Original article

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Low-volume centre *vs* high-volume: the role of a quality assurance programme in colon cancer surgery

P. Mroczkowski*†, R. Kube†‡, H. Ptok†‡, U. Schmidt§, S. Hac¶, F. Köckerling†, I. Gastinger†‡ and H. Lippert*†**

*Department of General, Visceral and Vascular Surgery, Otto-von-Guericke-University of Magdeburg, Magdeburg, †Institute of Quality Assurance in Operative Medicine Ltd, Otto-von-Guericke-University of Magdeburg, Magdeburg, ‡Department of Surgery, Carl-Thiem-Klinikum, Cottbus, §Statconsult Ltd, Magdeburg, Germany, ¶Department of General, Endocrine and Transplant Surgery, Medical University of Gdansk, Gdansk, Poland and **Department of Surgery, Vivantes-Klinikum-Spandau, Berlin, Germany

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Abstract

Aim The study aimed to determine whether hospitals within a quality assurance programme have outcomes of colon cancer surgery related to volume.

Method Data were used from an observational study to determine whether outcomes of colon cancer surgery are related to hospital volume. Hospitals were divided into three groups (low, medium and high) based on annual caseload. Cancer staging, resected lymph nodes, perioperative complications and follow up were monitored. Between 2000 and 2004, 345 hospitals entered 31 261 patients into the study: 202 hospitals (group I) were classified as low volume (< 30 operations; 7760 patients; 24.8%), 111 (group II) as medium volume (30–60; 14 008 patients; 44.8%) and 32 (groups III) as high volume (> 60; 9493 patients; 30.4%).

Results High-volume centres treated more patients in UICC stages 0, I and IV, whereas low-volume centres treated more in stages II and III ($P < 0.001$). There was no significant difference for intra-operative complications and anastomotic leakage. The difference in 30-day mortality between the low and high-volume groups was 0.8% ($P = 0.023$).Local recurrence at 5 years was highest in the medium group. Overall survival was highest in the high-volume group; however, the difference was only significant between the medium and high-volume groups. For the low and high-volume groups, there was no significant difference in the 5-year overall survival rates.

Conclusion A definitive statement on outcome differences between low-volume and high-volume centres participating in a quality assurance programme cannot be made because of the heterogeneity of results and levels of significance. Studies on volume-outcome effects should be regarded critically.

Keywords Colon cancer, outcome, hospital volume, intraoperative complications, local recurrence, survival

What is new in this paper?

The current literature often shows that low-volume hospitals have inferior results for colon cancer surgery compared with higher volume centres, but these results were not confirmed in this large observational study. Studies on volume-outcome effects should be regarded critically.

Introduction

Measurement of the components of high quality care is a challenging aspect of healthcare. Surgical oncology requires an ongoing approach to the question of quality, reflecting the current development of the multimodal therapeutic regimes. Although colon cancer is one of the most common malignancies, there is limited evidence to support different surgical options [1]. There is a bidirectional influence of quality control, on the one hand defining whether the treatment is conducted in accordance with the guidelines and on the other whether the results of standardized treatment influence changes within the guidelines [2].

Oncosurgical procedures are conducted in hospitals of different reference levels. One of the known parameters in surgical oncology is the volume of clinical activity of the provider. The influence of hospital procedure volume on outcomes following surgery for colon cancer has been

Correspondence to: Pawel Mroczkowski MD, Department of General, Visceral and Vascular Surgery, Otto-von-Guericke University, Leipziger Str. 44, D-39120 Magdeburg, Germany.
E-mail: pawel.mroczkowski@med.ovgu.de

analysed in recent years [2–5]. There are data suggesting that hospital volume is a predictor of clinical outcome in a wide variety of surgical procedures. This has even led to the suggestion to discontinue some complex surgical procedures in low-volume centres [6] and the centralization of care is already in progress [2]. The majority of these publications is based on data collected for financial reasons and clinical reports are rare. Also, it is not clear whether the volume-to-outcome relationship is dependent on the type of surgical procedure, and how it changes in the different volume groups. Volume is a direct measurable variable characterizing a provider. However, it might not reflect aspects of performance such as teaching/academic hospital, dedicated services or specialized care. The classification criteria for volume groups are not precisely defined. The transferability of volume-related results between different countries and different medical care systems is questionable. It is possible that the volume influence is as different as these national systems are. The most important quality parameters in oncology are the local recurrence and survival. These long-term parameters are, however, influenced by all therapeutic modalities used. To extract the surgical component, short-term results play the primary role and can also be used as a proxy for long-term results.

We used data from an observational study conducted in Germany to determine whether the outcome of surgery for colon cancer is related to surgical centre volume.

Method

The records of 31 261 patients who underwent surgery for colon cancer between 2000 and 2004 in 345 surgical departments in Germany were analysed. The participating surgical centres were divided into three volume groups according to the number of operations performed for colon cancer annually: group I, low volume (< 30 operations, 202 hospitals); group II, medium volume (between 30 and 60 operations, 111 hospitals); group III, high volume (more than 60 operations, 32 hospitals). For hospitals qualifying for different volume groups in different years, the highest achieved volume was used. Not all hospitals participated every year and therefore an average number of patients per hospital in the respective groups would reflect a number that would be lower than expected. The patients were part of the cohort participating in the observational study 'Quality of surgical treatment in colorectal cancer'. Excluded from the present analysis were all the patients with rectal cancer (defined as a tumour located at or below 16 cm from the anal verge in rigid rectoscopy). The hospitals were required to deliver data on every patient treated for colon cancer and the total number of reported patients was cross-checked with the hospital's financial report for the insurance companies to avoid a selection bias.

The enrollment questionnaire consisted of 68 questions related to personal data, risk factors, reason for hospitalization, diagnosis prior to surgery, surgical procedure, complications of surgery, results of pathology, and discharge (total: 334 items). Risk factors were defined according to the estimation prior to surgery and categorized into: none, cardiac, respiratory, renal, hepatogenic, nicotine abuse, alcohol abuse, diabetes mellitus, varicosis and other. The patient's body mass index and American Society of Anesthesiologists (ASA) score were also recorded. The surgical procedures were classified according to the surgeon and divided into right hemicolectomy, extended right hemicolectomy, left hemicolectomy, extended left hemicolectomy, sigmoid resection and others. The intra-operative course was described by duration of the surgery, presence and technique of anastomosis, and intra-operative complications (bladder injury, bleeding necessitating > 2 red blood cell concentrates, ureter lesion, iatrogenic tumour perforation, spleen injury, intestinal injury, internal genital injury, problem regarding the capnoperitoneum, and anastomosis complication). The postoperative complications included general complications and special complications. The postoperative general complications were lung embolism, pulmonary (pleural effusion and atelectasis), pneumonia, urinary tract infection, fever (> 38°, > 2 days), cardiac, multiple organ failure, thrombosis, and renal. The postoperative special complications were bleeding (necessitating surgery), wound abscess, sepsis, anastomosis insufficiency, aseptic wound healing dysfunction, wound infection, intra-abdominal/retrorectal abscess, mechanical ileus (necessitating surgery), faecal fistula, peritonitis, atony > 3 days, peristalsis dysfunction (not necessitating surgery), wound dehiscence, and colostomy complication. The number of resected lymph nodes and UICC (Union Internationale Contre le Cancer, Geneva, Switzerland) classification [7] were estimated based on the pathological report.

The study was conducted on an independent basis by the Department for General, Visceral and Vascular Surgery and the Institute for Quality Assurance in Operative Medicine, both belonging to the University of Magdeburg (Germany). Each year the participating hospitals received a detailed report showing its results and statistical distribution of the collected items, as well as the median results with statistical distribution over the whole study population. The results obtained and trends are also presented at an annual conference of the study

group, which is open to all participants; however, the performance of individual centres remains anonymous to others. The collection of treatment and follow-up data was based on informed consent of the patients.

Improvement of outcome with higher hospital volume (proportional relationship) was considered a null hypothesis. Overall survival, local recurrence, 30-day mortality, number of resected lymph nodes and anastomotic leakage were treated as primary outcome measures; duration of surgery, other intra-operative and postoperative complications and discontinuity resections were used as secondary outcome measures.

Statistical analysis

The statistical analysis was performed using SPSS 13.0 (SPSS Inc., Chicago, Illinois, USA). All statistical tests were two-sided, with the χ^2 test (Pearson correlation, linear by linear association) for categorical variables, ANOVA for quantitative variables (duration of surgery, for example) and Kaplan–Meier curves for survival and local recurrence estimation.

Results

Preoperative data

There were 7760 patients treated in group I, 14 008 in group II and 9493 in group III. The distribution of risk factors showed a nonsignificant trend towards risk factors related to a worse health status situation (obesity, alcoholism, smoking and varicose veins) being less frequently present in the group treated by high-volume centres and significant differences in the distribution of ASA classification stages (Table 1).

High-volume hospitals treated patients with cancer diagnosed prior to the admission more often (group I, 58.4% were already diagnosed; group II, 63.4%; group III, 65.1%; $P < 0.001$), whereas the low-volume group more often had patients referred for further diagnostic testing due to unclear symptoms. 'Primary tumour search' was the reason for admission in 11.5% of the patients in group I, 12.0% in group II and 7.6% in group III ($P < 0.001$). 'Unclear symptoms' were the reason for admission in 8.6% (I), 8.1% (II) and 6.3% (III) ($P < 0.001$). The patients with ileus were more often treated in low-volume hospitals (I: 10.9%, II: 9.1%; III: 8.2%, $P < 0.001$). High-volume centres treated more patients in UICC stages 0, I and IV, and low-volume centres treated more patients in stages II and III ($P < 0.001$) (Table 2).

Table 2 UICC stage stratification (%).

	I (< 30) % of 7760 patients	II (30–60) % of 14 008 patients	III (> 60) % of 9493 patients
UICC 0	1.3	1.2	2.0
UICC I	17.6	17.3	19.3
UICC II	32.8	32.3	30.4
UICC III	29.0	29.0	27.3
UICC IV	19.3	20.3	20.9

$P < 0.001$(Pearson), $P = 0.205$ (linear-by-linear).

Surgery and postoperative period

Discontinuity resection (without anastomosis) was most often carried out in high volume hospitals; the rate of surgery with anastomosis was 94.6% in group I, 95.2% in group II and 93.7% in group III ($P < 0.001$). High-volume centres performed hand-sewn anastomosis with single row sutures more frequently (I, 38.7% of anastomosis; II, 42.8%; III, 49.0%; $P < 0.001$). A hand-sewn two layer anastomosis was most common in the low-volume group (I, 22.9% of anastomosis; II, 17.2%; III, 16.4%; $P < 0.001$), and a stapled anastomosis in the medium-volume group (I, 32.2% of anastomosis; II, 34.8%; III, 28.0%; $P < 0.001$). Duration of surgery did not differ considerably between the groups (Table 3); the differences did not exceed 9 min for procedures lasting between 2 and 3 h. The number of resected lymph nodes varied no more than one lymph node per procedure, as shown in Table 4.

Table 1 The ASA classification of patients who were operated on.

	I (< 30) (7760 patients)	II (30–60) (14 008 patients)	III (> 60) (9493 patients)
ASA I	7.8% (606 patients)	7.4% (1037 patients)	7.5% (710 patients)
ASA II	47.1% (3655 patients)	49.3% (6906 patients)	49.4% (4687 patients)
ASA III	41.1% (3189 patients)	39.3% (5505 patients)	40.1% (3804 patients)
ASA IV	4.0% (310 patients)	4.0% (560 patients)	3.1% (292 patients)

Pearson $P < 0.001$, linear-by-linear $P = 0.016$.

Table 3 Duration of the most common procedures and standard deviation (min).

	I (< 30) Mean (min) ± (SD) Range Median	II (30–60) Mean (min) ± (SD) Range Median	III (> 60) Mean (min) ± (SD) Range Median	*P*
Right hemicolectomy (*n* = 9784)	127 ± 46 17–435 min 120 min	125 ± 44 12–453 min 120 min	126 ± 43 30–460 min 120 min	0.061
Extended right hemicolectomy (*n* = 2105)	148 ± 54 50–535 min 140 min	143 ± 50 31–370 min 135 min	152 ± 61 35–537 min 145 min	0.006
Left hemicolectomy (*n* = 3351)	165 ± 61 50–496 min 155 min	162 ± 52 50–425 min 160 min	157 ± 54 45–395 min 150 min	0.008
Extended left hemicolectomy (*n* = 1031)	177 ± 70 21–575 min 172.5 min	178 ± 63 17–540 min 170 min	172 ± 58 50–465 min 165 min	0.494
Sigmoid resection (*n* = 7606)	145 ± 56 35–450 min 135 min	140 ± 54 15–530 min 130 min	141 ± 57 40–635 min 130 min	0.011

Table 4 Number of resected lymph nodes for the most common procedures.

	I (< 30) (*n* ± SD)	II (30–60) (*n* ± SD)	III (> 60) (*n* ± SD)	*P*
Right hemicolectomy	18.0 ± 7.6	18.7 ± 8.6	18.9 ± 8.4	< 0.001
Extended right hemicolectomy	19.8 ± 9.1	20.3 ± 10.6	20.9 ± 10.1	0.225
Left hemicolectomy	15.5 ± 7.5	16.2 ± 8.1	16.3 ± 8.0	0.049
Extended left hemicolectomy	16.9 ± 8.8	17.5 ± 8.6	18.1 ± 9.2	0.266
Sigmoid resection	14.1 ± 7.1	15.5 ± 8.0	15.2 ± 7.7	< 0.001

Table 5 Complication rate and 30-day mortality in %.

	I (< 30) (%)	II (30–60) (%)	III (> 60) (%)	*P*
Intra-operative complications (≥ 1)	4.3	4.4	3.9	0.108
Postoperative general complications (≥ 1)	26.1	23.0	22.8	< 0.001
Postoperative surgical complications (≥ 1)	18.4	17.0	16.7	0.008
Anastomotic leakage	2.8	3.0	3.0	0.670
30-day mortality	3.4	2.8	2.6	0.023

There were no differences in intra-operative complications between the groups (Table 5). The low-volume group reported the highest amount of patients with postoperative complications, which included general complications and special complications. There was no difference in occurrence of anastomotic leakage. The difference in 30-day mortality between the low and high-volume groups was 0.8% ($P = 0.023$).

Table 6 shows that the 5-year local recurrence is highest in the medium group. Only the difference between the medium and high-volume groups is significant for local recurrence and overall survival. There is no significant difference between low and high-volume groups for local recurrence and overall survival. Figures 1 and 2 show the graphical depiction of local recurrence and overall survival, respectively, for the 5 years after surgery.

Table 6 Five-year local recurrence and overall survival per volume group.

	I (< 30) (SE)	II (30–60) (SE)	III (> 60) (SE)	I *vs* II	I *vs* III	II *vs* III
5-year LR	5.6% (0.9%)	6.6% (1.6%)	4.0% (0.4%)	$P = 0.5895$	$P = 0.2128$	$P = 0.0481$
5-year OS	51.1% (3.3%)	52.3% (1.6%)	56.3% (1.2%)	$P = 0.4585$	$P = 0.1120$	$P = 0.0118$

LR, local recurrence; OS, overall survival; SE, standard error.

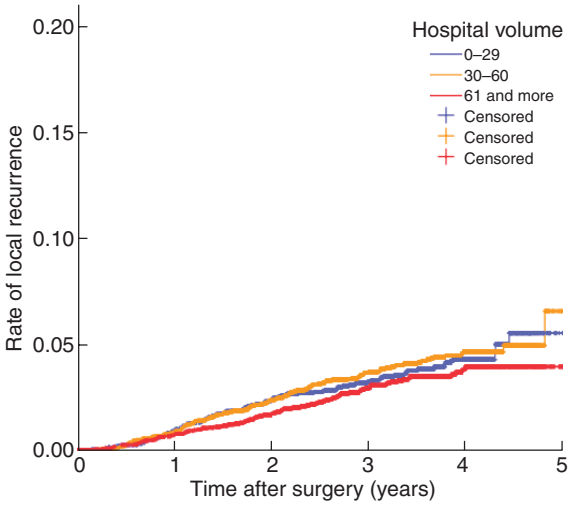

Figure 1 Local recurrence at 5 years after surgery.

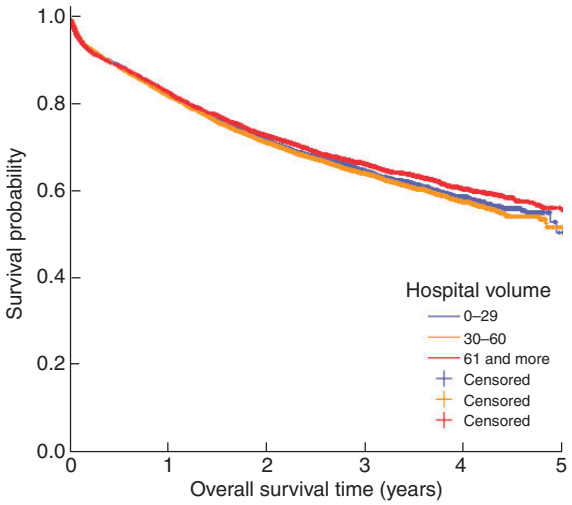

Figure 2 Five-year survival.

Discussion

An observational study can deliver results that are not inferior to randomized clinical studies [8,9]. The majority of patients with colon cancer are treated outside clinical trials and relevant patient subgroups are excluded from clinical trials due to age or comorbidity. An observational study gives the opportunity to collect data on every patient.

There are many recent publications addressing the issue of surgical outcome in relation to hospital case volume, particularly in colon cancer [4,6,10–33]. Most are based on administrative data from Medicare and SEER (Surveillance, Epidemiology and End Results Program of the National Cancer Institute, Bethesda, Maryland, USA) [34]. One major advantage of this type of data source is the large cohort groups. However, these are not research medical databases. They are designed to focus on the financial aspect of patient care therefore it is difficult to recognize causative relationships from these databases. The limitations of using data collected for billing purposes to analyse real clinical outcomes are well known [35–38]. The other criticism of these publications is the small size of the cohort in low-volume hospitals.

Hospital volume seems to be a better proxy than surgeon volume for the relationship between experience and outcome. It is very unlikely that procedures performed by an experienced professor of surgery with a caseload of hundreds of resections annually and procedures performed by a resident with the assistance/supervision of the same expert will not produce a similar outcome. However, in the analysis of surgeon caseload, these two scenarios would be situated at opposite ends of the scale. Hospital volume denotes that the organizational structure has the necessary experience, including surgeons responsible for the volume. The definition of the volume limits was set arbitrarily prior to the investigation and reflects the clinical reality of a colon cancer procedure performed less than every 2 weeks (< 30), approximately every 2 weeks (30–60) or approximately every week (> 60). There is no universal definition of the volume available. The popular method of dividing the population into equal parts (for example quartiles) is also arbitrary, producing a switch towards high volume in countries with limited numbers of providers and a switch towards low volume in countries with no limitations for providers. In the study reported by Harmon *et al.* [30], the cohort of patients from Maryland who underwent colorectal resection from 1992 to 1996 had 81% of surgeons perform 36% of operations at an average of 1.8 cases per year. The high-volume surgeons (5%) performed 27% of the procedures at an average rate of 14.0

cases per year. There was a statistically significant 36% reduction in the risk of in-hospital death for high-volume operators. The differences among high, medium and low-volume hospitals were, however, not significant.

Billingsley *et al.* [10] analysed 30-day postoperative mortality and interventions due to surgical complications in 22 672 Medicare patients treated for colon cancer between 1992 and 1996 within the SEER program and found a positive correlation between postoperative interventions and the surgeon's case volume, and also between high and very-high hospital volume and postoperative mortality. However, the median total number of surgeries performed by surgeons in the low-volume group (67.1% of surgeons) was 5 in 5 years, and the median total number of surgeries in hospitals from the low-volume group (71.9% of hospitals) was 30 in 5 years.

It is difficult to assess the quality of oncological surgery. Every operation is different and depends on a very individual constellation of a patient, a tumour and a surgeon. However, there are objective outcome measures correlated with procedural quality. Duration of surgery is easy to measure and gives some information about the surgical skill of the operator, if analysed together with pathological evaluation of the produced specimen. In our results, a right hemicolectomy lasted 127 min in group I, 125 min in group II and 126 min in group III. The largest difference occurred in left hemicolectomy, which was completed in 157 min in high-volume hospitals; the medium-volume group needed 5 min more and the low-volume group needed 8 min. These small differences probably would not influence the outcomes. The next proof of surgical quality is the number of resected lymph nodes found in the resected specimen [39–41]. Even if the difference between 18.9 and 18.0 lymph nodes for right hemicolectomy or between 15.2 and 14.1 lymph nodes for sigmoid resection were statistically significant ($P < 0.001$), we do not think that they reflect any clinical reality because the standard deviation for these procedures is about 8 (7.1–8.6) lymph nodes. However, the number of examined lymph nodes for all procedures in all volume groups exceeds the required minimum of 12 [39–41], suggesting that hospitals (regardless of volume) participating in a quality assurance programme have a higher standard of quality. These results were achieved together with no difference in intra-operative complications and in anastomotic leakage, as the most sensible direct criteria of surgical quality. Miller *et al.* [42] have shown, in contrast to the present study, a significant hospital-to-hospital variation in lymph node detection (recovery from specimen) after colorectal resection. Low-volume hospitals were more likely to recover fewer lymph nodes and to underestimate the cancer stage. Wong *et al.* [41] found wide variation in the number of examined lymph nodes between hospitals with different procedure volumes, but not in the ability to find node-positive tumours. In their study, the number of lymph nodes examined following colectomy for colon cancer was not associated with staging, use of adjuvant chemotherapy or patient survival.

The present study showed that 24.8% of the patients were treated in low-volume centres, whereas 30.4% were treated in high-volume centres. However, there were differences with regard to ASA grade. The low-volume group had 1.0% more patients in ASA-grade III and 0.9% more in ASA-grade IV, compared with the high-volume group. Furthermore, there were also differences in the patients' status of diagnosis upon arrival. The high-volume group had the highest rate of cancer diagnoses, whereas the low-volume group had the highest rate of 'unclear symptoms' and ileus as the reason for admission. This provides a description of what the situation is before the surgeon is involved. With regard to the UICC stages upon admission, the high-volume group had more UICC stages 0, I and IV, whereas the low-volume group had more UICC stages II and III. There was also a 0.8% difference in 30-day mortality between low and high-volume hospitals (3.4% *vs* 2.6%) ($P = 0.023$). It is worth noting that in another analysis by Birkmeyer *et al.* [23] in which the participants were not necessarily involved in quality assurance programmes, the operative mortality rate for colectomy was about 50% higher, varying between 7.4% in the very-low-volume group (< 33 procedures annually) and 5.4% in the very-high-volume group (more than 124 procedures). Shrag *et al.* [29], analysing Medicare and SEER data, found significant differences in 30-day postoperative mortality in patients treated in low *vs* high-volume hospitals. The overall 30-day mortality ranged from 5.5% in the low group to 3.5% in the very-high-volume group ($P < 0.001$). Also, in a previous analysis from our group [28] based on 75 hospitals and 2293 patients, no differences in hospital mortality and 30-day mortality were observed. A contrary effect is documented in the analysis carried out by Hayanga *et al.* [43], where teaching hospitals were associated with increased odds of death (odds ratio 1.14). This paper shows that the question regarding the influence of caseload volume in colon cancer surgery remains open.

Attempts to create models to estimate improvement of life expectancy have been made to favour high-volume hospitals. Finlayson and Birkmeyer [18] created a model comparing operative mortality and long-term survival for pancreatic, lung and colon cancer. For colon cancer, the life expectancy ranged from 6.8 years at very-low-volume hospitals to 7.4 years at very-high-volume hospitals.

The observed volume-outcome effect was different for different parameters, delivering better results for postoperative general complications, postoperative surgical complications and 30-day mortality in the high-volume group compared with the low-volume group. However, for intra-operative complications and anastomotic leakage, there were no significant differences between the groups. Furthermore, for local recurrence and overall survival, there was no significant difference between low and high-volume groups, but there was between medium and high-volume groups. A definitive statement regarding low or high-volume groups and outcome can therefore not be made.

Why are the present results different from the majority of published literature? First of all, the patients analysed in the present study were treated later than patients in some of the cited publications and the permanent improvement in postoperative mortality of patients treated for colon cancer is obvious [44,45]. Second, the definition of volume groups significantly influences the results. In many papers showing a significant relationship between hospital volume and outcome, the low-volume hospitals are in reality 'no-volume' hospitals, performing colon surgery very rarely. However, the most substantial difference between our study and others is due to the composition of our group. We analysed hospitals participating voluntarily in a quality assurance programme.

According to our analysis, the hypothesis that hospital volume has an influence on colon cancer can be questioned. If this were true, there would be a proportional dependence between the volume and outcome effect, starting with the worst results in the low-volume group, getting better in the medium-volume group and finally the best in the high-volume group. This is not the case in our analysis.

Studies based on volume should be regarded critically, given the arbitrary nature of how low-, medium- and high-volume groups are determined. A definitive statement about outcome differences between low-volume and high-volume centres participating in a quality assurance program cannot be made because of the heterogeneity of results and significance levels.

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