Validation of the German version of the subarachnoid haemorrhage outcome tool (SAHOT)



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Andreas Ziebart¹, Amr Abdulazim¹, Fabian Wenz¹, Nikolaus Kleindienst², Maria Mocarz-Kleindienst^{2,3}, Ian Galea⁴, Gabriel JE Rinkel¹ and Nima Etminan¹

Abstract

Objective: The subarachnoid haemorrhage (SAH) outcome tool (SAHOT) is the first SAH-specific patient reported outcome measure, and was developed in the UK. We aimed to validate the SAHOT outside the UK, and therefore endeavored to adapt the SAHOT into German and to test its psychometric properties.

Methods: We adapted and pilot tested the German version. We applied the SAHOT, Quality of Life after Brain Injury, Hospital Anxiety and Depression Scale, and EuroQol questionnaires in a cohort of 89 patients with spontaneous SAH after discharge. We assessed internal consistency by Cronbach's α , test-retest reliability by intraclass correlation, and validity by Pearson correlations with established measures. Sensitivity to change was evaluated following neurorehabilitation by effect sizes.

Results: The translation of SAHOT resulted in a German version that is semantically and conceptually equivalent to the English version. Internal consistency was good regarding the physical domain ($\alpha = 0.83$) and excellent for the other domains ($\alpha = 0.92-0.93$). Test-retest reliability indicated a high level of stability with an intraclass correlation of 0.85 (95% CI: 0.83-0.86). All domains correlated moderately or strongly with established measures (r=0.41-0.74; p < 0.01). SAHOT total scores showed moderate sensitivity to change (Cohen's d=-0.68), while mRS and GOSE showed no significant sensitivity to change.

Conclusion: The SAHOT can be adapted to other health care systems and societies than the UK. The German version of the SAHOT is a reliable and valid instrument, and can be used in future clinical studies and individual assessment after spontaneous SAH.

Keywords

Subarachnoid haemorrhage, aneurysmal subarachnoid haemorrhage, intracranial aneurysm, vascular disorders, patientreported outcome

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Introduction

Spontaneous subarachnoid haemorrhage (SAH) is a subtype of stroke with severe impact on society. The mean young age of onset and the poor outcome explain why the loss of productive life years from SAH is as large as that of ischemic stroke, the most common type of stroke. Despite improvements in management, case-fatality after 1 month still is around 35% and many patients have long-term sequelae.^{1–3} Almost a third of the patients who survive the initial weeks struggle with fatigue and cognitive and emotional problems in the chronic phase and are not able to resume their previous work.⁴ Department of Neurosurgery, Medical Faculty Mannheim, Heidelberg University, Mannheim, Germany

²Department of Psychosomatic Medicine and Psychotherapy, Central Institute of Mental Health, Medical Faculty Mannheim, Heidelberg University, Mannheim, Germany

³Department of Translation Studies and Slavic Languages, The John Paul II Catholic University of Lublin, Lublin, Poland

⁴Clinical Neurosciences, Clinical & Experimental Sciences, Faculty of Medicine, University of Southampton, Southampton, UK

Corresponding author:

Nima Etminan, Department of Neurosurgery, Medical Faculty Mannheim, Heidelberg University, Theodor-Kutzer-Ufer 1-3, Mannheim 68167, Germany. Email: nima.etminan@umm.de The modified Rankin Scale (mRS) and the extended version of the Glasgow Outcome Scale (GOSE) are the most frequently applied measures for functional outcome in randomized controlled trials for SAH.^{5,6} Such functional outcome measures often do not capture impact on daily life from non-physical complaints.^{7,8} Outcomes directly reported by patients or next-of-kin, so called patientreported outcome measures (PROMs) are increasingly recognized as a crucial part of outcome reporting.⁹ The subarachnoid haemorrhage outcome tool (SAHOT) is the first PROM specifically developed for spontaneous SAH, irrespective of the presence or absence of an aneurysm.¹⁰

In the development phase of the SAHOT, patients, nextof-kin, and multidisciplinary professionals were involved to more completely assess cognitive, psychological, and physical complaints than established scores.¹¹ The SAHOT was developed in the UK and validated in a separate SAH patient cohort from the UK but has not yet been assessed outside the UK.

We therefore endeavored to provide a cross-cultural translation of the SAHOT in German and assess its reliability, validity, and sensitivity to change in German SAH patients.

Methods

The study was approved by the Ethics Committee II of the University of Heidelberg, Medical Faculty Mannheim (IRB number 2020-602N). Patients or their caregivers provided their written informed consent prior to participating in this study.

Translation and back-translation of the SAHOT

Permission to develop a German version of the SAHOT was obtained from the corresponding author of the original SAHOT development and validation study.

We performed a cross-cultural translation (including adaptation) following a standardized procedure as recommended in established guidelines.¹² The first step involved two independent translations into German by two professional translators whose native language was English. Second, both versions were discussed with the first author (A.Z.) until a consensus translation was reached. Next, a third professional translator, who was not part of the aforementioned steps, performed a back-translation; this backward translated version was reviewed for compliance with the original SAHOT questionnaire. Additionally, the corresponding author of the original publication reviewed the back-translation and confirmed that the content of the original version conforms to the back-translation. Subsequently, the pre-final version was tested for lack of ambiguity in six SAH patients (four female, two male; age range 42-63 years), who completed the scale, which took approximately 20 min. Based on the interviews no alterations of the last version were needed. Semantic, idiomatic, and

conceptual (including cultural adaptation) equivalencies were discussed and amendments were consensually integrated resulting in the final questionnaire.

Finally, a fourth professional translator (M.M.K.), who had not participated in the translation process, confirmed semantic equivalence. The final version of the German translation of the SAHOT is included in Supplemental Material 1.

Patient inclusion

From August 1st 2020 to February 15th 2022 we aimed to approach all consecutive patients who were admitted to our center to participate in the study if they were 18 years or older and had a spontaneous subarachnoid haemorrhage. We excluded non-German speaking persons and patients with serious psychiatric diseases. Due to the strict visiting restrictions for ICU patients during the lockdown period of the COVID-19 pandemic, not all poor grade patients and their next-of-kin could be approached, since family members or legal representatives could not assess the patients' condition properly. All patients were recruited by a physician after discharge from the tertiary care hospital and were asked to complete the questionnaire a second time after 1-3 days and a third time following neurorehabilitation. Patients were asked to send the questionnaires back via mail or complete them prior to visits in our neurovascular clinic. Patients were discharged between 1 and 3 weeks after ictus from the tertiary care facility depending on the cause of the SAH (aneurysmal or non-aneurysmal) and on the clinical condition. Patients in a good or acceptable clinical condition (i.e. mRS < 2) were discharged home until the beginning of their rehabilitation program or directly to a specialized neurological rehabilitation center. If patients were in a poor clinical condition, they were transferred directly to a specialized neurological rehabilitation center.

To assess test-retest reliability, we estimated that at least 50 patients were needed to complete the SAHOT questionnaire a second time after the initial participation. We readministered the tool following neurorehabilitation to analyze sensitivity to change, approximately 3 months after initial administration and estimated 25 patients needed to participate for the analysis.

Patient data, baseline characteristics, and outcome measures

Demographic data, SAH characteristics, mRS, and GOSE were prospectively recorded.^{13–15} Demographic data included clinical patient data and radiological measures as well as grading according to the World Federation of Neurological Societies (WFNS) grading system, the Fisher scale, and aneurysm treatment modality.^{16,17}

The SAHOT was developed involving patients, next-ofkin, and multidisciplinary professionals engaged in SAH management incorporating their perspectives.¹¹ It consists of 56 items, divided in the four domains *general aspects of daily life, physical function, cognition,* and *behavioral and psychological function* and can be used as both an interval and ordinal scale. Each item is scored on a 3 point Likert scale ("no change," "some change," or "large or severe change") resulting in a raw score ranging from 0 (best outcome) to 112 (worst outcome). The raw score can be transformed to ordinal categories including death.

Established scores were applied to analyze linear association of the respective SAHOT domains and total scores evaluating convergent validity. We limited the total number of items to avoid overburdening study participants, while trying to use as many instruments as possible. The QOLIBRI Overall Scale was validated in aneurysmal SAH patients, however, it consists of 12 items.¹⁸ We thought it is more reasonable to use its extended version for this validation study. The Quality of Life After Brain Injury (QOLIBRI) consists of six domains, including personal and social life, function in daily life, cognition, physical condition, and emotions accounting for 30 out of 37 items, therefore correlations with the SAHOT domains can be properly studied. The questionnaire was specifically developed for persons with Traumatic Brain Injury.¹⁹ Responses are coded on a 1-5 scale, where 1 represents "not at all satisfied" and 5 states "very satisfied" and the total score is calculated as a mean score. Responses to the "bothered" items are coded reversely. The EuroQol Quality of Life Scale-5D (EQ-5D) is a generic health-related quality of life measure that evaluates five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.²⁰ The short items of the EO-5D are similar to the respective SAHOT domains and do not add significant burden for study participants. The EuroOol Visual Analogue Scale (EO VAS) was designed to rate quality of life on a line from 0 to 100, which is feasible to do in a short of time. One of the primary goals of PROMs for SAH patients represents detection of cognitive, psychological and emotional distress. Hence, we applied the Hospital Anxiety and Depression Scale (HADS) to assess non-physical symptoms of depression and anxiety.^{21,22} The questionnaire consists of 14 items rated on 4 point Likert scales, where scores range from 0 to 3. High values indicate depression and anxiety and it can be used to reliably and validly detect these two mental health states. The HADS has been used as a screening instrument in several languages and is particularly appropriate for hospitalized patients, including individuals with stroke.²³

Psychometric evaluation

The internal consistency of the German version of the SAHOT was assessed using Cronbach's α . We considered a score higher than 0.70 as a desirable threshold.²⁴

Floor and ceiling effects were calculated as the percentage of participants with the minimum or maximum score in each of the four domains of the SAHOT. Floor and ceiling frequencies higher than 15% were considered substantial.

In patients with a stable disease status, defined by the absence of new symptoms, we analyzed test–retest reliability with the intraclass correlation coefficient.

The construct validity of the SAHOT was assessed by determining Pearson correlation coefficients of subscores of the SAHOT with quality of life scores (QOLIBRI, EQ-5D, and HADS) and total scores. Based on the original validation study of the SAHOT we anticipated moderate (>0.30) to large (>0.50) correlations with the respective domains from established scores. We hypothesized during the design of our study significant negative correlations with disease-specific quality of life measures (QOLIBRI) and moderate positive correlations with generic quality of life measures (EQ-5D) and clinician-reported outcome measures (mRS) and a moderate negative correlation with the GOSE. We also hypothesized significant positive correlations with global psychological and emotional distress measures (HADS).

Sensitivity to change was tested by measuring SAHOT scores between discharge and follow-up visits after patients completed neurorehabilitation by analyzing pre-post effect sizes (Cohen's d). An effect size |d| 0.2 was considered small, 0.5 as medium, and 0.8 as large.

The direction of change for the item "Quality of relationship with those closest" was not further specified as worse or better. Since only a few respondents reported a positive impact of SAH for most items in the original validation as well as in this validation study, positive changes were rescored as "no change."

Statistical analysis

Data analysis was performed using the SPSS statistical software (version 23). The SAHOT raw score was used exclusively for data analysis, unless otherwise stated. When respondents chose the "not applicable" option or left questions without an answer, items were treated as missing data. Missing data were replaced for further analysis by multiple imputation based on automatic imputation with a previous data scan in SPSS, when no more than two items per domain were missing. Only data from the SAHOT have been replaced and the imputation was exclusively based on previous data of the SAHOT, not implying other measures. Structural validity was assessed by an exploratory factorial analysis with a varimax rotation. We analyzed construct validity using patient scores, and next-of-kin scores when patients scores were not available. Calculation of Cohen's d was based on the pooled standard deviation. Transformation for SAHOT raw scores to ordinal categories was done according to the original validation study with values from 1 (best outcome) to 9 (death). We performed a subgroup analysis for those patients with a proven aneurysm as cause of the SAH.

	Responders (n=89)
Age, mean (SD)	54.2 (10.6)
Gender, n (%)	
Female	65 (73)
Subarachnoid haemorrhage subtype and lo	ocation (%)
Aneurysmal	73 (82)
Anterior circulation	63 (86)
Posterior circulation	10 (14)
Other	16 (18)
Treatment modality, <i>n</i> (%)	
Microsurgical clipping	41 (46)
Endovascular coiling	28 (31)
Endovascular flow diversion	4 (4)
WFNS Grade, n (%)	
WFNS Grade I	44 (49)
WFNS Grade II	12 (14)
WFNS Grade III	10 (11)
WFNS Grade IV	15 (17)
WFNS Grade V	8 (9)
Fisher Grade, n (%)	
Fisher Grade I	8 (9)
Fisher Grade II	19 (21)
Fisher Grade III	33 (37)
Fisher Grade IV	29 (33)
Modified Rankin Scale at discharge, n (%)	
0 no symptoms	9 (10)
l no significant disability	33 (37)
2 slight	21 (24)
3 moderate disability	13 (15)
4 moderately severe disability	9 (10)
5 severe disability	4 (4)

 Table I. Demographic and subarachnoid haemorrhage characteristics.

Results

The forward- and back-translation process showed small differences in semantics in two items, which were resolved through consensus discussions. The item "low mood" was back-translated to "depression." Since both forward-translation and reconciliation were exact in everyone's opinion, the back-translation was considered not exact, which was confirmed through the corresponding author of the UK SAHOT study. The item "agitation" was back-translated to "inner unrest." For "agitation," the UK study group had started from "Feeling agitated/can't sit still" and this had come from a patient focus group. The "can't sit still" suggests the patients were referring to a physical need to move, not just an internal feeling. Further discussion with patients resulted in a separation of the mental and physical aspects of this, resulting with agitation and restlessness (inability to stand still) as separate items. Hence, the consensus was reached to qualify agitation with "inner unrest." During the pre-test on the sample of six patients, all items were clearly understood and none of the patients had difficulties with the

instructions, wording of questions, or length of the questionnaire. Patients in the test cohort did not propose any additional items. The final report of semantic equivalence confirmed a satisfactory match in semantic meaning between the original, the back-translated SAHOT items, and the items of the final German version of the SAHOT.

Cohort characteristics

A total of 89 out of 91 approached patients participated in this study (Table 1). The response rate for the test-retest analysis was 69% (n=61) and 44% (n=28) for the evaluation of sensitivity to change, requiring completion of neurorehabilitation. The mean age of patients was 54.2 ± 10.6 years and 73% of them were women. The mean interval between ictus and the first attempt of the questionnaire was 19.7 ± 12.9 days. Patients and next-of-kin completed the SAHOT questionnaire in approximately 20 min.

Descriptive statistics

The rate of missing items was 2.3%. The most frequently missing item was "learning a new skill" with 17% of responses missing.

We found no substantial floor or ceiling effects (Table 2). Skewness was not present, defined by a value below -1.0 or above 1.0. Results were essentially the same in the subgroup of patients with aneurysmal SAH (Supplemental Table 1).

Internal consistency, reliability, and structural validity

The internal consistency was good for the physical domain and excellent for the other three domains (Table 3) with Cronbach's α ranging from 0.83 to 0.93. Cronbach's α for the total score was 0.97. Single item correlations for each domain showed that all items correlated significantly among each other with moderate to large correlations in the expected direction. A total of 61 patients returned the retest and the intraclass correlation coefficients (ICC) indicated stability ranging from 0.83 to 0.86. The subgroup of aneurysmal SAH patients showed similar results (Cronbach's $\alpha = 0.83 - 0.94$; ICC = 0.84 - 0.87; Supplemental Table 2). According to an exploratory principal component analysis there was one dominant eigenvalue supporting the unidimensional solution of the SAHOT. As illustrated in the scree plot (Supplemental Figure 1) a two-dimensional solution might also be justified.

Convergent validity

The correlations between the SAHOT domains and the criterion-related measures are presented in Table 4. We found significant moderate-to-large correlations between

	ltems	Mean (SD)	Median	IQR	Range	Skewness	% score 0	% score 2	Mean inter-item correlation
Four domains									
Social	14	l (0.84)	I	2	0–2	0.01	1.1	3.8	0.49
Physical	13	1.33 (0.78)	2	I	0–2	-0.64	0	2.2	0.27
Cognitive	13	1.32 (0.76)	I	I.	0–2	-0.6 I	1.1	3.8	0.47
Emotional	16	1.33 (0.78)	2	I	0–2	-0.65	0	0	0.36
Total SAHOT	56	1.19 (0.81)	I	2	0–2	-0.35	0	0	0.32

Table 4. Construct validity.

Table 2. Descriptive statistics of the German version of the subarachnoid haemorrhage outcome tool (n=89).

IQR: Interquartile Range; SAHOT: Subarachnoid Haemorrhage Outcome Tool.

% score 0, percentage of lowest possible score.

% score 2, percentage of highest possible score.

 Table 3. Reliability – internal consistency and test-retest reliability.

SAHOT domain	No. of items	Cronbach's α (n = 89)	Intraclass correlation coefficient (n=61)		
Social	14	0.93	0.86		
Physical	13	0.83	0.86		
Cognitive	13	0.92	0.85		
Emotional	16	0.92	0.83		
SAHOT total	56	0.97	0.85		

SD: standard deviation.

all SAHOT subscores on the one hand and QOLIBRI and EQ-5D subscores on the other hand. The emotional domain of the German version of the SAHOT correlated strongly with HADS total scores. SAHOT total scores showed a strong correlation with QOLIBRI and EQ-5D total scores and the EuroQOI Visual Analogue Scale, while mRS and GOSE scores showed a moderate correlation.

In our study, we found no significant correlation between prognostic scores, the WFNS or Fisher Scale, and total SAHOT scores. Overall, no significant differences between aneurysmal and non-aneurysmal etiology were detected (Supplemental Table 3).

Sensitivity to change

Sensitivity to change of the German version of the SAHOT was assessed by measuring its ability to detect improvement by neurorehabilitation, measuring time points between subsequent questionnaires approximately 3 months apart. We found moderate-to-large effect sizes for single domains (Cohen's d=-0.35-(-0.80)) and a moderate effect size for the total score (Table 5). While the SAHOT raw scores and ordinal scores were significantly sensitive to change, mRS and GOSE were not significantly sensitive to change. Aneurysm patients also had small or moderate effect sizes for each of the SAHOT domains, the total score, mRS, and GOSE (Supplemental Table 4).

	-	
SAHOT domain	Measure	Pearson correlation (n=84)
General/social roles	QOLIBRI	-0.53**
	EQ-5D	0.51**
Physical	QOLIBRI	-0.64**
	EQ-5D Mobility	0.65**
	EQ-5D Pain	0.41*
Cognitive	QOLIBRI	-0.66**
Emotional	HADS	0.55*
	QOLIBRI	-0.39**
	EQ-5D	0.62**
SAHOT total	QOLIBRI	-0.74**
	EQ-5D	0.73**
	EQ VAS	-0.58**
	mRS	0.47**
	GOSE	-0.49**

SAHOT: Subarachnoid Haemorrhage Outcome Tool; QOLIBRI: Quality of Life After Brain Injury; HADS: Hospital Anxiety and Depression Scale; EQ-5D: EuroQol Quality of Life Scale-5D; EQ VAS: EuroQol Visual Analogue Scale; mRS: modified Rankin Scale; GOSE: extended version of the Glasgow Outcome Scale. **p < 0.01. *p < 0.05.

Discussion

We showed that it is possible to adapt and validate the SAHOT outside of the UK. The German version showed no floor or ceiling effects, sufficient internal consistency and high test-retest reliability for all domains and the total score. Each item contributed to Cronbach's α . The results of an exploratory factor analysis were in line with both a one- and a two-dimensional solution. In order to keep the German version fully consistent with the original version of the SAHOT we did not alter the original items and structure of the SAHOT. Furthermore, the German version of the SAHOT revealed a satisfying convergent validity, with moderate-to-large correlations with established PROMs, and showed a moderate sensitivity to change.

To our current knowledge, this study is the first external validation of the SAHOT. The SAHOT is an attempt to

Measure	Discharge score: median (range)	3 month score: median(range)	Þ	Effect size $(n=37)$	
Four domains					
Social	19 (1–28)	12 (0–28)	0.001	-0.80	
Physical	21 (11–26)	18 (1–26)	0.014	-0.58	
Cognitive	22 (5–26)	19 (0–26)	0.135	-0.35	
Emotional	26 (2–31)	23 (2–31)	0.047	-0.47	
Raw total score SAHOT	86 (22–111)	70 (2–111)	0.005	-0.68	
Ordinal SAHOT	7 (3–8)	6 (1–8)	0.010	-0.61	
mRS	2 (0–5)	I (0–5)	0.131	-0.34	
GOSE	6 (3–8)	7 (3–8)	0.252	0.26	

Table 5. Responsiveness – subarachnoid haemorrhage outcome measures.

SAHOT: Subarachnoid Haemorrhage Outcome Tool; mRS: modified Rankin Scale; GOSE: extended version of the Glasgow Outcome Scale.

more accurately illustrate patients' struggle to regain functional independence and overcome cognitive and behavioral deficits, since the most common persisting morbidities after SAH are executive dysfunction, short-term memory impairment, impulsivity, difficulty with concentration and making decisions, anxiety, depression, and fatigue.^{1,25}

Despite distinct improvement in the management of SAH patients, which have also resulted in reduction of mortality and morbidity over the past decades, results from the most recent clinical trials failed to document further improvement of outcome after SAH. Factors that may explain the lack of outcome improvement in the latest clinical trials include ineffective treatment targets, sample size and, moreover, insensitive outcome measures.^{26,27} Subarachnoid haemorrhage is detrimental to neuropsychological function, irrespective of the cause of haemorrhage.²⁸ In the past, attempts to assess patient reported outcomes for SAH patients were made based on questionnaires originally developed as generic PROMs such as the EQ-5D, or other condition-specific PROMs such as the Stroke-specific Ouality of Life scale or its short version.^{29–31} However, the unique pathophysiology and complications such as delayed cerebral ischemia induced by SAH affect the Health-Related Quality of Life (HRQoL) potentially in other ways than other stroke subtypes or traumatic brain injury.^{32,33} The QOLIBRI was originally developed for patients with traumatic brain injury and has been validated in SAH patients solely in its short form, the QOLIBRI Overall Scale.^{18,34} Another recently introduced and condition-specific PROM is the "questionnaire for the screening of symptoms in aneurysmal subarachnoid haemorrhage" (SOS-SAH) developed in the Netherlands.35 The SOS-SAH consists of 40 items and nine additional proxy questions for family members. The answering categories register direction of change on a 5 point Likert scale. It includes existing PROMs available in multiple languages and has not been validated clinically so far.

There are different interpretations to our findings: The lack of floor or ceiling effects is likely explained by the broad questions in all domains, whereby relevant complaints are unlikely to be missed. Further, the short items may have let patients to not choose the "not applicable" option. We expected strong correlations with disease-specific quality of life measures (QOLIBRI) and moderate correlations with generic quality of life measures (EQ-5D) and clinician-reported outcome measures (mRS and GOSE). We found moderate correlations for all tested measures. The moderate correlation with OOLIBRI may be explained by the different brain pathology underlying both conditions. We expected negative effect sizes due to potential improvement by neurorehabilitation. We found a moderate effect size regarding sensitivity to change for the raw score of the SAHOT and the ordinal scale. The original SAHOT study reported small effect sizes for the interval and ordinal SAHOT as well as the GOSE, while there was a less than small effect size for the mRS. The fact that we found a moderate effect size for change over time, while the original study found a small effect size might be explained by the course of rehabilitation that was obligatory in our study, whereas it was not in the original validation study, since questionnaires were completed at similar time points in both studies.

We do not know whether the effect size of the social domain and therefore the total score would have been scored differently, if the initial questionnaires had been completed longer after leaving the tertiary care hospital. Patients and next-of-kin might rate their social situation in a different way, shortly after a long hospital stay. Some patients were directly transferred from the tertiary care hospital to a rehabilitation facility, which may have contributed to higher change of scores after rehabilitation.

We expected SAHOT total scores to correlate with prognostic scores, the WFNS, and Fisher Scale as described in the original validation study. Interestingly, the original study showed a moderate correlation between the WFNS score and Fisher Scale, while this study could not confirm this correlation. In the UK SAHOT study, the proportion of poor WFNS grade patients was lower than in our cohort (16% WFNS IV-V vs 26% WFNS IV-V, respectively), which would be expected to make it more difficult to detect a correlation. However, the present study had fewer patients with poor outcome (mRS 3–5) and this is why the likelihood of finding a correlation with prognostic scores is possibly reduced. The other possible explanation is the time from ictus until assessment of the SAHOT. This study applied the SAHOT only a few weeks after ictus. In the UK SAHOT study, this was done at a fixed interval of 6 months. One would expect the data to be more sensitive to picking up a correlation if there is a good enough interval to allow patients to recover clinically, socially, and psychologically and approximate their outcome plateau.

One strength of this study is the fact that the proportion of missing data was very low. Other strong points are the prospective design of the study and the sample size. We used a multitude of questionnaires and items which were validated in SAH patients to assess convergent validity.

Since there were limited opportunities to visit the patients during the pandemic, family members or legal representatives could not assess the patients' condition properly and these patients couldn't be included. The original SAHOT was developed in collaboration with SAH patients and next-of-kin by a multidisciplinary working group using Rasch-based and classical approaches for development and validation. Since no significant divergence between patient and next-of-kin responses was evident in the original study, it is reasonable to expect that there will be no differences between patients and next-of-kin in the German version. Hence, the German SAHOT could be deployable even when patients are not able to complete the questionnaire by themselves but future studies should address this methodologically to support this assumption. While the original published study indicated unidimensionality of the questionnaire, we were not able to clearly support this assumption, since our data support a one- or two-dimensional solution. Due to the fact that this is a single study with a relatively small cohort, sensitivity to change may be overor underestimated by the effect sizes.

In conclusion, we demonstrated that it is possible to adapt the UK SAHOT to another health care system, population, and language. The clinical implication of this finding is that adaptation of the SAHOT to other countries, cultures, or languages may be possible; of course it is always good to also perform a validation. While many clinical studies use 3 month outcome measures, the UK SAHOT assessed outcomes 1, 3, and 6 months post-SAH, which is why the German version could also be applied within 6 months after ictus. The high Cronbach's α values for the general, cognitive, and emotional domains indicate that it may be possible to develop a short version of the SAHOT to simplify its use in clinical practice. Since the German version is a valid tool to assess HRQoL and response to therapy after spontaneous SAH, it can be implemented in clinical research and service settings in Germany.

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Declaration of conflicting interests

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Ethical approval

Ethical approval for this study was obtained from the Ethics Committee II of the University of Heidelberg, Medical Faculty Mannheim (IRB number 2020-602N).

Informed consent

Written informed consent was obtained from all participants or their legally authorized representatives before the study. All patients were provided with a written explanation of the study. The patients or their representatives were given the opportunity to refuse participation.

Guarantor

NE

Trial registration

Not applicable because health-related intervention was not conducted in this study.

Contributorship

AZ and NE designed the study. AZ did the statistical analysis with input from NK. AZ wrote the first draft of the report with input from GJER and NE. IG reviewed the back-translation and conceptual equivalence. MMK wrote a report on semantic equivalence of the final translation. AZ, AA, and FW contributed to the collection of data and all authors contributed to the writing of the manuscript, had full access to all data in the study, and had final responsibility for the decision to submit for publication.

ORCID iD

Andreas Ziebart D https://orcid.org/0000-0001-7065-9319

Supplemental material

Supplemental material for this article is available online.

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