

BMJ Open Cohort profile: The Swedish National Register of Urinary Bladder Cancer (SNRUBC) and the Bladder Cancer Data Base Sweden (BladderBaSe)

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To cite: Häggström C, Liedberg F, Hagberg O, *et al.* Cohort profile: The Swedish National Register of Urinary Bladder Cancer (SNRUBC) and the Bladder Cancer Data Base Sweden (BladderBaSe). *BMJ Open* 2017;7:e016606. doi:10.1136/bmjopen-2017-016606

► Prepublication history and additional material for this paper are available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-016606>).

Received 24 February 2017
Revised 5 July 2017
Accepted 19 July 2017



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ABSTRACT

Purpose To monitor the quality of bladder cancer care, the Swedish National Register of Urinary Bladder Cancer (SNRUBC) was initiated in 1997. During 2015, in order to study trends in incidence, effects of treatment and survival of men and women with bladder cancer, we linked the SNRUBC to other national healthcare and demographic registers and constructed the Bladder Cancer Data Base Sweden (BladderBaSe).

Participants The SNRUBC is a nationwide register with detailed information on 97% of bladder cancer cases in Sweden as compared with the Swedish Cancer Register. Participants in the SNRUBC have registered data on tumour characteristics at diagnosis, and for 98% of these treatment data have been captured. From 2009, the SNRUBC holds data on 88% of eligible participants for follow-up 5 years after diagnosis of non-muscle invasive bladder cancer, and from 2011, data on surgery details and complications for 85% of participants treated with radical cystectomy. The BladderBaSe includes all data in the SNRUBC from 1997 to 2014, and additional covariates and follow-up data from linked national register sources on comorbidity, socioeconomic factors, detailed information on readmissions and treatment side effects, and causes of death.

Findings to date Studies based on data in the SNRUBC have shown inequalities in survival and treatment indication by gender, regions and hospital volume. The BladderBaSe includes 38 658 participants registered in SNRUBC with bladder cancer diagnosed from 1 January 1997 to 31 December 2014. The BladderBaSe initiators are currently in collaboration with researchers from the SNRUBC investigating different aspects of bladder cancer survival.

Future plans The SNRUBC and the BladderBaSe project are open for collaborations with national and international research teams. Collaborators can submit proposals for studies and study files can be uploaded to servers for remote access and analysis. For more information, please contact the corresponding author.

Strengths and limitations of this study

- The Swedish National Register of Urinary Bladder Cancer (SNRUBC) is used for monitoring the quality of care of bladder cancer and has captured data on 97% of bladder cancer cases in Sweden in the period 1997–2014. We linked data in the SNRUBC to national healthcare and demographic registers and constructed the Bladder Cancer Data Base Sweden (BladderBaSe).
- To our knowledge, with 38 658 cases based on an unselected population with very high coverage from an entire nation, BladderBaSe forms the largest and most comprehensive clinical bladder cancer database.
- In addition to bladder cancer tumour characteristics and treatment, the BladderBaSe includes information on comorbidity, socioeconomic factors, detailed information on readmissions and treatment side effects, and causes of death.
- We have no information or systematic evaluation of the 3% with bladder cancer not registered in the SNRUBC and no validation studies of the data in the SNRUBC against individual patient records.

INTRODUCTION

Bladder cancer imposes an important health problem worldwide; it is the fourth most common cancer among men in developed countries,¹ with no improvement in survival over the last decades,^{2,3} in addition to a high cost of treatment on a per-patient basis.⁴

The Swedish National Register of Urinary Bladder Cancer (SNRUBC) was initiated in 1997 to register all new cases of bladder cancer with detailed information on tumour location, size and extension (tumour, node, metastases classification of malignant tumours), grade, and primary treatment. The SNRUBC registration expanded in 2009 to register data from 5-year follow-up of non-muscle invasive bladder cancer, and

in 2011 to register data on radical cystectomy. The main aim of the SNRUBC is quality assurance of bladder cancer healthcare; a secondary aim is to use the data for clinical research. Examples of quality indicators monitored by the SNRUBC are lead times and proportions of patients seen at multidisciplinary conferences. The SNRUBC is administered by the Regional Cancer Centre (RCC) in each of the six healthcare regions in Sweden and collated to a national register.

In 2015, we linked the SNRUBC to a number of national healthcare and demographic registers to construct the Bladder Cancer Data Base Sweden (BladderBaSe). The aim was to create a comprehensive cohort of patients with bladder cancer to study trends in incidence, effects of treatment, and overall as well as disease-specific survival, with detailed data on patient and tumour characteristics, treatment, socioeconomic factors and comorbidity.

COHORT DESCRIPTION

Swedish National Register of Urinary Bladder Cancer

In Sweden, new histologically, cytologically or clinically diagnosed tumours are mandated by law to be reported to the national Swedish Cancer Registry.⁵ All new diagnoses of a tumour in the bladder with International Classification of Diseases for Oncology, 3rd revision (ICD-O-3) code C67.0–C67.6 and C67.8–C67.9 for individuals 18 years or older are additionally requested to be reported into the SNRUBC. Data are collected by the six RCCs, which report to the national databases for the Swedish Cancer Registry and the SNRUBC. The records are validated and checked for completeness by each RCC. In the period 1997–2014 the coverage of bladder cancer cases in the SNRUBC was 97% as compared with the Swedish Cancer Register with regional variation from 92% to 100% (figure 1).

Patient records in the SNRUBC are standardised into four forms with data on (1) characteristics of the primary tumour at diagnosis; (2) primary treatment; (3) follow-up at 5 years after diagnosis for non-muscle invasive bladder cancer; and (4) preoperative, perioperative and post-operative events in conjunction with radical cystectomy. The number of participants and the coverage of the four registration forms in the SNRUBC from 1997 to 2014 are shown in figure 2. In short, all participants have registered data on diagnosis, and of these 98% have data on treatment; of the eligible participants with non-muscle invasive bladder cancer, 88% have data on 5-year follow-up, and of eligible participants treated with radical cystectomy 85% have registered details of the surgery, complications and reoperations.

The forms for tumour information at diagnosis and treatment have been in use since the initiation in 1 January 1997. From 1 January 2009, participants with non-muscle invasive bladder cancer (stage Ta, Tis or T1) without metastases are registered with data on time to relapse, progress and death 5 years after date of diagnosis (ie, for participants with year of diagnosis 2004 and

forward).⁶ From 1 January 2011, detailed data on radical cystectomy are registered with surgical details, complications and reoperations up to 90 days postoperatively according to the Clavien-Dindo classification of surgical complications.^{7,8}

An overview of variables registered in the four standardised registration forms in the SNRUBC is listed in table 1. Detailed information on variables and captured ratios from 1997 to 2014 in the four forms are shown in online supplementary tables 1–4. In addition, the radical cystectomy form includes data on complications and reoperations within 90 days of the surgery, shown in online supplementary table 5.

Bladder Cancer Data Base Sweden

In 2015, data on participants in the SNRUBC with date of registration from 1 January 1997 to 31 December 2014 were linked to a number of healthcare and demographic registries at the National Board of Health and Welfare and the Statistics Sweden by use of the personal identification number (PIN) to form the BladderBaSe (figure 3). The PIN is a unique 10-digit number assigned to each individual in the Swedish population, and allows for virtually 100% coverage in the Swedish healthcare system.⁹ Participants in the BladderBaSe have been assigned an internal identification (ID) number, for which the key between the PIN and internal ID number is kept exclusively by Statistics Sweden. Participants with no date of diagnosis or less than 18 years of age at date of diagnosis were excluded. Last day of follow-up for participants in the BladderBaSe was date of death, date of emigration or 31 December 2014, whichever happened first.

The BladderBaSe includes information from 28 814 men and 9844 women with bladder cancer. Baseline characteristics of participants registered and lost to follow-up in the four standardised registration forms in the SNRUBC are shown in online supplementary table 6. An overview of variables retrieved from each register is shown in table 2. More details of each register and selected variables are described below.

The Patient Register

The Swedish Patient Register is administered by the National Board of Health and Welfare and includes nationwide information regarding inpatient and outpatient care from 1987. Each record holds dates of admission and discharge, hospital unit, procedures and diagnoses coded according to the ICD-9 or ICD-10.¹⁰ The Charlson Comorbidity Index (CCI) was calculated with data from the Patient Register to estimate the concomitant disease burden of the participants in BladderBaSe. The CCI is based on a list of diseases with a specific weight assigned to each disease category. The separate weights are collated to an overall score, categorised into 0 for no comorbidity, 1 for mild comorbidity, 2 for intermediate and 3 or more for severe comorbidity.¹¹ For participants with metastatic bladder cancer at date of diagnosis, data on metastatic cancer was not included in

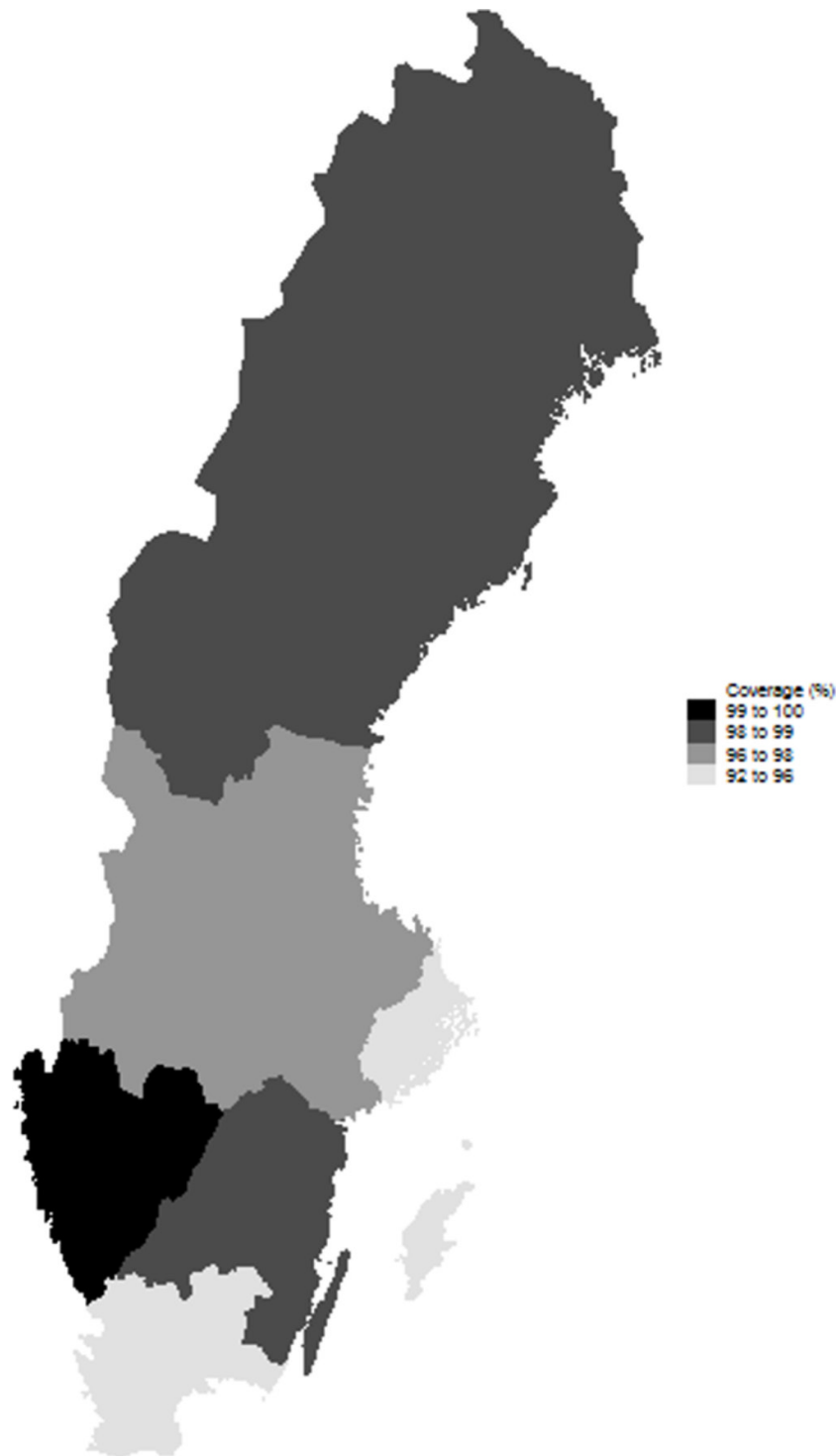


Figure 1 Coverage of bladder cancer in the Swedish National Register of Urinary Bladder Cancer, separately for the six healthcare regions in Sweden, as compared with the Swedish Cancer Register.

the calculations of CCI. A validation study of the Patient Register reported high validity for most diagnoses, with a positive predictive value of 85%–95%.¹² Furthermore, data were retrieved both prior to and after the date of bladder cancer diagnosis from the Patient Register on risk factors for bladder cancer, risk factors of treatment side effects, and/or modifiers of treatment response and natural history of the disease. Examples of such data are

urinary tract infections, type 2 diabetes mellitus, chronic obstructive pulmonary disease and prior abdominal or pelvic surgery.

The Cancer Register

The Swedish Cancer Register was initiated 1958 and has due to mandatory reporting high validity.¹³ We retrieved data on all other cancer diagnoses and their dates,

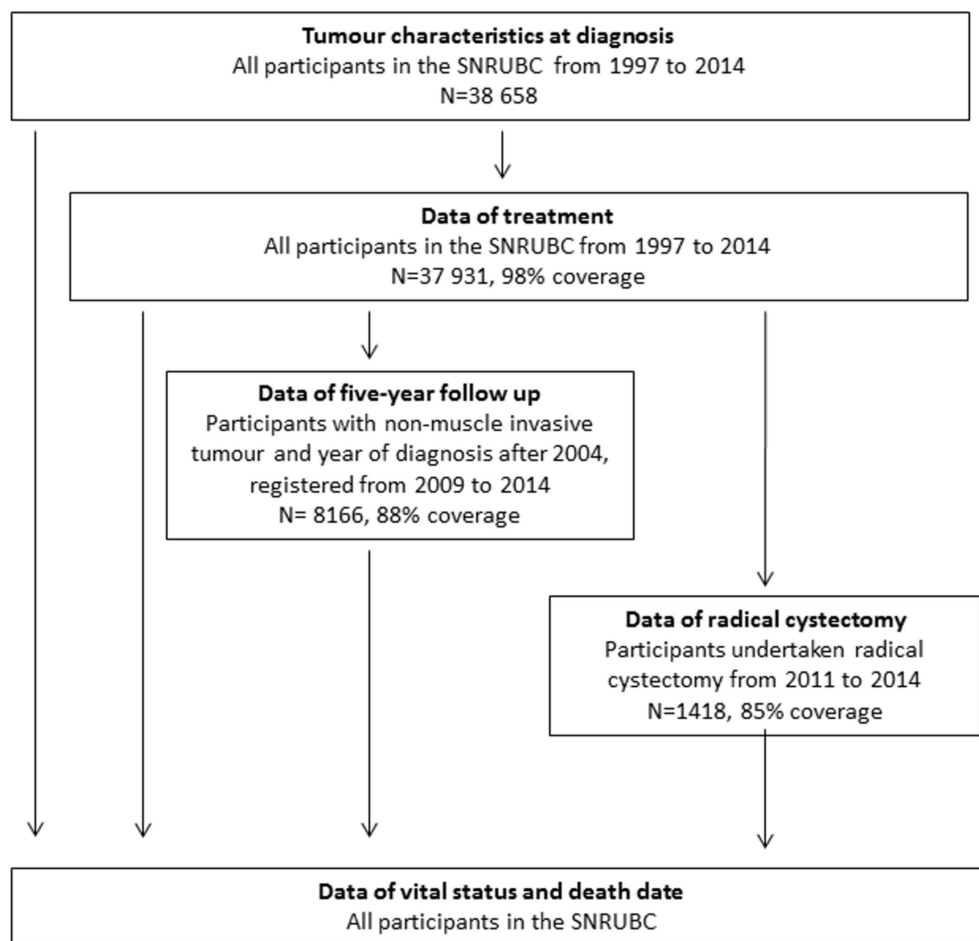


Figure 2 Flow diagram of data collected in the Swedish National Register of Urinary Bladder Cancer (SNRUBC), with number of participants and capture rates from 1997 to 2014.

Table 1 Overview of data included in the four standardised forms in the Swedish National Register of Urinary Bladder Cancer

Registration form	Data recorded
Tumour characteristics at diagnosis	Reporter information: hospital and department Tumour information: TNM stage, grade, tumour diameter, number of tumours, histology and morphological codes Dates of: diagnosis, referral, received referral, first visit to specialist and TUR/px Alternatives for referral reason and morphological confirmation
Treatment	Reporter information: hospital and department Primary investigation options: data on multidisciplinary conference, single-dose chemotherapy and reresection Date and details of given treatment: intravesical instillations, systemic chemotherapy, radical cystectomy, radiotherapy or other treatments
Five-year follow-up for non-muscle invasive bladder cancer	Reporter information: hospital and department Status and date of recurrence and progression
Radical cystectomy	Reporter information: hospital and department Preoperative data: TNM stage, weight, height, body mass index, American Society of Anesthesiologists score, previous pelvic surgery, radiation or neoadjuvant chemotherapy Perioperative data: type of surgery, type of lymphadenectomy, type of urinary diversion, blood loss, duration of surgery, accidental organ injury during surgery Postoperative data: complications, reoperations and readmissions within 90 days, length of hospital stay, pathological T stage, number of excised lymph nodes, and number of excised and metastatic lymph nodes

TNM, tumour, node, metastases; TUR/px, transurethral resection.

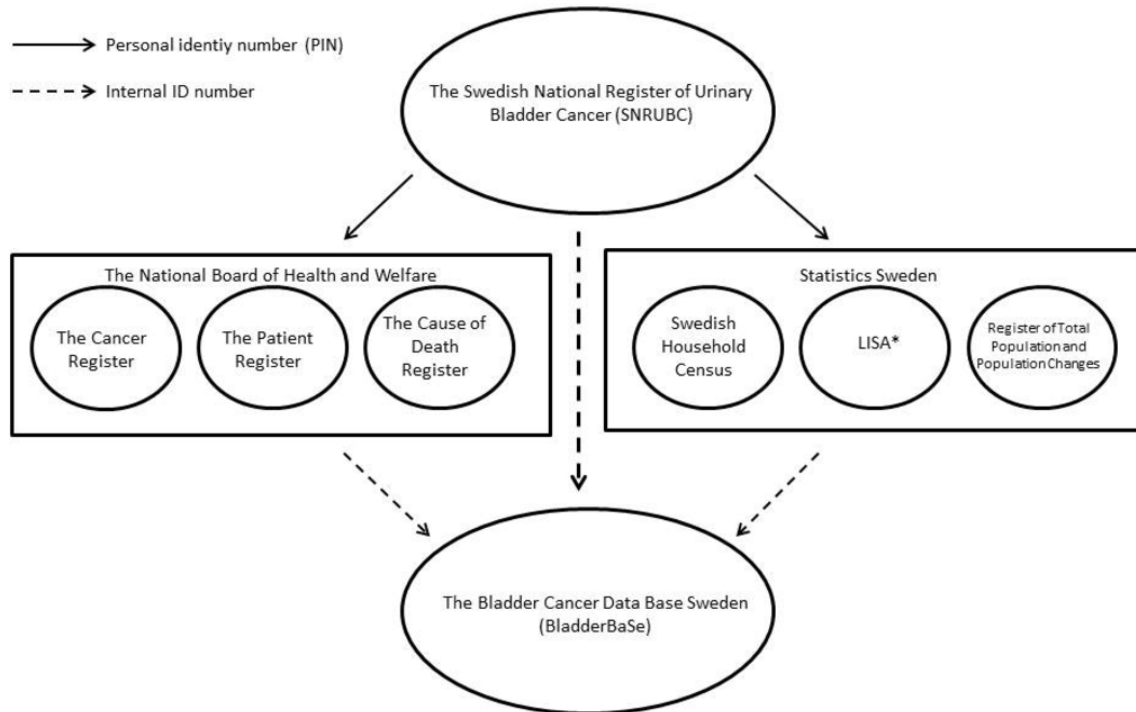


Figure 3 Data from the Swedish National Register of Urinary Bladder Cancer (SNRUBC) were linked to nationwide healthcare and demographic registries to construct the Bladder Cancer Data Base Sweden (BladderBaSe). *Longitudinal Integration Database for Health Insurance and Labour Market Studies.

Table 2 Retrieved register information from nationwide healthcare and demographic registries included in the Bladder Cancer Data Base Sweden

National registries	Retrieved data
The Cancer Register	Data on cancer diagnoses including site and date
The Patient Register	Inpatient and outpatient data with data on diagnoses, medical procedures and surgeries
The Causes of Death Register	Date of death, and underlying and contributing causes of death
Swedish Household Census	Data from 1990 of socioeconomic status and profession
Longitudinal Integration Database for Health Insurance and Labour Market Studies	Annual data with socioeconomic factors such as marital status, education level, annual income and profession
Register of Total Population and Population Changes	Personal identification number of all Swedish residents and their country of birth; data on immigration and emigration

irrespective of date of bladder cancer diagnosis for all participants in the BladderBaSe.

The Causes of Death Register

From the Causes of Death Register we retrieved data on underlying and contributing causes of death and dates of death. The Causes of Death Register was initiated in 1953, and the proportion of missing death certificates in 2014 was 1%.¹⁴

Swedish Household Census and the Register of Total Population and Population Changes

From the Statistics Sweden we retrieved data from the Register of Total Population and Population Changes and the Swedish Household Census on marital status, country of birth, dates of immigration and emigration.¹⁵

Furthermore, we retrieved data from the Swedish Household Census from year 1990 on socioeconomic status based on the Swedish Socio-Economic Index and profession.

Longitudinal Integration Database for Health Insurance and Labour Market Studies

The Longitudinal Integration Database for Health Insurance and Labour Market Studies (LISA) database administered by the Statistics Sweden holds annual registers from 1990 of data based on the labour market, educational and social sectors. The LISA database has information at an individual level, and at group level such as families, companies and places of employment. From the LISA database we retrieved information about socioeconomic

Table 3 Descriptive statistics at date of diagnosis of participants included in the Bladder Cancer Data Base Sweden (BladderBaSe)

	Men (n=28 814)		Women (n=9844)	
	N	%	N	%
Year of diagnosis				
1 January 1997 to 31 December 2002	8610	30	3062	31
1 January 2003 to 31 December 2008	9405	33	3138	32
1 January 2009 to 31 December 2014	10 799	37	3644	37
Type of bladder cancer				
Non-muscle invasive	21 330	74	6734	68
Muscle invasive	6920	24	2891	29
T stage X or missing	564	2	219	2
Age at diagnosis				
Less than 65 years	6653	23	2306	23
65–69 years	4257	15	1272	13
70–74 years	5110	18	1412	14
75–79 years	5227	18	1734	18
80–84 years	4349	15	1600	16
85 years and above	3218	11	1520	15
Marital status				
Married	18 118	63	3888	39
Divorced	3959	14	1593	16
Unmarried	2859	10	904	9
Widowed	3570	12	3383	34
Missing	308	1	76	1
Education level*				
Low	12 944	45	4641	47
Intermediate	10 118	35	3286	33
High	4833	17	1467	15
Missing	919	3	450	5
Charlson Comorbidity Index prior to diagnosis†				
No comorbidity (0)	16 274	56	6413	65
Mild comorbidity (1)	5034	17	1549	16
Intermediate comorbidity (2)	4154	14	1066	11
Severe comorbidity (3 or more)	3352	12	816	8

*Educational level categorised as low (≤ 9 years of school), intermediate (10–12 years) and high (≥ 13 years), corresponding to mandatory school, high school and college or university.

†Charlson Comorbidity Index is calculated during a 10-year period prior to diagnosis. Comorbidity scores for metastatic cancer are not included in the Charlson Comorbidity Index for participants with metastatic bladder cancer at date of diagnosis.

variables such as educational level, profession, annual family and individual income.

Findings to date

A list of publications based on the SNRUBC is shown in online supplementary table 7. The SNRUBC steering committee has published annual reports online, and from 2011 separate reports for radical cystectomy.^{6,7}

In the SNRUBC, female gender has been associated with more aggressive tumours, less probability of optimal treatment and shorter survival, in comparison to men.¹⁶

Time trends over 15 years in SNRUBC revealed a rising mean age at diagnosis, a larger proportion of non-muscle invasive tumours and no improvement of survival.³ Studies on muscle invasive bladder cancer showed that curative treatment was less likely to be given at low-volume as compared with high-volume hospitals, for female gender as compared with male gender, and for older patients as compared with younger.¹⁷ Studies on non-muscle invasive bladder cancer showed large regional variations of disease progression 5 years after diagnosis,¹⁸ an underuse

of bacillus Calmette–Guérin (BCG) for stage T1 bladder cancer,¹⁹ and large regional variations in treatment of stage Ta and T1 bladder cancer.²⁰ Studies on radical cystectomy have shown high risk of complications within 90 days for long surgery duration and higher patient age,²¹ and a higher reoperation rate for patients receiving a continent diversion as compared with an ileal conduit.²² Moreover, patients treated with radical cystectomy at high-volume hospitals had longer survival and lower risk of local recurrence as compared with patients treated at low-volume hospitals,²³ and university hospitals more often used continent reconstruction as urinary diversion after radical cystectomy as compared with county hospitals, but with regional variations.²⁴

In BladderBaSe, 24% of male and 29% of the female participants were diagnosed with muscle invasive bladder cancer. Tabulated information of other variables at diagnosis is shown in table 3. Data on education level and marital status were retrieved at date of diagnosis, and data on CCI were calculated based on data from 10 years' time prior to date of diagnosis. The BladderBaSe project group in collaboration with researchers from the SNRUBC is currently investigating survival after a diagnosis of muscle invasive bladder cancer, readmissions and side effects after radical cystectomy, temporal and regional trends of treatment, and survival for non-muscle invasive bladder cancer.

STRENGTHS AND LIMITATIONS

To our knowledge, with 38 658 cases based on an unselected population in a register with very high coverage from an entire nation, BladderBaSe forms the largest clinical bladder cancer database. The main strengths of the BladderBaSe are detailed information on tumour characteristics, treatments and follow-up, and in addition data on important confounding factors such as socioeconomic variables and comorbidity. The main weaknesses are the lacking information on the 3% with bladder cancer not registered in the SNRUBC and no validation studies of the data in the SNRUBC against individual patient records.

COLLABORATION

The steering group of the SNRUBC and the project group working with the BladderBaSe are open for collaboration with national and international research teams. Collaborators can propose and apply for studies in the BladderBaSe using a standardised form. After approved application, the project data administrators upload study-specific files with selected variables to a server for statistical analysis through remote access. Users of this system will be charged for software licences, data administration and for preprocessing of study files.

Studies within the aim of the BladderBaSe as stated in the introduction have approval from Research Ethics Board and included registries. Collaborators who wish to study other objectives need to apply to the Research

Ethics Board. When reporting studies from BladderBaSe, authors are encouraged to use the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) checklist for cohort studies. For more information of collaboration with the SNRUBC or the BladderBaSe, contact the corresponding author (CH), email: christel.haggstrom@umu.se.

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Acknowledgements This project was made possible with help of the data collected in the SNRUBC, and we would like to thank the members of the SNRUBC: VS, FA, Johan Johansson, P-UM, Malcolm Carringer, AH, TG, AS, Roland Rux, Markus Johansson, Petter Kollberg, Anna-Karin Lind, Jenny Wanegård, Magdalena Cwikel, Elisabeth Överholm, Anders Ullen, Erika Jonsson, Helena Thulin, Gun Danielsson, Helene Hummer, Fredrik Liedberg, and SJ. We also thank Pär Stattin for guidance in with database administration.

Contributors CH, FL, SJ and LH initiated the study and drafted the manuscript. FL, FA, VS, AH, TG, AS, P-UM and SJ contributed with data, and CH, OH and HG analysed data. All authors revised the manuscript and approved the final version to be published.

Funding This work was supported by the Swedish Cancer Society, grant number CAN 2013/472.

Competing interests None declared.

Ethics approval This study was approved by the Research Ethics Board at Uppsala University, Sweden.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Annual reports from the SNRUBC are available online at <http://www.cancercentrum.se/vast/cancerdiagnoser/urinvagur/urinblase-och-urinvagscancer/kvalitetsregister/>. Collaborators can propose and apply for studies in the BladderBaSe using a standardised form. After approved application, the project data administrators can upload study-specific files with selected variables to a server for statistical analysis through remote access. Users of this system will be charged for software licences, data administration and for preprocessing of study files. For more information contact the corresponding author.

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