

Development of a questionnaire to measure patient-reported postoperative recovery: content validity and intra-patient reliability

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Abstract

Aims and objectives In this study we describe the development of a short, easy-to-use questionnaire to measure postoperative recovery and evaluate its content validity and intra-patient reliability. The questionnaire is designed to evaluate the progress of postoperative recovery and the long-term follow-up of possible effects of interventions during recovery.

Methods The study involved four steps. (1) A conceptualization and item definitions were based on a theoretical framework and a description of patients' postoperative recovery from the perspective of patients, registered nurses and surgeons; (2) Content validity of items was tested through expert judgements; (3) A test run of the questionnaire was performed to confirm its feasibility and workload requirement; and (4) The stability of the questionnaire was evaluated through intra-patient reliability assessment.

Results As a result of the operationalization process of the concept postoperative recovery, five dimensions (physical symptoms, physical functions, psychological, social, activity) and 19 items were identified. Each item was formulated as a statement in the questionnaire. Content validity was judged to be high. After the pre-test of the questionnaire a revision with refinements in the layout was made. The vast majority of items showed a high level of intra-patient reliability.

Conclusion Based on a theoretical framework and empirical data, we developed a short and easy-to-use tentative questionnaire to measure patient-reported postoperative recovery. Initial support for content validity was established. The vast majority of items showed a high level of test-retest reliability.

Introduction

Postoperative recovery is a consequence of a surgical procedure. It is a dynamic process where patients strive to regain previous functions and re-establish preoperative activities [1]. The length of hospital stay after surgical procedures has decreased. Many studies have examined the effect of surgical techniques [2], postoperative analgesic regimes [3] and multimodal programmes [4] on patient outcomes, focusing on early discharge. A reduced length of stay

has shifted much of the postoperative recovery process to the home environment, which lack the presence of health care professionals [5]. Most of the literature has focused on conventional, clinically oriented patient outcomes, for example, morbidity and mortality during the postoperative period. Few studies examine patient-reported outcomes [3] during the immediate postoperative period and in a longer perspective.

Several instruments have been developed to measure postoperative recovery. Most of these instruments aim to clinically assess the

physical status of patients recovering from anaesthesia and to follow the recovery process after ambulatory surgery. For instance, the Post-Anaesthesia Recovery score [6,7] measures physical conditions in the postanesthesia care unit and serves as a basis for discharge decisions from the unit. The 24-Hour Functional Ability Questionnaire [8] was developed to compare alternative anaesthetic regimens. It measures final recovery and patient satisfaction 24 hours after ambulatory surgery. The Postdischarge Surgical Recovery score [9] measures postoperative recovery in the home environment after ambulatory surgery, focusing on five concepts: health status, activity, fatigue, work ability and expectations. Furthermore, Postanaesthesia Short-term Quality of Life [10] measures the effect of anaesthesia on short-term quality of life. These instruments were developed to measure important aspects of postoperative recovery, but are restricted mainly to the early and intermediate recovery phases [11].

Some instruments have been developed for inpatient use. The Recovery Inventory [12] measures patient welfare during recovery after surgery, primarily in terms of physical condition. Myles and collaborators [13] have developed the Quality of Recovery score (QoR) and QoR-40 [14] to measure quality of recovery after anaesthesia and surgery. The QoR consists of nine items that measure physical and functional dimensions, while QoR-40 is an extensive instrument consisting of 40 items sorted in five domains: emotional state, physical comfort, psychological support, physical independence and pain. Even the instruments intended for inpatient use focus partly on recovery after anaesthesia.

We found no short, easy-to-use questionnaire that covers the important dimensions [15] and allows for evaluation of the progress of postoperative recovery and long-term follow-up of possible effects of interventions during recovery. Hence, this study aims to develop such a questionnaire and evaluate its content validity and intra-patient reliability.

The study

The study involved four steps: (1) conceptualization and item definitions; (2) content validity of items; (3) test run of the questionnaire; and (4) evaluation of reliability. We present the method and result of each step separately. Different sample groups were used in steps 2 to 4. The study, conducted at a university hospital in central Sweden, aimed at measuring progress during the recovery process through a short questionnaire feasible for use by patients of different ages and backgrounds after different surgical procedures.

Methods and results

Conceptualization and item definitions

Underlying the development of the questionnaire was a concept analysis [15] and a description of patients' postoperative recovery from the perspective of patients, registered nurses and surgeons [1]. In the concept analysis, *postoperative recovery* was defined as an energy-requiring process of returning to normality and wholeness. This was achieved as patients regained control over physical, psychological, social and habitual functions [15]. The patients, registered nurses and surgeons described the core of the recovery process as a desire to decrease unpleasant physical symptoms,

reach a level of emotional well-being, regain former functions and re-establish previous activities [1]. Dimensions and potential items for the questionnaire were generated from previous studies. Current literature is used to illustrate each item.

Five dimensions and 19 items were identified as being part of the operationalization process in the postoperative recovery concept (Fig. 1). Table 1 presents the items, rationale and supporting literature.

Content validity of items

Content validity relates to the degree to which a sample of items constitutes an adequate operational definition of a concept [16]. To determine the content validity of the items, 15 staff members (eight registered nurses, seven surgeons) and 16 patients participated as key informants, systematically judging the relevance and usefulness of the items [16]. Head nurses in the departments of surgery, orthopaedics and gynaecology selected staff members for participation. Staff members were selected primarily on the basis of their area of responsibility, interest and experiences regarding patient postoperative recovery. In selecting patients, a purposeful sampling [16] was used to identify respondents according to type of surgery, gender and age. Participant demographics (Table 2) describe the background variables. A study protocol was compiled to elicit feedback on the relevance of the items (Fig. 2). Participants were informed about the purpose of the questionnaire and the intent to use it for repeated measurements during the recovery process. The participants assessed whether the items seemed to cover essential aspects of the postoperative recovery process by choosing one of the following five response alternatives: strongly disagree, disagree, uncertain, agree or strongly agree.

On average, 85% (range 71% to 97%) of the participants chose the alternatives strongly agree/agree in their assessments of 18 items (out of 19), and thereby considered them essential in the postoperative recovery process. One item (*interest in surroundings*) was considered to be essential by 52% participants (Fig. 3). Seven staff participants made one or more comments each concerning the following items: *sexual activity*, *muscle weakness*, *feeling lonely/abandoned*, *dependence on others*, *social activities*, *difficulty in concentration* and *interest in surroundings*. These seven participants reported having limited or no experience regarding these items during the part of the recovery process that they could observe during hospitalization. At this stage in the process we decided to retain all items in the questionnaire.

Test run of the questionnaire

The items were formulated as statements, for example, 'Right now: I do not experience ...' (for instance, '... any pain'), or 'Right now: I experience ...' (for instance, '... pain'). We used a 3-point scale, with the verbal descriptive response categories mild, moderate and severe. Fifteen patients were asked to fill in a draft of the postoperative recovery questionnaire on day 2 or 3 after surgery, and to document the length of time it took. We wanted to know whether: (1) the items were realistic to carry out; (2) the layout was easy to use; and (3) the workload required was acceptable. Participants were given the questionnaire in the afternoon and asked to provide verbal feedback to one of the researchers

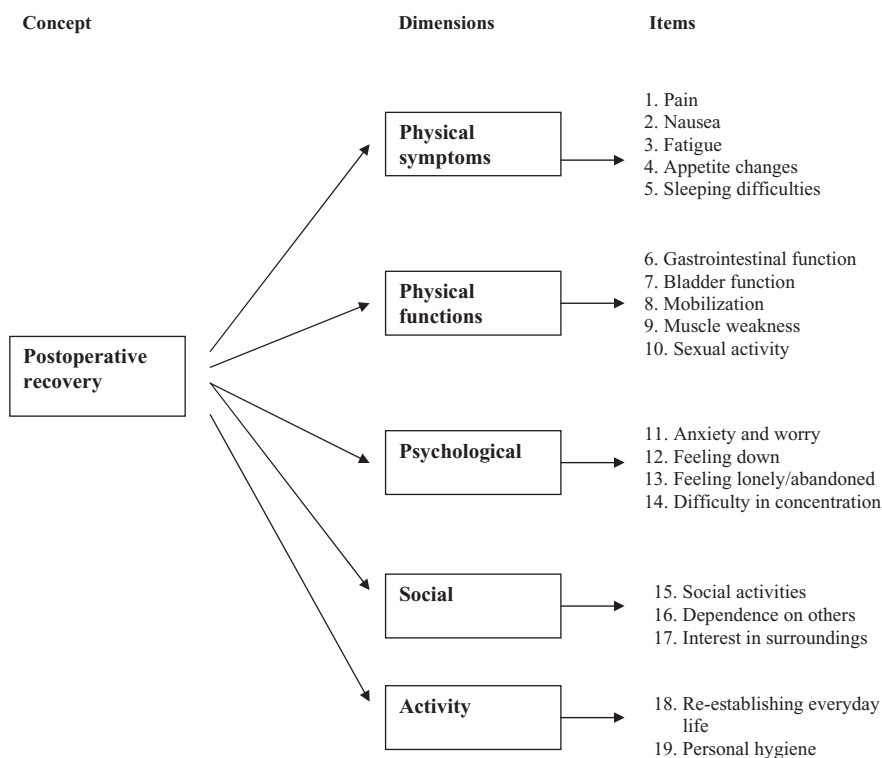


Figure 1 Diagram of operationalization of postoperative recovery.

(RA) on the following day. A purposeful sampling [16] was used to identify various respondents according to type of surgery, gender and age. Table 2 presents the background variables.

The results showed that 14 of the 15 patients who participated in the pre-test of the questionnaire considered it to be easy to complete. Seven participants requested an easier layout to avoid misunderstanding. Five participants considered the items on *sexual activity* and *re-establishing everyday life* to be irrelevant during hospitalization. As the questionnaire is intended for longitudinal use during the recovery process, *sexual activity* and *re-establishing everyday life* will be added in the follow-up assessments after discharge from hospital. Furthermore, the three participants having a urinary catheter pointed out that the question about emptying the bladder was not relevant. Participants needed 9 minutes (range 6 to 15) to complete the questionnaire. After scrutinizing the data from the test run, we revised the questionnaire and refined its layout.

Evaluation of reliability

To evaluate the stability in test–retest assessments, 25 patients participated in the intra-patient reliability study that was performed 3–4 days after surgery (Table 2). Based on the results in step 3, two items (*sexual activity* and *re-establishing everyday life*) were excluded. The postoperative recovery questionnaire was administered twice. The first assessment was conducted in the morning, and the second in the afternoon. This time interval was considered to be sufficient [16]. Participants were not informed in advance about the retest assessment.

Statistical analysis

Since reliability means a high level of agreement in the test–retest assessments, the percentage agreement (PA) was calculated, and the level of disagreement was explained in terms of systematic disagreement (bias) in common for the group of patients and additional individual variability when present [17]. We calculated systematic disagreement in position of the scale assessments between the two assessments, that is, relative position (RP), and the relative concentration (RC), which measures systematic disagreement in how the assessments were concentrated on the scale in the two assessments. Possible values range from –1 to 1. Zero values for RP and RC indicate a lack of systematic disagreement in position and in concentration respectively. The RP value expresses the difference between the proportions of overestimated and underestimated retest assessments when compared with the first test. Hence, a positive RP value indicates that the group has used higher categories on the second occasion than on the first. When central categories tend to get higher proportions of assessments on the second than on the first occasion, the RC value is positive. The relative rank variance (RV) is a measure of additional individual variability that cannot be explained by the measures of systematic disagreement. Non-zero RV indicates the presence of individual variability, and the higher the RV value the more dispersed the test–retest assessments, which is a sign of uncertainty in interpreting the items. The measures and the 95% confidence intervals (CI) of the measures were calculated by means of a free programme <http://www.oru.se/esi/svensson> [17,18]. Statistically significant

Table 1 Dimensions, items, rationale and supporting literature

Dimension	Item	Rationale	Supporting literature apart from our theoretical framework*
Physical symptoms	1. Pain	Pain is a commonly reported symptom after surgery. Effective pain relief is a prerequisite for postoperative recovery and convalescence.	Dolin 2002 [26] Zalon 2004 [27] Carr 2005 [28] Wu <i>et al.</i> 2005 [29]
	2. Postoperative nausea and vomiting (PONV)	PONV is considered to be a major problem and an inconvenience after surgery. Avoiding PONV is a key concern for postoperative patients.	Tramer 2001 [30] Dolin 2005 [31] Wu <i>et al.</i> 2005 [29] Williams 2007 [32]
	3. Fatigue	Postoperative fatigue is common and remains for a longer period after surgery. Fatigue has a negative influence on the recovery process.	DeCherney 2002 [33] Rubin & Hotopf 2002 [34] Zalon 2004 [27] Wagner 2005 [5]
	4. Appetite changes	Problems with eating have been reported during the first days after surgery.	Barthelsson 2003 [35] Cox & O'Connell 2003 [36]
	5. Sleeping difficulties	Reduced or fragmented sleep is a prevalent symptom during postoperative recovery.	Redeker & Hedges 2002 [37] Williams 2007 [32]
Physical functions	6. Gastrointestinal function	Resuming normal functioning of the digestive system is reported to be troublesome. Bowel dysfunction can delay recovery and nutritional intake.	Kehlet & Dahl 2003 [38] Wagner 2005 [5]
	7. Bladder function	Having a urinary catheter is reported to absorb energy. Urine leakage and incontinence cause frustration.	Burt 2004 [39]
	8. Mobilization	Efforts should be made to enforce postoperative mobilization. Bed rest increases muscle loss and weakness. Being mobilized is part of re-establishing activities in the early recovery phase.	Kehlet & Wilmore 2002 [40] Archibald 2003 [41] Cox & O'Connell 2003 [36]
	9. Muscle weakness	Postoperative muscle atrophy plays an important role in postoperative fatigue and in overall recovery. It takes time to regain the preoperative level of muscle strength.	Kehlet 1997 [42] Kehlet & Wilmore 2002 [40]
	10. Sexual activity	Patients express worries about the impact of the surgery on sex life.	Roovers 2003 [43] Burt 2004 [39] Wagner 2005 [5]
Psychological	11. Anxiety and worry	Patient experiences anxiety after surgery. Anxiety has an impact on the experience of pain.	Carr 2005 [28]
	12. Feeling down	Depression is reported during the later recovery phase. Depression is related to patient's self-perception of recovery and functional status. Depression is implicated in the experience of pain.	Zalon 2004 [27] Carr 2005 [28]
	13. Feeling lonely/abandoned	Patients report feelings of being left on their own.	Olsson 2002 [44]
	14. Difficulty in concentration	Decreased concentration level has been reported during the first postoperative days. Postoperative cognitive dysfunction exists for a longer period after surgery.	Moller 1998 [45] Abildström 2000 [41] Hanning 2005 [46]
Social	15. Social activities	Being able to communicate and spend time with family and friends is a part of regaining preoperative social functions.	Kirkevold 1996 [47] Barthelsson 2003 [35]
	16. Dependence on others	Regaining independence is a key factor in postoperative recovery.	Archibald 2003 [41] Cox & O'Connell 2003 [36]
	17. Interest in surroundings		
Activity	18. Re-establishing everyday life	Going back to work, domestic work and/or leisure activities are a part of re-establishing everyday life after surgery.	Barthelsson 2003 [35]
	19. Personal hygiene	Taking care of personal hygiene is a part of re-establishing activities during the early recovery phase.	Archibald 2003 [41]

*The identification of items is based on findings in previous studies [1,15] and illustrated by additional literature, which has been limited to maximum four papers per item.

Table 2 Participant demographics

Participants	Content validity			Test run	Test-retest reliability
	Patients (n = 16)	Registered Nurses (n = 8)	Surgeons (n = 7)	Patients (n = 15)	Patients (n = 25)
Female	9	7	2	7	13
Male	7	1	5	8	12
Age (years)					
Median	62			62	61
Range	18–76			21–86	18–78
General surgery	6	2	1	3	8
Gynaecology	2	2	2	2	4
Orthopaedic	5	2	2	6	11
Urology	3	2	2	4	2
Type of surgery	Colonic surgery			Colonic surgery	Colonic surgery
	Hip replacement			Femur fracture	Hip replacement
	Knee replacement			Gastric bypass	Hysterectomy
	Hysterectomy			Hysterectomy	Knee replacement
	Prostatectomy			Knee replacement	Prostatectomy
				Nephrectomy	
				Prostatectomy	
				Tibia fracture	

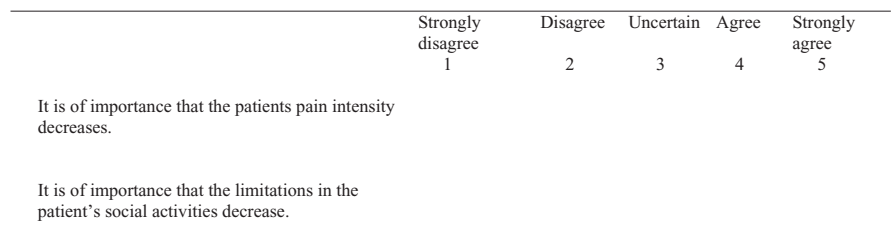


Figure 2 Examples from the questionnaire for item validation.

RP, RC and RV values on at least a 5% level are indicated by 95% confidence intervals that do not cover zero values.

Table 3 shows the results of the measures of agreement and also systematic and occasional disagreement. PA measures ranged from 72% to 100%, which means that at least 18 of 25 patients were completely stable in their test-retest assessments. The RV values of occasional disagreement were negligible except for *dependence on others*. The observed disagreement could be explained mainly by systematic disagreement. The highest levels of systematic disagreement in position (RP) were found in the test-retest assessments of *sleeping difficulties*, *muscle weakness* and *dependence on others*. The paired assessments of *pain* and *sleeping difficulties* in concentration on the two occasions differed systematically, RC -0.12 and 0.22 respectively. This difference in the concentration of scale categories explains the observed disagreement in the test-retest assessments by seven (28%) of the patients (Table 3).

Figure 4a and 4b show the square contingency table and the ROC curve for *sleeping difficulties*. Five of the 25 patients disagreed in responses on the test and retest occasions. The curve deviated below the diagonal, suggesting that the patients used the category moderate sleeping difficulties more frequently than mild sleeping difficulties on the first occasion as compared with the second. Hence, these two categories did not sufficiently discriminate the variable.

Figure 5a and 5b show that five of the 25 patients disagreed in the test-retest assessments of *dependence on others*. One explanation is the systematic shift from mild to no dependence on others, that is, a non-zero RP value. The main contribution to the RV value came from two patients who changed from moderate to no dependence between the occasions.

Disagreement in the assessment of *muscle weakness* could be explained mainly by the negative RP value indicating, that the patients tended to use higher categorical levels on the first than on the second occasion. The opposite holds for the test-retest assessments of *dependence on others* and *sleeping difficulties* with positive RP values. Regarding *sleeping difficulties*, the assessments also tended to be more concentrated on the first than on the second occasion, RC = 0.22. In most items, the 95% confidence intervals cover zero value asymmetrically, because of the small number of patients.

Ethical considerations

This study was planned and implemented based on common ethical principles applied in clinical research. There might be a risk that some statements in the questionnaire could be viewed as an intrusion of personal integrity. However, participants had the opportunity to decide whether or not to answer the questions. All

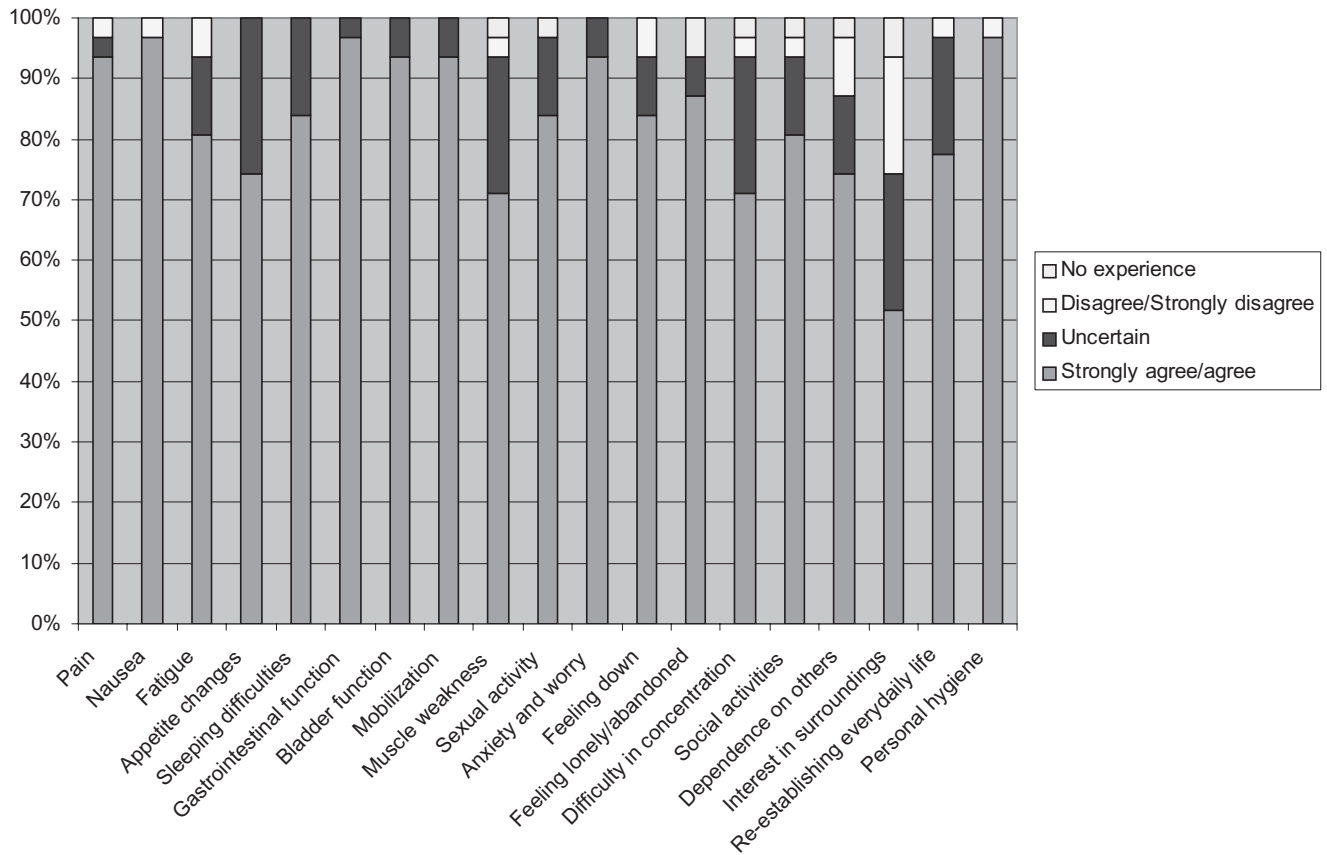


Figure 3 Items considered essential by patients and staff during the postoperative recovery process ($n = 31$).

Table 3 Results from test–retest analysis, displayed by percentage agreement (PA) (number of participants), relative position (RP), relative concentration (RC) and relative rank variance (RV). Figures in parentheses are 95% confidence intervals (CI) of the measures

Item	PA % (<i>n</i>)	RP (95% CI)	RC (95% CI)	RV (95% CI)
Pain	88 (25)	-0.03 (0.12 to 0.07)	-0.12 (-0.25 to 0.01)	
Nausea	100 (24)			
Fatigue	84 (25)	0.08 (-0.05 to 0.22)	0.07 (-0.10 to 0.24)	0.05 (0 to 0.16)
Appetite changes	72 (25)	-0.06 (-0.16 to 0.06)	-0.12 (-0.30 to 0.06)	
Sleeping difficulties	80 (25)	0.14 (0.009 to 0.27)	0.22 (0.034 to 0.40)	0.01 (0 to 0.04)
Gastrointestinal function	84 (25)			0.0015 (0 to 0.004)
Bladder function	96 (25)	-0.002 (-0.005 to 0.003)		
Mobilization	80 (25)	0.07 (0.01 to 0.15)	0.03 (-0.12 to 0.18)	0.001 (0 to 0.003)
Muscle weakness	80 (25)	-0.12 (-0.26 to 0.02)	0.03 (-0.19 to 0.25)	0.03 (0 to 0.50)
Anxiety and worry	92 (25)	0.08 (-0.02 to 0.18)		
Feeling down	100 (25)			
Feeling lonely/abandoned	96 (24)	-0.04 (-0.12 to 0.04)		
Difficulty in concentration	92 (25)			0.0008 (0 to 0.002)
Social activities	92 (25)	-0.02 (-0.05 to 0.01)	-0.10 (-0.22 to 0.03)	
Dependence on others	80 (25)	0.22 (0.04 to 0.40)	-0.06 (-0.22 to 0.10)	0.13 (0 to 0.31)
Interest in surroundings	100 (25)			
Personal hygiene	84 (25)	0.03 (-0.10 to 0.15)	-0.06 (-0.18 to 0.05)	0.002 (0 to 0.008)

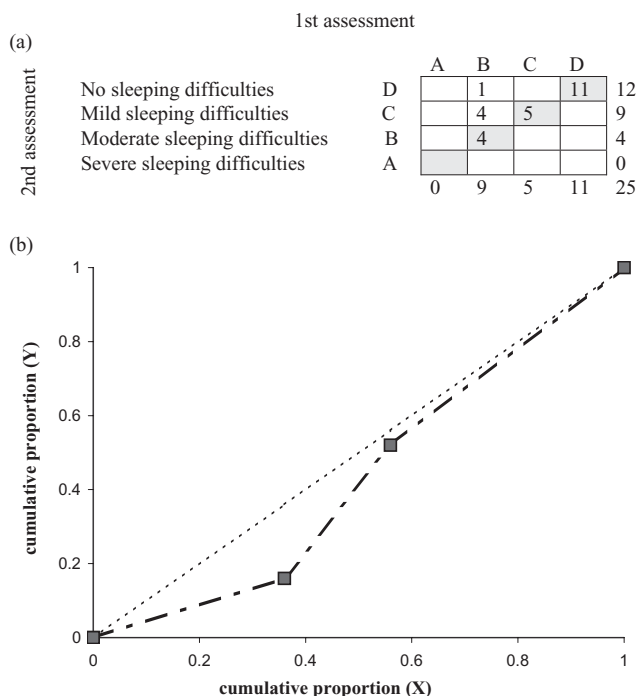


Figure 4 The contingency table (a) and the ROC curve (b) show a systematic change in concentration between the two assessments of *sleeping difficulties*. ROC, relative operating characteristic.

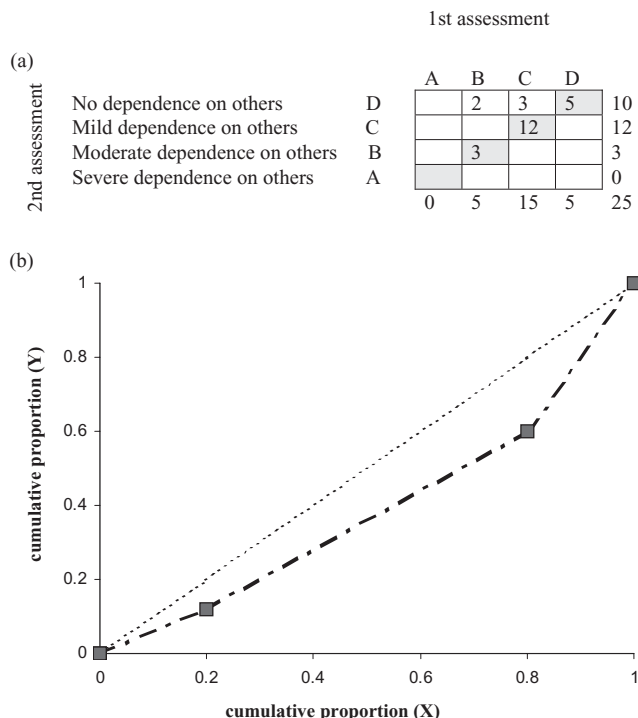


Figure 5 The contingency table (a) and the ROC curve (b) show a systematic change in position between the two assessments of *dependence on others*. ROC, relative operating characteristic.

respondents were given oral and written information about the study and were informed that participation was voluntary. All participants gave their informed consent to enter the study and were guaranteed confidentiality. The Regional Ethical Review Board in Uppsala approved the study (2006/047).

Discussion

This study addresses the development of a questionnaire to measure patient-reported postoperative recovery. Questionnaire items were identified through our previous studies [1,15], and initial support was given for content validity and intra-patient reliability.

To avoid the risk of unreliable measurement, considerable effort was put into the development of items. We consider that the use of a conceptual framework with a theoretical definition [15] combined with individual and focus group interviews with patients, registered nurses and surgeons [1] provides a thorough analyses underlying the development of the questionnaire. There is no consensus on the number of experts needed in the content validity process – some authors suggest three participants [19] while others suggest between 10 and 20 [20]. However, some authors have been using even larger numbers [21]. The intent of the present study has been to include the number of experts that we considered necessary to acquire detailed information. To capture the core of the postoperative recovery process, we found it important to include both patients and staff as content experts and analyse the data as a joint group. There could be objections against the use of staff members as experts when developing a patient-oriented measurement tool. However, although patients are the only ones having subjective experiences, staff members may be the best observers of the outward manifestations of postoperative recovery.

A limitation of this study is that only hospitalized patients participated in judging content validity. Hence, their ability to judge the relevance of items for the entire recovery process might be questioned. However, they were informed that the questionnaire had been developed for repeated measurements during a longer period and was not restricted to the specific moment in time when they responded to the questions. Furthermore, the description of patient experiences of recovery that constituted the base for developing questionnaire items included experiences up to 1 year after surgery [1]. Another limitation could be that all patients and staff included in the study are affiliated with orthopaedic and abdominal surgery departments. It can be argued whether or not this limits the result from the content validity process to patients that have undergone orthopaedic and abdominal surgeries. Furthermore, it might be argued that a 19-item instrument is too extensive. (We have ongoing studies to further simplify the questionnaire without losing the key features.)

A conversation between participant and researcher was a satisfactory way to acquire direct feedback in the test-run of the questionnaire. Participants had the opportunity to describe their viewpoints in detail and to ask clarifying questions. Correspondingly, the researcher could check that the participants had understood the task they were given.

The test-retest assessments were performed during hospitalization, and therefore the items *sexual activity* and *re-establishing everyday life* were excluded. However, these items should be

tested in the future. When participants were presented the second assessment they were informed about the importance of filling in the questionnaire to describe the current situation, and instructed not to try recalling their responses in the first assessment. In the test–retest assessment we used a rank-invariant method [17], developed and used to analyse pairs of ordered categorical data from rating scales and measurement instruments [22–24]. The method developed by Svensson was chosen as it evaluates reliability concerning the level of agreement in paired assessments and takes into account the non-metric properties of data from rating scales. The main property of ordered categories is that they represent only a rank order according to the amount or intensity of the variable. This means that one ordered set of labels can be replaced by another, for example numerals by letters or vice versa [25]. The use of a set of numerals to represent an ordered category is common. However, numerical labels do not represent a mathematical value, except for ordering. Although commonly used, the non-metric property of categorical data means that sums and scores of data from rating scales are inappropriate [18].

We did not need to eliminate any items after the judgement of content validity. The rigorous definition of the postoperative recovery concept could be one explanation for this. Some staff members reported difficulties in judging the degree to which some of the items were essential for the recovery process as their experience was limited to patients during hospitalization. This supports the need for an instrument that measures all recovery dimensions in a longer perspective, extending beyond hospitalization and the time around discharge.

The test-run of the questionnaire showed that it was easy to understand, even if some minor layout adjustments were necessary to make it easier to use. Furthermore, the result of the test-run demonstrated that it was not time-consuming (average 9 minutes), although we found variation in the time needed to complete the questionnaire. This could probably be explained by individual variances in reading skills, the ability to absorb information and the time needed to reflect before answering a question. It could also be age-related.

Determining the value of a measure should also be based on information regarding stability. All items, except for *appetite changes*, showed a high level of test–retest reliability (range 80% to 100%). This study showed that the disagreement of 20% in the test–retest assessment of *dependence on others* could be explained by both systematic and individual disagreement, and that the 20% disagreement in *sleeping difficulties* was caused by systematic differences in the use of the scale categories. This result indicates that the questions are clearly formulated and that the participants understood the questions. Only two postoperative recovery instruments have presented test–retest assessment as part of their development [13,14].

The progress of the multidimensional postoperative recovery process remains to be studied from a patient perspective. The patient-reported questionnaire addressed in this study could be useful to study postoperative recovery after different surgical procedures. Nurses and surgeons on regular wards should find that increased knowledge about recovery is useful in daily practice to support their patients and in evaluating interventions performed during the recovery process.

Conclusion

Based on a theoretical framework and empirical data, we developed a short and easy-to-use tentative questionnaire to measure patient-reported postoperative recovery. Initial support for content validity was established. The vast majority of items showed a high level of test–retest reliability. Further studies should focus on measuring recovery profiles after different types of surgery.

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