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A new instrument for measuring anticoagulation-related quality of life: development and preliminary validation

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Abstract

Background: Anticoagulation can reduce quality of life, and different models of anticoagulation management might have different impacts on satisfaction with this component of medical care. Yet, to our knowledge, there are no scales measuring quality of life and satisfaction with anticoagulation that can be generalized across different models of anticoagulation management. We describe the development and preliminary validation of such an instrument – the Duke Anticoagulation Satisfaction Scale (DASS).

Methods: The DASS is a 25-item scale addressing the (a) negative impacts of anticoagulation (limitations, hassles and burdens); and (b) positive impacts of anticoagulation (confidence, reassurance, satisfaction). Each item has 7 possible responses. The DASS was administered to 262 patients currently receiving oral anticoagulation. Scales measuring generic quality of life, satisfaction with medical care, and tendency to provide socially desirable responses were also administered. Statistical analysis included assessment of item variability, internal consistency (Cronbach's alpha), scale structure (factor analysis), and correlations between the DASS and demographic variables, clinical characteristics, and scores on the above scales. A follow-up study of 105 additional patients assessed test-retest reliability.

Results: 220 subjects answered all items. Ceiling and floor effects were modest, and 25 of the 27 proposed items grouped into 2 factors (positive impacts, negative impacts, this latter factor being potentially subdivided into limitations versus hassles and burdens). Each factor had a high degree of internal consistency (Cronbach's alpha 0.78–0.91). The limitations and hassles factors consistently correlated with the SF-36 scales measuring generic quality of life, while the positive psychological impact scale correlated with age and time on anticoagulation. The intra-class correlation coefficient for test-retest reliability was 0.80.

Conclusions: The DASS has demonstrated reasonable psychometric properties to date. Further validation is ongoing. To the degree that dissatisfaction with anticoagulation leads to decreased adherence, poorer INR control, and poor clinical outcomes, the DASS has the potential to help identify reasons for dissatisfaction (and positive satisfaction), and thus help to develop interventions to break this cycle. As an instrument designed to be applicable across multiple models of anticoagulation management, the DASS could be crucial in the scientific comparison between those models of care.

Background

Oral anticoagulation is indicated for a number of conditions, including prevention of systemic embolism in patients with mechanical heart valves, valvular heart disease, myocardial infarction, and atrial fibrillation [1]. It is often intended that anticoagulation be maintained over the long term; for example, one of the considerations in placing a mechanical heart valve is the ability of the patient to comply with a regimen of anticoagulation for the remainder of his of her lifetime.

Long-term anticoagulation can be provided in various fashions; for example, under the direction of a generalist physician such as an internist, under the direction of a specialist physician such as a cardiologist, under the direction of an anticoagulation service managed by a pharmacist or nurse, or primarily through patient self-management. Blood can be obtained for testing using a vein or a fingerstick, and results can be made available immediately (using a point-of-care testing device) or can be provided subsequently through an outside laboratory. Contact between the provider and the patient can be in-person, by telephone, by mail, or through the internet.

Regardless of the model of care, there are a number of characteristics of anticoagulation that can potentially induce dissatisfaction and reduce quality of life. Among these characteristics are the need for regular blood testing and other contacts with the medical system, lifestyle limitations (e.g., restrictions on diet and activities), and possible worry about bleeding and/or bruising. Anticoagulation might also have a number of positive effects; for example, the reassurance provided by effective treatment and contact with supportive providers.

There are two basic approaches to measuring health-related quality of life among patients receiving anticoagulation: generic and condition-specific. Generic scales assess constructs that are common to a wide range of individuals. For example, the eight subscales of the widely used SF-36 instrument are physical function, physical role, bodily pain, general health, vitality, social function, emotional role, and mental health. Generic instruments not only facilitate comparisons with other populations (e.g., between patients undergoing anticoagulation and those with asthma), but their comprehensiveness can help identify aspects of the condition under study that might not have been anticipated by the developers of condition-specific scales.

In contrast to generic scales, condition-specific scales are intended to be much more narrowly focused toward those aspects of health-related quality of life that are of the greatest salience for that condition. For example, an arthritis-specific scale might include questions about joint pain, the number of joints that are swollen or tender, and so forth. Ideally, generic and condition-specific scales can provide information that is complementary; the former being broad although not necessarily detailed, and the latter being detailed but not necessarily broad. The text by McDowell and Newell provides an excellent introduction to generic and condition-specific scales, including a description of various scales such as the SF-36 [2].

There are relatively few extant condition-specific scales that measure quality of life and satisfaction with anticoagulation, and to our knowledge none of these scales can be generalized across models of medical care. For research purposes, having such a scale would be particularly important in support of studies designed to determine which approach to anticoagulation management is superior. In clinical practice, being able to measure quality of life and satisfaction with anticoagulation management could help support interventions that increase time in therapeutic range and reduce adverse thromboembolic or bleeding events.

Our goal was to develop and validate a scale that could be administered to anticoagulation patients generally; that is, across indication for anticoagulation and across models of anticoagulation management. This report describes the development and preliminary validation of this scale – the Duke Anticoagulation Satisfaction Scale (DASS).

Methods

Preliminary studies

We began by identifying various dimensions of anticoagulation-related quality of life, using as sources the literature, patient focus groups, and expert opinion. The literature review involved a Medline search, from 1985–2000, using the terms "anticoagulation" and "quality of life". The articles resulting from this initial search were supplemented by a review of their bibliographies, a review of the reports from various large randomized trials of warfarin, and a hand-review of the Archives of Internal Medicine (this journal being particularly noteworthy for its attention to issues of anticoagulation) from 1985–2000 [3-9].

After Institutional Review Board approval, two patient focus groups were organized to help identify the domains of interest and also to record the phrasing of the patients' comments (so as to reflect this phrasing, if possible, in the actual wording of the DASS items). Patients were recruited from local anticoagulation services. A majority of these patients had undergone anticoagulation for an extended period of time.

We conducted initial interviews with five experts (a physician assistant, a pharmacist, and three physicians, all of

whom are widely experienced in anticoagulation practice), then asked these experts to comment on the proposed dimensions and item wording.

Once a preliminary set of items was developed, we administered an initial draft of the instrument in "talk-through interviews" with nine patients. Items were modified, and the process was repeated with another set of nine patients.

We then administered the resulting 26-item instrument to 122 patients in the Duke anticoagulation service. Of these, 105 had a single interview, and 17 also had a second interview approximately one month later. The results of this study were examined: (a) at the item level, with frequency distributions, means and standard deviations; and (b) at the scale level, in order to determine which items seemed to group together. Briefly, most items had sufficient variation and grouped into the expected dimensions. Five to seven items did not, and were thus the strongest candidates for deletion or revision.

To create the current version of the DASS, the above version was revised, paying particular attention to the items that had performed poorly in the previous study. In addition, the wording of the items was reviewed by a linguistic consultant, in order to help simplify the instrument as much as possible.

Description of the DASS

The resulting 27 items, 25 of which are included in the final version of the DASS, are provided in Additional file: 1. All items have seven response categories: "not at all", "a little", "somewhat", "moderately", "quite a bit", "a lot", and "very much". The pattern of the questions is arranged to roughly correspond to three possible dimensions pertaining to anticoagulation: *limitations* (e.g., limitations on physical activities due to fear of bleeding, dietary restrictions); *hassles and burdens* (e.g., both daily hassles such as remembering to take the medicine, as well as occasional hassles such as having to wait while visiting a provider for blood testing), and *positive psychological impacts* (e.g., reassurance because of anticoagulation treatment).

Item content in the DASS varies from specific (e.g., "How much does the possibility of bleeding or bruising limit you from taking part in physical activities?") to general (e.g., "Overall, how much does the possibility of bleeding or bruising affect your daily life?"). A few items (e.g., "How much does anti-clot treatment limit the alcoholic beverages you might wish to drink?") apply to a subset of patients (e.g., those that consume alcohol); when an item does not apply, the patient is requested to answer "not at all".

Validation study design

The above 27-item version of the DASS was administered to 262 patients, 125 of whom were managed by a physician assistant in an anticoagulation service within the Department of Veterans Affairs, and 137 of whom were managed by physicians in general community practices. In addition to the DASS, we recorded various demographic and clinical characteristics (table 1) as well as three other scales: the SF-36 (generic quality of life), the PSQ-18 (satisfaction with medical care), and the SDS-5 (tendency to give socially desirable responses) [10,11]. Two of the above 27 items were subsequently dropped, yielding a final instrument containing 25 items.

We then performed an additional study in order to assess the test-retest reliability of the final 25-item version of the DASS. For this study, 105 subjects were surveyed approximately 7–14 days apart, 103 of whom completed both interviews and are included in the analysis. One item ("Overall, how much has anti-clot treatment had a negative impact on your life?") was inadvertently excluded from the instrument.

Analysis

The statistical analysis began with assessment of the pattern of missing values among the DASS items. Among patients that completed all the DASS items, we then assessed the degree of variability among individual items using frequency distributions, means and standard deviations. In order to assess internal consistency, we then examined the factor structure of the DASS, using the techniques of exploratory factor analysis with orthogonal rotations. Cronbach's alpha and item-total correlations were calculated for the overall DASS, treating the scale as a simple summation of the items, and also for its various possible subscales. Finally, in order to assess concurrent validity both the summated DASS scale score, as well as its subscales, were correlated with demographic variables, clinical characteristics, and scores on the above scales. Test-retest reliability, as applied to the overall summated DASS score, was assessed using the intra-class correlation coefficient, and also by summary statistics (mean, standard deviation) describing the differences between the DASS scores at the two time periods. The items from the first time point in the test-retest study were also used as inputs into a confirmatory factor analysis.

For consistency of presentation, all analyses involved first reverse-coding six items, as noted in the legend of Additional file: 1. (After this reverse-coding, for all items lower scores indicate greater satisfaction.)

Results

Table 1 describes the demographic and clinical characteristics of the subjects. A typical subject was a married white

Table 1: Demographic characteristics, clinical characteristics, co-administered scales

Age (mean, standard deviation)	68.70 (12.34)
Years on coumadin	4.40 (4.94)
Number of medications	6.45 (4.47)
How survey completed (%)	
On own	71
Asked questions	9
Read to respondent	20
Male gender (%)	76
White race (%)	78
Currently married (%)	68
Education (%)	
Grade school or some high school	23
High school	29
Some college	21
Completed college	26
Money to pay the bills (%)	
More than enough	44
Just enough	41
Not enough	15
Currently working for pay (%)	22
More than one dose change last year (%)	63
Hospitalized for bleeding last year (%)	5
Taken antibiotics last month (%)	22
Blood drawn (%)	
Fingerstick	14
Vein	82
Both	4
Self-reported medical history (%)	
Atrial fibrillation	57
Stroke	18
Transient ischemic attack	18
Myocardial infarction	25
Deep vein thrombosis	17
Mechanical heart valve	17
Uses pillbox to track medicines (%)	58
Emotional distress last 5 years (%)	14
SDS-5	20.29 (3.21)
PSQ-18	40.37 (8.89)
SF-36	
Physical function	52.82 (30.58)
Physical role	45.29 (42.35)
Bodily pain	60.84 (23.39)
General health	53.30 (16.48)
Vitality	51.80 (23.49)
Social function	75.90 (26.67)
Emotional role	71.28 (39.96)
Mental health	76.13 (18.09)

The SF-36 is scored on a 0–100 scale, with higher scores indicating better functioning. The PSQ-18 is scored on a 18–90 scale, with higher scores indicating greater satisfaction with medical care. The SDS-5 is scored on a 5–25 scale, with higher scores indicating greater tendency to provide socially desirable responses.

male, aged 69 years, having been receiving anticoagulation for over 4 years and taking multiple medications. Approximately three quarters of the sample completed high school. Various indications for anticoagulation were represented, of which atrial fibrillation was the most common (57%). Table 1 also presents the results of the co-administered scales. Of particular note, the SF-36 scales describing physical functioning were lower than those describing social functioning. The SDS-5 scores showed that the subjects had a tendency to give socially desirable responses; the PSQ-18 indicated generally high satisfaction with the medical care system as a whole.

Table 2: DASS Item-level summary statistics

Item	1	2	3	4	5	6	7	Mean	s.d.	Miss
1a	134	43	12	14	11	4	2	1.84	1.37	3
1b	184	17	7	4	4	4	0	1.36	0.99	3
1c	154	33	7	12	6	4	4	1.69	1.36	4
1d	167	14	7	5	6	8	13	1.84	1.78	14
1e	116	61	22	8	5	4	4	1.88	1.31	2
2a	75	54	35	15	25	12	4	2.60	1.66	0
2b	160	13	11	6	5	9	16	1.97	1.89	8
2c	75	39	37	14	14	12	29	3.02	2.12	1
2d	89	67	27	19	10	3	5	2.20	1.43	3
3a	123	62	15	10	4	3	3	1.78	1.22	1
3b	86	78	25	18	8	4	1	2.09	1.25	0
3c	135	54	15	8	6	0	2	1.65	1.09	0
3d	108	80	14	13	5	0	0	1.76	0.97	3
3e	128	57	15	9	5	3	3	1.76	1.24	3
3f	171	33	7	5	1	2	1	1.37	0.90	4
3g	109	78	15	10	2	3	3	1.81	1.17	3
3h	87	42	25	14	5	17	30	2.90	2.19	6
4a	102	42	32	16	12	8	8	2.32	1.67	3
4b	62	55	33	32	20	13	5	2.78	1.66	4
4d	70	66	33	20	13	10	8	2.55	1.64	3
4f	29	27	43	24	19	37	41	4.15	2.08	8
4g	106	63	20	18	6	4	3	2.00	1.34	4
4h	84	38	33	37	19	4	5	2.55	1.60	4
4i	132	53	12	14	2	5	2	1.75	1.23	6
4j	99	35	36	25	8	4	13	2.42	1.73	6

See additional file 1 for item descriptions. Items 3h, 4a, 4b, 4f, 4h and 4j have been reverse coded. Items 4c and 4e were deleted. The first 7 columns give the frequencies of each of the 7 response categories (after reverse-coding, as appropriate). Column 10 gives the number (out of 261 subjects with responses to at least 1 DASS item) of subjects with a missing response to the item in question.

Table 2 summarizes the DASS data at the level of the item. Of 262 subjects, 1 did not fill out any of the DASS items, 41 had at least one missing item, and 220 had complete data on the DASS. The items most commonly left missing pertained to work limitations, alcohol limitations, overall positive impact and, to a lesser extent, overall confidence, difficulty in managing anticoagulation, and whether the subject would recommend their current model of anticoagulation to others. We believe it is likely that that, for the questions about work and alcohol limitations, most of those with missing responses did not drink alcohol or were not currently working, and failed follow the directions to answer "not at all" under those circumstances. Based on the talk-through interviews, the other items listed above tended to be those which at least some respondents had difficulty in conceptualization. All items evidenced a noteworthy degree of variation (e.g., standard deviations of approximately one unit or more).

Tables 3 and 4 present a summary of the factor analysis. The six eigenvalues exceeding unity were 8.73, 3.25, 1.66, 1.43, 1.16, and 1.04. These latter two eigenvalues were close to unity, suggesting that no more than four factors should be considered.

Accordingly, rotated factor solutions were fit with 2, 3 and 4 factors. The 4-factor solution had inconsistent loadings (i.e., multiple items loaded on more than one factor), and is not considered further. The two items pertaining to "worry about anti-clot treatment" and "worry about the bad things anti-clot treatment is intended to prevent" had inconsistent loadings in the 3-factor solution, and were dropped. (In part, this decision was made because these items addressed a different construct than other items in the limitations, hassles and burdens factor(s) on which they would have been placed. In the 2-factor solution, the two items in question clearly loaded onto the "negative impacts" scale.)

Considering the 2-factor solution, 24 of the 25 items showed "simple structure" by having the rotated factor loading exceed 0.40 for only one of the factors. The only exception was the item pertaining to alcohol, which had a loading of only 0.26, perhaps because of the difficulties induced by having large numbers of patients respond "not

Table 3: DASS factor analysis results: 2-factor solution

Item	Loading: Negative	Loading: Positive	Communality	New alpha	Item-total
1a	**0.72**	-0.16	0.54	0.91	0.66
1b	**0.68**	-0.14	0.48	0.91	0.63
1c	**0.41**	-0.15	0.19	0.92	0.37
1d	**0.63**	-0.29	0.48	0.91	0.56
1e	**0.79**	-0.20	0.66	0.91	0.72
2a	**0.62**	-0.21	0.43	0.91	0.56
2b	**0.26**	-0.09	0.07	0.92	0.24
2c	**0.49**	-0.11	0.26	0.91	0.46
2d	**0.82**	-0.11	0.68	0.91	0.77
4d	**0.67**	0.01	0.46	0.91	0.63
3a	**0.79**	0.02	0.62	0.91	0.74
3b	**0.70**	0.15	0.52	0.91	0.61
3c	**0.59**	0.21	0.39	0.91	0.53
3d	**0.69**	0.11	0.49	0.91	0.64
3e	**0.67**	0.20	0.48	0.91	0.61
3f	**0.51**	0.11	0.26	0.91	0.45
3g	**0.69**	0.20	0.53	0.91	0.64
4g	**0.66**	0.13	0.45	0.91	0.61
4i	**0.54**	0.23	0.34	0.91	0.47
3h	-0.10	**0.41**	0.17	0.80	0.33
4a	-0.01	**0.66**	0.43	0.74	0.57
4b	0.08	**0.79**	0.63	0.71	0.70
p4f	-0.24	**0.57**	0.38	0.78	0.42
4h	0.25	**0.79**	0.69	0.73	0.62
4j	0.03	**0.74**	0.55	0.74	0.58

The elements are rotated factor loadings (columns 2–3), communalities (column 4), Cronbach's alpha coefficient with the item in question deleted, calculated using standardized variables (column 5), and the item-total correlation, calculated using standardized variables (column 6).

at all". All items grouped onto their anticipated factors. The variance explained by the "negative" and "positive" factors was 7.97 (32% of 25) and 3.22 (13% of 25), respectively.

Considering the 3-factor solution, the anticipated grouping of items into the factors of "limitations", "hassles", and "positive impacts" was observed; in essence, the items in the "negative" factor in the 2-factor model were disaggregated into two sub-factors. This delineation was reasonably consistent, albeit not always completely clear-cut; for example, the item asking about the hassle of the daily anti-coagulation related tasks had a rotated factor loading of 0.60 onto "hassles" and 0.51 onto "limitations". The variance explained by the hassles, limitations and positive impact factors was 5.05, 4,82 and 2.96, respectively.

The various Cronbach's alpha coefficients were as follows: 0.88 for the overall DASS summary score, 0.78 for the positive impact sub-scale, 0.91 for the negative impact sub-scale, 0.87 for the limitations sub-scale, and 0.88 for the hassles sub-scale.

In the confirmatory factor analysis on the test-retest sample, the original 2-factor solution was replicated, to a notably high degree of fidelity (data not shown). The results of the 3-factor solution were roughly similar to the previous factor analysis in the sense that all of the six items from the positive impact sub-scale were as before, and that most of the negative items disaggregated themselves into two other scales. The placement of items into the "hassles" versus "limitations" factors was mostly, but not entirely, consistent with the results of the previous factor analysis. However, simple structure was not maintained, as some items appeared to load onto both the "hassles" and "limitations" factors.

Table 5 reports correlations between the DASS summary scale, its sub-scales, and various subject characteristics and co-administered scales. The overall DASS score, the negative impacts sub-scale, the hassles sub-scale, and the limitations sub-scale behaved similarly; in particular, these were consistently correlated with the sub-scales of the SF-36. Also, these scales were positively correlated with the experience of being hospitalized for bleeding during the last year and of having more than one dosage adjustment during that period of time. The positive impact sub-scale

Table 4: DASS factor analysis results: 3-factor solution

Item	Loading: Limits	Loading: Hassles	Loading: Positive	Communality	New alpha	Item-total
1a	**0.68**	0.34	-0.07	0.58	0.85	0.67
1b	**0.67**	0.30	-0.04	0.54	0.85	0.65
1c	**0.50**	0.09	-0.04	0.26	0.87	0.40
1d	**0.77**	0.13	-0.12	0.63	0.85	0.65
1e	**0.81**	0.31	-0.06	0.76	0.84	0.77
2a	**0.56**	0.32	-0.16	0.44	0.86	0.56
2b	**0.43**	-0.06	0.06	0.19	0.88	0.31
2c	**0.48**	0.22	-0.04	0.28	0.87	0.48
2d	**0.75**	0.41	-0.02	0.73	0.84	0.78
4d	**0.58**	0.38	0.07	0.49	0.86	0.60
3a	0.51	**0.60**	-0.01	0.62	0.87	0.69
3b	0.34	**0.65**	0.06	0.54	0.87	0.64
3c	0.19	**0.64**	0.08	0.46	0.87	0.59
3d	0.26	**0.71**	-0.02	0.58	0.87	0.68
3e	0.12	**0.81**	0.00	0.67	0.86	0.74
3f	0.27	**0.44**	-0.05	0.27	0.88	0.46
3g	0.20	**0.77**	0.06	0.64	0.86	0.74
4g	0.29	**0.64**	0.03	0.49	0.87	0.58
4i	0.07	**0.68**	0.06	0.47	0.88	0.56
3h	0.04	-0.17	**0.51**	0.29	0.80	0.33
4a	0.06	-0.06	**0.76**	0.58	0.74	0.57
4b	0.01	0.11	**0.83**	0.70	0.71	0.70
4f	-0.25	-0.07	**0.57**	0.39	0.78	0.42
4h	-0.02	0.38	**0.74**	0.69	0.73	0.67
4j	-0.15	0.20	**0.70**	0.56	0.74	0.58

The elements are rotated factor loadings (columns 1–3), communalities (column 4), Cronbach's alpha coefficient with the item in question deleted, calculated using standardized variables (column 5), and the item-total correlation, calculated using standardized variables (column 6).

was less strongly correlated with the other quality-of-life measures, although it was more strongly correlated with age and time on anticoagulation.

The 103 subjects used in the test-retest study were similar to those of the main study for the SF-36 scales and most demographic characteristics (data not shown). By way of exception, the test-retest subjects were more likely to be female (38%) and to have completed high school (93%). Approximately 91% reported no significant changes in health between the two interviews. The mean DASS scores (standard deviation in parentheses) were 53.4 (17.6) and 54.9 (18.9) at interviews 1 and 2, respectively. Table 6 describes the distribution of the difference scores summarizing the changes in the DASS over the approximately 2-week period between measurements. The majority of scores were within 10 units of the initial score, and the intra-class correlation coefficient (estimated from a random effects model using subject, visit and error) was 0.80.

Discussion

We have described the development and preliminary validation of the DASS, a scale to measure satisfaction and quality of life with anticoagulation. Individual DASS items showed sufficient variation, and the large majority of items clearly grouped into scales reflecting positive and negative impacts of anticoagulation. This latter scale can, if desired, be further sub-divided into sub-scales reflecting limitations imposed by anticoagulation versus the hassles and burdens of anticoagulation management. The internal consistency of the overall scale is good (Cronbach's alpha 0.88), with the sub-scales falling into a similar range (alpha 0.78 to 0.91). The sub-scales correlate with various measures of health status and satisfaction with medical care. The level of variation from test to test (intra-class correlation 0.80) is higher than the ideal, but acceptable.

Although these initial results appear promising, various limitations should be noted. Validation is a multi-step process, requiring numerous positive findings, across a variety of applications, before a scale can be invested with full confidence. Some natural follow-up studies would include, among others, administration across a broader cross-section of patients. The DASS does not yet have norms to quantify, for example, clinically significant dif-

Table 5: Correlation with DASS total score and subscales

	Total	Negative impact	Limitations	Hassles	Positive impact
Age	-0.17 *	-0.27**	-0.24**	-0.24**	0.19**
Years on coumadin	-0.05	0.01	0.01	0.01	-0.14*
<3 months on coumadin	0.04	-0.05	-0.05	-0.03	0.19**
Number of medications	0.00	0.02	0.05	-0.03	-0.04
Completed survey alone	0.14	0.17*	0.18**	0.12	-0.05
Male	-0.08	-0.06	-0.03	-0.09	-0.05
White	-0.12	-0.15*	-0.18	-0.08	0.05
HS education	0.03	0.11	0.10	0.10	-0.16*
Low income	0.12	0.09	0.10	0.05	0.08
Work for pay	0.01	0.02	-0.02	0.07	-0.01
Dose change last year	0.18**	0.20**	0.18**	0.19**	-0.01
Hospitalized for bleed	0.19**	0.22**	0.23**	0.16*	-0.04
Antibiotics last month	0.00	-0.02	0.01	-0.6	0.06
Fingerstick	0.05	0.01	0.00	0.03	0.09
Atrial fibrillation	0.00	-0.03	-0.05	0.00	0.07
Stroke	0.19**	0.20**	0.14	0.22**	0.02
TIA	0.12	0.12	0.06	0.16*	0.04
Myocardial infarction	0.02	0.08	0.08	0.06	-0.12
DVT	0.00	0.09	0.11	0.04	-0.18**
Mechanical heart valve	0.06	0.11	0.10	0.10	-0.10
Pillbox	0.11	0.14	0.14*	0.10	-0.02
Emotional distress	0.21**	0.21**	0.17	0.22**	0.04
PSQ-18	0.19**	0.07	0.01	0.15*	0.28**
SF-36 physical function	-0.23**	-0.18**	-0.20**	-0.11	-0.16*
SF-36 physical role	-0.31**	-0.28**	-0.28**	-0.21**	-0.12
SF-36 bodily pain	-0.27**	-0.26**	-0.27**	-0.19**	-0.08
SF-36 general health	-0.17**	-0.23**	-0.20**	-0.21**	0.09
SF-36 vitality	0.28**	0.27**	0.26**	0.23**	0.07
SF-36 social function	-0.40**	-0.39**	-0.36**	-0.35**	-0.09
SF-36 emotional role	-0.32**	-0.28**	-0.24**	-0.27**	-0.14*
SF-36 mental health	-0.40**	-0.39**	-0.29**	-0.45**	-0.09
Mean(std)	54.0 (17.6)	36.9 (16.1)	20.9 (10.4)	16.0 (7.5)	17.1 (7.5)

One asterisk denotes $p < .05$, 2 asterisks denote $p < .01$.

ferences in quality of life, although generic methods might be used as at least a first approximation [12].

Another limitation pertains to the definition of the sub-scales. Although the overall pattern of the data was consistent with the ideal of simple structure, some items did load onto their respective sub-scales less strongly than others. For some items, this might reflect a moderate ceiling effect. In other cases, this might reflect a tendency for different respondents to conceptualize these items differently. The willingness to accept differing interpretations of the various items was consistent with the philosophy under which the DASS was developed; namely, that in order to be relevant to individual patients and extendable across a wide variety of applications, the scale should address its constructs as generically as possible.

How best to conceptualize quality of life associated with anticoagulation management was an ongoing challenge during the scale development process, a particular difficulty being that our experts (as well as the literature) tended to make somewhat finer distinctions (e.g., between limitations versus hassles and burdens) than were typically made by patients. Our solution was to structure the instrument with into separate sets of questions representing these fine distinctions (e.g., "limitations" comprising one such set), but to retain the option of combining the items in these sets into more general sub-scales. When applying the DASS to other models of anticoagulation management, the questions themselves could be retained (e.g., as they were designed to be applicable across models of care), but some of the text in their stems might be changed. For example, the list of possible daily and occasional tasks would likely differ according to the model of care.

The primary decision for the user that wishes to apply the DASS at the level of the sub-scale is whether to break the

Table 6: Difference Scores on Re-administration, Approximately Two Weeks Apart

Difference score (t2-t1)	Frequency
<= -21	2
-16 to -20	3
-15 to -11	9
-10 to -6	16
-5 to -1	16
0	1
1 to 5	20
6 to 10	15
11 to 15	14
16 to 20	1
> = 21	6

"negative impact" scale into two component parts. As discussed above, the structure of the instrument and, indeed, our original expectations regarding the factor analysis, was based on the notion that the negative impact scale would be sub-divided. However, both the original factor analysis and a subsequent confirmatory factor analysis showed somewhat stronger support for the simpler model including positive and negative factors only. The size of the test-retest sample (i.e., 103 subjects) was near the lower limit for a factor analysis, so we do not interpret this confirmatory factor analysis as definitive; nevertheless, its conclusions were quite similar to those of the original factor analysis. Taken as a whole, our interpretation is that a 2-factor solution may be the most natural, but that a user with a specific need to utilize three factors could reasonably do so. The current comparison between the 2- and 3-factor solutions is not definitive and, indeed, it is quite conceivable that choice of sub-scale could differ according to the patient population or the model of anticoagulation management under study.

When considering the sub-scales, the internal consistency, as measured by Cronbach's alpha, approached 0.90 for the negative impacts, hassles and limitations sub-scales, but was closer to 0.80 for the positive impact scale. The lower figure for the positive impact sub-scale might in part be a result of the number of items (i.e., on average, the more items the higher the alpha coefficient), but also because the items address a construct that is broader, and perhaps more subject to individual interpretation, than is the case for the items pertaining to the negative impact of anticoagulation. Authorities disagree on the precise benchmarks that should be applied to psychometric measures such as alpha coefficients (these benchmarks in part depending on the application; for example, with lower correlations being acceptable for scales that are intended to compare groups than for scales use to measure change within individuals). Nevertheless, the internal consistency evidenced by the DASS, both in terms of the rotated factor loadings and the Cronbach's alpha coefficients of its sub-scales, is quite consistent with usual practice for measures that are intended to be used at the level of the group. A similar interpretation applies to the test-retest analysis.

A final challenge in the item development process involved the strong socialization of patients undergoing long-term anticoagulation. Often, patients have been informed that long-term anticoagulation is a medical necessity, without an equally good alternative. (One of the conditions for receiving a heart valve is acceptance of anticoagulation for the remainder of the patient's life. In other circumstances, such as atrial fibrillation, alternatives such as aspirin that are less burdensome yet less effective are available, thus implying that patients that receive anticoagulation have self-selected, at least initially, as perceiving the burdens of this therapy as being less than its benefits.) Any life style modifications (such as eliminating activities likely to result in bleeding and bruising) required by this therapy may have been made long ago, and the effects of these modifications, although initially distressing, may no longer be considered by the patient as reducing quality of life. Nevertheless, it is quite reasonable to speculate that if the patient were managed using a less burdensome model of care, perceived quality of life would improve. Some of the final items in the DASS (e.g., whether the patient would recommend this form of anticoagulation) are an attempt to address this issue, but our talk-through interviews suggested that a non-trivial number of patients found such an exercise in visualization to be conceptually difficult. We know of no ideal solution to this problem, which is by no means limited to the present application.

The clinical relevance of the DASS lies in its ability to summarize satisfaction with anticoagulation and in particular to help identify aspects of anticoagulation that may hinder individual patients from maintaining a PT-INR within therapeutic range. Some of these aspects might be amenable to direct intervention; for example, those patients that find anticoagulation management to be extraordinarily complicated might benefit from either additional anticoagulation-related education, or perhaps from a mode of management that requires less regular testing. Other aspects might not be as directly amenable. For example, those patients who had experienced an outcome such as hospitalization for bleeding or multiple dosage changes during the past year also tended to report higher scores for hassles and limitations; in effect, becoming more sensitized to anticoagulation's potentially negative aspects. However, even in the absence of a more direct

intervention, providers might at least maintain increased vigilance for such patients.

In this spirit, providers need not only focus on the negative aspects of anticoagulation, but might also choose to especially reinforce those positive aspects that are considered to be particularly salient by each individual patient. In any event, the ultimate goal is that from identifying the limitations, hassles and burdens, and positive psychological impacts experienced by patients, the cycle of dissatisfaction, leading to poor adherence, leading to poor INR control, leading to poor clinical outcomes, can be broken. The scientific relevance of the DASS is that when interventions to break this cycle are designed, a standard of comparison will be required that is applicable across all the models of care being compared. Our intention is that the DASS can help provide a way forward in developing such a standard. Additional research is needed in order to better understand the relationship between anticoagulation-related quality of life and adherence to treatment regimens, as well as how these regimens can be improved.

Conclusion

Using the DASS we were able to identify less-than-complete satisfaction among outpatients receiving anticoagulation. An initial psychometric analysis of the statistical properties of the DASS is encouraging. The clinical relevance of the DASS lies in its ability to summarize satisfaction with anticoagulation and to identify aspects of anticoagulation that may hinder individual patients from maintaining a PT-INR within therapeutic range. From identifying the limitations, hassles and burdens, and positive psychological impacts experienced by patients, many interventions can potentially be designed to improve anticoagulation quality of care, and thus reduce the time spent outside therapeutic range and, ultimately, thromoembolic and bleeding events. The scientific relevance of the DASS is that when such interventions are designed, a standard of comparison will be required that is applicable across all the models of care being compared. Our intention is that the DASS can help provide a way forward in developing such a standard. Recognizing that instrument development and validation is by no means a one-time event, efforts at assessing and improving the DASS are ongoing.

List of abbreviations

DASS Duke Anticoagulation Satisfaction Scale

PSQ-18 Satisfaction with Medical Care Scale

SDS-5 Socially Desirable Response Set Scale

SF-36 Short-Form 36 Generic Health-Related Quality of Life Scale

Authors' contributions

Conceptualization and study design GS, DBM, RJD, IW, OH

Data collection GS, DBM, RJD

Statistical analysis GS

Manuscript preparation GS

Critical comment GS, DBM, RJD, IW, EH, GW, OH, CM, RE

Additional material

Additional file 1

Click here for file
[http://www.biomedcentral.com/content/supplementary/1477-7525-2-22-S1.doc]

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References

1. Hirsh J, Dalen JE, Anderson DR, Poller L, Bussey H, Ansell J, Deykin D, Brandt JT: **Oral anticoagulants: mechanism of action, clinical effectiveness, and optimal therapeutic range.** *Chest* 1998, **114(5 suppl):**445S-469S.
2. McDowell I, Newell C: *Measuring Health: A Guide to Rating Scales and Questionnaire*s 2nd edition. Oxford University Press, New York NY; 1996.
3. Ansell JE, Patel N, Ostrovsky D, Nozzolillo E, Peterson AM: **Long-term patient self-management of oral anticoagulation.** *Arch Intern Med* 1995, **155:**2185-2189.
4. Gage BF, Cardinalli AB, Owens DK: **The effect of stroke and stroke prophylaxis with aspirin or warfarin on quality of life.** *Arch Intern Med* 1996, **156:**1829-1836.
5. Hirsh J: **Influence of low-intensity warfarin treatment on patients' perceptions of quality of life.** *Arch Intern Med* 1991, **151:**1921-1922.
6. Lancaster TR, Singer DE, Sheehan MA, Oertel LB, Maraventano SW, Hughes RA, Kistler JP, for the Boston Area Anticoagulation Trial for Atrial Fibrillation Investigators: **The impact of long-term warfarin therapy on quality of life: evidence from a randomized trial.** *Arch Intern Med* 1991, **151:**1944-1949.

7. Man-Son-Hang M, Laupacis A, O'Conner A, Wells G, Lemelin J, Wood W, Dermer M: **Warfarin for atrial fibrillation: the patient's perspective.** *Arch Intern Med* 1996, **156:**1841-1848.
8. Sawicki PT: **A structured teaching and self-management program for patients receiving oral anticoagulation: a randomized controlled trial.** *J Am Med Assn* 1999, **281(2):**145-150.
9. Stigendal L, Andre U, Christenson B: **[Better AVK treatment with self monitoring: dosage can be regulated in time].** *Lakartidningen* 1999, **96(20):**2485-2487. Swedish
10. Ware JE, Snow KK, Kosinski M, Gandek B: *SF-36 Health Survey: Manual and Interpretation Guide* Boston: The Health Institute, New England Medical Center; 1993.
11. Ware JE, Snyder MK, Wright WR, Davies AR: **Defining and measuring patient satisfaction with medical care.** *Eval Planning* 1983, **6:**247-263.
12. Samsa GP, Edelman D, Rothman ML, Williams GR, Lipscomb J, Matchar DB: **Determining clinically important differences in health status measures: a general approach with illustration to the Health Utilities Index Mark II.** *PharmacoEconomics* 1999, **15:**141-155.