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European Journal of Cancer 37 (2001) 1729–1735

European Journal of Cancer

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Response shift in the perception of health for utility evaluation: an explorative investigation

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Received 23 April 2001; accepted 23 May 2001

Abstract

We previously showed that patients with newly diagnosed colon cancer change the internal standards on which they base their quality of life estimation. In the present investigation, we explored whether this response shift similarly affects the perception of health for utility evaluation in cancer clinical trials. After radical resection of adenocarcinoma of the colon (pT1-4 pN > 0 M0 and pT3-4 pN0 M0) and perioperative chemotherapy, patients were randomised to three treatment arms: observation only (A), 5-fluorouracil (5-FU) 450 mg/m^2 plus levamisol (B), or 5-FU 600 mg/m^2 (C). Subjective health was assessed by a linear analogue self-assessment (LASA) scale anchored at 'perfect health–worst health' developed for serial assessment of utility values (Hürny C, van Wegberg B, Bacchi M, *et al*. Subjective health estimations (SHE) in patients with advanced breast cancer: an adapted utility concept for clinical trials. *Br J Cancer* 1998, **77**, 985–991). Patients estimated their pre-surgery health among various quality of life indicators both before surgery and retrospectively thereafter, and their pre-adjuvant health both at the beginning of randomly assigned chemotherapy or observation and retrospectively approximately 2 months later. Thereafter, current subjective health was assessed. Paired *t*-tests were used to test the hypotheses of no change. Patients' estimated pre-surgery health was worse after surgery than before ($n = 127$, mean change $= -6.7$, standard deviation (S.D.) $= 30$, $P = 0.01$), and their estimated pre-adjuvant health was worse under treatment or observation than at the beginning ($n = 132$, mean change $= -7.1$, S.D. $= 23.8$, $P = 0.001$), in agreement with the quality of life indicators. Chemotherapy had no impact on these changes attributed to a response shift. Conventionally assessed changes between the beginning of adjuvant treatment or observation and 2 months later indicated no change in subjective health. Change scores relative to patients' retrospective estimation revealed an improvement ($n = 122$, mean change $= 6.6$, S.D. $= 24.8$, $P = 0.004$) in this period. Patients with colon cancer substantially reframe their internal standard of health as they do for quality of life. This explorative finding questions the assumption, generally made in decision models, that health estimates for utility evaluation are independent of time. Given that patients may change their standards, comparisons of health estimates across different populations and clinical situations are to be interpreted with caution.

Keywords: Utility evaluation; Quality of life; Response shift; Reframing; Adjuvant therapy; Colon cancer

1. Introduction

In evaluating patient utilities under cancer treatment, a patient's state of health within the periods of treatment or follow-up is often assumed to be stable at least until recurrence. This assumption is the basis for cross-sectional comparisons of different interventions. Regarding health-related quality of life (QL), however, there is increasing evidence that patients with a chronic disease may change the internal standards on which they base their QL estimation in the process of becoming and remaining ill. This phenomenon has been described as 'response shift' [1,2].

We previously showed that patients with newly diagnosed colon cancer changed their internal standards of QL [1,3]. This observation was made with regard to radical resection with perioperative chemotherapy and to randomly assigned post-operative adjuvant

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0959-8049/01/$ - see front matter
PII: S0959-8049(01)00196-4

chemotherapy or observation within a clinical trial of the Swiss Group for Clinical Cancer Research (SAKK 40/93). We described these changes as 'reframing', as used for similar phenomena in psychology. 'Reframing' signifies that patients do not assess their health against a fixed reference point (i.e. a 'true' baseline) but against a frame of reference which shifts in the light of experience.

Whether this phenomenon similarly affects patient-estimated health status is not known. This question is relevant for cost-utility evaluations in oncology. As an alternative to formal utility assessment, health status has been assessed in many studies by visual analogue scales, rated either by the patients or by clinicians [4]. In both cases, it is assumed that these estimates reflect a 'true' value for a given health status which may be compared among different populations and clinical situations. This amounts to an assumption of stable internal reference points which allow an assessment of health status at any given point in time.

Such a visual analogue scale was included in the trial cited above. It was developed for serial assessment of health status for utility evaluation in cancer clinical trials [5]. Patients were asked to imagine they would have to live the rest of their life in their current condition and to indicate how they would rate a life in this condition between perfect health and worst health.

In this report, we explore the question of whether health status estimates by patients are similarly affected by a response shift as has been shown for QL indicators, and whether this effect changes the interpretation of health status estimates.

2. Patients and methods

2.1. The trial

The trial (SAKK 40/93) was open for all patients with radically-resected and histologically-proven adenocarcinoma of the colon with pathologically confirmed stages pT1-4 pN > 0 M0 and pT3-4 pN0 M0. The patients had to have a potentially curative resection (R0-resection) and no additional rectal carcinoma. The perioperative intraportal chemotherapy was a 7-day infusion of 5-fluorouracil (5-FU) starting immediately after surgery and interrupted by a 2-h infusion of Mitomycin-C after the first 24 h. It had to be stopped in case of serious toxicity. In cases of technical problems with the recommended intraportal catheter, switching to the intravenous (i.v.) route was possible.

Randomisation for post-operative adjuvant chemotherapy had to take place between 7 and 28 days after surgery, and was recommended 2–3 days before hospital discharge. The patients were assigned to three treatment arms: observation only (A); 5-FU 450 mg/m^2 i.v. once weekly for 1 year plus every second week 50 mg levamisol orally (p.o.) every 8 h for 3 days (B); 5-FU 600 mg/m^2 i.v. once weekly for 1 year (C). Stratification included institution, age, tumour stage and administration of peri-operative chemotherapy. Criteria for dose modifications were specified in the protocol. Toxicity was rated by physicians according to Early Clinical Trials Group guidelines.

The QL investigation including the health status measure was restricted to centres in German speaking areas of Switzerland, and to selected centres in Germany.

2.2. Quality of life and health status

Linear analogue self assessment (LASA) indicators of components of QL, ranging from 0 to 100, were part of a patient questionnaire. Global measures of well-being and functioning were complemented by specific measures of tumour symptoms and treatment side-effects, as described elsewhere [3]. Included was also an indicator for subjective health estimation [5] anchored at 'perfect health–worst health' (range: 0–100), as described in the Appendix. This measure was designed for the serial assessment of health status for utility evaluation in cancer clinical trials.

In the present analysis, we explored whether the previously observed response shift in QL indicators [3] similarly affects the perception of health. We contrasted the findings of the subjective health indicator with those of physical well-being and global QL.

As shown in Fig. 1, patients were asked to estimate their pre-surgery QL and subjective health both before surgery (surgery pre-test): "... We would like to know how you felt during the last week before your surgery or any other treatment ...", and retrospectively after surgery (surgery "then-test" [6]): "... Please think back a moment to the time before your surgery when you filled in the first questionnaire for us. Indicate on the enclosed questionnaire how you felt during the last week before your surgery ...". The difference of the pre- and then-test was used as a measure for the response shift [7].

Both the surgery pre- and then-test were assessed in the hospital after oral instruction of the patient by a

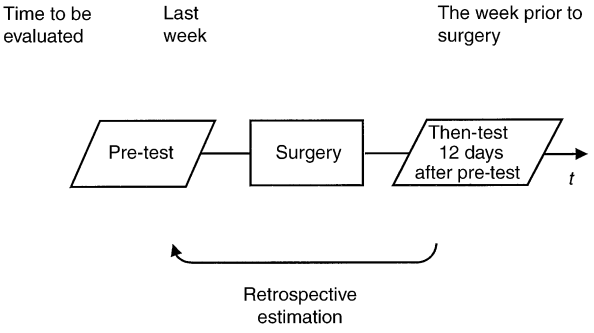

Fig. 1. Quality of life assessment schedule regarding surgery.

physician or nurse, in addition to the written instruction indicated above. The surgery pre-test was to be assessed by all patients eligible for the clinical trial, regardless of whether they were actually randomised after surgery. The surgery then-test was to be completed on the day of randomisation (i.e. close to hospital discharge). Sociodemographic data were also collected by the staff.

Similarly, following discharge, patients were asked to estimate their QL and subjective health at the beginning of randomly-assigned adjuvant chemotherapy or observation (adjuvant pre-test), as shown in Fig. 2: "... Now that you are back at home, we would like to follow-up on how you are doing ...", and retrospectively approximately 2 months later (adjuvant then-test): "... We are interested to find out what you now think about your well-being two months ago ...". Finally, patients' current QL and subjective health under treatment or observation (adjuvant post-test) was assessed approximately 2 weeks after the adjuvant then-test: "... Please respond to all questions regarding how you felt during the last week ...". For all assessments, the time to be evaluated was also specified in the introductory statement to the questions on both pages of the questionnaire. The wording of the indicators for subjective health and global quality of life was adjusted.

The adjuvant pre-test, then-test and post-test were completed at home. Questionnaires were sent to patients with a covering letter including the relevant instructions and a stamped addressed envelope.

2.3. Statistical analysis

Submission rates of the questionnaires were defined as the ratio of the number of received and evaluable questionnaires to the number of expected questionnaires. The responders were compared with the non-responders regarding their biomedical and sociodemographic characteristics, separately for the comparisons related to surgery and the adjuvant phase. There was no difference in terms of such characteristics.

The association among the three indicators at the beginning of the adjuvant phase was described with Pearson correlation coefficients.

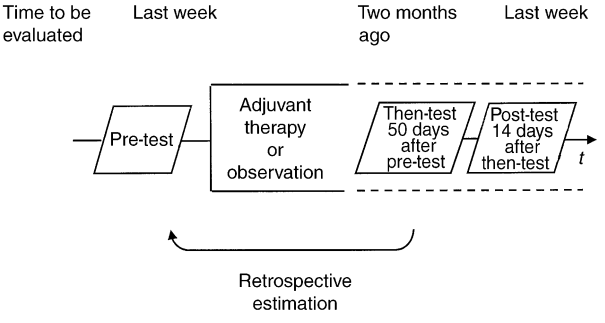

Fig. 2. Quality of life assessment schedule regarding the adjuvant phase.

To investigate changes across different clinical situations, the pre-test scores at surgery and at the beginning of the adjuvant phase were compared by paired *t*-tests. The question whether there was a response shift in patients undergoing surgery or adjuvant therapy/observation was investigated by paired *t*-tests between the pre- and then-test assessments separately for surgery and the adjuvant phase, the latter separately by treatment and overall. The question of whether this effect is different in patients with versus without chemotherapy was investigated by a global F-test for the comparison of the three treatment groups on changes between the pre- and then-tests. All tests were two-sided.

Changes under adjuvant treatment or observation were conventionally investigated by paired *t*-tests between the pre- and post-test assessments separately by treatment and overall. In addition, response shift was taken into account by comparing the post-test to the then-test instead of the conventional pre-test [7].

We faced ranges in the timing of the QL assessment going beyond the schedule defined in the protocol. However, we preferred to include all observations in the analysis instead of cutting the extremes. As described in the original report [3], we conducted additional analyses of the adjuvant then- minus pre-test, post- minus pre-test and post-minus then-test in a subsample with correct timing ($n=66$). These analyses showed findings consistent with the analysis on all observations and are not reported here.

For illustrative purposes, we transformed the subjective health scores to standard gamble equivalents using the power transformation proposed by Torrance [8]: $u=1-(1-v)^{2.29}$, where v is the visual analogue score (i.e. subjective health). This transformation has been used for cross-reference to utility studies in various cancer diseases [4], although it is not a true (preference-based) utility. It should also be stressed that this formula is based on a visual analogue scale with different wording compared with the scale used in our study and therefore may serve for orientation only.

To explore the role of biomedical and sociodemographic characteristics in reframing, the effects attributed to reframing (then- minus pre-test) were investigated by a multiple linear regression analysis. The best predictive model was chosen using Mallow's Cp as criterion [9]. Based on clinical experience, we selected those factors which have a potential impact on patients' perception of disease or treatment. Biomedical factors included sex, age, family history of colorectal carcinomas, type of surgery and lymph nodes involved. For the comparison related to surgery, surgical and medical complications and duration of hospital stay were also included; for the comparison in the adjuvant situation we used treatment assignment and the timing of QL assessment relative to the beginning of chemotherapy. Sociodemographic factors included education, professional

position and living situation. Finally, for both comparisons, institution, a well-known prognostic factor in colon cancer surgery, and the time interval between pre- and then-test were included.

This study is explorative in nature. We did not adjust for multiple testing. Lines indicating 95% confidence intervals (CI) around observed mean effects help to visually assess patterns of response shift.

3. Results

3.1. Sample description

As described in the original report [3], 215 patients were randomised in German speaking centres. For this investigation, 187 patients with at least one pair of corresponding questionnaires for either pre/then-test comparison were selected (87%). At the time of surgery, the main reasons for missing QL data were administrative problems at the local centres. In the adjuvant phase, QL data were mainly missing due to patients' failure to send back the questionnaire.

Biomedical and sociodemographic characteristics were described in the original report [3]. In brief, 59% of the patients were male. The median age was 62 years, ranging from 27 to 88. 14% had a family history of colorectal cancer. The majority underwent standard surgical procedures. 53% had no nodal involvement. 83% lived with next of kin or friends. 78% had formal job training. A minority had an upper level or academic position.

3.2. Reframing under surgery

Surgery pre- and then-test assessments were available in 132 patients (71%) of which 2 had missing clinical information and were excluded. The median time between the two assessments was 12 days (range: 6–73 days), close to the duration of hospital stay (median = 14 days, range: 6–56 days).

The mean values of the surgery pre-test are shown in Table 1. Before surgery, the subjective health estimates were more impaired than the two QL indicators.

Table 1
Surgery and adjuvant pre-test scores[a]

Indicator	Surgery		Adjuvant phase	
	n	SEM	*n*	SEM
Subjective health estimation	130	62 (2.5)	134	69 (1.9)
Physical well-being	130	73 (2.2)	137	71 (2.1)
Global quality of life	128	70 (2.1)	134	68 (1.9)

SEM, standard error of the mean.

[a] All indicators range from 0 to 100. Higher scores indicate *better* QL (e.g. better health).

To investigate reframing, the surgery pre-test scores were compared with their retrospective estimates assessed after surgery. After surgery, patients' estimated pre-surgery health was poorer than the estimates they had made at the time ($n = 127$, mean change $= -6.7$, S.D. $= 30.0$, $P = 0.01$), in agreement with their estimates of physical well-being and global QL (Fig. 3).

To illustrate the magnitude of this effect in terms of utilities, we used a power transformation for standard gamble equivalents [8]. Based on this transformation, the change in subjective health corresponds to a change in utilities from 0.79 to 0.74 ($P = 0.1$).

3.3. Reframing under adjuvant therapy or observation

Adjuvant pre- and then-test assessments were available in 137 patients (73%). The median time between filling in the questionnaire at beginning of adjuvant therapy or observation and the retrospective assessment was 50 days (range: 13–80 days). Adjuvant pre- and then-test as well as the post-test assessment at 2 months were available in 132 patients (71%). The median time between the assessments of pre- and post-test was 64 days (range: 21–143 days), and 14 days (range: 0–93 days) between the assessments of the then-test and the subsequent post-test.

The mean values of the adjuvant pre-test are shown in Table 1; they did not differ significantly among the randomised treatment arms. The three indicators showed comparable means. In comparison to the scores before surgery, the health estimates were improved ($n = 113$, mean change $= 7.5$, S.D. $= 35.1$, $P = 0.03$).

At the beginning of the adjuvant phase, subjective health was moderately correlated with physical well-being ($r = 0.60$) and overall quality of life ($r = 0.68$), according to the different although overlapping constructs of subjective health and the other two indicators.

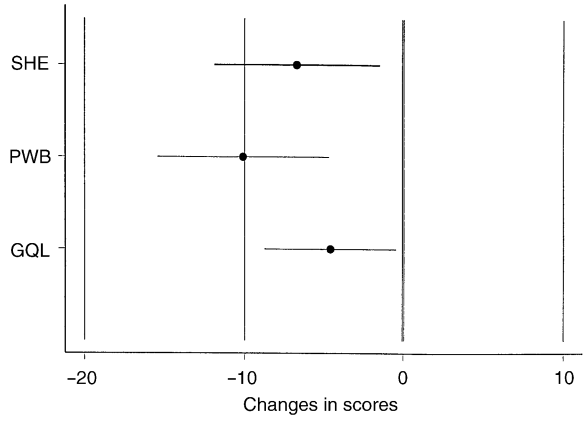

Fig. 3. Reframing under radical resection and perioperative chemotherapy ($n = 130$). Negative differences between then- and pre-test (means with 95% confidence interval (CI)) indicate worse scores of the retrospective estimation (then-test). SHE: subjective health estimation; PWB: physical well-being; GQL: global quality of life.

To investigate reframing, the adjuvant pre-test scores were compared with their retrospective estimates assessed 2 months later. The changes between the assessment at the beginning of the adjuvant phase (pre-test) and the retrospective estimation (then-test) were not significantly affected by treatment. The three treatment arms were therefore investigated together. Patients' pre-adjuvant estimates of health were worse under treatment/observation than at the beginning ($n=132$, mean change $=-7.1$, S.D. $=23.8$, $P=0.001$), in agreement with the retrospective estimates of physical well-being and global QL (Fig. 4).

Using the transformation for standard gamble equivalents to illustrate this effect, this change in subjective health corresponds to a change in utilities from 0.88 to 0.81 ($P=0.001$).

To investigate changes in subjective health during the adjuvant phase, we compared the estimates at 2 months into adjuvant treatment/observation (post-test) to the estimates assessed at the beginning (pre-test). These conventionally assessed changes were not significantly affected by treatment. The three treatment arms were therefore investigated together. Based on this comparison (post- minus pre-test), patients' estimates of subjective health did not change for the first 2 months on adjuvant treatment or observation ($n=122$, mean change $=-0.6$, S.D. $=19.6$), as shown in Fig. 5.

To clarify whether the observed effect of reframing affects the interpretation of the pre-/post-test comparison, patients' reframing was taken into account by comparing the current health estimates under treatment/observation (post-test at 2 months) to the retrospective estimates (then-test) instead of the conventional assessment at beginning of the adjuvant phase (pre-test) (Fig. 5). Using the then-test instead of the pre-test, there was an apparent improvement in subjective health ($n=122$, mean change $=6.6$, S.D. $=24.8$, $P=0.004$) (Fig. 5). This improvement was consistent with that in physical well-being and global QL.

3.4. Factors associated with reframing

The impact of biomedical and sociodemographic factors on patients' reframing of subjective health was explored by multiple linear regression analyses on the differences between the then- and pre-test. None of the investigated factors substantially affected the reframing effect, neither regarding surgery (best predictive model, $R^2_{adj}=0.04$) nor the adjuvant phase (best predictive model, $R^2_{adj}=0.03$). The two QL indicators showed similar findings.

4. Discussion

In this report, we explored the question of response shift in perception of health for utility evaluation and contrasted the findings with those of physical well-being and global QL, which were previously described [3].

Baseline correlations among the three indicators were moderate, related to the fact that QL and subjective health are different although overlapping constructs. However, we found similar effects of reframing. After surgery, patients' retrospective estimates of their pre-surgery health state were lower than the estimates they had made at the time. After 2 months on adjuvant therapy/observation, patients' estimates of their health state before adjuvant therapy/observation were also

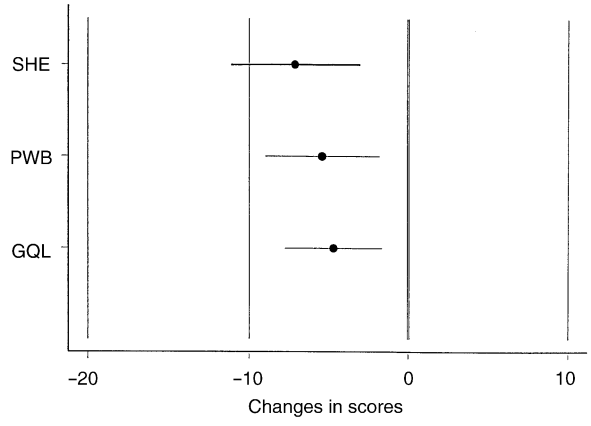

Fig. 4. Reframing under post-operative adjuvant chemotherapy or observation ($n=137$). Negative differences between then- and pre-test (means with 95% confidence interval (CI)) indicate worse scores of the retrospective estimation (then-test) across treatments. SHE: subjective health estimation; PWB: physical well-being; GQL: global quality of life.

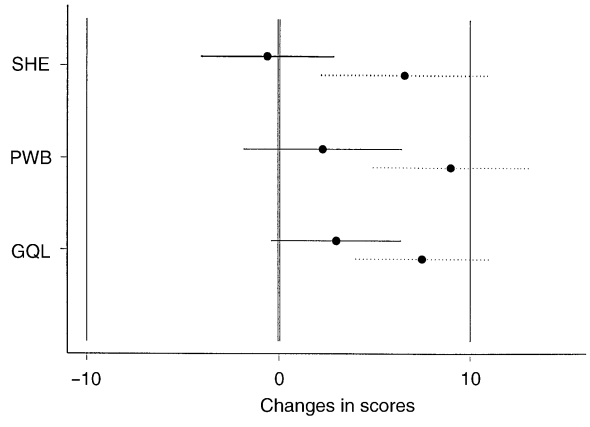

Fig. 5. Changes across treatments relative to beginning of adjuvant treatment versus retrospective estimation ($n=132$). The solid lines refer to conventionally assessed changes over the first 2 months from randomisation (post- minus pre-test), the dashed lines to changes adjusted to patients' retrospective estimation (post- minus then-test): Positive differences (means with 95% confidence interval (CI)) indicate an improvement. SHE: subjective health estimation; PWB: physical well-being; GQL: global quality of life.

lower than the estimates they had made at the time. The latter effect was not influenced by chemotherapy. In the adjuvant situation, it is plausible that a change in perception is not primarily introduced by an intervention (e.g. chemotherapy), but by coping with the disease itself [3].

There was no change in subjective health when comparing estimates at 2 months into adjuvant treatment/observation (post-test) to the estimates assessed at beginning (pre-test). However, relating the current estimates under adjuvant therapy/observation to patients' retrospective estimation (then-test) instead of the conventional assessment at beginning revealed an improvement. In other words, even though the patients estimated their health status about the same on two different occasions during recovery from surgery, from the perspective of 2 months following discharge their perception of their impairment at discharge had changed.

In the first months after surgery (i.e. time point of post-test) most patients are expected to have physically recovered [10]. This improvement in health status would suggest better health status estimates, which was not the case. Does the concept of response shift help in understanding this finding?

Given that a patient's estimate of their health status is derived from objective health status and individual expectations, a change may be induced by an alteration of either factor. Jansen and colleagues investigated the hypothesis that impaired health states are valued more positively when experienced than when hypothetical [11]. Breast cancer patients reported higher utilities regarding their concurrently experienced health status during radiotherapy as compared with a radiotherapy scenario assessed before treatment. A visual analogue indicator for health status showed the same trend. Further evaluations suggested that the description of the radiotherapy scenario did not fully correspond to patients' actual experience and that this resulted in the observed discrepancy.

Our findings point to a different explanation. Patients were asked to imagine they would have to live the rest of their life in their current condition. Thus, our measure was defined both by the experienced health status as well as a scenario. It is reasonable to assume that patients' perception of their health altered over time. This assumption is supported by the finding that the reframing effect was also present in the no-treatment group of the adjuvant phase, when there was little or no change in specific clinical factors. We interpret the observed response shift as an effect of patients' adaptation to the malignant disease and to the surgery sequelae [3]. We theorise that a general tendency exists for patients to shift their frame of reference in the light of experience ('reframing').

Our findings suggest that patients' perception of health may be different from that documented by serial measurements. The magnitude of the reframing effect corresponds to the change between the assessments before surgery and at the beginning of the adjuvant phase, i.e. a clinically plausible and relevant change. To illustrate this in terms of utility, we transformed the subjective health scores to standard gamble equivalents [8]. It has been used for cross-reference to utility studies in various cancer diseases [4], although it does not yield a true (preference-based) utility. This transformation showed a substantial effect regarding reframing in the adjuvant phase.

These explorative findings may be relevant for cost-utility evaluations in oncology. As an alternative to formal utility assessment, health status has been assessed in many studies by visual analogue scales [4]. Given that reframing takes place in patients undergoing a clinically relevant transition, the assumption of stable internal reference points allowing an assessment of health status at any given point in time has to be questioned. Comparisons of health status estimates (and approximate utilities derived from them) across different populations and clinical situations are therefore to be interpreted with caution.

Most often, this type of evaluation of medical interventions is based on cross-sectional comparisons. Our findings suggest caution in interpreting single point estimates of self-report rating scales of health status. Variation across different clinical situations is plausible, as it was the case for the difference between the pre-surgery and the pre-adjuvant assessment in our trial. However, within a clinically stable period, the assumption that health status estimates are constant over time is generally made in decision models without empirical evidence. As discussed by de Haes and colleagues for utilities, the method of insertion of utility values into decision models by means of the multiplication of utility values and time assumes the independence of time and values [12]. Studies in cancer patients with repeated assessment showed both reasonably stable [13,14] and unstable utilities [15]. Regarding health status assessment by visual analogue scales, our findings suggest that, whenever health status is assessed, the clinical situation should be explicitly defined.

The fact that there were similar effects of reframing in two different clinical situations, regardless of hospital (surgery) or home assessment (adjuvant situation) and despite variations in the timing of assessment, supports the validity of these effects [3]. The major criticism to this type of investigation is related to patients' difficulties in estimating the past experience [16]. As argued in our original report of this trial [3], if poor memory were the only factor influencing the retrospective estimations, we would expect patients to report better and worse retrospective scores in roughly equal proportions. This was not the case. However, a systematic effect of experience on recall (i.e. a true recall bias) cannot be

excluded. Future trials should include an inquiry on patients' understanding in responding to the then-test.

In conclusion, as previously shown for QL indicators, patients with colon cancer substantially reframe their internal standard of health both under radical resection and under adjuvant chemotherapy or observation. This explorative finding questions the assumption, generally made in decision models, that health estimates for utility evaluation are independent of time. Given that patients may change their standards, comparisons of health estimates across different populations and clinical situations are to be interpreted with caution. Further investigation of this effect should include different utility approaches in different stages of disease.

Acknowledgements

To study reframing of QL and health perception within a clinical trial needed considerable persuasiveness and logistic efforts. We would like to thank the patients who took the time to complete the questionnaires, the data managers, nurses and surgeons who took care of this study in the centres, Heidi Gusset for central data management, and Brigitte van Wegberg for trial coordination at the beginning.

Appendix. Assessment of subjective health status

	Subjective health status assessment	
	Surgery	Adjuvant phase
Pre-test	*During the past week:*	*During the past week:*
	Imagine that you would have to live the rest of your life in your condition during the last week. Please indicate how you would rate a life in this condition between perfect health and worst health.	
Then-test	*During the past week before the operation:*	*During the time of about 2 months ago:*
	Imagine that you would have to live the rest of your life in your condition during that time. Please indicate how you would rate a life in this condition between perfect health and worst health.	

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