# Thirst measurement in the Intensive Care Unit:

Validity and Reliability of the 'Thirst Distress Scale for patients with Heart Failure' in adult intensive care unit patients

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Date June 27, 2018

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Journal Intensive and Critical Care Nursing

Word count article 3794

Reporting criteria STARD 2015

Word count Nederlandse 277

samenvatting

Word count abstract 266

#### Abstract

**Background:** Thirst is one of the most intense and distressing symptoms experienced by patients in the intensive care unit (ICU), and no validated measurement tools exist. Validating a thirst measurement tool for the ICU population could be a first step in gaining a better understanding of thirst in ICU patients and aid the development and implementation of strategies regarding the prevention and control of thirst. Aim: The objective of this study was to determine the validity and reliability of the 'Thirst distress scale for patients with heart failure (TDS-HF)' in measuring thirst distress in adult ICU patients. Methods: In this crosssectional study content validity was established by an expert panel consisting of ICU nurses, intensivists and ICU patients. Concurrent validity, known-groups validity, and internal consistency were determined in a consecutive sample of awake and oriented ICU patients. Results: The expert panel consisted of 12 members, whereof 5 patients. The sample of ICU patients consisted of 56 patients, with a median age of 70 years (IQR 57-74). Content validity was low with item-content validity indexes between 0.25 and 0.75. Concurrent validity was high as Spearman's correlation between TDS-HF and the numeric rating score (0-10) for thirst distress was r0.71. Internal consistency was high (Cronbach's alpha 0.78). When comparing groups, only higher blood urea nitrogen proved significant for higher scores on the TDS-HF (p0.003). Conclusion and Recommendations: The TDS-HF has high concurrent validity and reliability in measuring thirst distress in ICU patients. Nevertheless, questions remain regarding the applicability and content validity of the scale, which should be further explored before the TDS-HF can be used in the ICU.

Keywords: Thirst, Intensive Care, Symptom, Measurement tool

# Nederlandse samenvatting

Achtergrond: Dorst is een van de meest intense en hinderlijke symptomen die intensive care (IC) patiënten ervaren, en er bestaan geen gevalideerde meetinstrumenten voor. Het valideren van een dorst-meetinstrument voor de IC populatie zou een eerste stap kunnen zijn om een beter begrip van dorst bij IC patiënten te verkrijgen, en kan helpen bij de ontwikkeling en implementatie van strategieën voor de preventie en beheersing van dorst. Doel: Het doel van deze studie was om de validiteit en betrouwbaarheid van de 'Thirst distress scale voor patiënten met HartFalen(TDS-HF)' vast te stellen voor het meten van hoe vervelend dorst is voor volwassen IC-patiënten. Methode: In dit dwarsdoorsnede-onderzoek werd de inhoudsvaliditeit vastgesteld door een expert-panel bestaande uit ICverpleegkundigen, intensivisten en IC-patiënten. De concurrent validiteit, de known-groups validiteit en de interne consistentie werden vastgesteld in een opeenvolgende steekproef van IC-patiënten. Resultaten: Het expert-panel bestond uit 12 leden, waarvan 5 patiënten. In de steekproef werden 56 IC-patiënten geïncludeerd, met een mediane leeftijd van 70 jaar (IQR 57-74). De inhoudsvaliditeit bleek laag, met item-contentvaliditeits-indexen tussen de 0.25 en 0.75. De concurrent validiteit was hoog, wat bleek uit een Spearman's correlatie van r0.71 tussen de TDS-HF en een numerieke score (0-10) van 'hoe vervelend' dorst voor IC patiënten was. Bij het vergelijken van groepen, bleek alleen het ureum significant voorspellend voor hogere scores op de TDS-HF (p0.003). De interne consistentie was hoog (Cronbach's alpha 0.78). Conclusie en Aanbevelingen: De TDS-HF heeft een hoge concurrent validiteit en betrouwbaarheid in het meten van 'hoe vervelend' dorst is voor IC patiënten. Niettemin zijn er nog vraagtekens over de toepasbaarheid en de inhoudsvaliditeit. Deze moeten verder verkend worden alvorens de TDS-HF gebruikt kan worden op de IC.

Trefwoorden: Intensive Care, Dorst, Symptoom, Meetinstrument, Klinimetrie

#### Introduction

Thirst is one of the most intense and distressing symptoms experienced by patients in the intensive care unit (ICU), as was observed in clinical practice and confirmed in several studies<sup>1–8</sup>. In adult ICU patients, thirst has a prevalence of 71 to 80% and is experienced as moderately intense and distressing<sup>2,3,9</sup>.

One of the main goals in nursing is to alleviate suffering and discomfort<sup>10,11</sup> This is especially relevant to ICU patients which often experience limited self-management possibilities.

Despite its high prevalence and burden, thirst is not routinely measured in the ICU. This contrasts with for example pain measurements, even though thirst has a higher prevalence and is being experienced as more bothersome by ICU patients than pain<sup>1,5</sup>.

Moreover, no validated tools for thirst measurement in the ICU exist. This hampers our insight into the symptom burden of thirst in daily practice and limits the evaluation of thirst interventions.

Several factors linked to ICU admission make this population susceptible to experiencing thirst. Predictors of thirst in the ICU are the use of opioids and diuretics, mechanical ventilation (MV), not receiving oral fluids and admission for gastrointestinal reasons<sup>12</sup>. Additionally, xerostomia (dry mouth or throat) occurs often because many ICU patients are on a nil-per-os regimen related to having dysphagia<sup>13</sup>, and orally intubated patients have difficulties closing their mouths.

Reduced consciousness due to sedation<sup>14</sup> and delirium,<sup>15</sup> are common in ICU patients, which might impair the expression of thirst by patients, and impede the appraisal of patients' thirst by their nurses as well. There is a tendency to sedate ICU patients less deeply<sup>16</sup>. Light sedation offers the possibility to discuss symptoms and symptom management with patients, but it also leads to increased and more vivid memories of being in the ICU, including thirst experiences<sup>1,6,8</sup>. In fact, even after six months to two years, patients mentioned thirst as one of the most bothersome symptoms they experienced during their ICU admission<sup>4,17</sup>.

Various definitions of thirst are used, which have in common that the sensation of thirst is subjective<sup>18–20</sup>. In this study, being thirsty is considered 'the conscious and subjective sensation of desiring fluids' <sup>21</sup>. Thirst can arise of physiologic causes, like lack of fluid, or out of habit, taste or xerostomia<sup>19,22,23</sup>.

Thirst as a symptom has four dimensions, being: intensity, quality, timing (when, how long) and distress <sup>21</sup>. 'Distress' is defined as 'the degree to which a person is bothered by thirst or its associated discomfort' and is the symptom dimension that most promotes searching for relief <sup>21,24</sup>.

Currently, thirst intensity and distress in the ICU have been measured with Numeric Rating Scales (NRS) or modified Edmonton Symptom Assessment Scales (ESAS), neither of which were validated for this purpose<sup>2,3,9</sup>.

Welch et al. developed and validated the Thirst Distress Scale (TDS) for measuring thirst distress in kidney failure patients<sup>21</sup>. Recently this scale was translated, modified and validated for use in heart failure (HF) patients (TDS-HF) in Sweden, Japan, and the Netherlands<sup>25</sup>. Factor analysis showed that this scale was unidimensional, Cronbach's alpha was 0.90 and item-total correlations varied between 0.63-0.75.

There are similarities in the factors contributing to thirst in HF and ICU patients, such as limitations in fluid intake and the frequent use of diuretics<sup>26</sup>, and using existing scales is preferred over developing new scales because of generalisability<sup>27</sup>.

However, considering differences between HF and ICU populations, expressed in the acuteness of illness and varying levels of consciousness in ICU patients, the validation of the TDS-HF in ICU patients is needed before using it for research purposes or to monitor thirst in daily practice<sup>28</sup>.

The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) offers a taxonomy of measurement properties to evaluate when using existing scales in new populations<sup>29</sup>. These measurement properties are divided into three groups: Reliability, defined as 'the degree to which the measurement is free from measurement error'<sup>30</sup>, validity, defined as 'the degree to which an instrument truly measures the construct it purports to measure'<sup>30</sup> and responsiveness, defined as 'the ability of an instrument to detect change over time in the construct to be measured'<sup>30</sup>

Validating a thirst measurement tool for the ICU population could be a first step in gaining a better understanding of thirst in ICU patients and aid the development and implementation of strategies regarding the prevention and control of thirst.

# Objective

The objective of this study was to determine the reliability and validity of the 'Thirst distress scale for patients with heart failure (TDS-HF)' in measuring thirst distress in adult ICU patients.

# Method

# Design

A Cross-sectional design with prospective data-collection was used. Content validity was determined by an expert panel. Concurrent validity, known-groups validity and internal consistency were determined in a sample of ICU patients.

Reporting of this study followed the Standards for Reporting of Diagnostic Accuracy Studies (STARD 2015) guidelines<sup>31</sup>.

# Setting

This study was performed in a 14-bed medical-surgical ICU in a teaching hospital in the Netherlands. Approximately 800 patients are admitted yearly, with a median length of stay of 1.7 days. The vast majority of patients are admitted for medical reasons<sup>32</sup>.

# **Participants**

The expert panel consisted of ICU nurses, intensivists and current or recently discharged (<7 days) ICU patients that had experienced thirst during ICU admission.

Inclusion criteria for the sample of ICU patients were: Adults (≥18 years), ICU admission ≥24 hours, being awake, defined as a Richmond Agitation and Sedation Scale (RASS)<sup>33</sup> score of -1 to 1 (i.e. not sedated or agitated) and the absence of delirium, defined as a negative score on the Confusion Assessment Method for the Intensive Care Unit (CAMICU) <sup>34</sup>.

Patients were not eligible for participation in the panel or the sample if language barriers, impaired vision or impaired hearing were expected to limit fulfilling the tests adequately or if they were admitted to the ICU for other reasons than critical illness (e.g. patients on home-mechanical ventilation admitted for non-respiratory reasons).

#### Ethical considerations

The study protocol was approved by the institutional ethical review board, which judged this study not to be subject to the Scientific Research with People Act (in Dutch: *Wet Medisch-Wetenschappelijk onderzoek met Mensen(WMO)*) due to the observational nature of the study. The study complied with the Declaration of Helsinki<sup>35</sup>, the Code of Conduct for Health Research<sup>36</sup>, the General Data protection Act<sup>37</sup> and the Medical Treatment Agreement Act<sup>38</sup>. Although legally not mandatory, we chose to obtain written informed consent from all participants, because of the vulnerability of this population.

## Procedures

## Expert panel

Content validity (the degree to which a multi-item instrument has an appropriate set of relevant items reflecting the full content of the construct domain to be measured<sup>39</sup>) of the TDS-HF was assessed by means of a written survey. A convenience sample was obtained with respect to variety in the panel. Eligible subjects were invited to participate personally by the researcher.

## Sample of ICU patients

Concurrent validity (the degree to which scores on an instrument are correlated with an external criterion<sup>39</sup>), known-groups validity (the degree to which a measure is capable of discriminating between groups known or expected to differ with regard to the construct of interest<sup>39</sup>) and internal consistency (the degree to which the subparts of a composite scale are interrelated and are all measuring the same attribute or dimension<sup>39</sup>), were established in a sample of ICU patients.

To obtain a consecutive sample, all admitted patients were screened two to three times per week between January and May 2019 for meeting inclusion criteria. All eligible patients were invited to participate. Assessment of RASS and CAM-ICU scores, which were necessary to determine eligibility, were part of routine care.

The reference tests, numeric rating scores (NRS) of thirst intensity and thirst distress<sup>40</sup>, were taken orally by the researcher. Directly following, the index test, being the TDS-HF, was completed by the participants themselves to resemble with previous studies evaluating this scale<sup>21,25</sup>. The measurements were taken once in each participant.

#### Instruments

## Content validity survey

Panel members scored each item of the TDS-HF regarding its relevance to thirst distress in the ICU as follows: 1=not relevant, 2= somewhat relevant, 3= quite relevant, 4= highly relevant<sup>39,41</sup>. Additionally, participants were invited to provide comments on the clarity of each item. Finally, to determine completeness, they were asked to note items that they thought relevant to thirst distress in the ICU, but which were not addressed in the TDS-HF.

#### TDS-HF

The TDS-HF consists of eight statements, which are answered on a Likert-type scale, ranging from 1 (totally disagree) to 5 (totally agree), resulting in a score between 8-40, with higher scores indicating higher thirst distress (appendix 1). If completing the scale was troublesome, participants were given help by reading aloud or filling out the test. If help was

provided, this was noted because this could influence reliability<sup>41</sup>. After completing the TDS-HF participants were asked if they had any comments on the scale concerning practicality or content. Given comments were noted by the researcher.

# Numeric rating scales

Thirst distress was assessed by asking: On a scale of 0 to 10, how bothersome is your thirst at this moment? At which 0 resembles that it does not bother you at all, and 10 means it bothers you immensely. Thirst intensity was assessed by asking: On a scale of 0 to 10, how intense is your thirst at this moment? At which 0 resembles that you are not thirsty and 10 means that you have the worst thirst imaginable.

Finally, demographic data and data on factors known to contribute to thirst distress were taken from the medical record<sup>12,42</sup>. An overview of study procedures is provided in figure one.

[Insert Figure 1]

# Analyses

## Content Validity

The relevance of items was determined by item-level content validity index (I-CVI) and scale content validity index (S-CVI). I-CVI was computed as the number of experts giving a rating of 3 (*quite relevant*) or 4 (*highly relevant*), divided by the number of experts and was considered acceptable if it was >0.78 for each item<sup>39</sup>. S-CVI was computed by averaging the I-CVIs and was desirably ≥0.90. Qualitative data from the surveys were merged per scale item or by topic and presented descriptively.

#### Concurrent Validity

Correlations between the TDS-HF and NRSs' of thirst distress and thirst intensity were determined by Pearson's rho for normal distribution or Spearman's rho for non-normal distribution<sup>39</sup>. A correlation of >0.70 was considered acceptable<sup>29</sup>.

#### Known-groups Validity

Testing of groups was performed with a priori hypotheses,<sup>39</sup> to limit the risk of bias<sup>27</sup>. Because a clinically relevant difference or cut-off point is unknown for the TDS-HF<sup>25</sup> it was chosen to divide the participants into two equal groups by median TDS-HF score, resulting in a TDS-HF<sub>low</sub> and a TDS-HF<sub>high</sub> group. Next, Students T-tests for continuous normally distributed data, Mann-Whitney U tests for not normally distributed data or Fisher's exact tests for dichotomous data were executed to determine if TDS-HF scores matched the hypotheses. Participants were hypothesized to have higher thirst distress if (1) their reason for admission was 'gastrointestinal' or 'other', if (2) they were on MV, if (3) they used anti-hypertensive medication or (4) diuretics or if (5) they had a higher blood urea nitrogen<sup>12</sup>. A

significance level of 0.05 was applied. Correction for multiple testing was done by applying Bonferroni correction.

## Reliability and data quality

Internal consistency was determined by Cronbach's alpha<sup>39</sup>. A value between 0.70 and 0.90 was considered acceptable<sup>29</sup>. Item-total correlations were calculated and because the TDS-HF appeared unidimensional in previous research, correlations between 0.2 and 0.5 were considered desirable<sup>29</sup>. Data were analyzed for floor and ceiling effects by evaluating the percentages of responses in the lowest, respectively highest answering option and were considered relevant if ≥15%<sup>43</sup>. Only data from participants that answered all items of the TDS-HF were used for validity and reliability analyses to prevent influencing sum scores and to resemble with previous work on the TDS-HF<sup>25</sup>.

## Sample sizes

No formal power calculations are designated for the psychometric properties tested in this study, but a sample of at least 50 is adviced<sup>29,39,44</sup>. When using quantitative scores of agreement on item relevance, an expert panel should consist of at least five experts to reach a sufficient level of control of chance agreement<sup>45</sup>. Because patients as well as professionals were included, a minimum of five participants was recruited in each group.

Data are presented as number and percentage for nominal data, mean and standard deviation for normally distributed data or median and interquartile range for not normally distributed data. Distribution of quantitative data was judged after visual inspection of histograms and Kolmogorov-Smirnov testing. All analyses were performed using the Statistical Package for the Social Sciences (SPSS, version 25, IBM).

# Results

#### Sample characteristics

The expert panel consisted of 12 participants: 7 ICU professionals, of which 5 had more than 10 years of experience in ICU care, and 5 patients, with a median age of 45 (range 25-60) (table 1). Patients were admitted to the ICU during participation, except for one that was on a general ward and completed the survey within a week after ICU discharge. Help with the survey was provided in four of the patients.

[Insert Table 1]

For the sample of ICU patients, 239 patients were screened, of which 102 were considered eligible and 56 of them could be included in the study (figure 2). Participants had

a median age of 70 (IQR 57-74) and the majority were male (61%). A large proportion of the sample (64%) was not able to complete the TDS-HF independently (table 2).

[Insert Table 2]
[Insert Figure 2]

# Data quality

All participants in the expert panel completed all the questions of the survey. The NRSs of thirst intensity and thirst distress had no missing items. Missing items in the TDS-HF occurred in six (11%) of the participants. More than one missing answer in the TDS-HF occurred in items 5 (n=3) and 6 (n=4).

# **Content Validity**

As displayed in Table 3, I-CVI was low for most items ranging from 0.25 for item 6 to 0.75 for item 1, with none of the items reaching the 0.78 threshold. S-CVI was 0.51, which is well below the 0.90 threshold. Professionals in the panel rewarded higher scores to most items than patients, except for item 5.

[Insert table 3]

Qualitative comments revealed that nurses and intensivists concerns about the number of questions related to a short span of concentration in ICU patients. Furthermore, they added that thirst distress might be influenced by whether patients were allowed or able to drink and moreover, that the ability to communicate could highly influence the feeling of distress. Patients in the panel emphasized that they thought it more important that when they were thirsty this discomfort would be attended rather than asking many questions about it. Both professionals and patients indicated that items 3, 4 and 5 seemed to address the same construct: a dry feeling in the mouth.

#### Concurrent validity

Data from TDS-HF (figure 3) and NRSs were not normally distributed. The median TDS-HF score was 29.5(IQR 22.8-34.0), whereas median NRSs of thirst distress and thirst intensity were 6.0(IQR 4.5-8.0) and 6.0(IQR 3.0-8.0). Spearman's correlations were positive and strong (figure 4). The correlation between TDS-HF and NRS for thirst distress was *r*0.714 and between TDS-HF and NRS for thirst intensity, this was *r*0.743.

[Insert figure 3] [Insert figure 4]

## Known-groups validity

Several hypotheses were tested based on available literature of which only blood urea nitrogen was significantly higher in the TDS-HF<sub>high</sub> group after correction for multiple testing as displayed in Table 4.

[Insert table 4]

## Reliability

Cronbach's alpha was 0.88, which is between the stated thresholds (table 5). In the histograms, we observed left skewness in most individual items of the TDS-HF. Ceiling effects were confirmed as the percentages of answers in option 5 (totally agree) had an average of 32 percent (range 18-43).

[Insert table 5]

Several participants hesitated when answering item 6 and 8. When asked by the researcher, participants declared that item 6 was regarded as confusing with respect to the question being positively or negatively asked. For item 8, several participants stated that they did not know the meaning of 'difficult to overcome' (in Dutch: *onoverkomelijk*).

Item-total correlations show high values for all items, indicating that all items contribute to measuring the same construct.

# Discussion

The objective of this study was to determine the validity and reliability of the 'Thirst distress scale for patients with heart failure (TDS-HF)' in measuring thirst distress in adult ICU patients. The current study showed low scores on content validity, but concurrent validity yielded high scores. In assessment of known-groups validity most hypotheses were not confirmed. Reliability assessment revealed a high internal consistency.

Thirst levels in our sample are comparable with those in previous studies on thirst in awake and oriented ICU patients. The pre-intervention measurements in the Puntillo 2014 RCT(n=252) found means of 4.6 (Cl 4.1-5.0) for distress and 5.6 (Cl 5.2-6.0) for intensity <sup>9</sup> which is considered 'moderate' thirst, as do our medians of 6.0 for thirst distress and intensity.

Thirst levels appeared substantially different between HF and ICU patients. Waldréus et al. found a prevalence of 20% and intensity of 16mm(IQR 4-44) on a visual analog scale<sup>25</sup>, which contrasts with Puntillo et al. finding a prevalence of 71% and thirst intensity of 5.6 (CI 5.2-6.0) in ICU patients<sup>9</sup>. Waldréus obtained TDS-HF scores of 16.4±7.8 (mean±SD) in

hospital-admitted and outpatient HF patients<sup>25</sup>, which contrasts with the current study were the median TDS-HF score was 29.5(IQR 22.8-34.0). Additionally, in our study, we observed considerable ceiling effects in the TDS-HF items, which can occur when applying an instrument in a new population that is more diseased<sup>29</sup>. Adaptation of the instrument might thus be necessary to measure the complete range of thirst distress in ICU patients.

Some uncertainty arose about the applicability of the TDS-HF in the ICU because it became clear that a large proportion (64%) of the participants were not able to complete the TDS-HF by themselves. Dependency on nursing staff or relatives is common for ICU patients because of limitations in mobility<sup>46</sup>, illustrated by the fact that up to 65% of ICU patients experience ICU-acquired weakness<sup>47</sup> and experience struggling with infusion lines or wires<sup>5</sup>. This was confirmed in our study, as limited self-care being a restriction in thirst relieve also emerged from our qualitative data.

Considering the high concurrent validity, our study, vice versa, indicates that NRSs might be fit to get an impression of thirst distress in the ICU. To our knowledge, this has not been shown before.

Most of the posed hypotheses were not supported by our data. As the literature on factors contributing to thirst in the ICU is scarce, hypotheses were based on one single article<sup>12</sup>. Although the study of Stotts et al. included a large sample (n= 353) and seems methodologically sound, this is a small knowledge base. Blood urea nitrogen, the only hypotheses confirmed significantly in our results, proved to increase thirst distress in more studies<sup>48,49</sup>. As cell counts of <5 occurred in our contingency tables, these results presumably have limited reliability.

A strong asset of the TDS-HF is that it is a multi-item scale, opposed to single-item scales used for other symptoms, like NRSs or modified ESAS, as previous studies on thirst in the ICU have used<sup>3,9,12</sup>. This was confirmed by the high internal consistency in our study. On the other hand, the responsiveness of the TDS-HF has not yet been addressed which is seen as one of the three essential elements of a measurement instrument by the COSMIN<sup>29</sup>.

This study has some limitations. Firstly, in assessing content validity, patients in the expert panel tended to reflect on their own thirst experience, rather than holding ICU patients in general in mind, and professionals in the panel tended to focus on possible thirst interventions, rather than thirst assessment. In conclusion, it is uncertain if the methods used to assess content validity were adequate. Using other methods, like think-aloud interviews or group-discussions, could have been more suitable.

Secondly, in the sample of ICU patients, first NRSs' on thirst intensity and distress were asked on a 0-10 unidirectional scale and directly after, the TDS-HF had to be scored on a 1-5 Likert-type scale. It cannot be ruled out that the sequence, the different range and the

type of scale (unidirectional versus Likert-type) of the questions might have influenced the reliability of the responses<sup>41</sup>.

Thirdly, it should be noted that there is an ongoing debate on using specific analyses techniques on Likert-scale type of data, like ordinal correlations or polychoric alpha<sup>41,50,51</sup>. For this study it was chosen to consider the data as continuous and not ordinal, to be able to make better comparisons with former work on the TDS and TDS-HF<sup>21,25</sup>.

# Implications for clinical practice and future research

The importance of reducing discomfort in ICU patients is illustrated by the fact that patients who reported a higher symptom burden are more likely to develop post-traumatic stress disorder<sup>52</sup>. Nursing care is aimed at reducing discomfort, but before interventions can be applied, the assessment of symptoms is essential. Therefore availability of valid and reliable tools is required.

The TDS-HF can be helpful to get a thorough view of thirst distress, since scales with multiple items have a larger reliability<sup>41</sup>. This is especially important when using scales for research purposes. For clinical practice, an NRS might be more appropriate since it is less complicated to apply and less time-consuming. Consequently, the adage 'form follows function' is at its place in making choices for the instrument to be applied.

Similar to other studies on thirst in ICU patients, our study sample consisted of awake and oriented participants. These patients were almost ready to be discharged, as was reflected in the time point of participation in the study (77% of total admission days). To adequately measure symptom burden in the complete target population, additionally, the availability of observational scales is essential. This was demonstrated in the development of the Critical Pain Observation Tool (CPOT) used to measure pain in ICU patients under various levels of consciousness<sup>53</sup>. When further developing thirst measurement tools, this should be taken into account.

There seems to be a contradiction between several components in this study. The content validity of the TDS-HF and the known-groups comparisons resulted in low scores, whereas concurrent validity and internal consistency yielded high scores. It would be useful to enlarge the sample and include a minimum of ten participants per item<sup>29,41</sup>, to be able to perform structural factor analysis. Additionally, content validity should be further explored. Subsequently, the TDS-HF could be adapted and possibly shortened, which would make it more suitable for use in the ICU and would also meet the demands expressed by patients and professionals in this study.

# Conclusions

This study showed that the TDS-HF has a high concurrent validity and reliability in measuring thirst distress in ICU patients. Nevertheless, questions remain regarding the applicability and content validity of the scale, which should be further explored before the TDS-HF can be used in the ICU.

#### Reference list

- 1. Chanques GG, Nelson J, Puntillo K. Five patient symptoms that you should evaluate every day. Intensive Care Med. 2015 Jul;41(7):1347–50.
- 2. Li DT, Puntillo K, DT L, Puntillo K, Li DT, Puntillo K, et al. A pilot study on coexisting symptoms in intensive care patients. Appl Nurs Res. 2006 Nov;19(4):216–9.
- 3. Puntillo KA, Arai S, Cohen NH, Gropper MA, Neuhaus J, Paul SM, et al. Symptoms experienced by intensive care unit patients at high risk of dying. Crit Care Med. 2010 Nov;38(11):2155–60.
- 4. Rose L, Nonoyama M, Rezaie S, Fraser I. Psychological wellbeing, health related quality of life and memories of intensive care and a specialised weaning centre reported by survivors of prolonged mechanical ventilation. Intensive Crit care Nurs. 2014 Jun;30(3):145–51.
- 5. Kalfon P, Mimoz O, Auquier P, Loundou A, Gauzit RR, Lepape A, et al. Development and validation of a questionnaire for quantitative assessment of perceived discomforts in critically ill patients. Intensive Care Med. 2010 Oct;36(10):1751–8.
- Kjeldsen CL, Hansen MS, Jensen K, Holm A, Haahr A, Dreyer P. Patients' experience of thirst while being conscious and mechanically ventilated in the intensive care unit. Nurs Crit Care. 2017 Jan;23(2):75–81.
- 7. Persenius MW, Hall-Lord ML, Wilde-Larsson B. Grasping the nutritional situation: a grounded theory study of patients' experiences in intensive care. Nurs Crit Care. 2009;14(4):166–74.
- 8. Holm A, Dreyer P. Intensive care unit patients' experience of being conscious during endotracheal intubation and mechanical ventilation. Nurs Crit Care. 2017

  Mar;22(2):81–8.
- 9. Puntillo K, Arai SR, Cooper BA, Stotts NA, Nelson JE. A randomized clinical trial of an intervention to relieve thirst and dry mouth in intensive care unit patients. Intensive Care Med. 2014 Sep;40(9):1295–302.
- 10. CGMV vakorganisatie voor christenen, CNV Z& W, FNV Z& W, HCF N, NU' 91, RMU SG en W 'Het R, et al. Beroepscode van Verpleegkundigen en Verzorgenden [Internet]. Nursing. 2015 [cited 2019 Jun 19]. p. 16. Available from: https://www.venvn.nl/Portals/1/Thema's/Beroepscode/De Nationale Beroepscode voor Verpleegkundigen en Verzorgenden.pdf
- 11. Schuurmans M, Lambregts J, Grotendorst A. Beroepsprofiel verpleegkundige. 2011;1–41.
- 12. Stotts NA, Arai SR, Cooper BA, Nelson JE, Puntillo KA. Predictors of thirst in intensive

- care unit patients. J Pain Symptom Manage. 2015 Mar;49(3):530-8.
- 13. Skoretz SA, Flowers HL, Martino R. The incidence of dysphagia following endotracheal intubation a systematic review. Vol. 137, Chest. 2010. p. 665–73.
- 14. Payen J-F, Chanques G, Mantz J, Hercule C, Auriant I, Leguillou J-L, et al. Current Practices in Sedation and Analgesia for Mechanically Ventilated Critically III Patients. Anesthesiology. 2007 Apr 1;106(4):687–95.
- 15. Rood P, Huisman de Waal G, Vermeulen H, Schoonhoven L, Pickkers P, van den Boogaard M. Effect of organisational factors on the variation in incidence of delirium in intensive care unit patients: A systematic review and meta-regression analysis. Aust Crit Care. 2018 Mar 12;
- 16. Barr J, Fraser GL, Puntillo K, Ely EW, Gélinas C, Dasta JF, et al. Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit: Executive summary. Am J Heal Pharm. 2013 Jan;70(1):53–8.
- Hofhuis JGM, Spronk PE, van Stel HF, Schrijvers AJP, Rommes JH, Bakker J. Experiences of critically ill patients in the ICU. Intensive Crit Care Nurs. 2008 Oct;24(5):300–13.
- 18. Silbernagl S, Despopoulos A, Trador (Wijk bij Duurstede). Sesam atlas van de fysiologie. SESAM/HBuitgevers; 2001.
- 19. Fitzsimons JT. Thirst. Physiol Rev. 1972 Apr;52(2):468–561.
- 20. Greenleaf JE. Problem: thirst, drinking behavior, and involuntary dehydration. Med Sci Sports Exerc. 1992 Jun;24(6):645–56.
- 21. Welch JL. Development of the thirst distress scale. Nephrol Nurs J. 2002 Aug;29(4):337–41; discussion 343.
- 22. McKinley MJ. The Physiological Regulation of Thirst and Fluid Intake. News Physiol Sci. 2004;19(1):1–6.
- 23. Garcia AKA, Fonseca LF, Aroni P, Galvão CM. Strategies for thirst relief: integrative literature review. Rev Bras Enferm. 2016;69(6):1215–22.
- 24. Lenz ER, Pugh LC, Milligan RA, Gift A, Suppe F. The middle-range theory of unpleasant symptoms: an update. ANS Adv Nurs Sci. 1997;19(3):14–27.
- 25. Waldréus N, Jaarsma T, van der Wal MHL, Kato NP. Development and psychometric evaluation of the Thirst Distress Scale for patients with heart failure. Eur J Cardiovasc Nurs. 2018;17(3):226–34.
- 26. Waldréus N, Hahn RG, Jaarsma T. Thirst in heart failure: A systematic literature review. Eur J Heart Fail. 2013;15(2):141–9.
- 27. Mokkink LB, de Vet HCW, Prinsen CAC, Patrick DL, Alonso J, Bouter LM, et al.

- COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. Qual Life Res. 2017;27(5):1171–9.
- 28. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. Br Med J. 2007 Mar 3;334(7591):455–9.
- 29. de Vet HCW, Terwee CB, Mokkink LB, Knol DL. measurement in medicine: a practical guide. The Lancet. 2011.
- Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010 Jul 1;63(7):737–45.
- 31. Irwig L, Rennie D, Hooft L, Glasziou PP, Cohen JF, Bossuyt PM, et al. STARD 2015: An Updated List of Essential Items for Reporting Diagnostic Accuracy Studies. Clin Chem. 2015;61(12):1446–52.
- 32. Stichting Nationale Intensive Care Evaluatie (NICE). www.stichtingNICE.nl [Internet]. [cited 2019 May 3]. Available from: https://www.stichting-nice.nl
- Sessler CN, Gosnell MS, Grap MJ, Brophy GM, O'Neal P V, Keane KA, et al. The Richmond Agitation

  Sedation Scale. Am J Respir Crit Care Med. 2002 Nov;166(10):1338

  44.
- 34. Ely EW, Inouye SK, Bernard GR, Gordon S, Francis J, May L, et al. Delirium in Mechanically Ventilated Patients: Validity and Reliability of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). JAMA. 2001;286(21):2703–10.
- 35. Introduction A. Declaration of Helsinki World Medical Association Declaration of Helsinki. 2001;79(June 1964).
- 36. FMWV Code of Conduct for Health Research CODE OF CONDUCT FOR MEDICAL RESEARCH.
- 37. European\_Parliament. General Data Protection Act. L119, 4 May 2016, pp. 1–88 2016.
- 38. Rijksoverheid. Wet op de geneeskundige behandelingsovereenkomst (WGBO). In: Burgerlijk Wetboek (Nederland). 1997.
- 39. Polit D, Beck C. Nursing research: generating and assessing evidence for nursing practice. 10th ed. London: Wolters Kluwer; 2017.
- 40. Chanques G, Viel E, Constantin JM, Jung B, Lattre S De, Carr J, et al. The measurement of pain in intensive care unit: Comparison of 5 self-report intensity scales. Pain. 2010 Dec;151(3):711–21.

- 41. Streiner DL, Norman GR. Health measurement scales. 3. ed. Oxford [u.a.]: Oxford Univ. Press; 2003.
- 42. Waldréus N. Thirst in Patients with Heart Failure Description of thirst dimensions and associated factors with thirst. Linköping University Medical Dissertations. 2016.
- 43. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995 Aug;4(4):293–307.
- 44. Javali SB. Effect of Varying Sample Size in Estimation of Coefficients of Internal Consistency. 2011;
- 45. LYNN MR. Determination and Quantification Of Content Validity. Nurs Res. 1986 Nov;35(6):382???386.
- 46. Engström Å, Nyström N, Sundelin G, Rattray J. People's experiences of being mechanically ventilated in an ICU: A qualitative study. Intensive Crit care Nurs. 2012 Apr;29(2):88.
- 47. Hermans G, Van den Berghe G. Clinical review: intensive care unit acquired weakness. Crit Care. 2015 Dec 5;19(1):274.
- 48. Waldréus N, Hahn RG, Lyngå P, Van Der Wal MHL, Hägglund E, Jaarsma T. Changes in Thirst Intensity during Optimization of Heart Failure Medical Therapy by Nurses at the Outpatient Clinic. J Cardiovasc Nurs. 2016;31(5):E17–24.
- 49. Allida SM, Hayward CS, Newton PJ. Thirst in heart failure. Curr Opin Support Palliat Care. 2017 Nov;12(1):1.
- 50. Chalmers R. On Misconceptions and the Limited Usefulness of Ordinal Alpha. Educational and Psychological Measurement. 2017. 001316441772703 p.
- 51. Gadermann AM, Guhn M, Zumbo BD. Estimating Ordinal Reliability for Likert-Type and Ordinal Item Response Data: A Conceptual, Empirical, and Practical Guide Practical Assessment, Research & Evaluation. Cortina. 2007;17(3).
- 52. Kalfon P, Alessandrini M, Boucekine M, Renoult S, Geantot M-A, Deparis-Dusautois S, et al. Tailored multicomponent program for discomfort reduction in critically ill patients may decrease post-traumatic stress disorder in general ICU survivors at 1 year. Intensive Care Med. 2019 Feb;45(2):223–35.
- 53. Gélinas C, Fillion L, Puntillo KA, Viens C, Fortier M. Validation of the critical-care pain observation tool in adult patients. Am J Crit Care. 2006 Jul 1;15(4):420–7.

# Table 1:

Table 1: Characteristics of expert panel members

Expert panel	N=12
Professional members, <i>n</i>	7
ICU nurses	5
Intensivists	2
Age(years), <i>median(range)</i>	45(25-60)
Female, <i>n</i>	7
≥ 10 years of experience in ICU care, <i>n</i>	5
Patient members, n	5
Age(years), <i>median(range)</i>	72(57-82)
Female, n	3

Abbreviations: ICU: Intensive Care Unit

Table 2:

Table 2: Characteristics of sample of ICU patients

Table 2: Characteristics of sample of ICU patients	N 50
Sample of ICU patients	N=56
General	
Age(years)	70(57-74)
Male	34(61)
Apache II	17(13-21)
RASS	0(0-0)
ICU length of stay(days)	4.5(3.0-9.0)
Hospital length of stay(days)	16(9-27)
Study participation day (as % of total ICU days)	77(59-100)
Needed help with TDS-HF(n=55)	36(64)
Type of admission	
Medical	42(75)
Emergency surgical	6(11)
Elective surgical	8(14)
Diagnosis	· ,
Respiratory	23(41)
Cardiovascular	15(27)
Gastro intestinal	10(18)
Other	7(13)
Neurological	1(2)
Type of respiratory support	( )
No support	21(38)
Low-flow oxygen	23(41)
High-flow oxygen	7(13)
Non-invasive ventilation	1(2)
Invasive mechanical ventilation	4(7)
Airway	( )
Natural airway	48(86)
Tracheostomized	6(Ì1) ´
Orally intubated	2(4)
Medication	( )
Diuretics	16(29)
Anti-hypertensive medication	11(20)
Fluid balance	( )
Day of participation(ml)	152(-262-1195)
Total admission(ml)	3056(1204-6889)
Laboratory values	- ( )
Sodium (n=55)	138±3.8
Potassium (n-55)	4.1±0.4
Urea (n=55)	11.3±7.4
Creatinine (n=55)	112±94
Glucose (n=51)	8.2±3.0
Albertation IOII I ( ) O III ( A I III A I DI )	J

**Abbreviations:** ICU: Intensive Care Unit; Apache II; Acute Physiology, Age, Chronic Health Evaluation II; RASS: Richmond Agitation and Sedation Scale; TDS-HF: Thirst Distress Scale for patients with Heart Failure. Variables are presented as number (percentage) for nominal data. Ordinal and continuous data are presented as mean ±SD or median (interquartile range) when skewed. Percentages do not always add up to 100% due to roundoff error.

# Table 3:

Table 3: Item-level Content Validity Index and Scale Content Validity Index

TDS-H	F item		I-CVI <sub>tot</sub>	I-CVI <sub>pat</sub>	I-CVI <sub>prof</sub>
1.	My thirst bothers me a lot		0.75	0.40	1.00
2.	I am very uncomfortable when I am thirsty		0.67	0.60	0.71
3.	May mouth feels like sandpaper when I am thirsty		0.33	0.00	0.57
4.	My mouth feels dry when I am thirsty		0.50	0.40	0.57
5.	My saliva is very thick when I am thirsty		0.50	0.80	0.29
6.	When I drink less water, my thirst gets worse		0.25	0.20	0.29
7.	I am so thirsty I could drink water uncontrollably		0.50	0.20	0.71
8.	My thirst feels difficult to overcome		0.58	0.20	0.71
	Total S-CVI	0.51			

Patient S-CVI 0.51
Patient S-CVI 0.35
Professional S-CVI 0.61

**Abbreviations:** TDS-HF: Thirst Distress Scale for patients with Heart Failure; I-CVI: item-level content validity index; S-CVI: scale content validity index.

#### Table 4:

Table 4: Known-groups comparisons

Hypotheses for higher thirst distress	TDS- HFhigh	TDS- HFhigh TDS-HFlow		<i>p</i> -value*	
-	(n=25)	(n=25)			
Disease category GI or Other	29%	40%	-11%	.53ª	
Mechanical ventilation	8%	4%	4%	1.00 <sup>a</sup>	
Diuretics	32%	20%	12%	.52a	
Anti-hypertensive medication	12%	28%	-16%	.29a	
Higher blood urea nitrogen	31**	19**	12**	.003 <sup>b</sup>	

**Abbreviations:** TDS-HF: Thirst Distress Scale for patients with Heart Failure; TDS- HF<sub>high</sub>: participants with scores >median; TDS-HF<sub>low</sub>: participants with scores  $\leq$  median; GI: gastro intestinal; a: Fishers exact test; b: Mann-Whitney U test; \*After Bonferroni correction p-values significant at 0.01(p0.05/5); \*\*mean rank.

#### Table 5:

Table 5: Reliability properties of scores on Reference and Index tests

Items	Score Median(IQR)	Floor effect, %	Ceiling effect, %	Cronbach's alpha/if item deleted*	Item-total correlation
NRS thirst distress (0-10)	6.0(4.0-8.5)	14	20	na	na
NRS thirst intensity (0-10)	6.0(3.5-8.0)	13	11	na	na
TDS-HF (8- 40)	29.5(22.8-34.0)	0	7	.88	na
TDS-HF item 1 (1-5)	4.0(3.0-5.0)	9	32	.86*	.71
TDS-HF item 2 (1-5)	4.0(3.0-5.0)	4	40	.88*	.52
TDS-HF item 3 (1-5)	4.0(3.0-5.0)	5	41	.87*	.61
TDS-HF item 4 (1-5)	4.0(4.0-5.0)	4	43	.87*	.65
TDS-HF item 5 (1-5)	4.0(2.0-5.0)	14	29	.87*	.60
TDS-HF item 6 (1-5)	4.0(2.0-4.0)	9	20	.87*	.59
TDS-HF item 7 (1-5)	4.0(2.0-5.0)	21	20	.85*	.74
TDS-HF item 8 (1-5)	3.0(2.0-4.0)	20	18	.85*	.73

**Abbreviations:** NRS: Numeric Rating Scale (n=56); TDS-HF: Thirst Distress Scale for patients with Heart Failure (n=50); Floor effect %: percentage of scores in the lowest possible scale score; Ceiling effect %: percentage of scores in the highest possible scale score.

Figure 1: Study procedures

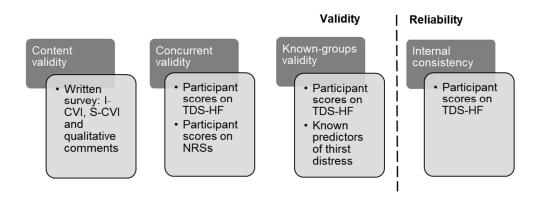


Figure 2: Flowchart

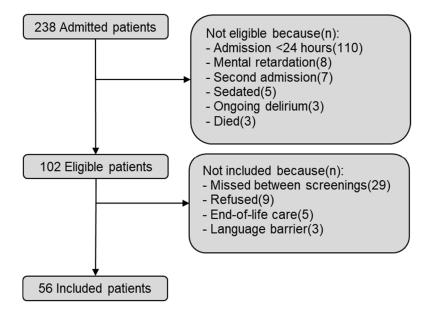


Figure 3: Histogram of TDS-HF(8-40) sum score

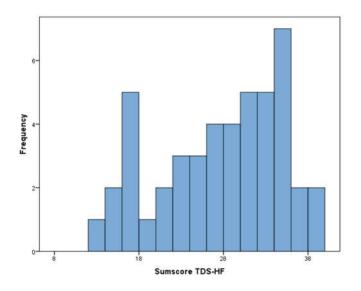
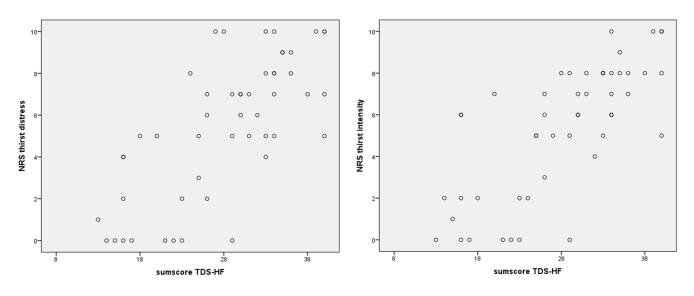


Figure 4: Correlation plots of Sumscore TDS-HF and NRSs for thirst distress and thirst intensity



# Appendix 1

# Thirst Distress Scale for patients with heart failure (TDS-HF)

Below you will find statements about your experience of thirst. Read each statement carefully. Choose one of five possible answers for each statement that best describes your experience of thirst between strongly disagree (number 1) and strongly agree (number 5). Mark your chosen number with a circle.

		Strongly disagree				Strongly agree	
tatement							
1.	My thirst bothers me a lot	1	2	3	4	5	
2.	I am very uncomfortable when I am thirsty	1	2	3	4	5	
3.	My mouth feels like sandpaper when I am thirsty	1	2	3	4	5	
4.	My mouth feels dry when I am thirsty	1	2	3	4	5	
5.	My saliva is very thick when I am thirsty	1	2	3	4	5	
6.	When I drink less water, my thirst gets worse	1	2	3	4	5	
7.	I am so thirsty I could drink water uncontrollably	1 II	2	3	4	5	
8.	My thirst feels difficult to overcome	1	2	3	4	5	

Waldréus N, Jaarsma T, van der Wal M, Kato N. Development and psychometric evaluation of the Thirst Distress Scale for patients with heart failure. Eur J Cardiovasc Nurs 2018: 17(3): 226-234.