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Patient-Reported Outcomes

Quality of Life in the First 6 Weeks Following Laparoscopic and Open Colorectal Surgery

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ABSTRACT

Objectives: Evidence of how health-related quality of life (HRQOL) changes following laparoscopic and open colorectal surgery in the first 6 weeks of postoperative recovery is needed to inform cost-effectiveness evaluations. **Methods:** Pragmatic prospective cohort study design. Consecutive patients requiring elective colorectal surgery were allocated to either laparoscopic or open surgery by administrative staff in a district general hospital in England, 2006-2007. Patients completed two validated, generic measures of HRQOL at baseline (preoperatively) and on multiple occasions in the first 6 weeks postsurgery using diaries (EuroQol five-dimensional [EQ-5D] questionnaire: 16 times; short-form 36 health survey [SF-36]: 4 times; HRQOL was compared between groups at each time point, and overall using repeated-measures analysis. **Results:** Of 201 consecutive patients recruited, 32 (15.1%) were unable to complete diaries. Of the remaining 169 patients, 120 (71%) returned completed diaries at 28 days and 105 (62.1%) at 42 days. There was no difference in preoperative HRQOL scores between surgical groups, but the postoperative EQ-5D questionnaire and SF-36 scores were significantly higher in the laparoscopic group (EQ-5D questionnaire $P = 0.005$, SF-36 $P = 0.007$). Subgroup analysis showed that patients with a stoma have worse HRQOL than those without. HRQOL did not differ between the laparoscopic and open stoma patients. **Conclusions:** This study presents unique prospective data demonstrating that laparoscopic surgery confers HRQOL benefits for patients in the early recovery period following colorectal surgery, compared with open surgery. Consideration of these data in the context of a cost-effectiveness analysis will be reported separately.

Keywords: colorectal surgery, costs, laparoscopy, quality of life.

Introduction

Laparoscopic colonic resections were first described in 1991 [1], and since then their clinical efficacy for both cancer and benign conditions has been confirmed by randomized controlled trials [2–4], other studies, and reviews [5–9]. The laparoscopic approach has been shown to have clinical outcomes at least equivalent to those of open surgery, and short-term benefits with reduced blood loss and postoperative pain and a shorter hospital stay.

Health-related quality of life (HRQOL) is an important patient-reported outcome [10], indicating a patient's self-assessment of how his or her state of health affects his or her physical and psychological functioning [11]. Prior work concludes that there is no significant difference between HRQOL outcomes from open and laparoscopic approaches [12–16], but most studies focused on longer term effects (3–12 months [17], 1–2 years [18], several years [19,20] beyond surgery). Of the studies that have researched HRQOL in the early postoperative period, when differences between surgical approaches with respect to HRQOL are potentially greatest, one study found no difference between groups at 2 and 6 weeks within an enhanced recovery program [21], and two (involving patients with colon cancer) report selective benefits in favor of laparoscopy (two at 2 weeks [22,23], one at 4 weeks [22].) A detailed picture of how HRQOL changes throughout the early recovery period cannot be obtained from these three studies, and quality-adjusted life-year (QALY) differences, which are required to inform cost-effectiveness evaluations, were not included.

In the absence of data on QALY differences between laparoscopic and open surgery approaches in the early postoperative period, a health technology appraisal concluded that laparoscopic

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surgery for colorectal cancer would be cost-effective if it generated a QALY gain (compared with open methods) of between 0.009 and 0.010 [15]. The research reported in this article addresses this gap in evidence. It aimed to collect HRQOL measurements from patients following laparoscopic and open colorectal surgery on multiple occasions during the first 6 weeks of postoperative recovery to document changes accurately and compare results between the two surgical groups. It sought to capture any HRQOL benefits that the faster healing following laparoscopic surgery might convey in QALY metrics, as a basis for future cost-effectiveness evaluations of the two approaches, which are required to inform practice guidelines.

Methods

The study was set in a district general hospital in the south of England and used a population representative of patients found in other district general hospitals throughout the British National Health Service. A pragmatic prospective cohort study design was used. Two colorectal teams operate at the study hospital, one using open methods and the other laparoscopic. Patients are referred by their general practitioners, and are allocated to surgical teams by hospital administrative staff, on the basis of the timely availability of appointments with either surgical team or any specific request by the referring general practitioner.

Consecutive patients requiring elective colorectal surgery were recruited to the study between February 2006 and July 2007. All patients with a colorectal condition (including colorectal cancer, polyps, inflammatory bowel disease, diverticular disease, and other benign conditions) were eligible for the study, except those admitted as an emergency, younger than 18 years, with endometriosis, or unable to consent. Surgery in both groups consisted of a resectional procedure (including right hemicolectomy, left hemicolectomy, sigmoid colectomy, anterior resection, abdominoperineal resection, subtotal or proctocolectomy), a pouch procedure, or abdominal rectopexy. Ethical approval and research governance were obtained prior to the commencement of the study from the local Research Ethics Committee and the hospital's Research and Development Committee.

Informed consent was taken, and baseline demographic information (age, sex, body mass index) and HRQOL outcomes were collected by means of patient interview preoperatively. Clinical and operative details were extracted from hospital records and covered American Society of Anesthesiologists (ASA) grade, diagnosis, operation type (right, left, or rectal procedure), and presence of a stoma (or not). The main outcome measure was generic HRQOL. Because the target group was patients receiving major surgery, and the purpose of the study was to collect multiple HRQOL measures during the early recovery period, instruments that were simple and quick to use were required. Two well-validated and widely used generic measures suitable for self-completion were selected. EuroQol five-dimensional (EQ-5D) questionnaire is a short profile measure that is validated for use on a daily basis [24,25]. It has five domains—mobility, self-care, usual activities, pain/discomfort, and anxiety/depression—each scored by respondents according to three levels (no problem, some problem, extreme problem), for which quality weights (to enable calculation of QALYs for use in economic evaluations) are available. Short-form 36 health survey (SF-36) comprises 36 separate items across eight dimensions—physical functioning (10 items), social functioning (2), role limitations due to physical problems (4), role limitations due to emotional problems (3), mental health (5), energy and vitality (4), pain (2), and general perception of health (6)—each of which is transformed to a scale ranging from 0 (worst possible health state) to 100 (best possible) [26]. In addition, an algorithm combines the eight dimensions into physical and mental component summaries (physical component summary [PCS], mental component summary [MCS]). The acute version is validated for weekly use [11], has been translated into many languages [27], and is recommended for the evaluation of patients after laparoscopic and open colorectal surgery [28,29].

Patients were asked to complete the EQ-5D questionnaire on alternate days for 4 weeks, and at the end of weeks 5 and 6 (16 times), while SF-36 scores were taken at the end of weeks 1, 2, 4, and 6 weeks (4 times). Participants were also asked to record when they resumed normal activities (partly and fully), and resumed driving. For the convenience of participants, HRQOL questionnaires were arranged chronologically in a diary covering the first 6 weeks postsurgery.

Analysis

All data were entered into a secure database (SPSS version 12; SPSS, Chicago, IL, USA). Patients were excluded from the analysis if more than 2 (of the 14) EQ-5D questionnaire observations in the first 28 days were missing, and the remaining missing items were estimated by using mean imputation. The data were interrogated as to distribution. Means and SDs were calculated for parametric data (including all HRQOL scores), and median and interquartile range for nonparametric data. Baseline demographic and clinical characteristics of patients in the laparoscopic and open surgery groups were compared by using the chi-square test, the unpaired *t* –test, and the Mann Whitney *U* test, as appropriate. Group mean HRQOL scores were compared between groups at each assessment point, and overall, using a repeated-measures analysis, with adjustment for baseline demographic and patient characteristics (age, sex, ASA grade, diagnosis [cancer vs. not cancer], operation type (right, left, or rectal procedure), stoma [vs. no stoma]). Repeated-measures analyses were also conducted separately for patients with and without a stoma. The analysis was also performed over the full 42-day period (16 observations), although some further participants were lost to follow-up beyond 28 days because of missing data.

Results

Recruitment

Clinical data were available for 201 patients (131, 65.2% in the laparoscopic group). Of these, HRQOL data were not collected for 32 (17.9%), (11 because of dementia, blindness [making self-completion problematic], or other medical problems, 15 missed when the main researcher was away, 6 refused). Among the remaining 169 patients, 49 had more than 2 of the 14 EQ-5D questionnaire observations in the first 28 days missing and were excluded. This left 120 patients in the HRQOL analysis, of which 80 (66.7%) were in the laparoscopic group. Reductions in the clinical sample due to the unavailability of HRQOL data at 28 days were 38.9% for the laparoscopic group (51 of 131) and 42.9% for the open group (30 of 70). Included in the laparoscopic group were one patient who was transferred to the open group before surgery and another patient who was converted to open during the surgery. Fourteen of the remaining participants had one or two missing EQ-5D questionnaire observations in the first 28 days, and these were filled by imputing the means between adjacent readings. At 42 days, there were 105 (52.2% of the clinical sample of 201) patients with HRQOL data available for analysis, of which 71 (67.6%) were in the laparoscopic group.

There were no significant differences with respect to sex, age, body mass index, operative procedure, stoma, readmissions, and