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Original article

Quality of life measurement in the postoperative period in general and gastrointestinal surgery

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ARTICLE INFORMATION

Article history:
Received January 26, 2010
Accepted March 7, 2010

Keywords:
General and gastroenterological surgery
Health related quality of life
Short form-36

ABSTRACT

Introduction: Health related quality of life measurement (HRQL) is widely accepted as an appropriate outcome of surgical care for assessing effectiveness and for risk adjusted outcomes. Nevertheless its use in the immediate postoperative period has show limitations. The aim of this study is to prove that is possible, with a specific new tool, to assess the HRQL during this period.

Patients and methods: The study is designed to create a specific close questionnaire related to the patient's condition after surgery, structured in domains, with the subsequent use of: literature searches, patient interviews (n=30), and a Delphi survey with health care providers. Finally the tool was validated using a pre-test (n=36) and a prospective observational cohort trial (n=250), to assess the discriminant validity for different cohorts of patients, reliability, responsiveness, and convergent validity, and to compare with the widely used generic tool, Short Form 36 (SF-36).

Results: The questionnaire was shown to have good sensitivity to change (single index and domains score), as well as good sensitivity to distinguish cohorts of patients, a high internal consistency (Cronbach's alpha 0.88), absence of redundancy between domains (Spearman's rho range, 0.29-0.84), and good convergent validity with patient opinion. The SF-36 questionnaire showed poor discriminant validity, and lack of convergent validity with patient opinion.

Conclusions: These results support that the created questionnaire is appropriate to assess HRQL in the immediate postoperative period; and was more specific than SF-36.

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0009-739X/$ - see front matter

Evaluación de la calidad de vida en el periodo postoperatorio inmediato en cirugía general

Palabras clave:
Cirugía general y del aparato digestivo
Calidad de vida relacionada con la salud
Short form-36

R E S U M E N

Introducción: La calidad de vida relacionada con la salud es un resultado aceptado en cirugía para medir efectividad y para ajuste de riesgos, si bien su medición en el postoperatorio precoz ha presentado limitaciones. El propósito de este estudio es probar que es posible medir la calidad de vida relacionada con la salud en dicho periodo mediante un instrumento específico.

Material y método: Se obtuvo un cuestionario específico estructurado en dominios con el uso consecutivo de 3 fuentes: la revisión bibliográfica, la entrevista con pacientes (n = 30) y métodos de consenso Delphi con profesionales. Finalmente el instrumento es validado sometiéndolo a preprueba (n = 36) y mediante un estudio clínico observacional prospectivo (n = 250) analizando su capacidad de discriminar cohortes de pacientes por tipo de intervención, complicaciones, estado clínico, su evolución temporal y sus propiedades como medida, comparándolo con el short form-36.

Resultados: El instrumento mostró buena sensibilidad al cambio y capacidad de discriminación para las diferentes cohortes de pacientes, además de facilidad de uso, alta coherencia interna (alfa de Cronbach 0,88), ausencia de redundancia entre dominios (rho de Spearman entre 0,29-0,84) y adecuada convergencia con la opinión de los pacientes. En cambio el short form-36 no mostró adecuada capacidad de discriminación, ni idoneidad para su uso en dicho periodo.

Conclusiones: Estos resultados sugieren que el cuestionario elaborado es válido para evaluar la calidad de vida relacionada con la salud en el periodo postoperatorio inmediato, siendo más sensible y específico que el short form-36.

Introduction

Surgery is a different kind of healthcare intervention because of the way it is provided and because it requires a recovery with a magnitude and duration related to the extent of the wound,[1-3] complications,[4,5] previous physical condition,[6,7] psychological factors[8,9] and healthcare strategies.[10] Patients in the surgical processes suffer changes in their functional capacity and independence, physiology and body image, emotional and psychological well-being, and social relationships, as well as requiring care from others.

Measuring health-related quality of life (HRQL) integrates these aspects into the right surgical outcome which measures effectiveness and limits risks,[11-14] although its use in the immediate postoperative period suffers from a lack of sensitivity due to the speed of the changes and the limited suitability of the instruments used.[15,16] Our hypothesis is that it is possible to measure HRQL during this period with sufficient psychometric guarantees, differentiating between groups of patients by the consequences of the surgery and the factors influencing recovery.

Material and method

Between 2003 and 2006 we carried out a quali-quantitative experimental study using a standardised procedure in phases,[17] the result of which is a specific instrument for measuring HRQL in the immediate post-operative period (PGSQL: post general surgery quality of life). We validated it through an observational, single-blind, controlled clinical trial.

Population

Sixty-six patients were recruited for the generation of the items and protest analysis by simple random sampling from the medical area of the Infanta Elena and Juan Ramon Jimenez hospitals in Huelva, following the recommendations of the EORTC Quality of Life Group.[17,18] Two hundred and fifty patients were recruited by stratified random sampling to investigate its validity, estimating a difference between the maximum and minimum scores of 25%, with α errors =.05 and β errors=.10, and a drop-out rate of 20%. Patient groups were organised by 5 types of surgical intervention on the basis of the stress associated with the diagnosis and surgery, hospital stay and postoperative care (Figure 1). The inclusion criteria were: being over 18 years of age; follow-up until definitive discharge; and ability to speak, write and read in Spanish. Exclusion criteria were: cognitive, psychiatric or physical disorders which stopped patients from performing a 30 min self-assessment of their state of health. For the consensus technique, the following qualified healthcare providers were selected by stratified random sampling from a

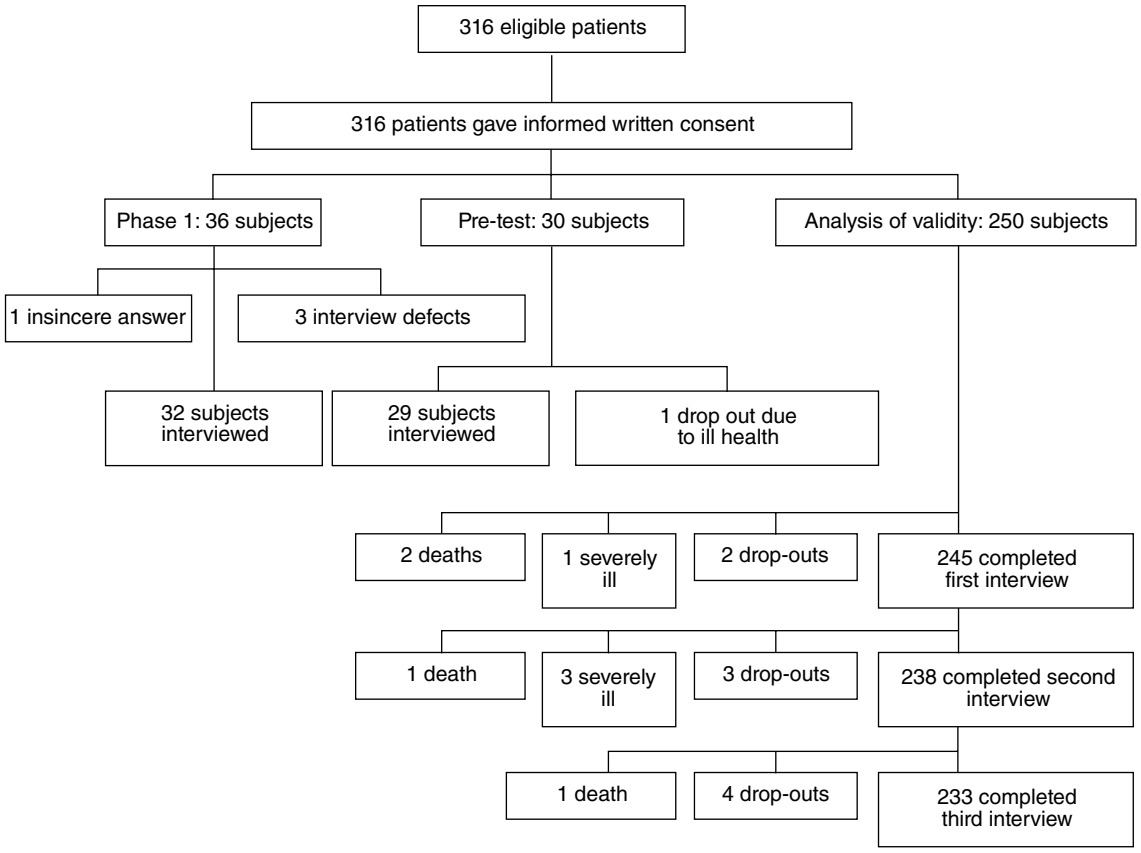

Figure 1 – Recruitment, follow-up and drop-outs in the sample.

list of 35: 5 general surgeons, a clinical psychologist, 3 nurses, and an auxiliary nurse. Inclusion criteria were 10-year clinical experience, full-time employment in surgical care (part-time for the psychologist), and exclusion criteria were a statement of conflict of interest with the aims of the study and breaching the limits of the technique. Patients and healthcare providers gave their specific written consent (accepted by the local committee for clinical trials) and the latter also signed a statement of confidentiality.

Development of the instrument

An exhaustive list was put together of the relevant aspects for quantifying postoperative HRQL, including in the following order: published evidence from indexed databases with search profiles and filters about "HRQL and postoperative period", qualitative research with patients through semi-structured standardised interviews (n=33), and consensus methods with experts (Delphi, RAND corporation) (Figure 2).

Then, a questionnaire was designed with 32 items in 7 dimensions, assigning each item a question and multiple choice answers in accordance with the criteria prevalence, impact and ease of analysis. The 32 questions and 5 instructions were submitted to pre-test analysis (n=29), obtaining the definitive questionnaire by adding some instructions and modifying some answers (Table 1).

Assessment of validity

The questionnaire was applied to 250 patients, 233 of whom completed the interviews at 24 h, 5 days and 1 month after surgery, without the help of relatives or healthcare staff. Earlier or later (chosen randomly) on the same day, after a break of 1 hour, the patients competed the SF-36 (short form-36, VE 1.4, Medical Outcomes Trust) and answered 2 questions which measured their opinion about their clinical progress (better, same or worse) and their return to normality (yes, no). The blinded researcher who delivered the questionnaire first carried out a clinical assessment using an adapted ordinal scale of the ECOG Performance Status Index with 4 states (from asymptomatic [I] to postoperative sequelae which require treatment, cause complete disability and confine patients to bed [IV]). Defective questionnaires were used for the analysis purposes (error of discrimination), and drop-outs were excluded. The healthcare process was standardised for each type of intervention and pro-active searches for bias were carried out using 47 audits of cases chosen at random without warning.

Dependent variables were taken to be the final raw score, those of each domain in the PGSQL questionnaire, and the transformed scores for each domain in the SF-36,[19] the assigned variables were: surgery, complications, postoperative clinical situation, and interview order. Due

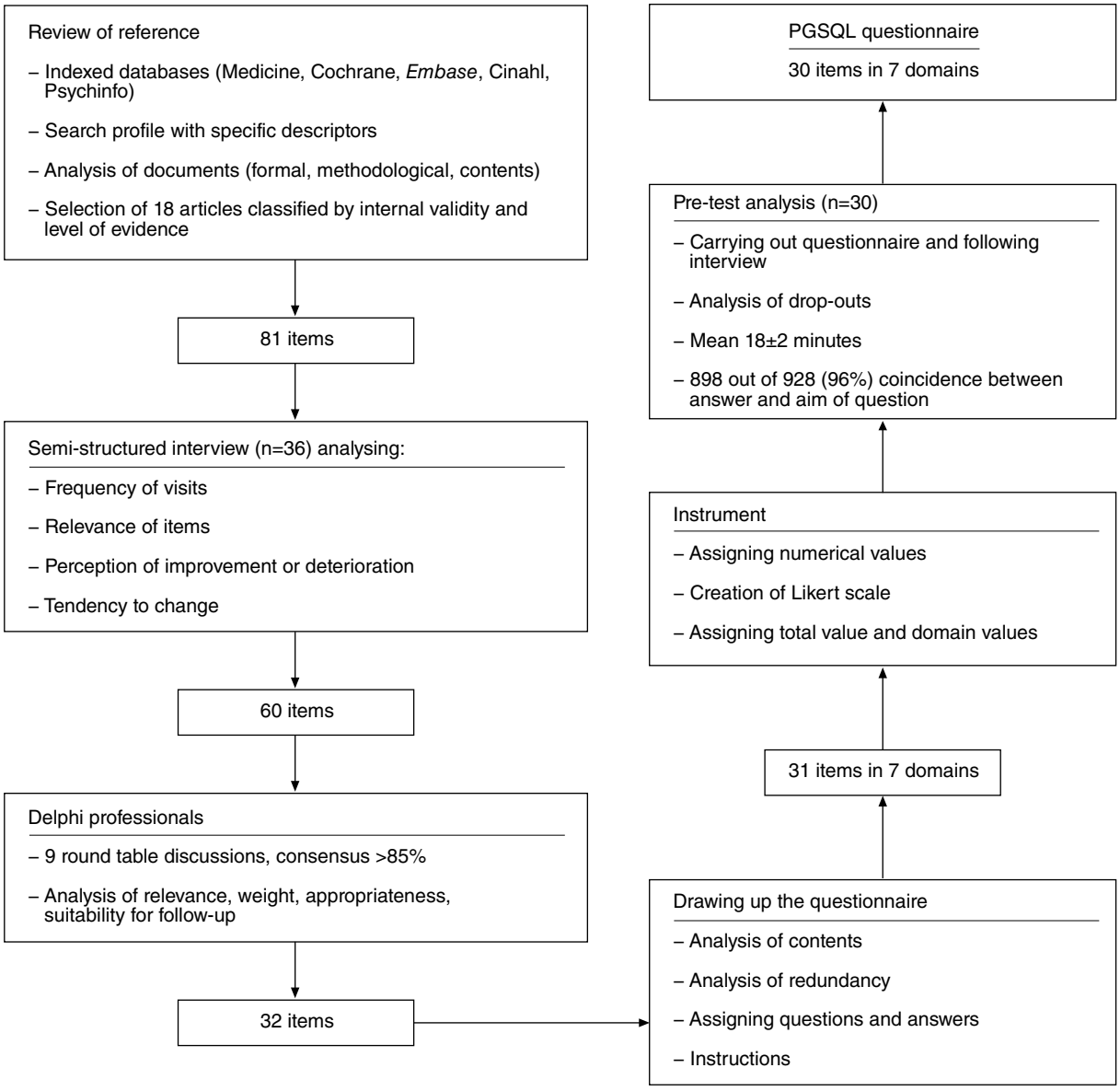

Figure 2 – Procedure for developing the instrument. PGSQL indicates post-general surgery quality of life.

to the lack of normality found by the Kolmogorov-Smirnov test with Lilliefors correction, the statistical analysis was carried out using the Kruskal-Wallis, Mann-Whitney and Friedman tests. The following were used for the psychometric analysis: time taken to complete questionnaire; percentage of completed questions; relevance of the questions according to the interviewee; internal consistency using Cronbach's alpha (acceptable value 0.8), redundancy (values above 0.8) or independence (values below 0.2) of the items using Spearman's rho; the construct validity using concordance with the index questions (Kruskal-Wallis test), with effect size estimates ($[\mu_2-\mu_1]/\sigma[\mu_1]$),[20] construct independence using a dissimilarity matrix (Minkowski procedure) (values above 0.2). The minimum level of significance was considered to be $P<.05$, the calculations being performed by a blinded statistician with the SPSS software 10.0 (SPSS Inc. Chicago).

Results

The clinical and demographic characteristics were representative of the population at the institutions where the study was performed (Table 2), with a mean age of 58, a slight predominance of women, from urban areas or large rural populations, low to middle educational level, mainly in the labour force population, married and with a medium-level of income. The different cohorts by assigned variable showed no statistically significant differences, except sex in the type of surgery ($P<.01$), with more women undergoing cholecystectomy, mastectomy and thyroidectomy, and more men undergoing hernioplasty and colectomy.

The modified scale of the Performance Status Index was validated confirming the increase in patients in status I from

Table 1 – Contents of the questionnaire

Domain	Item	Content	Code	Min-max scores
Physical functioning	1	Pain	inverse	6-28
	2	Fever	inverse	
	3	Ileus abdominal distention	direct	
	4	Nausea	direct	
	28	Requires nursing	direct	
	5	Difficulty moving	inverse	
Emotional well-being	6	Comfort	direct	5-18
	7	Energy	direct	
	8	Sadness	direct	
	9	Agitation	direct	
	10	Confrontation	inverse	
Functional well-being	11	Breathing	direct	6-34
	12	Ingestion-digestion	direct	
	13	Defecation	direct	
	14	Sleep	direct	
	15	Cognitive state	inverse	
	16	State of consciousness	direct	
Physical performance	17	Washing-dressing	inverse	5-10
	18	Walking without help	inverse	
	19	Eating without help	inverse	
	20	Everyday activities	direct	
	21	Moderate effort	direct	
Satisfaction	22	Information given	inverse	3-15
	23	State of health	inverse	
	24	Healthcare given	direct	
	25	Prior expectations	inverse	
	26	Relationships with healthcare providers	direct	
Attitude-predisposition	27	Cure expectations	inverse	3-15
	29	Expectations for near future	direct	
	30	Pessimism declared	direct	
Total score		Summary value of questionnaire		28-120

none in the first interview to 190 of the 233 in the third interview (81.5%), and a reduction of statuses III and IV from 242 of the 245 patients (98.7%) in the first interview to 6 in the third one (2.5%; $P<.01$), with a correlation of -0.85 ($P<.001$); also, analysing the complications (second interview) 7 out of 21 patients (52%) with major complications were in status iii and iv, 10 out of 33 (48%) had minor complications and only 10 out of 114 (8%) had no complications ($P=.03$), correlation of 0.86 ($P<.01$).

Both questionnaires were assessed for their discrimination and psychometric properties.

PGSQL

The scores for the domains and the total score increase over time from the first to the third interview (Table 3, Figure 3), and considering it a repeated measures design, significance is maintained (Friedman test, $P<.06$). The clinical condition variable revealed decreasing scores from stage I to iv ($P<.01$). Decreasing values were observed in the total score by pathology, in this order: colectomy, mastectomy, cholecystectomy, hernioplasty, and thyroidectomy ($P<.01$). A similar sequence was seen in the domains: physical performance, functional well-being, and attitude. There were 54 complications, and only 1 in the first interview, which was excluded from the analysis. The total scores and those for each domain decreased from no complications to major complications in the second and third interview.

The patients completed the questionnaire in a mean time of 15 (9) min and considered 7433 (99.6%) of a total of 7456 questions in the 699 questionnaires analysed to be relevant; 6 questionnaires were incomplete (0.8%). With high internal consistency ($\alpha=.88$), no redundancy or independence was observed between domains. Regarding the convergent validity, the scores for all the domains and for the total are lower if the patient thinks that "their condition is getting worse" ($P<.01$ in all cases), with effect size intervals for the domains between 0.67–1.82 and 1.50 for the total. Scores are higher in those patients who are "back to normality" ($P<.001$ in all cases), with effect size intervals from .54-1.38 depending on the domain, and 1.30 for the total. Regarding construct independence compared to the SF-36, all the values were above 0.3, reaching values of 1 in some cases.

SF-36

In general, the differences increased over time. There was insufficient discrimination for the clinical condition variable between the physical functioning, pain, and emotional role domains, and for the type of surgery variable between the physical functioning, physical role and emotional role domains, and it was unable discriminate between complications in any of the domains. In some cases there were contradictory results with worse scores in patients with a better clinical condition and in those with minor

Table 2 – Clinical and demographic characteristics of the samples for generating and validating the questionnaire (percentage in brackets)

	Generation items	Questionnaire validation
No.	62	233
Age	57.19±13	59.97±14
Sex		
Women	36 (58.0)	153 (65.6)
Men	26 (41.9)	80 (34.3)
Origin		
Rural	26 (41.9)	105 (45.0)
Urban	30 (48.3)	119 (51.0)
Small village	6 (9.6)	9 (3.8)
Education		
Elementary	35 (56.4)	140 (60.0)
Middle	18 (29.0)	59 (25.3)
Higher	9 (14.5)	34 (14.5)
Marital status		
Married	46 (74.1)	184 (78.9)
Single	7 (11.2)	8 (3.4)
Widowed	6 (9.6)	24 (10.3)
Divorced	3 (4.8)	17 (7.2)
Income (€/year)		
<30 000	5 (8.6)	16 (6.8)
<40 000	20 (32.2)	64 (27.4)
<50 000	26 (41.9)	107 (45.9)
>50 000	11 (17.7)	46 (19.7)
Occupation		
Active	45 (72.5)	165 (70.0)
Retired	11 (17.7)	46 (19.7)
Sick leave	6 (9.6)	22 (9.4)
Clinical condition		
I	36 (58.0)	117 (50.6)
II	18 (29.0)	79 (34.3)
III	8 (12.9)	34 (15.0)
IV	0	3 (0.1)
Complications		
None	48 (77.4)	179 (76.8)
Minor	11 (17.7)	33 (14.1)
Major	3 (4.8)	21 (9.0)
Mean stay	3.36±1	3.90±2

complications compared to major ones, and also in the interview order.

Six thousand and eighteen (71.7%) of the 8388 questions were considered relevant; the mean time for completing the questionnaire was 16 (3) min, and 26 (4%) were incomplete. Internal consistency was high (α=.81), with an absence of redundancy and independence in the correlation between domains. The analysis of convergence showed very slight differences between the scores of patients declaring they were better or the same, with a lack of significance in the physical functioning, physical role, pain, general health, and emotional role domains, with effect size intervals between 0.1

Table 3 – Discrimination of PGSQL and SF-36 by clinical condition, complications and time of interview (max. and min. values in square brackets)

Domain	Clinical condition					Complications				Time of interview			
	I	II	III	IV	P	No	Minor	Major	P	24 h	6th day	Month	Ps
PGSQL													
Physical condition	28 [11-29]	24 [14-28]	19 [10-28]	17 [14-22]	<.001	24 [14-28]	23 [20-26]	18 [17-25]	.049	18 [10-26]	24 [14-28]	28 [11-26]	<.001
Emotional condition	15 [7-17]	15 [6-17]	13 [7-17]	12 [10-16]	<.001	15 [6-17]	13 [9-16]	11 [8-15]	.002	12 [7-17]	14 [6-17]	15 [7-17]	<.001
Functional well-being	33 [10-34]	32 [20-34]	27 [12-34]	23 [17-29]	<.001	32 [20-34]	29 [25-33]	28 [24-32]	.001	24 [12-34]	31 [20-34]	33 [10-34]	<.001
Physical performance	10 [6-10]	9 [6-12]	7 [5-10]	6 [5-7]	<.001	9 [6-10]	8 [6-10]	8 [7-9]	<.001	7 [5-10]	9 [6-10]	10 [6–12]	<.001
Satisfaction	16 [10-18]	15 [13-18]	16 [10-18]	15 [13-17]	ns	16 [13-18]	15 [12-17]	15 [13-16]	.021	15 [10-18]	16 [12-18]	16 [10-18]	.018
Attitude	13 [7-15]	13 [7-15]	12 [6-15]	11 [11-13]	<.001	13 [7-15]	12 [9-13]	10 [9-13]	.036	12 [6-15]	12 [7-15]	13 [7-15]	<.001
SF-36													
Physical functioning	85 [0-100]	85 [5-100]	77 [0-100]	77 [20-100]	ns	80 [5-100]	85 [0-100]	80 [0-100]	Ns	75 [0-100]	80 [5-100]	85 [0-100]	<.001
Physical role	100 [0-100]	100 [0-100]	75 [0-100]	100 [0-100]	.001	100 [0-100]	100 [0-100]	100 [0-100]	ns	25 [0-100]	50 [0-100]	100 [0-100]	.009
Pain	95 [22-100]	74 [0-100]	74 [0-100]	62 [42-100]	ns	80 [05-97]	74 [5-100]	84 [22-100]	ns	62 [0-100]	56 [05-97]	84 [22-100]	<.001
General health	67 [10-100]	57 [5-97]	55 [25-90]	48 [30-77]	.031	57 [5-100]	52 [30-85]	57 [25-92]	ns	55 [25-90]	57 [15-95]	62 [10-100]	<.001
Vitality	60 [5-100]	60 [15-97]	55 [0-90]	50 [25-60]	.024	60 [0-100]	50 [25-85]	50 [30-90]	ns	55 [0-90]	87 [0-100]	87 [12-100]	<.001
Social functioning	100 [12-100]	87 [0-100]	75 [0-100]	75 [37-100]	.003	87 [0-100]	75 [25-100]	75 [50-100]	ns	75 [0-100]	100 [0-100]	75 [0-100]	<.001
Emotional role	100 [0-100]	100 [0-100]	100 [0-100]	100 [33-100]	ns	100 [0-100]	100 [0-100]	100 [0-100]	ns	100 [0-100]	100 [0-100]	100 [0-100]	<.001
Mental health	72 [4-100]	68 [24-100]	68 [8-96]	60 [44-80]	.029	72 [4-100]	60 [24-–96]	60 [36-96]	ns	68 [8-–68]	68 [32-100]	72 [4-100]	<.001

PGSQL indicates post-general surgery quality of life; SF-36, short form-36.

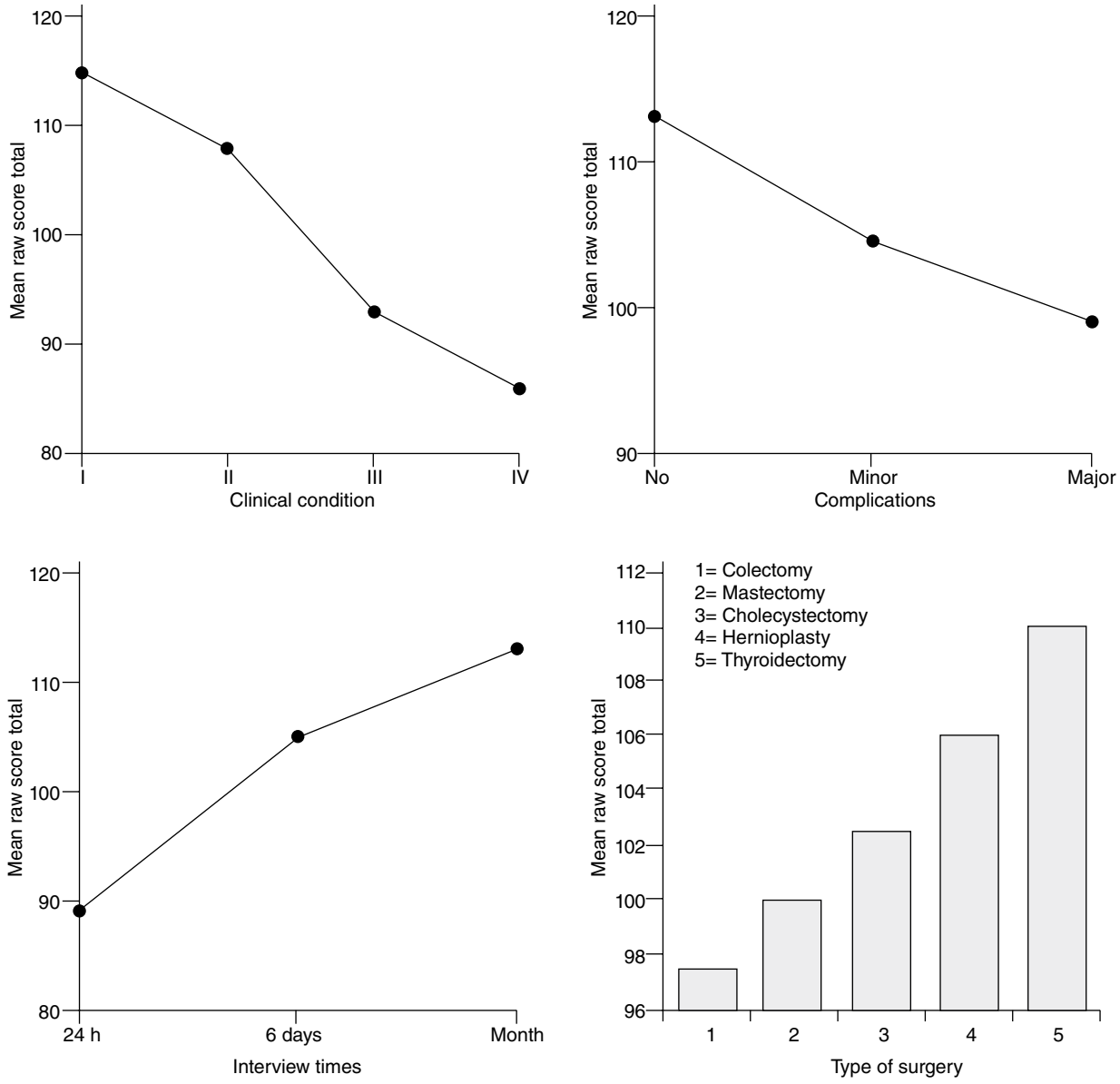

Figure 3 – Results of the total score for the different variables (P<.01 in all cases).

and 0.7, depending on the domain. The SF-36 discriminates suitably the return to normality (P<.01), except in emotional role, which was not significant and with an effect size ranging between 0.13 and 0.68.

Discussion

Measures of HRQL have been used experimentally in elective surgery[21,22] and have been widely accepted as a relevant outcome in gastrointestinal surgery.[14,23,24] However, some authors have identified the need to create an instrument for use in the immediate postoperative period, when the different aspects constituting HRQL change quickly and have an important influence on the trauma caused by surgery.[13,14] The Quality of Life Group[17] developed a procedure in phases to obtain instruments for measuring HRQL which makes it possible to integrate different aspects of quality of life which have been identified in major surgery.[25] With this aim and methodology, we developed a tool which had to: be able to discriminate between groups of patients and moments during the early postoperative period; be able to obtain data easily from the population under study; have properties ensuring objectivity, accuracy and reliability.

The results of the instrument validation confirmed that the global score and those of nearly all the domains have sufficient capacity to discriminate between groups of patients undergoing different operations, the presence of complications, and their clinical condition quantified by the intensity of symptoms. It was consistent with the changes over time predicted in the recovery model of surgical stress. However, the satisfaction domain lacks statistical significance for the clinical condition variable, and we decided to analyse this as an absence of discrimination. This domain was created

to determine satisfaction with the healthcare provided (information, expectations of the process, relationship with staff), following the tendency of authors such as Heidegger et al,[26] so it does not assess the outcome (like the others), but the process. This aspect, together with small differences between values in all the variables and their low correlation with the total score (rho=0.19), raised doubts about the questionnaire's construct validity. Its provisional withdrawal from the questionnaire was analysed, confirming that this reduced the questionnaire's internal validity (α=.83). Since its aim is to compare opinions about the quality of the care given by different healthcare providers, we considered the future possibility of separating it from the total score and giving its values separately.

Regarding the results by pathologies, the total score shows a gradation which is apparently related to diagnostic and surgical stress, but this is not present in all the domains. This would permit interpretations such as that in the postoperative period, mastectomised patients have worse HRQL than those who have undergone hernioplasty, due to worse emotional and physical states, but patients have the same degree of physical performance and a better functional condition. As Sailer et al[27] point out, the absence of reference data, and the possibility that 2 interventions have similar values in certain domains, does not allow these interpretations to be ruled out, although this type of analysis requires a different experimental design.

Regarding its psychometric qualities, the new tool is easy to use, can be applied to different time periods, has high internal consistency, without redundancy and is convergent with patient opinion regarding convalescence. However, the score intervals overlap, affecting the accuracy of the measures when the subjects are not their own control. This effect in this type of results is due to them including variables which cause confusion (experiences, expectations, beliefs, etc.), whose weight is too great for discriminating between a small number of patients. By analysing effect size, our instrument discriminates between groups of 19 patients (CI 95%, between 17 and 20).

One controversial aspect is offering a summary result (total score[28]), but we consider this to be acceptable because it fulfils the criteria required of the instrument and because over time this strategy has been incorporated into the use of other questionnaires (physical and mental constructs in SF-36). The use of raw values is also controversial since transforming them into a range of percentages (as in the SF-36) makes it possible to increase differences and obtain values that are easier to use. However, as other experimental guarantees exist with the raw scores in the analysis of the instrument's validity, we decided to present the values in this way.

With regard to the SF-36, methodological problems have been highlighted in the immediate postoperative period due to the content of the questions and its use in short time intervals.[15,29] However, as there is no other suitable measure of comparison it was chosen as the control because it is widely accepted in surgery and there is plenty of information about it in the references. Our results confirm that it is not ideal for discriminating between stresses caused by different types of surgery, it is not able to discriminate between clinical condition and complications, and it lacks convergence with the condition declared by patients.

Our results may raise doubts since no gold standard exists for measuring postsurgical recovery and because the Performance Status Index has been adapted, although this does not affect the study's internal validity. Furthermore, a preoperation reference value is not available as its use is not possible with individuals who have not undergone surgery, and a reliable test-retest analysis is not possible due to the speed of patients' recovery after the operation. Despite these drawbacks, the PGCQL has proven to be a specific tool for the immediate post-operative period which is able to discriminate between groups of patients and is sensitive to the course of time, while the SF-36's poor discriminant validity raises doubts about its use as a tool for measuring HRQL in this period.

Funding

Consejería de Salud (Regional department of health). Resolution of 27th December, 2004. Subsidies for health research projects. *File:* 122/04. *Fund manager:* Fundación Salud y Progreso (Health and Progress Foundation).

Conflicts of interest

The authors affirm that they have no conflicts of interests.

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