

A cost-utility analysis of laparoscopic vs open colectomy of colorectal cancer in a public hospital of the Greek National Health System

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Summary

Purpose: Laparoscopic colectomy has been reported as a safe and oncologically similar operation to open colectomy. A number of expensive surgical instruments are necessary for the procedure which should be applied if it is cost-effective for the patient and the health system in general. The purpose of the current study was the economic evaluation of laparoscopic compared to open colectomy for the treatment of colon cancer in the Greek national health system.

Methods: Fifty patients undergoing open colectomy and 42 undergoing laparoscopic colectomy were enrolled in this case-control study. Length of hospital stay, duration of operation, complication rates, cost of equipment used, total costs and three questionnaires measuring quality of life /QoL (EQ-5D, SF-36 and QLQ-C30) at baseline, 1 and 3 months after the operation were recorded.

Results: No statistically significant difference in QoL measured by QALYs between laparoscopic and open colectomy was observed. On the other hand, cost utility analysis revealed that laparoscopic colectomy was more expensive considering the advantages it offers.

Conclusions: Laparoscopic colectomy is not superior to open colectomy on a QoL basis in the Greek public hospital system and is less cost-effective compared to the open procedure. Since the expensive equipment used in laparoscopic colectomy seems to be the causative factor for the high cost of this type of operation, an effort should be made to reduce it either by using reusable instruments or by implementing policies aiming at suppliers cutting down equipment charges.

Key words: colon cancer, cost utility analysis, health related quality of life, laparoscopic colectomy, open colectomy

Introduction

The implementation of new surgical procedures applying advanced technology may result in an increase of treatment direct and indirect costs. Taking into account that health resources are limited, it is extremely important to evaluate the cost of such techniques according to the effectiveness/advantages they provide.

Laparoscopic operations are being increasingly used for the treatment of many diseases. During the 90's laparoscopic cholecystectomy became the treatment of choice for gallbladder diseases since the increased cost of the necessary surgical equipment for the operation was far outweighed by the fast recovery, less pain and optimal cosmesis of the patients. The tremendous success of laparoscopic cholecystectomy along with the flood of new technology into general surgery, stimulated surgeons to apply laparoscopic techniques to treat other gastrointestinal diseases.

Laparoscopic colectomy is already being performed during the last two decades and its advantages include reduced postoperative ileus and disability as well as improved cosmesis and shorter hospitalization. On the other hand, these benefits come at the cost of prolonged operative time and associated expense. In addition, surgeons who perform these operations need more advanced laparoscopic skills and training [1].

Moreover, several controversial issues surround the application of laparoscopic techniques to colonic surgery. The biggest and potentially most severe issue concerns the appropriateness of laparoscopic colectomy for malignancy. The present standard of care dictates that generous mesenteric lymphadenectomy be performed when resecting a carcinoma. Resection through the laparoscope was initially thought to entail a less extensive lymphadenectomy, and thus concerns regarding the adequacy of laparoscopic colon resection for carcinoma have arisen. Recently, a randomized controlled trial has shown no significant difference in recurrence rate between laparoscopic and open surgery for colorectal cancer [2].

Laparoscopic colectomy represents the main minimal invasive technique applied in order to decrease the morbidity associated with colorectal procedures. It is a technically demanding procedure and requires

expensive laparoscopic equipment. Thus, it is crucial to determine whether its benefits compensate for the higher cost of the procedure.

In the present single-center case-control study we aimed at investigating the cost of laparoscopic colectomy as well as its impact on QoL and to compare these parameters with the ones of the classic open colectomy in the context of the Greek national health system.

Methods

Patients

For a period of 10 months, adult patients admitted to our department for colorectal cancer were assessed for study eligibility. A total of 92 patients with colorectal cancer were assigned in the present study.

The study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and was therefore approved by the hospital's ethics committee. All patients gave informed consent prior to study inclusion. Each patient had preoperative histological proof of cancer and was subjected to preoperative staging with abdominal CT scan. Elective colectomy was performed by a surgical team experienced in laparoscopic (>50 previous laparoscopic resections) as well as open colorectal surgery. Exclusion criteria included intestinal obstruction, concurrent infection, tumors located at the transverse colon, tumors invading adjacent anatomical structures and distant metastases. Forty-two patients underwent laparoscopic colectomy and were compared with 50 patients undergoing open resection at the same time period. The type of resection (laparoscopic or open) was based upon patient's decision.

Data recorded for each patient included age, sex, history of smoking, previous abdominal operations, diabetes, hypertension, chronic obstructive pulmonary disease, coronary artery disease, as well as body mass index, tumor location, performed surgical procedure, length of operation, intra- or post-operative complications, conversion to laparotomy, time to oral intake and length of hospital stay. Patients' demographic and clinical data are shown in Table 1.

Laparoscopic and open colorectal procedures

Table 1. Demographic, clinical and operative parameters of patients with colorectal cancer that underwent open or laparoscopic colectomy

| Parameters | Open colectomy | Laparoscopic colectomy | p-value |
|-------------------------------|------------------|------------------------|---------|
| | (N=50) N (%) | (N=42) N (%) | |
| Gender | | | 0.1 |
| Male | 30 (60) | 18 (42.9) | |
| Female | 20 (40) | 24 (57.1) | |
| Diabetes mellitus | | | 0.03 |
| Yes | 14 (28) | 4 (9.5) | |
| No | 36 (72) | 38 (90.5) | |
| Hypertension | | | 0.126 |
| Yes | 16 (32) | 20 (47.6) | |
| No | 34 (68) | 22 (52.4) | |
| Coronary artery disease | | | 0.684 |
| Yes | 4 (8) | 2 (4.8) | |
| No | 46 (92) | 40 (95.2) | |
| Chronic lung disease | | | 0.122 |
| Yes | 4 (8) | 0 (0) | |
| No | 46 (92) | 42 (100) | |
| Smoking | | | 0.304 |
| Yes | 14 (28) | 16 (38.1) | |
| No | 36 (72) | 26 (61.9) | |
| Previous abdominal operation | | | 0.043 |
| Yes | 18 (36) | 24 (57.1) | |
| No | 32 (64) | 18 (42.9) | |
| Tumor location | | | 0.813 |
| Right colon | 10 (20) | 10 (23.8) | |
| Sigmoid colon | 28 (56) | 24 (57.1) | |
| Rectum | 12 (24) | 8 (19.1) | |
| Type of surgical procedure | | | 0.886 |
| Right hemicolectomy | 10 (20) | 10 (23.8) | |
| Sigmoidectomy | 24 (48) | 20 (47.6) | |
| Low anterior resection | 16 (32) | 12 (28.6) | |
| Complications | | | 0.503 |
| Yes | 4 (8) | 6 (14.3) | |
| No | 46 (92) | 36 (85.7) | |
| <i>Quantitative variables</i> | <i>Mean ± SD</i> | <i>Mean ± SD</i> | |
| Age (years) | 71.4 ± 9.9 | 67.8 ± 8.8 | 0.022 |
| Operation time (min) | 145.4 ± 44.4 | 203.8 ± 41.6 | <0.0001 |
| Hospital stay (days) | 9.0 ± 1.6 | 6.5 ± 1.9 | <0.0001 |
| Total cost (€) | 3600 ± 1074 | 5748 ± 1319 | <0.0001 |

were performed according to standard protocols [3]. All patients were treated on a strictly controlled protocol with regard to bowel preparation, antibiotic prophylaxis, blood transfusion criteria, analgesic administration, feeding and postoperative care. Patients were discharged after meeting the following criteria:

passage of flatus, tolerance of oral food intake and absence of pyrexia.

Calculation of costs

Cost details were collected for each patient from the day of admission to the day of discharge. Cost analysis

Table 2. Multivariate analysis of open vs laparoscopic colectomy adjusted for patients' demographics, medical history and intra- and post-operative parameters

| Variables | OR (95% CI) | p-value |
|----------------------|--------------------------|---------|
| Operation time (min) | 1.06 (1.02 – 1.09) | 0 |
| Hospital stay (days) | 0.30 (0.16 – 0.57) | <0.001 |
| Total cost (€) | 1.0016 (1.0007 – 1.0025) | 1.0 |

OR: odds ratio, CI: confidence interval

Table 3. QALYs measured by EQ-5D and SF-36 questionnaires correlated with the type of operation

| Type of operation | QALYs (EQ-5D) | | QALYs (SF-6D) | |
|-------------------|---------------|---------|---------------|---------|
| | Mean ± SD | p-value | Mean ± SD | p-value |
| Open | 0.161 ± 0.095 | | 0.192 ± 0.036 | |
| Laparoscopic | 0.167 ± 0.071 | 0.969 | 0.191 ± 0.032 | 0.702 |

Table 4. Total cost (€) of open and laparoscopic colectomy

| Type of operation | Total cost (mean ± SD) | p-value |
|-------------------|------------------------|---------|
| Open | 3600 ± 1074 | |
| Laparoscopic | 5748 ± 1319 | <0.001 |

incorporated cost of surgical ward stay, cost of theatre time and specific equipment costs. Overall costs were calculated by adding costs of possible readmissions and reoperations. It should be stated that all specifically laparoscopic equipment used was disposable.

Quality of life measures

Preference-based measures of health have become an important set of instruments for estimating the health state values used to calculate quality adjusted life years (QALYs) and are widely used in economic evaluations alongside clinical trials to value the benefits of health care. QALYs are used in cost-utility analysis to calculate the ratio of cost to QALYs saved for a particular health care intervention.

The European Association for Endoscopic Surgery has recently proposed validated QoL instruments to be used in clinical studies [4]. These include Short-Form 36 (SF36) and the European Organization for Research and Treatment of Cancer (EORTC QLQ-C30) that were used in the present study. The 3rd instrument selected to measure postoperative QoL was the EuroQoL EQ-5D questionnaire.

Short-Form 36 Health Status Survey (SF-36)

The SF-36 is a multi-purpose, short-form health survey with only 36 questions. It consists of 8 scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The 8 sections are: vitality, physical functioning, body pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health.

In 2002 a very promising approach to scoring the SF-36 was reported [5]. It is a preference-based health utility index, labelled SF-6D, because it uses a 6-domain classification of health states (about 18,000 in all) and is the first preference-based index constructed from a "psychometric" measure of health status. The SF-6D preferences can be applied to any SF-36 dataset for purposes of economic evaluation (e.g., estimation of QALYs).

EuroQoL (EQ-5D)

The EQ-5D instrument was developed by a multidisciplinary group of researchers from seven centres in Finland, the Netherlands, Norway, Sweden and the UK. The 5 dimensions are mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 qualifying levels of response roughly corresponding to 'no problems', 'some difficulties/problems', and 'extreme difficulties' and together define 243 health states. EQ-5D is a stand-

ardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. The most often used algorithm to calculate EQ-5D utility scores is the York A1 Tariff, published in 1997 [6].

European Organization for Research and Treatment of Cancer (QLQ-C30)

The EORTC QLQ-C30 questionnaire is a cancer-specific, self-administered, structured questionnaire that contains 30 questions, 24 of which form 9 multi-item scales representing various aspects, or dimensions of health related QoL: one global scale, 5 functional scales (Physical, Role, Emotional, Cognitive and Social), and 8 symptom scales (Fatigue, Pain, Nausea, Dyspnea, Insomnia, Appetite loss, Constipation, Diarrhoea, Financial difficulties).

QoL in both groups was measured 1 day preoperatively (baseline) and at 1 and 3 months after surgery. The questionnaires were completed by the patients themselves in all cases. Specific 1- and 3-month post-operative appointments were arranged to the patients at discharge to complete the follow up questionnaires.

The method employed to calculate patient level QALYs has been described elsewhere [7]. Both EQ-5D and SF-36 are suitable instruments to produce QALYs. On the other hand, QLQ-C30 represents a cancer specific tool for calculating qualitative characteristics but not QALYs. Scoring of the EQ-5D and SF-36 questionnaires were performed by using the EQ-5D Tariff and SF-6D preference-based health utility indexes respectively.

Statistical analysis

Statistical analysis was performed with STATA statistical package (Stata Corporation College Station, TX, USA). All quantitative variables are presented as mean \pm standard deviation (SD), mean \pm standard error (SE) or median.

Differences between two continuous variables for independent samples were analysed with Student's t-test if the variables were normally distributed. In cases that normality was not achieved even with statistical transformation of the data, non parametric

Mann-Whitney U test was performed.

Chi square test was performed for analysis of qualitative variables with the Fisher's exact test where applicable.

For dependent samples relevant parametric Student's t-test for paired data or non-parametric Wilcoxon test were performed.

Two continuous variables were analysed using Pearson linear correlation for normally distributed data or with the non parametric Spearman's rho test if the normality assumption was not achieved even with transformation.

Analysis of variance for non-normally distributed data was performed with the Kruskal-Wallis test for independent samples or with Friedman test for paired data if the variables did not satisfy the normal distribution.

Multivariate logistic regression analysis was performed if the dependent variable was categorical or for continuous data that did not follow normal distribution and were categorized at their median value.

Backward selection analysis was performed in multivariate analysis for variables proved to be statistically significant in univariate analysis.

P values <0.05 were considered as statistically significant.

Post hoc multiple comparisons were adjusted by using the Bonferroni's correction.

Results

Ninety-two colorectal cancer patients were operated either with laparotomy (n=50) or laparoscopically (n=42).

Univariate analysis followed by multivariate analysis revealed statistical significant correlation between the type of operation and the duration of the procedure (p=0.001) as well as the length of hospital stay (p<0.001) (Tables 1, 2). Mean operative time for laparoscopic colectomy was 204 min vs 145 min for open colectomy (p<0.0001), but patients who underwent the laparoscopic procedure had on average 2.5 days less hospitalization (p<0.0001). Only minor complications occurred in both groups (urinary tract infections, atelectasis, minor wound infections) that were not translated into any significant morbidity or

Table 5. Cost utility analysis (with EQ-5D or SF-6D) of various patient demographic, pre- and post-operative data

| | CUA (EQ-5D) Mean \pm SD | p-value | CUA (SF-6D) Mean \pm SD | p-value |
|------------------------------|------------------------------|---------|------------------------------|---------|
| Type of operation | | <0.0001 | | <0.0001 |
| Open | 18499.2 \pm 49857.1 | | 19095.7 \pm 7028.6 | |
| Laparoscopic | 42426.1 \pm 23097.7 | | 30612.8 \pm 9239.0 | |
| Gender | | 0.403 | | 0.581 |
| Male | 27958.8 \pm 43610.0 | | 24050.8 \pm 10939.6 | |
| Female | 31018.8 \pm 39514.9 | | 24772.5 \pm 8762.3 | |
| Diabetes | | 0.148 | | 0.070 |
| Yes | 29506.3 \pm 24424.7 | | 21033.3 \pm 9159.9 | |
| No | 29401.8 \pm 44813.2 | | 25206.3 \pm 9990.7 | |
| Hypertension | | 0.419 | | 0.046 |
| Yes | 29671.5 \pm 42527.3 | | 26110 \pm 8342.3 | |
| No | 29262.1 \pm 41217.5 | | 23288.1 \pm 10747.3 | |
| Coronary artery disease | | 0.420 | | 0.477 |
| Yes | 23367.7 \pm 11206.5 | | 21218.9 \pm 8011.7 | |
| No | 29844.7 \pm 42823.7 | | 24584.3 \pm 10035.6 | |
| Chronic lung disease | | 0.688 | | 0.175 |
| Yes | 25381.9 \pm 11426.5 | | 18328.0 \pm 3422.4 | |
| No | 29605.9 \pm 42383.3 | | 24683.1 \pm 10047.8 | |
| Smoking | | 0.702 | | 0.119 |
| Yes | 30418.4 \pm 20257.4 | | 25983.0 \pm 8871.4 | |
| No | 28940.3 \pm 48720.9 | | 23594.9 \pm 10390.5 | |
| Previous abdominal operation | | 0.025 | | 0.062 |
| Yes | 35151.4 \pm 47981.5 | | 26530.6 \pm 11063.4 | |
| No | 24609.8 \pm 34938.6 | | 22652.4 \pm 8620.8 | |
| Tumor location | | 0.654 | | 0.338 |
| Right colon | 32295.1 \pm 21520.9 | | 24136.0 \pm 13279.0 | |
| Sigmoid colon | 29328.7 \pm 53004.2 | | 25373.4 \pm 9578.5 | |
| Rectum | 26792.7 \pm 15142.9 | | 22177.1 \pm 6076.5 | |
| Type of surgical procedure | | 0.969 | | 0.299 |
| Right hemicolectomy | 32295.1 \pm 21520.9 | | 24136.0 \pm 13279.0 | |
| Sigmoidectomy | 27172.1 \pm 56506.6 | | 25779.0 \pm 9845.9 | |
| Low anterior resection | 30906.2 \pm 19430.9 | | 22523.3 \pm 6691.6 | |
| Complications | | 0.387 | | 0.350 |
| Yes | 34213.7 \pm 15995.8 | | 26592.6 \pm 8782.3 | |
| No | 28838.0 \pm 43628.9 | | 24136.9 \pm 10066.1 | |
| <i>Continuous variables</i> | | | | |
| Age (years) | | 0.190 | | 0.466 |
| <72 (median) | 39089.7 \pm 32057.4 | | 26168.8 \pm 11495.2 | |
| \geq 72 (median) | 20166.2 \pm 47386.5 | | 22653.4 \pm 7849.1 | |
| Operation duration (min) | | 0.002 | | 0.0006 |
| <180 (median) | 20165.6 \pm 53739.5 | | 20595.0 \pm 8363.4 | |
| \geq 181 (median) | 38285.1 \pm 21931.3 | | 28100.5 \pm 10005.8 | |
| Hospital stay (days) | | 0.020 | | 0.0001 |
| <8 (median) | 32674.0 \pm 45449.7 | | 27688.8 \pm 9306.4 | |
| \geq 8 (median) | 26690.8 \pm 38127.7 | | 21711.4 \pm 9684.2 | |

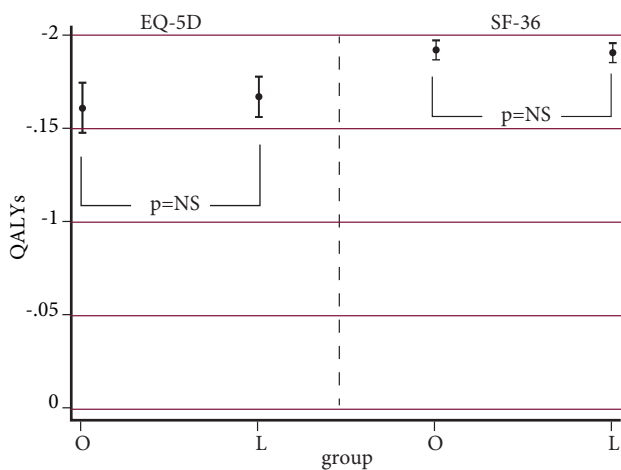
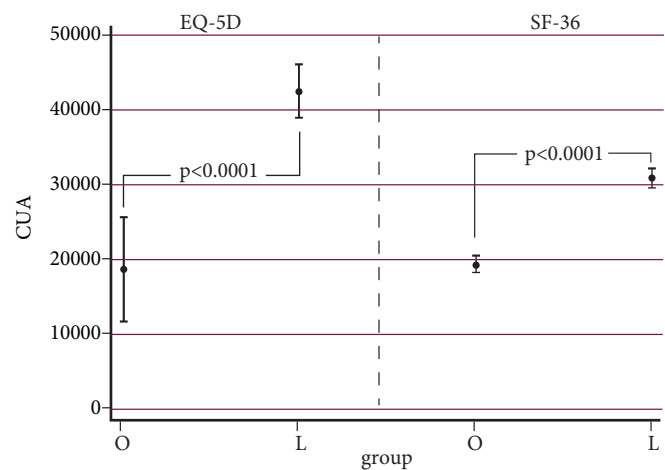
Table 6. Cost utility analysis based on EQ-5D of various patient demographic, pre- and post-operative data. Multivariate logistic regression analysis with the dependent variable categorized at its median value

| Variables | Increment | OR (95% CI) | p-value |
|---------------------|----------------------|---------------------|---------|
| Type of operation | Laparoscopic vs open | 4.73 (1.90 – 11.81) | 0.001 |
| Previous operations | Yes vs no | 2.41 (0.97 – 6.00) | 0.059 |

Table 7. Cost utility analysis based on SF-6D of various patient demographic, pre- and post-operative data. Multivariate logistic regression analysis was performed with the SF-6D categorized at its median value

| Variables | Increment | OR (95% CI) | p-value |
|-------------------|----------------------|-----------------------|---------|
| Type of operation | Laparoscopic vs open | 32.44 (9.28 – 113.44) | <0.001 |
| Hypertension | Yes vs No | 3.27 (0.95 – 11.3) | 0.061 |

OR: odds ratio, CI: confidence interval

**Figure 1.** QALYs of open and laparoscopic colectomy measured by EQ-5D and SF-36 instruments (mean \pm SE). O: open colectomy, L: laparoscopic colectomy, NS: non significant.**Figure 2.** Cost utility analysis of open vs laparoscopic colectomy by using the EQ-5D and SF-36 tools of measuring quality of life (mean \pm SE). CUA: cost utility analysis, O: open colectomy, L: laparoscopic colectomy.

lengthening of hospital stay. As a result, cost utility analysis did not demonstrate any significantly additional costs for the complicated cases (Tables 1,5).

All the aforementioned parameters were then compared with QoL measured in QALYs by EQ-5D and SF-6D tools for both open and laparoscopic colectomy. No statistically significant correlation was identified (Table 3, Figure 1).

On the other hand, estimation of total costs of these procedures showed a statistical significant increase in the charges of laparoscopic compared to open colectomy (€5748 vs €3600, $p < 0.001$) (Table 4).

The higher cost of instruments used in laparoscopy proved to be the most important factor resulting in increased total costs. The latter was shown by the statistical significant positive linear correlation of the total cost with the costs of the instruments (Spearman's $\rho = 0.9453$; $p < 0.001$).

The next step was to perform a cost-utility analysis by dividing the total costs for each operation by QALYs as measured by EQ-5D York A1 Tariff and SF-6D. Cost-utility analysis revealed statistically significant differences between laparoscopic and open colectomy, indicating that laparoscopic operation

Table 8. QLQ-C30 scales at baseline, 1 month and 3 months after the operation

| | <i>Baseline</i> | <i>1 month</i> | <i>p-value</i> | <i>3 months</i> | <i>p-value</i> |
|--|-----------------|----------------|----------------|-----------------|----------------|
| Global Health Status - Quality of life (QoL) | 65.8 ± 23.2 | 67.1 ± 22.8 | 0.516 | 71.6 ± 16.4 | 0.173 |
| Physical Functioning (PF) | 77.2 ± 18.8 | 74.0 ± 18.9 | 0.187 | 78.4 ± 21.6 | 0.853 |
| Role Functioning (RF) | 78.8 ± 29.4 | 68.5 ± 32.4 | 0.011 | 75.9 ± 34.7 | 0.247 |
| Emotional Functioning (EF) | 72.1 ± 26.4 | 78.0 ± 24.5 | 0.002 | 81.5 ± 22.1 | 0.059 |
| Cognitive Functioning (CF) | 86.1 ± 18.3 | 89.9 ± 14.5 | 0.034 | 90.1 ± 13.9 | 0.680 |
| Social Functioning (SF) | 89.0 ± 23.2 | 82.1 ± 28.8 | 0.006 | 79.6 ± 32.5 | 0.025 |
| Fatigue (FA) | 34.6 ± 23.9 | 39.6 ± 22.4 | 0.063 | 36.8 ± 22.0 | 0.424 |
| Nausea -Vomiting (NV) | 4.2 ± 10.7 | 5.2 ± 11.1 | 0.276 | 3.1 ± 8.0 | 0.609 |
| Pain (PA) | 17.8 ± 25.2 | 15.2 ± 21.4 | 0.937 | 11.7 ± 20.4 | 0.305 |
| Dyspnoea (DY) | 27.5 ± 31.7 | 19.3 ± 24.5 | 0.067 | 18.5 ± 24.8 | 0.467 |
| Insomnia (SL) | 32.6 ± 32.2 | 30.4 ± 31.1 | 0.512 | 25.9 ± 28.0 | 0.812 |
| Appetite loss (AP) | 12.5 ± 19.7 | 27.8 ± 31.3 | 0.0002 | 24.7 ± 27.6 | 0.057 |
| Constipation (CO) | 32.6 ± 36.8 | 25.2 ± 36.8 | 0.044 | 27.2 ± 35.5 | 0.667 |
| Diarrhoea (DI) | 17.9 ± 26.9 | 22.6 ± 27.7 | 0.149 | 18.5 ± 29.4 | 0.659 |
| Financial difficulties (FI) | 15.4 ± 26.9 | 13.2 ± 24.8 | 0.268 | 17.3 ± 33.5 | 0.563 |

is less cost-effective than open colectomy ($p < 0.001$) (Table 5, Figure 2). When EQ-5D and SF-6D were applied, utility scores were significantly lower for open compared to laparoscopic colectomy (EQ-5d: 18499 ± 49857 vs 42426 ± 23098 and SF-6D: 19096 ± 7029 and 30613 ± 9239 respectively).

Univariate analysis has shown significant correlations between the utilities and the collected data. As measured by EQ-5D questionnaire, patients who had a history of previous operation in their abdomen demonstrated higher costs than those who did not have any previous abdominal surgery ($p = 0.025$) (Table 5). Moreover, as measured by SF-6D questionnaire, patients who had a medical history of hypertension demonstrated higher costs than those who had normal blood pressure ($p = 0.046$) (Table 5). Both findings however were not conserved in multivariate analysis (Tables 6,7).

Statistical analysis of QoL measured by QLQ-C30 questionnaire was carried out separately for the first and third postoperative month. In all of the patients at the first postoperative month, regardless of the type of surgery, deterioration in the scales of role functioning, social functioning as well as the appetite loss and

improvement in the scales of emotional and cognitive functioning as well as constipation were observed. At the third postoperative month, only deterioration of the social functioning was conserved (Table 8).

Statistical analysis of QoL measurements between the two different types of operations showed that patients who had been subjected to laparoscopic colectomy displayed more optimal characteristics in role, emotional and cognitive functioning as well as in the symptom of constipation than those who underwent an open procedure (Table 9). At the third postoperative month, the improvements in emotional and cognitive functioning were conserved (Table 10).

Discussion

Surgeons are increasingly performing laparoscopic colectomies, benefiting from both the advancements made in instrumentation and their own accumulating experience. Laparoscopic colorectal resection was first described in 1991 [8], however, early reports of port site recurrence [9, 10], concerns about safety and questions about long term survival led to limited acceptance of this new technique.

Up until now more than 30 randomized controlled

Table 9. QLQ-C30 scales in correlation with the type of operation. d scale is the subtraction of 1st month scale – baseline scale

| | <i>Open colectomy</i> | <i>Laprosopic colectomy</i> | <i>p-value</i> | <i>3 months</i> | <i>p-value</i> |
|---------|-----------------------|-----------------------------|----------------|-----------------|----------------|
| d (QoL) | +3.2 ± 21.9 | -0.8 ± 28.0 | 0.621 | 71.6 ± 16.4 | 0.173 |
| d (PF) | -5.9 ± 22.6 | -0.2 ± 19.7 | 0.096 | 78.4 ± 21.6 | 0.853 |
| d (RF) | -18.0 ± 37.6 | -0.4 ± 35.5 | 0.030 | 75.9 ± 34.7 | 0.247 |
| d (EF) | +1.2 ± 20.2 | +11.0 ± 15.7 | 0.015 | 81.5 ± 22.1 | 0.059 |
| d (CF) | -0.3 ± 20.6 | +8.9 ± 14.5 | 0.002 | 90.1 ± 13.9 | 0.680 |
| d (SF) | -14.0 ± 26.4 | +1.6 ± 36.7 | 0.103 | 79.6 ± 32.5 | 0.025 |
| d (FA) | +2.04 ± 19.5 | +9.2 ± 30.7 | 0.108 | 36.8 ± 22.0 | 0.424 |
| d (NV) | +1.4 ± 13.5 | +0.4 ± 14.7 | 0.781 | 3.1 ± 8.0 | 0.609 |
| d (PA) | -7.8 ± 29.5 | +3.3 ± 37.9 | 0.047 | 11.7 ± 20.4 | 0.305 |
| d (DY) | -6.1 ± 28.6 | -10.6 ± 34.5 | 0.587 | 18.5 ± 24.8 | 0.467 |
| d (SL) | -0.7 ± 32.3 | -4.1 ± 21.3 | 0.629 | 25.9 ± 28.0 | 0.812 |
| d (AP) | +11.6 ± 35.1 | +19.5 ± 35.7 | 0.149 | 24.7 ± 27.6 | 0.057 |
| d (CO) | 0 ± 46.1 | -17.1 ± 41.6 | 0.015 | 27.2 ± 35.5 | 0.667 |
| d (DI) | +6.8 ± 31.2 | +1.6 ± 48.8 | 0.966 | 18.5 ± 29.4 | 0.659 |
| d (FI) | +2.7 ± 35.5 | -8.1 ± 25.6 | 0.194 | 17.3 ± 33.5 | 0.563 |

For abbreviations see Table 8

trials evaluating the clinical and cost-effectiveness of both open and laparoscopic colorectal operations have been reported. The initial scepticism regarding the oncological safety of laparoscopic colectomy has been withdrawn since new studies have shown that local recurrences as well as survival rates are similar in both operations [11-14].

In order to be established as an alternative to open colectomy, the laparoscopic procedure should provide, apart from at least the same clinical benefit, a comparable cost. There is a wide range of opinions regarding the cost-effectiveness of laparoscopic colectomy for colorectal cancer. Some studies have reported that the total costs, excluding indirect costs, are higher for laparoscopic than for open operations in the treatment of colorectal cancer [15-18], but other studies have concluded that laparoscopic treatment is not associated with any real increase in costs [19-28].

These conflicting results may arise from lack of consensus concerning study methodology, differences between medical service systems in different countries, and, especially, variations in the level of experience of surgeons [16,29,30]. A relatively recent review considered data from over 4500 randomised

participants across 18 randomized controlled trials of generally good quality [31] and concluded that laparoscopic surgery was generally more costly than open surgery as the former seems to involve longer operation times and higher equipment costs. The authors were reluctant to clarify whether the benefits associated with earlier recovery are worth this extra cost.

A possible explanation lies on the surgeons' experience to perform these technically demanding operations. Many studies have found laparoscopic resection to be associated with significantly longer operating times compared to the open equivalent [32-34]. A prospective randomized study proved that during the early learning period longer operative time and higher consumable costs are necessary, whereas when laparoscopic experience is increased, the operating times are significantly reduced, becoming closer to those of open resection [35]. The results of our team, experienced in both procedures, reinforce these observations with operative times significantly higher for the laparoscopic group (204 min) than the open group (145 min) ($p < 0.0001$) (Table 1).

Methods used for analysing the efficacy of various interventions have a common approach towards the

Table 10. QLQ-C30 scales in relation to the type of operation. d scale is the subtraction of 3rd month scale – baseline scale

| | <i>Open colectomy</i> | <i>Laparoscopic colectomy</i> | <i>p-value</i> |
|---------|-----------------------|-------------------------------|----------------|
| d (QoL) | +5.8 ± 25.3 | +4.5 ± 25.9 | 0.786 |
| d (PF) | -4.2 ± 25.2 | 8.6 ± 25.1 | 0.063 |
| d (RF) | -10 ± 37.5 | 0 ± 44.0 | 0.276 |
| d (EF) | -2.2 ± 22.0 | +16.0 ± 33.4 | 0.006 |
| d (CF) | -4.4 ± 19.0 | +8.3 ± 23.6 | 0.044 |
| d (SF) | -14.4 ± 23.1 | -2.8 ± 56 | 0.284 |
| d (FA) | +1.9 ± 23.2 | +6.5 ± 31.6 | 0.675 |
| d (NV) | 0 ± 10.7 | +1.4 ± 12.9 | 0.786 |
| d (PA) | -3.3 ± 29.8 | -12.5 ± 34.8 | 0.609 |
| d (DY) | -6.7 ± 33.2 | -5.6 ± 36.3 | 0.828 |
| d (SL) | 0 ± 30.3 | -2.8 ± 25.9 | 0.598 |
| d (AP) | +5.6 ± 32.9 | +18.1 ± 39.3 | 0.134 |
| d (CO) | +8.9 ± 53.2 | -16.7 ± 45.0 | 0.058 |
| d (DI) | +8.9 ± 38.1 | -2.8 ± 45.0 | 0.225 |
| d (FI) | +11.1 ± 40.4 | -2.8 ± 32.5 | 0.225 |

For abbreviations see Table 8

parameter “Cost”, however they differ in the way they approach the parameter “benefit”. The most commonly used types of economic evaluation are cost-benefit, cost-effectiveness and cost-utility analyses.

Cost-benefit analysis involves measuring costs and benefits in commensurate terms, usually monetary. However, practical measurement difficulties and objections to valuing health benefits in monetary terms have limited the use of cost-benefit analysis in health care. Cost-effectiveness analysis measures health benefits in natural units such as life years saved or improvements in functional status (e.g. units of blood pressure or cholesterol). A major limitation of cost-effectiveness analysis is its inability to compare interventions with differing natural effects, such as the increased life years and the improved physical functioning [36]. Cost-utility analysis combines the advantages of both cost-benefit and cost-effectiveness techniques and provides a means of estimating quantitative aspects of health such as years of survival together with QoL. It uses a utility-based measure such as QALYs.

In the Greek national health system an economic evaluation of laparoscopic vs open colorectal surgery has not been carried out up until now. We have chosen to perform a cost-utility analysis in order to estimate the possible effect of incremental cost of laparoscopic colectomy to the QoL of the patients. The variety of QoL instruments used as well as the timing of the measurements were chosen in order to provide reliable results for the early postoperative period.

EQ-5D and SF-36 instruments failed to demonstrate an advantage of the laparoscopic approach compared to open surgery. Aiming at evaluating more precisely our patients’ postoperative qualitative characteristics we applied QLQ-C30, a cancer-specific questionnaire. QLQ-C30 proved to be more sensitive in detecting QoL alterations, at least in the early postoperative period and showed that laparoscopic colectomy has benefits in certain functions and symptoms affecting QoL but not in the global health status (Table 8). These benefits, however, seem to disappear in a 3-month period of time (Tables 9,10). A good quality randomized controlled trial reports similar findings regarding health related QoL in patients treated with laparoscopic and open colectomy [37].

As far as costs are concerned, laparoscopic colectomy was significantly correlated with increased costs, mainly due to the higher cost of laparoscopic equipment used. As no differences in QoL were identified, but the cost of laparoscopic procedure was significantly increased compared to open surgery, cost-utility analysis proved that laparoscopic colectomy was not as cost-effective as the standard open procedure ($p < 0.0001$).

Conclusions

Laparoscopic surgery in the Greek public hospital system costs approximately €2150 per patient more than open surgery. This higher cost is mainly caused by the additional equipment used and does not seem to be fully compensated by an improvement in QoL in the long run. Benefits, such as reductions in length of hospital stay, do not seem to have a significant impact on minimizing total costs.

By using cancer-specific instruments of measuring QoL, such as the EORTC QLQ-C30 questionnaire, a

number of benefits of laparoscopic colectomy can be identified. However, these benefits tend to disappear shortly after the 1st postoperative month.

Taking into account that the main factor leading to the additional cost of laparoscopy is the use of expensive laparoscopic instruments, one useful conclusion of this study is to reduce their cost either by using nondisposable instruments or by implementing a national strategy to urge the suppliers of healthcare products charge in lower prices. Only then laparoscopic colectomy can be considered as a cost-effective alternative to open surgery.

This is one of the limited number of studies done in a less well developed health system, from the financial and managerial view, as costs in the public university and non-university departments are covered by governmental resources and not by private organizations or the patients themselves. Thus, the effect of the *a priori* well known high cost of the laparoscopic instruments is immediately apparent. In the meantime the lack of strict audit on the costs affects even more the difference in expenses.

The choice of disposable or not laparoscopic instruments is mainly driven by the surgeon's preference and his experience; as a result the non-reusable instruments' industry support may affect more the type and number of the instruments, a fact that may have a direct impact on the cost.

It is true that the main public insurance organization in Greece, which covers the largest portion of the country's population, has recently implemented financial limits on the permissible cost of the advanced laparoscopic procedures and it seems that the rest of the public organizations will follow the implemented economic guidance. Private insurance companies in Greece have also started to set limits on laparoscopic expenses, following the paradigm of the dominant public insurance organization.

As a result there is an increasing interest in public hospitals for purchasing reusable laparoscopic instrumentation with an aim of reducing the costs. A new analysis in the upcoming era of reusable instruments, at least for the lap colectomies, would be extremely interesting.

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