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Validating the perioperative thirst discomfort scale for measuring thirst discomfort prior to procedures

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Cover Letter

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Editorial Board

To the editor,

On behalf of my co-authors, I am pleased to submit our manuscript entitled "Validating the perioperative thirst discomfort scale for measuring thirst discomfort prior to procedures".

Prior research indicates that most patients do not spontaneously verbalize thirst discomfort even when experiencing intense distress. As such, providing perioperative nurses with a validated tool that accurately measures thirst discomfort is vital. Results from our study provide additional insight regarding the validity of perioperative thirst discomfort scale in patients who were fasted before diagnostic or interventional procedures. We have not published this data previously.

Regards,

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Thank you for providing us with the opportunity to revise out manuscript. We have made revisions to the paper and provide detailed responses to the reviewers' comments below.

Reviewer 1

Minor note not affecting publication decision: Your acronym (PTDS) is very close to PTSD (post-traumatic stress disorder): would you consider shortening it to TDS (thirst discomfort score)? Just a suggestion in an effort not to confuse this with something else widely noted in the professional literature.

> Thank you for the suggestion. We have chosen not to remove the 'P' as it stands for perioperative, which is an important concept for this scale.

Pages 1-2: Excellent introduction, clear, easy to understand, prepares the reader for the balance of the paper.

> Thank you

Page 3 Line 54: You wrote, "The Cronbach alpha score was 0.91." This should be in the results section, it is the only outcome datum you have in the methods section.

> This Cronbach alpha reported in the methods section was that reported by the previous validation study of the original version of the Perioperative Thirst Discomfort Scale. We had already provided an overview of the previous validation studies for the scale in the Introduction so we have removed it from the methods to reduce duplication of content.

Page 4 line 241 you wrote, "To investigate construct validity we hypothesized that higher scores on the PTDS would be associated with greater fasting duration." Very nicely done, this is helpful

> Thank you

Page 4 line 253 you wrote, "All data and R code, along with instructions for how to completely reproduce results of the analyses, is available here." This is quite helpful allowing for replication of your study.

> Thank you

Page 6 line 318 you wrote, "As shown in Figure 2, there was a positive correlation between PTDS-5 scores and the global thirst discomfort rating (tau = 0.54; 95% CI = 0.43 to 0.63). The correlation between PTDS-5 scores and thirst intensity was also high (tau =0.49; 95% CI = 0.38 to 0.59)." Were these correlations statistically significant? Therefore, since n = 193, then for your first tau, the z-score exceeds 11! Very low p-score ($p < 0.0001$), and for the second test the z-score exceeds 10, also a very low p score... I'd go back to your software and doublecheck my math, but would include these points.

> Your math is correct - the p-values for these correlations are very low. We prefer however to report the confidence intervals for the correlations as they are more informative than the very low p-value. Confidence intervals have been reported for all correlations.

Page 6, line 329, you wrote, "Longer duration of fasting was not linearly associated with PTDS-5 scores for fluids (Spearman's rho = 0.1; 95% CI = -0.05 to 0.23) or food (Spearman's rho = 0.13; 95% CI = -0.01 to 0.27)." Did you look at curvilinear or exponential relationships? Just curious, as not all physiologic mechanisms (indeed, quite few) are linear in nature. Your scatterplots in figure 3 reflect the lack of linear association but there might be a sine wave type line from lower left to upper right, you might consider checking this.

> Thank you for the suggestion. We have not explored other potential relationships between fasting duration and PTDS-5 scores because this analysis was performed to test our stated hypothesis to evaluate construct validity that higher scores on the PTDS-5 would be associated with longer fasting duration. We believe a linear association is correct to evaluate this correlation.

Page 7 line 382 you wrote, "We did not observe an association between PTDS-5 and fasting duration for either food or fluids. This would suggest that it is important to assess thirst discomfort periodically, regardless of the duration of fasting. If thirst discomfort is present, and fasting is still indicated, interventions to alleviate

symptoms should be implemented." This is an excellent take home message for your reader, very practical and useful.

Thank you very much for your detailed review and suggestions for our paper.

Overall: this could go to press as is... I would add the p scores and run the scatterplot curves myself, but that does not preclude publication of the MS. Very nicely done.

Reviewer 2

Thank you for the opportunity to review your document. This is an interesting study and is well-written. Just a few issues that need attention.

Page 1, line 12 - I would use a newer reference unless this is a landmark publication.

> There is surprisingly little research on the patient experience of thirst in the perioperative literature. We have no reason to believe that the patient experience of thirst before surgery has changed since this paper was published because excessive fasting prior to procedures is still prevalent, as demonstrated in our study and the other recent studies we have cited.

Page 1, line 15 - See reference below. If you have an article that is not dated, (n.d.) is used.

Dobson G, Chow L, Filteau L, Flexman A, Hurdle H, Kurrek M, Milkovich R, Perrault MA, Sparrow K, Swart PA, Wong M. Guidelines to the Practice of Anesthesia - Revised Edition 2020. Can J Anaesth. 2020 Jan;67(1):64-99. doi: 10.1007/s12630-019-01507-4. Epub 2019 Nov 27.

> The date for this reference has been corrected

Page 1, line 22 - I would reword this sentence. It reads disjointed.

> Changed to: "It is not common for fasting instructions to be updated even when there are significant delays in procedure start time."

Page 1, line 26-34 - I would agree with the thesis of this paragraph if it was written before 2017; however, the fasting guidelines dramatically changed in 2017 and all these articles predate the change. I would provide more recent evidence that patients are fasting for long periods despite the changes. Also, you should discuss what the current fasting recommendations are. The current ASA fasting guidelines allow for clear liquids up to 2 hours before the procedure so I would assume that 12.8 hours average fasting would decrease. NOTE: If long fasting times are specific to your institution, you would need to disclose this to support why this study was important to perform or even the utility of the instrument.

> Excessive pre-procedural fasting is a long-standing issue, which by no means is specific to the institution in which this study was conducted. Guidelines from the American Society of Anesthesiology as far back as 1999 recommended 2 hour fasting for clear fluids and 6 hours for a light meal (for healthy patients who are undergiong elective procedures. (Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures: A Report by the American Society of Anesthesiologists Task Force on Preoperative Fasting. Anesthesiology. 1999;90(3):896-905.)

Page 2, line 52-75 - I would explain in more detail the limitations of the Martins' study. For example, postoperative instrument use is confounded by the surgical procedure where insensible fluid losses can occur or the effect of medications like glycopyrrolate have on thirst. This will validate the aim of your study. NOTE: I would clarify with the authors of the Martins' study that this was indeed only used and validated postoperatively. I read the article and it is unclear to me whether they performed ALL instrument interviewing in the postoperative period.

> We have included some additional content to describe the potential influence of events that occur during surgery on the psychometric properties of the PTDS:

"It should be noted that the initial validation of the PTDS was conducted in one specific point in the perioperative journey (i.e. post-surgical patients). The psychometric properties of the scale may be influenced by events that occur during the surgical procedure, such as fluid loss and administrations of medications that induce thirst, such as glycopyrrolate. A recent large study showed that use of glycopyrrolate was an independent risk factor for moderate to severe post-operative thirst.(Lee et al., 2020) As such, validation of the scale for measuring thirst discomfort before procedures is required."

It stated in the article by Martins et al, that participants were recruited from the Post-Anesthetic Care Unit.

Page 2, line 102 - I would write this in paragraph form or put it into a table.

Converted to a paragraph:

"Patients were not eligible for the study if they were under 16 years of age, scheduled for an emergency procedure, unable to understand or speak English (unless a translator was available) or if the nurse in pre-procedure bay considered that there was insufficient time prior to anticipated commencement of the procedure for participation in the study."

Page 3, line 135 - Need reference and it would be nice to actually have a visual depicting the instrument somewhere in the article.

We have included the reference to the initial scale validation study. We have also provided a visual of the PTDS-5 (Table 3).

Page 4, line 256 - Is there any reason that recruiting stopped at 198? An explanation as to how you came about this sample size is warranted. A recent article discussing sample size choice and Mokken scaling have been published. (see attachment)

The sample size was decided upon in terms of the resources available. We have added to the statistics section that a formal sample size calculation was not conducted.

Page 7, line 396 - You may want to note that sample size may be an issue.

We have included a comment in the limitations section about the potential that the sample size was insufficient:

"A recent study empirically evaluated the sample size required for a scale and found that a minimum of 250 participants would be required to establish scalability of the whole scale.(Watson et al., 2018) It was unclear, however, if this minimum threshold would apply to other scales.

Page 8, line 409 - This is a strong statement which I believe needs to be reworded due to issues related to external validity. I would use "may provide a way to measure thirst" instead of what is written.

Changed to 'may provide'.

The main issue I struggle with is the utility of this instrument especially with new fasting guidelines. Some would suggest updating your NPO strategies. I can see reordering patients as its primary use making it indeed important in that context. However, I would provide more compelling evidence as to why measuring thirst and case reordering is needed in your background section.

We totally agree that NPO strategies should be addressed in order to reduce the potential for thirst discomfort in patients scheduled for procedures. Unfortunately, this is a difficult problem to solve (Hewson, David W., and Iain Moppett. "Preoperative fasting and prevention of pulmonary aspiration in adults: research feast, quality improvement famine."British Journal of Anaesthesia 124.4 (2020): 361-363.) We conducted this study to validate the PTDS as the first step in an ongoing program of research aiming to address this issue. However, we believe that for the purposes of this current paper, it is best to restrict the discussion to the validation of the scale rather than about the need to address the causes of thirst.

We hadn't considered the potential that cases could be re-ordered based on severity of thirst, but agree this is one way that standardized assessment of thirst discomfort could be useful for practice. We have added content to the discussion:

"One additional potential course of action could be to rearrange the order of procedures on a schedule based on results of periodic thirst discomfort assessments using the PTDS. For example, circumstance may arise where a patient who reports severe thirst discomfort is scheduled to have their procedure later in the day than a patient who is not currently bothered by thirst symptoms. Reordering the procedure schedule would reduce the duration of fasting for the patient who is bothered by symptoms of thirst. Further research would be required to confirm the effectiveness of this strategy in practice on overall patient satisfaction."

Highlights

- The items in the 5-item perioperative thirst discomfort scale may provide a reliable and precise way to order patients according to their thirst discomfort before procedures in interventional radiology or cardiac cath lab settings.
- The hierarchical pattern of responses to items in the 5-item perioperative thirst discomfort scale is interpretable in terms of respondents more easily endorsing items related to a general desire to drink water through to first endorsing more specific symptoms related to dryness of the mouth and lips prior to endorsing discomfort associated with the sensations of 'thick' saliva and 'thick' tongue.
- In more practical terms, a patient who reports feeling bothered by a sensation of thick saliva could be interpreted as experiencing worse thirst discomfort than a patient who did not endorse any of the items lower down on the item difficulty hierarchy (i.e. 'my lips are dry' and 'my mouth is dry').

Validating the perioperative thirst discomfort scale for measuring thirst discomfort prior to procedures

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Validating the perioperative thirst discomfort scale for measuring thirst discomfort prior to procedures

Blinded for peer review

Introduction: **Thirst discomfort is common because patients are required to undergo long periods of fasting before medical and surgical procedures. The aim of this study was to examine the validity and reliability of the perioperative thirst discomfort scale (PTDS) for measuring thirst discomfort before procedures.** ***Methods:*** **Fasting patients who were scheduled for an elective cardiac or interventional radiology procedure were included in a prospective observational study. Mokken scaling analysis was used to investigate the dimensionality and hierarchical nature of the PTDS. PTDS scores were compared with fasting duration to evaluate construct validity. Convergent validity was evaluated by comparing the PTDS with global thirst discomfort and thirst intensity ratings.** ***Results:*** **Five items from the perioperative thirst discomfort scale (PTDS-5) formed a Mokken scale with evidence of invariant item ordering. Participants most easily endorsed the item related to the desire to drink water through to first endorsing symptoms related to dryness of the mouth and lips before those related to the abnormal sensations of 'thick' saliva and a 'thick' tongue. Scale reliability was adequate (rho = 0.84). There was a positive correlation between PTDS-5 scores and the global thirst discomfort rating (tau = 0.54; 95% CI = 0.43 to 0.63), as well as thirst intensity (tau = 0.49; 95% CI = 0.38 to 0.59). Duration of fasting was not associated with PTDS-5 scores.** ***Conclusion:*** **The items in the PTDS-5 form a strong Mokken scale, meaning it is a reliable and precise way to order patients according to their thirst discomfort.**

fasting | anesthesia | thirst discomfort | patient-reported outcomes | scale validation | mokken scale analysis

Introduction

Pre-procedure fasting is used to reduce the risk of vomiting and aspiration pneumonia during sedation and general anaesthesia, or in case emergency intubation is required due to unexpected cardiac arrest (Hamid *et al.*, 2014; Osborne, 2002). However, prolonged fluid restriction causes thirst symptoms to develop (e.g., dry mouth, swollen tongue), which can lead to great discomfort (Madsen *et al.*, 1998). Current guidelines related to pre-procedure fasting for elective procedures recommend a minimum fasting period of 2 hours nil-per-os (NPO) for clear fluids (Dobson *et al.*, 2020). Despite these recommendations, current practice is for patients undergoing surgical and other medical procedures that require sedation or anesthesia to receive standardized 'nil-by-mouth' fasting instructions at a pre-specified time interval before procedures. For example, 'no eating or drinking after midnight' is most common. It is not common for fasting instructions to be updated even when there are significant delays in procedure start time. As a result, fasting durations far exceed the recommended requirement for most patients undergoing medical and surgical procedures (Aguilar-Nascimento *et al.*, 2014; Sorita *et al.*, 2015; Spitz *et al.*, 2016). For example, in a recent study of 3641 fasting orders at a large academic institution in the USA, it was found that the median fasting duration was 12.8 hours, averaging 2 missed meals (Sorita *et al.*, 2015).

As a direct result of prolonged pre-procedure fasting, symptoms of thirst discomfort have been reported as common and severe. In a qualitative study where 12 participants were interviewed from a tertiary hospital in Australia, surgical patients and patients who adhered to prolonged fasting instructions described the discomfort from thirst symptoms to be the worst physical effect of fasting

(Carey *et al.*, 2015). Similarly, (Madsen *et al.*, 1998) interviewed a convenience sample of 50 adult surgical patients who reported that thirst symptoms caused more discomfort than hunger, sleep, or anxiety related to the procedure. However, thirst and its symptoms continue to be undervalued, under-reported and infrequently assessed by health care providers, including the nursing team (Milani Pavani *et al.*, 2016).

Despite the relevance and value of assessing thirst-discomfort of patients, the subjective experience of thirst presents challenges in developing a valid and reliable tool to succinctly and accurately measure its symptoms and level of discomfort prior to procedures. A thirst-discomfort scale for perioperative use was developed at a surgical centre affiliated with an accredited public hospital in Brazil (Martins *et al.*, 2017). The seven-item perioperative thirst-discomfort scale (PTDS) was developed in three stages, including face and content validation and reliability, and based on the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist (Mokkink *et al.*, 2010). Inter-rater reliability was tested through inter-observer equivalence where a pair of nurses independently, but simultaneously administered the scale among 70 patients. Six items on the scale had a weighted kappa coefficient of 1, while the item "I feel like drinking water" was 0.97 (Martins *et al.*, 2017). Cronbach's alpha was used to test the internal consistency of the scale with a value of 0.91 (Martins *et al.*, 2017). It should be noted that the initial validation of the PTDS was conducted in one specific point in the perioperative journey (i.e. *post*-surgical patients). The psychometric properties of the scale may be influenced by events that occur during the surgical procedure, such as fluid loss and administrations of medications that induce thirst, such as glycopyrrolate. A recent large study showed that use of glycopyrrolate was an independent risk factor for moderate to severe post-operative thirst.(Lee *et al.*, 2020) As such, validation of the scale for measuring thirst discomfort before procedures is required.

The PTDS demonstrates strong potential for accurately assessing thirst-discomfort more generally for peri-operative use. The aim of this study was to examine the validity and reliability of the PTDS for measuring thirst discomfort for patients who are fasting *before* medical procedures.

Methods

Study Design. This study used a prospective, observational design. No changes to usual clinical practice were made for this study in regard to pre-procedure fasting. Patients who were scheduled for a morning procedure were typically asked to remain nil-per-os (NPO) from midnight. Patients with afternoon procedures can have a small breakfast but must remain NPO from 6:00am on the day of the procedure. Ethical approval for this study (Ethical Committee N° 19-5585) was provided by the University Health Network Research Ethics Board, Toronto, Canada on October 31 2019.

Participants. Adult patients who were fasted and scheduled for an elective procedure in the Cardiac Catheterization Laboratories or in Interventional Radiology at an academic teaching hospital in Canada

were included.

Exclusion criteria. Patients were not eligible for the study if they were under 16 years of age, scheduled for an emergency procedure, unable to understand or speak English (unless a translator was available) or if the nurse in pre-procedure bay considered that there was insufficient time prior to anticipated commencement of the procedure for participation in the study.

Data collection. A Research Assistant administered a brief questionnaire prior to procedures. It comprised the following components:

- the Perioperative Thirst Discomfort Scale (7 items);
- a one-item global thirst discomfort rating;
- a one-item thirst intensity rating;
- an item to determine if the participant is currently on oxygen therapy;
- an item to evaluate the presence of pain;
- the time the patient last had any clear fluids;
- the time the patient last had any food;
- age, sex of patient and type of procedure to be performed.

Measures. The seven-item Perioperative Thirst Discomfort Scale (PTDS-7) is a 7-item self-reported, composite score evaluating the severity of dry mouth, lips, and throat, thick tongue and saliva, a bad taste in the mouth, and a desire to drink water.(Martins *et al.*, 2017) The total score can range from 0 to 14, with 14 representing the "most extreme" intensity of discomfort related to perioperative thirst.(Martins *et al.*, 2017)

Participants used a global thirst discomfort score to rate their overall level of thirst discomfort on a rating scale with scores ranging from "extreme thirst discomfort" to "extreme comfort". Intensity of their thirst was rated on a scale ranging from 0 to 10, where 0 represents "No thirst" and 10 represents "Most intense thirst". The experience of pain may influence the participant's perception of thirst.(Pierotti *et al.*, 2018) Participants were asked to rate their current level of pain on a scale of 0 to 10, where 0 represents "no pain" and 10 represents that their pain as "unimaginable/unspeakable". The use of oxygen therapy (e.g., via nasal prongs) may contribute to the experience of thirst symptoms (e.g., dry mouth, dry throat).(Conchon *et al.*, 2015) The research assistant recorded "yes" or "no" as to whether the participant was currently receiving oxygen therapy at the time the questionnaire was administered.

Statistical analysis. Mokken scaling is a method for establishing if items in a scale conform to a cumulative, hierarchical structure (Perng and Watson, 2012). When an instrument contains hierarchically ordered items, the items can be ordered from those indicating mild to severe symptoms. An intentionally simple example of a hierarchical scale is a set of items enquiring about height that increases in

increments of 10cm from 100cm to 200cm. In this example, taller people would endorse more items than those who were shorter (Watson *et al.*, 2008).

To determine if items conform to a hierarchical structure, Mokken scaling analyses properties of individual items as described by the item characteristic curve. Item characteristic curves show the association between the score on an item to the level of the latent trait being measured. Mokken scaling makes only the assumption of monotone homogeneity about the association between the score on an item and the level of the latent trait. This means that as the trait increases, so does the item score. "Difficulty", is a term used in Mokken Scale Analysis to refer to the extent to which items are endorsed by respondents. Items at the upper end of the range of the latent trait are characterized as being more difficult. Items in a Mokken Scale are arranged along the latent trait in terms of their difficulty. The properties of items can be measured using the scalability coefficient, H (Loevinger's coefficient). H measures the extent to which items are arranged as expected by their mean values along the latent trait. $H > 0.3$ is the minimum acceptable value, with values > 0.4 indicating a moderate scale and > 0.5 indicates a strong scale.

Invariant item ordering, where the order of items along the latent trait is the same for all respondents at all levels of the latent trait, is a desirable property of a Mokken Scale. It can be assessed mathematically to look for significant violations of this property. The accuracy of the invariant item ordering can also be assessed by calculating the H_{TRANS} ($\mathbf{H_T}$) coefficient. Values of $\mathbf{H_T}$ exceeding 0.3 indicates acceptable accuracy of invariant item ordering.

Mokken scale analysis was conducted in this study to explore whether there were hierarchical properties in participant ratings of thirst discomfort and to explore the dimensions of the PTDS. Mokken scale analysis proceeded by first checking the PTDS-7 scalability coefficients. If $\mathbf{H_i}$ was below 0.3 or if the lower limit of the 95% CI (confidence interval) for H_i was below 0.3, the item was to be excluded. Then, scale partitioning was carried out to explore the dimensions of the PTDS through increasing c (lower bound c defines the minimum value of coefficients $\mathbf{H_i}$ in the Mokken scale by 0.05 increments) (Molenaar and Sijtsma, 2000). Monotone homogeneity and invariant item ordering were investigated at the whole scale level, as no sub-scales were identified. To assess for violations of invariant item ordering, crit values <40 were considered acceptable.(Molenaar and Sijtsma, 2000) Provided invariant item ordering holds for a set of items, the coefficient $\mathbf{H_T}$ expresses the accuracy of the ordering, with values below 0.3 being unacceptable and above 0.4 indicating moderate invariant item ordering.(Ligtvoet *et al.*, 2010) The coefficient score (rho), which is similar to Cronbach's alpha, was used to assess reliability of the scale.

Construct validity was evaluated by using correlations to identify associations between scores on the PTDS and fasting duration. To investigate construct validity we hypothesized that higher scores on the PTDS would be associated with greater fasting duration. Convergent validity was assessed by using Kendall's *tau* to compare the PTDS score with the global thirst discomfort score. Convergent validity was assessed by using the Spearman's rank correlation to compare the PTDS with the thirst intensity

Table 1. Participant characteristics

Characteristic	N = 193
Age	62 (48, 72)
Gender	
Male	111 (58%)
Female	80 (42%)
Prefer not to say	1 (0.5%)
Procedure	
Angiogram or Percutaneous Coronary Intervention (PCI)	58 (30%)
Cardiac Implantable Electronic Device (CIED)	15 (7.8%)
Electrophysiology Study (EPS)	5 (2.6%)
Structural heart intervention	5 (2.6%)
Vascular angiography or intervention	17 (8.9%)
Biopsy	62 (32%)
Port-a-cath	4 (2.1%)
Radiofrequency ablation of a tumour (RFA)	9 (4.7%)
Vascular embolization (e.g., renal)	1 (0.5%)
Other procedure	16 (8.3%)
Time since last clear fluids (hours)	9.5 (5.0, 13.0)
Time since last food (hours)	13.0 (11.0, 15.0)

[1] Statistics presented: median (IQR); n (%)

rating and pain scale rating.

The R statistical program was used to conduct all analyses (R Core Team, 2020). All data and R code, along with instructions for how to completely reproduce results of the analyses, is available here. A formal sample size calculation was not conducted.

Results

From November 2019 to March 2020, we screened 203 patients for inclusion in the study. A total of 198 were eligible and 194 participated. One participant did not complete 1 of the PTDS-7 items and was excluded from the analysis. A summary of participant characteristics is displayed in Table 1. The median age was 62 (IQR 48 - 72) and 58% (n=111) were female. 43% of patients were scheduled to have their procedure in the cardiac catheterization laboratory. A biopsy was the most common interventional radiology procedure (n=62; 32%), but a wide range of other procedures were included. The mean duration of fasting from food and non-clear fluids was 12.7 (SD 3.8) hours and clear fluids was 9 (SD 4.5) hours.

Mokken scale analysis. No items required removal from the PTDS-7 based on the condition that scalability coefficients (H_i and lower bound of 95% CI) should be over 0.3. We used a lower bound for c, starting from 0.05 and increasing to 0.80 in 0.05 increments, to explore the dimensionality of the PTDS-7. From 0.05 to 0.45, all of the items formed a single scale. The item, '*I have a bad taste in my mouth*', was excluded by selecting the remaining items which showed uni-dimensionality at a threshold level of .50. The 6 remaining items (PTDS-6) were further examined for the criteria of a Mokken scale and item invariant ordering. The PTDS-6 item set had a homogeneity value *H(se)* of

Table 2. Item hierarchy of the PTDS-5

item	mean	Hi	se
I want to drink water	1.10	0.56	0.054
My mouth is dry	0.80	0.62	0.044
My lips are dry	0.69	0.63	0.041
My saliva is thick	0.51	0.57	0.050
My tongue is thick	0.43	0.65	0.042

0.599, which indicated a strong Mokken scale. No items were removed based on the criteria that there should be no significant violations of the assumption of monotonicity.

Invariant item ordering. Analysis of invariant item ordering for the PTDS-6 revealed violations for the dry throat/dry lips item pair. Although there were no *significant* intersections between items, due to the intersection between the dry throat and dry lips items, crit values were above 40. For this reason, we excluded one of these items (dry throat), and re-assessed the remaining 5 items for the assumptions of a Mokken scale. With the dry throat item removed, none of the items violated the assumption of invariant item ordering.

Accuracy and reliability. The accuracy of the item ordering was found to be acceptable with a H_T coefficient of 0.397. Scale reliability was adequate with a coefficient score (Rho) of 0.84.

Item difficulty hierarchy. The item difficult hierarchy for the PTDS-5 is presented in Table 2. The most highly endorsed symptom (i.e. the least severe symptom of thirst discomfort in the PTDS-5) was being bothered by a desire to drink water. The least endorsed symptom (i.e. the most severe symptom of thirst discomfort in the PTDS-5) was being bothered by the perception of a 'thick tongue'. The items in the PTDS-5 form a strong Mokken scale ($H_s = 0.605$).

Construct and convergent validity. The distribution of PTDS-5 scores in the sample was right-skewed, with a median score of 3 (IQR 1, 6). (Figure 1). As shown in Figure 2, there was a positive correlation between PTDS-5 scores and the global thirst discomfort rating (*tau* = 0.54; 95% CI = 0.43 to 0.63; 0). The correlation between PTDS-5 scores and thirst intensity was also high (*tau* = 0.49; 95% CI = 0.38 to 0.59). Likewise, the correlation between pain and PTDS-5 scores was not significant (Spearman's rho = 0.07; 95% CI = -0.07 to 0.21).

The associations between PTDS-5 scores with food and fluid duration are displayed in Figure 3. Longer duration of fasting was not linearly associated with PTDS-5 scores for fluids (Spearman's rho = 0.1; 95% CI = -0.05 to 0.23) or food (Spearman's rho = 0.13; 95% CI = -0.01 to 0.27).

Discussion

Results indicate that the PTDS-5 is a reliable and precise way to order patients according to their thirst discomfort in the *pre-procedure* period. In addition, an acceptable accuracy for invariant item

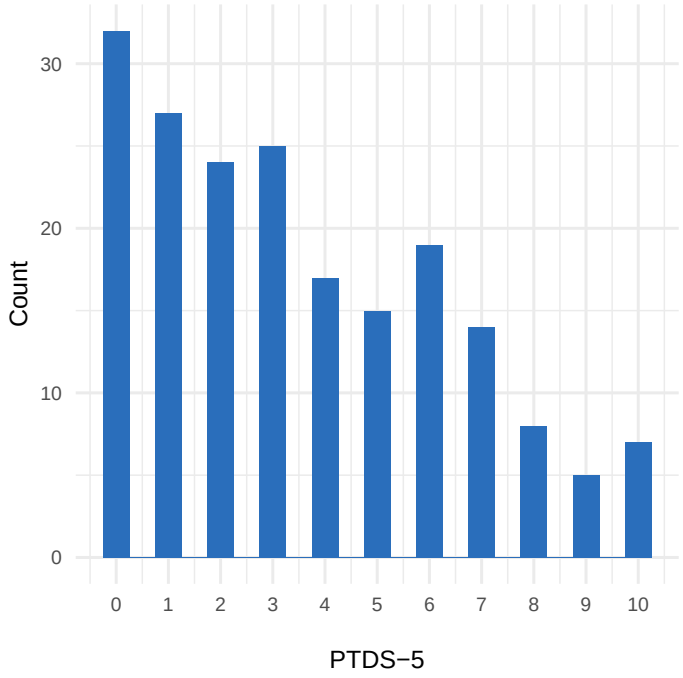

Fig. 1. Distribution of PTDS-5 scores (higher scores indicate worse thirst discomfort)

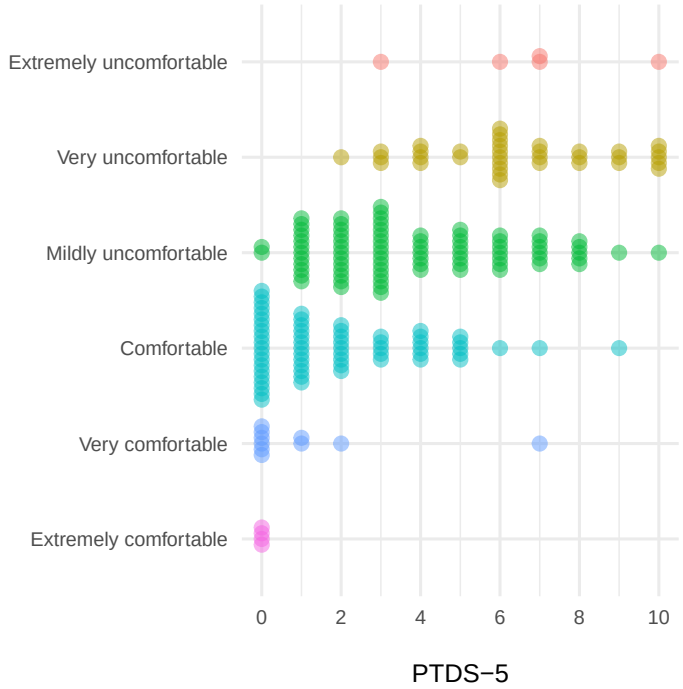

Fig. 2. Association between PTDS-5 and global thirst rating

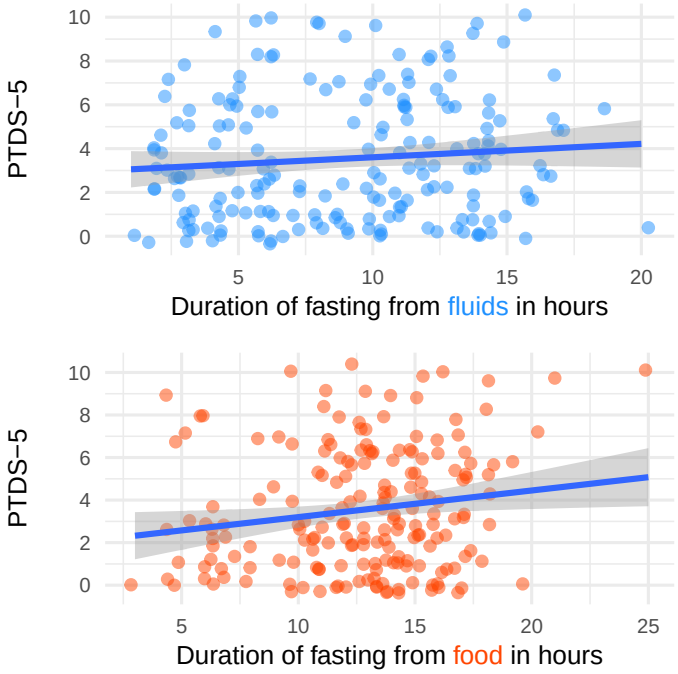

Fig. 3. Association between PTDS-5 and duration of fasting

ordering was identified, meaning patients are likely to rank the PTDS-5 symptoms of thirst discomfort in the same way. As such, the item difficulty hierarchy, presented in Table 2, can be used as a guide to easily determine which patients are experiencing worse thirst discomfort. The hierarchical pattern of responses to items in the Mokken scale is interpretable in terms of respondents more easily endorsing items related to a general desire to drink water through to first endorsing more specific symptoms related to dryness of the mouth and lips prior to endorsing discomfort associated with the sensations of 'thick' saliva and 'thick' tongue. In more practical terms, a patient who reports feeling bothered by a sensation of thick saliva could be interpreted as experiencing worse thirst discomfort than a patient who did not endorse any of the items lower down on the item difficulty hierarchy (i.e. 'my lips are dry' and 'my mouth is dry').

The original (7-item) perioperative thirst-discomfort scale has previously been used to determine the relationship between thirst intensity and thirst-discomfort in the immediate postoperative period during anesthesia recovery.(Pierotti *et al.*, 2018) In a non-probabilistic sample of 203 adult participants in post-operative recovery following elective, urgent and emergency surgeries, the investigators found no association between fasting duration, or patient age, and the intensity of thirst and degree of discomfort (Pierotti *et al.*, 2018). However, the mean fasting duration among participants was uniformly high (mean 16.2 [SD 8.7] hours), which may have prevented the researchers from discerning a correlation between fasting duration. Even in the subgroup of participant who reported 8 hours of fasting, all reported thirst (Aroni *et al.*, 2012; Pierotti *et al.*, 2018).

It should be noted that an investigation of the dimensionality of the 7-item PTDS had not been performed prior to our study. A uni-dimensional solution was identified in our analysis. This should be

Table 3. 5-item perioperative thirst discomfort scale (PTDS-5)

How bothered are you by the following?	Not at all	Slightly	Extremely
I want to drink water	0	1	2
My mouth is dry	0	1	2
My lips is dry	0	1	2
My saliva is thick	0	1	2
My tongue is thick	0	1	2

expected considering the small number of items that were evaluated.

We did not observe an association between PTDS-5 and fasting duration for either food or fluids. This would suggest that it is important to assess thirst discomfort periodically, regardless of the duration of fasting. If thirst discomfort is present, and fasting is still indicated, interventions to alleviate symptoms should be implemented. There is a lack of evidence regarding the efficacy of interventions to alleviate perioperative thirst discomfort. However, recent randomized controlled trials have identified clinically relevant reductions in thirst discomfort with menthol chewing gum and 30mL menthol popsicles (Garcia *et al.*, 2019; Nascimento *et al.*, 2020). One additional potential course of action could be to rearrange the order of procedures on a schedule based on results of periodic thirst discomfort assessments using the PTDS. For example, circumstance may arise where a patient who reports severe thirst discomfort is scheduled to have their procedure later in the day than a patient who is not currently bothered by thirst symptoms. Reordering the procedure schedule would reduce the duration of fasting for the patient who is bothered by symptoms of thirst. Further research would be required to confirm the effectiveness of this strategy in practice on overall patient satisfaction.

Limitations. Selection bias should be considered because a convenience sample was used for this study. Also, it is uncertain if similar results would be obtained for patients who are fasted prior to undergoing procedures in other settings. Only one patient was excluded from the analysis due to missing data, so it is unlikely attrition bias would have exerted a major influence on the results. Further research is required to evaluate the minimal detectable difference for the PTDS-5 as well as the minimal clinically important difference prior to use of this scale as an outcome measure in research. The potential that the sample size was insufficient for Mokken scale analysis should be considered. A recent study empirically evaluated the sample size required for a scale and found that a minimum of 250 participants would be required to establish scalability of the whole scale.(Watson *et al.*, 2018) It was unclear, however, if this minimum threshold would apply to other scales.

Conclusion. The items in the PTDS-5 may provide a reliable and precise way to order patients according to their thirst discomfort. Nurses may use this scale to assess the severity of thirst discomfort in patients who are fasted prior to procedures and initiate interventions according to individual needs. The PTDS-5 with the rating scale is presented in Table 3.

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