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Validation of the Self Regulation Questionnaire as a Measure of Health in Quality of Life Research

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Abstract
Objectives: Several epidemiological studies address psychosomatic `self regulation´ as a measure of quality of life aspects. However, although widely used in studies with a focus on complementary cancer treatment, and recognized to be associated with better survival of cancer patients, it is unclear what the `self regulation´ questionnaire exactly measures.
Design and Setting: In a sample of 444 individuals (27% healthy, 33% cancer, 40% other internal diseases), we performed reliability and exploratory factor analyses, and correlated the 16-item instrument with external measures such as the Hospital Anxiety and Depression Scale, the Herdecke Quality of Life questionnaire, and autonomic regulation questionnaire.
Results: The 16-item pool had a very good internal consistency (Cronbach´s alpha = 0.948) and satisfying/good (r_{rt} = 0.796) test-retest reliability after 3 months. Exploratory factor analysis indicated 2 subconstructs: (1) Ability to change behaviour in order to reach goals, and (2) Achieve satisfaction and well-being. Both sub-scales correlated well with quality of life aspects, particularly with Initiative Power/Interest, Social Interactions, Mental Balance, and negatively with anxiety and depression.
Conclusions: The Self Regulation Questionnaire (SRQ) was found to be a valid and reliable tool which measures unique psychosomatic abilities. Self regulation deals with competence and autonomy and can be regarded as a problem solving capacity in terms of an active adaptation to stressful situations to restore well-being. The tool is an interesting option to be used particularly in complementary medicine research with a focus on behavioural modification.

Introduction

In the last decade the large application of health-related quality of life (HRQL) questionnaires in medicine brought important new aspects for the treatment of patients with chronic conditions, but disclosed the limitations of generic and disease specific HRQL questionnaires [1]. New studies gave some evidence that questionnaires capturing the individual skills of adaptation, i.e., as sense of coherence or self-regulation, could be more appropriate as prognostic tools in oncology or in different chronic conditions than classical HRQL scales [2, 3]. One of these measures is the psychosomatic `self-regulation´ [4-8] which was exclusively used in studies with a focus on complementary cancer treatments. Self-regulation (SR) was reported to represent the "ability actively to achieve well-being, inner equilibrium, appropriate stimulation, a feeling of competence, and a sense of being able to control stressful situations" [4].

However, until now it is unclear what the 16-item SR instrument exactly measures, and thus whether the assessment of SR is in fact a measure of HRQL aspects as suggested by Grossarth-Maticek and Ziegler [4, 9], or is a facet of other concepts such as coping, coherence, locus of health control to achieve well-being. To address these questions is of outstanding relevance, because higher SR scores were found to be associated with the unwillingness of cancer patients to participate in double-blind clinical studies [4], but were nevertheless associated with longer survival times when treated with plant extracts from *Viscum album L.* [5-9] which are widely used in Europe for complementary cancer treatment.

In the presented study we intended to investigate reliability, factorial structure and validity of the SR questionnaire in a group of internal medicine patients and healthy controls to draw valid conclusions about the association between survival, self regulation and usage of complementary medicine.

Materials and Methods

Participants

In this survey, we analyzed the data of 444 individuals. Patients and healthy control persons were informed of the purpose of the study, assured of confidentiality, gave consent to participate, and completed the questionnaire by themselves. The patients were recruited consecutively in 2000 and 2001 from the Departments of General Internal Medicine, Gastroenterology and Cardiology at the Gemeinschaftskrankenhaus Havelhöhe, the specialist oncology practice at the same hospital, at an oncological practice in Öschelbronn, and

an endocrinological practice in Wuppertal. Healthy controls were recruited among the hospital staff, their families and among visitors (convenience sample).

Seventy-two % were women, 28% men (mean age 57 ± 14 years). Twenty-seven % were healthy, 21% had breast cancer, 11% colorectal cancers, 13% diabetes mellitus (types 1 and 2), 6% rheumatic diseases, 9% coronary heart diseases, 7% Hashimoto´s thyreoiditis, and 5% multiple conditions. 227 participants have been retested 13.1 ± 7.8 weeks later.

Among the healthy individuals, 71% were female and 29% male (mean age 54.2 ± 14.3 years).

Patients were slightly older than healthy controls. With the exception of coronary heart diseases (33% women, 67% men), and diabetes (48% women, 52% men), women were predominating in the respective disease groups (i.e., breast cancer 100%; Hashimoto´s thyreoiditis 100%; rheumatic diseases 79%; colon carcinoma 61%).

Measures

SR was measured with a 16-item pool [4, 10], and uses 6-point likert scales ranging from 1 (very weak) to 6 (very strong). Scores 5-6 of the primary tool were assumed to indicate very good SR, scores 4-5 good SR, scores 3.5-4 moderate SR, scores 2-3.5 weak SR, and scores 1-2 very poor SR [4, 10]. For the re-validated instrument (SRQ), we decided to use the primary ratings (scores 1-6) and referred them to a 100% level. Thus, scores < 50 will represent lower SR, while scores > 50% indicate higher SR.

To test the external validity of the scale and to make statements about the conceptual relationships between SR and quality of life, we enrolled several other instruments:

Quality of life:
The HLQ-questionnaire (with five point Likert-scale; Cronbach´s alpha = 0.935) differentiates the following factors: Initiative Power & Interest; Social Interactions; Mental Balance; Motility; Physical Complaints; Digestive Well-Being [11]. For this analysis the HLQ scales Initiative Power & Interest (i.e. good ideas, decisive, take initiative, spontaneous reactions, adaption to others and situations, put plans into action, etc.), Social Interactions (i.e., feelings of comfort with others, over-directed, left out, abandoning community life, family life a burden, etc.) and Mental Balance (i.e., nervous/irascibly, well-balanced, happy) were of particular relevance.

Anxiety and depression:
The Hospital Anxiety and Depression Scale (HADS) is a highly reliable and valid 14-item instrument which differentiates anxiety and depression. It is a four point Likert-scale with a range from 0 – 21 for both. Higher scoring indicate more symptoms, i.e., ≥ 11 points anxiety or depression are probable, ≥8 – 10 possible cases, <7 no cases [12, 13].

Autonomic functioning:
The 12-item `Autonomic regulation´ (aR) scale measures the state of regulation of different *autonomic* functions in the rhythmic change of rest and activity (and thus is not identically with the *cognitive* concept of `self-regulation´). The respective subscales of the long version Orthostatic-Circulatory, Rest/Activity and Digestive Regulation had a satisfying internal consistency (Cronbach-α: rα = 0.65 – 0.75), and satisfying / good test-retest reliability (r_{rt} = 0.70 – 85), and good validity [14, 15]. We used a 12-item short form (three point Likert-scale) which includes items which pertain to autonomic functions such as rest/activity rhythms, vertigo, orthostatic regulation, and thermoregulation. Additional questions on activity aim to record self-reported sleep duration and quality, as well as day-time functioning which could reflect the rest/activity rhythm.

Statistical Analysis

All data were treated as ordinal data. Cronbach's coefficient alpha [16] was used to evaluate the reliability of our questionnaire and inter-item correlations as published previously [17]. The reliability of the scale was evaluated with internal consistency coefficients. To combine several items with similar content, we relied on the technique of factor analysis (principal component analysis) using Varimax Rotation with Kaiser Normalization. Test-retest reliability has been measured with Spearman Correlation.

Reliability and factor analyses, analyses of variance (ANOVA), and correlation analyses were performed with SPSS 15.0 for Windows (SPSS GmbH Software, Munich). We judged $p < 0.05$ as significant.

Results

Reliability and Factor Analysis

Reliability analysis of the 16-item pool (Table 1) revealed that the construct had a very good internal consistency (Cronbach´s alpha = 0.95). The item difficulty (3.99 [mean value] / 6) was 0.66. Exploratory factor analysis (main components; eigenvalues > 1) pointed to a 2-factor solution, which explains 63.2% of variance (Table 1). With respect to side-loadings, item SR8 from scale 2 would fit also to scale 1 (0.517), and item SR 7 from scale 1 also on scale 2 (0.421); side-loadings <0.4 were not addressed.

Factor 1 can be described as "Ability to Change Behaviour in order to reach goals", and factor 2 as "Achieve Satisfaction and Well-Being", which thus has a hedonistic / eudemonistic connotation. The test-retest reliability of the sum-scale was r_{rt} = 0.80, of the factor 1 r_{rt} = 0.76, and of the factor 2 r_{rt} = 0.73.

Self Regulation Scores in Patients and Healthy

The Ability to Change Behaviour was significantly higher in men than in women (Table 2), while there were no age-depended differences (data not shown). Patients and healthy individuals differed significantly with respect to their Ability to Change Behaviour and Achieve Satisfaction and Well-Being (Table 2). The highest SR scores were found in healthy controls (which are predominantly of female gender) and pa-

Table 1. Mean values and reliability parameters of SRQ questionnaire.

		Mean values ± SD	Difficulty Index (0.66)	Factor loading	Corrected Item-Total Correlation	Alpha if Item deleted (α = 0.948)
	1. Ability to Change Behaviour in Order to Reach Goals (α = 0.909; 31.8 % of variance)					
SR12	new behaviour pattern	3.93 ± 0.97	0.66	.790	.735	.944
SR11	change behaviour to reach pleasant outcome	3.97 ± 0.98	0.66	.763	.752	.944
SR6	threatening situations: behave to emerge safe	4.27 ± 1.02	0.71	.726	.685	.945
SR10	find standpoints / behaviour pattern which allow pleasant problem solving	4.03 ± 1.01	0.67	.718	.746	.944
SR7	attain most important objectives	4.15 ± 0.98	0.69	.695	.752	.944
SR9	disappointment: no reason for resignation, but cause to change behaviour	4.07 ± 1.02	0.68	.674	.672	.946
SR13	because of behaviour desired proximity and required distance to important others	4.17 ± 0.99	0.70	.627	.669	.946
SR4	expand various activities until states change to total satisfaction	3.66 ± 1.11	0.61	.614	.577	.948
	2. Achieve Satisfaction and Well-Being (α = 0.848; 31.5 % of variance)					
SR15	well-being by daily activities	4.02 ± 1.06	0.67	.822	.713	.945
SR14	inner satisfaction over and over again by daily activities	4.13 ± 1.05	0.69	.737	.757	.944
SR2	actualize wishes and satisfy needs	3.85 ± 1.07	0.64	.735	.700	.945
SR5	arrange different areas of life optimal	3.93 ± 1.03	0.66	.726	.744	.944
SR3	situations / states which restore well-being	3.87 ± 1.04	0.65	.720	.755	.944
SR1	situations / states which motivate	3.97 ± 1.07	0.66	.668	.671	.946
SR8	situations / states which satisfy wishes and needs optimal	3.95 ± 1.00	0.67	.651	.794	.943
SR16	behaviour gives rise to situations which cause experiences full of relish	3.76 ± 1.03	0.63	.628	.658	.946

Varimax Rotation with Kaiser Normalization (rotation converged in 3 Iterations);
Kaiser-Mayer-Olkin value = 0.95; Barlett´s test for non-sphericity p <0,001

tients with coronary heart disease (which are predominantly male), and the lowest in patients with Hashimoto´s thyreoiditis and with multi-conditions.

If one analyses the inter-subject effects of the variables gender, age and disease, it became evident that for the scale Ability to Change Behaviour gender was of significant relevance (F = 5.28; p = 0.022), while for the scale Achieve Satisfaction and Well-Being only the disease group was of importance (F = 2.64; p = 0.008).

External Validity

The Ability to Achieve Satisfaction and Well-Being was strongly (r >0.5) and negatively correlated with anxiety and depression, and positively with HRQL, particularly with Initiative Power/Interest. There were several moderate correlations between the SRQ scales and HRQL dimensions and aR (Table 3). In contrast, Physical complaints correlated just weakly with SR. When controlled for age, the magnitude of the respective correlations did not change considerably (data not shown).

Discussion

The 16-item SRQ had a very good internal consistence and differentiates Ability to Change Behaviour in order to reach goals, and Achieve Satisfaction and Well-Being. The later factor has an obvious hedonistic / eudemonistic connotation, while the first factor can be viewed in the context of problem solving and coping which approaches to the concept of an internal `locus of control´ [18, 19] and also Antonovsky's coherence concept (with the three principles of comprehensibility, meaningfulness, manageability) [20].

With respect to external validity, the SRQ sub-scales correlated best with Initiative Power / Interest (and also with Social Interaction and Mental balance), and negatively with anxiety and depression, which underlines the aspect of a creative problem solving capacity.

Table 2. Mean values of SRQ scores differentiated with respect to gender, and disease status of tested individuals.

	Ability to Change Behaviour in order to reach goals	**Achieve Satisfaction and Well-Being**
all individuals (n=444)	67.3 ± 13.2	65.9 ± 14.5
Gender		
Female (73%)	66.1 ± 13.3	65.2 ± 14.5
Male (27%)	70.5 ± 12.4	67.5 ± 14.3
F-value	10.591	2.272
p-value	**0.001**	n.s.
Individuals		
Healthy controls	71.6 ± 10.5	71.0 ± 11.0
Breast cancer	64.1 ± 13.5	63.7 ± 14.6
Colorectal cancer	67.0 ± 14.2	65.3 ± 13.6
Diabetes mellitus	65.2 ± 16.9	63.4 ± 20.7
Rheumatic diseases	66.4 ± 13.6	63.8 ± 13.8
Coronary heart diseases	70.2 ± 12.7	67.8 ± 13.7
Hashimoto´s thyreoiditis	64.6 ± 8.3	62.3 ± 10.4
multi conditions	64.2 ± 12.0	59.3 ± 13.7
F-value	3.131	3.417
p-value	**0.002**	**0.001**

Table 3. Correlation analyses between SRQ subscales and other psychological variables.

	SRQ Factors	
	Ability to Change Behaviour in order to reach goals	**Achieve Satisfaction and Well-Being**
SRQ - Ability to Change Behaviour	1.00	**.77**
SRQ - Achieve Satisfaction and Well-Being	**.77**	1.00
HADS - Anxiety	-.41	**-.52**
HADS - Depression	-.45	**-.65**
HLQ Sum Score	.40	**.55**
Initiative Power / Interest	.46	**.58**
Social interaction	.37	.48
Mental balance	.33	.48
Motility	.26	.37
Digestive well-being	.20	.33
Physical complaints	.17	.28
Autonomic regulation	.27	.34

* all correlations are significant at the 0.01 level (Spearman´s rho; 2-tailed)

The HLQ scale Initiative Power and Interests heeds topics such as decisiveness, spontaneous reactions, planful actions, adaptation to persons and situations, enhanced personality feeling of security, etc. and thus is in line with the primary concept of the SR. With respect to construct validity, the SRQ deals with competence and autonomy in social concerns, with an active initiative problem solving capacity. SR can be regarded as an active cognitive process in terms of an adaptation to stressful situations (i.e., illness) or displeasing conditions. In contrast to the coping concept of Folkman and Lazarus [21], SR does not focus on the regulation of emotions to avoid stressful situations, but to actively change the unpleasant conditions and to restore well-being. Thus, the SRQ heeds both intrinsic abilities to change behaviour and attitudes, and extrinsic abilities to modify external life concerns. Particularly problem-solving coping strategies were inversely re-

lated to psychological distress [22]; and this may be related with higher survival times as observed in cancer patients treated with complementary medicine and higher SR scores [23].

Taken together, the SRQ was found to be a valid and reliable tool which deals with competence and autonomy and can be regarded as a problem solving capacity in terms of an active adaptation to stressful situations to restore well-being. We can not draw any conclusion whether higher SR may impact the courses of disease and thus quality of life - or whether HRQL and autonomic regulation are the `regulators´ of SR. Further studies have to clarify the possible clinical implications of low SR as contrasted with high SR, as indicated by the finding of higher survival times in cancer patients with higher SR scores [23]. Nevertheless, the tool is an interesting option to be used particularly in complementary medicine research with a focus on behavioural modification.

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