Hitting The Bullseye: The Psychometric Properties of the Assessment of Burden of Chronic Conditions (ABCC)-Scale in The Netherlands

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Research Article

Keywords: Burden of disease, chronic disease, ABCC-tool, questionnaire, validity, reliability, asthma, diabetes mellitus type 2, COPD, person-centered care.

Posted Date: September 20th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-861720/v1

Version of Record: A version of this preprint was published at The Annals of Family Medicine on March 28th, 2023. See the published version at https://doi.org/10.1370/afm.2954.

Abstract

Background

Chronic conditions impose a major impact on quality of life and on healthcare. The Assessment of Burden of Chronic Conditions (ABCC-)tool was developed to improve experienced quality of care and quality of life by facilitating shared decision-making and self-management. It assesses the experienced burden of one or multiple conditions, and visualises and integrates the burden in daily care. However, its scale's validity and reliability are yet unknown. The aim of this study is to evaluate whether the ABCC-scale is valid and reliable in people with Chronic Obstructive Pulmonary Disease (COPD), asthma, or Type 2 Diabetes Mellitus (T2DM).

Methods

The Saint George Respiratory Questionnaire (SGRQ), the Standardized Asthma Quality of Life Questionnaire (AQLQ-S), and the Audit of Diabetes Dependent Quality of Life Questionnaire (ADDQoL19) were compared to the ABCC-scale to assess convergent validity. Convergent validity was assumed when at least 75% of the postulated correlations were higher than 0.7, or between 0.3 and 0.7 for single-item subscales. To measure known-group validity, participants were categorized according to exacerbation status, depression, asthma control, insulin dependence, complications and obesity. The ABCC-scale was deemed internally consistency upon a Cronbach's alpha ≥ 0.90 for the total scale, and ≥ 0.70 for subscales. Test-retest reliability was evaluated at a two-week interval.

Results

A total of 65, 62, and 60 people with COPD, asthma, T2DM respectively were included. The ABCC-scale correlated, in accordance with hypotheses, with the SGRQ (75%), AQLQ-S (100%), and ADDQoL19 (75%). Differentiation of known-groups based on the ABCC-scale was possible for all specified groups. The total score and subscores of the ABCC-scale were internally consistent with a Cronbach's alpha of 0.90, 0.92, and 0.91 for the total score for people with COPD, asthma, and T2DM respectively. The ABCC-scale had a good test-retest reliability with an Intraclass Correlation Coefficient of 0.95, 0.93, and 0.95 for people with COPD, asthma and T2DM respectively.

Conclusions

The ABCC-scale is a valid and reliable questionnaire that can be used within the ABCC-tool for people with COPD, asthma or T2DM. Future research should indicate whether this also applies to people with multimorbidity, and what the effects and experiences are upon clinical use.

Background

Chronic conditions impose an enormous impact on healthcare in general as well as on people living with chronic conditions (1, 2). A substantial proportion of people has multiple chronic conditions (i.e. 41.8% in primary care in the Netherlands in 2016), which relates to an even greater impact (2, 3). Disease management is a central focus in care for people with chronic conditions. Self-management and shared decision-making are a key pillars of this focus, but remain difficult to achieve (4, 5). In order to manage chronic conditions, one must first understand the burden they impose on one's life (5). This applies to both patient and healthcare provider.

To support disease management, the Assessment of Burden of Chronic Conditions (ABCC-)tool was developed. The tool facilitates shared decision-making, self-management and patient-healthcare provider communication about experienced burden and burden-guided care plans (6). The ABCC-tool is currently developed for people with Chronic Obstructive Pulmonary Disease (COPD), asthma, and Type 2 Diabetes Mellitus (T2DM), and is designed for expansion to other chronic conditions (additional file 1). The ABCC-tool can be used during consultations, and consists of the following steps: 1) assessing experienced burden with a short scale, 2) a visualization of the outcomes, 3) a shared decision-making conversation between patient and healthcare provider supported by treatment advice, 4) formulating personalized care goals. The ABCC-scale, assessing the experienced burden of disease for a person with one or multiple chronic conditions, is the focus of this paper. It consists of generic core set of burden-related questions that are relevant to anyone with the earlier mentioned chronic conditions and disease-specific sets of questions that are added for these conditions (additional file 1). Additional to these burden-related questions, the scale includes five lifestyle questions regarding physical exercise, smoking, alcohol use, weight and height (additional file 1). The generic, disease-specific, and lifestyle questions combine into a single questionnaire, regardless of whether someone has one or more chronic conditions. The total questionnaire assesses the experienced burden of disease for a patient. However, it is yet unknown whether the ABCC-scale validly and reliably assesses experienced burden.

The ABCC-tool aims at a personalised approach to care, which is reflected by the experienced burden of one with chronic conditions. Validation of the ABCC-scale is a necessary step prior to bringing the ABCC-tool to clinical practice. The aim of this study is to evaluate whether the ABCC-scale validly and reliably measures experienced burden in people with COPD, asthma, or T2DM.

Methods

A questionnaire study with two measurement moments was conducted in the Netherlands from April 2019 until March 2020, and reported considering the COSMIN guidelines (7).

Participant selection and recruitment

Participants were eligible if they were self-reportedly diagnosed with either COPD, asthma, T2DM. Additional inclusion criteria were: age over 18 years, and being able to read and understand Dutch

language. Participants were excluded in case of a lung attack within a period of six weeks prior to study onset (COPD or asthma), or being diagnosed with T2DM within a period of three months prior to study onset. Participants with asthma or COPD were recruited by the patient organization Lung Foundation Netherlands. Participants with T2DM were recruited by the patient organization Dutch Diabetes Association, the Dutch Institute for Rational use of Medicine, and subsequently by using recruitment posters in waiting rooms of general practices and three internal medicine departments throughout the Netherlands.

Sample size

There is no golden standard describing the sample size calculation for studies validating patient-reported outcome measures (PROMs), such as the ABCC-tool (8). Recommendations state that the participant-to-item ratio should be in between 2 and 20 participants per item (8). The ABCC-tool consists of 3 scales with 15, 16 and 14 items for COPD, asthma and T2DM respectively. Considering these numbers of items and a participant-to-item ratio of about four, the sample size needed was estimated at 60 participants per scale for each single chronic condition.

Data collection

All participants completed a self-administered questionnaire on paper at home, including their baseline characteristics, the ABCC-scale, and a disease-specific set of questionnaires upon inclusion at baseline (T0). The ABCC-scale measures experienced burden. Experienced burden of disease is the impact of a chronic condition on a person's life in terms of symptom severity, functioning, and Quality of Life (QoL) (9). However, experienced burden is rarely fully evaluated. More regularly, QoL is assessed, which is an integrated part of the experienced burden (9, 10). In the absence of measures that evaluate experienced burden, QoL was used as a comparative measure. As such, the ABCC-scale will be compared to commonly used QoL measures. For people with COPD this included the Saint George Respiratory Questionnaire (SGRQ). For people with asthma, this included the Standardized Asthma Quality of Life Questionnaire (AQLQ-S). For people with T2DM, this included the Audit of Diabetes-Dependent Quality of Life (ADDQoL19). Additional to these questionnaires, the Hospital Anxiety and Depression Scale (HADS) will be completed by people with COPD to assess known-group validity. Two weeks after completing the first set of questionnaires (i.e. T1), all participants completed the ABCC-scale again, with an additional question whether their health status had changed since T0 (i.e. worse, the same, or better since the previous questionnaire).

ABCC-scale

The ABCC-scale is a multicomponent questionnaire in the Dutch language (6). It consists of a generic core set of questions that might be relevant to anyone with the aforementioned chronic conditions (i.e. either COPD, asthma or T2DM), and additional disease-specific questions that are added for these conditions (additional file 1). The generic part consists of ten items that are represented in seven domains: physical limitations (3 items), fatigue (1 item), night's rest (1 item), feelings/emotions (2 items),

sexuality (1 item), relations and work (1 item), and medicines (1 item). For someone with COPD, six additional items are represented in two additional domains (pulmonary complaints (4 item) and lung attacks (exacerbations; 1 item)) and in one existing domain (feelings/emotions (1 item)). For someone with asthma, seven additional items are added into three additional domains (asthma complaints (4 items), lung attacks (exacerbations; 1 item), and nasal complaints (1 item)) and one existing domain (feelings/emotions (1 item)). For someone with T2DM, four additional items are added into four additional domains: hypoglycemia (described as hypo; 1 item), worry about blood glucose (1 item), leg- and feet complaints (1 item), and eating and drinking (1 item). The domain lung attacks for people with COPD or asthma regards the frequency of exacerbations in a year, which in is not a subjective evaluation of burden. It will therefore not be included in the assessment of validity and reliability. The same applies to the lifestyle questions. At the end of the questionnaire, an open-ended question presents the opportunity to add anything that gives rise to their experience of burden of disease. Due to the variability of this last question, this will not be taken into account in the analyses. All burden-related items are scored on a 7-point Likert scale from 0 (no burden) to 6 (highest burden). Multi-item domains are scored as the sum of responses divided by the amount of items. The total score is calculated by the sum of domain scores, divided by the number of domains, in which it is assumed that all domains are equally relevant to the total score. One missing value was tolerated for multi-item domains, with exceptions for items C13 and A14 because these items add unique information to the domain based on expert opinion (additional file 1). A missing item was imputed by the participant's mean score of the other items in that domain except for single-item domains. In that case, that particular domain was excluded from the total score calculation. All ABCC-scales are presented in additional file 1.

SGRQ

The Dutch version of the SGRQ was used, which is a disease-specific 50-item QoL questionnaire for people with COPD. The SGRQ consists of three subscales: symptoms (8 items), activity (16 items), and impact (26 items). Thirty-nine questions are dichotomous (i.e. yes/no) and 11 items are scored on a 5-point Likert scale. Total and subscale score calculation and handling of missing data were performed according to the scoring manual (11). The total and subscale scores range from 0 (no impairment) to 100 (worst impairment).

HADS

The Dutch version of the HADS is a 14-item screening scale for anxiety and depression (12–14). It contains two subscales: anxiety (7 items), and depression (7 items). All items range from 0 (no sign of anxiety/depression) to 3 (clear sign of anxiety/depression). For this study, only the depression subscale was used, which is scored by the sum of the depression items of the scale. One missing value was tolerated, and imputed by the participant's mean of the remaining items. A depression subscale score of eight or higher discriminated between (borderline) depression and no depression (14).

AQLQ-S

The Dutch version of the AQLQ-S is a 32-item disease-specific QoL scale for people with asthma (15). It contains four subscales: symptoms (12 items), activity limitations (11 items), emotional function (5 items), and environmental stimuli (4 items). All items are scored on a 7-point Likert scale, ranging from 1 (i.e. severe impairment) to 7 (i.e. no impairment). The subscale scores were calculated as the sum of the items divided by the number of items. The total score was calculated as the sum of all items divided by the total number of items. A maximum of three missing values was tolerated for the total score, and only one missing value was tolerated for the symptoms and activity limitation subscales. Missing values were imputed with the participant's mean of the other items. These calculations are based on the scoring manual that is available upon request from the original author of the AQLQ-S.

ADDQoL19

The ADDQoL19 is a 19-item questionnaire measuring disease-specific QoL for people with T2DM (16). Each of the 19 items is scored based on how a person's QoL would be without T2DM and its importance to that person. The impact of each item is scored from − 3 (QoL is much better without T2DM) to + 1 (QoL is worse without T2DM), and the importance is scored from 0 (not important at all) to 3 (very important). Both scores are multiplied to create the weighted impact (WI) of that item. The total score is the Average Weighted Impact (AWI), and is calculated by averaging the sum of WIs over the number of items included. Missing values are not tolerated in calculation of the item WIs, and up to six missing items are tolerated for calculation of the AWI. These calculations are based on the scoring manual that is available upon request from the original author of the ADDQoL19.

Data analysis

Validity was evaluated based on the assessment of convergent validity and the questionnaire's discriminative properties regarding known groups. Either t-tests or Mann Whitney U tests were used to evaluate validity based on whether the data were approximately normally distributed (histogram and QQ-plot). Convergent validity was implied in case at least 75% of the absolute value of the postulated correlations was higher than 0.7 for the total score or multi-item subscales or in between 0.3 and 0.7 in case of single item-subscales (17). Statistical significance was credited to p-values of $p \leq 0.05$. All statistical analyses were performed using IBM's SPSS version 25.0 software.

Construct validity for people with COPD

The SGRQ was used as comparator to evaluate the convergent validity of the ABCC-scale for people with COPD. It was hypothesized that the correlation between the total scores of the ABCC-scale and the SGRQ was higher than 0.70. This level of correlation was also hypothesized between the ABCC-subscales physical limitations and pulmonary complaints and the SGRQ subscales. To assess the discriminative properties of the ABCC-scale for people with COPD, two pairs of groups were created based on exacerbation status (< 2 versus ≥ 2 exacerbations in the past year) and the HADS depression subscale (depression score < 8 versus ≥ 8) (18). It was hypothesized that patients with two or more exacerbations scored worse on the total scale and the subscales night's rest, feelings/emotions, physical limitation,

relations and work, and pulmonary complaints (19–23). Besides, it was hypothesized that patients with (borderline) depression scored worse on the total scale and the subscales fatigue, feelings/emotions, physical limitations, relations and work, and pulmonary complaints (24, 25).

Construct validity for people with asthma

The AQLQ-S was used to assess the convergent validity of the ABCC-scale for people with asthma. It was hypothesized that the correlation between the total score of the ABCC-scale and AQLQ-S was lower than − 0.70. This level of correlation was also hypothesized for the ABCC-scale domains physical limitation and asthma complaints versus the total score and the symptoms and activity limitation subscales of the AQLQ-S. Additionally, the domain feelings/emotions of the ABCC-scale was hypothesized to meet the cut-off point in correlation with the emotional function domain of the AQLQ-S. To check the discriminative properties of the ABCC-scale for known groups of people with asthma, two pairs of groups were created based on exacerbation status (0 versus ≥ 1 exacerbation in the past year) and asthma control status according to the Global Initiative for Asthma (GINA; controlled versus uncontrolled) (26–29). It was hypothesized that patients with exacerbations would have higher scores on the total scale and subscales night's rest, feelings/emotions, physical limitation, relations and work, and asthma complaints (26). Furthermore, patients with uncontrolled asthma were hypothesized to score worse on the total scale and subscales night's rest, feelings/emotions, physical limitations, relations and work, sexuality, and asthma complaints (27, 28).

Construct validity for people with T2DM

The ADDQoL19 was used as a comparator to evaluate the convergent validity of the ABCC-scale for people with T2DM. It was hypothesized that the correlation between the total score of the ABCC-scale and the ADDQoL19 was lower than − 0.70. Because both scales have single-item domains, domains were hypothesized to significantly correlate on a moderate level ($-0.3 < r < -0.7$) (30). The ABCC-domain feelings/emotions was hypothesized to correlate with ADDQoL19 items self-confidence and feelings about the future. The ABCC-domain physical limitation was hypothesized to correlate with ADDQoL19 items physical and depend on others. The ABCC-domain relations and work was hypothesized to correlate with ADDQoL19 items leisure, work, family life, and friendships and social life. The ABCC-domain sexuality was hypothesized to correlate with ADDQoL19 item sex life. The ABCC-domain eating and drinking was hypothesized to correlate with ADDQoL19 items freedom to eat, and freedom to drink. To check the discriminative properties of the ABCC-scale for known groups of people with T2DM, three pairs of groups were created based on insulin use (insulin-independent versus insulin-dependent), presence of complications (no complications versus the presence of any the following conditions: nephropathy, neuropathy, retinopathy, sexual dysfunction, amputation of any limb, diabetic foot, or cardiovascular disease), and obesity (Body mass Index (BMI) ≥ 30) (31–33). It was hypothesized that people with T2DM who use insulin score worse on the total scale and subscales feelings/emotions, physical limitations, relations and work, hypoglycemia and worry about the future (31, 32, 34). Furthermore it was hypothesized that people with T2DM and complications score worse on the total scale and subscales feelings/emotions, physical limitation, relations and work (33, 35–37). Lastly, it was

hypothesized that people with T2DM and obesity score worse on the total score and subscales feelings/emotions, physical limitation, relations and work, and eating and drinking (35, 37–39).

Reliability

The reliability of the ABCC-scale was assessed through internal consistency and test-retest analysis. A Cronbach's alpha of $\alpha \geq 0.90$ for the total scale or $\alpha \geq 0.70$ for subscales with multiple items was maintained as cut-off point for determining adequate internal consistency (40, 41). Test-retest reliability was evaluated for those subjects who had an unchanged self-reported health status at T1. An intraclass correlation coefficient (ICC) of 0.90 was considered acceptable for evaluating the ABCC-scale as sufficiently reproducible (17, 42).

Results

A total of 187 participants were included in this study, namely 65 people with COPD, 62 people with asthma, and 60 people with T2DM. One participant with asthma and one with T2DM were lost to follow-up between T0 and T1. The baseline characteristics of the population are presented in Table 1. Between T0 and T1, 5 people with COPD, 11 people with asthma, and 6 people with T2DM indicated a changed health status and were thus excluded from test-retest analyses. An additional list of participant characteristics is presented in additional file 2. Outcomes on the various questionnaires are presented in additional file 3.

Table 1
Baseline characteristics per condition

Condition	COPD	Asthma	T2DM
Total included, n	65	62	60
Male sex, n (%)	39 (60.0)	19 (30.6)	30 (50.0)
Mean age, years (SD)	66.2 (6.9)	55.8 (13.4)	66.4 (9.5)
Highest level of education (43), n (%)	26 (40.0)	18 (29.0)	29 (48.3)
- Low[a]	3 (4.6)	10 (16.1)	6 (10.0)
- Middle[b]	36 (55.4)	34 (54.8)	25 (41.7)
- High[c]			
Diagnosed since, n (%)	1 (1.5)	1 (1.6)	1 (1.7)
- < 1 year	4 (6.2)	4 (6.5)	-
- 1–3 years	60 (92.3)	57 (91.9)	-
- > 3 years	-	-	40 (66.7)
- 1–15 years	-	-	19 (31.7)
- > 15 years			
Smoking status, n (%)	6 (9.2)	34 (54.8)	-
- Never	58 (89.2)	28 (45.2)	-
- Former	1 (1.5)	0 (0.0)	-
- Current			
Treated by, n (%)	11 (17.5)	17 (31.5)	48 (82.8)
- General practitioner	52 (82.5)	37 (68.5)	10 (17.2)
- Medical specialist	2	8	2
- Unknown			

[a]elementary school, pre-vocational secondary education and training, or secondary vocational education and training, [b]classified as: senior general secondary education or pre-university education, [c]classified as: higher professional education or university education, [d]Short-acting β2-agonist, [e]Short-acting Muscarinic Antagonists, [f]Long-acting β2-agonist, [g]Long-acting Muscarinic Antagonists, [h]Inhaled Corticosteroids, -= not applicable to this population

Condition	COPD	Asthma	T2DM
Exacerbations, previous year, n (%)	19 (29.2)	16 (25.8)	-
- 0	19 (29.2)	8 (12.9)	-
- 1	9 (13.8)	15 (24.2)	-
- 2	18 (27.7)	23 (37.1)	-
- > 2			
Medication, n (%)	0 (0.0)	1 (1.6)	5 (8.3)
No medication	40 (61.5)	45 (72.6)	-
Any of the following:	49 (75.4)	22 (35.5)	-
- SABA[d]/SAMA[e]	17 (26.2)	37 (59.7)	-
- LABA[f]/LAMA[g]	35 (53.8)	43 (69.4)	-
- ICS[h]	-	-	40 (66.7)
- Combination medication	-	-	22 (36.7)
(ICS + LABA/LAMA)	-	-	27 (45.0)
- Metformin			
- Gliclazide, Glimepiride, or Tolbutamide			
- Insulin			

[a]elementary school, pre-vocational secondary education and training, or secondary vocational education and training, [b]classified as: senior general secondary education or pre-university education, [c]classified as: higher professional education or university education, [d]Short-acting β2-agonist, [e]Short-acting Muscarinic Antagonists, [f]Long-acting β2-agonist, [g]Long-acting Muscarinic Antagonists, [h]Inhaled Corticosteroids, -= not applicable to this population

Validity and reliability of the ABCC-scale for people with COPD

The total score of the ABCC-scale for people with COPD correlated with the SGRQ total score (r = 0.866), as well as with all subscales (Table 2). The domains physical limitations and pulmonary complaints of the ABCC-scale correlated with the SGRQ total score (r = 0.829, and r = 0.761, respectively). Out of the 12 postulated correlations, 9 were higher than 0.7, indicating that 75% of these hypotheses were met (Table 2). People with two or more exacerbations scored significantly higher on the ABCC-scale total, as well as on the hypothesized domains. People with COPD of whom the HADS indicated a depression scored significantly higher on the ABCC-scale total, as well as on the fatigue, feelings/emotions, and relations

and work domains. The Cronbach's alpha of the ABCC-scale total for people with COPD was 0.90. Domain scores had a Cronbach's alpha of 0.92, 0.77, and 0.65 for physical limitations, feelings/emotions, and pulmonary complaints respectively. The ICC for the ABCC-scale for people with COPD was 0.95.

Table 2
Psychometric properties of the ABCC-scale for people with COPD

2.1 Convergent validity – r (n = 65)				
	SGRQ			
	Total	**Activity**	**Impact**	**Symptoms**
ABCC total	0.866*	0.797*	0.806*	0.734*
Physical limitation	0.829*	0.831*	0.743*	0.668
Pulmonary complaints	0.761*	0.636	0.697	0.773*
2.2 Known-group validity - median (IQR)				
	< 2 exacerbations (n = 33)	**≥ 2 exacerbations (n = 32)**	**p-value**	
ABCC total	1.6 (0.9–2.6)	2.6 (2.4–3.6)	< 0.001	
Night's rest	2.0 (0.5–2.5)	2.5 (2.0–3.0)	0.006	
Feelings/emotions	1.0 (0.3-2.0)	2.0 (1.0-2.7)	0.010	
Physical limitations	2.3 (1.0-4.2)	3.7 (3.0-4.9)	0.003	
Relations and work	1.0 (0.5-3.0)	3.0 (2.0–4.0)	< 0.001	
Pulmonary complaints	2.3 (1.6-3.0)	3.3 (2.6–3.9)	< 0.001	
	HADS			
	Not depressed (n = 50)	**Depressed (n = 15)**	**p-value**	
ABCC total	2.1 (1.2–2.9)	3.1 (2.5–3.9)	0.001	
Fatigue	3.0 (2.0–4.0)	4.0 (3.0–5.0)	0.022	
Feelings/emotions	1.0 (0.3-2.0)	2.0 (1.7–2.7)	0.001	
Physical limitations	3.0 (1.3–4.3)	3.7 (3.0-4.7)	0.057	
Relations and work	2.0 (1.0–3.0)	3.0 (3.0–4.0)	0.002	
Pulmonary complaints	2.6 (1.8–3.5)	3.0 (2.5-4.0)	0.061	
2.3 Reliability measures				
	Cronbach's α (95% CI)			
IC total scale	0.90 (0.86–0.93)			
IC physical limitations	0.92 (0.88–0.95)			

* r > 0.7

2.1 Convergent validity – r (n = 65)	
IC feelings/ emotions	0.77 (0.64–0.85)
IC pulmonary complaints	0.65 (0.49–0.77)
	ICC (95% CI)
Test-retest reliability (n = 60)	0.95 (0.92–0.97)
* r > 0.7	

Validity and reliability of the ABCC-scale for people with asthma

The total score of the ABCC-scale for people with asthma correlated with the AQLQ-S total score (r=-0.851) as well as with all subscales (Table 3). The physical limitations and asthma complaints domains of the ABCC-scale correlated with the total scores (r=-0.777, and r=-0.835, respectively). All ten correlations were lower than 0.7, indicating that 100% of the hypotheses were met (Table 3). People who had exacerbations and people with uncontrolled asthma scored significantly higher on the ABCC-scale total, as well as on the hypothesized domains (Table 3). The Cronbach's alpha of the ABCC-scale total for people with asthma was 0.92. Domain scores had a Cronbach's alpha of 0.88, 0.74, and 0.73 for physical limitations, feelings/emotions, and asthma complaints respectively. The ICC for the ABCC-scale for people with asthma was 0.93.

Table 3
Psychometric properties of the ABCC-scale for people with asthma

3.1 Convergent validity – r (n = 62)				
	AQLQ			
	Total	Symptoms	Activity limitation	Emotional function
ABCC total	-0.851*	-0.842*	-0.831*	-
Feelings/emotions	-	-	-	-0.725*
Physical limitation	-0.777*	-0.782*	-0.797*	-
Asthma complaints	-0.835*	-0.865*	-0.805*	-

3.2 Known-group validity – median (IQR)			
	No exacerbations (n = 16)	≥ 1 exacerbations (n = 46)	p-value
ABCC total	1.5 (0.9–1.9)	2.5 (1.8–3.1)	< 0.001
Night's rest	2.0 (1.0–2.0)	3.0 (2.0–4.0)	0.001
Feelings/emotions	1.0 (0.8–1.3)	1.3 (0.6-2.0)	0.049
Physical limitations	1.7 (0.7-2.0)	2.3 (1.7–3.3)	< 0.001
Relations and work	1.0 (0.0–2.0)	3.0 (2.0–4.0)	0.001
Asthma complaints	0.8 (0.5–1.6)	3.0 (2.0-3.8)	< 0.001
	GINA		
	Controlled[a] (n = 18)	Uncontrolled (n = 43)	p-value
ABCC total	1.4 (1.0-1.8)	2.7 (2.0-3.2)	< 0.001
Night's rest	2.0 (1.0–3.0)	3.0 (2.0–4.0)	0.003
Feelings/emotions	0.5 (0.0–1.0)	1.3 (1.0–2.0)	< 0.001
Physical limitations	1.0 (0.7-2.0)	2.3 (1.7–3.3)	< 0.001
Relations and work	1.0 (0.0–2.0)	3.0 (2.0–4.0)	< 0.001
Sexuality	0.5 (0.0–2.0)	2.0 (0.0–3.0)	0.042
Asthma complaints	0.8 (0.2–1.5)	3.0 (2.3–3.8)	< 0.001

[a] Well and partially controlled combined into one group

* r<-0.7

3.1 Convergent validity – r (n = 62)	
3.3 Reliability measures	
	Cronbach's α (95% CI)
IC total scale	0.92 (0.89–0.95)
IC physical limitations	0.88 (0.82–0.93)
IC feelings/ emotions	0.74 (0.60–0.83)
IC asthma complaints	0.73 (0.61–0.83)
	ICC (95% CI)
Test-retest reliability (n = 50)	0.93 (0.87–0.96)
[a] Well and partially controlled combined into one group	
* r<-0.7	

Validity and reliability of the ABCC-scale for people with asthma

The total score of the ABCC-scale for people with asthma correlated with the AQLQ-S total score (r=-0.851) as well as with all subscales (Table 3). The physical limitations and asthma complaints domains of the ABCC-scale correlated with the total scores (r=-0.777, and r=-0.835, respectively). All ten correlations were lower than 0.7, indicating that 100% of the hypotheses were met (Table 3). People who had exacerbations and people with uncontrolled asthma scored significantly higher on the ABCC-scale total, as well as on the hypothesized domains (Table 3). The Cronbach's alpha of the ABCC-scale total for people with asthma was 0.92. Domain scores had a Cronbach's alpha of 0.88, 0.74, and 0.73 for physical limitations, feelings/emotions, and asthma complaints respectively. The ICC for the ABCC-scale for people with asthma was 0.93.

Table 4
Psychometric properties of the ABCC-tool for people with diabetes

4.1 Convergent validity – r (n = 60)			
ABCC-scale	**ADDQoL19 WI**	**Pearsons coefficient**	
ABCC total	**Average (AWI)**	-0.548	
Feelings/emotions	Self-confidence	-0.260	
	Feelings about the future	-0.379*	
Physical limitations	Physical	-0.391*	
	Depend on others	-0.459*	
Relations and work	Leisure	-0.441*	
	Work	-0.664*	
	Family life	-0.413*	
	Friendships and social life	-0.448*	
Sexuality	Sex life	-0.650*	
Eating and drinking	Freedom to eat	-0.346*	
	Freedom to drink	-0.167	
4.2 Known-group validity – median (IQR)			
	Insulin dependence		
	Independent (n = 32)	**Dependent (n = 27)**	**p-value**
ABCC total	1.1 (0.7–1.5)	1.9 (1.4–2.7)	0.001*
Feelings/emotions	1.0 (0.5–1.9)	1.5 (1.0–3.0)	0.025*
Physical limitations	1.0 (0.3–1.7)	2.7 (1.3-3.0)	0.004*
Relations and work	0.0 (0.0–1.0)	2.0 (0.0–3.0)	0.005*
Hypoglycaemia	1.0 (0.0-1.8)	2.0 (0.0–2.0)	0.038*
Worry about future	1.0 (0.0–2.0)	2.0 (1.0–3.0)	0.051
	No complications (n = 12)	**≥ 1 complications (n = 48)**	**p-value**
ABCC total	0.9 (0.4–1.3)	1.7 (1.1–2.6)	0.001*
Feelings/emotions	0.5 (0.0–1.0)	1.3 (1.0-2.5)	0.001*
Physical limitations	0.5 (0.0-1.5)	1.7 (1.0–3.0)	0.007*

* r<-0.7 for total scales or -0.7 < r<-0.3 for single item-correlations

4.1 Convergent validity – r (n = 60)			
Relations and work	0.0 (0.0–1.0)	1.0 (0.0–2.0)	0.031*
	BMI < 30 (n = 44)	**BMI ≥ 30 (n = 16)**	**p-value**
ABCC total	1.2 (0.8–2.1)	1.9 (1.5–2.8)	0.008*
Feelings/emotions	1.0 (0.5–1.9)	1.8 (1.0-2.5)	0.031*
Physical limitations	1.2 (0.3–2.6)	2.9 (1.4–3.6)	0.003*
Relations and work	0.0 (0.0–2.0)	2.0 (1.0–2.0)	0.018*
Eating and drinking	2.0 (1.0-2.8)	1.5 (1.0-3.8)	0.830
4.3 Reliability measures			
	Cronbach's α (95% CI)		
IC total scale	0.91 (0.87–0.94)		
IC physical limitations	0.87 (0.80–0.92)		
IC feelings/ emotions	0.76 (0.60–0.85)		
	ICC (95% CI)		
Test-retest reliability (n = 53)	0.95 (0.91–0.97)		
* r<-0.7 for total scales or -0.7 < r<-0.3 for single item-correlations			

Validity and reliability for people with T2DM

The total score of the ABCC-scale for people with T2DM correlated moderately (i.e. -0.7 < r<-0.3) with the ADDQoL19 AWI (r=-0.548) (Table 4). The ABCC-domains correlated for each hypothesized comparison, except for the comparison between ABCC-domain eating and drinking and ADDQoL19 item freedom to drink (Table 4). Out of the 12 postulated correlations, 9 were between − 0.7 and − 0.3, indicating that 75% of the hypotheses were met. People who were insulin-dependent scored significantly higher on the ABCC-scale total as well as on the hypothesized domains, except for the domain worry about future (Table 4). People with at least one complication scored significantly higher on the ABCC-scale total, as well as on the hypothesized domains. People who were obese scored significantly higher on the ABCC-scale total as well as for the hypothesized domains, except on the domain eating and drinking. The Cronbach's alpha of the ABCC-scale total for people with T2DM was 0.91. Domain scores had a Cronbach's alpha of 0.87 for physical limitations, and 0.76 for feelings/emotions. The ICC for the ABCC-scale for people with T2DM was 0.95.

Discussion

This study shows the ABCC-scale to be a valid and reliable instrument for evaluating the experienced burden of disease for people with COPD, asthma or T2DM. Firstly, the ABCC-scale showed to correlate in at least 75% of the postulated hypotheses, thereby confirming its construct validity. Secondly, the ABCC-scale was in most cases able to differentiate known groups of people with COPD, asthma, and T2DM. Thirdly, the ABCC-scale has adequate internal consistency for the total score and multi-item domains (i.e. physical limitations, feelings/emotions and asthma complaints). Lastly, the ABCC-scale showed to have excellent test-retest reliability.

These results indicate that the ABCC-scale can be used as a valid and reliable scale to measure and evaluate the experienced burden of disease for people with COPD, asthma, or T2DM. People with these chronic conditions can thus identify which domains are most prominent in their experienced burden. The results will be visualised during consultation with the healthcare provider. Based on these results, the healthcare provider and patient can select a domain that is most relevant to be discussed. Using shared decision-making, personalised goals can be formulated, which can help the patient to mitigate the burden of disease. The ability to differentiate known clinical groups enables the caregiver to step into a more detailed conversation regarding that particular domain. Therefore, the ABCC-tool focusses the conversation towards the domains that need attention and the domains that both caregiver and patient would like to discuss.

The results should be reviewed with several notions. First, recruitment bias may have occurred. Upon careful examination of the outcomes of all questionnaires, one may conclude that the participants of this study experienced low levels of burden. The experienced burden ranged roughly from 0 (“never in the past week/month” or “not at all limited”) to 3 (“several times in the past week/month” or “moderately limited”), on a scale from 0 to 6. That means that the validity and reliability may not hold true for people that experience high levels of burden. This may relate to the possible drawbacks of recruiting people from patient advocate groups, which are in general highly educated people, who are well-connected to the patient group (44). Second, the efforts in the recruitment phase eventually led to sample sizes of 65, 62, and 60 for people with COPD, asthma and T2DM respectively. This means that our participant-to-item ratio was roughly four. The sample was thus within recommended sample sizes (8). Third, this study has evaluated the validity and reliability of the same scale for three different conditions, thereby strengthening the assumption of validity and reliability of the generic part of the scale for multiple conditions. Fourth, the ability to differentiate known groups from the literature adds to the relevance of the ABCC-tool for scientific and clinical use.

To our knowledge, this is the first study of a questionnaire that combines the experienced burden of disease for people with COPD, asthma or T2DM into a single questionnaire. The validity and reliability of the ABCC-scale for these conditions separately justify investigation of its psychometric properties for people with multimorbidity. Additionally, in contrast to many other questionnaires, the ABCC-scale largely consists of single-item domains. This means that it suits for brief and efficient clinical application, where more robust questionnaires are simply too time consuming. The results of the current study are in line with the results from the ABCC-tool’s predecessor, the Assessment of Burden of COPD (ABC)-tool (45).

Although the content of the ABC-scale was changed while developing the ABCC-scale for multiple chronic conditions, the resulting domains are still valid. The ABCC-scale is able to differentiate people with COPD regarding exacerbation status and an indication of depression. The results of this study justify the use of the ABCC-scale within the ABCC-tool for people with COPD, asthma or T2DM.

This study builds on the development of the ABCC-tool, and facilitates future research in several ways. The conversation is guided by the domain scores of the ABCC-tool. In the current score calculation, all domains are assumed to be equally relevant to the total score. This may not necessarily be the case, and should be studied by for example performing a discrete choice experiment (46, 47). A weighted total score can be used by caregivers to monitor overall progression or deterioration, or for example to compare on a group level. Furthermore, knowledge of the psychometric properties of the ABCC-tool in the single conditions serves as a basis and a prerequisite to study its properties in people with multiple conditions. Lastly, to test the effectiveness of the ABCC-tool and evaluate user experiences upon applying the tool in clinical practice, further research should be performed (48).

Conclusions

The ABCC-scale is a brief self-administered questionnaire that measures the experienced burden of disease for people with COPD, asthma or T2DM. This study provides evidence for the validity and reliability of the ABCC-scale in a Dutch population.

Declarations

All methods have been performed according to COSMIN guidelines for measurement properties on health status instruments (7).

Ethics approval and consent to participate

The Medical Ethics Committee of Zuyderland Hospital, Heerlen, approved the study (METCZ20180131). All participants provided written informed consent prior to participation.

Consent for publication

Not applicable

Availability of data and materials

The data that is used and analyzed in this study are available from the corresponding author upon reasonable request. The ABCC-scale is included in additional file 1, though these scales are developed and validated in Dutch language, and not in English. The presented translation serves the sole purpose of supporting the manuscript but is not intended to be used, nor is it validated for English-speaking patients. Moreover, the ABCC-scale should always be used together with the visualization and treatment advice as present in the ABCC-tool.

Competing interests

All authors declare no conflicts of interest.

Funding

This study was funded by the Netherlands Organisation for Health Research and Development (104006001). The funding party had no role in the design of the study, nor in the collection, analysis or interpretation of the data, or in writing the manuscript.

Author contributions

DC and EB designed the questionnaire study and conducted it with LK. DC and EB conducted the analyses. BW assisted with the analysis and interpretation of the data as a methodological expert. AG and OS supervised all phases of the study. DC wrote the first version of the manuscript. All authors have read and approved the final version of the manuscript.

Acknowledgements

We would like to acknowledge the great help of the patient organizations Lung Foundation Netherlands and Diabetes Association Netherlands, and the Dutch Institute for Rational use of Medicine, in recruiting participants. We also would like to thank all participants who completed the questionnaires. Additionally we would like to express gratitude to Mascha Twellaar for her assistance in conducting this study.

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