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Broe, Martin Oskar; Jensen, Peter Bjødstrup; Mattsson, Thea Otto; Pottegård, Anton

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Validity of antineoplastic procedure codes in the Danish National Patient Registry: the case of colorectal cancer

Martin Oskar Broe[1, BScMed]

Peter Bjødstrup Jensen[1, MSc PhD]

Thea Otto Mattsson[2, MD PhD]

Anton Pottegård[1, MScPharm PhD]

(1) Clinical Pharmacology and Pharmacy, Department of Public Health, University of Southern Denmark, Odense, Denmark

(2) Department of Oncology, Odense University Hospital, Odense.

Correspondence
Anton Pottegård
Professor
Clinical Pharmacology and Pharmacy
University of Southern Denmark
JB Winsløwsvej 19, 2
DK-5000 Odense C, Denmark
E-mail: apottegaard@health.sdu.dk
Phone: 0045 28913340

Abstract

Background

Procedure codes in the Danish National Patient Registry are used for administrative purposes and constitute a potentially valuable resource for epidemiological research. The validity of antineoplastic procedure codes has, however, only been evaluated in one study.

Methods

We obtained a random extracted sample of 420 patients in the Southern Region of Denmark with a diagnosis of colorectal cancer and an oncological contact during 2016-2018. Using the medical record as gold standard, we computed the positive predictive value (PPV) and sensitivity of antineoplastic procedure codes recorded in the Danish National Patient Registry.

Results

We identified 2243 and 2299 codes of antineoplastic treatments in the registry and in the medical records, respectively. We confirmed 213 of 214 patients with registered therapies in the Danish National Patient Registry received therapy, corresponding to a PPV of 'any registration' of 1.00 (95% CI, 0.97 – 1.00). Considering single registrations, the overall PPV was 0.95 (95% CI, 0.94-0.95), and the overall sensitivity was 0.90 (95% CI, 0.89-0.91). There was a strong correlation between number of recorded treatments and treatments administrated. Considering the most frequent single antineoplastic regimens, the PPV ranged from 0.90, (95% CI, 0.87-0.92) for capecitabin to 0.98 (95% CI, 0.95-1.00) for cetuximab, while the sensitivity ranged from 0.81 (95% CI, 0.75-0.87) for FOLFIRI-regimen (5-fluorouracil and irinotecan) to 0.97 (95% CI, 0.94-0.99) for bevacizumab. Analysis per hospital showed the highest validity of registrations at the University Hospital.

Conclusion

The validity of antineoplastic procedure codes in the Danish National Patient Registry is generally high and thus usable for epidemiological research.

Introduction

The Danish National Patient Registry is a unique nationwide register, covering all hospital admissions, treatments and diagnoses at Danish hospitals since 1977.[1] Data can be linked at the individual level by using the Civil Personal Registry[2] which enables patient identification if needed. The Patient Registry thus constitutes a central resource to Danish epidemiological research.[1] One such use could be to conduct analysis on the use patterns and effects of use of antineoplastic treatments. Chemotherapy is not recorded in the Danish National Prescription Registry[3], and it is currently neither included in the newly established Registry for Hospital Medication (Sygehusmedicinregisteret)[4]. This leaves researchers with using procedure codes registered in the Patient Registry. However, the validity of antineoplastic procedure codes included in the Patient Registry is not clear. One previous study, Lund et al (2013),[5] concluded that the validity is generally high. However, this study only included 50 colorectal patients with nodal involvement, only assessed the validity of 'any/ever' antineoplastic treatment and provided no details as to the validity of the timing of antineoplastic treatments recorded in the Patient Registry. As such, it is largely unknown to what extent the Patient Registry can facilitate studies on the use of antineoplastic treatments. We therefore aimed to evaluate the validity of antineoplastic procedure codes in the Patient Registry, using colorectal cancer treatments as a case.

Methods

This validation study was conducted in the Region of Southern Denmark among patients with a diagnose of colorectal cancer. To obtain the positive predictive value (PPV) and sensitivity of the Patient Registry, we compared the procedure codes in the Patient Registry to the antineoplastic treatments prescription and administration as recorded in the medical records.

Data Sources

Denmark is divided into five regions which are comparable in sociodemographic and health related characteristics.[6] Each region typically comprise one university hospital and several smaller hospitals. The antineoplastic treatments for the approximately 35,000 prevalent colorectal cancer patients in Denmark[7] are administered by the oncological departments in the regions. The Region of Southern Denmark have four oncological departments placed at Odense University Hospital, Hospital of Southern Jutland, Hospital Little Belt and South-west Jutland Hospital. In this study, we used medical records obtained from each of the four hospitals while data from the Patient Registry was obtained from the Danish Health Data Authority.
We considered the medical record to have the highest validity and therefore it acted as our gold standard reference.

The Patient Registry has been collecting nationwide administrative data of hospitals admissions since 1977.[1] One of the main purposes is to enable monitoring of diseases and treatments.[1] The Patient Registry uses ICD-10 diagnose codes and the validity among ICD-10 colorectal cancer diagnoses is found to be very high.[8]

Validation

We estimated the validity of antineoplastic procedure codes in the Patient Registry, on a random sample of colorectal patients with a contact to an oncological department. To identify our sample, we first sampled 800 random patients in the Region of Southern Denmark, with an ICD-10 diagnosis of colorectal cancer and a contact to any hospital in the region within 1st May 2016 and 1st May 2018, from the Patient Registry. Because antineoplastic treatments only are administrated by specialists at the oncological departments, we could narrow down the included patients to those with an oncological contact within our study period, which restricted our sample to 431 patients. The initial sample size of 800 was largely arbitrary, mainly due to uncertainty in the proportion ultimately eligible for inclusion. However, it was judged that 431 patients was sufficient to allow reasonably precise estimates of validity, even in subgroups, and it was therefore decided not to expand the material further.

For the 431 patients, individual medical records were obtained directly from the oncological departments in the region. This was possible by using the unique personal identification code (Central Patient Registry number)[2] to link medical records to the data from the Patient Registry. The medical records included all records from nurses and doctors between 1st May 2016 and 1st May 2018. The medical records were examined manually for any antineoplastic treatments in the study period. For all administered therapies, the date and type of antineoplastic treatment was recorded for each individual patient. All data from the medical records were entered into REDCap[9], which is a secure data capture web application.

We validated each treatment code (type of treatment) separately. For each round of validation, we considered a specific coding instance as valid if it fulfilled one of the three following criteria. First, and most commonly, a match on the exact code (either specifying a single treatment or a combination treatment). Second, we accepted a match by any combination of codes giving the same result, e.g. validating CAPOX (capacitabin/oxaliplatin), we accepted two single codes specifying capecitabin and oxaliplatin. As a notable exception, we accepted a code as true for oxaliplatin containing combination treatments even though oxaliplatin was not administrated. This was done based on clinical input, as oxaliplatin is often discontinued, due to side effects, while the remaining treatment is continued. In supplementary analyses, we performed analyses without making this exception. Third, we accepted a match of a code for a single component with a code for a combination including that component, e.g. when validating 5-fluorouracil, we accepted a code for the 5-fluorouracil containing regimen FOLFOX (5-fluorouracil/oxaliplatin).

The handling of combination codes as described above is clinically sensible and ensures consistency in the 2x2 matrices for each validated code. It does, however, mean that some registrations in Patient Registry and the medical records may be involved in the validation of more than one treatment code. Unless otherwise specified, we accepted a one-day deviation between the registration in the Patient Registry and the medical record.

Statistical analysis

To evaluate the validity of registrations for antineoplastic treatments in the Patient Registry, we applied four different analyses. First, we calculated the PPV, negative predictive value (NPV), and sensitivity of 'any chemotherapy', comparing the registrations in the Patient Registry to the medical record, while accepting a one-month displacement between registrations. The PPV was defined as the number of confirmed chemotherapy recipients divided by total number of patients recorded as having received chemotherapy according to the Patient Registry. The NPV value defined as the number of patients confirmed not to have received any chemotherapy divided by total number of patients recorded as not having received chemotherapy according to the Patient Registry. The sensitivity was defined as the number of confirmed chemotherapy recipients divided by the total number of chemotherapy recipients according to the medical records. Second, we assessed how well the number of registrations of antineoplastic treatments per patient correlated with the number of administrated therapies per patient. Third, we investigated the validity of the recording of specific treatment regimens and the differences in validity across individual hospitals (n=4). Lastly, we investigated the validity of the timing of registrations by calculating the PPV and sensitivity for any antineoplastic treatment overall and per hospital, allowing a deviation of 5 and 1 day, respectively. We calculated exact 95% confidence intervals for proportions. Analyses were performed using STATA 16 (Stata-Corp, TX).

Approvals

We obtained permission to access the medical journals from the Danish Patient Safety Authority (record no. 3-3013-2494/1). In terms of data protection, the study was registered at the University of Southern Denmark's inventory (record no. 18/12145). Approval from the Ethics Committee was not required.

Results

For our sample of 431 patients with a diagnosis of colorectal cancer and a contact to an oncological department, we obtained all antineoplastic treatment procedure codes from Patient Registry during 1st May 2016 – 1st May 2018. Of the 431 patients, we excluded 11 patients that, while correctly identified as patients with a history of colorectal cancer, had other reasons for their current oncological contact (that is, other cancers). Of the 420

eligible patients, 220 patients had at least one antineoplastic treatment registered in the medical record, comprising in total 2299 antineoplastic treatment visits. In the Patient Registry 214 patients had at least one antineoplastic treatment registered, with a total of 2243 antineoplastic registred treatments (Table 1). The main reasons for an oncological contact not accompanied by any treatment of interest were planned follow up visits, multi-disciplinary team conferences, patients only receiving radiotherapy and patients whose health condition did not allow antineoplastic treatment.

Assessing the validity of having at least one registration of antineoplastic treatment in the Patient Registry (Table 1), we found a PPV of 1.00 (0.97 – 1.00), that is, 213 out of 214 patients in the Patient Registry actually received antineoplastic treatment. The corresponding sensitivity was 0.97 (0.94 – 0.99), that is, 213 out of 220 patients receiving antineoplastic treatment were captured by the Patient Registry. Conversely, the NPV, that is the certainty that a patient classified as not receiving any chemotherapy according to the Patient Registry did in fact not receive therapy was 0.97 (93 – 99).

In figure 1, we show the percentage of antineoplastic treatments registered in the medical record, which are also found in the Patient Registry, for a given individual. The percentages are generally high, regardless of the number of antineoplastic treatments found in the medical records. With a few exceptions, more than 75 % of all individuals had all their treatments recorded in the Patient Registry, and almost everyone had 'all-but-one' treatments recorded (Figure 1). These estimates did not change if allowing a 30-day deviation between registrations (data not shown).

The overall PPV and sensitivity for individual registrations was 0.95 (0.94 – 0.95) and 0.90 (0.89 – 0.91), respectively (Table 2). The highest overall PPV and sensitivity was found for the regional university hospital at 0.95 (0.95 – 0.96) and 0.91 (0.90 – 0.92), respectively. The overall PPV of the three other (non-university) hospitals within the region ranged from 0.84 (0.76 – 0.91) to 0.93 (0.91 – 0.95), and the overall sensitivity ranged from 0.79 (0.71 – 0.87) to 0.87 (0.83 – 0.90) (Supplementary).

For the most frequent specific treatments, the overall PPV ranged from 0.90, (95% CI, 0.87-0.92) for Capecitabin to 0.98 (95% CI, 0.95-1.00) for cetuximab, while the sensitivity ranged from 0.81 (95% CI, 0.75-0.87) for FOLFIRI-regimen (5-fluorouracil and irinotecan) to 0.97 (95% CI, 0.94-0.99) for bevacizumab (Table 2).

Lastly, we investigated the timing of registrations by allowing a 5-day deviation between a registration in the Patient Registry and the medical record, which did not change the PPV and sensitivity for either the overall values, specific treatments or per hospital (data not shown).

Discussion

In this validation study of antineoplastic procedure codes in colorectal cancer patients in the Danish National Patient Registry, we found a high completeness and validity both for 'any use' and for individual administrations.

When specifying by the individual antineoplastic regimens or hospitals, some variation was identified, however, the validity generally remained high. Analysis of timing of registrations showed no variation.

The most important strength of this study is the large and randomly extracted sample of patients. Our study also had several limitations. First, we only included one out of five regions in Denmark, although we did include all hospitals within the region. Further, the medical records were only reviewed by one author and only included data from 2016-2018. While the calendar restriction was found to be necessary to ensure a high retrieval rate of patient records, it is unknown whether the validity of registrations has changed over time. Also, the selection of patients was by the diagnosis code of colorectal cancer in the Patient Registry and therefore depending on the sensitivity hereof. However, Helqvist et al (2012)[8] found a sensitivity 93.4% (95% CI, 91.1-93.7) of the ICD-10 colorectal cancer diagnosis. Lastly, our results are based on patients diagnosed with colorectal cancer, in which treatment is mainly intravenously administered (except capecitabine) in an ambulatory setting. Whether our findings can be extrapolated to other cancer diagnoses and treatments in the Patient Registry, e.g. cancers where oral treatment is more common, remains unknown. However, oral chemotherapy is in Denmark prescribed and dispensed via the same systems, and as such it is likely that the results can be generalized to other cancers and other chemotherapy regimens. Nevertheless, it would be valuable for future studies to address the validity of registrations both within other cancers as well as other aspects of cancer treatment, e.g. radiation or surgery.

To our knowledge, only three previous studies have investigated procedure codes in the Patient Registry. They all showed a high PPV and sensitivity values the register.[5,10,11] Nielson et al (2012) investigated procedure codes for intravenous bisphosphonate administration[10], Adelborg et al (2016) cardiac procedures[11] and Lund et al (2013) antineoplastic treatments among colorectal patients[5]. Most of the studies included patients from University Hospitals, whereas we included all hospitals within the region. Our findings showed a slightly lower validity of specific treatments among non-university hospitals, which emphasises the need for including all hospitals when doing validation studies.

Like our study, Lund et al (2013)[5] investigated antineoplastic treatments among patients with colorectal cancer. They used both medical records and pharmacy production data to construct a reference standard, where we only used the medical record. To enhance the likelihood of patients receiving therapy, Lund et al (2013)[5] included patients by a diagnose of colorectal cancer with nodal involvement. In our study, we made no such selection of the diseases stage.

In conclusion, our study show that the validity of antineoplastic procedure codes in the Danish National Patient Registry is generally high and thus usable for epidemiological research.

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Conflicts of interest
The authors report no conflict of interest.

Data access
Data cannot be shared with third parties as case sensitive material is protected by Danish law.

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Tables and figures

TABLE 1. Overview of patients and observations of patients with a diagnose of colorectal cancer in the Region of Southern Denmark during 1st May 2016 – 1st May 2018.

n = 420

Median age and quartiles	71 [64 – 76]
Male sex	57%
No. of patients receiving treatment according the medical records	220
No. of observations in Danish National Patient Registry	2243
No. of observations in the medical records	2299
The positive predictive value of patients who receives any treatment (95% CI)	100% [97-100] 213/214
The sensitivity of patients who receives any treatment (95% CI)	97% [94-99] 213/220
The negative predictive value of patients classified as not having received any treatment (95% CI)	97% (93-99) 199/206

CI indicates confidence interval

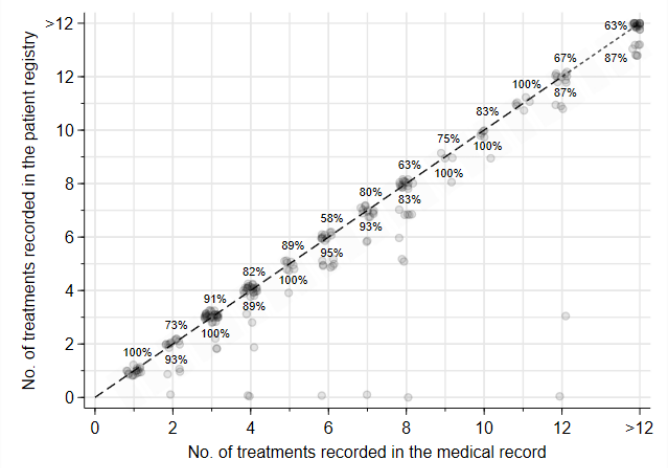
TABLE 2. Positive predictive value (PPV), sensitivity and 95% CIs for all antineoplastic procedure codes and specific treatments for all departments in the Region of Southern Denmark, accepting one-day deviation between registrations and using the medical record as the gold standard reference.

	All (n = 420)	
	PPV [95% CI)	Sensitivity (95% CI)
All codes	95% [94-95] 3282/3465	90%% [89-91] 3282/3663
All cytostatic	95% [94-95] 2851/3013	90% [88-91] 2851/3184
All biological	95% [93-97] 431/452	90% [87-93] 431/479
Specific regimes		
CAPOX*	95% [91-98] 184/194	90% [85-94] 184/204
FOLFOX*	95% [92-97] 268/282	90% [86-93] 268/298
Capecitabin	90% [87-92] 563/625	92% [90-94] 563/610
FOLFIRI	95% [90-98] 148/156	81% [75-87] 148/182
Irinotecan	97% [95-98] 356/367	85% [81-88] 356/420
5-Fluorouracil	97% [95-98] 536/552	90% [87-92] 536/598
Bevacizumab	93% [89-96] 233/251	97% [94-99] 233/241
Cetuximab	98% [95-1.00] 174/177	85% [80-90] 274/204

CI indicates confidence interval

*8% of CAPOX and 20% of FOLFOX treatments, according to medical records, were without oxaliplatin.

Figure 1. Proportion of correct registered treatments, matched by any treatment, per patient in the Region of Southern of Denmark, accepting one-day deviation between registrations and using the medical record as the gold standard refence.



Appendix / Supplementary

TABLE S1. Procedure codes used to identify antineoplastic treatments in the Danish National Patient Registry.

Oxaliplatin	BWHA108
5-Fluorouracil	BWHA110
Capecitabin	BWHA123
Irinotecan	BWHA212
Capecitabin + oxaliplatin (CAPOX)	BWHA222
5-Fluorouracil + oxaliplatin (FOLFOX)	BWHA231
5-Fluorouracil + irinotecan (FOLFIRI)	BWHA233
Bevacizumab	BOHJ19B1
Cetuximab	BOHJ17
Basic cytostatic treatment (non-specific)	BWHA1

TABLE S2. Overview of patients and observations of patients with a diagnose of colorectal cancer in the Region of Southern Denmark during 1st May 2016 – 1st May 2018.

	OUH	HSJ	HLB	SWJH	**Overall**
	n = 246	n = 40	n = 131	n = 24	n = 420
Median age and quartiles	70 (62 – 75)	73 (67 – 78)	71 (63 – 75)	71 (64 – 78)	71 (64 – 76)
Male sex (%)	57%	43%	58%	67%	57%
No. of patients receiving antineoplastic treatment according to the medical record	111	29	75	15	220
No. of observations in Danish National Patient Registry	1550	278	352	75	2243
No. of observations in medical record	1592	257	361	77	2299
The positive predictive value of patients who receives any treatment (95% CI)	100% [97-100] 107/107	100% [87-100] 27/27	97% [90-100] 71/73	100% [77-100] 14/14	100% [97-100] 213/214
The sensitivity of patients who receives any treatment (95% CI)	96% [91-99] 107/111	93% [77-99] 27/29	95% [87-99] 71/75	93% [68-100] 14/15	97% [94-99] 213/220

Abbreviation: Hospital Little Belt (HLB), Hospital of Southern Jutland (HSJ), Odense University Hospital (OUH), and South-west Jutland Hospital (SWJH).

TABLE S3. Positive predictive value (PPV), sensitivity and 95% CIs for all procedure codes and specific treatments for all departments in the Region of Southern Denmark, accepting one-day deviation between registrations and using the medical record as the gold standard reference.

	Odense University Hospital		Hospital Little Belt		Hospital of Southern Jutland		South-West Jutland Hospital	
All procedure codes	PPV 95% CI	Sensitivity 95% CI	PPV 95% CI	Sensitivity 95% CI	PPV 95% CI	Sensitivity 95% CI	PPV 95% CI	Sensitivity 95% CI
All procedure codes	96% [95-96] 2314/2418	92% [90-93] 2314/2526	93% [91-95] 526/563	84% [81-87] 526/628	91% [88-94] 350/383	87% [83-90] 350/402	84% [76-91] 85/101	79% [71-87] 85/107
All cytostatic treatments	96% [95-97] 1928/2012	92% [90-93] 1928/2104	93% [91-95] 510/547	84% [81-87] 510/605	91% [87-94] 321/353	87% [83-90] 321/368	84% [76-91] 85/101	79% [71-87] 85/107
All biological treatments	95% [92-97] 386/406	91% [88-94] 386/422	100% [80-100] 16/16	70% [47-87] 16/23	97% [83-100] 29/30	85% [69-95] 29/34	-	-
Specific regimes								
CAPOX	96% [90-99] 73/74	91% [83-99] 73/80	95% [88-99] 78/82	92% [84-97] 78/85	85% [65-96] 22/26	92% [73-99] 22/24	75% [43-95] 9/12	60% [32-84] 9/15
FOLFOX	97% [94-99] 239/247	93% [90-96] 239/256	100% [75-100] 13/13	52% [31-72] 13/25	76% [53-92] 16/21	94% [71-100] 16/17	0% [-] 0/1	-
Capecitabin	89% [84-93] 186/209	93% [88-96] 186/201	91% [86-94] 239/264	94% [90-97] 239/254	87% [78-94] 68/78	87% [78-94] 68/78	91% [81-96] 67/74	87% [74-94] 67/77
FOLFIRI	96% [95-99] 110/115	83% [75-89] 110/133	92% [74-99] 23/25	82% [63-94] 23/28	94% [70-100] 15/16	71% [48-89] 15/21	-	-
Irinotecan	98% [95-99] 313/321	89% [86-92] 313/350	93% [78-99] 28/30	57% [42-71] 28/49	94% [70-100] 15/16	71% [48-89] 15/21	-	-
5-Fluorouracil	97% [95-98] 370/382	95% [90-93] 370/410	100% [91-100] 38/38	70% [56-82] 38/54	98% [93-100] 128/131	96% [91-98] 128/134	-	-
Bevacizumab	92% [88-96] 208/225	100% [97-100] 208/209	100% [79-100] 16/16	84% [60-97] 16/19	90% [55-100] 9/10	69% [39-91] 9/13	-	-
Cetuximab	98% [95-100] 166/169	87% [81-91] 166/191	-	-	100% [63-100] 8/8	89% [52-100] 8/9	-	-
BWHA1	96% [93-98] 235/245	95% [92-97] 235/247	-	-	-	-	-	-

Abbreviation: 95%-Confidens interval (95% CI),