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SURGICAL ENDOSCOPY
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Impact of hospital case volume on short-term outcome after laparoscopic operation for colonic cancer

COLOR Study Group

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Abstract
Background: High hospital case volume has been associated with improved outcome after open operation for colorectal malignancies.
Methods: To assess the impact of hospital case volume on short-term outcome after laparoscopic operation for colon cancer, we conducted an analysis of patients who underwent laparoscopic colon resection within the COlon Cancer Laparoscopic or Open Resection (COLOR) trial.
Results: A total of 536 patients with adenocarcinoma of the colon were included in the analysis. Median operating time was 240, 210 and 188 min in centers with low, medium, and high case volumes, respectively ($p < 0.001$). A significant difference in conversion rate was observed among low, medium, and high case volume hospitals (24% vs 24% vs 9%; $p < 0.001$). A higher number of lymph nodes were harvested at high case volume hospitals ($p < 0.001$). After operation, fewer complications ($p = 0.006$) and a shorter hospital stay ($p < 0.001$) were observed in patients treated at hospitals with high caseloads.
Conclusions: Laparoscopic operation for colon cancer at hospitals with high caseloads appears to be associated with improved short-term results.

Key words: Laparoscopy — Colon cancer — Case volume — Caseload — Cancer

Quality of care is generally addressed by studies on efficacy and morbidity. One of the important determining factors of quality of care is caseload per hospital. High hospital case volumes have been associated with improved outcomes after complex surgical procedures, such as cardiovascular and cancer surgery [4].

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The application of minimally invasive techniques to colorectal surgery has been expanding during the past decade. The feasibility of laparoscopic colorectal surgery has been demonstrated for both benign disease and cancer [14]. Laparoscopic colectomy appears to be associated with less morbidity and an earlier recovery than open colectomy [6, 11]. However, laparoscopic colorectal surgery is technically demanding and therefore associated with a considerable learning curve [2, 15, 17].

To determine the impact of hospital case volume on short-term outcome after laparoscopic colon resection for cancer, all patients who underwent laparoscopic operation within the framework of the COLOR (COlon Cancer Laparoscopic or Open Resection) trial were analyzed. The primary endpoint of the COLOR trial, which started in 1997, was cancer-free survival 3 years after surgery.

Patients and methods

The COLOR trial is an international clinical trial that randomizes patients with colon cancer to undergo either laparoscopic or open operation. Patients with a solitary tumor located in the cecum, ascending colon, descending colon, or sigmoid, orally to the peritoneal reflection, were included. Patients with distant metastases, signs of acute intestinal obstruction, or a body mass index exceeding 30 kg/m^2 were not eligible. Patients with a history of malignancies or ipsilateral colon surgery and patients with absolute contraindications for general anesthesia or a prolonged pneumoperitoneum were excluded as well. Randomizations were performed at the central coordinating center using a computer-generated randomization list. Randomization was done either by fax or by telephone. The trial design involved the randomization of all suitable consecutive patients with colon cancer into either a laparoscopic or an open procedure. Stratification was performed for participating center and type of resection. Analyses were conducted according to the intention-to-treat principle; patients who did not receive the allocated procedure were analyzed in the treatment arm to which they had been assigned.

To ensure quality control, one member of the surgical team should have experience with ≥20 procedures to be qualified to perform either a laparoscopic or an open procedure within the framework of the trial. In total, 29 centers from Western Europe participated in the trial. The trial was approved by the medical ethics committee of each partici-

pating hospital. According to the guidelines of the local ethical committee, informed consent was obtained from patients prior to randomization. Data were collected centrally in the coordinating center in Rotterdam, The Netherlands.

To assess the impact of hospital case volume on short-term outcome after laparoscopic operation for colon cancer, hospitals were classified according to the number of laparoscopic colon resections performed. Classification was based on the rate of inclusion of patients into the COLOR trial. All participating hospitals assessed the eligibility for the COLOR trial of all patients with colon cancer referred for surgical treatment.

Hospitals were classified into three groups. Definitions of case volume were chosen in such a way that the total number of surgical cases was approximately evenly distributed among the three groups. A high case volume hospital was defined as one that performed >10 laparoscopic procedures per year and >10 laparoscopic procedures during the term of the trial. Medium case volume hospitals were defined as those performing five to 10 laparoscopic procedures per year and >10 laparoscopic procedures during the term of the trial. Hospitals that performed less than five laparoscopic procedures per year or <10 laparoscopic procedures during the term of the trial were classified as low case volume hospitals.

Age, sex, number of previous abdominal operations, type of operative procedure, comorbidity, and tumor stage were compared among groups to determine the potential presence of confounding factors. Assessment of the presence of comorbidity factors in patients was based on the classification of the American Society of Anesthesiologists (ASA).

Laparoscopic colonic procedures were all performed according to the same protocol. Skin-to-skin time was defined as time between first incision and closure of the skin. The total time spent in the operating theatre was called "theatre time."

After operation, an objective measurement of recovery of bowel function was obtained by recording the date of first defecation after surgery. The postoperative period was defined as the first 28 days after the operation. Tumor staging was based on the American Joint Committee on Cancer/International Union Against Cancer (AJCC/UICC) TNM staging criteria [8].

Short-term outcome after laparoscopic operation for colon cancer was compared among high, medium, and low volume hospitals. Sex, ASA classification, tumor stage, operative procedures, inadvertent events, conversion rates, complications, and mortality were compared using the chi-square test. Age, number of previous operations, blood loss, skin-to-skin time, theater time, and number of lymph nodes harvested were compared among the three groups using the Kruskal-Wallis test. In case of differences, the Mann-Whitney test was used to compare any two groups. To account for imbalances in ASA distribution and type of procedure, multivariate analysis (multiple regression) was used to compare hospital stay, skin-to-skin and theater time, days until first defecation, and blood loss among the three groups. In these analyses, outcomes had to be transformed logarithmically to obtain approximate normal distributions. The categorical outcomes, such as postoperative complications, were evaluated multivariately using logistic regression. The limit of significance was set at $p = 0.05$ (two-sided).

The sponsor of the trial (Ethicon Endo-Surgery (Europe), Hummelsbütteler Steindamm 71, Norderstedt, Germany) had no influence on the initiation and design of the study or on data collection, analysis, and interpretation.

Results

From March 1997 until March 2003, 627 patients underwent laparoscopic operation for colon cancer within the context of the COLOR trial. Eight patients could not be analyzed due to missing data and 83 patients were excluded from the trial after randomization, leaving 536 cases for further analysis. Reasons for postrandomization exclusion were distant metastases discovered during the operation ($n = 37$), benign lesions ($n = 29$), withdrawal of informed consent ($n = 6$) or other reasons ($n = 11$). For details regarding exclusions after randomization, see Fig. 1.

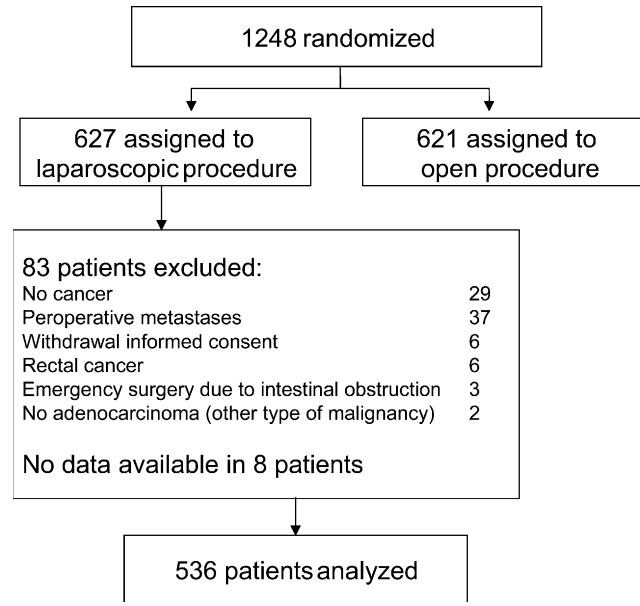

Fig. 1. Exclusions after randomization.

Twenty-nine centers from eight different Western European countries participated in the trial. According to our definitions, three of these centers were classified as high case volume hospitals for laparoscopic colon surgery and eight centers were classified as medium case volume hospitals. The remaining hospitals ($n = 18$) were classified as low case volume hospitals. The average number of surgeons who reported cases was five, four, and two for high, medium, and low case volume hospitals, respectively.

There were no significant differences among the three groups in terms of sex ($p = 0.21$), age ($p = 0.33$), or number of previous abdominal operations ($p = 0.30$). More were there any dissimilarities in terms of tumor stage ($p = 0.69$). A significant difference in ASA classification ($p = 0.02$) and type of operative procedure performed ($p = 0.001$) was observed. Patients with an ASA III classification were more prevalent at high and low case volume hospitals than at medium case volume hospitals. Fewer right hemicolectomies and more left hemicolectomies were performed at high caseload hospitals. Patient, tumor, and treatment characteristics are shown in Table 1.

Inadvertent events occurred perioperatively in a higher number of patients undergoing colectomy at low case volume hospitals than in those treated at hospitals with medium or high caseloads ($p = 0.004$). These differences were mainly attributable to problems encountered when performing an anastomosis. For details on the intraoperative problems, see Table 2.

Average intraoperative blood loss was 185 ml, 205 ml, and 150 ml at low, medium, and high case volume hospitals, respectively ($p = 0.78$). Median skin-to-skin time for laparoscopic colon resections was 160 min at low case volume hospitals, 153 min at medium case volume hospitals, and 130 min at high case volume

Table 1. Patient, tumor, and treatment characteristics

	Low (n = 161)	Medium (n = 186)	High (n = 189)	p value
Sex (%)				
Male	47	51	57	NS
Female	53	49	43	NS
Age (yr) (mean)	70.3	70.2	69.3	NS
No. of previous abdominal operations (mean)	0.52	0.42	0.52	NS
Operative procedure (%)				
Left	6	8	18	0.001
Right	53	57	37	0.001
Sigmoidectomy	38	33	38	NS
Other	4	3	5	NS
ASA classification (%)				
I	24	32	23	NS
II	58	58	56	NS
III	18	10	21	0.019
IV	0	0	0	—
Tumor stage (%)				
I	24	23	26	NS
II	41	45	38	NS
III	35	31	36	NS

Data given as means or percentages (within volume group)

Table 2. Operative findings

	Low (n = 161)	Medium (n = 186)	High (n = 189)	p value
Perioperative inadvertent events (n)				
Hypercapnia	1	0	0	NS
Bleeding	3	8	6	NS
Fixation of tumor	11	4	8	NS
Perforations	3	0	0	NS
Adhesions	13	7	6	NS
Problems with anastomosis	6	0	3	0.03
Other	9	11	10	NS
Total no. of patients with inadvertant events	36	18	26	0.004
Median (mean) blood loss (ml)	100 (185)	100 (205)	100 (150)	NS
Median skin-to-skin time (min)	160	153	130	<0.001
Median theater time (min)	240	210	188	<0.001
Conversion rate (%)	24	24	9	<0.001
Median no. of lymph nodes harvested	9	8	12	<0.001

hospitals. For this reason, low and medium caseload hospitals reported significantly longer skin-to-skin times than to high volume hospitals ($p < 0.001$). Median time in the operating theater was 240 min for laparoscopic colon resection at hospitals with a low case volume vs 210 min at medium case volume hospitals and 188 min at high case volume hospitals. All comparisons of low, medium, and high case volume hospitals showed significant differences in total time spent in the operating theater ($p < 0.001$).

There was a significant difference in the conversion rate among low, medium, and high case volume hospitals (24% vs 24% vs 9%; $p < 0.001$). At low and medium case volume hospitals, the median number of lymph nodes harvested during the surgical procedure was nine and eight respectively; whereas at high volume hospitals, the median number of harvested lymph nodes was 12 ($p < 0.001$).

Six patients died during the postoperative period. Four of these patients were treated at low volume hospitals. ($p = 0.14$). In two of these cases, the death was not related to the surgical procedure. One patient died due to multiple organ failure (MOF) after an anastomotic leak. In another patient, necropsy revealed a large bleeding of undetermined origin. The other causes of death were sepsis, ruptured inflammatory aneurysm, CVA, and MOF with unknown cause. In the patients who died due to MOF with unknown cause or sepsis, no signs of anastomotic leakage were found at reoperation.

Complications occurred significantly less often at medium and high volume hospitals than in those with a low caseload ($p = 0.006$) Table 3.

The number of reinterventions during the first 28 days after surgery showed no significant correlation with hospital caseload ($p = 0.261$). There were significantly fewer readmissions to high case volume centers than to hospitals with a medium or low caseload ($p = 0.011$).

In patients at high caseload hospitals, the first defecation was noted after an average of 3 days postoperatively, whereas at medium and low case volume

Table 3. Postoperative outcome

	Low (n = 161)	Medium (n = 186)	High (n = 189)	p value
Mortality (n)	4	1	1	NS
Complications (n)	48	29	34	0.006
Pulmonary	7	1	0	0.004
Cardiac	1	2	1	NS
Anastomosis-related	6	3	6	NS
Urinary tract infections	6	0	6	NS
Wound infections	14	4	2	NS
Bleeding	6	2	5	NS
Ileus	4	2	4	NS
Wound dehiscence	0	1	1	NS
Other	17	16	12	NS
Reinterventions (n)	13	14	10	NS
Readmissions (n)	9	11	1	0.011
First defecation[a]	3	4	3	0.004
Day of discharge[a]	8	7	6	<0.001

[a] Median number of days

hospitals the first postoperative defecation occurred after an average of 4 and 3 days, respectively ($p = 0.004$ and $p = 0.78$). Median time until discharge from hospital was 6, 7, and 8 days for high, medium, and low volume hospitals, respectively ($p < 0.001$).

Because the three groups differed in terms of ASA distribution and operative procedures performed, multivariate analyses were done to account for these imbalances. After adjustment for these two factors, all significant differences found in the univariate analysis still remained.

Discussion

Approximately 90% of patients with colon cancer currently undergo a surgical procedure [1], and most such procedures are performed via the open approach. Although minimal-access surgery for colon cancer was introduced more than a decade ago, the laparocopic approach was not as readily accepted in the field of colorectal surgery as it has been in other areas of general surgery. In the early 1990, serious doubts about the role of laparoscopy in colorectal cancer surgery were raised by reports documenting high occurrences of port site metastases [3, 13]. Although the level of evidence presented in these case series was very low, they alarmed manny surgeons. Ever since, laparoscopic colectomy for cancer has been performed primarily within the framework of randomized trials.

Known short-term benefits of laparoscopic colectomy for cancer include a lower morbidity rate, a shorter recovery period, earlier discharge from hospital, and less postoperative pain [6, 11, 19]. However, whenever a treatment for cancer, is evaluated, survival must be the primary endpoint. Two large randomized trials with data on survival have been published so far [5, 11]. In the Barcelona trial, laparoscopic colectomy for nonmetastasized cancer was associated with an improved cancer-related survival, which was mainly attributable to a better outcome in patients with stage III colonic cancer [11]. In the multicenter Clinical Outcomes of Surgical Therapy (COST) trial, no differences in survival were observed between laparoscopically assisted and open operation for adenocarcinoma of the colon. The Cost Study Group concluded that laparoscopic colonic resection is an acceptable alternative to the open procedure for colon cancer [5].

The COLOR trial was initiated in 1997 to compare laparoscopic and open surgery for nonmetastasized colon cancer. In the current analysis, which includes patients who underwent laparoscopic colectomy within the framework of this trial, the impact of hospital case volume on short-term outcome after laparoscopic operation for colon cancer was studied. A significant correlation was found between hospital case volume and intraoperative problems, operating time, conversion rate, number of lymph nodes harvested, recovery of bowel function, complications, and hospital stay.

To our knowledge, no studies have been conducted on the impact of caseload volume on operative and postoperative outcome within one database of patients undergoing laparoscopic operation. However, there is some evidence that the short-term outcome of patients undergoing open colorectal operation is better at high volume hospitals. Most such studies comprise retrospective analyses of large cancer registries and databases, with no analysis of confounding factors.

Simons et al. analyzed 2,006 patients with rectal cancer using the Los Angeles County Cancer Surveillance Program database [18]. Patients who underwent open rectal surgery for localized disease at high case volume hospitals were more likely to have a sphincter-sparing procedure than patients treated at low case volume hospitals (69% vs 63%; $p = 0.049$). Furthermore, survival was significantly better at hospitals with a high caseload ($p < 0.001$).

Similar results on the likelihood of receiving a sphincter-sparing procedure were obtained by Meyerhardt et al., who studied a cohort of patients participating in a chemotherapy trial [12]. They found significant differences in the rate of abdominoperineal resection among hospitals with low, medium, and high caseloads (46.3% vs 41.3% vs 31.8%, respectively; $p < 0.001$). However, they found that hospital caseload was not associated with survival or recurrence rates after open operation for rectal cancer. Kee et al. studied mortality in 3,217 patients registered in a colorectal cancer database [10]. They concluded that, althoug the specific surgeon had no effect on caseload, patients treated at high caseload hospitals had a slightly worse 2-year survival rate than patients treated at low case volume hospitals. They suggested that there could be factors other than surgical case volume that might be far more important in improving quality of care.

The impact of hospital caseload on short-term outcomes after colorectal operation, other than the likelihood of receiving a sphincter-sparing procedure, has not been studied in any detail. In a retrospective cohort study by Schrag et al., modest differences in the 30-day postoperative mortality rate were observed between patients treated for colon cancer at hospitals with low vs high case volume (5.5% vs 3.5%) [16]. In addition, they

found that the long-term survival of patients treated at high case volume hospitals was better ($p < 0.001$). Dimick et al. reported that postoperative mortality rates after open colorectal surgery for cancer were lower in patients treated at high case volume hospitals than those treated at low case volume hospitals (2.5% vs 3.7%; $p = 0.006$) [7]. The differences were even more pronounced in elderly patients. In a study by Harmon et al., no significant impact of hospital case volume on in-hospital mortality was observed [9]. But Zingmond et al., who used the California hospital discharge database to identify patients who had previously undergone colorectal operation for cancer [20], found a lower complication rate in patients treated at hospitals with high caseloads.

The present study has clearly shown that surgical outcome is related to case volume. This observation should provide further stimulus to examine the efficacy of both the teaching and the performance of laparoscopic colectomy. Good results in such variables as operating time, blood loss, and conversion rates are the end product of multiple factors. To suggest that the expertise of the surgeon is the determining factor is a somewhat myopic view that ignores other elements critical for surgical success, such as per instance postoperative care. However, precise knowledge of laparoscopic surgical anatomy, mastery of the various steps of a procedure, well-developd skills, and the skillful use of auxiliary devices are indeed of paramount importance to a good outcome. Effective teaching of these components of laparoscopic colectomy will enable more patients to benefit from its advantages.

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Appendix. Participants in the COLOR trial

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