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Evidence-based quality standards improve prognosis in colon cancer care

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ABSTRACT

Background: Colon cancer requires interdisciplinary care with quality of initial surgical treatment being a major prognostic factor. Implementation of quality standards based on structural and procedural indicators in routine care via certification (Germany) or accreditation (USA) is an established quality assurance method. However, evidence on effects is scarce. We undertook a population-based cohort study to investigate the effectiveness of colon cancer care in certified vs non-certified hospitals.
Materials and methods: We utilized data of a large statutory health insurance including in- and outpatient data from 2005 to 2015 of >2 million individuals from Saxony, Germany. Case definitions were based on diagnosis, medical procedures and prescriptions. Patients treated in certified hospitals (CH) were compared to patients treated in non-certified hospitals (NCH) using logistic and Cox regression models adjusting for relevant confounders concerning overall survival (OS), disease-specific survival (DSS), 30-day mortality, recurrence, complications and second resections within 6 months after first resection (SR).
Results: Overall, 6186 patients with incident colon cancer undergoing surgery were identified (mean age 74.1 ± 11.0 years, 51.1% male) with 2120 (34.3%) patients treated in a CH. Confounder-adjusted regression models indicated positive effects in CH on OS (HR = 0.90, 95%CI: 0.83–0.97), DSS (HR = 0.71, 95%CI: 0.57–0.88), 30-day mortality (OR = 0.69, 95%CI: 0.55–0.87) and SR (OR = 0.51, 95%CI: 0.30–0.87). These results remained stable after adjustment for hospital volume. 30-day mortality in 2014 was 41% lower in CH (7.4%) compared to NCH (12.6%).
Conclusions: This study indicates that the implementation and assurance of evidence-based quality standards has substantial positive effects on various patient-relevant outcomes in colon cancer care.

Introduction

Treatment of colon cancer – one of the most common cancers – is multimodal with complete resection being crucial for prognosis and survival [1,2]. To increase the quality of colorectal cancer, care a variety of quality measures such as minimum hospital and surgeon caseload, regulations regarding training and expertise of surgeons, decision making in interdisciplinary treatment conferences, the establishment of multidisciplinary teams and regular audits have been recommended [3–7].

Whilst high quality standards are prerequisites for treatment in some European countries, e.g. the UK, hospital accreditation in the US (e.g. Cancer Program of the Commission on Cancer [8] or the

Abbreviations: AIC, Akaike information criterion; ATC, Anatomical Therapeutic Chemical code; CH, Certified hospital; DGAV, "Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie" (German Society for General and Visceral surgery); DKG, "Deutsche Krebsgesellschaft" (German Cancer Society); DSS, Disease-specific survival; EBM, "Einheitlicher Bewertungsmaßstab" (Uniform Value Scale); HR, Hazard Ratio; NCH, Non-certified hospital; OPS, "Operationen-und Prozedurenschlüssel" (German modification of the International Classification of Procedures in Medicine); OR, Odds Ratio; OS, Overall survival; PZN, pharmaceutical registration numbers; SR, second resections within 6 months after first resection; UICC, Union international contre le cancer; 95%CI, 95% confidence intervals.

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National Cancer Institute Cancer Center Program [9]) and certification in Germany are main strategies to increase the quality of cancer care. Introduced in 2003 entity specific certification requests hospitals to meet specific structural and processual requirements based on evidence-based clinical guidelines [10] with respect to qualification, equipment as well as transsectoral, interdisciplinary and interprofessional collaboration. Compliance with defined quality standards is reviewed through annual audits [11,12]. Hospital certification is voluntary but encouraged by policy makers.

Despite medical and political recommendations to implement certification in oncological care, studies analyzing the effects of the German model of certification on treatment outcomes are scarce, especially for colon cancer. Studies are limited by the high risk of bias regarding the quality of data collection, differences in patient characteristics and missing information on methodological approaches. An independent evaluation of certification programs is therefore suggested [13].

We undertook a large cohort study using comprehensive health care data of a national statutory health insurance to assess the effects of certification on cancer care in hospitals treating colon cancer. We hypothesized that certification is associated with better survival, lower mortality and lower rates of recurrence, complications and second resections within 6 months past initial surgery.

Materials and methods

We undertook a cohort study utilizing a health services research database of a large German statutory health insurance (AOK PLUS) covering approximately 2 million people living in the German federal state of Saxony [14]. The study population includes 51% of the general population in the study region [15] and is representative in terms of sex and age distribution with follow-up from January 2005 until December 2015 [16]. Pseudonymized data on inpatient care (diagnosis, medical procedures, treatment time), outpatient care (diagnoses, medical procedures, healthcare providers, and drug prescriptions) as well as individual patient-related data (age, sex, ZIP-code, date of death, date of leaving insurance) are documented on the patient level. Due to data protection guidelines hospitals are anonymized. To approximate hospital volume, the annual caseload of patients with colorectal cancer in the surgical department of the treating hospital was provided in quartiles by the data owner at the case-level.

To identify incident cases of colon cancer and events reliably we applied internal case validation methods following the national standards for Good Practice in Secondary Data Analysis [17]. Case definitions were based on the respective coding systems for diagnosis (ICD-10-GM), procedures (Uniform Value Scale (EBM); German modification of the International Classification of Procedures in Medicine (OPS)) and prescriptions (Anatomical Therapeutic Chemical code (ATC); pharmaceutical registration numbers (PZN)) (Appendix A).

Inclusion and exclusion criteria

The study cohort comprised continuously insured patients with an inpatient diagnosis of *incident* colon cancer (ICD-10-GM C18/C19 - malignant neoplasm of colon/rectosigmoid junction), which were undergoing surgery between January 2008 and December 2014 in a hospital located in the federal state of Saxony. Date of diagnosis was defined as the first hospital admission within the observation period. Disease severity following the UICC stages (*Union international contre le cancer*) was approximated using information on the presence of distant metastasis and chemotherapy. For case definitions see Appendix A.

Exposure

As the two major types of certification for colorectal cancer care we investigated the certification of the German Cancer Society (Deutsche Krebsgesellschaft, DKG) for colorectal cancer centers and the certification of the German Society for General and Visceral surgery (DGAV) for coloproctology and minimally invasive surgery. DGAV focuses primarily on surgical requirements, DKG primarily on multidisciplinarity and procedural quality. DGAV certification was considered assuming that hospitals performing specific surgical colon procedures are representing an overall cancer care additionally. There are 54 hospitals in the federal state of Saxony with a surgical department. Of these, eight hospitals were DKG-certified, three hospitals were DGAV-certified and three hospitals were DKG- and DGAV-certified during the observational period.

Information on certification was available on the individual patient level with cases being considered as treated in a certified center if the hospital was already or became certified within the observational period. To assess the potential bias introduced, we conducted sensitivity analysis five (sensitivity analysis 5).

Outcomes

Primary outcomes were overall, disease specific and recurrence-free survival time. Secondary outcomes were 30-day mortality, postoperative complications, tumor recurrence, and distant metastasis. Additionally, we investigated second resections within 6 months as a quality indicator for surgical procedures as repeated resections after hemicolectomy within 6 months are undesirable. Detailed outcome definitions are provided in Appendix A.

Confounding and effect modification

Age at diagnosis (<60, 60–69, 70–79, ≥80 years), sex, other malignant neoplasms more than 12 months before or after colon cancer diagnosis (yes/no), multivisceral resection and participation in colorectal cancer screening before diagnosis (yes/no) as a proxy for health behavior were considered as confounders. We also considered the number (0–4) of specific comorbidities (hypertension, cardiovascular diseases, type 2 diabetes and renal insufficiency). Age at diagnosis, sex, disease severity and participation in colorectal cancer screening were also regarded as potential effect modifiers using interaction terms and stratified analysis.

Data analysis

All analyses were conducted using Stata® version 14.2. Overall survival, disease specific survival, and recurrence-free survival were analyzed using log-rank tests, univariate and multivariate Cox regression models as well as Kaplan Meier estimates. The proportional hazards assumption was tested based on Schoenfeld residuals. If the proportional hazards assumption was violated, variables were included in the model as time varying covariates. Effect estimators were obtained as hazard ratios (HR) with corresponding 95% confidence intervals (95%CI). Minimal follow-up was one year ("last patient in" 31st December 2014; end of period of observation 12/2015). All binary outcomes were analyzed applying chi-squared tests and logistic regression models obtaining odds ratios (OR) with 95%CI. When analyzing recurrence-free survival and recurrence rate, patients who died during the observation period without recurrence were excluded, since an association between death and progression of the disease cannot be excluded.

Confounding was analyzed for each outcome separately. Variables were considered as confounders if there was a statistically significant association with both the exposure (certification) and

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