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Quality of life after surgery of the alimentary tract

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Abstract

In recent decades, patient-reported outcomes have become important in clinical medicine. Nowadays, health-related quality of life (HRQOL) is considered a primary outcome in many clinical trials, and it is often the major criterion for judging treatment success. At the beginning of the 21st century, morbidity and mortality rates after surgery of the alimentary tract have dropped dramatically and they can no longer be considered the only outcome measures to determine the success of a surgical procedure. QOL can yield a definitely more patient-orientated measure of outcome that provides us with a more formal measure of the patient's judgment and desires, which can influence treatment decisions. Nevertheless, despite a very large number of published papers on HRQOL, there is some skepticism on the value of HRQOL and other patient-related outcomes. Therefore, this topic highlight aims to assess how QOL after surgery of the alimentary tract is covered in the medical literature. Different reviews have analyzed the topic according to different points of view: benign and malignant disease; curative and palliative treatment; open and minimally invasive surgical approach; traditional and newly introduced surgical procedures. This topic highlight does not aim to cover all the possible diseases or different surgical procedures, but it does describe the different approaches in order to give the reader a broad spectrum of analysis of QOL after surgery. This quick overview

could stimulate the reader to form his/her own opinion about how to use this primary outcome measure.

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INTRODUCTION

In recent decades, patient-reported outcomes have become important in clinical medicine. Nowadays, health-related quality of life (HRQOL) is considered a primary outcome in many clinical trials, and it is often the major criterion for judging treatment success^[1]. Evidence of improved QOL life before approving therapeutic interventions is often demanded by regulatory agencies, insurance companies and third-party payers, because many authorities now regard it as a key measurement in clinical trials^[2,3]. However, most of the QOL measures and studies that measure QOL lack a proper definition or conceptualization of what QOL really is^[4]. Despite the explosion of interest in QOL, the consensus regarding its limits or the optimal method for measuring it is somehow still debated^[5].

QOL IN CLINICAL SETTINGS

In 1947, the World Health Organization (WHO) defined health as "a state of complete physical, mental and social

well-being and not merely the absence of disease^[6]. These domains of physical, emotional and social well-being are incorporated by this definition into the concept of QOL^[7]. Although some authors have rejected the romantic/holistic WHO definition^[8], many have used it as the basis for conceptualizing QOL. The notions that QOL should be assessed by or considered from the patient's point of view, that it can fluctuate over time, and that there are cross-cultural differences in how it is defined, have also been accepted. In the literature, health status and QOL are often confused or poorly distinguished, and both terms are used for the instruments that are used to measure them. Defining QOL is difficult because it is an abstract, complex and often highly individualized concept. For these reasons, it is agreed that, in a clinical setting, QOL analysis should be limited to HRQOL. In fact, HRQOL reflects an attempt to restrict the complex concept of QOL to those aspects of life specifically related to individual health, and potentially modified by healthcare^[9]. The paradox is that HRQOL, when assessed in patients, is focused on health (as it is commonly argued in textbooks and journals), but it is rather focused on disease^[5]. Current QOL questionnaires have been developed for and validated with ill people. The psychological predicament and consequently the concept of QOL of ill people might differ considerably from that of healthy or normal people. Specifically, patients have something socially and personally undesirable, namely an illness and the psychological state, thus, questionnaire responses can be affected by the patients' abnormal physiological state^[7].

QOL AFTER SURGERY OF THE ALIMENTARY TRACT

Why could be it useful to measure QOL after surgery of the alimentary tract? As clearly and exhaustively explained by McLeod in 1999, the traditional outcome measures for assessing the outcome of a surgical procedure have been morbidity and mortality^[5]. During the 20th century these measures were appropriate because most gastrointestinal surgical procedures were associated with high complication and operative mortality rates^[5]. Thus, survival was of utmost importance in assessing the success of a surgical procedure, and consequently, the decision to adopt an operative technique was largely based on operative mortality and long-term survival^[5]. At the beginning of the 21st century, operative mortality rates have dropped dramatically, and fortunately, this parameter has become of limited use as an outcome measure to discriminate between two surgical techniques, or determine the value of a surgical technique as compared with medical therapy^[5]. Therefore, morbidity and mortality can no longer be considered the only outcome measure and alternative ones should be adopted.

PHYSIOLOGICAL PARAMETERS AND QOL

Physiological parameters can be adopted and compared to discriminate between two surgical techniques. However,

measuring QOL can yield a definitely more patient-oriented measure of outcome that provides us with a more formal measure of the patient's judgment and desires, which can influence treatment decisions. In fact, although physiological outcomes are easier to measure, they might not necessarily correlate with patients' perception of their status^[5]. Clinical experience suggests that some patients rate their overall QOL as quite good when they are clearly very ill. In aggregate patient samples, regression analyses have shown that objective health variables and self-reported health variables do not fully explain the variance of global QOL^[10,11]. In one of our studies that has focused on QOL in patients with Crohn's disease, who underwent ileo-colonic resection, the main predictor of HRQOL after surgery was clinical and surgical recurrence, but the variability of the HRQOL score explained by these two clinical parameter was relatively low^[12]. In fact, physiological outcomes provide information to the clinicians but are of limited interest to patients, and often correlate poorly with well-being. Furthermore, even though two patients might be in the same state of health, their perceptions of their QOL can be different. After reconstructive surgery for ulcerative colitis, for example, surgeons usually assess outcome in terms of stool frequency^[13]. However, evidence suggests that these physiological parameters do not always correlate with patients' perceived QOL and satisfaction with the outcome of their surgery^[5]. In fact, several complex indexes have been developed to assess function or disease activity but measurement of functional status alone is of limited value. In fact, not only the physical domain is involved in the patient's well-being, but also the psychosocial domain might have an impact on QOL. A famous example is the work of Brickman *et al*^[14], who have shown that, after an adaptation period of 1 year, paraplegic accident victims and lottery winners reported practically the same level of overall well-being; a phenomenon known as the well-being paradox. Apparently, an overall judgment of QOL includes not only physical and psychosocial components, but also a component of coping^[15].

LIMITS OF QOL MEASUREMENT

QOL analysis can have its limits. Despite a very large number of published papers on HRQOL, there is some skepticism on the value of HRQOL and other patient-related outcomes^[16]. In fact, very often, the intrinsic characteristics of the questionnaires (reliability, validity *etc.*) are well defined criteria, and no recommendations are made about interpretation of HRQOL results; especially regarding the clinical significance of a change in HRQOL that leads to a therapeutic approach. Furthermore, although some scientific societies have created working groups to debate the role of HRQOL in clinical research, the true value of HRQOL evaluations in clinical trials has not yet been completely defined^[17]. Moreover, different questionnaire can lead to different results with the same subset of patients^[18]. In the clinical setting, this intrinsic subjectivity has been always regarded with suspicion and skepticism that is exemplified by a comment made by Wulff: "Scientists

may use rating scales and visual analogue scales to measure pain, and they may even invent scoring systems quantifying types of handicaps; but when they talk about measuring quality of life they have gone too far"^[19]. This statement reflects a model of medicine and human experience in which objective facts are clearly distinguished from subjective values^[19]. Nevertheless, in our opinion, QOL analysis is an extremely powerful instrument to evaluate the outcome of patients that can give unexpected and important insight about how patients cope with surgery. At the same time, it is also a delicate tool that should be handled with care and it should not be abused. Conclusions should be drawn only after a careful choice of questionnaires and after adequate analysis of the results and the literature.

AIM OF THE TOPIC HIGHLIGHT

By taking these precautions into account, analysis of QOL after surgery of the alimentary tract is mandatory if we want to answer correctly the main questions that patients ask when they are about to undergo surgery: "How will I feel after the operation; what will my life be like?" These sorts of questions are even more important if surgery is proposed for patients who have experienced failure of medical therapy. Therefore, this topic highlight aims to analyze patient-related outcomes of surgery of the alimentary tract with a specific focus on postoperative QOL.

OUTLINE OF TOPIC HIGHLIGHT

The first review from the University of Padova, Italy, has analyzed the impact of surgery for diverticular disease on HRQOL^[20]. Various studies have suggested that diverticular disease has a negative impact on HRQOL, which affects bowel function and general health. Nevertheless, several studies have observed a significant improvement in QOL and, in particular, of the social function domain following elective sigmoid resection in the majority of patients^[20]. However, both surgery-related complications and disease activity have a significant impact on patients' HRQOL^[20]. Finally, no significant differences in HRQOL between different laparoscopic and open colectomy procedures for diverticular disease were revealed in the non-randomized population. On the contrary, the only prospective, double-blind randomized study that has compared laparoscopic and open colectomy has found that laparoscopic colectomy seemed to reduce major postoperative complication rates and achieved better HRQOL scores.

The second review was a systematic review from the University of Amsterdam, The Netherlands, which aimed to examine the latest evidence of QOL in patients after laparoscopic or open colorectal surgery. The clinical heterogeneity among the included studies limited the possibility of performing a proper meta-analysis of the data. In fact, virtually every study used different QOL instruments and did not present exact data. Furthermore, the recruited patients were treated for a range of different disorders. Therefore, it was impossible to perform the statistical analyses or a meaningful meta-analysis. Future random-

ized trials that compare open and laparoscopic surgery are needed, and should be well-designed, sufficiently powered, and focus on QOL, particularly shortly after the operation, i.e. within 1 wk, in which time, most of the differences are likely to occur. This systematic review suggests that, when introducing and comparing new surgical procedures, the standardization of questionnaires and the timing should be strongly encouraged^[16].

The third review was from the Venetian Oncology Institute of Padova, Italy, and aimed to assess the long-term HRQOL of patients with esophageal cancer who underwent curative surgery. The HRQOL of these patients was compared to the established norms, and the evolution of HRQOL during follow-up after esophageal resection was described. Even in this case, the clinical heterogeneity limited the possibility of performing a complete meta-analysis of the data. However, the standardization performed by the European Organization for Research and Treatment of Cancer (EORTC) allowed the investigators to overcome this problem, at least partially. In fact, EORTC QLQ30 and optical emission spectrometry 18 were the most commonly used questionnaires. Therefore, although based on low-level evidence from uncontrolled studies, this systematic review showed a trend for improvement of the generic and disease-specific HRQOL in the first 12 mo follow-up after esophageal resection. Nevertheless, in long-term survivors, the pooled physical function, role physical, social function, vitality, and general health perception scores were lower than the general population norms.

The fourth review was from the University of Chicago, United States, and it analyzed the available data in the literature regarding HRQOL in patients with ulcerative colitis or Crohn's disease after surgery. Although these two diseases might have some similarities in their management, clearly their impact on QOL is different. The authors concluded that not a single HRQOL instrument, general or inflammatory bowel disease (IBD)-specific, satisfactorily covers all of the critical criteria of reproducibility, reliability, validity, ease of use, responsiveness to change, and meaningfulness of results. Only by using a combination of general and IBD-specific instruments is it possible to capture and properly evaluate HRQOL prospectively in interventional studies of IBD patients. Only by utilizing the appropriate instruments and by integrating and thoroughly analyzing the results is it possible to capture accurately the complexity of HRQOL in IBD.

The fifth review was from the University of Leuven, Belgium, aimed to evaluate QOL in patients affected by obstructed defecation syndrome (ODS), which is one of the most complex clinical problems in colorectal surgery, who underwent stapled transanal rectal resection. Limited data exist on QOL following this surgical procedure. Therefore, other patient-reported outcomes played a major role: Cleveland Continence Scale obstructed defecation syndrome-score (ODS-score), or a modified ODS score were used, as well as patient satisfaction after the procedure. However, patient satisfaction is a patient-related outcome measure, but it could be greatly influenced by factors such as, the personal relationship between the patient and the

nurse/doctor. For this reason, we agree with Arpinelli and Bamfi^[16], and we believe that patient satisfaction should be considered as a less important indicator than HRQOL.

The sixth review was from the Venetian Oncology Institute of Padova, Italy, and aimed to assess the long-term HRQOL in patients with esophageal cancer who underwent palliative endoscopic surgery. In such a situation, where the indication for treatment is not to improve the survival but to ameliorate poor QOL, it is essential that QOL should be measured to determine whether the therapeutic intervention has been worthwhile^[5].

The seventh review was from the Venetian Oncology Institute of Padova, Italy and the San Giovanni Hospital of Bellinzona, Switzerland, and aimed to investigate the QOL in adults after cholecystectomy. This study revealed that there has been only a limited number of studies that have reported on HRQOL following cholecystectomy, and these studies usually have used generic instruments (i.e. SF-36 and Gastrointestinal Quality of Life). Patients with symptomatic cholelithiasis and low surgical risk achieve the best HRQOL results after laparoscopic cholecystectomy, whereas patients with asymptomatic cholelithiasis or high surgical risk usually do not seem to have the same improvement. HRQOL perception is usually better for those patients who have undergone minimally invasive surgery compared to open surgery. However, there is no validated disease-specific HRQOL questionnaire for use in the context of hepatobiliary or pancreatic disease, and further studies are warranted.

CONCLUSION

In conclusion, this topic highlight aimed to assess how QOL after surgery of the alimentary tract has been covered in the medical literature. Different reviews have analyzed the topic from different points of view: benign and malignant diseases; curative and palliative treatment; open and minimally invasive surgical approaches; and traditional and newly introduced surgical procedures. This topic highlight did not aim to cover all the possible diseases or surgical procedures, but to show different approaches in order to give the reader a broad spectrum of QOL analysis after surgery. This brief overview could stimulate the reader to form his/her own opinion about how to use this primary outcome measure.

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