



Aalborg Universitet

AALBORG UNIVERSITY  
DENMARK

## Development of the Comprehensive Pain Assessment Tool Short Form for Chronic Pancreatitis

### *Validity and Reliability Testing*

Kuhlmann, Louise; Teo, Keith; Olesen, Søren Schou; Phillips, Anna Edwards; Faghih, Mahya; Tuck, Natalie; Afghani, Elham; Singh, Vikesh K.; Yadav, Dhiraj; Windsor, John A.; Drewes, Asbjørn Mohr

*Published in:*  
Clinical Gastroenterology and Hepatology

*DOI (link to publication from Publisher):*  
[10.1016/j.cgh.2021.05.055](https://doi.org/10.1016/j.cgh.2021.05.055)

*Creative Commons License*  
CC BY 4.0

*Publication date:*  
2022

*Document Version*  
Publisher's PDF, also known as Version of record

[Link to publication from Aalborg University](#)

*Citation for published version (APA):*  
Kuhlmann, L., Teo, K., Olesen, S. S., Phillips, A. E., Faghih, M., Tuck, N., Afghani, E., Singh, V. K., Yadav, D., Windsor, J. A., & Drewes, A. M. (2022). Development of the Comprehensive Pain Assessment Tool Short Form for Chronic Pancreatitis: Validity and Reliability Testing. *Clinical Gastroenterology and Hepatology*, 20(4), e770-e783. Advance online publication. <https://doi.org/10.1016/j.cgh.2021.05.055>

### **General rights**

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal -

# ELECTRONIC PANCREAS, BILIARY TRACT, AND LIVER

## Development of the Comprehensive Pain Assessment Tool Short Form for Chronic Pancreatitis: Validity and Reliability Testing



Louise Kuhlmann,<sup>\*,‡,§</sup> Keith Teo,<sup>||</sup> Søren Schou Olesen,<sup>\*,§</sup> Anna Edwards Phillips,<sup>¶</sup> Mahya Faghih,<sup>#</sup> Natalie Tuck,<sup>\*\*</sup> Elham Afghani,<sup>#</sup> Vikesh K. Singh,<sup>#</sup> Dhiraj Yadav,<sup>¶</sup> John A. Windsor,<sup>||</sup> and Asbjørn Mohr Drewes<sup>\*,§</sup>

<sup>\*</sup>Centre for Pancreatic Diseases & Mech-Sense, Department of Gastroenterology and Hepatology, Aalborg University Hospital, Aalborg, Denmark, <sup>‡</sup>Department of Internal Medicine, Randers Regional Hospital, Randers, Denmark, <sup>§</sup>Department of Clinical Medicine, Aalborg University, Aalborg, Denmark, <sup>||</sup>Department of Surgery, School of Medicine, Faculty of Medicine and Health Science, University of Auckland, New Zealand, <sup>¶</sup>Division of Gastroenterology, Hepatology, and Nutrition, UPMC, Pittsburgh, Pennsylvania, <sup>#</sup>Division of Gastroenterology, Department of Medicine, Johns Hopkins Medical Institutions, Baltimore, Maryland, and <sup>\*\*</sup>The Auckland Regional Pain Service, Auckland District Health Board, Auckland, New Zealand

**BACKGROUND & AIMS:** Pain is the foremost complication to chronic pancreatitis (CP), but no validated questionnaires for assessment exist. The COMPAT questionnaire includes all relevant pain dimensions in CP, but a short form is needed to make it usable in clinical practice.

**METHODS:** The full COMPAT questionnaire was completed by 91 patients and systematically reduced to 6 questions. Pain severity and analgesic use were merged, leaving 5 pain dimensions. The pain dimension ratings were normalized to a 0–100 scale, and the weighted total score was calculated, where 3 dimensions were weighted double. Reliability of the short form was tested in a test-retest study in 76 patients, and concurrent validity tested against the Brief Pain Inventory and Izbicki pain questionnaire. Convergent validity was verified using confirmatory factor analysis, and criterion validity tested against quality-of-life and hospitalization rates.

**RESULTS:** The COMPAT-SF questionnaire consisted of the following pain dimensions: a) pain severity, b) pain pattern, c) factors provoking pain, d) widespread pain, and e) a qualitative pain-describing dimension. Quality of life correlated with the total score and all pain dimensions ( $P < .05$ ). The total score, pain severity, pain pattern, and factors provoking pain were correlated with hospitalization rates ( $P < .05$ ). The total score correlated with the Izbicki and Brief Pain Inventory scores ( $P < .0001$ ). The reliability of the questionnaire in patients in a stable phase was good with an interclass correlation coefficient of 0.89.

**CONCLUSION:** The COMPAT-SF questionnaire includes the most relevant aspects of pain in CP and is a feasible, reliable, and valid pain assessment instrument recommended to be used in future trials.

**Keywords:** Chronic Pain; Chronic Pancreatitis; Pain Measurement; Surveys and Questionnaires.

Chronic abdominal pain has a prevalence of up to 70% in chronic pancreatitis (CP).<sup>1</sup> It causes significant morbidity affecting the quality of life and is a major treatment challenge.<sup>2,3</sup> Pain is difficult to assess in clinical practice due to its complex, multidimensional, and subjective nature, and there is a significant need for validated and reliable questionnaires to assess pain.<sup>4</sup> A variety of such instruments exist,<sup>5</sup> with the most commonly used in CP being the Izbicki pain scale<sup>6</sup> and the Brief Pain Inventory (BPI).<sup>7</sup> The Izbicki pain scale was explicitly developed for pancreatic pain, but has never been adequately validated. The questionnaire is relatively simple, with 4 domains, but does not include

all aspects of pancreatic pain.<sup>5</sup> The BPI was developed for patients with cancer pain<sup>7</sup> but has been validated for nonmalignant chronic pain conditions, including CP.<sup>2,8</sup>

**Abbreviations used in this paper:** BPI, Brief Pain Inventory; CFA, confirmatory factor analysis; COMPAT, Comprehensive Pain Assessment Tool for Chronic Pancreatitis; CP, chronic pancreatitis; ICC, intraclass correlation coefficient.

Most current article

© 2022 by the AGA Institute. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

1542-3565

<https://doi.org/10.1016/j.cgh.2021.05.055>

However, the BPI does not cover many domains that are specific for CP. Given these limitations with the currently available pain assessment tools, Teo et al developed the Comprehensive Pain Assessment Tool for Chronic Pancreatitis (COMPAT).<sup>9</sup> This includes general aspects of pain and features that separate patients with CP from other patients with chronic pain.<sup>5</sup> The questionnaire contains 23 primary questions and 180 secondary questions, including both the Pancreatitis Quality Of Life Instrument<sup>10</sup> and the McGill Pain Questionnaire short form-2.<sup>11</sup> Unfortunately, the COMPAT questionnaire is time-consuming and difficult to complete in the clinical setting.

This study aims: (1) to develop a short-form version of the COMPAT questionnaire (COMPAT-SF) that can be completed within 10 minutes and still preserves the most important aspects of pain assessment from the full COMPAT; (2) to test the COMPAT-SF for validity; and (3) to test the COMPAT-SF for reliability.

## Methods

The development, validation, and reliability testing of the COMPAT-SF were performed in 2 studies. The study flow is summarized in [Figure 1](#).

### *Patient Cohorts for the 2 Studies*

The developmental study included patients from 3 pancreas centers (Auckland City Hospital and Middlemore Hospital, Auckland, New Zealand, and Aalborg University Hospital, Aalborg, Denmark). Patients were eligible for inclusion if they had painful CP, according to the Mayo Clinic Diagnostic Criteria.<sup>12</sup> Exclusion criteria were age <18 years and malignancies.

Patients completed the full COMPAT questionnaire. They could ask for explanations of the questions, but this information was given neutrally without influencing their answers.

The reliability study included patients from 3 pancreas centers (University of Pittsburgh Medical Center, Pittsburgh, PA; Johns Hopkins Hospital, Baltimore, MD; and Aalborg University Hospital, Aalborg, Denmark). Inclusion and exclusion criteria were the same as the developmental study. Patients from Aalborg and Pittsburgh were included as a 'stable pain group' if they had a stable pain pattern with no endoscopic or surgical interventions within the last 6 months. Patients from Baltimore were included as an 'unstable pain group,' without focusing on a stable pain pattern to elucidate problems in reliability testing in patients with fluctuating pain.

At baseline, patients completed the COMPAT-SF, the BPI,<sup>8</sup> and the Izbicki pain scale.<sup>13</sup> Clinical information regarding disease duration and pain treatment were also recorded. After 2 to 6 weeks, the patients completed the COMPAT-SF again.

## What You Need to Know

### Background

As no feasible, validated pain assessment tool for chronic pancreatitis exists, this study aimed to develop a short form of the newly developed COMPAT questionnaire.

### Findings

A short form that could be completed within 10 minutes was developed, validated, and tested for reliability. The developed short-form is comprised of 5 pain dimensions and included 6 questions.

### Implications for patient care

The questionnaire can be used in pain assessment in chronic pancreatitis, including the possibility to assess pancreatitis-specific domains, including pain-provoking factors.

### *Translation of the Questionnaire into Danish*

The full COMPAT questionnaire was translated into Danish and back-translated by a native Danish-speaking translator with in-depth knowledge of the English language, attested by an International English Language Testing System score of 8.5. The back-translation was reviewed to detect any linguistic loss. For the incorporated McGill Pain Questionnaire, a previously validated translation was used.<sup>14</sup>

### *Development of the COMPAT-SF*

Six steps were taken to develop the short-form from the full COMPAT questionnaire:<sup>5</sup>

1. If the completion rate for any questions was less than 75%, it was excluded as being unclear/irrelevant.<sup>15</sup>
2. If the distribution of answers revealed floor or ceiling effects above 20%, the questions were excluded because of insufficient measurement precision.<sup>16</sup>
3. All supplementary questions not directly related to pain were excluded.
4. All remaining questions were allocated to 1 of 5 pain dimensions based on consensus. These 5 pain dimensions were: pain severity, pain pattern, pain provocation, spreading pain, and a qualitative pain description.
5. The questions relating to pain severity that were answered by subgroups of patients according to

Flowchart of short-form development, validation, and reliability testing

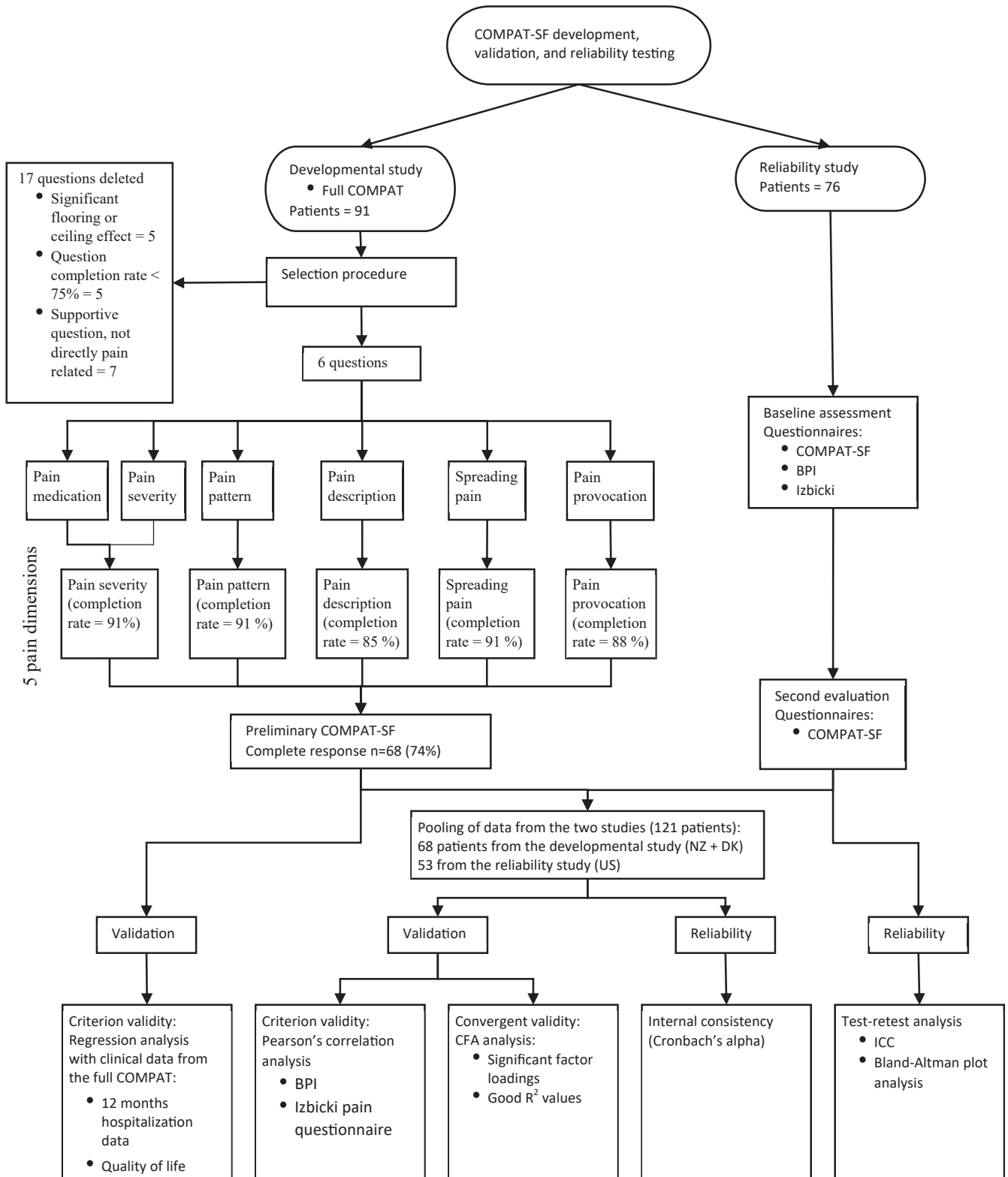


Figure 1. Flowchart of short-form development, validation, and reliability testing.

pain pattern, were merged (Q10 secondary question 1-3, Q11 secondary question 1-3, Q12 secondary question 1.1, 1.3, and 2.2., Q13 secondary question 1.1, 1.2, and 1.3).

6. The pain severity dimension consisted of 2 questions: pain intensity and analgesic requirements. No questions concerning interventional procedures were included in the pain severity dimension

due to floor or ceiling effect in the answers (see item 2 above).

7. A detailed scoring system was developed (Supplementary Appendix A)

### *Patient and Public Involvement*

Patients were involved in evaluating the questions included in the full COMPAT questionnaire. Patient assessments were, however, not included in the evaluation of the COMPAT-SF as all questions were previously evaluated for importance, relevance, and comprehensibility in the full COMPAT.

### *Validation*

Three general types of validation were investigated. Face validity is commonly used as the fourth measure to determine whether the test appears valid to novices in methodology.<sup>17</sup> The value of this validation is disputed<sup>18</sup> and was not included.

1. Content validity is a systematic evaluation of the questionnaire content by an expert panel to ensure that all important aspects are included. Content validity was previously investigated for the full COMPAT questionnaire using an independent expert group from New Zealand, Australia, Asia, and Scandinavia.<sup>9</sup> For the COMPAT-SF, an internal expert panel, including 5 researchers from New Zealand and 3 from Denmark, determined the most clinically relevant pain dimensions from the full COMPAT through consensus.<sup>19</sup>
2. Construct validity is a determination of the degree to which the COMPAT-SF measures the intended aspects.<sup>20</sup> In this study, the construct validity was assessed with confirmatory factor analysis (CFA).<sup>21</sup>
3. Criterion validity is the extent to which the COMPAT-SF is related to relevant clinical outcomes.<sup>18</sup> Criterion validity was examined in 4 ways, comparing COMPAT-SF total scores to: (1) Total BPI,<sup>8</sup> (2) Izbicki pain scores,<sup>13</sup> (3) the last 12 months' hospitalization data, and (4) quality-of-life data (Pancreatitis Quality Of Life Instrument).

### *Reliability*

Reliability was assessed by comparing the 2 COMPAT-SF questionnaires from the reliability study to determine test-retest reliability. Furthermore, the internal consistency of the short form was examined.

### *Statistical Analysis*

**Development.** Descriptive statistics are shown as median and range for continuous data, and absolute

frequencies and percentages for categorical data. If <10% of secondary questions were left blank, the answers were interpolated to allow for statistical calculations. All interpolations were performed by the first author (LK). The interpolation was performed by carefully identifying 2 patients with similar answers for pain intensity and pattern. To accept interpolation from the patient with complete answers, less than 10% of questions concerning pain-provoking factors, spreading pain, and pain-describing adjectives should diverge, and the divergence in the individual subscore should maximally be of 20% (1 point). The selected questionnaires were used to choose the most plausible value of the missing answer. If no patient questionnaire was similar or a primary question was entirely omitted, no interpolation was performed.

**Validation.** Construct validity was examined with CFA on the final COMPAT-SF questionnaire answers using structural equation modeling.<sup>22</sup> Concurrent validity was assessed by examining how COMPAT-SF scores affected the number of hospitalizations and quality-of-life scores using negative binomial regression and linear regression as appropriate.<sup>23</sup> Pearson's correlation coefficient was used to examine correlations between the COMPAT-SF scores, the Izbicki pain scale, and the BPI.

**Reliability.** Test-retest reliability was examined by calculating the 2-way mixed-effects intraclass correlation coefficient (ICC) on single measurements. Bland-Altman plots were analyzed to ensure acceptable 95% limits of agreement, defined as mean difference  $\pm 1.96$  standard deviation. ICC values >0.5 were considered moderate, >0.75 good, and >0.9 excellent.<sup>24</sup> Internal consistency was examined using Cronbach's alpha, where values above 0.7 were considered acceptable.<sup>25</sup>

Statistical analysis was performed using STATA version 16 (StataCorp LP, College Station, TX). *P* values <.05 were considered significant.

## **Results**

The development study included 91 patients and the reliability study 76 patients (Table 1). In the latter, patients either had stable pain severity (n=51) or unstable pain severity (n=25).

### *Development of the COMPAT-SF*

The COMPAT-SF comprises 5 pain dimensions containing 6 questions. Six primary questions in the full COMPAT were excluded because they were not directly pain-related (Q1, Q2, Q3, Q15, Q20, Q21). Eight primary questions were excluded due to low completion rate or pronounced floor/ceiling effect (Q5, Q6, Q7, Q17, Q18, Q19, Q22, Q23). Two questions concerning pain intensity (the merged intensity subquestions Q10-13) and analgesic medications (Q16) were merged into the pain severity dimension. The qualitative pain description

**Table 1.** Demographic Characteristics of Included Patients

Demographic characteristics	Developmental study				P value	Validation and reproducibility study			
	Overall	COMPAT-SF score (n=68)				Overall	Stable	Unstable	P value
		0-40	40-60	60-100					
Patients	91	19	23	26		76	51	25	
Male sex	52 (57.1)	9 (47)	15 (65)	16 (62)	.7710	38 (50)	27 (53)	11 (44)	.464
Age, y	54 (19-86)	54 (19-81)	56 (29-70)	45 (21-68)	.0109	56.5 (20-83)	59 (26-89)	50 (20-79)	.0615
Disease duration, y	7.5 (0-46)	10 (2-46)	7 (0-22)	11.5 (2-34)	.1679	6 (0.5-26)	6 (0.5-26)	6 (2-15)	.6111
Average VAS score	6 (0-10)	5 (0-10)	5 (1-9)	7 (3-10)	.0038	5 (0-10)	4 (0-10)	5 (0-9)	.2769
Constant pain pattern	51 (61)	4 (21)	11 (48)	26 (100)	<.0001	40 (53)	24 (48)	16 (64)	.417
Daily use of opioids	38 (42)	0 (0)	13 (57)	21 (81)	<.0001	47 (62)	33 (65)	16 (64)	.786
Opioid consumption, MEQ	10 (0-840)	0 (0-550)	10 (0-840)	33 (0-670)	.5697	-	-	-	-
Surgical interventions	1 (0-37)	1 (0-18)	2 (0-16)	3 (0-37)	.0280	-	-	-	-
Daily use of more than 4 units of alcohol	32 (35)	5 (26)	6 (26)	10 (38)	.5670	-	-	-	-
Cigarette pack years	23.75 (0-169)	31.8 (2.5-100)	25 (0.125-169)	19.6 (0-60)	.5170	-	-	-	-

NOTE: Data are given in number (%) or median (range) as appropriate unless stated otherwise. MEQ, morphine equivalents; VAS, Visual Analog Scale.

dimension was reduced to the original McGill short form pain questionnaire (Q14.1-Q14.15).<sup>26</sup> The final COMPAT-SF questionnaire is shown in [Supplementary Appendix A](#). The median scores of all pain dimensions and the total scores are presented in [Figure 2](#).

### Validation

**Content validity.** The experts agreed that the 5 pain dimensions of the COMPAT-SF comprised the essential parts of the COMPAT questionnaire.

**Construct validity.** CFA was performed on the final COMPAT-SF questionnaire on answers from the developmental study and the American patients from the reliability study, excluding the Danish patients to eliminate potential duplicates. Thereby, 121 patients were included in the CFA, ensuring a patient-to-item ratio above 20.

All factor loadings were significant and ranged from 0.44 to 0.78, with *P*-values <.001. The severity dimension, descriptive dimension, provocation dimension, and pain pattern dimension all had *R*<sup>2</sup> values >.3, corresponding to a good equation fit. The pain spreading dimension had an *R*<sup>2</sup> value of .19 and was the weakest dimension. The CFA is summarized in [Table 2](#). The overall *R*<sup>2</sup> value was .81.

**Criterion validity.** COMPAT-SF total scores from the developmental study were significantly correlated with both quality of life and hospitalizations ([Table 3](#)). All individual subscores were correlated to hospitalizations,

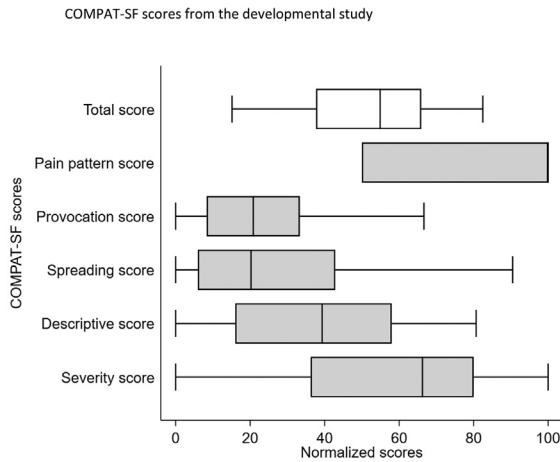
and the 3 most clinically relevant subscores (pain severity, pain pattern, and pain provocation) also correlated with quality-of-life scores. The Izbicki pain scale and the BPI both correlated with the COMPAT-SF score with a correlation coefficient of 0.78 (*P* <.0001) and 0.61 (*P* <.0001) ([Supplementary Figure 1](#)).

### Reliability

For the reliability testing, the ICC was calculated to be 0.89 in the stable pain severity group and 0.61 in the unstable pain severity group. Bland-Altman plots are presented in [Figure 3](#), including limits of agreement ranging from -15.4 to 16.8 in the stable pain group and -27.9 to 30.1 in the unstable pain group. Cronbach's alpha was calculated at 0.76, with a confidence interval from 0.70 to 0.82 in the stable/unstable groups.

### Discussion

COMPAT-SF is the first validated, reliable, and clinically feasible questionnaire developed primarily for assessing pain in patients with CP. The full version of COMPAT was developed by Teo et al<sup>9</sup> and included all relevant aspects of pain, and while comprehensive, it was too time-consuming. The questionnaire includes 5 pain dimensions that correlated with hospitalization needs in the previous year. The total score and the most clinically relevant dimensions also correlated with quality-of-life



Pain pattern score is a variable with two possible scores, 50 and 100, which is the cause of the answers' shown distribution.

**Figure 2.** COMPAT-SF scores from the developmental study. Pain pattern score is a variable with two possible scores, 50 and 100, which is the cause of the answers' shown distribution.

scores. The questionnaire was tested for the most important validity measures, and the COMPAT-SF total score correlated with the questionnaires that are more commonly used to assess pain in CP. Finally, the COMPAT-SF questionnaire was found to be reliable in patients with CP with stable pain.

### Development of the COMPAT-SF

Short forms are frequently developed from extensive original instruments, as the most significant limitation

**Table 2.** Confirmatory Factor Analysis

	Coefficient	P value	R <sup>2</sup>
Fluctuation score	0.66	<.001	0.44
Provocation score	0.58	<.001	0.34
Spreading score	0.44	<.001	0.19
Descriptive score	0.78	<.001	0.61
Severity score	0.73	<.001	0.54
Overall			0.81
Overall model level fit indices	Value	P value	
Chi <sup>2</sup>	6.846	.232	
RMSEA	0.055	.388	
Comparative fit index	0.988		
Tucker-Lewis index	0.975		
SRMR	0.037		
CD	0.811		

CD, coefficient of determination; RMSEA, root mean squared error of approximation; SRMR, standardized root mean square of residuals.

**Table 3.** Outcome Association Between COMPAT-SF Scores, Hospitalizations During the Last Year, and PANQOLI Score

	12-month hospitalizations			PANQOLI		
	n	IRR	P	n	Coefficient	P
COMPAT-SF subscores						
Pain pattern	89	1.21	<b>.005</b>	55	-0.24	<b>&lt;.001</b>
Pain severity	82	1.17	<b>.01</b>	50	-0.21	<b>.003</b>
Pain provocation	79	1.21	<b>.02</b>	51	-0.45	<b>&lt;.001</b>
Pain spreading	82	0.97	.62	53	-0.19	<b>.03</b>
Pain description	77	1.14	.10	49	-0.37	<b>&lt;.001</b>
COMPAT-SF score	67	1.29	<b>.012</b>	42	-0.57	<b>&lt;.001</b>

NOTE: Reported ratios correspond to a 10-point change on the corresponding pain score. Bold values indicate significant results.

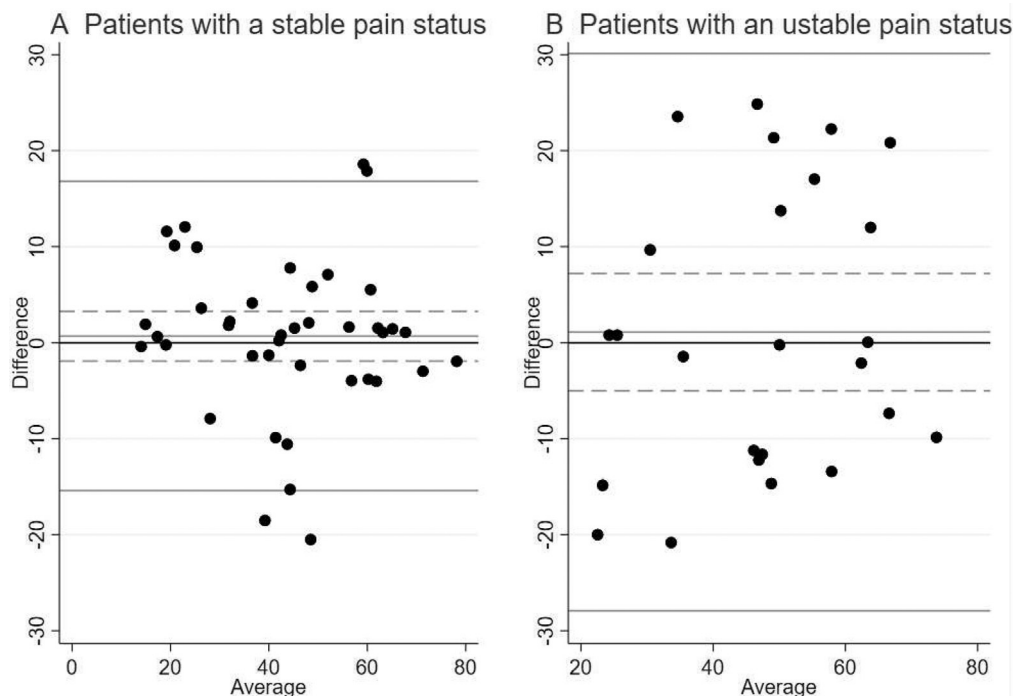
COMPAT-SF, Comprehensive Pain Assessment Tool-Short Form; IRR, incidence-rate ratio; PANQOLI, Pancreatitis Quality Of Life Instrument.

for comprehensive questionnaires is low completion rate.<sup>27</sup> When used in clinical research, achieving a high completion rate is essential, as missing data are challenging for statistical analysis and inference.<sup>28</sup> However, developing a short-form questionnaire comes at the price of potentially losing psychometric properties and precision.<sup>29</sup>

There are different approaches to reduce the number of questions in an original instrument, and the selection of questions is dependent on several factors, including the structure of the questionnaire.<sup>9</sup> The approach can be based on item-total correlations, item discrimination parameters, and factor loadings, among others.<sup>30</sup> The design of the original COMPAT complicates statistical calculations and does not allow explanatory factor analysis. Hence, we chose to exclude all questions not directly pain-related.<sup>30</sup> Secondly, we excluded questions concerning psychological, mental, and social aspects of pain, although these are often recommended.<sup>31</sup> These dimensions were excluded in the COMPAT-SF for pragmatic reasons, noting that they are available in the full version of COMPAT, which can be used in studies where there is a special focus on psychological well-being or coping mechanisms. [Supplementary questionnaires](#) can then be added to the COMPAT-SF when needed.

### Validation

The establishment of validity is essential as this ensures an adequate assessment of the theoretical construct (ie, evaluates the patient in a manner commensurate to the full instrument). The full COMPAT is only validated on content validity, and therefore, the COMPAT-SF was validated as a newly developed instrument.



**Figure 3.** Bland-Altman plots from the 2 patient groups from the reproducibility study. (A) Patients with a stable pain status; (B) Patients with an unstable pain status.

In this study, content validity, established by an expert group, was satisfactory.

Construct validity was assessed by CFA, concluding that all factor loadings were significant.

For criterion validity, the questionnaire results were compared with other pain questionnaires that are routinely used in CP pain. Therefore, it gives us comparable data concerning pain severity, but also additional information on pain triggers, widespread pain, and a qualitative description of the pain.<sup>8,13</sup>

A further test of criterion validity correlated the COMPAT-SF score to the patients' quality-of-life scores. The significant correlation indicated that life quality decreases with higher COMPAT-SF total scores. Therefore, the COMPAT-SF measures a clinically relevant score. The questionnaire scores also correlated with the number of hospital admissions due to pain during the last year, indicating that the COMPAT-SF total score is related to the impact of CP-related pain and the associated economic burden.

### Reliability

When assessing the reliability of a pain questionnaire, a stable pain pattern is essential. Although chronic pain typically fluctuates during the day,<sup>32</sup> pain fluctuations over time, both in intensity and pain pattern, can substantially decrease reliability.<sup>33</sup>

Fluctuating pain in CP has recently been confirmed and is similar to other kinds of visceral pain.<sup>34</sup> Therefore, reliability assessment is challenging in this patient group. Two groups were included to evaluate reliability. For the stable pain group, both ICC and limits of agreement were

acceptable. The differences in the level of fluctuations stress the need for a feasible short form, as it can be repeated on multiple occasions.

### Clinical Aspects of Pancreatic Pain Assessment

Previous clinical trials of pain in CP have been heavily biased because they relied on questionnaires that are either not validated in CP or developed for other types of pain. Although chronic pain to a high degree is comparable between diseases,<sup>31</sup> pain triggers are typically different. For example, postprandial pain is common in CP and can be a sign of obstructive complications. However, this dimension is not included in most questionnaires used for CP, and data on how pain triggers interfere with treatment effect and patient-reported outcomes are lacking.<sup>5</sup>

The pain dimensions that were included in the COMPAT-SF were all considered to be of particular clinical relevance. Pain severity and pain pattern have been shown to affect many factors such as quality of life, days in hospital, and socioeconomic factors.<sup>2,3,35,36</sup> Widespread pain has been associated with psychological distress, low self-care levels, and mental and physical fatigue.<sup>37</sup> McGill short form scores as included in COMPAT-SF are shown to be associated with mental anxiety and depression.<sup>11</sup> Pain provocative factors are a previously undescribed dimension but include several aspects specific to pancreatic pain, including postprandial pain, smoking, and alcohol, and could be interesting to include in future studies.<sup>38,39</sup>

Of note, question 1 and 2 must be adjusted if the questionnaire is used in treatment studies with shorter



duration than 12 months. The usability of the questionnaire would be enhanced if a smartphone app is produced, and we aim to produce that in near future.

### Limitations

A long-form questionnaire can be overwhelming for many patients, resulting in incomplete answers or answers of inferior quality. In this study, missing answers from the full COMPAT were also a problem. The lack of complete answers led to the need for interpolation to allow for statistical analysis. Although interpolation was performed carefully after thorough review of patients' answers, it does introduce potential errors.

Leaving out important aspects of pain, such as psychological, mental, and social aspects, also poses a limitation to the use of COMPAT-SF and prevents a full characterization of pain. However, there is a trade-off between having a short, easy-to-use questionnaire that can be readily used in the clinic and a questionnaire that takes too long to complete.

In the development of the COMPAT-SF, evaluation by patients was not done. Future studies must examine whether all important patient-reported outcomes are included. Potential differences in answers depending on etiology or demographics should also be examined, and predictive validity should also be examined in a prospective study.

### Conclusion

The COMPAT-SF is the first valid and reliable, clinically feasible pain questionnaire for patients with CP. It includes the most important aspects of pain in patients with CP, and the score reflects their quality of life. We recommend that it be used in future research and as a clinical instrument to evaluate and monitor pancreatic pain.

### Supplementary Material

Note: To access the supplementary material accompanying this article, please click [here](#).

### References

- Olesen SS, Poulsen JL, Drewes AM, et al. Scandinavian Baltic Pancreatic Club (SBPC). The Scandinavian Baltic Pancreatic Club (SBPC) database: design, rationale and characterisation of the study cohort. *Scand J Gastroenterol* 2017;52:909–915.
- Olesen SS, Juel J, Nielsen AK, Frøkjær JB, Wilder-Smith OHG, Drewes AM. Pain severity reduces life quality in chronic pancreatitis: implications for design of future outcome trials. *Pancreatology* 2014;14:497–502.
- Machicado JD, Amann ST, Anderson MA, et al. Quality of life in chronic pancreatitis is determined by constant pain, disability/unemployment, current smoking, and associated co-morbidities. *Am J Gastroenterol* 2017;112:633–642.
- Bendinger T, Plunkett N. Measurement in pain medicine. *BJA Educ* 2016;16:310–315.
- Teo K, Johnson MH, Truter S, Pandanaboyana S, Windsor JA. Pain assessment in chronic pancreatitis: a comparative review of methods. *Pancreatology* 2016;16:931–939.
- Bloechle C, Izbicki JR, Knoefel WT, Kuechler T, Broelsch CE. Quality of life in chronic pancreatitis, results after duodenum-preserving resection of the head of the pancreas. *Pancreas* 1995;11:77–85.
- Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singapore* 1994;23:129–138.
- Tan G, Jensen MP, Thornby JL, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. *J Pain* 2004; 5:133–137.
- Teo K, Johnson MH, Drewes AM, Windsor JA. A comprehensive pain assessment tool (COMPAT) for chronic pancreatitis: development, face validation and pilot evaluation. *Pancreatology* 2017;17:706–719.
- Wassef W, Bova C, Barton B, Hartigan C. Pancreatitis Quality of Life Instrument: development of a new instrument. *SAGE Open Med* 2014;2:2050312114520856.
- Dworkin RH, Turk DC, Revicki DA, et al. Development and initial validation of an expanded and revised version of the Short-form McGill Pain Questionnaire (SF-MPQ-2). *Pain* 2009; 144:35–42.
- Layer P, Yamamoto H, Kalthoff L, et al. The different courses of early- and late-onset idiopathic and alcoholic chronic pancreatitis. *Gastroenterology* 1994;107:1481–1487.
- Izbicki JR, Bloechle C, Broering DC, Knoefel WT, Kuechler T, Broelsch CE. Extended drainage versus resection in surgery for chronic pancreatitis a prospective randomized trial comparing the longitudinal pancreaticojejunostomy combined with local pancreatic head excision with the pylorus-preserving pancreatoduodenectomy. *Ann Surg* 1998;220:771–779.
- Drewes AM, Helweg-Larsen S, Petersen P, et al. McGill Pain Questionnaire translated into Danish: experimental and clinical findings. *Clin J Pain* 1993;9:80–87.
- Tsang S, Royse CF, Terkawi AS. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. *Saudi J Anaesth* 2017;11(Suppl):S80–89.
- Ho AD, Yu CC. Descriptive statistics for modern test score distributions: skewness, kurtosis, discreteness, and ceiling effects. *Educ Psychol Meas* 2015;75:365–388.
- Mosier CI. A critical examination of the concepts of face validity. *Educ Psychol Meas* 1947;7:191–205.
- Taherdoost H. Validity and reliability of the research instrument; how to test the validation of a questionnaire/survey in a research. *Int J Acad Res* 2016;5:28–36.
- Lynn MR. Determination and quantification of content validity. *Nurs Res* 1986;35:382–385.
- Cronbach LJ, Meehl PE. Construct validity in psychological tests. *Psychol Bull* 1955;52:281–302.
- O'Leary-Kelly SW, Vokurka RJ. The empirical assessment of construct validity. *J Oper Manag* 1998;16:387–405.
- Schreiber JB, Stage FK, King J, Nora A, Barlow EA. Reporting structural equation modeling and confirmatory factor analysis results: a review. *J Educ Res* 2006;99:323–338.
- Lawless JF. Negative binomial and mixed Poisson regression. *Can J Stat* 1987;15:209–255.

24. Faucher M, Poiraudou S, Lefevre-Colau MM, Rannou F, Fermanian J, Revel M. Assessment of the test-retest reliability and construct validity of a modified Lequesne index in knee osteoarthritis. *Joint Bone Spine* 2003;70:520–525.
25. Bonett DG, Wright TA. Cronbach's alpha reliability: Interval estimation, hypothesis testing, and sample size planning. *J Organ Behav* 2015;36:3–15.
26. Melzack R. The short-form McGill pain questionnaire. *Pain* 1987;30:191–197.
27. Haroutianian S, Donaldson G, Yu J, Lipman AG. Development and validation of shortened, restructured Treatment Outcomes in Pain Survey instrument (the S-TOPS) for assessment of individual pain patients' health-related quality of life. *Pain* 2012;153:1593–1601.
28. Tambs K, Røysamb E. Selection of questions to short-form versions of original psychometric instruments in MoBa. *Norsk Epidemiol* 2014;24:195–201.
29. Nicholas MK, McGuire BE, Asghari A. A 2-item short form of the pain self-efficacy questionnaire: development and psychometric evaluation of PSEQ-2. *J Pain* 2015;16:153–163.
30. Hagtvet KA, Sipos K. Creating short forms for construct measures: the role of exchangeable forms. *Pedagogika* 2016;66:689–713.
31. Edwards RR, Dworkin RH, Turk DC, et al. Patient phenotyping in clinical trials of chronic pain treatments: IMMPACT recommendations. *Pain* 2016;157:1851–1871.
32. Jensen MP, McFarland CA. Increasing the reliability and validity of pain intensity measurement in chronic pain patients. *Pain* 1993;55:195–203.
33. Morley S. Bias and reliability in pain ratings. *Pain* 2016;157:993–994.
34. Kempeneers MA, Issa Y, Verdonk RC, et al. Dutch Pancreatitis Study Group. Pain patterns in chronic pancreatitis : a nationwide longitudinal cohort study. *Gut* 2020:Online ahead of print.
35. Mullady DK, Yadav D, Amann ST, et al. , NAPS2 Consortium. Type of pain, pain-associated complications, quality of life, disability and resource utilisation in chronic pancreatitis: a prospective cohort study. *Gut* 2011;60:77–84.
36. Wehler M, Nichterlein R, Fischer B, et al. Factors associated with health-related quality of life in chronic pancreatitis. *Am J Gastroenterol* 2004;99:138–146.
37. Hunt IM, Silman AJ, Benjamin S, Mcbeth J, Macfarlane GJ. The prevalence and associated features of chronic widespread pain in the community using the “Manchester” definition of chronic widespread pain. *Rheumatology (Oxford)* 1999;38:275–279.
38. Drewes AM, Krarup AL, Detlefsen S, Malmstrøm M-L, Dimcevski G, Funch-Jensen P. Pain in chronic pancreatitis: the role of neuropathic pain mechanisms. *Gut* 2008;57:1616–1627.
39. Poulsen JL, Olesen SS, Malver LP, Frøkjær JB, Drewes AM. Pain and chronic pancreatitis: a complex interplay of multiple mechanisms. *World J Gastroenterol* 2013;19:7282–7291.

---

#### Reprint requests

Address requests for reprints to: Asbjørn Mohr Drewes, MD, PhD, DMSc, Centre for Pancreatic Diseases, Department of Gastroenterology and Hepatology, Aalborg University Hospital, Mølleparkvej 4, 9000 Aalborg, Denmark. e-mail: amd@m.dk.

#### Acknowledgment

The authors would like to acknowledge Mr Rasmus Bach Nedergaard for his back-translation of the questionnaire as well as Mr Andrew MacCormick and Dr Gajan Srikuma for their work with the full COMPAT questionnaire.

#### CRedit Authorship Contributions

Louise Kuhlmann, MD (Conceptualization: Equal; Data curation: Equal; Formal analysis: Lead; Investigation: Lead; Project administration: Lead; Writing – original draft: Lead; Writing – review & editing: Equal)

Keith Teo, MD (Conceptualization: Equal; Data curation: Equal; Investigation: Equal; Writing – review & editing: Equal)

Søren Schou Olesen, MD, PhD (Conceptualization: Equal; Formal analysis: Supporting; Methodology: Equal; Supervision: Supporting; Writing – review & editing: Equal)

Anna Edwards Phillips, MD (Conceptualization: Equal; Data curation: Equal; Methodology: Equal; Writing – review & editing: Equal)

Mahya Faghhih, MD (Conceptualization: Equal; Data curation: Equal; Investigation: Equal; Writing – review & editing: Equal)

Natalie Tuck, MD (Conceptualization: Equal; Investigation: Equal; Methodology: Equal; Writing – review & editing: Equal)

Elham Afghani, MD (Conceptualization: Equal; Data curation: Equal; Methodology: Equal; Writing – review & editing: Equal)

Vikesh K. Singh, MD, MSc (Conceptualization: Equal; Methodology: Equal; Writing – review & editing: Equal)

Dhiraj Yadav, MD, DMSc (Conceptualization: Equal; Methodology: Equal; Writing – review & editing: Equal)

John A. Windsor, MD, DMSc (Conceptualization: Equal; Methodology: Equal; Writing – review & editing: Equal)

Asbjørn Mohr Drewes, MD, PhD, DMSc (Conceptualization: Equal; Methodology: Equal; Project administration: Supporting; Supervision: Lead; Writing – review & editing: Equal)

#### Conflicts of interest

The authors disclose no conflicts.

#### Funding

VKS was supported by a sub-agreement to the Johns Hopkins Medical Institutions through grant #4 U44 AA026111-03 from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to Theryly Fibrosis, Inc.

### Supplementary Appendix A

## Comprehensive Pain Assessment Tool-Short Form (COMPAT-SF) for Chronic Pancreatitis.

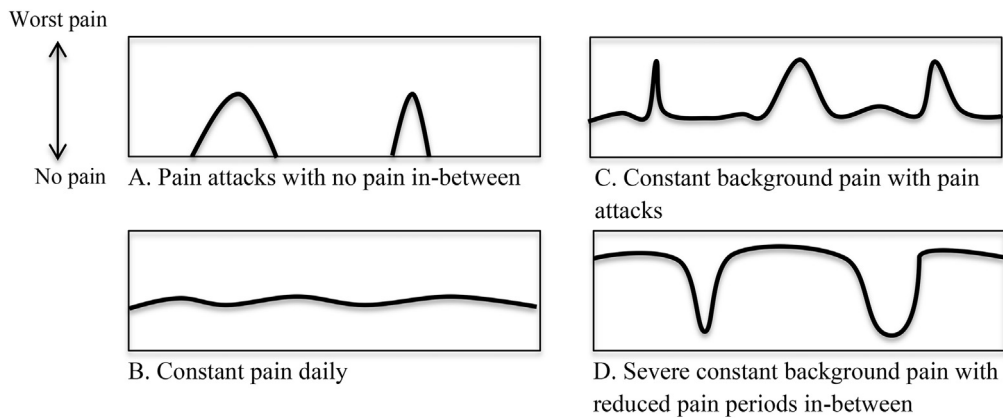
Date: \_\_\_\_\_

Patient name:	Patient NHI:	Gender:
Ethnicity:	Age:	Occupation:

Thank you for participating in this study. Please fill in your particulars below or affix a patient label.

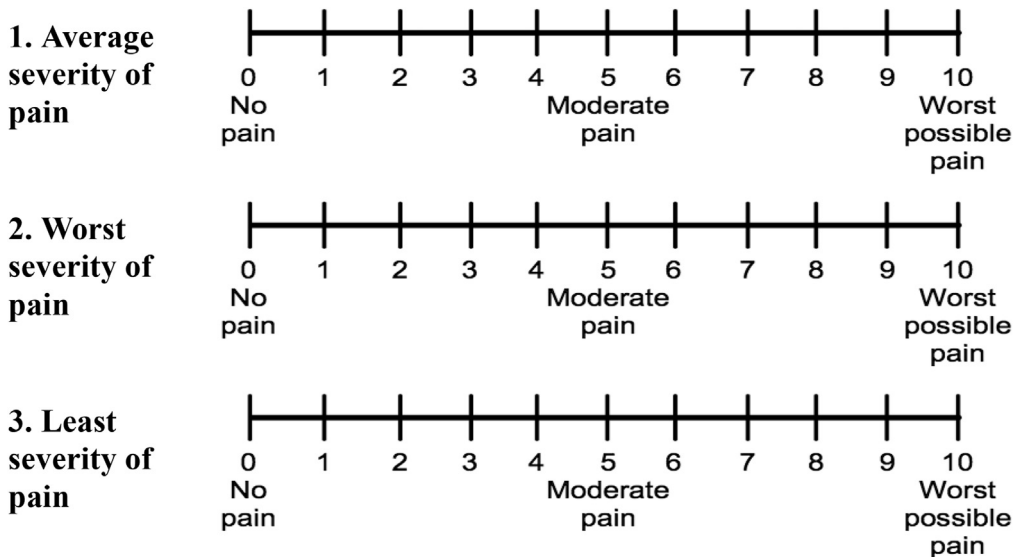
**Instructions:** The following questions ask about your pancreatic pain experience in chronic pancreatitis. This is usually felt somewhere in the upper abdomen.

**Q1. Please circle the pancreatic pain pattern that best represents your pain experience during the last 12 months.**



**Q2. Severity of pain during the last 12 months.**

Please put an X on each of these scales



**Q3. Please write your current pain medications and dose below and circle your answers for frequency**

Medicine	Dose	Frequency
_____	_____	PRN / OD / BD / TDS / QID
_____	_____	PRN / OD / BD / TDS / QID
_____	_____	PRN / OD / BD / TDS / QID
_____	_____	PRN / OD / BD / TDS / QID
_____	_____	PRN / OD / BD / TDS / QID
_____	_____	PRN / OD / BD / TDS / QID

PRN: when needed, OD: once daily, BD: twice daily, TDS: three times daily, QID: four times daily

**Q4. Please rate each item that brings on your pancreatic pain.**

Items	Never	Rarely	Sometimes	Very often	Always	Not applicable
1. Any food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Fatty food	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Drinking fluids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Drinking alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Cigarette smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Socialising	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Weather changes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Light touch on skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Cold/Heat on skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Pressure on skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Others (Please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q5. Apart from your typical pancreatic pain, please rate each item that you experience.**

Items	Never	Rarely	Sometimes	Very often	Always
1. Head and/or facial pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Joint pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Upper and/or /lower Limb pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Back and/or neck pain (not related to pancreas pain)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Abdominal and/or pelvic pain (not related to pancreas pain)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Muscle pain e.g. fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Chest pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Others (Please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q6. Below is a list of words that describe some of the different qualities of pain and related symptoms. Please circle the numbers that best describe the intensity of each of the pain and related symptoms you felt during the last 12 months. Use 0 if the word does not describe your pain or related symptoms.**

1. Throbbing Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
2. Shooting Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
3. Stabbing Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
4. Sharp Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
5. Cramping Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
6. Gnawing Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
7. Hot-burning Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
8. Aching Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
9. Heavy Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
10. Tender	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
11. Splitting Pain	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
12. Tiring-Exhausting	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
13. Sickening	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
14. Fearful	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible
15. Punishing-cruel	none	0	1	2	3	4	5	6	7	8	9	10	Worst possible

**Thank you for your participation.**

## Scoring Manual

**Pain severity dimension.** The pain severity score is based on question 2 (Q2.x) and question 3 (Q3) answers. Q2 consists of the average pain experienced (Q2.1), the worst pain experienced (Q2.2), and the least pain experienced (Q2.3), and the score is calculated as a mean of the three values. The scores are normalized on a 0–100 scale. Q3 is scored due to analgesic treatment, 100 for opioids, 75 for weak opioids, 50 for adjuvant analgesics including cannabinoids, 25 for weak analgesics including acetaminophen and nonsteroidal anti-inflammatory drugs. All questions and subquestions must be filled out to calculate a pain severity dimension score.

$$\text{Score} = ((Q2.1 + Q2.2 + Q2.3) / 3) + Q3) / 2$$

**Pain fluctuation dimension.** The pain fluctuation score is based on the answer to question 1. Any variant of constant pain scores 100. Intermittent pain scores 50.

**Pain provocation dimension.** The pain provocation score is based on the 12 question 4 (Q4.x) answers. If a patient has left a subquestion unfilled, this is given the score 0. Pain provocation dimension score can only be calculated if at least four subquestions are filled out.

Never and not applicable scored 0, rarely scored 1, sometimes scored 2, very often scored 3, and always scored 4. All question scores are then normalized on a 0–100 scale.

$$\begin{aligned} \text{Score} = & (Q4.1 + Q4.2 + Q4.3 + Q4.4 + Q4.5 + Q4.6 \\ & + Q4.7 + Q4.8 + Q4.9 + Q4.10 + Q4.11 \\ & + Q4.12) / 12 \end{aligned}$$

**Spreading pain dimension.** The spreading pain score is based on the 7 question 5 (Q5.x) answers. If a patient

has left a subquestion unfilled, this is given the score 0. Spreading pain dimension score can only be calculated if at least three subquestions are filled out.

Never scored 0, rarely scored 1, sometimes scored 2, very often scored 3, and always scored 4. All question scores are normalized on a 0–100 scale.

$$\begin{aligned} \text{Score} = & (Q5.1 + Q5.2 + Q5.3 + Q5.4 + Q5.5 + Q5.6 \\ & + Q5.7) / 7 \end{aligned}$$

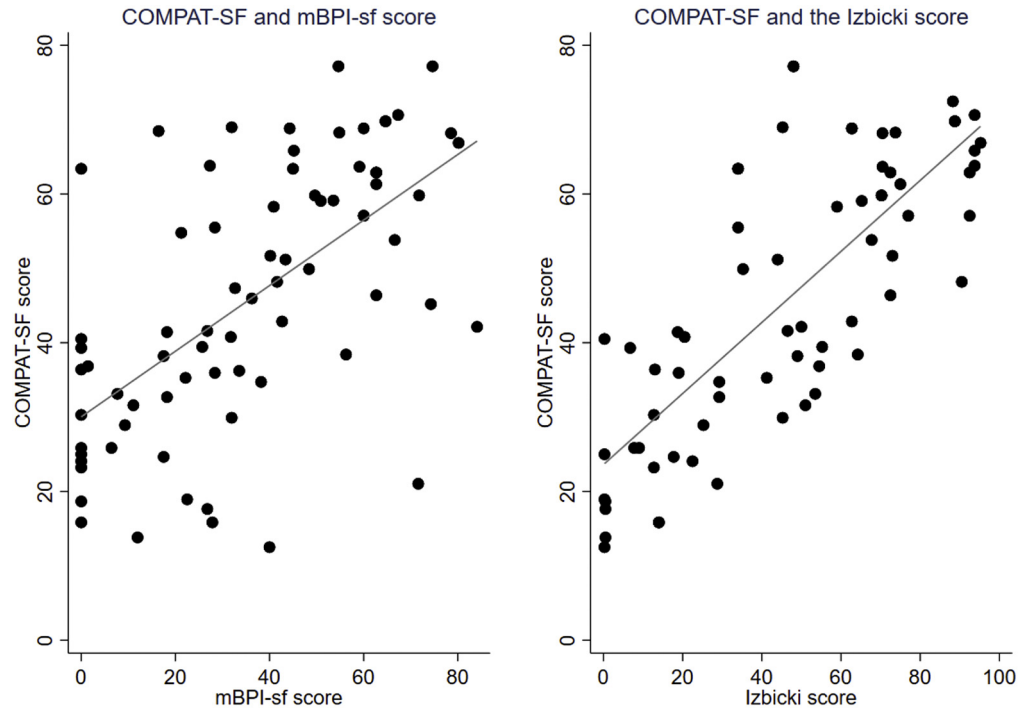
**Qualitative pain-describing dimension.** The qualitative pain-describing score is based on the 15 question 6 (Q6.x) answers. If a patient has left a subquestion unfilled, this is given the score 0. All subquestion scores are normalized on a 0–100 scale. Qualitative pain-describing dimension score can only be calculated if at least five subquestions are filled out.

$$\begin{aligned} \text{Score} = & (Q6.1 + Q6.2 + Q6.3 + Q6.4 + Q6.5 + Q6.6 \\ & + Q6.7 + Q6.8 + Q6.9 + Q6.10 + Q6.11 + Q6.12 \\ & + Q6.13 + Q6.14 + Q6.15) / 15 \end{aligned}$$

The total score can only be calculated if at least four dimension scores are calculated, where one has to be the severity dimension score.

$$\begin{aligned} \text{Total score} = & (2 \times \text{pain severity score} + 2 \times \text{pain} \\ & \text{fluctuation score} + 2 \times \text{pain provocation} \\ & \text{score} + \text{spreading pain score} + \\ & \text{qualitative pain - describing score}) / 8 \end{aligned}$$

**Note:** for treatment studies, the evaluation period of question 1 and question 2 must be changed to fit the study's evaluation period.



**Supplementary Figure 1.** Scatterplots for the correlations between COMPAT-SF, mBPI-sf, and the Izbicki pain scale.