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A psychometric study

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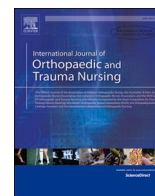
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# Validity and reliability of the Danish version of the Hospital Anxiety and Depression Scale (HADS) in patients with major lower extremity amputations: A psychometric study

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## ABSTRACT

**Background:** Patients undergoing major lower extremity amputation (LEA) due to vascular disease face an increased risk of post-surgery anxiety and depression. *The Hospital Anxiety and Depression Scale (HADS)*, widely used to identify anxiety and depressive symptoms, has been translated into Danish, but its content validity has not previously been tested in LEA patients. This study aims to test the validity and reliability of HADS in this population.

**Method:** This methodological study involved cognitive interviews with 10 major LEA patients to assess content validity and HADS responses from 100 patients to evaluate the floor and ceiling effects, construct validity, and internal consistency reliability. Data were collected from seven orthopedic departments across Denmark.

**Results:** In this hospital-based study, 20% had anxiety symptoms and 18% had depressive symptoms before discharge. Patients found the questionnaire relevant but had concerns about the one-week timeframe and the comprehensibility of certain items (“butterflies in the stomach” in item 9 and the term “things” in items 2 and 12). Floor effects were present across all items, with no ceiling effects. Confirmatory factor analysis supported both the original two-factor and a three-factor structure. Internal consistency reliability was good for both subscales.

**Conclusion:** This study supports the validity and reliability of the Danish version of HADS for assessing anxiety and depression in patients with major lower extremity amputation (LEA). The questionnaire serves as a valuable tool for addressing psychosocial challenges, enabling patients to reflect on their mental health and recognize potential symptoms needing medical attention in the future.

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## 1. Introduction

Patients undergoing major lower extremity amputation (LEA) due to vascular disease are at an increased risk of experiencing anxiety and depression in the post-surgery period (Calabrese et al., 2023; Horgan and MacLachlan, 2004). A Danish Registry study revealed that 7% of patients undergoing major LEA during 2010 and 2011 were diagnosed with depression preoperatively (Jensen et al., 2017). Following major amputation, one in five patients experience anxiety up to one year postoperatively, and up to one-third display depressive symptoms within 2–3 years (Cai et al., 2023; Horgan and MacLachlan, 2004; Luza et al., 2020; Singh et al., 2009). A recent review found that depression is the most common negative factor hindering psychological and physical recovery after lower extremity amputation and that anxiety is manifested in a fear associated with the loss of physical function and mobility (Calabrese et al., 2023). Furthermore, studies have shown that the healthcare system does not always meet patients' psychosocial needs after major LEA (Bennett, 2016; Liu et al., 2010; Norlyk et al., 2013, 2016).

Among patients with heart failure, untreated depression can increase morbidity and mortality two to three times compared to patients without depression (Sokoreli et al., 2016; Wu and Kling, 2016). Furthermore, depression is a barrier to the completion of rehabilitation among patients with ischemic heart disease (Beswick et al., 2005). Therefore, timely identifying patients with depression is an important step for clinicians towards treating depression, ensuring higher completion of rehabilitation and increased quality of life for the patients. Clinicians have historically paid limited attention to identifying anxiety and depression among patients with LEA. However, in 2021, a Danish clinical guideline for rehabilitation and prosthetic use following major LEA recommended screening the psychosocial status post-operatively (Madsen et al., 2021). *The Hospital Anxiety and Depression Scale (HADS)*, originally developed for medical outpatients, has previously been used to study anxiety and depressive symptoms in patients with major LEA in Jordan, Ireland, and Portugal (Desmond and MacLachlan, 2006; Hawamdeh et al., 2008; Pedras et al., 2018, 2019, 2020).

However, the psychometric properties of HADS have been minimally explored among patients with major LEA (Desmond and MacLachlan, 2005; Pedras et al., 2018). The internal consistency reliability of the Portuguese version was satisfactory for both anxiety and depression scales with Cronbach Alpha values above 0.8 (Pedras et al., 2018). Furthermore, the Irish HADS version's structural validity indicated that a three-factor model encompassing negative affectivity, autonomic anxiety, and anhedonic depression, better explained the data for patients with major LEA compared to the original two-factor model of HADS, which included only anxiety and depression (Desmond and MacLachlan, 2005). To our knowledge, content validity - including relevance, comprehensiveness, and comprehensibility of all HADS items - and floor and ceiling effects have not been studied in this population (Bjelland et al., 2002).

HADS has been translated into Danish by Mapi Research Trust (*HADS - Danish translation*), but the translation and cultural adaption to the Danish setting have not been published. Furthermore, the psychometric properties of the Danish version of HADS have solely been tested among patients with ischemic heart disease (Christensen et al., 2020).

To address patients' psychosocial needs in alignment with the Danish clinical guideline, it is crucial to ensure that the HADS scale is considered relevant, comprehensive, and comprehensible, for individuals with major LEA. Therefore, this study aimed to examine three key aspects of the HADS scale: 1) content validity, which includes assessing the relevance, comprehensiveness, and comprehensibility of items, along with identifying potential floor and ceiling effects; 2) construct validity through confirmatory factor analysis; and 3) internal consistency reliability.

## 2. Method

### 2.1. Study design

In this methodological study cognitive interviews were conducted with 10 patients who had undergone major LEA to evaluate content validity. Additionally, responses to the HADS questionnaire from 100 patients with major LEA were analyzed to assess floor and ceiling effects, construct validity, and internal consistency reliability (de Vet et al., 2011; Mokkink et al., 2010). The study adhered to the guidelines and definitions provided by the CONsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) group, following their taxonomy of measurement properties (Mokkink et al., 2010). The Patient Council at the Orthopaedic Research Unit of Odense University Hospital was consulted in the early phase of the study, and their perspectives on the protocol and the written patient information were taken into account.

### 2.2. Data collection and sample

Data were collected from Orthopaedic wards in six out of the 21 hospitals performing major LEA in Denmark. These hospitals represent all five regions in Denmark, including the University Hospitals in Aalborg, Aarhus, and Odense, as well as Hospital Lillebaelt in Kolding, Holbaek Hospital, and Hvidovre Hospital. Ten patients across the hospitals were recruited for cognitive interviews, utilizing a combination of think-aloud and verbal probing techniques (Willis and Artino, 2013). The selection prioritized diversity in age, gender, amputation level, cohabitation status, and geographical residence.

From April 2023 to May 2024, 100 patients undergoing major LEA due to vascular diseases completed the HADS questionnaire. The questionnaire was administered on the day of discharge or the day before. Exclusions comprised patients under 18 years, those with cognitive impairment (a diagnosis of dementia or acute confusion) hindering questionnaire response, and individuals not proficient in Danish. Furthermore, patients treated with anti-depressant medicine were not included.

### 2.3. The hospital anxiety and depression scale (HADS)

The Hospital Anxiety and Depression Scale is a 14-item self-report screening scale (Appendix 1) originally developed to indicate the possible presence of anxiety and depressive states in a medical outpatient clinic setting. (Zigmond and Snaith, 1983). It consists of two 7-item scales: one for anxiety (HADS-A) and one for depression (HADS-D). Each item is rated on a four-point Likert scale from 0 to 3, with each subscale score ranging from 0 to 21. Higher scores indicate more severe anxiety and/or depressive symptoms. The recommended cut-off values are 8–10 for the possible presence of a mood disorder and  $\geq 11$  for the probable presence of a mood disorder (Zigmond and Snaith, 1983). This implies that subscale scores of 0–7 signify no anxiety/depression, 8 to 10 mild to moderate anxiety or depression, and 11 to 21 suggest moderate to severe anxiety or depression.

The Hospital Anxiety and Depression Scale© (HADS) is protected worldwide by international copyright laws in all languages, with all rights reserved to GL Assessment, UK. A Master User License Agreement has been established between Mapi Research Trust and the the University of Southern Denmark/Kolding Hospital a part of Hospital Lillebaelt (Work order No. 2213514), granting the use of HADS for screening patients with major LEA in Denmark. The license to use the Danish version of the HADS scale has been issued ("HADS - Danish translation, Mapi Research Trust. Available online: <https://eprovide.mapi-trust.org/instruments/hospital-anxiety-and-depression-scale> (accessed 3. October 2022),").

#### 2.4. Demographic and clinical characteristics

Demographic and clinical characteristics including age, sex, amputation level, cohabitation status, educational level, diabetes, prior experience of depression, prior amputation, and geographical residence, were collected. We presented the prevalence of demographic and clinical characteristics using frequencies and median with 25% and 75% interquartile range. The distribution of scores per item was displayed using frequencies and proportions.

#### 2.5. Psychometrics properties of HADS among patients with LEA

The following psychometric properties of the HADS were evaluated.

##### 2.5.1. Content validity

Content validity was assessed using 10 cognitive interviews following the 'Think aloud' method (de Vet et al., 2011; Willis and Artino, 2013). During the interviews, as the patients completed the questionnaire, they were asked to verbalize their thoughts about the relevance, comprehensiveness, and comprehensibility of the instructions, items, and response options. All interviews were recorded and analyzed using the thematic approach described by Willis and Artino (Willis and Artino, 2013). Floor and ceiling effects were examined using data from the completed HADS questionnaires. Floor and ceiling effects occur if more than 15% of the patients select the lowest or highest possible score of an item (McHorney and Tarlov, 1995).

##### 2.5.2. Construct validity

Construct validity indicates the extent to which the instrument measures what it is intended to measure. One aspect of construct validity is structural validity. To assess structural validity, a confirmatory factor analysis was conducted using 100 questionnaire responses (Terwee et al., 2007). This analysis evaluated both the original two-factor structure (Zigmond and Snaith, 1983) and a three-factor structure, as a Danish psychometric study among patients with ischemic heart disease supported the latter (Christensen et al., 2020). The goodness of fit was evaluated using the standardised root mean squared residual, root mean square error of approximation, and comparative fit index. The model is considered 'good fitting' if the following criteria are met: Comparative fit index with a value close to 0.95 or higher. Standardised root mean squared residual close to 0.08 or lower, and a root mean square error of approximation close to 0.06 or lower (de Vet et al., 2011; Hu and Bentler, 1999).

##### 2.5.3. Internal consistency reliability

Internal consistency reliability is an indicator of how well the items of the questionnaire are internally correlated and therefore measure the same construct (anxiety or depression). Data from the HADS questionnaire were used to assess internal consistency reliability by calculating Cronbach's alpha for the two subscales. Cronbach's alpha of between 0.70 and 0.90 is an indication of good internal consistency (Bland and Altman, 1986; Terwee et al., 2007).

All statistical analyses were performed using Stata 17 (StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC)

#### 2.6. Ethics

All patients received written and oral information about the study and response to the questionnaire was an indication of voluntary consent to participation. In addition, the 10 patients in the think-aloud interviews provided written consent beforehand. A physician was informed if a patient scored eight points or more on either sub-scale. Furthermore, patients were advised to contact their general practitioner if their symptoms worsened. According to Danish legislation, this study does not require ethical approval from the [Committee on Health](#)

[Research Ethics](#), 2011 National Committee on Health Research Ethics §14, 2 (<https://en.nvk.dk/rules-and-guidelines/act-on-research-ethics-review-of-health-research-projects>). The study is registered in the Records of Processing Activities in the Region of Southern Denmark regarding research and quality projects (23/9882).

### 3. Results

#### 3.1. Demographic and clinical characteristics

The sample of 100 patients was aged between 43 years and 97 years, with a median age of 74 years. There were slightly more men than women, and 48% were cohabited. Further demographic and clinical characteristics are detailed in [Table 1](#).

#### 3.2. HADS score statistics

The 100 patients that fulfilled the questionnaire had a median score of anxiety of 4 points (0 points - 20 points) and a median score of depression of 3 points (0 points - 17 points). Item score statistics are outlined in [Table 2](#). On the sub-scale HADS-A, item 3 had the highest score, and item 9 had the lowest score. Within the sub-scale HADS-D, item 8 had the highest score, while item 4 and item 12 had the lowest score. Among the 100 patients, 80% did not have symptoms of anxiety and 82% did not have symptoms of depression. 11% exhibited moderate anxiety symptoms, and 9% exhibited severe anxiety symptoms. For depression, 13% had moderate symptoms, and 5% had severe symptoms.

#### 3.3. Content validity

Content validity consisted of cognitive interviews and floor and ceiling effects.

**Table 1**

Demographic and clinical characteristics of the 100 patients responding to the Hospital Anxiety and Depression Scale (HADS) questionnaire.

Male	56%
Age, median (IQR: 25%–75%)	74 years (67–79) years
Cohabitation status	
Cohabitation	48%
Alone	50%
Unknown	2%
Diabetic diagnosis	
Yes	46%
No	49%
Unknown	5%
Prior amputation	
Yes	22%
No	77%
Unknown	1%
Prior diagnosis of depression	
Yes	23%
No	75%
Unknown	2%
Amputation level	
Knee or below	27%
Above knee	73%
Education level	
Primary school 7 years	38%
Vocational school or college	35%
2–4 years of secondary education	20%
University degrees	5%
Unknown	2%
Geographical residence	
Capital Region	10%
Zealand Region	20%
Southern Denmark Region	40%
Central Denmark Region	22%
Northern Denmark Region	8%

**Table 2**

Item and score statistics of 100 patients responding to the Hospital Anxiety and Depression Scale (HADS) questionnaire.

	No:	Item description	Score distribution, % (n = 100)				$\alpha$
			0 point	1 point	2 points	3 points	
<b>HADS-A</b>	1:	I feel tense or "wound up"	48	41	5	3	0.81
	3:	I get a sort of frightened feeling as if something awful is about to happen	49	30	11	10	0.82
	5:	Worrying thoughts go through my mind	41	40	10	9	0.83
	7:	I can sit at ease and feel relaxed	49	36	12	3	0.84
	9:	I get a sort of frightened feeling like "butterflies" in the stomach	68	22	8	2	0.82
	11:	I feel restless as I have to be on the move	50	26	19	5	0.84
	13:	I get sudden feelings of panic	69	23	4	4	0.82
		Total HADS-A					0.85
<b>HADS-D</b>	2:	I still enjoy the things I used to enjoy	68	24	6	2	0.69
	4:	I can laugh and see the funny side of things	68	28	3	1	0.67
	6:	I feel cheerful	73	18	4	5	0.68
	8:	I feel as if I am slowed down	27	52	10	11	0.70
	10:	I have lost interest in my appearance	50	30	16	4	0.76
	12:	I look forward with enjoyment to things	57	35	7	1	0.68
	14:	I can enjoy a good book or radio or Tv program	68	14	9	9	0.74
		Total HADS-D					0.73

**HADS-A:** Hospital Anxiety Depression Scale-Anxiety, **HADS-D:** Hospital Anxiety Depression Scale- Depression. Higher scores indicate more severe anxiety and/or depressive symptoms.

### 3.3.1. Cognitive interview

The 10 patients included in cognitive interviews were a subset of the 100, who responded to the HADS questionnaire. They were aged between 49 years and 78 years, with a median age of 70 years. Furthermore, this subgroup was more likely to cohabit (60% vs. 48%) and undergo a below-knee amputation (40% vs. 27%) than the total study population. Additionally, they had more experience with prior amputations (60% vs. 22%). There were no differences in relation to prior depression or the occurrence of diabetes.

Overall, patients found items and response options relevant. Patients questioned the relevance of the time frame in the instruction of the questionnaire, which asked, 'how you have been feeling in the past week'. The difficulty probably stemmed from the patients having undergone amputation during that week, leading to different emotions before and after the surgery. Their comments on item 1 ("feeling tense") and item 3 ("feeling frightened") indicated how their responses would

have differed had the questions been asked before the amputation. Furthermore, patients argued that item 8's concept of feeling 'slowed down' was likely due to their use of opiates rather than their psychological condition, making it a less relevant symptom of anxiety and depression for them. Completing the questionnaire prompted patients to reflect on their existential experiences and recognize mental symptoms to monitor post-discharge. As one stated: "The big question has come up again. This matter of life and death ... you know ..." (P4). Moreover, during the interviews, all patients added their narratives about their context, sharing details about their lives and identities before the amputation. Although they viewed amputation as an invasive life-changing event, there was a collective sense of relief and a focus on the future. One patient stated: "I'm pleased this is over and done with so I can get on with my life" (P8). Thus, the questionnaire served as a platform to address: "the difficult stuff" (P5).

The patients found the questionnaire comprehensible overall but noted that item 9 needed clarification because, in Danish, the proverb "butterflies in the stomach" is associated with positive feelings such as excitement, anticipation, or joy. Additionally, the wording "things" used in Items 2 and 12 was unclear, as the patients did not understand what was meant by the broad term. The patients found the response options comprehensible.

The questionnaire was found comprehensive by the patients and none of the patients requested additional items or additional response options. Some patients noted overlap among items in the same domain; between items 12 and 14, as well as items 9 and 13.

Nearly all patients expressed a desire for the questionnaires to be read aloud, citing various reasons such as visual impairment: "I do not see very well" (P4), or difficulty in reading: "I am not good at reading" (P7); and the preference for better understanding through the auditory presentation: "it is easier and I understand it better when you read it out loud" (P9). These observations indicate challenges, related to literacy, eyesight, and concentration among patients.

### 3.3.2. Floor and ceiling effects

Floor effect was found in all items, with percentages ranging from 27% to 73% (Table 2). There were no ceiling effects on any items.

### 3.4. Structural validity

The confirmatory factor analysis supported both the 2-factor model (Fig. 1), and the 3-factor model as standardised root mean squared residual were 0.078 and 0.075 and root mean square error of approximation were 0.057 and 0.053, respectively. The 3-factor model had a slightly better comparative fit index with 0.954 than the 2-factor model with 0.933.

### 3.5. Internal consistency reliability

The internal consistency reliability had a Cronbach's  $\alpha$  of 0.86 for the total scale of the HADS and a Cronbach's  $\alpha$  of 0.85 and 0.73 for the sub-scale HADS-A and HADS-D, respectively.

## 4. Discussion

In this psychometric study, we investigated content validity, structural validity, and internal consistency reliability of the Danish version of HADS in patients with major LEA. Among this in-hospital cohort, 20% exhibited anxiety symptoms, while 18% exhibited depressive symptoms. Patients generally considered the questionnaire relevant, comprehensible, and comprehensive. However, they raised concerns about the relevance of the one-week time frame in the instructions and noted that item 8 might be less applicable due to opioid use. They also found the expression "butterflies in the stomach" in item 9 difficult to understand, as it conveys positive feelings in Danish culture. Moreover, the term "things" in items 2 and 12 was deemed too vague. Floor effects were

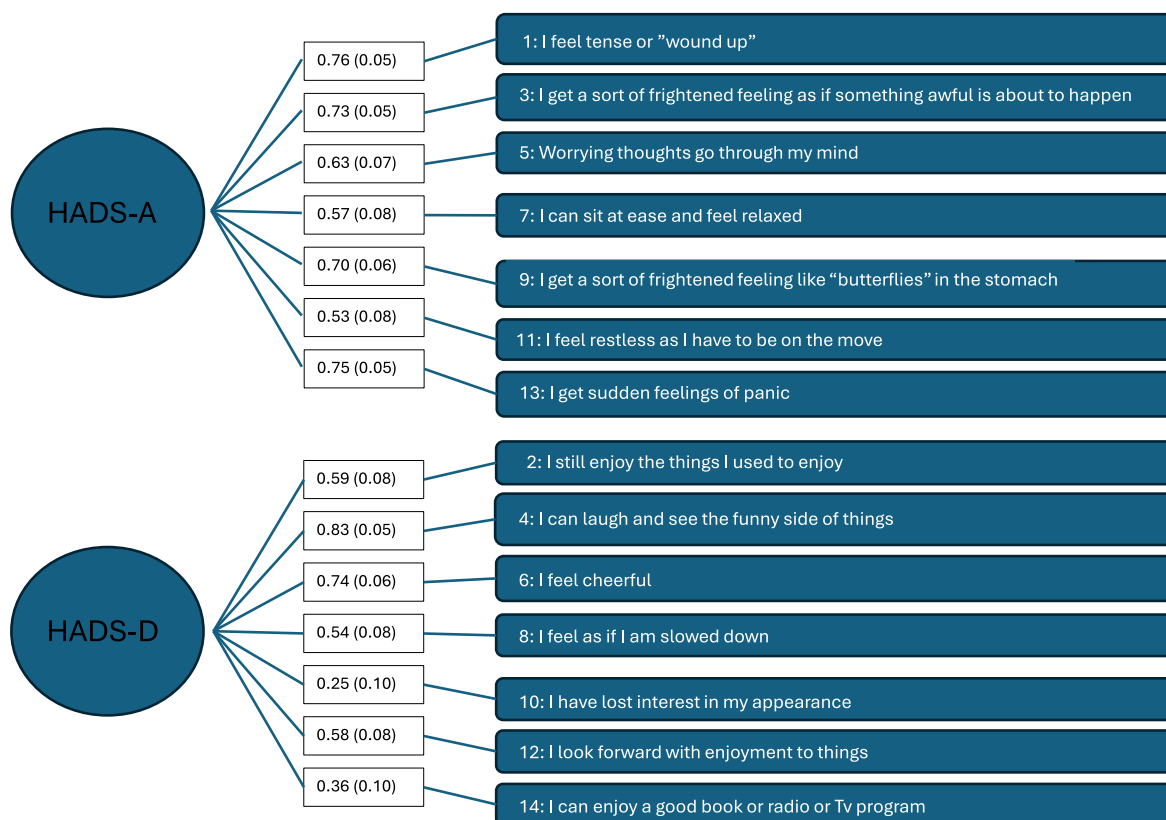


Fig. 1. Diagram of the confirmatory factor analysis.

observed across all items, but there were no ceiling effects. Confirmatory factor analysis supported both the original two-factor structure and an alternative three-factor structure of the scale. The internal consistency reliability was good for both subscales.

No previous studies have examined the content validity, including floor and ceiling effects, of the HADS in patients with major LEA. Additionally, no research has evaluated the content validity of the Danish or other Scandinavian versions of HADS. Consequently, comparison with prior studies is not feasible. However, our findings suggest that the HADS questions are relevant for patients with major LEA in an inpatient surgical setting, even though it was originally designed for outpatient medical use.

In our study, 80% of patients with major LEA showed no symptoms of anxiety, and 82% showed no symptoms of depression when tested postoperatively before discharge from hospital. These prevalence rates, observed with a median hospital stay of 11 days, are not directly comparable to a previous study among patients with major LEA, with a median follow-up period of 8.4 years (Hawamdeh et al., 2008). The floor effect for all items was expected, as the HADS functions as a screening tool, and most of the patients will not have symptoms of anxiety and depression. We found no ceiling effect in our study. However, a ceiling effect on item 8 of the Danish version of HADS was previously observed among patients with ischemic heart disease (Christensen et al., 2020). In our think-aloud interviews, Item 8 was questioned for relevance due to opioid treatment, as such treatment could potentially increase feelings of being slowed down.

Furthermore, in the think-aloud interviews, patients noted an overlap between items 12 and 14 in the anxiety scale (HADS-A), and items 9 and 13 in the depression scale (HADS-D). Since this overlap occurred within the same construct and HADS is a reflective model, overlap between items within the same construct is not a concern.

In our study, we found acceptable internal consistency reliability, consistent with previous Cronbach's alpha values reported for the

Danish version of HADS used among patients with ischemic heart disease.

The structural validity of HADS among patients with major LEA was previously studied by Desmond et al., in 2005 using goodness-of-fit parameters, which values align closely with our values. Alternative fit models, such as a three-factor model, have been discussed previously among Danish patients with ischemic heart disease (Christensen et al., 2020). Our results support both two and three-factor models, but from a clinical perspective, it is only necessary to distinguish between anxiety and depression.

Finally, the HADS questionnaire was found to serve as a platform to address psychosocial challenges and allow patients to reflect on their mental health and become aware of potential future symptoms that may require medical attention.

#### 4.1. Strength and limitations

In this study, we utilized a widely recognized cognitive interview method to assess the content validity of the HADS. The 'Think Aloud' method facilitated the acquisition of significant and valuable insights into the patient's psychological state following a major LEA, as well as their thoughts regarding a questionnaire assessing depression and anxiety. The strengths of this study lie in the application of widely recognized international COSMIN guidelines, its large sample size, its high response rate, and the substantial representation of patients from seven hospitals across Denmark. This study is limited by its focus on content validity only during the hospital phase. Collecting additional data after discharge could have provided further insights. Moreover, psychometric properties such as test-retest reliability and concurrent validity were not addressed in this study.

## 5. Conclusion

The results of this study support the content validity, structural validity, and internal consistency reliability of the Danish version of HADS. Furthermore, it adds to prior psychometric studies on HADS among patients with major LEA. The findings suggest that the HADS can be used to systematically screen for anxiety and depression among patients with major LEA. The questionnaire was found to serve as a platform to address psychosocial challenges and allow patients to reflect on their mental health and become aware of potential future symptoms that may require medical attention. Clinicians should note that questions 2, 9, and 12 in the Danish version of HADS may be less clear for patients with major LEA. Moreover, these patients may benefit from assistance from healthcare professionals when completing the questionnaire.

## CRedit authorship contribution statement

**Charlotte Abrahamsen:** Writing – original draft, Project administration, Investigation, Formal analysis, Data curation, Conceptualization. **Ulla Riis Madsen:** Writing – review & editing, Investigation, Conceptualization. **Ann Pia S e Jensen:** Writing – review & editing, Investigation, Conceptualization. **Karin Bundgaard:** Writing – review & editing, Investigation, Conceptualization. **Charlotte Myhre Jensen:** Writing – review & editing, Investigation, Conceptualization. **Pia Kj r Kristensen:** Writing – original draft, Investigation, Formal analysis, Conceptualization.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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