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Positive Predictive Values of Procedure Codes on the Treatment of Non-Muscle Invasive Bladder Cancer in the Danish National Patient Registry

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Purpose: Globally non-muscle invasive bladder cancer (NMIBC) is a high-incidence disease. There is a large heterogeneity within NMIBC regarding recurrence- and progression risks, and large-scale studies of treatment patterns and prognoses in an everyday setting could result in NMIBC-subgroup treatment optimization, benefiting both patients and the economy. The Danish national registries provide such an opportunity if the registered procedure codes are valid. Therefore, the aim of the study was to validate the International Classification of Diseases, 10th Edition (ICD-10) codes of NMIBC treatment used in the Danish National Patient Registry (DNPR).

Patients and Methods: From the DNPR, we randomly selected 200 NMIBC treatment courses identified by the dates of the course and the codes of transurethral resection of the bladder ((TURB), $n = 125$), photodynamic diagnosis ((PDD), $n = 25$), bladder instillation with Bacillus Calmette vaccine ((BCG), $n = 25$), or bladder instillation with chemotherapy/Mitomycin C ((MMC), $n = 25$). We used medical record reviews as the reference standard and estimated positive predictive values (PPVs) of all procedure codes and negative predictive values (NPVs) of PDD- and the perioperative single-shot MMC codes.

Results: We identified the medical records in 150 (75%) of the 200 treatment courses (149 individual patients). The overall PPVs were TURB: 98.9% (95% confidence interval: 93.8; 100.0%), PDD: 95.8% (78.9; 99.9%), adjuvant BCG: 90.0% (68.3; 98.8%), perioperative single-shot MMC 1/5, and adjuvant MMC: 69.2% (38.6; 90.9%). The overall NPVs were PDD: 64.8% (54.4; 73.9%) and perioperative single-shot MMC: 97.7% (92.1; 99.4%).

Conclusion: The ICD-10 NMIBC procedure codes recorded in the DNPR are generally valid with high PPVs. The NPV of the PDD code is acceptable. However, the code for perioperative single-shot MMC is uncertain with low PPV, but a high NPV.

Keywords: validation, procedure codes, non-muscle invasive bladder cancer, Danish National Patient Registry

Introduction

Bladder cancer is the 10th most commonly diagnosed cancer in the world when both genders are considered.¹ The incidence rates are highest in developed countries, and almost three times higher in men than in women.² Annually, around 2000 new patients are diagnosed with bladder cancer in Denmark.³ Approximately 75% of patients with bladder cancer present with non-muscle invasive bladder cancer (NMIBC), and in patients under the age of 40, this percentage is even higher.⁴

Transurethral resection of the bladder (TURB), with or without the use of fluorescence (photodynamic diagnosis (PDD)) as a diagnostic enhancing tool used during the TURB,^{5–7} and bladder instillations are the most important procedures in NMIBC-treatment. For instillations, either chemotherapy, which in Denmark is Mitomycin C (MMC), or immunotherapy with Bacillus Calmette vaccine (BCG) is used. MMC can be used perioperatively, within 24 hours from the TURB, as a single-shot instillation in the bladder to prevent an early recurrence or as adjuvant treatment.⁸ BCG is only given as adjuvant bladder instillations.⁸ The additional code of PDD has been used in Denmark since the 1st of January 2007, and the

use of MMC as a perioperative single-shot treatment started at about the same time. Because of the often lifelong need for follow-up of NMIBC with repeated TURBs, follow-up cystoscopies, and instillation therapy, NMIBC is one of the most costly cancers from diagnosis to death.^{9,10} However, large-scale national studies on non-selected patients providing routine clinical data of the NMIBC disease pattern, outside a clinical study setting, are lacking.

Information from large-scale registry-based studies assessing risks of recurrence and progression in different NMIBC pathological sub-groups could aid in treatment optimization and benefit both the patients and the healthcare economy.

The Danish healthcare databases allow data linkage across registries on an individual level, and data on long-term follow-up are a potential source of unique and valuable information on the disease pattern of NMIBC if the procedure codes registered are valid.¹¹ The Danish National Patient Registry (DNPR) was created in 1977 and is internationally considered one of the most comprehensive of its kind.¹² Since 1994, the International Classification of Diseases, 10th Edition (ICD-10) has been used to classify the diagnoses and procedures in the DNPR, and since 2000, the DNPR registration has been the basis for payment to hospitals, further enhancing the completeness of the registration. DNPR is known to be a valuable tool for research, but the positive predictive values (PPVs) of diseases and treatments are found to vary widely (<15–100%).¹³

The diagnosis codes of urological cancers in DNPR have overall a high validity,¹³ but the validity of NMIBC-related ICD-10 procedure codes has, to the best of our knowledge, not previously been assessed. We, therefore, aimed to investigate the PPVs of TURB, PDD, BCG, and MMC (single-shot and adjuvant use), as well as the NPVs of PDD and perioperative single-shot MMC in the DNPR.

Materials and Methods

Setting

Between 2002 and 2017, Denmark had 20 individual public urological departments. Because of centralization, this number had decreased to 14 in 2017. The Danish population was approximately 5.7 million in 2017.¹⁴ The Danish healthcare system provides free medical services to all Danes, including surgical procedures and adjuvant treatment at hospitals and outpatient clinics. Thus, the vast majority of all Danes are treated at public hospitals. The DNPR contains all discharge information from the Danish public hospitals since 1977 and all information from the public outpatient clinics since 1995; this includes information on diagnoses and procedures delimited on the date of admission and discharge to the hospital or the start and end date of the specific outpatient treatment course.^{12,13,15} The data from specific patients are collected prospectively by the treating department and updated daily in the DNPR.¹⁵

All information in the Danish registries can be linked at an individual level through the unique ten-digit Civil Personal Register (CPR) number assigned to all Danes at birth.¹⁶ This gives the opportunity of linking diagnoses and treatments to, eg, pathology data.¹⁷

The registration at private hospitals has been a part of DNPR since 2003 but is known to be less complete with regard to procedures and diagnoses.¹² Only very few patients in Denmark are treated for NMIBC in a private setting, with the vast majority being treated at public hospitals.

Study Population

We identified all procedures registered in Denmark from 2002 to 2017 with the code TURB, PDD (additional code), BCG, or MMC through the DNPR (codebook, [Table 1](#)). We excluded information from private hospitals in this study (2.9%). We collected data for each specific treatment course identified by the procedure code and the start and end dates.

We used the STATA function: “sample, count” to make a random sample of 200 treatment courses, using the entire period (2002–2017) and the entire country as the sampling cohort. The sample composition was 125 registrations of TURB without simultaneous PDD or MMC codes, 25 registrations with the PDD procedure code, 25 registrations with the BCG procedure code, and 25 registrations with the MMC procedure code, which could be registered either at the same time as TURB (within 24 hours from the TURB code) or as adjuvant treatment. Instillation treatment with either BCG or MMC must be coded at least two weeks after the TURB according to Danish guidelines for adjuvant bladder instillation treatment.¹⁸ TURB without simultaneous PDD or MMC requires no code of PDD together with the TURB

Table I Codebook ICD-10 Codes in the DNPR Used in NMIBC Treatment

Procedure	ICD-10 Code	Further Specification
TURB	KKCD32	
PDD	KZXF45	Additional code
Perioperative MMC	BJHE12/BJHE12A	Code for TURB required registered within 24 hours before BJHE12/BJHE12A
BCG	BJHE11	
MMC	BJHE12/BJHE12A	

Abbreviations: ICD-10, The International Classification of Diseases, 10th Revision; DNPR, Danish National Patient Registry; NMIBC, Non-muscle invasive bladder cancer; TURB, Transurethral resection of the bladder; PDD, Photodynamic diagnosis; BCG, Bladder instillation with Bacillus Calmette vaccine; MMC, Bladder instillation with chemotherapy/Mitomycin C.

code and no code of MMC within 24 hours from the TURB code. The selected larger sampling on TURB alone enabled NPV-calculation of the two other procedures possible during the operative procedure of a TURB; the PDD- and the perioperative single-shot MMC procedure codes.

Medical Record Review

The first author (LBR) reviewed all medical records in their entirety within the dates of the specific treatment courses and recorded information on TURB, use of PDD and MMC during the TURB (PDD) or within 24 hours from the TURB (single-shot perioperative MMC), and adjuvant instillation treatment with BCG or MMC. The procedure was only recorded as performed if it was specifically mentioned in the medical record. In case clarification was required, one of the other authors (JBJ) could be consulted; however, this was not needed. All data, collected during the medical record review, were entered directly into a specifically designed database in REDCap (Research Electronic Data Capture).

Statistical Analysis

We used the reported output from the medical records as the reference standard in the analysis. We computed PPV for all the procedure codes, as the proportion of procedures in the DNPR confirmed by medical record review with a corresponding 95% confidence interval (95% CI), using the `diagt` function.¹⁹ The NPVs of the PDD- and the perioperative single-shot MMC procedure codes were calculated as the proportion of TURB procedures without simultaneous PDD or MMC codes in the DNPR confirmed by medical record review. The corresponding 95% CIs of the NPVs were estimated using confidence intervals for proportions (the Wilson Score method).^{20,21}

Since not all codes were available during the entire period, and to assess the validity of the whole period, we computed PPVs and NPVs stratified by calendar year group (2002–2008, 2009–2013, and 2014–2017) for each procedure code possible.

STATA 17 statistical software was used for all analyses.

Results

Figure 1 illustrates the inclusion flow. Through the DNPR, we identified 141,140 individual procedures identified with a specific set of dates and the procedure code TURB without simultaneous PDD or MMC codes or the procedure code PDD, BCG, or MMC. We excluded 4,094 treatment courses registered at a private hospital. The 25 treatment courses of MMC installation randomly included 6 courses of perioperative single-shot MMC and 19 courses of adjuvant MMC installation. The 200 treatment courses corresponded to 199 unique patients as one patient was sampled for two treatment courses. In total, 73 treatment courses (36.5%) occurred between 2002 and 2008, 60 (30.0%) between 2009 and 2013, and 67 (33.5%) between 2014 and 2017. All 199 patients were identified, but in 50 cases, it was not possible to retrieve the medical record covering the specific treatment course. The final study cohort, therefore, consisted of 150 treatment courses (149 unique patients) corresponding to a completeness of 75%. The median age at diagnosis was 71 years (interquartile range (IQR): 63–79), and 114 (76.5%) were men. Out of the 20 urological departments in Denmark, 18

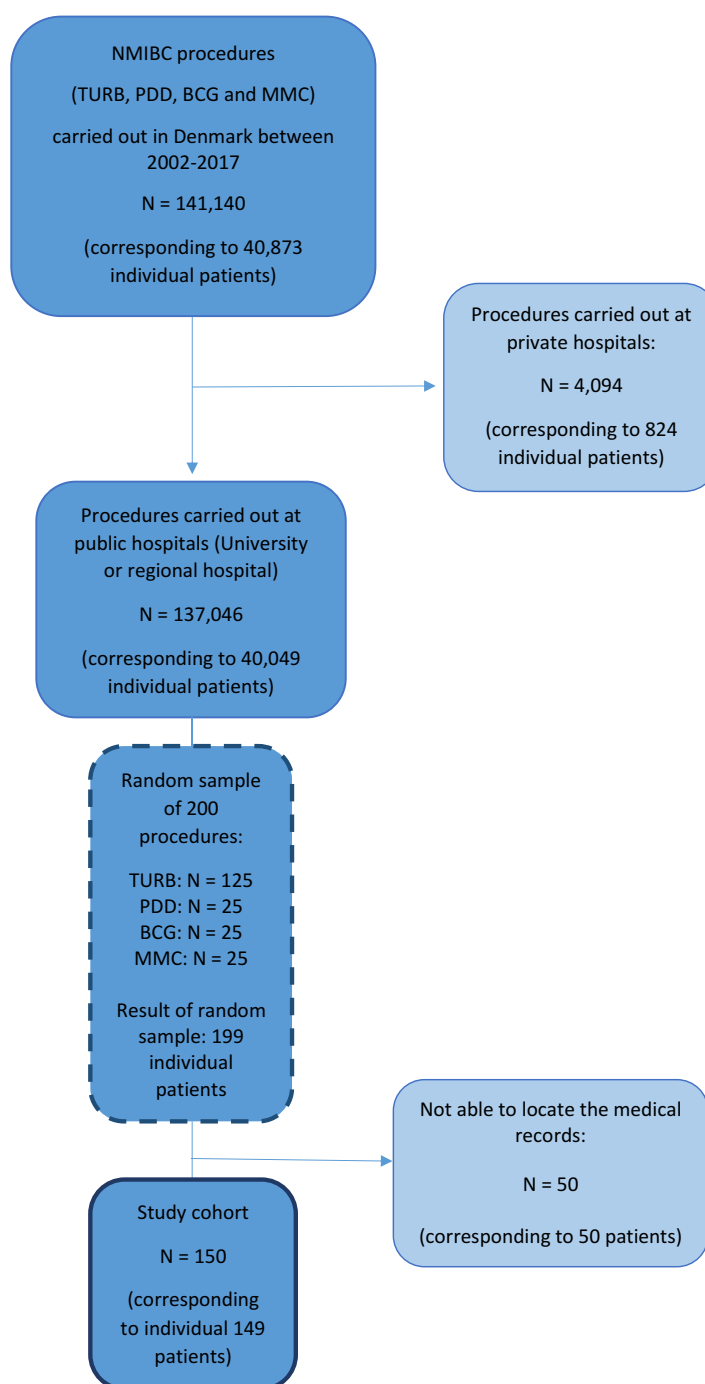


Figure 1 Sampling flow.

Abbreviations: N, sample size, number of individuals; NMIBC, non-muscle invasive bladder cancer; TURB, transurethral bladder resection; PDD, photodynamic diagnosis; BCG, bladder instillation with *Bacillus Calmette vaccine*; MMC, bladder instillation with chemotherapy/Mitomycin C.

were represented in the study cohort. Of the 50 unidentified treatment courses (TURB: 37, PDD: 1, MMC single shot: 1, BCG: 5, MMC adjuvant: 6) 42 (84%) occurred between 2002 and 2008, 7 between 2009 and 2013, and only 1 between 2014 and 2017, corresponding to a calendar year group completeness distribution of 42.5%, 88.3%, and 98.5%, respectively.

Table 2 shows the PPVs of the procedure codes correlated to the operative procedure; the TURB and the use of PDD. The PPV calculation of the perioperative single-shot MMC code is excluded from table 2 because the numbers were too

Table 2 Positive Predictive Values of the Procedure Codes in the Operative Procedure

	Sampling	Verified/Reviewed	PPV (95% CI)
<u>TURB</u>			
Overall	125	87/88	98.9% (93.8; 100.0)
Calendar Year			
2002–2008	61	28/28	100.0% (87.7; 100.0)
2009–2013	30	26/27	96.3% (81.0; 99.9)
2014–2017	34	33/33	100.0% (89.4; 100.0)
<u>PDD</u>			
Overall	25	23/24	95.8% (78.9; 99.9)
Calendar Year			
2002–2008	1	1/1	–
2009–2013	13	11/12	91.7% (61.5; 99.8)
2014–2017	11	11/11	100.0% (71.5; 100.0)

Abbreviations: TURB, Transurethral resection of the bladder; PPV, Positive predictive value; CI, Confidence interval; PDD, Photodynamic diagnosis.

small for a reasonable calculation, verified/reviewed ratio: 1/5, 0/0, 1/3, and 0/2 overall, in the year groups 2002–2008, 2009–2013, and 2014–2017, respectively. Table 3 shows the NPVs of the PDD- and the perioperative single-shot MMC codes, and Table 4 shows the PPVs of the adjuvant instillation treatment codes, overall and stratified by calendar year

Table 3 Negative Predictive Values of the PDD- and the Perioperative Single-Shot MMC Codes

	Sampling	Verified Negative/ Reviewed	NPV (95% CI)
<u>PDD</u>			
Overall	125	57/88	64.8% (54.4; 73.9)
Calendar Year			
2002–2008	61	25/28	89.3% (72.8; 96.3)
2009–2013	30	16/27	59.3% (40.7; 75.5)
2014–2017	34	16/33	48.5% (32.5; 64.8)
<u>Single-shot MMC</u>			
Overall	125	86/88	97.7% (92.1; 99.4)
Calendar Year			
2002–2008	61	27/28	96.4% (82.3; 99.3)
2009–2013	30	26/27	96.3% (81.7; 99.3)
2014–2017	34	32/33	97.0% (84.7; 99.5)

Abbreviations: PDD, Photodynamic diagnosis; NPV, Negative predictive value; CI, Confidence interval; Single-shot, Refers to the perioperative procedure (within 24 hours from the transurethral resection of the bladder) of one bladder instillation with MMC; MMC, Bladder instillation with chemotherapy/Mitomycin C.

Table 4 Positive Predictive Values of the Adjuvant Instillation Treatment Codes

	Sampling	Verified/Reviewed	PPV (95% CI)
BCG			
Overall	25	18/20	90.0% (68.3; 98.8)
Calendar Year			
2002–2008	5	1/1	–
2009–2013	10	8/9	88.9% (51.8; 99.7)
2014–2017	10	9/10	90.0% (55.5; 99.7)
MMC			
Overall	19	9/13	69.2% (38.6; 90.9)
Calendar Year			
2002–2008	6	1/1	–
2009–2013	3	2/2	–
2014–2017	10	6/10	60.0% (26.2; 87.8)

Abbreviations: BCG, Bladder instillation with Bacillus Calmette vaccine; PPV, Positive predictive value; CI, Confidence interval; MMC, Bladder instillation with chemotherapy/Mitomycin C.

group. In addition to the PPVs/NPVs, the tables show the amounts of reviewed medical records randomly selected and retrieved with the respective code, as well as the amounts of courses where the code was verified within the medical record; verified/reviewed ratio. The procedure of TURB without simultaneous PDD or MMC codes was confirmed by medical record review in 87 out of 88 cases, resulting in an overall PPV of 98.9% (95% CI: 93.8; 100.0%). The PPVs were >96% in all calendar year groups. The additional procedure code of PDD-use had an overall PPV of 95.8% (78.9; 99.9%) and an overall NPV of 64.8% (54.4; 73.9%). The perioperative single-shot MMC procedure code had a low overall PPV of 20.0% (0.5; 71.6%) though conducted on very small number of case (one out of five), but a high overall NPV of 97.7% (92.1; 99.4%). The procedure codes of adjuvant instillation treatment had PPVs from 69.2% (38.6; 90.9%) (overall MMC) to 90.0% (68.3; 98.8%) (overall BCG).

Discussion

This study assessed the validity of NMIBC-related procedure codes in the NDPR, and we found that they in general were coded with high accuracy except for the procedure code of perioperative single-shot MMC; this was, however, based on a very small sample size.

The ICD-10 bladder cancer diagnoses have previously been assessed and found to be valid with a high PPV of 88.2% in national registry data from 2004 to 2009.²² Previous validation studies in NMIBC have focused on other aspects of the procedures, such as the service provider in different healthcare settings,²³ whereas the procedures per se have not been investigated systematically. Our study is the first to validate urological procedure codes related to NMIBC retrieved from a national registry. Other studies have assessed the PPVs of non-urological procedure codes and found similar or slightly higher values.^{24,25} However, these validation studies were conducted in a single Danish region only and, therefore, they did not take potential regional variation in registration practices into account. The completeness of our medical-records-collection varied, resulting in the highest certainty of the results in the later year group, where we also had the most complete identification of the medical records (2009–2017). This is likely due to not all records being available in electronic form for the early part of our study period, and non-electronic records were more difficult to retrieve. If compromised medical record collection led to less-detailed information on a non-missing treatment course, this could have resulted in an underestimation of the PPV of the code.

The lack of data for the codes of PDD and perioperative single-shot MMC for the period 2002–2007 was expected due to the introduction of PDD and perioperative single-shot MMC codes in the latter part of this period in Denmark.²⁶ We therefore had low statistical precision in the PPV for the procedure code of perioperative single-shot MMC. Still, we do not think that low statistical precision entirely explains why we found a lower PPV for this procedure. The procedure of perioperative single-shot MMC should be performed within 24 hours of the TURB, but not necessarily while the patient is still in the operation room (unlike the PDD code which is a visually diagnostic enhancing tool used during the TURB). If perioperative single-shot MMC is intended by the surgeon, and the coding is done just after the TURB but before the actual procedure, this could be a possible explanation for the low PPV. A contra-indication of MMC, eg, continuous hematuria, may occur within the first 24 hours resulting in abstaining from the perioperative single-shot MMC procedure despite the fact that it was prescribed and possibly coded. We were able to estimate the NPVs of the PDD- and the perioperative single-shot MMC procedure codes using our selected sampling of TURB procedures, which were treatment courses selected on the procedure code of TURB without simultaneous registration of PDD or instillation therapy. The PDD- and the perioperative single-shot MMC procedures are a possible add-on to the surgical procedure of a TURB, those procedures would therefore occur under the same treatment course as the TURB in the medical record, enabling us to compute both true- and false-negative recordings. It would not be reasonable to use the same set-up for the adjuvant treatment procedure codes since the adjuvant instillation treatments are performed after the TURB (a minimum of two weeks after, according to guidelines¹⁸) and will therefore, most likely, not occur under the same treatment course as the TURB.

Other limitations of the current study include the lack of a control group without the procedure codes in the DNPR. This unfortunately meant we were unable to estimate the negative predictive value of the procedure codes of TURB and adjuvant treatment with BCG and MMC. Similarly, we were not able to estimate the sensitivity or the specificity of the codes, and this would have required a weighted sampling of the treatment courses. This is a limitation in providing complete data validity, but the importance of a high PPV in research assessing treatment-patterns and prognosis of a disease should still be emphasized.

The DNPR is useful for observational studies due to the possibility of individual-level linkage to other registries and routine, longitudinal registration of medical history.^{16,17} Assessing data quality is therefore of importance. A high PPV is particularly important when identifying cohorts for prognostic studies or in sub-analyses restricted to bladder cancer patients undergoing specific interventions (eg, adjuvant instillation therapies). We, therefore, found the high PPVs reassuring. Future observational studies on NMIBC patients with data from an everyday setting would provide valuable information on this large-scale patient group.

Conclusion

The DNPR-data on TURB, PDD, and adjuvant bladder-instillation treatment with BCG and MMC have high validity. The overall validity of the perioperative single-shot MMC procedure code seemed remarkably lower, but the NPV was high, this could be due to the logistical formalities associated with perioperative single-shot MMC. The DNPR remains a valuable source of epidemiologic NMIBC research.

Ethics Approval

The Danish Patient Safety Authority approved this study (reference number: 3-3013-2587/1).

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in the drafting, writing, revising, or critically reviewing of the article. All authors have agreed on the journal to which the article has been

submitted; have reviewed and agreed on the final version to be published; and agree to take responsibility and be accountable for all aspects of the article.

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