EJSO (2005) **31**, 512–520

Available online at www.sciencedirect.com

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EJSO
the Journal of Cancer Surgery
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# Influence of hospital volume on local recurrence and survival in a population sample of rectal cancer patients

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Accepted for publication 14 February 2005

**KEYWORDS**
Rectal cancer;
Local recurrence;
Survival;
Hospital volume;
Cancer registry

**Abstract** *Aims*: To investigate the role of hospital volume and individual hospitals on long term outcomes (local recurrence and survival) of rectal cancer patients.
*Methods*: One thousand thirty-eight patients with rectal cancer were diagnosed between 1996 and 1998. From these, we analysed 884 patients with a resected invasive primary rectal cancer. Median follow-up was 5.7 years. The impact of hospital volume (<10, 10–30 and >30 rectal cancer patients annually) on local recurrence and survival was examined in a Cox model. Differences between the four largest clinics in the high volume group were also investigated.
*Results*: In the multivariate model predicting survival the following variables were significant: UICC stage, grade, age, local recurrence, and (neo-) adjuvant therapy treatment. In the multivariate model predicting local recurrence UICC stage, tumour localisation, and neoadjuvant therapy treatment were significant variables. Hospital volume was not a significant factor for survival or local recurrence. Within the high volume category one hospital showed significantly worse local recurrence rates than all other hospitals, but no survival difference could be seen between the four largest hospitals of the high volume group.
*Conclusions*: This analysis of a rectal cancer population found that hospital volume did not determine survival or local recurrence. Detailed clinical data with long term follow-up from cancer registries are vital to demonstrate the quality of routine care.


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0748-7983/$ - see front matter 
doi:10.1016/j.ejso.2005.02.027

## Introduction

The role of hospital volume in rectal cancer surgery is still unclear. This uncertainty is partly due to reports with different data sources (trial and registry data for example); differences in the length of follow-up, definition of caseload, and analysis; and rectal cancer patients being considered together with colon cancer patients. The evidence, however, has mounted recently and indicates that there may not be a significant association between hospital volume and long term survival, when multivariate analyses are conducted on rectal cancer patients alone.[1-4] Other studies have shown surgeon volume effects and institutional variability,[5-10] but this paper will focus on hospital volume. Although great variability in local recurrence rates have been reported for rectal cancer,[10-12] which may partly explain survival differences, few studies have investigated local recurrence in terms of hospital volume. The available trial and registry data, however, also suggest no effect of hospital volume on local recurrence.[1,3,13] Table 1 presents a summary of the most recent survival studies.[1-4,8,14,15] Over half the studies reported no significant effect of hospital volume on survival. Although multivariate analyses with at least 5 year follow-up were employed for these four 'no effect' studies, two were trials with restricted patient samples and one of the population based studies did not adjust for adjuvant therapy treatment. For the evidence to be more convincing, long term follow-up from a cancer registry database with detailed information about patient, tumour, and treatment characteristics is required.

This paper aims to present data on local recurrence and survival from the Munich Cancer Registry (MCR), adjusting for multiple clinical factors. The influence of hospital volume and differences between the four largest clinics will be investigated. Evidence from a population based study with good follow-up and clinical details should contribute to the debate on the role of hospital volume in long term rectal cancer outcomes.

## Patients and methods

### Data collection

The MCR records all cancer patients treated in Munich and the surrounding area. All MCR data are registered according to the official documentation guidelines for cancer registries. At the time of this study, population size was around 2.3 million (currently it stands at 3.7 million, because in 2002, the catchment area was enlarged). This paper reports the results of the Munich Field Study, which monitored all rectal and breast cancer patients diagnosed between 1.4.1996 and 31.3.1998 and resident in the Munich region. Pathology reports for solid tumours from all pathology laboratories in the Munich area were sent to the MCR. From these reports, the total number of rectal cancer patients in the region was systematically known and the main prognostic factors were ascertained. In parallel, clinicians completed standardized forms concerning patients' domicile, age, tumour diagnosis, primary therapy, follow-up and palliative care. Doctors' letters were also available. Life-status is maintained systematically through death certificates and the inhabitants' registration office.

### Patient sample

Tumours found 16 cm or less from the anal margin were recorded as rectal cancer. A total of 1038 patients (living in the Munich region) were diagnosed with rectal cancer over the 2-year study period. Palliative resection or no resection patients were excluded ($N=60$). Patients with an in situ carcinoma ($N=5$) or evidence of another previous or synchronous cancer ($N=89$) were also barred. Therefore, only those who had a resected invasive

**Table 1** Studies investigating hospital volume and survival in rectal cancer patients

| First author | Study period | Caseload | Volume effect | Data source |
|---|---|---|---|---|
| Holm[1] | 1980-1993 | ≤5, 6-10, >10 mean per year | Not significant | Trial |
| Jessup[2] | 1985-1995 | Not reported | Not significant | National database |
| Simunovic[4] | 1990 | ≤11, 12-17,18+ per year | Not significant | Registry |
| Meyerhardt[3] | 1990-1992 | 0-8.3, 8.4-16.7, 17-92 mean per year | Not significant | Trial |
| Simons[15] | 1988-1992 | ≤25, >25 over 5 years | Significant | Registry |
| Schrag[8] | 1992-1996 | 1-5, 6-11, 12-20, 21-57 over 5 years | Significant | Registry |
| Hodgson[14] | 1994-1997 | <7, 7-13, 14-20, >20 per year | Significant | Registry |

primary rectal tumour were included in these analyses ($N=884$).

## Hospital volume

Patients were operated on in 39 different hospitals. Hospital volume varies in the literature depending on the sample size, ranging from five or less patients per year to over 200.[6,9,12] In our study, hospital volume was created from the number of patients treated per year and divided into three groups: <10 low, 10–30 mid and >30 high. There were 25 low volume, 10 mid volume and four high volume hospitals. The four clinics in the high volume category were also each compared to all other clinics (not in the high volume group).

## Outcome measures

The primary outcome for the analysis was overall and relative survival. Survival status was assessed in June 2003 allowing at least 5 years of follow-up. A secondary outcome was local recurrence. Although published studies speak of local recurrence, the definitions given indicate that they mean loco-regional recurrence.[11,13] For consistency, the term local recurrence in this paper is defined as any recurrence of rectal cancer within the pelvis.

## Prognostic variables

The UICC (International Union Against Cancer) stage classification is used throughout this paper. UICC stages II–IV were compared with stage I. Patients with one and two tumour grades were compared with those with grades 3 and 4. Age was divided into under 70 and 70 years and over. Patients' gender was also available (men as reference variable). There were four tumour locations: less than 4 cm (reference variable), 4 cm to less than 8 cm, 8 cm to less than 12 cm and over 12 cm (to 16 cm). The operative procedure sphincter preservation or not was compared. Five adjuvant therapy possibilities were also recorded: no therapy, radiation therapy only, chemotherapy only, combined radiation and chemotherapy, and neoadjuvant therapy. Neoadjuvant patients did not have a traditional post-operative stage, other than those patients with disease progression (UICC IV). When neoadjuvant patients had a pre-operative stage, however, this was adopted as their UICC stage.

## Statistical analyses

The MCR data are managed in an Oracle database. The statistical analyses were run in SAS (version 6.1) and SPSS (version 11.5). Frequency data were analysed using the chi-square test. When results are presented for individual hospitals, only percentages have been given to protect clinic identity, which could be established if case numbers were known. Overall (observed) survival was first estimated with the Kaplan–Meier method and tested with the log-rank procedure. The Kaplan–Meier curves discontinue when less than 10 patients at risk remain. Relative survival was computed by the ratio of the observed survival rate to the expected survival rate.[16] The expected survival time of age and gender matched individuals was calculated from the life tables of the 'normal' German population. Relative survival is thus used as an estimate for disease specific survival. Overall survival and local recurrence were investigated with a Cox proportional hazards regression model. Hazard ratios (HRs) and 95% confidence intervals (CIs) are presented. The following factors were entered as independent variables in the multivariate analyses: UICC stage, grade, age, gender, tumour location, local recurrence, sphincter preservation, adjuvant therapy, and hospital volume or individual hospitals. Those factors with missing values were entered as dummy variables in the model. These values are not shown.

First, unadjusted differences between the hospitals were investigated. The influence of clinical variables, treatment factors, and hospital volume on local recurrence and survival was then explored in a multivariate Cox model. The same model was re-run, this time comparing the four largest clinics with all other clinics. Due to the large variation in grade between the large hospitals, the model was repeated without grade as an independent variable.

# Results

## Patient sample and characteristics

Of the 1038 newly diagnosed rectal cancer patients from 1996 to 1998, 884 had invasive primary tumours which were resected. Of these 884 patients in the analyses, 31 had no information regarding survival status. Twenty-four patients had no UICC stage. Seventeen were missing a precise tumour location. Forty-four patients did not receive a tumour grade. Ninety-four patients did not qualify for the sphincter preservation or not variable because they received local excision or the Hartman procedure. Of the 411 patients who died during the study period only 18 deaths occurred within 30 days of surgery.

Overall survival was 51.3% at the time of this analysis with up to 8 years follow-up data. Local recurrence for the whole period was 16.1%. A third of patients had stage III disease and two thirds were under 70 years of age. For the majority of patients their sphincter was preserved. Only 9.4% received pre-operative therapy. Table 2 shows the patient characteristics for the whole sample and for the three hospital volume groups. Chi-square tests indicated that high volume hospitals had significantly fewer older patients, and treated more patients with neoadjuvant therapy. Patient characteristics for the four clinics in the high volume category are presented and compared in Table 3. There was significant variability between the four clinics for grade, tumour location, local recurrence, sphincter preservation and adjuvant therapy. Grades 3 and 4 (diagnosed by the pathologist) was very high for clinic C (47.7%).

## Relative survival for hospital volume and the four largest hospitals

Five year relative survival was 65.2% for the whole sample. Fig. 1 shows the relative survival curves for the three hospital volumes. Five year relative survival rates were 64.1% for the low volume group, 62.1% for the mid group and 66.9% for the high volume hospitals. Interestingly, the low volume hospitals had higher survival rates than the mid volume hospitals. Fig. 2 shows the relative survival curves for each of the four largest hospitals and all other hospitals together. Hospital A had a 68% 5 year relative survival rate; hospital B, 59%; hospital C, 69%; and hospital D, 74%.

## Multivariate survival analyses

Table 4 shows the results of the Cox regression analyses for survival and local recurrence controlling for patient, tumour and treatment variables. Hospital volume did not play a significant role in survival or local recurrence. When the four individual hospitals in the high workload group were compared to all other hospitals in an identical model, patients in hospital B were significantly more likely to present with local recurrence. The already mentioned significant increased proportion of grades 3 and 4 in clinic C caused in the Cox model to a pseudo-protective effect in hospital C. Therefore, when grade was removed from the model, there was no more significant survival benefit for hospital C. Thus, no survival differences exist between the four largest hospitals.

**Table 2** Patient characteristics for whole sample and by hospital volume ($n=884$)

| Variable | All patients *N* (%) | Low volume *N* (%) | Mid volume *N* (%) | High volume *N* (%) | *P* value |
|---|---|---|---|---|---|
| UICC I | 225 (26.2) | 31 (27.9) | 55 (23.3) | 139 (27.1) | |
| UICC II | 198 (23.0) | 26 (23.4) | 58 (24.6) | 114 (22.2) | |
| UICC III | 288 (33.5) | 34 (30.6) | 81 (34.3) | 173 (33.7) | |
| UICC IV | 149 (17.3) | 20 (18.0) | 42 (17.8) | 87 (17.0) | NS |
| Grades 1 and 2 | 700 (83.3) | 106 (90.6) | 198 (83.2) | 396 (81.6) | |
| Grades 3 and 4 | 140 (16.7) | 11 (9.4) | 40 (16.8) | 89 (18.4) | NS |
| <70 years | 553 (62.6) | 66 (54.5) | 129 (53.5) | 358 (68.6) | |
| 70+ years | 331 (37.4) | 55 (45.5) | 112 (46.5) | 164 (31.4) | .001 |
| Men | 505 (57.1) | 67 (55.4) | 126 (52.3) | 312 (59.8) | |
| Women | 379 (42.9) | 54 (44.6) | 115 (47.7) | 210 (40.2) | NS |
| <4 cm | 55 (6.3) | 8 (7.1) | 13 (5.4) | 34 (6.6) | |
| 4-8 cm | 285 (32.9) | 35 (31.3) | 75 (31.3) | 175 (34.0) | |
| 8-<12 cm | 290 (33.4) | 29 (25.9) | 79 (32.9) | 182 (35.3) | |
| 12+cm | 237 (27.3) | 40 (35.7) | 73 (30.4) | 124 (24.1) | NS |
| No recurrence | 742 (83.9) | 97 (80.2) | 213 (88.4) | 432 (82.8) | |
| Local recurrence | 142 (16.1) | 24 (19.8) | 28 (11.6) | 90 (17.2) | NS |
| No sphincter | 155 (19.6) | 18 (18.9) | 51 (23.2) | 86 (18.1) | |
| Sphincter preserved | 635 (80.4) | 77 (81.1) | 169 (76.8) | 389 (81.9) | NS |
| No therapy | 519 (58.7) | 77 (63.6) | 148 (61.4) | 294 (56.3) | |
| Radiotherapy only | 17 (1.9) | 1 (0.8) | 7 (2.9) | 9 (1.7) | |
| Chemotherapy only | 112 (12.7) | 17 (14.0) | 42 (17.4) | 53 (10.2) | |
| Combined therapy | 153 (17.3) | 21 (17.4) | 37 (15.4) | 95 (18.2) | |
| Neoadjuvant therapy | 83 (9.4) | 5 (4.1) | 7 (2.9) | 71 (13.6) | .001 |

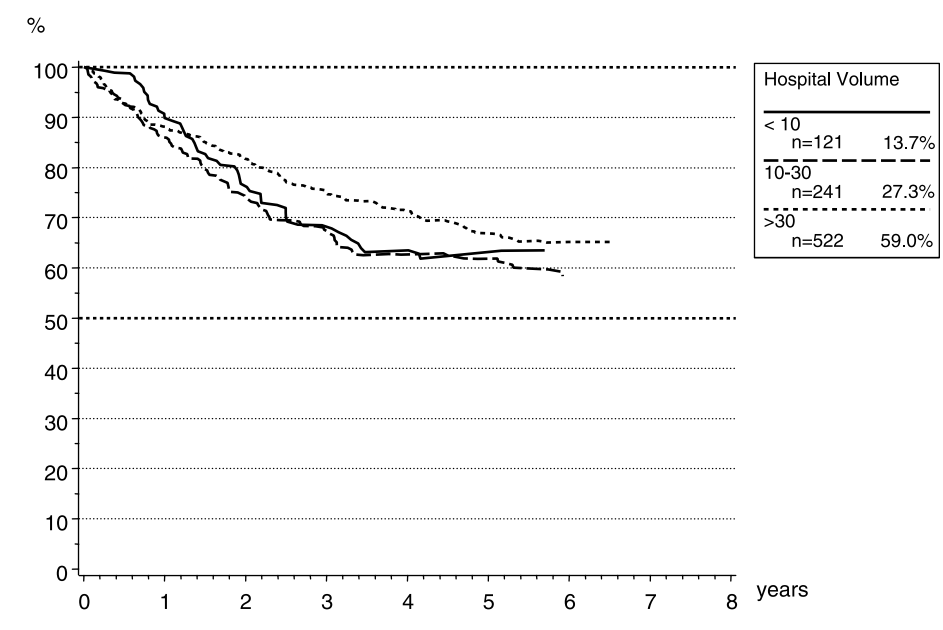
**Table 3** Patient characteristics for the four high volume hospitals, percentages only

| Variable | A | B | C | D | *P* value |
|---|---|---|---|---|---|
| UICC I | 27.5 | 27.3 | 22.4 | 31.7 | |
| UICC II | 23.3 | 22.7 | 25.9 | 11.7 | |
| UICC III | 33.3 | 31.8 | 34.1 | 38.3 | |
| UICC IV | 15.9 | 18.2 | 17.6 | 18.3 | NS |
| Grades 3 and 4 | 11.7 | 11.7 | 47.7 | 14.0 | .001 |
| <4 cm | 5.8 | 2.7 | 8.1 | 15.0 | |
| 4-8 cm | 33.7 | 36.9 | 40.7 | 20.0 | |
| 8-<12 cm | 37.6 | 32.4 | 32.6 | 35.0 | |
| 12+cm | 22.9 | 27.9 | 18.6 | 30.0 | .04 |
| Local recurrence | 16.6 | 26.1 | 15.1 | 6.7 | .01 |
| Sphincter preserved | 86.6 | 74.8 | 76.3 | 83.3 | .03 |
| No therapy | 63.4 | 52.3 | 46.5 | 46.7 | |
| Radiotherapy only | 0 | 1.8 | 7.0 | 1.7 | |
| Chemotherapy only | 9.8 | 9.9 | 9.3 | 13.3 | |
| Combined therapy | 11.3 | 32.4 | 32.6 | 1.7 | |
| Neoadjuvant therapy | 15.5 | 3.6 | 4.7 | 36.7 | .001 |

## Discussion

### Volume effect in the presented data

There was no hospital volume effect on survival or local recurrence, in the multivariate analysis with up to 8 years follow-up, in rectal cancer patients diagnosed in the 2 years between 1996 and 1998 and treated in Munich. Five year relative survival ranged from 62.1 to 66.9%. The largest variability was between the mid and high volume group. Moreover, 5 year relative survival varied greatly between the




| Hospital volume category | patients at risk at year 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| < 10 | 121 | 102 | 84 | 72 | 65 | 62 | 36 |
| 10-30 | 241 | 196 | 163 | 143 | 125 | 115 | 60 |
| >30 | 522 | 439 | 392 | 348 | 318 | 285 | 159 |

**Figure 1** Relative survival curves for each hospital volume (low <10, mid 10-30 and high >30 patients annually).

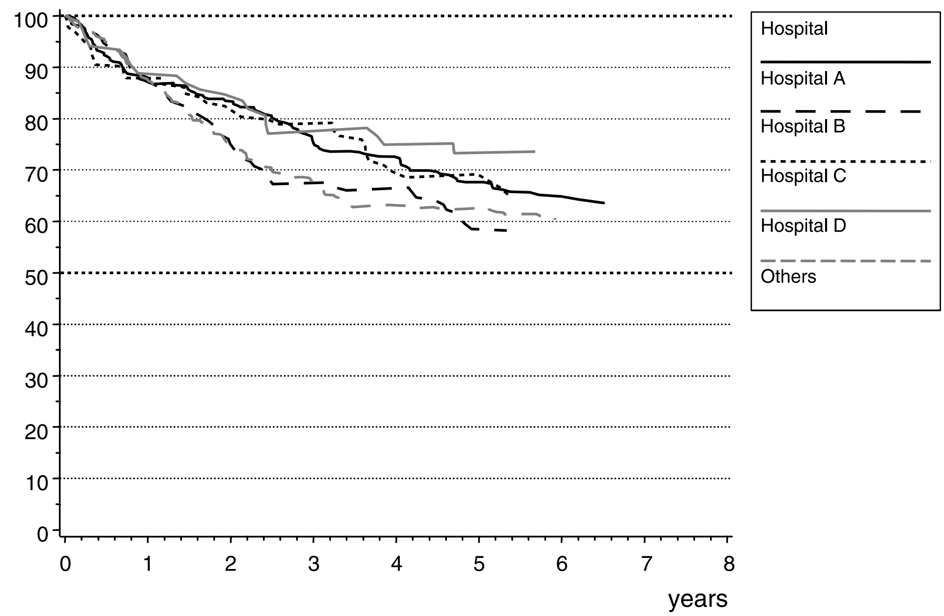



**Figure 2** Relative survival curves for the four largest hospitals compared with all other hospitals.

four hospitals in the high volume group (58.8-74.1%). It would, therefore, be misleading for patients to choose a hospital for rectal cancer treatment based on its caseload, or for health authorities to rule that only certain sized clinics should treat rectal cancer patients. Further research may indicate that surgeons with more experience have higher survival rates, but as a starting point this study indicates that hospital volume may not be relevant.

## Importance of risk adjustment and international studies about the volume effect

This study shows the importance of multivariate analyses for registry data, where there is treatment and patient variability, unlike clinical trials. For example, hospital D appeared to have the highest 5 year relative survival rate, but did not have the greatest survival benefit when controlling for patient, tumour and treatment characteristics. This suggests that the Simons et al. results which reported a univariate hospital volume effect should not be considered in the current debate.[15] Simunovic et al., for example, also found an effect of hospital volume on long term survival which disappeared when tumour variables were controlled for in addition to patient factors.[4] This highlights the importance of multivariate models controlling for patient and tumour variability, particularly in registry data.

The other two studies in Table 1 that showed a significant volume effect, however, should be examined more closely. For example, although Schrag et al. found a hospital volume effect on 2 year survival from patients in the surveillance, epidemiology and end results database, this effect was no longer significant once surgeon-specific volume was controlled for.[8] This emphasizes the importance of surgeon variability, which should be investigated further. The Schrag study results may not be generalisable, however, in light of the shorter follow-up period and because the sample only included patients who were 65 years and older.

Second, Hodgson et al., analysing a population sample of UICC I–III patients registered in California between 1994 and 1997 ($n=7257$), reported a 76.6% unadjusted 2 year survival rate for hospitals treating less than seven patients, which was significantly different from the 83.7% survival rate of hospitals treating over 20 patients in a multivariate model.[14] In our study, using the same sample selection criteria ($n=650$) 2 year overall survival was 79.1–85.5% for our lowest and highest volume hospitals. Although the variability was similar, in contrast, we found no volume or individual clinic effect on 2 year survival in a fully Cox regression model (not shown). Percentages of men and women in the two samples were almost identical and median age varied only by a few months. Two sample differences are noteworthy: firstly, the differences in sample size, thousands compared with hundreds and secondly, the greater percentage of UICC III patients in our sample (40.5% (when UICC IV excluded from total) vs. 32.7%). It will be interesting to see if the volume effect

**Table 4** Cox proportional hazard analyses for survival and local recurrence

| | Survival | | Local recurrence | |
|---|---|---|---|---|
| $N=884$ | HR | 95% CI | HR | 95% CI |
| UICC I | Ref | | | |
| UICC II | 2.8 | 1.9-4.2 | 3.2 | 1.8-6.0 |
| UICC III | 4.6 | 3.1-6.6 | 4.5 | 2.5-8.1 |
| UICC IV | 22.5 | 15.2-33.4 | 7.6 | 3.8-15.3 |
| Grades 1 and 2 | Ref | | | |
| Grades 3 and 4 | 1.8 | 1.4-2.3 | 0.8 | NS |
| <70 years | Ref | | | |
| ≥70 years | 1.5 | 1.2-1.9 | 0.8 | NS |
| Men | Ref | | | |
| Women | 0.8 | NS | 0.8 | NS |
| <4 cm | Ref | | | |
| 4-<8 cm | 0.9 | NS | 0.5 | 0.2-0.9 |
| 8-<12 cm | 0.9 | NS | 0.4 | 0.2-0.9 |
| 12+cm | 0.8 | NS | 0.4 | 0.2-0.9 |
| No local recurrence | Ref | | | |
| Local recurrence | 1.6 | 1.3-2.0 | - | |
| No sphincter | Ref | | | |
| Sphincter | 0.7 | NS | 1.0 | NS |
| No adjuvant therapy | Ref | | | |
| Radiation therapy alone | 0.7 | NS | 0.6 | NS |
| Chemotherapy alone | 0.6 | 0.5-0.9 | 0.8 | NS |
| Chemo and radiation therapy | 0.6 | 0.4-0.8 | 0.6 | NS |
| Neoadjuvant therapy | 0.6 | 0.4-0.9 | 0.4 | 0.2-0.8 |
| Low volume <10 patients per year | Ref | | | |
| Mid volume 10-30 patients per year | 1.0 | NS | 0.6 | NS |
| High volume >30 patients year | 0.8 | NS | 0.8 | NS |
| Models repeated with individual clinics instead of hospital volume and without grade | | | | |
| Other hospitals | Ref | | | |
| Hospital A | 0.9 | NS | 1.2 | NS |
| Hospital B | 1.0 | NS | 2.1 | 1.3-3.4 |
| Hospital C | 0.8 | NS[a] | 1.0 | NS |
| Hospital D | 0.7 | NS | 0.4 | NS |

[a] Significant when grade in model (HR: 0.6, 95% CI: 0.4-0.9).

remains over a longer period in the California data. Importantly, this study did not adjust for adjuvant therapy treatment which varied greatly between hospitals in our study and had a significant effect on survival.

In contrast, four recent studies have found no significant effect of hospital volume on long term survival. The NCDB report of 36,007 rectal cancer cases diagnosed between in 1989 and 1990 (52% of the US rectal cancer population) showed no hospital caseload effect on survival in a Cox proportional hazards model.[2] Adjuvant therapy treatment details were available for this sample, but unfortunately no further caseload particulars were discussed in this report. The other registry data from Ont., Canada ($n=1072$, 418 with pathological details) found no significant effect in a multivariate model, but was unable to adjust for adjuvant therapy use.[4] Two of the studies with no hospital volume effect were not population based. Meyerhardt et al. found no hospital volume effect in a multi centred nested cohort of UICC II and III patients ($n = 1330$) with a median follow-up of 10 years.[3] Since, this study was an adjuvant chemoradiotherapy trial, however, there was less variability in treatment than in a population sample. Holm et al. ($n = 1399$) from two prospective randomized pre-operative radiotherapy trials in 14 hospitals also found no effect of hospital or surgeon volume.[1] Those surgeons with more than 10 years experience, however, did have a survival advantage in an adjusted model.

## Conclusions

This study demonstrates the value of detailed cancer registry data. We were able to analyse long term follow-up of a population based sample controlling for patient, tumour and treatment variables. This study shows that hospital volume may not affect long-term rectal cancer outcomes. Variation between hospitals can be expected and quality audits are vital to maintain uniform standards in all hospitals. It is important that cancer registries give regular feedback to individual hospitals on their performance. Data of single surgeon's case load are not available until now in the Munich Cancer Registry. In future, details for individual surgeons should also be recorded in order to investigate the role of surgeon experience in long term rectal cancer outcomes.

## Acknowledgements

Financial support: The Munich Field Study was funded by the Federal Ministry of Health. The Munich Field Study was integrated in the Munich Cancer Registry (MCR), which is part of the Munich Comprehensive Cancer Centre (MCCC), an institution of the Ludwig-Maximilians University and the Technical University. Additional funding was given by the Deutsche Krebshilfe, and the Bavarian Ministry of Health. The authors would like to thank Fr E. Liebetruth, Fr A. Hucke and Fr B. Stegmann for processing the data and all colleagues of the MCR for the cooperation and the reliable infrastructure. Such a work-intensive observational study is impossible without dedicated staff. Additionally we thank all the following hospitals and surgical departments that participated in the documentation of the medical data: Klinikum der Ludwig Maximilians Universität-Groβhadern; Klinikum der Ludwig Maximilians Universität-Innenstadt; Klinikum rechts der Isar der TU; Städt. Krankenhaus München-Neuperlach; Städt. Krankenhaus München-Schwabing; Städt. Krankenhaus München-Harlaching; Städt. Krankenhaus München-Bogenhausen, Abteilung für Allgemein- und Unfallchirurgie; Kreisklinik Fürstenfeldbruck; Rotkreuzkrankenhaus; Krankenhaus des Dritten Ordens; Krankenhaus der Barmherzigen Brüder; Maria-Theresia-Klinik; Privatklinik Dr Rinecker; Kreiskrankenhaus München-Pasing; Kreiskrankenhaus Landshut-Achdorf; Klinikum Landshut; Privatklinik Bogenhausen; Kreiskrankenhaus Starnberg; Chirurgische Klinik Seefeld; Kreisklinik Dachau; Kreiskrankenhaus Ebersberg; Krankenhaus der Missionsbenediktinerinnen Tutzing; Kreiskrankenhaus Erding; Privatklinik Josephinum; Kreiskrankenhaus Freising; Klinik Dr Wolfart; Klinik Dr Schreiber; Krankenhaus Martha Maria; Kreiskrankenhaus München-Perlach; Klinik Olympiapark.

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