (1.15-5.89)	.022
Yes	No	23	94	1.41 (0.59-3.38)	.440
No	Yes	7	36	0.98 (0.32-3.04)	.980
No	No	7	48	1 (reference)	

Abbreviation: CI, Confidence interval.

<sup>a</sup>Mixed effect Cox regression model with cluster as random effect adjusted for: age, sex, body mass index, multimorbidity and mild cognitive impairment.

health failed to show evidence of effect modification (aHR = 0.98, 95% CI: 0.93-1.05,  $P = .600$ ). The analysis of the four variations in exposure showed an aHR for mortality of 3.12 (95% CI: 1.41-6.89,  $P = .022$ ; Table 3) among participants with poor oral health combined with swallowing dysfunction than those with good oral health and normal swallowing.

## 4 | DISCUSSION

This prospective cohort study of older people in intermediate care revealed that swallowing dysfunction and poor oral health were independent mortality risk factors. In addition, swallowing dysfunction combined with poor oral health predicted the highest mortality among participants. Thus, systematic screening and treatment of swallowing dysfunction and poor oral health among older people in intermediate care could be beneficial to minimize the potential consequences of these conditions.

In this study, the mortality was higher among older people with swallowing dysfunction (31.0%) than those with normal swallowing function (17.0%), which resulted in a 1.7-fold higher mortality risk within 1-year. Similar findings have been reported for other care settings.<sup>8,10,12</sup> Carrion and colleagues<sup>10</sup> found that oropharyngeal dysphagia was a risk factor for 1-year mortality in hospitalized older individuals, independent of functional status, malnutrition or comorbidities. They revealed a 1.7-fold higher risk of 1-year mortality in patients with oropharyngeal dysphagia than those with normal swallowing function. Thus, swallowing dysfunction is a risk factor of mortality among older individuals in various settings.

This study also revealed a higher mortality among older people with poor oral health (28.5%) than those with good oral health (15.0%). Poor oral health was independently associated with a 2.0-fold higher risk of 1-year mortality, after adjusting for possible confounders. This finding was consistent with that of Klotz and colleagues,<sup>35</sup> who revealed a 2.3-fold higher mortality risk among residents of nursing homes with poor oral health, based on ROAG assessments. Improvements in oral health care and disease prevention have resulted in older people retaining more natural teeth.<sup>17</sup> However, natural teeth require good oral hygiene and dental care and therefore, the remaining teeth do not always result in maintained oral health in this population. We also found that low BMI was

associated with higher risk of mortality in comparison with normal BMI, whereas high BMI was associated with a lower risk of mortality. Our results are in agreement with earlier studies of mortality-associated factors among older people in different care settings; higher BMI is beneficial for healthy ageing.<sup>1,8,29,36</sup>

The highest 1-year mortality (35.0%) was found among older people with swallowing dysfunction combined with poor oral health; in contrast, 13% mortality was observed among participants with normal swallowing and good oral health. The adjusted analysis of four groups showed that older people with combined swallowing dysfunction and poor oral health had 2.6 times higher mortality risk compare with those with normal swallowing and good oral health. Other studies have found that there is an association between poor nutritional status, chewing problems and swallowing dysfunction among older individuals<sup>37,38</sup> and that swallowing dysfunction along with low BMI are independent risk factors for mortality among nursing homes residents.<sup>8</sup> Poor oral health, including periodontitis, has been shown to be associated with higher risk of cardiovascular disease for example myocardial infarction.<sup>39,40</sup> Oral infection increases the amount and composition of bacteria that can leak into the blood circulation adding to the inflammatory process in the cardiovascular structures and, if combined with swallowing dysfunction, when mixed with saliva, liquid or solid food, the microbes can leak into the trachea and cause pneumonia and death.

This study showed that mortality was significantly higher when the participants suffered from both swallowing dysfunction and poor oral health. However, there was no evidence of a synergistic effect on mortality when the conditions were combined. The CI ranged from 0.51 to 5.23 in the univariable interaction analysis, which suggests that the sample size was too small to provide sufficient statistical power for validating a synergistic effect. Since aspiration-related pneumonia is highly related to death,<sup>4</sup> we might have observed a significant interaction effect with stricter definitions; for example, swallowing dysfunction could have been measured as aspiration (rather than efficacy), and oral health could have been assessed by diagnosing oral infection specifically rather than using ROAG. Nevertheless, the findings of this study indicate that impaired swallowing and poor oral health are associated with higher mortality. Based on these findings, we advocate comprehensive multidisciplinary management of older individuals. This objective should be implemented both on an educational level, for students, and on the professional level, with interdisciplinary teams. A minimal-massive



intervention (MMI) approach, including evaluation and treatment of swallowing dysfunction, nutritional status and oral health and hygiene has been suggested for residents in intermediate care. MMI has shown increased survival, reduced respiratory infections and improved nutrition and functional status in older people with swallowing dysfunction.<sup>7</sup>

We found no significant association between mortality and age, sex, mild cognition impairments or multimorbidity. Previous studies have reported discrepant findings regarding the association between cognitive impairment and mortality.<sup>2,41,42</sup> Cano et al<sup>2</sup> found that cognitive impairment did not predict mortality among older people, after adjusting for frailty status. In contrast, Nguyen et al<sup>41</sup> found that both mild and moderate-to-severe cognitive impairments significantly greater mortality risk among older individuals. However, those studies used different diagnostic methods, used different follow-up periods and adjusted for different variables in their models.

The main strengths of this study were the prospective design, high participation rate (86%) and the inclusion of older people with a wide educational and demographical distribution, representing the variety of the Swedish population. The examinations were performed by trained RDHs and a SLP. Additionally, our multivariable model included several relevant confounders that could potentially impact mortality among older individuals.

Care dependency was not included in the multivariable model, since it is likely to otherwise act as a collider between swallowing dysfunction and mortality. Impaired swallowing may result in either a direct risk of mortality due to aspiration, especially in combination with poor oral health,<sup>15,16</sup> or indirectly by increased risk of undernutrition<sup>8,10,13</sup> resulting in weak immune system, risk of sarcopenia and deteriorated functional capacity, which also increases the mortality risk.<sup>4</sup> However, what impacts the mortality is complex in a setting with the present population. There might be other potential confounders with an impact on mortality, that were not accounted for in our model, which should be further investigated for example depression and socioeconomic deprivation.

The main limitation of this study was that that we only investigated all-cause of death. In particular, it would have been interesting to specifically explore pneumonia-related death, which was not registered. Also, our oral health and swallowing dysfunction assessments were based on clinical examinations; additional instrumental examinations (eg dental examination and videoendoscopy or videofluoroscopy) might have provided more accurate diagnoses. However, those options were not available in the study context. Instead of assessing mild cognitive impairment based on medical records and subjective judgements, it would have been preferable to conduct a complete Mini Mental State Examination (MMSE)<sup>43</sup> of the participants for accurate assessment, since cognitive impairment is highly associated with mortality.<sup>41</sup> However, adding MMSE to the full study protocol could have made the examinations too extensive and tiring for the participants.

## 5 | CONCLUSION

Older people in intermediate care with swallowing dysfunction and poor oral health show higher risk of mortality than their counterparts with normal swallowing and good oral health. Although further studies are required to verify the findings, they suggest that systematic assessment of swallowing function and oral health status among older people in intermediate care could improve care planning.

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## AUTHORS' CONTRIBUTIONS

All authors contributed to the conception and design of the work. All authors contributed to the acquisition of data. Per Liv, certified statistician (acknowledged) and PH were responsible for the statistical analyses. PH and SK drafted the first version of the manuscript. All authors critically revised the manuscript for important intellectual content. All authors gave final approval for publication.

## ETHICAL APPROVAL

This study was approved by the Uppsala Regional Ethics Review Board, Sweden (Dnr 2013/100).

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