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**ORIGINAL ARTICLE**

# Quality of treatment in routine care in a population sample of rectal cancer patients

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**Abstract**

Variations in compliance with rectal cancer treatment guidelines and the effect of quality indicators on long-term outcomes were investigated with data from the Munich Cancer Registry. Patients diagnosed between 1996 and 1998 with an invasive primary rectal tumor which was resected were included in these analyses (n = 884). Median follow up was 5.7 years. Relative and overall survival was examined. Adjusted survival was predicted by UICC stage, grade, age, local recurrence, and residual tumor status. UICC III patients receiving the recommended adjuvant therapy had a significant survival advantage in the multivariate model; UICC II patients did not. Even if there were no significant survival differences there were significant treatment and outcome (regarding local recurrence) variations between hospitals. The variations between hospitals refer to different quality indicators in the individual hospitals. The outcome (regarding survival) appears good in Munich and is comparable with other population studies. Fewer local recurrences, better reporting of the TME technique, greater use of combined therapy and fewer stomas, however, may improve the quality of care in Munich. Variations in care between hospitals should therefore be monitored and controlled. Detailed and frequent feedback to the clinicians is vital to improve quality of care and is possible with cancer registries.

## Introduction

Quality of care in cancer is essential. In addition to the key long-term quality indicators such as survival and local recurrence, compliance with operative and adjuvant treatment guidelines is also a measure of quality of care. Cancer registries can show quality of routine care in different hospitals and the effect of quality indicators on survival. This paper will focus on rectal cancer where there has been much progress in treatment in the last 20 years [1].

Total Mesorectal Excision (TME) is now considered the gold standard in rectal cancer surgery. TME was first reported in 1986 by Heald and Ryall [2] and over one hundred studies have been published since then. Reviews suggest that there are several factors in surgical technique that are important for long-term outcomes, including use of TME and avoidance of residual tumor as well as attention to lateral margins [3–5]. Every attempt should be made by the surgeon to achieve an R0 resection, for example [6]. TNM guidelines also suggest that pN classification should usually be based on the histological examination of 12 or more regional lymph nodes [7]. Lymph node status is important to determine adjuvant therapy [8]. Examining a greater number of nodes increases the likelihood of proper staging and thus appropriate treatment. The number of lymph nodes examined not only varies by surgeon, however [9]. A further surgical quality indicator is stoma construction. Patients with stomas tend to report lower scores on quality of life measures [10–12]. There are no official guidelines, however, that discourage stoma use.

In addition to the operative guidelines, compliance with adjuvant therapy guidelines is also vital as they

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are based on research that shows survival benefits. The 1990 National Institute of Health (NIH) consensus panel stated that following a curative resection of cancer of the rectum, postoperative adjuvant treatment combining chemotherapy and radiation therapy was effective for stages II and III disease and should be offered to all patients who may benefit [13]. The NIH consensus for combined adjuvant therapy in stage II and III tumors was accepted at the German Cancer Conference in 1994 and first recommended in the 1997 regional treatment guidelines [14]. However, the benefit of the recommended treatment was questioned by German surgeons because the randomized trials that supported the consensus had local failure rates of up to 30%, indicating poor quality surgery [15].

This paper aims to present data on the quality of care in the Munich region of Germany, adjusting for multiple clinical factors. The implementation of operative and adjuvant treatment guidelines in the population and their affect on survival will be assessed. Further, the differences between individual clinics will be investigated in terms of the key quality indicators. Implications for rectal cancer care and the implementation of treatment guidelines will be discussed.

## Material and methods

The MCR routinely 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. This paper reports the results of the Munich Field Study, which monitored all rectal and breast cancer patients diagnosed between 1 April 1996 and 31 March 1998, who were resident in the Munich region. Pathology reports for solid tumors from all pathology laboratories in the Munich area were sent, on a monthly basis, to the MCR. From these reports, the total number of rectal cancer patients in the region was systematically known and the main prognostic factors, such as TNM stage, histology, lymph node harvest, and resection margins, were ascertained. In parallel, clinicians completed standardized forms concerning patients' domicile, tumor diagnosis, primary therapy, follow-up, and palliative care. Doctors' letters and radiotherapy reports were also available. Life status is maintained systematically through death certificates and the inhabitants' registration office.

Tumors 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 two years of the study. 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 primary rectal tumor invading at least the submucosa, which was resected, were included in these analyses (n = 884). Patients were operated on in 39 different hospitals. In this report, the four largest hospitals (treating over 30 rectal cancer patients annually) were compared with all other hospitals.

Survival status was assessed in June 2003 allowing at least five years of follow up. The effect of several operative quality indicators was also investigated, namely local recurrence, residual tumor status, TME use, lymph node yield, and stoma construction. Residual tumor status was R0 compared with RX, R1, and R2 combined. TME was recorded in the original operation reports and extracted from these. This may have led to under-documentation because surgeons did not necessarily use the term TME. German surgeons claim to have been performing a similar high-quality operation before TME was recommended and may thus have been reluctant to use the term in operation reports [16]. Number of lymph nodes examined was grouped from 0–11 and 12 and over. Stoma patients included abdominoperineal extirpation (APE) patients who had no sphincter and a permanent stoma, and anterior resection (AR) patients where the sphincter was preserved but a protective stoma was constructed. Hartmann patients were also considered to have a stoma.

A further process outcome was compliance with adjuvant therapy guidelines. Four adjuvant therapy possibilities were recorded: no therapy, radiation therapy only, chemotherapy only, radiation and chemotherapy (pre- and postoperative or post- only). Compliance with the 1990 NIH guidelines was only applicable to disease stages II and III. Accordingly, compliance was considered as treatment with combined radiation and chemotherapy compared with all other treatment combinations in these stages.

The UICC (International Union Against Cancer) stage classification (fifth edition) is used throughout this paper [7]. The AJCC (American Joint Committee on Cancer) stages are identical to the UICC stages but only the UICC name will be used here. UICC stages II, III, and IV were compared with stage I. For patients who received preoperative therapy their disease stage before treatment was used. Patients with tumor grades 1 and 2 were compared with those with grades 3 and 4. Age was divided into under 70 years and 70 years and over. Patients' gender was also available with men being the referent. There were four tumor location classifications: less than 4 cm, which was used as the

referent, 4 cm to less than 8 cm, 8 cm to less than 12 cm, and over 12 cm (to 16 cm).

*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 $\chi^2$ test. When results are presented for each hospital, only percentages have been given to protect clinic identity. Survival was investigated by the Kaplan–Meier method. Relative survival was computed by the ratio of the observed survival rate to the expected survival rate [17]. 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. The Kaplan–Meier curves discontinue when less than 10 patients at risk remain. Overall survival was also investigated with a Cox proportional hazards regression model. Hazard ratios (HRs) and 95% confidence intervals (CIs) are presented. Logistic regression analyses were performed for multivariate analyses with non-time-dependent dichotomous outcome variables. Odds ratios (ORs) and 95% CIs are reported.

First, the role of patient, tumor, treatment, and procedural characteristics was investigated to see which quality indicators predicted survival. Correct use of those factors considered quality indicators (local recurrence, residual tumor status, TME use, number of investigated lymph nodes, stoma constructed, and adjuvant therapy) by the largest four clinics compared with all others was then examined. The effect of the recommended adjuvant therapy on survival and the role of the four clinics were then assessed in the two stages for which the adjuvant therapy guidelines apply. At the end of the results a time trend of some variables and a summary of the clinic effects on the key quality indicators is given.

## Results

Of the 1 038 newly diagnosed rectal cancer patients over the two years from 1996 to 1998, 884 had invasive primary tumors 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 patients were missing a precise tumor location. For forty-four patients tumor grade was not available. Residual tumor status was unavailable for 111 patients. Eighty-three patients (9.4%) received pre- and post-operative adjuvant therapy. Of the 411 patients who died during the study period only 18 deaths occurred within 30 days of surgery (this is 2.0% of the whole cohort of 884 patients).

Overall survival was 51.3% (relative survival 65.0% respectively) at the time of this analysis with up to 7 years' follow-up data. Table I shows the patient characteristics for the whole sample. A third of patients had stage III disease. Over a third of patients were 70 years of age or older. Most patients had no local recurrence and no residual tumor. TME, as documented in the operation reports, appeared to have been performed in only 22% of patients but over two-thirds achieved a lymph node yield equal to or higher than 12. Compliance with the 1990 NIH guidelines was 31.3% (n = 62) for UICC II patients and 45.1% (n = 130) for UICC III patients. In UICC II, 123 patients received no adjuvant therapy, 7 radiation therapy alone, and 6 chemotherapy alone. In UICC III, 111 received no therapy, 10 radiation therapy alone, and 37 chemotherapy alone. A total of 83 (9.4%) patients with combined therapy received pre- and postoperative therapy, with a range of 3.6% to 36.7% between the four largest hospitals. Patient characteristics and compliance with operative and treatment guidelines for the four largest clinics are also presented and compared in Table I. Apart from residual tumor status, there was significant variation between the four largest clinics for all the considered quality indicators (local recurrence, TME use, lymph node yield, stoma construction, and adjuvant therapy).

Table II shows the results of the Cox regression survival analysis. Not all those factors considered to be quality indicators were significant in the model. Reported TME use and lymph node yield were not significant. Stoma construction, which is considered important for quality of life (but not normally related to survival), was significant in this model; this probably reflects emergency operations and patient comorbidity. Local recurrence and residual tumor status both strongly predicted survival. For the whole sample, treatment with chemotherapy alone or in combination with radiotherapy was significant. When grade was removed from the model, there was no significant survival effect for hospital C, which had a significantly higher grade.

Even if there was no more a significant survival difference there have been univariate differences in the other quality indicators between the four largest hospitals. These quality indicators were investigated further in multivariate models. Table III shows that, even when controlling for tumor and patient characteristics, some hospitals were more likely to have better outcomes and use the recommended treatments more often than others. For example, Hospital B had higher local recurrence rates. Hospitals A and C were more likely to report TME use and

Table I. Patient characteristics and treatment compliance for all patients and the 4 largest hospitals (A–D) separately.

| Variable | All patients | A | B | C | D | p-value |
|---|---|---|---|---|---|---|
| UICC I | 225 (26.2) | 27.5 | 27.3 | 22.4 | 31.7 | |
| UICC II | 198 (23.0) | 23.3 | 22.7 | 25.9 | 11.7 | |
| UICC III | 288 (33.5) | 33.3 | 31.8 | 34.1 | 38.3 | |
| UICC IV | 149 (17.3) | 15.9 | 18.2 | 17.6 | 18.3 | NS |
| Grade 3 & 4 | 140 (16.7) | 11.7 | 11.7 | 47.7 | 14.0 | 0.001 |
| 70+years | 331 (37.4) | 30.6 | 28.8 | 37.2 | 31.7 | 0.02 |
| Women | 379 (42.9) | 43.8 | 42.3 | 30.2 | 35.0 | NS |
| <4 cm | 55 (6.3) | 5.8 | 2.7 | 8.1 | 15.0 | |
| 4–8 cm | 285 (32.9) | 33.7 | 36.9 | 40.7 | 20.0 | |
| 8– <12 cm | 290 (33.4) | 37.6 | 32.4 | 32.6 | 35.0 | |
| 12+cm | 237 (27.3) | 22.9 | 27.9 | 18.6 | 30.0 | NS |
| Local recurrence | 142 (16.1) | 16.6 | 26.1 | 15.1 | 6.7 | 0.01 |
| RX, R1, R2 | 91 (11.8) | 10.8 | 7.5 | 8.5 | 7.9 | NS |
| Reported TME | 195 (22.1) | 26.8 | 15.3 | 40.7 | 26.7 | 0.001 |
| 12+lymph nodes examined | 595 (67.3) | 78.1 | 78.4 | 80.2 | 66.7 | 0.001 |
| Stoma (temporary and permanent) | 398 (45.0) | 48.7 | 42.3 | 72.1 | 58.3 | 0.001 |
| No therapy | 519 (58.7) | 63.4 | 52.3 | 46.5 | 46.7 | |
| Radiotherapy only | 17 (1.9) | 0 | 1.8 | 7.0 | 1.7 | |
| Chemotherapy only | 112 (12.7) | 9.8 | 9.9 | 9.3 | 13.3 | |
| Combined therapy (pre and post or post only) | 236 (26.7) | 26.8 | 36.0 | 37.2 | 38.3 | 0.001 |
| NIH compliance UICC II | 62 (31.3) | 23.3 | 48.0 | 36.4 | 71.4 | NS |
| NIH compliance UICC III | 130 (45.1) | 44.2 | 60.0 | 65.5 | 69.6 | 0.02 |

three hospitals were more likely to comply with the NIH adjuvant therapy guidelines.

The multivariate Cox regression model presented in Table 2 indicated that both chemotherapy alone and in combination with radiation therapy improved survival. In order to assess the effect of treatment on survival in more detail the Cox regression analyses were re-run for the two UICC stages referred to in the NIH guidelines (see Table IV). UICC III patients significantly benefited from combined therapy, in accordance with the NIH guidelines, in comparison with no therapy. UICC II patients showed a decrease in mortality with combined therapy in comparison with the surgery only group, which was not significant. Only 62 UICC II patients were treated with the recommended combination therapy. The Kaplan–Meier curves for UICC II and III patients are illustrated in Figures 1 and 2. The five-year relative survival rates indicate a 7.3% benefit for UICC II patients treated with combined radiation and chemotherapy and surgery compared with surgery alone. Compared with no therapy, UICC III patients with the recommended combined treatment had a 16.1% five-year relative survival advantage. UICC III patients treated with chemotherapy alone had a 2.9% lower five-year relative survival rate than the combined therapy patients.

Considering the amount of data presented in the various models, a summary table has been provided (see Table V) to clarify the role of the four largest hospitals in delivering quality care. Hospital A had significantly higher TME use and lymph node yield. Despite not following treatment guidelines for UICC II patients, Hospital A was the only clinic to significantly improve survival in this patient group. Patients treated in Hospital B experienced significantly more local recurrence; the compliance with the NIH adjuvant therapy guidelines, however, was significantly higher than in all other hospitals. Hospital C tended to follow the guidelines for TME use, lymph node extraction and combined adjuvant therapy. Hospital D consistently demonstrated associations in the preferred direction across the quality indicators but these were mostly not significant.

Finally, because this study was conducted between 1996 and 1998 and the TME and NIH guidelines only became established in the 1990s, changes over time were investigated. In 1996, TME was reported in 14.3% of cases; in 1997, 26.7%; and 1998, 29.3%. TME rates increased significantly over this study period ($p < 0.001$). The yearly percentages for therapy guideline compliance in UICC III patients also increased significantly ($p < 0.002$) from 33.0% to 64.5%. Compliance in UICC II patients improved

Table II. Cox survival analysis: hazard ratios (HRs) and 95% confidence intervals (CIs).

| Variable | HR | 95% CIs |
|---|---|---|
| UICC I | Ref | |
| UICC II | 2.4 | 1.6–3.5 |
| UICC III | 3.9 | 2.7–5.6 |
| UICC IV | 18.4 | 12.2–27.6 |
| Grade 1&2 | Ref | |
| Grade 3&4 | 2.0 | 1.5–2.6 |
| <70 years | Ref | |
| 70+years | 1.5 | 1.2–1.9 |
| Men | Ref | |
| Women | 0.9 | NS |
| <4 cm | Ref | |
| 4–8 cm | 0.9 | NS |
| 8– <12 cm | 1.0 | NS |
| 12+cm | 0.9 | NS |
| No local recurrence | Ref | |
| Local recurrence | 1.5 | 1.2–1.9 |
| R0 | Ref | |
| RX, R1, R2 | 2.1 | 1.6–2.7 |
| No TME | Ref | |
| Reported TME | 0.8 | NS |
| 0–11 lymph nodes examined | Ref | |
| 12+lymph nodes examined | 0.8 | NS |
| No stoma | Ref | |
| Stoma (temporary and permanent) | 1.5 | 1.2–1.9 |
| No therapy | Ref | |
| Radiotherapy only | 0.7 | NS |
| Chemotherapy only | 0.6 | 0.4–0.8 |
| Combined therapy (pre and post or post only) | 0.6 | 0.4–0.8 |
| All other hospitals | Ref | |
| Hospital A | 0.8 | NS |
| Hospital B | 1.0 | NS |
| Hospital C | 0.6 | 0.4–0.9 |
| Hospital D | 0.7 | NS |
| Hospital effects without grade in model | | |
| Hospital A | 0.8 | NS |
| Hospital B | 1.0 | NS |
| Hospital C | 0.8 | NS |
| Hospital D | 0.7 | NS |

from 24.6% to 43.3%, but this was not significant. No other quality indicator improved or worsened significantly over the study period.

## Discussion

Overall survival was predicted by UICC stage, grade, and age. These factors mostly had a greater effect on survival than any of the recognized quality indicators. Of the known quality indicators, only local recurrence, residual tumor status, and adjuvant therapy in UICC III patients significantly influenced survival. The outcomes from this study and compliance rates can be compared with previous results.

Kapiteijn et al. studied a Dutch population sample of resected patients with no exclusion criteria between 1988 and 1992 in 12 hospitals (n = 668) [18]. With three to seven years' follow-up, the overall local recurrence rate was 22.5% with large variability (9–36%) between the institutions, which was not significant, however. In our comparable complete sample, the local recurrence rate was lower at 16.1% with five to seven years' follow-up. In our multivariate analysis, however, one larger clinic was shown to have significantly higher local recurrence rates (26.1%). Local recurrence was predicted by disease stage, tumor location, and residual tumor status. No other quality indicator affected local recurrence rates in this study.

Residual tumor status appeared to be the strongest predictor of survival in our multivariate model after UICC stage. R0 rates seemed high in this study at 88.2%. Most published studies have excluded residual tumor patients so comparison is difficult. A Dutch population study indicated a 93% R0 rate [18]. In a study of 75 German hospitals, 83.8% had histologically clear margins [19]. Residual tumor status is probably the most important indicator of operation quality [6] and was also strongly related to local recurrence rates in our analysis. There was no significant difference in R0 rates between clinics. TME was also a significant predictor of residual tumor status so differences in TME practice are vital.

TME is considered the gold standard in surgical treatment because of the survival advantage in quality controlled studies [6,20]. Regional treatment guidelines are published about every four years by the Munich Comprehensive Cancer Centre in association with the relevant cancer project groups. The rectal cancer guidelines that applied to this study were published in 1993 and 1997 [14,21]. TME was recommended in 1993 and illustrated in detail in the 1997 guidelines. TME use in this study was low (22.1%), however, and was not significantly associated with survival in the multivariate model. In another German study, for example, TME rates were 58.6–61.8% in 1999 [19]. This raises questions about the validity of the TME variable employed in this report. At the time of this study TME was ascertained from the operation report. Nowadays it is documented more reliably in the initial treatment questionnaire filled in by all doctors. Surgeons may have been reluctant to use the term TME in their reports because the high-quality operation they performed was one that they had been performing before TME became widely known. Essentially they thought TME was not new;

Table III. Logistic regression analyses for known quality indicators: odds ratios (ORs) and 95% confidence intervals (CIs) for 4 largest hospitals compared with all others.

| Dependent variable | Hospital A OR (95%CIs) | Hospital B OR (95%CIs) | Hospital C OR (95%CIs) | Hospital D OR (95%CIs) |
|---|---|---|---|---|
| Local recurrence | 1.3 (NS) | 2.2 (1.2–3.8) | 1.4 (NS) | 0.5 (NS) |
| Residualtumor | 0.9 (NS) | 0.6 (NS) | 0.4 (NS) | 0.6 (NS) |
| Reported TME | 1.6 (1.0–2.4) | 0.8 (NS) | 2.9 (1.6–5.3) | 1.1 (NS) |
| 12+lymph nodes examined | 3.8 (2.5–5.7) | 3.1 (1.8–5.3) | 2.3 (1.2–4.4) | 2.1 (1.1–3.9) |
| Stoma | 1.6 (1.1–2.5) | 1.8 (1.1–3.1) | 6.6 (3.4–12.6) | 2.3 (1.1–4.7) |
| NIH compliance UICC II | 0.2 (0.04–0.6) | 4.3 (1.3–13.5) | 1.30 (NS) | 3.00 (NS) |
| NIH compliance UICC III | 1.0 (NS) | 2.8 (1.1–7.5) | 5.7 (1.7–19.0) | 1.3 (NS) |

Model controlled for local recurrence, residual tumor status, TME, lymph node yield, stoma and adjuvant therapy (except when the variable was the dependent variable). Additionally UICC stage, grade, age, gender, and tumor location were controlled for in each model.

they had always removed the mesorectum when appropriate [16].

Despite this belief, operative documentation recommendations indicate that TME should be explicitly stated in an operation report [22]. Further, we do not consider the current TME variable as totally invalid because it showed some effect on the outcomes: 76.2% five-year relative survival compared with 58.5% without TME, as well as a significant impact on residual tumor status, which in turn affected local recurrence and survival. Further, reporting of TME in Munich increased over the two years of the study. The results are also comparable with other reports. For example, five-year relative survival for the reported TME was 76.2%, compared with 80% when Heald himself, the founder of TME, operated [23]. Enker, who provided more details about the study sample, reported a 74.2% cancer-specific survival rate in Duke's B and C cases [3]. In a recent review of the literature, local recurrence rates with TME ranged from 1.6% to 17.8% [3]. Two- and five-year local recurrence rates following TME in Munich were 7.2% and 12.8%, respectively.

Table IV. Cox proportional hazard analyses for UICC II and III separately to investigate the role of adjuvant treatment and hospital on survival (hazard ratios and 95% confidence intervals).

| | UICC II n=198 | UICC III n=288 |
|---|---|---|
| No therapy | Ref | Ref |
| Radiation therapy alone | 0.3 (NS) | 0.9 (NS) |
| Chemotherapy alone | – | 0.7 (NS) |
| Combined therapy | 0.6 (NS) | 0.6 (0.4–0.9) |
| Other hospitals | Ref | Ref |
| Hospital A | 0.5 (0.3–0.9) | 1.0 (NS) |
| Hospital B | 0.6 (NS) | 1.0 (NS) |
| Hospital C | 0.7 (NS) | 0.5 (0.2–0.9)* |
| Hospital D | – | 0.5 (NS) |

Other variables in model: local recurrence, residual tumor status, TME, lymph node yield, stoma, grade, age, gender, and tumor location.

– =values not reported when <10 patients in group.

* Not significant when grade removed from model.

In addition, those who reported TME use were also more likely to have at least 12 lymph nodes examined. Essentially, 12 lymph nodes are seen as the minimum for a successful investigation. Although number of lymph nodes examined was not associated with increased survival in our study, it can be seen as an additional quality control measure. Surgeons alone, however, are not responsible for lymph node yield. Other studies have also found variability between the pathology laboratories examining lymph nodes, and age and therapy effects [9].

Furthermore, suggestions of number of regional lymph nodes refer to both colon and rectum but are much more appropriate for colon than rectum. Particularly after preoperative therapy, it may be difficult to identify as many as 12 nodes. It is positive, however, that this was detected in most of the patients at most hospitals.

Stoma rates are an additional measure of quality of care because patients with stomas appear to have lower quality of life [10–12]. There are no official guidelines on this topic, however, and some parties still argue in favor of stoma construction [24]. Hodgson reported permanent colostomy rates of 33.1% in those undergoing surgery and in disease stages I–III [25]. Using the same sample criteria, abdominoperineal extirpation rates with a permanent stoma were much lower in the Munich area (17.2%). This lower rate of stomas is noteworthy

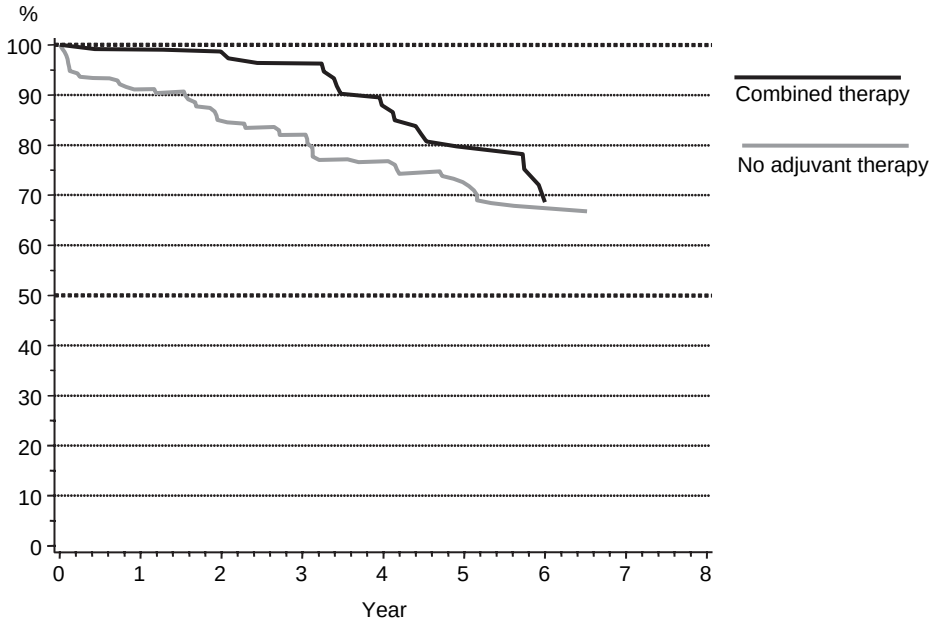


Figure 1. Relative survival curves for resected UICC II patients without adjuvant therapy or with combined chemo- and radiotherapy.

considering our sample had an identical percentage of male patients (55%), more patients with proximal tumors (71.1 vs. 57.8%), and a higher rate of UICC III patients (40.5% (when UICC IV excluded from total) vs. 32.7%), three contributors to stoma rate identified by Hodgson et al. [25]. In two population samples in Canada, permanent stoma rates were 33.1% and 31.0% [26,27]. In a German study, permanent stoma rates were lower, varying from 26.4% to 34.0% [19]. Although abdominoperineal extirpation rates with a permanent stoma in Munich were lower (19.6% in the sample including UICC IV) than other population reports, total stoma rates were high (45%).

The NIH Guidelines for stage II and III rectal cancer patients were published in 1990 [13]. As mentioned earlier, the regional guidelines that applied to this study period were published in 1993 and 1997 [14,21]. In the 1993 guidelines, combined therapy in UICC stage II was not recommended. In the 1997

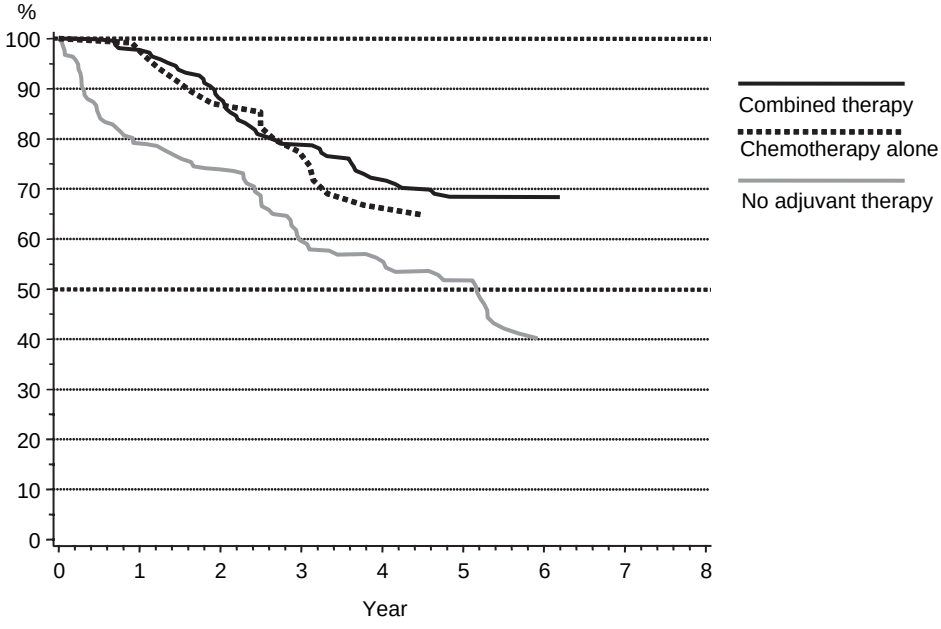


Figure 2. Relative survival curves for resected UICC III patients without adjuvant therapy, with chemotherapy alone, or with combined chemo- and radiotherapy.

Table V. Summary of the clinic effects on the key quality indicators from the multivariate analyses.

| Variable (preferred direction of relationship) | A | B | C | D |
|---|---|---|---|---|
| Local recurrence (−) | +NS | +Sig | +NS | −NS |
| Residual tumor (−) | −NS | −NS | −NS | −NS |
| TME (+) | **+Sig** | −NS | **+Sig** | +NS |
| Lymph node yield (+) | **+Sig** | **+Sig** | **+Sig** | **+Sig** |
| Stoma (−) | +NS | +NS | +Sig | +NS |
| Therapy compliance UICC II (+) | −Sig | **+Sig** | +NS | +NS |
| Therapy compliance UICC III (+) | 0NS | **+Sig** | **+Sig** | +NS |
| UICC II survival without grade in model(+) | **+Sig** | +NS | +NS | N/A |
| UICC III survival without grade in model (+) | 0NS | 0NS | +NS | +NS |
| Whole sample survival without grade in model (+) | +NS | 0NS | +NS | +NS |

Significant associations in the preferred direction are highlighted in **bold**.
+ =positive association.
0 =no association.
− =negative association.
NS =not significant.
Sig =significant.
N/A =not available (sample size too small).

guidelines, it is stated that the NIH guidelines were accepted at the German Cancer Conference in 1994 and that the regional guidelines now recommended combined treatment in UICC stages II and III. In 1998, the German Cancer Society Consensus Conference adopted the recommendations outside clinical trials [15]. It is clear, therefore, that there was some reluctance to adopt the guidelines, especially for UICC II patients. The reason for this doubt was the high local recurrence rates in the studies, which did not reflect good operative control. This hesitancy is reflected in the combined therapy practice rates in the Munich study. From 1996 to 1998 guideline compliance was 24.6–43.3% for UICC II patients and 33.0–64.5% for UICC III patients. The National Cancer Data Base (NCDB) in the US reported compliance rates of 40.3% and 52.3% for UICC II & III patients, respectively, between 1994 and 1995 [28]. Data from the Californian cancer registries also showed compliance rates of 44% (UICC II) and 60% (UICC III) between 1994 and 1996 [29]. Although the Munich rates are slightly lower, essentially the 1998 rates are comparable. However, even if some patients refuse treatment or have clinical contraindications, Ayanian et al. suggest that an 80% compliance rate is possible in community practice [30].

In our data, five-year relative survival rates for UICC II patients with combined therapy were 7.3% higher than for those without adjuvant therapy. The survival advantage in the multivariate model was not significant. For UICC III patients the five-year relative survival benefit was 16.1%. In the multivariate model, combined adjuvant therapy provided a significant survival advantage for UICC III patients. The high mortality of both 'non adjuvant therapy' groups in the first year (see Figures 1 and 2) shows medical limitations of a population-based implementation of guidelines, probably due to contraindications. The 1989–1990 results of the NCDB study indicated a 6.6% higher five-year relative survival rate for UICC II patients with combined therapy and a 10.6% five-year relative survival improvement for UICC III patients compared with the surgery alone group [28]. The small improvement for UICC II patients in both studies indicates the need for further investigation in randomized trials with modern operative standards, and partly justifies the German surgeons' reluctance to adopt the NIH recommendations. Considering the larger effect on survival following treatment for UICC III patients, however, combined therapy should be prescribed more often.

There is strong evidence that preoperative radiotherapy is more effective than postoperative [1]. A Dutch population-based study reported a significant increase in preoperative radiotherapy (up to 17%) in the period 1995–2000 [31] and mentioned this as one reason for improved population-based survival among patients aged less than 75 years. In the Munich area in the period 1996–1998 only 9.4% of the patients received neoadjuvant therapy with a wide range between the hospitals. Nowadays more preoperative therapy is recommended and the percentage is increasing. The uniform realization of preoperative therapy and a population-based impact on survival remains to be demonstrated in the future.

In conclusion, while this study indicates a good outcome (regarding survival) in Munich, there is still room for improvement. This study has shown that even if there were no more significant survival differences there were significant treatment and outcome (regarding local recurrence) variations between hospitals. Because the four largest hospitals (treating

over 30 rectal cancer patients annually) were compared with all other hospitals, caseload cannot be the reason for the variations between them. It could also be shown that the variations between hospitals refer to different quality indicators in the individual hospitals. Unfortunately, it cannot be shown whether variation in compliance was because guidelines were not known or not trusted. Detailed and frequent feedback to the hospital departments is vital to improve quality of care. Fewer local recurrences, better reporting of the TME technique, greater use of combined therapy, and fewer stomas may improve the quality of care in Munich. The additional experience was that quality assurance can be integrated into a cancer registry without enlargement of the database. These data show therefore that providing regular feedback to clinicians on their performance across quality measures to ensure uniform care is possible with cancer registries.

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