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Completeness and registration bias in PROCARE, a Belgian multidisciplinary project on cancer of the rectum with participation on a voluntary basis

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Abstract ***Background:*** PROCARE, a Belgian multidisciplinary project on rectal cancer, started in 2006 with participation on a voluntary basis. Completeness and bias of registration in PROCARE were assessed.
Methods: Data from 6353 patients with rectal cancer were extracted from the population based Belgian Cancer Registry for the period 2006–2008. Registration bias was studied by comparing patient, tumour and treatment characteristics of cases registered and non-registered in PROCARE. Relative survival (RS) of patient subgroups was analysed.
Results: PROCARE included 37% of all Belgian rectal cancer patients. Registration was highly variable between participating centres which recorded on average 56% of their patients. Significant differences in patient, tumour and treatment related characteristics were observed between registered and non-registered patients. The 5-year RS was 77% (95% confidence

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interval (CI): 74–80%) for registered patients and 56% (95% CI: 53–59%) for non-registered patients. After adjustment for patient, tumour characteristics and volume of centre, the relative excess risk of dying (RER) between registered and non-registered patients was 2.15 (95% CI: 1.85–2.50, $p < 0.001$). The 5-year RS of patients treated in centres that never participated in the project was 59% (95% CI: 55–63%) and, after adjustment, the RER was 1.16 (95% CI: 1.00–1.35, $p < 0.050$) compared to patients of the participating centres.

Conclusion: Registration of PROCARE patient data was incomplete, biased and variable between centres. Participation on a voluntary basis should be avoided for further projects. Quality assurance on a centre level requires compulsory and complete registration with a minimal but relevant data set for all patients treated in all centres.

1. Introduction

Rectal cancer registries have been set up in several European countries to allow clinically relevant analyses of the quality of care and its variability between centres. Some registries cover all patients with rectal cancer while others mainly cover surgical patients [1,2]. Participation of centres may be either compulsory or voluntary. Completeness of registration on a voluntary basis may be variable and may not represent national data [3–5]. Population-based cancer registries were designed to collect, analyse and report data on all patients with cancer and may also serve to check the completeness of patient registration in specific clinical databases. Both clinical databases and cancer registry databases may be hampered by data quality issues [6]. In addition, clinical databases may be biased because of incomplete or selective participation and/or registration. Randomised clinical trials could be a way to avoid such selection bias, but observational studies are still needed to assess general practice on a population basis [7,8].

In the context of PROCARE [9], a multidisciplinary project on cancer of the rectum with as main objective the reduction of diagnostic and therapeutic variability and improvement of outcome in patients, every medical discipline (gastroenterology, endoscopy, pathology, surgery, radiotherapy, radiology, oncology) defined its own and specific goals in the project to achieve this main objective [10]. All Belgian centres involved in the management of rectal cancer patients were invited to participate and to register data on a voluntary basis. Data were registered in a specific database held at the Belgian Cancer Registry.

The aim of this study was to assess the completeness of registration and potential bias of patient registration in the context of PROCARE. A first estimation of participation done by Penninckx et al. [11] indicated that 44% of patients who underwent radical resection between 2006 and mid 2008 were registered in PROCARE. Consequences of registration bias on relative survival were evaluated.

2. Patients and methods

2.1. Data sources

Three databases were used: the population-based Belgian Cancer Registry (BCR) database, the InterMutualistic Agency (IMA) database [12] and the PROCARE rectal cancer database. The BCR collects basic information such as incidence date, gender, age, region, tumour localisation and histology, World Health Organisation (WHO) performance score, multiple tumour status, clinical and pathological stage. According to the Belgian legislation, cancer registration is mandatory for pathology laboratories and hospitals. The IMA is an association of the seven Belgian health insurance companies and integrates data related to reimbursed treatment of all Belgian patients. Health insurance is obligatory in Belgium. The PROCARE database consists of specific, detailed and prospectively collected data from patients with any stage of an invasive rectal adenocarcinoma up to 15 cm above the anal verge [13].

2.2. Study population

All patients with rectal cancer (coded as C20, International Classification of Disease-10) having an incidence date between 1st January 2006 and 31st December 2008 were selected from the BCR database. In order to make the BCR and PROCARE databases more comparable, the following patients were excluded from the extracted BCR patient list: non-adenocarcinomas, non-invasive adenocarcinomas (pTis), patients with synchronous cancer (i.e. cancer at a second location diagnosed within a time period of 3 months prior to or following the rectal cancer incidence date) and non-Belgian citizens.

BCR data were linked to the IMA database allowing identification of (neo)adjuvant treatment and type of surgery. The time window allowed for (neo)adjuvant treatment was set at 3 months prior to or after the date of surgical resection. This linkage also revealed the centre where treatment was performed. Patients were assigned to the centre where the surgery was performed

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