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Original Article

Time since Vertebral Fracture: An Important Variable Concerning Quality of Life in Patients with Postmenopausal Osteoporosis

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Abstract. The aim of the study was to identify factors affecting patients with postmenopausal osteoporosis who had experienced one or more vertebral fractures. The overall hypothesis was that time after fracture would influence patients' perception of pain and well-being. The sample (50 patients) was split into two groups (group A, time after fracture $\leqslant$24 months; group B, time after fracture >24 months). A fracture was defined as a vertebral height reduction of more than 20% or at least 4 mm. The assessment was carried out using the Spine Deformity Index and was confirmed by an experienced radiologist. To assess quality of life (QoL) the following measures were used: 'well-being scale' including social extroversion as a subscale, pain scale, and limitations in everyday life. The Sense of Coherence questionnaire developed by Antonovsky measures the ability of a person to see life meaningful, manageable and explicable. This questionnaire may reflect patients' coping abilities and was introduced to establish whether these influence the perception of pain and well-being after vertebral fracture. Variance and covariance analysis was carried out using SPSS (version 6.1). Differences between groups A and B were found for perception of average pain ($p = 0.017$), social extroversion ($p = 0.003$) and well-being ($p = 0.024$). No differences were found for limitations in everyday life ($p = 0.607$), Sense of Coherence ($p = 0.638$), the Spine Deformity Index ($p = 0.171$) and loss of height ($p = 0.619$). All analyses were corrected for age. Concurrent medication was not found to influence the results. Findings suggest that time after fracture is an important variable when considering QoL and well-being after vertebral fracture and should, therefore, be considered in future studies.

Keywords: Pain; Postmenopausal osteoporosis; Quality of life; Rehabilitative care; Vertebral fractures; Well-being

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Introduction

Physical, mental and social well-being have been of increased importance to the provision of health care and research since Quality of Life (QoL) aspects were included in the WHO's definition of health [1].

Osteoporosis has become a major health care problem, with vertebral fracture among the most common outcomes of postmenopausal osteoporosis with clinical implications for aspects of women's lives [2]. While loss of height and increased kyphosis combined with loss of stature lead to a reduction in self-confidence, increased pain in activities of daily living limit mobility and social activities [3,4]. Educational programs therefore play an important part in the management of osteoporosis [5,6]. There is a large discrepancy in clinical practice between the perception of complaints and objective findings such as radiographs. Patients with the same degree of vertebral deformity may have very different intensities of pain and varied feelings of discomfort [7–11].

Huang et al. [12] have identified that time after fracture influences back pain and pain-dependent limitations. The present study's aim was to gain a better insight into the effects of time since the last

fracture on aspects of QoL. It is hypothesized that QoL in postmenopausal osteoporotic women is positively influenced by the time elapsed since the last vertebral fracture.

Methods

Study Population

The participants of this study were women aged 62.3 ± 7.5 years suffering from postmenopausal osteoporosis (at least 5 years after menopause). Written informed consent was obtained from all participants and the study protocol was reviewed by the ethics committee responsible for our clinic. The selection criterion was a densitometry assessment (*T*-score) in the lumbar spine area below −2.5 (WHO definition; QDR 2000, Hologic, Waltham, MA). Exclusion criteria were disorders affecting bone mineral metabolism (e.g., hyperthyroidism, primary hyperparathyroidism, hypercortisolism and osteomalacia), severe degenerative diseases of the spine such as osteoarthritis, scolioses, and malignancies. In suspicious cases bone biopsy, bone scintigraphy or magnetic resonance tomography was performed to exclude secondary osteoporosis.

Fifty patients were recruited from a medical rehabilitation clinic for diseases of bone and mineral metabolism in Bad Pyrmont (Clinic 'Der Fürstenhof'). All patients had experienced one or more symptomatic vertebral fractures. A 2-year post-fracture period was used as separation criterion for two groups. In one group (group A; $n = 30$) the most recent fracture had occurred within the previous 24 months while in the other group (group B; $n = 20$) the most recent fracture was at least 2 years previously. Duration of the study was 3 years and comprised both cross-sectional and longitudinal analyses.

Medical History and Physical Examination

Subjects' case histories included circumstances and dates of the diagnosis, number and severity of falls within the previous 5 years, the first bone densitometry test, and fractures documented by radiography. Concurrent and earlier medication, use of analgesics, dietary habits including alcohol consumption and nicotine use, previous diseases and immobilization phases, and family history were also recorded. Gynecologic history included age at menarche and menopause, the number of pregnancies and lactation periods. The Kupperman Index was used to measure menopausal symptoms.

Physical examination of the spine and whole body was undertaken in order to exclude secondary osteoporosis. Height reduction was calculated as the difference between body height at the age of 25 years, as documented in the subjects' passports, and the current measured height.

Functional Testing

Angles of kyphosis and lordosis of the spine were quantified via stereo-photomorphometry of the back while the patient was standing in a standardized position and at a standardized distance from a computerized camera (Aesculap Meditech, Zeiss-Jena, Germany).

Radiologic Assessment

Morphometry of the spine was carried out for all patients. Anterior, middle and posterior heights of all vertebrae between T4 and L5 were measured using lateral radiographs of the thoracic and lumbar spine. The heights obtained were then related to T4 and the Spine Deformity Index (SDI) was calculated as previously described [7–9]. Differences in magnification were avoided by use of a constant film–focus distance of 115 cm. A fracture was defined as a height reduction of a vertebra of more than 20% or at least 4 mm, according to FDA guidelines. Assessment was carried out by an experienced radiologist [9].

Patients included in the study had at least one baseline radiograph 2 years prior to the start of the investigation. Radiographs were taken shortly after admission to our clinic, and SDI was calculated for every patient. Because all patients undergo radiography on entry to the clinic in order to design a specific and individual rehabilitation program, it was possible to determine the point in time of the last fracture, enabling patients to be allocated to either group A or group B.

Questionnaires

Data on various aspects of quality of life were collected using the following questionnaires. Limitations in everyday life were assessed using a questionnaire developed by Leidig-Bruckner et al. [10]. This measure has been validated for patients with osteoporosis and has been shown to be reliable for this sample of patients. The questionnaire provides: (1) a disability score based on six items dealing with motion in general and (2) an impairment of self-care score based on six items (see Appendix).

Perception of average pain was judged using Miltner's rating scale, which was developed in a German-speaking environment and has been found to be reliable. The score is easy to apply and independent of age [13]. Patients are asked how strong their perceived pain was over the last 4 weeks and are instructed to select from four categories: low, moderate, severe or very severe.

Patients' well-being was assessed using the well-being scale devised by Hobi [14] (see Appendix). The scale was selected because it had been developed and validated within the German-speaking area and has been shown to be reliable. The scale consists of 16 opposing pairs of adjectives that characterize actual states and moods but not personality traits. Patients were

requested to select the mood they felt best described themselves out of seven gradations, of which the two opposites are at either end of the scale. For example, social extroversion is a subscale of well-being and can be calculated by using the following four pairs of adjectives: 'talkative' versus 'discreet', 'reserved' versus 'communicative', 'sociable' versus 'shy' and 'reclusive' versus 'gregarious'. Scores may range from 16 to 112, with a higher score indicating a higher degree of well-being. Normal values from a representative population were available (mean 98.8 ± 20.5 for the total scale and 26.5 ± 6.0 for the subscale of social extroversion) [14].

The Sense of Coherence (SOC) questionnaire, validated in several languages including German, consists of 29 bipolar items on the 'comprehensibility' (11 items), 'manageability' (10 items) and 'meaningfulness' (8 items) of life (see Appendix). The concept of the questionnaire is based on the theory that some patients maintain a higher level of self-perceived well-being and QoL than others although they have the same level of chronicity [15]. Since coping behavior plays an important part in the management of chronic diseases the SOC questionnaire was used to measure patients' coping abilities and was self-completed by patients with sum scores for the evaluation. Scores may range from 29 to 203. Normative data exist from studies using the SOC questionnaire: 136 ± 20 for an Israeli national sample, 133 ± 20 for American undergraduates and 140 ± 22 for a German sample [4].

Statistical Analysis

Statistical analysis was carried out using SPSS (version 6.01). Analysis of variance and covariance was performed (α = 0.05). *F* weightings illustrate the relevance of differences between the two groups of patients. All analyses were controlled for age. The analysis of variance (ANOVA) is a method of testing the null hypothesis that several group means are equal in the population, by comparing the sample variance estimated from the group means with that estimated within the groups. In addition, the effects of covariates are included to control the main effect for other influences. Furthermore, Cronbach's alpha coefficients were calculated for both groups.

Results

The study population (women, mean age 62.3 ± 7.5 years) was divided according to the time of their most recent vertebral fracture. Group A ($n = 30$; mean age 62.0 ± 7.5 years) had had their most recent vertebral fracture within the previous 24 months. The occurrence of the last vertebral fracture in group B ($n = 20$; mean age 62.7 ± 7.8 years) was more than 2 years previously.

No difference was recorded between the two groups for the SDI, height loss, lordosis and kyphosis (Table 1), indicating that the severity of the vertebral fractures did not differ between the two groups and adjustment for the severity of the vertebral fractures did not influence the results. However, perception of average pain was significantly higher in women whose fracture due to osteoporosis occurred less than 24 months prior to the start of the study (Fig. 1). While 47% of patients from group A (20% in group B) reported their pain to be either 'severe' or 'very severe', 20% of the patients in group B and 3% in group A judged their pain to be 'low' (Table 1).

A relationship was found between time since last fracture and improved well-being (81.6 ± 26.6 in group B vs 70.2 ± 28.1 in group A; $p = 0.024$). This relationship is maintained when looking at subdimen-

Table 1. Patients with vertebral fractures were divided according to the time elapsed since last fracture: group A consisted of postmenopausal women with recent fractures within the last 24 months, group B consisted of the same population with their last fracture at least 2 years previously

	Group A (0–24 months)	Group B (>24 months)	*p* value
Age (years)	62.0 ± 7.3	62.7 ± 7.8	0.747
Perception of pain (%)			0.017
Low	3	20	
Moderate	50	60	
Severe	40	15	
Very severe	7	5	
Well-being (total)[a]	70.2 ± 28.1	81.6 ± 26.6	0.024
Well-being (social extroversion)[b]	16.5 ± 8.6	22.7 ± 5.6	0.003
Limitations in everyday life[c]	4.0 ± 4.0	4.0 ± 3.0	0.607
Sense of Coherence[d]	136 ± 43	143 ± 41	0.638
Spine Deformity Index	2.1 ± 2.0	1.3 ± 1.2	0.171
Loss of height (cm)	7.1 ± 7.0	6.7 ± 6.3	0.619
Angle of kyphosis (deg)	63.5 ± 20.4	60.8 ± 11.9	0.742
Angle of lordosis (deg)	37.9 ± 14.7	42.6 ± 13.2	0.235

Values are the mean ± SD; all analyses were corrected for age.
[a] Scores may range from 16 to 112, with a higher score indicating a higher degree of well-being.
[b] Scores may range from 4 to 28, with a higher score indicating a higher degree of social extroversion.
[c] Scores may range from 0 to 12, with a higher score indicating a higher degree of limitations.
[d] Scores may range from 29 to 203, with a higher score indicating a higher capability to see life as meaningful, manageable and explicable.

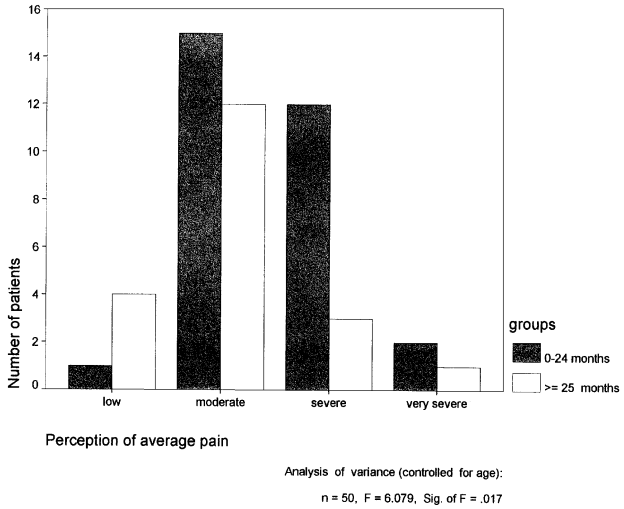

Fig. 1. Perception of average pain in two groups of women with postmenopausal osteoporosis differentiated according to the time elapsed since the last vertebral fracture. Forty percent of women with recent fractures reported their pain to be severe, and only 2% described their pain to be low.

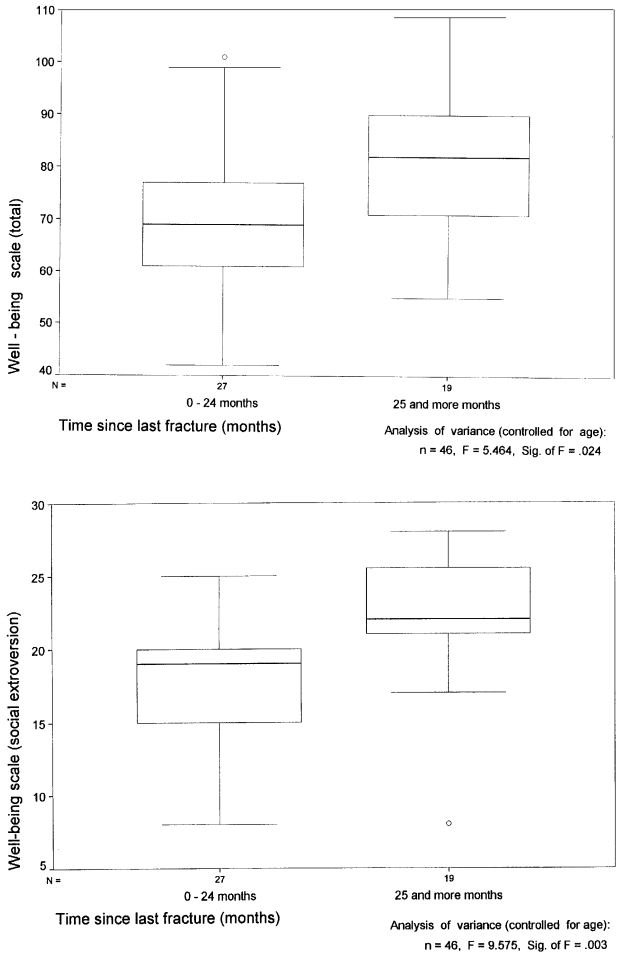

Fig. 2a, b. Well-being in two groups of women with postmenopausal osteoporosis differentiated according to the time elapsed since the last vertebral fracture. **a** Total score for well-being; **b** social extroversion as a subscale of well-being. Both aspects of quality of life improve significantly 2 years after the last vertebral fracture.

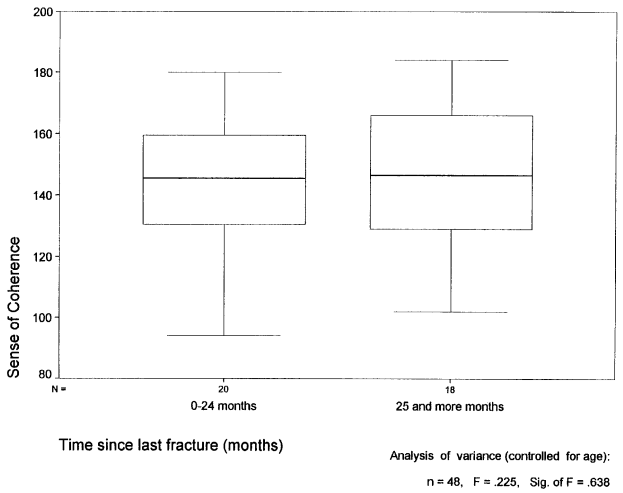

Fig. 3. Sense of coherence (SOC) in two groups of women with osteoporotic vertebral factures is not affected by the time elapsed since the last fracture. SOC expresses the extent to which life is seen as meaningful, manageable and explicable.

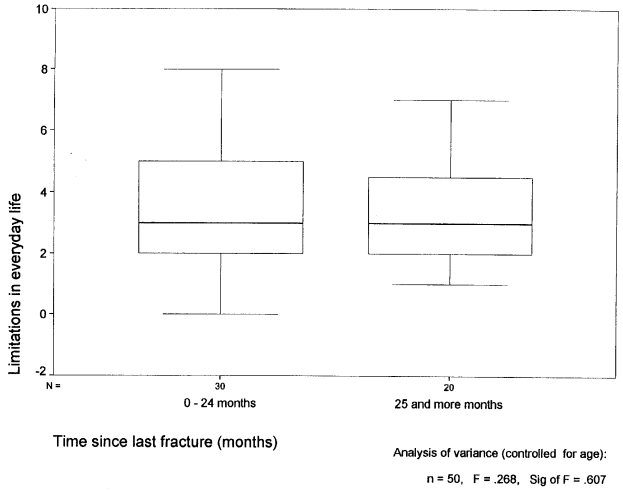

Fig. 4. Limitations in everyday life in two groups of postmenopausal women with osteoporotic vertebral fractures. There is no change with time, indicating that difficulties in self-care remain once they are present.

sions in isolation, such as social extroversion (22.7 $\pm$ 5.6 vs 16.5 $\pm$ 8.6; $p = 0.003$) (Fig. 2). Cronbach's alpha coefficients for the well-being scale were 0.88 for group A and 0.91 for group B, respectively.

No difference between the two groups was found when comparing the sum score for the SOC (143 $\pm$ 41 for group B vs 136 $\pm$ 43 for group A; $p = 0.638$) (Fig. 3). Cronbach's alpha coefficients for the SOC were 0.89 for group A and 0.90 for group B, respectively. No differences were found for limitations in everyday life (Fig. 4).

Nonvertebral fractures did not affect these results. Only two distal forearm fractures were reported in group B. Other fractures related to osteoporosis, such as hip

fractures, did not occur in our sample. The use of analgesics was sporadic in both groups. Only 8 women in group A (27%) took analgesics two or three times a week, whereas 2 women in group B (10%) used analgesics two or three times a week.

Discussion

Current therapeutic regimens for postmenopausal osteoporosis are attempting to address issues of health-related quality of life. Relationships between the clinical picture and subjective aspects of QoL are therefore of importance.

The current literature suggests that there is only a weak link between results obtained from QoL assessments and clinical measurements, the latter usually being performed as part of a differential diagnosis [16–18]. Questionnaires referring to pain or well-being may not correspond well with the outcomes of osteoporosis such as height reduction, kyphosis or spinal deformation due to vertebral fracturing [19]. Ettinger et al. [20], for instance, have found the degree of kyphosis not to influence pain and disability within a recent population-based study. In 1993 Cook et al. [21], supported by Leidig-Bruckner et al. [10], pointed out that the objectively assessed degree of skeletal spinal deformity is not necessarily correlated with subjective well-being and functioning. However, their data concerning the relationship between pain and clinical description of disease relate only to groups with severe deformities [10,21].

The sample was subdivided into two groups according to time of last fracture in order to investigate possible associations between questionnaires and technical measurements. The separation allows for the comparison of similiar somatic conditions. Time is a variable that has to be considered when addressing QoL parameters, as patients' perceptions and coping strategies might change over time.

Results for average pain showed a reduction in the level of pain perceived within the 2-year time span. This observation is supported by recent work by Huang et al. [12], who found a decrease in lower back pain within a 4-year interval. Furthermore, the results show that it is the time after fracture rather than the varying stages of disease that explain perceptions of pain, well-being and social extroversion (Table 1). Time after fracture can thus be considered an important predictor of QoL – more so than height reduction, number of vertebral fractures or the SDI.

Limitations in everyday life, as described by Burger et al. [22] and by ourselves [8,10], may occur as soon as vertebral fractures appear. However, osteoporosis is sometimes called the 'silent disease' [23] because women can have 'silent fractures' or vertebral fractures that are falsely diagnosed as low back pain or lumbago [10]. Since deformities and fractures were equally distributed in the two groups, differences concerning limitations in everyday life would not be expected.

The SOC is, according to Antonovsky [15], a global orientation that expresses the extent to which individuals regard life as meaningful, manageable and explicable. These resources may affect patients' coping strategies. Patients' coping behaviors play an important role in the management of osteoporosis [5,6] and may affect patients' well-being as well as their perception of pain. The two groups did not differ with regard to the SOC, thus indicating that coping strategies were not responsible for the results – at least as far as the SOC is concerned.

In the last 2 years other questionnaires have been developed to assess QoL in patients with osteoporosis. The European Foundation for Osteoporosis questionnaire (QUALEFFO) has been shown in a sample of 751 women with low bone mineral density to discriminate between those women with and those without vertebral fractures [24]. Another questionnaire (the OPTQoL) was developed and validated as a tool for population- or community-based studies to characterize the burden of osteoporosis. This questionnaire was used as part of a continuing community study in France on a sample of 725 women with osteoporosis and varying disease severity. It demonstrated that there was pain, limited physical functioning and fear associated with future fractures among the women in question [25]. However, neither of these studies considers time since vertebral fracture as a variable affecting QoL.

Though this study does suggest recovery with regard to pain and well-being, functional impairment persists and leads to a vicious circle: further decline in physical functioning with loss of neuromuscular abilities increases the risk of falling [23,26] and further fractures. Moreover, fear of falling restricts patients' mobility and independence [27]. Consequently, there is an 8- to 10-fold risk of further fractures following pre-existing ones [28]. Following a clinically diagnosed vertebral fracture, the survival rate decreases gradually in relation to that expected in women without fractures [29].

These data emphasize the urgent need for preventive efforts such as medical therapy for patients with an increased risk of further fractures. There are currently several pharmaceutical agents available that not only augment bone mineral density but also restore bone quality and thus minimize fracture incidence [30,31]. Means of overcoming the acute situation of vertebral fracturing should be provided to patients with progressive disease. Adequate rehabilitative care should not omit heat application or physical therapy, and should include exercise therapy, pain relief to restore activities of everyday life, and general self-care. Finally, the importance of a multidisciplinary team approach including psychosocial aspects and education programs in the management of osteoporosis is highlighted by Gold et al. [2,5,6,16,32].

This study provides evidence that there is no need for acute discomfort due to vertebral fracturing to last longer than 2 years. In conclusion, this work shows for the first time that within 2 years since the last vertebral fracture aspects of QoL such as well-being may improve and lead

to a reduction in pain, but do not seem to restore activities of daily living. Teaching patients coping strategies may therefore be an important part of the rehabilitation of patients with osteoporosis.

Appendix

Limitations in Everyday Life

Motion in General. Six abilities of everyday life (walking, bending, climbing stairs, getting up from a lying position, dressing, carrying bags) are rated from 0 to 2 (easily possible, possible with difficulty, possible only with extra help). Finally a sum score is calculated ranging from 0 to 12.

Self-care in General. The assessment should be answered as follows: 1 = possible without extra help; 2 = generally possible, dependent on help in some cases (cleaning windows, drawing curtains, carrying heavy bags); 3 = possible but with difficulty and increased time, dependent on help in some cases; 4 = possible but with difficulty and increased time, dependent on help even in routine cases (shopping, ironing, cleaning floor); 5 = dependent on extra help for everyday routine functions (cleaning, cooking); 6 = nursing care needed.

Well-being

The questionnaire consists of four subscales each containing four bipolar pairs of adjectives to be scored in one of seven gradations.

Vitality								
tired	1	2	3	4	5	6	7	fresh
strong	1	2	3	4	5	6	7	weak
feeble	1	2	3	4	5	6	7	energetic
healthy	1	2	3	4	5	6	7	sick
Inner psychological balance								
calm	1	2	3	4	5	6	7	nervous
unbalanced	1	2	3	4	5	6	7	well-balanced
confident	1	2	3	4	5	6	7	insecure
anxious	1	2	3	4	5	6	7	fearless
Social extroversion								
talkative	1	2	3	4	5	6	7	discreet
reserved	1	2	3	4	5	6	7	communicative
sociable	1	2	3	4	5	6	7	shy
reclusive	1	2	3	4	5	6	7	gregarious
Vigilance								
attentive	1	2	3	4	5	6	7	inattentive
alert	1	2	3	4	5	6	7	absent-minded
concentrated	1	2	3	4	5	6	7	not concentrated
focused	1	2	3	4	5	6	7	divertable

The Sense of Coherence Questionnaire

This instrument calculates a score for the subscales comprehensibility (C, 11 items), manageability (M, 10 items) and meaningfulness (ME, 8 items). Each question offers seven possible answers. Patients are asked to circle the number that best expresses best their feelings.

Comprehensibility

1. When you talk to people, do you have the feeling that they don't understand you?
   1 2 3 4 5 6 7
   never have the feeling … always have the feeling
2. Think of the people with whom you come into contact daily, aside from the ones to whom you feel closest. How well do you know most of them?
   1 2 3 4 5 6 7
   you feel that they are strangers … you know them very well
3. Has it happened in the past that you were surprised by the behavior of people whom you thought you knew well?
   1 2 3 4 5 6 7
   never happened … always happened
4. In the past ten years your life has been:
   1 2 3 4 5 6 7
   full of changes without your knowing what will happen next … completely consistent and clear
5. Do you have the feeling that you are in an unfamiliar situation and don't know what to do?
   1 2 3 4 5 6 7
   very often … very seldom or never
6. When you face a difficult problem, the choice of a solution is:
   1 2 3 4 5 6 7
   always confusing and hard to find … always completely clear
7. Your life in the future will probably be:
   1 2 3 4 5 6 7
   full of changes without your knowing what will happen next … completely consistent and clear

8. Do you have very mixed-up feelings and ideas?
   1 2 3 4 5 6 7
   very often — very seldom or never
9. Does it happen that you have feelings inside you would rather not feel?
   1 2 3 4 5 6 7
   very often — very seldom or never
10. Does it happen that you have the feeling that you don't know exactly what's about to happen?
    1 2 3 4 5 6 7
    very often — very seldom or never
11. When something happens, have you generally found that:
    1 2 3 4 5 6 7
    you over-estimated or under-estimated its importance — you saw things in the right proportion

Manageability

1. In the past, when you had to do something which depended upon cooperation with others, did you have the feeling that it:
   1 2 3 4 5 6 7
   surely wouldn't get done — surely would get done
2. Has it happened that people whom you counted on disappointed you?
   1 2 3 4 5 6 7
   never happened — always happened
3. Do you have the feeling that you're being treated unfairly?
   1 2 3 4 5 6 7
   very often — very seldom or never
4. What best describes how you see life?
   1 2 3 4 5 6 7
   one can always find a solution to painful things in life — there is no solution to painful things in life
5. When something unpleasant happened in the past your tendency was:
   1 2 3 4 5 6 7
   'to eat yourself up about it' — to say 'OK, that's that, I have to live with it,' and go on
6. When you do something that gives you a good feeling:
   1 2 3 4 5 6 7
   it's certain that you'll go on feeling good — it's certain that something will happen to spoil that feeling
7. Do you think that there will always be people whom you'll be able to count on in the future?
   1 2 3 4 5 6 7
   you're certain — you doubt
8. Many people – even those with a strong character – sometimes feel like sad sacks (losers) in certain situations. How often have you felt this way in the past?
   1 2 3 4 5 6 7
   never — very often
9. When you think of difficulties you are likely to face in important aspects of your life, do you have the feeling that:
   1 2 3 4 5 6 7
   you will always succeed in overcoming the difficulties — you won't succeed in overcoming the difficulties
10. How often do you have feelings that you're not sure you can keep under control?
    1 2 3 4 5 6 7
    very often — very seldom or never

Meaningfulness

1. Do you have the feeling that you don't really care about what goes on around you?
   1 2 3 4 5 6 7
   very seldom or never — very often
2. Life is:
   1 2 3 4 5 6 7
   full of interest — completely routine
3. Until now your life has had:
   1 2 3 4 5 6 7
   no clear goals or purpose at all — very clear goals and purpose
4. Most of the things you do in the future will probably be:
   1 2 3 4 5 6 7
   completely fascinating — deadly boring

5. When you think about your life, you very often:

1	2	3	4	5	6	7
feel how good it is to be alive						ask yourself why you exist at all

6. Doing the things you do every day is:

1	2	3	4	5	6	7
a source of deep pleasure and satisfaction						a source of pain and boredom

7. You anticipate that your personal life in the future will be:

1	2	3	4	5	6	7
totally without meaning or purpose						full of meaning and purpose

8. How often do you have the feeling that there's little meaning in the things you do in your daily life?

1	2	3	4	5	6	7
very often						very seldom or never

From Antonovsky [15].

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