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SURGICAL ENDOSCOPY and Other Interventional Techniques

Evaluation of quality of life after laparoscopic surgery

Evidence-based guidelines of the European Association for Endoscopic Surgery

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Abstract
Background: Measuring health-related quality of life (QoL) after surgery is essential for decision making by patients, surgeons, and payers. The aim of this consensus conference was twofold. First, it was to determine for which diseases endoscopic surgery results in better postoperative QoL than open surgery. Second, it was to recommend QoL instruments for clinical research.
Methods: An expert panel selected 12 conditions in which QoL and endoscopic surgery are important. For each condition, studies comparing endoscopic and open surgery in terms of QoL were identified. The expert panel reached consensus on the relative benefits of endoscopic surgery and recommended generic and disease-specific QoL instruments for use in clinical research.
Results: Randomized trials indicate that QoL improves earlier after endoscopic than open surgery for gastroesophageal reflux disease (GERD), cholecystolithiasis, colorectal cancer, inguinal hernia, obesity (gastric bypass), and uterine disorders that require hysterectomy. For spleen, prostate, malignant kidney, benign colorectal, and benign non-GERD esophageal diseases, evidence from nonrandomized trials supports the use of laparoscopic surgery. However, many studies failed to collect long-term results, used nonvalidated questionnaires, or measured QoL components only incompletely. The following QoL instruments can be recommended: for benign esophageal and gallbladder disease, the GIQLI or the QOLRAD together with SF-36 or the PGWB; for obesity surgery, the IWQOL-Lite with the SF-36; for colorectal cancer, the FACT-C or the EORTC QLQ-C30/CR38; for inguinal and renal surgery, the

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VAS for pain with the SF-36 (or the EORTC QLQ-C30 in case of malignancy); and after hysterectomy, the SF-36 together with an evaluation of urinary and sexual function.
Conclusions: Laparoscopic surgery provides better postoperative QoL in many clinical situations. Researchers would improve the quality of future studies by using validated QoL instruments such as those recommended here.

When a new procedure or technology is introduced, it is expected to achieve "better" or at least equal results than the more traditional approaches. Classical outcomes for the evaluation of surgical procedures are usually perioperative case fatality, morbidity, recurrence rate, and long-term survival. However, from the patient's point of view, the so-called heuristic endpoints, such as symptom resolution, duration of convalescence, patient satisfaction and well-being, and quality of life (QoL), are at least as important as the "classical" outcomes. Furthermore, although of particular interest to caregivers and payers, they are rarely considered in studies testing the efficacy and effectiveness of new surgical approaches [12].

Minimally invasive (laparoscopic) surgery promised to improve health-related outcomes. The classical outcomes of laparoscopic and open surgery have been extensively compared according to the literature and discussed in the previous consensus development conferences organized by the European Association for Endoscopic Surgery (E.A.E.S) [87]. Approximately 15 years after the first laparoscopic cholecystectomy, it is essential to answer the question of whether laparoscopic surgery, compared to open surgery, improves the patient's QoL.

An evidence-based approach was therefore undertaken to evaluate existing information about different areas of laparoscopic surgery and to assess for which diseases laparoscopic surgery results in better postoperative QoL compared to open surgery. QoL is a multidimensional construct comprising physical, psychological, social, and functional domains [88]. Our second aim was to appraise QoL instruments used in the literature and to give recommendations for their future use in laparoscopic surgery. These recommendations are based on a systematic review combined with a formal consensus development conference (CDC).

Methods

Selection of topics

At the meeting of the scientific committee and the executive board of the E.A.E.S. in Lisbon in June 2002, there was a unanimous vote to implement a mechanism to evaluate QoL after laparoscopic surgery. Topics of interest were selected according to their overall prevalence and the use of laparoscopic surgery as an operative approach: gastroesophageal reflux disease (GERD), achalasia, paraesophageal hernia, obesity, cholecystolithiasis, inguinal hernia, and colorectal spleen, kidney, ovarian, and uterine diseases. In addition, the pediatric aspects of some of these diseases were addressed. The Cologne Group was asked to organize a CDC, according to previously established methodology [86]. For this purpose, the methods of a systematic review and a CDC were combined.

Table 1. The Oxford evidence hierarchy for therapeutic studies. Modified from Sackett et al. [110].

Level of evidence	Study design
1a	Systematic review of RCTs
1b	Individual RCT
1c	All-or-none case series
2a	Systematic review of cohort studies
2b	Individual cohort study
2c	"Outcomes" research
3a	Systematic review of case–control studies
3b	Individual case–control study
4	Case series
5	Expert opinion, bench or animal research

RCT, randomized controlled trial

Literature searches

Under the guidance of a clinical epidemiologist (S.S.), a surgeon with education and experience in evidence-based medicine and systematic reviews (D.K.) performed comprehensive literature searches in Medline, Embase, the Cochrane Library, and other sources. The medical subject headings "Laparoscopy" and "Quality of life" were used. Additionally, Medline was searched using the words "laparosc*," "gynecol*," "urolog*," and "quality of life." The reference lists of obtained articles were also checked. There were no language restrictions. The search was limited to the years 1990–2002. Additionally, abstracts presented at the E.A.E.S. congresses in 2001 and 2002 were searched by hand. If related abstracts were identified, contacts were made with the authors to obtain complete results.

Our primary intention was to identify existing systematic reviews or meta-analyses and relevant randomized controlled trials (RCTs). In the absence of such evidence, we searched for concurrent cohorts (CCHs), externally or historically controlled cohorts population-based outcome studies, and case series. All articles were graded according the hierarchy of evidence defined by Sackett et al. [110], as shown in Table 1. Critical appraisal of papers was carried out as recommended by Muir Gray [84]. Articles were considered relevant if they reported QoL outcomes using standardized or self-developed questionnaires. Multiple publications of the same study were included only once in the review. For each study, the first author, publication year, number of patients analyzed, type of questionnaire, type of procedure, length of follow-up, level of improvement, and characteristics of the control group were extracted.

As the surgical articles were being reviewed, QoL measures that had been employed as outcomes were noted. The focus was on known and standardized generic and disease-specific measures, but "ad hoc" questionnaires and single-item questions were also listed. Generic instruments include health profiles, which describe patient feelings and behaviors on a number of domains, as well as preference or utility measures, which reflect the value people place on specific disease states or outcomes of care, and can incorporate death. These instruments can be used across a wide variety of populations and patient samples with different levels of disease severity to compare either the impact of different diseases or the effectiveness of different approaches to care. Disease-specific measures concentrate on the problems faced by the patient due to the disease and incorporate symptoms. They are known to be responsive to change in patient status. It is common to find that a generic measure and a disease-specific measure are used in a study. Ad hoc questionnaires have often been originally designed for clinical practice and then incorporated in a study as an outcome measure. Questions tend to use different formats and different response sets. Most questions are treated

Table 2. Systematic reviews, meta-analyses (SR/MA), randomized controlled trials (RCT), and concurrent cohorts (CCHs) on quality of life after laparoscopic versus open surgery

Disease/procedure	SR/MA	RCT	CCHs	Total
GERD	—	7	7	14
GERD in childhood	—	—	1	1
Obesity	—	2	—	2
Splenectomy	—	—	1	1
Achalasia	—	—	2	2
Paraesophageal hernia	—	—	1	1
Cholecystolithiasis	—	2	8	10
Colorectal	—	4	3	7
Groin hernia	5	10	1	16
Nephrectomy	—	—	4	4
Hysterectomy	—	5	4	9
Prostatectomy	—	—	1	1

as individual pieces of information, and usually questions are not summed to create overall scores. No data are available on the measurement properties of these instruments: thus, the term ad hoc is applied.

Single-item questions are also used and may ask about symptoms, function, or QoL, but the most frequent request is for patients to estimate the time (weeks or days) from operation to a pain-free state or return to usual activities or to work.

In addition to extracting measures from the literature review, members of the consensus group were asked to provide the names of QoL instruments that they knew or had used. These suggestions were added to the list of measures. All measures were then divided into the four groups defined previously. The generic measures were reviewed in terms of their psychometric or measurement properties, reliability, validity, and responsiveness [116]. Reliability reflects the degree to which a measure is free from random error, and it includes estimates of precision or how well the questions within a scale "hang together" as well as estimates of stability over time. Validity evaluates the degree to which the instrument actually assesses what it is supposed to measure. It determines if the content of the instrument is adequately representative of the construct under study, in this case QoL. It also tests if the measure performs according to theoretical expectations by examining the direction and magnitude of relationships with other variables. This is called construct validity. Criterion validity demonstrates the extent to which the measure being reviewed relates to a criterion measure or "gold standard" concurrently or in the future. Finally, responsiveness or the ability to accurately detect chance in patient status over time is determined. All this information was recorded, but we were particularly interested to find out if any of the generic measures had been validated on patient samples of interest to the consensus group. The psychometric properties of the disease-specific instruments were also recorded, and information on content of the ad hoc questionnaires and the single-item questions was added to our files.

Expert panel

For the CDC, the conference organizers in Cologne, together with the scientific committee of the E.A.E.S., nominated a multidisciplinary expert panel. The selection criteria were clinical and scientific expertise in the field of laparoscopy, open surgery, methodology, or QoL assessment, together with a geographical location in Europe. Four months before the conference, a methodologic plan and the results of the initial literature search were sent to the panelists. They were asked to check the literature list for completeness and to answer the following questions regarding QoL after laparoscopic surgery for a given disease:

- What is the patient's major problem at different time points after surgery?
- Which domains of quality of life are affected after surgery?
- Which instruments are useful to evaluate quality of life after surgery?

The answers of the experts regarding the literature were compared with the systematic reviews completed in February and March 2003. As noted previously, the QoL questionnaires used in the literature were critically appraised and compared with the questionnaires recommended by the expert panel. After integration of the existing evidence and recommendations of the experts, the first draft of the CDC guidelines was prepared and sent to the experts at the end of April 2003, along with the rankings of the affected domains that contained the average values for the different time-points.

Members of the expert panel were asked to review the preconsensus material and to attend the CDC in Cologne on May 16th, 2003. At that meeting, comments of the experts and conference organizers were discussed. Disagreements between the experts were resolved through the use of a nominal group process. Initially, 11 topics had been selected. At the Cologne meeting several additional topics were proposed by the expert panel. After discussion and voting it was decided to include radical prostatectomy as one additional topic. Adrenalectomy was proposed but not included because QoL data are sparse for this procedure. Appendectomy was not included because it is an acute illness, in which QoL is not usually affected in the long term. Finally, because there are no QoL data available for laparoscopic adhesiolysis in patients with chronic pain or chronic intestinal obstruction, the panel decided not to include this topic.

For each selected topic, consensus as to the level of evidence of QoL improvement after laparoscopic compared with open surgery was reached. Because there are no existing levels of recommendations for QoL instrument use, this was not done. The suggestions for QoL assessment tools were made according to the appraisals made in Table 4 and the consensus reached during the CDC meeting in Cologne. After the meeting, changes were added to the material and the second draft of the CDC guidelines was produced.

The CDC results were presented in a 1.5-hour session to the attendees of the annual congress of the E.A.E.S. in Glasgow on June 16, 2003. All suggestions made by the audience were discussed by the panelists. The resulting statement was mailed to all the experts for final approval (Delphi process) before publication.

Results

Literature search results

The search of the literature resulted in an initial set of 272 titles. The papers that used QoL questionnaires were selected (154 titles) and sent to the panel. After further articles had been retrieved from the experts, all 182 articles were assessed for study design, clinical relevance, and QoL evaluation. The final list included 67 papers that reported on QoL outcomes after laparoscopic compared to open surgery (Table 2).

Carefully developed and standardized questionnaires were used in 38 papers. Twenty-nine papers used questionnaires developed by the authors without prior psychometric testing (ad hoc questionnaires). The results are presented in Table 3. The number of validated questionnaires exceeds the number of selected papers because some authors used more than one questionnaire. The domains of QoL included in the ad hoc questionnaires are presented in Table 4.

Validation of a measure is never complete. One should ask, "valid for which patient population and in which setting?" Psychometricians advocate that measures be reexamined for their measurement properties, particularly validity, prior to applying them to a new patient population. Measurement studies revalidating the generic measures using appropriate diagnostic patient samples for this CDC were not found. Rather,

Table 3. The use of validated and *ad hoc* questionnaires[a]

Disease/procedure	No. of validated questionnaires		No. of *ad hoc* questionnaires	Total
GERD	9	GIQLI ($n = 2$); Gerd-HRQL; SF-36; Visick ($n = 3$); PGWB ($n = 2$); GSRS ($n = 2$); VAS-reflux; VAS-pain, fatigue; VAS-dysphagia, flatus, bloating	5	14
GERD in childhood	—		1	1
Obesity	1	BAROS	1	2
Splenectomy	1	SF-36	0	1
Achalasia	1	SF-36	1	2
Paraesophageal hernia	1	SF-36	—	1
Cholecystolithiasis	8	GIQLI ($n = 5$), NHP ($n = 2$), VAS ($n = 2$), HADS, SF-36 ($n = 2$), QLI	2	10
Colorectal	4	SDS, QLI; GRS; SF-36 ($n = 2$); GIQLI; BIQ; EORTC QLQ-C30	3	7
Groin hernia	10	SF-36 ($n = 6$); VAS-pain ($n = 6$), SIP, P-o-M; NHP; Kald; LASA, EuroQol, LAS-pain	6	16
Nephrectomy	1	PRS, VAS-pain	3	4
Hysterectomy	2	SF-36, EuroQol	7	9
Prostatectomy	1	EORTC prostate cancer QoL, IIEF-5, ICS_{male}	0	1

[a] Numbers refer to the number of studies, even if one study used more than one questionnaire. Abbreviations are defined in the text and in the footnote to Table 5

Table 4. Ad hoc questionnaires and domains covered[a]

	No. of studies	Physical	Psychological	Social relations	Functional capacity
GERD	5	[5, 20, 66, 103 106]	[20, 66, 103 106]	[103, 106]	[103, 106]
GERD in childhood	1	[75]		[75]	[75]
Obesity	1	[144]	[144]	[144]	[144]
Splenectomy	—				
Achalasia	1	[24]	[24]	[24]	[24]
Paraesophageal hernia	—				
Cholecystolithlosis	2	[56, 111]	[56, 111]	[56, 111]	[56, 111]
Colorectal	2	[71, 97]	[97]	[13, 71, 97]	[13, 71, 97]
Groin hernia	6	[18, 21, 77 112, 113, 125]	[113, 125]	[18, 21, 77 112, 113, 125]	[18, 21, 77 112, 113, 125]
Nephrectomy	3	[3, 43, 78]		[43, 78]	[43, 78]
Hysterectomy	7	[31, 39, 59, 89 101, 114, 118]	[31, 39, 89 101, 114]	[31, 39, 59, 89, 101, 114, 118]	[31, 39, 59, 89 101, 114, 118]
Prostatectomy	—				

[a] The numbers in brackets represent the references that report on particular domains

investigators relied on information from patients with other diagnoses and used the measures. This leap of faith is often made in clinical research. It is probably reasonable since all the generic instruments have been extensively tested for reliability, validity, and responsiveness to change on a variety of patient samples. This statement pertains to the Short Form (SF)-36 [138], Quality of Life Index [119], Sickness Impact Profile [8], Nottingham Health Profile [50], EuroQol [34], Psychological General Well-Being Index [29], Hospital Anxiety and Depression Scale (HADS) [147], Linear Analogue Self Assessment (LASA) [22] scales, and, to a lesser extent, the Health and Activity Limitation Index, which is relatively new [32].

Information about the content, mode of administration, scoring, and psychometric properties of the specific instruments is presented in Table 5. In addition, one investigator used a battery of standardized measures to capture QoL of people with inguinal hernia repair [41], and other investigators used the Visick Classification [94, 96, 102], which is very old and not well validated but traditionally accepted by the surgical community.

A number of investigators in each surgical area used ad hoc questionnaires or individual questions related to symptoms or QoL variables. Items in the ad hoc questionnaires were of interest to surgeons and often reflected the recovery of the patients postoperatively as well as their satisfaction with the surgery. Each item in the questionnaire was treated statistically as a unique piece of information; item scores (if present) were not summed. Items were compared by surgical group (i.e., open laparoscopic surgery).

Other investigators asked individual questions. Sometimes, questions were scaled in terms of response categories (i.e., no, mild, moderate, or severe pain), but

Table 5. Condition-specific measures of quality of life in related literature

	Gastrointestinal					Colorectal					Obesity		Groin hernia	Nephrectomy
Appraisal properties	GIQLI	GSRS	QOLRAD	GERD-HRQL	Achalasia QOL Index	FACT-C	FIQL	BIQ	SDS	EORTC QLQ-C30	IWQOL-lite	BAROS	Pain-O meter (tool)	PRS
Dimensions														
Physical	+		+		+	+	+	+	+	+	+	+		+
Emotional	+		+		+	+	+	+		+	+	+		
Cognitive									+	+				
Social	+		+		+	+	+			+	+	+		+
Symptoms	+	+	+	+		+			+	+		+	+	+
Response format														
Categorical	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Mixed														+
VAS													+	+
Administrative mode														
Self-report	+	+	+	+	+	+	+	+	+	+	+	+		+
Interview		+								+			+	
Caregiver												+		
Scoring														
Subscale scores	+	+	+		+	+	+	+		+	+			
Total score	+	+	+	+		+			+		+		+	+
Classification												+		
Reliability														
Internal consistency	+	+	+			+	+	+	+	+	+			
Test–retest	+	+	+				+				+			+
Validity														
Content	+	+	+	+		+				+	+	+		
Criterion	+										+			
Construct-convergent	+	+	+			+	+	+	+	+	+	+		
Contruct-divergent	+	+	+	+		+	+	+	+	+	+	+		
Factorial								+		+				
Responsivness	+	+	+	+		+		+	+	+	+			+
Estimated time to administer														
< 2 min				+	+									
3–10 min		+	+				+	+	+					
> 10 min	+					+				+	+	+	+	+

GIQLI, Gastrointestinal Quality of life Index [37]; GSRS, Gastrointestinal Symptom Rating Scale [122]; QOLRAD, Quality of Life in Reflux and Dyspepsia Patients [146]; GERD-HRQL, Gastroesophageal Reflux Disease-Health, Related Quality of Life [133]; Achalasia QOL Index [83]; FACT-C, Functional Assessment of Cancer Therapy-Colorectal [135]; FIQL, Fecal Incontinence Quality of Life scale [108]; BIQ, Body Image Questionnaire [28]; SDS, Symptoms Distress Scale [76]; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer [2]; IWQOL-Lite, Impact of Weight on Quality of Life-Lite questionnaire [60]; BAROS, Bariatric Analysis and Reporting Outcome System [92]; Pain-O-Meter [40]; PRS, Postoperative Recovery Scale [136]

most often the patient was asked to report time from operation (in days or weeks) to recovery of full physical activities or to return to usual social activities, to a "normal" lifestyle, to work, or to a pain-free state. Occasionally, patients were asked to provide information on medication use. As with the ad hoc questionnaires, responses between surgical groups were compared.

The answers of the experts were used at the CDC in Cologne when specific time points for QoL instrument application had been suggested. For example, if there were two QoL measures that addressed different domains, we selected the measure that included the clinically more relevant domain.

Gastroesophageal reflux disease

Key points and suggestion for QoL assessment. Laparoscopic fundoplication provides faster improvement of QoL when compared with open fundoplication (EL 1b). Long-term improvement of QoL is not different when compared to open surgery (EL 1b).

For GERD we suggest the use of the SF-36 or the PGWB (generic measures) in addition to the GIQLI and the QOLRAD (disease-specific measures). If the interest is primarily in symptom resolution the GSRS or the GERD-HRQL (symptom scales) are alternatives. Preoperative QoL assessment may be a useful adjunct in clinical decision-making. The suggestion is that the first postoperative evaluation of QoL should be done between 1 and 3 months after surgery and repeated at least at 1 year.

Background and evidence. Seven randomized trials and seven nonrandomized trials compared laparoscopic and open antireflux procedures. When assessing the trials, we did not differentiate between Nissen and Toupet fundoplication. In GERD, more than in other diseases, QoL assessment is very important for patient selection in routine practice. Kamolz et al. [55] have shown that some patient populations, such as those with major depression, showed less QoL improvement than other groups of patients, despite normal physiologic postoperative data.

In one of the seven RCTs, Heikkinen et al. [48, 49] compared laparoscopic and open Nissen fundoplication 1, 3, and 24 months after surgery (1b). They used the Gastrointestinal Quality of Life Index (GIQLI) [37] and a Visual Analogue Scale (VAS) [104] for pain as well as an ad hoc questionnaire on patient satisfaction. The laparoscopic group experienced less postoperative pain and returned earlier to work and normal life. Two years after the surgery, GIQLI scores were significantly improved, compared to preoperative data, but did not differ between the laparoscopic and open groups. In a similar study by Chrysos et al. [20], patients were given an ad hoc questionnaire after laparoscopic and open Nissen fundoplication (1b). Follow-up at 12 months included 106 patients. One year after surgery, the laparoscopic group reported significantly greater postoperative satisfaction when compared with the open group. Laine et al. [66] studied a total of 110 patients over a period of 12 months (1b). They used an ad hoc questionnaire. One year after surgery, all patients in the laparoscopic group and 86% of patients in the open group were satisfied with the operation. The fourth RCT by Bais et al. [5] also compared laparoscopic and open Nissen fundoplication (1b). They analyzed data on 103 patients from an ad hoc questionnaire. The follow-up was 2 years. The primary endpoints were dysphagia, recurrent GERD, and intrathoracic hernia. The laparoscopic group had significantly more patients with dysphagia 3 months after surgery. A further study by Nilsson et al. [91] compared laparoscopic Nissen with open Nissen fundoplication (1b). They used the standardized Psychological General Well-Being Index (PGWB) [29], together with an ad hoc questionnaire developed by the authors. The follow-up was for 6 months and included 60 patients. One and 6 months after surgery, there were no significant differences between the groups with regard to PGWB scores. Six months after surgery, the laparoscopic group reported significantly more sleep disturbances on the ad hoc questionnaire. In another publication from the same study, the authors used the Gastrointestinal Symptom Rating Scale (GSRS) [122] to analyze the differences in QoL between the two surgical approaches [143]. The GSRS scores did not differ between the two groups 1 and 6 months after surgery. Velanovich [130] compared laparoscopic and open Nissen and Toupet fundoplication (2b). The follow-up at 6 weeks used the Gastroesophageal Reflux Disease Health Related Quality-of-Life (GERD-HRQL) [133] questionnaire and the SF-36, the generic QoL instrument developed for the Medical Outcomes Study [138]. There were 80 patients included in the study. The laparoscopic group had better results in the physical functioning scale of the SF-36. The results on the GERD-HRQL (symptoms) scale were not different between the groups.

Among the nonrandomized studies, Peters et al. [96] used the Visick score [134] and an ad hoc questionnaire to compare laparoscopic and open Nissen (2b). The follow-up was 54 months and incorporated 70 patients. There were no significant differences between the two groups. Blomqvist et al. [9] used three standardized scales to compare laparoscopic and open Nissen and Toupet patients (2b). Specifically, they applied the PGWB questionnaire [29], the Gastrointestinal Symptom Rating Scale (GSRS) [122] and a visual analog scale depicting specific reflux-related symptoms (RVAS) [4]. The follow-up was 12 months for the 50 patients enrolled in the study. There were no significant differences in PGWB scales. In the GSRS scale, differences were shown between the two procedures, with more dyspeptic and indigestion symptoms in patients having undergone a laparoscopic Nissen procedure. Rantanen et al. [102] compared laparoscopic and open Nissen groups (2b). Using the Visick scale [134] and VAS [4] for dysphagia, flatus, and bloating, they studied a total of 57 patients. Three years after the operation, there were no differences

between the two groups except for belching ability and temporary dysphagia. Richards et al. [106] compared laparoscopic and open Nissen groups with an ad hoc questionnaire (2b) given to 232 patients over a 3-month period. The laparoscopic group returned to work and reported better general health earlier than the open group. In the study by Rattner and Brocks [103], 86 patients were evaluated over 12 months after laparoscopic and open Nissen fundoplication approaches (2b). The laparoscopic group returned to work earlier than the open group. Overall satisfaction scores as measured with an ad hoc questionnaire were similar, irrespective of the operative technique. Finally, a nonrandomized study reported by Pelgrims et al. [94] compared 210 patients after laparoscopic and open Nissen procedures (2b). One year after surgery, there were no significant differences in Visick scores between the groups.

GERD in childhood

Key points and suggestion for QoL assessment. In children, there is no evidence that laparoscopic antireflux surgery provides different QoL when compared to open antireflux surgery (EL 2b).

For children with GERD we suggest that the use of the Child Health Questionnaire (CHQ) [68] or the Pediatric Quality of Life Inventory (PedsQL) [128] be tried. Both questionnaires are generic and need to be evaluated for this condition. Disease-specific instruments are not available. QoL assessment is suggested 3, 6, and 12 months after surgery.

Background and evidence. In children, many diseases are treated laparoscopically, but only GERD has been evaluated on QoL outcomes. Mattioli et al. [75] compared laparoscopic and open Nissen fundoplication in children aged 1–14 years (2b). Data on 66 children from an ad hoc questionnaire were analyzed. Six months after surgery, there were no differences between the groups in terms of pain relief and ability to play without symptoms. As in adults, the preoperative assessment of QoL is very important for patient selection, and further studies on QoL improvement after laparoscopic pediatric surgery are needed.

Obesity

Key points and suggestion for QoL assessment. Randomized studies comparing open and laparoscopic vertical gastroplasty or gastric banding have not examined QoL. Laparoscopic gastric bypass provides QoL faster improvement of QoL when compared to open gastric bypass (EL 1b), but long-term results are similar (EL 1b).

For obesity surgery, we suggest the use of the SF-36 (generic measure) and the Impact of Weight on Quality of Life (IWQOL-Lite) (disease-specific measure). We recommend QoL evaluations for at least 2 years, but ideally they should be continued lifelong.

Background and evidence. Two randomized trials compared laparoscopic and open gastric bypass for morbid obesity: On a sample of 155 patients, Nguyen et al. [90] used two standardized questionnaires to assess QoL (1b); the SF-36 [138] and the Moorhead–Ardelt quality-of-life questionnaire (BAROS) [92]. One month after surgery, SF-36 scores in four of the eight domains (physical functioning, social functioning, general health, and bodily pain) were significantly better in the laparoscopic group than in the open group. At 3 months after surgery, SF-36 scores in all eight domains had improved in the laparoscopic group and were equal to U.S. norms, although physical functioning was still significantly impaired in the open group. Six months after surgery, SF-36 scores on all eight domains for both the laparoscopic and the open group were comparable with U.S. norms and were not significantly different between the groups. The Moorhead–Ardelt scores (BAROS) for sexual interest/activity at 3 months after surgery were significantly higher after laparoscopic surgery. At 6 months, there were no significant differences in any of the five QoL domains. Weight loss outcomes were comparable between the two groups at 1-year follow-up, but the laparoscopic group had significantly greater weight loss at 3 and 6 months. Westling and Gustavsson [144] administered an ad hoc questionnaire to 51 patients (1b). The laparoscopic group experienced less postoperative pain and shorter sick leave compared to the open group. One year after surgery there were no significant differences between the laparoscopic and open groups in weight loss and patient satisfaction, which was high in both groups.

QoL measurements in morbidly obese patients require long-term observations since weight loss takes time to complete and the incidence of complications, such as incisional hernia or band slippage, does not decrease considerably after the first postoperative year.

Splenectomy for benign diseases

Key points and suggestion for QoL assessment. Laparoscopic splenectomy produces less pain in the early postoperative period compared to open splenectomy (EL 2b).

When splenectomy is undertaken for benign diseases, further information is required to make a recommendation for using the SF-36 (generic) or another instrument. QoL should be evaluated in the early postoperative period.

Background and evidence. Only one nonrandomized study of 44 patients compared QoL results between laparoscopic and open splenectomy. In the study by Velanovich and Shurafa [132], the SF-36 was administered 6 weeks after the operation (2b). The laparoscopic group had significantly better scores in only one of eight domains (bodily pain).

Achalasia

Key points and suggestion for QoL assessment. Laparoscopic Heller myotomy provides faster improvement of QoL when compared with open Heller myotomy (EL 2b).

For achalasia, we suggest the use of the SF-36 or the PGWB (generic measures) in addition to the GIQLI or the QOLRAD (disease-specific measures). If the interest is primarily in symptom resolution, the GSRS or the GERD-HRQL (symptom scales) are alternatives. The suggestion is that the first postoperative evaluation of QoL should be done between 1 and 3 months after surgery and repeated at least at 1 year.

Background and evidence. In achalasia, short-term data are important in comparing results between laparoscopic and open surgery. However, achalasia is a disease that attacks the whole esophagus; therefore, long-term follow-up is more relevant for the patient's outcome. When examining GIQLI scores between 1 and 3 years after surgery, Decker et al. [23] noted a significant deterioration, but in their 40 patients postoperative results were still better than preoperative ones.

Two small nonrandomized studies compared laparoscopic and open Heller myotomy. Katilius and Velanovich [57] used a validated generic questionnaire (SF-36 [138]) to evaluate QoL (2b). Although the study included only 26 patients, they were able to detect significant differences: six weeks after the operation, the laparoscopic group scored better on the subscales reflecting physical functioning, role-physical, and vitality. Dempsey et al. [24] used an ad hoc questionnaire that covered all domains of QoL (2b). The study examined the postoperative course of 22 patients over a 16 month follow-up. The laparoscopic group experienced less postoperative pain and returned to work earlier than the open surgery group. Notably, follow-up length differed between the groups.

Paraesophageal hernia

Key points and suggestion for QoL assessment. Laparoscopic paraesophageal hernia repair provides better QoL when compared to open surgery (EL 2b). Until further data are available, we suggest the same instruments and time shedule for paraesophageal hernia as for GERD.

Background and evidence. Only one study compared laparoscopic and open paraesophageal hernia repair. Velanovich and Karmy-Jones [13] used the SF-36 [138] to evaluate QoL 6 weeks after the procedure (2b). The study included 38 patients. Patients in the laparoscopic group reported better scores in the physical functioning, role-physical, role-emotional, vitality, and social functioning scales. The authors did not report on the long-term QoL scores.

Cholecystolithiasis

Key points and suggestion for QoL assessment. Laparoscopic cholecystectomy improves QoL faster than open surgery (EL 1b). Long-term results after laparoscopic cholecystectomy are slightly better or not different compared to those of open surgery (EL 1b).

The suggestion is to use the SF-36 or the PGWB (generic instrument) in conjunction with the GIQLI (disease-specific instrument). If time and resources are limited, the GIQLI may be used alone because it incorporates all domains of a QoL assessment. Postoperatively, a QoL assessment is suggested at 1 and 6 months.

Background and evidence. Two randomized and eight nonrandomized trials reported on QoL after laparoscopic or open cholecystectomy. Whereas the results on short-term outcomes are homogeneous, long-term data are conflicting.

In a randomized trial of laparoscopic versus open cholecystectomy, Barkun et al. [6] used the Nottingham Health Profile (NHP), the GIQLI, and the VAS for QoL assessment (1b). Using paired analysis, significant improvement in the laparoscopic group was detected as early as 10 days after surgery with the VAS ($p = 0.047$) and at 1 month with the NHP and the GIQLI ($p = 0.0001$). The open group did not show significant improvement until 1 month after surgery with the GIQLI ($p = 0.002$) and until 3 months with the NHP ($p = 0.03$). The extent of improvement in all QoL scores after surgery was similar in both groups. The second randomized trial was performed by McMahon et al. (1b) [81]. QoL results in terms of a modified SF-36 score and the Hospital Anxiety and Depression Scale (HADS [147]) were reported at the 1-, 4-, and 12-week follow-ups. The only significant long-term advantage for laparoscopic surgery was a higher satisfaction rate with the appearance of the scar. As early as 1993, Sanabria et al. (2b [111]) studied 120 patients over an 8-week period after laparoscopic or open cholecystectomy. A significantly faster recovery was found, but at the final evaluation, the patients' answers did not differ when asked to subjectively rate the change in the quality of their lives. In the second nonrandomized trial, Eypasch et al. [36] in 1993 compared QoL after open ($n = 21$) and laparoscopic ($n = 158$) cholecystectomy (2b). The GIQLI, the QOL-Index (QLI) [119], and a VAS were used to assess QoL 2 and 6 weeks after surgery. At both time points, there was a trend toward better QoL in the laparoscopic group. Similar data were reported by Ludwig et al. [113] in a comparative study of 103 patients (2b). The authors modified the GIQLI and found a slightly quicker convalescence after laparoscopic cholecystectomy. However, in the final evaluation 5 weeks after surgery, both groups experienced a similar QoL. In a prospective controlled study of 31 patients, Plaisier [98] reported NHP data for the 3-, 6-, and 12-month intervals after surgery (2b). A significant difference in favor of laparoscopic surgery was found 6 months after cholecystectomy, but this difference vanished after

1 year with the exception of questions related to nausea, stomach swelling, and fatty food avoidance. A study from China also confirmed that GIQLI scores were initially better after laparoscopic cholecystectomy, but Chen et al. [19] did not find any long-term benefit of laparoscopic surgery in their series of 51 patients over 16 weeks (2b). In a large study by Kane et al. (2b) [56], 2,481 patients were mailed a questionnaire 6 months after cholecystectomy. After adjusting for baseline differences, it was found that patients were more likely to perform their usual activities after laparoscopic surgery. There were no differences in pain, symptoms, or general health as measured with an ad hoc questionnaire.

Topcu et al. (2b) [124] performed a retrospective comparative study on 200 patients. Prior to surgery, both groups were comparable, but 4 years after surgery laparoscopically treated patients reported significantly better QoL in all eight domains of the SF-36. In another study, Quintana et al. [99] used the SF-36 and GIQLI to compare laparoscopic and open cholecystectomy (2b). There were 887 patients followed during the first three postoperative months. Additionally, the authors used ad hoc questions that focused on satisfaction with the intervention and the number of days before returning to work and daily activities. No significant differences between the open and laparoscopic groups either in the SF-36 scores or in the GIQLI scores were detected.

The occurrence of a bile duct injury has a significant impact on QoL in the long term. Moreover, the incidence of bile duct injury remains as high as 1.4%. Boerma et al. [10] used the SF-36 to examine QoL 5 years after bile duct injury during laparoscopic cholecystectomy. Despite the excellent objective outcome, QoL was both physically and mentally reduced when compared with controls ($p < 0.05$). In a similar observational study by Melton et al. [82], 89 patients were asked about their QoL after successful surgical repair of a major bile duct injury. However, the QoL instrument used in that study was developed for and validated in cancer patients only. QoL scores of bile duct injured patients were comparable to those of patients undergoing uncomplicated laparoscopic cholecystectomy and healthy controls in the physical and social domains but were significantly worse in the psychological domain.

Colorectal diseases

Colorectal cancer

Key points and suggestion for QoL assessment. Laparoscopic colectomy produces less postoperative pain compared to open colectomy (EL 1b). In the early postoperative period, a higher QoL is reported earlier after laparoscopic than after open colectomy (EL 1b).

For patients with colorectal carcinoma, either the FACT-C or the EORTC QLQ-C30/CR38 will provide comprehensive information about all QoL domains, including symptoms. If fecal incontinence is an issue, the FIQL could be added. Because significant differences have been shown as long as 1 month after surgery but not at 2 months, QoL should be measured at least during the short-term follow-up. Long-term studies are needed.

Background and evidence. Four randomized controlled trials and two nonrandomized trials reported on QoL outcomes in laparoscopic versus open colorectal procedures. Weeks et al. [141] used the Symptoms Distress Scale (SDS [76]), the QLI [119], and the Global Rating Scale (GRS) [126] to study 428 patients over 2 months (1b). The laparoscopic group had significantly better GRS scores 2 weeks after surgery. This group also needed less postoperative analgesics. Two months after surgery there were no significant differences between the laparoscopic and open groups. The second randomized study, by Schwenk et al. [115], used the EORTC QLQ-C30 to compare QoL after laparoscopic or open colorectal resection (1b). One week after surgery, physical and emotional functions were more impaired in the open group ($p < 0.05$). Four weeks after surgery, only physical function differed between the two groups, and after 3 months the differences were no longer detectable. In addition to the QLQ-C30, a disease-specific add-on module, the QLQ-CR38, has been developed and validated by the EORTC [120].

Braga et al. [13] measured early postoperative morbidity in a randomized trial that included 269 patients. They used the time until return to full physical and social activities as a surrogate for QoL. The laparoscopic group recovered after 32 days, compared to 65 days for the open group. Finally, Liang et al. [71] reported on pain and return to partial activity, full activity, and work after laparoscopic or open sigmoid resection for large sigmoid polyps. Despite the small sample size, the authors found that patients in the laparoscopic group had a significantly lower incidence of pain. Return to full functional recovery was measured blindly and was 2 weeks earlier in the laparoscopic group ($p < 0.05$).

Dunker et al. [27] followed 35 patients over a period of 15 months (2b). They used the SF-36, the GIQLI, and the Body Image Questionnaire (BIQ [28]).The laparoscopic group was significantly more often satisfied with the cosmetic result of the operation. There were no significant differences in other QoL scores. Pfeifer et al. [97] used an ad hoc questionnaire to assess QoL in 69 patients undergoing colorectal resection for a variety of diseases, including cancer (2b). There were no significant differences 2 months after surgery. In addition to the previous comments, some experts noted that there are no data on QoL outcomes from randomized controlled trials with total mesorectal excision.

Diverticular disease

Key points and suggestion for QoL assessment. For diverticular disease, laparoscopic and open approaches have similar long-term results in QoL improvement (EL 2b).

For patients with diverticular disease, the SF-36 will provide comprehensive information about QoL. If fecal incontinence is an issue, the FIQL could be added. QoL

should be measured 1 month after surgery and repeated after 12 months. Further studies comparing QoL outcomes after laparoscopic and open surgery are needed.

Background and evidence. There is only one retrospective comparative study on QoL after laparoscopic and open surgery for diverticular disease. Five years after surgery, Roblick et al. [107] asked 45 matched patient pairs to assess their QoL using the SF-36 (2b). No significant differences were found at this late point in time after the surgery. Short or intermediate-term results were not available.

Groin hernia

Key points and suggestion for QoL assessment. Compared to open hernia repair, laparoscopic surgery (TAPP and TEP) improves QoL more quickly (EL 1a). This is also true for bilateral hernia repair (EL 1b). Long-term restoration of QoL is not different (EL 1a).

The SF-36 (generic measure) is suggested as the primary HRQL measure of outcome. In addition, the VAS or a single-item rating of pain is recommended. The status of QoL should be measured after 1 and, at least, 6 and 12 months postoperatively.

Background and evidence. Three meta-analyses, one systematic review, 10 randomized trials, and nonrandomized trial compared QoL outcomes using standardized or ad hoc questionnaires.

The Cochrane review by the European Hernia Trialists was first published in 2000 and updated in 2003 (1a) [77]. The reviewers compared TAPP and TEP with open mesh and nonmesh procedures. As can be expected from the large number of primary trials, the duration and completeness of follow-up varied considerably among the studies. In the meta-analysis, a significant reduction in persisting postoperative pain (overall 290/2101 versus 459/2399; Peto OR = 0.54; 95% CI, 0.46–0.64; $p < 0.0001$) and in sick leave (HR 0.56; 95% CI, 0.51–0.61; $p < 0.0001$; equivalent to 7 days) was found. The other systematic reviews by Chung and Rowland (1a) [21], Cheek et al. (1a) [18], and Schmedt et al. (1a) [113] gave very similar results since they mainly included the same primary studies.

Among these primary RCTs, the study by Lawrence et al. [69] was one of the first that examined QoL (1b). A linear analogue scale for pain, the SF-36, and the Euroqol (linear analogue section) [34] were used to compare TAPP with Lichtenstein repair in 124 patients. The laparoscopic group had less pain and significantly higher scores in social function and energy by 10 days and at 6 weeks after the operation. When describing later results, 3 and 6 months postoperatively (1b) [70], the SF-36 demonstrated no differences in scores. In a second RCT including 258 patients, Liem et al. [72] used the SF-36 to compare laparoscopic extraperitoneal hernia repair with the Lichtenstein procedure (1b). QoL was better in the laparoscopic group both 1 and 6 weeks after surgery. The differences were significant for physical functioning, role-physical, bodily pain, social functioning. In a smaller third trial of only 53 patients, the Sickness Impact Profile (SIP) [8] and the Pain-o-Meter [40] were applied to compare the 6-week results after TAPP or Lichtenstein repair (1b) [40]. The laparoscopic group had less pain postoperatively and returned to work earlier, but the differences were not significant. Barkun et al. [7] used the Nottingham Health Profile (NHP [50]) and the VAS to compare laparoscopic transabdominal with open tension and nontension repair (1b). Ninety-two patients were followed over 3 months. One month after surgery, the laparoscopic group had better QoL scores on the NHP ($p = 0.035$), but there were no differences in pain.

Another RCT from the United Kingdom by Wellwood et al. [142] used the SF-36 to compare laparoscopic transabdominal with Lichtenstein repair (1b). The follow-up was 3 months and included 392 patients. One month after surgery the laparoscopic group had significantly better SF-36 scores for role-physical, bodily pain, vitality, social functioning, and mental health. At 3 months after surgery there were greater improvements in mean scores from baseline in the laparoscopic group for all scales except general health, but none of these differences reached significance. Tschudi et al. [125] compared laparoscopic abdominal with Shouldice repair (1b). They used an ad hoc questionnaire and followed 84 patients over 5 years. The laparoscopic group had less postoperative pain and returned to work earlier, but at 5 years postsurgery there was only 1 patient in each treatment arm who had persistent pain and impaired capability (not statistically different). In a three-armed RCT, Bringman et al. [15] compared TEP with Lichtenstein and open mesh-plug procedures (1b). There were 294 patients, who were followed for 3 months. They used the questionnaire developed by Kald and Nilsson [54] and the VAS for pain. The laparoscopic group returned to work earlier and had less postoperative pain. Fleming et al. [41] compared TEP and the Shouldice technique after enrolling 232 patients (1b). They employed a battery of standardized measures to assess QoL [22]. The follow-up was 12 months. The laparoscopic group had less postoperative pain and returned to full activity earlier. Sarli et al. [112] used an ad hoc questionnaire to compare bilateral laparoscopic transabdominal repair with bilateral Lichtenstein repair in 43 patients (1b). The laparoscopic group returned to work earlier and had less pain postoperatively. In the long term, at 36 months QoL was similar. Stengel and Lange [121] compared laparoscopic transabdominal with Lichtenstein and Shouldice repair in 269 patients (2b). They used the SF-36 and a VAS for pain and followed patients for 6 months. The laparoscopic group had less pain postoperatively and returned to work earlier than the open group. Jones et al. [53] analyzed return to work in 93 patients operated by one surgical group. In a bivariate analysis they showed that age, educational level, occupation, symptoms of depression, and expected time to work acounted for 61% of the variation in actual return to work. According to this evidence, the expert panel concluded that other factors besides the surgical technique used influence the return to work. To examine the impact of chronic pain and recurrence on QoL, annual

long-term follow-up for 5 years is necessary. The details of different laparoscopic (endoscopic) techniques are beyond the scope of this article.

Nephrectomy for malignancy

Key points and suggestion for QoL assessment. No RCTs on QoL that compared laparoscopic and open nephrectomy either for benign or for malignant disease were identified. Laparoscopic nephrectomy (transabdominal or retroperitoneal) produces less pain in the postoperative period and enables earlier return to normal activities when compared to open surgery (EL 2b).

In addition to the use of a VAS for pain, we tentatively suggest the use of the SF-36 or the EORTC QLQ-C30 (generic measures). This recommendation for the generic measure has no basis in data. Because differences have been shown at 1 year after surgery, measurement of QoL in future trials should be done within this time frame.

Background and evidence. Four nonrandomized trials compared laparoscopic and open nephrectomy with regard to postoperative QoL. McDougall et al. [78] compared radical laparoscopic transabdominal nephrectomy with its open counterpart (2b). Using an ad hoc questionnaire, it was shown in a sample of 24 patients that the laparoscopic group had significantly less postoperative pain. The laparoscopic group returned earlier to normal activities, and full recovery was also reached more rapidly. Gill et al. [43] compared radical laparoscopic (retroperitoneal) with open nephrectomy in 68 patients (2b). They used an ad hoc questionnaire. The laparoscopic group experienced less postoperative pain and returned to normal activities sooner. From a sample of 58 patients, Abbou et al. [3] showed that the laparoscopic (retroperitoneal) group experienced less pain in the postoperative period compared to the open nephrectomy group (2b). In the fourth study, Pace et al. [93] compared laparoscopic (transperitoneal) with open nephrectomy in a series of 61 patients (2b). They used the Postoperative Recovery Scale (PRS), which is based on the acute version of the SF-36 [136]. The laparoscopic group had significantly higher QoL scores at the 1-, 2-, 3-, and 6-month and 1-year postoperative assessments. This indicates a potential long-term benefit of laparoscopic nephrectomy.

Hysterectomy

Key points and suggestion for QoL assessment. Laparoscopic-assisted hysterectomy improves QoL faster than abdominal hysterectomy (EL 1b). Long-term results of QoL status are similar (EL 1b).

For women undergoing a hysterectomy, the SF-36 (generic measure) may be used. Additional standardized questionaires related to urinary and sexual function might be useful. Because differences have been shown at 6 months after surgery, measurement of QoL in future trials should be done at least 6 months.

Background and evidences. Five randomized and four nonrandomized trials compared laparoscopic with open hysterectomy. Ellström et al. [30] administered the SF-36 to 76 patients (1b). Three weeks after operation, the laparoscopic group had significantly better scores in physical functioning, role-physical, bodily pain, and social functioning. At the end of follow-up, 12 weeks after surgery, there were no significant differences between the two patient groups. Lumsden et al. [74] used the Euroqol Health Questionnaire (Euroqol HQ [34]) for 166 hysterectomy patients (1b). The groups were compared 1, 6, and 12 months after surgery, but there were no significant differences in QoL. Schütz et al. [114] used an ad hoc questionnaire for QoL evaluation and the VAS for pain. A total of 35 patients were followed for 12 months (1b). The laparoscopic group had less postoperative pain and reported greater satisfaction with the operation. Falcone et al. [39] studied 48 patients using an ad hoc questionnaire and VASs for pain and activity (1b). Follow-up lasted 6 weeks. The laparoscopic group reported a shorter duration of fatigue and an earlier return to work. Eighty patients, randomized by Raju and Aold [101], were given an ad hoc questionnaire to evaluate return to normal activities over a 6-week postoperative period (1b). Laparoscopic hysterectomy with adnexectomy as opposed to open hysterectomy with adnexectomy resulted in an earlier return to normal activities.

In a similarly designed but nonrandomized study of 30 patients, Spirtos et al. [118] compared laparoscopic with open hysterectomy (2b). They used an ad hoc questionnaire to monitor the recovery of women over 17 weeks. Return to normal activity occurred earlier in the laparoscopic group. An ad hoc questionnaire was also used by Kolmorgen et al. [59], who studied 132 women over a 3-month follow-up period (2b). Again, less pain and an earlier return to normal activity were noted. In a small study of only 20 women, Nezhat et al. [89] confirmed that an earlier resumption of normal activities can be achieved by the use of laparoscopic hysterectomy (2b). Follow-up was 6 weeks. In the only study comparing QoL after open and laparoscopic hysterectomy for endometraial carcinoma, Eltabbakh et al. [31] followed 143 patients over a period of 17 months (2b). The laparoscopic group reported higher satisfaction with the procedure and returned earlier to full activity.

Prostatectomy

Key points and suggestion for QoL assessment. Postoperative improvements in QoL are faster after laparoscopic than after open prostatectomy (EL 2b), but long-term results are similar (EL 2b).

Before and after prostatectomy, men should be assessed with the SF-36 or the EORTC QLQ-C30 questionnaire (generic measures). In addition, continence, sexual potency, and voiding symptoms may be evaluated separately, or they may be evaluated jointly with the new EORTC prostate-specific module. All QoL measurements should be done at least during the first 6 months.

Background and evidence. Only one nonrandomized trail has compared laparoscopic with open prostatectomy with regard to QoL: Hara et al. [47] found no differences in QoL 6 months after surgery, but patient satisfaction was higher after laparoscopic surgery (2b). This study used a prostate-specific QoL questionnaire, which was under development by the EORTC. As symptom-specific instruments, the International Index of Erectile Function 5 (IIEF-5) and the International Continence Society Male (ICS_{male}) questionnaire were used to evaluate urinary and erectile function. Both instruments have been validated [26, 109]. Currently, the disease-specific EORTC module, the QLQ-PR25, is being tested for validity and reliability.

Discussion

The scope of this CDC was broad since we wanted to evaluate QoL after laparoscopic compared to open surgery for many different conditions. We have tried to include the most important diseases in laparoscopic surgery, for which evidence on QoL assessment is available. Although there are a large number of studies reporting QoL after laparoscopic surgery, only one-third have compared laparoscopic with open surgery.

Here we provide some general remarks on QoL assessment in clinical and research settings. First, it should be kept in mind that no single QoL measure is ideal for all diseases or patient groups or settings. This implies that all instruments must be checked carefully for the psychometric properties in the context of endoscopic surgery. Occasionally, it may be necessary to extend existing instruments to fit the scope of a specific clinical problem or patient group, but only the reporting of standard measures allows readers to compare results across studies. Any modification of existing measures requires a new validation of the new measure. Second, it is often recommended to combine a generic instrument and a disease-specific instrument. For most diseases, the generic instruments have lower responsiveness compared to specific ones [145], but the generic measures are useful to compare the patient cohort against cohorts with other diseases or with the normal population. Third, the proof of superior QoL after one type of surgery is a strong but not a sufficient argument to use this type of surgery. Although QoL is a broad construct, it does not necessarily include all aspects that are relevant for clinical decision making. Therefore, we did not use grades of recommendations for the key statements.

With regard to choosing a QoL instrument, there is no hierarchy for grading the quality of QoL assessment tools. Since the different psychometric properties of an instrument are not a unidimensional issue, the choice of an instrument depends on the various practical and theoretical aspects of a study. Some projects on the development of such classifications are in progress and are the focus of experts in that field. A further methodologic problem is the difference between choosing a valid study design and a valid outcome measure: We think that a RCT should not automatically be considered high-level evidence, if the study does not report clinically relevant outcomes such as QoL via the use of standardized measures.

The overall quality of QoL research in endoscopic surgery compares well with other fields. In 1989, Guyatt et al. [46] found that less than half the RCTs in major journals examined QoL as an outcome, and two-thirds of these QoL measures had not been validated. Similarly, Gill and Feinstein [44] criticized that most clinical studies of QoL failed to define QoL, lacked a reliable QoL measure, and mixed up symptom checklists, proxy outcomes, QoL, and health-related QoL measures. Nevertheless, surgical researchers should increase the use of QoL measures in clinical trials. Since many validated instruments are obtainable free of charge from the primary investigators, there are no real obstacles to conduction more patient-centered research. For the well-known general instruments, further information can be found on the Internet.

Again, the importance of QoL assessment in laparoscopic surgery should be noted. QoL as an outcome is much more important to the patient than, for example, laboratory values and other traditional clinical endpoints. After biliary duct injury and successful repair of the injury, patients can have normal laboratory findings but permanently impaired QoL [45, 82]. This reinforces the question as to whether we are measuring what is relevant for the patients. Furthermore, the experts pointed out the importance of the preoperative QoL assessment for patient selection for laparoscopic surgery in specific diseases. This is especially true for GERD, for example, when deciding on surgery for depressed patients [55].

Evidence on QoL after laparoscopic compared to open surgery reported in this article represents all relevant data regarding this issue. Suggestions made for QoL assessment in different conditions are universal and can be used in every European country. We believe that the use of these suggestions will increase the quality of care in everyday practice as well as the quality of research. Implementation strategies and the evaluation of the impact of these guidelines need further discussion and will present a basis for further research.

Appendix: information on recommended measures

Child Health Questionnaire (CHQ)

The CHQ, designed to measure the physical and psychological well-being of children 5 years or older, has several forms related to the age of the child and who completes the questionnaire [67]. There are three parent forms and a form to be completed by children aged 10 years or older (87 items). The questionnaires tap 14 concepts related to health and well-being. Item responses are on 4- to 6-point scales. Scale scores are transformed to range from 0 to 100. Higher scores reflect better health. Physical and psychological summary measures can be calculated. In addition to self-comple-

tion by child or parent, the forms may be administered in person or over the phone.

Psychometric performance is adequate in terms of internal consistency and test–retest reliability as well as content, criterion, and construct validity [67, 95, 139, 140]. the measure has been translated, adapted, and revalidated for use in a number of countries [68]. To obtain a manual and the questionnaire, contact J.M. Landgraf (Fax: 617-375-7801).

European Organization for Research and Treatment of Cancer (EORTC)

The EORTC is a cancer-specific questionnaire that has a core component to be used in conjunction with one of a number of modules reflecting different sites of cancer [1, 2]. The core questionnaire EORTC QLQ-C30 contains 30 items that form seven subscales: physical functioning, role functioning, common physical symptoms of cancer and its treatment, emotional functioning, role functioning, financial impact, and overall perceived health status and global QoL. Most items are scored on a 4-point scale ranging from "not at all" to "very much"; the physical and role functioning subscales are scored dichotomously, and the global questions on health status and QoL have been expanded to a 7-point scale. The time frame of the questions is the past week. For the functional and global subscale, a higher score represents a higher QoL, whereas for the symptom subscales the reverse is true. The site-specific modules provide more detailed information on symptoms related to the specific tumor site and may tap additional areas.

A variety of studies attest to the adequate reliability and validity of the questionnaire. In particular, the symptom scales have shown sensitivity to clinical change. The questionnaire was developed by an international group of researchers. In consequence, careful attention was given to ensuring that the questions had a similar meaning across languages and cultures. The modules for colorectal and prostate cancer are forthcoming [120].

Fecal Incontinence Quality of Life (FIQL) scale

The FIQL scale is a symptom-specific measure of QoL developed from input from both patients and caregivers [108]. It is composed of 29 items that form four scales; Lifestyle (10), Coping/Behavior (9), Depression/Self-Perception (7), and Embarrassment (3). Each item has four to six response categories. Scale scores are the mean response to all items in a scale. A total score was not calculated by the developer, but one has been used by Jess and colleagues [52].

Confirmatory factor analysis supported use of four scales. Internal consistency estimates were 0.80 or greater for each scale. Mean scale scores of a test–retest situation were not significantly different, but agreement was not measured directly. Each scale was able to differentiate between a group of individuals with fecal incontinence and patients with other gastrointestinal problems. Convergent validity was demonstrated by significant correlations with selected scales of the SF-36. A Danish version of the measure has been developed, and the psychometric evaluation of this version produced results similar to those of the developers except that total scores were included [52]. The measure is included as an appendix in the original article [108].

Functional Assessment of Cancer Therapy (FACT)

The FACT-G is a general measure of QoL for use with people who have cancer. It is the core instrument of the measurement system [16, 17]. FACT-G contains 29 items that constitute five subscales: physical well-being, social/family well-being, relationship with doctor, emotional well-being, and functional well-being. Items are scored on a 5-point scale and summed to provide subscale and total scores. The five subscales are included in the site-specific scales, and each has an additional subscale containing items related to the cancer, its symptoms, or its treatment. A number of site-specific scales, including the FACT-C (colorectal) [135] and the FACT-P (prostate), [33] are available.

Extensive documentation exists on the psychometric properties of FACT-G and its various versions. A manual is available [16] and the scales have been translated and adapted for use in different countries and cultures [11]. For information about using the measurement system, see www.facit.org.

Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL)

The GERD-HRQL is a measure of symptom severity for use with individuals who have GERD [130, 133]. Ten common and distressing symptoms are listed. The first six are ordered in terms of their relative annoyance to patients. Each symptom is rated on a 6-point categorical scale that ranges from 0 (no symptoms) to 5 (symptoms are incapacitating—unable to do daily activities). The overall score is from 0 to 50, but there is an additional question asking about satisfaction with the patient's "present condition."

No data were found on test–retest reliability, but the developers reported evidence supporting construct validity and responsiveness to clinical change. When patients were grouped according to their level of satisfaction with their present condition, the median scores discriminated between those who were satisfied and those who were not. Sensitivity to the effects of both medical and surgical treatment provided preliminary evidence of responsiveness. A copy of the scale is provided in the article by Valanovich [130].

Gastrointestinal Quality of Life Index (GIQLI)

The GIQLI is a self-reported, system-specific measure designed for use with people who have different gastrointestinal disorders [35, 37, 38]. The 36 items, re-

flecting physical, emotional, and social function as well as typical gastrointestinal symptoms, are each scored on a 5-point scale. Items are summed to produce a total score ranging from 0 to 176, with higher scores denoting better QoL. The measure was developed in German and English. French and Spanish GIQLI versions have been validated [100, 117].

A comprehensive process of development assured content validity. The internal consistency estimates were high, suggesting that the measure reflects an underlying dimension, QoL. Test–retest reliability was demonstrated in clinically stable patients (ICC = 0.92). Correlations between the GIQLI and appropriate measures supported construct validity. Scores on the measure were also able to differentiate groups of gastrointestinal patients with different levels of function, as well as between those with gastrointestinal disease and those who were ostensibly normal. Responsiveness is obviously highest in gastroesophageal disorders, but the GIQLI has also been used with variable responsiveness in other abdominal operations [14, 19, 42, 65, 73]. The GIQLI is available on the Quality of Life Database developed by the nonprofit Mapi Research Institute. This database can be found at www.qolid.org.

Gastrointestinal Symptom Rating Scale (GSRS)

The GSRS is a clinical symptom rating scale originally designed for patients with irritable bowel syndrome and peptic ulcer disease [122]. It has subsequently been evaluated in patients with GERD [105, 123]. GSRS for use with GERD patients contains 15 items, each assessed on a 1 to 7-point scale, with 7 representing extreme discomfort. The items combine into five syndromes labeled reflux, abdominal pain, indigestion, diarrhea, and constipation. Mean scores are calculated from the items in each syndrome. The measure may be administered as a self-report or by an interviewer. The GSRS has been used in UK, Scandinavian, and U.S. populations. It demonstrates acceptable reliability, both internal consistency and stability, evidence of construct and discriminative validity, as well as responsiveness to change. A copy of the U.S. version of the GSRS is included in the article by Revicki and colleagues [105].

Impact of Weight on Quality of Life (IWQOL)-Lite

The IWQOL-Lite is a 31-item version of its parent instrument, the Impact of Weight on Quality of Life (IWQOL) questionnaire [63, 64]. Data collected from 996 obese patients and controls were used to develop the shorter measure [61]. Items were selected by predefined criteria. The items are divided among five scales: physical function (11), self-esteem (7), public distress (5), sexual life (4), and work (4). Each item is scored on a 5-point scale (always true—never true). Lower scores indicate higher QoL. Exploratory factor analysis supported the scale structure.

Based on data from the cross-validation sample (n = 991), individual scales and the total IWQOL-Lite questionnaire demonstrated strong measurement properties. Confirmatory factor analyses confirmed the adequacy of the scale structure. Internal consistency coefficients (alphas) ranged from 0.90 to 0.94 across the scales, with an overall alpha coefficient of 0.96. Correlations between appropriate IWQOL-Lite scales and appropriate standardized measures upheld construct validity. The measure also demonstrated the ability to differentiate between adjacent groups of obese individuals. Changes to scales over time correlated with changes in weight, verifying responsiveness to change. According to the authors, the IWQOL-Lite has been translated and pilot-tested for use in 23 countries [62]. To obtain further information, contact R.L. Kolotkin (1004 Norwood Avenue, Durham, NC, USA; e-mail: kolot001@mc.duke.edu).

Pediatric Quality of Life Inventory (PedsQL)

The PedsQL is a generic instrument developed in modular format for measuring health-related QoL in children and adolescents ages 2 to 18 years [128, 129]. The PedsQL 4.0 Generic Core Scales assess functioning in four areas; Physical (8), Emotional (5), Social (5), and School (5). Both parent and child versions of the inventory are available and use different response sets for scoring items. For parents and children ages 8–18, the inventory is generally self-administered, and for children ages 5–7 it is normally interviewer administered. Modules are available for a number of pediatric conditions, including cancer [127]. Higher PedsQL scores indicate better QoL.

The inventory has been extensively tested for reliability and validity. Internal consistency is adequate for group comparisons and the measure correlated moderately with measures of morbidity and illness burden as well as distinguishing between healthy children and those with a variety of acute and chronic illnesses. It is available in English and Spanish. Further information about the PedsQl is available at www.pedsql.org. To order the PedsQL, contact Caroline Anfray at the Mapi Research Institute (canfray@mapi.fr).

Psychological General Well-Being (PSGWB) index

The PSGWB index was developed as a measure of subjective well-being or distress [29]. This self-administered index contains 22 items, reflecting both positive and negative affect. These are divided into six dimensions: anxiety (5), depressed mood (3), positive well-being (4), self-control (3), general health (3), and vitality (4). Each item is scored on a 6-category scale (0–5 or 1–6). The dimension scores combine for a total score ranging from 0–110 or 22–132.

Extensive tests of reliability and validity have been conducted, most often on the original version of the measure that contained 68 items and was referred to as the General Well-Being Schedule. These psychometric tests were carried out in a variety of normal populations and patient samples. Many have been reviewed by Dupuy [29]. Internal consistency estimates have most often been between 0.70 and 0.90, and test–retest relia-

bility coefficients have ranged from moderate to strong. Construct validity has been shown by moderately strong correlations with a number of depression scales. Correlations with stressful life events and the use of health services were lower. Norms for the PSGWB index have been described for the Swedish population [25]. When used in a trial of patients with reflux disease, estimates of internal consistency were above 0.92 and decreased symptoms corresponded to an increase in PGWB scores [91]. Concurrent validity has also been confirmed in a variety of studies [85].

Quality of Life in Reflux and Dyspepsia (QOLRAD) questionnaire

The QOLRAD is a disease-specific QoL questionnaire designed to address the health concerns of people with GERD or dyspepsia [146]. The measure contains 25 items encompassing five domains of importance to patients: emotional distress, sleep disturbance, eating and drinking issues, physical/social functioning, and vitality. Each item is scored on a 7-point scale and domain scores are calculated by averaging the item scores in that domain.

Good reliability in terms of both internal consistence and stability has been reported [123, 146]. Content, convergent, and discriminant validity as well as responsiveness to clinical change have been carefully documented, and results support the use of the measure in clinical studies [123, 146]. The measure was developed in English and French. For information on how to obtain the measure, contact Ingula Wiklund (Quality of Life Research, Astra Hassle AB, SE-431 83 MoIndal, Sweden).

Short Form (SF)-36

The SF-36 is a generic measure of perceived health status that incorporates behavioral functioning, subjective well-being, and perceptions of health by assessing eight health concepts: limitations in physical activities due to health problems, limitations in role activities due to physical health problems, pain, limitations in social activities due to health problems, general mental health, limitations in usual role activities due to, emotional problems, vitality (energy and fatigue), and general health perceptions [138]. The questionnaire is made up of 36 items that are divided into eight scales. The scores on all scales range from 0 to 100, with higher scores reflecting better health. The SF-36 takes 10–15 min to complete. It can be self-administered or used by a trained interviewer in person or over the telephone.

Reliability has been demonstrated, as have content, criterion, and construct validity [58, 79, 80, 138] and responsiveness to clinical change [58]. Recently, a method of scoring two components, physical and mental health, has been developed. Each component has been standardized to have a mean of 50 and a standard deviation of 10 [137]. There is also an acute version of the SF-36 that uses a 1-week recall, making it useful when treatment effects occur rapidly. As part of an international initiative that used a standard protocol, the SF-36 has been translated, culturally adapted, and revalidated in more than 50 languages. Norms for many countries are available [51].

For further information about the SF-36 and instructions for use, visit the SF-36 Web site (www.sf-36.com or www.qlmed.org/mot). The IQOLA Wet site (www.iqola.org) provides information about the international project, and information on the availability of the translations can be found on the SF-36 Web site.

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